

ICH M9 EWG Work Plan

11 February 2019

Topic Adoption date: 14 June 2016

Rapporteur: Dr. Jan Welink – EC, Europe

Regulatory Chair: Dr. Paul Seo – FDA, United States

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Nov. 2016</i>	<i>Concept Paper endorsement</i>
<i>Nov. 2016</i>	<i>Business Plan endorsement</i>
<i>Jun. 2018</i>	<i>Reaching Step 1 on document</i>
<i>Jun. 2018</i>	<i>Reaching Step 2a/b on document</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jul. 2018</i>	<i>Public consultation period</i>
<i>Feb. 2019</i>	<i>Ending public consultation period</i>
<i>Jun. 2019</i>	<i>Steps 3 and 4 adoption of the Final Guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Feb. 2019</i>	<i>Feb. 2019</i>	<i>Review of comments received during public consultation</i>	<i>Compilation of all the comments</i>
<i>Mar. 2019</i>	<i>Mar. 2019</i>	<i>Teleconference</i>	<i>Discussion on the comments received during public consultation. Incorporation of the comments in the guideline.</i>
<i>Apr. 2019</i>	<i>Apr. 2019</i>	<i>Teleconference</i>	<i>Discussion on the comments received during public consultation. Incorporation of the comments in the guideline.</i>
<i>May. 2019</i>	<i>May. 2019</i>	<i>Teleconference</i>	<i>Discussion on the comments received during public consultation. Update guideline.</i>
<i>Jun. 2019</i>	<i>Jun. 2019</i>	<i>Face to face meeting Amsterdam if needed and Adoption of the Final Guideline</i>	<i>Finalisation of the guideline.</i>