Abstracts from 44th EMWA conference Poster session

At this year's Spring Conference in Birmingham, UK, EMWA held its second annual poster session. Six poster presentations were selected from abstracts submitted to the Educational Committee. Abstracts could be on any subject related to medical writing or of relevance to medical writers. The poster session is an excellent way for EMWA members to see the latest thinking and research in a "snapshot", and has been introduced as an annual addition to the educational offering from EMWA. Entry to the poster session is included in the conference registration fee.

SECTION EDITOR

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P1 - EMA Policy 0070: Perspectives on today's implementation and the expectations for future implementation

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Introduction: European Medicines Agency (EMA) Policy 0070 requires regulatory documents submitted as a part of a Marketing Authorisation Application (MAA) as of 01 January 2015 to be made public. Sponsors must anonymise these documents prior to publication. Anonymisation is the act of altering the text so that individuals (patients and study administrators) cannot be personally identified.

Methods: The pharmaceutical industry has experience utilising various anonymisation techniques to de-identify data sets, but has limited experience using these techniques on unstructured data or text based documents. Given this and the fact that anonymisation is being conducted retrospectively on documents that were written prior to publication of Policy 0070, most sponsors are relying upon an anonymisation technique called redaction. This technique requires replacing personally identifying information with shaded boxes.

Results: This method can effectively protect privacy, but it limits data utility – the EMA's primary purposes for publishing these documents. With each submission, sponsors must provide an anonymisation report explaining their anonymisation methods and how data utility was maintained.

I have overseen the preparation of 4,000+ redacted documents. In the past year, I have supported the preparation of 10+ submissions for Policy 0070. I am able to present the challenges with the redaction technique, the challenges created by the anonymization report, and thoughts on the future direction of Policy 0070.

Conclusions: Policy 0070 created a new era in clinical trial transparency. The current method of meeting this requirement is thorough redaction. There are challenges with this technique and balancing data utility, but future innovations will create options for other techniques.

P2 - Orphan drug development: The regulatory writer's role in paving the road to approval

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Introduction: Pharmaceutical companies have increasing interest in pursuing development of treatments for rare diseases. Regulatory agencies across the world have offered incentives to encourage drug development for orphan diseases. While most of the same extensive documentation is required as for more common disease treatments, there are additional regulatory processes and document requirements unique to orphan drug development. Regulatory writing is required throughout the process to build the evidence supporting eventual approval of drugs for rare diseases.

Methods: Currently approved documentation and guidance for orphan drug development will be reviewed and summarised. Agency requirements will be compared between the EU and US. Case studies will be identified and presented to provide examples of specific types of challenges.

Results: Unique documentation is required for orphan drug development, from designation of orphan drug status through submission of the regulatory application to agencies. Issues specific to development of rare diseases are known and can be addressed. Similarities and differences between the EU and US will be highlighted.

Conclusions: Developing drugs for the treatment of rare diseases presents a unique set of challenges. The regulatory writer is an integral component of the cross functional development team, providing strategic input and high quality documentation that supports the demonstration of effectiveness and safety required for orphan drug approval.

P3 - Creation of patient-centric patient lay summary in the local language

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Introduction:
Prior to this project, no patient lay summary (PLS) had ever been developed locally in Japan. Although we had distributed PLSs for two clinical studies, they were originally written in English and translated into Japanese. In order to create a PLS that is more tailored to local patients, we attempted to develop a PLS in Japanese from scratch for the first time in Japan. We will introduce how we developed a PLS, along with the lessons learned during the process.

Methods: We formed two teams: one was for drafting a PLS, and the other for researching and developing a template and patients communication.

A PLS was drafted based on disclosed information including Basic Results. We took a composite approach in refining the PLS by researching lay language and patient-friendly design, ensuring scientific accuracy with experts such as physicians and statisticians, conducting due diligence on regulatory and legal aspect, and incorporating patients' voice by consulting with a local patient advocacy group.

Results: The locally-developed PLS was more patient-centric in language, content and design as well as non-promotional. Our attempt also resulted in a patient-friendly template with default text in Japanese as well as a process document, though some issues still remain to be solved. The PLS was posted on a public website with access limited to study participants.

Conclusion: We successfully created a PLS in the Japanese language for the first time in Japan. The locally-developed PLS was more patient-centric than those translated from another language.

P4 - Medical writing services – review of the selection criteria

Paneet Nand, PHASTAR

Introduction: Outsourcing activities have increased over the last two decades and recent analyses suggest the Contract Research Organisation (CRO) market will grow at an annual rate of 9.83% between 2014 and 2019. In parallel, there is an increased demand for experienced medical writers, but do companies actually know what they are getting when selecting a medical writing service provider? If companies go down the route of selecting a service provider, rather than a freelancer, what attributes qualify and which are considered to be most important? Do these same attributes apply to a freelance writer? This review analyses some of the challenging attributes a service provider may or should consider when prospecting a new client.

Methodology: We selected pharmaceutical and biotech companies that had various R&D expenditure to compare the typical criteria used for evaluating medical writing service providers between high- and low-spending companies.

Results: Fifty-two companies provided information regarding what evidence they would expect to see regarding capability. The results were broken down into seven categories, presenting results in which large pharmaceutical companies followed a strict approach for their selection process; a process where capability focused more than just experience and qualifications.

Conclusion: Many service providers miss and perhaps overlook many aspects of a criteria used by large or small pharmaceutical/biotech companies. Meticulous and rigorous methods are in place, therefore service providers should be detailing and organising the evidence needed to provide assurance for a potential client.

P5 - Commitment to data sharing by pharmaceutical companies: The evolving environment

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Introduction: With requirements for data transparency becoming more extensive, we assessed the status of responsible clinical trial (CT) data sharing by European Federation of Pharmaceutical Industries and Associations (EFPIA) member and non-member companies.

Methods: EFPIA membership was determined for the top 50 pharmaceutical companies by 2014 global sales (EvaluatePharma). Public global company websites were searched in August 2016 using the terms "EFPIA", "data sharing", "clinical trials" and "transparency". If no relevant results were obtained, websites were searched manually for statements relating to CT data sharing and EFPIA compliance.

Results: Of the top 50 companies, 27 were EFPIA members (including three affiliates). A CT data sharing policy was found on all EFPIA member and 4/23 non-member websites, with an explicit reference to EFPIA principles found for 22/27 members and 1/23 non-members. References to all five EFPIA principles were found for 15/27 members and 1/23 non-

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members. For EFPIA members and non-members, respectively, references to sharing CT data with researchers were found for 25/27 and 2/23 companies, making Clinical Study Report (CSR) synopses publicly available for 23/27 and 1/23, making CT results available to trial participants for 24/27 and 1/23, publicly certifying the adoption of EFPIA commitments for 26/27 and 1/23, and committing to the publication of CT data for 26/27 and 3/23.

Conclusions: The majority of pharmaceutical companies investigated have publicly committed to responsible CT data sharing. All EFPIA members have made such commitments compared with few non-members.

P6 - Ladles and jellyspoons: involving children and young people in the assessment of informed assent and consent form comprehension

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Introduction: Writing for lay audiences is recognised as a particular skill in clinical research. However, no matter how experienced the writer, the real experts in lay writing are considered to be the target audience. Listening to patients has been at the heart of GW Pharmaceutical's (GW's) research efforts since the company was founded. In line with this ethos, we sought the opinions of children and young people regarding our informed assent form (IAF) and consent form (ICF) templates.

Methods: Using published best practice techniques regarding formatting and writing style of patient information sheets, we redesigned GW's clinical trial IAF and ICF templates, focussing on overall readability whilst still ensuring compliance with ICH GCP. We consulted experts in the understanding of how children interpret clinical trial information at the Young Person's Advisory Group (YPAG) at the NIHR Alder Hey Clinical Research Facility; requesting their assessment of the overall comprehension of the templates (i.e., format, clarity, readability).

Results: Two IAFs written for children with chronic and debilitating conditions, and one ICF written for parents were assessed. Overall the feedback from YPAG was positive and the templates were considered easy for children to understand. However, guidance was provided regarding design and imagery used in the IAFs, as well as pointing out unnecessary repetition within the ICF. The templates were adjusted accordingly.

Conclusions: Best practice alone is not sufficient when writing clinical trial information for lay audiences. The involvement of lay groups is recommended during trial development to ensure material is fit for purpose.

The daily life of a medical writer in medical devices

A Monday morning

8:55am: red light, keycard, the door clicks, I open it and my dog trots up the stairs. I follow her up and through the common area to my office where she's greeting an officemate who's just back from an off-the-grid holiday in the Balkans. He has his 2-year-old daughter with him because the day-sitter is at the dentist until 9:30. I turn on my computer, put the dog's blanket on the floor, fill her water bowl, and make myself a bowl of muesli from my muesli stash. Back up to the office, my two other officemates have arrived. I log in to my computer and have to change my expired password. The just-back-from-holiday officemate has given me two cans of beer. We have a tradition where we bring each other back local beer and/or wine from our travels. I was in Italy over the weekend so there's a bottle of artisanal Italian beer on his desk from me. I'll be in Bavaria this week, I'll get him something to redress the imbalance. The dog has finished

silently greeting the other officemates and has lay down. The tail is now at rest.

Eight or nine emails: trip reports, company announcements. 1 piece of junk mail. I turn my attention to the immediately relevant: feedback from a Powerpoint presentation I made for some authors. I had sent it to the representative of our company on Wednesday. She's the contact person between me at headquarters and the surgeons at the clinics. I work through the feedback/questions (probably from the surgeon) which strike me as foolish; I'm irritated to have worked hard to make the presentation on their data then have them ask me questions that are the result of having given it only a cursory reading. What other emails? The statistician resolved an issue, good. Something else I can address later; an invitation to an e-learning. I write a testy email to the contact person, hesitate, soften it a bit but don't send it. I complain to my officemate. I get a coffee and return to the office. Other co-workers