

## ICH E2D(R1) EWG Work Plan

*January 28, 2022*

**Topic Adoption date:** *November 2019*

**Rapporteur:** *Ms. Vicki Edwards - EFPIA*

**Regulatory Chair:** *TBD*

**Last Face-to-Face Meeting:** *Nov/Dec 2021 (Virtual F2F)*

### 1. Key milestones

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

<b>Past completion date</b>	<b>Milestone</b>
<i>Jun. 2019</i>	<i>Topic endorsed by ICH Assembly</i>
<i>Sep. 2019</i>	<i>ICH approval to form Informal Working Group</i>
<i>Nov. 2019</i>	<i>Endorsement of formal EWG by ICH Management Committee</i>
<i>Nov. 2019</i>	<i>Concept Paper Endorsement by ICH Management Committee</i>
<i>Nov. 2019</i>	<i>Business Plan Endorsement by ICH Management Committee</i>

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

<b>Expected future completion date</b>	<b>Milestone</b>
<i>Feb. 2023</i>	<i>Plenary Working Party (PWP) Consultation</i>
<i>Apr. 2023</i>	<i>Step 1 Experts sign off</i>
<i>May 2023</i>	<i>Step 2a Endorsement by Members of the Assembly/Step 2b Endorsement by Regulatory Members of the Assembly. Release for public consultation</i>
<i>Sep. 2023</i>	<i>Step 3 Regulatory Consultation and Discussion</i>
<i>Feb. 2024</i>	<i>Plenary Working Party (PWP) Consultation</i>

<b>Apr. 2024</b>	<i>Step 3 Regulatory Experts sign-off</i>
<b>May 2024</b>	<i>Step 4 Adoption of ICH Harmonized Guideline by Regulatory Members of the Assembly</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Jan. 2022</b>	<b>Dec. 2022</b>	<i>EWG will meet monthly for 2 hours via tele/web conferences</i>	<i>The EWG SubTeams will present specific topics on interest including recommendations and proposed language for the guideline to the entire EWG for consensus building and endorsement.</i>
<b>Jan. 2022</b>	<b>May 2022</b>	<i>SubTeams continue to work on proposals and revisions to E2D guideline on assigned topics.</i>	<i>SubTeam members work within their assigned teams to progress the proposed revisions to the E2D guideline. Subteams include 1) Industry Sponsored Programs (ISPs) 2) Literature, Special Situations (medication errors, off label use, outcome only reports, and lack of efficacy), and Information and Communication Technology.</i>
<b>May 2021</b>	<b>May 2022</b> <b>Nov. 2022</b>	<i>EWG biannual virtual face-to-face meetings</i>	<i>Start/continue with revisions to E2D guideline. Allocated Team leads and subteams provide revisions on key sections (sections 3, 4, and 5) of guideline.</i>