

ICH M13 EWG Work Plan

18 February 2026

Topic Adoption Date: November 2019

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Last Face-to-Face Meeting: Singapore, November 2025

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
Nov. 2019	Concept Paper Outline endorsement
Feb. 2020	Informal Working Group endorsement
Jul. 2020	Concept Paper endorsement, Business Plan endorsement
Jul. 2020	Expert Working Group (EWG) establishment
Jul. 2020	M13A (document with Tier 1 topics) initiation
Nov. 2022	M13B (document with Tier 2 topic) initiation
Dec. 2022	Step 1 on M13A draft guideline (document with Tier 1 topics)
Dec. 2022	Step 2a/b on M13A draft guideline (document with Tier 1 topics)
Dec. 2022	Public consultation started on M13A draft guideline (document with Tier 1 topics)
Mar. 2023	Endorsement of Concept Paper Supplement: M13B
May. 2023	Public consultation ended on M13A draft guideline (document with Tier 1 topics)
Jul. 2024	Step 3 sign-off on M13A final guideline (document with Tier 1 topics)
Jul. 2024	Step 4 adoption on M13A final guideline
Jul. 2024	Step 4 adoption on M13A Question and Answer document
Jul. 2024	Posting of M13A Step 4 Presentation
Jan. 2025	Endorsement of Concept Paper Supplement: M13C
Feb. 2025	Step 1 on M13B draft guideline (document with Tier 2 topics)

Feb. 2025	<i>M13C (document with Tier 3 topics) initiation</i>
Mar. 2025	<i>Step 2a/b on M13B draft guideline (document with Tier 2 topics)</i>
Mar. 2025	<i>Public consultation started on M13B draft guideline (document with Tier 2 topics)</i>
Oct. 2025	<i>Public consultation ended on M13B draft guideline (document with Tier 2 topics)</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
Jul. 2020	<i>Endorsement of Concept Paper and Business plan for development of M13A, M13B and M13C Guidelines</i>
Nov. 2023	<i>M13A Question and Answer document</i>
Nov. 2025	<i>M13B Question and Answer document</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
May-Jun. 2026	<i>Face-to-Face meeting</i>
Jun-Jul. 2026	<i>Step 3 sign-off and Step 4 adoption on M13B and M13B Q&A; Develop Step 4 Presentation on M13B</i>
Aug. 2026	<i>Posting of Step 4 Presentation on M13B</i>
Jun-Jul. 2027	<i>Step 1 Sign-off and 2a/b endorsement by ICH Assembly on M13C</i>
Oct-Nov. 2028	<i>Step 3 sign-off and Step 4 adoption on M13C</i>

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 meeting** (recommended 4 – 10 tasks).*

Beginning date	End date	Task / Activity	Details
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Feb. 2026	<i>May. 2026</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	• Continue to review and discuss comments received on M13B draft guideline • Finalise M13B based on comments received • Develop Question and Answer document for M13B
May. 2026	<i>Jun. 2026</i>	<i>Face-to-Face meeting</i>	• Finalise M13B for Step 3 sign-off • Finalise M13B Question and Answer document for M13B • Develop Step 4 Presentation • Continue to work on M13C draft document (if time permits)
Jun. 2026	<i>Jun. 2026</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	• M13B Step 4 adoption • M13B Question and Answer document endorsement • Finalise and post Step 4 Presentation • Continue to work on M13C draft document
Aug. 2026	<i>Nov. 2026</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	• Continue to develop M13C draft document
Nov. 2026	<i>Nov. 2026</i>	<i>Face-to-Face meeting (subject to ICH MC approval)</i>	• Continue to develop M13C draft document • Address comments received from EWG member internal clearance