

ICH M15 EWG Work Plan

March 11, 2024

Topic Adoption date: *November 2021*

Rapporteur: *Dr. Scott Marshall, PhRMA*

Regulatory Chair: *Dr. Kristin Karlsson, EC, Europe*

Last Face-to-Face Meeting: *Prague, Czech Republic, November 2023*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Sep. 2022</i>	<i>1st ICH M15 Informal WG meeting</i>
<i>Nov. 2022</i>	<i>M15 Concept Paper & Business Plan endorsement & EWG formed</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Apr. 2024</i>	<i>Revision of guideline to address party SME comments</i>
<i>May. 2024</i>	<i>EWG Final Review</i>
<i>Jun. 2024</i>	<i>F2F and final updates</i>
<i>Jul. 2024</i>	<i>Plenary Working Party Review</i>
<i>Sep. 2024</i>	<i>Step 1 draft Technical document signed off by Topic Leaders Step 2a Parties consensus on Technical Document Step 2b draft Guideline adoption by Regulators</i>
<i>Q3 2024</i>	<i>Step 3 Regulatory Consultation & Discussion (including public consultation)</i>
<i>Q4 2025</i>	<i>Step 3 Sign-off of draft Guideline and Step 4 Adoption of M15 guideline</i>
<i>2026</i>	<i>Implementation of Guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2023	<i>Apr. 2024</i>	<i>Revision of guideline</i>	<i>EWG Review and update to comments from party SMEs</i>
Apr. 2024	<i>May. 2024</i>	<i>Final Review of new version</i>	<i>EWG Final Review of updated version prior to June F2F</i>
Jun. 2024	<i>June 2024</i>	<i>F2F and Final Updates</i>	<i>Resolve EWG comments and Finalize draft Technical Document</i>
Jul. 2024	<i>Jul. 2024</i>	<i>Plenary Working Group Review</i>	<i>Review of draft Technical Document by Plenary working group & associated Response</i>
Sep. 2024	<i>Sep. 2024</i>	<i>Step 1 and 2a/b Sign-Off</i>	<i>Technical document signed off by topic leaders Parties consensus on technical document Draft Guideline adoption by Regulators</i>