Clarity and Openness in Reporting: E3-based

EMWA and AMWA develop the new CORE Reference

EMWA and AMWA are delighted to partner in initiating a collaborative effort to develop an open-access end-user resource that will complement International Conference on Harmonisation (ICH) E3 guidance (and subsequent updates) for authoring of clinical study reports (CSRs). This ambitious commitment is intended to benefit the many Stakeholders in the process of advancing therapeutic options. These include medical writers, the pharmaceutical industry, regulators, and patients.

The all-new CORE (**C**larity and **O**penness in **R**eporting: **E**3-based) Reference is scheduled to be available by mid-2016. CORE will take the form of a User Manual intended to assist CSR authors, thereby complementing the existing 1995 ICH E3 guidance and 2012 ICH E3 Q&A update. The development of the CORE Reference considers all available resources, including unpublished recommendations from the 2012 Q&A consultation process.

The project is currently running to schedule. EMWA and AMWA's *de novo* review and oversight evaluation teams are consolidating their detailed analyses, and will be ready to share these with Stakeholder Reviewers in March 2015.

Although there may not be an opportunity for ICH to formally consider CORE recommendations on the E3 Guidance, this would not impede the provision of a valuable "go-to" reference. Industry professionals (including representatives from the Drug Information Association [DIA] Medical Writing Community, TransCelerate and Clinical Data Interchange Standards Consortium [CDISC]) as well as regulators (from EMA, FDA and HealthCanada) speak strongly to us of a perceived need for this "product". The CORE Reference will be developed in close collaboration with all relevant Stakeholders, including medical establishment, patient advocates, industry and regulators. This Stakeholder participation aims to encourage broad acceptance of the interpretations and recommendations captured in the Reference. Individual Stakeholder endorsement of the final CORE Reference will be predicated on their approval of the final document.

The CORE Reference project began as a detailed review and recommendation project on ICH E3, led by the EMWA Budapest Working Group (BWG). It is strengthened by its evolution into this international EMWA-AMWA partnership with global reach.

In a separate, but closely related work stream, the BWG initiative also includes the development of new content guidance for the preparation of clinical study protocols. This work stream is currently seeking alignment with ongoing industry initiatives into which our group has been warmly welcomed.

For the Budapest Working Group:

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