

ICH Concept Papers & Business Plans

Any of the ICH Parties or ICH Observers can propose a new harmonisation initiative. This is done by submitting a short summary of the proposal – a “Concept Paper” – (maximum 2 pages), to the ICH Steering Committee for consideration.

Outline of Concept Papers

- **Type of Harmonisation Action Proposed:** Whether a new harmonised tripartite guideline/recommendation, or a revision of an existing guideline is proposed;
- **Statement of the Perceived Problem:** Brief description with an indication of the magnitude of the problems currently caused by a lack of harmonisation, or - in the case of new scientific developments - anticipated if harmonisation action is not taken;
- **Issues to be Resolved:** A summary of the main technical and scientific issues, which require harmonisation;
- **Background to the Proposal:** Further relevant information, e.g., the origin of the proposal, references to publications, discussions in other fora;
- **Type of Expert Working Group:** Recommendation on whether the EWG should include experts from any Interested Party in addition to those from the 6 ICH Parties and ICH Observers.

Depending on the type of harmonisation activity proposed, the ICH Steering Committee can either proceed with endorsing the proposal or if it agrees that a topic may warrant further consideration it can request that a Business Plan also be developed.

Outline of Business Plans

- **The issue and its costs:** *What problem/issue is the proposal expected to tackle? What are the costs (social/health & financial) to ICH stakeholders associated with the current situation or associated with “non action”?*
- **Planning:** *What are the main deliverables? What resources (financial & human) would be required? What is the time frame of the project? What will be the key milestones?*
- **The impacts of the project:** *What are the likely benefits (social/health & financial) to ICH key stakeholders of the fulfilment of the objective? What are the regulatory implications of the proposed work – is the topic feasible (implementable) from a regulatory standpoint?*
- **Post-hoc evaluation:** *How & when will the results of the work be evaluated?*

In general, Business Plans are requested only for topics which are new for harmonisation by ICH and are not requested for revisions. Business Plans may sometimes be requested when the development of Q&As is proposed.

If a Business Plan has not been provided by the proposing Party the ICH Steering Committee will establish an informal Expert Working Group / Implementation Working Group and task it with finalising the Concept Paper and developing and agreeing a Business Plan. The revised Concept Paper and the Business Plan will then be considered by the ICH Steering Committee for endorsement.