

ICH M8 EWG/IWG Work Plan

14 January 2019

Topic Adoption date: *November 2011*

Rapporteur: *Mr. Mark Gray – FDA, United States*

Regulatory Chair: *Ms. Kristiina Puusaari – 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>Step 4 eCTD v3 Questions and Answers and Specification Change Request Document v1.31</i>
<i>Jun. 2018</i>	<i>Step 4 eCTD v4 Implementation Package v1.3</i>
<i>Jun. 2018</i>	<i>Step 4 Specification for Submission Formats for CTD v1.2</i>
<i>Jun. 2018</i>	<i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.2</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jun. 2019</i>	<i>Step 4 eCTD v3 Questions and Answers and Specification Change Request Document v1.32 (if Change Requests are received)</i>
<i>Jun. 2019</i>	<i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.3 (if Change Requests are received)</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Nov. 2018</i>	<i>Jun. 2019</i>	<i>Update v3.2.2 v1.32 and v4.0 Q&A to v1.3</i>	<ul style="list-style-type: none">• <i>Discuss change requests (if any)</i>• <i>Update and agree to the Q&As (if needed)</i>