ICH New Topic Proposal Template

1. Topic Title

2. ICH Topic Description

Type of Harmonisation Action: New guideline ☐ Guideline revision ☐ Q&A ☐ Other (to be specified below) ☐

Category: Quality ☐ Safety ☐ Efficacy ☐ Multidisciplinary ☐ Multiple guidelines (to be specified) ☐

If "other" and/or "multiple", please specify the intended ICH action(s) linked to the proposal: ……

Brief statement of perceived problem (caused by lack of harmonisation/ICH guideline misalignment or other cause):

Approximately 200-400 words

Main technical and scientific issues to be addressed (which require harmonisation):

Please provide a list of bullets with a high-level description of the issues to be harmonised - Approximately 200-400 words.

Objective and expected deliverable(s) of proposed harmonisation work:

Provide a short statement (approx. 200 words) describing the overarching goal(s) to be achieved through this proposal and why the chosen ICH action is considered the most fit for this purpose. If more than a single ICH action is proposed (e.g., update to multiple guidelines; new guideline + minor pre-specified revisions to existing ICH documents, tiered approach to guideline development/revisions, etc.), please outline and justify the chosen approach (including whether the multiple topics would be addressed in parallel or sequentially, if applicable). Please also justify the level of detail expected for the guidance (e.g., high-level principles, detailed technical guidance, a combination of these). For revisions to existing guidelines, an annotated guideline file can be annexed to this paper, if available.

How does the proposed topic relate, potentially complement, or conflict with existing ICH guidelines? If a close relation (or conflict) to an existing ICH document is identified, how does this proposal seek to avoid misalignment?

3. Strategic Importance of Topic

Why is this important for international harmonisation? If applicable, specify the ICH strategic priority or reflection paper that this proposal will support and how it will advance the related objectives.

1. How does the proposal potentially conserve regulatory/industry resources? Which specific areas are likely to benefit more (e.g., generics, NCEs, biologics)?
2. How does the proposal potentially improve the time to approval and/or continued availability of medicines to patients?
3. Given the new construct, which industries and which regulators are likely to most benefit?
4. If this proposal is approved, will it be necessary to consult with patient organisations on guideline development outside of the standard opportunities provided during the public consultation process?*

4. Feasibility

1. Level of effort required to complete the guideline (Low, Medium, High)
2. Expertise and skillsets required for the potential working group representatives to achieve the intended goals
3. Expected time to complete the guideline (ICH recommends that working groups aim to complete guidelines within 3 years depending on the harmonization work to be undertaken where development of a new guideline would take approximately 18 months to reach steps 2a and 2b and revision of an existing guideline would take approximately 12 months to reach steps 2a/b. Please indicate whether it is envisioned that the guideline development could be completed in 3 years or if more time would be needed, please provide a justification – e.g., high impact, large scope, need for parallel activities: data, IT standard development, etc.)

* If so, the Expert Working Group will be required to develop a Stakeholder Engagement Plan.

4. When benefits of the completed guideline would be realized (i.e., are formal implementation actions after finalisation of the proposed ICH action foreseen to realise these benefits?)

5. How does the proposed topic relate, potentially complement, or conflict with existing guidelines? If a close relation (or conflict) to an existing ICH document is identified, how does this proposal seek to avoid misalignment?

6. Would the proposed topic potentially compete for ICH resourcing within and across categories (Q, S, E, M)

7. Does any of the ICH regions already have a domestic guideline relating to the new topic? (If so, please specify those regions and related respective guidelines)

8. To the best of your knowledge, would the proposal be in alignment with current laws and regulations in the ICH regions? (If not, identify regions in which incompatibilities or obstacles could be expected, and how these could be overcome)

5. Source of Proposed Topic

Topic proposed by (Organisation): _____

CONTACT NAME:_____