

ICH E8(R1) EWG Work Plan

13 July 2018

Topic Adoption date: *November 2017*

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Regulatory Chair: *Dr. Fergus Sweeney (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>Nov. 2017</i>	<i>Concept Paper endorsement, Business Plan endorsement</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Nov. 2018</i>	<i>Confirmation of consensus on the Technical Document</i>
<i>Jan. 2019</i>	<i>Feedback from internal ICH Stakeholders, including webinar</i>
<i>Jan. 2019</i>	<i>Step 1. All experts Sign-off on the technical Document (electronically)</i>
<i>Feb. 2019</i>	<i>Step 2a and 2b: Adoption of draft Guideline by Regulatory Members of the Assembly (electronically)</i>
<i>Aug. 2019</i>	<i>End of Public Consultation Period</i>
<i>After Aug 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>Jul. 2018</i>	<i>Jul. 2018</i>	<i>EWG teleconference</i>	<i>Revise and Clarify Document Remove redundancy</i>
<i>Aug. 2018</i>	<i>Aug. 2018</i>	<i>EWG teleconference</i>	<i>Revise and Clarify Document Remove redundancy</i>
<i>Sep. 2018</i>	<i>Sep. 2018</i>	<i>EWG teleconference</i>	<i>Revise and Clarify Document Remove redundancy</i>
<i>Oct. 2018</i>	<i>Oct. 2018</i>	<i>EWG teleconference</i>	<i>Revise and Clarify Document Remove redundancy</i>