

ICH E2D(R1)EWG Work Plan

July 08, 2025

Topic Adoption date: *January 2020*

Rapporteur: *Anja van Haren, EC, Europe*

Regulatory Chair: *Robert Ball, FDA, United States*

Last Face-to-Face Meeting: *Montreal, Canada, November 2024*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2019</i>	<i>Topic endorsed by ICH Assembly</i>
<i>Nov. 2019</i>	<i>Business Plan Endorsement by ICH Management Committee</i>
<i>Jan. 2020</i>	<i>Concept Paper Endorsement by ICH Management Committee</i>
<i>Jul. 2023</i>	<i>Plenary Working Party (PWP) Consultation</i>
<i>Jan. 2024</i>	<i>Step 1 Experts sign off</i>
<i>Feb. 2024</i>	<i>Step 2a Endorsement by Members of the Assembly/Step 2b Endorsement by Regulatory Members of the Assembly. Release for public consultation</i>
<i>April 2025</i>	<i>Plenary Working Party (PWP) consultation</i>

1.b. Key Deliverables

MC Approval Date	Deliverable
<i>November 2019</i>	<i>Revised E2D guideline (referred to as E2D(R1))</i>
<i>March 2025</i>	<i>E2D(R1) training material</i>

1.c. Future anticipated key milestones

Expected future completion date	Milestone
<i>Aug 2025</i>	<i>Step 3 Regulatory Experts sign-off</i>
<i>Aug 2025</i>	<i>Step 4 Presentation deck</i>

Aug 2025	<i>Step 4 Adoption of E2D(R1) guideline by regulatory members of the Assembly</i>
Oct 2025	<i>E2D(R1) Training Material</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2025	<i>Aug. 2025</i>	<i>E2B(R3) Information Paper</i>	<i>Sub-team to work with ICH E2B(R3) on information paper</i>
Jan. 2025	<i>Jul. 2025</i>	<i>Weekly Teleconferences</i>	<i>Continue weekly teleconferences to finalise guideline and other tasks (step 4 presentation, E2B(R3) information paper)</i>
Mar. 2025	<i>Oct. 2025</i>	<i>Develop training material</i>	<i>Sub-team to develop training material</i>
May. 2025	<i>Aug. 2025</i>	<i>Step 4 presentation</i>	<i>Prepare step 4 presentation deck</i>
May. 2025	<i>Jul. 2025</i>	<i>Finalise guideline</i>	<i>Process comments from PWP and regulatory review.</i>
Aug. 2025	<i>Aug. 2025</i>	<i>Step 3 Regulatory Experts sign off</i>	<i>Final regulatory check and Step 3 Regulatory Experts sign off</i>
Aug. 2025	<i>Aug. 2025</i>	<i>Step 4 adoption of guideline by regulatory members of the Assembly</i>	