

ICH M8 EWG/IWG Work Plan

05 February 2018

Topic Adoption date: November 2011

Rapporteur: Mr. Mark Gray (FDA, US) (Acting Rapporteur)

Regulatory Chair: Dr. Klaus Menges (EC, Europe)

Last Face-to-Face Meeting: Geneva, Switzerland – November 2017

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2016	<i>Step 4 eCTD v3.2.2 Questions and Answers and Specification Change Request Document v1.30</i>
Nov. 2016	<i>Step 4 eCTD v4 Implementation Package v1.1</i>
Nov. 2016	<i>Step 4 Specification for Submission Formats for CTD v1.1</i>
Nov. 2017	<i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.1</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jun. 2018	<i>Step 4 eCTD v3.2.2 Questions and Answers and Specification Change Request Document v1.31</i>
Jun. 2018	<i>Step 4 eCTD v4 Implementation Package v1.2</i>
Jun. 2018	<i>Step 4 Specification for Submission Formats for CTD v1.2</i>
Jun. 2018	<i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.2</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2017	<i>Jun. 2018</i>	<i>Update v3 and v4.0 Q&A to v1.2</i>	<ul style="list-style-type: none"> • <i>Discuss change requests</i> • <i>Update and agree to the Q&As</i>
Nov. 2017	<i>Jun. 2018</i>	<i>Update v4.0 Implementation Package to 1.3</i>	<ul style="list-style-type: none"> • <i>Discuss change requests</i> • <i>Update and agree to the Implementation Guide, CVs, etc.</i>
Nov. 2017	<i>Jun. 2018</i>	<i>Update Specification for Submission Formats for CTD v1.2</i>	<ul style="list-style-type: none"> • <i>Review M2 PDF Specification and determine changes/update the Specification for Submission Formats for CTD v1.2</i>
Nov. 2017	<i>Jun. 2018</i>	<i>Work with the ICH Secretariat on ICH Guideline Process Change</i>	<ul style="list-style-type: none"> • <i>Identify options for process improvement change</i> • <i>Document recommendation ICH Guideline process change</i>