Final Concept Paper
E2D(R1): Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
Endorsed by the Management Committee on 31 January 2020

Type of Harmonisation Action Proposed

An update of the existing ICH E2D (Post Approval Safety Data Management: Definition and Standards for Expedited Reporting E2D) guideline is proposed to clarify the management of post-approval safety information from new or increasingly used data sources including the need to adapt definitions and standards.

Statement of the Perceived Problem

The ICH E2D guideline was agreed in May 2003. In the meantime, new sources of post-approval safety information have emerged or are more frequently applied (e.g. social media, market research programs, patient support and assistance programs) which vary in characteristics and contribution to quality of post-approval safety information. The definitions and regulatory guidance in ICH E2D are no longer sufficient to provide guidance on the current practices and needs. Therefore, the definitions and standards for the management of post-approval safety information need to be revisited in order to support appropriate safety surveillance and actions.

Issues to be Resolved

Careful consideration and regulatory guidance are needed by adapting the existing concepts, principles and definitions of the ICH E2D guideline to the management of new sources of safety information.

In addition, there is also an opportunity to adapt the guideline to address other issues which may include, but are not limited to:

- ambiguous, out of date or missing definitions and terminology,
- sources of ICSRs,
- standards for post-market regulatory reporting,
- good case management practices (e.g. detection and management of duplicate reports, identifiability of patients and reporters, management of literature reports, observations with no associated adverse outcome and outcome-only reports)

Furthermore, it is important that any adaptations of the ICH E2D guideline take into account the need for consistency between other pertinent documents such as ICH E2A, ICH E2B, ICH E2C and ICH E19 (e.g. ongoing development of ICH E19 and selective data collection for interventional clinical trials and non-interventional studies). A potential need for additional sub-categories in the ICH E2B(R3) implementation guide to categorize ICSRs originating from the new sources of safety information may become apparent. The title of ICH E2D may also need be re-considered as a consequence of this proposed revision.

Background to the Proposal

Patient safety is a key priority for patients, industry and regulators alike. Since 2003 the science of pharmacovigilance has evolved and the potential sources of safety data have increased, justifying a revision of this guidance (1-4). The revision of ICH E2D is considered an important opportunity to improve the generation of information that is relevant to patient safety.

Type of Expert Working Group and Resources

An EWG is recommended that should consist of experts in the field of pharmacovigilance.

Timing

EWG should begin working following ICH Assembly endorsement and is anticipated to take up to 24 months to reach step 2.

References

1) Jokinen J et al. Industry Assessment of the Contribution of Patient Support Programs, Market Research Programs, and Social Media to Patient Safety. Therapeutic Innovation & Regulatory Science (2019)

2) Harinstein et al L et al. Evaluation of Postmarketing Reports from Industry-Sponsored Programs in Drug Safety Surveillance. Drug Safety (2019) 42: 649–655

3) Stergiopoulos S et al. Adverse Drug Reaction Case Safety Practices in Large Biopharmaceutical Organizations from 2007 to 2017: An Industry Survey. Pharm Med (2019) 1-12

4) Brosch S et al. Establishing a Framework for the Use of Social Media in Pharmacovigilance in Europe Drug Safety (2019) 42:921–930