

Profile

An interview with Art Gertel on the Budapest Working Group

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Art Gertel (AG), with nearly 40 years of increasingly senior management level positions in the pharmaceutical industry, is an expert in the preparation of large, complex corporate and regulatory documents and is thoroughly familiar with relevant US, Canadian, European Union, and International Conference on Harmonisation (ICH) guidance documents. He has also held leadership roles in professional organisations, as past President of the American Medical Writers Association (AMWA), a fellow of AMWA and EMWA, a member of the Clinical Data Interchange Standards Consortium (CDISC) Glossary and Protocol Modelling groups, and serves on the Advisory Boards of The International Publication Planners Association and Hummingbird Institutional Review Board. He has been awarded the AMWA Swanberg Medal for distinguished contributions to medical communications, and he is a founding Member of the Global Alliance of Publication Professionals. Art is a Registered Agent with the US Food and Drug Administration (FDA), a Senior Research Fellow with the Centre for Innovation in Regulatory Science, and has recently established a strategic regulatory consultancy – MedSciCom, LLC. He may be familiar to many EMWA members as a perennial workshop leader and for his positions on the Nick Thompson Fellowship and Geoff Hall Scholarship Committees.

Art is presently involved in the EMWA Budapest Working Group (BWG), an ICH E3 (clinical study report (CSR)) and E6 (good clinical practice) forensics project, and we have turned to him to enlighten us on key aspects of the project.

Medical Writing (MEW): ICH E3 and ICH E6 are 20 years old, and thus, the need for a review is clear, but why now?

AG: Over the past two decades there have been many advances in the process of developing, registering, and communicating about new medicines. The core source documents upon which these efforts are based, at least from the clinical perspective, are the CSR and the clinical study protocol (CSP). These are addressed by ICH E3 and E6, respectively. When we brainstormed at the EMWA Budapest meeting in May 2014, we wondered

whether there might be a way to provide a resource to those who prepare these critical documents via written guidance that reflects current practices and anticipates, to the extent possible, future developments. Many new considerations are being integrated into the new drug calculus, including disclosure and transparency, structured risk-benefit analyses, electronic data capture, and electronic filings for marketing approval. These have all arisen since the ICH E3 and E6 guidances were promulgated.

MEW: What is the hoped for outcome of this ambitious enterprise?

AG: We hope to provide a ‘Users’ Guide’, if you will. This will be an interpretive document that will provide medical writers and others who are involved in the preparation of CSRs and CSPs with a pragmatic tool that will make it easier to follow a consistent pathway. I should emphasise that we have assembled a broad-based coalition of partners who will be involved in all stages of the process. In particular, we have ensured that there will be a high-level ‘Stakeholder Review’, conducted by representatives of the pharmaceutical industry, regulators (including the US FDA, the European Medicines Agency, and HealthCanada), and professional associations (EMWA, AMWA, and the Drug Information Association). Importantly, we continue to engage and collaborate with other organisations which are in the process of developing protocol models – CDISC, and TransCelerate Biopharma, a collaboration of pharmaceutical companies focused on advancing innovation in research and development. Thus, we hope to create a synergy among these organisations to ensure that we will be able to leverage the accomplishments of the others in pursuing our common goal.

MEW: At what stage is the project now?

AG: As reported at the EMWA meeting in Florence, we have made significant progress in the forensic review of the ICH E3 guidance. Oversight evaluation is nearly complete for E3, and stakeholder introduction packs have been distributed. *De novo* review has begun for the CSP guidance. We expect that the BWG reviews will be completed in

January 2015, and that stakeholder reviews will commence in March. We concluded a total of 17 hours of round table discussions by spending a full 9-hour face-to-face meeting day prior to the Florence Conference, labouriously going through the first series of consolidated comments, and assessing how best to communicate the myriad of subtleties and nuances contained in the existing E3 guidance. In this context, extensive work has been necessary in respect of the CSR. The protocol sections of ICH E6 are much more skeletal, allowing more opportunity for *de novo* interpretation.

I must emphasise that despite the labourious process, the team has been a pleasure to collaborate with – we take this effort seriously; however, we enjoy the interaction and respect each member's expertise. Of course, Sam Hamilton has been a tireless 'Ringmaster'.

MEW: What is your specific role in this process?

AG: While I have an extensive medical writing background, I long ago strayed from hands-on CSR writing, so I hope that what I can provide is knowledge of process and application. I bring a gestalt view of drug development, review, and approval and an ongoing involvement with CDISC protocol modelling. Terminology is also a critical element, since we have to be able to clearly communicate concepts in commonly understood terms. My role in developing the CDISC glossary will allow us to tap into this existing lexicon. Finally, my greatest contribution may be as a connector. I have been employed in and around the pharma industry for a long time and this has afforded me many points of contact with experts in many of the areas touching on the CSR and CSP. Thankfully, many of them do return my calls and emails, and I have been able to bring them into the BWG effort as reviewers and stakeholders. To my mind, the multi-party collaboration is a key to the success of this daunting effort. If we can represent a consensus across the broad spectrum of applications influenced by these guidances, we have a better chance

of establishing an invaluable reference tool for our industry, investigators, and patients.

AG has given us a broad view of what the BWG project entails, and it really seems to be an outstanding initiative. We do hope this important effort will be considered in any possible revision of or addition to ICH guidance documents. We thank him and all the BWG team for their work!

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In May 2014, EMWA initiated collaboration with many stakeholders to review ICH E3 in a 2-year project. ICH E3 (effective 1995) and ICH E6 (effective 1996) are the main current ICH regulatory guidance documents for developing CSRs and CSPs, respectively.

The initiative comprises experts in ICH E3, ICH E6, CSP, and CSR templates; experts with experience in clinical trial disclosure and transparency; and a strategist who is working with partner and stakeholder organisations.

The review will:

- align guidance documents with current practices,
- increase transparency in the reporting of clinical trial data, and
- focus on protecting the anonymity of trial participants, since CSRs are to be made publicly available.

This is a major step along the way to ensuring that all sponsors of clinical trials adhere to the principles of responsible clinical trial data sharing.

Walther Seiler and Sam Hamilton presented their first publication of the project at the EMWA Conference in Florence last November, followed by an open access paper that was published in MEW last December (<http://www.maneyonline.com/doi/full/10.1179/2047480614Z.0000000254>).