

Summary of Stakeholder Engagement to Support the Development of ICH E21

1. Introduction and rationale for stakeholder engagement

Data on the safety and efficacy of medicinal products when used in pregnancy and breastfeeding is lacking for most medicinal products and can result in suboptimal treatment decisions, potentially compromising the health of both mother and child. Pregnant and breastfeeding individuals are often excluded from clinical trials and those who become pregnant while participating in a clinical trial are frequently discontinued from the clinical trial. The objective of the ICH E21 Guideline is to provide recommendations for the appropriate inclusion of pregnant and breastfeeding individuals in clinical trials and facilitate the generation of robust clinical data that allow for evidence-based decision making by these individuals and their healthcare providers on the safe and effective use of medicinal products during pregnancy and breastfeeding. The scope of the ICH E21 Guideline includes pre- and postmarketing clinical trials of investigational products for indications in the general population and indications specific to pregnant or breastfeeding individuals. The ICH E21 expert working group (EWG) is committed to engaging with stakeholders, including patients, patient representatives, healthcare providers, clinical researchers, developers of medicinal products, regulatory authorities, IRBs/Ethics Committees, and others who can offer valuable insights into the design and conduct of clinical trials. As the first international Guideline addressing technical aspects of clinical trials with pregnant and breastfeeding individuals, early engagement with relevant stakeholders is crucial and will support successful implementation of the ICH E21 Guideline.

By incorporating the insights of stakeholders during the development of the ICH E21 Guideline, the Guideline can more effectively meet their needs. ICH values these engagements highly, recognizing their substantial benefits and deeming the effort and time invested in organizing them to be well justified.

2. Objective of the engagement approach

This approach will ensure early engagement with stakeholders during Guideline development to help raise awareness of the Guideline and to ensure that stakeholders' perspectives on and experiences with clinical trials are considered in developing the ICH E21 Guideline. These engagements should result in:

- Supporting development of a responsive Guideline with stakeholders' perspectives and advances in technology and clinical trial design.
- Encourage constructive feedback on the subject matter content during the public consultation process.
- Improving understanding and implementation of the ICH E21 Guideline and any challenges for implementation.
- Informing the development of potential training material, supporting smoother adoption by stakeholders.
- Providing transparency and responsiveness to stakeholders' needs for further involvement during development of medicinal products.

3. Approach methodology for engagement

The ICH E21 EWG will 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 ICH E21 EWG will develop and provide resources to support engagement approaches.

Regional public engagements are optional.

The ICH E21 EWG may also engage with all relevant stakeholders face- to- face, by teleconference, workshops, or at EWG meetings, as appropriate.

Stakeholders' input will be sought on relevant issues, such as experiences with clinical trials and insights on the most challenging aspects of applying the guidance as drafted in ICH E21 and ways to overcome. Stakeholders may be invited to 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.