

# ICH M10 EWG Work Plan

## 10 March 2017

**Topic Adopted:** June 2016

**Last Face-to-Face Meeting:** Osaka, Japan – November 2016

### 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	<ul style="list-style-type: none"> <li>➤ Concept paper and Business plan were established.</li> <li>➤ Agenda and discussion materials for Osaka meeting were prepared.</li> </ul>
7-10 November 2016	1 <sup>st</sup> Face-to-face meeting (Osaka)	<ul style="list-style-type: none"> <li>➤ Consensus on outline of the 1<sup>st</sup> draft guideline was build based on the gap analysis of current regional guidelines/guidances.</li> </ul>
10 February 2017	Submission via e-mail	<ul style="list-style-type: none"> <li>➤ Drafted text for the technical document was submitted to the rapporteur from each regulatory Member.</li> </ul>
14-21 February 2017	E-mail consultation	<ul style="list-style-type: none"> <li>➤ The preliminary draft version 0.0 was established and reviewed by regulatory members.</li> </ul>
21 February - 2 March 2017	E-mail consultation	<ul style="list-style-type: none"> <li>➤ The draft version 0.1 was shared by all EWG members and comments were collected.</li> </ul>
7 March 2017	E-mail consultation	<ul style="list-style-type: none"> <li>➤ Comments on the draft were shared by EWG members.</li> </ul>
9 March 2017	EWG teleconference	<ul style="list-style-type: none"> <li>➤ Major issues on the draft (Scope, Matrix effect, Accuracy and Precision, Stability) were discussed.</li> </ul>
19 April 2017	EWG teleconference	<ul style="list-style-type: none"> <li>➤ Major issues of the draft (Stability, Cross validation, Reference standard, ISR, Selectivity and Specificity) will be</li> </ul>

		discussed.
10 May 2017	EWG teleconference	➤ Other important issues of the draft (Partial validation, Overall structure etc.) will be discussed.
11 May -28 May 2017	EWG e-mail consultation	➤ The draft will be revised based on the discussion in three teleconferences and establish the draft version 1.0
29 May -1 June 2017	2 <sup>nd</sup> Face-to-face meeting (Montreal)	➤ Issues that still be controversial will be discussed for updating the draft.