Transparency of clinical trial data – where does medical writing fit in?

2nd EMWA Symposium

Thursday 15 May 2014
Hilton Hotel, Budapest
Hungary

With the participation of the European Medicines Agency
Transparency of clinical trial data – where does medical writing fit in?

Clinical trial disclosure and ‘Transparency of clinical trial data’ are terms familiar to those working on documentation for clinical trials and peer-reviewed publications based on clinical trials. These terms represent requirements imposed by law that demand greater transparency of drug development. Regardless of the sponsor, details of trial protocols and results disclosure of completed studies must be made available on a publicly accessible Internet site. These are independent and legally-binding requirements made by the USA, EU, and several countries worldwide. The topic is evolving fast, with transparency of clinical trial information taking on new dimensions, including demands seeking the release of clinical trial participant-level data in a format that can be used to re-evaluate the data by independent external experts. It is not yet clear how – and how far – this will affect medical writers. This symposium will explore in depth the immediate and future implications for medical writing.

Morning

09:30 - 09:40 Welcome and Introduction

09:40 - 10:20 The Medical Writer's Perspective
Kathy B. Thomas, Independent medical writing consultant, Meersburg, Germany

This presentation will focus on introducing the topic of Clinical Trial Disclosure, highlighting the role of medical writers in this area. A brief summary will be made of the requirements for Clinical Trial Disclosure in the USA and especially in the EU, where this topic is the subject of a great deal of activity at present. Registration of clinical study protocols for new and ongoing studies and disclosure of results for completed studies will be clarified for these two geographic regions.

Medical writers have the best skills to prepare documents based on information from clinical studies. The documents include study protocols, patient information, study results, lay language summaries of study results, and peer-review publications of clinical studies. Medical writers are well aware of the internal and external partners who are in the supply chain of information for these documents. Thus, medical writers play an essential gate-keeping role to ensure clarity as well as consistency and alignment across all documents that are based on information from clinical studies. Furthermore, medical writers with their knowledge of document structures are eminently suitable to ensure that retrospective clinical studies, which also fall under the legislation, are presented in a compliant manner for transparent and consistent sharing of information on public databases, while respecting the relevant privacy laws.

10:25 - 11:00 The European Medicines Agency Perspective
A speaker from the EMA has been confirmed and will also be acting as a panel member throughout the day.

11:00 - 11:20 Panel discussion

11:20 - 11:40 Coffee and refreshments

11:40 - 12:20 The Industry Perspective
Hans-Jürgen Lomp, Global Head of Statistics, Boehringer Ingelheim, Germany; Co-Chair of the Boehringer Ingelheim Transparency Initiative

The presentation will focus on the (already available) options to gain access to analysable patient-level clinical trial data for any well-justified research proposals. This will allow interested professional researchers from academia and competitor companies to verify the original sponsor analysis as well as to perform secondary analysis - at the trial level, across-trial level and even across-project level. The necessary framework and the challenges in setting up this
new opportunity will be presented. Using existing examples of secondary research proposals, we will discuss the potential impact of the expected “wave” of secondary analysis. One key topic is that standards for Good Statistical Practice and Good Document Writing Practice for such secondary research have not been agreed upon. Another topic is the impact on document writing standards for the original clinical documents, which now will have a potentially broader audience than just regulatory reviewers.

12:20 - 12:40  Panel discussion
12:45 - 14:00  Lunch

Afternoon Session

Moderator: Kathy B. Thomas

14:00 - 14:10  Introduction
14:10 - 14:45  The Association Perspective
Susan Forda, Vice-President, Global Regulatory Affairs International, Lilly UK, European Federation of Pharmaceutical Industries and Associations

The area of transparency of clinical trial data is currently under review by regulators worldwide and it is not clear what the industry can expect from the final EMA policy on ‘publication and access to clinical trial data’ to be issued in March 2014. This presentation will cover the industry response to the final EMA policy, guidance on how to interpret and implement the requirements in the context of industry-generated initiatives, and how medical writers might be involved in this process.

14:45 - 15:05  Panel discussion

15:10 - 15:45  The Patient Perspective
Transparency and beyond - the changing role of the patient
David Gilbert, Co-Chair, Centre for Patient Leadership, London, England

Consumer expectations have helped fuel recent moves towards disclosure of data, including patients having access to their own medical records and receiving high quality evidence-based information about treatment options. But, in the patient’s relationship with medical professionals, regulators and policy making, the patient is still viewed as a passive recipient of information, rather than as an equal partner in health care decision making. Drawing on recent work in the UK that sees patients as leaders - people who seek to influence change by working in partnership with professionals - David will explore the role of the patient in the changing health care policy environment. By shifting the debate, he will outline some possible future roles for patients, within their own individual care, and at strategic level. This reframing has significant implications for regulators, the pharmaceutical industry and policy makers. It is important that professionals involved in drug development, including medical writers, are aware of these new initiatives so that they can take account of them when preparing the documentation required.

15:45 - 16:05  Panel Discussion
16:05 - 16:30  Wrap-up and closing remarks
Kathy B. Thomas

Transparency Symposium – Non-Member Registration

The Symposium is open to members and non-members. The fees for non-members are shown on the right and include lunch and all refreshments.

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http://www.emwa.org/conferences/Budapest-2014.html
Speakers and panellists

**Susane Forda**
Sue trained as a pharmacist. After completing a PhD in neuropharmacology, she worked as a post-doctoral research fellow at St George’s Hospital Medical School, University of London. She later joined Beecham, subsequently SmithKline Beecham Pharmaceuticals, as a regulatory associate in their Worldwide Regulatory Affairs Department where she held different positions for 9 years. Eighteen years ago she joined the Lilly European Regulatory Group and became its director in 1997. She is now responsible for all International regulatory aspects of Lilly's current and future products. In May 2003; she was awarded an MSc in the Economic Evaluation of Healthcare. Sue participates in industry association regulatory initiatives and has been Chair of the European Federation of Pharmaceutical Industries and Associations (EFPIA) “Scientific, Regulatory Manufacturing Policy Committee” since 2004.

**David Gilbert**
David was a consumer activist, with Health Action International and the Consumers Association in the UK helping to campaign for openness in pharmaceutical licensing and against over-promotion of medicines. He was a consumer representative at the EMEA and UK Medicines Control Agency. He then focused on supporting national and local organisations in the UK to better engage with patients and the public, and worked at the Commission for Health Improvement (the UK inspectorate), the Kings Fund and founded the NHS Centre for Involvement. In 2006, he founded InHealth Associates, a network of engagement specialists, before teaming up with Mark Doughty three years ago to form the Centre for Patient Leadership (www.cpl-uk.com) that supports patients as influential partners and agents of change.

**Hans-Jürgen Lomp**
Hans-Jürgen has more than 20 years of pharma industry experience as a statistician. He worked for 10 years for Hoechst, now Sanofi, as a project statistician on diabetes and cardiovascular projects, and was also a statistics manager. He switched to Boehringer Ingelheim (BI) to become Group Head Statistics, covering all statistical aspects from basic research, non-clinical development, pharma production development, clinical development, and medical affairs support. He chaired the Statistics Leader Group in the VFA (Association of German research-based pharma companies) for several years. In 2013, he was appointed Global Head of Statistics for BI worldwide. He is co-chair of the BI Transparency Initiative.

**Tatjana Poplazarova**
Tatjana is currently Head of Medical Governance and Bioethics at GSK Biologicals and leads a team of experts promoting industry-leading medical governance and bioethical excellence for GSK. Previously, as Director of Scientific and Public Disclosure at GSK Biologicals, Tatjana headed an international team with representatives in Asia-Pacific, Europe and the USA which was involved in both regulatory submissions (writing of protocols, study reports, clinical study summaries) and disclosure activities (both web-based disclosure and publications). Tatjana is one of the founders of the disclosure team at GSK Biologicals and spearheads both strategic and operational aspects related to Disclosure of Human Subject Research. Tatjana is also the Biologist representative at the GSK decision-making body on disclosure activities.

**Kathy B. Thomas**
Kathy is an independent consultant with an extensive background in the area of Clinical Trial Disclosure. She has followed the development and consolidation of the law in the US (FDAAA 2007, ClinicalTrials.gov platform) and is currently observing the developments on this topic in the European Union and European Economic Area (EU Clinical Trial Regulation 2014, EudraCT platform). She has a broad knowledge of and experience in preparing entries for registries, and developing internal guidelines and processes to assure compliance with clinical trial disclosure policies. She is an active member of professional international work groups on this topic. Kathy is also a medical writer, with more than 18 years of experience in the academic and pharmaceutical industry setting, preparing a wide range of clinical and drug safety documents for modules of the Common Technical Document for regulatory submissions, investigator's brochures, aggregate drug safety documents (PSUR, DSUR), manuscripts for peer-review journals, abstracts, posters, and slide presentations for international scientific and medical conferences. Kathy served as the Head of Medical Writing from 2001-2007 at Altana Pharma AG, Konstanz, Germany. She lives in southern Germany and speaks English, German, Czech, and Slovak fluently.

**Keith Veitch**
Since giving up academic biochemical research 18 years ago, Keith has been working on medical communications in the vaccine industry for several of the leading manufacturers, leading and creating publication groups at GSK Bio, Sanofi Pasteur and Novartis Vaccines, located in different countries up and down Europe. He recently set up his own company to provide consultancy and writing services to the industry. Throughout his career he has been involved in monitoring and responding to the various aspects of data disclosure as they have developed, from trial registration to patient-level data sharing.

In his time, Keith has served in EMWA, from writing the Newsletter back in the days when EMWA was simply a chapter of AMWA, to being EMWA President in 2000-2001. He has also served on the board of TIPPA, on committees in ISMMP, and advised on the CBI Publications and Disclosure conferences.