21 April 2020

Summary of Stakeholder Engagement to Support the Development of ICH E6(R3)

1. Introduction and rationale for stakeholder engagement approach

The ICH-E6 Good Clinical Practice (GCP) guideline impacts clinical research beyond the core membership of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), including regions with no other guidelines for GCP. The guideline is the reference standard for the conduct of clinical trials at a global level, including for non-traditional trial types, such as adaptive trials, trials utilizing master protocols, decentralized clinical trials and others in a clinical environment that is drawing on ever increasing data sources enabled by digitalisation of processes and information. In addition, while ICH-E6 is intended as a guidance for clinical trials that support regulatory submission of drugs, it may be applied to clinical trials in general. Patients, academic clinical researchers, and other stakeholders can provide unique and important insights into the design and conduct of clinical trials, as well as the ethical considerations that should be addressed.

ICH committed to stakeholder engagement with academic clinical researchers and patient representatives in its Reflection paper on Renovation of Good Clinical Practice and in the Concept Paper for the revision of ICH-E6. Understanding these groups' perspectives as the working group develops ICH-E6(R3) will help to ensure that the guidelines are responsive to the needs of those conducting or participating in clinical trials. ICH considers the benefits from these engagements to be substantial and worth the effort and time to organise them.

2. Objective of the engagement approach

This approach will engage patient representatives and academic clinical researchers during guideline development to ensure that stakeholders' perspectives on and experiences with clinical trials, specifically with GCP guidelines, are considered in developing ICH-E6(R3). These engagements should result in:

- Supporting development of a responsive guideline with stakeholders' perspectives and advances in technology and clinical trial design.
- Improving understanding and implementation of ICH-E6(R3) supporting smoother adoption by stakeholders.
- Providing transparency and responsiveness to stakeholders' needs for further involvement during medicines development.

3. Approach and methodology

This proposal outlines two types of engagement with stakeholders: (1) regional public engagement approach held by ICH member organizations, and (2) meetings with the expert working group (EWG).

3.1. Regional public engagement approach

Regulatory Management Committee (MC) member organisations may identify and engage regional representatives of patients, academic clinical researchers, and other appropriate stakeholders and determine their engagement process. Engagements may be open and public and designed for input from diverse stakeholder groups. The EWG will develop and provide resources to guide engagement

approaches (e.g., questions for surveys, general agendas for workshops and public meetings, core slide set(s)).

Public engagement at regional level will not involve sharing of confidential contents. The outcome of this engagement will be captured in a high-level, informal report to the EWG.

Stakeholder representatives will be selected at the regional level by the Regulatory MC member organisation using, where available, existing mechanisms for public engagement. Each Regulatory MC member organisation will outline conditions for participation in their region. Regional public engagements are optional.

3.2. Direct Engagements with stakeholders during EWG meetings

The EWG will engage with academic clinical researchers, and potentially other relevant stakeholders at EWG meetings, face to face and if necessary, by teleconference, but the engagement will be separate from the EWG standard deliberations.

- Stakeholders' input will be sought on relevant issues, such as experiences with clinical trials and insights on the most challenging aspects of applying GCP. Stakeholders will provide their individual views and/or the views of their organizations, as appropriate. Overall, all engagements should be based on principles of equal opportunity, fairness, transparency, relevant expertise and the stakeholder representative's experience.

This engagement approach will be piloted during the first drafting stage prior to the public consultation of ICH-E6(R3). Following this stage, the ICH engagement approaches will include public input and workshops, as necessary. Such engagements may occur during the ICH regular meetings (in-person) and if necessary, during the EWG calls and teleconferences.

3.3. Evaluation of the engagement approach and logistics

- Following each EWG engagement, a report will be prepared with feedback, the engagement experience, the added value, and challenges and process improvements for the MC.
- The report will inform the decision on whether to proceed with additional engagements in similar pattern or to modify the approach.