Final Business Plan
E2D(R1): Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
Endorsed by the Management Committee on 18 November 2019

1. The issue and its costs

- *What problem/issue is the proposal expected to tackle?*

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 utilised (e.g. social media, market research programs, patient support and assistance programs) which vary in characteristics and contribution to the 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.

- *What are the costs (social/health and financial) to our stakeholders associated with the current situation or associated with "non action"?*

In the current situation significant resources are being spent on handling increasing volumes of ICSRs that are of variable value to post market safety surveillance. There is a need to establish principles on how to manage these more effectively to support patient safety.

2. Planning

- *What are the main deliverables and key milestones?*

  The main deliverable is the final revised ICH E2D Guideline in accordance with finalized concept paper. Key milestones are in line with the ICH Working Group Step Process.

- *What resources (financial and human) would be required?*

  The convening of an Expert Working Group to work on this project is required. Monthly meeting by teleconference and face to face meeting twice a year are anticipated. Financial resources to attend face-to-face meetings are required.

- *What is the time frame of the project?*

  It is anticipated that it will take 2 years (3-4 face to face meetings) to reach step 2. After 6 months consultation it will take a further 1 year to complete step 4.

- *What special actions to advance the topic through ICH, e.g. stakeholder engagement or training, can be anticipated either in the development of the guideline or for its implementation?*
  It is anticipated that there may be the need for an Implementation Working Group to develop training support material including Q&A document.

3. The impacts of the project

- *What are the likely benefits (social, health and financial) to our key stakeholders of the fulfilment of the objective?*

  To provide pragmatic solutions that can be adopted globally to ensure consistent collection, review, analysis and reporting of safety information from various data sources to ensure global data can be leveraged to optimise patient safety.

- *What are the regulatory implications of the proposed work – is the topic feasible (implementable) from a regulatory standpoint?*

  The proposal is intended to harmonize the way of reporting information from new or more frequently utilised sources of post-approval safety information. We believe harmonization and implementation are feasible.

  The aim is to implement ICH E2D (R1) under the current respective legislative frameworks with adaptations in local regulatory guidance where applicable. Regulatory feasibility will need to be assessed at regional level.

4. Post-hoc evaluation

- *How and when will the results of the work be evaluated?*
  An evaluation will be proposed once the guideline is finalized.