

## ICH M8 EWG/IWG Work Plan

*January 28, 2022*

**Topic Adoption date:** *November 2011*

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**Regulatory Chair:** *Kristiina Puusaari - EC, Europe*

**Last Face-to-Face Meeting:** *Kobe, Japan – June 2018*

### 1. Key milestones

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

| Past completion date | Milestone                                                                                   |
|----------------------|---------------------------------------------------------------------------------------------|
| <b>Nov. 2021</b>     | <i>Step 4 eCTD v3 Questions and Answers and Specification Change Request Document v1.32</i> |
| <b>Nov. 2021</b>     | <i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.6</i>  |
| <b>Jun. 2021</b>     | <i>Step 4 eCTD v4 Implementation Package v1.4</i>                                           |
| <b>Jun. 2021</b>     | <i>Step 4 Specification for Submission Formats for CTD v1.3</i>                             |

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

| Expected future completion date | Milestone                                                                                                                     |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| <b>May. 2022</b>                | <i>Step 4 eCTD v3 Questions and Answers and Specification Change Request Document v1.33 (if Change Requests are received)</i> |
| <b>May. 2022</b>                | <i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.7</i>                                    |
| <b>May. 2022</b>                | <i>Step 4 eCTD v4.0 Implementation Package v1.5</i>                                                                           |
| <b>Nov. 2022</b>                | <i>eCTD v4.0 Controlled Vocabulary Maintenance Process</i>                                                                    |

### 2. Timeline for specific tasks

## eCTD v3.2.2

| Beginning date   | End date         | Task / Activity                | Details                                                                                                                                                 |
|------------------|------------------|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Nov. 2021</b> | <i>May. 2022</i> | <i>Update v3 Q&amp;A v1.33</i> | <ul style="list-style-type: none"><li>• <i>Discuss change requests (if any)</i></li><li>• <i>Update and agree to the Q&amp;As (if needed)</i></li></ul> |

## eCTD v4.0

| Beginning date   | End date         | Task / Activity                                            | Details                                                                                                                                                                                                                                    |
|------------------|------------------|------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Nov. 2021</b> | <i>May. 2022</i> | <i>Update v4 Q&amp;A to v1.7</i>                           | <ul style="list-style-type: none"><li>• <i>Discuss change requests</i></li><li>• <i>Update and agree to the Q&amp;As</i></li><li>• <i>Update status of Change Request incorporated into the eCTD v4.0 Implementation Package</i></li></ul> |
| <b>Nov. 2021</b> | <i>May. 2022</i> | <i>Update eCTD v4 Implementation Package v1.5</i>          | <ul style="list-style-type: none"><li>• <i>Incorporate Change Requests recommendations into the eCTD v4.0 Implementation Package</i></li></ul>                                                                                             |
| <b>Nov. 2021</b> | <i>Nov. 2022</i> | <i>eCTD v4.0 Controlled Vocabulary Maintenance Process</i> | <ul style="list-style-type: none"><li>• <i>Discuss the eCTD v4.0 Controlled Vocabulary Maintenance Process and any implementation issues that need to be addressed</i></li></ul>                                                           |