

ICH M10 EWG Work Plan

5 August 2017

Topic Adopted: June 2016

Last Face-to-Face Meeting: Montreal, Canada – May 29 – June 1, 2017

1. Anticipated Milestones

Completion Date	Deliverable
June 2018	Endorsement of <i>Step 2 a/b</i> document
June 2019	Adoption of <i>Step 4</i> document

2. Timelines

Date	Task / Activity	Details
June 2016 - Nov 2016	E-mail consultation within informal WG/EWG	➤ Concept paper and Business plan were established.
7-10 November 2016	1 st Face-to-face meeting (Osaka)	➤ Consensus on outline of the 1 st draft guideline was build based on the gap analysis of current regional guidelines/guidances.
29 May -1 June 2017	2 nd Face-to-face meeting (Montreal)	➤ Major issues in Technical Document draft ver.1 were discussed.
9 June 2017 - 16 June 2017	E-mail consultation	➤ Minutes of the Montreal meeting was shared and reviewed.
19 June 2017	E-mail consultation	➤ Technical Document draft ver.2.0 reflecting the discussion in Montreal was shared.
7 July 2017	E-mail consultation	➤ Deadline of comments on the draft from each Member.
4 Aug 2017	E-mail consultation	➤ Deadline of the revised text of each section of the draft.
18 Aug 2017	E-mail consultation	➤ Technical Document draft ver.2.1 will be shared and reviewed.
8 Sept 2017	E-mail consultation	➤ Deadline of comments on the draft from each Member.
22 Sept 2017	EWG teleconference	➤ Major issues in the draft (Validation of chromatographic assay) will be discussed.

6 Oct 2017	EWG teleconference	➤ Major issues in the draft (Validation of ligand binding assay) will be discussed.
16 Oct 2017	E-mail consultation	➤ Revised Technical Document draft will be shared.
Nov 2017	3 rd Face-to-face meeting (Geneva)	➤ Description in Technical Document draft ver.3 will be discussed and revised.