

ICH E2C(R2) IWG Work Plan

28 February 2014

Topic Adopted: 15 November 2012

Last Face-to-Face Meeting: Osaka, Japan – November 2013

1. Anticipated Milestones

Completion Date	Deliverable
<i>November 2013</i>	Technical content of ICH E2C(R2) Questions and Answers document agreed by consensus of the IWG parties
<i>Q1 2014</i>	Questions and Answers document, incorporating Points to Consider available as <i>Step 4</i> documents for publication on ICH website
<i>March 2014</i>	Agreement and common understanding that the work of the ICH E2C(R2) IWG is complete and in line with mandate of the Concept paper.

2. Timelines

Date	Task / Activity	Details
<i>December 2013 – February 2014</i>	IWG web- conferences Working via email	3 web-conferences and work via email to continue streamlining technical content wording, and agree near final wording and editing changes to Q&A document
<i>25 February 2014</i>	IWG final review	Content of Q&A document agreed by all parties
<i>26 February 2014</i>	Communication to ICH Secretariat by Rapporteur and Regulatory Chair	Final Q&A document sent to ICH secretariat to prepare for <i>Step 4</i> sign- off by regulatory authority parties.