

# ICH S1(R1) EWG Work Plan

## 18 February 2019

**Topic Adoption date:** *May 2012*

**Rapporteur:** *Dr. Frank D. Sistare - PhRMA*

**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
<b>Aug. 2013</b>	<i>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).</i>
<b>Jan. 2016</b>	<i>Substantially revised RND posted to ICH Website that redefined the target to 20 Category 3 CADs/FSRs, and extending the PEP for 2 yrs and setting a milestone of Dec 2017 for the 20 Category 3 CADs</i>
<b>Jun. 2017</b>	<i>Alignment reached on interpretation of 14 FSRs/CADs and the favorable results supported initiating the drafting of an ICHS1B Addendum</i>
<b>Dec. 2017</b>	<i>48 CADs total with 24 Category 3 received, so PEP agreed to be successfully terminated. Status Report posted to the ICH Website in Feb 2018 providing a public view to the strong progress.</i>
<b>Nov. 2018</b>	<i>With 14 additional to reach a total set of 28 matching FSRs/CADs we have confirmation of favorable results, and several additional topics have been raised for discussion in anticipation of preparing for step 1 in Nov 2019.</i>

#### 1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>November 2019</i>	<i>Step 2 Guideline</i>
<i>November 2020</i>	<i>Step 4 Guideline</i>

## 2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<b>Nov. 2018</b>	<i>Nov. 2019</i>	<p>EWG members to meet every other month by telecon.</p> <p>DRA members to meet separately to review all new CADs and FSRs.</p> <p>DRA members to draft updated PEP Status Report to ICH Website disseminating insights to evaluations of summary reports.</p> <p>Drafting of modifications to S1B to continue.</p>	<p>EWG to review progress, feedback, on CAD submissions and align on plans for meeting face-to-face in November 2019 to review regulatory member conclusions from all FSRs received and reviewed; and to continue drafting revisions to S1B and review and align on new proposed guidance that reflects the experience and value of the CADs/ FSRs during the prospective evaluation.</p>