Final Concept Paper
E19: Optimisation of Safety Data Collection
dated 27 June 2017
Endorsed by the Management Committee on 12 July 2017

Type of Harmonisation Action Proposed

A new guideline is proposed to provide internationally harmonised guidance on when it would be appropriate to use a targeted approach to safety data collection in some late-stage pre-marketing or post-marketing studies, and how such an approach would be implemented.

Statement of the Perceived Problem

Recognising that protection of patient welfare during drug development is critically important, unnecessary data collection may be burdensome to patients, and serve as a disincentive to participation in clinical research. Regulators and industry have a shared interest in reducing the burden to patients and facilitating the conduct of studies that could yield important new medical knowledge and advance public health.

Specifically, in the later stages of drug development, when the common side effects of a drug are well-understood and documented, a more targeted approach to safety data collection may be appropriate, as long as patient welfare is not compromised. Under such circumstances, some of the data routinely collected in clinical studies may provide only limited additional knowledge. These data may include: non-serious adverse events, routine laboratory assessments, physical examinations, vital signs, and concomitant medications.

By tailoring safety data collection in some circumstances, the burden to patients would be reduced, a larger number of informative clinical studies could be carried out with greater efficiency, studies could be conducted with greater global participation, and the public health would be better served.

Issues to be Resolved

There is no widely adopted guidance on when the use of targeted safety data collection would be appropriate in late-stage pre-marketing or post-marketing studies, or on how to implement such an approach. Thus, this topic represents an ideal opportunity for international harmonisation.

Background to the Proposal

The FDA currently provides guidance for situations where selected data collection may be sufficient (see FDA Guidance for Industry: Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Post-approval Clinical Investigations, February, 2016, available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm291158.pdf).

The proposed Guideline would be consistent with risk-based approaches and quality-by-design principles.

Type of Expert Working Group Recommended

The EWG will require experts in clinical medicine, biostatistics, pharmacy, drug safety, and regulatory science, to be nominated from the Members and Observers in line with the applicable Rules of Procedure. It is expected that consultation will be sought from patient representative(s) during development of the Guideline.

Timing

- First face-to-face informal Working Group Meeting: May 2017
- Endorsement of Concept Paper: July 2017
- First face-to-face EWG Meeting: November 2017; *Step 1* draft