

**ICH E17 IWG Work Plan**  
**04 February 2019**

**Topic Adoption date:** *February 2018*

**Rapporteur:** *Dr. Kristina Dunder - EC, Europe*

**Regulatory Chair:** *Mr. Yasuto Otsubo - MHLW/PMDA, Japan*

**Last Face-to-Face Meeting:** *Charlotte, NC, USA, November 2018*

**1. Key milestones**

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

<b>Past completion date</b>	<b>Milestone</b>
<b><i>Feb. 2018</i></b>	<i>Concept Paper endorsement</i>
<b><i>Nov. 2018</i></b>	<i>Face to face meeting in Charlotte. Drafting of training material consisting of 7 separate modules reflecting different parts of the E17 guideline</i>

**1.b. Future anticipated key milestones**

<b>Expected future completion date</b>	<b>Milestone</b>
<b><i>January – May 2019</i></b>	<i>Monthly teleconferences; updates and finalization of training materials</i>
<b><i>Jun. 2019</i></b>	<i>Face to face meeting in Amsterdam to finalize training modules</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Mar. 2018</b>	<i>Mar. 2018</i>	<i>Establishment of IWG</i>	<i>Nominate and assign IWG members</i>
<b>Mar. 2018</b>	<i>Nov. 2018</i>	<i>Web-conference or teleconference</i>	<i>Discuss contents of training materials</i>
<b>Nov. 2018</b>	<i>Nov. 2018</i>	<i>Face-to-face IWG Meeting</i>	<i>Finalize first set of training materials</i>
<b>Jan. 2019</b>	<i>May. 2019</i>	<i>Finalization of draft training material</i>	
<b>Jun. 2019</b>	<i>Jun. 2019</i>	<i>Finalization, Editing and Publication</i>	<i>Editing of some of the modules at the FDA studios and publication of training materials on ICH website.</i>