

# ICH M11 EWG Work Plan

**23 July 2026**

**Topic Adoption Date:** November 2018

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**Regulatory Chair:** Dr. Noemie Manent, EC, Europe

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

## 1 Key Milestones

### 1.1 Current Status of Key Milestones

| Completion date       | Milestone                                                                                                                                                                                                      |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>June 2018</b>      | <i>Concept Paper outline endorsed at Kobe meeting by ICH Assembly</i>                                                                                                                                          |
| <b>September 2018</b> | <i>Establishment of informal working group</i>                                                                                                                                                                 |
| <b>November 2018</b>  | <ul style="list-style-type: none"><li>• <i>Endorsement of final Concept Paper, Business Plan and Work Plan by ICH MC</i></li><li>• <i>Establishment of formal Expert Working Group (EWG)</i></li></ul>         |
| <b>September 2022</b> | <i>Step 1 signoff of draft Guideline, Template and Technical Specification</i>                                                                                                                                 |
| <b>September 2022</b> | <i>Step 2a/2b signoff and endorsement of draft Guideline, Template and Technical Specification</i>                                                                                                             |
| <b>October 2022</b>   | <i>Step 3 Public Consultation</i>                                                                                                                                                                              |
| <b>March 2023</b>     | <i>Closure of Step 3 Public Consultation period</i>                                                                                                                                                            |
| <b>Feb 2025</b>       | <i>Step 2 approval of draft updated Technical Specification</i>                                                                                                                                                |
| <b>April 2025</b>     | <i>Regional Public Consultation and adjudication of comments on the updated draft Technical Specification</i>                                                                                                  |
| <b>July 2025</b>      | <i>Closure of Step 3 Regional Public Consultation period</i>                                                                                                                                                   |
| <b>November 2025</b>  | <ul style="list-style-type: none"><li>• <i>Step 3 signoff of Guideline, Template and Technical Specification</i></li><li>• <i>Step 4 adoption of Guideline, Template and Technical Specification</i></li></ul> |
| <b>February 2026</b>  | <i>Delivery of Step 4 Presentation</i>                                                                                                                                                                         |

## 1.2 ICH MC Key Deliverables

| MC Approval Date     | Deliverable                                                                                                                                                                                                                                                                                                    |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>November 2018</b> | <i>Guideline that explains the need for a harmonised clinical protocol template and outlines the development process of the template and technical specification.</i>                                                                                                                                          |
| <b>November 2018</b> | <i>Clinical protocol template that specifies headers, common text, instructions, data fields, and terminologies.</i>                                                                                                                                                                                           |
| <b>November 2018</b> | <i>Technical specification that aligns with the guideline and template to enable electronic exchange of the clinical protocol information.</i>                                                                                                                                                                 |
| <b>June 2023</b>     | <i>ICH Technical Implementation Guide (TIG) for Fast Healthcare Interoperability Resources (FHIR) was added to the M11 deliverables at an interim EWG meeting in Berlin and reported to the MC. The TIG will be completed after the Guideline, Template and Technical Specification are adopted at Step 4.</i> |
| <b>October 2023</b>  | <i>Development of training materials approved by the Assembly in Prague.</i>                                                                                                                                                                                                                                   |

## 1.3 Future Anticipated Milestones

| Expected future completion date | Milestone                                                                  |
|---------------------------------|----------------------------------------------------------------------------|
| <b>August 2026</b>              | <i>Finalised training materials</i>                                        |
| <b>November 2026</b>            | <i>Collaborate with M2 on publication of TIG for FHIR on M2 ESTR1 page</i> |
| <b>November 2026</b>            | <i>Transition M11 EWG to Implementation Working Group (IWG)</i>            |

## 2. Timeline for Specific Tasks

| Beginning date       | End date    | Task / Activity                                                                               | Details                                                                                                                                                                                            |
|----------------------|-------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>November 2025</b> | August 2026 | Complete development of training materials (Guideline, Template and Technical Specification). | <ul style="list-style-type: none"><li>• Complete drafting of training materials.</li><li>• EWG review and consensus on training materials.</li><li>• Finalisation of training materials.</li></ul> |

|                             |                      |                                                                            |                                                                                                                                                                              |
|-----------------------------|----------------------|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b><i>December 2025</i></b> | <i>November 2026</i> | <i>Collaborate with M2 on publication of TIG for FHIR on M2 ESTRl page</i> | <i>Collaborate with M2 on review of TIG for FHIR.</i>                                                                                                                        |
| <b><i>November 2026</i></b> | <i>November 2026</i> | <i>Transition M11 EWG to IWG</i>                                           | <ul style="list-style-type: none"> <li>• <i>Confirm IWG membership</i></li> <li>• <i>Establish communication pathways and setup of virtual quarterly meetings</i></li> </ul> |