

# 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
<b>Nov. 2016</b>	<i>Step 4 eCTD v3.2.2 Questions and Answers and Specification Change Request Document v1.30</i>
<b>Nov. 2016</b>	<i>Step 4 eCTD v4 Implementation Package v1.1</i>
<b>Nov. 2016</b>	<i>Step 4 Specification for Submission Formats for CTD v1.1</i>
<b>Nov. 2017</b>	<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
<b>Jun. 2018</b>	<i>Step 4 eCTD v3.2.2 Questions and Answers and Specification Change Request Document v1.31</i>
<b>Jun. 2018</b>	<i>Step 4 eCTD v4 Implementation Package v1.2</i>
<b>Jun. 2018</b>	<i>Step 4 Specification for Submission Formats for CTD v1.2</i>
<b>Jun. 2018</b>	<i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.2</i>

## 2. Timeline for specific tasks

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