

ICH S11 EWG Work Plan

20 July 2018

Topic Adoption date: *November 2014*

Rapporteur: *Dr. Douglas Kelle (PhRMA)*

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

Last Face-to-Face Meeting: *Kobe, Japan, June 2018*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2018</i>	<i>Agreement on Step 1 document</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Aug. 2018</i>	<i>Step 1 sign-off</i>
<i>Aug. 2018</i>	<i>Step 2a/b endorsement by ICH Assembly and Appointment of FDA as Regulatory Rapporteur for the next steps</i>
<i>Sep. 2018</i>	<i>Start of public consultation period</i>
<i>Mar-Jun 2019</i>	<i>Monthly TCs to review and discuss comments</i>
<i>Jun. 2019</i>	<i>Face-to-face meeting to discuss comments and revise document</i>
<i>Jun-Nov. 2019</i>	<i>Monthly TCs to prepare final document</i>
<i>Nov. 2019</i>	<i>Face-to-face meeting finalize Step 4 document</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Aug. 2018	<i>Aug. 2018</i>	<i>Step 1 sign-off</i>	<i>Each ICH party approves the Step 1 document</i>
Sep. 2018	<i>Mar. 2019</i>	<i>Public consultation period, review of submitted comments</i>	<i>EWG review of public comments as they are submitted</i>
Mar. 2019	<i>Jun. 2019</i>	<i>Review of submitted comments</i>	<i>Detailed review of all comments, teleconferences to discuss comments and preparation for June, 2019 meeting</i>