

ICH Q2(R2)/Q14 IWG Work Plan

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Topic Adoption date: *November 2023*

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Regulatory Chair: *Dr. David Keire, FDA, United States*

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>Nov. 2023</i>	<i>Q2(R2) and Q14 guidelines reached Step 4 Adoption by ICH Assembly</i>
<i>Nov. 2023</i>	<i>Concept paper for Implementation Working Group for Q2(R2) and Q14 approved by ICH MC.</i>
<i>Dec. 2023</i>	<i>Training materials development started.</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jun. 2024</i>	<i>All training material modules drafted</i>
<i>Nov. 2024</i>	<i>All training material modules finalized</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Dec. 2023</i>	<i>Mar. 2024</i>	<i>Key contents and early drafts of all modules</i>	<i>Through virtual sub group meetings, contents for training materials drafted.</i>
<i>Mar. 2024</i>	<i>Mar. 2024</i>	<i>High level review on training materials by plenary IWG</i>	<i>Review on all available modules by plenary IWG teleconference to identify key issues.</i>

Mar. 2024	<i>May. 2024</i>	<i>Continuation of training material editing</i>	<i>Through virtual sub group meetings, contents for training materials drafted.</i>
Jun. 2024	<i>Jun. 2024</i>	<i>4 day face to face meeting in Fukuoka</i>	<i>Detail review on training modules. Identify key issues and plan for next steps for editing.</i>
Jun. 2024	<i>Oct. 2024</i>	<i>Continuation of training material editing</i>	<i>Through virtual sub group meetings, refine the training modules.</i>
Nov. 2024	<i>Nov. 2024</i>	<i>4 day face to face meeting in Montreal</i>	<i>Finalization of all the training modules.</i>