

ICH M13 EWG Work Plan

25 July 2026

Topic Adoption Date: November 2019

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Last Face-to-Face Meeting: Rio de Janeiro, Brazil, May-June 2026

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 3 sign-off on M13A Question and Answer document
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>
Jul. 2026	<i>Step 3 sign-off on M13B Final Guideline (document with Tier 2 topics)</i>
Jul. 2026	<i>Step 3 sign-off on M13B Question and Answer document</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
Aug. 2026	<i>Step 4 adoption on M13B Final Guideline</i>
Aug. 2026	<i>Step 4 adoption on M13B Question and Answer document</i>
Aug. 2026	<i>Posting of M13B Step 4 Presentation</i>
Nov. 2026	<i>Face-to-Face meeting</i>
Jun-Jul. 2027	<i>Step 1 Sign-off and Step 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
<i>Jun. 2026</i>	<i>Aug. 2026</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	• <i>Continue to develop M13C draft guideline</i>
<i>Aug. 2026</i>	<i>Nov. 2026</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	• <i>Step 3 sign-off on M13B final guideline</i> • <i>Step 3 sign-off on M13B Question and Answer document</i> • <i>Step 4 adoption on M13B Final Guideline</i> • <i>Step 4 adoption on M13B Question and Answer document</i> • <i>Finalise M13B Step 4 Presentation</i> • <i>Adopt and post M13B Step 4 Presentation</i> • <i>Develop M13B training materials</i> • <i>Prepare manuscripts to support M13B implementation</i> • <i>Draft various sections of M13C draft guideline</i> • <i>Prepare manuscripts to support M13C draft Guideline recommendations</i> • <i>Collect comments from internal groups on M13C draft Guideline to prepare for discussion at face-to-face meeting</i>
<i>Nov. 2026</i>	<i>Nov. 2026</i>	<i>Face-to-Face meeting</i>	• <i>Develop and discuss M13B training materials</i> • <i>Continue to develop M13C draft guideline</i> • <i>Address comments received</i>