

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

1. The issue and its costs

- *What problem/issue is the proposal expected to tackle?*
In situations where some, but not all, regulatory authorities would accept an approach that relies on targeted safety data collection, companies will collect comprehensive data in all regions. There is no widespread agreement on when, or even whether, targeted data collection is appropriate. It would be useful, therefore, to develop internationally harmonised guidance on when and how use of an approach that relies on targeted safety data collection would be appropriate. Thus, this topic represents an ideal opportunity for international harmonisation.
- *What are the costs (social/health and financial) to our stakeholders associated with the current situation or associated with “non-action”?*
In the later stages of drug development, when the common side-effects of a drug are well-understood and documented, excessive data collection may be unnecessarily burdensome to patients and investigators. By allowing targeted safety data collection in some circumstances, a larger number of informative clinical studies could be carried out, drug development could be more efficient, inclusive of more regions, and the public health would be better served.

2. Planning

- *What are the main deliverables?*
The main deliverable will be a new guideline defining when it may be appropriate to follow an approach that relies on targeted safety data collection and how this approach can be implemented.
- *What resources (financial and human) would be required?*
The convening of an Expert Working Group to work on this project is required. Financial resources to attend face to face meetings are required.
- *What is the time frame of the project?*
3 years.
- *What will be the key milestones?*
Step 1-May 2018, Step 2-November 2018, Step 3-November 2019 and Step 4-June 2020.

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?*

It is hoped that implementation of the guideline will reduce the burden to patients and investigators, result in a larger number of informative, generalizable, clinical studies, and improve public health.

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

We believe that harmonization and implementation are feasible.

4. Post-hoc evaluation

- *How and when will the results of the work be evaluated?*

Data from various sources (i.e., survey of manufacturers, clinical trial registries, and experience with specific products that implemented the principles of the guideline in their development) will be used to evaluate the impact of the guideline. This will occur after implementation of the final guideline.