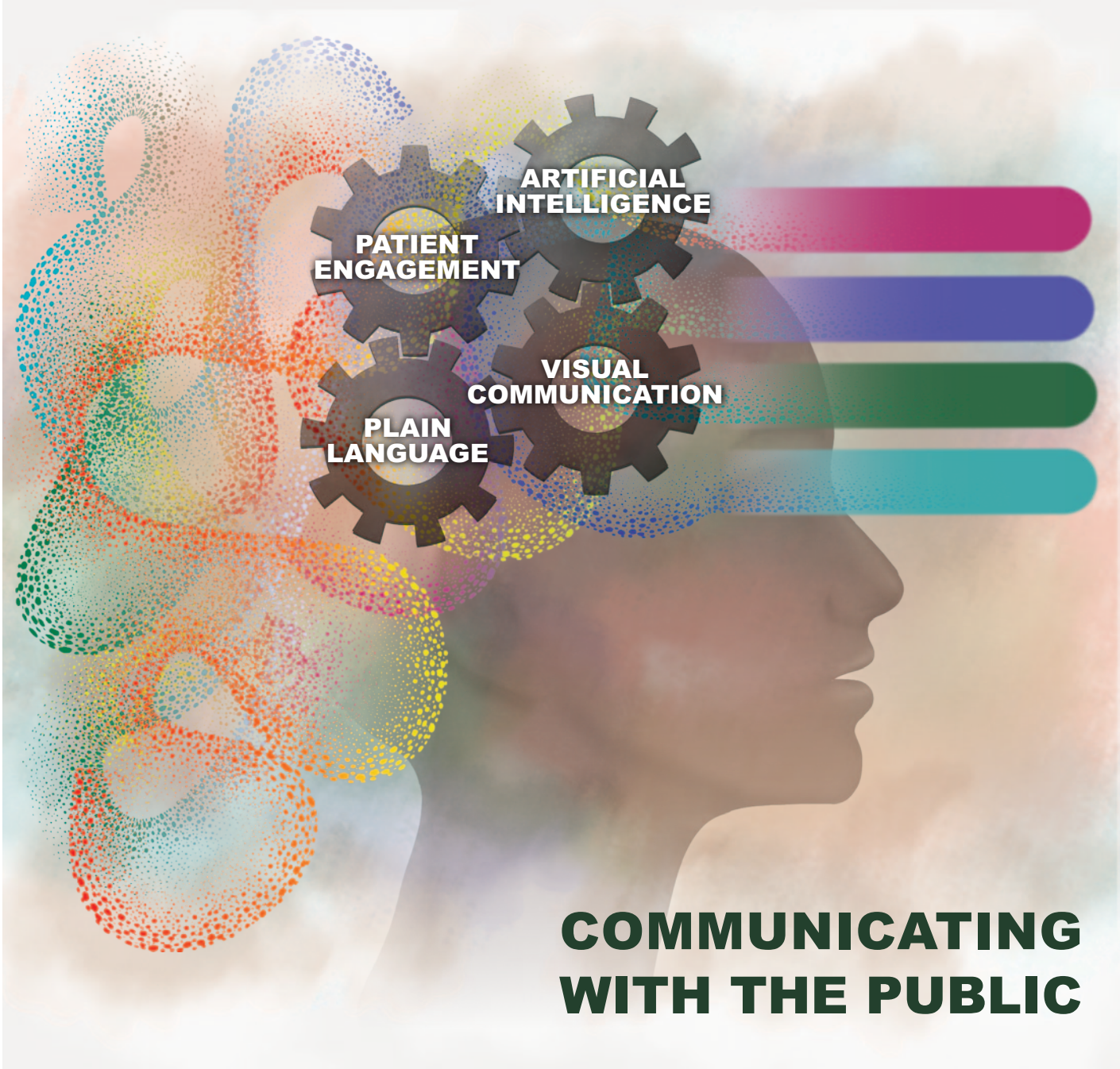
Medical Writing



COMMUNICATING WITH THE PUBLIC

ALSO IN THIS ISSUE...

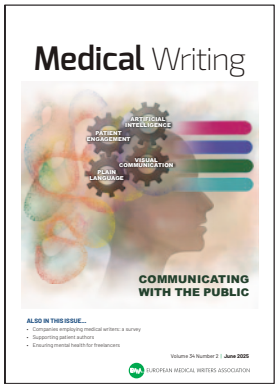
- Companies employing medical writers: A survey
- Supporting patient authors
- Ensuring mental health for freelancers

Volume 34 Number 2 | **June 2025**

EMWA EUROPEAN MEDICAL WRITERS ASSOCIATION

Medical Writing is the official journal of the European Medical Writers Association (EMWA). It is a quarterly journal that publishes articles on topics relevant to professional medical writers. Members of EMWA receive *Medical Writing* as part of their membership. For more information, contact mew@emwa.org.

Medical Writing



Joana Corte-Real/EMWA Creative Team

THIS ISSUE **June 2025** | Volume 34 Number 2

Communicating with the public

"Communicating with the public, be it patients, research participants, or anyone seeking health information, is now one of the core activities of the medical writing profession."

Guest Editors Sampoorna Rappaz and Lisa Chamberlain James, p. 2

Communicating with the public:

Bringing together plain language, patient engagement, inclusive communication, and AI

In 2015, *Medical Writing* published an issue on "Plain language and readability", the first issue to focus on the value and practice of writing in plain language.[1] The issue provided medical communicators with a consolidated view on a more challenging form of communication, one that required the communicator to consider the needs of a very diverse set of readers. The goal: the reader should be able to quickly and easily understand the information provided to them and be able to use that information in their

doi: 10.56012/ofdv3305

healthcare decisions.

Five years after this landmark issue came the issue on "Writing for patients",[2] with a focus on how to apply the principles of plain language communication when developing different types of documents with different purposes and for use in different avenues. This issue explored disparate medical writing domains, such as clinical trial disclosure and reporting, ethics submission, publication planning, translation, health communication, all connected by the principles of plain language communication.

Plain language communication has become a key skill for medical communicators, and rightfully so. Effective plain language is crucial for ensuring that medical information is accessible and understandable to everyone, improving patient outcomes and fostering trust. Articles discussing the application of plain language

GUEST EDITORS

Sampoorna Rappaz
sampoorna.rappaz@unibe.ch

Lisa Chamberlain James
lisa@trilogywriting.com

communication in specialised writing domains appear in many issues of *Medical Writing*, especially those themed on medical journalism,[3] open science and open pharma,[4] clinical trials,[5,6] translation,[7] and clinical trial transparency and disclosure.[9-11] Communicating with the public, be it patients, research participants, or anyone seeking health information, is now one of the core activities of the medical writing profession.

Ten years after that first issue on plain language, we are ready for another consolidated look at how the field of communicating with the public has evolved, and what the future entails for the medical writing profession. We are thrilled to present to you in this issue of *Medical Writing*, 11 features that provide historical perspectives and explore new horizons in the realm of communicating with the public from the nuanced viewpoints of the EMA, regulatory writers, patient advocates, patient engagement experts, clinical research organizations, scientific writers, plain language specialists, translators, and visual communicators. The issue covers everything from communicating drug or medical device information to the public, improving patient engagement, practicing inclusive and trustworthy communication, to using artificial intelligence (AI) in communicating health information and clinical research findings.

The EMA has been at the forefront of patient and public communication efforts. As the EMA celebrates its 30th anniversary this year, **Nacho Mbaeliachi** reflects on the evolution of the agency's crowning achievement in transparent public communication, the European Public Assessment Report, and outlines the agency's vision for the future of public communication and patient engagement. This gives us insights into how the EMA plans to improve transparency, accessibility, and engagement to build public trust.

One of the latest initiatives by the EMA to make information about approved drugs easier to access is the electronic Product Information (ePI). **Behtash Bahador et al.** discuss the transition from paper-based product information to the ePI, the implications of this transition, and how the ePI can be further evolved to benefit different stakeholders. Medical writers will be involved in shaping the future of the ePI, so understanding the strategies for creating accessible and user-friendly ePI that meets the needs of patients, clinicians, and regulators is paramount.

In the medical device sector, manufacturers are now required to submit the Summary of Safety and Clinical Performance (SSCP), a document introduced by the European Medical Device Regulation (MDR 2017/745). The SSCP is meant to clearly and concisely communicate a medical device's safety and performance to healthcare professionals *and patients*. The SSCP is intended for two audiences, and with that comes many challenges. **Katharina Friedrich** outlines the challenges faced when writing the SSCP sections meant for patients and how to address them effectively using plain language principles – a must-read for medical writers in the medical device space!

Patient and public involvement and engagement in clinical trials leads to useful trial design, efficient trial conduct, and clear reporting. **Diana Daniel et al.** discuss a patient-centric writing strategy that medical

EUROPEAN MEDICAL WRITERS ASSOCIATION

Submissions:
For instructions to authors, go to the journal section of EMWA's website (www.journal.emwa.org).
All manuscripts should be submitted to mew@emwa.org.

MIX
Paper | Supporting responsible forestry
FSC® C126839

writers can use to support patient engagement activities across the clinical trial lifecycle, from protocol writing to results dissemination. When it comes to clinical trial enrolment specifically, **Ekaterina Bulaeva** and **Amalia Iljasova** explain how patient-centric landing pages can be used to address challenges in trial enrolment. Landing pages with clear and accessible information have the potential to increase enrolment and improve patient engagement. Taking the broader view on patient engagement, **Fatima Auwal et al.** encourage medical writers to think holistically and develop a unified approach to patient engagement, bringing together medicine development and research communication, and thereby help develop and maintain meaningful and sustainable patient engagement practices. They base their insightful recommendations on their ongoing research efforts at King's College London in the patient engagement field. For medical writers, the article underscores the importance of establishing evidence-based patient engagement practices.

Effective patient and public involvement and engagement in healthcare is built upon inclusive communication. Inclusive communication ensures that everyone, regardless of their background, can access and understand medical information, making healthcare equitable. **Ana Sofia Correia** discusses the crucial role medical translators play in improving patient safety and equitable healthcare access. She also provides an actionable translation strategy that can make language services sustainable, efficient, and impactful. Also, translating complex medical concepts into well-designed visual aids, such as infographics and diagrams, can help empower patients and the public to make informed decisions about their health. But visual aids remain underused! **Helena Jambor et al.** walk us through the history of visual communication in medicine, bringing us to the present and potential application of visual communication in clinical development and clinical care. They provide excellent (downloadable) PowerPoint templates that medical communicators can use to create visual Clinical Study Report synopsis and graphical abstracts.

Communicating with the public effectively is a trust-building exercise. Our word choices can either build or break trust. In this vein, **Crystal Herron** argues for choosing language that shows our respect, empathy, compassion, and kindness for people who participate in research, in order to preserve their autonomy and humanity. Medical communicators can also build trust by ensuring the accuracy and transparency of health information provided to the public. But if they were to use AI to generate health information, how would the public perceive it? Medical communicators can learn about the public's concerns and the factors influencing the public's trust regarding AI-generated health information in the article by **Jumana Ashkanani**, where she presents the findings of her Master's project on public perception of AI-generated health information.

> While the landscape of medical communication is ever-evolving, effectively communicating medical and health information to the public remains our immutable mission.

Without a doubt, AI is revolutionising medical writing; however, guidelines for its use are still being developed and discussed. In this issue, we are delighted to offer the latest guidance on how AI should be used to create Lay Summaries of Clinical Trial Results. This guidance document, by **Kimbra Edwards** on behalf of the working group, is the result of a collaboration between experts from over 15 organisations in the US and the EU, including industry, academia, and a patient-focused nonprofit. It provides excellent recommendations for AI implementation, highlighting the necessity of human oversight and expertise. For medical writers, this pragmatic and insightful paper underscores the importance of combining AI with human input to achieve high standards in accuracy, transparency, and compliance, whilst offering practical advice for how to approach the use of AI in this space.

Though the landscape of medical communication is ever-evolving, effectively communicating medical and health information to the public remains our immutable mission. We hope that you enjoy reading this issue as much as we have enjoyed working with the authors to compile the latest thinking in this area. We thank everyone involved for their continued support of EMWA, and the medical writing profession.

References

1. Gilliver S. Plain language and readability. Med Writ. 2015;24(1):1–2. doi:10.1179/2047480614Z.000000000258
2. Chamberlain James L, Whereat A. Writing for patients. Med Writ. 2020;29(4):1–2. Available from: https://journal.emwa.org/writing-for-patients/writing-for-patients/
3. Chamberlain James L, Beeby R. Plain language summaries of publications: What has COVID-19 taught us? Med Writ. 2021;30(4):34–8. Available from: https://journal.emwa.org/medical-journalism/plain-language-summaries-of-publications-what-has-covid-19-taught-us/
4. Griffiths S, Appiah A, Rosenberg A, et al. Landscaping the terminology of accessible language document types. Med Writ. 2022;31(4):24–30. doi:10.56012/cbxl1493
5. Chamberlain James L. The lay protocol synopsis: Requirements and feasibility. Med Writ. 2023;32(1):34–6. doi:10.56012/dwxn7122
6. Leithold LHE, Brown CM, Hild JA, et al. Lay titles for clinical trials: Is industry achieving the balance? Med Writ. 2023;32(1):38–44. doi:10.56012/lnhw1492
7. Sparano RM. Five "translation" strategies to adapt technical content for lay audiences. Med Writ. 2024;33(1):20–5. doi:10.56012/gbfd2844
8. Jenkins R, Todd J, Alexander O. How can we maximise patient engagement with Plain Language Summary of Publication articles (PLSPs)? A publisher perspective. Med Writ. 2024;33(1):26–9. doi:10.56012/ppko1083
9. Chamberlain James L. Plain language summaries of clinical trial results: What is their role, and should patients and AI be involved? Med Writ. 2024;33(3);34–7. doi:10.56012/yayy4394
10. Thavarajah D, Kassis SB, Panton A, et al. Creating educational material about clinical research data for patients and the public: A multifaceted journey in the current digital age. Med Writ. 2024;33(3):46–53. doi:10.56012/gyeg6536
11. Baronikova S, Rosenberg A, Winchester CC, et al. Med Writ. 2024;33(3):54–61. doi:10.56012/pzwh6593

About the Guest Editors

Dr Sampoorna Rappaz
Sampoorna is an academic writing tutor at the Medical and Natural Sciences Library at the University of Bern, Switzerland. She delivers workshops and courses that cover topics such as ethical academic writing, plain language writing, inclusive visual communication, responsible use of AI for academic writing, and publication planning. A Geoff Hall Scholarship recipient, she is a supporting member of EMWA's Communicating with the Public SIG and an associate editor of *Medical Writing*. She was the Chief Operations Officer of Publisher Pro AG, a start-up that developed a web-based application for academic writing. She has worked as a freelance medical editor, fact-checker, and medical writer for global pharmaceutical companies. She is a trained molecular and cell biologist, with a master's degree in human genetics from the University of Leeds and a PhD in cancer biology from the University of Zurich.

Dr Lisa Chamberlain James
Lisa is a Senior Partner of Trilogy Writing & Consulting. Aside from management activities, she leads client projects, with extensive experience in a variety of documents. Lisa has a special interest in writing for the public, pharmacovigilance (PV), and in patient information. Following a PhD and post doc. in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then, she has been involved in EMWA as a member of the Educational Committee, mentor, leader, and assessor of workshops, and is a member of the American Medical Writers Association (AMWA) Executive Forum, AI Task Force, and teaches and reviews workshops for AMWA. Lisa regularly takes part in podcasts, articles, and is a member of several global, pan-industry panels and committees, holds an EMWA professional development certificate, is a visiting lecturer for King's College London and the University of Lisbon, has initiated and chaired EMWA's first Special Interest Group (SIG, in PV) and is the current chair of the Communicating with the Public SIG, and the Geoff Hall Scholarship Committee. She is section editor of the "Medical Communications and Writing for the Public" section of *Medical Writing*, serves on the advisory board for the Pharmaceutical Business Conference Group, is an EMWA Nick Thompson Fellow, and is a Fellow of the Royal Society of Medicine.

From the Editor

Raquel Billiones
Editor-in-Chief
editor@emwa.org
0000-0003-1975-8762

doi: 10.56012/qavi7840

Medical Writing goes exclusively digital!

Before *Medical Writing* (*MEW*), there were the *Newsletter* and *The Write Stuff*. For over 20 years, we have been delivering print versions to our membership, at the same time making the pdf version available online. But as EMWA continue to learn and evolve as an organisation, our official publication follows suit.

It is my pleasure to announce that *MEW* is going exclusively digital!

Print-related costs currently represent approximately 57% of journal expenses and 1% of EMWA's carbon footprint. This digital transformation aligns with EMWA's 2023–27 Strategic Plan focusing on sustainability initiatives while potentially providing substantial cost savings and enhanced member value.

This *MEW* June 2025 edition will be the last issue available in print. From September 2025 onwards, MEW will be available as member-only digital publication downloadable pdfs and the print edition will be completely eliminated. A curated selection of articles will be available publicly as a freely accessible digital compendium. Our current EMWA President Martin Delahunty and his publishing expertise are especially instrumental in this transformation.

As we move to this next chapter of our publication, we shouldn't lose sight of our mission–communication. Replacing a paper issue with a digital flipbook doesn't change the need for clear and accurate content especially in communicating with the public, an audience that spans across different socio-demographics and geography.

For medical writers and communicators, our superpower lies in words. This issue underlines this power is accompanied by a huge responsibility. A big, big thanks to superladies Sampoorna Rappaz and Lisa Chamberlain James for doing the heavy lifting in putting this issue together.

And to our membership, our readership, and our contributors, our heartfelt gratitude for accompanying us all the way!

Incoming President's Message

Embracing change and building connection: Reflections from Riga

Martin Delahunty
EMWA President 2025–26
president@emwa.org

doi: 10.56012/xsqx3837

Dear Friends, Colleagues, and EMWA Members,

As I write this message, I'm still energised by the exceptional EMWA Spring Conference we experienced together in Riga, (see picture at right). Four intensive days delivered an outstanding programme of 45 workshops, a symposium, four expert seminars, EMWA's Get into Medical Writing session for new medical writers, the Freelance Business Forum, and an update on The CORE Reference Project, which will celebrate its 10th anniversary in 2026.

While virtual events serve their purpose, there is something irreplaceable about in-person connections – those spontaneous conversations between sessions, meaningful exchanges over coffee and a walking tour, and candid insights from peers that simply don't translate in a virtual world.

I was particularly struck by the energy and enthusiasm of our many first-time EMWA members and conference attendees, and their positive experiences with the welcoming nature of the EMWA family reinforced what makes our community so special. This truly exemplifies that EMWA is by members, for members – a community where experienced professionals genuinely invest in supporting newcomers and each other.

With this in mind, I am already looking forward to next year's EMWA Spring Conference in Barcelona.

My journey to the presidency

It was in Riga at the annual meeting that I transitioned from President-Elect to President, and this vibrant conference sets the scene for my 12-month tenure. My first conference was EMWA's 2016 Spring Conference in Munich.

I was invited as a medical and scientific publisher to present and was immediately struck by the open and welcoming family that is EMWA. Despite not being a medical writer, I found that I and other publishing colleagues were able to bring an important perspective to help advance the profession of medical writing and medical communications.

When then President-Elect Sarah Tilly invited me to apply for this role, I felt both honoured and privileged, knowing the wealth of experienced medical writers in our organisation. The transition for me from President-Elect to President has been both humbling and inspiring, building on the exceptional foundation laid by Sarah's strong and inspiring leadership.

I am committed to following in her footsteps and continuing the excellent work of our organisation.

Acknowledging those who made this journey possible

I would like to thank the people who made my EMWA journey possible.

Slávka Baróniková, our Conference Director, originally invited me to present at the EMWA 2016 Spring Conference in Munich. Slávka has made a significant contribution to EMWA over the past 11 years and greatly encouraged me to support the organisation in whatever ways I can. Her dedication to creating exceptional conference experiences has been truly inspirational.

Outgoing EMWA President Sarah Tilly (2024-25), expertly guided me through my President-Elect year and has set a high bar for my presidential term. Thank you, Sarah, for your mentorship, strategic vision, and the countless hours you dedicated to advancing our profession during particularly challenging times.

Maria Kołtowska-Häggström, EMWA President 2023–24, worked with me on conference symposia and gave me valuable insight into how to create impactful and practical conference experiences for EMWA members. Her innovative approach to restructuring our Expert Seminar Series has had lasting benefits for our community.

Former EMWA Treasurer John Dixon deserves special recognition for his good humour and tireless, detailed work to help EMWA through a difficult transition of Head Office to our excellent new partner, CJ Association Management. His financial stewardship during this period was exemplary.

And thank you to many others who make my interactions with EMWA a real pleasure, including all our dedicated volunteers who contribute so generously to our mission.

Strategic progress and achievements

It has been my privilege to join the Executive Committee as EMWA's first President-Elect with a medical and scientific publishing background. During my President-Elect year, we navigated particularly challenging times while making significant progress on our strategic initiatives.

Our Special Interest Groups (SIGs) continue to flourish, having grown from our first Pharmacovigilance SIG established in 2015 to nine active SIGs today. Our newest addition, the Visual Communications SIG, chaired by Judit Mészáros, exemplifies how these focus groups bring together EMWA members who share common interests and collaborate on topics shaping the future of medical writing. All SIGs and their dedicated volunteers actively contribute to EMWA through journal articles, webinars, workshops, seminars, and conference sessions.

Our Local EMWA Groups (LEG) in Italy and Poland have been instrumental in supporting existing regional members and actively recruiting new ones. Last year, in addition to LEG-hosted hubs, EMWA organised eight regional networking hubs, attracting 243 attendees collectively. Our post-event survey revealed that

networking was participants' primary motivation for attending, with 50% being existing EMWA members and 13% of non-members indicating they were very likely to join.

Fostering strategic partnerships

A key component of EMWA's 2023–27 strategic plan focuses on fostering existing relationships and building new ones to drive inter-organisational initiatives and strengthen partnerships with regulatory and associated agencies. We've engaged in several discussions about potential collaborations, most recently with TOPRA (The Organisation for Professionals in Regulatory Affairs).

To better focus on this objective, we've implemented a more systematic approach to identifying valuable partner organisations through a two-tiered framework ranging from information exchange to educational collaborations. Moving forward, we will ensure all collaborations deliver clear benefits to EMWA members, develop practical and sustainable implementation processes, and establish metrics to evaluate success.

Embracing technological innovation

We established an EMWA AI Working Group comprising Sarah Tilly, Namrata Singh, Slávka Baróniková, and myself, with each SIG appointing a dedicated AI liaison. Our activities included a full-day AI Symposium in Valencia, follow-up webinars throughout the year, and virtual conference sessions featuring publisher perspectives on AI with input from editors at *The Lancet* and *JAMA*. Our ongoing aim is to empower EMWA members to be better informed and more confident when discussing AI with research authors, agencies, and clients as this field continues to evolve.

Medical Writing

Drawing on my academic publishing background, I've worked closely with Journal Editor Raquel Billiones and Web Manager Andrew Balkin to ensure our official journal, *Medical Writing*, continues to provide members with a valuable and practical resource.

Sarah Tilly, Maria Kołtowska-Häggström, Martin Delahunty

EMWA Executive Committee

We aim to transition *Medical Writing* from its current print and basic online format to an exclusively digital publication. The journal landing page on the website will also be reworked to minimise disruption.

These plans align with EMWA's 2023–27 Strategic Plan focusing on sustainability initiatives and *enhancing* membership value.

Recognising our community

I extend my sincere thanks to all our conference organisers and Head Office staff who work tirelessly to deliver exceptional experiences for our members. Special recognition goes to our Education Officers and the entire EMWA Professional Development Committee, as well as all our workshop leaders who contribute their expertise to advance professional development within our community.

Finally, I would like to thank all members of the previous Executive Committee who have welcomed me and made this transition seamless. It's important to remember that despite it feeling many times like a full-time job, all 12 members of the EMWA Executive Committee are volunteers.

Thank you also to Somsuvro Basu, the outgoing Honorary Secretary, for his humility and great humour over many years in his volunteering for EMWA. We are in a much better position thanks to his organisational work.

Thanks also to Diana Ribeiro, outgoing Public Relations Officer, whose tireless support and keen eye for member communications and building community online has made a huge difference.

I look forward to supporting our experienced Executive Committee and collaborating with our new members: Katrin Zaragoza Dörr (President-Elect), Sarah Choudhury (Honorary Secretary), Johanna Chester (Press Relations Officer) and Wendy Kingdom and Julie Cooper (Co-Treasurers).

I am confident that as a strong team with diverse skills and competencies, we will continue to grow the association for the benefit and professional development of EMWA members.

Looking forward

As we move forward, I am committed to upholding EMWA's values and mission of promoting the medical communication profession and impacting the industry positively. My expertise and passion for medical publications, combined with the collective strength of our Executive Committee and dedicated volunteers, positions us well to drive the organisation forward and ensure its continued growth and influence.

I look forward to serving as your President and working collaboratively with all stakeholders to advance our profession, strengthen our community, and deliver meaningful value to every EMWA member. Together, we will continue to build on our proud tradition of excellence in medical writing and communications.

Outgoing President's Message

Passing the torch: Reflections on my tenure as president

Sarah Tilly
EMWA President 2024–25
president@emwa.org

doi: 10.56012/ohoz5167

Dear EMWA Colleagues,

As I prepare to step down from my role as President of our medical writing association, I do so with a deep sense of gratitude and pride. It has been a genuine privilege to serve this extraordinary community—one rooted in friendship, purpose, and a shared commitment to clarity in healthcare communication.

When I began my tenure, I expected challenges, opportunities, and learning. What I did not anticipate was the sheer scale of collective progress we would achieve together. Over the past few years, we have navigated a rapidly evolving profession—from the integration of recent technologies to shifting regulatory landscapes and the changing role of medical communication.

Among the milestones I am most proud of are two key achievements that mark a new era for EMWA: the successful transition to a new Head Office, CJ Association Management, and the launch of our redesigned, future-ready website. Both initiatives reflect not only operational progress but a commitment to improving how we serve and connect with our members. These were significant undertakings that were only made possible by the collaboration, vision, and hard work of many.

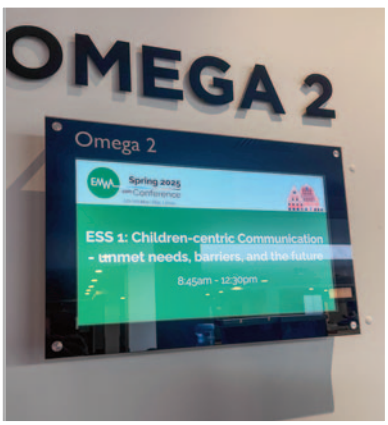
Beyond these projects, we have continued to champion professional development, extend our reach globally, and elevate the visibility of medical writing as a profession. Whether supporting early-career writers or advocating for ethical standards across the industry, EMWA has demonstrated time and again what a resolute community can accomplish.

Medical communicators are often invisible architects of clarity— transforming complex medical and scientific data into clear, impactful communication that drives better health outcomes. It is demanding work and being part of a network that values and uplifts our role has been both humbling and energising.

Of course, nothing we have achieved would have been possible without the outstanding commitment of the Executive Committee, our tireless volunteers, and the wider membership. You have challenged, supported, and inspired me every step of the way.

Leadership is not a destination but a transition. I am delighted to be handing over the presidency to Martin Delahunty, whose experience, integrity, and passion for the field will guide the association into its next exciting chapter. With Martin at the helm, I have every confidence that our momentum will continue to build.

Thank you for the honour of serving as your President. It has been one of the most fulfilling roles of my professional life.



Photos of the 59th EMWA Conference

Riga, Latvia, May 2025

"Medical writers have a significant impact on the lives of people like me, and their words help drive more inclusive, respectful, and human-centred healthcare communication. Thank you, EMWA, in particular, for truly listening."

Daniel Newman

Posted on LinkedIn: https://www.linkedin.com/in/daniel-newman-15275436

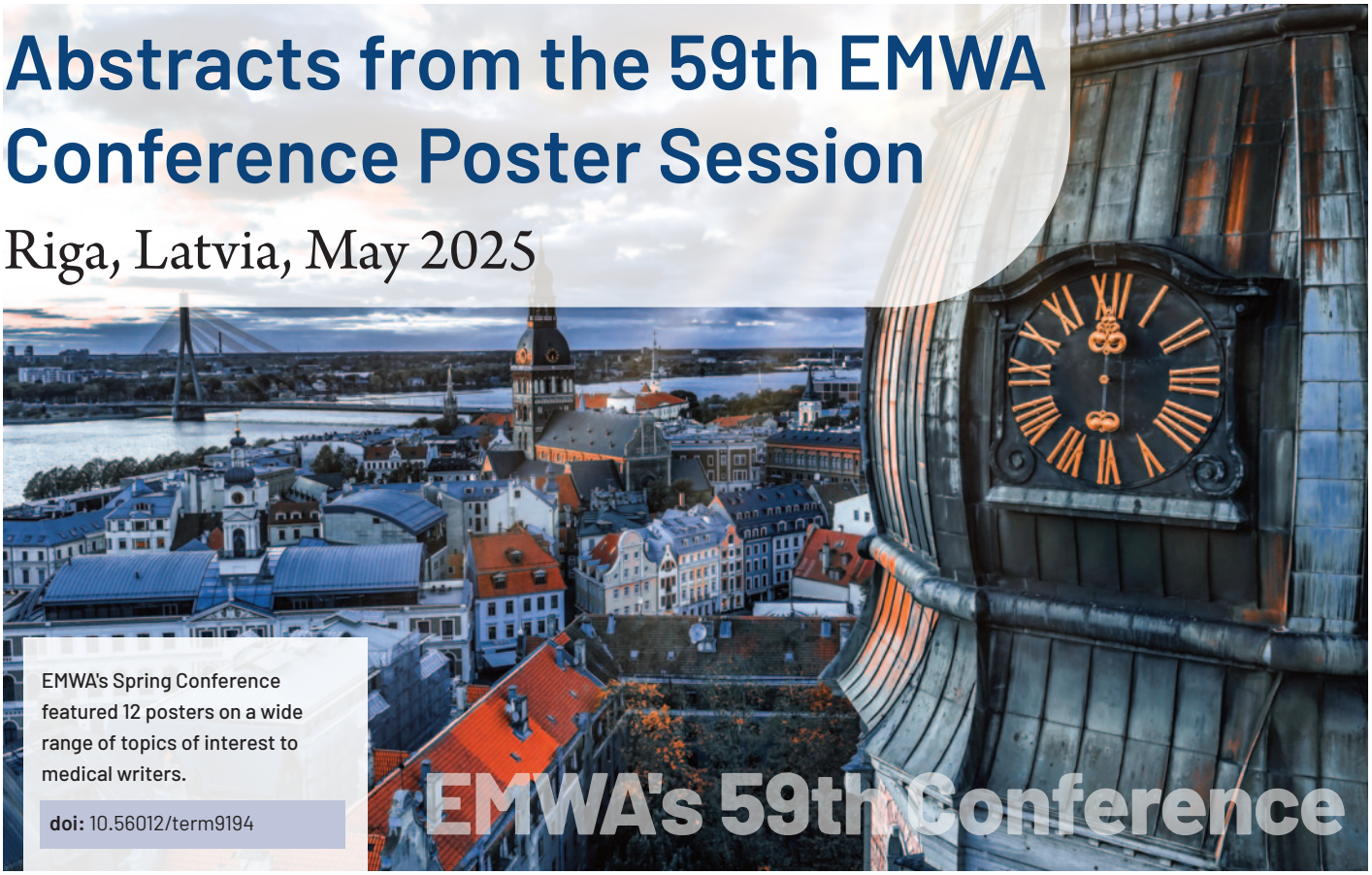
"To the Ones in Purple
So here's to those who choose to give,
Who help the writer's voice to live.
They wear their purple, proud and bright,
With care and craft, they spark the light.
They work each day, without delay –
Quiet heroes, in their way. 👏 (chatGPT)"

Olga Mezeine, referring to the EMWA Executive Committee

Posted on LinkedIn: https://www.linkedin.com/in/olgamezeine/

Abstracts from the 59th EMWA Conference Poster Session

Riga, Latvia, May 2025



EMWA's Spring Conference featured 12 posters on a wide range of topics of interest to medical writers.

doi: 10.56012/term9194

P1 Authoring of peer-reviewed articles on the experiences of patients with rare diseases by patients and their caregivers: A rapid review

Phil Leventhal[1]
Danielle Drachmann[2]
Rienne Schinner[2]
Soren Skovlund[2]
[1] PPD Clinical Research Business of Thermo Fisher Scientific
[2] Evidera, a business unit of PPD, a Thermo Fisher Scientific company

Introduction

Partnering with patients and caregivers as authors can help improve the relevance and reach of peer-reviewed publications, especially when they describe patients' experiences. Here, we examined the practice of including patients and caregivers as authors of peer-reviewed publications on the experiences of people with rare diseases.

Methods

Embase and Medline were searched on June 20, 2024, for peer-reviewed articles in English on the experiences, views, and values of patients with rare diseases using a validated search filter. Articles with patients, caregivers, or patient organizations as affiliations were selected automatically using search terms and then screened manually.

Results

One-hundred and ninety-seven articles with patients, caregivers, or patient organisations as author affiliations were identified. Since the first published in 2004, numbers have increased. The 197 articles represent 13% of the 1494 total peer-reviewed articles found on the experiences, views, and values of patients with rare diseases published in 2004–24. The proportion increased steadily with time to 22% in 2021 but has fallen since. The most frequent article types were qualitative study/survey (31%), consensus/guideline/recommendation (22%), and reviews (16%). 95% of authors identified as patients or caregivers were affiliated with rare disease associations. The term "patient author", promoted recently, was listed as the affiliation for only a single article.

Conclusions

Patients and caregivers are increasingly visible as co-authors of peer-reviewed articles on the experiences, views, and values of patients with rare diseases. A consistent way of identifying patient and caregiver authors in databases is needed to better understand their role and impact.

P2 Use of plain language summaries by healthcare professionals: an Open Pharma survey

Pippa Hadland – Evidence Generation, Publications and Partnerships, Oncology Business Unit, AstraZeneca, Cambridge, UK
Sarah Thomas – Ipsen, Wrexham, UK
Géraldine Drevon – GSK, Wavre, Belgium
Sophie Nobes – Oxford PharmaGenesis, Oxford, UK
Slávka Baróniková – Alfasigma S.p.A., Mechelen, Belgium
Jo Gordon – Oxford PharmaGenesis, Oxford, UK
Tim Koder – Oxford PharmaGenesis, Oxford, UK
Vicky Sanders - Oxford PharmaGenesis, Oxford, UK

Introduction

Plain language summaries (PLS) are easy-to-read summaries of scientific research articles.[1] Few articles are published with easy-to-find PLS.[2] However, healthcare professionals (HCPs) and other audiences value PLS,[3–5] and pharmaceutical companies are increasingly writing PLS to accompany articles.[6] Little is known about how HCPs find and use PLS; we developed a survey to find out.

Methods

An 18-question online survey was sent by email (24 April–17 June 2024) to 5141 individuals who had previously contributed to articles sponsored by AstraZeneca, Ipsen, or GSK.

Results

Of 188 respondents, three (2%) were excluded for not being HCPs. Most eligible respondents had >20 years' experience in clinical practice (62%, 115/185); 60% (111/185) did not speak English as their first language. Most respondents (72%, 133/185) had read/contributed to at least one PLS. These respondents found short, text-based (78%, 104/133) and infographic (71%, 94/133) PLS formats most useful; 73% (97/133) would like all Phase 3 articles to include a PLS. However, 5% (7/133) had never read/used the PLS when an article included one. The 126 respondents (95%, 126/133) who had read/used PLS used them to: quickly understand an article (76%, 96/126); keep up to date with topics outside their speciality (33%, 42/126); help interactions with patients/advocates (32%, 40/126); and/or share with patients/carers to read alone (32%, 40/126). Most respondents (71%, 89/126) found PLS by chance alongside articles.

Conclusions

PLS help communicate scientific research to time-poor HCPs. Publishing more PLS and improving how they are found will help broaden the impact of scientific research.

References

1. Rosenberg A, et al. Curr Med Res Opin. 2021;37:2015–6.
2. Gattrell W, et al. Curr Med Res Opin. 2022;38(Suppl 2):41–2
3. Lobban D, et al. Curr Med Res Opin. 2022;38(Suppl 1):32–3
4. Southey L, et al. Presented at the 2024 European Meeting of ISMPP, London, UK
5. Pushparajah DS, et al. Ther Innov Regul Sci. 2018;52:474–81
6. Ipsen. Available from: www.ipsen.com/general/our-pledge-summaries-in-plainlanguage-for-all-journal-publications. (Accessed 2024 August 28).

P3 Readability in medical and scientific writing: Current status and emerging trends from cognitive science

Florencia Garro - Freelance Regulatory Scientific Writer, Writthink Studio

Introduction

Good readability in medical and scientific writing ensures clarity, precision, and accessibility – three pillars of effective communication.[1] Yet, it has steadily declined over the past few decades.[2] Most readability metrics rely on grammatical or surface level features such as sentence and word length.[3] Recent research incorporates cognitive theories and AI-based approaches that better model how the brain processes text.[4-7] However, these advancements remain underutilised, with limited diffusion and practical applications in medical and scientific writing.

Methods

We conducted a narrative review, examining relevant peer-reviewed articles and tools to evaluate current readability metrics and their limitations. The analysis also identified emerging trends and novel applications for medical writing. The review is structured into five sections: a history of readability, cognitive theories of reading, the state of readability in science, new approaches to quantify readability, and barriers to effective implementation in medical and scientific writing.

Results

New readability metrics extend beyond surface-level features, including insights into cognitive mechanisms such as working memory, comprehension, and predictive processes. We identified key practical gaps for their adoption, including: 1. the lack of effective tools integrating these metrics into readability assessment, and 2. proper training and methodological frameworks for writers.

Conclusions

This review highlights advancements in readability methods that integrate cognitive factors. These can be developed into user-friendly tools for practical application, significantly improving clarity, precision, and accessibility – thereby enhancing and facilitating effective communication in medical and scientific manuscripts.

References

1. Vergoulis T, Kanellos I, Tzerefos A, et al. A study on the readability of scientific publications. In: Doucet A, Isaac A, Golub K, et al, editors., Digital Libraries for Open Knowledge. Cham: Springer International Publishing, 2019, pp. 136–144. doi:10.1007/978-3- 030-30760-8_12.
2. Plavén-Sigray P, Matheson GJ, Schiffler BC, et al. The readability of scientific texts is decreasing over time. eLife, vol. 6, p. e27725, Sep. 2017. doi:10.7554/eLife.27725.
3. Benjamin RG. Reconstructing readability: Recent developments and recommendations in the analysis of text difficulty. Educ Psychol Rev, 2012;24;1, pp. 63–88. doi:10.1007/s10648-011-9181-8.
4. Crossley SA, Skalicky S, and Dascalu M. Moving beyond classic readability formulas: New methods and new models. Journal of Research in Reading. 2019;42(3–4):541–61. doi: 10.1111/1467- 9817.12283
5. Crossley SA, Greenfield J, and McNamara DS. Assessing text readability using cognitively based indices. TESOL Quarterly. 2008;42(3):475–93. doi: 10.1002/j.1545-7249.2008.tb00142.x.
6. Zai AH, Faro JM, and Allison J. Unveiling readability challenges: An extensive analysis of consent document accessibility in clinical trials. Journal of Clinical and Translational Science. 2024;8(1):e125. doi:10.1017/cts.2024.595.
7. Ante L. The relationship between readability and scientific impact: Evidence from emerging technology discourses. Journal of Informetrics. 2022;16(1):101252. doi: 10.1016/j.joi.2022.101252.

P4 Simultaneous interpretation of live dental webinars: Views of an experienced international team

Diarmuid De Faoite – Align Technology
Richard Baker – Align Technology
Stefan Schalansky – Align Technology
Patrizia Mignani – M&A Consulting

Introduction

The Digital Excellence Series features a 90-minute-long webinar on a variety

of topics of interest to dental practitioners. Each webinar is simultaneously interpreted from English to French, Italian, German, Spanish, Polish and Turkish. Feedback is solicited from the presenters and audience at each webinar. This survey gave a voice to the interpreting team.

Methods

The team comprised 12 people, 2 per translated language who change over every 20 minutes. The interpreters completed an online survey to explore how they cope with the demands of these webinars.

Results

Table 1. Demographic information

Category	*N*
Mother tongue	
Spanish	3*
Turkish	2
German	2
Italian	2
Polish	2
French	2
Languages interpreted from	
English	12
Spanish	4
French	3
Italian	3
German	2
Catalan	2
Polish	1
Turkish	1
Years of experience in simultaneous interpretation	
15+ years	12
15 years or less	0
Background	
Interpreter specialised in dentistry/medicine	12
Dentist turned interpreter	0
Interpreting Education / Training (highest level obtained)**	
Masters' degree	7
Bachelors' degree	1
Yes but level not specified	3
None	1
Work status	
Full time	7
Part time	2
Freelancer	3

*One respondent indicated that they have 2 mother tongues.

** Five respondents have 2 or more linguistic-related degrees.

Conclusions

Simultaneous interpretation of dental webinars can be successfully carried out by non-dentists who are trained and very experienced in simultaneous interpretation with an ongoing commitment to learning about topics in dentistry.

P5 Informed consent forms (ICFs): Deploying AI and lean principles to make them simpler and more concise

Azuka Iwobi – Staburo GmbH
Tatiana R. Martins – Staburo GmbH
Ulrike Fischer - Staburo GmbH
Kathi Künnemann - Staburo GmbH
Seyma Öztürk - Staburo GmbH
Roelof Maarten Van Dijk - Staburo GmbH
Habib Esmaeili - Staburo GmbH

Introduction

Informed consent is a fundamental right for trial participants. Federal regulations emphasise that documents should be brief and presented in lay language. Currently, many ICFs score low in metrics assessing ease of readability, clarity, and appropriate length. In an age where infographics and media are increasingly popular, bloated and wordy documents impede understanding, and an overhaul of current practices is essential.

Using specific strategies, we present a useful approach to making informed consent fit for purpose.

Methods

Specific strategies to reduce verbiage and simplify writing with lean principles in mind will be discussed, with examples. The skillful use of infographics and icons to increase engagement, and the value of leveraging artificial intelligence (AI) to create impactful and leaner documents will also be highlighted.

Results

We show how tried approaches such as writing short and direct sentences in active voice will improve readability and length of ICFs. Through skillful deployment of prompts, we show how AI can be used to create brief and impactful text, while incorporating mandatory elements.

Drawing on lean principles, we additionally show how focusing on the key message can help reduce redundancies and eliminate excessive verbiage. Lastly, we show the effectiveness of infographics and pictures in portraying otherwise complex ideas.

Conclusions

Simplified ICFs will go a long way in enhancing reader experience and engagement. Trial participants will be better able to understand the "whys", "whats", and "ifs" of a study and be in a better position to give consent (or not) in such a transparent setting.

P6 Enhancing clinical and regulatory documentation with structured content authoring and AI integration

Mati Kargren – Parexel International Co., Ltd., Taipei, Taiwan
Jonathan Mackinnon – Parexel International S.L., Madrid, Spain

Introduction

The pharmaceutical industry is transitioning from manual, unstructured document development to a content-based approach using structured content management (SCM) tools. This shift aims to streamline workflows, improve consistency, and enhance efficiency in clinical and regulatory documentation. As the industry explores generative artificial intelligence (GenAI), structured content authoring (SCA) emerges as a key enabler for integrating AI-based solutions into regulatory and medical writing processes.

Methods

Parexel Medical Writing Services implemented SCA for various clinical study documents and periodic safety reports in 2022. Recently, we have been augmenting SCA with GenAI functionality, allowing pre-configured AI prompts and user-derived GenAI content incorporation. We have collated qualitative lessons learned from the implementation of SCA and GenAI augmentation of our SCM system.

Results

SCA implementation demonstrated decreased document production time, enhanced first-time quality, and improved content strategy implementation through metadata-driven standardised content incorporation and configurable templates. GenAI augmentation further enhanced efficiency by reducing adoption barriers through programmable prompts, allowing targeted control of prompt usage, and offering users enhanced flexibility in content generation and modification.

Conclusions

The integration of SCA with GenAI enhances efficiency, consistency, and quality in the development of clinical and regulatory documents. This combination streamlines workflows, improves information summarisation, and enhances quality control. As these technologies evolve, they promise to transform traditional content creation processes, potentially accelerating time-to-market for new products while maintaining compliance with industry standards, marking a significant advancement in regulatory and medical writing.

P7 Poster withdrawn

P8 Update On master clinical study protocol preparation: Roll out and future considerations

Petra Delgado Romero – Global Medical Writing, Merck Healthcare KGaA, Darmstadt, Germany
Sabrina Stoehr – Global Medical Writing, Merck Healthcare KGaA, Darmstadt, Germany

Introduction

We developed a master clinical study protocol (CSP) to evaluate the clinical activity of a new drug across multiple indications, following the structure presented at the EMWA 2024 Conference in Valencia, Spain.

Methods

The master protocol included the common trial elements, while disease-specific aspects were presented as separate sub-study protocols. To enhance clarity and avoid confusion, we outlined the overall protocol structure at the beginning of the master protocol. Recognising the complexity of a master CSP, we briefed internal reviewers and the quality control (QC) team prior to their evaluations.

Results

As medical writers we prioritised clear, unambiguous language and a consistent structure, aiming for simplification to facilitate efficient trial implementation and execution. This approach has been validated by successful submissions and approvals in multiple countries, with no issues regarding structure, complexity, or readability raised by regulatory authorities or ethics committees.

The flexibility of the master CSP enables compliance with country-specific requirements while maintaining a harmonised global protocol and allows for adaptations as the study progresses. Careful documentation of amendments and version relationships will be essential for quality assurance.

Conclusions

The successful development of this master CSP demonstrates the potential for innovative trial designs to accelerate drug development and sets a precedent for our future clinical initiatives. This experience underscores the importance of strategic planning, regulatory alignment, and cross-functional collaboration in the effective implementation of complex clinical trials, ultimately demystifying the process of preparing a master CSP.

P9 From complexity to clarity: The power of lean and deductive medical writing

Maria Wendt – Merck Healthcare KGaA, Darmstadt, Germany
Michael Gyulay – EMD Serono Research & Development Institute, Inc., Billerica, MA USA

Introduction

Deductive writing and lean writing techniques are essential in the regulatory environment, where clarity and efficiency significantly impact the review and approval process. Deductive writing emphasises presenting conclusions upfront, followed by supporting details, ensuring that critical information is immediately accessible. Lean writing eliminates redundancies and focuses on delivering concise content, saving reviewers' time, and facilitating swift data extraction. Here we report on the steps taken to implement these writing styles in our company.

Methods

We collected and evaluated different approaches, tools, and training materials that were used in our company to see which were most successful and why. We also examined the impact of these writing techniques on clarity, efficiency, and stakeholder engagement and identified best practices.

Results

To promote the adoption of deductive writing among stakeholders, it is essential to emphasise its advantages, such as improved document clarity and reduced review times, while addressing potential drawbacks like perceived rigidity and resistance from stakeholders accustomed to more traditional writing styles. By providing tools such as training sessions and practical examples, stakeholders can be convinced of the benefits of deductive and lean writing in regulatory contexts. Consistent training is crucial especially within high turnover teams.

Conclusions

Implementing deductive and lean writing techniques is pivotal in optimizing the regulatory review process. By prioritizing clarity and brevity, these methods enable reviewers to locate critical data efficiently, reducing overall review timelines and enhancing decision-making. However, implementing these techniques requires a combination of structured training, practical tools, and active stakeholder engagement.

P10 The 7Ps and the 7Cs of Medical Writing

Asha Liju – Parexel International Ltd.
Kavita Muchandi – Parexel International Ltd.

Introduction

Medical Writing encompasses two crucial components: the "writing" aspect and the "project management" aspect (Figure 1). Both are equally important and require deliberate effort to master. By honing skills in both areas, one can advance from being a good medical writer to an excellent one.

Figure 1. Components of Medical Writing

Methods

To address the need for comprehensive training for interns and new writers, we conducted a brainstorming session to identify critical aspects of medical writing that are essential for project success. This collaborative effort led to the development of training material focused on Project Management and Good Medical Writing Practices – what we termed as "The 7Ps and the 7Cs of Medical Writing."

Results

The 7Ps and the 7Cs of Medical Writing are depicted in Figure 2 and Figure 3. These will be discussed in detail during the session with real-life examples.

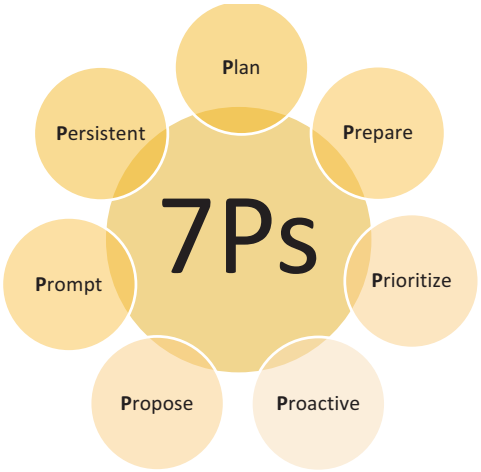


Figure 2. The 7Ps of Medical Writing

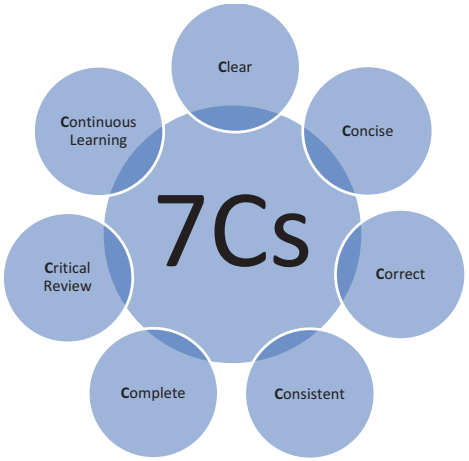


Figure 3. The 7Cs of Medical Writing

Conclusions

Progressing from a good writer to an excellent writer requires dedication and continuous effort. Continuous learning is a fundamental aspect of a writer's journey – we learn and grow every day. Embedding the principles of the 7Ps and the 7Cs has helped writers enhance their skills, produce higher quality work, and contribute more effectively to the field of medical writing. We hope that these insights will support new medical writers as they embark on their career journey, as well as provide valuable enhancements for experienced writers in the industry.

P11 Building a supportive framework for effective onboarding and integration of medical writers in a remote/office hybrid team environment

Inge Leysen - SGS Health Science, Mechelen, Belgium
Julie Tobback - SGS Health Science, Mechelen, Belgium

Introduction

Despite a solid onboarding procedure, our first online onboarding was not a success story, partly because we failed to adjust to the then new online environment. We also experienced obstacles to the peer experience sharing that our medical writing (MW) team has always relied on to increase quality of deliverables, which continued in the current hybrid working environment.

Methods

What we implemented:

- Intense training with daily (face-to-face) contact during first 2 weeks
- Designated contacts for questions
- Mentoring by dedicated experienced MW
- Twice weekly prebooked slots for questions (MW group until 1 or 2 years experience)
- 4-weekly check-ins for all team members with ongoing feedback
- Monthly team meetings
- 4-monthly experience sharing workshops for entire team
- Generally encouraging team spirit, asking questions, and sharing experience

Results

Intense training with lower threshold for asking and receiving support led to smoother onboarding and rapid learning. Client feedback regarding quality generally does not differ between newly onboarded MWs and the rest of the team. A major contributing factor to the success of this system is the lowering of threshold for asking and receiving support, achieved by the mix of individual contacts and prebooked (partial) team meetings.

Conclusions

Medical writing requires a unique set of competencies that need to be developed in situ. The flexibility inherent in a CRO setting demands long-term ongoing training. The supportive framework we implemented allows us to leverage individually acquired experience to serve the entire team in our current remote/office hybrid environment.

P12 Role of a disclosure manager – much more than study registration and results disclosure

Azuka Iwobi – Staburo GmbH, Munich, Germany
Edith Küpper – Staburo GmbH, Munich, Germany
Roelof Maarten Van Dijk – Staburo GmbH, Munich, Germany
Enrica Zanuttigh - Staburo GmbH, Munich, Germany
Habib Esmaeili – Staburo GmbH, Munich, Germany

Introduction

The clinical transparency landscape is an ever evolving one, with revised regulations and requirements changing the way we publicly disclose study information. At the heart of these processes are disclosure managers or data transparency specialists. They bridge the gap between the complex regulatory clinical research environment and the public. But how exactly do they do this and how does their expertise complement the work we do as medical writers?

Methods

Disclosure managers are involved in a study throughout its entire lifecycle – from protocol draft to sharing of individual patient data. Along the way, they interact with many stakeholders, including medical writers, trial leads, statisticians, programmers, regulatory affairs specialists, pharmacologists, and patent attorneys.

This poster aims to explore the typical day of a disclosure manager. We show with examples how a disclosure manager liaises with the medical writer and others to ensure that trial protocols and reports, before finalisation, are ready for disclosure on public registries, and that structured data are properly disclosed.

Results

We present results of how the disclosure manager's valuable input throughout a study's lifecycle results in fit-for-purpose disclosure data. We show specific examples of how they ensure that disclosed endpoints match study objectives, study synopses meet regulatory requirements, and adverse event reporting among others is properly implemented. Through their input at the draft stages of study documents, multiple revisions and review rounds are prevented.

Conclusions

We highlight how strong interdisciplinary communication between transparency specialists and medical writers and other stakeholders is imperative for successful disclosure activities.

P13 Patient expert review of data privacy graphic in informed consent

Karen Hinkle – Boehringer Ingelheim
Kristi Malone – Boehringer Ingelheim
Sebastian Florescu – Boehringer Ingelheim

Introduction

Data privacy is a crucial yet complex concept to convey to potential clinical trial participants in informed consent forms. To enhance participant understanding of trial data privacy, we developed a straightforward data privacy graphic. A recent review by patient experts led to significant improvements in the graphic, aligning with our goal of maximising patient comprehension in the informed consent process.

Methods

We gathered feedback on the data privacy graphic from 30 international patient experts. This feedback was collected through a pre-meeting survey and a face-to-face meeting. Quantitative and qualitative feedback were summarised and used to inform updates to the privacy graphic. The consultants provided insights on various components, including clarity of the information presented, effectiveness of the visual elements, and overall layout of the graphic.

Results

Based on the patient expert feedback, we implemented several improvements to the graphic. These included enhancements to the layout, text, and imagery to make the information more accessible and easier to understand. The revised graphic was then re-tested with patient experts to ensure that the changes led to better comprehension. The feedback from this second round of testing indicated that the improvements were successful in making the graphic more accessible.

Conclusions

The results of this ongoing study will be shared with meeting participants. Overall, the study underscores the importance of incorporating patient feedback in informed consent forms to improve the understanding of trial participants. This approach supports best practices in patient-centred communication and highlights the value of engaging patients in the development of clinical trial materials.

EMWA News

SECTION EDITOR

Somsuvro Basu
basu.somsuvro@gmail.com

doi: 10.56012/frnz8066

Ambassador Programme

The EMWA Ambassador Programme is continuing its efforts to reach out to new audiences to promote medical writing and EMWA and has supported the following events:

On February 14, **Andrea Rossi** and **Johanna Chester** gave a presentation about careers in medical writing and the benefits of joining EMWA to participants in a Masters of Regulatory Activities course at the University of Sienna. Andrea and Johanna also discussed EMWA's Professional Development Programme, mentoring, and the Geoff Hall Scholarship for 2025.

On February 19, **Philip Burridge** of Morula Health, in cooperation with the EMWA Ambassador Programme, gave a presentation at the University of Surrey at a seminar series aimed at PhD students and postdocs from the biosciences. Phillip promoted EMWA as a resource to learn more about medical writing in the pharmaceutical industry.

On February 25, **Katrin Zaragoza Dörr** gave a presentation at the University of Barcelona for the master's students in molecular biotechnology. The roundtable was part of a course on "Legal issues, Research & Development management, start-up creation, and entrepreneurship in biotechnology and biomedicine." Katrin shared copies of *Medical Writing*, EMWA flyers, QR codes to the *Getting Into Medical Writing Career Guide*, and the journal issue dedicated to *Careers in Medical Writing* that is posted on the EMWA website.

If you are an experienced medical writer and EMWA volunteer and are interested in becoming an EMWA Ambassador or if you know of any upcoming career events in your locality, please contact the EMWA Head Office (info@emwa.org) or Abe Shevack (aspscientist@gmail.com).

EMWA volunteers

EMWA volunteers help to further the development of your association.

You can get involved in a very limited way or become part of a larger project. The choice is yours, and everyone shares in the benefits.

- Help promote the role of medical writers and strengthen our association.
- Help to raise the standards of your field.
- Increase your visibility and communication opportunities with other medical writing members.
- Add some prestige to your CV while participating in exciting activities.
- Improve your knowledge of medical writing and related topics.

If you are a member of EMWA and eager to support ongoing initiatives, please check the following page: https://www.emwa.org/about-us/emwa-volunteers/ Alternatively, contact the Public Relations officer (pr@emwa.org) to discuss other opportunities available.

Did you know?

Existing EMWA members can receive a 10% discount off their next year's subscription for referring a new member to EMWA. For more information, please contact Head Office at info@emwa.org

Check out the back issues of EMWA's journal *Medical Writing* at https://journal.emwa.org!

EMWA Special Interest Groups

EMWA membership allows you to participate in any **Special Interest Group** (SIG) Meet and Share, even if you are not an active member of that SIG.

These events are announced in the EMWA newsletter and in a separate mailing closer to the event date. The Meet and Share sessions are great opportunities to learn more about a particular topic in an informal setting. Some sessions may be recorded, but many are not.

SIG members, on the other hand, participate in all SIG meetings (as their availability permits) and/or are more involved in the SIG activities, requiring an active role in providing more in-depth knowledge about what is going on in the SIG area.

If you are interested in knowing more about the SIGs, please read this: https://emwa.org/communities-engagement/find-communities/special-interest-groups-working-groups/

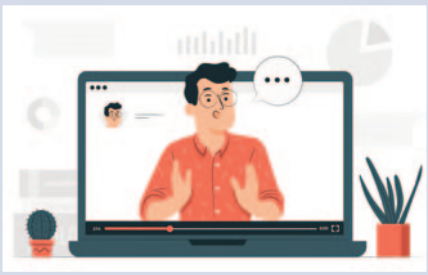
CORE Reference

The CORE Reference Project is moving.

It is moving away from email and onto LinkedIn to streamline our distribution of educational materials, including the monthly News Summaries: https://www.linkedin.com/company/the-core-reference-project/

News Summaries and useful information up to the end of 2024 are archived at: https://www.core-reference.org/news-summaries/

webinar



EMWA Professional Development Committee Webinar

EMWA webinars help members to develop skills and keep up to date with new or rapidly developing areas.

Most of our webinars are live, online seminars with the opportunity for participant interaction.

Webinar access is reserved for EMWA members only and requires registration. For the planned or past webinars, please refer to this page: https://emwa.org/education/emwa-webinars-programme/

Photo: Freepik

Celebrating its past, European Medicines Agency looks to the future of public communication

Nacho Mbaeliachi
European Medicines Agency
Amsterdam, The Netherlands

doi: 10.56012/jkzv5290

Correspondence to:
Nacho Mbaeliachi
nacho.mbaeliachi@ema.europa.eu

Abstract

As the European Medicines Agency (EMA) marks its 30th anniversary with a series of events at its offices in Amsterdam, one area in the spotlight is EMA's communication with the public. The Agency has made significant strides in this area over the past three decades, and it faces new challenges today. There are also exciting opportunities brought about by changes to the pharmaceutical and technological landscape.

As the European Medicines Agency (EMA) marks its 30th anniversary this year with a series of events at its offices in Amsterdam, one area in the spotlight is EMA's communication with patients and the public.

It is an area in which EMA's practices have evolved considerably over the past 30 years and one which, given ongoing societal and technological trends, could be on the cusp of an even greater transformation.

From its creation in the 1990s, the decade during which the internet became commercialised and available to everyday people, the Agency has had to contend with the challenges and opportunities of transparency from the start.

The European public assessment report

Early on, EMA introduced the concept of the European public assessment report (EPAR). A world first, the EPAR generated significant disquiet at the time, with some industry insiders certain that it would sound the death knell for the pharmaceutical industry in Europe. Up to that point, the ins and outs of a marketing authorisation application were considered secret and the careful weighing of the evidence by regulators something that should be beyond the gaze of the wider public. Absurdly, some even considered the summary of product characteristics (SmPC), which contains valuable information for healthcare professionals, to be proprietary information not for publication on a regulator's website.

> European public assessment reports were a sea change in how the Agency saw its role in connecting with the public.

Today, the EPAR is a standard transparency tool underpinned by EU legislation. Each centrally authorised medicine has an assessment report, detailing the Agency's evaluation of the medicine, accompanied by a short summary in lay language, the SmPC and package leaflet as well as other authorisation details, all published as part of an EPAR.

To meet the goal of reaching the lay public, EMA hired professional medical writers who produce "medicine overviews" – previously called EPAR summaries – which are available in all official EU languages and serve as landing pages for each medicine on EMA's website.

EMA took the EPAR concept further with the publication of assessment reports, which include plain-language question-and-answer summaries, for medicines that were refused authorisation or for which companies decided to withdraw their applications.

This was a sea change in how the Agency saw its role in connecting with the public. If a patient had the right to know why a medicine was authorised, they should also have the right to know why a medicine might have been denied to them. Sometimes a medicine might miss out on an authorisation because of less-than-robust efficacy or safety data. Sometimes it could be because the company had failed to address some uncertainties or because they encountered good manufacturing practice (GMP) problems and could therefore not guarantee the quality of the medicine. Today, the Agency releases information of this kind routinely, but it had to overcome stiff resistance from an industry not used to having information on failed applications freely available to the public.[1]

The principle behind the EPAR has been extended to other major procedures at EMA, such as EU-wide safety, harmonisation, and arbitration procedures (also known as referrals). For each of these, the Agency publishes an assessment report detailing the basis for the opinion of its committees (the Committee for Medicinal Products Human Use [CHMP] or Pharmacovigilance Risk Assessment Committee [PRAC]), preceded by a lay language document or news item for the public.

> The concept of the European public assessment report has now grown beyond the European Union to become a global standard.

The concept of the EPAR has now grown beyond the European Union to become a global standard. Many types of public assessment reports (PARs) are published today by different regulators across the world. And a PAR, with or without a lay summary, for approved and rejected applications is now a requirement of the WHO's benchmarking tool for national regulatory systems.[2]

Current communication challenges

But publishing information is just the start of the challenge. As the Agency, along with other regulators around the world, has increased its output, including information targeted at the public, so have other sources. The rise of social media platforms has changed how public information gets shared and received.

> While the proliferation of sources of information can be of great value, it also brings the risks of misunderstanding as well as mis- and disinformation, which can negatively impact people's health and their trust in the regulatory system.

While the proliferation of sources of information can be of great value, it also brings the risks of misunderstanding as well as mis- and disinformation, which can negatively impact people's health and their trust in the regulatory system. The challenge is particularly acute in times of crisis, such as during pandemics when heightened interest in the regulation of medicines comes face-to-face with direct concerns about government policies and fears for the future.

And just as the internet brought challenges and opportunities for transparency about medicines regulation in the 1990s, so also, and perhaps to a greater degree, will artificial intelligence (AI) come with its own unique challenges and opportunities. Sources of information – both credible and not – are already increasing as more people use AI to generate and search for information. In this new setting, AI could be used to help guide people through the vast amount of information that regulatory authorities provide.

In some ways it feels just like the 1990s again with a new technology coming into widespread use, except that the stakes seem higher. We operate in a society with higher expectations and more distrust of authorities than 30 years ago. And while it is easier to find reliable information about medicines, it is also easier to come across information that is unreliable, misleading, or intentionally false, and harder than ever to tell them apart.

EMA prioritises communication with the public

Difficulties in telling reliable information from false information is why the latest strategy of EU regulators prioritises communication with the public and the use of technologies such as AI.[3] EMA is also looking for ways to improve the readability of the materials it publishes and to ensure that they are easily accessible to the public. A prime example of work on accessibility is the electronic product information (ePI) initiative, which aims to make the production information (including SmPC and package leaflet) more accessible and searchable in all EU languages. A recent ePI pilot programme has paved the way for implementation in routine regulatory processes.

EMA's strategy for the coming years goes beyond communication and focuses too on engaging effectively with stakeholders, building on the work already done

Photo: Freepik

with them throughout the medicines lifecycle.[4] EMA intends to continue increasing the participation of patients and consumers in a variety of pre- and post-authorisation activities, even as more patient involvement is expected following the proposed revision to the EU pharmaceutical legislation.[5]

Industry also has a critical role to play. Medical writers working in the private sector produce many of the documents that patients will eventually read, including lay summaries for clinical trials.

Final remark

If we want to avoid mis- and disinformation and anti-science narratives taking over, work with all stakeholders will remain crucial. It is important that the European public is not only adequately informed about the medicines they use but can also be confident in the regulatory system that authorises them.

> While it is easier to find reliable information about medicines, it is also easier to come across information that is unreliable, misleading, or intentionally false and harder than ever to tell them apart.

Disclaimers

The views expressed in this article are the personal views of the author and may not be understood or quoted as being made on behalf of or reflecting the position of the EMA or EMWA.

Disclosures and conflicts of interest

The author is employed by the EMA.

References

1. EMA. What we publish on medicines and when. 2025 [cited 2025 Feb 10]. Available from: https://www.ema.europa.eu/en/medicines/ what-we-publish-medicines-when
2. WHO. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medicines and vaccines. 2025 [cited 2025 Feb 10]. Available from: https://www.who.int/tools/global-benchmarking-tools/VI
3. EMA. European medicines agencies network strategy. 2025 [cited 2025 Feb 10]. Available from: https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/european-medicines-agencies-network-strategy
4. Silva I, Gabrielli G, Garcia Burgos J, et al. A decade of collaboration in medicines regulation: healthcare professionals engaging with the European Medicines Agency. Front Med (Lausanne). 2024;11:1399947. doi:10.3389/fmed.2024.1399947
5. The European Commission. Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency. 2025 [cited 2025 Feb 10]. Available from: https://health.ec.europa.eu/publications/proposal-regulation-laying-down-union-procedures-authorisation-and-supervision-medicinal-products_en

Author information

Nacho Mbaeliachi works at the Stakeholders and Communications Division at the European Medicines Agency. He had worked previously as a medical writer for contract research organisations in the UK and Switzerland.

Towards electronic product information that meets the needs of everyone: Implications for patients, clinicians, and medical writers

Behtash Bahador,[1] **Trishna Bharadia,**[2] **Derek Stewart,**[3] **Christopher C. Winchester**[4,5]

[1] Center for Information and Study on Clinical Research Participation (CISCRP), Boston, MA, USA
[2] The Spark Global, Buckinghamshire, UK; Patient Author; Visiting Lecturer, Centre for Pharmaceutical Medicine Research, King's College London, London, UK
[3] Patient Advocate; Patient Author, Nottingham, UK
[4] Oxford PharmaGenesis Ltd, Oxford, UK
[5] Green Templeton College, University of Oxford, Oxford, UK

doi: 10.56012tcvr4151

Correspondence to
Christopher C. Winchester
chris.winchester@pharmagenesis.com

Abstract

In an age of increasing digitisation, pharmaceutical product information is evolving. This transformation reflects growing recognition among regulators of the value of patient engagement and widespread societal calls for increased transparency of and access to medical information. We consider the future of pharmaceutical product information, reimagining the electronic product information (ePI) as an interoperable and informative platform that links core product information to a range of supporting medical information resources. We consider the benefits that this evolution can afford different stakeholder groups in terms of increased transparency, enriched information provision, and tailored information solutions, as well as the potential challenges that will need to be addressed. We also discuss the critical role that medical writers can play in informing and shaping the future of ePI for the benefit of all.

ePI: What it is, where it began, and how it is beginning to evolve

"Product information" is the information about the efficacy, safety, and appropriate use of a drug that is approved by medicines regulators for distribution to healthcare professionals, patients, and the public. The term encompasses the product label, the packaging leaflet, and a more in-depth technical document that summarises the data underpinning the product approval and its approved use.[1] The packaging leaflet is the patient-facing information included within the medicine box that provides instructions for use and information about possible side effects. The more technical document is referred to as the "prescribing information" in the USA and as the "summary of product characteristics" in Europe. Product information has huge potential to support patient care and inform clinical decision-making, particularly if it evolves in response to user needs to embody principles of trust and transparency.[2]

Product information is already evolving. It was originally a paper-based document designed by regulators primarily for expert audiences, but regulators are already recognising the potential value in making the information more user-friendly so that it can meet the needs of a range of different stakeholders, including patients.[3] These changing attitudes to product information have been accompanied by several complementary drivers and enablers of change, including environmental initiatives to reduce packaging,[4] the progressive shift towards digitisation of information, increased emphasis on patient–physician shared decision-making practices, and calls for increased transparency in healthcare information (Figure 1). Together, these social and regulatory factors have converged to create a unique opportunity to reimagine product information as an accessible and transparent electronic resource tailored to a range of stakeholder needs.

As part of an ongoing movement towards digital transformation, the package leaflet is already available in some regions in an online PDF format, as a complement to the traditional paper-based form.[5] The content of the PDF mirrors the paper-based product information,[4] but it has the advantage of being searchable and shareable, and it can also be easily enlarged to aid legibility. The next step is to transition towards true electronic product information (ePI) – an interoperable and informative platform linking core product information to a range of supporting medical information resources, including links to additional patient information resources.

> Traditionally, discussions about product information evolving from paper-based to digital formats have been approached from an environmental and sustainability perspective.

Traditionally, discussions about product information evolving from paper-based to digital formats have been approached from an environmental and sustainability perspective.[6] These considerations should be expanded to reflect the potential that ePI offers for improved transparency of medical information, the associated health equity benefits, and the potential for companies to roll out new medicines more quickly with real-time updates to safety information to reflect post-authorisation studies, should a paper leaflet not be

required. Realising ePI as a layered content platform would allow all stakeholders (including healthcare professionals, patients, carers, and policymakers), to access information relevant to and appropriate for their own specific needs; in the case of patients, potentially supporting them with medication compliance and to engage in more informed, shared decision-making.

Recent revisions to traditional regulatory positions on product information reflect growing recognition of the importance of engaging patients as partners in healthcare decision-making.[7] The official US Food and Drug Administration (FDA) position (1938) stated that product information should be for expert audiences and not necessarily understandable by the lay person.[8] A FDA consultation published in 2023 highlighted evolving regulatory attitudes to product information, driven by increased recognition that providing transparent, patient-friendly, written information about prescription drugs can improve health outcomes.[3] In addition, in 2020, the European Medicines Agency (EMA) published key principles to guide the development and use of ePI, with a focus on improving accessibility, searchability, and multilingual capabilities.[9] The EMA's adoption of the HL7 Fast Healthcare Interoperability Resources standard and participation in a one-year ePI pilot project in Denmark, the Netherlands, Spain, and Sweden between July 2023 to August 2024 have further advanced digital interoperability within healthcare systems.[10] In addition, technical requirements for structuring product information from Japan and the USA have laid the foundations for ePI in these regions.[11,12] The increasing digitisation, standardisation, and interoperability of medical information creates an environment ripe for collaborative approaches to reimagining ePI for the benefit of all.

Photo: Freepik

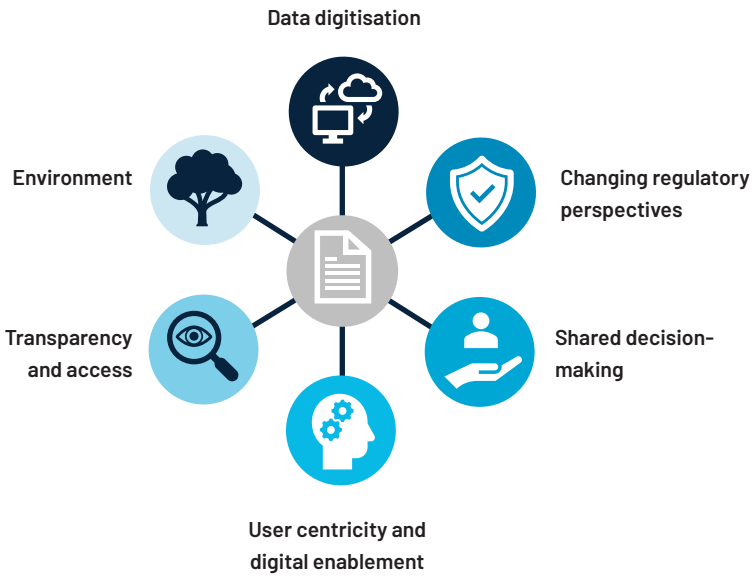


Figure 1. Key factors driving the evolution of product information

ePI can optimise access to product information that meets the needs of all stakeholders

By harnessing the opportunities presented by digitisation of information, ePI platforms could provide an opportunity to tailor information for all stakeholders, ensuring everyone has access to reliable, transparent, verified, compliant, and appropriate product information relevant to their needs.

There is already a wealth of high-quality medical information available online or in a digital format, and ePI offers an opportunity to link these materials together to increase discoverability and transparency. Including live links in ePI has the potential to increase access to the highest-quality, peer-reviewed evidence and aggregate key medical information at a single, centralised location. This could also increase the discoverability of assets that might otherwise be overlooked in supplementary materials, such as plain language summaries of publications, infographics, and guidance for non-healthcare professionals on how to interpret clinical trial data. Indeed, ePI could become a tool to improve health literacy and to enhance accountability, transparency, and trust in medical research.

Table 1. Considerations, opportunities, and challenges/risks associated with ePI

Consideration	Opportunity to:
Cultures/languages	Adapt materials to align with different cultural practices and languages in order to maximise impact across a wide range of audiences
User attitudes and behaviours	Address different users' attitudes and behaviours to healthcare information in order to increase engagement
Health literacy	Develop and link to a broad range of materials suitable for differing levels of health literacy and information needs among users (e.g., plain language summaries for patients and non-specialist healthcare professionals; linked clinical trial information for healthcare professionals and researchers)
Usability	Consider features such as font size controls, and using a narrator to read text aloud in order to increase access for users with vision and/or reading challenges
Learning modes	Develop and clearly signpost materials appropriate for different learning styles (e.g., formats tailored to auditory, visual, and reading/writing learners)
Digital equity	Offer digital formats as an addition to paper-based ePI materials to support a transition from paper-to-digital formats, recognising differing levels of digital access and comfort across potential user groups
Empowering caregivers	Enable caregivers (local or remote) to provide informed support for relatives/friends by allowing them digital access to medicines information
Trust	Counteract medical misinformation by linking to high-quality, evidence-based materials (e.g., peer-reviewed and regulatory-approved information), ideally aggregated through effective use of metadata

Abbreviations: ePI, electronic product information

Examples of the ways in which ePI could potentially benefit different stakeholders include:

- Improving patient care by directly linking ePI to healthcare applications that support patients in self-management
- Offering patients and carers links to additional information about possible drug–drug interactions and contraindications for newly and currently prescribed medications with real-time updates to safety information, as required, to reflect emerging data from post-authorisation studies
- Allowing a carer who may be in a different city to the family member they are caring for to access information on appropriate dosing to help "guide their relative at a distance"
- Enabling patients to access a translation (or more easily understood version) of the product information for their newly prescribed medication that is specific to their indication
- Supporting visually impaired patients owing to the adaptability of font size and compatibility with software that reads text aloud
- Countering misinformation about prescribed medicines through enhanced transparency – linking users with reliable source information (e.g., ClinicalTrial.gov records, plain language summaries [including clinical trial lay summaries], and peer-reviewed journal publications of the study results).

By initiating conversations around digitally optimised ePI early in the development of a medicine, a wide range of linkable resources could be efficiently developed in anticipation of drug approval, including materials that supplement the required paper-based product information leaflet and address additional stakeholder needs. Thinking digitally from the outset allows materials to be prepared throughout the development and lifecycle of a drug with the potential for ePI curation in mind. The report from the aforementioned European ePI pilot included recommendations for supplementary guidance and business process updates to support integration of ePI alongside existing practices.[10]

In summary, a standardised ePI template to address the considerations outlined in Table 1 has the potential to reduce health inequity, improve understanding, increase transparency, promote global engagement for all stakeholders, and help to support informed shared decision-making. As with all innovations, however, an evolution to ePI would need to be handled with consideration to optimise the potential benefits while minimising possible unwanted implications, such as exacerbation of existing inequalities in digital and health literacy.

Barriers to realising the positive potential of ePI may need to be overcome

It is important to recognise that digital literacy and digital access vary between different demographic and sociodemographic subgroups, and between different regional and national locations. Until substantial improvements are made towards global digital equity, it is important for regulators, healthcare professionals, and medical writers to be mindful of ensuring that printed paper copies

of all components of product information remain available to those who might otherwise be at risk of digital exclusion.[6,13]

The potential drawbacks of digitising product information should also be considered from the perspective of healthcare professionals and pharmacists who may fear that ePI could increase the time and cost burden associated with providing accessible and up-to-date information to patients and caregivers. Furthermore, despite the focus on the environmental benefits of ePI, the digital storage requirements for ePI combined with the necessary retention of the paper format do not necessarily make ePI a carbon-free alternative to paper-based product information.[6]

Key considerations and opportunities for ePI, as well as associated challenges and risks, are detailed in Table 1.

Considerations for the future of ePI

ePI has the potential to address challenges associated with understanding product information, to offer patients, healthcare providers, and other stakeholders options and variety in the format and scope of the information available about a product. Ultimately, by linking to additional medical information sources, ePI could support patients to improve self-management and informed, shared decision-making. Currently, extensive work is ongoing to increase the availability of online patient information in multimedia formats, and the opportunity to integrate this with ePI should be explored in the future.[14]

The future success of a transition to ePI is part of a broader societal move towards digitisation. This will require medical writers and healthcare communications professionals to continue to build a solid foundation of high-quality, accessible, and discoverable medical information that is suitable for everyone. The continued evolution of the ePI landscape will also be contingent on the pharmaceutical industry, regulators, healthcare professionals, and medical writers working together to allocate resources to the development of ePI platforms and build multi-stakeholder partnerships to share best practices and communicate the value of ePI for all. This should be accompanied by raising awareness of the importance of providing appropriate, tailored information about ePI to all stakeholders.

Meanwhile, medical writers have a key role in developing the information infrastructure to help optimise ePI (see Figure 2) by:

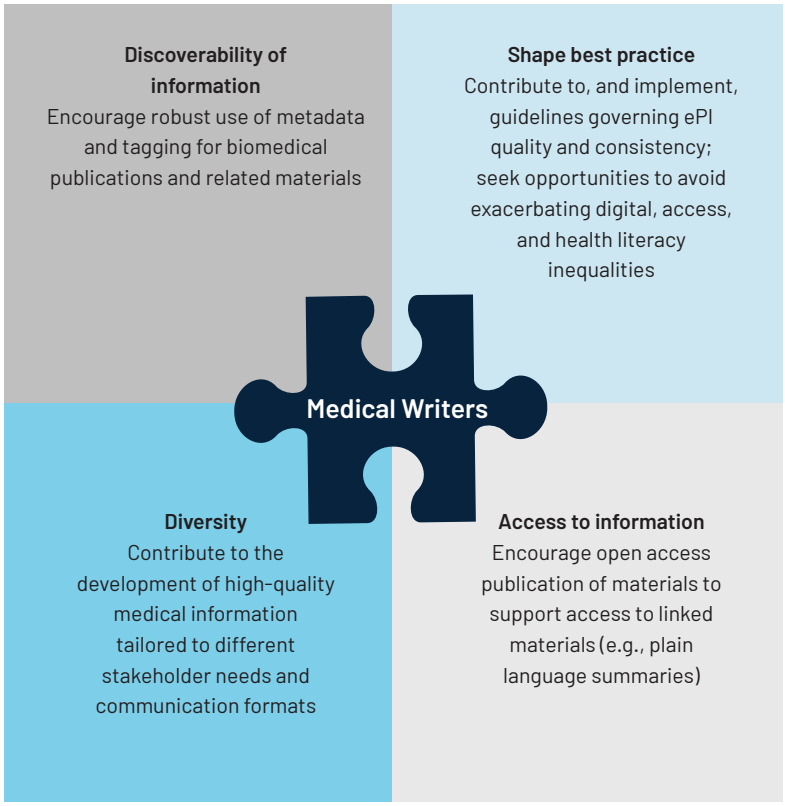


Figure 2. Medical writers have a key role to play in the evolution of ePI

Abbreviations: ePI, electronic product information.

- Publishing with open access to support transparency and trust
- Using metadata and tagging to support discoverability and content linkage
- Developing accessible summaries, such as plain language summaries, infographics, animations, and other multimedia-based resources to support the needs of stakeholders with different levels of health literacy and learning modes
- Conveying complex medical information in a more human-centred way
- Developing peer-reviewed articles cognisant of the fact that the data and interpretation they contain, and extenders they carry (e.g., accessible summaries, podcasts, videos), might one day (subject to future regulatory agreement) be linked through the ePI to aid user comprehension
- Creating guidelines for the development of ePI to support quality and consistency
- Ensuring that ePI ameliorates rather than exacerbates existing challenges and inequities in access to health information
- Leveraging existing tools, including considered use of artificial intelligence capabilities, to help adapt, translate, and aggregate medical content
- Proposing viable and streamlined processes for linking ePI to relevant sources

Medical writers have a key role to play in the flow of information from research studies to healthcare professionals, patients, and other stakeholders. They can therefore make valuable contributions to inform and shape the evolution of the ePI landscape and the medical materials that could help to realise the potential of ePI, and can raise awareness of the potential benefits of ePI for everyone.

Acknowledgements

Medical writing support was provided by Joanna Donnelly, PhD, and Alison Chisholm, MPH, MSc, MA, of Oxford PharmaGenesis, Oxford, UK. The opinions expressed in this article are the author's own and not necessarily shared by their employer or EMWA.

Disclaimers

This work was supported by Oxford PharmaGenesis.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

References

1. EMA. Guidance on product information. 2025 [cited 2025 Mar 3]. Available from: https://www.ema.europa.eu/en/glossary-terms/product-information
2. Hung A, Sieluk J, Doshi P. The untapped potential of pharmacy leaflets for informing patients about drug benefits and risks. JAMA Intern Med. 2016;176(1):11–2. doi:10.1001/jamainternmed.2015.6656
3. FDA. Consultation on patient medication information. 2023 [cited 2025 Mar 3]. Available from: https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-medication-information-pmi
4. Lambot N, Ginste MV. Electronic leaflet pilot in Belgium and Luxembourg hospitals. Regulatory Rapporteur. 2022;19(4):3–5.
5. Sullivan HW, Squire C, Aikin KJ, et al. Physicians' use of and preferences for FDA-approved prescribing information. Res Social Adm Pharm. 2022;18(6):3027–37. doi: 10.1016/j.sapharm.2021.07.028
6. The Health Policy Partnership. Electronic product information (ePI): Securing the future for accessible delivery of medicine information through digitalisation. 2024 [cited 2025 Mar 3]. Available from: https://www.healthpolicypartnership.com/app/uploads/Electronic-product-information-ePI-Securing-the-future-for-accessible-delivery-of-medicine-information-through-digitalisation.pdf
7. Vanstone M, Canfeld C, Evans C, et al. Towards conceptualizing patients as partners in health systems: a systematic review and descriptive synthesis. Health Res Policy and Syst. 2023;21(1):1–14. doi:10.1186/s12961-022-00954-8
8. FDA. Guidance on product information. 1938 [cited 2025 Mar 3]. Available from: https://www.govinfo.gov/content/pkg/FR-1938-12-28/pdf/FR-1938-12-28.pdf
9. EMA. Guidance on electronic product information. 2025 [cited 2025 Mar 3]. Available from:https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi
10. European Commission, European Medicines Agency, and Heads of Medicines Agency. ePI pilot report: Experience gained from creation of ePI during regulatory procedures for EU human medicines. 2024 [cited 2025 Mar 3]. Available from: https://www.ema.europa.eu/en/documents/report/electronic-product-information-epi-report-experience-gained-creation-epi-during-regulatory-procedures-eu-human-medicines_en.pdf
11. e-Gov. Act on securing quality, efficacy and safety of products including pharmaceuticals and medical devices. 2019 [cited 2025 Mar 3]. Available from: https://elaws.e-gov.go.jp/document?lawid=335AC0000000145_20210801_501AC0000000063
12. Prescription Information Modernization Act of 2023 [cited 2025 Mar 3]. Available from: https://www.congress.gov/bill/118th-congress/house-bill/1503
13. Pharmaceutical Group of the European Union. Position paper on electronic product information. 2021 [cited 2025 Mar 3]. Available from: https://www.pgeu.eu/wp-content/uploads/2021/05/PGEU-PP-on-ePI-WEB.pdf
14. Gravitate Health. 2025 [cited 2025 Mar 3]. Available from: https://www.gravitatehealth.eu/

Author information

Behtash Bahador is the Director of Health Literacy at the non-profit organisation Center for Information and Study on Clinical Reserach Participation (CISCRP) and holds a Master of Science in Health Communication from the Tufts University School of Medicine. He has collaborated with a range of stakeholders to establish and implement patient- and public-centric initiatives across the drug lifecycle.

Trishna Bharadia is a visiting lecturer on patient engagement at King's College London's Centre for Pharmaceutical Medicine Research and has won multiple awards during her 15 years of working in patient advocacy and engagement with a range of stakeholders.

Derek Stewart is Honorary Professor at the University of Galway for his work as a patient advocate involved in health research. He was founding Chair of the National Cancer Research Institute's Consumer Liaison Group; former positions include Associate Directorship of the National Institute for Health Research – Clinical Research Network.

Christopher C. Winchester is Chief Executive Officer of Oxford PharmaGenesis Ltd and Associate Fellow of Green Templeton College, University of Oxford, Oxford, UK. He co-founded Open Pharma, is a former Chair of the International Society for Medical Publications Professionals, and has over 20 years of European and global communications experience.

Writing in plain language for the Summary of Safety and Clinical Performance: Communicating medical device safety and performance data to patients

Katharina Friedrich
Katylistic GmbH, Basel, Switzerland

doi: 10.56012/lozv7387

Correspondence to:
Katharina Friedrich
k.friedrich@katylistic.com

Abstract

Effective communication with patients is paramount in the medical field, particularly in the medical device sector, where the complexity of information can create barriers to understanding. The Summary of Safety and Clinical Performance (SSCP) has been introduced under the European Medical Device Regulation (MDR 2017/745) as a new document to bridge this gap, ensuring transparency and accessibility for patients and healthcare professionals. This article explores the best practices for writing the SSCP in plain language, including strategies to ensure clarity, accuracy, and engagement. It also highlights the current limitations of the SSCP.

The European Medical Device Regulation (MDR 2017/745) sets higher requirements for manufacturers to ensure the safety and performance of medical devices than the previous Medical Devices Directive (MDD). An additional goal of the MDR is to improve transparency to the public, including healthcare professionals (HCPs) and patients. This is reflected in Recital 43 of the regulation:[1]

"(43) **Transparency and adequate access to information**, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to **make informed decisions**, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system."

The Summary of Safety and Clinical Performance (SSCP) was introduced under the European Medical Device Regulation (MDR 2017/745) to provide a clear and concise summary of a medical device's safety and performance. It is required for class III and implantable devices. Writing the SSCP in plain language is not just a regulatory requirement but a step toward better access for patients to relevant performance and safety data about medical devices.

The SSCP:

- Can be seen as a summary of the Clinical Evaluation Report.
- Will be made available to the public.
- Always includes a section for HCPs.
- Should include a section for patients for the following devices:
  - Implantable devices with an implant card for patients; and
  - Class III devices directly used by patients.
  - May include a section for patients for any other device where patient information could be relevant. In general, manufacturers are expected to provide a rationale when they don't draft a section for patients.

Challenges when writing the SSCP for patients

The SSCP is often intended for a dual audience: HCPs and patients. While writing for HCPs may come more naturally to medical writers, writing the SSCP section for patients presents some challenges. Since the content of the SSCP should be sourced entirely from the technical documentation, the main difficulty for medical writers lies in balancing a sufficient level of detail with readability (discussed further in next sections). Also, according to MDCG 2019-19,[2] "it should not be assumed that the patient has any formal education in a medical discipline or any prior knowledge of medical terminology or clinical research." This makes it difficult to present results adequately.

> Testing the readability of the SSCP with laypersons is essential to ensure the document meets patient needs.

In Table 1,[3–4] I elaborate on the challenges presented by the different sections of SSCP when written for the patient audience and how to address them.

Principles of plain language writing

Principles of plain language writing are often in line with principles of clear writing in general. Therefore, they are helpful not only for writing the patient section of the SSCP but also for any other document. Using the active voice, writing shorter sentences, and limiting abbreviations can improve every text, independent of the audience.[5] The most relevant and useful principles of plain language writing are summarised in Table 2.

Keeping literacy levels in mind is one of the most challenging parts of writing the SSCP. The Programme for the International Assessment of Adult Competencies (PIAAC) regularly assesses the literacy skills of people aged 16 to 65 among the Organization for Economic Co-operation and Development (OECD) countries on a scale from Level 1 (lowest level) to Level 5 (highest level). According to their latest survey, only 12% of participants rated Level 4 to 5, the highest proficiency level, can comprehend and evaluate long texts or grasp complex or hidden meanings.[6] This also means that most readers of the SSCP likely have a lower proficiency level. As medical writers, we are used to reading and digesting complex information in our daily routine and hence may be unable to fully grasp the needs of general audiences. Therefore, it is essential to test the readability of the SSCP.

Testing the readability of the SSCP

According to MDCG 2019-9 Rev.1, "(…) the readability of the part of the SSCP intended for patients is assessed for example by a test given to lay persons."[2] Other methods, such as software, can also be used to evaluate the readability of the SSCP. Most software solutions, such as Readable or Microsoft Word, use the Flesch Reading Ease and Flesch-Kincaid Grade Level tests. Both tests are briefly described in Table 3.

Considering the limitations of these scores, readability tests with a group of laypersons may

Photo: Freepik

Table 1. SSCP sections for patients

Main sections according to SSCP template MDCG 2019-9 Rev.1	Subsections according to SSCP template MDCG 2019-9 Rev.	Potential challenges and tips to address them
1. Identification of the device and the manufacturer	• Device trade name • Manufacturer; name and address • Basic UDI-DI • Year when the device was first CE-marked	This section is straightforward and can be copied from the section for healthcare professionals.
2. Intended use of the device	• Intended purpose • Indications and intended patient groups • Contraindications	Many manufacturers simply copy this information from the Instructions for Use. However, the intended purpose of the device and related information must also be provided in plain language. This requires an explanation of all medical terms. Consider including a glossary to explain all terms and abbreviations in sufficient detail, especially for complex medical devices and conditions.
3. Device description	• Device description and material/substances in contact with patient tissues • Information about medicinal substances in the device, if any • Description of how the device is achieving its intended mode of action • Description of accessories, if any	Most device descriptions are written with healthcare professionals and Notified Bodies in mind. For the SSCP, think about the most relevant information for the patient and adapt the device description accordingly. For example, it makes sense to precisely describe all relevant accessories to insert a hip implant for the surgeon, whereas such details are likely overwhelming for the patient. However, patients are probably more interested in the general procedure of a hip implant surgery, and it makes sense to clearly describe how the device achieves its mode of action, including pictures when available.
4. Risks and warnings	• How potential risks have been controlled or managed • Remaining risks and undesirable effects • Warnings and precautions • Summary of any field safety corrective action, including field safety notice, if applicable	This section describes the manufacturer's risk management and post-market surveillance system in plain language. Patients should be informed about how the manufacturer identifies, controls, and manages risks. Moreover, all risks provided in the Instructions for Use must be described here in plain language. For many risks, this requires an explanation in one or two sentences rather than replacing a single word. Glossaries for plain language are of great help here, such as the *Plain Language Dictionary* of the Michigan Library[3] or the *Plain Language Thesaurus for Health Communications*[4] provided by the CDC. Warnings and precautions can be restricted to information relevant to the patient. For example, it is not necessary to describe warnings or precautions related to the assembly of a hip implant in plain language. Regarding field safety corrective actions, the patient should be informed about the underlying reason and how the manufacturer addressed the issue.
5. Summary of the clinical evaluation, including post-market clinical follow-up	• Clinical background of the device • The clinical evidence for the CE-marking • Safety	As the heading implies, this section is nothing less than a lay summary of the Clinical Evaluation Report, including performance and safety data from clinical investigations, registries, scientific publications, and any other sources. Similar to the section for healthcare professionals, it makes sense to provide these data in a tabular format. The most relevant performance and safety parameters should be compared with the state-of-the-art. This allows the patient to understand how the device performs when compared to the standard of care.

Main sections according to SSCP template MDCG 2019-9 Rev.1	Subsections according to SSCP template MDCG 2019-9 Rev.	Potential challenges and tips to address them
6. General description of therapeutic alternatives	• General description of therapeutic alternatives	Patients should be informed that they should consult their healthcare professional about alternative diagnostics or treatments. It is important to communicate to the patient that the SSCP is not supposed to provide treatment recommendations. Hence, this section should briefly describe the most relevant alternatives, including their benefits and disadvantages. This can also be done in a tabular format.
7. Suggested training for users	• Suggested training for users	This section is straightforward and can be copied from the section for healthcare professionals.

Abbreviations: CDC, Centers for Disease Control and Prevention; CE, conformité européenne [European conformity]; MDCG, Medical Device Coordination Group; SSCP, Summary of Safety and Clinical Performance; UDI-DI, Unique Device Identification – Device Identifier.

Table 2. Principles of plain language writing

Principles of plain language writing			
1. Clarity and simplicity	Use clear and simple language	✓ Write short sentences. ✓ Avoid jargon, technical, or medical terms. ✓ Use abbreviations consistently.	✓ Use active voice. ✓ Avoid nominalisation. ✓ Use whole numbers, if possible.
2. Structure	Structure in a logic way	✓ Organise information in a clear, logical flow: start with the broader picture and get into detail step by step. ✓ Use headings, subheadings, and bullet points to break down content into manageable sections.	
3. Engagement	Use visuals for more engagement	✓ Incorporate visuals such as diagrams, tables, or flow charts to explain complex data. ✓ Use white space effectively to make the document less intimidating.	
4. Empathy and inclusivity	Write with empathy and be inclusive	✓ Consider the diverse backgrounds and literacy levels of readers. ✓ Avoid language that could inadvertently stigmatise or alienate readers. For example, do not write "the patient" but rather address the reader directly in the SSCP.	

Abbreviation: SSCP, Summary of Safety and Clinical Performance

be the more robust option. However, such tests are expected to be performed with a representative group of people (note: employees of a medical device manufacturer are usually not representative of the standard reader). The tests should be conducted according to a predefined plan and with an appropriate sample size with a statistical rationale. The plan should also describe how updates of the SSCP affect the document's readability and should define criteria when readability tests have to be repeated.

Limitations of the SSCP

The SSCP can potentially improve patient empowerment and transparency but faces significant hurdles in practice. Here are a few thoughts on current limitations:

- Limited awareness: Many patients may not know the document exists. It is also unclear when the European Database on Medical Devices (EUDAMED) will be fully operational and whether the platform will be user friendly.
- Inconsistency in content and detail: The level of detail provided in SSCPs from different manufacturers varies significantly, limiting the ability to make informed decisions.
- Inconsistency in readability: The readability of SSCPs also varies significantly. So far, there seems to be no consistent way of evaluating

Table 3. Overview of standard readability tests

	Flesch Reading Ease Score	Flesch-Kincaid Grade Level Test
Description	This score rates text on a scale of 0 to 100, where higher scores indicate easier readability. It is calculated based on the average sentence length (in words) and the average number of syllables per word.	This score translates the readability of a document into a US school grade level, e.g., a score of 8.0 means the text is understandable by an 8th grader. It uses the same factors as the Flesch Reading Ease Score but provides results in grade levels instead of a numerical scale.
Benefits	• Easy to interpret: A higher score directly correlates to simpler text. • Useful for targeting audiences of different reading abilities.	• More intuitive for educators or writers aiming to match content to a specific grade level. • Useful in educational contexts or for writing age-appropriate materials.
Drawbacks	• May oversimplify readability, as it focuses only on sentence and word length without considering content complexity or context. • Less effective for non-English texts or highly technical content.	• Similar to the Flesch Reading Ease, it doesn't consider deeper semantic and structural complexities. • May not reflect the actual difficulty of content beyond syntax

the readability of SSPCs. Patients may find it difficult to understand critical safety and performance data.

- Limited to specific device types: As described above, the patient section of the SSCP is limited to certain device types. However, many manufacturers create a patient section, even if it is optional.

Conclusion

Writing the SSCP in plain language is critical to improving transparency and trust in the medical device industry. However, the SSCP's impact on patients will become more apparent with the full implementation of EUDAMED. So far, there is no strategy to increase awareness of this document, limiting its reach. Medical writers are crucial in ensuring the document's readability by prioritising clarity, empathy, and inclusivity. When possible, medical writers can also encourage manufacturers to make their SSCPs more visible, for example, by presenting them on their websites or including links in their social media channels.

Acknowledgments

The author would like to thank Sampoorna Rappaz for reviewing this article.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

References

1. EUR-Lex. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [cited 2025 Mar 19]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/ ?uri=CELEX%3A32017R0745
2. European Commission. MDCG 2019-9 Summary of safety and clinical performance. A guide for manufacturers and notified bodies. August 2019 [cited 2025 Mar 19]. Available from: https://ec.europa.eu/docsroom/documents/37323
3. University of Michigan Library. Plain Language Medical Dictionary [cited 2025 Mar 19]. Available from: https://medicaldictionary.lib.umich.edu/
4. Centers for Disease Control and Prevention (CDC). Plain language thesaurus for health communications 2007 [cited 2025 Mar 19]. Available from: https://stacks.cdc.gov/view/cdc/11500
5. Collada Ali L, Friedrich K. First experiences writing summaries of safety and clinical performance for medical devices. Med Writ. 2020;29(4):62–5. https://journal.emwa.org/medical-devices/post-market-clinical-follow-up-insights/article/11817/post-market-clinical-follow-up-insights.pdf
6. Organisation for Economic Co-operation and Development. Adult literacy skills [cited 2025 Mar 19]. Available from: https://www.oecd.org/en/topics/literacy-skills.html

Author information

Katharina Friedrich is a medical writer with experience in MDR regulatory writing and is the founder of Katylistic GmbH in Basel, Switzerland. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports, and SSCPs in compliance with MDR 2017/745 for class I to class III devices.

Spread the word

Reach out to the
EMWA Creative Team
for any support you need with designing and creating your graphic content.*

creativeteam@emwa.onmicrosoft.com

*EMWA members only and limited to content destined for EMWA publications, Medical Writing Journal, online content and conference graphics.

Medical writers moving the needle on patient-centred communication and engagement

Diana Daniel[1],
Simin Khaleeluzzama Takidar[2],
Jonathan Mackinnon[3]

[1] Parexel International Ltd., Bangalore, India
[2] Parexel International LLC., Durham, USA
[3] Parexel International S.L., Madrid, Spain

doi: 10.56012/oajb2549

Correspondence to:
Diana Daniel
diana.daniel@parexel.com

Abstract

Patient and public involvement and engagement (PPIE) in clinical trial design, conduct, and reporting provides an opportunity for patients and members of the public to provide input on what is important to them. This supports patient-centric trial design, more efficient trial conduct, and more transparent trial reporting. Patient input can enhance the trial's purpose by ensuring the trial's goals are meaningful and relevant, can allow exploration of the barriers and facilitators of compliance and adherence, improving recruitment and retention, and can ensure that studies address real-world issues. Medical writers can support the communication of PPIE activities across the clinical trial lifecycle through clear and effective writing.

Good clinical practice and ethics guidelines have always emphasised the rights of clinical trial participants.[1,2] This focus has sharpened over time, shifting the role of patients from passive participants to active partners in the research process and giving rise to Patient and Public Involvement and Engagement (PPIE) initiatives. PPIE promotes the "Nothing About Us Without Us" statement, where patients and the public regularly contribute their insights throughout the clinical research process.[3]

Public contributors include not only trial participants but also individuals with a disease or condition, members of patient advocacy groups, caregivers or family members, and providers of social services.[4] By providing real-life lived experiences, they can provide meaningful insight into the disease or condition being investigated (Figure 1). Adopting a more patient-centric approach can ensure that the design and conduct of clinical trials are tailored to the needs of the participants and limit the increasing complexity and cost of clinical research.[5]

PPIE is not one-size-fits-all. Country-specific regulatory frameworks provide a variety of ways through which public involvement can improve the relevance and quality of research. These frameworks provide a mutually beneficial environment in which all trial stakeholders can work together.[6-15] To understand the full impact of PPIE, let us examine how patients can influence clinical research throughout its lifecycle.

From design to dissemination: how patients can influence clinical research

Patients' unmet needs are the main driver in the development of medicines. Researchers now recognise that PPIE can improve the quality of clinical trials (Figure 2). Patients, caregivers, and the public can be involved at all stages of a clinical research project.[16] They can set and refine research questions based on their perspectives and lived experiences, for example, by providing input on endpoints that are meaningful to them. They can also participate in key decisions relating to the design and conduct of trials, such as identifying appropriate eligibility criteria and selecting benefit and risk assessments. Patients and the public can explain how they engage with instruments and activities, helping researchers determine the most effective way of assessing patient-reported adverse events, outcomes, and quality of life. Additionally, patients and the public can support the dissemination of research findings by participating in patient reviews and contributing to lay summaries. Patients can also act as reviewers and co-authors of peer-reviewed journal publications resulting from clinical research.[17]

The TransCelerate P-PET User Guide[18] is a practical resource that helps clinical research teams systematically incorporate patient and public input early in the clinical trial protocol development. It recommends that research teams responsible for the design, planning, and conduct of a clinical programme or clinical trial should consider implementing PPIE as early as possible in the clinical trial protocol development lifecycle. Doing this can boost the success of a clinical trial in several ways, such as:

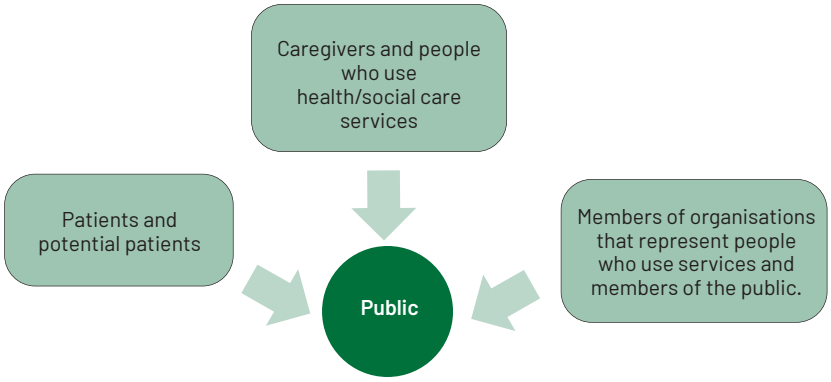


Figure 1. Who represents the public when designing clinical research?

- **Aligning a clinical trial with the experiences, preferences, needs, and concerns of people with lived experience which is crucial for developing effective therapies.** Scientists and those living with a disease or medical condition may interpret "unmet needs" differently, leading to potential oversights in important outcomes, such as symptom scores or quality of life measures that affect an individual's ability to live a full life.[19] To address this and incorporate patient perspectives effectively, several strategies can be implemented:
  - Early engagement: Involve patients in trial design through focus groups or advisory boards.
  - Protocol development: Include patient representatives on review committees.
  - Endpoint selection: Incorporate patient-reported outcomes alongside traditional clinical measures.
  - Informed consent: Collaborate with patients to create clear, understandable documents.
  - Trial implementation: Consult patients on schedules and procedures to minimise the burden.[19-21]
- **Increasing participant enrolment and retention in research.** Patients may feel more inclined to participate in trials that are inclusive and transparent, represent their needs and interests, interfere little with their daily lives, and avoid unnecessary discomfort.[22] Patient insights can also support clinical trial protocol design. For example, clinical trials with lengthy and complex clinical procedures and unnecessarily invasive diagnostic procedures are likely to be unattractive to patients and to have poor recruitment and retention.[21,23] Pharmaceutical companies that decide not to implement patient input into the protocol or do it too late may face enrolment and retention challenges, as well as increased costs and time needed to complete their trials (Figure 3).[21]
- **Building trust.** Including patients in decisions about trial design and dissemination may help trial participants feel more in control of the process and outcome, foster trust and collaboration, and broaden the impact and application of the findings.[24]
- **Improving relevance, quality, and outcomes of drug development.** Soliciting patient input early in the drug development process can identify endpoints that address unmet needs that are important to them.[25] Clinicals using trial endpoints based solely on pathophysiology may miss aspects of the disease that affect quality of life or increase burden on patients.[26,27]

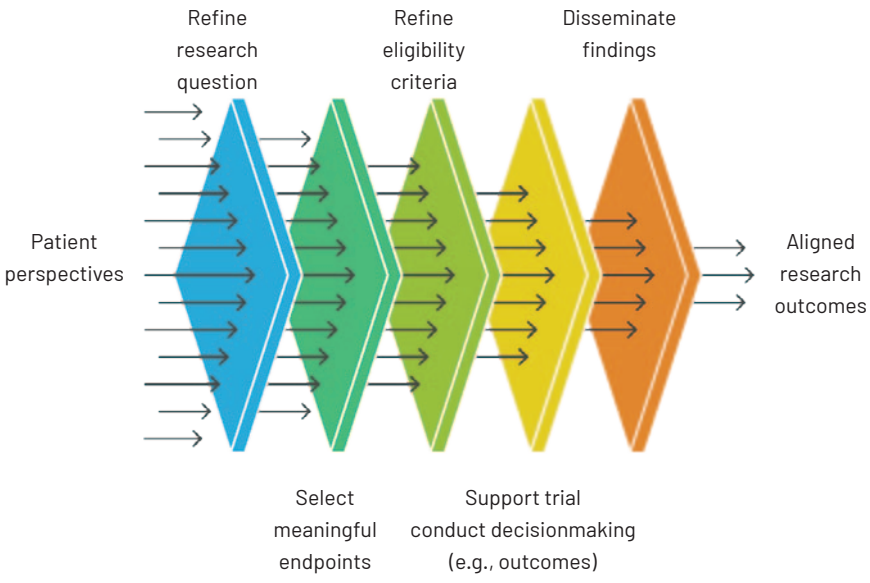


Figure 2. Patient and public involvement in research stages

Guidelines and standards for effective PPIE in research

Many global initiatives have developed frameworks, training, and tools to enhance PPIE in clinical trials (Table 1). The National Institute for Health Research in the UK provides comprehensive guidelines for incorporating patient perspectives in all stages of research to ensure inclusivity and diversity in clinical trial design

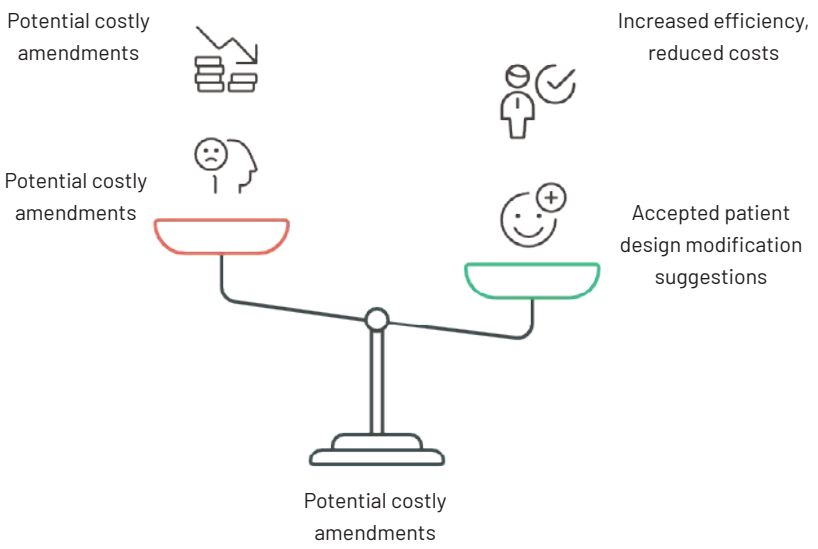


Figure 3. Timely patient feedback enhances protocol efficiency

and implementation.[2,8] The Patient-Focused Drug Development and the Patient-Centred Outcomes Research Institute in the US provide guidelines to design research around patient's concerns and priorities.[6,7] The European Patients' Academy on Therapeutic Innovation provides education and training initiatives for patients, as well as guidance for including PPIE in ethics committees, regulatory authorities, and health technology assessments, further embedding the patient's voice in the drug development process.[8–11] Additionally, initiatives like TransCelerate's Patient Experience[12] and Clinical Trials Transformation Initiative[13] emphasise involving patients and caregivers early in trial design and execution, with the aim of improving feasibility, recruitment, and retention, and ensuring trial outcomes reflect real-world patient experiences. Also, the Public Involvement Impact Assessment Framework[14] and Guidance for Reporting the Involvement of Patients and the Public[15] chart and assess the impact of PPIE in research, ensuring that clinical trials continually improve based on patient feedback.

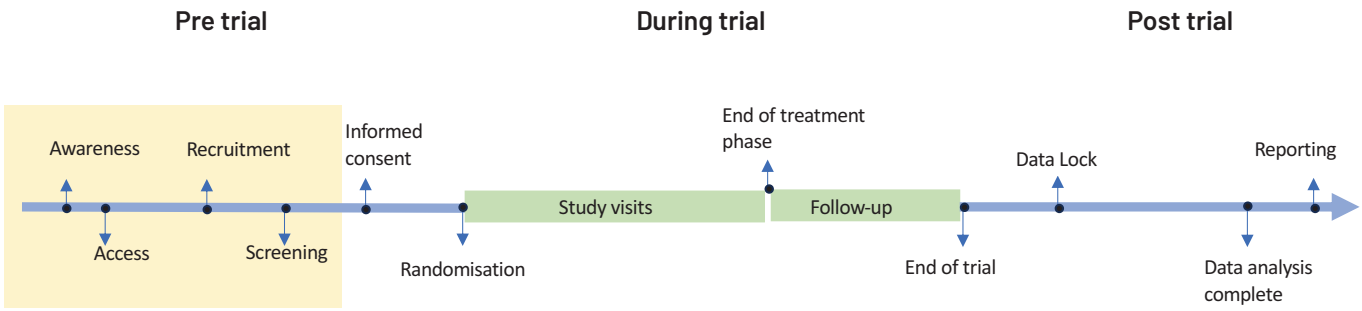
While these guidelines provide a framework for PPIE, implementing effective patient engagement strategies is crucial for their success.

Patient engagement strategies

Clinical trial researchers must balance patient input with scientific understanding and business, legal, and regulatory requirements. Researchers have traditionally used unidirectional approaches, like surveys or questionnaires, to gather feedback on trial participants' experiences, but they have been shifting towards strategies that

Table 1. Global frameworks and initiatives for patient engagement in clinical research

Organisation/Initiative	Description	Link
Clinical Trials Transformation Initiative (CTTI)	Recommendations for patient group engagement in clinical trials	CTTI Recommendations
European Patient Academy (EUPATI)	Network supporting patient involvement in medicines research and providing training across Europe	EUPATI
Guidance for Reporting Involvement of Patients and the Public (GRIPP2)	Reporting checklists for improving documentation of patient and public involvement in research	GRIPP2 Checklist
National Institute for Health and Care Research (NIHR)	UK standards for public involvement in research	NIHR Standards
Patient Centred Outcomes Research Institute (PCORI)	US standards and engagement rubric for patient centred research	PCORI Standards
Patient-Focused Drug Development (PFDD)	FDA guidance on collecting and submitting patient experience data for medical product development	PFDD Guidance
Public Involvement Impact Assessment Framework (PiiAF)	Framework for assessing the impact of public involvement in research	PiiAF
TransCelerate Patient Experience (PE) Initiative	Initiative to improve patient experience in clinical trials	TransCelerate PE



- Aim for demographic diversity in regional and site selection
- Engage communities
- Provide education to improve population research readiness
- Develop action plans and targets for representativeness, aiming for a participant-to-prevalence ratio of 0.8-1.2
- Use broad inclusion criteria

- Simplify and customise the informed consent process
- Apply strategies to make trial participation less burdensome
- Provide cultural competency training
- Ensure representation among investigators and trial committees
- Ensure that sociodemographic information is collected and reported
- Consider novel trial designs
  - Embedded
  - Registry-based RCTs
  - Decentralised
  - Adaptive
- Monitor the representativeness of participants through interim analyses

- Ensure data protection
- Provide plain language summaries including culturally competent, accessible information
- Involve participants indissemination
- Engage diverse investigators in the authorship of primary and secondary anaysis

Abbreviations: RCT: randomised controlled trials.

Figure 4. Strategies to increase representativeness in clinical trials

increase involvement, collaboration, and engagement with patients and caregivers (Figure 4).[21]

These strategies include conducting periodic surveys to gather input on clinical trials, partnering with patient advocacy groups and caregivers to keep abreast of patients' unmet needs, and maintaining a bank of patient insights for key opinion leaders and scientific staff to consider when designing clinical trials.[29] Following are additional suggestions for strategies to improve patient engagement:

- **Create organisational standard operating procedures (SOPs) for patient engagement.** SOPs that consider local regulations can be used to define roles and responsibilities for patient partners, patient advocates, and pharmaceutical industry stakeholders.[30] When used as a standardised framework, these SOPs ensure quality, consistency, and relevance in patient engagement strategies, while allowing room for adaptation and accommodation of different therapeutic areas. A standardised internal process can help maintain ongoing, mutually beneficial partnerships between researchers and patient partners; establish knowledge banks of patient insights, develop contextual online surveys, or organise virtual meetings with patient partners to help prepare for clinical trials; and ensure timely stakeholder feedback before initiating or modifying clinical trial protocols.
- **Allocate budget, timelines, and resources to support patient engagement.** Dedicated budgets may be needed for infrastructural costs, preparation and delivery of training and educational materials, compensation (financial or non-financial) of patient partners, and translation of patient input into actionable research strategies by key opinion leaders. Putting these patient engagement strategies into action and managing timelines for them will also require adequately trained resources and their management by strategic leads.[21]
- **Specify goals for patient engagement initiatives.** The backgrounds, perceptions, and interests of researchers and their patient collaborators may not always be aligned.[5] To avoid potentially costly conflicts and delays, expectations and rules of engagement must be clarified from the outset.[31] Key aspects include: having a simple contract of understanding and confidentiality or non-disclosure agreements to protect the researcher's interests; compensating participants; having a regular touchpoint with participants; developing a plan for how the data resulting from patient engagement activities will be collected, shared, stored, assessed, and utilised in designing the trial; and establishing the role of an institutional review board.

With the increasing emphasis on PPIE, medical writers play a crucial role in ensuring that patient perspectives are effectively integrated into all aspects of clinical trial documentation and communication.

The role of medical writers in integrating patient perspectives

Medical writers play a crucial role in ensuring that patient experiences and insights are included in research materials, such as clinical trial protocols, lay language summaries, thank-you communications, and educational materials. Also, according to regulatory requirements, clinical trial results must now be shared with study participants.[32] This implies translation of complex medical concepts into plain language for a range of non-specialist audiences. Medical writers can help bridge the gap between researchers' intentions and patients' needs by creating well-crafted, patient-facing materials that are not just scientifically accurate but also inclusive and accessible to patients.

Table 2. Medical writer considerations for incorporating patient input into clinical trial protocols

Protocol element	Patient input	Medical writer considerations
Trial objectives and endpoints	Unmet needs, disease burden, important endpoints	Clearly articulate patient-identified unmet needs and how trial objectives address them. Explain how objectives or endpoints that are important to patients have been incorporated.
Trial design	Concerns about travel, invasive procedures, technical support needs	Describe what patient input has been achieved and how the trial design accommodates patient preferences (e.g., decentralised visits, minimised invasive procedures). Explain any patient support systems in place.
Eligibility and participation	Representation, support during screening, withdrawal process	Highlight how eligibility criteria have been modified to encourage diverse representation. Clearly describe the informed consent process, including withdrawal procedures.
Trial drug	Administration concerns, expectations about side effects	Explain how patient concerns about drug administration are addressed. Clearly communicate expected side effects and their management.
Patient-reported outcomes (PROs)	Relevance, complexity, administration of PROs	Describe how PROs were selected or modified based on patient input. Explain measures taken to ensure PRO accessibility and ease of completion.
Trial results	How and when patients will receive results	Clearly state in the protocol how and when trial results will be communicated to participants.

Incorporating patient input into clinical trial protocols

Medical writers can weave patient experiences and insights into clinical trial documents. Starting with the clinical trial protocol, the writer can make it clear that patient input into the document is an expected part of the clinical trial design. This should be expected by the trial team because most clinical trial protocol templates (based on the Common Protocol Template by TransCelerate) include a subsection on patient input into the trial design.[33] Also, recent ICH E8(R1) and ICH E6(R3) guidance highlights the need for a "Quality by Design" approach, where quality factors are built into the scientific and operational design of the trial, ensuring that the trial meets its objectives.[1,34] Patient input into the trial design is a fundamental part of this approach. In alignment with this, the medical writer can ensure that patient input is transparently included in the clinical trial protocol (Table 2). This information can be reused or repurposed at later stages in the clinical trial.

Adapting language for diverse audiences

Medical writers optimise accessibility and understanding of communications by tailoring them to the targeted cultural backgrounds and literacy levels. Although approximately three-quarters of clinical trial participants value receiving lay language summaries, including the trial results, only approximately one-third actually receive them.[35] About 90% of clinical trial participants are likely to enrol if they know that a study summary will be provided after the trial.[35] Medical writers can help by creating clear, concise, and accessible summaries that translate complex scientific terms into understandable language.

Improving recruitment and retention materials

Over 20% of patients either trust the medical decision of the investigator for their enrolment or are unaware that clinical trials involve more clinical visits and tests than standard care.[36] Medical writers can help by producing informed consent forms that include plain language descriptions of the clinical trial and incorporate patient feedback to better reflect patient priorities. Medical writers can collaborate with patients and the public to develop relatable messaging that addresses their concerns and explains how the clinical trial has been adapted to suit their needs. Retention can also be improved by connecting with trial participants and supporting them with follow-up communications.[37] Medical writers may also collaborate with patients to create recruitment materials that address common concerns and emphasise the benefits of participating in clinical trials and to produce follow-up communications that can enhance retention.[38,39]

Concluding remarks

PPIE has become an essential part of clinical trial development. Medical writers are well-positioned to support it by asking targeted questions when developing clinical trial documentation and ensuring that these insights are communicated throughout the trial lifecycle and the documents. Detailed and accurate reporting of PPIE helps increase its visibility and promote its adoption by the clinical research community.

Acknowledgements

The authors would like to thank Kristina Reeder and Sarah Yelling for their support in reviewing the manuscript.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employer or EMWA.

Disclosures and conflicts of interest

The authors are employed by Parexel International Ltd.

References

1. ICH Harmonised Guideline. Good Clinical Practice (GCP) E6(R3) [cited 03 Feb 2025]. Available from: https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf
2. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants [cited 03 Feb 2025]. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki/.
3. Charlton JI. Nothing about us without us. In: Nothing about us without us. University of California Press; 1998. Available from: https://www.ucpress.edu/books/nothing-about-us-without-us/paper
4. National Institute for Health and Care Research. Briefing notes for researchers - public involvement in NHS, health and social care research. 2021 [cited 14 Apr 2025]. Available from: https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371
5. Den R. 3 Surefire ways to design trials that patients want and need. Clinical Leader. 2024 [cited 2025 Feb 03]. Available from: https://www.clinicalleader.com/doc/surefire-ways-to-design-trials-that-patients-want-and-need-0001
6. FDA. Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making. 2024. [cited 03 Feb 2025]. Available from: https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical
7. PCORI. Patient-centred outcome research institute [cited 03 Feb 2025]. Available from: https://www.pcori.org/
8. EUPATI. Guidance for patient involvement in HTA [cited 03 Feb 2025]. Available from: https://toolbox.eupati.eu/resources/patient-toolbox/guidance-for-patient-involvement-in-hta/
9. EUPATI. Guidance for patient involvement in ethical review of clinical trials [cited 03 Feb 2025]. Available from: https://toolbox.eupati.eu/resources/patient-toolbox/guidance-for-patient-involvement-in-ethical-review-of-clinical-trials/
10. EUPATI. Guidance for patient involvement in regulatory processes [cited 03 Feb 2025]. Available from: https://toolbox.eupati.eu/resources/patient-toolbox/guidance-for-patient-involvement-in-regulatory-processes/
11. EUPATI. Guidance for patient involvement in industry-led medicines R&D [cited 03 Feb 2025]. Available from: https://toolbox.eupati.eu/resources/patient-toolbox/guidance-for-patient-involvement-in-industry-led-medicines-rd/
12. TransCelerate. Patient Experience [cited 03 Feb 2025]. Available from: https://www.transceleratebiopharmainc.com/initiatives/patient-experience/
13. CTTI Recommendations: Patient Group Engagement. 2015 [cited 03 Feb 2025]. Available from: https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Patient_Group_Engagement_Recs.pdf
14. Public Involvement Impact Assessment Framework (PiiAF) [cited 03 Feb 2025]. Available from: https://piiaf.org.uk/
15. Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research BMJ. 2017;358:j3453. doi:10.1136/bmj.j3453
16. Geißler J, Isham E, Hickey G, et al. Patient involvement in clinical trials. Commun Med. (Lond) 2022;2(1):94. doi:10.1038/s43856-022-00156-x.
17. Leventhal P, Drachmann D, Skovlund S. Can patients and caregivers be authors of peer-reviewed publications? Med Writ. 2024;33(4):98–100. doi:10.56012/idde2040
18. Transcelerate Patient Protocol Engagement Toolkit (P-PET) [cited 03 Feb 2025]. Available from: https://www.transceleratebiopharmainc.com/ppet/planning-for-patient-engagement/.
19. Sacristán JA, Aguarón A, Avendaño-Solá C, et al. Patient involvement in clinical research: why, when, and how. Patient Prefer Adherence. 2016;10:631–40. doi: 10.2147/PPA.S104259
20. Domecq JP, Prutsky G, Elraiyah T, et al. Patient engagement in research: a systematic review. BMC Health Serv Res. 2014;14(1):89. doi:10.1186/1472-6963-14-89
21. Levitan B, Getz K, Eisenstein EL, et al. Assessing the financial value of patient engagement: A quantitative approach from CTTI's patient groups and clinical trials project. Ther Innov Regul Sci. 2018;52(2):220–9. doi:10.1177/2168479017716715
22. Zannad F, Berwanger O, Corda S, et al. How to make cardiology clinical trials more inclusive. Nat Med. 2024;30(10):2745–55. doi:10.1038/s41591-024-03273-3
23. State of patient centricity 2020: Advancing from patient-first intentions to true co-creation. Economist Impact. 2020 [cited 03 Feb 2025]. Available from: https://impact.economist.com/perspectives/sites/default/files/eiu_-_medidata_-_state_of_patient_centricity_2020_0.pdf
24. Crocker JC, Ricci-Cabello I, Parker A, Hirst JA, Chant A, Petit-Zeman S, et al. Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. BMJ. 2018;363:k4738. doi:10.1136/bmj.k4738
25. Scott N. Putting patients first: Advancing patient-centric approaches in rare disease drug development. LinkedIn. 2023 [cited 14 April 2025]. Available from: https://www.linkedin.com/pulse/putting-patients-first-advancing-patient-centric-rare-freeman-phd-nkxje/
26. Miseta E. Tufts finds substantial net benefits to using decentralized trials. Clinical Leader. 2022 [cited 03 Feb 2025]. Available from: https://www.clinicalleader.com/doc/tufts-finds-substantial-net-benefits-to-using-decentralized-trials-0001

27. US FDA. Focus Area: Patient-Reported Outcomes and other Clinical Outcome Assessments. Silver Spring (MD): FDA; [cited 28 April 2025]. Available from: https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-patient-reported-outcomes-and-other-clinical-outcome-assessments
28. National Institute for Health Research. UK standards for public involvement. NIHR [cited 14 Apr 2025]. Available from: https://sites.google.com/nihr.ac.uk/pi-standards/home.
29. Hoos A, Anderson J, Boutin M, et al. Partnering with patients in the development and lifecycle of medicines: A call for action. Ther Innov Regul Sci. 2015;49(6):929–39. doi:10.1177/2168479015580384
30. Deane K, Delbecque L, Gorbenko O, et al. Co-creation of patient engagement quality guidance for medicines development: an international multistakeholder initiative. BMJ Innov. 2019;5(1):43–55. doi:10.1136/bmjinnov-2018-000317
31. Geissler J, Ryll B, di Priolo SL, et al. Improving patient involvement in medicines research and development: A practical roadmap. Ther Innov Regul Sci. 2017;51(5):612–9. doi:10.1177/2168479017706405
32. U.S. Department of Health and Human Services. Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11). Fed Regist 2016 Sep; 81(183):64981–5157 [cited 2023 May 24]. Available from: https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-part11.xml.
33. TransCelerate BioPharma Inc. Clinical content reuse solutions. TransCelerate BioPharma Inc. [cited 14 Apr 2025]. Available from: https://www.transceleratebiopharmainc.com/assets/clinical-content-reuse-solutions/
34. ICH Harmonised Guideline. General Considerations For Clinical Studies E8(R1). [cited 03 February 2025]. Available from: https://database.ich.org/sites/default/files/E8-R1_Guideline_Step4_2021_1006.pdf
35. Annderson A. patient perspectives on seeing trial results. Applied Clinical Trials 2018;27(5):6. Available from: https://www.appliedclinicaltrialsonline.com/view/patient-perspectives-seeing-trial-results
36. Juan-Salvadores P, Michel Gómez MS, Jiménez Díaz VA, et al. Patients' knowledge about their involvement in clinical trials. A non-randomized controlled trial. Front Med (Lausanne). 2022;9:993086. doi:10.3389/fmed.2022.993086
37. Lindus Health. Effective strategies for patient recruitment for clinical trials. Lindus Health [cited 14 Apr 2025]. Available from: https://www.lindushealth.com/blog/effective-strategies-for-patient-recruitment-for-clinical-trials.
38. Kremidas. Recruitment Roles. Appl Clin Trials 2011;20(9):32–4. Available from: https://www.appliedclinicaltrialsonline.com/view/recruitment-roles
39. Chaudhari N, Ravi R, Gogtay NJ, et al. Recruitment and retention of the participants in clinical trials: Challenges and solutions. Perspect Clin Res. 2020;11(2):64–9. doi:10.4103/picr.PICR_206_19

Author information

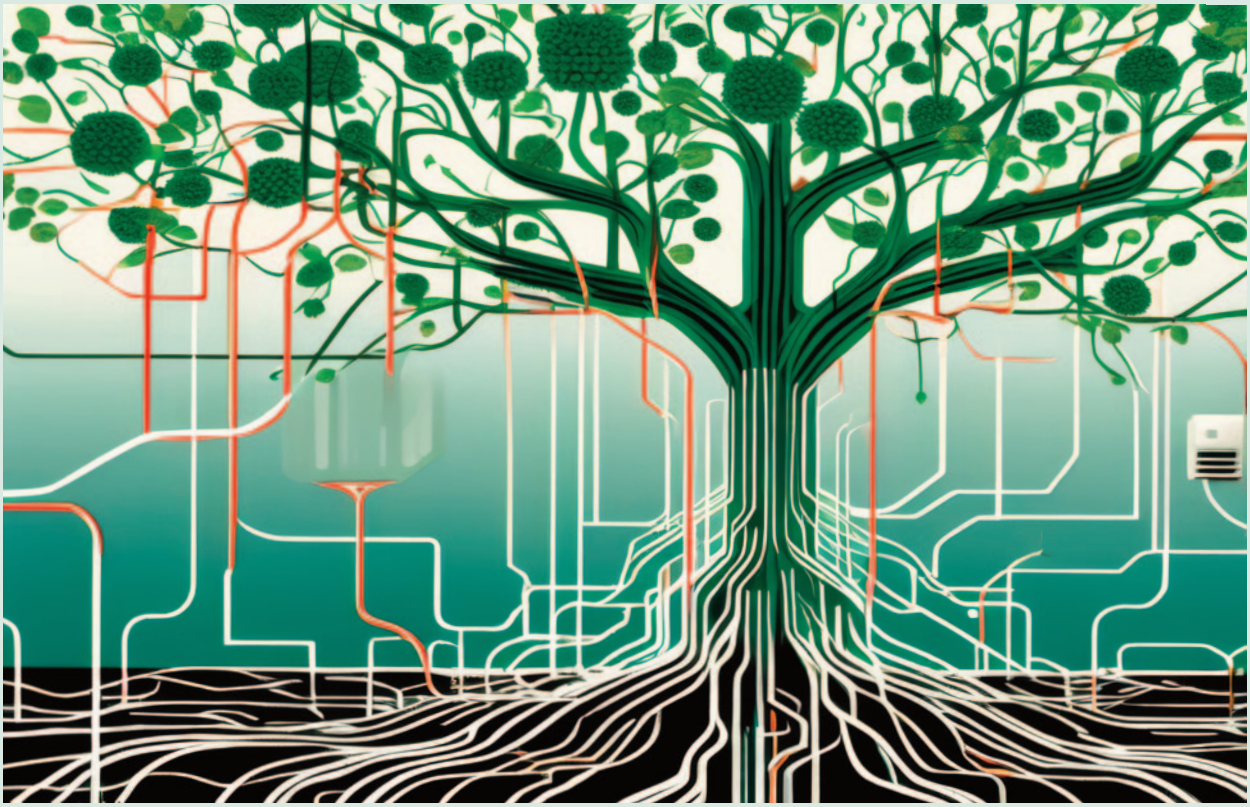
Diana Daniel, PhD, has been a Senior Medical Writer at Parexel since 2022. She is experienced in regulatory medical writing, especially in the preparation of trial protocols and clinical study reports and has delivered high-quality documents for local and global markets in various therapeutic areas.

Simin Khaleeluzzama Takidar is a Senior Principal Medical Writer at Parexel with 15 years of experience in regulatory medical writing. Simin serves as a Subject Matter Expert for plain language summary writing, transparency and disclosure activities, and real-world evidence studies. She is also an instructor for the Medical Writing module for the Parexel Academy/IU University of Applied Science programme.

Jonathan Mackinnon, PhD, is an Associate Medical Writing Services Director at Parexel and is their lead Protocol Subject Matter Expert. He supports clients with protocol development across many therapeutic areas and participates in multiple protocol-related initiatives on including patient input in trial design and ensuring patient diversity. Jonathan teaches postgraduate modules for Protocol Development and Trial Designs at the London School of Hygiene and Tropical Medicine, UK.

Don't miss!

The September 2025 edition



Real world data/ real world evidence

Real-world data and real-world evidence have become integral to medical research and healthcare decision-making. Their value lies in providing insights into how healthcare treatments and interventions perform in everyday settings, which can differ significantly from controlled clinical trial environments. This issue of Medical Writing will include a broad range of articles on the issue theme covering critical aspects for medical writers working with these types of data.

Guest Editor: Maria Kołtowska-Häggström and Laura Collada Alì
The deadline for feature submissions has now passed.

Harnessing landing pages for effective patient enrolment in clinical trials

Ekaterina Bulaeva, Amalia Iljasova
OCT, Saint Petersburg, Russia

doi: 10.56012/giwf3698

Correspondence to:
Ekaterina Bulaeva
ebulaeva@oct-cro.com

Abstract

This article highlights that patient-centric landing pages offer a powerful and effective solution to the persistent challenges of clinical trial enrolment. Besides, implementing these strategies can also bridge the awareness gap and accelerate access to vital new treatments. By addressing patient needs and offering clear, accessible information and addressing patients' concerns directly, we can overcome all the above-mentioned barriers. The potential for increased recruitment and patient engagement underscores the value of this strategy.

The statistics are stark: Scientific Research Publishing[1] reports that over 80% of clinical trials struggle with enrolment, causing costly delays and requiring the addition of new research sites. While traditional recruitment methods like physician referrals and printed materials remain relevant, innovative approaches are needed to boost awareness and engagement, particularly in regions with low levels of clinical trial understanding.

Despite the critical role of clinical trials in advancing medical breakthroughs, awareness remains shockingly low in many parts of the world. In Eastern Europe, for example, surveys reveal that a significant percentage of the population has never heard of clinical trials, while others lack essential knowledge about the trial process and how to participate in a trial. This knowledge gap underscores the need for proactive and accessible communication and enrolment strategies. One effective approach for connecting with potential trial subjects is the use of landing pages. These dedicated single-page websites serve as a dynamic communication channel, delivering accessible and compelling information about specific studies. They provide a valuable solution in that they offer patient-centric information online in a readily digestible format. The key lies in understanding that the target audience is not composed of scientific experts, so clear, accessible language is essential. Here are the key elements of an effective landing page for clinical trial recruitment:

- **Address the pain point**
  Start by directly addressing the problem the study aims to solve. For example: "Struggling with insomnia?" or, as in Figure 1, "Are you suffering from constant lower back pain?". Connect with potential participants by immediately acknowledging their unmet needs (see figure 1).

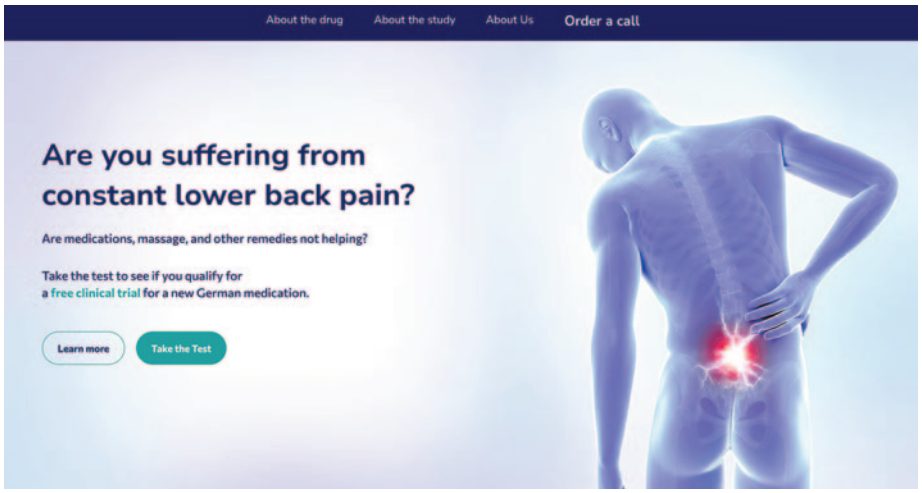


Figure 1. Example of a section of a landing page addressing a particular pain point of a potential trial candidate

Figure 2. Example of a section of a landing page with information about the investigational product

- **Give clear information about investigational products**
  Provide concise information about the investigational drug and its manufacturer. Mentioning a well-known pharmaceutical company can significantly enhance trust and credibility, as people tend to trust information which they are already familiar with. See Figure 2 for examples of what to include in this section.

- **Demystify the process**
  Include a dedicated section outlining "What to expect during the study." Provide a clear overview of each stage, including the number of injections, clinic visit frequency (including whether a nurse will visit the subject at home), and the duration of the observation period. Transparency builds confidence. As illustrated in Figure 3, you can clearly outline the patient journey, detailing preliminary screening, injection procedures, observation and monitoring stages, and doctor consultations.

- **Highlight CRO relevant expertise**
  Showcase the CRO's experience and successful track record. Displaying logos of global pharmaceutical partners or highlighting previous successful projects can positively influence potential trial participants' decisions. Including demonstrable evidence of experience, like years in the industry, the number of patients recruited across various studies, a map showing office locations, can influence potential participants' decisions.

- **List the benefits**
  Clearly state any additional benefits of participating, such as free study medication or coverage of travel expenses. Figure 4 shows how a CRO can offer patients reimbursement for transportation costs for visits to the research centre. While financial compensation is not always the primary motivator (especially for those seeking access to innovative treatments), transparency regarding costs is essential.

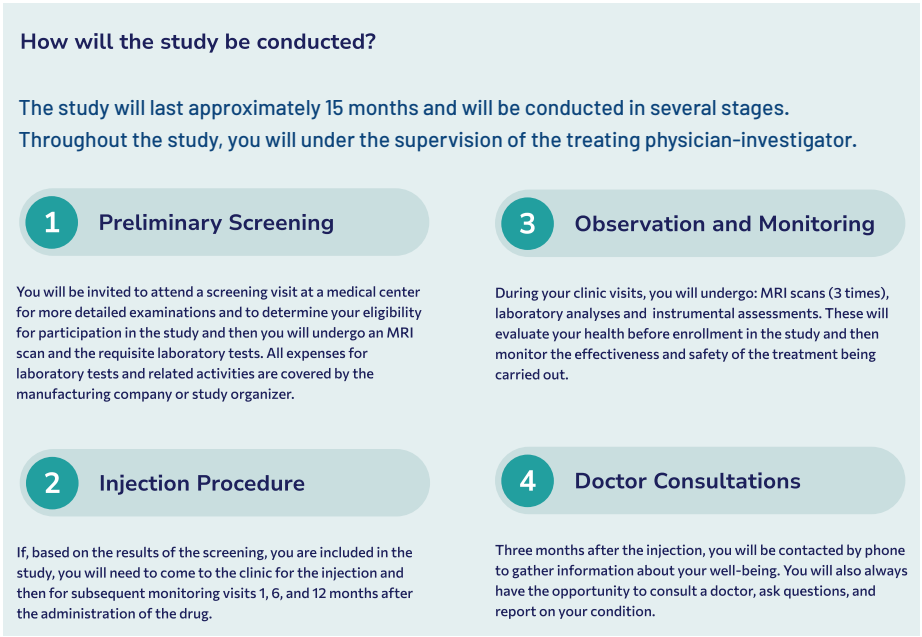


Figure 3. Example of a section of a landing page outlining the study stages that participants can expect

Patient transportation costs for visits to the research center will be covered by the study budget. Travel from regional towns to the main regional center will also be arranged and paid for in full.

Figure 4. Example of a section of a landing page dedicated to optional benefits of participating in a trial

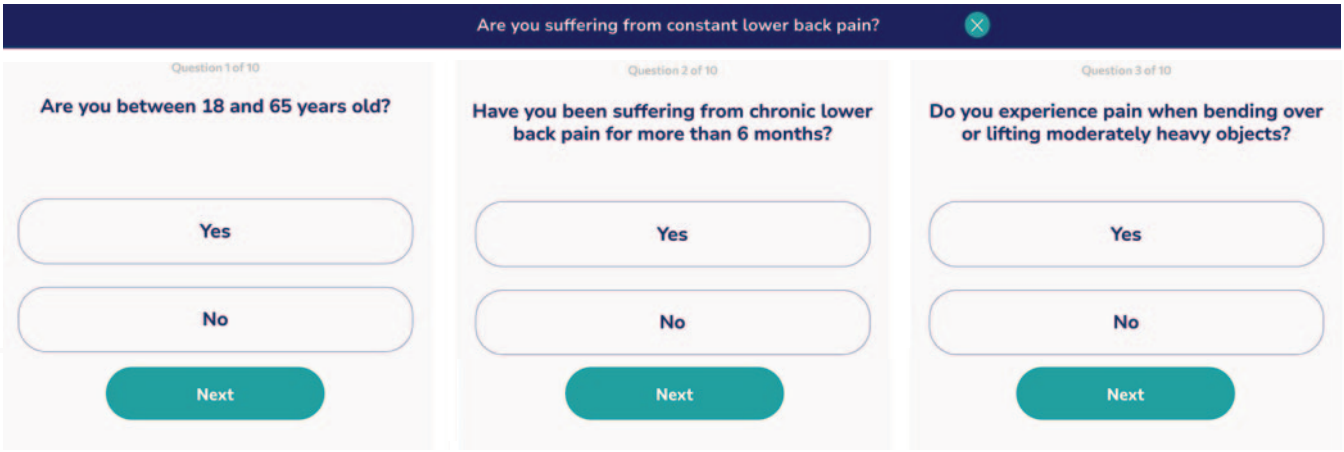


Figure 5. Example of questions that can be used in an online eligibility test to determine if a user qualifies for a trial

- **Post an eligibility test**
  Placing the online test if a user qualifies for a trial is a unique strategy for a CRO. The goal is to quickly get information from a potential candidate. In this test, you can ask basic questions, such as those presented in Figure 5: Are you between 18 and 65 years of age? Experiencing pain? What kind of pain? As a common result, a significant number of those completing the questionnaire can be identified as potentially eligible and advance to the screening process.

- **Answer questions**
  Include a frequently asked questions (FAQs) section to address common concerns and provide additional details about the study.

Where to promote a landing page

Landing page links can be strategically distributed across various online channels, including:

- Pharmacy and clinic websites;
- Medical forums;
- Social media platforms (targeted ads);
- Patient advocacy groups;
- Online support communities;
- Partnerships with healthcare providers.

Positive outcomes

Implementing patient-centric landing pages for clinical trial recruitment has yielded tangible improvements. Beyond accelerating enrolment timelines, with recruitment speeds increasing compared to average enrolment rates in similar studies, landing pages contribute to several positive outcomes. For example, they enhance the quality of candidate leads, reduce screen-failure rates by ensuring better-informed participants, and increase overall patient engagement throughout the trial process. Ultimately, a well-designed landing page empowers potential subjects to carefully evaluate their goals and interests in relation to the specific trial and its potential benefits.

Landing pages, therefore, represent a transformative tool for enhancing patient communication, optimising recruitment efficiency, and improving overall clinical trial success. By prioritising a patient-centric approach, providing clear and accessible information, and strategically leveraging online distribution channels, clinical research organisations can not only bridge the awareness gap but also fundamentally transform the patient experience and accelerate the delivery of life-changing treatments.

Disclosures and conflicts of interest

The authors declare no conflicts of interest. This article was prepared with the support of artificial intelligence tools.

References

1. Wandile PM. Patient recruitment in clinical trials: Areas of challenges and success, a practical aspect at the privater research site. J Biosci Med (Irvine)2023;11(10);103–13 doi:10.4236/jbm.2023.1110010

Author information

Ekaterina Bulaeva is a Content Director at OCT, the leading organisation for conducting clinical trials in Russia and the Eurasian Economic Union (EAEU). (A team of 130 professionals provides a full range of high-quality services for Phase I-IV and BE studies across 29 therapeutic areas including oncology, infectious diseases, and rheumatology.) Ekaterina has contributed articles and insights to industry publications since 2018, bringing years of experience to the field.

Amalia Iljasova is the Director of Marketing and Public Relations at OCT. She joined OCT in 2018 and has since contributed to various industry publications. Amalia is also a member of the EUCROF Communications working group.

Don't miss!

The December 2025 edition

Safety Writing

As the regulatory landscape continues to evolve, the importance of precise and thorough safety reporting has never been more critical. This issue will provide insights into the latest methodologies, best practices, and innovative approaches that are shaping the future of safety writing. The issue will feature articles on the development and submission of safety data, offering expert guidance on handling complex safety data.

Guest Editors: Iva Cvetkovic and Pavle Simeunovic
The deadline for feature articles is September 1, 2025.

Ongoing patient engagement research efforts at the Centre for Pharmaceutical Medicine Research, King's College London

Fatima Auwal[1,2], **Adeline Rosenberg**[1,3,4]
Liz Clark[1], **Stuart A. Jones**[1],
Graham R. McClelland[1]

[1] Centre for Pharmaceutical Medicine Research, King's College London, London, UK
[2] Ahmadu Bello University, Zaria, Nigeria,
[3] Oxford PharmaGenesis, Oxford, UK
[4] Patient author

doi: 10.56012/jcbd5834

Correspondence to:
Adeline Rosenberg
adeline.rosenberg@kcl.ac.uk

Abstract

Research efforts within the Centre for Pharmaceutical Medicine Research, King's College London, are advancing patient engagement in medicine development and communications through evidence generation. This article presents the ongoing work of two doctoral researchers within the department, whose joint efforts aim to contribute to the evidence base on the integration of meaningful and sustainable patient engagement and involvement across the medicine development lifecycle and within peer-reviewed publications. These works have so far included a systematic literature review as well as qualitative interview-based analyses of both the perceived value of patient engagement across stakeholders and the landscape of patient involvement practices within peer-reviewed publications. Together, these research themes share foundational values, activities, and aspirations that this article explores within a framework of patients communicating to industry, industry communicating to patients, and patients and industry communicating with each other.

Plain language summary

Researchers at the Centre for Pharmaceutical Medicine Research at King's College London are working to improve the ways that patients are involved in medical and pharmaceutical research. Their research aims to make sure that patients' opinions and experiences are incorporated into the development of new medicines and the public sharing of research results. They have reviewed previous studies and interviewed patients and other researchers, including those working in the pharmaceutical industry, to better understand their perspectives and experiences. In this article, the researchers consider where their projects overlap and discuss the flow of communication between patients and the pharmaceutical industry.

Background

Patient engagement in clinical research and medicine development has grown significantly since it first began in the 1980s.[1] As the concept of involving patients in research has gained broader acceptance, both the practice and related academic literature have expanded considerably.[2] At the Centre for Pharmaceutical Medicine Research (CPMR), King's College London, patient engagement in medicine development is one of three primary research themes, with the goals of generating a research base and embedding patient engagement in the practice of future generations of researchers and other stakeholders in this field.[3] Here, we outline the ongoing research efforts of two of our doctoral researchers (FA and AR) working in the patient engagement space, explore the intersections between the themes of engagement and communication, and share relevant learnings for the medical writing community.

> We conducted a systematic literature review of patient engagement models in medicine development to assess the current landscape.

Patient engagement across the medicine development lifecycle

Although several initiatives[4-7] have been established to support patient engagement, there is limited evidence that these are consistently implemented in a meaningful and sustainable manner throughout the medicine development process. To better understand why, FA's research focuses on the generation of evidence for patient engagement in the development and use of medicines. To begin, we conducted a systematic literature review of patient engagement models in medicine development to assess the current landscape.[8]

Key findings from this review are as follows:

- Patient engagement in research is widely recognised as a process that positions patients as valued partners who should be actively involved and respected throughout the development and lifecycle management of medicines. Despite the shared emphasis on the value of patient inputs, the lack of unified definition and understanding of patient engagement hinders its consistent application. This lack of standardisation is further compounded by the absence of consensus on which aspects of patient engagement are most critical or should be prioritised.
- Current patient engagement guidelines are nonbinding and nonprescriptive, serving only as general frameworks for stake-holders seeking to incorporate patient engagement into their practices. Despite numerous initiatives intended to promote patient engagement, evidence of its consistent,

King's College London

Photo: Wikimedia

meaningful, and sustainable application in drug development remains sparse.

- Some of the challenges identified that hinder the systematic implementation of patient engagement include insufficient training and expertise among stakeholders; lack of practical tools and industry-specific metrics to evaluate the impact of patient contributions; behavioural resistance to valuing patient engagement; lack of skills, awareness, and competencies for undertaking effective patient engagement; and unclear definitions of the scope, expectations, and responsibilities associated with patient engagement.
- Addressing these barriers is essential for advancing patient engagement and translating theoretical frameworks into actionable practice. In addition, existing frameworks for assessing the impact of patient engagement must undergo rigorous validation to establish robust evidence supporting its routine integration into drug development processes.

The research gaps identified in this review led to our current study, which explores the perceived value of patient engagement in medicine development from the perspectives of key stakeholders: pharmaceutical industry professionals, patients and patient support groups, and regulators. Our goal is for these insights to guide the future integration of meaningful and sustainable patient engagement in medicine development.

Patient involvement in peer-reviewed publications

The research communications community, including scholarly publishing, has recognised patients as important stakeholders with potential for involvement throughout the publication lifecycle,[9] and in recent years, several reviews and analyses have characterised different aspects of this rapidly evolving practice.[10-12] Meanwhile, pharmaceutical companies are beginning to adopt and formalise broader frameworks for patient engagement in medicine development, including internal policies for publication processes.[13-15] However, owing to the novel and innovative nature of the practice as well as challenges associated with identifying such involvement, consistency across the industry is still being established and best practices are evolving.[10] To better support such frameworks and contribute towards building an evidence base for best practices, AR's ongoing research is a qualitative mapping of the current landscape of patient involvement in publications within the pharmaceutical industry. Current efforts so far include a thematic analysis of scoping interviews with multistakeholder experts in the field – such as patients and other publication professionals – to translate experiential knowledge into theory and evidence.[16]

> Our ongoing research is a qualitative mapping of the current landscape of patient involvement in publications within the pharmaceutical industry.

Where do these research themes intersect?

Although these two bodies of research focus on distinct aspects of patient engagement and involvement within the pharmaceutical industry, they share foundational values, with overlapping and heterogenous concepts and best practices across three broad and not readily delineated domains (see Figure 1).

This overview is intended to reflect the top-line themes and elements common to our combined research efforts, spanning research and development, regulatory,

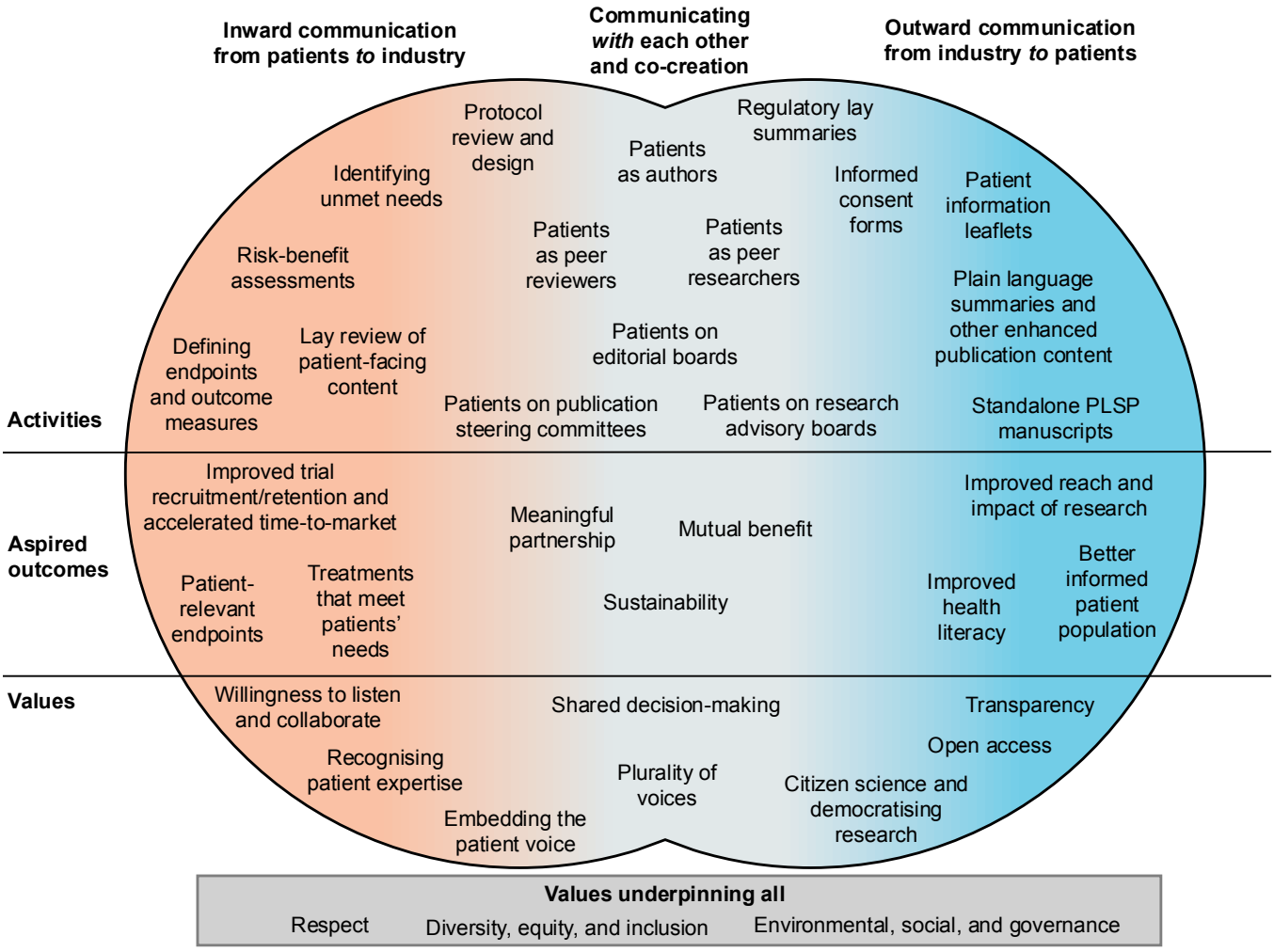


Figure 1. Intersecting research themes.

The activities, aspired outcomes, and values that are shared across our combined research efforts. PLSP, Plain Language Summary Publications

market access, and publications contexts. We recognise that there is a wealth of further activities, aspired outcomes, and values within the broader patient engagement space that we have not included within the scope of this non-exhaustive summary.

1. Inward communication from patients to industry

Patients are actively contributing to pharmaceutical industry processes by communicating their priorities and perspectives. Many of these interactions and engagements may be solicited by industry and happening on industry's terms – i.e., industry seeking input from patients – but patients are also leading the charge in ensuring their voices are heard. These activities and their associated values, for example identifying unmet needs and trial protocol reviews, are largely intended to embed the patient voice across industry processes and practice patient-centric medicine development. This domain drives a shift towards patient-relevant outcomes and sustainable models of patient engagement that foster better alignment between research objectives and patient priorities.[8,17]

2. Outward communication from industry to patients

Through both fulfilment of regulatory requirements as well as a broader move towards open science principles, pharmaceutical companies are communicating research information to patient communities through multiple channels and formats. These methods of communication, for example plain language summaries of publications and regulatory lay summaries, are an important opportunity for industry to demonstrate transparency and trustworthiness. Through this domain, industry aims to bridge the gap between scientific research and patient understanding, promoting an accessible approach and an ethical commitment towards enhancing health literacy and information equity.[18]

3. Communicating with each other and co-creation

At the intersection of these themes is the domain of bidirectional communication and collaborative exchange between stakeholders. Here, patients and industry are communicating together, with, and alongside each other. In cases of best practice and genuine co-creation, they are doing so from a position of equals. The increasing prevalence of patients within pharmaceutical and scientific processes – in such roles as peer researchers and advisory board members to co-authors and journal editorial board members[9,19] – is a result of the increasing recognition of

patients as lived experience experts and experiential knowledge as an equally robust form of knowledge or epistemology as other forms of scientific knowledge.[20,21] This domain of (intended) co-creation, built on values of inclusivity and plurality, acknowledges that there is rarely such a clear-cut distinction between stakeholders on a personal level, with individuals capable of bringing multiple perspectives, identities, and experiences to the table.[16]

At the foundation of these three domains are core values that guide meaningful patient engagement and interactions – respect; diversity, equity, and inclusion; and environmental, social, and governance (ESG) goals.[9,18,22-24] These principles help industry work within ethical and responsible frameworks to maximise the impact of patient engagement across all processes and stages of medicine development.

Photo: Wikimedia

Recommendations arising from our research efforts so far

Through continued multistakeholder communication and concerted efforts between patient and industry communities, future work on patient engagement and involvement in medicines development and research communications should focus on the following:

- Establishing a universal, global framework of shared values and principles which can inform the choices involved in good practice. For example, this can include unified terminology as well as an adaptable code of practice that aligns with global regulatory standards.
- Fostering a pre-competitive space to avoid duplication of efforts and resource waste by stakeholders. For example, there may be a role for global industry/regulatory organisations to facilitate collaboration and conversation, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, the World Health Organization, or the Council for International Organizations of Medical Sciences, as well as professional organisations such as EMWA.
- Harmonising guidance and training, tailored for specific stakeholder groups and ideally accessible on a digital platform, to provide a common standard whilst saving duplication of effort. For example, standards can be established through publishing case studies of best practices.
- Testing and validating tools, frameworks, and impact measures over time to form a robust evidence base that supports good practice. For example, communications professionals are implementing more meaningful publication metrics.[25]
- Assessing the equity of digital platforms and accessibility of content for all patient populations and particularly under-served communities, to build inclusive and reputable practices, as well as to support the ESG targets for companies. For example, accreditation of health content creators via the Patient Information Forum's PIF TICK scheme helps communities identify trustworthy health content.[26]

These recommendations will help medical writers and industry professionals create a comprehensive, sustainable, and more systematic patient engagement practice that can be effectively integrated into routine medicine development and communications processes. By doing so, we believe that the effectiveness of research will improve, leading to medicines that are more likely to meet the real needs of patients, and thereby benefitting all stakeholders.

Take-home message

The intersection of research themes presented here represents the potential starting point for a coherent approach for the evolution of patient engagement in medicine development and research communications. Additionally, based on our collective research efforts so far, we have found that researchers and sponsors have generally maintained a positive attitude toward patient engagement. However, the regulatory "push" from governments and the "pull" from patients and their representatives have yet to achieve consistent and sustainable patient engagement practices across medicine development and communications processes. We encourage medical writers and industry professionals to focus on identifying and developing a unified patient engagement approach whereby all stakeholders drive progress and harmonisation and ensure long-term momentum in the interests of patients.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employers or EMWA.

Disclosures and conflicts of interest

Adeline Rosenberg is an employee of Oxford PharmaGenesis, Oxford, UK, but this work is independent of her employment. There are no disclosures to provide for the other authors.

Data availability statement

For enquiries about data and other supplemental information, please contact the corresponding author.

References

1. Robbins DA, Curro FA, Fox CH. Defining patient-centricity: Opportunities, challenges, and implications for clinical care and research. Ther Innov Regul Sci. 2013;47(3):349–55. doi:10.1177/2168479013484159
2. Harrington RL, Hanna ML, Oehrlein EM, et al. Defining patient engagement in research: Results of a systematic review and analysis: Report of the ISPOR patient-centered special interest group. Value Health. 2020;23(6):677–88. doi:10.1016/j.jval.2020.01.019
3. McCool K, Clark L. Multistakeholder perspectives on patient and public collaboration in medicines development: Highlights of the spring 2024 patient engagement workshop. The Evidence Base; 2024 [cited 2024 Nov 14]. Available from: https://becarispublishing.com/digital-content/blog-post/multistakeholder-perspectives-patient-and-public-engagement-medicines-development.
4. PFMD. Framework for Patient Engagement. 2021 [cited 2024 Nov 14]. Available from: https://patientfocusedmedicine.org/framework-for-patient-engagement/.
5. Innovative Medicines Initative. PARADIGM. 2021 [cited 2024 Nov 08]. Available from: https://imi-paradigm.eu/.
6. US FDA. Patient-focused drug development: Incorporating clinical outcome assessments into endpoints for regulatory decision-making. 2023 [cited 2024 Nov 14]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-incorporating-clinical-outcome-assessments-endpoints-regulatory.
7. European Patients Academy on Therapeutic Innovation. EUPATI: Education That Empowers. 2024 [cited 2024 Nov 08]. Available from: https://eupati.eu/.
8. Auwal FI, Copeland C, Clark EJ, et al. A systematic review of models of patient engagement in the development and life cycle management of medicines. Drug Discov Today. 2023;28(9):103702. doi:10.1016/j.drudis.2023.103702
9. Woolley KL, Stones SR, Stephens R, et al. Patient authorship of medical research publications: An evolution, revolution, and solution? Learn Publ. 2024;37(3):e1607. doi:10.1002/leap.1607
10. Oliver J, Lobban D, Dormer L, et al. Hidden in plain sight? Identifying patient-authored publications. Res Involv Engagem. 2022;8(1):12. doi:10.1186/s40900-022-00346-w
11. Arnstein L, Wadsworth AC, Yamamoto BA, et al. Patient involvement in preparing health research peer-reviewed publications or results summaries: a systematic review and evidence-based recommendations. Res Involv Engagem. 2020;6:34. doi:10.1186/s40900-020-00190-w
12. Richards DP, Birnie KA, Eubanks K, et al. Guidance on authorship with and acknowledgement of patient partners in patient-oriented research. Res Involv Engagem. 2020;6:38. doi:10.1186/s40900-020-00213-6
13. Gorbenko O, Cavillon P, Giles RH, et al. Co-creating with patients an impact framework across the medicine's life cycle: a qualitative study exploring patients' experiences of involvement in and perceptions of impact measures. Res Involv Engagem. 2022;8(1):1. doi:10.1186/s40900-022-00334-0

Author information

Fatima Auwal, MSc, is a current PhD student at the Centre for Pharmaceutical Medicine Research (CPMR), King's College London. Prior to starting her PhD, Fatima served as an academic staff member of the Department of Clinical Pharmacy and Pharmacy Practice, Ahmadu Bello University, Zaria, Nigeria.

ORCID: 0000-0001-6454-9965.

Adeline Rosenberg, MSc, is a doctoral researcher at CPMR, King's College London, a senior medical writer in patient engagement at Oxford PharmaGenesis, and a patient research partner/steering committee member of the Oxford Patient Engagement Network for Arthritis and Musculoskeletal Conditions, University of Oxford.

ORCID: 0000-0003-4599-4291.

14. Klein B, Perfetto EM, Oehrlein EM, et al. Measuring and demonstrating the value of patient engagement across the medicines lifecycle: A patient engagement impact measurement framework. Patient. 2024;18:3–18. doi:10.1007/s40271-024-00713-7
15. Bittante A, Stevens P, Wulund L, et al. Developing a framework for patient involvement in publications. Curr Med Res Opin. 2024;40(S2 - Original abstracts from the 2024 European Meeting of ISMPP):S45–S6. doi:10.1080/03007995.2024.2314805
16. Rosenberg A, Clark L, McClelland G. Patients and publications: ongoing qualitative landscape mapping. Spring 2024 Patient Engagement Workshop; Centre for Pharmaceutical Medicine Research, King's College London, London, UK. doi:10.6084/m9.figshare.25805212.v1.
17. Hoos A, Anderson J, Boutin M, et al. Partnering with patients in the development and lifecycle of medicines: A call for action. Ther Innov Regul Sci. 2015;49(6):929–39. doi:10.1177/2168479015580384
18. Rosenberg A, Walker J, Griffiths S, Jenkins R. Plain language summaries: Enabling increased diversity, equity, inclusion and accessibility in scholarly publishing. Learn Publ. 2023;36(1):109-18. doi:10.1002/leap.1524
19. Dwyer CP, Joyce RA, Rogers F, et al. Comparing the effects of a patient-designed-and-informed participant information leaflet in comparison with a standard, researcher-designed information leaflet on recruitment, retention and understanding: A study-within-a-trial. Contemp Clin Trials Commun. 2022;28:100936. doi:10.1016/j.conctc.2022.100936
20. Dumez V, L'Esperance A. Beyond experiential knowledge: a classification of patient knowledge. Soc Theory Health. 2024;22:173–86. doi:10.1057/s41285-024-00208-3
21. Vázquez E, Kim M, Santaella ME. Lived experience experts: a name created by us for us. Exp Rev Hematol. 2023;16(sup1):7–11. doi:10.1080/17474086.2023.2178410
22. Skobe C, Sykes A, Winchester C. Equity, diversity, and inclusion: Defining a roadmap for our profession. The MAP Newsletter. 2020 [cited 2024 Nov 21]. Available from: https://www.ismpp-newsletter.com/2020/10/21/equity-diversity-and-inclusion-defining-a-roadmap-for-our-profession/.
23. Cavaller-Bellaubi M, Faulkner SD, Teixeira B, et al. Sustaining meaningful patient engagement across the lifecycle of medicines: A roadmap for action. Ther Innov Regul Sci. 2021;55(5):936–53. doi:10.1007/s43441-021-00282-z
24. Furtner D, Hutas G, Tan BJW, et al. Journey from an enabler to a strategic leader: Integration of the medical affairs function in ESG initiatives and values. Pharmaceut Med. 2023;37(6):405–16. doi:10.1007/s40290-023-00485-9
25. Rees T. Obtaining meaningful insights from publication metrics. Med Writ. 2022;31(4):50–3. doi:10.56012/vjht8689
26. Patient Information Forum (PIF). PIF TICK. 2023 [cited 2025 Jan 02]. Available from: https://piftick.org.uk/.

Liz Clark, MSc MBBS FFPM, undertakes a wide-ranging portfolio of activities as an independent pharmaceutical physician, is Patient Engagement Theme Lead and Visiting Lecturer at King's College London, Board member of Patient Focused Medicines Development, co-chairs the Faculty of Pharmaceutical Medicine's Working with Patients and Communities forum, and previously spent 27 years in pharma.

ORCID: 0009-0004-9271-1180

Stuart Jones, PhD, holds a chair in Pharmaceutical Medicine and is the Director of CPMR, King's College London. He started his career in the pharmaceutical industry at Pfizer, left to study for a PhD, and then spent the last 19 years as an academic.

ORCID: 0000-0001-5078-0250

Graham McClelland, PhD, is Professor of Pharmaceutical Medicine and Course Director of the Integrated MSc Apprenticeship in Clinical Pharmacology at King's College London, Deputy Chair of Quantum Care, a leading UK not-for-profit provider of residential care for the elderly, and previously had a long career in clinical research and development within the pharmaceutical industry.

ORCID: 0000-0001-7395-4065

Making medical communication accessible to all: A translator's perspective

Ana Sofia Correia
Freelance medical translator and writer
Lousã, Portugal

doi: 10.56012/oIIx2709

Correspondence to:
Ana Sofia Correia
ana@anasofiacorreia.com

Abstract

Language barriers in healthcare can put patients at risk, leading to misdiagnoses, delays in treatment, and exclusion from clinical trials. Clear communication requires cultural adaptation to ensure patients understand and trust the information they receive. Professional medical translation plays a key role in preventing errors. A smart approach to language access can make healthcare more inclusive and efficient. Investing in better communication helps patients follow treatment plans, reduces health disparities, and builds trust. By making language access a priority, healthcare providers can ensure that every patient, no matter their native language, gets the care they need.

Imagine the panic of rushing your child to the hospital during a medical emergency – perhaps they have a dangerously high fever, severe breathing difficulties, or a sudden allergic reaction. You expect immediate, life-saving care. But upon arrival, you face an unexpected and overwhelming obstacle: no one at the hospital speaks your language.

You try to explain your child's symptoms, medical history, and any allergies, but the doctors and nurses don't understand you. They attempt to communicate using gestures, fragmented phrases, or even a translation app that struggles with medical terminology. The stress of the emergency is compounded by the fear that something critical will be lost in translation – and that fear quickly becomes reality.

Now, imagine you have been diagnosed with a severe, life-threatening condition. Standard treatments have failed, and your best hope is an experimental therapy in a clinical trial. The study offers a promising, cutting-edge treatment. However, when you try to enrol, you are excluded – not due to medical ineligibility, but because the trial's materials, including informed consent forms, patient instructions, and follow-up assessments, are only available in the local language. There are no translation services, no multilingual support, and no accommodations for non-native speakers.

Language barriers in healthcare can lead to life-threatening consequences, making professional translation services essential for patient safety and effective treatment.

Consider a global crisis, such as a pandemic, where clear and timely communication is crucial. Governments, health organisations, and companies rush to release safety guidelines, prevention measures, and testing instructions to the public. However, when this life-saving information is translated using unsupervised AI translation without human oversight, the consequences become dangerously clear – misinterpretations, misinformation, and preventable harm.

These are not hypothetical scenarios. These are real risks faced by patients worldwide due to inadequate language support in healthcare settings. The need for professional language services is critical to ensuring accurate communication between healthcare providers and patients, safeguarding health and well-being.

Language barriers in healthcare can lead to life-threatening consequences, making professional translation services essential for patient safety and effective treatment.

Why should healthcare speak your language?

Effective communication in healthcare empowers patients to engage actively in their treatment, leading to improved health outcomes and higher satisfaction with care. When patients understand medical instructions – facilitated by materials in their native language – they are more likely to adhere to prescribed treatments and communicate openly with healthcare providers, fostering a trusting relationship that benefits both parties.[1]

Beyond individual patient care, ensuring language accessibility enhances healthcare efficiency. However, despite the growing recognition of the need for quality patient information in native languages, health disparities persist among populations with limited access to translated materials. Many patients encounter barriers that lead to poorer health outcomes, underscoring the urgency for inclusive strategies that bridge these gaps. Without accessible language support, patients may rely on family members or online tools, increasing the risk of misinterpretation and medical errors.[2]

Patients who do not speak the local language often face delays in care, misunderstand diagnoses, and struggle to follow treatment plans. Implementing targeted language access strategies can help healthcare systems bridge these gaps, creating a more equitable patient experience.

By prioritising accessible, high-quality healthcare communication, we can improve patient outcomes, reduce disparities, and foster trust between patients and healthcare providers.[3]

How do we make healthcare information culturally relevant, not just translated?

Health beliefs, perceptions of illness, and attitudes toward medical interventions vary widely across cultures, shaping how patients interpret symptoms, treatments, and preventive care.[4] Direct translation alone is often insufficient – without proper cultural adaptation, even well intended health messages can lead to misunderstanding, distrust, or non-adherence to treatment plans.

By prioritising cultural adaptation in medical translation, healthcare providers can improve patient education, support treatment adherence, and build trust in medical interventions. Aligning translated materials with local expectations and healthcare realities significantly enhances the effectiveness of health communication.[5]

Cultural adaptation involves understanding health perceptions, using appropriate tone and language, adapting medical terminology, and incorporating culturally relevant visuals. This ensures that information is not only accurate but also meaningful and actionable for diverse patient populations. By prioritising multilingual health resources, organisations can bridge language gaps, improve patient engagement, and ultimately enhance global health equity.[6] (Table 1).

Photo: freepik

By prioritising accessible, high-quality healthcare communication, we can improve patient outcomes, reduce disparities, and foster trust between patients and healthcare providers

How do we make sure medical translations are accurate every time?

Ensuring accuracy in medical translations requires a structured, multistep review process. A well-defined workflow minimises errors, enhances clarity, and improves the overall effectiveness of patient communication. The Translation, Editing, and Proofreading (TEP) model is a widely accepted best practice that ensures quality at every stage of translation.[7]

By implementing a robust, multistep review process, organisations can safeguard accuracy, clarity, consistency, as well as compliance with local regulations and ethical standards. Whenever possible, usability testing with native speakers helps validate patient-facing materials before distribution.

How do we make language access affordable without cutting corners?

Implementing language services requires a strategic balance between quality, cost, and efficiency. While comprehensive multilingual support is ideal, budget and time constraints often limit what can be immediately achieved. However, a well-planned translation strategy ensures that essential language services remain sustainable, efficient, and impactful.

A well-planned translation strategy ensures that essential language services remain sustainable, efficient, and impactful.

1. Prioritise high-impact materials

- Focus on translating documents that directly affect patient care and compliance, such as informed consent forms, discharge instructions, emergency department signage, and medication guides.
- If full translation is not feasible, start with core materials and expand based on patient needs, risk factors, and available funding.

2. Optimise translation workflows for efficiency

- Plan translation workflows in advance to allow sufficient time for review, quality assurance, and regulatory compliance checks.
- Standardise processes across departments to streamline translation efforts and prevent duplicated work.
- Assign dedicated project managers to oversee translation requests, standardise terminology, and ensure timely execution.

Table 1. Making medical information culturally relevant: Key considerations and approaches

Key consideration	Approach
Understand cultural perceptions of health and illness	Messaging should be crafted in a sensitive and unbiased way to encourage patient engagement without reinforcing stigma or fear.
Ensure culturally appropriate language and tone	Some cultures favour a direct, authoritative tone from medical professionals, while others prefer a more collaborative, patient-centred approach. Content should be adapted accordingly to build trust and engagement. Certain idiomatic expressions, metaphors, or humour used in health education materials need careful adaptation and localisation to maintain clarity and relevance
Adapt medical terminology to local use	Even when a language is shared across multiple regions (e.g., Portuguese in Portugal vs. Brazil), medical terminology and common usage can differ. Additionally, some medical terms have direct translations that are technically correct but may not be commonly understood. Ensuring local adaptations avoids confusion and enhances patient understanding.
Use visuals that reflect the target audience	Including diverse representations in patient education materials helps foster inclusivity. Patients are more likely to trust information that visually reflects their community and lifestyle. Imagery, colours, and symbols should align with cultural expectations. For example, white represents mourning in some Asian cultures, while it symbolises cleanliness in Western contexts.
Adapt educational materials to different literacy levels	Many patients, even in developed countries, have low health literacy. Using plain language principles ensures that materials are clear, concise, and actionable. Instead of long paragraphs, use bullet points, numbered steps, and infographics to present critical health information. Visual adaptations should also consider literacy levels, ensuring that pictograms, icons, and step-by-step illustrations are intuitive and support comprehension.
Align with local healthcare policies and medical practices	Healthcare protocols, treatment guidelines, and healthcare systems vary between countries. Translated materials should accurately reflect the medical landscape of the target region. Consent forms, prescription instructions, and discharge summaries should comply with both legal requirements and patient expectations in each country. Materials should reflect these norms to ensure patients feel comfortable engaging with their care.
Provide digital and print accessibility	Not all patients have reliable internet access or the ability to navigate digital health portals. Providing printed versions of translated materials ensures accessibility for older patients, rural populations, and those without digital literacy. For digital formats, ensuring text-to-speech compatibility and mobile-friendly design enhances usability for diverse populations.
Train healthcare providers on cultural sensitivity	Even the best-translated materials cannot replace culturally competent healthcare providers. Training programmes that teach providers how to use these materials effectively and communicate across cultural boundaries improve overall patient care.
Gather feedback from native speakers and patients	The most effective way to ensure cultural appropriateness is to involve local healthcare professionals, patient advocates, and community representatives. Conducting usability tests and gathering real-world patient feedback can reveal hidden barriers and provide insights for continuous improvement.

Table 2. Best practices for medical translation

Key strategy	Best practice
Prioritise clarity over literal accuracy	Use plain language principles to make medical information more digestible, avoiding complex jargon where possible. A technically correct translation may not always be understandable to patients. Instead, messages should be clear, simple, and patient-friendly. Provide alternative phrasing or explanatory footnotes for medical terms that may not have a widely recognised equivalent in the target language.
Advocate for early involvement in content development	Engage translators from the outset rather than at the final stage of content production. This minimises the need for extensive revisions later. Implement a collaborative workflow where all stakeholders work together to ensure the content is structured in a way that facilitates translation.
Emphasise contextual and cultural understanding	Consider literacy levels, medical practices, and attitudes toward healthcare in the target audience's community. Localise examples, recommendations, and treatment references to align with regional norms and accessibility.
Encourage continuous improvement and feedback loops	Engage with healthcare providers and patient advocacy groups to gather feedback on translated materials. Identify terms or phrases that may be confusing and refine accordingly. Regularly update translations to align with evolving guidelines and advancements in healthcare and communication.
Monitor and continuously improve AI outputs	Perform regular audits of AI-translated content to identify common errors and areas for improvement. Evaluate AI performance using feedback from healthcare professionals, patients, and linguists to refine translation quality.

3. Develop reusable translation assets

- Create pre-approved, frequently used multilingual templates for common patient materials, such as appointment reminders, discharge instructions, and medication guides.
- Structure content in modular, reusable segments to minimise redundant translation work.
- Maintain an updated glossary of standardised medical terminology to ensure consistency across translations.

4. Leverage AI-assisted translation with human oversight

- AI-powered translation tools can assist with handling large volumes of content, thus accelerating workflows and reducing costs. However, human editing remains essential to ensure medical accuracy and cultural appropriateness.
- Consider using a tiered approach:
  High-priority materials: Invest in full professional human translation for critical medical documents like patient safety materials, informed consent forms, and emergency guidelines.
  Moderate priority materials: Use AI-assisted translation with human post-editing for patient education materials and general healthcare guidance.
  Low-priority materials: For internal use or administrative documents, AI translation with minimal human review may be sufficient, helping scale efforts while keeping costs down.

5. Monitor performance and adjust strategies

- Track key metrics such as patient satisfaction, reduced miscommunication incidents, and compliance improvements to evaluate the effectiveness of translation efforts.
- Identify which translated materials are most frequently used and address existing language gaps to refine future translation priorities.
- Regularly revisit translation strategies to maintain cost-efficiency while ensuring accessibility.

A translator's perspective: Some final recommendations

As a freelance medical translator, I have witnessed first-hand the challenges of making patient information technically accurate and accessible to diverse audiences. (Table 2).

> Engaging skilled medical translators ensures that patient materials are not only linguistically accurate but also culturally appropriate and patient-friendly.

Quality patient information in native languages is not a convenience – it is a fundamental component of patient safety, empowerment, and equitable healthcare access. Prioritising language accessibility is essential for a more inclusive and effective healthcare system. Engaging skilled medical translators ensures that patient materials are not only linguistically accurate but also culturally appropriate and patient-friendly.

To conclude, I invite you to read the March 2024 issue of this journal on Translation [https://journal.emwa. org/translation/] which explores the transformative role of translation in advancing medical communications and improving access to healthcare. Lastly, I leave you with a reflection: Medical translation is essentially medical writing, but in another language.

Cirsten Verleger/EMWA Creative Team.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

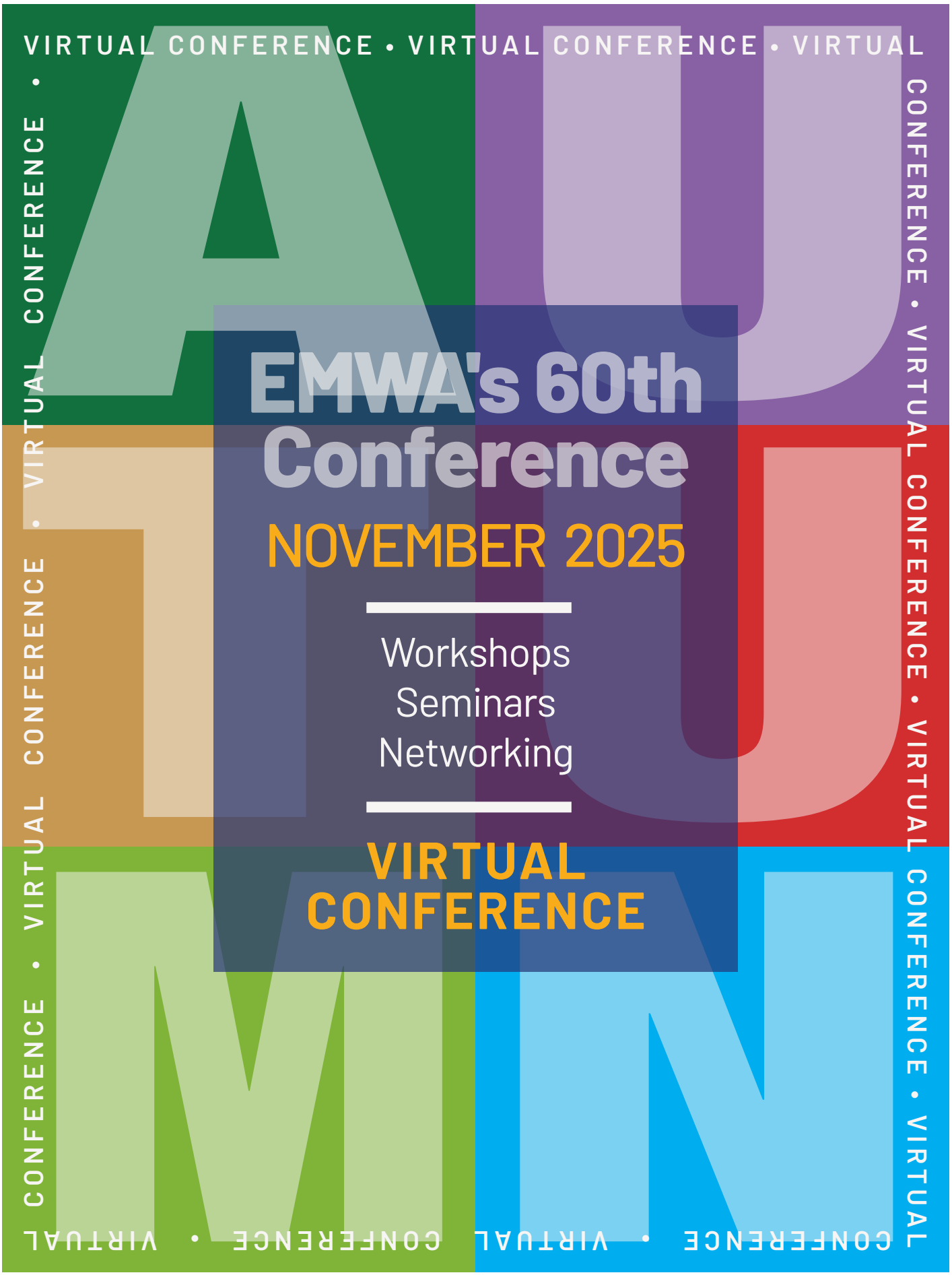
References

1. Geyer C. Empathy and language in the clinician–patient relationship: improving the translation of evidence to practice. Am J Health Promot. 2021;35(4):590–2. doi:10.1177/ 08901171211002328b
2. Ellahham S. Communication in health care: impact of language and accent on health care safety, quality, and patient experience. Am J Med Qual. 2021;36(5):355–64. doi:10.1097/01.JMQ. 0000735476.37189.90
3. Squires A. Strategies for overcoming language barriers in healthcare. Nurs Manage. 2018;49(4):20–7. doi:10.1097/01. NUMA.0000531166.24481.15
4. Institute of Medicine (US) Committee on Health Literacy. Culture and society. In: Nielsen-Bohlman L, Panzer AM, Kindig DA, editors. Health literacy: a prescription to end confusion. Washington (DC): National Academies Press (US); 2004 [cited 2025 Apr 18].
5. European Centre for Disease Prevention and Control. Translation is not enough – Cultural adaptation of health communication materials: A five-step guide. Stockholm: ECDC; 2016. doi:10.2900/40099
6. Bombard Y, Baker GR, Orlando E, et al. Engaging patients to improve quality of care: a systematic review. Implement Sci. 2018;13:98. doi:10.1186/s13012-018-0784-z
7. International Organization for Standardization. ISO 17100:2015 – Translation services – Requirements for translation services. Geneva: ISO; 2015. Available from: https://www.iso.org/standard/59149.html

Author information

Ana Sofia Correia is a medical translator and writer with 18 years of experience. She collaborates with life sciences companies and medical communication agencies, writes the *Perspectives on Medical Translation & Writing* newsletter, co-authors the *Med & Mark* blog, and runs the Medical Translation Mentoring programme. She currently serves as Vice-President of the Portuguese Medical Writers Association (APMW) and Marketing Manager of Women in Localisation Portugal Chapter. Within EMWA, she leads the Translation Enthusiasts' subgroup of the MedComms Special Interest Group while editing the Gained in Translation section of *Medical Writing*.

0009-0003-8213-4108


VIRTUAL CONFERENCE • VIRTUAL CONFERENCE • VIRTUAL
EMWA's 60th Conference
NOVEMBER 2025
Workshops
Seminars
Networking
VIRTUAL CONFERENCE

Visual aids in patient-focused drug development and routine clinical practice

Helena K. Jambor[1], **Carola Krause**[2], **Judit Mészáros**[3]

[1] University of Applied Sciences of the Grisons, DAViS, Chur, Switzerland
[2] Trilogy Writing & Consulting GmbH, Frankfurt am Main, Germany
[3] Grünenthal GmbH, Berlin, Germany

doi: 10.56012/ucgj1753

Correspondence to:
Judit Mészáros
jud.meszaros@gmail.com
Carola Krause
carola.krause@trilogywriting.com

Abstract

Effective medical communication is critical for patient consent, adherence to treatment, and improved health outcomes. Visual aids, such as infographics, diagrams, and charts, have proven invaluable for enhancing comprehension, particularly of complex medical concepts like risks and numerical data. Historically, medical visualisations have played a vital role, from Renaissance anatomical atlases to modern-day graphical abstracts and patient-centred infographics. Innovations in visual communication underscore their transformative power in healthcare. Despite their long-standing utility, visual aids remain underused in patient information, which often suffers from overly complex language and poor design.

The integration of visuals into clinical trial reporting, informed consent forms, and treatment plans has gained momentum, supported by guidelines advocating for patient-focused communication. Recent studies confirm that well-designed visuals improve comprehension, engagement, and equity in healthcare communication. As user-friendly tools become more accessible, visual aids will become integral in advancing patient-centred, inclusive healthcare practices.

Introduction

Understandable medical communication is important for consent, adherence to therapy, and positive health outcomes, and is foundational for high-quality care. Pictures and visual aids have demonstrable benefits for comprehension, particularly for risk, uncertainty, and numerical information.[1] The importance of visualisations for medical writing has been highlighted in the March 2020 issue of *Medical Writing*, which showcased example explanatory visualisations, designs for study protocols, and graphical abstracts.[2-4] A notable article was even entitled with the well-known adage "A picture is worth a thousand words" and emphasised why humans are drawn to pictures and memorise information better when supplemented with visual components.[5] It is therefore not surprising that today data visualisations and visual aids are becoming more frequent in medical communication.

Pictures and visual aids in medicine – a look back

Pictures are not a new addition to the field of medicine: they have always been integral in medical practice and research and can be traced back to antiquity. Medical atlases were essential for physicians, offering illustrations of human anatomy and botanical diagrams of medicinal plants, but they were also admired by the elite.[6] Illustrations of the typical appearance of a plant or animal would serve as a reference and were passed along among scholars and regularly transcribed.[6] Atlases provided an accessible way to summarise and convey complex information in an era when literacy was limited, linguistic barriers were high. They were a portable means of communication.[7]

During the Renaissance, more systematic approaches to medical visualisation were developed, fuelled by technological advancements such as the printing press. Then in the 19th century extraordinary progress was made in data visualisation with the development of diagrams.[8] Notably, the advent of diagrams was largely driven by the need to communicate medicine and healthcare issues to politicians, patients (also those with no or low literacy), and newly trained healthcare workers. Several data visualisation pioneers were working in the medical sector at this time, namely Florence Nightingale, John Snow, and Étienne-Jules Marey. Among these three: Nightingale developed the "coxcomb" diagram to visually demonstrate the positive effect of healthcare reforms for saving soldiers' lives; Snow established cartographic maps as a tool to trace cholera cases and visually reveal epidemiological hot spots; and Marey invented movie animations to capture the intricacies of human motion.[9,10]

Notably, the advent of diagrams was largely driven by the need to communicate medicine and healthcare issues to politicians, patients, and newly trained healthcare workers.

The recent Coronavirus 2019 (COVID-19) pandemic once more underscored the critical importance of the healthcare sector, and its role in tracking, exploring, and explaining diseases to empower individuals and policymakers to make informed decisions. In addition, today's digital tools and user-friendly software power the adoption of data visualisations widely in the healthcare sector. A non-exhaustive summary of open-source user-friendly software, icon libraries, and web-based illustration tools is provided in Table 1.

Health literacy challenges and the need for visual aids

Patients' involvement in clinical trial design, such as identifying key endpoints and measures, has received increasing attention in recent years. In the EU, the EMA has introduced initiatives to enhance patient involvement in regulatory decision-making, such as the Patient Engagement in the Benefit-Risk Assessment of Medicines

Table 1. Tools and resources for prototyping visual aids

Name	What is it used for?	Website
General icons		
SVGrepo	Large scalable vector graphic icon library, search function for icon style and appearances (colour, line style).	https://www.svgrepo.com
Fontawesome	Unicode-based icon library with many free icons, individual/batch download as scalable vector graphic (SVG).	https://fontawesome.com
PowerPoint	Inbuild image and icon libraries and many pre-drawn shapes that are free to use.	
Biology icons		
Bioicons	Expanding repository of biology and laboratory icons from petri dishes to model organisms available under free licenses (CC0).	https://bioicons.com
NIH BioArt	A collection of free, high-quality, vectors, icons – created by professional illustrators.	https://bioart.niaid.nih.gov
Phylopic	Shapes of numerous animals, plants and further model organisms, e.g., for phylogenetic trees.	https://www.phylopic.org
Reactome	Provides scientific pictograms and chemical drawings for free re-use and encourages the upload of user-designed pictograms for sharing with the scientific community.	https://reactome.org/icon-lib
SciDraw	Free repository of high-quality icons.	https://scidraw.io
Medical icons		
HealthIcons	A global volunteer effort to create common icons for many specialised medical scenarios available under creative commons license (CC0).	https://healthicons.org
SmartServier	A free collection of medical drawings from Servier Medical Art that can be downloaded as a full slide-deck and used with attribution	https://smart.servier.com
Design tools		
Figma	Online prototyping, free form, charts, and icons can be integrated.	
Inkscape	Open-source, offline, professional vector graphic program, compatible with programming approaches, expandable functionality with packages.	

project. This initiative aims to ensure that clinical trials and drug development processes reflect patient priorities and improve accessibility.[11] The US FDA released a set of guidelines to facilitate patient-focused drug development to help clinical trial sponsors identify what matters to patients, and to ultimately design more clinically meaningful trials.[12]

However, while involving patients in drug development is gaining more traction, informed consent documents (e.g., for procedures, surgery, or medical treatments with material risks such as radiation therapy) are often focused on information necessary to protect against litigation.[13] A comprehensive analysis of consent forms from across US hospitals for surgical or invasive procedures revealed that these are written for a high reading level with a mean reading score of 12.6 (high-school graduate level) and additionally are often printed in non-legible print.[14] Similarly, in Europe, studies have shown that patient information leaflets and consent forms often exceed the recommended readability level. The European Commission has

guidelines encouraging the use of clear and simple language in medical documents, but implementation varies across member states.[15]

Likewise, oral communication is often too complex to be understood fully, and medical teams regularly overestimate the literacy of their patients.[16-19] Thus, many patients may not be able to effectively use health information and are at increased risk for adverse outcomes. Indeed, health literacy is one of the strongest predictors of an individual's health, and using visuals can help enhance comprehension and literacy.[20]

Visual aids in healthcare and clinical development

Despite their long history and benefits for communication, pictures and visual aids are still underused in most patient information. This is even more surprising considering the increasingly well-documented literacy and numeracy gaps between medical staff and patients, particularly in those experiencing cognitive decline due to age or stress brought on by health issues and medical interventions. These gaps challenge effective communication in healthcare settings. Visuals can help bridge this gap by improving comprehension and ensuring that information is accessible to a broader audience.

Visual aids in patient-focused drug development

The drug development process can be broken down into three broad phases: pre-clinical development, clinical development, and clinical practice. Visual aids are mostly used during the second and third phases for the purpose of communicating with the public (here defined as patients, carers, and other lay persons) (Figure 1). During drug discovery in the pre-clinical phase, most documents are prepared for expert audiences or regulatory authorities; therefore, the visuals' primary purpose is to communicate the research data in graphs and charts.

Many patients may not be able to effectively use health information and are at increased risk for adverse outcomes. Indeed, health literacy is one of the strongest predictors of an individual's health, and using visuals can help enhance comprehension and literacy.

Once a drug enters clinical development, presenting information to the public, investigators, and clinical trial personnel in a digestible way becomes more important. Clinical studies are lengthy, quality controlled, and regulated procedures with documents that are tens to hundreds of pages long. As patients are more and more actively involved (for instance, through patient boards), it is increasingly mandated that trial information is accessible to them, i.e., with lay-person summaries and visual aids. In the EU, since 2014 the EMA has required lay summaries of clinical trial results under the Clinical Trials

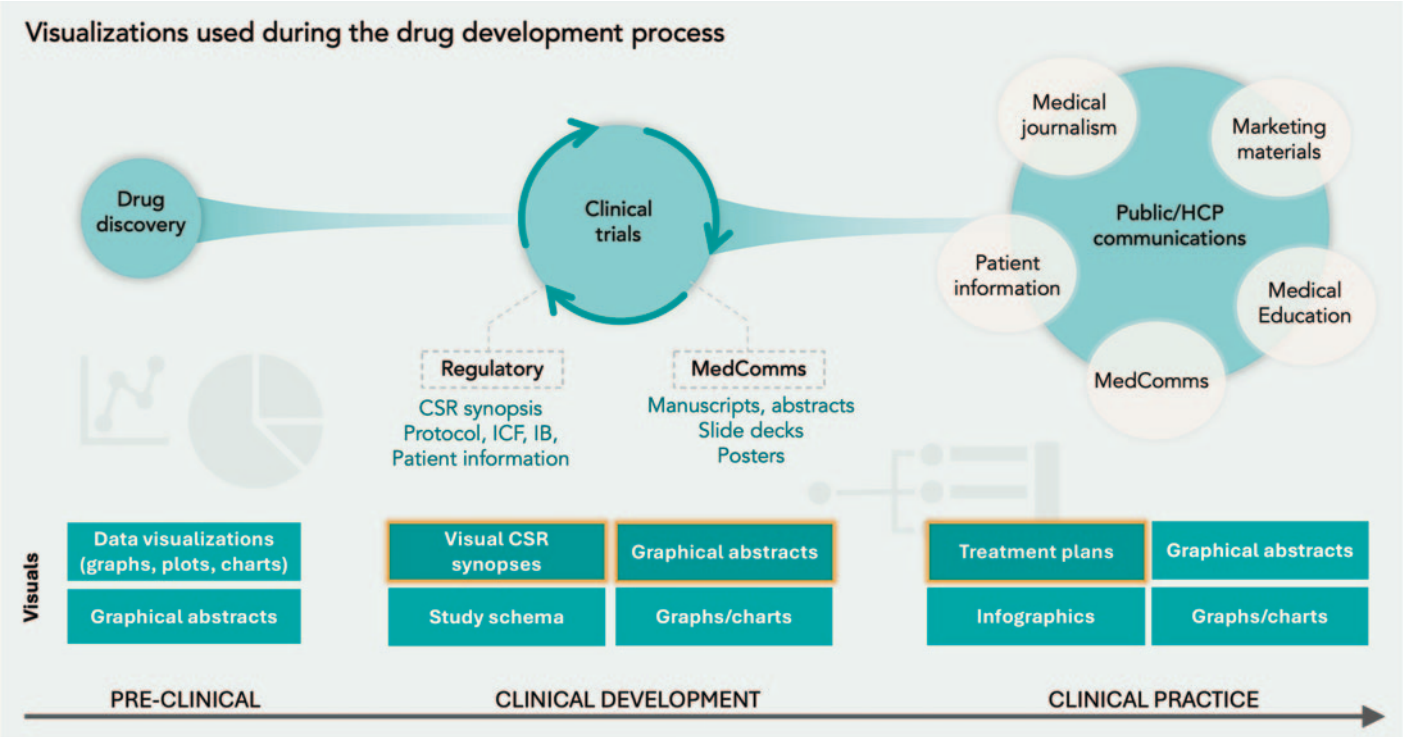


Figure 1. Overview of selected key documents and visualisations during the drug development process

Broadly, drug development can be broken down into three phases of pre-clinical research and development, clinical development, and marketing and clinical practice. During the pre-clinical drug discovery phase, visuals are mainly used to present research results to other experts using data visualisations, and graphical abstracts can accompany research manuscripts. During the clinical development phase, patient focused communication becomes more important, where explanatory visuals can used in regulatory documents (study schema in protocols or visual CSR synopsis). In addition, medical communications are used to communicate trial results in manuscripts, slide decks, posters, etc., and these are often accompanied by visualisations. In routine clinical practice, accessible public and HCP communications become even more crucial. Here visuals can be used to enhance content for medical education, patient information, marketing and other materials.

Abbreviations: CSR, clinical study report; HCP, healthcare personnel; IB, Investigator's Brochure; ICF, informed consent form; MedComms, medical communications.

Regulation (EU No. 536/2014), ensuring that patients can access comprehensible trial data.[21]

One of the most crucial documents at the beginning of a clinical trial is the clinical study protocol, which is meant to be an easy-to-use reference for investigators throughout the study. Study schemas are diagrams used in the protocol synopsis to present the most important milestones and interventions of the trial, and a well-designed schema can be of great help to investigators and used for quick reference. However, a poorly designed or inconsistent diagram can slow processes and hinder understanding; therefore, study schemas always need to be checked for consistency with the rest of the protocol. The Investigator's Brochure is another important document at this stage, which summarises all available information about a drug that the investigator can reference. Here, visualisations are primarily used for presenting data, e.g., as graphs and charts.

Two key public-facing regulatory documents in clinical trials are the informed consent form (ICF) and the lay summary of the clinical trial results (the second being a requirement by the EMA for submissions within the EU). An ICF explains to patients what is going to happen to them during the trial and importantly, what risks and potential benefits they may see – it is their primary source of information for the procedures they agreed to participate in. While the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines (E6[R3]) outline the requirements for the *content* of an ICF, the *presentation* should enhance understanding using design principles and simple graphics.[22] In Europe, the Plain Language Summaries initiative is gaining traction, aiming to improve patient understanding of complex medical information through simplified text and visuals.[21,23]

On the other end, the clinical trial lay summary explains the key results and takeaways of a trial. For this document, the official guidelines already suggest supplementing the text with infographics.[21] Interestingly, the International Kidney Cancer Coalition has been one of the first alliances that offer downloadable, patient-friendly infographics for clinical trial results, but the documents' design has its drawbacks.[24] The downloadable documents include overcrowded graphs and densely packed data that can make interpretation challenging. The combination of small fonts, insufficient contrast, and complex visual elements may reduce readability and accessibility for some readers. Additionally, the document's findability is hindered by a lack of descriptive metadata, such as searchable keywords, alternative text for visuals, or clear tagging within the file. This

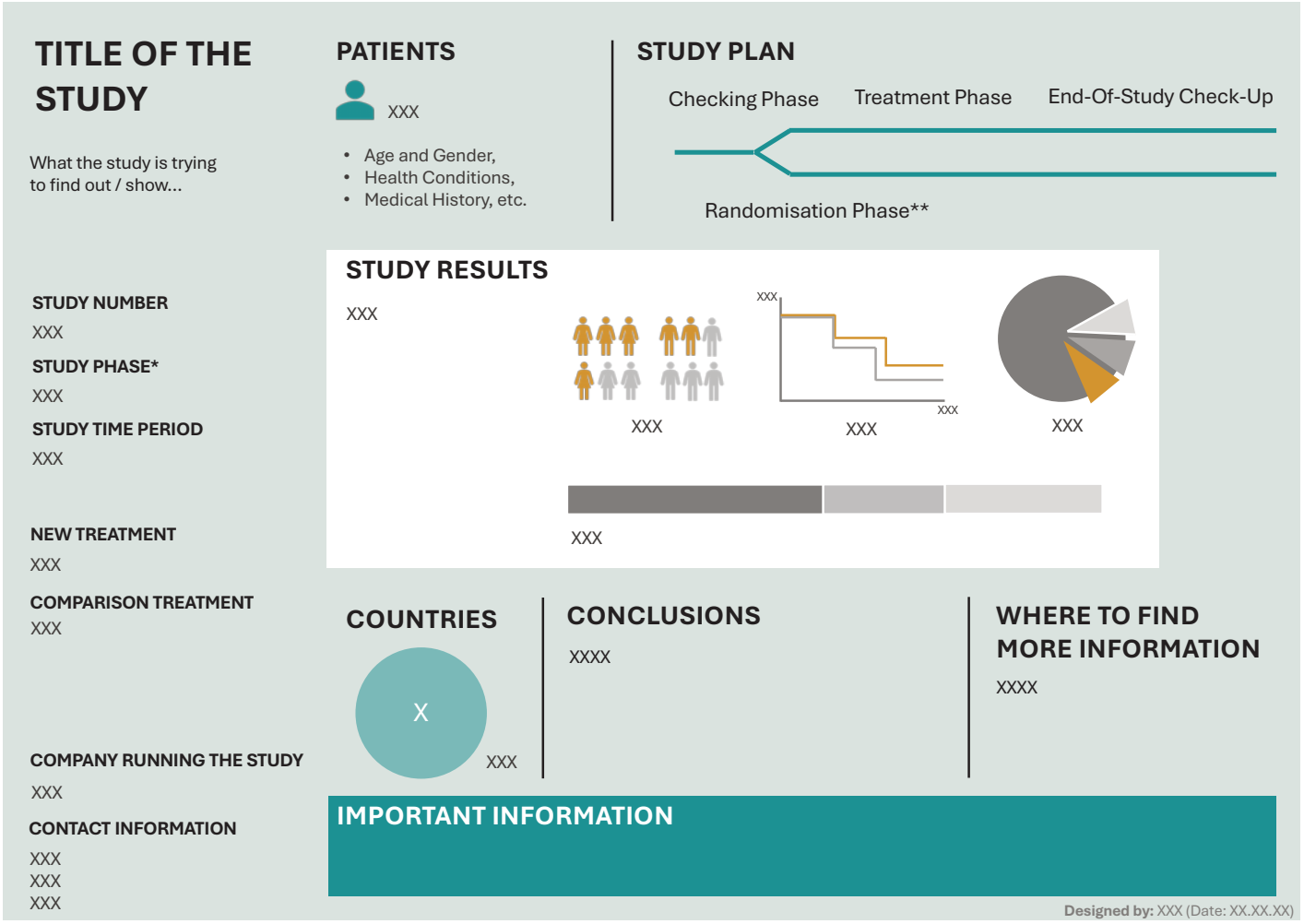


Figure 2. Template for a visual clinical study report (CSR) synopsis in lay language

*The study phase is an optional element that may require further plain language explanation in a callout box.

**The term "randomisation" requires explanation in plain language in a callout box. Please feel free to download the original .pptx template (size: 71 KB) here: https://drive.google.com/drive/folders/1iS5ZV1-GBCoZO5kbvGFdM5ZuEph2bMOw?usp=sharing

omission can make it difficult for lay audiences to locate relevant information or navigate the content efficiently.

Once a trial is finished and the results can be publicly disclosed, various tools of medical communications are used to explain the results, e.g., graphical abstracts to accompany manuscripts, educational slide decks, and patient information documents. Typically, visual aids are heavily used to support these communications.

Simplifying layouts and enhancing the clarity ot charts can improve the visual effectiveness of the above documents. For that reason, we created downloadable, exemplar PowerPoint templates for a visual CSR synopsis (Figure 2) and a graphical abstract (Figure 3) in lay language.

Key elements of our templates:

1. **Structured layout**: A4 size (CSR synopsis) or A5 size (graphical abstract), horizontal layout with clearly divided sections, such as "Study Plan", "Study Results", "Sites", "Countries", etc.
2. **Icons and graphics**: Use of simplified icons (e.g., for patients), charts, and graphs (e.g., bar chart, pie chart, survival curves) to visualise datc
3. **Colour coding**: Minimal use of colours to differentiate sections or elements, focus on colour accessibility (e.g., visible to audiences with colour vision deficiency).
   In our example the following colours were used:
   - Teal: RGB (63, 143, 146), Hex #3f8f92
   - Orange-brown: RGB (200, 148, 71), Hex #c89447
   - Black: RGB (0, 0, 0), Hex #000000
   - White: RGB (255, 255, 255), Hex #ffffff
   - Medium grey: RGB (127, 127, 127), Hex #7f7f7f
   - Light grey: RGB (217, 217, 217), Hex #d9d9d9
4. **Typography**: Bold headings and readable font sizes to emphasize key points. In our example the typography uses a **sans serif** font (e.g., Aptos, Arial, Helvetica), which is commonly chosen for clean, modern layouts in presentations and infographics.
5. **Infographic style**: Presents complex information in a concise, visual format.

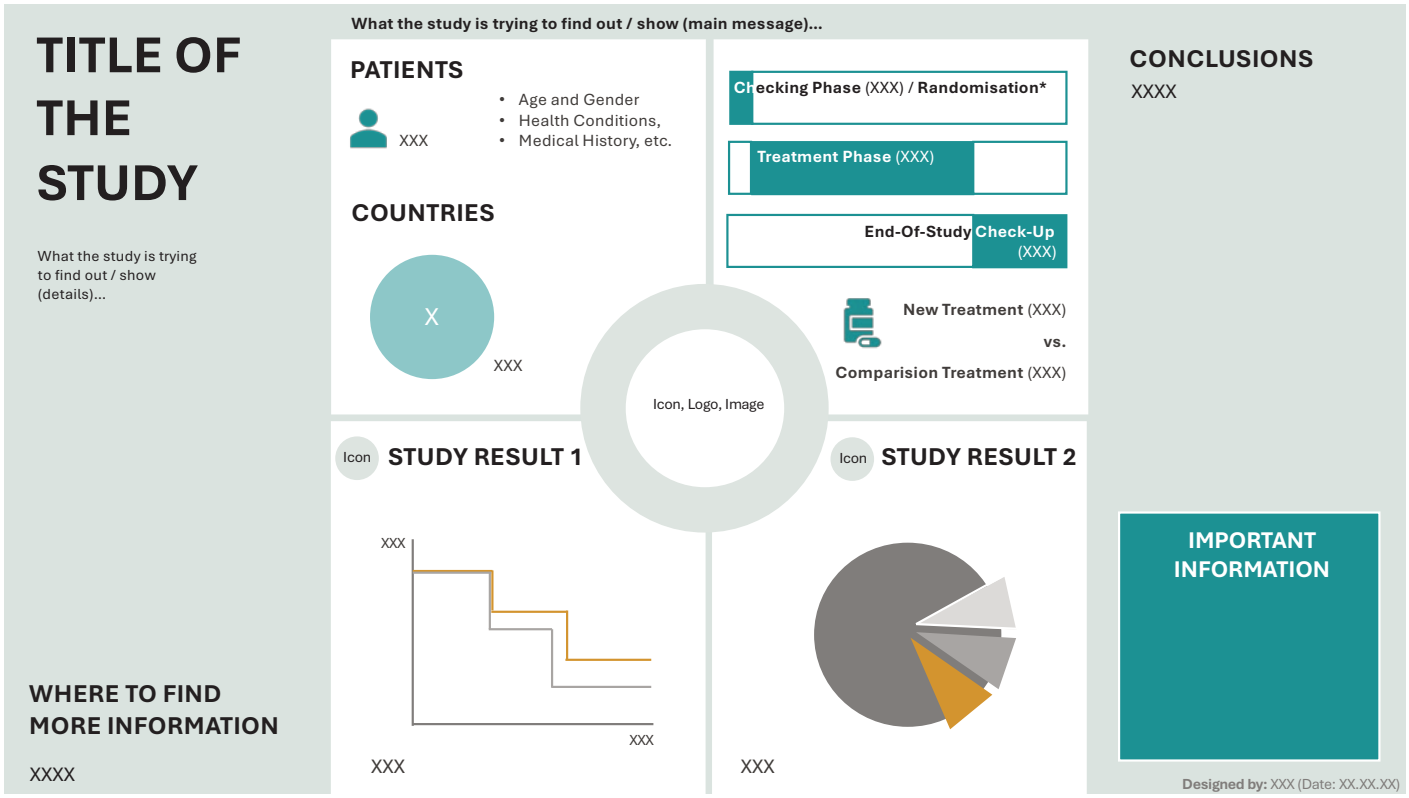


Figure 3. Template for a graphical abstract in lay language

*The term "randomisation" requires an explanation in plain language in a callout box. Please feel free to download the original .pptx template (size 104 KB) here: https://drive.google.com/drive/folders/1iS5ZV1-GBCoZO5kbvGFdM5ZuEph2bMOw?usp=sharing

We envisiage that a visual CSR synopsis in lay language may become an integral part of the CSR, whereas a graphical abstract in lay language could be an encore element in publications and social media communications.[25] However, visual aids in patient-focused drug development are often not findable by lay audiences due to several key challenges. They typically lack standardised metadata, such as keywords or descriptive tags, which hinders indexing by search engines and databases. Stored as non-searchable image files (e.g., PNG, JPEG, or PDFs), these visuals are rarely enhanced with alt-text or optical character recognition, making them inaccessible to search algorithms. Additionally, visual aids are often isolated from the full text of a clinical document or a publication and are not linked to related content, limiting their discoverability.[26] Poor integration with search systems and a lack of standardised terminology in captions or descriptions further reduce their visibility. To improve findability, medical communicators could enrich metadata, integrate image recognition technologies, adopt standardised formats, and ensure better indexing within scientific databases.

Visual aids in routine clinical practice

Once a product has received marketing authorisation and can be used in clinical practice, visualisations could take a more central stage. A wide range of visuals could be integrated in clinical care for different purposes, from eye-catching illustrations and simpler graphics for educational/informational content (e.g., for patient information leaflets, healthcare personnel training/advice materials) to more detailed infographics and visual abstracts (e.g., for study results).

To improve findability, medical communicators could enrich metadata, integrate image recognition technologies, adopt standardised formats, and ensure better indexing within scientific databases.

Explanatory visualisations have already become essential diagrams in clinical trials, prominently featured in graphical abstracts and participant education materials, and we recently contributed a comprehensive guide to their design.[27] Building on this, Jambor et al. recently conducted a comprehensive study and clinical evaluation of pictogram-based timeline visualisations for routine clinical practice, specifically in treating patients with haematological neoplasms.[28] These visual cancer treatment timelines were developed collaboratively with patient representatives and physicians and designed to summarise complex treatment timelines (Figure 4).

The study revealed that these visual aids significantly enhanced comprehension among participants and instilled a greater sense of security regarding their treatment. By comparing different formats for encoding key

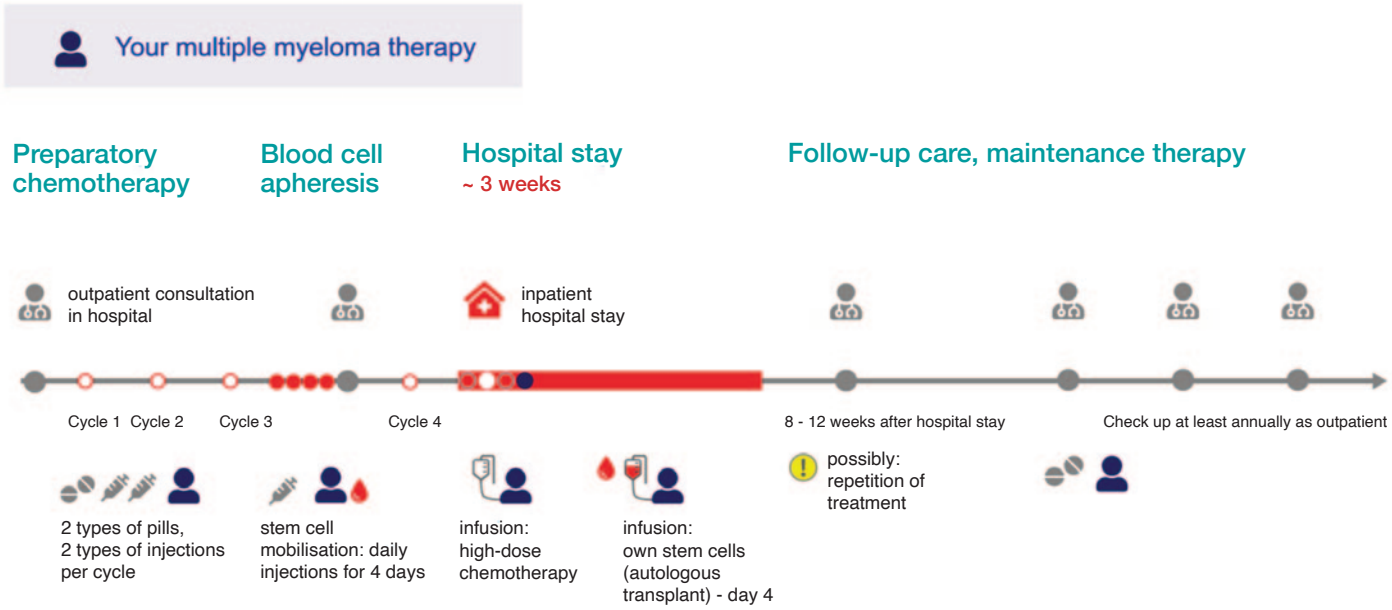


Figure 4. Example of a cancer treatment timeline visualisations (28)

information, the study demonstrated that abstract pictograms performed as well as, and in some cases better than, more realistic comics or photographs. These simplified visuals were particularly effective across all age groups, including older adults who are more frequently affected by haematological neoplasms.

In the EU, various healthcare initiatives have embraced visual tools to improve patient communication. For instance, the European Patients' Forum advocates for better use of pictograms and simplified visuals in patient information leaflets across EU languages, ensuring consistency and accessibility.[29]

Clinical evaluations further validated the utility of these visual cancer treatment timelines. Participants demonstrated improved information retention, and both patients and physicians perceived the aids as beneficial.[28] Importantly, these visuals made complex medical information more accessible to a diverse patient population, offering a promising strategy for enhancing equity in healthcare communication and outcomes.

Conclusions

Visual aids present a transformative opportunity to improve healthcare communication, aligning with the Institute of Medicine's quality criteria for patient-centeredness and equitable care.[30,31] The increasing availability of user-friendly software, icon libraries, and web-based illustration tools makes it easier than ever to design accessible and effective visual aids, even for non-experts.

By empowering patients to make informed decisions, these tools complement traditional methods of medical communication. Their adoption in informed consent processes, treatment plans, and clinical trial reporting is likely to become more widespread – and perhaps even mandatory – in the future. Incorporating visuals into healthcare dialogues fosters a more inclusive, engaging, and impactful approach to patient education, ultimately contributing to improved patient outcomes and equity in care.

Acknowledgements

The authors would like to express sincere gratitude to Lisa Chamberlain James for her critical feedback on the lay language of the visual CSR synopsis and the graphical abstract template.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

References

1. Spiegelhalter D, Pearson M, Short I. Visualizing uncertainty about the future. Science. 2011;333(6048):1393–400. doi:10.1126/science.1191181
2. Franker MA. Visualisations in science communication: Friend or foe? Med Writ. 2020;29(1):11–5.
3. Silva T. Clinical trial design: Cosiderations for medical writers developing clinical trial protocols. Med Writ. 2020;29(11):56–61.
4. Schindler TM, Summerer K, Leithold LH, et al. Enhancing accessibility of study data: The development of a graphical abstract for lay summaries of clinical trial results. Med Writ. 2020;29(1):48–53.
5. Martin K. A picture is worth a thousand words. Med Writ. 2020;29(1):28–34. Available from: https://www.researchgate.net/publication/341293384_A_picture_is_worth_a_thousand_words
6. Stückelberger A. Bild und Wort: Das illustrierte Fachbuch in der antiken Naturwissenschaft, Medizin und Technik. von Zabern. German; 1994. ISBN: 3805316984.
7. Correll M, Garrison L. When the body became data: Historical data cultures and anatomical illustration. In: Proceedings of

Photo: freepik

the CHI Conference on Human Factors in Computing Systems. 2024;764:1–18. doi:10.1145/3613904.3642056
8. Costa AC, Bakker J, Plucinska G. How and why it works: The principles and history behind visual communications. Med Writ. 2020;29(1):16–21.
9. Friendly M, Wainer H. A history of data visualization and graphic communication. Illustrated edition. Cambridge, Massachusetts: Harvard University Press; 2021, p. 320. ISBN: 0674975235.
10. Marey EJ. La méthode graphique dans les sciences expérimentales et principalement en physiologie et en médecine. G. Masson. French; 1885, p. 768.
11. Patients and consumers. EMA. 2025 [cited 2025 Feb 09]. Available from: https://www.ema.europa.eu/en/partners-networks/patients-consumers.
12. FDA patient-focused drug development guidance series for enhancing the incorporation of the patient's voice in medical product development and regulatory decision making. 2025 [cited 2025 Jan 28]. Available from: https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical
13. Spatz ES, Krumholz HM, Moulton BW. The new rra of informed consent: Getting to a reasonable-patient standard through shared decision making. JAMA. 2016;315(19):2063–4. doi:10.1001/jama.2016.3070
14. Hopper KD, TenHave TR, Tully DA, et al. The readability of currently used surgical/procedure consent forms in the United States. Surgery. 1998;123(5):496–503. doi:10.1067/msy.1998.87236.
15. Guideline on the readability of the labelling and package leaflet of medicinal products for human use. 2025 [cited 2025 Feb 09]. Available from: https://health.ec.europa.eu/system/files/2016-11/2009_01_12_readability_guideline_final_en_0.pdf
16. Houts PS, Doak CC, Doak LG, et al. The role of pictures in improving health communication: A review of research on attention, comprehension, recall, and adherence. Patient Educ Couns. 2006;61(2):173–90. doi:10.1016/j.pec.2005.05.004.
17. Bass PFI, Wilson JF, Griffith CH, et al. Residents' ability to identify patients with poor literacy skills. Acad Med. 2002;77(10):1039–41. doi:10.1097/00001888-200210000-00021.

18. Ha JF, Longnecker N. Doctor-patient communication: A review. Ochsner J. 2010;10(1):38–43. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC3096184/
19. Kelly PA, Haidet P. Physician overestimation of patient literacy: A potential source of health care disparities. Patient Educ Couns. 2007;66(1):119–22. doi:10.1016/j.pec.2006.10.007
20. Weiss. Health literacy and patient safety: Help patients understand. Manual for clinicians: Health literacy and patient safety: Help patients understand. 2025 [cited 2025 Jan 28]. Available from: http://www.hhvna.com/files/Courses/HealthLiteracy/Health_Literacy_Manual_AMA_Revised.pdf
21. Summaries of clinical trial results for laypersons. 2025 [cited 2025 Feb 09]. Available from: https://health.ec.europa.eu/system/files/2020-02/2017_01_26_summaries_of_ct_results_for_laypersons_0.pdf
22. ICH Harmonised Guideline – Guideline for good clinical practice E6(R3). 2025 [cited 2025 Jan 28]. Available from: https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
23. Good Lay Summary Practice. 2025 [cited 2025 Feb 09]. Available from: https://health.ec.europa.eu/document/download/8a42b8f5-4ec3-4667-969c-3dd89ea8b270_en.
24. Infographics for study results. 2025 [cited 2025 Jan 28]. Available from: https://ikcc.org/infohubpost/graphic-trial-results/
25. Ibrahim AM. Use of a visual abstract to disseminate scientific research. 2025 [cited 2025 Jan 28]. Available from: https://www.surgeryredesign.com/s/VisualAbstract_Primer_v4_1.pdf.
26. Hoonakker JD, Adeline-Duflot F, Orcel Veronique, et al. Use of visual aids in general practice consultations: A questionnaire-based survey. PEC Innov. 2023;2:100159. doi:10.1016/j.pecinn.2023.100159
27. Jambor HK, Bornhäuser M. Ten simple rules for designing graphical abstracts. PLOS Comput Biol. 2024;20(2):e1011789. doi:10.1371/journal.pcbi.1011789
28. Jambor HK, Ketges J, Otto AL, et al. Communicating cancer treatment with pictogram-based timeline visualizations. J Am Med Inform Assoc. 2025;32(3):480–91. doi:10.1093/jamia/ocae319.
29. European Patients Forum. 2025 [cited 2025 Feb 09]. Available from: https://www.eu-patient.eu/
30. Wolfe A. Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the quality chasm: A new health care system for the 21st Century. Policy Polit Nurs Pract. 2001;2(3):233–5. doi:10.1177/152715440100200312
31. General Medical Council. Decision making and consent. 2025 [cited 2025 Jan 28]. Available from: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent.

Author information

Helena Jambor, PhD, is an Associate Professor for Data Visualisation at the University of Applied Sciences of the Grisons, Switzerland, and Associate Member of the Medical Faculty Carl Gustav Carus at the Technische Universität Dresden, Germany. Previously she worked as biomedical data scientists at EMBL Heidelberg, Max-Planck Institute Dresden, and at the TU Dresden. Additionally she provides training and consulting in biomedical data visualisation.

Carola Krause, PhD, is an Associate Principal Medical Writer at Trilogy Writing & Consulting GmbH. As a long-term EMWA member, Carola founded EMWA's Creative team, chaired EMWA's Sustainability Special Interest Group, and contributes to EMWA's educational programme. Carola is an EMWA ambassador and proudly served EMWA as Vice President and President from 2020 to 2022.

Judit Mészáros, PhD, is a Medical Writer at Grünenthal GmbH where she supports regulatory writing activities. Previously she worked in medcomms projects, and she currently chairs the Creative Team within EMWA, providing graphical support to members. Judit is passionate about visual communications and works part-time in 3D medical animations.

EMWA NEEDS YOU

EMWA is a member-run organisation

When you volunteer to assist EMWA in any capacity, you are furthering the development of our association.

You can choose how you want to get involved: in a very limited way or as part of a larger project. The choice is yours, and everyone shares the benefits.

EMWA members can volunteer in the following areas:

Conference
- Planning Committee
- Advertising

Finance

Journal
- Submitting articles

Website
- Contributions
- Web team

Freelance Business Group

Social Media Team

Training
- Leading workshops
- Professional development
- Webinar contributions
- Webinar team

Special Interest Groups
- Entrepreneurship
- Communicating with the Public
- Medical Communications
- Medical Devices
- Pharmacovigilance
- Regulatory Writing
- Sustainability
- Veterinary Medical Writing

Ambassador Programme

Getting Into Medical Writing Group

Executive Committee
- President
- President-Elect
- Journal Editor
- Public Relations Chair
- Conference Chair
- Honorary Secretary
- Education Officer
- Treasurer
- EMWA Web Manager

WHY VOLUNTEER?
- Help promote the role of medical writers and strengthen our association
- Help to raise standards in our field
- Increase your visibility and communication opportunities within the medical writing community
- Add some prestige to your CV
- Improve your knowledge of medical writing and related topics

TO FIND OUT MORE

If you are a member of EMWA and eager to support ongoing initiatives, please contact info@emwa.org.

Choosing language that recognises the contributions of people who take part in research

Crystal R. Herron
Redwood Ink, LLC, San Rafael, CA, USA

doi: 10.56012/wakl7985

Correspondence to:
Crystal R. Herron
crystal.herron@redwoodink.com

Abstract

Medical communicators can choose words that influence how people perceive individuals and populations who take part in research. For many years, the term *subjects* was used ubiquitously and internationally in clinical research. However, this term can fuel disrespect, mistrust, and bias in clinical practice and research. As a result, *subjects* has been increasingly replaced with the more precise and respectful term *participants*. However, other terms may more accurately and precisely describe people who take part in clinical research while also recognising their contributions, autonomy, humanity, and individuality with respect, empathy, compassion, and kindness.

Introduction

Medical communicators have the power to choose words that influence how people perceive individuals and populations who take part in research. They can choose precise language that empowers, humanises, and builds trust with respect, empathy, compassion, and kindness. Or they can choose language that erodes trust, disregards the humanity and individuality of people, and contributes to explicit and implicit bias in health care.[1-4]

For many years, people who took part in clinical research were ubiquitously and internationally referred to as *subjects*. However, over the past three decades, *subjects* has been increasingly replaced with the term *participants*. This shift is due to differences in the denotations and connotations of these terms.

Denotation vs. connotation

Denotation refers to the direct and specific meaning of a word (i.e., the definition).[5] On the other hand, connotation refers to the suggested meaning of a word separate from the explicit name or definition (i.e., the ideas or feelings associated with that word).[6] In other words, denotation is the *explicit* or *objective* meaning of a word, and connotation is the *implicit* or *subjective* meaning of a word. For example, the denotation of "public speaking" is "the act or process of making speeches in public."[7] However, for many people, the connotation of "public speaking" includes feelings of anxiety, fear, and dread.

The denotations and connotations of the terms *subjects* and *participants* can give insight into the reasoning for shifting away from using *subjects* toward using *participants*. The word *subject* can be used as a noun, adjective, or verb and, therefore, has many definitions. As a result, use of *subjects* is imprecise and risks creating confusion and misunderstanding. As a noun (the appropriate use in the case of referring to study participants), the word "subject" can mean "an individual whose reactions or responses are studied."[8] This definition may seem appropriate in research and relatively harmless. However, other definitions include "one that is placed under authority or control" and "one that is acted on."[8] These definitions connote a power differential that can fuel a perception of people who participate in research as "less than". This connotation is disrespectful and contributes to bias.[9,10]

On the other hand, the definition of *participant* is "one that participates."[11] With this singular and clear definition, there is no room for interpretation or misunderstanding. This term also does not connote a power differential and, thus, is more respectful to people who take part in research. Based on these definitions alone, one can deduce that the term *participants* is a better choice than *subjects*.

> Medical communicators have the power to choose words that influence how people perceive individuals and populations who take part in research.

Alternatives to *participants*

Although *participants* is now the preferred term, some people argue that *participants* is not always the appropriate choice. For example, some believe that the term *subjects* more accurately and honestly represents a participant's vulnerability within research that requires formal protections.[12,13] Others acknowledge that they do not like the term *subject*, but they believe that the word is a clearer choice than *participants*. They argue that everyone who is involved in a study – patients, investigators, study coordinators, committee members, etc. – are all "participants" in a study.[14,15]

Given these perspectives, are there alternatives to the terms *subjects* and *participants*? One possibility is to use the term *volunteers*. However, this term may be most appropriate for non-therapeutic research[14] or in reference to a comparison group. For example, the National Institutes of Health (NIH) defines a *healthy volunteer* as "someone with no known significant health problems who participates in research to test a new drug, device, or intervention" and whose "health information can be used as a comparison."[16] Alternatively, the *AMA Manual of Style* defines such a person as a *control participant*, albeit with a more nuanced definition: "a person who does not have at least some of the characteristics under study or does not receive the intervention but provides a basis of comparison."[9] This definition infers that the control participant may not be "healthy," supporting that *healthy volunteers* may not be the most accurate choice for a comparison group.

Photo: Freepik

The term *volunteer* also may not be appropriate in other cases, such as studies involving people who could not consent or willingly participate (e.g., people who have died, people whose family provided consent on their behalf).

Another option is to use *patients*. However, this term may not be appropriate in all circumstances. For example, the *AMA Manual of Style* describes a *patient* as "a particular person under medical care."[9] Similarly, the *Publication Manual of the American Psychological Association* describes a *patient* as "an individual diagnosed with a mental health, behavioural health, and/or medical disease, disorder, or problem who is receiving services from a health care provider."[17] Given these definitions, *patients* may not be appropriate for studies in which people are not receiving medical care, such as survey research or community projects.

In some studies, *sample* might be the most appropriate term. This term would be most applicable to analyses of large, de-identified data sets. This term would also be appropriate when discussing established statistical terms and describing study designs (e.g., "between-samples estimate").[17]

Another consideration is to use the term *case,* but only with caution. Like *subject*, the term *case* can be dehumanising when referring to a specific person.[9] To distinguish *case* from *participant*, both the *AMA Manual of Style* and *Publication Manual of the American Psychological Association* specify that a *case* is an instance of a disease or disorder, and a *patient* or *person* is affected by a disease or disorder and is receiving care from a health care professional.[9,17] Thus, *case* is more appropriate for describing case-control studies (e.g., *cases, patients in the case group*, or *case patients* and *controls*).[9]

For example, use terms that clearly define the person or population, such as *children, adults, women, men, respondents,* or people with a certain condition (e.g., *patients with breast cancer*).

Other options include the terms *clients* and *consumers*. However, these terms are appropriate in limited settings. For example, *clients* might be appropriate in some academic, business, school, or other settings.[17] This term might also be appropriate for referring to people under the care of psychologists or enrolled in treatment programs for substance misuse or other disorders.[9] Occasionally, *consumer* might also be appropriate, such as describing people who "consume" information on the internet. However, this term should not be used to refer to patients.[9]

An ideal option is to choose the most specific language possible to describe people who take part in research.[17] For example, use terms that clearly define the person or population, such as *children, adults, women, men, respondents*, or people with a certain condition (e.g., *patients with breast cancer*). This approach ensures accuracy, precision, and clarity while respecting people who take part in research.

Recommendations

Many different terms can be used to refer to people who take part in clinical research. But is there one best term? Unfortunately, no. In many situations, *participants* is the most clear and respectful choice. In others, medical communicators must carefully consider the context and refer to people in a way that accurately acknowledges their contributions and autonomy. And in every case, medical communicators must use language that recognises people's humanity and individuality with respect, empathy, compassion, and kindness.

Acknowledgements

The author thanks Sampoorna Rappaz, PhD, for support with guiding the topic development and reviewing the article.

Photo: Freepik

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by EMWA.

Disclosures and conflicts of interest

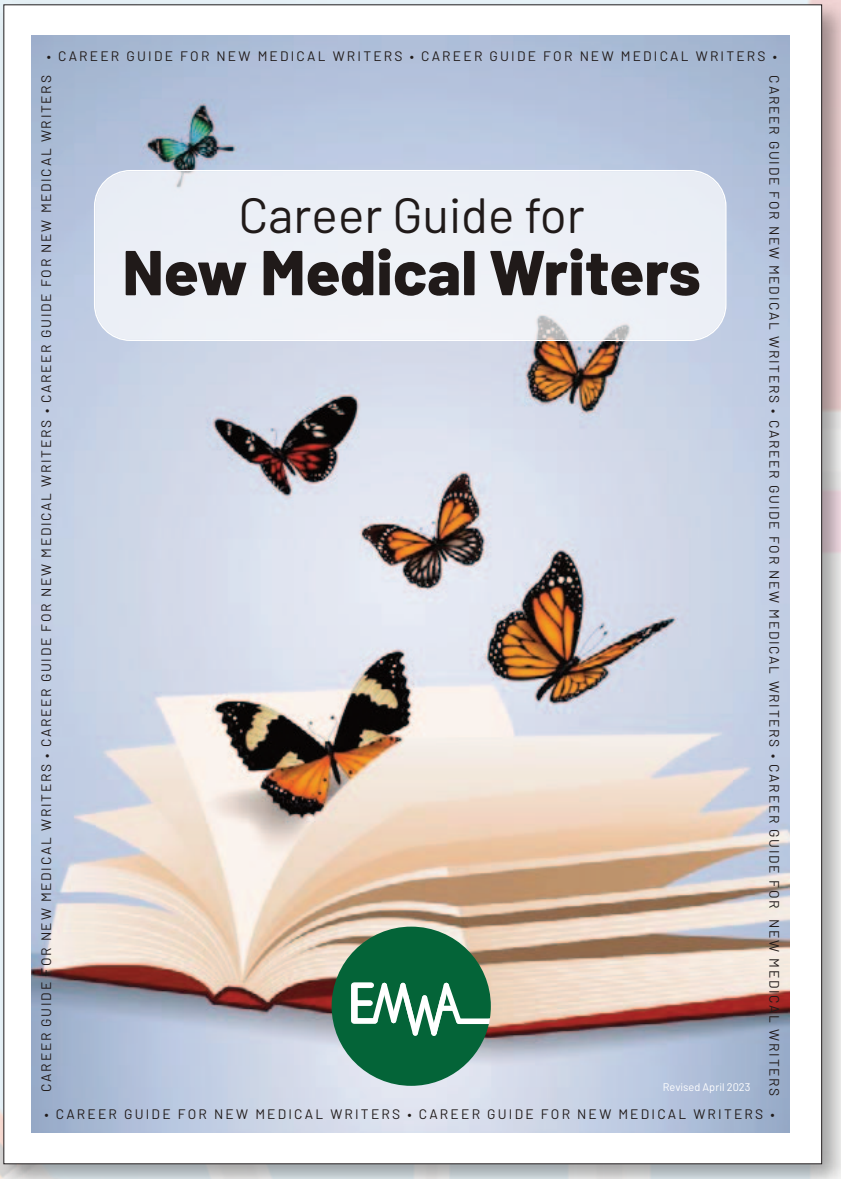
The author declares no conflicts of interest.

References

1. Devine PG. Stereotypes and prejudice: Their automatic and controlled components. J Pers Soc Psychol. 1989;56(1):5–18. doi:10.1037/0022-3514.56.1.5
2. Chapman EN, Kaatz A, Carnes M. Physicians and implicit bias: How doctors may unwittingly perpetuate health care disparities. J Gen Intern Med. 2013;28(11):1504–10. doi:10.1007/s11606-013-2441-1
3. Dovidio JF, Penner LA, Albrecht TL, et al. Disparities and distrust: The implications of psychological processes for understanding racial disparities in health and health care. Soc Sci Med. 2008;67(3):478–86. doi:10.1016/j.socscimed.2008.03.019
4. Herron C. Inclusive language matters: Recommendations for health care providers to address implicit bias and equitable health care. J Maine Med Cent [Internet]. 2021;3(2):9 [cited 2024 Nov 27]. Available from: doi:10.46804/2641-2225.1093
5. Merriam-Webster. c2024 [cited 2025 Feb 20]. Definition of DENOTATION. Available from: https://www.merriam-webster.com/dictionary/denotation
6. Merriam-Webster. c2024 [cited 2025 Feb 20]. Definition of CONNOTATION. Available from: https://www.merriam-webster.com/dictionary/connotation
7. Merriam-Webster. c2024 [cited 2025 Feb 20]. Definition of PUBLIC SPEAKING. Available from: https://www.merriam-webster.com/dictionary/public%20speaking
8. Merriam-Webster. c2024 [cited 2024 Nov 27]. Definition of SUBJECT. Available from: https://www.merriam-webster.com/dictionary/subject
9. Christiansen S, Iverson C, Flanagin A, et al. AMA manual of style: A guide for authors and editors. 11th ed. Oxford University Press; 2020. Available from: https://www.amamanualofstyle.com/
10. Corpuz JC. Reconsidering the terminology: Study participants as "subjects" or not? Subst Abuse. 2023;17:11782218231217783. doi:10.1177/11782218231217783
11. Merriam-Webster. c2024 [cited 2024 Nov 27]. Definition of PARTICIPANT. Available from: https://www.merriam-webster.com/dictionary/participant
12. Hall A. What's in a name? Research "participant" versus research "subject". 2014 [cited 2024 Nov 27]. Public Responsibility in Medicine and Research. Available from: https://blog.primr.org/whats-in-name-research-participan/
13. Hurley EA. From the Director: Why we need to keep the term "Research Subject" in our research ethics vocabulary. Primer. Public Responsibility in Medicine and Research [cited 2024 Nov 29]. Available from: https://blog.primr.org/research-subject-vs-research-participant/
14. Chalmers I. People are "participants" in research. BMJ. 1999 Apr 24;318(7191):1141.
15. Jackson W. People are "participants" in research. Many people are not "participants" in sense that this term was initially defined. BMJ. 1999;318(7191):1141. doi:10.1136/bmj.318.7191.1141a
16. NIH Clinical Center. Healthy Volunteers [cited 2024 Nov 27]. National Institutes of Health. Available from: https://www.cc.nih.gov/recruit/volunteers
17. American Psychological Association. Publication Manual of the American Psychological Association. 7th ed. American Psychological Association; 2020. doi:10.1037/0000165-000

Author information

Crystal Herron, PhD, ELS, is an editor, educator, coach and speaker. She equips scientists, clinicians, and other professional writers with the principles and resources to make their writing clear, concise, and compelling.



Career Guide for New Medical Writers

EMWA's Getting into Medical Writing group has created an updated *Career Guide for New Medical Writers*, which is available on the EMWA website. If you're new to medical writing, it's a useful resource that will help you take your first steps on this rewarding career path. You can email us at gettingintoMW@emwa.org with comments.

Public perceptions of health information generated by AI: A research study

Jumana Ashkanani
Kuwait Ministry of Health

doi: 10.56012/itdm3913

Correspondence to:
Jumana Ashkanani
jumana2000@me.com

Abstract

Artificial Intelligence (AI) integration in clinical practice has intensified in the last few years, from systems analysing and interpreting existing data to generative AI systems capable of creating new information and offering new possibilities for patient communication.[1] However, the public's perception of AI-generated health information remains largely unexplored. This study aimed to assess public trust in AI-generated health information, identifying influencing factors on their trust and evaluating the accuracy of AI-produced content. A mixed-method approach was employed, involving a survey distributed via social media to individuals with recent access to health information. Results revealed that while the public knew AI systems' capabilities, their trust in AI-generated content was moderate. Key concerns included: the accuracy of the information, potential biases in AI algorithms, and ethical issues related to privacy. Results showed that transparency, healthcare professional endorsements, and clear evidence of accuracy are critical in building trust in AI-generated health information. Addressing these concerns is essential for successfully integrating AI into patient communication, to enable the reliability and use of AI as an ethical tool in healthcare.

Background

Artificial Intelligence (AI)'s previous use in healthcare was initially focused on data analysis and interpretation. Generative AI can now create de novo documents and "new" information. Though AI has proven its benefits in patient education[2] and diagnostics, public doubt and trust in this technology remain. AI's capability to generate de novo health information raises concerns about the information's accuracy, transparency, and the risk of AI hallucinations (where incorrect or fabricated data can be generated). Meeting these concerns is essential for AI developers to continue developing better versions of the tools for use in healthcare and decision-making.[3] The gap between developer knowledge and public concerns formed the basis for the research featured in this article, which was aimed at exploring public trust and concerns regarding AI-generated health information and identifying any influencing factors.

Evolution of AI in healthcare

Communication with patients has taken on new dimensions throughout the evolving medical writing landscape, particularly with the advent of AI. AI's integration into clinical practice has been transformative, specifically in generating health information. Tools such as ChatGPT, Google's Bard, and Microsoft's Copilot represent the beginning of what generative AI can offer in developing new, context-specific health information in real-time. These advancements can potentially revolutionise patients' access to medical information, as this gives them quick and personalised insights without healthcare professionals. However, the integration of AI-generated content into healthcare communication does come with challenges. It is important to note the increasing questions about its accuracy, public trust in the information produced, and the ethical implications of its use.[4] Trust is a cornerstone of efficient communication within healthcare. Trust erosion results in poor patient outcomes due to disengagement from healthcare services.[5] This article, derived from a dissertation submitted to King's College, London, explores the public perception of AI-generated health information, discussing public trust, their concerns, and the influencing factors shaping this evolving relationship.

Examining these aspects of AI-generated health information should help medical writers to effectively communicate and understand the nuances of the complex topic of AI-generated health information, contributing to the academic discourse on AI in healthcare. Furthermore, this work offers evidence-based insights into public perceptions, with practical recommendations for improving patient communications and ensuring the ethical use of AI in accordance with the guidelines in place.[6]

Study methodology

A mixed-methods approach was employed, using quantitative and qualitative methods to gather data. An online survey was disseminated from May–June 2024 via Instagram and shared through friends and family. Instagram was chosen due to its widespread use, specifically among the younger populations who are more engaged with AI tools. Furthermore, the survey was shared through personal networks to prevent the limitation of younger populations and to increase the response rate. A sampling strategy approach targeted individuals aged 18 and above with recent access to health information (within the past 3 months[3]) to aid in the accuracy of participant responses. The survey included Likert-scale questions to measure public trust in AI-generated content and open-ended responses to capture public concerns and suggestions. In a related project, the accuracy of AI-generated health information was also assessed through cross-verification of the information with trusted medical sources. The study responses were gathered anonymously and the information was secured per King's College London's data protection policies.

The survey received 75 responses, of which 60 responses were included in the final analysis. The remaining participants either did not meet the inclusion criteria or did not complete the survey. Most respondents (65%) were 18–24 years old; 15% were 25–54 years old; 11.7% were 55–64; and 8.3% were 65 years or older. The survey was open to global participation, but the social networks used for recruitment were in

Kuwait and the UK. Gender data were not collected.

What was the public perception of information generated by AI?

The public perception of AI presented a complex mix of optimism and scepticism. While most respondents (68.5%) demonstrated a willingness to engage with AI-produced content, there were significant concerns about the accuracy, biases, and ethical implications of the information generated. Most participants had a moderate understanding of how AI produces health information. The study highlighted varying levels of awareness, trust, and knowledge of AI-generated health data. Survey results indicated that while 27.8% of respondents would be willing to read AI-produced health information without hesitation, the majority were open to its use but were concerned about fully trusting the information. Another prominent concern voiced by participants (83.3%) was the accuracy of this health information. Respondents were worried that AI systems might provide inaccurate information, resulting in poor health decisions. This concern was compounded by "AI hallucinations" (AI tools adding information to fill in gaps in some cases). Many respondents were unaware of this, highlighting the need for greater transparency in AI systems. This was voiced particularly by a respondent as quoted: *"AI hallucinations being a big issue at the moment possibly misleading the public about healthcare but also the key difference of using the right prompt to extract much more accurate healthcare information that most people aren't aware of."*

This lack of exposure to AI technologies can affect public perception, limiting their trust and acceptance of such technologies. Privacy was another critical issue for respondents, as there is an increasing apprehension surrounding data security, specifically with the potential of unauthorised access to health information. Ethical concerns were raised around the transparency of AI systems' decision-making processes, reflecting a broader unease with the adaption of AI in healthcare without robust safeguards.[7]

Why were people searching for health information?

The motivation of individuals seeking health information plays a critical role in understanding how and why they engage with AI-generated content. The survey revealed that most people searched for health information through general curiosity, the desire to manage personal or family health, or seeking health information after recommendations from healthcare professionals. This motivation often drove individuals to explore symptoms, treatment, and preventative measures. Motivations to manage personal or family health stem from patient empowerment and self-care, seeking to actively manage their health conditions and the importance of sharing health information with others.

Is there a link between various age groups and trust in AI-generated health information?

The relationship between age and trust in AI-generated health information is critical in understanding how various age groups engage with healthcare technologies. The study revealed significant correlations between age and trust levels. A t-test analysis revealed that younger age groups were more trusting and familiar with AI-generated health information than older groups (t=2.14[58]; p=.036). Younger participants, mainly those aged 18–24, exhibited the highest levels of trust in AI-generated health information. This age group had more exposure to AI technologies such as chatbots and digital health platforms. Respondents in this age group (75%) were aware of AI capabilities in generating health information, and a significant portion were open to using AI for health-related inquiries. Despite this overall trust, some participants still expressed concerns about the accuracy of the

Photo: Freepik

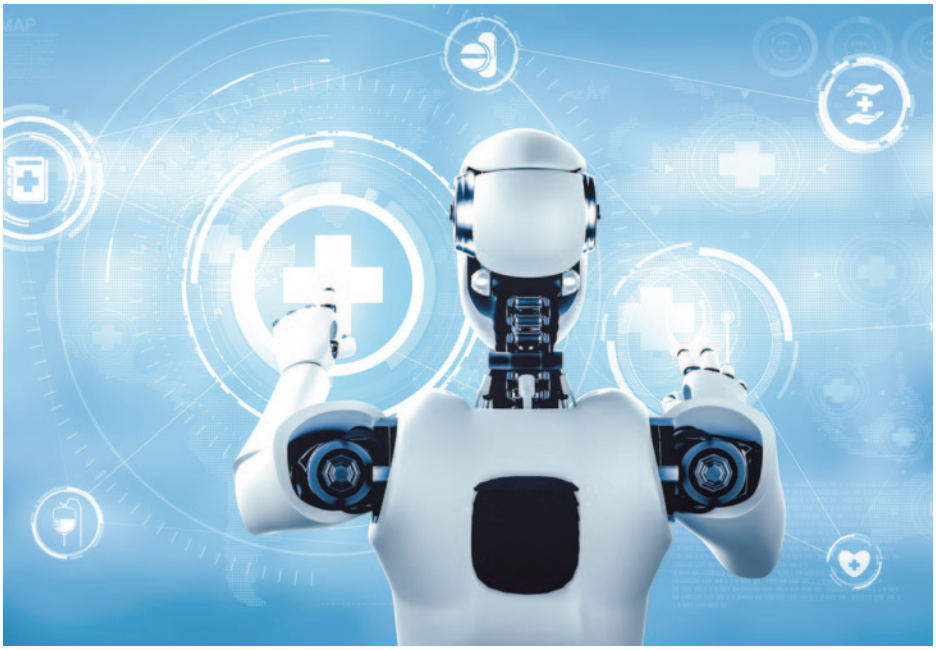


Photo: Freepik

information provided by AI systems.

Examination of trust among older adults revealed a lower level of awareness of AI capabilities. Many expressed their scepticism about the accuracy of AI systems and were more inclined to trust advice from healthcare professionals instead. Several factors contributed to this mistrust, including lower digital literacy levels, limited exposure to AI technologies, and data privacy concerns.

What are the main benefits of health information generated by AI?

AI-generated health information presents various benefits with the potential to revolutionise how healthcare providers and patients access and utilise health data. Respondents identified the primary benefits of AI-generated health information as efficient and rapid access to information, reduced workload for healthcare professionals, provision of personalised health advice, and the ability to deliver up-to-date health information. Overall, it was observed that most participants were optimistic about the potential use of AI in improving healthcare in the future. A respondent emphasised this: *"I am very critical about technology but in terms of AI being implemented in healthcare, I look forward to that day as it would make it easier for me to enquire about my health online."*

What factors Influenced public perception of AI-generated health information?

Technological, social, and ethical factors shaped public perception of AI-generated health information. The study identified several vital factors influencing respondents' perception of AI-produced health content, including a clear explanation of how health information was produced, evidence of data accuracy, endorsements from healthcare professionals, and the ability to provide feedback. This was particularly voiced by respondents as followed: *"Information may be biased based on the region and be personalised to a specific area."*

Another respondent quoted: *"I believe AI needs more endorsements from healthcare providers."*

How accurate is health information generated by AI vs. trusted medical sources?

A companion project involved cross-verifying the accuracy of AI-generated health information, with information from trusted medical sources (e.g. BNF, NICE, WHO). Prompts were entered into ChatGPT to request information on symptoms, treatments, and lifestyle advice for the common health conditions of hypertension, Type 2 diabetes, depression, and tuberculosis. The results of this analysis showed that AI-generated content generally aligned closely with information from medical sources. Although the information was not always fully detailed, it did not fail to provide accurate content. However, it is important to note that lack of detail in medical information can result in damage and misinterpretation, thus it is vital for this information to be verified clinically.

This was specifically emphasised by a respondent as followed: *"I find AI produced health information very convenient and I use it often for starting my research. However, I always double check with trusted sources like UK guidance. I'm sure that AI tech will keep getting better and making our lives easier by giving reliable health information quickly."*

Recommendations for the future

Based on the data gathered from the study, there are several recommendations for future research in enhancing the fields of AI-generated health information. This research should be specific to elderly age groups as this demographic varies in their trust and familiarity with AI. Developing user-friendly tools may help healthcare providers and patients understand AI-generated health information. Assessing the long-term effect of AI technologies, patient satisfaction, and healthcare costs would help AI developers enhance their AI systems.[8] Furthermore, mitigating potential biases in AI algorithms could ensure accurate and equitable healthcare recommendations.

Moreover, addressing AI hallucinations and limiting this issue could increase public trust and ensure patient safety. Finally, implementing educational programmes to increase patient literacy around AI tools could help patients to comprehend AI's capabilities and limitations. These enhancements can improve patient care and health outcomes globally.

Discussion and conclusion

This article explored the public's perception and trust regarding AI-generated health information. Key findings revealed general openness to using AI for health-related inquiries, but significant concerns remained about the accuracy and transparency of AI-generated content. Younger individuals exhibited higher trust levels due to their exposure to technology. The trust gap suggests that targeted educational campaigns or more user-friendly AI tools designed for elderly populations may be necessary to bridge this gap and increase confidence and comfort with AI use. Healthcare providers and AI developers must focus on transparency, accuracy and ethical considerations to address the trust gap between age groups.

The general interest in health information reflects a proactive approach and the public's willingness to become well-informed and take ownership of their healthcare decisions. It is

crucial to understand further the public's motives behind their access to health information, as this aids in developing efficient strategies to enhance how reliable the health information is.

Individuals can adhere better to treatment plans and healthier lifestyles if they have personalised health advice. Thus, AI can assist in rapidly disseminating the latest evidence-based information and ensuring that healthcare providers and the public are informed of the most recent developments in healthcare. Easy and rapid healthcare access is advantageous in situations where individuals seek immediate information about symptoms, treatment options or preventative care.[9] This convenience allows users to obtain relevant health information without the delays typically associated with clinical consultations. Moreover, as AI tools can automate administrative and informational duties, healthcare professionals can focus on more complex tasks, enhancing the efficiency of healthcare systems and improving patient outcomes.

On the other hand, users need to be aware of AI algorithms and data types (whether medical databases, peer-reviewed databases, etc.) as this transparency can help foster trust and acceptance of AI technologies. Cross-referencing AI output with trusted medical outlets could help enhance AI accuracy and user trust.[10] Incorporating feedback from healthcare providers could help refine AI applications by making users feel more engaged throughout. Through addressing these needs, the benefits of AI technologies can be ensured by stakeholders, guaranteeing public engagement with AI tools. Furthermore, rigorous validations and manual verification processes could be implemented to achieve reliable healthcare outcomes. Implementing robust data-cleaning techniques and quality control would avoid inconsistencies in AI algorithms,[11] and if implemented accurately, this could be one of the first steps in enhancing data quality. Although AI-generated health information has the potential to enhance healthcare delivery, addressing concerns around accuracy and ethical implications is essential in building public trust and ensuring the correct use of AI in healthcare.[12] Furthermore, increasing public awareness is crucial in limiting public scepticism of AI tools. This can be fulfilled through implementing educational programmes (teaching the foundation of AI tools in healthcare), collaborating with trusted media outlets to reach a broader audience, and involving healthcare providers in supporting these technologies. Implementation of AI systems in clinical settings can help them achieve their full potential, allowing members of the public to overcome their scepticism of AI tools.

Once public trust in AI tools is enhanced, patient engagement, which provides health insights that are reliable and accessible in increasing public engagement's decision-making in healthcare, could also be enhanced.

Acknowledgements

The author would like to thank Dr Lisa Chamberlain James for her invaluable guidance and insightful feedback throughout this research and for the opportunity to be featured in *Medical Writing*.

Conflicts of interest and disclaimers

The author declares no conflicts of interest. The opinions expressed in this article are the author's own and are based on the survey results conducted for the research.

References

1. Copeland B. (2024) Artificial Intelligence. Encyclopedia Britannica [cited 2024 Sep 17]. Available from: https://www.britannica.com/technology/artificial-intelligence
2. Flanagin A, Pirracchio R, Khera R, et al. Reporting use of AI in research and scholarly publication – JAMA network guidance. JAMA. 2024;331(13):1096–8. doi:10.1001/jama.2024.3471
3. AIContentfy. The impact of AI on content accuracy and reliability. AIContentfy Blog [cited 2024 Sep 12]. Available from: https://aicontentfy.com/en/blog/impact-of-ai-on-content-accuracy-and-reliability
4. Witkowski K, Okhai R, Neely SR. Public perceptions of artificial intelligence in healthcare: Ethical concerns and opportunities for patient-centered care. BMC Med Ethics. 2024;25(1);74. doi:10.1186/s12910-024-01066-4
5. Thornton N, Hardie T, Horton T, et al. The Health Foundation. Priorities for an AI in health care strategy. 2024 [cited 2024 Dec 10]. Available at: https://www.health.org.uk/publications/long-reads/priorities-for-an-ai-in-health-care-strategy
6. European Commission (2019). Ethics guidelines for trustworthy AI [cited 2024 Sep 20]. Available from: https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai
7. Farhud DD , Zokaei S. Ethical issues of artificial intelligence in medicine and healthcare. Iran J Public Health. 2021:50(11), i–v. doi:10.18502/ijph.v50i11.7600
8. Davenport T, Kalakota R. The potential for artificial intelligence in healthcare. Future Healthc J. 2019;6(2):94–8. doi:10.7861/futurehosp.6-2-94
9. Accenture. How AI provides specialized patient support [cited 2024 Sep 20]. Available from: https://www.accenture.com/
10. Abramov M. Real-life applications of AI: Enhancing efficiency and accuracy. AI Soc. 2024;X:65–75.
11. Bhasker S, Bruce D, Lamb J. Tackling healthcare's biggest burdens with generative AI. McKinsey & Company. 2023 [cited 2024 Sep 10]. Available from: https://www.mckinsey.com/industries/healthcare/our-insights/tackling-healthcares-biggest-burdens-with-generative-ai?utm_source=chatgpt.com
12. Gao S, He L, Chen Y, Li D, Lai K. Public perception of artificial intelligence in medical care: content analysis of social media. J Med Internet Res. 2020;22(7):e16649

Author information

Jumana Ashkanani is a Pharmacist (MPharm) in Kuwait City at the Kuwait Ministry of Health. She earned an MSc in Medical Affairs from King's College London. Her research interests include the integration of artificial intelligence in healthcare advancements in medical affairs and improving patient outcomes through innovative clinical practices.

Considerations for the use of artificial intelligence in the creation of lay summaries of clinical trial results

Kimbra Edwards[1]
On behalf of the working group members
[1] Health Communication Services, Center for Information & Study on Clinical Research Participation, Boston, Massschusetts, USA

doi: 10.56012vmag9372

Correspondence
Kimbra Edwards
kedwards@ciscrp.org

Abstract

The clinical research landscape is constantly evolving, as new regulations and innovations come together to help accelerate scientific discoveries and medical advances. A prominent example of this is the rapidly emerging technology of artificial intelligence (AI). Using AI to develop lay summaries (LS) of clinical trial results can enhance transparency and accessibility, while maximising efficiencies and facilitating scalability. This document is a product of collaboration between experts from over 15 organisations in the US and the EU, including industry, academia, and a patient-focused nonprofit. It aims to explore how AI can be responsibly applied to LS development. While aligning with current industry standards, this document provides several recommendations for AI implementation that highlight the necessity of human oversight and expertise. This joint effort between human and machine can help LS achieve high standards in accuracy, transparency, and compliance, while building public trust and empowering patients to make informed healthcare decisions.

Introduction

The landscape of pharmaceutical research is constantly evolving as emerging technologies reshape conventional practices. One such advancement is the use of artificial intelligence (AI) to support the development of lay summaries (LS) of clinical trial results. LS play a crucial role in increasing transparency and ensuring that trial results are accessible and understandable to patients, their caregivers, and the wider public. As AI technology rapidly evolves, it presents both considerable benefits while also introducing risks that must be thoughtfully managed in the context of LS development.

This document reflects the collaborative efforts of a diverse working group consisting of over 15 organisations from the US and EU, representing industry, academia, and a non-profit patient-focused organisation. The working group is composed of professionals with expertise in medical writing, technology, clinical operations, plain language, clinical trial transparency, and patient engagement. Together, they explored how AI can be responsibly applied to the creation of LS.

This document aligns with all broadly accepted industry standards, particularly the Good Lay Summary Practice (GLSP) guidance.

Background

Lay summaries are designed to make clinical research results more accessible to non-scientific audiences by translating complex medical information into plain language. AI can improve the efficiency of drafting LS by reducing manual effort (i.e., time and resources). Whereas the lack of sufficient human oversight can lead to inaccuracies or misinterpretations. For example, using data solely from sources like ClinicalTrials.gov may lack the proper context to appropriately develop an accurate and complete LS.

AI applications in health care are increasingly subject to oversight from regulatory authorities. At the time this document was authored, the US and EU are developing frameworks aimed at ensuring data privacy, accuracy, and ethics, such as the US Blueprint for an AI Bill of Rights,[1] the NIST AI Risk Management Framework,[2] the EU Artificial Intelligence Act,[3] the EU Ethics

Working group members

Sanjay Bagani, Vice President, Clinical Trials Transparency, Xogene
Behtash Bahador, Director, Health Literacy, Center for Information & Study on Clinical Research Participation (CISCRP)
Sudipta Chakraborty, Associate Director, Head of Health Literacy & Plain Language Center of Excellence, Biogen
Kimbra Edwards, Senior Director, Health Communication Services, CISCRP
Julia Farides-Mitchell, Director, Health Communication Services, CISCRP
Zack Fey, Manager, Medical Writing, CISCRP
Ken Getz, Founder, Board Chair, CISCRP; Director, Tufts CSDD
Julie Holtzople, Independent Consultant, Clinical Trial Transparency Thought Leader
Jennifer Menzer, Senior Expert Clinical Trial Transparency, Merck Healthcare KGaA, Darmstadt, Germany
Anne McClain, Transparency Operations Lead, UCB
Madison Reider, Senior Manager, R&D Patient Partnerships, CSL Behring
Malgorzata Sztolsztener, Director, Clinical Trial Transparency Patient Engagement, AstraZeneca
Woo Song, Co-founder, Xogene
Jamila Watkins, Clin-Ops, Patient, Site and Community Engagement Expert
Kristi Whiteside, Clinical Trial Transparency Expert

AI and LS terminology

> In this document, **AI** will be used to refer primarily to large language models (LLMs) that generate text,such as GPT, Gemini, Claude, and Llama.
> Additionally, **lay summaries (LS)** of clinical trial results are also known as lay language summaries (LLS) of clinical trial results, plain language summaries (PLS) of trial results, or trial results summaries (TRS).

Guidelines for Trustworthy AI,[4] and the FDA's Guidance on the use of AI in the development of drugs and biological products.[5] In addition, organisations like ICMJE, AMWA, EMWA, and ISMPP emphasised the need for transparency, accuracy, and human oversight in AI-generated medical writing. In turn, at the enterprise level, sponsor organisations are developing and deploying AI use cases and policy documents, including tools for drafting scientific and public- or patient-facing documents.

As AI regulatory frameworks, guidelines, and technology evolve, stakeholders must stay informed and adopt best practices to ensure high quality and compliant LS. At the time of this writing, there were limited guidelines on AI use in medical information, and none specifically addressing LS or other patient-facing clinical research information.

This document was initially drafted using AI to evaluate the feasibility of the outlined recommendations and considerations we have developed. Human experts reviewed and revised the content through multiple iterations, including feedback from a public comment period. The feedback received during this period was largely from research professionals, but also included some patients or members of the public. Both human review and AI were used to review and revise drafts for tone, spelling, and grammar.

Opportunities and risks

AI has the potential to enhance the efficiency of LS creation and promote health literacy by supporting broader dissemination of clinical trial results to patients and the public in a faster and cost-effective way. When used effectively, AI can streamline development, allowing for quicker delivery of clear, concise content. With reduced resource demands, research sponsors may be able to develop LS for more trials. However, without appropriate safeguards, AI-generated LS may contain inaccuracies. Potential issues include hallucinations (false, fabricated or misleading information that may arise when the AI model does not have adequate input and training), lack nuance (especially as it relates to scientific data), and insensitivity to tone and culture.

A hybrid approach, where AI supports drafting and experts ensure accuracy and appropriateness, can maximise benefits while minimising risks. This way, sponsors can maintain regulatory compliance while ensuring the public and patients receive timely, understandable, and accurate information to make effective decisions about their health.

Application and scope

This document supplements existing LS development practices, including the GLSP guidance, which remains the accepted industry standard for creating and delivering high quality LS. The GLSP has been adopted by the Clinical Trials Expert Group, a working group of the European Commission. It is not the intent of this document to replace general best practices for writing LS. Instead, it offers key considerations for incorporating AI into established LS workflows. These principles could also apply to other public- and patient-facing materials, such as lay language protocol synopses.

The recommended approach emphasises that responsible AI use is critical – it is to complement, not replace, human expertise. By combining thoughtful AI use with expert review, we aim to create clear and useful materials that enhance public and patient understanding of clinical research and promote accuracy, transparency and trust.

Considerations

Human involvement

Standalone use of AI for creating LS concerns clinical trial sponsors because AI lacks the nuanced understanding and contextual knowledge human experts provide in understanding complex clinical trial data. Without proper oversight, AI-generated LS may misrepresent these data or miss critical details leading to inaccurate summaries. This concern was observed in 2023 in a large-scale instance of publicly posted, AI-generated LS that lacked proper human oversight. These lay summaries were eventually removed from the public domain after significant concerns were raised regarding their accuracy. To better ensure accuracy and appropriate tone, AI should complement, not replace, human expertise and review, with professionals and members of the target readership reviewing and refining content.

Disclosure of AI use

Transparency regarding AI involvement in developing LS is essential for maintaining public trust and upholding ethical standards. Failure to disclose AI involvement can lead to skepticism, undermine confidence in the information, and damage the credibility of the author or organisation.

As AI capabilities continue to advance, open communication helps address misconceptions about the technology and build a more informed and trusting relationship between the public and the research community. To support this, clear disclosure of AI involvement, the extent of human oversight, compliance with regulations such as the EU AI Act, and acknowledgment of sponsor or patient community involvement are important considerations. See Appendix C for additional guidance and example disclosure statements.

Research sponsor involvement

Research sponsors are responsible for the study design, objectives, endpoints, and interpretation of results. Their input is vital for ensuring that LS accurately reflect trial findings and for precise interpretation of complex data. As public access to trial results increases, isolated creation of LS by external parties risks misinterpretation and loss of important context. While improved accessibility tools can promote equity in information dissemination, the absence of sponsor oversight has been demonstrated to lead to misinterpretation or omission of important details in the LS.

EU Artificial Intelligence Act disclosure guidance

> Per Chapter 4, Article 50, Paragraph 4 of the EU Artificial Intelligence Act:
> *Deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall disclose that the text has been artificially generated or manipulated.*

Misinformation and disinformation

Misinformation refers to unintentional errors, that can occur when AI misinterprets data or lacks the context to understand scientific concepts. Disinformation, on the other hand, is the deliberate distortion of facts with the intent to mislead. Either issue may arise if the AI systems being utilised are open-source or trained on public data without proper vetting. The opaque nature of AI decision-making compounds these risks.

Implicit bias and cultural sensitivity

Bias in training date or user prompts – whether intentional or unintentional – can lead to biased outputs. When AI models are trained on large datasets that may not fully reflect the diverse cultural backgrounds, the generated content can lack cultural awareness and sensitivity. AI can reproduce and even amplify those biases, resulting in skewed summaries that compromise the objectivity of information shared with patients and the public.

Promotional tone

LS should be written in a neutral, non-promotional tone. AI models are trained on large datasets, potentially including marketing content, which may result in the use of persuasive or overly positive language. This can bias the presentation of results, potentially misleading readers about the study's significance, benefits, or risks. In a clinical research context, maintaining a neutral, factual tone is essential to accurately convey findings and uphold public trust.

Rapid technological change

AI technologies evolve quickly, and using outdated models may lead to inaccuracies and inconsistencies in the generated content. This rapid pace of change may also make it challenging to keep AI tools aligned with the latest standards and best practices. This could increase the risk that LS may not meet current regulatory or quality expectations. With appropriate AI governance (see Appendix B for more details) this risk can be mitigated effectively.

Data privacy

Clinical study data sets contain sensitive personal health information about the participants. To ensure data privacy is maintained, all inputs used to create the LS should not include identifiable patient data. Aggregated data should be used, and organizations must ensure that AI models are not retaining sensitive information. Good data stewardship is required.

Recommendations for effective AI use in LS development

AI is a transformative tool that can enhance productivity in LS development. Examples of productivity include handling repetitive tasks like drafting, organising information, and simplifying technical language. It's important to ensure that all machine-generated outputs are reviewed by humans, who bring essential judgment in areas where AI may fall short. By using AI to support –not replace – human expertise, organisations can improve efficiency while ensuring LS remain accurate, appropriately written for their target audience, and aligned with regulatory standards.

Suggested additions to process flow

AI should be integrated at specific points in the existing LS development process, such as the best practices and overall process (as laid out in the GLSP) with clear roles for human review and approval (see Figure 1).

Key stakeholders and expertise

The effectiveness of AI in generating LS is contingent upon the expertise of the humans involved in its training, prompting, oversight, generation and revisions of LS. To ensure adherence to best practices and maintain quality and accountability, all reviewers and approvers recommended by the GLSP should retain their essential roles, skills, and qualifications in the LS process, even when AI tools are integrated. While standard operating procedures and resourcing at organisations may vary, stakeholders possessing the following additional AI knowledge and experience may play critical roles at various stages:

- **AI training and development experts**: AI development experience is required to design and calibrate the AI systems to properly train the system on relevant inputs and datasets.
- **Health literacy specialists**: Expertise in health literacy and plain language writing should be leveraged to help train the AI on simplifying complex medical language into terms that are understandable, including guiding AI on which terminologies, explanations, and formatting best align with the needs of the reader.
- **Legal and compliance teams**: To ensure that AI systems use data safely and in accordance with approved AI and/or data use laws and policies (such as GDPR or HIPAA), appropriate expertise should be incorporated into training, building the appropriate framework. Data privacy monitoring can be achieved through standard LS review procedures.
- **LS and medical writers**: Once AI generates a draft, medical writers will need to ensure the AI's interpretation of clinical results are factual and that no critical scientific nuances are absent in the LS. This will be different than what they have traditionally done in authoring this information for the LS.

Additional considerations

It is important to recognise that while LLMs are capable of generating human-like text, they still have limitations to be managed. This section outlines several additional considerations when implementing AI for LS.

- **Templates and glossaries**: Standardised templates can help ensure consistency and compliance with regulatory requirements. AI should be trained to work within these templates while allowing for necessary flexibility such as study design and/or different therapeutic areas. AI should also be trained to use a glossary for preferred terminology within a particular document or set of documents and previously completed summaries.
- **Data inputs**: The quality and comprehensiveness of data inputs are crucial for generating accurate and relevant LS. Reducing the risk of

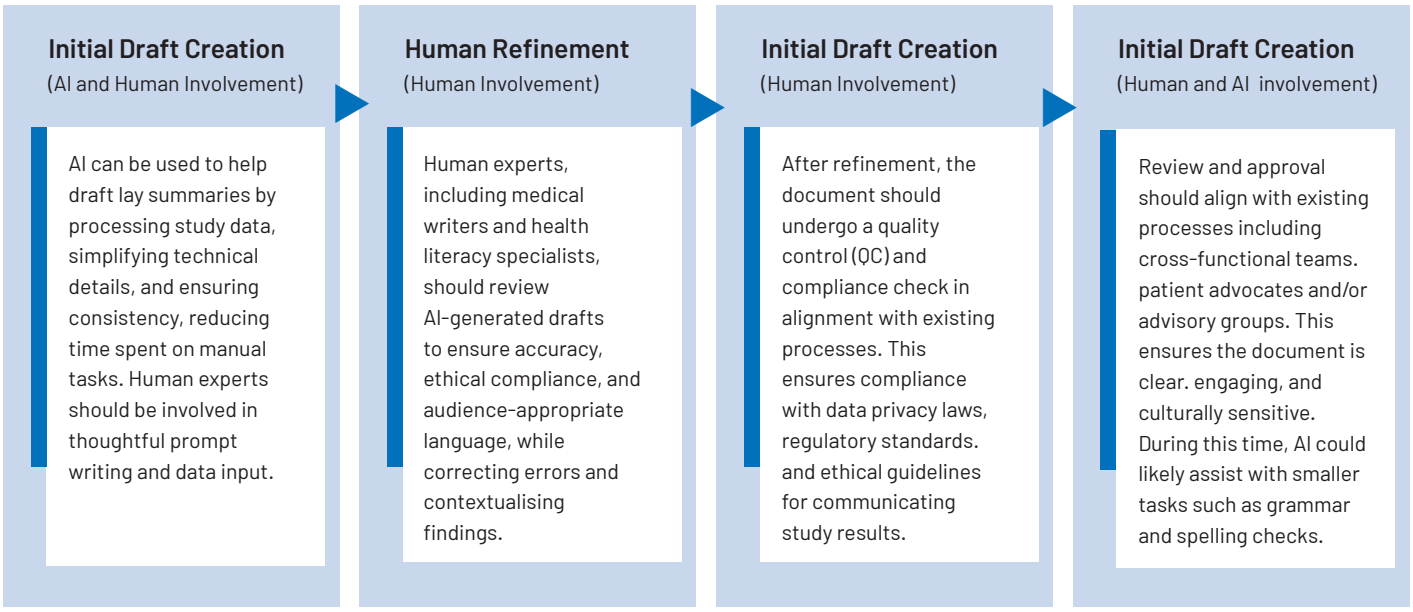


Figure 1. Suggested additions to process flow

AI hallucinations or overconfidence helps prevent seemingly legitimate responses that may omit critical information or draw incorrect conclusions. It would be beneficial for AI models to include references from source documents from which data and information are being pulled. Key data sources may include:

- Aggregate tables, figures, and listings (TFLs)
- Clinical study protocols (CSP)
- Clinical study reports (CSR)
- Informed consent forms (ICF)
- Lay protocol synopsis
- Other nonpromotional public or patient-facing documents
- Glossaries of medical terms and plain language equivalents

- **Prompt engineering:** A critical component of using AI effectively is prompt engineering, which guides the AI in creating accurate, understandable, and public- and patient-appropriate content. For each LS document to be drafted multiple and sequential prompts should be provided to the AI for drafting individual sections and for clear context setting. Specific instructions on tone and style, and guidelines for simplifying complex concepts should be provided. These prompts help the AI create the right tone, ensure consistency with approved medical terminology, and address potential biases. By including reminders to provide necessary context and caveats, prompt engineering can help ensure that AI-generated content is both informative and patient-friendly. Please see Appendix A for components of good prompts and example prompts.
- **Governance**: Robust AI governance is essential for overseeing any new system including an AI system. Implementing AI is an iterative process that requires initial testing and continuous improvement. Please see Appendix B for additional considerations.
- **Advanced AI architectures**: Leveraging AI most effectively may require more advanced architecture, such as AI agent networks. Agent networks employ multiple AI agents, each with a specialised role such as a medical fact-checker, readability optimiser, and bias and sensitivity detector. Orchestrator agents can also be integrated into the architecture to coordinate the work of specialised agents, like a project manager, while humans continue to provide expert oversight and intervention at key points.

Organisations can harness the potential of AI to enhance their LS processes through carefully addressing both opportunities and risks outlined in this document, and through continuous learning. Regular monitoring and updates to processes and AI models with the latest medical and regulatory information will likely be essential to mitigate associated risks and maintain the highest standards of accuracy, clarity, and ethical LS practice.

Conclusion

Incorporating AI into LS development presents both opportunities and risks, underscoring the need for thorough planning and careful implementation. While AI can improve efficiency and reach, its output must be guided by human expertise to ensure accuracy, sensitivity, and compliance. Successful implementation will be an ongoing process that requires continuous monitoring, evaluation, and refinement. Ultimately, integrating AI into LS development necessitates balancing innovation with oversight, ensuring each summary meets the highest standards of quality, accuracy, and transparency, better ensuring trust and clarity for patients and the public.

References

1. The White House, Office of Science and Technology Policy. Blueprint for an AI Bill of Rights: Making automated systems work for the American people. Washington, DC: The White House; 2022 [cited 2025 Apr 10]. Available from: https://bidenwhitehouse.archives.gov/wp-content/uploads/2022/10/Blueprint-for-an-AI-Bill-of-Rights.pdf
2. National Institute of Standards and Technology. Artificial Intelligence Risk Management Framework (AI RMF 1.0). Gaithersburg (MD): U.S. Department of Commerce; 2023 [cited 2025 Apr 10]. Available from: https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.100-1.pdf

3. European Union. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) 2018/858, (EU) 2019/2144 and (EU) 2023/1230 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 [Internet]. Brussels: EUR-Lex; 2024 [cited 2025 Apr 10]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689
4. European Commission, High-Level Expert Group on Artificial Intelligence. Ethics guidelines for trustworthy AI. Brussels: European Commission; 2019 [cited 2025 Apr 10]. Available from: https://ec.europa.eu/futurium/en/ai-alliance-consultation.1.html
5. FDA. Considerations for the use of artificial intelligence to support regulatory decision-making for drug and biological products. Silver Spring, MD: FDA; 2025 [cited 2025 Apr 10]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological

Author information

Kimbra Edwards, PhD, is the Senior Director of Health Communication Services at the Center for Information and Study on Clinical Research Information (CISCRP), where she oversees the creation of easy-to-understand trial resources for patients, participants, and the public.

Appendix A – Prompt engineering considerations

Components of good prompts:

- Clear context setting (e.g., "You are writing a lay summary for a clinical trial on [condition] for people with a 6th-grade reading level.")
- Specific instructions on tone and style (e.g., "Use a compassionate and encouraging tone while maintaining factual accuracy.")
- Guidelines for simplifying complex concepts (e.g., "Explain [medical term] in simple language a non-expert can understand.")
- Reminders to include necessary context and caveats (e.g., "Ensure to mention that these results may not apply to all patients and individual responses may vary.")
- Use of sequential prompts for refinement can help improve the quality of a draft.

Example prompts:

- "Please create a lay summary of clinical trial results for a new diabetes medication. Your audience is the general public, including patients with type 2 diabetes, who have a 6th-grade reading level. Use a compassionate and encouraging tone while maintaining factual accuracy. Simplify complex medical terms but include them in parentheses after the simplified explanation. Ensure you mention the study's limitations and that results may not apply to all patients. Structure the summary with understandable headings and bullet points for easy readability."
- "Please write a 3-paragraph explanation for why this trial: [trial name and NCT number from publicly available website] is being done. In the first paragraph please explain the condition, in the second paragraph please explain the study drug and why it is being developed, and in the third paragraph please discuss the trial design and restate the hypothesis for the final sentence. Please write the entire explanation at a 12 year old reading level."
- "You are tasked with creating a lay summary of clinical trial results for a new diabetes medication. Your audience is the general public, including patients with type 2 diabetes, who have a 6th-grade reading level.
- Here are the clinical trial results you will be summarising: [insert documentation if within LLM capabilities/applicable].

Follow these guidelines to create your summary:

1. Use a compassionate and encouraging tone throughout the summary. Be warm and supportive but maintain factual accuracy.
2. Write at a 6th-grade reading level. Use simple words and short sentences. Avoid jargon or complex medical terminology.
3. Structure your summary with the following headings:
   - What was the study about?
   - What did the study find?
   - What does this mean for me?
   - What are the next steps?
4. Under each heading, use bullet points to present information clearly and concisely.
5. When introducing medical terms or concepts, first provide a simple explanation, then include the technical term in parentheses. For example: "sugar in the blood (glucose)".
6. Mention the study's limitations and clearly state that the results may not apply to all patients.
7. Begin your summary with a brief overview of the study's purpose (2–3 sentences).

Write your complete summary inside <summary> tags. Ensure that your summary is factually accurate based on the provided clinical trial results, while being easy to understand for the target audience."

Appendix B – Considerations for AI governance

Effective governance is crucial when implementing AI for plain language summaries. A well-structured governance framework ensures that the use of AI aligns with organisational goals, regulatory requirements, and ethical standards. Key components of governance should include:

- **Internal collaboration & standards development/implementation**
  - Establish a cross-functional team including medical writers, statisticians, legal experts, patient advocates, and AI specialists.
  - Develop clear guidelines and standard operating procedures (SOPs) for AI use in patient communications.
  - Implement a review and approval process involving subject matter experts to validate AI-generated content.
  - Create a feedback loop to continuously improve AI performance based on human expert input.

- **Initial testing**
  - Develop a comprehensive test suite covering various scenarios, e.g., study phase, design, endpoints, safety data sets, patient populations
  - Conduct A/B testing comparing AI-generated content with human-written content for patient preference and understanding
  - Implement a feedback loop incorporating input from patients, healthcare providers, and subject matter experts
  - Regularly update and retrain AI models based on new data, feedback, and evolving best practices
  - Testing process example:

1. Generate initial content using AI
2. Review by humans for accuracy, readability, and health literacy levels using validated tools
3. Incorporate public and patient involvement for feedback on understandability and relevance
4. Iterate based on feedback, making necessary adjustments to prompts or AI models
5. Repeat steps 1–5 until satisfactory results are achieved
6. Implement in a limited rollout and monitor performance

Scale implementation based on successful performance metrics

- **Ongoing monitoring given AI's continuous learning**
  - Implement a phased rollout, starting with low-risk applications and gradually expanding to more complex tasks.
  - Establish key performance indicators (KPIs) to measure the accuracy, readability, and effectiveness of AI-generated communications.
  - Conduct regular audits to assess AI performance.
  - Implement a system for ongoing monitoring of AI outputs, including random sampling and human expert review.
  - Develop protocols for addressing and correcting any errors or biases identified in AI-generated content.
  - Stay informed about advancements in AI technology and update systems accordingly to maintain state-of-the-art performance.

- **Regulatory compliance**
  - Ensure compliance with relevant regulations, such as the EU AI Act, GDPR, and FDA guidelines.
  - Maintain detailed documentation of AI training data, algorithms, and decision-making processes for regulatory audits.
  - Establish a process for staying updated on evolving regulations and adjusting AI systems and governance practices accordingly.

- **Ethical considerations**
  - Develop an ethical framework for AI use in patient communications, addressing issues such as bias, privacy, and transparency.
  - Implement safeguards to protect patient data and ensure confidentiality throughout the AI-assisted communication process.
  - Regularly assess the ethical implications of AI use and make necessary adjustments to maintain alignment with organisational values, industry best practices, and societal expectations.

- **Training and education**
  - Provide comprehensive training for staff involved in AI-assisted patient communication processes.
  - Develop resources to help team members understand AI capabilities, limitations, and best practices for collaboration between humans and AI systems.

- **Continuous improvement**
  - Establish a process for collecting and analysing feedback from patients, healthcare providers, and other stakeholders on AI-generated communications.
  - Use insights gained from feedback and performance monitoring to refine AI models and improve the quality of patient communications over time.

Appendix C – Considerations for AI disclosure

Transparency regarding the use of generative AI in creating patient communications is essential for maintaining trust, ethical standards, and regulatory compliance. Proper disclosure practices should address the following aspects:

- Where and when should the use of AI be disclosed and to what extent
  - Include a clear statement about AI involvement in the creation of the document, typically in the introduction or a dedicated section.
  - Disclose the extent of AI use, such as whether it was used for initial drafting, language simplification, or spelling/ grammar checking.
  - Consider including a brief explanation of how AI was used in conjunction with human expertise to ensure accuracy and relevance.
  - Make the disclosure easily understandable for the target audience, avoiding technical jargon.

- AI regulation compliance
  - Ensure that disclosure practices align with the requirements of the EU AI Act or similar, applicable regulations.
  - Provide information on the AI system's purpose, capabilities, and limitations as required by applicable laws.
  - Include contact information for inquiries about the AI system or its outputs.

- Disclosure of sponsor or other human involvement:
  - Clearly state the level of involvement of the study sponsor and medical experts in reviewing and approving the LS.
  - Acknowledge any public or patient community involvement in the development or review of the LS.
  - If there was limited or no human involvement, this should also be disclosed transparently.

Example disclosure statements to include in LS:

- AI involvement disclosure
  - "This summary was initially drafted using artificial intelligence (AI) technology. After the first draft was created, it was reviewed, revised, and approved by qualified medical professionals to ensure accuracy, clarity, and relevance."

- Extent of AI use
  - "Artificial intelligence was used to assist in simplifying complex medical language and organising information in this summary. All content has been verified and approved by the study team and patient representatives."

- Sponsor involvement
  - "The study sponsor, [sponsor name], has reviewed this AI-assisted summary to ensure its accuracy and alignment with the clinical trial results."

- Public and patient involvement
  - "Members of the public, patients, and patient advocates were also involved in the review of this summary to help ensure it is understandable and relevant."

- AI regulation compliance
  - "This document was created with the assistance of an AI system developed by [company name]. The system is designed to simplify medical language and organise information for LS. For more information about the AI system used, please contact [contact information]."

Appendix D – Example of advanced AI architecture for LS creation

Advanced AI systems for creating LS benefit from specialised agentic architectures that divide complex tasks among multiple AI components working in coordination. This approach mirrors team-based document creation in traditional settings but offers enhanced consistency, scalability, and traceability. In a sense, this approach is modeling human excellence.

Key components of an agentic architecture

Planning and creation agents

- **Strategy planning agent**:
  Analyses source documents and develops structural approach
  - Maps information complexity and creates audience-appropriate templates
  - Sets measurable objectives (reading level, length, key messages)
- **Initial drafter agent**:
  Transforms clinical documents into first-draft summaries
  - Structures information logically while maintaining appropriate detail balance
  - Adheres to target reading level parameters
- **Medical accuracy checker agent**:
  Verifies factual correctness
  - Cross-references claims against source documentation
  - Flags statistical information requiring expert verification
- **Readability optimiser agent**:
  Refines language for target audience
  - Adjusts text using readability metrics
  - Suggests simpler terminology while preserving meaning
- **Bias and sensitivity reviewer agent**: Ensure inclusive content
  - Identifies potentially exclusionary or stereotyping language
  - Checks for balanced representation and culturally sensitive explanations

Coordination and feedback

- **Orchestrator agent**:
  Manages workflow and integration
  - Routes content between specialised agents
  - Resolves conflicts and maintains document integrity
  - Identifies areas requiring human intervention
- **Feedback integration agent**:
  Processes human expert input
  - Categorises and prioritises feedback
  - Updates agent parameters based on feedback patterns

Human integration

- **Human expert touchpoints**:
  Strategic oversight at key junctures
  - Review of planning outputs and initial parameters
  - Evaluation of flagged uncertainties requiring domain expertise
  - Provision of structured feedback and final approval

Implementation workflow

1. **Planning**: Strategy agent analyses source documents and establishes approach.
2. **First draft**: Initial drafter produces structured summary based on planning.
3. **Multi-agent review**: Medical accuracy, readability, and bias agents evaluate draft.
4. **Integration**: Orchestrator consolidates agent inputs into revised draft.
5. **Human feedback**: Experts review and provide structured feedback.
6. **Refinement**: Agents implement changes based on feedback.
7. **Iteration**: Steps 5-6 repeat as needed until quality thresholds are met.
8. **System Learning**: Feedback patterns update agent parameters for future projects.
9. **Approval**: Human experts provide final sign-off with complete process documentation.

Benefits

- **Specialisation**: Optimised agents for specific tasks
- **Traceability**: Clear documentation of decisions
- **Adaptability**: System learns from expert feedback
- **Scalability**: Consistent approach across document types

Testing and monitoring of advanced AI Architecture systems is critical and should be implemented according to the guidelines outlined in Appendix B.

Appendix E – Helpful tools and resources

Leverage existing tools and resources and develop additional, use-specific comprehensive resources to guide the development and use of AI for LS creation. The following tools, resources, and topics should be considered.

A. Quality control checklists

- Verification of medical facts and statistics against source documents (e.g., clinical study reports, published literature)
- Consistency checks, inter- and intra-document, with approved messaging and terminology
- Assessment of readability and health literacy levels
- Evaluation of cultural sensitivity and inclusivity
- Identification of potential biases or misleading statements
- Identification of oversimplified or illogical statements
- Compliance with regulatory requirements and internal guidelines

B. AI implementation, evaluation and benchmarking tools

- Quality assessment frameworks for measuring accuracy and readability
- If using AI agents, developer tools to help understand agentic decision-making processes
- Performance benchmarking tools to compare AI outputs against human-generated content
- Annotation tools for providing feedback on AI-generated content

C. Data privacy safeguards

- Data anonymisation and de-identification tools
- Secure file transfer protocols for sensitive information
- Access control systems to limit data exposure
- Encryption tools for data at rest and in transit
- Privacy impact assessment templates

D. Collaborative platforms

- Implement secure platforms for collaboration between AI systems and human experts
- Version control systems to track changes and approvals
- Annotation tools for providing feedback on AI-generated content
- Project management software to coordinate review and approval processes

E. Training resources for staff involved in using AI

- Develop comprehensive training materials for staff involved in AI-assisted LS creation
- E-learning modules on AI capabilities and limitations
- Good practices for human-AI collaboration
- Regular workshops and webinars on emerging AI technologies and ethical considerations

F. Additional resources

- Good Lay Summary Practice Guidance (GLSP)
- International Society for Medical Publication Professionals (ISMPP) position statement and call to action on artificial intelligence
- EMA artificial intelligence workplan
- Four principles for safe and responsible use of LLMs (EMA)
- Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities (EMA)
- European Union (EU) Artificial Intelligence Act

List of abbreviations in this article

AI	artificial intelligence
AMWA	American Medical Writers Association
CSP	clinical study protocol
CSR	clinical study report
CTEG	Clinical Trials Expert Group
EMWA	European Medical Writers Association
EU	European Union
FDA	Federal Drug Association
GDPR	General Data Protection Regulation
GLSP	Good Lay Summary Practice
GPT	Generative Pre-trained Transformer
HIPAA	Health Insurance Portability and Accountability Act
ICF	informed consent form
ICMJE	International Committee of Medical Journal Editors
ISMPP	International Society for Medical Publication Professionals
LLM	large language model
LLS	lay language summary
LS	lay summary
NIST	National Institute of Standards and Technology
PLS	plain language summary
TFL	tables, figures, listings
TRS	trial results summary
US	United States

News from the EMA

The articles included in this section are a selection from the European Medicines Agency (EMA)'s News and Press Releases archive.
More information can be found on the Agency's website: www.ema.europa.eu.

SECTION EDITOR

Section Editor:
Anuradha Alahari
Anuradha.Alahari@parexel.com

EMA contact:
Monika Benstetter
press@ema.europa.eu

Photo: Freepik

New clinical trial map launched in the EU

March 3, 2025

A new clinical trial map is now accessible from the public website of the Clinical Trials Information System (CTIS). The map is designed to provide patients and healthcare professionals with easy access to comprehensive, real-time information about clinical trials conducted in their area, increasing access to clinical research in the (European Union) EU.

Building on the public information contained in CTIS, the map improves how people use the system and find information about clinical trials. Users can look for ongoing trials by geographic area and medical condition. The search supports queries in lay language and includes an autocorrect system that provides suggestions in case of misspellings. Search results offer investigator's contact details, enabling members of the public to directly enquire about potential enrolment into a given trial. The first version of the map is provided in English. Additional EU languages will be added in future releases.

The creation of the map is an action of the Accelerating Clinical Trials in the European Union (ACT EU) initiative workplan for 2025–2026. It responds to requests for a simple, patient-friendly dashboard for CTIS to help stakeholders, particularly patients, locate clinical trials of interest in Europe. EMA hosted a public webinar on March 7, 2025, to provide a live demonstration on how to use all the features. A recording of the session will be available.

CTIS includes a public searchable database for healthcare professionals, patients and citizens to deliver the high level of transparency foreseen by the Clinical Trials Regulation. The authorisation and oversight of clinical trials is the responsibility of EU/EEA Member States while EMA is responsible for maintaining CTIS. The European Commission oversees the implementation of the Clinical Trials Regulation.

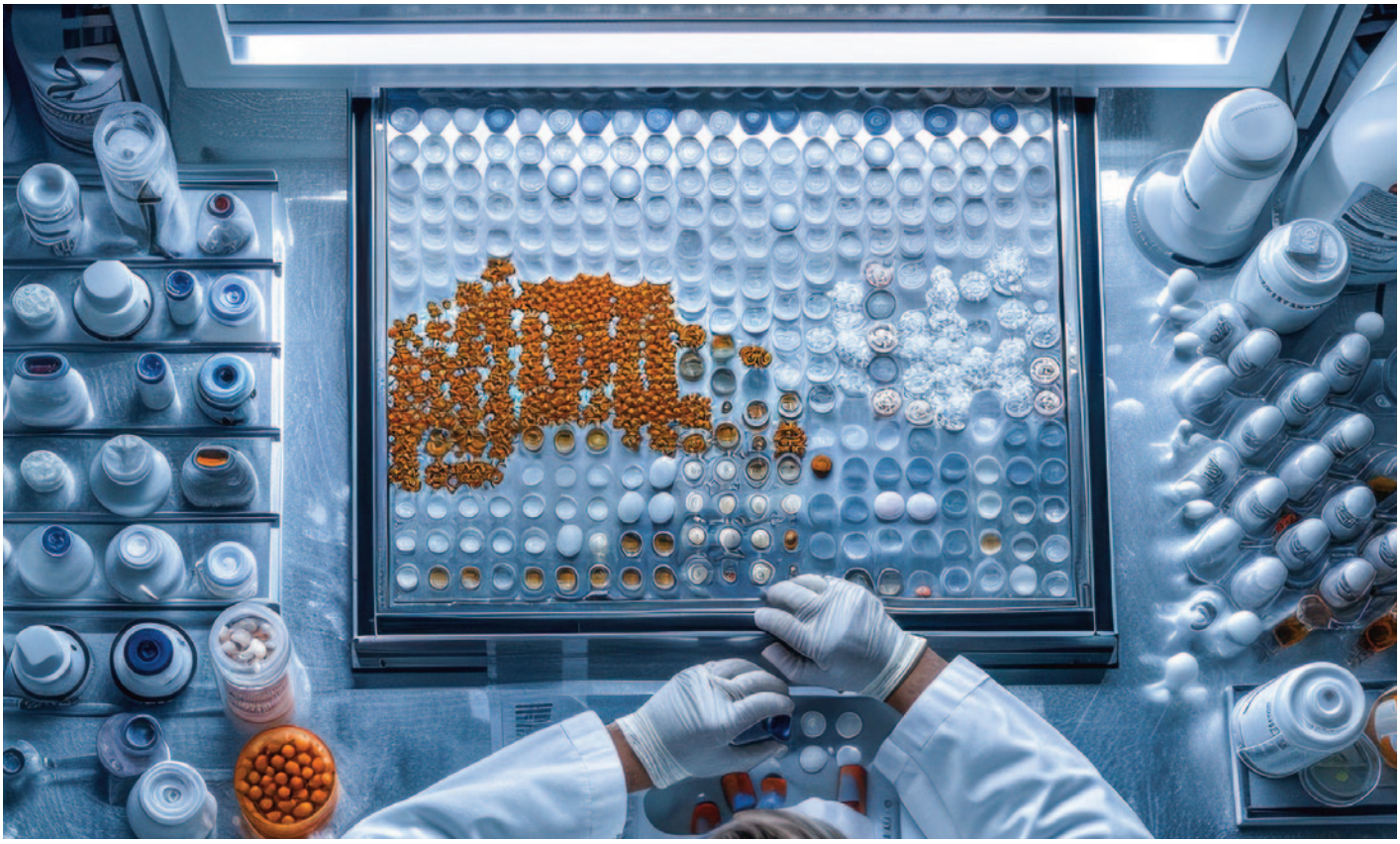


Photo: Freepik

Joint strategy sets direction of EMA and EU medicines regulatory agencies to 2028

March 18, 2025

EMA and the Heads of Medicines Agencies (HMA) have published their joint EU medicines agencies' network strategy to 2028 (EMANS), following its recent adoption by the HMA and the EMA Management Board.

The strategy, titled "Seizing opportunities in a changing medicines landscape",[1] is a comprehensive update of the five-year strategy which was developed to cover the period 2021 to 2025 (EMANS 2025). The updated document will guide the European medicines regulatory network over the next few years to meet the challenges ahead, including preparing for, and responding to, public health emergencies and threats such as antimicrobial resistance.

Prepared in a post-pandemic setting, the strategy draws on the extensive experience gained from tackling COVID-19. It also takes into account the ongoing revision of the EU's pharmaceutical legislation, laying the groundwork for its implementation. The six focus areas of the strategy to 2028 build upon those in the EMANS to 2025 with the updated strategy placing more emphasis on the competitiveness of the EU in the development and manufacture of medicines, as well as the use of artificial intelligence throughout the medicines' lifecycle.

The "One Health Approach" is introduced as a key aspect of the strategy, recognising that the health of humans, animals and the wider environment are closely intertwined. The six strategic focus areas of EMANS to 2028 are as follows:

1. Accessibility – to facilitate pathways for access to medicines through healthcare systems in the EU.
2. Leveraging data, digitalisation and artificial intelligence – to improve decision making, optimise processes and increase efficiency.
3. Regulatory science, innovation and competitiveness – to create a regulatory and research environment that accelerates the translation of innovation and improves competitiveness of the EU's healthcare sector.
4. Antimicrobial resistance and other health threats – to prepare the EU for potential threats including antimicrobial resistance.
5. Availability and supply – to strengthen the availability of medicines to protect public and animal health.
6. Sustainability of the network – to ensure that the network has available resources to support its scientific and regulatory decision making, taking full advantage of technological advances.

The strategy was developed through extensive collaboration with experts and stakeholders across the EU medicines regulatory network. A public consultation took place in late 2024, during which 77 submissions from the public and stakeholders provided valuable feedback which helped shape the strategy. EMA and the HMA, in partnership with the EU Polish presidency, also held a webinar with stakeholders in February 2025 to further refine and finalise the text.

EMA and HMA will now implement the strategy via their respective multi-annual workplans and at national level. The network will monitor its implementation, report back and adjust as needed. The final strategy is published with an overview of the comments received during the public consultation.

Reference

1. Seizing opportunities in a changing medicines landscape: The EMA network strategy 2018. Available from: https://www.ema.europa.eu/en/documents/other/seizing-opportunities-changing-medicines-landscape-european-medicines-agencies-network-strategy-2028-final_en.pdf doi:10.2809/8994389

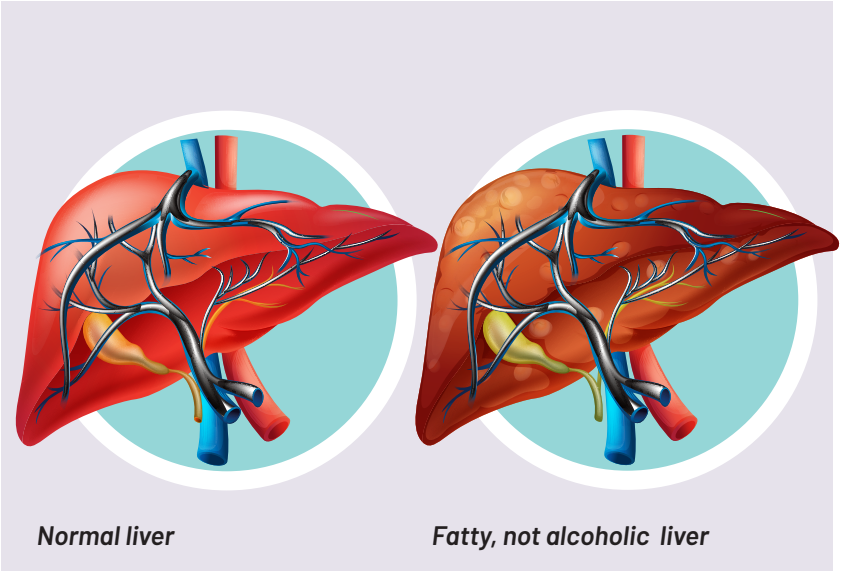


Photo: Freepik

EMA qualifies first artificial intelligence tool to diagnose inflammatory liver disease (MASH) in biopsy samples

March 20, 2025

EMA's human medicines committee (CHMP) has issued the first Qualification Opinion on an innovative development methodology based on artificial intelligence (AI). The tool, called AIM-NASH, helps pathologists analyse liver biopsy scans to identify the severity of MASH (metabolic dysfunction associated steatohepatitis; formerly known as non-alcoholic steatohepatitis, NASH) in clinical trials.

MASH is a condition where fat builds up in the liver, causing inflammation, irritation and scarring over time, without significant alcohol use or other reasons for liver injury. MASH is linked to obesity, Type 2 diabetes, high blood pressure, abnormal cholesterol, and belly fat. If untreated, it can lead to advanced liver disease. The AIM-NASH tool is expected to enhance the reliability and efficiency of clinical trials for new MASH treatments by reducing variability in measuring disease activity (inflammation and fibrosis).

Testing new MASH treatments often relies on liver biopsies, where small pieces of liver tissue are taken to confirm inflammation and scarring. These biopsies are the gold standard for demonstrating the efficacy of new, investigational medicines. However, high variability in MASH/ NASH clinical trials is a challenge, as specialists who review biopsy samples may not always agree on the severity of inflammation or scarring. AIM-NASH is an AI-based system that employs a machine learning model trained on more than 100,000 annotations from 59 pathologists who assessed over 5000 liver biopsies across nine large clinical trials. The qualified tool is "locked" which means the machine learning model cannot be modified or replaced.

The evidence submitted to CHMP shows that AIM-NASH biopsy readings, verified by one expert pathologist, can reliably determine MASH disease activity with less variability than the current standard used in clinical trials, which relies on a consensus by three independent pathologists. Following a public consultation, CHMP issued an opinion to qualify this method, which means that the committee can accept evidence generated by the tool as scientifically valid in future applications. CHMP agreed that the tool can increase reproducibility and repeatability in assessments for new MASH treatments. It can help researchers obtain clearer evidence on the benefits of new treatments in clinical trials that include fewer patients. Ultimately, this can bring effective treatments to patients faster.

CHMP encourages the optimisation of the model, acknowledging that major changes may require re-qualification of the tool. All EMA's activities on AI are co-ordinated under the multi-annual AI workplan by EMA and the HMA, aiming to ensure safe and responsible use of AI across the European medicines regulatory network.

Photo: Freepik

EMA establishes regular procedure for scientific advice on certain high-risk medical devices

March 24, 2025

EMA, in close collaboration with the European Commission, has established a standard procedure for manufacturers of certain high-risk medical devices to request scientific advice on their intended clinical development strategy and proposals for clinical investigation.

Manufacturers of class III devices and class IIb active devices intended to administer or remove medicines can now submit their request for advice via a portal and consult the medical device expert panels at different stages of the clinical development. Advice given by the medical device expert panels is a key tool to foster innovation and promote faster patient access to safer and more effective devices. This regular scientific advice procedure follows a pilot launched in February 2023,[1] which has helped to establish this procedure and gathered positive feedback from manufacturers and panel experts. EMA will publish a report on the pilot in the coming weeks.

There are currently no fees associated with these requests. More information on the submission process, including step-by-step instructions for applicants and monthly submission deadlines is available on EMA's website. Manufacturers of high-risk medical devices intended for the treatment of a rare condition should apply for advice via the ongoing pilot programme to support orphan medical devices.

Reference

1. Pilot on the Advice from the Expert Panels to Manufacturers of High-Risk Medical Devices Interim report on the experience with the pilot from February 2023 to December 2024. Available from https://www.ema.europa.eu/en/documents/report/pilot-advice-expert-panels-manufacturers-high-risk-medical-devices-interim-report-experience-pilot-february-2023-december-2024_en.pdf.

Photo: Freepik

First report on EU-wide sales and use of antimicrobials in animals

March 31, 2025

For the first time, all the 27 countries of the European Union (EU27) together with Iceland and Norway, have collected and reported data on both sales and use of antimicrobials in animals in their countries. The findings are presented in the first European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) annual surveillance report.[1] The data cover the year 2023, marking the beginning of a regular exercise that will result in yearly reports.

Data on sales

Sales of antibiotics for food-producing animals accounted for 98% of total EU sales of veterinary medicines containing substances with antibiotic activity. The highest selling antimicrobial class for food-producing animals were penicillins, followed by tetracyclines and sulfonamides. According to the Antimicrobial Advice Ad Hoc Expert Group (AMEG) categorisation of antibiotics for use in animals for prudent and responsible use, developed by EMA's ad hoc expert group, approximately 65% of total EU sales for food-producing animals corresponded to substances that belong to category D (which should be used as first line treatments, whenever possible), 29% corresponded to category C (which should be considered only when there are no antibiotics in Category D that could be clinically effective), and 6% corresponded to category B (which are critically important in human medicine but use in animals should be restricted to mitigate the risk to public health).

Data on use

Data on use were collected for four main food-producing animal species in 2023: cattle, pigs, chickens and turkeys. Veterinarians played a key role in gathering data, as they were selected as the sole data providers by 16 reporting countries. The remaining 13 reporting countries used other data providers in addition to veterinarians, including pharmacies, feed mills, farmers or breeders, and retailers.

This is the first time that data on use has been collected across the EU. Many countries are still in the process of setting up or improving data collection systems for antimicrobial use. Therefore, the shared data for 2023 were not complete and accurate enough to start reporting quantitative information. Member States are committed to consolidating their use data collection systems, aiming to increase accuracy and coverage. This initiative has already shown a strong cooperation between reporting countries, as those with experience in data collection on antimicrobial use offered guidance and support, fostering a productive and collaborative environment.

Antimicrobial Sales and Use (ASU) Platform

The ESUAvet report builds on the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a voluntary initiative between national authorities and EMA to collect reliable sales data across Europe over the course of 12 years. A 50% drop in sales of veterinary antibiotics was observed during this time, thanks to the collective efforts of countries who provided the data and developed national strategies to encourage responsible use as well as to practitioners and farmers in the field.

The ESVAC initiative was considered so successful that it has formalised and expanded under EU legislation to include mandatory data collection on the sales and use of antimicrobials in animals. Member States report their data to EMA via the ASU Platform, a centralised system designed to standardise and streamline the data received from countries.

The data in the annual ESUAvet reports, collected via the ASU Platform, will help to identify trends in antimicrobial consumption in animals more accurately and with more granularity, enabling decision-makers to address the increasing complexity of antimicrobial resistance and to take appropriate measures to protect both animal and human health in Europe.

Reference

1. European sales and use of antimicrobials for veterinary medicine: Annual surveillance report for 2023 (EMA/CVMP/ESUAVET/80289/2025). 2025. https://www.ema.europa.eu/en/documents/report/european-sales-use-antimicrobials-veterinary-medicine-annual-surveillance-report-2023_en.pdf. doi: 10.2809/4487470.

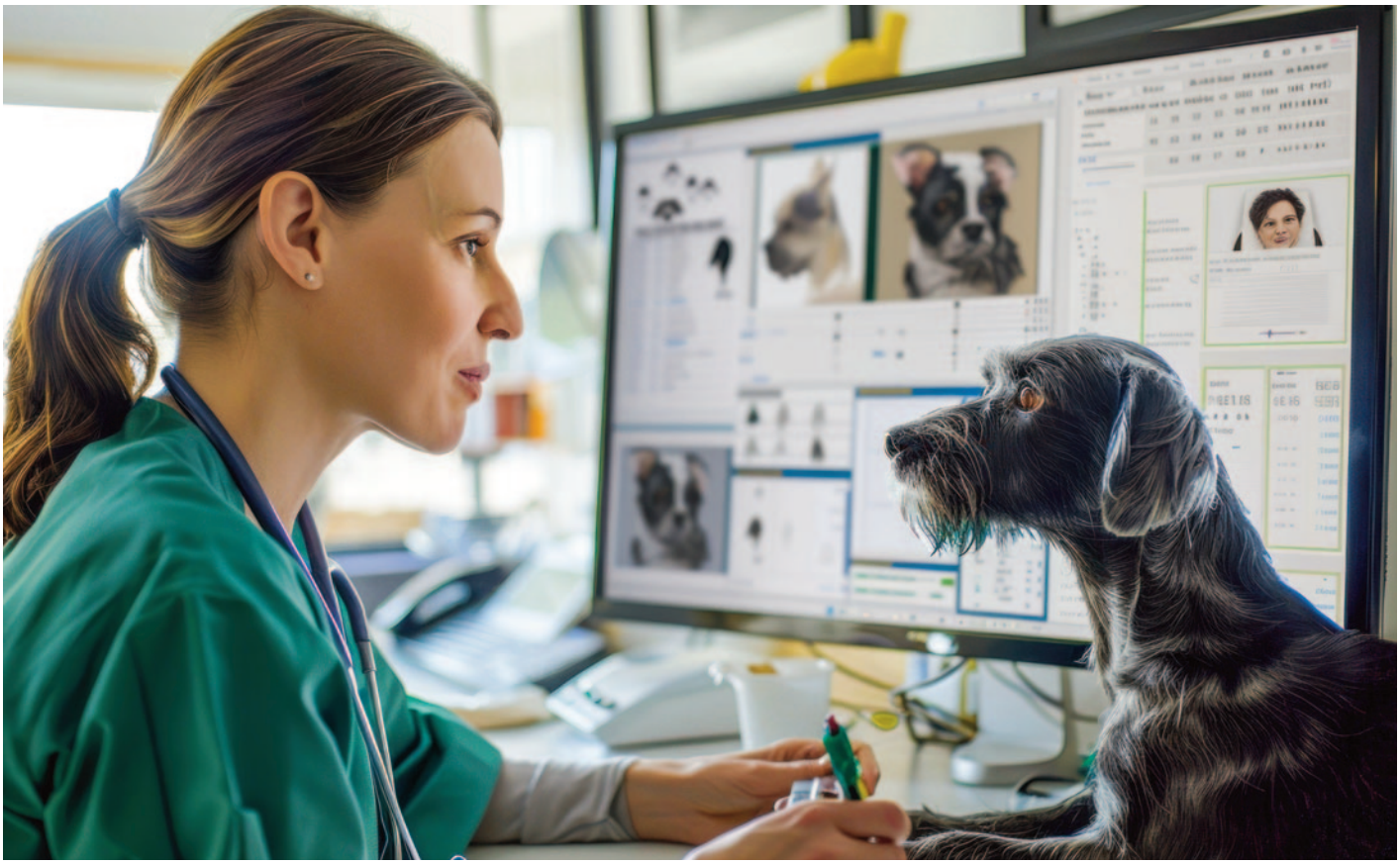


Photo: Freepik

Leveraging the power of data for public and animal health

May 7, 2025

EMA and the HMA have published a joint workplan "Data and AI in medicines regulation to 2028".[1] It sets out how the European medicines regulatory network plans to leverage large volumes of regulatory and health data as well as new tools to encourage research, innovation, and to support regulatory decision making for better medicines that reach patients faster.

The workplan lays out a roadmap for managing, analysing, and sharing data across the network, while adhering to high security and ethical standards. It also provides a framework for coordination to address new legislative initiatives in the European Union (EU), notably the pharmaceutical legislation, the European Health Data Space (EHDS), the Interoperable Europe Act and the AI Act. This new strategic advisory group, combining the former Big Data Steering Group and the Network Data Board, will oversee the implementation of the workplan.

The workplan translates the objectives of the European medicines agencies network strategy to 2028 into concrete deliverables. These include strengthening the network's data analytics capabilities to generate high-quality evidence using both established and novel methods. The clinical study data pilot by EMA's CHMP will continue to clarify the benefits and practicalities of accessing individual patient data from clinical trials. The Data Analysis and Real World Interrogation Network, DARWIN EU®, will further expand and deliver evidence that helps fill knowledge gaps and understand the use, safety and benefits of medicines.

A review of methodologies, including biostatistics, modelling and simulation, AI and pharmacoepidemiology and lesser-used data types, including genomic data, synthetic data, digital twins data and patient experience data, will help the network establish shared understanding and position the future use of such methods and data types.

The workplan aims to enable efficient discovery, access, and use of the network's data assets through cataloguing and strengthening data quality, starting with real world data, adverse drug reaction data and medicinal product master data. Master data, the core data needed for the operations of the network, is essential for increasing the interoperability of data assets and systems. The workplan will advance and harmonise the implementation of the Product Management Service (PMS), recognised as the network's source of product master data for all EU medicinal products, supporting EU-wide use cases.

AI offers clear opportunities across the medicines lifecycle. Key initiatives of the workplan include supporting EMA's scientific committees and the pharmaceutical industry in evaluating AI through the medicines lifecycle, developing guidance on AI in clinical development and in pharmacovigilance, fostering EU-wide and international collaboration, and providing the network with training on AI and a framework for sharing and collaborating on AI tools. The aim is to facilitate safe and responsible use of AI that benefits public and animal health.

Reference

1. Network Data Steering Group workplan 2025-2028: Data and AI in medicines regulation. Joint HMA/EMA Network Data Steering Group VERSION 1.1 – May 2025. Available from https://www.ema.europa.eu/en/documents/other/network-data-steering-group-workplan-2025-2028_en.pdf.

AI/Automation

SECTION EDITORS

Daniela Kamir
Daniela.kamir@gmail.com

Medical writing and AI: Stronger together

AI is transforming medical writing by complementing human abilities in powerful ways: detecting subtle signals in massive datasets, parsing complex tables quickly, and managing the scale of today's large, adaptive trials like platform and umbrella studies. These tools bring speed, precision, and consistency – helping ensure that signals aren't missed and data isn't lost in complexity. Applications such as ChatGPT for drafting standard sections, NLP tools for systematic literature reviews, and Clinical Language Processing platforms for extracting insights from medical records are already delivering measurable efficiency gains in document development.

Still, AI can't replace the human mind. Medical writers and communicators contribute critical thinking, narrative strategy, and audience-specific nuance that machines cannot replicate. Whether developing clinical documents, scientific publications, or lay summaries, human expertise remains essential for clear, meaningful, and responsible communication. Just as importantly, humans provide the ethical judgment and scientific rigour required to ensure that medical information maintains its integrity and accuracy, regardless of the technologies used to produce it.

The future isn't about choosing between human or machine – it's about collaboration. When medical writers and AI tools work hand in hand, the results are faster, more accurate, and more impactful. This partnership requires thoughtful implementation: writers who work fluently with AI can effectively guide, verify, and refine outputs, particularly when communicating complex medical concepts where precision and context are critical. This collaborative approach is shaping the future of medical writing as a whole, enhancing its quality and reach across all forms of communication.

The medical communications landscape is rapidly evolving, with the most innovative organisations finding balanced approaches that leverage both technological efficiency and human expertise. By embracing this synergy, the field can overcome traditional constraints of time and resources while maintaining its integrity, strategic thinking, and scientific clarity that makes medical writing such a vital contributor to healthcare advancement.

Daniela

ChatGPT use among medical writers: A knowledge, attitude, and practices survey

Simran Kaur Juneja, Shital Sarah Ahaley, Ankita Pandey, Sujatha Vijayakumar
Hashtag Medical Writing Solutions Private Limited, Chennai, India

doi: 10.56012/bqup6837

Correspondence to:
Sujatha Vijayakumar
sujatha.v@hashtagco.in

Abstract

There are numerous publications on ChatGPT but the trends of its usage in the medical writing field are unknown. We conducted an online survey to understand the knowledge, attitude, and practices of professionals in medical writing regarding ChatGPT usage. A total of 106 respondents from 21 countries participated in the survey. Most respondents were females (65.1%), aged 25-44 years (71.6%), Indians (61.3%), doctoral degree holders (45.3%), from the medical communications sector (55.7%), and with 1-5 years of experience (47.2%). Regarding knowledge about ChatGPT, most respondents (44.3%) had intermediate knowledge. The respondents with a high understanding showed certain significant correlations with the attitude and practice patterns such as agreeing on the ability of ChatGPT and other AI tools in saving time while writing ($p<0.001$) but also acknowledging its potential risks ($p=0.001$) and the need for guidelines for using ChatGPT ($p<0.001$). Thus, the working knowledge of ChatGPT influences the adoption of ChatGPT among medical writers and determines the perspectives on practices for the use of AI tools in medical writing.

Introduction

Medical writers have used artificial intelligence (AI)-based applications like grammar-check tools, reference managers, and data analysis software for over a decade.[1,2] But the use of AI in other areas such as literature search, data organisation and presentation, and writing had been relatively unexplored until the last couple of years. The introduction of advanced large language models (LLMs) in healthcare and medical research has paved the way for the unexplored potential of AI in medical writing.[3]

The current generation of LLMs is based on a natural language processing (NLP) model and trained on a large dataset of conversational text to create responses to user input in a conversational context.[4] Several NLP-based LLM tools such as Gemini from Google™ and CoPilot from Microsoft® are now integrated into the programs actively used in day-to-day work.[5,6] But ChatGPT, developed by OpenAI, was the first of its kind and one of the most sophisticated AI tools on the GPT (generative pre-training transformer) architecture. It stands apart from its predecessors as the first LLM that was open to the general public and thus made AI accessible to a larger community.[4,7] It was the most familiar AI tool for medical writers with several studies being actively published to study its uses at the time of

the conception of this study. Hence, we chose ChatGPT to capture the trend of AI use in medical writing.[8-10]

ChatGPT makes a strong case for medical writers to save time and increase their writing efficiency.[11] In medical writing, it can be used as an intermediary for ideation, as a search engine, for text generation and summarisation, language translation, writing abstracts, and much more.[3,11] However, ethical and legal concerns must be carefully considered, such as the potential for inaccuracies, bias, misinformation, hallucinations, and plagiarism in the generated content.[3] As a result, there is still considerable debate on using ChatGPT for writing parts or a complete scientific manuscript.[12,13]

The field of regulatory writing is also evolving with advances in AI. The number of regulatory submissions involving AI or machine learning increased almost 10-fold between 2020 and 2021.[14] LLMs like ChatGPT and several new software such as DistillerSR and fern.ai™ can help streamline processes for writers such as technical documentation, clinical evaluation, and surveys for post-marketing surveillance among others. AI is also transforming the way clinical trials are conducted. Generation of a clinical study report (CSR) with a substantial number of narratives can make the process significantly long, tedious, and complex for the medical writers.[15] Specialised AI tools such as TriloDocs™ are now being developed and harnessed to automate clinical data management and CSRs through generative AI and machine learning.[16] However, such tools need rigorous assessment and validation in line with the nature of the regulatory field and compliance with international guidelines.[17-19]

Overall, the medical writing community seems divided on the practical use of ChatGPT. While some medical writers recognise its potential to enhance their work by offering a strong foundational framework, others are hesitant to embrace it due to concerns about inaccurate information and potential errors it may produce.[20]

This knowledge, attitude, and practice (KAP) survey aims to understand the opinions and usage patterns of ChatGPT and other AI tools among medical writers. We conducted an online survey and examined how demographics and knowledge may influence attitude and practice patterns. The study also discusses the potential implications for the future of AI tools in medical writing based on the results of the survey.

> ChatGPT has the potential to be a versatile tool for medical writers. However, the current perception of such tools and their usage within the medical writing community remain unclear.

Methods

Study design

This is an observational, questionnaire-based study. Participation in the survey was voluntary. An online survey collected responses from professionals in medical writing worldwide. The selection criteria were not restricted to any one specific kind of medical writing. Google Forms (Google LLC, Mountain View, CA, USA), used as the survey tool, automatically verified that the survey was fully completed prior to submission and could not be submitted twice. Participant responses were anonymous and confidentiality was maintained throughout the study.

Questionnaire development

The first draft of the questionnaire was developed with the help of ChatGPT (*ChatGPT.* GPT-3.5 OpenAI; 2023).[21] The resulting questionnaire (see Appendix I) was then modified and re-developed based on the inputs and review of this study's authors who are practicing medical writers specialising in medical communications and manuscript writing.

The questionnaire consisted of 4 sections and 35 questions: 1. Demographic information (11 questions) followed by 2. Knowledge, 3. Attitude, and 4. Practice (8 questions each) on the use of ChatGPT in medical communications.

The questionnaire was piloted among 14 expert medical writers to assess the clarity of the survey. Based on the feedback of the participants in the pilot survey, the questionnaire was finalised.

Study participants and survey dissemination

The source population for the survey consisted of medical writers worldwide. The survey was distributed on the social networking platform LinkedIn™ and by personal communication through an online link directing to the questionnaire on Google Forms. The survey was launched on June 14, 2023, and remained open till September 24, 2023 (Figure 1).

Statistical analysis

The completed questionnaires were automatically coded on Microsoft® Excel 2016 through Google Forms and manually verified. Data analysis was performed using SPSS version 28. Descriptive statistics such as frequencies and percentages for each survey item were calculated. Pearson's Chi-square analysis (Monte-Carlo simulation) was used to investigate associations between the categorical variables: demographics and knowledge, knowledge and attitude, and knowledge and practice of ChatGPT among the respondents.[22,23] Only the significant correlations are presented.

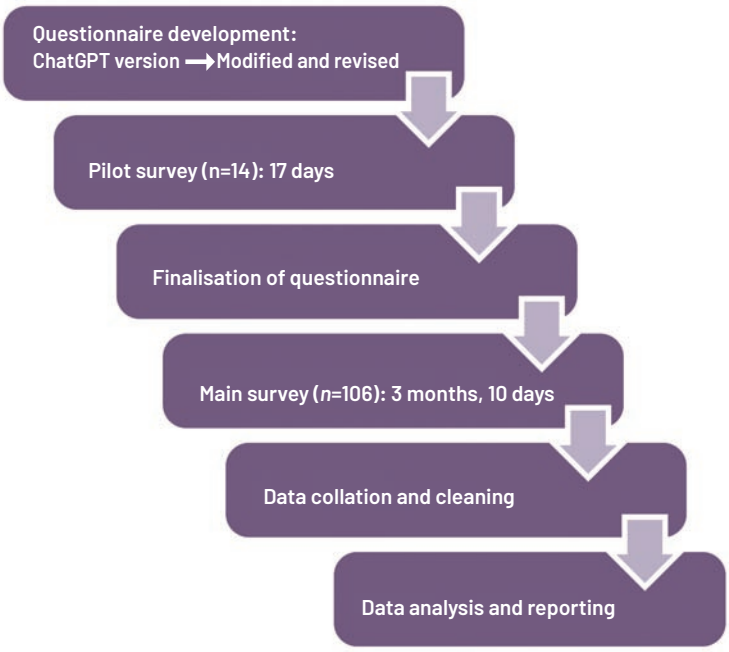


Figure 1. Study flow chart

Table 1. Descriptive statistics of survey respondents N = 106

Gender						
Female	Male	Not to say				
69 (65.1)	36 (34.0)	1 (0.9)				
Age						
<25	25-34	35-44	45-54	55-64	>65	
8 (7.5)	38 (35.8)	38 (35.8)	18 (17.0)	2 (1.9)	2 (1.9)	
Level of education						
Bachelors	Post graduate	Doctoral				
18 (17.0)	40 (37.7)	48 (45.3)				
Sector of work						
Pharma-ceutical industry	Medical communi-cations	Academic institution	Healthcare organisation	Other		
9 (8.5)	59 (55.7)	11 (10.4)	21 (19.8)	6 (5.7)		

Years of experience in medical writing					
<1 year	1-5 years	6-10 years	11-15 years	>15 years	
16 (15.1)	50 (47.2)	20 (18.9)	10 (9.4)	10 (9.4)	
Professional certification in medical writing or editing					
No	Yes				
87 (82.1)	19 (17.9)				
Membership of a professional organisation of medical writing					
No	Yes				
76 (71.7)	30 (28.3)				
Formal training in medical writing					
No	Yes				
70 (66.0)	36 (34.0)				
Experience in using AI-powered tools for medical communications					
No	Yes				
58 (54.7)	48 (45.3)				

Results

Demographic characteristics

A total of 106 respondents from 21 countries took the survey and were included in the final analyses (Table 1).

The majority of the respondents were female (65.1%), aged 25-44 years (71.6%), and had an advanced academic degree (doctoral degree, 45.3%). The majority had limited experience in medical writing, with 47.2% reporting 1-5 years of work experience. Even though the majority of the respondent population was from India (61.3%), respondents from countries worldwide including Europe, Australia, Canada, USA, and other Asian countries also participated in the survey (Figure 2).

Their specialisation in writing ranged from medical education writing (48%), regulatory writing (14%), health economics and outcomes research (~6%) to medico-marketing (35%), science journalism (17%), and blog writing (~2%). Most respondents lacked a professional certification in medical writing or editing (82.1%) and were not members of any professional organisation for medical communications (71.7%). Almost half of the respondents affirmed using AI-powered tools for medical communications (45.3%).

Figure 2. Distribution of the survey respondents. The colour scale represents the number of participants.

Knowledge about ChatGPT

This section's questions were intended to assess the respondents' general understanding of ChatGPT, without focusing on its usage. Overall, 82.1% of the respondents indicated that they have a general understanding of how ChatGPT functions. The knowledge related to the working of ChatGPT was assessed by seven single-choice questions for ease of scoring. Figure 3 shows the percentage of respondents who provided the correct answer response to each question.

The responses were given a score of one for each correct answer. Based on their total scores, the respondents were divided as having "low" (score 0-2), "average" (score 3-4), or "high" knowledge (score≥ 5). Most of the participants (44.3%) had average knowledge of ChatGPT (Figure 4).

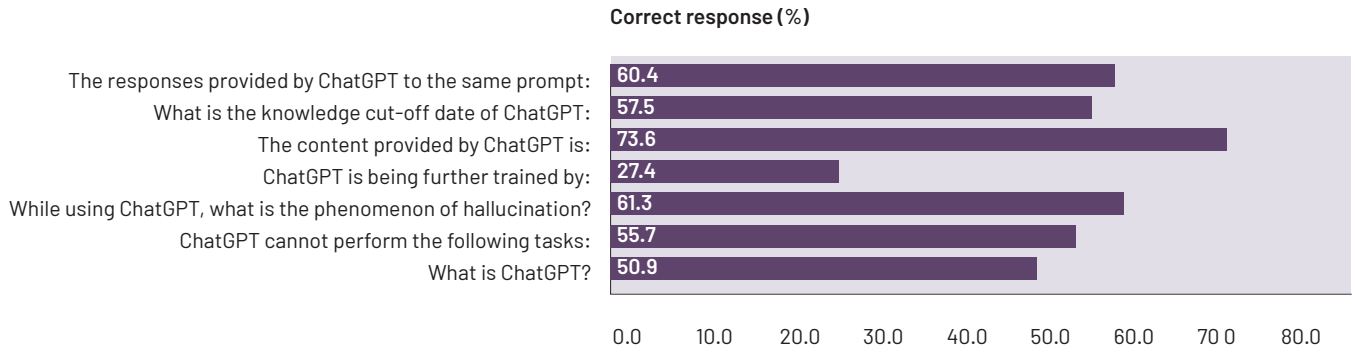


Figure 3. Percentage of respondents correctly answering the questions in the knowledge section of the survey

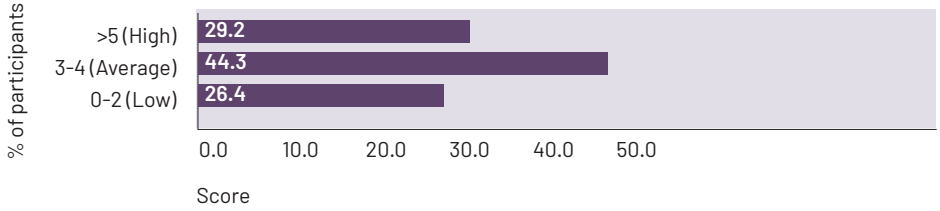


Figure 4. ChatGPT knowledge among survey participants based on an arbitrary scoring

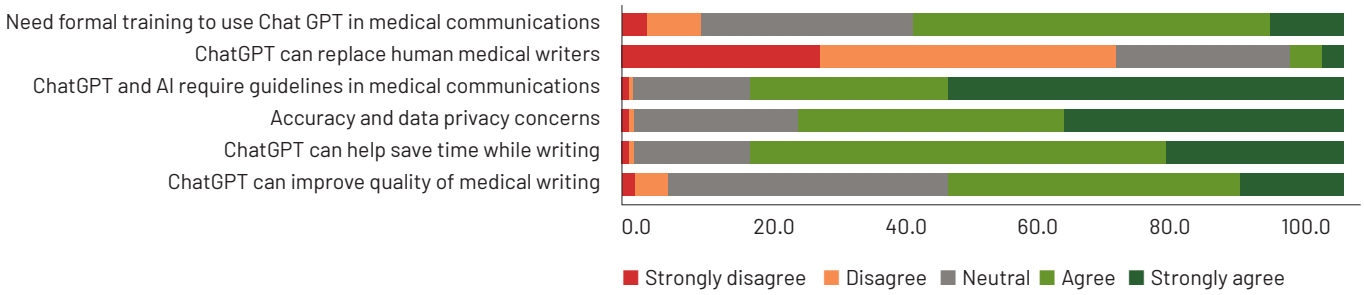


Figure 5. Attitude of respondents towards ChatGPT

Abbreviations: AI, artificial intelligence

Attitude towards ChatGPT

Figure 5 gives the respondents' responses to the questions on their attitude towards ChatGPT. Most of the respondents (40.6%) agreed that ChatGPT can improve the quality of medical writing and 57.5% believed it can save time. However, 38.7% strongly agreed with concerns about the accuracy and privacy of the data generated. A strong agreement (54.7%) was observed on the need for guidelines to regulate the use of ChatGPT and other AI technologies, as well as the necessity for formal training to use it effectively (49.1%). The majority of respondents (40.6%) disagreed with the idea that ChatGPT could replace human writers. Responses varied widely on the suitability of ChatGPT for creating specific types of communication aids, such as slide decks, patient brochures, manuscripts, or books. This variation indicates that medical writers use ChatGPT differently depending on the type of writing. However, most respondents identified plain language summaries and blogs as the most suitable for ChatGPT use (Figure 6A). Likewise, most respondents believe that ChatGPT can be particularly useful for drafting the Abstract or Introduction of a manuscript (Figure 6B).

Practice patterns of ChatGPT

Table 2 gives the respondents' responses to the questions on usage of ChatGPT. The frequency of usage of ChatGPT among the respondents varied but most of them used it sometimes (39.6%). The respondents largely used ChatGPT for writing summaries (24.4%) followed by routine tasks like composing emails or drafting letters (19.5%), organising scattered points into a coherent paragraph (18.3%), and understanding complex topics (15.9%) (Figure 7). They did not seem to find it particularly easy or difficult to use and 33.0% responded neutral to the question on ease of usage. Most respondents find the quality of content generated by ChatGPT fair (42.5%) or good (32.1%). Despite only using it sometimes, almost half of the respondents (48.1%) responded that they may recommend the use of ChatGPT to other medical writers. Almost one-fourth of the respondents thought that ChatGPT had improved their writing efficiency (28.3%). Among the challenges faced by the respondents, the requirement of multiple attempts (prompts) to get the desired response and inaccuracy of the content were the most encountered (Figure 8).

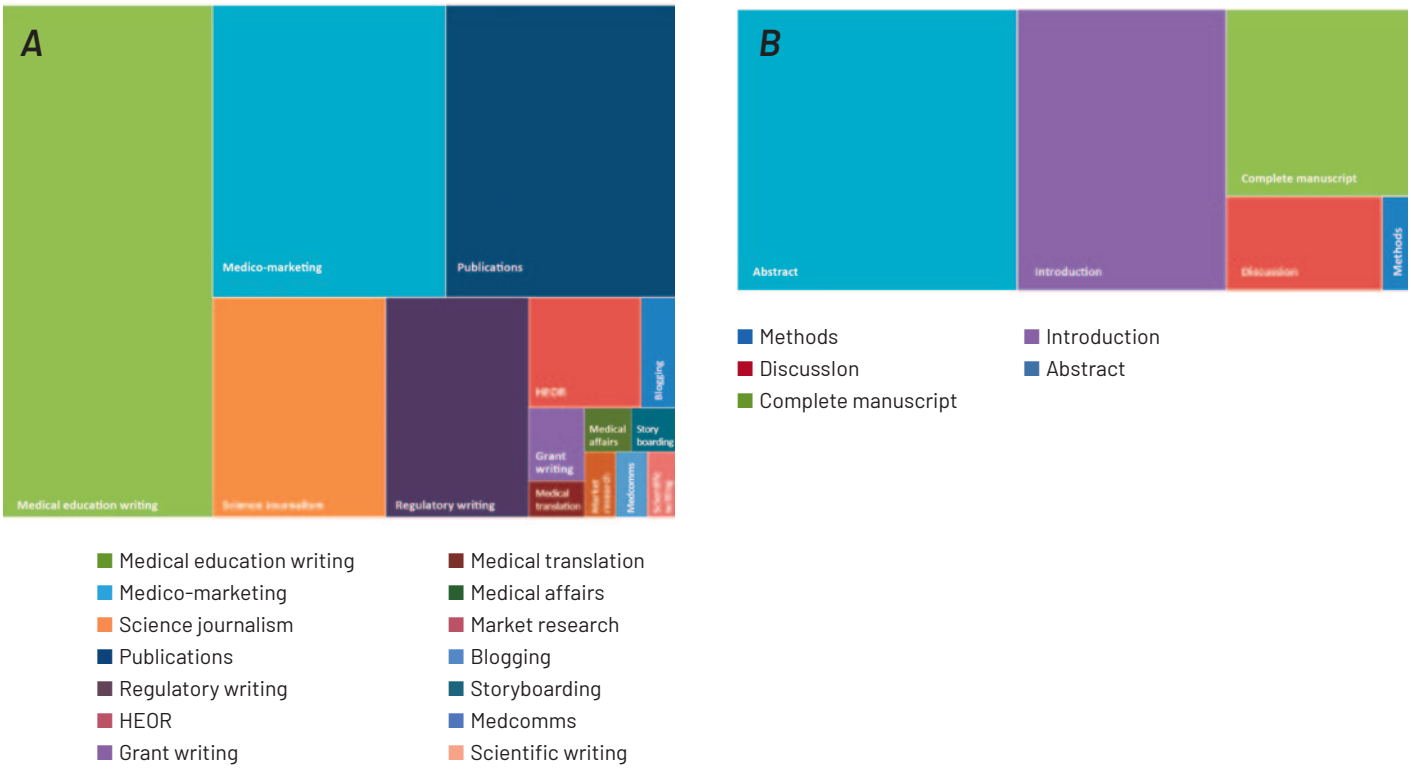


Figure 6. In the opinion of the respondents, ChatGPT is suitable for writing: A. Different types of content, B. Different parts of a manuscript

Abbreviations: HEOR, Health Economics and Outcomes Research

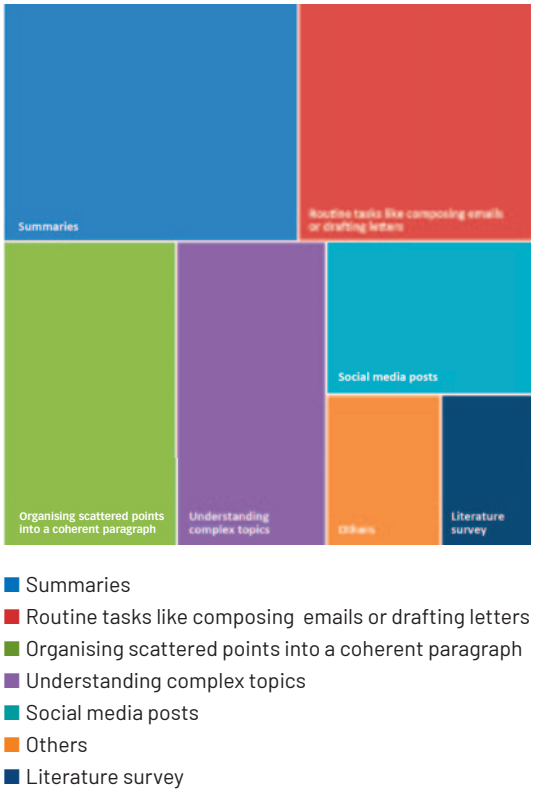


Figure 7. Respondent data on ChatGPT use for different types of content

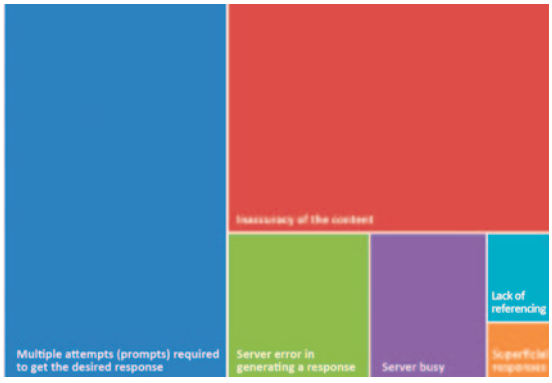


Figure 8. Challenges faced by respondents while using ChatGPT

Table 2. ChatGPT practice patterns of respondents

How often do you use ChatGPT?					
Never	Rarely	Sometimes	Always		
21 (19.8)	27 (25.5)	42 (39.6)	16 (15.1)		
In your experience, ChatGPT is easy to use for medical writing:					
Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable
3 (2.8)	16 (15.1)	35 (33.0)	26 (24.5)	12 (11.3)	14 (13.2)
How do you rate the quality of the content generated by ChatGPT?					
Poor	Fair	Good	Excellent	Not applicable	
6 (5.7)	45 (42.5)	34 (32.1)	4 (3.8)	17 (16.0)	
Would you recommend using ChatGPT to other medical writers?					
No	Yes	May be			
15 (14.2)	40 (37.7)	51 (48.1)			
Does your organisation/institution allow you to use ChatGPT?					
No	Yes	There are no guidelines	Do not know		
15 (14.2)	33 (31.1)	36 (34.0)	22 (20.8)		
Do you think ChatGPT has improved your writing efficiency?					
No	Yes	May be	Not applicable		
14 (13.2)	30 (28.3)	39 (36.8)	23 (21.7)		

Correlation analyses

The respondents from the medical communications sector are associated with high knowledge levels of ChatGPT whereas those from the healthcare sector tend to have lower knowledge levels compared to other sectors (p=0.001) (Table 3).

Most of the survey respondents, especially those with high or average knowledge tend to agree or strongly agree on the utility of ChatGPT in saving time while writing (p<0.001). There was also a clear variation in responses that co-related with different knowledge levels on accuracy and data privacy concerns with ChatGPT. The respondents with high knowledge tend to agree strongly with the concerns while those with low knowledge are predominantly neutral (p=0.001). Similarly, respondents with high knowledge appear to align more strongly with the need for guidelines for using ChatGPT and other AI tools (p<0.001).

The respondents with limited understanding of the technology behind ChatGPT tend to use it less frequently, whereas those with a deeper understanding of its underlying technology are more likely to use it (p<0.001). The knowledge levels also directly determine the tendency of respondents to recommend the use of ChatGPT to others. Respondents with limited knowledge of ChatGPT are more likely to answer "Maybe" or "No", indicating uncertainty, while those with a greater knowledge are more likely to answer "Yes", demonstrating a willingness to recommend ChatGPT to others (p=0.016). This indicates that the knowledge of ChatGPT plays a pivotal role in the adoption and utilisation of ChatGPT among medical writers.

Discussion

The results of this survey present the knowledge, attitude, and practices of medical writers regarding ChatGPT. The responses reflected a varied trend of ChatGPT usage among medical writers. The ChatGPT knowledge levels showed certain significant correlations with the attitude and practice of ChatGPT, indicating that the knowledge about this tool influences the attitudes and practices of medical writers.

Medical writers, including scientific and regulatory writers, use different tools and resources to be updated on the constantly growing medical literature as well as content formulation and presentation.[17,24] There have been several reports for and against the utility of AI tools like ChatGPT in medical writing. However, it is important to understand the actual perspectives and practices of medical writers to understand the current pulse of the field.[20] Even though there are several studies demonstrating the application of ChatGPT and other AI tools in different aspects of medical writing, there is no information on the actual implementation by medical writers.[25,26] This is the first study, to our knowledge, that has assessed the knowledge, practice, and attitude of practicing medical writers towards ChatGPT globally via an online survey.

The first version of the survey questionnaire was generated by ChatGPT based on a specific prompt provided by the authors. It gave a basic framework of the questionnaire that had to be modified extensively to align it as per the requirement of the survey. This is in line with several recent studies that recommend using ChatGPT for simple tasks and emphasise the responsibility of writers in authorship and accountability of the content generated by AI.[27–29] In this survey, 15.1% of respondents used ChatGPT for routine tasks like composing emails or drafting letters.

The survey respondents were from all over the world, mainly from India. The majority (47.2%) of the respondents were new writers with an experience of ≤5 years. The respondents had diverse specialisation under the umbrella of medical writing but less than half of them reported having any experience of using AI tools for their writing. This suggests that the use of AI tools in medical writing is yet to become a norm among the writers as there may still be an inhibition or dilemma due to the apparent limitations of these tools.[30]

Most of the medical writers who participated in the survey have an intermediate knowledge of ChatGPT. The ones with high knowledge predominantly belong to the medical communications sector, whereas those with low knowledge are associated with the healthcare sector. The medical communications field is an ever-evolving field demanding medical writers to stay updated with recent advances.[20,31] This may explain the high knowledge of the respondents from the medical communications field. The usage of AI tools for writing in healthcare sectors may be preferentially less due to challenges related to legal ethics, patient privacy, and the accuracy and reliability of information.[32] The writers may prefer to be self-reliant to avoid errors and maintain the integrity and trust of the healthcare profession. However, some tasks do not jeopardise data privacy and ethics, and most of the survey respondents largely use ChatGPT for understanding complex topics, organising scattered points into a coherent paragraph, and

Table 3. Correlation between knowledge, demographics, attitude, and practice responses

Demographics	AI knowledge levels Low	Average	High	p value[a]
In which sector do you work?				
Academic institution	4	2	5	0.001
Healthcare organisation	11	5	5	
Medical communications	5	20	34	
Pharmaceutical Industry	5	3	1	
Others	3	1	2	
Attitude				
Do you think that ChatGPT can help save time while writing?				
Strongly disagree	1	0	0	<0.001
Disagree	0	1	0	
Neutral	10	5	2	
Agree	14	12	35	
Strongly agree	3	13	10	
Are you concerned about accuracy and data privacy while using ChatGPT in medical writing?				
Strongly disagree	0	1	0	0.001
Disagree	0	1	0	
Neutral	13	8	3	
Agree	9	10	20	
Strongly agree	6	11	24	
Do you think ChatGPT and other AI technologies require guidelines for use in medical communications?				
Strongly disagree	0	1	0	<0.001
Disagree	0	0	1	
Neutral	13	2	2	
Agree	8	9	12	
Strongly agree	7	19	32	
Practice				
How often do you use ChatGPT?				
Never	15	4	1	<0.001
Rarely	4	10	14	
Sometimes	8	12	22	
Always	1	5	10	
Would you recommend using ChatGPT to other medical writers?				
No	6	4	5	0.016
Maybe	19	12	20	
Yes	3	15	22	

[a]Values with statistical correlation. Fisher's Chi square test (Monte Carlo simulations)

drafting letters, emails, and social media posts.

One of the most recognised utilities of ChatGPT is its potential to save time in writing by helping with the more mundane tasks like data screening, organisation, simplification, and summarisation.[20] This was also reflected across the respondent population, especially in the respondents with high knowledge of ChatGPT. Knowledge of ChatGPT seems to play a significant role in the adoption of ChatGPT in practice as writers with higher knowledge use it more frequently in practice and also show a greater propensity of recommending ChatGPT to other medical writers.

A significant amount of AI-generated text is finding its way into scientific papers.[33] This is a concerning trend since the unethical use of AI may result in inaccuracy of the reported data, plagiarism, and even citations from non-existent references. Several leading scientific journals have highlighted the risks of using ChatGPT without caution which may lead to serious breaches in data integrity and article retractions.[34] Such scientific misconduct is often a by-product of a lack of attention both from the writers and the reviewers.[33] As per a study by Gao et al., reviewers missed up to 32% of abstracts generated wholly by ChatGPT, despite a thorough screening process.[35] A study by Alser et al. found plagiarism ranging from 5% to 49% in published and pre-print articles authored by ChatGPT with some phrases copied verbatim from sources like LinkedIn and Wikipedia.[36] This number is not too different from the plagiarism or self-plagiarism found in human-authored articles (similarity reports ranging from 0% to 60%) and has led to the implementation of strict plagiarism-related policies by several journals.[37] Similarly, AI-generated content also warrants careful and critical evaluation with meticulous human supervision throughout the process.[37-39] Many journals have now started formulating guidelines and editorial policies on either complete barring of AI-generated text or figures or giving full disclosure of its use in the relevant sections.[13]

> In our survey, medical writers with high knowledge of Chat GPT acknowledged concerns regarding the data accuracy and privacy concerns while using it.

The strength of this study lies in being the first of its kind to give insights into the actual perspectives and practicing habits of ChatGPT among medical writers. The survey responses yielded a very diverse dataset due to the diverse demographics of the survey respondents that enriched our understanding of the current trends in the field.

The study has certain limitations. First, the sample size is small, which may prevent the findings from being extrapolated to the field as a whole and may undermine the validity of the results.[40] Hence, Pearson's Chi-square analysis with Monte Carlo simulation was used to ensure the significance of findings even with the small sample size. Second, there may be an inherent bias in the sampling as the mode of dissemination of the survey was only through an online

medium, yet the respondents of this survey had varied demographics. Third, there may be a potential language barrier in survey participation as the survey was in English, although this can be justified as up to 95% of the scientific publications are in English.[41] Fourth, the survey was conducted in 2023 and may not reflect the latest trend in the field. However, the incidents of AI-generated errors in published articles in peer-reviewed journals are still frequently observed.[42] Walters et al. studied a particular hallucination frequently observed with ChatGPT and found that 55% of GPT-3.5 and 18% of GPT-4 generated citations for literature reviews were fabricated.[43] Thus, the results of this study are still relevant.

Conclusion

This study represents a small but one of the first snapshots of the trends of AI tool usage in the field of medical writing. An understanding of the perspectives of the medical writers will help in adopting these tools with proper policies in place. A correct perspective on ChatGPT and other latest AI tools relies on a good understanding of these tools, which is essential to both formulate and follow guidelines related to the use of LLMs in medical writing. The guidelines will support medical writers to produce quality work and maintain publication ethics while minimising errors and overcoming limitations.

Acknowledgments

The authors would like to thank Dr Gokulakannan Vijayaraman for assistance with the statistical analysis.

Disclaimers

None

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

Data availability statement

For inquiries about data and other supplemental information, please contact the corresponding author.

References

1. Joubert PH, Rogers SM. Strategic Scientific and Medical Writing. Berlin: Springer; 2015. doi:10.4103/2229-3485.71845
2. Sharma S. How to become a competent medical writer? Perspect Clin Res. 2010;1(1):33–7. https://pubmed.ncbi.nlm.nih.gov/21829780/
3. Dave T, Athaluri SA, Singh S. ChatGPT in medicine: an overview of its applications, advantages, limitations, future prospects, and ethical considerations. Front Artif Intell. 2023;6:1169595. doi:10.3389/frai.2023.1169595
4. De Angelis L, Baglivo F, Arzilli G, et al. ChatGPT and the rise of large language models: the new AI-driven infodemic threat in public health. Front Public Health. 2023;11:1166120. doi:10.3389/fpubh.2023.1166120
5. Google Gemini [cited 2024 June 3] Available from: https://gemini.google.com
6. Microsoft Copilot [cited 2024 December 12] Available from: https://copilot.microsoft.com/onboarding
7. OpenAI. Introducing ChatGPT [cited 2024 May 27] Available from: https://www.openai.com/blog/chatgpt
8. Kim SG. Using ChatGPT for language editing in scientific articles. Maxillofac Plast Reconstr Surg. 2023; 45:13. doi:10.1186/s40902-023-00381-x
9. Goto A, Katanoda K. Should we acknowledge ChatGPT as an author? J Epidemiol. 2023;33:333-4. doi:10.2188/jea.JE20230078
10. Wittmann J. Science fact versus science fiction: A ChatGPT immunological review experiment gone awry. Immunol Lett. 2023;256–7:42–7. doi:10.1016/j.imlet.2023.04.002
11. Doyal AS, Sender D, Nanda M, et al. ChatGPT and artificial intelligence in medical writing: concerns and ethical considerations. Cureus. 2023;15(8):e43292. doi:10.7759/cureus.43292
12. Aghemo A, Forner A, Valenti L. Should Artificial Intelligence-based language models be allowed in developing scientific manuscripts? A debate between ChatGPT and the editors of Liver International. Liver Int. 2023;43(5):956–7. doi:10.1111/liv.15580
13. Nafea AA, AL-Ani MM, Khalaf MA, et al. A review of using ChatGPT for scientific manuscript writing. Babylonian Journal of Artificial Intelligence. 2024; 2024:9–13. doi:10.58496/BJAI/2024/002
14. Bose A. Regulatory initiatives for artificial intelligence applications: Regulatory writing implications. Med Writ. 2023; 32:12–5. doi:10.56012/kdyv1106
15. Cobb L, Haycock N. Narratives for a clinical study report: The evolution of automation and artificial intelligence. Med Writ. 2023; 32:28–31. doi:10.56012/kcca1211
16. Trilogy Writing and Consulting. TriloDocs [cited 2025 January 29]. Available from: 404
17. Gramoun A. Digital tools for the clinical evaluation of medical devices: a guide to empower regulatory writers. Med Writ. 2023;32(3):16–21. doi:10.56012/hmts9332
18. Distiller SR: Literature review software [cited 2024 December 15]. Available from: https://www.distillersr.com/products/distillersr-systematic-review-software
19. Fern.ai: the clinical evidence platform [cited 2024 December 15]. Available from: https://fern.ai/
20. Ahaley SS, Pandey A, Juneja SK, et al. ChatGPT in medical writing: A game-changer or a gimmick? Perspect Clin Res. 2024;15(4):165–71. doi:10.4103/picr.picr_167_23
21. ChatGPT, prompt "Can you suggest demographics questions in this case?" (cited 2024 Nov 25) OpenAI. Available from: https://chatgpt.com/share/672d9919-9134-8013-b9ff-547fa7edc47f.
22. Kim HY. Statistical notes for clinical researchers: Chi-squared test and Fisher's exact test. Restor Dent Endod. 2017;42(2):152–5. doi:10.5395/rde.2017.42.2.152
23. Mussa Reshid T. Monte Carlo simulation and derivation of Chi-Square statistics. Am J Theor Appl Stat. 2023;12(3):51–65. doi:10.11648/j.ajtas.20231203.13.
24. Sharma S. Development of medical writing in India: Past, present and future. Perspect Clin Res. 2017;8(1):45-50. doi:10.4103/2229-3485.198556
25. Salvagno M, Taccone FS, Gerli AG. Can artificial intelligence help for scientific writing? Crit Care. 2023;27(1):75. doi:10.1186/s13054-023-04380-2
26. Liebrenz M, Schleifer R, Buadze A, et al. Generating scholarly content with ChatGPT: ethical challenges for medical publishing. Lancet Digit Health. 2023;5(3):e105-6. doi:10.1016/S2589-7500(23)00019-5
27. Carobene A, Padoan A, Cabitza F, et al. Rising adoption of artificial intelligence in scientific publishing: evaluating the role, risks, and ethical implications in paper drafting and review process. Clin Chem Lab Med. 2024;62(5):835-43. doi:10.1515/cclm-2023-1136

Photo: Freepiok

28. Amirjalili F, Neysani M, Nikbakht A. Exploring the boundaries of authorship: a comparative analysis of AI-generated text and human academic writing in English literature. Front Educ: (Lausanne). 2024: doi.10.3389/feduc.2024.1347421
29. Rane NL, Choudhary SP, Tawde A, et al. ChatGPT is not capable of serving as an author: Ethical concerns and challenges of large language models in education. Int Res J Mod Eng Technol Sci. 2023;5(10):851–74. doi:10.56726/IRJMETS45212
30. Shen Y, Heacock L, Elias J, et al. ChatGPT and other large language models are double-edged swords. Radiology. 2023;307(2):e230163. doi:10.1148/radiol.230163
31. Shirke S. Medical writing on an accelerated path in India. Perspect Clin Res. 2015;6(3):125–8. doi:10.4103/2229-3485.159934
32. Wang C, Liu S, Yang H, Guo J, Wu Y, Liu J. Ethical considerations of using ChatGPT in health care. J Med Internet Res. 2023;25:e48009. doi:10.2196/48009
33. Thorp HH. ChatGPT is fun, but not an author. Science. 2023;379(6630):313. doi: 10.1126/science.adg7879
34. Ambrosio L, Schol J, La Pietra VA, et al. Threats and opportunities of using ChatGPT in scientific writing – The risk of getting spineless. JOR Spine. 2023;7(1):e1296. doi:10.1002/jsp2.1296
35. Gao CA, Howard FM, Markov NS, et al. Comparing scientific abstracts generated by ChatGPT to real abstracts with detectors and blinded human reviewers. NPJ Digit Med. 2023;6(1):75. doi:10.1038/s41746-023-00819-6
36. Alser M, Waisberg E. Concerns with the usage of ChatGPT in Academia and Medicine: A viewpoint. Am J Med Open. 2023;9:100036. doi:10.1016/j.ajmo.2023.100036
37. Menshawey R, Menshawey E, Mitkees A, et al. A plagiarism paperdemic: determining plagiarism among COVID-19 articles in infectious disease journals between 2020 and 2021. Bull Natl Res Cent. 2023;47(1):151. doi:10.1186/s42269-023-01129-3.
38. AlZaabi A, ALamri A, Albalushi H, et al. ChatGPT applications in academic research: A review of benefits, concerns, and recommendations. Biorxiv. Preprint posted online August 8, 2023. doi:10.1101/2023.08.17.553688
39. Garg RK, Urs VL, Agarwal AA, et al. Exploring the role of ChatGPT in patient care (diagnosis and treatment) and medical research: A systematic review. Health Promot Perspect. 2023;13(3):183. doi:10.34172/hpp.2023.22
40. Faber J, Fonseca LM. How sample size influences research outcomes. Dental Press J Orthod. 2014;19(4):27–9. doi:10.1590/2176-9451.19.4.027-029.ebo
41. Bahji A, Acion L, Laslett AM, Adinoff B. Exclusion of the non-English-speaking world from the scientific literature: recommendations for change for addiction journals and publishers. Nord Alkohol-Narkotikatidskrift. 2023;40(1):6–13. doi:10.1177/14550725221102227
42. Frontiers Editorial Office. Retraction: Cellular functions of spermatogonial stem cells in relation to JAK/STAT signaling pathway. Front Cell Dev Biol.2024; 12:1386861. doi:10.3389/fcell.2024.1386861
43. Walters WH, Wilder EI. Fabrication and errors in the bibliographic citations generated by ChatGPT. Sci Rep. 2023;13(1):14045. doi: 10.1038/s41598-023-41032-5.

Appendix 1. Survey questions

Section 1 of 5:

The purpose of this survey is to gather information on the use of ChatGPT in medical communications. Your participation in this survey is completely voluntary. All responses are anonymous and confidential. By completing this survey, you are giving your informed consent to participate in this study. The data collected will be used for research purposes and may be published in a scientific journal. If you have any question or concern about the survey, please contact the study organisers at sujatha.v@hashtagco.in. Please note that this survey may have limitations, such as potential biases in the sampling or the self-reported nature of the responses.

*Single choice; † Short answer; ¥ Multiple choice

Section 2 of 5:Demographic information

Q1: What is your age?*
- ☐ Under 25
- ☐ 25-34
- ☐ 35-44
- ☐ 45-54
- ☐ 55-64
- ☐ Over 65

Q2: What is your gender?*
- ☐ Male
- ☐ Female
- ☐ Non-binary
- ☐ Prefer not to say

Q3: What is the highest level of education?*
- ☐ Bachelor's degree
- ☐ Master's degree
- ☐ Doctoral degree
- ☐ Other_____

Q4: In which sector do you work?*
- ☐ Pharmaceutical industry
- ☐ Medical communications
- ☐ Academic institution
- ☐ Healthcare organisation
- ☐ Other_____

Q5: How many years of experience do you have in medical communications?*
- ☐ Less than 1 year
- ☐ 1-5 years
- ☐ 6-10 years
- ☐ 11-15 years
- ☐ Over 15 years

Q6: What is your primary country of residence?†

Q7: Which type of medical writing do you specialise in?¥
- ☐ Regulatory writing
- ☐ Medical education writing
- ☐ Publications
- ☐ Medico-marketing
- ☐ Market access writing/ Health Economics and Outreach Research
- ☐ Science journalism
- ☐ Other_____

Q8:Do you hold any professional certification in medical writing or editing? *
- ☐ Yes
- ☐ No
- ☐ If you have selected 'yes' for the previous question, please specify below: †

_____

Q9. Are you a member of any professional organisation for medical communications?*
- ☐ Yes
- ☐ No
- ☐ If you have selected 'yes' for the previous question, please specify below: †

_____

Q10: Have you received any formal training in medical writing or medical communications?*
- ☐ Yes
- ☐ No

Q11: Do you have experience using AI-powered tools for medical communications?*
- ☐ Yes
- ☐ No
- ☐ If you have selected 'yes' for the previous question, please specify below: †

Section 3 of 5: Knowledge Questions

Q1: What is ChatGPT?*
- ☐ ChatGPT is a social media app designed to generate human-like text based on the input provided to it
- ☐ ChatGPT is a large language model based on the GPT architecture, designed to generate human-like text based on the input provided to it
- ☐ ChatGPT is an open-source live chat software by OpenAI designed for answering questions in a conversational manner
- ☐ ChatGPT is a virtual personal assistant that can answer follow-up questions, admit its mistakes, challenge incorrect premises, and reject inappropriate requests
- ☐ I don't know

Q2: Do you have a general idea of how ChatGPT works?*
- ☐ Yes
- ☐ No

Q3: ChatGPT cannot perform the following task:*
- ☐ Assist in generating text for medical content
- ☐ Suggest wording and phrasing in medical writing for sorting jargon
- ☐ Perform literature survey
- ☐ Assist in writing plain language summaries from provided content
- ☐ I don't know

Q4: While using ChatGPT, what is the phenomenon of hallucination?*
- ☐ Plausible-sounding but inaccurate information
- ☐ Harmful content
- ☐ Information from spurious sources
- ☐ Overuse of certain phrases
- ☐ I don't know

Q5: ChatGPT is being further trained by:*
- ☐ Collecting data from ChatGPT users wherein the users vote the responses and submit additional feedback
- ☐ Storing input data and using it to improve the performance of the module
- ☐ Using 175 billion parameters that enable the model to learn more complex patterns
- ☐ Asking clarifying questions when provided with an ambiguous query/prompt
- ☐ I don't know

Q6: The content provided by ChatGPT is:*
- ☐ Subject to potential bias
- ☐ Free of any kind of bias
- ☐ I don' t know

Q7: What is the knowledge cut-off date of ChatGPT?*
- ☐ There is no cut-off date. ChatGPT has current information.
- ☐ Sept 2021
- ☐ April 2023
- ☐ Nov 2022
- ☐ I don't know

Q8: The responses provided by ChatGPT to the same prompt: *
- ☐ Can vary with different users
- ☐ Can vary for the same user at different time points
- ☐ Both 1st and 2nd options are correct
- ☐ Do not vary in core content
- ☐ I don't know

Section 4 of 5: Attitude Questions

Q1: Do you believe that ChatGPT can improve the quality of medical writing?*
☐ Strongly agree ☐ Agree
☐ Neutral ☐ Disagree
☐ Strongly disagree

Q2: Do you think that ChatGPT can help save time while writing?*
☐ Strongly agree ☐ Agree
☐ Neutral ☐ Disagree
☐ Strongly disagree

Q3: Are you concerned about accuracy and data privacy while using ChatGPT in medical writing?*
☐ Strongly agree ☐ Agree
☐ Neutral ☐ Disagree
☐ Strongly disagree

Q4: Do you think ChatGPT and other AI technologies require guidelines for use in medical communications?*
☐ Strongly agree ☐ Agree
☐ Neutral ☐ Disagree
☐ Strongly disagree

Q5: Do you think ChatGPT can replace human medical writers?*
☐ Strongly agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Strongly disagree

Q6: Do you think you need formal training to use ChatGPT for medical communications?*
☐ Strongly agree ☐ Agree
☐ Neutral ☐ Disagree
☐ Strongly disagree

Q7: In your opinion, ChatGPT is most suitable for writing:¥
☐ Slide decks
☐ Patient brochures
☐ Manuscripts
☐ Plain language summaries
☐ Medical education content
☐ Books
☐ Blogs

Q8: In your opinion, ChatGPT is most suitable for writing which portion of the manuscript?*
☐ Complete manuscript
☐ Abstract
☐ Results
☐ Introduction
☐ Methods
☐ Discussion
☐ None

Section 5 of 5: Practice Questions

Q1: How often do you use ChatGPT?*
☐ Always ☐ Rarely
☐ Sometimes ☐ Never

Q2: What do you use ChatGPT largely for?*
☐ Understanding complex topics
☐ Literature survey
☐ Summaries
☐ Organising scattered points into a coherent paragraph
☐ Routine tasks like composing emails or drafting letters
☐ Social media posts
☐ Not applicable

Q3: In your experience, ChatGPT is easy to use for medical writing:*
☐ Strongly agree ☐ Agree
☐ Neutral ☐ Disagree
☐ Strongly disagree

Q4: What challenges have you faced while using ChatGPT for medical writing?¥
☐ Server error in generating a response
☐ Server busy
☐ Inaccuracy of the content
☐ Multiple attempts (prompts) required to get the desired response
☐ Not applicable
☐ Other_____

Q5: Do you think ChatGPT has improved your writing efficiency?*
☐ Yes ☐ No
☐ Maybe
☐ Not applicable

Q6: How do you rate the quality of the content generated by ChatGPT?*
☐ Excellent ☐ Good
☐ Fair ☐ Poor
☐ Not applicable

Q7: Would you recommend using ChatGPT to other medical writers?*
☐ Yes ☐ No
☐ Maybe

Q8: Does your organisation/ institution allow you to use ChatGPT?*
☐ Yes ☐ No
☐ There are no rules or guidelines
☐ I don't know

*Single choice; † Short answer; ¥ Multiple choice

Author information

Simran Kaur Juneja, MSc, is a Medical Writer at Hashtag Medical Writing Solutions Pvt. Ltd., India for the past 3 years. She specialises in developing scientific communication for healthcare professionals and patients.

Shital Sarah Ahaley, PhD, has been a consultant medical writer at Hashtag Medical Writing Solutions Pvt. Ltd., India, for the past 4 years. She was a developmental biologist in academia for more than 12 years with a PhD in developmental biology.

Ankita Pandey, PhD, is a Medical Writer with more than 10 years of experience in the field. She has been working at Hashtag Medical Writing Solutions Pvt. Ltd., India since 2021 where she specialises in writing scientific content for healthcare professionals.

Dr Sujatha Vijayakumar, BDS MPH, is the founder and CEO of Hashtag Medical Writing Solutions Pvt. Ltd. She has been working in the field of medical affairs and medical communications since 2012.

AI in medical writing – tools, tantrums, and testimonies

Lisa Chamberlain James
Trilogy Writing & Consulting Ltd.
Cambridge, UK

doi: 10.56012/zdsk2809

Correspondence to:
Lisa Chamberlain James
lisa@trilogywriting.com

Abstract

This article explores the impact of artificial intelligence (AI) on medical writing from an insider's perspective. It discusses the various AI tools available, and the practical benefits observed through real-world applications. It also addresses the initial resistance and fears surrounding AI adoption. The article emphasises the importance of critical thinking and human oversight in using AI tools effectively, highlighting the balance between embracing technology and maintaining the unique skills of medical writers. The future is bright for medical writers – this article explains why!

Photo: Freepiok

The term "artificial intelligence" or 'AI" is ubiquitous at the moment. It has become part of everyone's lives, and everyone is wondering how we will be affected by it, both personally and professionally. AI is now advancing into "Generative AI" or "GenAI", where innovative ontologies and graph models are applied to create semantic text relationships. These technologies are now being explored as powerful tools to aid medical writers in their work, opening up new possibilities for enhancing productivity and efficiency.

Medical writers, too, are experiencing the transformation that AI brings. But before diving into the potential impacts of AI, it's essential to clarify what we mean by the term. "AI" is a catch-all term that is often misused, conflated, or misinterpreted, and encompasses everything from machine learning and natural language processing through to ChatGPT! For the purposes of this article, I will use AI to mean any tool that is using automation, including generative and rule-based elements, to complete tasks in the production of medical writing documents.

The rise of AI tools

By the time this article goes to press, the landscape of AI tools available to medical writers will have likely expanded even further, with new releases and updates continually reshaping the field. This renders any discussion of "available tools" almost meaningless. It would also be inappropriate here to name any commercial products or imply any kind of advocacy for them.

However, the incredible promises surrounding AI in terms of time and cost savings speak volumes. It's clear that medical writing is ripe for a technological revolution.

There is no doubt that there are routine aspects to a medical writer's job – summarisation of large amounts of dense text, combing through pages and pages of data tables to identify signals or anomalies, even compilation of summary tables or subset tables … the list goes on! Most of us would happily hand these tasks to a computer to parse the data and present us with a neat, concise summary. These tasks are perfect candidates for automation, freeing up time for medical writers to focus on higher-level analysis and creative problem-solving. The good news is that AI tools already exist to assist with these mundane tasks, significantly boosting efficiency and accuracy.

Sophisticated AI: A helping hand

AI tools today range from those using rule-based engines, where the machine follows pre-programmed instructions to process data and text, to more advanced generative systems, which learn from vast datasets to generate new, contextually relevant content. This can lead to "hallucinations" – errors put into the data or text as the machine fills in the gaps or makes a conclusion, and this issue is being actively addressed. AI systems are constantly improving, and methods for detecting and correcting these errors are emerging, providing greater confidence in their reliability. Additionally, not all hallucinations are errors. It can be argued that a tool producing a conclusion may not be incorrect, and if viewed as a "suggestion" could even help the medical writer as a starting point for their own conclusion, offering valuable suggestions that can serve as starting points for further human analysis. There is also some very interesting work happening that is using one AI tool to "QC" another to check for hallucinations. Although in its infancy, the problem of hallucinations is already being actively addressed.

Tantrums – or is AI an ally for medical writers?

The initial belief that medical writing can be completely accomplished through AI is not only technically unrealistic because of the concerns around accuracy (hallucinations) and security of the highly confidential data being parsed, but also risks doing a grave disservice to the end users of the document being produced. Whether the document is a dossier for the regulatory agencies or a plain language document aimed at the

general public, the medical writer offers much more to the process than the ability to summarise complex data and information. Medical writers offer what computer algorithms cannot – critical thinking, contextualisation, and a nuanced understanding that AI cannot replicate. However, AI can assist by taking on repetitive, data-intensive tasks, allowing human writers to focus on higher-level judgment, contextualization, and decision-making. Therefore, it is important to explore where it is appropriate to apply AI, and what the experienced medical writer should be looking for in the evaluation of technology to ensure it is truly helping them with their work.

At Trilogy, we've embraced AI as a powerful tool that has already led to significant time savings and positive outcomes (see "Testimonies"). One of the most compelling benefits we've seen is AI's ability to detect important signals in data that human writers may have overlooked. AI tools can also be used to verify signals identified by human writers, ensuring greater consistency and accuracy in clinical data analysis. This is particularly valuable as clinical trials grow in complexity.

One of the key (and arguably the most important) skills needed by any medical writer is that of critical thinking. It is crucial in every aspect of our work to critically appraise the information before us, to question the sources, and to ensure that the conclusions can be supported and are fair and unbiased. These skills have never been more necessary than when appraising an AI tool. There are lots of astonishing figures and claims made by AI companies in terms of time saving and efficiencies, but these should be looked at through the lens of any extra checks and balances that will be needed – along with any changes to inputs for the tool to function and outputs that will be generated.

Testimonies

It is absolutely true that humans also make mistakes, and also need to have checks and balances to ensure that errors are identified and corrected.

Therefore, the need for checks and balances aside, there is no doubt that there is a very important role for AI tools to play in the medical writing world. I have seen this first hand with software that detected an important signal that the sponsor's human medical writers had missed. We have been using an AI tool not only to help detect signals and relationships within data, but also to double check that the signals and relationships that human medical writers have identified are the same as those identified by the tool. This is a significant step towards uncovering many signals and relationships within clinical data that might otherwise be overlooked, especially with the increasing complexity of trials, such as platform and umbrella study designs.

A balanced approach to AI integration

The "human in the loop" is of vital importance in the medical writing world – people's lives are literally at stake – and so passing the task of medical writing to a computer without a critical human mind being involved is utterly irresponsible.

However, it is equally irresponsible to ignore the potential of AI tools to relieve writers from time-consuming tasks and allow them to focus on their unique skills. With AI handling data parsing, signal detection, and even suggesting potential conclusions, medical writers can devote more time to high-level thinking, contextualisation, and collaboration with clinical teams.

The ability of an AI tool to "double check" signal detection, parse huge amounts of data quickly, and to suggest possible conclusions, not only provides a layer of comfort that nothing has been missed, but frees the medical writer to focus on the higher-level tasks and have meaningful discussions with the clinical team at a much earlier stage.

The future of medical writing

Looking to the future, emerging AI technologies will continue to evolve, potentially reaching a point where AI can function autonomously in some areas, learning independently and enhancing its own capabilities. The upcoming "agentic"AI (the use of agents that do not need humans to provide prompts or guide the system to make decisions) will allow AI tools to work with minimal or no human input and to "learn" independently, turbo-charging the ability of AI and freeing more time for humans to use their critical thinking skills to enhance and evaluate the outputs.

As with most aspects of life – this is not "black or white". Using an AI tool should not be a binary choice, any more than it should signal the end of the medical writing profession. Rather, it's about finding the right balance between human expertise and machine assistance. Our experience has been that the current breed of AI tools, with the promised pipeline of increasing number of applications and documents to which they can be applied, offer huge advantages to medical writers. By embracing the tools available today, medical writers can significantly enhance their efficiency and effectiveness. AI tools are not here to replace the medical writing profession; they're here to help it evolve, offering incredible potential to tackle complex tasks with ease.

As we move forward in this paradigm shift, what is needed is critical appraisal and the medical writing experience to know which tool is the right tool for the job. It's crucial for medical writers to critically evaluate each tool, considering its strengths, limitations, and the specific tasks it can enhance. The rapid pace of AI development means that staying informed and adaptable is essential. Plus – in this fast-moving area of computer science – how future-proof is the tool? What pipeline does it offer?

The future of medical writing is bright. Embracing AI will undoubtedly lead to greater opportunities, benefiting both medical writers and the industry as a whole. It's exciting, but it's more important than ever to embrace the technology that can enhance and make our tasks more efficient, whilst ensuring that a human's ability to sense-check is retained. If we can crack that combination, great things are in store for all of us!

Disclosures and conflicts of interest

The author is employed by Trilogy Writing, an Indegene company, which produces AI tools for healthcare companies.

Author information

Lisa Chamberlain James is a Senior Partner of Trilogy Writing & Consulting. Aside from management activities, she leads client projects, with extensive experience in a variety of documents. Lisa received a PhD and post doc in Pathology at the University of Cambridge. She is a visiting lecturer at King's College London, a Fellow of the Royal Society of Medicine, and editor of the "Medical Communications and Writing for the Public" section of this journal. She has a special interest in writing for the public, pharmacovigilance, and patient information.

Regulatory Public Disclosure

doi: 10.56012/qbev3223

SECTION EDITOR

Sam Hamilton
samhamiltonmwservices@gmail.com

0000-0003-3610-8251

Editorial

The Riga conference was fun! Besides the learning, as usual, we all enjoyed getting together and chatting between sessions. These for me were the moments that it became more apparent than ever that regulatory medical writing is undergoing mass workforce change. Certainly, there are still plenty of highly experienced medical writers producing rigorous study level documents fit for public disclosure – as we see from the now abundant clinical trial application documents published by the Clinical Trials Information System (CTIS). However, as less experienced, entry level colleagues join our profession at a time when artificial intelligence (AI) tools are really beginning to take hold, it is important to remember that there is simply no substitute for the deep foundational knowledge that underpins clinical document content. **There is no short cut, even with AI**. As newer writers join our ranks, and as we integrate AI tools into our workforce and workflows, we must not lose sight that the deeply knowledgeable medical writer remains the back stop – the expert – who provides the sanity check, scrutiny, and balance for outputs, whether they are created using AI support or not.

How can less experienced regulatory medical writers attain a deep level of knowledge and understanding, given such a complex writing environment? A reasonable place to start is to tune into the content requirements of the seminal study level document, the clinical study report (CSR). The free-to-download best practice guidance interpretation document, the CORE Reference manual (doi:10.56012/copjhc4062) written by a team of EMWA experts and published in May 2016, provides a detailed and granular "how to" guide for CSR authoring for newer medical writers – as well as being a constant reference companion for more experienced professionals. So, now you have your flying start, but you must also consider how to keep up with the ever-evolving clinical documents and public disclosure ecosystems. That means staying on top of all that is relevant as it is published. Without the requisite experience, it can be difficult to pick out which piece of information is important and which is interesting, but perhaps less important in terms of actual document preparation, and then contextualise that to reporting and public disclosure.

These days, LinkedIn postings and the deluge of information hitting our phones and laptops daily can almost drown us. So, besides using an AI Agent (yes, they are coming!) to sift material, how do you capture the relevant guidance, best practice, and news for reporting clinical trials and addressing public disclosure of clinical documents? You (or your Agent) don't have to do that and then wonder what you may have missed – because the EMWA CORE Reference Project Team is doing just that already. We also contextualise the information so that you understand why it is relevant and how to use it in your writing. We make what we find freely available in a downloadable News Summary that includes comprehensive links to all the cited sources (https://www.linkedin.com/company/the-core-reference-project). **So, our News Summaries only contain the relevant clinical trial-related and transparency and disclosure-related news and information that you can trust.** Sam

Spotlight on CORE Reference News Summaries

The topics that are covered in our monthly News Summaries typically include:

Medicines and Vaccines
ICH; CTR and CTIS; EU Regulatory; UK and MHRA guidance and news; FDA guidance and news; EMA guidance and news; real world data and evidence; transparency and disclosure resources and news; development strategy news; AI/machine learning; news from Asia regulators; news from US that may impact the clinical trial ecosystem.

Medical Devices
General updates and news; EU transparency; EUDAMED news; EU COMBINE initiative; UK MHRA.

For many of us working in drug development and medical writing, the inclusion of the "Medicines and Vaccines" section with its well-considered sub-topic areas seems logical to support drugs, biologics and vaccines reporting. It may not be quite so apparent why we also cover specific topics within a "Medical Devices" section. To clarify, the "Medical Devices" section is intended to cover transparency in relation to medical devices, and the emerging intersection of the regulatory medical devices and the regulatory drugs spaces. Devices information or regulations that impact the reporting of device studies are also covered. Combination products including pharmaceutical and medical device components, may need to be reported under pharmaceutical legislation, depending on what the product is, and how regulatory authorities in different global regions assess combination products. Contextualisation is provided, where possible, to help readers navigate the information. This is a hot topic as we heard in the "Combination Products Symposium Day" in Riga, which delved into regulatory, scientific, and communication aspects of this evolving field.

If you have suggestions for other relevant subsections for the News Summary to fit with the scope of the CORE Reference Project remit, please do get in touch. **New from May 2025: Updates from the 2025 US Administration (links to initiatives that may impact the clinical trial ecosystem).**

Abbreviations: CTIS, Clinical Trials Information System; CTR, Clinical Trials Regulation; EUDAMED, European Database on Medical Devices; ICH, International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; MHRA, Medicines and Healthcare products Regulatory Agency

Meeting you in Riga: Learning and Sharing with EMWA Regulatory Medical Writers

Thanks to EMWA conference delegates who attended the CORE Reference Project "Learn and Share" at the EMWA Spring Conference in Riga, Latvia, on May 8, 2025.

At the May 2025 EMWA Riga conference, the CORE Reference Team held a "Learn and Share" lunch session, explaining the new ways in which we now connect with you. We also spoke of our plans for a new website. We took your suggestions for new topic areas for the monthly News Summary, so watch LinkedIn to see new topics appearing. The session ended with an open discussion on the Policy 0070 relaunch (Step 2) where we shared best practice and tips for addressing potential challenges of the expanded scope of Policy 0070. Finally, we reminded everyone that May 2026 will mark the tenth anniversary of the publication of the original CORE Reference resources – and we look forward to marking that milestone in Barcelona at the 60th EMWA conference. We were happy to announce our next external presenter, Obaraboye Olude, of Privacy Analytics (an IQVIA company) would present the June 11, 2025 webinar "Statistical anonymisation software for utility-preserving privacy protection in clinical documents for public disclosure".

As ever, Vivien Fagan and I were delighted to teach our Foundation Workshop on CORE Reference (DDF38). In this we demonstrate the granularity of the main clarity and transparency points integrated into the May 2016 publishedbest practice manual, CORE Reference (https://doi.org/10.56012/copjhc4062) and explain its value to medical writers for clinical study reporting. Remember to sign up for our next Workshop if you missed us in May 2025.

The CORE Reference Project on LinkedIn

We are enjoying our 2025 revamp and especially our LinkedIn page to communicate with followers. This is easier than before when we did everything by email, and hopefully we can increase our reach. Please follow us on https://www.linkedin.com/company/the-core-reference-project to receive our monthly News Summaries, and other materials to support your continuing professional development (CPD). Share our page information widely – it's free for everyone. Also check out our informational graphic at the end of this section for QR codes and dois for our main resources, and watch our YouTube video for a reminder of project aims: https://youtu.be/1UAHdKCKN3w.

A distillation of the most relevant information in the world of clinical study reporting and public disclosure in the last few months is in Table 1. Enjoy! To see the full News Summaries – you now know where to look!

Follow us on LinkedIn (https://www.linkedin.com/company/the-core-reference-project) to receive monthly News Summaries, with current information on regulatory reporting and public disclosure which support the continuing professional development (CPD) needs of medical and regulatory writers. The topics covered include FDA and EMA guidance and news, real-world data, transparency and disclosure resources and news, development strategy news, AI in the regulatory arena, the intersection of drugs and devices including in vitro diagnostics (IVDs), transparency in relation to medical devices, news from Asia regulators, and regulatory guidance open for public consultation. Archived News Summaries to December 2024 are here: https://www.core-reference.org/news-summaries/. News Summaries from January 2025 are all available at our LinkedIn page.

Table 1 provides a selection of key information shared by the CORE Reference Project Team between March and May 2025.

Table 1. A selection of key information shared by the CORE Reference Project Team between March – May, 2025

Disseminated information	Brief description	Link
March 2025 highlights		
ICH M11 guideline, clinical study protocol template and technical specifications – Scientific guideline – are updated	The updated template (Step 2 draft dated March 13, 2025) is provided as reference only for the second round of public consultation of the M11 Technical Specification (document dated Feb 3, 2025). The technical specifications consultation period closed on 22 April 2025	Guideline, protocol template, technical specifications:https://www.ema.europa.eu/en/ich-m11-guideline-clinical-study-protocol-template-technical-specifications-scientific-guideline
An integrated map of clinical trials in the EU and published within the CTIS public portal is active	The map provides real-time information about clinical trials by geographic area. A public webinar with a demo of the map's features was held on March 7, 2025	Meeting recording: https://www.slopeclinical.com/l/webinar-the-impact-of-ich-e6-r3-on-biospecimen-management
Regulation (EU) 2025/327 of the European Parliament and of the Council of February 11, 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 was published on March – May, 2025.	The aim of this regulation is to "establish the European Health Data Space (EHDS) in order to improve natural persons' access to and control over their personal electronic health data in the context of healthcare." The EFPIA Press Release titled "A Call for Effective Stakeholder Engagement and Capacity Building during the Implementation of the EHDS" calls on policymakers to guarantee an actionable process for involvement in this new health data ecosystem. EFPIA have published a position paper on the regulation on the European Health Data Space (EHDS) and an FAQs document on the European Health Data Space has also been updated	Regulation: https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng FPIA press release: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/a-call-for-effective-stakeholder-engagement-and-capacity-building-during-the-implementation-of-the-european-health-data-space/ EFPIA position paper: https://www.efpia.eu/media/2t2dem05/efpia-position-on-ehds.pdf FAQs: https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en
The FDA publication "Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together" (first published in March 2024) was revised in February 2025	The paper aims to provide greater transparency around how FDA's medical product centres are collaborating to safeguard public health whilst fostering responsible and ethical innovation. Four areas are focussed on regarding development and use of AI across the medical product lifecycle	https://www.fda.gov/media/177030/download?attachment
EMA and other European National Health Agencies have published 'Clinical Evidence 2030'	By 2030, clinical evidence generation is expected to be "further guided by the patient voice [...]; study design will be driven by research questions [...]; clinical trials will be more efficient and impactful; real-world evidence (RWE) will be enabled and its value fully established; and trust will be built through transparency. This document outlines the 6 guiding principles for generating clinical evidence. Although all principles are important, at a time where diversity is being rolled back, Principle 1 is particularly significant as it reinforces the need for patient representation at every step of evidence generation.	https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3596?af=R

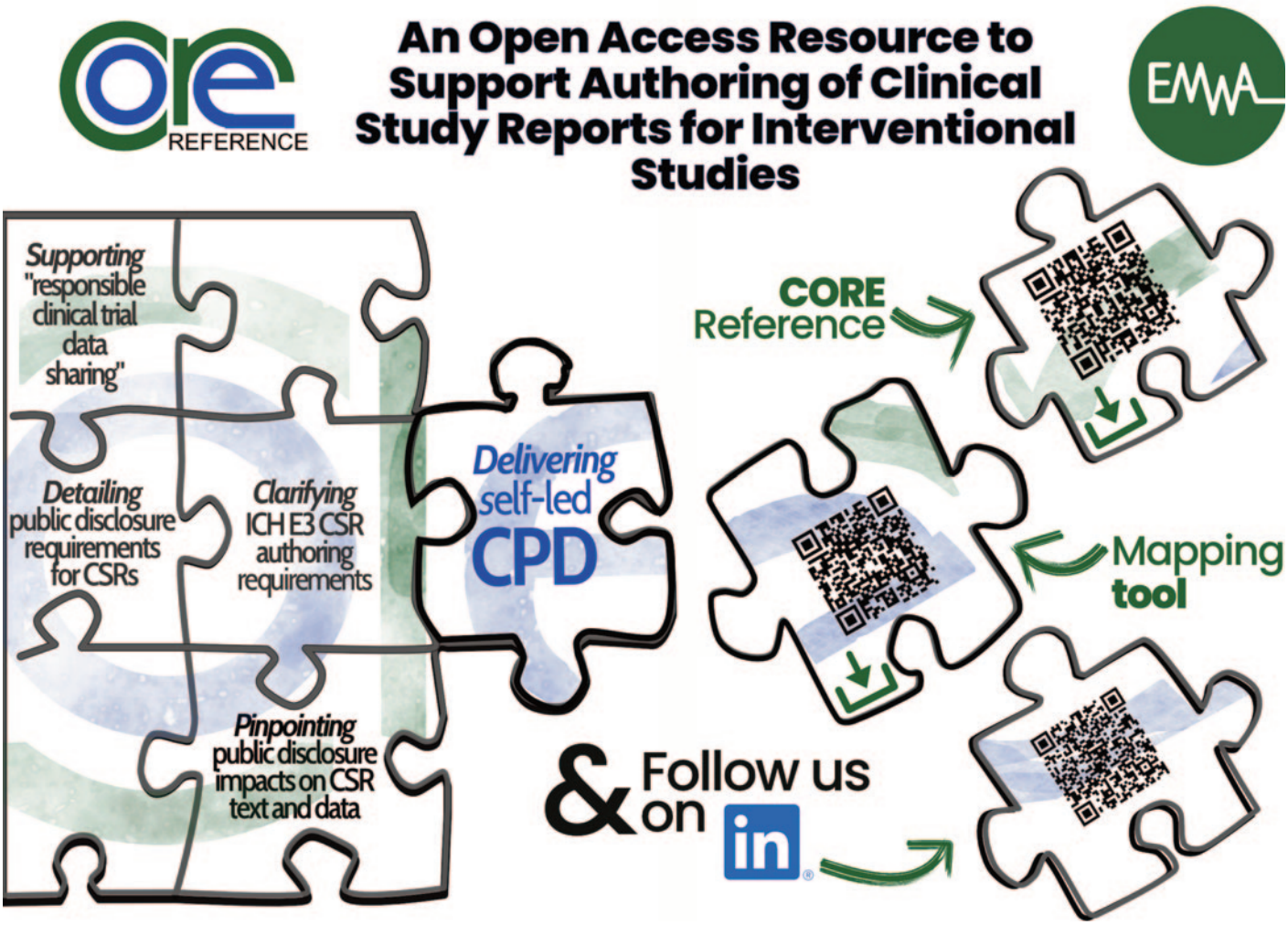
Disseminated information	Brief description	Link
EU lawmakers question the viability of the transatlantic data transfer pact between the US and Europe.	This is significant because: • The DPRC is charged with protecting Europeans' privacy from US government surveillance by hearing privacy complaints from EU citizens. • The DPRC was created by Executive Order to ensure that the US complies with privacy rights obligations under the EU-US Data Privacy Framework. Its existence allows data transfers between the US and Europe to continue happening for now. • Privacy and Civil Liberties Oversight Board (PCLOB) members have resigned and been fired. This Board oversees the DPRC and acts as a critical safeguard against US surveillance overreach. • EU lawmakers are pressing the EC to consider suspending the DPF, as they no longer believe that the PCLOB can operate independently.	https://www.mlex.com/mlex/data-privacy-security/articles/2299678
Califf et al. published "The importance of ClinicalTrials.gov in informing trial design, conduct, and results"	Commentary is provided on the progress of clinicaltrials.gov in clinical trial design transparency, as well as reporting.	https://resolve.cambridge.org/core/journals/journal-of-clinical-and-translational-science/article/importance-of-clinicaltrialsgov-in-informing-trial-design-conduct-and-results/125B3C69C8923DC03550090EBB7E7A12
EMA has qualified the first AI tool, called AIM-NASH	The tool helps pathologists analyse liver biopsy scans to identify the severity of an inflammatory liver disease (MASH) in clinical trials. It is expected to help researchers obtain clearer evidence on the benefits of new treatments. This qualification marks a significant step towards integrating AI in medicine development. The tool is trained on more than 100,000 annotations from 59 pathologists who assessed over 5,000 liver biopsies across nine large clinical trials.	Press release: https://www.ema.europa.eu/en/news/ema-qualifies-first-artificial-intelligence-tool-diagnose-inflammatory-liver-disease-mash-biopsy-samples
The European Organization for Research and Treatment of Cancer (EORTC) published "Navigating EU Clinical Trials: Adapting to a New Era of Regulations"	The document outlines challenges between the EU's separate regulations. For example, drug-device protocols that have an IMP and medical device require submission under EU-CTR and MDR/IVDR – one (EU-CTR) requiring a centralised submission and the other requiring separate Member State submissions. This process is further complicated if an AI component is involved.	https://pubmed.ncbi.nlm.nih.gov/39961402/

Disseminated information	Brief description	Link
April 2025 highlights		
Transcelerate has developed an ICH E6 Asset Library	The tools are designed to help with the adoption of the latest good clinical practice (GCP) guidance, focusing on key areas of change including data governance, risk-based quality management, stakeholder collaboration, and risk proportionality.	https://www.transceleratebiopharmainc.com/assets/ich-e6-asset-library/?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz-9cJB_7DEffbEw2z_rtUmUHS_3JFqtSNwsuXdmhv17W0KRSfhUMzVmrTMN5E2WDEt3_j0Ip#TrialDesign
EMA released the latest version (7.1) of the Clinical Trials Regulation (EU) No. 536/2014 Q&A document in March 2025	This version includes updates to Annex II: Language requirements for part I documents.	https://health.ec.europa.eu/document/download/bd165522-8acf-433a-9ab1-d7dceae58112_en?filename=regulation5362014_qa_en.pdf
The Clinical Trials Information System (CTIS) officially joined the Primary Registry Network of International Clinical Trials Registry Platform (ICTRP)	According to the WHO "Primary Registries in the WHO Registry Network meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries meet the requirements of the ICMJE."	https://www.who.int/tools/clinical-trials-registry-platform/network/primary-registries
EMA Clinical Data Publication Policy to cover all new marketing authorisation applications, line extensions and major clinical type II variations starting Q2 2025	From April 2025 onwards, Policy 0070 will cover all clinical data submitted under new marketing authorisation applications (MAAs) for medicinal products as well as any applications for line extensions or new indications, or where the MAA results in a negative opinion or is otherwise withdrawn.	https://www.insideeulifesciences.com/2024/11/27/ema-clinical-data-publication-policy-to-cover-all-new-marketing-authorization-applications-line-extensions-and-major-clinical-type-ii-variations-starting-q2-2025/
The new European Health Data Space regulation was enforced from March 26, 2025	The new regulation aims to facilitate access to and reuse of electronic health data across the EU. There will be a four-year transition period to establish the necessary electronic health data exchange infrastructures. This is significant and aims to revolutionise healthcare data management across the EU by enhancing accessibility, interoperability, and patient control over personal health data.	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32025R0327
New regulations for running clinical trials in the UK have been signed into law	A 12-month roll-out begins April 11, 2025, and will take full effect from April 10, 2026. Of note is that "... for the first time [the regulations will] legally require trial registration on a WHO-recognised public register and the publication of results summaries".	https://www.gov.uk/government/news/clinical-trials-regulations-signed-into-law
EMA has published a reflection paper on non-interventional studies that use real-world data (RWD) to generate real-world evidence for regulatory purposes	This reflection paper covers the aspects of design, conduct, and analysis of non-interventional studies, and focuses on methodological principles that are considered important for the conduct and assessment of non-interventional studies using RWD and used for regulatory decision-making throughout a medicine's lifecycle.	https://www.ema.europa.eu/en/documents/other/reflection-paper-use-real-world-data-non-interventional-studies-generate-real-world-evidence-regulatory-purposes_en.pdf

Disseminated information	Brief description	Link
European commissioner discusses EU-US Data Privacy Framework (DPF), potential GDPR reform. Comments on the emerging questions around EU-US DPF	The EU-US DPF is a set of rules designed to protect personal data transferred between the EU and the US. The EU is exploring a softened approach to digital regulation that aligns with US calls for deregulation to support digital innovation.	https://iapp.org/news/a/european-commissioner-discusses-eu-us-data-privacy-framework-potential-gdpr-reform https://iapp.org/news/a/schrems-addresses-emerging-questions-around-eu-us-data-privacy-framework
The European Association of Medical Devices Notified Bodies (Team-NB) has released v3 of their position paper on Best Practice Guidance for Technical Documentation under EU MDR	The Technical Documentation is the dossier submitted to NBs for conformity assessment of medical devices (MDs), equivalent to the CTD for medicinal product.	https://www.team-nb.org/wp-content/uploads/2025/04/Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V3-20250409.pdf
Team-NB also released v2 of the position paper on European Artificial Intelligence Regulation (AI ACT)	Provides an overview of the Team-NB perspective on the challenges of the AI Act with particular attention to its implementation.	https://www.team-nb.org/team-nb-position-paper-on-european-artificial-intelligence-regulation-v2/
The MHRA has published a guidance on how to apply for an Exceptional Use Authorisation (EUA) for MDs	EUA is a provision that allows non-UKCA/CE marked MDs to be placed on the UK market in exceptional circumstances, where this is necessary to protect public health.	https://www.gov.uk/guidance/exceptional-use-authorisation
May 2025 highlights		
EMA CTIS Simplification Task Force Topics for analysis was released last month	The Task force recommends a revised roles matrix for CTIS that reduces complexity and also the creation of a new safety module, with the aim to simplify the overall business rules for the Annual Safety Report.	https://www.ema.europa.eu/en/documents/other/ctis-simplification-task-force-topics-analysis_en.pdf
CTIS newsflash – 16 May 2025	EMA is redesigning the CTIS training materials for sponsor users, based on stakeholder feedback. The launch dates will be announced in upcoming issues of newsflash.	https://www.ema.europa.eu/en/documents/newsletter/ctis-newsflash-16-may-2025_en.pdf
FDA announced completion of first AI-assisted scientific review pilot and an aggressive agency-wide AI rollout timeline	The generative AI tools enable FDA scientists and subject-matter experts to minimise time spent on monotonous, repetitive tasks that typically hinder the review process.	https://www.fda.gov/news-events/press-announcements/fda-announces-completion-first-ai-assisted-scientific-review-pilot-and-aggressive-agency-wide-ai

Disseminated information	Brief description	Link
FDA released draft guidance "Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway" in January 2025.	For drugs granted accelerated approval, sponsors have been required to conduct confirmatory studies post-approval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. This guidance is developed following an amendment in the FD&C Act to help ensure timely completion of such trials. Allowing late comments.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accelerated-approval-and-considerations-determining-whether-confirmatory-trial-underway Comments: https://www.regulations.gov/docket/FDA-2024-D-3334/document
On May 14, 2025, EMA released the revised external guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use – Version 1.5 – along with the summary of changes document	Policy 0070 updates include: Clarification on the current scope of the policy and adding reference to Regulation 123/2022 on public health emergencies requirements for transparency; Clarifications aimed on the publication scope of individual patient data listings contained within the body of the Clinical Study Report and on the possibility for applicants/MAHs to propose additional redactions to protect from study unblind; Including the relevant and updated references to the current EU data protection legislation as well as additional relevant pieces of guidance issued by data protection authorities and professional organisations active within the data protection space.	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use-version-15_en.pdf https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/summary-changes-external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use-version-15_en.pdf
Canada's Drug Agency published their 2025 Watch List	This year's list focused on the use of AI technologies in health care in Canada.	https://www.cda-amc.ca/2025-watch-list#Issue3
New topic for May 2025: Possible Impact on Clinical Trial Ecosystem	Impact of a diversity, equity, and inclusion ban on the clinical research ecosystem. A Reuters news report of Robert F. Kennedy Jr., Health and Human Services Secretary, Congressional interview on May 14 2025	https://www.appliedclinicaltrialsonline.com/view/the-impact-of-dei-ban-on-clinical-research-ecosystem https://www.reuters.com/business/healthcare-pharmaceuticals/us-health-chief-kennedy-face-lawmakers-questions-mass-firings-measles-2025-05-14/

Abbreviations – AI: Artificial Intelligence; AI Act: Artificial Intelligence Act; AIM-NASH: Artificial Intelligence-based Measurement of Non-alcoholic Steatohepatitis Histology; CBER: Center for Biologics Evaluation and Research; CDER: Center for Drug Evaluation and Research; CDRH: Center for Devices and Radiological Health; CMS: Centers for Medicare & Medicaid Services; CTD: Common Technical Document; CTIS: Clinical Trials Information System; CTR: Clinical Trial Regulation; DPF: Data Privacy Framework; DPRC: Data Protection Review Court; EFPIA: European Federation of Pharmaceutical Industries and Associations; EHDS: European Health Data Space; EMA: European Medicines Agency; EORTC: European Organization for Research and Treatment of Cancer; EU: European Union; EUA: Exceptional Use Authorisation; FDA: Food and Drug Administration; GCP: Good Clinical Practice; GDPR: General Data Protection Regulation; HHS: Department of Health and Human Services; ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; ICMJE: International Committee of Medical Journal Editors; I CTRP: International Clinical Trials Registry Platform; IMP: Investigational Medicinal Product; IVDR: In Vitro Diagnostic Regulation; MAA marketing authorisation application; MAH: Marketing Authorisation Holder; MASH: Metabolic dysfunction-associated steatohepatitis; MD: Medical Device; MDR: Medical Device Regulation; MHRA: Medicines and Healthcare products Regulatory Agency; NIH: National Institutes of Health; OCP: Office of Combination Products; PCLOB: Privacy and Civil Liberties Oversight Board; RWD: Real-World Data; RWE: Real-World Evidence; Team-NB: European Association of Medical Devices Notified Bodies; UKCA/CE: UK Conformity Assessed/Conformité Européenne; US: United States; WHO: World Health Organisation.



Diversity of EMWA's SIGs

Welcome to our new special interest groups!

Getting Your Foot in the Door

SECTION EDITOR

Ivana Turek
ivana.turek@gmail.com

Editorial

Starting a new medical writing career and don't know where to start? Or are you just curious and would like to learn about the potential employers in Europe? In this article, Sarah and her colleagues offer a helpful overview of medical writing companies across Europe. **Ivana**

Medical writing in Europe: A survey

Suneeta Narumanchi[1], **Maria I D'Amico**[2], **Martina Colucci**[3], **Lauren Hanna**[4], **Rajni Sarma**[5], **Sarah L Nelson**[6]

[1] Unit of Cardiovascular Research, Minerva Institute for Medical Research, Biomedicum Helsinki, Helsinki, Finland
[2] London, UK
[3] QMENTA, Barcelona, Spain
[4] Institute of Health Metrics and Evaluation, Washington USA
[5] Klarity Health, UK
[6] Green Pen Solutions Ltd, UK

doi: 10.56012/iaae8793

Correspondence to:
Suneeta Narumanchi
suneeta.narumanchi@helsinki.fi

Abstract

Medical writing is a global discipline, and its visibility is currently limited. While medical writing is a well-established career in central and southern Europe, it is an emerging profession in the Nordics and eastern Europe. The information on medical writing employers across Europe is limited online. Therefore, we conducted a survey in late 2023 to address this knowledge gap and provide a resource for experienced and aspiring medical writers alike. This article provides an overview of the types of organisations in which medical writers work across Europe.

Introduction

We are a group of five aspiring medical writers from diverse backgrounds (medicine, biomedical research, project management, and clinical trial management). There is limited information available via online platforms like Linkedln for beginners in the field of medical writing. Our survey covers employers in medical writing in continental Europe and Ireland (excluding UK). Countries with limited opportunities for medical writers outside of remote or freelance positions were excluded. This article is not intended to be an exhaustive list of employers, but rather a snapshot of the current employers of medical writing on Linkedln as of the end of 2023.

Methods

Study design

This survey was conducted by a group of five aspiring medical writers led by Sarah Nelson. Online surveys were developed in English using SurveyMonkey, which enabled secure and anonymous data collection. The results from the survey were analysed using Microsoft Excel. The potential participants were approached online via LinkedIn and by email with a link to the survey, through the authors' professional networks. The surveys were also publicised on social media platforms.

Questionnaires

Questionnaires were designed to be completed in under 5 minutes using SurveyMonkey. There were 7 questions to answer including country of work, type of organisation (pharmaceutical company, business consulting and medical writing company, medical writing company, medical device company, contract research organisation, digital comms and technical consultancy, etc) and contact information.

Data analysis

Participant responses were collected automatically and exported into a Microsoft Excel spreadsheet. The information was cross-checked using search engines like Google search. A total of 44 responses were collected. Results summarise the information collected in the survey.

Results of the survey

Central and Southern Europe

Medical writing is well established in Central and Southern Europe.

- France is home to many employers of medical writers, especially in regulatory writing. Many of the consultancies, agencies and CROs are based in Paris, while pharmaceutical and biotechnology companies are located in other regions.
- Belgium is a growing hub for biopharmaceutical expansion, with global companies already established throughout the country.
- Multiple well-established healthcare and life sciences organisations can be found throughout Germany. In addition to pharmaceutical giants, major players include a growing number of agencies, consultancies, and CROs.
- Ireland offers many exciting opportunities in medical writing in medical communications agencies, pharma, healthcare, and CROs. Company offices and headquarters are mainly located in Dublin. Medical writers in Northern Ireland can also work for UK companies remotely.
- In Netherlands, medical writers are employed across the country, with headquarters in Amsterdam. Opportunities are centred around the pharmaceutical industry with a handful of medcomms agencies and CROs.

- Pharma organisations with a presence in Poland employ both in-house writers and work with agencies or consultancies for technical writing. Warsaw is emerging as a growth centre for medical communications. Opportunities in these neighbouring countries include a range of medical, scientific and technical writing roles.
- Employers in Austria include a growing number of consulting companies and CROs. Switzerland, as a vibrant hub for pharma, biotech, and NGOs, attracts medical writers of every kind.
- Spain and Italy have several agencies and consultancies employing medical writers. Medical writers are mainly employed within satellite offices of prominent global organisations, mainly pharma companies and CROs (Table 1).

Nordics

Medical writing is emerging as a recognised profession in the Nordic countries of Finland, Sweden, and Denmark, although opportunities remain fairly limited in this region (Table 2). Several organisations like Inizio, MedEngine, Medtronic and LINK Medical are situated in multiple locations in the Nordics.

Eastern Europe

Medical writing opportunities in Eastern European countries appear mostly in CROs. Budapest in Hungary appears to be a growing hub for pharma and supporting services (Table 3). There are several Pharma, Device, Biotech and CROs with offices throughout the Eastern European region, for example, ADAX International, Bayer, BiTrial, Comac Medical, Medtronic and Worldwide Clinical Trials.

Table 1. Central and Southern Europe

Country	Agencies and consultancies	Pharmaceutical, device, and biotech organisations	Contract research organisations (CROs)
Belgium	• Emtex Life Science • Modis	• AstraZeneca • Bayer AG • C.H.Boehringer Sohn AG and Ko.KG • Roche Pharmaceuticals	• 4Clinics • Archer Research • Cropha • ICON • Keyrus Life Science
France	• Azur Health Science • Evidera • McCann Health (IPG Health) • Publicis Health France • Strategik & Numerik • TBWA/Adelphi	• Biocorp (Novo Nordisk) • Genethon • Genomic Vision • Sanofi • Servier	• 4Clinics • Aixial Group • Apices • Biotrial • Excelya • Keyrus Life Science • NAMSA • Veristat (formerly Scinopsis) • Venn Life Science (hVIVO)

Continued overleaf

Table 1 continued

Country	Agencies and consultancies	Pharmaceutical, device, and biotech organisations	Contract research organisations (CROs)
Germany	• Co.medical • Cast Pharma • Cerner Enviza • Fleishman Hillard • Kyoups • M:werk • McCann Health (IPG Health) • Medperion • Trilogy Writing & Consulting	• Bayer • BioNTech • Boehringer Ingelheim • Grünenthal • Merck KGaA	• ClinStat • ICRC-Weyer • OCT Clinical • Scope International
Ireland	• Affinity • Edelman • Inizio • InkLab • Med Media • NIIT • Synergy Vision	• Gilead Sciences • Grifols • LetsGetChecked • Novartis • Regeneron	• Cromos Pharma • Syneos Health
Netherlands	• Blue Novius • Excerpta Medica (Adelphi group) • Medical Digitals • Synterex	• AM-Pharma • Euro Trol • Thermo Fisher Scientific (Evidera)	• Venn Life Science (hVIVO)
Poland	• Bioconvey Health Communications • CB Health Spark (IPG Health) • HealthWay Medical Communications Sp.z.o.o. • Proper Medical Writing • Publicis Groupe	• GSK	• JSS Medical Research • ICON • Pharmaxi
Austria	• DREHM Pharma • Gouya Insights • Medperion • NeuroScios	• Boehringer Ingelheim • Med-El	• CW-Research & Mgmt • Joanneum Research • SGS • ZAK Clinical Research Services
Switzerland	• Emtex Life Science • Infinity Communications • MedComms Experts • Medperion • nspm	• Idorsia • Johnson & Johnson • Novartis • Roche	None found
Spain	• CDM Barcelona (Omnicom) • Kalispera Medical Writing • PharmaLex • mPhaR	• AstraZeneca (Alexion) • Bayer Hispania	• Apices • MEDSIR • Syneos Health
Italy	• Alecria Healthcare • CDM Milan (Omnicom) • Connexia • EDRA S.p.A	• Osmosia S.r.l • Chiesi • GSK • Medtronic	• Syneos Health

Figure 1. Countries in Europe where multinational companies employ medical writers

Table 2. Nordics

Country	Organisations
Finland	• Bayer • Biocodex PhaMe
Sweden	• Sobi • Immuneed • Scandinavian CRO • TFS HealthScience
Denmark	• Coloplast • Novo Nordisk • Publicis Denmark

Table 3. Eastern Europe

Country	Organisations
Hungary	• Syntesia Medical Communications • Cortex Pharma Services • Pharma-Regist • Roche Services & Solutions
Ukraine	• AstraZeneca • Bayer Hispania
Bulgaria	• Bulgarian Organized Research Activities • Rotrial Contract Research

Multinational Companies

Numerous multinational organisations have office locations scattered throughout Europe. Many of these organisations are large, with a presence in multiple countries (Figure 1). In addition, some global giants operate subsidiary agencies with names that differ from that of the parent company, e.g., PPD is part of Thermo Fisher Scientific. Some examples of organisations with multiple locations across Europe include: Abbvie, AstraZeneca, Edelman, Inizio, IPG Health, IQVIA, Omnicom Health Group, Parexel, SanaClis, Syneos Health, Thermo Fisher Scientific, and CRO Directory.

Conclusions

In general, writers can apply for a job in organisations with a physical presence in the country in which they reside. Jobseekers can try searching the organisations listed in Tables 1, 2, and 3 to find local roles and find out more about medical writing.

Acknowledgements

This work was supported by a personal grant from Finnish Foundation for Cardiovascular Research (Suneeta Narumanchi).

Disclaimers

The authors do not have affiliation with any of the organisations listed. Appearance on the list does not imply that organisations are actively hiring or recruiting entry level writers. The information was accurate at the time of survey response collection and research.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

Data availability statement

For inquiries about data and other supplemental information, please contact the corresponding author.

Regulatory Matters

SECTION EDITORS

Clare Chang
clarechangphd@gmail.com

Zuo Yen Lee
zuoyen.lee@gmail.com

Editorial

The briefing document is one of the many types of documents that a medical writer prepares during a clinical development programme. It is an essential document for facilitating interactions between pharmaceutical companies and health authorities, mainly to seek scientific advice for drug development. There are different guidelines provided by health authorities to guide companies in preparing the meetings/interactions and the briefing documents. In this article, Clare Chang helps us understand what a briefing document is and the medical writer's role in preparing the document.

Zuo Yen

Briefing documents: Facilitating health authority interactions

Clare Chang
AstraZeneca
clarechangephd@gmail.com

doi: 10.56012/ucdt2648

Abstract

Briefing documents, essential for facilitating interactions between pharmaceutical companies and health authorities like the US FDA and EMA, provide critical information necessary for obtaining scientific advice throughout drug development. These documents encompass product background, development status, regulatory interactions, and specific questions from Sponsors, significantly influencing regulatory decision-making. The complexity of briefing documents varies based on development stages, requiring detailed preparation by medical writers to ensure clarity and relevance. Successful interactions rely on effective collaboration, flexibility, and thorough documentation of outcomes, enabling Sponsors to make informed decisions and continuously refine their clinical development programmes based on health authority feedback.

Introduction

Briefing documents, also known as briefing packages or briefing books, are documents developed by pharmaceutical or biotechnology company that help to facilitate their interaction with the intended health authority. These interactions, such as meetings or written responses, may happen at different stages of drug development and the intention is often to obtain scientific advice on development that would eventually shape product and clinical development through to market authorisation and beyond. Product development includes those for new molecular entities and new therapeutic biological products, biosimilars, and generics. Here, the focus will be preparing briefing documents for new molecular entities and new therapeutic biological products.

Different health authorities around the world have their own guidelines on the types of interactions and the contents of briefing documents.

Overview of the type of meetings with the US FDA and EMA

Different health authorities around the world have their own guidelines on the types of interactions and the contents of briefing documents. The types of meetings available with the US FDA and the EMA are listed in Table 1. The latest guidance for regulatory meetings with the US FDA was recently updated per July 17, 2024.[1]

Content of the briefing document

In general, the structure and content of briefing documents are similar for the US FDA and EMA with some regional differences.[2] The US FDA provides general guidance on topics to be included depending on the meeting type or purpose without a strict structure, whereas the EMA provides templates for the specific interactions.[3]

General content of briefing documents include:

1. Product background information (e.g., proposed indication and other relevant background information including for the targeted disease)
2. Current development status and plans (chemistry, manufacturing and controls, non-clinical, clinical)
3. Regulatory status and regulatory interactions
4. Purpose of meeting
5. List of questions and company's rationale and positions (including scientific data to support position)
6. Meeting attendees (role and function)

Table 1. Type of Health Authority Interactions with the FDA and EMA

Meeting type examples	Timing and logistics
US FDA [a,1]	
Type A Development stalled; urgent FDA input required (e.g., important safety issue)	Response to request: 14 days Meeting package receipt: With meeting request Preliminary responses: No later than 2 days before meeting Meeting date: Within 30 days from request Meeting minutes receipt: 30 days after meeting
Type B Pre-IND, pre-EUA, pre-BLA/NDA, overall development of Breakthrough Therapy Designation, regenerative medicine and advanced therapy	Response to request: 21 days Meeting package receipt: No later than 30 days before meeting or WRO Preliminary responses: No later than 2 days before meeting Meeting date: Within 60 days from request Meeting minutes receipt: 30 days after meeting
Type B (EOP) Meeting EOP1 (for products that will be considered for market approval), EOP2/Pre-Phase 3	Response to request: 14 days Meeting package receipt: No later than 50 days before meeting or WRO Preliminary responses: No later than 5 days before meeting Meeting date: Within 70 days from request Meeting minutes receipt: 30 days after meeting
Type C Others, not A, B, C, D, or INTERACT. Can be about product development or review	Response to request: 21 days Meeting package receipt: No later than 47 days before meeting or WRO Preliminary responses: No later than 5 days before meeting Meeting date: Within 75 days from request Meeting minutes receipt: 30 days after meeting Note: for consultation on new surrogate endpoints, logistics may differ
Type D Focuses on a narrow set of issues (<2 topics)	Response to request: 14 days Meeting package receipt: With meeting request Preliminary responses: No later than 5 days before meeting Meeting date: Within 50 days from request Meeting minutes receipt: 30 days after meeting
INTERACT For very novel products and development programmes (e.g., pre-IND)	Response to request: 21 days Meeting package receipt: With meeting request Preliminary responses: No later than 5 days before meeting Meeting date: Within 75 days from request Meeting minutes receipt: preliminary responses are annotated and resent within 30 calendar days if advice provided changes as a result of the meeting
EMA [3,4,5]	
Scientific advice and protocol assistance Advice at any stage of drug development (e.g., consult about appropriateness of study designs and robustness of data)	The EMA typically follows a timeline for their procedures. It is recommended to check the procedure date being followed for the respective applications. • Scientific advice and protocol assistance: Usually written response only. Meeting only when discussion is required. • PRIME: In exploratory clinical trial phase with preliminary clinical evidence. Early PRIME entry is available for academia and small medium enterprises. Pre-submission support is available to assess eligibility. • Orphan designation: Pre-submission meeting is recommended (at least 2 months before the planned submission date) to increase success rate.
PRIME Priority medicines, similar to FDA Breakthrough Therapy Designation (special support provided)	
Orphan designation	

Abbreviations: BLA, biologic license application; EOP, end of phase; EUA, emergency use authorisation; IND, investigational new drug; INTERACT, Initial Targeted Engagement for Regulatory Advice on CBER/CDER ProducTs; NDA, new drug application; WRO, written response only

[a] The FDA has a number of meeting types based on the drug products such as biosimilar, generics, and prescription drugs. This table only shows the interaction for prescription drugs.

Medical writer's role in briefing documents and what to expect

Depending on the stage of development, complexities in the product's development programme, and the project teams' dynamics, briefing documents can range vastly in their complexity. As a medical writer, it is important to do some "research" and get to know the programme and its history before kicking off the project. This preparation helps not only to get the medical writer up to speed with the project, but it also sheds light on the current problem the project team is facing and hence the reason for the interaction.

In the content listed above (items 1-6), the core of the briefing document is item 5 – List of questions and company's rationale and positions (including scientific data to support said position). Besides item 5, the other sections are relatively straightforward and could be drafted well in advance of the kick-off if all the relevant background information can be provided ahead of time.

Consequently, important information to request includes documents related to the drug product (e.g., investigator's brochure and the study design or protocol) and documents related to prior interactions (e.g., briefing documents and meeting minutes from prior interactions). The information will help the writer understand the development history and understand what the intended health authority currently understands about the development program. This is important while developing the briefing document as the writer can help the team be mindful of gaps between the last interaction and the current one when developing the background and framing the questions/company positions.

The last and most important piece of content to ask for are the Sponsor's questions and preliminary company position (item 5). Oftentimes, it is not possible to obtain granular details on these, and during the briefing document's development, the most time will be spent on this content. Nonetheless, it is good to touch base with the team on a general direction so the writer can prepare a starting position and take things from there.

Another aspect is the logistics. Depending on the type of interactions, the logistics and timing differ and the feedback from the health authority need to fit into the Sponsor's clinical development programme. Table 1 provides an overview of logistics and timing and is useful in developing the briefing document's development timelines.

In general, it is good to obtain the information or background information described above from the project team prior to the kick-off meeting so that the team can agree on the proposed timelines and the preliminary content.

Briefing document kick-off

If time permits, the above preparations can be done ahead of the kick-off and a preliminary draft or a skeleton can be developed for the kick-off meeting. Working with the team, below is a checklist for the kick-off:

1. Background and rationale for the briefing document (usually led by the team).
2. Outline and agree on the logistics (how document development will work, timing of each step, who else will contribute content directly, who the reviewers and approvers are). This is best led by the medical writer.
3. Agree on the structure of the document (e.g., important sections to keep and the amount of detail). This is also best led by the medical writer.
   a. Background: Ideally the background would be in good shape at this point, provided the background materials were available ahead of the meeting. That being said, some further background may be required to support the company position, and these will need to be discussed and highlighted.
   b. Questions: A good amount of time should be spent on the list of questions. In a clinical programme there are often overlaps in topics and it is important to develop the logic and rationale of whether certain questions should be standalone questions or better placed as a subset of another question (e.g., Question 1 by itself or Question 1a and 1b).
   c. Company position: Each question would also contain a company position with the Sponsor's proposal for tackling the question asked. Again, a good amount of time should be allocated to this to obtain the team's thoughts and overall position.

Briefing document development

Depending on the complexity of the briefing document, the development process can be smooth or quite turbulent. If the briefing document is a very standard procedure and all the functions are prepared with their questions and their position, then the process can be quite smooth. On the contrary, there are times when the strategy continuously changes, and new information arises. Therefore, it is important to be flexible and be mindful of working with a lot of ambiguity.

As mentioned, the questions and company positions are the most important parts in the briefing document. Therefore, it is an art to frame the questions appropriately. It is recommended to frame the question in a positive light and in a way that can ascertain a clear answer. For example, one way of asking is, "Does the Agency agree that …?" rather than "What do you think about…?". Similarly, when framing the company position in relation to the question asked, it is important to back up the recommendation from the company with good scientific justifications.

The questions and company positions are the most important parts in the briefing document. Therefore, it is an art to frame the questions appropriately. It is recommended to frame the question in a positive light and in a way that can ascertain a clear answer.

A simple example of a question is as follows:

Question: Does the US FDA agree that a 4-month safety update is not required and can be waived for Drug A's proposed supplemental new drug application (sNDA) for the XXX indication?

Company Position: The clinical development programme for Drug A to support the XXX indication includes three clinical studies: one pharmacokinetic study (study 1); one long-term safety study (study 2); and one pivotal efficacy and safety study (study 3). All three studies will be provided in the sNDA to support the proposed indication. There are no further clinical studies that are ongoing following the proposed sNDA application. Therefore, a 4-month safety update report is not warranted.

Meeting preparations

On some occasions, the medical writer may also attend meetings with the health authorities. Regardless of whether medical writers attend or not, it is often beneficial to participate in the meeting rehearsals along with the team. Important discussions around potential questions and gaps in information submitted that may be challenged could arise. These discussions are important in understanding the rationale and proposed responses, which are important to further understand the project.

After the interaction

Once the interaction has taken place, the health authority often provides the Sponsor with the outcome of the meeting in the form of meeting minutes. These agreements are stored as part of the history of the clinical development programme. The Sponsor is often recommended to implement the suggestions but depending on the suggestion and the overall programme, the Sponsor may or may not implement all the recommendations due to the company's plans. If the medical writer continues the project, they will be able to work with the team and implement the required changes to relevant documents seamlessly.

Conclusion

In conclusion, briefing documents serve as crucial tools for facilitating interactions between pharmaceutical/biotechnology companies and health authorities. The medical writer plays a vital role in preparing these documents by understanding project history, identifying gaps, and formulating well-reasoned questions and positions. Effective collaboration and flexibility during the document development process enhance the likelihood of positive outcomes. At the end of the day, these documents help Sponsors make informed decisions regarding implementation of suggestions and recommendations for future clinical development.

Acknowledgements

Clare Chang would like to thank Zuo Yen for her patience and review of this article.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by her employer or EMWA.

Disclosures and conflicts of interest

The author is employed by AstraZeneca. The author declares no conflicts of interest.

References

1. US FDA. Formal Meetings and Requests for Feedback for CBER-Regulated Products. 2024 [cited 2025 Apr 04]. Available from: https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/formal-meetings-and-requests-feedback-cber-regulated-products.
2. Trilogy Writing and Consulting. How to streamline regulatory authority meetings. 2022 [cited 2025 Apr 04.]. Available from: https://trilogywriting.com/document/how-to-streamline-regulatory-authority-meetings/.
3. EMA. Scientific advice and protocol assistance. 2023 [cited 2025 Apr 04]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-advice-and-protocol-assistance
4. EMA. PRIME: priority medicines. 2025 [cited 2025 Apr 04]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines.
5. EMA. Applying for orphan designation. 2015 [cited 2025 Apr 04]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/research-and-

Author information

Clare Chang is a clinical regulatory writer at AstraZeneca with experience in both early and late-stage clinical development. She has been an EMWA volunteer since 2018 mostly involved with the journal. She enjoys coffee, hiking, travelling, reading, and gaming.

Publications

SECTION EDITOR

Maddy Dyer
maddy.dyer@ppd.com

Editorial

In the December 2024 issue, Phil Leventhal, Danielle Drachmann, and Soren Skovlund discussed whether patients and caregivers can be authors of peer-reviewed publications. The conclusion was: yes, they can and should be! If patients and caregivers meet the International Committee of Medical Journal Editors authorship criteria, they should be given the opportunity to be authors. People with lived experiences of a condition can provide unique perspectives about it.

In this instalment of Publications, Phil Leventhal, Danielle Drachmann, Stephen Gilliver, and Hui Zhang discuss some of the challenges that patient authors face when working on company-sponsored publications. They suggest how medical writers can collaborate with and support patient authors.

Maddy

How medical writers can support patient authors of company-sponsored publications

Phil Leventhal[1], **Danielle Drachmann**[2], **Stephen Gilliver**[3], **Hui Zhang**[4]

[1] PPD clinical research business of Thermo Fisher Scientific, Lyon, France
[2] Evidera, PPD clinical research business of Thermo Fisher Scientific, Skanderborg, Denmark
[3] PPD clinical research business of Thermo Fisher Scientific, Malmo, Sweden
[4] PPD clinical research business of Thermo Fisher Scientific, Princeton, NJ, USA

doi: 10.56012/tyeq1968

Correspondence to:
Phil Leventhal
phil.leventhal@ppd.com

Patient authorship

Patient authorship is where patients or caregivers are listed as byline authors of peer-reviewed publications.[1,2] In such cases, the patients or caregivers, collectively referred to as "patient authors", have played a meaningful role in producing and sometimes even leading the publication. This is common for publications where patient or caregiver experiences, needs, or expectations are described or where having a person with lived experience adds important perspective, such as in rare diseases, where clinicians and researchers may have limited knowledge.

Patient authorship is being encouraged by patient advocacy groups, healthcare professionals, medical journals, academic institutions, pharmaceutical companies, and regulatory and health technology assessment agencies.[1,3,4] As patient authorship of publications becomes more common, medical writers are more frequently being asked to collaborate with and support patient authors.

Who are patient and caregiver authors of company-sponsored publications and what do they need?

Increasingly, patients and caregivers are engaged in the work leading up to publication of company-sponsored research. For example, they may contribute to the design and conduct of the research[5] or may participate in publication steering committees.[6] In some cases, however, patient authors are brought in to lend their perspective only once writing starts. In the worst cases, they are added only to increase the credibility of a publication, also known as "tokenism".[7]

Patient authors of company-sponsored publications are often experienced patient advocates or leaders of patient organisations; some may even be researchers or clinicians themselves. In other cases, patient authors may have little experience in and knowledge of medicine or publications. Whatever their circumstances, patient authors are emotionally invested in helping to advance knowledge about a disease or condition affecting them or someone they care for, so they want to ensure their perspective is considered.

Patient authors often face a variety of challenges when collaborating on company-sponsored publications. Some major challenges they may need support overcoming include:[5,8,9]

- Lack of knowledge of the publication process, author responsibilities, ethical issues, and scientific or statistical issues
- Feeling intimidated or not respected by experienced clinicians or researchers, and not knowing how to navigate power dynamics during the publication process
- Dealing with any existing relations with other members of the authoring team, for example, with a physician who cares for them or their family member
- Not knowing how to collaborate with a professional medical writer
- Needing additional time to understand complex information or to complete work on the publication
- Needing resources to deal with physical challenges
- Not knowing where to seek advice and support

As patient authorship of publications becomes more common, medical writers are more frequently being asked to collaborate with and support patient authors.

Medical writers can support patient authors by offering training

One way that medical writers can help patient authors is by offering targeted training.[11,12] Because patient authors can have varying knowledge of medicine and experience contributing to publications, medical writers should first meet with them to determine their needs and the appropriate language to use.[5,8,9,12]

Photo: Freepik

For patient authors with little to no experience, a great place to start training is a summary of the relevant parts of the **International Committee of Medical Journal Editors (ICMJE) Recommendations** (Table 1).[13] Of particular importance is the part about roles and responsibilities of authors, including authorship criteria.[5,8,10] As part of this training, Richards et al. recommend insisting "that authorship is not token and that contributions are required by all authors."[5]

Guidance on the publication process, also provided in the ICMJE Recommendations, is another important aspect of training. This should include the steps in preparing and submitting a manuscript for publication, how peer review works, how to deal with reviewers' comments, and how and why to complete conflicts of interest disclosures. This information can help demystify the publication process, reinforce understanding of authors' responsibilities, and help patient and caregiver authors ensure that their perspective is incorporated.

Patient authors should also be informed about **Good Publication Practice (GPP)**, which is the principal best-practice guideline for company-sponsored biomedical research.[14] Relevant aspects of GPP include: the importance of reporting research in a complete, accurate, unbiased, and timely manner; the requirement to provide useful feedback at each stage of manuscript development; privacy of patient information; and confidentiality of intellectual property.[15]

Further, patient authors can benefit from guidance on **how to effectively navigate the power dynamics of the authoring team**, especially when they are not researchers or clinicians. Discussing the following can help:[5,8-10]

- Who will be on the authoring team and what their roles are
- The objective of the publication
- Who to turn to for help
- How to communicate openly and clearly
- The importance of the lived experience and how to ensure that it is incorporated in the publication
- How to avoid and deal with conflict
- Best practices for editing, reviewing, and providing comments
- The role of professional medical writers, including the difference between ghost writing and professional medical writing and the value that medical writers bring

Table 1. Recommended components of training for patient authors

Topic	Key components to include [5,8-10]
Key guidelines	• ICMJE Recommendations • GPP guidelines
Structure and format of publications	• The main sections of a publication and what is appropriate to include in each • Other key sections that need to be completed (e.g., acknowledgments, conflicts of interest, author contributions) • Formatting of publications • Instructions for authors
Publication process	• Overview of the steps involved in drafting and submitting a manuscript (drafts, quality checks, approvals) • How the journal is selected • The submission process and how decisions are made by the journal • The peer-review process and how to respond to feedback
Roles and responsibilities	• Authorship criteria • The patient author's role within the research and publication team • Expectations and responsibilities throughout the publication process, including timelines, reviews, and providing feedback
Ethical responsibilities of authors	• Confidentiality of intellectual property • Ensuring protection of patient privacy • Understanding consent and data protection regulations • Importance of maintaining ethical standards in research and publishing • Guidance on disclosing conflicts of interest and maintaining transparency • Plagiarism • Copyright, licensing, and sharing/reuse of published materials, including articles they may be an author on • Author rights
Working with medical writers	• Role and value of professional medical writers • Why medical writers are not ghost writers • How to collaborate effectively with a medical writer
How to balance personal experience with scientific data	• Guidance on how to effectively incorporate personal experiences and perspectives into the manuscript • The importance of balancing anecdotal evidence with scientific rigour
Communication skills	• How to effectively communicate with the team (e.g., active listening, providing constructive feedback, effective questioning, email etiquette) • Navigating power dynamics • How to effectively comment on and edit drafts
Project-specific training	• Familiarisation with key medical and scientific terms relevant to the research • Basic understanding of the study design and its objectives • Basic understanding of the statistics used in the study
Case studies	• Example publications where patient and caregiver authors have participated

Abbreviations: ICMJE, International Committee of Medical Journal Editors; GPP, Good Publication Practice

All training, even for experienced authors, should be presented in **plain language** to help ensure understanding and encourage engagement.[9] This does not mean dumbing down the content but rather using words, grammar, structure, and terminology that make it easy to understand.[16] For more experienced patient authors, this may simply mean avoiding complicated writing, while for less experienced ones, this may mean explaining things in lay language. In all cases, both the language and content need to be appropriate; an experienced patient author may be insulted by lay language, whereas a less experienced one may not understand or be intimidated by technical language.

Medical writers may wish to develop their own training materials, but some are already available for patient authors (Table 2). Also, providing a customised plain language glossary of technical terms may be helpful for less experienced patient authors.[8]

Medical writers can help patient authors by offering mentoring and support

Medical writers can also help patient authors by providing mentoring and support.[5,8-10] Patient authors may feel intimidated by or inferior to experienced clinicians and scientists on the authoring team, which can result in them not speaking up, not asking questions, and generally being overshadowed. In addition, even if they have received training, patient authors may need continued support during the publication process. Medical writers can help patient authors by providing:[5,8-10,17]

Medical writers can also help patient authors by providing mentoring and support.

- **Confidence:** Medical writers can reassure patient authors that their lived experience is valid and valuable and that it is the reason that they have been invited to be an author on the publication.
- **A collaborative and inclusive team environment:** Medical writers can work to ensure that the authoring team understands the value of lived experience and respects the role of patient authors.
- **A "safe space":** Patient authors may not feel comfortable asking questions or seeking advice during meetings within the full group. Medical writers can be someone patient authors can turn to, either spontaneously or in planned patient author meetings.
- **Mentorship on the publication process:** Medical writers can assist patient authors in navigating the publication process, fulfilling authorship responsibilities, and understanding technical terminology, study designs, and statistics.
- **Mentorship on effective communication:** Medical writers can advise patient authors on how to deal with strong personalities in the team, navigate difficult discussions, provide effective and constructive feedback on manuscript drafts, and generally gain the respect of expert clinicians and scientists.
- **Advocacy:** Medical writers can help ensure that patient authors understand and actively contribute to discussions, for example by paraphrasing discussion points in plain language or by intentionally asking patient authors for input. Medical writers can also ensure the inclusion of patient authors' feedback and contributions during the drafting and revision process.
- **Conflict resolution:** Medical writers can assist in resolving any conflicts that arise within the team, promoting a positive working environment.

Conclusion

Medical writers are increasingly being asked to work on company-sponsored publications that include patient authors. Patient authors, especially less experienced ones, may have difficulty understanding complex medical terminology, navigating the publication process, and effectively contributing their lived experience when working with experienced clinicians and researchers. Medical writers can provide training and support to patient authors so that their valuable perspective is respected and properly reflected in the publication.

Table 2. Available training for patient authors

Resource	Type	Content	URL
WECAN "Patients in Publications" course	Online, open-access course	• Module 1: Introduction • Module 2: Publication Planning • Module 3: Publication Writing • Module 4: Submission, Peer Review & Beyond	https://wecanadvocate.eu/patients-in-publications/
Envisage the Patient "Patient Authorship" website	Downloadable files written in plain language	• Guide for Patient Authors on Meeting the International Committee of Medical Journal Editors (ICMJE) Criteria (pdf) • Plain Language Overview of The Publications Process (pdf) • The Basics about Conference (and Other) Abstracts (infographic) • Guide For Patient Authors on Disclosures (pdf)	https://www.envisionthepatient.com/patient-authorship
Taylor & Francis "Guidance for patient authors"	Website	Basic information for patient authors	https://authorservices.taylorandfrancis.com/editorial-policies/guidance-for-patient-authors/

Abbreviations: WECAN, Workgroup of European Cancer Patient Advocacy Networks

Disclaimers

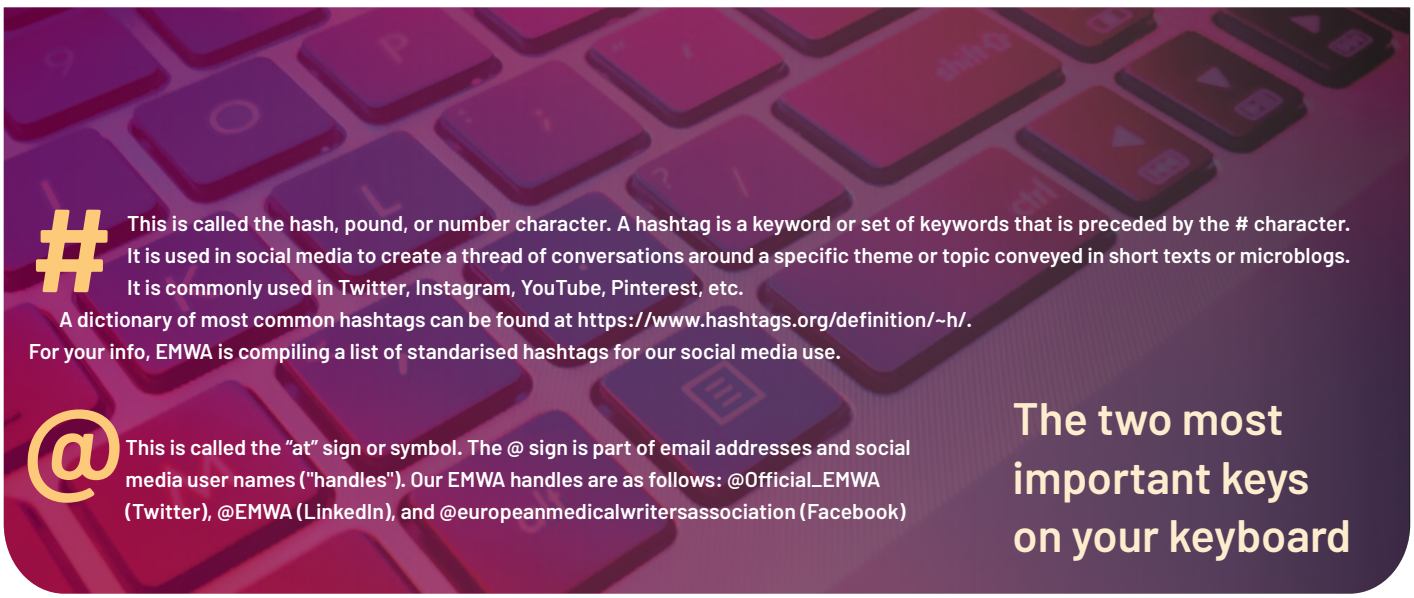
The opinions in this article are the authors' own and are not necessarily shared by EMWA or their employer.

Disclosures and conflicts of interest

All authors work on patient-authored publications for their employer.

References

1. Woolley KL, Stones SR, Stephens R, et al. Patient authorship of medical research publications: an evolution, revolution, and solution? Learn Publ. 2023;37(3):e1607. doi:10.1002/leap.1607
2. Leventhal P, Drachman D, Skovlund S. Can patients and caregivers be authors of peer-reviewed publications? Med Writ. 2024;33(4):98–100. doi:10.56012/idde2040
3. Oliver J, Lobban D, Dormer L, et al. Hidden in plain sight? Identifying patient-authored publications. Res Involv Engagem. 2022;8(1):12. doi:10.1186/s40900-022-00346-w
4. Woolley KB, Boughey A, Bharadia T, et al. Diversity in patient authors: a randomized bibliographic analysis. Cur Med Res Opin. 2023;39:S16–7. doi:10.1080/03007995.2023.2194075
5. Richards DP, Birnie KA, Eubanks K, et al. Guidance on authorship with and acknowledgement of patient partners in patient-oriented research. Res Involv Engagem. 2020;6(1):38. doi:10.1186/s40900-020-00213-6
6. Feighery L, Moutet A, Bharadia T, et al. Establishing a patient publication steering committee: A case study with insights for medical writers. Med Writ. 2020;29(4):32–8.
7. Hahn DL, Hoffmann AE, Felzien M, et al. Tokenism in patient engagement. Fam Pract. 2017;34(3):290–5. doi:10.1093/fampra/cmw097
8. Arnstein L, Wadsworth AC, Yamamoto BA, et al. Patient involvement in preparing health research peer-reviewed publications or results summaries: a systematic review and evidence-based recommendations. Res Involv Engagem. 2020;6(1):34 doi:10.1186/s40900-020-00190-w
9. Woolley K. Patient Authorship: Three Key Questions (& Answers!) for Medical Communication Professionals [Part B]. MAP Newsletter Web site [cited 2025 Mar 25]. Available from: https://www.ismpp-newsletter.com/2020/05/26/patient-authorship-three-key-questions-answers-for-medical-communication-professionals-part-b/
10. American Medical Writers Association. Patients as authors: The medical writer's role [cited 2025 Mar 25}. Available from: https://blog.amwa.org/patients-as-authors-the-medical-writers-role.
11. Lobban D, Stephens R, Porkess V. Involving patients as authors of company-sponsored journal publications [cited 2025 Mar 27]. Available from: https://globalforum.diaglobal.org/issue/august-2022/involving-patients-as-authors-of-company-sponsored-journal-publications/.
12. Envision Pharma Group. Powering patient voices. Patient Authorship Experience Tool [cited 2025 Mar 25]. Available from: https://patientfocusedmedicine.org/bogp/Attachment-1-Patient-Authorship-Experience-Tool.pdf
13. International Comittee of Medical Journal Editors. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals [cited 2025 Mar 25]. Available from: https://icmje.org/recommendations/
14. DeTora LM, Toroser D, Sykes A, et al. Good Publication Practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. Ann Intern Med. 2022;175(9):1298–304. doi:10.7326/M22-1460
15. Envision Pharma Group. Good Publication Practice (GPP) Guidelines. Summary for patient authors [cited 2025 Mar 25]. Available from: https://figshare.com/articles/poster/Plain_Language_Summary_of_Good_Publication_Practice_Guideline/11292047?file=20015405.
16. Plain Language Association International. What is plain language? [Cited 2025 Mar 25]. Available from: https://plainlanguagenetwork.org/plain-language/what-is-plain-language/
17. Harrison JD, Auerbach AD, Anderson W, et al. Patient stakeholder engagement in research: A narrative review to describe foundational principles and best practice activities. Health Expect. 2019;22(3):307–16. doi:10.1111/hex.12873



Biotechnology

SECTION EDITOR

Jennifer Bell
JenBellWS@outlook.com

Editorial

This article continues One Health discussions from earlier EMWA journal articles.[1–3] Earlier articles highlighted farmers' important role in One Health concerning the health of our planet. This article illustrates how biotechnology aligns with One Health and how definitions might apply. It should help many see vacant writing niches to be filled by aspiring medical writers and seasoned medical writers who want to transfer their skills. I hope it will help draw connections concerning how biotechnology is a routine part of our daily lives.

Jen

Where artisan, environmental, and medical biotechnology meet

Jennifer Bell
Ekrity, Dundalk, Ireland

doi: 10.56012/nsjh8018

Correspondence to:
Jennifer Bell
JenBellWS@outlook.com

It is important to highlight that biotechnology definitions of the pharmaceutical and medical device industries were established to ensure consumer safety when medical biotechnology applications were developed. The pharmaceutical and medical device industries produce biotechnology products often at molecular to whole organ levels, while artisan and environmental biotechnologies often happen at cellular to microorganism levels. Depending on the application, molecular techniques might be used in artisan and environmental biotechnology.

Biotechnology is a broad platform technology that applies to medical, artisan, and environmental applications, and it is good to have an idea of how these applications interface. Since the World Health Organization (WHO) has adopted One Health perspectives, it is becoming better known that the environment can affect the health of people and animals and *vice versa*, and this is good general knowledge to have. The European Medicines Agency (EMA) and four other European Union agencies are implementing a One Health approach – enter "European Medicines

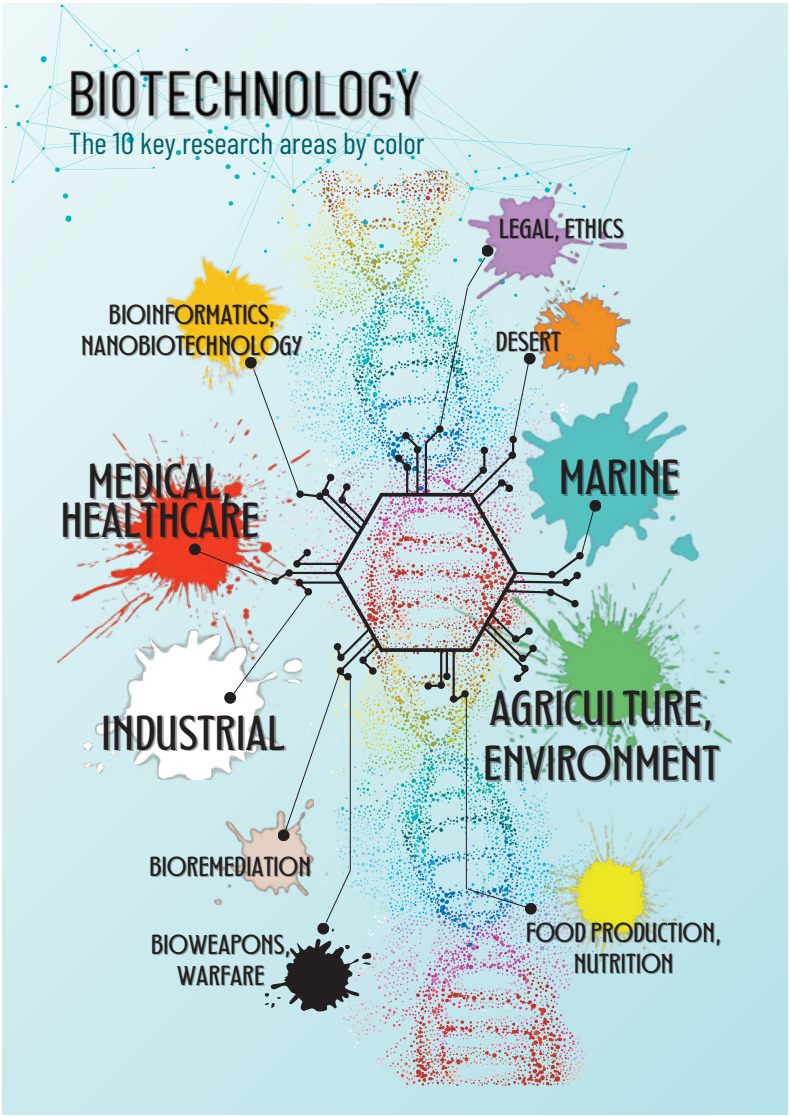


Illustration by Judit Mészáros

Figure 1. Biotechnology research areas[1]

Agency One Health" into your search browser to learn more.

As has been quoted previously in *Medical Writing*, "*Ask 10 people what "biotechnology" means, and you will get 10 different answers.*" (Figure 1)[4]

Figure 2 gives an outline of how each biotechnology might interface. Figure 2 is the product of the author brainstorming biotechnology ideas. There are many other examples where biotechnologies might interface, and some of the readership might have different opinions, which would be good to hear.

Tables 1 and 2 accompany the "Artisan" section of the Venn diagram in Figure 2.

To introduce the idea of artisan biotechnology, an artisan is "*a skilled craft worker who makes or creates material objects partly or entirely by hand.*"[5] Often, they might have a guild qualification, or their skills are recognised in some other way, like their reputations. Lucy Hargreaves described how biotechnology originated from "*ancient times when people harnessed living organisms for their benefit…*"[6] She also wrote about how "*a Hungarian agricultural engineer conceived the term biotechnology.*"[2] Since ancient times, biotechnologies have branched off as biotechnology innovations advance (Figure 3).

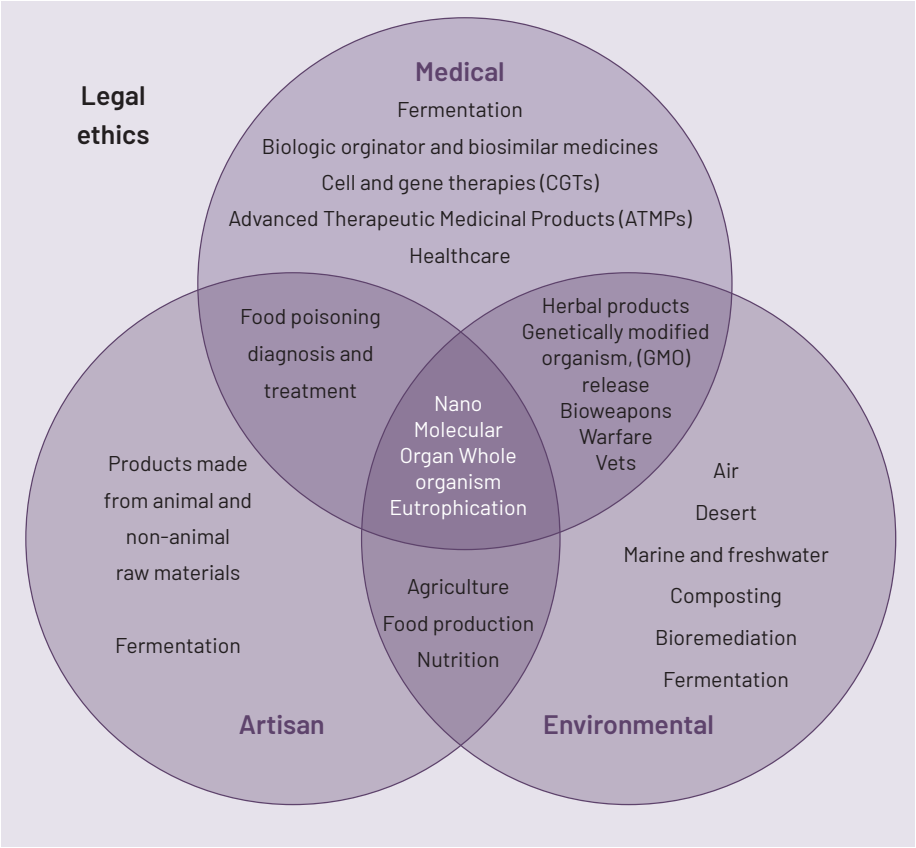


Figure 2. A Venn diagram roughly outlining where artisan, environmental, and medical biotechnologies meet

Table 1. Some raw materials used by some craftspeople

Who might use what raw product?

Some products

Animal products

- Red meat
- White meat
- Seafood
- Poultry
- Hair
- Feathers
- Skin
- Gut
- Oil
- Eggs
- Dairy products
  - Butter
  - Cheese
  - Cream
  - Milk

Non-animal products

- Beans
- Cereal stalks
- Fruit
- Fungi
- Grains
- Nuts
- Reeds
- Seeds
- Vegetables
- Wood

Tips for aspiring and seasoned medical writers

If you are an aspiring medical writer or a seasoned medical writer who wants to pivot into another area of medical writing, this is one way you could do it. You could figure out a medical angle your local biotechnologists fulfill, interview them about what they do, and write an article about it. An interview article in the EMWA journal December 2023 Biotechnology issue gives a good example of the shape you might like your article to take.[7] Think up some interview questions (Table 2), consider using a recording device to record your interview conversation(s), and either transcribe what is recorded by ear or, if you are interested in artificial intelligence (AI), figure out a way to incorporate transcription software which might help you. Most importantly, maintain a flexible approach and listen to what your interviewees say because their perspectives are very important. By the way, AI is probably more commonly known as artificial insemination in animal husbandry sectors. So, it might be a good idea to avoid using the AI

Table 2. Some questions for interviewing biotechnologists

- How is what you do sustainable?
- Why should your community buy directly from you?
- What obstacles are in the way of your business supplying directly to your community?
- Have you heard of the circular economy and how does it fit with what you do?
- Are you eligible for government incentives for what you do?
- What do you think is the best way to bring new business your way?
- How does what you do relate to what other producers do?

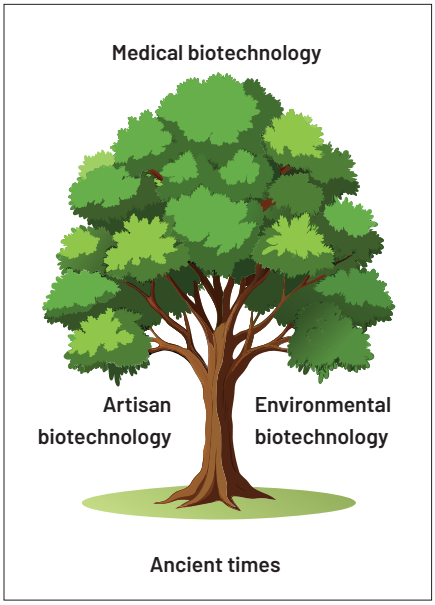


Figure 3. A schematic picture illustrating how biotechnology branched off from ancient times

acronym depending on who you interview and your article's target audience.

And the other area of medical writing I am referring to is One Health. One Health includes environmental health and is intended to lead to the better health of our planet – Gaia Theory is related and interesting to look up. The Gaia hypothesis emphasises how everything is connected on our planet which is a premise of One Health. The health of humans, animals and the environment are all interconnected.[8] Medical writing does not traditionally cover the environment's health, so there are many opportunities for medical writers here.

How is biotechnology defined?

In Europe

The European Commission says, *"…biotechnology can be used to manufacture bio-based products…"*[9] So, with this idea in mind, artisans are biotechnologists, or are they? Do governments need to change the definitions of biotechnologies to make them more straightforward to the public and help One Health filter into the global consciousness? Biotechnology fits the WHO's idea that One Health is *"an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes."* [10–12]

It is important to highlight that the European Commission uses the OECD definition of biotechnology, which encompasses artisan, environmental, and medical biotechnology, as outlined earlier in this article. The OECD definition is that *"… biotechnology applies science and technology to living organisms, as well as parts, products and models of them, to alter living or non-living materials to produce knowledge, goods and services. Biotechnology can be used to manufacture bio-based products (biomanufacturing). It can also be part of the solution to address many societal and environmental challenges, such as climate mitigation and adaptation, access to and sustainably using natural resources, restoring vital nature systems, food supply and security, and human health."*[13]

The OECD definition might help people draw a connection between what farmers produce, what craftspeople and food producers manufacture, and what is on our supermarket shelves and in our homes. Most of these things are at cellular to whole organism levels rather than molecular levels.

The OECD definition is quite broad compared to more specific medical biotechnology definitions. EMA defines biotechnology as *"The use of living organisms to create or modify products, including medicines."*[14] As already mentioned, the European Commission defines biotechnology in the same way as the OECD.[15]

EMA classifies many pharmaceutical industry-regulated medical *"biotechnology"* products under biologics and biosimilars, advanced therapy medicinal products (ATMPs) equivalent to US cell and gene therapies (CGTs), and herbal products. Many medical device diagnostic products strongly utilise molecular biotechnology within *in vitro* diagnostic devices. In contrast, many non-biological medical devices might have control over the biological aspects of a patient but are not obvious biotechnology products. For example, a heart pacemaker is an electronic device that modifies a patient's heart rhythm to normalise it, so according to the OECD definition, a pacemaker is a biotechnology.

If you are an aspiring medical writer or a seasoned medical writer who wants to pivot into another area of medical writing, this is one way you could do it.

Outside Europe

Regulations and definitions change over time, and regulatory harmonisation is constant, where the rest of the world often follows in the footsteps of Europe or the USA. It is important to mention that the USA is an OECD member country, although this might change under the current US governmental administration. All the same, the OECD definition has influenced the definitions

Photo: Freepik

of biotechnology in the USA over time.

In 1983, as genetic recombination emerged in industry, the article "*Biotechnology: the view from the FDA*" was published.[16] The abstract of this article says, "*What is biotechnology? This is not a naive question. The Office of Technology Assessment has found differing definitions of biotechnology emanating from eight foreign countries and three international organisations. FDA's working definition of biotechnology is the application of biological systems and organisms to technical and industrial processes. This definition is necessarily broad. It takes in both the "old" and "new" science: the age-old techniques for making beer or yogurt as well as the most advanced uses of recombinant DNA technology. It takes in many applications, from production of enzymes for laundry detergents, to selective breeding of plants and animals, to genetic engineering of bacteria to clean up oil spills. As with any new technology, ethical issues are raised. But in the case of genetic engineering and cloning, many of the primordial fears of man concerning the power of science are awakened.*"

So how many biotechnology definitions are there today? In 2017, the FDA published a 74-page document based on challenges faced by small and mid-sized businesses navigating various industry regulations.[17]

Photo: Freepik

Artisan and environmental biotechnology versus medical biotechnology

Biotechnology as a subject can be very confusing partly because it is a platform technology that can be broadly used, so pigeonholing it to define it is difficult. Many university courses that contain microbiology modules teach that biotechnology includes bread making, cheese making, and brewing, which are considered ways to make artisan products (note that these have a fermentation process step). Artisan products generally contain bio-based ingredients grown during agriculture (Table 1). Artisan products can include a fermentation process, such as steps like in cheese making, but they might not have one like in weaving. Agriculture pertains to the environment, and, as the WHO points out, the environment's health can affect human and animal health. Other university courses like biomedical science do not necessarily go into the details of "*environmental biotechnology.*" However, biologic and biosimilar drug product manufacture has a fermentation process step as well. So fermentation is used in artisan, environmental, and medical biotechnology, but each fermentation process is nuanced depending on the application.

The WHO describes One Health as *"an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes.*

To me, artisan biotechnology is where a skilled craftworker manufactures a product from a biological raw material; environmental biotechnology is applied in the environment to make it healthier; and medical biotechnology improves the health of humans and animals. So, the WHO's take on One Health is causing me to write about how environmental biotechnology, including agriculture and artisan biotechnology, might affect human and animal health. Environmental biotechnology is traditionally outside the scope of medical writing.

Final remarks

Biotechnology used in pharmaceutical and medical device production is a small proportion of the biotechnology used on the planet. And biotechnology is already used by people who don't always realise it. Figure 1 helps illustrate these statements.

I think connections between biotechnology and how it impacts everyday life can and should be drawn but is this medical writing? In addition, it is important to know that biotechnology might be animal or non-animal-based. Biotechnology should not be feared.

Acknowledgements

The author wants to thank everyone who has an opinion on biotechnology.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by her employer or EMWA.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

References

1. Philp J. Biomanufacturing and One Health. Med Writ. 2023;32(4):12–17. doi:10.56012/mrpm2606
2. Hargreaves L. The evolution of biotechnology: From ancient civilisations to modern day. Med Writ. 2023;32(4):40–44. doi:10.56012/gxcw4769
3. Bell J. Eutrophication of fresh and marine waterways: Can medical writers, biotechnologists, and others help solve this problem? Med Writ. 2024;33(4):84–8. doi:10.56012/wyfj9025
4. Billiones R. From the Editor. Biotechnology – diverse as the colours of the rainbow. Med Writ. 2023;32(4): 6–7. doi:10.56012/jewm8154
5. Wikipedia. Artisan entry. 2024 [cited 2025 Jan 02]. Available from: https://en.wikipedia.org/wiki/Artisan
6. Hargreaves L. The evolution of biotechnology: From ancient civilisations to modern day. *Med Writ.* 2023;32(4): 40–44. doi:10.56012/gxcw4769
7. Billiones R, Galici R. Five questions for Ruggero Galici on nonclinical medical writing. Med Writ. 2023;32(4): 18–9. doi:10.56012/msng4369
8. Wikipedia. Gaia hypothesis entry. 2024 [cited 2025 Jan 02]. Available from: https://en.wikipedia.org/wiki/Gaia_hypothesis
9. European Commission. Biotechnology [cited 2025 Jan 02]. Available from: https://single-market-economy.ec.europa.eu/sectors/biotechnology_en
10. WHO. One Health. 2017 [cited 2025 Jan 02]. Available from: https://www.who.int/news-room/questions-and-answers/item/one-health
11. WHO. Our Planet, Our Health, Our Future Discussion Paper, Human Health and the Rio Conventions: biological diversity, climate change and desertification. WHO. 2012. Available from: https://www.who.int/publications/m/item/human-health-and-the-rio-conventions
12. Lueddeke GR. Survival: One Health, One Planet, One Future. 1st ed. London:Routledge;2020. Available from: https://www.taylorfrancis.com/books/mono/10.4324/9780429444081/survival-one-health-one-planet-one-future-george-lueddeke.
13. European Commission. Biotechnology [cited 2025 Jan 02]. Available from: https://single-market-economy.ec.europa.eu/sectors/biotechnology_en
14. EMA. Biotechnology definition. 2025 [cited 2025 Jan 29]. Available from: https://www.ema.europa.eu/en/glossary-terms/biotechnology
15. European Commission. Biotechnology definition. 2025 [cited 2025 Jan 29]. Available from: https://single-market-economy.ec.europa.eu/sectors/biotechnology_en
16. Young FE. Biotechnology: the view from the FDA. Health Matrix. 1986;4(3):10–5.
17. FDA. Modernizing the regulatory system for biotechnology products: Final version of the 2017 update to the coordinated framework for the regulation of biotechnology. 2017 [cited 2025 Feb 08]. Available from: https://www.fda.gov/media/ 102658/download

Photo: Freepik

Author information

Jen Bell went to agricultural college when she left school. Then, for a few years, she travelled and did seasonal work on farms, in orchards, and in factories. After that, she continued her life science education. She worked in pharmaceutical and medical device manufacturing and distribution quality management roles from 2010 to 2018. She is interested in One Health which is concerned with threats to the animal-human-environment interface. Jen is passionate about the potential for biotechnology to improve lives. Today, she is a biotechnology consultant and freelance medical writer.

Freelancing

SECTION EDITOR

Adriana Rocha
freelance@emwa.org

Editorial

The COVID-19 pandemic started a conversation about mental health, especially as many began working from home for the first time – business as usual for us freelancers. During that time, in 2021, authors Shaun Foley and Matthew Knight contributed an insightful article to this journal section, focussing on the mental health of freelancers.

Fast-forward to 2025. We have more awareness around mental health, but also new and challenging stressors. What does this mean for freelancing? I invited Shaun and Matthew to revisit this topic and reflect on what has changed since 2021. What worries us today? What do the data say about our mental health? And, more importantly, how can we support ourselves and find help?

Prioritising our mental health is crucial not only for our overall wellbeing, but also for our freelance business. I'm confident that this article will be a useful resource to support us in both.

Happy reading!

Adriana Rocha

Supporting mental health for freelancers in medical communications in 2025

Shaun W. Foley[1], **Matthew Knight**[2]

[1] Freelance Medical Writer, Directory Owner, Biome Professionals
contact@biomeprofessionals.com

[2] Chief Freelance Officer, Leapers
matthew@leapers.co

doi: 10.56012/smor1177

Photo: Freepik

Stress and mental health as a med comms freelancer

It has been almost four years since we wrote our original article, "Supporting mental health for freelancers in med comms", in December 2021.[1] While all of us freelancers are now definitely older – and hopefully wiser – are we any less stressed? Have the stress triggers changed at all since 2021? And how do we cope in 2025?

Are we less stressed?

Back in December 2021, we found very little available information about stress and mental health in medical communications (med comms). How times have changed – and it only took a global pandemic to do so! Reducing stress and protecting our mental health are now widely discussed and prioritised as part of daily life. For example, the UK Government introduced a Mental Health bill in 2024, with the aim of modernising mental health legislature and preventing poor mental health.[2]

Now that we can talk more about stress and mental health, do we know whether freelancers

are still as stressed in 2025 as in 2021? The 2024 Leapers survey about mental health in freelancing is hot off the press, and captured data from 715 freelancers who shared information about their experiences.[3] Overall, 45% of freelancers saw their mental health decline in 2024, 90% experienced feelings of low confidence at some point, and 31% were unable to work for three or more days during the year due to poor mental health.[3] These statistics sadly suggest that freelancers overall still need support to protect their mental health.

In med comms, the MedComms Freelancing Barometer 2025[4] and WE3 Salary and Insight 2024 survey[5] both captured data on industry-specific sentiment and stress, and both had massive responses: 344 med comms freelancers and 712 med comms professionals (employees and freelancers), respectively. NetworkPharma.tv also ran a webinar in 2024 on "Working effectively in healthcare communications: Turning stress into a force for good".[6] The webinar concluded that stress in med comms remains an industry-wide problem and therefore industry-wide improvement is everyone's responsibility. This new focus on identifying and dealing with stress and burnout and protecting mental health is of course fantastic news for supporting freelancers in med comms.

But are we less stressed? In the WE3 Salary and Insight 2024 survey, nearly a third of respondents (employees and freelancers) felt neutral or disagreed that med comms was a good industry to work in.[5] Key factors included the demanding nature of med comms, which makes long-term sustainability difficult, and many med comms professionals feeling overworked, leading to burnout and mental health concerns.[5] Similarly in the MedComms Freelancing Barometer 2025, 26% of all respondents felt neutral to very dissatisfied about freelancing in med comms. One responder stated that *"[Freelancing is] becoming less attractive and quite stressful"*.[4]

Sources of stress

Freelancing comes with its own risk factors: variable and unpredictable workload, financial worries, work-life balance, and risk of burnout (Figure 1). When our original article was published in 2021 during the COVID-19 pandemic, we also had to contend with additional stresses such as changing workload, disruption to childcare/schooling, isolation, travel restrictions, and risk of coronavirus exposure.[1]

While the previous survey data show that there are still stress and burnout in med comms, the major causes for stress are different now. Over 2023 and 2024, we have seen new issues such as global economic instability and budget restrictions for our usual clients, resulting in less demand for work. The risk posed by artificial intelligence (AI) on writing opportunities has also been a major concern for med comms freelancers (Figure 1).

1. Economic instability and changing industry dynamics

Europe has been experiencing a period of economic instability since 2022, with persistent high inflation and market volatility, coupled with a cost-of-living crisis and a drop in household disposable income.

This instability has had a wide-reaching impact, directly affecting the biopharmaceutical and med comms industries. In particular, volatile job markets and political and economic instability have led to budget restrictions for our usual clients – typically biopharmaceutical companies and med comms agencies – as well as restructuring of biopharmaceutical companies.[7] In the MedComms Freelancing Barometer 2025, many freelancers were concerned about the rising cost of living, as well as professional uncertainty and instability in light of these industry changes.[4]

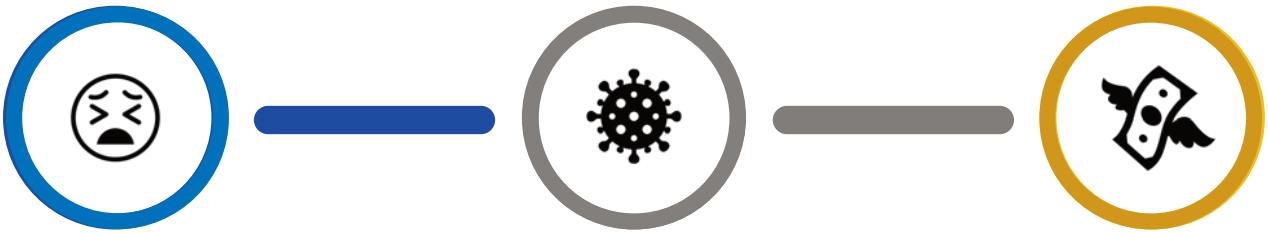
2. Demand for work

In the MedComms Freelancing Barometer 2025, 45% of freelancers didn't work as many hours as they wanted and 35% reported that their freelance income was less than expected.[4] Some individuals reported extensive quiet periods and delayed or cancelled work, with fewer opportunities since COVID-19. Others were "*worn down by the uncertainty of freelance workload*".[4]

Several factors may have contributed to this lower demand for freelance med comms opportunities. First, budget restrictions for biopharmaceutical companies have probably filtered down to med comms agencies, reducing their reliance on freelancers. Certainly, since COVID-19, many med comms agencies have also started medical writer in-house training programs, further reducing the need for freelance support. Lastly, and although it is hard to quantify, many think that there are just more freelancers in med comms in general, which increases the competition for work.[4]

3. Artificial intelligence

The rapid development of generative AI models such as ChatGPT has revolutionary potential for natural language processing tasks and assisted writing. It is clear that AI is here to stay, but there



Omnipresent
- Variable and unpredictable workload
- Financial worries/irregularity of income
- Work-life balance
- Risk of burnout

2020: Covid-19
- Changing workload
- Disruption to childcare/schooling
- Isolation
- Travel restrictions
- Coronavirus exposure

2025
- Economic instability/ cost of living crisis
- Changing industry dynamics
- Less demand for work/more freelancers
- Impact of artificial intelligence

Figure 1. Sources of stress as a freelancer in med comms

Photo: Freepik

are also serious concerns about job displacement. Norman and Chamberlain James described the paradox of AI in medical writing,[8] by outlining that, in a perfect world, we want AI to pay our bills, do our menial chores, and make working easier, so that we have more time to do the things that we like. But we don't want AI to do the things that we like for us so that we have more time to work, or replace our jobs altogether!

It seems that the biggest source of stress for freelancers in med comms regarding AI is the unknown. In the MedComms Freelancing Barometer 2025, 42% of freelancers were not routinely using AI and many worried about its potential to devalue their skills and the need to adapt to working with AI-generated content.[4] Similarly, in a 2024 survey by the MedCommsTech Medical Writers Collective, 44% of med comms freelancers believed that AI would have a detrimental impact on the available work and opportunities for freelance medical writers, and 27% believed that it would decrease job satisfaction.[9]

Leapers.co

Since the data paint a very clear picture of freelancers facing many challenges to their mental health – across macroeconomic factors, changes in technology and attitudes towards work, and an increasingly volatile and supply-heavy market – what can be done to take care of our mental health?

Leapers works with organisations who want to put support in place for their freelancers, through its research and resources. It has developed the ABC of wellbeing for freelancers:[10]

A: Active Awareness
B: Behaviours and Boundaries
C: Community and Connection

Active awareness

Since Leapers.co started work back in 2017,[10] there has been a notable improvement in conversations around mental health in freelancing. But while the conversation at large has improved, freelancers are still not always caring for their own mental health.

Active Awareness means taking a little bit of time every day, every week, or even just once a month, to check-in with yourself, ask "How am I doing?", and reflect on the root causes. Taking just 15 minutes a week to reflect on what contributes to positive and negative experiences as a freelancer can help you better understand what shapes your mental health. For example, late payments. Not a mental health issue *per se*, but one that can lead to it, as increased anxiety around cash flow or financial wellbeing has dramatic effects on our health.

Taking just 15 minutes a week to reflect on what contributes to positive and negative experiences as a freelancer can help you better understand what shapes your mental health.

Keeping track of what influences your emotional health, following patterns and trends over time, and realising when you're feeling stressed helps you to be more aware and take action.

Behaviours and boundaries

Once you understand what is affecting your emotional health, you can start improving or continuing to build positive influences. For example, if you're aware that you have a worse week when you're not sleeping well, improving your sleep health can be your priority. If you have a great week when you're working alongside others, finding collaborators can be at the top of your list for future projects. And if you realise you're less productive after weeks without rest, then putting a holiday policy in place can help.

When you're a freelancer, you no longer have an employer's work-place structure and habits. Putting some structure back in place, identifying positive behaviours, and avoiding negative ones will help.

We say Behaviours and Boundaries because stress can come from external sources outside of our control too. Last-minute changes, unpaid invoices, unclear communications, refusal to sign a contract, emails out of hours, ghosting… the

list is potentially endless. Putting boundaries in place is essential to protect ourselves wherever possible from bad external behaviours. Perhaps this is defining your own working hours, automation to deal with late invoices, or using a different email account for work than the one on your personal devices.

Community and connection

The final, and perhaps most important, pillar is Community and Connection. We know that isolation is an epidemic in the UK, and freelancers are three times more likely to face frequent feelings of loneliness at work than the employed population.[3] The causes are not surprising: we don't have a ready-made team or colleagues around us! This means that we need to proactively invest in building our own support networks.

Fortunately, it's never been easier to find supportive communities, fellow freelancers who understand the experience and can share their insights into tackling a problem, or just having a cuppa when needed. Indeed, within med comms freelancing, there are many communities to choose from.[11] Community doesn't need to be large online platforms, it can be a smaller intimate group offline in a coffee shop or coworking space, or a group of trusted people you turn to in times of need. And even if your mental health is absolutely fine, building a support network gives you the opportunity to support others who might need it more, folks who can step in when you need to take a break or are feeling unwell, or just be present. Whilst freelancers need to take individual responsibility for their own wellbeing, the entire freelancing ecosystem needs to play its part to support its freelancers. This includes communities, policy makers, unions, service providers, and of course the hirers themselves.

Freelancers can demand better behaviours from their clients – and not just accept poor practices such as late payments or lack of onboarding. Whilst not every freelancer can afford to turn down work, setting our own boundaries and establishing good ways of working with clients can go a long way to avoid situations which negatively impact mental health.

We are in a very different place today, compared with 2021, in terms of the conversation around mental health. However, preventing and dealing with poor mental health and stress continue to be a challenge for freelancers in med comms, and it is important that they are prioritised. The resources and support to do so are out there, but finding them, accessing them, and making the most of them takes a little bit of effort. And if freelancers aren't investing in their own mental health as a critical part of their business, there is a risk of their business being less sustainable.

References

1. Foley SW, Knight M. Supporting mental health for freelancers in med comms. Med Writ. 2021;30(4):86-88. Available from: https://journal.emwa.org/medical-journalism/out-on-our-own/
2. UK Government. Mental Health Bill 2025. 2024 [cited 2025 Mar 10]. Available from: https://www.gov.uk/government/collections/mental-health-bill-2025
3. Leapers.co. Mental health in freelancing during 2024. 2024 [cited 2025 Mar 10]. Available from: https://www.leapers.co/research/2024/
4. MedComms Workbook. MedComms Freelancing Barometer 2025. 2025 [cited 2025 Mar 10]. Available from: https://drive.google.com/file/d/10ignCuLLR6fbd7yshwWxXlMY-1q4Gg0f/view?pli=1
5. WE3 Consulting. 2024 Healthcare communications salary & insights survey. 2024 [cited 2025 Mar 10]. Available from: https://www.we3consulting.com/medcomms-salary-survey.html
6. Hutchings P, Keddie C. Working effectively in healthcare communications: Turning stress into a force for good. NetworkPharma.tv. [Webinar] 2024 [cited 2025 Mar 10]. Available from: https://networkpharma.tv/2024/02/28/working-effectively-in-healthcare-communications-turning-stress-into-a-force-for-good/
7. Rocha A, Steele E, Kehoe L. The worldwide landscape of freelance medical writing: Exploring challenges and opportunities. Med Writ. 2024;33(4):36–40. doi:10.56012/zeca2227
8. Norman J, Chamberlain James L. AI for medical writers: Friend or foe? Med Writ. 2023;32(3):64–8. doi:10.56012/qovt1204
9. MedCommsTech Medical Writers Collective. A survey of the experience, motivations and added value of freelance medical writing professionals. 2024 [cited 2025 Mar 10]. Available from: https://medcommstech.com/wp-content/uploads/2025/01/ISMPP-Europe-2025_Templar_Poster-44_Supplementary-Material.pdf
10. Leapers.co. 2025 [cited 2025 Mar 10]. Available from: https://www.leapers.co/
11. Llewellyn P. The need for community: The importance of networking as a freelance medical writer. Med Writ. 2023:32(2):36-40. doi:10.56012/etqg2327

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by EMWA.

Conflicts of interest

Shaun Foley is the proprietor of Biome Professionals and declares no disclosures or conflicts of interest. Matthew Knight is the proprietor of Leapers.co and declares no disclosures or conflicts of interest.

Author information

Shaun W. Foley is a freelance medical writer with 12 years' experience in MedComms. He is also the founder of the MedComms directory Biome Professionals.

Matthew Knight is founder of Leapers – an award winning project exploring and improving the mental health of the self-employed, which has supported over 250,000 people since 2018. Matthew writes on the topic of supporting freelancers to work effectively and sustainably, and his work has been featured in *The Guardian*, *BBC*, and the *Daily Mail*. He is on Mind UK's Mental Health at Work leadership council, and works with both businesses and individuals to support freelancers. He can be found at thinkplaymake.co

My First Medical Writing

SECTION EDITOR
Evguenia Alechine
ealechine@gmail.com

Editorial

In this release of *My First Medical Writing*, we spotlight another aspiring medical writer sharing insights on a topic of broad medical interest. Celina Galles, a PhD in Biological Sciences, brings over 15 years of expertise in molecular biology, microbiology, and recombinant protein expression. With a strong drive to advance biotechnological health solutions, she is passionate about using science communication to bridge the gap between research and real-world impact. Celina is keen to connect with peers in the medical writing community and contribute meaningfully to global scientific dialogue. This article reflects her dedication and enthusiasm – enjoy the read! **Evguenia**

Synbiotics: The power of virtuous interactions

Celina Galles
NOVA S. A. U., R&D Scientist
Cañada de Gómez, Argentina
celina.galles@gmail.com

doi: 10.56012/zflp8498

Synbiotics: The power of virtuous interactions

A growing tendency in microbiome-directed research is the combined use of probiotics (live microorganisms that confer health advantages when consumed) and specific non-digestible compounds that promote the growth of beneficial microorganisms (a.k.a., prebiotics), in what has been coined as synbiotics (yes, with an N, not an M).

An updated definition for synbiotics, carved by the International Scientific Association for Probiotics and Prebiotics, describes them as *a mixture comprising live microorganisms and substrates selectively utilised by host microorganisms that confer a health benefit to the host.*[1] In this way, the microbiota/substrate/host triangle is traced, supporting the logic that a health benefit or even the treatment of an illness can be achieved through the virtuous interaction of its three equally essential sides.

Synbiotic-based medical treatments could seriously reshape the future landscape of health-related processes such as immune modulation, nutrient absorption, and intestinal barrier function. But precisely what knowledge has been built on this subject? And what concrete applications can we expect to experience shortly?

Advances in synbiotics research and healthcare applications

In recent years, there has been a surge in research focusing on synbiotics. A quick literature search in PubMed on *synbiotics* will generate a list of more than 3,000 publications (https://pubmed.ncbi.nlm.nih.gov/?term=synbiotics). When studying the number of publications vs. time curve, one notices a steep and sustained yearly increase, starting to grow around the beginning of this century.

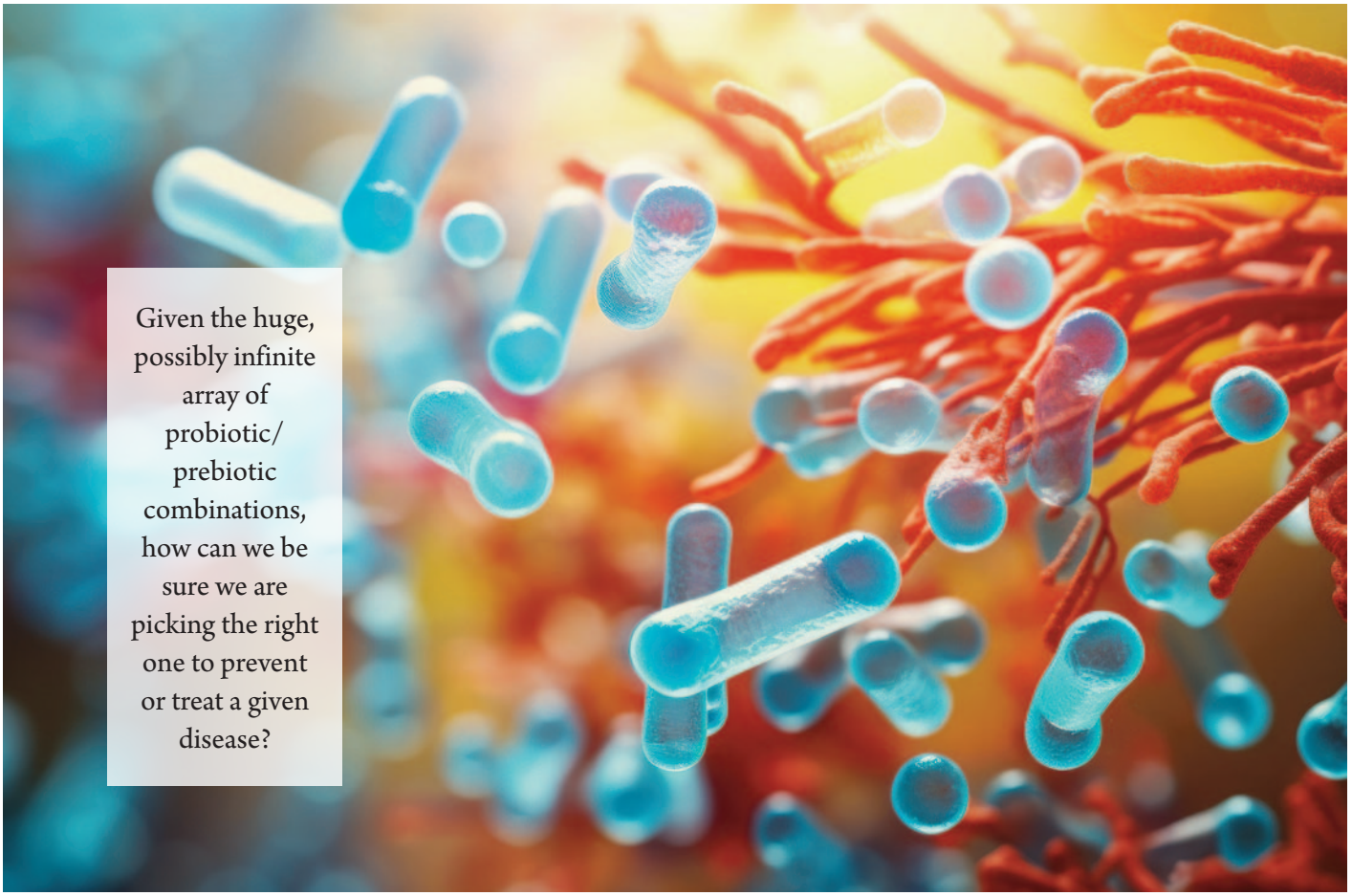
So, how can we start to explore this field in constant development?

A possible area to begin our exploration is that of antioxidants.[2] Antioxidant molecules can eliminate their toxic counterparts that bring about oxidative damage and stress and ultimately speed up ageing in cells. The body produces its antioxidants, but they may also be administered exogenously, as you surely recall from the advertisements of many commercial supplements. In our diet, antioxidants are present in raw fruits and vegetables and fermented foods. Science has recently discovered growing evidence of beneficial synbiotic effects on the oxidative damage pathways related to diseases such as Alzheimer's and diabetes, among others.[2]

Synbiotics can also improve gut health. A high gut microbiota diversity has been correlated with low responsiveness to dietary/microbiota treatments. By providing the strain and its specific growth substrate together, the synbiotic approach guarantees more predictable outcomes for many of these treatments. Health claims have been made for synbiotics to treat metabolic syndrome, alleviate lactose intolerance, and decrease colon cancer risk.[3] Synbiotics could also prevent and treat Irritable Bowel Syndrome and Inflammatory Bowel Disease, improving mucosal structure and general epithelial barrier function.[3]

The microbiota/substrate/host triangle is traced, supporting the logic that a health benefit or even the treatment of an illness can be achieved through the virtuous interaction of its three equally essential sides.

Synbiotics also benefit the gut-brain axis, a permanently active bidirectional communication highway that exchanges signals and influences physiological processes in both the gut and the brain. The production of neurotransmitters such as serotonin, dopamine, and GABA is influenced by gut microbiota; thus, synbiotics could indirectly affect mood regulation through these pathways.[4] Synbiotic modulation of the gut-brain axis can lead to improvements in central nervous system functions and help prevent or manage mental disorders, spanning depression, anxiety, and cognitive decline associated with neurodegenerative diseases like Alzheimer's.[3,5] Moreover, synbiotics may improve stress-related parameters by modulating the gut-brain axis.[6]



Given the huge, possibly infinite array of probiotic/prebiotic combinations, how can we be sure we are picking the right one to prevent or treat a given disease?

Synbiotic magic explained

What this mass of information clearly states is that synbiotics exert numerous and variable beneficial effects on human health, but exactly how and why does this happen? Translating this question into scientific jargon, one may ask what the underlying molecular mechanisms are that explain the observed effects of synbiotic treatments on so many varied health issues. It is worth mentioning that data and knowledge on synbiotics have accumulated over many years of research but have made major leaps with the recent expansion of metabolomic, proteomic, and sequencing technologies. Although I do not expect to answer this broad query in this brief article, we can venture to display the common players involved in synbiotics identified by scientists to date.

We first set our spotlight on a particular kind of lipids called Short-Chain Fatty Acids (SCFAs). Among the array of molecules present in living organisms, SCFAs are small in size and include the carboxylic acids acetate, butyrate, and propionate. And precisely, what is being promoted with certain synbiotic treatments is the production of these beneficial SCFAs in the gut by colonic bacteria, which can explain their positive consequences on health, involving anti-inflammatory effects and the regulation of gene expression.[3]

A second mechanism that can explain the positive action of synbiotics on health is the existence of communication routes between gut microflora and the immune system.[7,8] Probiotics secrete molecules that interact with gut immune and epithelial cells, allowing what may be conceived as a *cross-talk* or molecular conversation between them, that ultimately contributes to a robust immune system. In this way, a clear vertex constituted by two of the sides of the synbiotic triangle is identified in the microbiota-host interaction.

A third mechanism associated with synbiotics is related to their antimicrobial and anti-inflammatory effects. Synbiotics can produce antimicrobial substances and reduce inflammatory responses by regulating the production of cytokines and other immune mediators.[3,8]

Hold your (microbial) horses

Finally, we must discuss the immense challenges related to this new and exciting possibility of harnessing and strengthening human health and quality of life.

Given the huge, possibly infinite array of probiotic/prebiotic combinations, how can we be sure we are picking the right one to prevent or treat a given disease? And what about the third side of the triangle: The host? One could envisage an ideal, futuristic scenario where synbiotics are ordered *a la carte* or even specifically tailored for each disease and/or patient. Is this approach realistic? Can research and industry respond to this demand? If so, will this resource be available for the vast majority, or will it represent an exclusive, premium line of medicine?

Effective synbiotic clinical trials require careful consideration of dosage, controls, and strain-specific detection to demonstrate causality and ecological interactions, all of which elevate the complexity of the work being carried out.[9] While promising results exist from animal studies and human trials, more extensive clinical research is needed to establish these benefits across diverse populations.[9] Ecological constraints (e.g., competition with resident microbiota and substrate specificity) limit the efficacy of probiotics and prebiotics, contributing to inconsistent clinical outcomes. When it comes to the financial aspect, conducting extensive clinical trials to validate synbiotic health benefits is

expensive.[9] Using *in vitro* models can help reduce costs but may not fully replicate human conditions.[10]

These products also face concrete formulation challenges. The dosage of prebiotics can represent a hurdle: High doses are required for efficacy but may cause gastrointestinal side effects like bloating or flatulence, while lower doses risk reduced effectiveness.[11] Also related to this, many formulations prioritise cost and availability over functionality, with limited human trials showing consistent benefits. However, novel technologies such as microencapsulation may be the key to expanding the use of synbiotic treatments.[9] Microencapsulation protects probiotics and prebiotics from environmental factors such as heat, moisture, and oxygen. Consequently, thanks to this technology, the survival in the gut of probiotics and prebiotics is improved, their release in the gut is controlled and targeted, and the shelf life of the synbiotic products is extended.[9]

Regarding the commercialisation of synbiotics, although the global market for probiotics and prebiotics is growing, stringent regulatory steps still represent significant barriers. Regulatory requirements vary by region, so ensuring compliance across different markets can be tricky.[1] Also, compared to probiotics or prebiotics alone, consumer perception of synbiotics is less advanced, potentially affecting market demand.[12]

Concluding words

We invite you to consider this an open-ended story and remain alert to news on breakthroughs in the synbiotics field. As we continue to explore its vast potential, we look forward to future, insightful research that illuminates new, exciting pathways for human health and wellness.

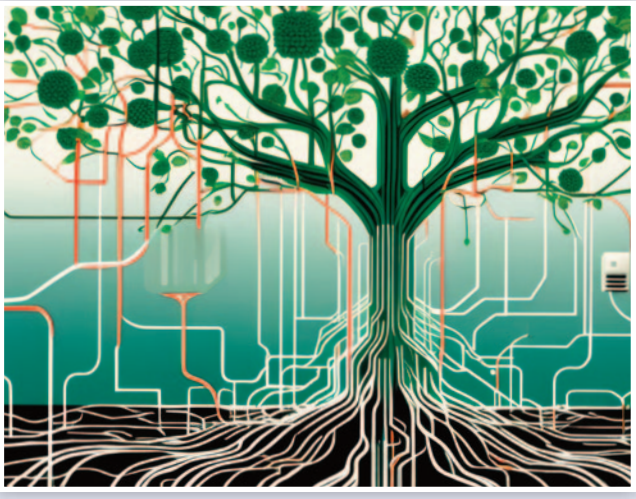
References

1. Swanson KS, Gibson GR, Hutkins R, et al. The International Scientific Association for Probiotics and Prebiotics (ISAPP) consensus statement on the definition and scope of synbiotics. Nat Rev Gastroenterol Hepatol. 2020;17: 687–701. doi:10.1038/s41575-020-0344-2
2. Mounir M, Ibijbijen A, Farih K, et al. Synbiotics and their antioxidant properties, mechanisms, and benefits on human and animal health: A narrative review. Biomolecules. 2022;12(10):1443. doi:10.3390/biom12101443
3. Krumbeck JA, Walter J, Hutkins RW. Synbiotics for improved human health: Recent developments, Challenges, and Opportunities. Annu Rev Food Sci Technol. 2018;11(7):451–79. doi:10.1146/annurev-food-030117-012757
4. Loh JS, Mak WQ, Tan LKS, et al. Microbiota–gut–brain axis and its therapeutic applications in neurodegenerative diseases. Signal Transduct Target Ther. 2024;9(1):37. doi:10.1038/s41392-024-01743-1
5. Fekete M, Lehoczki A, Major D, et al. Exploring the influence of gut–brain axis modulation on cognitive health: A comprehensive review of prebiotics, probiotics, and symbiotics. Nutrients. 2024;16(6):789. doi:10.3390/nu16060789
6. Lalitsuradej E, Sirilun S, Sittiprapaporn P, et al. The effects of synbiotics administration on stress-related parameters in Thai subjects – A preliminary study. Foods. 2022;11(5):759. doi:10.3390/foods11050759
7. Williams LM, Stoodley IL, Berthon BS, et al. The effects of prebiotics, synbiotics, and short-chain fatty acids on respiratory tract infections and immune function: A systematic review and meta-analysis. Adv in Nutr. 2022;13(1):167–92. doi:10.1093/advances/nmab114
8. Li X, Hu S, Yin J, et al. Effect of synbiotic supplementation on immune parameters and gut microbiota in healthy adults: A double-blind randomized controlled trial. Gut Microbes. 2023;15(2):2247025. doi:10.1080/19490976.2023.2247025
9. Gomez Quintero DF, Kok CR, Hutkins R. The future of synbiotics: Rational formulation and design. Front Microbiol. 2022;13:919725. doi:10.3389/fmicb.2022.919725
10. Markowiak P, Ślizewska K. Effects of probiotics, prebiotics, and synbiotics on human health. Nutrients. 2017;9(9):1021. doi:10.3390/nu9091021
11. Rau S, Gregg A, Yaceczko S, Limketkai B. Prebiotics and probiotics for gastrointestinal disorders. Nutrients. 2024; 16(6):778. doi:10.3390/nu16060778
12. Chaturvedi S, Chakraborty S. Synbiotic foods: Significance, applications and acceptance. 1st ed. Abingdon (Oxon): CRC Press; 2024. Available from: https://www.routledge.com/Synbiotic-Foods-Significance-Applications-and-Acceptance/Chaturvedi-Chakraborty/p/book/9781032293370

CONTACT US

If you have ideas for themes or would like to discuss any other issues, please write to mew@emwa.org.

Upcoming issues of **Medical Writing**



September 2025:

Real World Data/Real World Evidence

Real-world data and real-world evidence have become integral to medical research and healthcare decision-making. Their value lies in providing insights into how healthcare treatments and interventions perform in everyday settings, which can differ significantly from controlled clinical trial environments.
This issue of Medical Writing will include a broad range of articles on the issue theme covering critical aspects for medical writers working with these types of data.

Guest Editors: Maria Kołtowska-Häggström and Laura Collada Ali
The deadline for feature articles has now passed.

December 2025:

Safety Writing

As the regulatory landscape continues to evolve, the importance of precise and thorough safety reporting has never been more critical. This issue will provide insights into the latest methodologies, best practices, and innovative approaches that are shaping the future of safety writing. The issue will feature articles on the development and submission of safety data, offering expert guidance on handling complex safety data.

Guest Editors: Iva Cvetkovic and Pavle Simeunovic
The deadline for feature articles is September 1, 2025.

Themes for 2026:

Medical Writing Careers

Guest Editors: Jules Kovacevic and Andrew Balkin

Regulatory Submissions

Guest Editors: Clare Chang and Annie Joise

Inclusive Language

Guest Editors: Laura Collada Ali and Heather Mason

Publications: Integrity, Ethics and Peer Review

Guest Editors: Martin Delahunty and TBD

http://journal.emwa.org/