

# ICH Q12 IWG Work Plan

## *June 01, 2020*

**Topic Adoption date:** March 2020

**Rapporteur:** Ms. Ashley Boam - FDA, United States

**Regulatory Chair:** Ms. Nanna Kruse – EC, Europe

**Last Face-to-Face Meeting:** n/a

### 1. Key milestones

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

Past completion date	Milestone
<i>Mar. 2020</i>	<i>Concept Paper endorsement</i>

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

Expected future completion date	Milestone
<i>Nov. 2020</i>	<i>Completion of training materials and submission for posting</i>
<i>Spring 2021</i>	<i>Initiation of training activities</i>

### 2. Timeline for specific tasks

Beginning date	End Date	Task / Activity	Details
<i>Apr. 2020</i>	<i>Apr. 2020</i>	<i>IWG meeting via teleconference and exchange of proposed training slides via email</i>	<i>Continue discussion of proposed training slides.</i>
<i>May. 2020</i>	<i>May. 2020</i>	<i>IWG meeting via teleconference and exchange of proposed training slides via email</i>	<i>Continue discussion of proposed training slides. Gain IWG alignment on certain modules.</i>

<b><i>Jun 2020</i></b>	<b><i>Jun 2020</i></b>	<i>IWG meeting via teleconference and exchange of proposed training slides via email</i>	<i>Continue discussion of proposed training slides. Gain IWG alignment on certain modules.</i>
<b><i>Jul. 2020</i></b>	<b><i>Jul. 2020</i></b>	<i>IWG meeting via teleconference and exchange of proposed training slides, narrative text, and case studies via email</i>	<i>Continue discussion of proposed and gain alignment on training slides, narrative text, and selection of additional examples to be included in training materials.</i>
<b><i>Sep. 2020</i></b>	<b><i>Sep. 2020</i></b>	<i>IWG meeting via teleconference and exchange of narrative text and case studies via email</i>	<i>Continue discussion of proposed narrative text and case studies.</i>
<b><i>Oct. 2020</i></b>	<b><i>Oct. 2020</i></b>	<i>IWG meeting via teleconference to discuss narrative text and case study revisions and plan agenda for November F2F meeting</i>	<i>Continue discussion of any outstanding comments on narrative text and case studies. Finalize agenda for Nov 2020 meeting.</i>