

ICH M13 EWG Work Plan

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Topic Adoption date: *November 2019*

Rapporteur: *Dr. Lei Zhang, FDA, United States*

Regulatory Chair: *Dr. Jan Welink, EC, Europe*

Last Face-to-Face Meeting: *Fukuoka, Japan, June 2024*

1. Key milestones

1.a. Current status of key milestones

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

1.b. Key Deliverables

Approval Date	Deliverable
<i>Jul. 2020</i>	<i>M13A, M13B and M13C Guideline</i>

Nov. 2023	<i>M13A Question and Answer document</i>
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1.c. Future anticipated key milestones

Expected future completion date	Milestone
Nov. 2024	<i>Face-to-Face meeting to finalise M13B draft guideline (document with Tier 2 topic)</i>
Jan. 2025	<i>Step 1 on M13B draft guideline (document with Tier 2 topic)</i>
Jan. 2025	<i>Initiate work for the third guideline in the series with Tier 3 topics (M13C)</i>
Feb. 2025	<i>Step 2a/2b on M13B draft guideline</i>
Feb. 2025	<i>Public consultation starts on M13B draft guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Aug. 2024	<i>Oct. 2024</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	<ul style="list-style-type: none"> • <i>Continue to work on M13B draft document</i> • <i>Draft and finalise various sections of M13B draft technical document</i> • <i>Collect comments from internal groups to prepare for discussion at face-to-face meeting</i>
Nov. 2024	<i>Nov. 2024</i>	<i>Face-to-Face meeting in Montreal</i>	<ul style="list-style-type: none"> • <i>Address working group member comments and resolve differences</i> • <i>Finalise draft M13B for internal clearance prior to Step 1 topic leads sign-off</i> • <i>Develop M13B Step 2 presentation</i> • <i>Develop Concept Paper Supplement for M13C</i>
Nov. 2024	<i>Dec. 2024</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	<ul style="list-style-type: none"> • <i>Member internal clearance prior to Step 1 topic leads sign-off</i> • <i>Continue work on M13B Step 2 presentation</i>

Jan. 2025	<i>Jan. 2025</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	<ul style="list-style-type: none"> • <i>Step 1 topic lead sign-off on M13B</i> • <i>Finalise M13B Step 2 presentation</i>
Feb. 2025	<i>Feb. 2025</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	<ul style="list-style-type: none"> • <i>Step 2a/2b ICH endorsement on M13B draft guideline</i> • <i>Start public consultation on M13B draft guideline</i> • <i>M13B Step 2 presentation approval by ICH</i>
Feb. 2025	<i>May. 2025</i>	<i>Multiple EWG teleconferences monthly and email communications</i>	<ul style="list-style-type: none"> • <i>Initiate work on M13C by laying out scope and outline</i> • <i>Draft various sections of M13C</i>