

ICH M18 EWG Work Plan

18 August 2026

Topic Adoption Date: May 2025

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

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

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>May. 2025</i>	<i>Topic Proposal and Concept Paper Outline Endorsed</i>
<i>Nov. 2025</i>	<i>Concept Paper Endorsed</i>

1.2 ICH MC Key Deliverables

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

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
<i>Dec. 2026</i>	<i>Draft Technical Document</i>
<i>Jan. 2027</i>	<i>PWP and Constituent Review</i>
<i>Feb. 2027</i>	<i>Additional Constituent Review</i>
<i>Mar. 2027</i>	<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>PWP and 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 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
Jan. 2026	Jun. 2026	<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>