

ICH E8(R1) EWG Work Plan

07 January 2019

Topic Adoption date: *November 2017*

Rapporteur: *Dr. Lisa LaVange, FDA, United States*

Regulatory Chair: *Dr. Fergus Sweeney, 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
<i>Nov. 2017</i>	<i>Concept Paper endorsement, Business Plan endorsement</i>
<i>Jan. 2019</i>	<i>Feedback from internal ICH Stakeholders, including webinar</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Feb. 2019</i>	<i>Step 1. All experts Sign-off on the technical Document (electronically)</i>
<i>Mar. 2019</i>	<i>Step 2a and 2b: Endorsement of draft Guideline by Members and by Regulatory Members of the Assembly (electronically)</i>
<i>Oct. 2019</i>	<i>End of Public Consultation Period</i>
<i>After Oct. 2019</i>	<i>Public Meeting with Stakeholders</i>
<i>Jun. 2020</i>	<i>Step 4: Adoption of an ICH Harmonised Guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Jan. 2019</i>	<i>Jan. 2019</i>	<i>EWG teleconference</i>	<i>Revise and Clarify Document Remove redundancy</i>
<i>Feb. 2019</i>	<i>Feb. 2019</i>	<i>EWG teleconference</i>	<i>Revise and Clarify Document Remove redundancy</i>
<i>Mar. 2019</i>	<i>Mar. 2019</i>	<i>EWG teleconference</i>	<i>Plan presentation at DIA, draft training materials/examples</i>
<i>Apr. 2019</i>	<i>Apr. 2019</i>	<i>EWG teleconference</i>	<i>Draft training materials/examples</i>