

ICH CTD-Q / M4Q(R1) - IWG Work Plan

9 August 2016

Topic Adopted: November 2014

Last Face-to-Face Meeting: Not applicable

1. Anticipated Milestones

Completion Date	Deliverable
August 2016	The <i>Step 4</i> M4(R4) Guideline document was published on the ICH website, and now enters <i>Step 5</i> of the ICH process and is recommended for implementation in the ICH regions: the European Union, Japan, the USA, Canada and Switzerland.

2. Timelines

Date	Task / Activity	Details
Aug-Oct/2015	Compare alternative regional proposals and begin consensus development with regard to responses due back to the M8 EWG/IWG.	Multiple teleconferences to try to reach agreements on proposed revisions to the Granularity document and proposals for which attributes (keywords) to include in sections 2.3 and 3 of v.4.0 of the eCTD. (Completed.)
Nov/2015	Written response to M8 EWG/IWG	IWG provides written response to M8 EWG/IWG. (Completed.)
Dec/2015	Written response to ICH SC on final issue, dealing with potential future questions pertaining to CTD-Q	IWG provides draft written proposal to ICH Secretariat for dealing with potential future questions pertaining to CTD-Q. (Completed.)