

ICH M7(R2) Maintenance EWG/IWG Work Plan

January 28, 2022

Topic Adoption date: *June 2017*

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Regulatory Chair: *N/A*

Last Face-to-Face Meeting: *Amsterdam, June 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2014	<i>ICH-M7 was issued as Step4.</i>
Mar. 2017	<i>ICH-M7 (R1) was issued as Step 4. It contains Appendix 3 (Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes).</i>
Jul. 2018	<i>The concept paper of ICH-M7 (R2) is proposed which includes maintenance of ICH-M7 with the 2nd addendum (application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes) and Q&A topics proposed based on experience through implementation of ICH-M7.</i>
Nov. 2018	<i>The first Face-to-Face meeting of ICH-M7 (R2) was held in Charlotte, USA</i>
Jun. 2019	<i>The second Face-to-Face meeting of ICH-M7 (R2) was held in Amsterdam, The Netherlands</i>
Jun. 2020	<i>M7 Q&A reached Step 2b on 29 June 2020</i>
Oct. 2021	<i>M7 2nd addendum reached step 2b on 6 October 2021</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Oct. 2021	<i>Step 2b adoption, draft 2nd addendum</i>
Feb. 2022	<i>Draft Step 3 Q&A and revision of M7 main document sign off</i>
Mar. 2022	<i>Step 3 Public Consultation period, draft 2nd addendum</i>
May 2022	<i>Discussion of public comments on draft 2nd addendum</i>
May 2022	<i>Finalize draft Step 3 2nd addendum, document for sign off</i>
Jun. 2022	<i>Step 4 Q&A document, R2 of M7 main guideline, 2nd addendum document adoption</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jul. 2021	Feb. 2022	<i>Review public comments and prepare Step 3 draft document on Q&As</i>	<i>Review discuss and implement comments received on Step 2b Q&A-document. Prepare Step 3 draft Q&A document for sign off.</i>
Oct. 2021	Mar. 2022	<i>Step 3 public consultation 2nd addendum monographs</i>	<i>Public commenting period on 2nd addendum monographs</i>
Dec. 2021	May 2022	<i>Review of public comments on 2nd addendum monographs of M7(R2)</i>	<i>Collect and review the comments received on 2nd addendum monographs</i>
Mar. 2022	May 2022	<i>Prepare draft Step 3 document of 2nd addendum monographs and list of compound-specific AIs/PDEs for M7 R2</i>	<i>Implement relevant comments and prepare draft Step 3 document on 2nd addendum monographs and prepare responses to comments</i>
May 2022	Jun. 2022	<i>Prepare Step 4 Q&A, revision of M7 main document and 2nd addendum</i>	<i>Prepare Step 4 Q&A document, revision of M7 main document, and 2nd addendum for adoption</i>