

Final Concept Paper
ICH Implementation Working Group (IWG)
on ICH E2C(R2): Periodic Benefit-Risk Evaluation Report
Dated and endorsed by the Steering Committee on 15 November 2012

Type of harmonisation Action Proposed

Implementation Working Group.

Statement of the Perceived Problem

The revision to E2C has introduced new concepts and principles linked to an evolution of the traditional PSUR from an interval safety report to cumulative benefit-risk report and with a change in focus from individual case reports to more aggregate data evaluation. The broadening of the scope fundamentally increases the complexity of the document and the integration of information within the report. As the concepts and principles are novel in this context (i.e. periodic report production), it is important that proper implementation of these concepts is supported by the availability of an appropriate forum for experts to agree consistent and harmonised responses to questions linked to interpretation and application of the E2C R2 guidance.

Issues to be Resolved

The following issues have so far been identified and will need to be addressed:

- Technical issues and related documentation:
Common understanding of new concepts e.g. modular approach, risk proportionality.
- Additional implementation issues:
Interface with existing ICH guidelines.
Handling different periodicities with no Summary Bridging Reports
- Communication and training:
e.g., Q&A, external collaborations, workshops.
Example PBRERs, guidance on handling different periodicities/modular approach

Background to the Proposal

An ICH sponsored implementation is considered necessary to clarify the many questions that are likely to arise during implementation and prepare consistent and harmonised responses.

Type of Working Group

The IWG should comprise of the six ICH Parties (2 experts per Party), Observers to ICH (1 expert per observer), RHIs, DRAs and DoH (1 expert per RHI/DRA/DoH), and Interested Parties (WSMI, IGPA and Biotechnology Industry, 1 expert per Interested Party).

Meetings for IWG are expected to be held by TC or emails. The need for face to face meetings will be based on feedback received from regions and the number of issues to be addressed that are not well suited to a TC or email discussion.

Deliverables

The EWG has identified the following near term activities:

- Frequently asked Q&A document;
- Training slide set;
- Example PBRERs;
- Guidance on handling different periodicities/modular approach; and
- Collect list of items for clarification in potential future iterations of the E2C(R2) Guideline.