

ICH M7(R3) Maintenance IWG/EWG Work Plan

February 27, 2024

Topic Adoption date: June 2017

Rapporteur: Dr. Aisar Atrakchi, FDA, United States

Regulatory Chair: N/A

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

1. Key milestones

1.a. Current status of key milestones

The EWG is not Active at this time as Step 4 of ICH process has been completed in 2023.

Past completion date	Milestone
Jun. 2014	ICH M7 was issued as Step 4.
Mar. 2017	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).
Jul. 2018	The concept paper of ICH-M7 (R2) is proposed which includes maintenance of ICH-M7 with the 2 nd 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.
Nov. 2018	The first Face-to-Face meeting of ICH-M7 (R2) was held in Charlotte, USA
Jun. 2019	The second Face-to-Face meeting of ICH-M7 (R2) was held in Amsterdam, The Netherlands.
Jun. 2020	M7(R2) Q&A reached Step 2a/b on 29 June 2020.
Oct. 2021	M7(R2) 2 nd Addendum reached Step 2a/b on 6 October 2021.
Apr. 2022	M7(R2) Q&A reached Step 3 expert Sign-off 26 Apr 2022.
May. 2022	M7(R2) Q&A reached Step 4
Apr. 2023	M7(R2) Guideline and Addendum reached Step 4 of ICH process