

ICH E11(R1) EWG Work Plan

1 March 2017

Topic Adopted: August 2014

Last Face-to-Face Meeting: Lisbon, Portugal - June 2016

1. Anticipated Milestones

Completion Date	Deliverable
May – November 2017	<i>Step 3 phase</i> , discuss comments received on the <i>draft Guideline</i> to finalize <i>Step 3 Draft Guideline</i>
November 2017	<i>Adoption of Step 4 Guideline</i>

2. Timelines

Date	Task / Activity	Details
February 2017 to May 2017	E11 EWG revise <i>Step 2</i> document to draft <i>Step 3</i> document.	➤ <i>Step 2b</i> document is currently under public consultation in respective regions. EWG will analyze the comments received and start revision of <i>Step 2b</i> document to reflect relevant comments.
Jun 2017	F2F meeting at Montreal EWG requests the meeting to be 3.5 days (Monday AM through Thursday AM) in order to address every topic of E11(R1).	➤ EWG convenes to discuss in detail about revision of <i>Step 2b</i> document reflecting comments received. Because public consultation in EU ends in April resulting in a short time for preparation before F2F meeting, EWG do not expect to be able to sign off <i>Step 3 Draft Guideline</i> at Montreal meeting.
Jun 2017 to Nov 2017	Finalization of <i>Step 3 Draft Guideline</i>	➤ EWG continues revision of <i>Step 2b</i> and finalize <i>Step 3 Draft Guideline</i> .