Abstracts from the 59th EMWA Conference Poster Session

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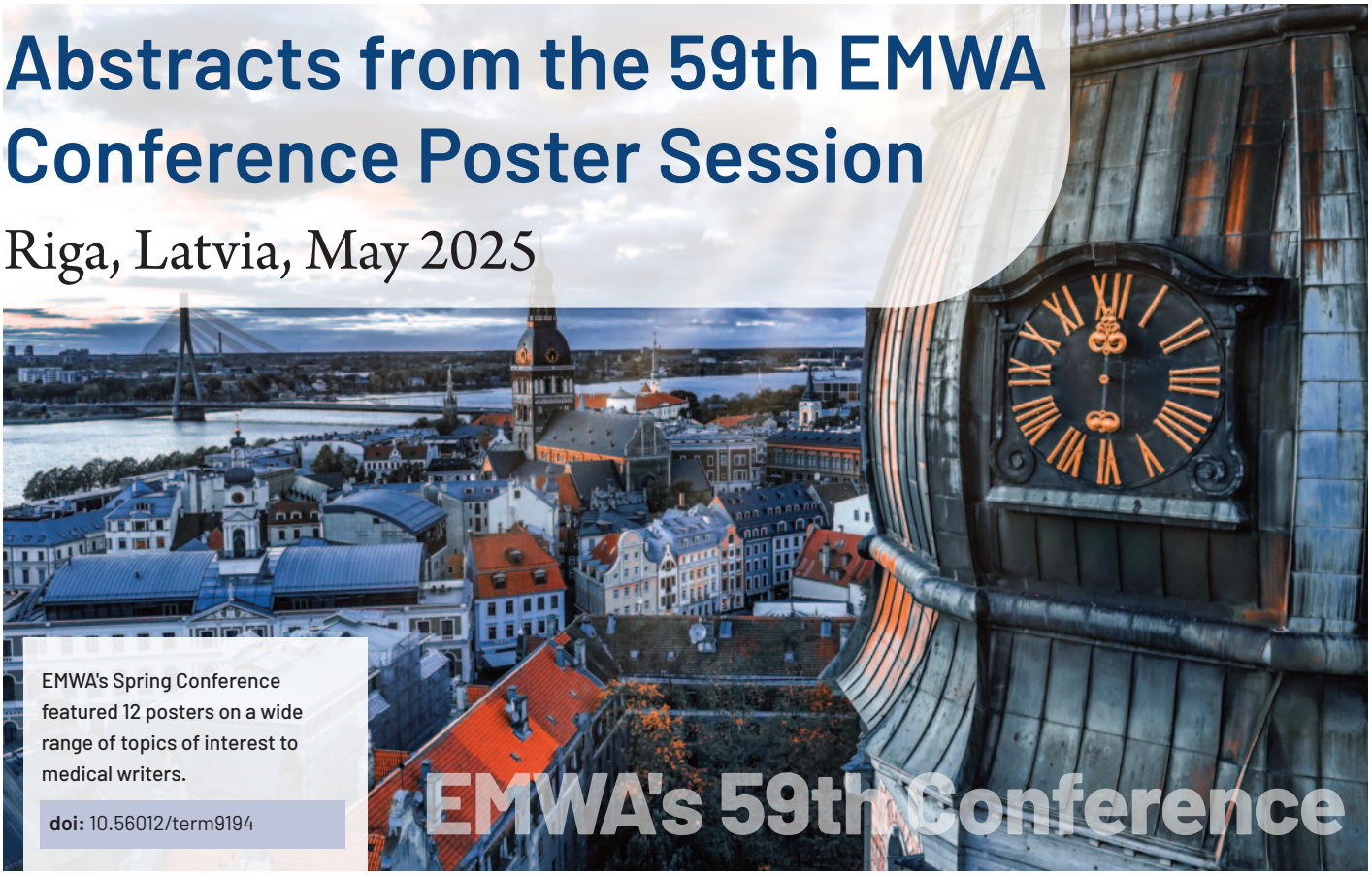

EMWA's Spring Conference featured 12 posters on a wide range of topics of interest to medical writers.

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

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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

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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.

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

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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.

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

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Richard Baker – Align Technology
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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

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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

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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

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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

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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

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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.

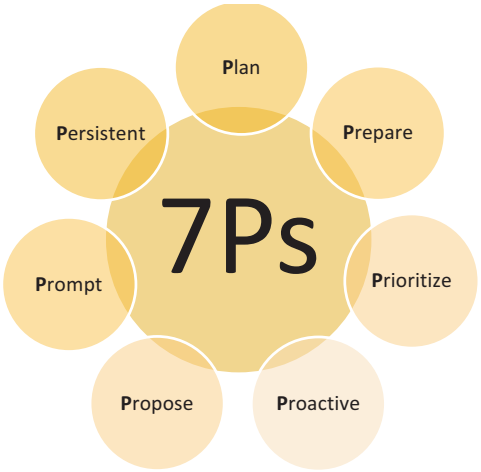

Figure 2. The 7Ps of Medical Writing

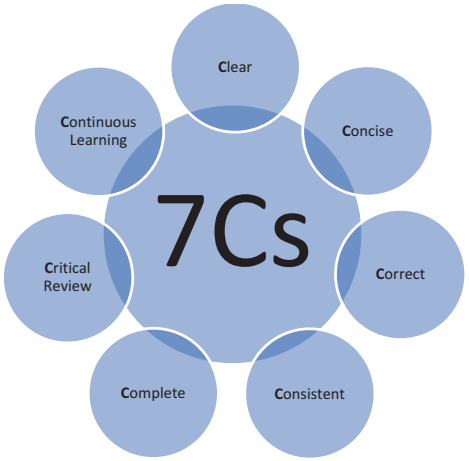

Figure 3. The 7Cs of Medical Writing

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

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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

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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

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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.