

ICH S1B(R1) IWG Work Plan

25 July 2026

Topic Adoption Date: *March 2024*

Rapporteur/s: *Dr. Andrew Goodwin, FDA, United States*

Regulatory Chair: *Dr. Kris Siezen, EC, Europe*

Last Face-to-Face Meeting *Athens, Greece, May 2022*

1 Key Milestones

1.1 Current Status of Key Milestones

- List key **past milestones** in the table for context.
- Key Milestones Include:
 - Concept Paper endorsement,
 - Completion of PWP Consultation (if applicable)
 - ICH *Step sign-off (Guidelines, Q&As, Implementation Packages)*
 - Completion of *Step 3* Public Consultation,
 - *Step 2* and *Step 4* Presentations
 - Stakeholder Engagement Activities
 - Training materials developed.
- **Choose only the most relevant achievements.**

Completion date	Milestone
August 2022	<i>Step 4 Document sign off (addendum to S1B(R1) Guideline)/ finalise training slide deck for posting on ICH website.</i>
March 2024	<i>Final Concept Paper for S1B(R1) IWG endorsed by Management Committee</i>

1.2 ICH MC Key Deliverables

- The table records **all deliverables** that the ICH MC has approved for development, either:
 - those listed in the **Concept Paper**, or
 - additional deliverables **approved later** by the MC.
- **“Approval Date”** = the date the MC **approved starting work** on that deliverable (either the **Concept Paper approval date** or a **later time point based on MC approval**).

MC Approval Date	Deliverable
March 2024	The MC approved the S1B(R1) IWG Concept Paper to ensure consistent and effective implementation of the S1B(R1) addendum via regular but infrequent teleconferences to: • Exchange information among DRAs with confidentiality agreements in place to establish the extent of regulatory alignment and share experience in evaluating WoE submissions. • Exchange anonymised information across the full IWG membership while maintaining confidentiality to discuss the extent of alignment in the review of WoE submissions based on DRA and industry perspectives. • Identify areas of inconsistency in evaluating WoE submissions and discuss ways to increase consistency, if warranted. • Identify issues to be addressed in a potential, future Q&A document

1.3 Future Anticipated Milestones

Please provide in the table below the **main deliverable(s) to be achieved in the next year(s):**

Dates or expected timeline (e.g. Q1 2026 etc.) should be provided for:

- PWP engagement (if applicable) ahead of Step 1 and Step 3 Sign off
- Step 1 sign-off and Step 2a/b endorsement and delivery of the Step 2 Presentation
- Step 3 sign-off and Step 4 adoption and delivery of the Step 4 Presentation
- Any other relevant high-level deliverables (finalised documents, public consultation period, special actions to advance the topic through ICH, e.g. stakeholder engagement or training, etc.)

Expected future completion date	Milestone
June 2027	Identify recommended next steps in developing best practices for submission and review of WOE documents, including consideration for training, proposal of a Q&A document, or other initiatives.

2. Timeline for Specific Tasks

Please provide in the table below **short-term high-level specific tasks for work to be done within the Working Group between now and the next ICH biannual meeting (recommended 4 – 10 tasks).**

Beginning date	End date	Task / Activity	Details
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September 2026	October 2026	<i>Full IWG Meeting</i>	<i>DRA's plus Industry working group session planned</i>
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