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European Federation of Pharmaceutical Industries and Associations

Best regulatory practice for companies leading IMI projects

1. Objective:

Multiple ongoing IMI research projects will have impact on regulatory guidance documents or require regulatory qualification, such as new endpoints, patient reporting tools, revisions of definition of study population etc.

In order to maximize the value of the outcome of the projects for the public health, it is important to systematically assess the regulatory impact and ensure regulatory milestones are built into the goals of the projects.

EFPIA and IMI have identified that the company regulatory personnel and the scientific project leader play a major role in helping to achieve this goal. EFPIA and IMI would like to ask the company's leading IMI projects to help achieving this goal by following some of the good regulatory practices outlined below.

2. Good practice #1: New idea generation stage – high level assessment of regulatory relevance

At the stage of new idea generation for a potential IMI project selected members of RDG and SRMPC should conduct a high level assessment of the potential regulatory/HTA relevance of or opportunities offered by the proposed project and, where appropriate, assist the writing team to include regulatory questions in the scope of the proposals.

3. Good practice #2: Call Topic proposal - include regulatory impact assessment

When the project proposal/call topic is drafted, regulatory impact assessment should be done to identify for example practice or guideline that will be impacted. This should ideally based on discussions between the scientific project lead and a regulatory professional of the company.

A succinct guidance tool on how to assess regulatory impact is available at the following link.

Based on the impact assessment the corresponding section of the call topic should be completed (link).

4. Good practice #3: New projects - include "in kind" contribution of regulatory resources

In order to be able to do a thorough regulatory impact assessment and establishing a path to regulatory acceptance with EMA and FDA an "in kind" contribution of 0.1 FTEs of a regulatory professional should be ensured throughout the project duration.

5. Good practice #4: Ongoing and new projects - include regulatory milestones in project plan

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Project that deliver outputs with regulatory relevance should integrate the regulatory milestones and identified regulatory procedures as part of the project plan and an update when and as required.

6. Good practice #5: Ongoing projects - review by company regulatory personnel

Step 1: In order to maximize the value of the outcome of ongoing IMI projects and in case this has not been done already, EFPIA and IMI propose that the company regulatory personnel and the company scientific project lead have discussions on the regulatory impact of the ongoing project. If an impact is identified the regulatory milestones/procedures should be retrospectively included in the project plan. The IMI office should be informed of any regulatory impact of the project in a timely manner in order to be able to provide maximum additional assistance to achieving regulatory acceptance.

Step 2: An update on regulatory milestones should be included in the annual project activity review and report.