

## ICH M10 EWG Work Plan

*15 February 2018*

**Topic Adoption date:** *June 2016*

**Rapporteur:** *Dr. Akiko Ishii-Watabe (MHLW/PMDA, Japan)*

**Regulatory Chair:** *Dr. Akiko Ishii-Watabe (MHLW/PMDA, Japan)*

**Last Face-to-Face Meeting:** *Geneva, Switzerland, November 2017*

### 1. Key milestones

#### 1.a. Current status of key milestones

Past completion date	Milestone
<i>Oct. 2016</i>	<i>Concept Paper endorsement</i>
<i>Oct. 2016</i>	<i>Business Plan endorsement</i>

#### 1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Nov. 2018</i>	<i>Step 1 sign-off and Steps 2a/b Endorsement of the Draft Guideline</i>
<i>Jan. 2019</i>	<i>Public consultation period</i>
<i>Jun. 2020</i>	<i>Step 3 sign-off and Step 4 Adoption of the Final Guideline</i>

### 2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Jan. 2018</i>	<i>Mar. 2018</i>	<i>Review and revision of the draft</i>	<i>M10 technical document draft v3.0 is reviewed. Draft v3.1 and draft addendum will be prepared</i>

<b>Mar. 2018</b>	<i>Mar. 2018</i>	<i>Teleconference on the draft addendum</i>	<i>Items and descriptions in the draft addendum will be discussed by regulators. (on March 1<sup>st</sup>)</i>
<b>Mar. 2018</b>	<i>Mar. 2018</i>	<i>Review of the draft</i>	<i>M10 technical document draft v3.1 and draft addendum will be reviewed.</i>
<b>Apr. 2018</b>	<i>Apr. 2018</i>	<i>Teleconferences</i>	<i>Issues in M10 technical document draft v3.1 and draft addendum will be discussed. (on April 6<sup>th</sup> and April 20<sup>th</sup>)</i>
<b>May. 2018</b>	<i>May. 2018</i>	<i>Revision of the draft</i>	<i>M10 technical document draft v3.2 will be prepared by reflecting the discussion through the teleconferences and email consultations.</i>