

ICH E8(R1) EWG Work Plan

January 14, 2021

Topic Adoption date: *November 2017*

Rapporteur: *Dr. Lisa LaVange,- FDA, United States*

Regulatory Chair: *Dr. Andreas Kirisits, - EC, Europe*

Last Face-to-Face Meeting: *Amsterdam, the Netherlands- June 2019*

1. Key milestones

1.a. Current status of key milestones

| Past completion date | Milestone |
|----------------------|---|
| <i>Nov. 2017</i> | <i>Concept Paper endorsement, Business Plan endorsement</i> |
| <i>May. 2019</i> | <i>Draft Guideline Endorsement by the Members of the ICH Assembly under Step 2 and released for public consultation</i> |
| <i>Jun. 2019</i> | <i>Step 2 Presentation posted to ICH site</i> |
| <i>Oct. 2019</i> | <i>End of Public Consultation Period</i> |
| <i>Oct. 2019</i> | <i>ICH E8(R1) public stakeholder meeting targeted at global stakeholders held</i> |

1.b. Future anticipated key milestones

| Expected future completion date | Milestone |
|---------------------------------|--|
| <i>May. 2021</i> | <i>Step 4: Adoption of an ICH Harmonised Guideline</i> |

2. Timeline for specific tasks

| Beginning date | End date | Task / Activity | Details |
|-----------------------|------------------|--|--|
| Jan. 2021 | <i>Jan. 2021</i> | <ul style="list-style-type: none"> • <i>EWG teleconferences</i> | <ul style="list-style-type: none"> • <i>Continue document revision based on stakeholder feedback</i> |
| Feb. 2021 | <i>Feb. 2021</i> | <ul style="list-style-type: none"> • <i>Review by E6 EWG</i> | <ul style="list-style-type: none"> • <i>Review to ensure that the document is consistent with work being done by E6</i> |
| Mar. 2021 | <i>Apr. 2021</i> | <ul style="list-style-type: none"> • <i>Stakeholder feedback</i> | <ul style="list-style-type: none"> • <i>EWG members take document back to their organizations for stakeholder review/feedback</i> |
| Apr. 2021 | <i>May. 2021</i> | <ul style="list-style-type: none"> • <i>EWG Teleconferences</i> | <ul style="list-style-type: none"> • <i>Revision based on stakeholder feedback</i> |
| May. 2021 | <i>May. 2021</i> | <ul style="list-style-type: none"> • <i>EWG sign-off on ICH E8(R1) final document</i> • <i>Continue work on training materials as required</i> | |