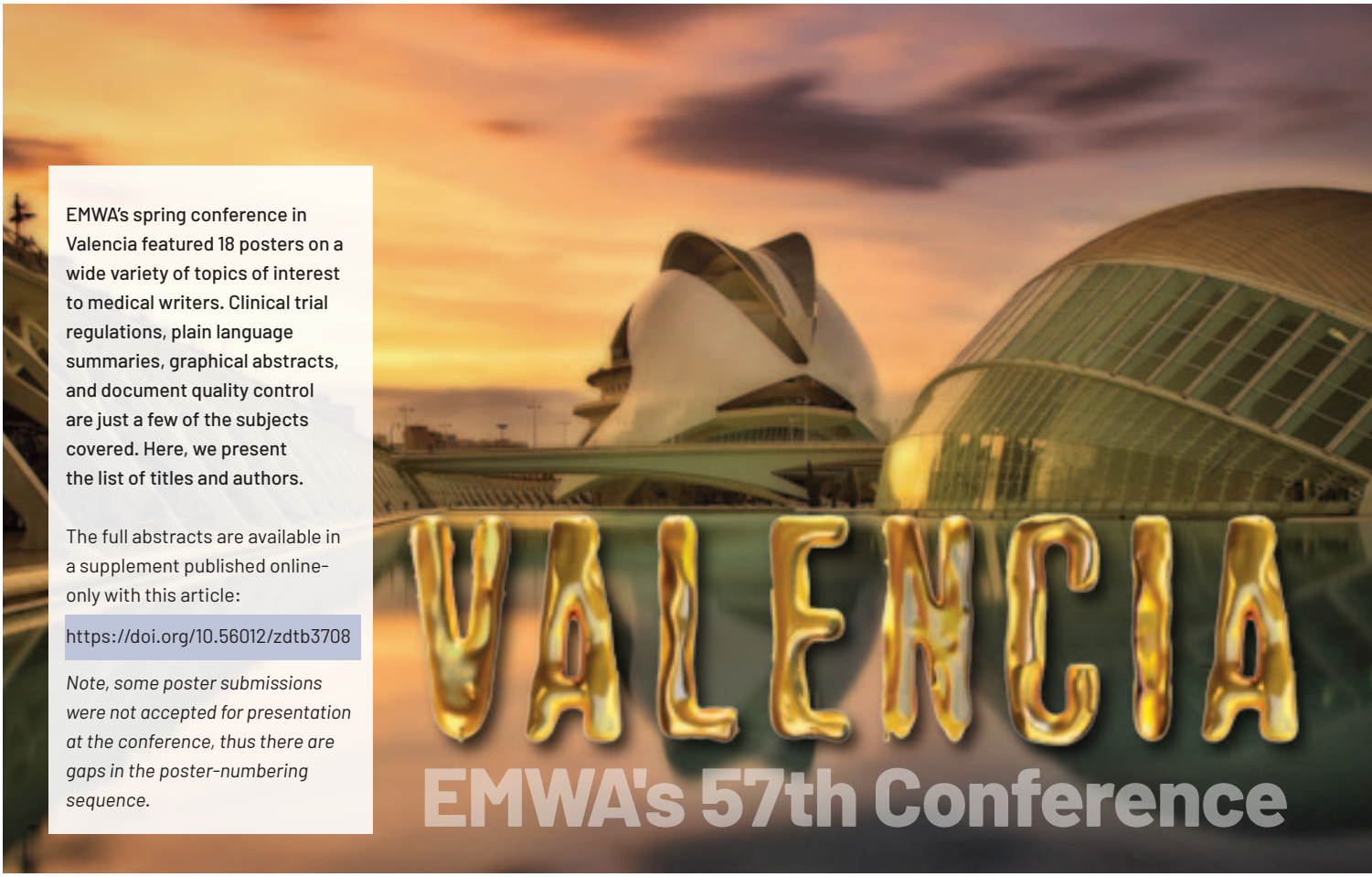
Abstracts from the 57th EMWA Conference Poster Session

Valencia, Spain, May 2024



EMWA's spring conference in Valencia featured 18 posters on a wide variety of topics of interest to medical writers. Clinical trial regulations, plain language summaries, graphical abstracts, and document quality control are just a few of the subjects covered. Here, we present the list of titles and authors.

The full abstracts are available in a supplement published online-only with this article:

https://doi.org/10.56012/zdtb3708

Note, some poster submissions were not accepted for presentation at the conference, thus there are gaps in the poster-numbering sequence.

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ICON plc

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Sujatha Vijayakumar[1], Shital Sarah Ahaley[1], Ankita Pandey[1], Simran Kaur Juneja[1], Tanvi Suhane Gupta[1], Prakash Muthuperumal[2]
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Marta Mas[1], Catherine Heddle[2], Alina Gavrus Ion[1], Nicole Bezuidenhout[3]
TFS HealthScience, Department of Medical Writing
[1] Barcelona, Spain
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[3] New York, USA

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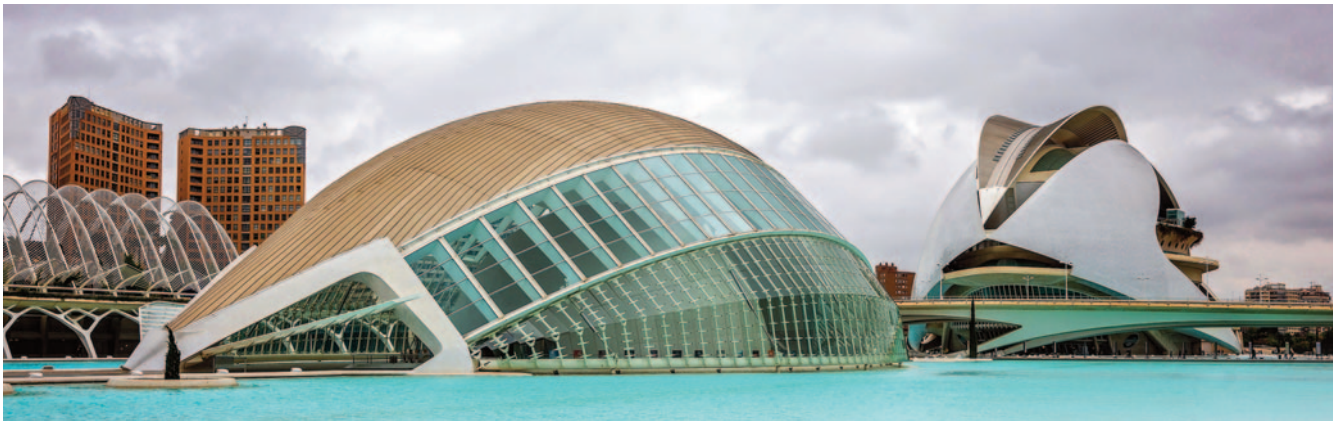

Online supplement:

Abstracts presented at EMWA's 57th conference

P1 The Impact of the EU clinical trials regulation (CTR)

Irene Lako - ICON plc
Jelmer de Jong - ICON plc
Cor van der Heide - ICON plc
Rouyanne Ras - ICON plc
Judith Hettinga - ICON plc
Tasnim Uddin - ICON plc
Koen Janssen - ICON plc
Noëlle Zweers - ICON plc
Alida Weeke-Klimp - ICON plc

Introduction

The Clinical Trials Regulation (CTR) harmonises the processes for the assessment and supervision of clinical trials throughout the EU. Prior to the CTR, clinical trials were submitted to competent authorities and ethics committees in each EU member country to receive regulatory approval per the Clinical Trials Directive (CTD). The impact of the CTR on pre-submission medical writing processes and timelines for single-site studies was investigated at the Phase 1 clinic at ICON plc in the Netherlands.

Methods

The medical writing processes and timelines for all regulatory submissions in the first year after full CTR implementation (Feb 2023 to Jan 2024) were compared to those in the last year of the CTD (Feb 2022 to Jan 2023).

Results

The time needed from start of protocol development up until regulatory approval increased under CTR. This increase was attributed to the introduction of redaction activities, changed processes for linguistic alignments of Dutch and English subject-facing documents, and the need to have final documents available earlier. Regulatory preparations for the actual submission took longer than previously. In addition, the lay protocol synopsis is a new type of document that needs to be prepared for CTR submissions.

Conclusions

While the CTR has harmonised the submission process throughout the EU, it has increased timelines for the regulatory submission process of Phase 1 studies at the Phase 1 clinic at ICON plc in the Netherlands. Parallel document development, detailed resource planning, and agreements on expedited timelines with regulatory authorities have partly mitigated the increase.

P2 Plain-language summaries of publications: Who, what, when, where, and why?

Louisa F. Ludwig-Begall – Evidera-PPD, a Thermo Fisher Company
Pablo Izquierdo – Evidera-PPD, a Thermo Fisher Company
Rienne Schinner - Evidera-PPD, a Thermo Fisher Company
Phil Leventhal – Evidera-PPD, a Thermo Fisher Company

Introduction

Plain-language summaries of publications (PLSPs) are full, standalone, peer-reviewed articles written in approachable, non-technical language intended to allow scholarly research to be understood by non-specialist audiences. PLSPs are relatively new, but increasingly in demand. This study examined the who, what, when, where, and why of published PLSPs.

Methods

Embase, MEDLINE, and CENTRAL were searched via Ovid for PLSPs published between January 1, 2004 and February 1, 2024. The following were extracted: publication date, journal, source study type, page length, medical writer involvement, and patient/ lay author involvement. The average grade level of the PLSP abstracts was assessed via readabilityformulas.com. Analysis of variance was performed with Bonferroni correction for multiple comparisons.

Results

151 PLSPs were identified. All were open access. The first was published in 2015; 85% were published since 2021. 14 journals have published PLSPs. Most PLSPs (67%) describe clinical trial results. Most were supported by medical writers (85%) but did not include patient/lay authors (17%). Median length was 9.3 pages (range, 2–23). Median grade level was 14 (range, 9–24); grade level was ≥12 for 85%. Grade level was lower with medical writer involvement ($p=0.0043$) but unchanged by patient/lay author involvement ($p>0.9999$).

Conclusions

Publication of PLSPs has been rapidly increasing since they first appeared in 2015. Although medical writing support appears to improve their readability, most may be too difficult and too long to be easily understood by patients or other non-specialists. Clearer guidance and more attention are needed to produce PLSPs that are effective at informing non-specialists.

P3 Medical Writers: A pivotal role in leading teams to compliance with EU CTR transparency requirements

Montserrat Cuadrado Lafoz – PPD Clinical Research Business of Thermo Fisher Scientific
Daniel Antoine - PPD Clinical Research Business of Thermo Fisher Scientific

Introduction

Transparency is at the heart of the EU Clinical Trial Regulation (Regulation No. 536/2014) and public interest in clinical trial data is growing. Under the regulation, documents that comprise the clinical trial application are subject to public disclosure. To protect the competitive interest of the sponsors, the Regulation introduces the concept of protection of commercially confidential information (CCI) as a ground to justify confidentiality of all or part of the data. Medical Writers are central to the preparation of documents impacted and are, therefore, perfectly placed to consult to address EMA's transparency requirements.

Methods

The team developed a process to guide clinical study teams through the identification of CCI in clinical trial documents. The main challenges and lessons learned based on the experience gathered from 11 development programmes over an 18-month period are presented.

Results

The assessment of what constitutes CCI requires a case-by-case analysis and depends on the stage of the clinical development program (and medicinal product). The Medical Writer's perspective of document development helps direct study teams to minimise the number of redacted concepts, which can evolve over time. Commercially confidential information requires robust rationale to provide a case for supporting its redaction.

Conclusions

Identification of CCI at document conception, and engagement and collaboration of cross- functional teams led by Medical Writers are key to a successful outcome. These practices expedite the redaction process and highlight, and potentially minimise, the level of CCI at the earliest opportunity.

P4 Working across therapeutic areas – boon or a challenge for MWs?

Reema B Acharya – Johnson & Johnson
Anne Madalijns – Johnson & Johnson

Introduction

Specialisation in "document writing" versus a "Therapeutic Area (TA)" has been a debatable topic within Medical Writing. A growing trend of working across TAs is widening the horizons for MWs and helping them stay relevant within the industry. However, reluctance to work across TAs within the MW community still exists. Hence, we decided to dive deep on this topic.

Methods

Informal chats and formal surveys targeted regulatory MWs at different career levels in different settings to seek out the benefits versus hurdles of working across TAs and the skills required to succeed.

Results

- Survey revealed that it's challenging to work across TAs, especially early in career. MWs like the familiarity and safety of the known topic/TA knowledge, teams, and environment.
- TA knowledge is not a must but an added advantage.
- Many MWs noted that working across TAs is rewarding and becomes easier as one gains experience and is a career booster.
- Few noted that MWs can quickly deepen and widen experience by working across TAs but requires extra effort.
- Agility, adaptability, critical-creative thinking, researching ability, influencing skills and a continuous learning mindset complimentary to strong writing proficiency, inter-disciplinary communication, and scientific literacy are required to excel as a cross-TA writer.

Conclusions

MWs are writing experts. Specific transferable skillsets help MWs to excel in a cross-TA environment and stay relevant. Though it may not be difficult for skilled MWs to utilise transferable skills across TAs, few like the comfort of the known and tested, while many are embracing the diversity and challenge.

P5 Turning waterfalls into swirls – can regulatory MW transform into agile MW?

Katharina Brauburger – Merck Healthcare KGaA
Michael Breunig – BMW Group

Introduction

Agile working practices were developed for the incremental development and deployment of products. The agile mindset allows a rapid and flexible response to change, often required for frequently changing product needs. We wanted to know if and how agile practices can be applied during clinical drug development, focusing on document preparation processes, to enhance collaboration, quality, and process efficiency.

Methods

We combined a scientific literature search to collect recent published experience and examples for agile practices in document authoring, and compared those results to agile methodology in general and our own experience in document authoring to identify how existing processes can be improved by agile practices. We also evaluated if agile concepts are already followed during document authoring.

Results

Few real-life-examples for agile document authoring have been published; some in the context of Covid-19 vaccines development and the corresponding challenges including short timelines and changing requirements. Agile (medical) writing requires a dedicated and well- defined team including writers and content contributors. This team should be empowered and self-organised using shared agile methods. We compiled an overview of real-life examples for agile practices related to clinical document authoring and show an example workflow for agile Briefing Book authoring.

Conclusions

Some sponsors and CROs tried to implement agile practices for circumstances requiring rapid adaptation to change. Agile practices might be easy to implement during the preparation of documents that are not strictly regulated, while modified agile practices can still be implemented when preparing more rigidly structured and tightly regulated documents.

P7 Growing role of regulatory medical writers in driving and optimising submissions

Anne Madalijns – Johnson & Johnson
Reema Bardhan Acharya – Johnson & Johnson

Introduction

The role of medical writers (MWs) has evolved over the past decades from merely being scribes to "submission strategists". In today's world, MWs play a major role in driving and optimising submissions. MWs contribute increasingly and creatively towards forging efficiencies through several innovative approaches. These creative approaches foster a collaborative environment, enhance communication, and streamline writing and review processes, ultimately contributing to more efficient and successful submissions.

Methods

We collected insights from experienced MWs about their role in driving teams toward successful submissions and developing and promoting innovative approaches to optimise future submissions.

Results

The collected findings illustrate the significant role of MWs in developing and optimising submissions through the creation and implementation of innovative strategies, such as:

- Optimised document development and delivery through early engagement, cross- functional collaborations, and strategic thinking.
- Development and implementation of efficient project management tools and resourcing strategies.
- Adaptive writing strategies, including lean writing, and risk assessment and mitigation strategies.
- Creative approaches to collaborative authoring and review leveraging technology.
- Facilitating a streamlined process to deliver high-quality documents and promote efficient and accelerated working methods.
- Focusing on continuous improvement initiatives, continually refining processes, identifying areas for improvement, and enhancing efficiency in future submissions.
- Developing and providing training to writers and cross-functional teams to ensure quality and compliance, and to promote effective teamwork.

Conclusions

MWs combine scientific and operational expertise with strategic contributions, leadership, and successful partnering with cross-functional stakeholders, and, as such, play a critical and fundamental role in driving teams toward successful submissions.

P8 The trends of ChatGPT usage in medical writing: Results from a KAP

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Introduction

Disruptive technologies that increase efficiency while saving time are continually explored by medical writers and the large language model (LLM) ChatGPT (Generative Pre-trained Transformer) is no exception. Despite several publications on ChatGPT, the trends of ChatGPT usage in the medical writing field are unknown.

Methods

We conducted an online survey to understand the knowledge, attitude, and practices of professionals in medical and scientific writing regarding ChatGPT usage; and performed a two- step cluster analysis to assess the attitude and practice patterns.

Results

A total of 106 respondents from 21 countries took the survey. Most respondents were females (65.1%), aged 25-44 years (71.6%), with a doctoral degree (45.3%), from the medical communications sector (54.7%), with 1-5 years of experience (47.2%), and of Indian origin (61.3%). Some of them have a professional certification (17.9%), are members of any professional organisation (28.3%), and have received formal training in medical writing or medical communications (34.0%). Almost half of them (45.3%) have experience using artificial intelligence (AI)-powered tools for medical communications. Most respondents had intermediate knowledge about ChatGPT. An exploratory analysis distributed the respondents based on attitude into three clusters of 8.5%, 25.5%, and 66.0% respondents; and based on practice patterns into two clusters of 39.0% and 61.0% respondents. Members of professional organisation had similar attitudes towards ChatGPT. Respondents using other AI tools had similar practice patterns.

Conclusions

Working knowledge of ChatGPT along with membership of professional organisations or prior use of AI-tools may influence the acceptance of ChatGPT by medical writers.

P9 Analysis of adverse events in early phase trials. A medical writing perspective.

Mădălina Nistor – ICON plc
Mauro Meloni – ICON plc
Rona Grunspan – ICON plc
Sara Fernandes – ICON plc
Joanna Lesiak – ICON plc

Introduction

Despite the low risk of severe harm in Phase 1 studies, accurate collection, reporting, and transcription of safety remains a priority. This analysis aims to provide a context for safety reporting in Phase 1 studies, from a medical writing perspective.

Methods

Safety data from 16 studies conducted in Europe between January and December 2023 were collected and analysed descriptively.

Results

A total of 648 participants were included in the analysis. Of those, 370 experienced 928 adverse events (AEs). The majority of the AEs were mild, and were experienced by 374 participants; 265 (71.6%) participants had AEs considered related to the study drug. Two SAEs (one mild and one severe) not related to the study drug were reported by 2 (0.5%) participants. No deaths were reported. The most commonly occurring AEs were nervous system disorders (headache), general disorders and administration site conditions (fatigue), and gastrointestinal disorders (diarrhoea).

Conclusions

Most of the AEs were mild and the 2 SAEs reported were not related to the study drugs, suggesting that Phase 1 studies do not pose great risk. This analysis contributes to the knowledge of risk stratification for interpretation of safety data and facilitates a comprehensive approach for safety reporting of early phase studies.

P10 Exploring the awareness and perceived utility of graphical abstracts in scientific publishing

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Introduction

Graphical abstracts (GAs) offer several benefits in scholarly publishing, including improving accessibility to research.1,2,3 Nevertheless, uptake varies across disciplines and is still relatively low – likely resulting from a lack of awareness of GAs and their potential benefits among authors and audiences.

Methods

To better understand the awareness and perceived usefulness of GAs, we conducted an online survey among individuals who are/have been involved in scientific publishing.

Results

Of 73 respondents, most were aware of the potential benefits of GAs (72.6%) and "agreed/strongly agreed" that they are beneficial (86.3%). Furthermore, 42.5% had previously published ≥2 GAs and found them useful, while 28.8% had not published any but planned to in the future. Most respondents (76.6%) found GAs useful at "facilitating the understanding of research", 69.6% of whom also found "improving accessibility to research" and "promoting research" important. "Necessity" was the predominant deciding factor among those in decision-making positions (40.9%), and 56.2% of respondents thought more/stronger evidence about the benefits of GAs would make them more likely to publish one. Most respondents (83.6%) had working knowledge of graphic design tools (Canva [28.8%], Adobe Illustrator [24.7%], Biorender [19.2%] and artificial intelligence (AI) [6.8%]), with 56.2% "agreeing/strongly agreeing" that AI tools could make it easier to create GAs

Conclusions

Awareness of GAs was high, and their use was perceived as mostly beneficial among individuals involved in scientific publishing. Necessity was highlighted as an important deciding factor to publish a GA, with more/stronger evidence of their benefits likely to drive uptake.

P13 Preparation is key to success: Use of the document content and messaging summary (DCAMS) in authoring regulatory submission documents

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Richard Grant – PTC Therapeutics, Inc.
Laura Hunter – PTC Therapeutics, Inc.
Jonathon Kaiser – PTC Therapeutics, Inc.
Dara Goldberg-Spar – PTC Therapeutics, Inc.

Introduction

Appropriate planning of content and messaging ahead of the writing stage of a submission document is essential to ensure strategic alignment with key stakeholders and streamline document development. Early alignment on messaging reduces late-breaking critical comments and prevents the need for significant rework, that can add additional reviews and delay document finalisation.

Here, we present our Document Content and Messaging Summary (DCAMS) for regulatory submission documents and how use can facilitate team alignment, engage stakeholders, and improve efficiency.

Methods

A DCAMS is a short tabular document that identifies key messaging, supportive data, and possible risks. This living document should be developed prior to authoring the intended document and undergo review cycles, and therefore, should be built into the overall timelines.

Results

Use of a DCAMS was well received by senior reviewers as a proactive time-saving approach that reduced reviewer burden during critical periods. We found it effectively facilitated discussion to allow the larger team to agree on the messaging, content, and data of the individual document prior to authoring. It also served as a concise summary for key stakeholders to review the team's plan, ensuring early agreement for the individual document. Critically, we observed it provided writers with a clear direction for efficient document development

Conclusions

While adding time for strategic development before document authoring begins may be a hard sell, the DCAMS has proven to be an effective tool for alignment within the team and management, ultimately saving time overall and smoothing the authoring and review processes.

P15 Maximising quality control review of regulatory documents

Patrick Barry – Head of Europe, Acumen Medical Communications
Kelly Danyow – Sr Director of Editorial Services, Acumen Medical Communications
Jamie Spagnuolo – Lead Editor, Acumen Medical Communications

Introduction
Quality control (QC) is often the "last line of defence" in regulatory documents prior to submission. The expectation is that all errors will be identified and corrected during this review, often saving from costly rework. However, this step is often rushed or overlooked due to compressed timelines and other confounding factors. So how does one ensure a quality review?

Methods
N/A

Results
Our process starts with educating the writer, focuses on communication throughout, and ends with closing the loop with any feedback to the QC reviewer and/or document owner. This submission will discuss maximising quality control output through process and best practices for industry.

Conclusions
QC in regulatory documentation is crucial. Follow these steps to improve your team outputs.

P16 An attempt to translate estimands into plain language

Ulrike Fischer
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Maarten van Dijk

Introduction
The estimand is a detailed description of an outcome measure assessing the treatment effect. The concept of estimands was formally introduced with the ICH E9 (R1) addendum and is part of the ICH M11 and the TransCelerate templates. Consequently, estimands are increasingly incorporated in clinical trial documents, especially in pivotal trials. While trial team members currently struggle to understand the concept and language of estimands, the EUCTR Clause 39 mandates the submission of a summary of results, including trial objectives, understandable to the layperson.

We sought to bridge the gap between the highly technical estimand language and plain language requirements by translating the 5 attributes and 5 strategies for intercurrent event handling into plain language, using published trials.

We aimed to provide these examples to medical writers, who play a pivotal role in managing and writing important clinical trial documents and to enable them to efficiently communicate the 5 attributes and 5 strategies to trial teams and the lay public.

Methods
We searched clinicaltrials.gov for trials with defined estimands and publicly available protocols. We extracted the primary estimands, their attributes and strategies for intercurrent event handling and tabulated them. We subsequently translated each of the 5 attributes and strategies into plain language and compared the translations of different trials to identify similarities and to generalise.

Results
We selected diverse trial examples with clearly defined estimand attributes. Based on these trials, we propose guidance on how to interpret and translate estimands into plain language suitable for a lay audience.

P19 Plain language summaries created with artificial intelligence – Can it save time or waste it?

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Seyma Öztürk – working student, Staburo GmbH
Sandra Martin – Disclosure manager/ statistician, Staburo GmbH

Introduction

Plain language summaries (PLS) are currently a requirement to accompany the summary of clinical trial results submissions according to the European Union Clinical Trials Regulation (EU CTR) 536/2014 Annex V. They aim to contribute to more transparency for people interested in learning about clinical study results, especially for those without medical background.

Artificial intelligence (AI) tools are fast evolving and play an increasingly important role in many fields, including healthcare and medicine. In medical writing (MW), AI could become a powerful tool to increase speed and efficiency in creating outputs, however legitimate concerns arise as to whether it could overtake medical writers in the future. A recent publication describes the creation of 50,000 PLS solely with AI tools (D). But can AI generate text with the same quality as written by an (experienced) Medical Writer, especially regarding correct interpretation of study results and requirements of lay language?

Methods

To find out, we will

- Analyse completeness, correctness, comprehensibility, and design of PLSs created from clinicaltrials.gov information by AI (using a checklist). Create PLSs with an AI tool using study synopses and perform a MW review to improve quality.
- Find the best balance in terms of PLS quality and MW working time between AI- created, MW-created, and AI-created + review by MW PLSs.
- Compare comprehensibility of AI vs MW-created PLSs in a group of lay persons (using questionnaire).

Results and conclusions

We expect that AI will help MWs to create PLSs faster but may not replace a MW's work completely.

P20 Videocast(s): Are they worth the effort as a digital enhancement?

Vandana Chaudhary – Director (Medical affairs & Publications), Rhodocyon Health

Introduction

Scientific content creators/viewers were surveyed to comprehend the practical challenges, measures to increase impact, and worthiness of videocast(s) as a digital enhancement.

Methods

An online 38-question survey spread was conducted (30 August-06 February 2024) via LinkedIn's medical and academic communities, involving scientific professionals from publishing and pharmaceutical sectors. 'Content Creators' and "Content Viewers" were focussed based on their exposure to videocast(s) and were queried regarding the challenges encountered in creating or viewing videocast(s).

Results

Respondents from USA, UK, Europe, Asia, North America, and Canada (n=42) participated, all of whom were adults: 52.4% (18- 40 years), 40.5% (40-60 years), and 7.1% (>60 years).

Though, only 19% respondents (8/42) by profession were creators of videocast(s), 88.1% (37/42) occasionally watched videocast(s) in some or the other form. Key creation challenges included budgeting for additional in-house digital enhancements versus the publisher/journal services, resource allocation during review/approval process, and quality of output. Despite these challenges, 62.5% of content creators (5/8) found audience engagement non-challenging. Content viewers preferred interactive formats (67.6%; 23/34), ranked videocast(s) to be informative and above 4 on a scale of 1- 5 (70.6%; 24/34), of good quality (82.4%; 28/34) and engaging (47.1%; 16/34). Personalised curated playlists (82.4%; 28/34) and subtitles (94.1%; 32/34) enhanced discoverability and comprehension with open access, short duration, infographic/animated format(s) being other suggested key measures. Overall, 81% respondents (34/42) believed that videocasts tend to expand the reach of main theme.

Conclusions

Majority of the respondents endorsed videocast(s) as a digital augmentation to widen the reach of scientific research.

P21 The art and science of medical writing amidst technological innovations

Vandana Chaudhary – Director (Medical affairs & Publications), Rhodocyon Health

Introduction

The landscape of medical writing is reshaping on a very fast pace due to synergism between human intelligence and spearhead technological innovations, particularly artificial intelligence (AI). The emergence of AI prompted us to do a critical examination of its impact on the complex but creative art of medical writing.

Methods

PubMed and other scholarly databases were reviewed (Jan 2000-Dec 2023) to understand the impact of AI on medical writing.

Results

While the efficiencies laid forth by AI are irrefutable, the indispensable value of human intellect cannot be ignored. Recent position statements on AI emphasise the ethical considerations and collaborative approaches essential for accountable utilisation of AI's potential. As per a literature search done on PubMed with keywords "AI" AND "publications", a steady annual increase of AIassisted publications has been observed. Medical writers are currently adapting to the shifting paradigm as outlined in position statements by ICMJE, ISMPP, and GPP regarding the call to action on AI. The inquisitiveness extends beyond theory to practicality, paving the path for strategic integration of AI tools into medical writing workflows. Through collaborations and case studies, ethical ways are being identified to synergise with AI to enhance efficiency in order to concentrate on aspects requiring nuanced human interpretation

Conclusions

The future of medical writing envisions an ethical equilibrium between the art and science of the profession with AI's transformative potential. The abstract urges a shared reflection amongst medical writers on steering through this evolving landscape while prioritising human intellect at the forefront.

P22 Enhancing patient-centricity in medical writing: the art and science of effective plain language summaries

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Dr Sonica Batra – MD, DNB. Indegene Ltd, Bangalore, India

Introduction

Patient-centricity has emerged as a pivotal concept in healthcare, emphasising the importance of prioritising patients' needs, preferences, and perspectives. In the realm of medical writing, particularly in the creation of plain language summaries, this principle plays a crucial role in ensuring that healthcare information is accessible, understandable, and empowering for patients. This presentation aims to explore strategies for enhancing patient-centricity in medical writing, focusing specifically on the art of crafting effective plain language summaries.

Methods

To explore actionable strategies for writing effective plain language summaries, a comprehensive review of literature on plain language summaries was conducted. Case studies and examples of successful plain language summaries, examining their structure, content, and impact were analysed. In addition, practical insights and strategies for developing impactful plain language summaries were identified through interviews and consultation(s) with patients, patient advocates and our medical writing experts.

Results

The research revealed the significance of the following essentials:

- Understanding patient perspectives to tailor language and content accordingly.
- Translating technical jargon and scientific concepts into layman terms without sacrificing accuracy or depth.
- Leveraging visuals and infographic elements to enhance comprehension and engagement.
- Considering factors such as language proficiency, health literacy, and cultural sensitivities to make summaries accessible to diverse patient populations.

Conclusions

Plain language summaries serve as vital tools for conveying complex medical information in a clear and comprehensible manner. Effective plain language summaries can bridge the communication gap between healthcare providers, researchers, and patients, ultimately fostering greater patient empowerment, engagement, and adherence to treatment plans.

P23 Quantifying sex bias in randomised clinical trials of major impact publications

Irene Mansilla – TFS HealthScience, Department of Medical Writing, Barcelona – Spain
Alina Gavrus – Ion TFS HealthScience, Department of Medical Writing, Barcelona, Spain
Anaïs EstradaGelonch – TFS HealthScience, Department of Medical Writing, Barcelona, Spain
Marta Mas – TFS HealthScience, Department of Medical Writing, Barcelona, Spain

Introduction

This study aimed to examine sex bias in randomised clinical trials (RCT) published in main scientific journals.

Methods

Three journals were chosen based on their 2021 impact factor (IF): New England Journal of Medicine, Lancet and Journal of the American Medical Association, including those specialised in areas in which sex differences had been documented previously (general/internal medicine, cardiac/cardiovascular systems, infectious diseases, and oncology). A PubMed search was performed to locate RCTs published in English during 2022. Sex-specific and paediatric studies were excluded. Information about first author's sex, absolute number of men and women enrolled, and diagnosis were collected. First author's sex was determined by name's inspection or with Internet searching, if ambiguous. All information was analysed by Microsoft Excel.

Results

PubMed search resulted in 517 articles; a sample of 150 RCTs were selected by randomisation. Twenty-nine were excluded and 121 articles were analysed. Globally, there were more men than women enrolled in RCTs (53% vs 47%). In 79% of the articles the first author was men.

First women author did not include more women than men (49% vs 51%). When considering only phase III RCTs (53%), more women than men were enrolled (55% vs 45%). Regarding treatment areas, women were clearly underestimated in cardiac and cardiovascular systems (35% vs 65%) possibly due to the prevalence of these diseases.

Conclusions

In the selected sample of articles in high IF journals, women were represented in almost the same proportion as men, so the historical sex bias is being redressed.

P25 Master Protocols: Implementing innovation in an evolving field

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Introduction

Master protocols are being proposed as a way to expedite drug development across therapeutic areas. These studies are highly complex and pose challenges for medical writers and subject matter experts. Currently, there are no standard protocol templates for different types of master protocols (e.g., umbrella, platform, basket), and consultations are ongoing among Health Authorities, Sponsors, Clinical Research Organisations, and professional associations to maximise their benefits and provide guidance on their execution.

Methods

To develop a master protocol, we are holding discussions with our stakeholders to accelerate the development of a novel drug while maintaining our scientific, medical, and statistical standards and ensuring patients' safety. We are considering best-practice recommendations and Health Authority guidance, including the recent FDA draft guidance on umbrella and platform studies, previous FDA guidance on basket protocols in oncology, and EMA guidelines, as well as initiatives by EU-PEARL and TransCelerate.

Results

In this evolving landscape, the Medical Writers and the Regulatory Affairs counterparts are playing a crucial role in guiding and leading multifunctional teams to structure the protocols and incorporate the flexibility for adaptive designs that the study team requires. At the conference, we will provide information on our experience and decision process following the state-of-the-art guidance and the potential protocol designs that best suited our case scenario.

Conclusions

Overall, master protocols offer opportunities for expediting drug development, but their successful implementation requires careful planning and strong collaboration with and early involvement of internal and external stakeholders.