

ICH M18 EWG Work Plan

20 March 2026

Topic Adoption Date: May 2025

Rapporteur/s: Dr. Sarah Yim, FDA, United States

Regulatory Chair Mr. João Tavares-Neto, ANVISA, Brazil

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

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
May. 2025	Topic Proposal and Concept Paper Outline Endorsed
Nov. 2025	Concept Paper Endorsed

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
Nov. 2025	ICH MC endorsed development of the ICH M18 Guideline: Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar Development Programs

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
May 2026	Draft Technical Document Outline
Dec. 2026	Draft Technical Document
Jan. 2027	Constituent Review
Feb. 2027	Additional Constituent Review

Mar. 2027	<i>Draft Technical Document submitted to Secretariat for editorial review</i>
Apr. 2027	Develop Step 2 Presentation
May. 2027	Step 1 and Step 2a/b sign-off email submission of Final Technical Document and Step 2 Presentation
Aug. 2027	<i>Initiate review of comments from public consultation</i>
Nov.2027	<i>Revised draft Guideline</i>
Dec. 2027	<i>Constituent Review</i>
Feb. 2028	<i>Additional Constituent Review(s) (if necessary)</i>
Apr. 2028	<i>Revised draft Guideline submitted to Secretariat for editorial review</i>
May. 2028	Develop Step 4 Presentation
May. 2028	Step 3 and Step 4 sign-off email submission of Final draft Guideline Document and Step 2 Presentation – 3-4 weeks approximate

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
Dec. 2025	<i>Apr. 2026</i>	<i>Monthly teleconferences</i>	<i>Align on guideline outline, issues to be resolved and draft guideline</i>
Dec. 2025	<i>May. 2026</i>	<i>Develop Technical Document Outline</i>	<i>Develop and align internally on outline for M18 Guideline</i>
Jan. 2026	<i>Feb. 2026</i>	<i>Update Work Plan</i>	<i>Update work plan for submission to ICH Secretariat</i>
Jan. 2026	<i>Jun. 2026</i>	<i>Develop First Draft</i>	<i>First draft of main document sections to serve as basis for internal agency discussions and EWG F2F discussion in Rio</i>