ICH S1B(R1) EWG Work Plan
January 26, 2022

Topic Adoption date: *May 2012*

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Regulatory Chair: *Dr. Jan Willem van der Laan - EC, Europe*

Last Face-to-Face Meeting: *Charlotte, NC, USA – November 2018*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Aug. 2013	*Regulatory Notice Document (RND) posted to ICH Website, formally launching the Prospective Evaluation Period (PEP) and calling upon the pharmaceutical industry to submit 50 Carcinogenicity Assessment Documents (CADs) and Final Study Reports (FSRs).*
Jan. 2016	*Substantially revised RND posted to ICH Website that redefined the target to 20 Category 3 CADs/FSRs, and extending the PEP for 2 years and setting a milestone of Dec 2017 for the 20 Category 3 CADs*
Jun. 2017	*Alignment reached in Montreal on interpretation of 14 FSRs/CADs and the favorable results supported initiating the drafting of an ICHS1B Addendum*
Dec. 2017	*48 CADs total with 24 Category 3 received, so PEP agreed to be successfully terminated. NOTE: 46 CADs remain viable as of Jan 2020.*
Feb. 2018/ Aug. 2019	*Status Reports posted to the ICH Website in Feb 2018 and Aug 2019 providing a public view to the steady progress.*
Nov. 2018	*14 additional FSRs/CADs reviewed in Charlotte to reach a total set of 28, providing confirmation of favorable results.*
Spring/Summer 2020	*20th and 21st Category 3 CAD/FSR received, thereby triggering drafting of Step 1 Document (addendum/guideline). Key negotiation points reflecting experience of PEP identified and an initial proposed addendum draft has been completed.*
Fall 2020/Winter 2021	*Draft Step 1 Document completed in preparation for final internal reviews, and subsequent approvals for sign off by each EWG member topic leader.*
Feb. 2021	*Step 1* Guideline

Apr. 2021	*Step 2A and 2B Document, which has been released for consultation by the member Drug Regulatory Authorities*
Aug. 2021	*Publication of 4th Status Report*
Nov. 2021	*Publication of JPMA-led publication on tumorigenic sensitivity in rasH2-Tg mice studies in J Toxicol Pathol supporting 50-fold exposure margin recommendation*
Dec. 2021	*End of Public Consultation Period*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
May. 2022	*Complete final Evaluative report of the complete dataset as the result of the Prospective Evaluative Period*
May. 2022	*Step 4 Document (addendum to S1 Guideline)*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Dec. 2021	*May. 2022*	S1 EWG members review comments submitted during public comment period, meet by regular teleconferences, and revise the S1 addendum to reach Step 4 document	*Review and address relevant comments; form sub-groups as warranted to achieve consensus final document.*
Nov. 2021	*May. 2022*	Writing final evaluative paper summarizing the background of all CAD decisions	*DRA representatives draft final paper; form sub-groups to address each section to finalize paper.*
May. 2022	*Jul. 2022*	*Develop training material for stakeholders*	*Draft training slide set to be posted on ICH website.*