

# ICH E19 EWG Work Plan

## 31 January 2019

**Topic Adoption date:** *September 2016*

**Rapporteur:** *Dr. Mary Thanh Hai - FDA, United States*

**Regulatory Chair:** *Dr. Peter Mol - EC, Europe*

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

### 1. Key milestones

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

Past completion date	Milestone
<i>Jul. 2017</i>	<i>Final concept paper endorsed by ICH Management Committee</i>

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

Expected future completion date	Milestone
<i>Feb. 2019</i>	<i>Finalise the technical document and Step 1 Experts sign-off</i>
<i>Mar. 2019</i>	<i>Step 2a/b Endorsement of the Draft Guideline</i>
<i>Jun. 2021</i>	<i>Finalise Step 3/Step 4 Adoption of the Final Guideline</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<i>Nov. 2017</i>	<i>Jun. 2018</i>	<i>E-mail consultation within EWG</i>	<ul style="list-style-type: none"> <li>➤ <i>Tasks distributed among members (action plan) as identified during the face to face meeting</i></li> <li>➤ <i>Continue to work on technical document</i></li> </ul>
<i>Feb. 2018</i>	<i>Apr. 2018</i>	<i>Teleconference</i>	<ul style="list-style-type: none"> <li>➤ <i>Discuss draft of the technical document</i></li> </ul>
<i>Jun. 2018</i>	<i>Jun. 2018</i>	<i>Face-to-Face meeting (Kobe, Japan)</i>	<ul style="list-style-type: none"> <li>➤ <i>Face-to-Face meeting to discuss resolve issues and draft as a group (achieve close to a final version of the technical document)</i></li> </ul>
<i>Jun. 2018</i>	<i>Aug. 2018</i>	<i>EWG Editorial team to edit technical document</i>	<ul style="list-style-type: none"> <li>➤ <i>Document clean-up and edit to create a consistent style and format</i></li> </ul>
<i>Aug. 2018</i>	<i>Sept. 2018</i>	<i>E-mail consultation within EWG</i>	<ul style="list-style-type: none"> <li>➤ <i>Continue to work on technical document</i></li> <li>➤ <i>Generate high-level comments on the draft technical document</i></li> </ul>
<i>Sept. 2018</i>	<i>Sept. 2018</i>	<i>Teleconference via WebEx</i>	<ul style="list-style-type: none"> <li>➤ <i>Discuss comments generated to the draft technical document</i></li> </ul>
<i>Sept. 2018</i>	<i>Nov. 2018</i>	<i>E-mail consultation within EWG</i>	<ul style="list-style-type: none"> <li>➤ <i>Continue to work on technical document</i></li> <li>➤ <i>Schedule teleconference(s) as needed</i></li> </ul>
<i>Nov. 2018</i>	<i>Nov. 2018</i>	<i>Face-to-face meeting (Charlotte, NC, USA)</i>	<ul style="list-style-type: none"> <li>➤ <i>Complete near draft final technical document</i></li> </ul>
<i>Nov. 2018</i>	<i>Jan. 2019</i>	<i>E-mail and Teleconference via WebEx consultation within EWG</i>	<ul style="list-style-type: none"> <li>➤ <i>Monthly teleconferences , e-mail, and document sharing to revise draft technical document</i></li> </ul>

<i>Feb. 2019</i>	<i>Feb. 2019</i>	<i>Step 1 expert sign-off</i>	➤ <i>Finalise technical document and electronic Step 1 Experts sign-off</i>
<i>Feb. 2019</i>	<i>Mar. 2019</i>	<i>E-mail consultation within EWG and Assembly</i>	➤ <i>Electronic Step 2a/b Endorsement of Draft Guideline by Assembly Members and by Assembly Regulatory Members</i>
<i>Apr. 2019</i>	<i>Apr. 2019</i>	<i>Start of Step 3- Regional public comment period</i>	<ul style="list-style-type: none"> <li>➤ <i>Start of regional public comments period</i></li> <li>➤ <i>range between 30 days to 6 months depending on regional requirements</i></li> </ul>
<i>Oct. 2019</i>	<i>Oct. 2019</i>	<i>End of regional public comment period</i>	<ul style="list-style-type: none"> <li>➤ <i>Receive public comments from all regions</i></li> <li>➤ <i>Review regional public comments</i></li> </ul>
<i>Nov. 2019</i>	<i>Nov. 2019</i>	<i>Face-to-face meeting (TBD)</i>	➤ <i>Revise technical document to address public comments</i>
<i>Jun. 2020</i>	<i>Jun. 2020</i>	<i>Face-to-face meeting (TBD)</i>	➤ <i>Revise technical document to address public comments</i>
<i>Nov. 2020</i>	<i>Nov. 2020</i>	<i>Face-to-face meeting (TBD)</i>	➤ <i>Revise technical document to address public comments</i>
<i>Jun. 2021</i>	<i>Jun. 2021</i>	<i>Face-to-face meeting (TBD)</i>	➤ <i>Finalise Step 3/Step 4 Adoption</i>