ICH
harmonisation for better health

ASSEMBLY

AGENDA PAPERS

19-20 November 2019

Singapore

Dated 31 October 2019

ICH ASSEMBLY MEETING

AGENDA

19 & 20 November 2019

Singapore

Opening of the ICH Assembly Meeting

Welcoming remarks from the ICH Assembly Chair Ms. Lenita Lindström-Gommers (EC, Europe) and ICH Assembly Vice-Chair Dr. Celia Lourenco (Health Canada, Canada).

- The Assembly is invited to note the Member Representatives and Observer Delegates appointed to the Assembly.

The ICH Secretariat will provide a brief presentation to the Assembly on the use of the online platform for Members and Observers to have access to the agenda papers and background documents during the meeting.

Adoption of the Agenda

- The Assembly is invited to adopt the agenda for the ICH Assembly meeting.

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1. Procedural Matters

General

The ICH Assembly Chair/Vice Chair will inform the Assembly on ICH MC consideration of changes to ICH procedural documents in view of recent MC and/or Assembly discussions, as well as the need identified for certain clarifications.

ICH Articles of Association and Assembly Rules of Procedure

The ICH Assembly Chair/Vice-Chair will inform the Assembly on amendments proposed to the ICH Articles of Association (AoA) and Assembly Rules of Procedures (RoP) which were last updated and approved by the Assembly in Amsterdam, the Netherlands in June 2019.

- The Assembly is invited to take a **decision** to adopt the revised AoA and Assembly RoP.

ICH Management Committee Rules of Procedure and Standard Operating Procedures of ICH Working Groups

The ICH MC will inform the Assembly on updates made by the ICH MC to the ICH MC RoP and the Standard Operating Procedures (SOPs) of ICH Working Groups (WGs) which were last updated and approved by the ICH MC in Amsterdam, the Netherlands in June 2019.

- The Assembly is invited to share its views on the report.

2. Membership and Observership

The ICH MC will inform the Assembly on any Membership and/or Observership application(s) processed by the ICH MC since the meeting in Amsterdam, the Netherlands in June 2019.

3. Update on MedDRA

The MedDRA MC Chair will provide a report on current MedDRA activities.

- The Assembly is invited to share its views on the report.

4. Financial Matters

The ICH MC will provide an update on ICH financial matters, including the revised 2020 ICH budget and 5-Year ICH budget projection for 2020-2024, as well as provisional 2021 ICH budget and Membership Fees.

- The Assembly is invited to share its views on the update;
- The Assembly is invited to take a **decision** to approve the revised 2020 ICH budget;
- The Assembly is invited to take a **decision** to approve the provisional 2021 ICH budget and 2021 Membership Fees.

The MedDRA MC Chair will provide an update on MedDRA financial matters, including the 2020 MedDRA budget, 2020 MedDRA subscription fees; and the 5-year MedDRA budget projection for 2020-2024.

- The Assembly is invited to share its views on the update;
- The Assembly is invited to take a **decision** to approve the 2020 MedDRA budget, including 2020 MedDRA subscription fees.

5. Collaboration with PIC/S

The ICH MC will inform the Assembly on considerations for interactions between ICH and the Pharmaceutical Inspection Co-operation Scheme PIC/S on ICH Guideline work with relevance to both Regulatory assessor and Inspector disciplines.

6. Annual Work Plan and Multi-Annual Strategic Plan of the Association

The ICH MC will present to the Assembly the 2020 Work Plan and Multi-Annual Strategic Plan of the Association.

- The Assembly is invited to take a **decision** to approve the 2020 Work Plan and Multi-Annual Strategic Plan of the Association.

The MedDRA MC Chair will present to the Assembly the 2020 MedDRA MC Work Plan.

- The Assembly is invited to take a **decision** to approve the 2020 MedDRA MC Work Plan.

7. General Operational Matters

ICH General Operational Matters

- The Assembly is invited to note the written report of the ICH Secretariat on general operational matters, including participation of Members' and Observers' experts in ICH, and share its views.

8. New Topic Process & Strategic Discussions

2019 New Topics Process

The ICH MC will provide an update on considerations on:

- The timeframe to initiate work on the New Topic proposal adopted by the Assembly in June 2019 on *Impurity: Assessment and Control of Extractables and Leachables (E&L) for Pharmaceuticals and Biologics* (code Q3E);
- The Concept Paper Outline on the revision of ICH Q9: *Quality Risk Management*, as per the New Topic proposal adopted by the Assembly in June 2019;
- The revision of the New Topic proposal and the Concept Paper Outline on *Bioequivalence for Immediate-Release Solid Oral Dosage Forms* in consultation with the Informal Generic drugs Discussion Groups (IGDG).

- The Assembly is invited to share its views on the update;
- The Assembly is invited to take a **decision** to approve the Concept Paper Outline for the revision of ICH Q9, further to which a Q9(R1) informal WG would be established;
- The Assembly is invited to take a **decision** to approve the Concept Paper Outline for the New Topic proposal on *Bioequivalence for Immediate-Release Solid Oral Dosage Forms*, further to which an informal WG would be established.

2020 New Topics Process

The ICH MC will provide an update on the New Topics process for the 2020 cycle, including the cut-off date for submission of any New Topics proposals by Assembly Members and Observers.

Reflection Papers

The ICH MC will present the status of work regarding development by PhRMA of the revised draft Reflection Paper on *Model Informed Drug Development (MIDD),* and status of work by EC, Europe in collaboration with FDA, United Sates on a draft Reflection Paper on patient-focused aspects of drug development.

- The Assembly is invited to provide its views.

9. Implementation of ICH Guidelines

The ICH MC will update the Assembly on activities related to the implementation of ICH Guidelines.

- The Assembly is invited to note the status of implementation of ICH Guidelines by ICH Regulatory Members published on the ICH website;
- The Assembly is invited to discuss ICH Guideline implementation and to share experiences and challenges.

Implementation Survey Publication

The ICH MC will provide an update on the finalisation of the publication on the outcome of the ICH implementation survey for monitoring the adequacy of implementation and adherence to ICH Guidelines for Regulators and Industry, as well as on considerations for future ICH implementation activities.

- The Assembly is invited to provide its views.

10. Training

General

The ICH MC will update the Assembly on the activities of the MC Training Subcommittee, including: status of work with training providers for ICH Recognised Training Programmes, including development of online training programmes; and support provided to ICH WGs developing training materials.

- The Assembly is invited to share its views on the update.

ICH Training Associates

The ICH MC will update the Assembly on the status of work regarding ICH Training Associates, aimed at contracting appropriate accredited non-profit training organisations/institutions to assist ICH in its efforts to address in a strategic manner the training needs of ICH Regulatory and Industry Members and Observers.

- The Assembly is invited to share its views on the update.

11. Communication

Commemoration of ICH's 30th Anniversary

The ICH MC will inform the Assembly on planning for the commemoration of the 30th Anniversary of ICH in 2020.

- The Assembly is invited to share its views.

Communication Activities

The ICH Secretariat will highlight the recent changes to the ICH website to improve ICH communication with stakeholders.

- The Assembly is invited to share its views.

ICH Regional Public Meetings

- The Assembly is invited to note that Members are invited to inform the ICH Secretariat on any ICH Regional Public Meetings in their respective regions prior to/following the ICH meeting in Singapore in November 2020, for publication on the ICH website.

12. Appointment of ICH Management Committee Elected Representatives

The applicants for the positions of Regulatory ICH MC Elected Representatives will be invited to provide a brief introduction and present their interest in joining the ICH MC.

The Assembly Members will note the applications put forward for ICH MC Elected Representative and the considerations of the MC regarding eligibility.

- The Assembly Members are invited to **vote** via secret ballot on the appointment of any MC Elected Representatives in line with the Assembly RoP Section 3.6.4;
- The Assembly is invited to note the results of the elections and the appointment of any MC Elected Representatives.

13. Q4B Maintenance

Representatives from the Pharmacopeial Discussion Group (PDG) will be invited to provide a short update on the timeframe for the next steps regarding the revision of the Q4B Guideline and Annexes, as per the Q4B Annexes maintenance process described in Annex 5 of the SOP of the WGs.

- The Assembly is invited to share its views.

14. WGs Meeting in Singapore

14.1. E2D(R1) informal WG: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting (Lead: Dr. Edwards – EFPIA)

The E2D(R1) informal WG Lead will report on the outcome of the meeting of the E2D(R1) informal WG and the progress made on the development of the E2D(R1) Concept Paper and Business Plan.

- The Assembly is invited to share its views on the report;
- The Assembly is invited to take a **decision** to endorse the E2D(R1) informal WG Lead for the role of E2D(R1) Rapporteur, to be effective when the E2D(R1) informal WG transitions into an EWG upon approval by the ICH MC of its Concept Paper and Business Plan.

The E2D(R1) Concept Paper and Business Plan are expected at the ICH meeting in Singapore.

14.2. E6(R3) informal WG: Good Clinical Practice (Lead: Dr. M. El Zarrad – FDA, United States; Regulatory Chair: Dr. Sweeney – EC, Europe)

The E6(R3) informal WG Lead will report on the outcome of the meeting of the E6(R3) informal WG and the progress made on the development of the E6(R3) Concept Paper and Business Plan.

- The Assembly is invited to share its views on the report;
- The Assembly is invited to take a **decision** to endorse the E6(R3) informal WG Lead for the role of E6(R3) Rapporteur, to be effective when the E6(R3) informal WG transitions into an EWG upon approval by the ICH MC of its Concept Paper and Business Plan.

The E6(R3) Concept Paper and Business Plan are expected at the ICH meeting in Singapore.

14.3. E11A EWG: Paediatric Extrapolation (Rapporteur: Dr. Yao – FDA, United States)

The E11A Rapporteur will report on the outcome of the meeting of the E11A EWG and the progress made on the E11A draft Technical Document.

- The Assembly is invited to share its views on the report.

Steps 1 and 2a/b are expected by November 2020.

Background Document:

- *E11A EWG Work Plan, dated 6 August 2019.*

14.4. E14/S7B IWG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Rapporteur: Dr. Strauss – FDA, United States; Regulatory Chair: Dr. Shinagawa – MHLW/PMDA, Japan)

The E14/S7B Rapporteur will report on the outcome of the meeting of the E14/S7B IWG and the progress made on the development of Q&As and the Integrated Risk Assessment for E14/S7B.

- The Assembly is invited to share its views on the report.

Finalisation of the first stage of Q&As is expected by June 2020. Furthermore, in line with the procedures, and as agreed by the MC during the MC Technical TC on 25 March 2019, a decision on whether the Q&As should proceed directly to Steps 3 and 4 without the need for public consultation would be taken by the MC when the final Q&As document is available for MC review depending on whether or not it sets forth substantial new interpretations of the E14 and S7B Guidelines.

Background Document:

- *E14/S7B IWG Work Plan, dated 31 July 2019.*

14.5. E19 EWG: Optimization of Safety Data Collection (Rapporteur: Dr. Thanh Hai – FDA, United States; Regulatory Chair: Dr. Mol - EC, Europe)

The E19 Rapporteur will report on the outcome of the meeting of the E19 EWG and the progress made on reviewing the comments received during the regional public consultations which ended in September 2019.

- The Assembly is invited to share its views on the report.

Steps 3 and 4 are expected by June 2021.

Background Document:

- *E19 EWG Work Plan, dated 29 July 2019.*

14.6. E20 informal WG: Adaptive Clinical Trials (informal WG Lead: Dr. Zhong - PhRMA; Regulatory Chair: Dr. Levin – FDA, United States)

The E20 acting Rapporteur will report on the outcome of the meeting of the E20 EWG and the progress made on the development of the E20 Work Plan and E20 Technical Document.

- The Assembly is invited to share its views on the report;
- The Assembly is invited to take a **decision** to endorse the E20 informal WG Lead for the role of E20 Rapporteur, to be effective when the E20 informal WG transitions into an EWG upon approval by the ICH MC of its Concept Paper and Business Plan.

14.7. M10 EWG: Bioanalytical Method Validation (Rapporteur: Dr. Ishii-Watabe – MHLW/PMDA, Japan; Regulatory Chair: Dr. Booth – FDA, United States)

The M10 Rapporteur will report on the outcome of the meeting of the M10 EWG and the progress made on reviewing the comments received during the regional public consultations which ended in September 2019.

- The Assembly is invited to share its views on the report.

Steps 3 and 4 are expected by November 2020.

Background Document:

- *M10 EWG Work Plan, dated 1 August 2019.*

14.8. M11 EWG: Clinical electronic Structured Harmonized Protocol (CeSHarP) (Rapporteur: Ms. Combs – PhRMA; Regulatory Chair: Dr. Fitzmartin – FDA, United States)

The M11 Rapporteur will report on the outcome of the meeting of the M11 EWG and the progress made on the development of the M11 Technical Document, the protocol template and the technical specification document, as well as on strategic engagement with other key WGs: E8(R1) EWG, E9(R1) EWG, and M2 EWG, and the progress made on early engagement of external stakeholders.

Steps 1 and 2a/b are expected by July 2020.

Background Document:

- *M11 EWG Work Plan, dated 6 August 2019.*

14.9. M12 informal WG: Drug Interaction Studies (Lead: Dr. Madabushi - FDA, United States; Regulatory Chair: Dr. Ishiguro)

The M12 informal WG Lead will report on the outcome of the meeting of the M12 informal WG and the progress made on the development of the M12 Concept Paper and Business Plan.

- The Assembly is invited to share its views on the report;
- The Assembly is invited to take a **decision** to endorse the M12 informal WG Lead for the role of M12 Rapporteur, to be effective when the M12 informal WG transitions into an EWG upon approval by the ICH MC of its Concept Paper and Business Plan.

The M12 Concept Paper and Business Plan are expected at the ICH meeting in Singapore.

14.10. Q2(R2)/Q14 EWG: Analytical Procedure Development and Revision of Q2(R1) Validation of Analytical Procedures (Rapporteur: Dr. Hiyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Keire – FDA, United States)

The Q2(R2)/Q14 Rapporteur will report on the outcome of the meeting of the Q2(R2)/Q14EWG and the progress made on the development of the Q2(R2)/Q14 Technical Document.

- The Assembly is invited to share its views on the report.

Steps 1 and 2a/b are expected by June 2020.

Background Document:

- *Q2(R2)/Q14 EWG Work Plan, dated 15 February 2019.*

14.11. Q5A(R2) informal WG: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (Lead: Dr. Welch - FDA, United States)

The Q5A(R2) informal WG Lead will report on the outcome of the meeting of the Q5A(R2) informal WG and the progress made on the development of the Q5A(R2) Concept Paper and Business Plan.

- The Assembly is invited to share its views on the report;
- The Assembly is invited to take a **decision** to endorse the Q5A(R2) informal WG Lead for the role of Q5A(R2) Rapporteur, to be effective when the Q5A(R2) informal WG transitions into an EWG upon approval by the ICH MC of its Concept Paper and Business Plan.

The Q5A(R2) Concept Paper and Business Plan are expected at the ICH meeting in Singapore.

14.12. Q12 EWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (Rapporteur: Ms. Boam – FDA, United States; Regulatory Chair: Ms. Kruse – EC, Europe)

The Q12 Rapporteur will report on the outcome of the meeting of the Q12 EWG and the progress made on the Q12 draft Guideline and Annex.

Steps 3 and 4 for the Q12 Guideline and Annex are expected by November 2019, further to which the Q12 EWG will work on the development of training materials.

Background Document:

- *Q12 EWG Work Plan, dated 12 August 2019.*

14.13. Q13 EWG: Continuous Manufacturing of Drug Substances and Drug Products (Rapporteur: Dr. Lee – FDA, United States; Regulatory Chair: Dr. Matsuda – MHLW/PMDA, Japan)

The Q13 Rapporteur will report on the outcome of the meeting of the Q13 EWG, the progress made on the development of the Q13 Technical Document, and the outcome and planning of informal regional Continuous Manufacturing site visits for interested Q13 EWG Regulatory Members experts.

Steps 1 and 2a/b are expected by June 2020.

Background Document:

- *Q13 EWG Work Plan, dated 2 August 2019.*

14.14. S12 informal WG: Biodistribution Studies for Gene Therapy Products (Lead: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Serabian – FDA, United States)

The S12 informal WG Lead will report on the outcome of the meeting of the S12 informal WG and the progress made on the development of the S12 Concept Paper and Business Plan.

- The Assembly is invited to share its views on the report;
- The Assembly is invited to take a **decision** to endorse the S12 informal WG Lead for the role of S12 Rapporteur, to be effective when the S12 informal WG transitions into an EWG upon approval by the ICH MC of its Concept Paper and Business Plan.

The S12 Concept Paper and Business Plan are expected at the ICH meeting in Singapore.

15. WGs Not Meeting in Singapore

The Assembly will note the written status reports and the work plans of the groups not meeting in Singapore.

The Coordinators will raise any items requiring discussion or decision by the Assembly.

- The Assembly is invited to provide any input requested and take any decision as needed.

15.1. Standing Paediatric EWG (Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Yao – FDA, United States)

The Standing Paediatric EWG did not receive any recent request for paediatric advice, and the group remains available for expert consultation and guidance to WGs charged with developing new or revised guidance which may be of relevance to paediatric drug development.

15.2. E2B(R3) EWG/IWG: Revision of the Electronic Submission of Individual Case Safety Reports (Rapporteur: Dr. Misu – MHLW/PMDA, Japan; Regulatory Chair: Mr. Chen – FDA, United States)

The E2B(R3) EWG/IWG continues its work, including on the revision of the EDQM User Guide incorporating the mapping table for the Route of Administration (RoA) between ICH and EDQM terms; on the Service Level Understanding (SLU) for terminology list management finalised in July 2019; and on the development of training material.

Background Document:

- *E2B(R3) EWG/IWG Work Plan, dated 9 August 2019.*

15.3. E8(R1) EWG: Revision on General Considerations for Clinical Studies (Rapporteur: Dr. LaVange – FDA, United States; Regulatory Chair: Dr. Sweeney – EC, Europe)

The E8(R1) EWG continues its work on reviewing the comments received during the regional public consultations which ended in October 2019.

The E8(R1) EWG held the E8(R1) global public stakeholder meeting on 31 October 2019 at the FDA, United States headquarters, and continues its work on the development of the E8(R1) draft Guideline.

- The Assembly is invited to share its views on the report on the E8(R1) global public stakeholder meeting.

The E8(R1) EWG will hold an interim meeting on 27-30 March 2020 in Tokyo, hosted by MHLW/PMDA, Japan and JPMA.

Steps 3 and 4 are expected by June 2020.

Background Document:

- *E8(R1) EWG Work Plan, dated 9 August 2019.*

15.4. E9(R1) EWG: Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses (Rapporteur: Dr. Petavy – EC, Europe; Regulatory Chair: Dr. Ando – MHLW/PMDA, Japan)

E9(R1) training materials, excluding videos, were finalised in October 2019.

The E9(R1) continues its work on the E9(R1) Addendum and the development of training videos.

Steps 3 and 4 on the E9(R1) Addendum are expected electronically by October/November 2019.

The E9(R1) training videos are expected to be finalised by end of 2019.

Background Document:

- *E9(R1) EWG Work Plan, dated 14 August 2019.*

15.5. E17 IWG Multi-Regional Clinical Trials (Rapporteur: Dr. Dunder – EC, Europe; Regulatory Chair: Mr. Otsubo – MHLW/PMDA, Japan)

Further to the completion of the E17 training materials in August 2019 and their publication on the ICH website and YouTube, the E17 IWG was disbanded in September 2019.

15.6. M1 PtC WG: MedDRA Points to Consider (Rapporteur: Dr. Winter – EFPIA; Regulatory Chair: Dr. Brajovic – FDA, United States)

The M1 PtC WG continues its work on the update of the Points to Consider documents with each MedDRA release.

Release of next versions of the "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (updated for MedDRA Version 22.1) are expected in September 2019.

Release of a second edition of the Companion Document is expected by December 2019.

Background Document:

- *M1 PtC WG Work Plan, dated 18 October 2019.*

15.7. M2 EWG: Electronic Standards for the Transfer of Regulatory Information (ESTRI) (Co-Rapporteurs: Ms. Slack – FDA, United States / Dr. Okada – MHLW/PMDA, Japan; Regulatory Chair: Dr. Jaermann – Swissmedic, Switzerland)

The M2 EWG continues to work on: 1) the assessment of and next steps for eCTD v4.0 and HL7 Fast Healthcare Interoperability Resources (FHIR) standards with the M8 EWG/IWG; 2) the finalisation of a Service Level Understanding for terminology list management with the E2B EWG/IWG; 3) the development of a technical specification with the M11 EWG; 4) the development of an opportunity proposal on standardized quality data; 5) the evaluation of new ICH topics (i.e. which are at *Step 1*) for technical risks and opportunities; and 6) consideration on rapid technology advancement of electronic standards impacting harmonization activities.

The publication of the OID maintenance process and the finalisation of the revision of the project opportunities proposal is expected by November 2019.

Background Documents:

- *M2 EWG Work Plan, dated 6 August 2019.*

15.8. M4Q(R1) IWG: (CTD-Quality) IWG: Addressing CTD-Q-Related Questions (Rapporteur: Dr. Schmuff – FDA, United States)

No questions were so far received following the implementation of the revised M4 Granularity Document which would need to be addressed by the M4Q(R1) IWG.

15.9. M7(R2) Maintenance EWG/IWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (Rapporteur: Dr. Froetschl – EC, Europe)

The M7(R2) Maintenance EWG/IWG continues its work on the M7(R2) revision; the development of the second Addendum; and on the development of the Q&As.

Steps 1 and 2a/b for the revised M7(R2) Draft Guideline (including the revised second Addendum) and Q&As are expected by January 2020.

Background Document:

- *M7(R2) Maintenance EWG/IWG Work Plan, dated 2 August 2019.*

15.10. M8 EWG/IWG: The Electronic Common Technical Document (eCTD) (Rapporteur: Mr. Gray – FDA, United States; Regulatory Chair: Ms. Puusaari – EC, Europe)

No Change Requests were received since the eCTD v4.0 Q&As and Specification Change Request Document v1.2, as well as the eCTD v3.2.2 Q&As and Specification Change Request Document v1.31 reached *Steps 3* and *4* at the meeting in Kobe, Japan, in June 2018.

The M8 EWG/IWG developed with the M2 EWG an assessment of and next steps for eCTD v4.0 and FHIR standards.

- The Assembly is invited to share its views on the M2 EWG / M8 EWG/IWG assessment of and next steps for eCTD v4.0 and FHIR standards, including the recommendation on whether to implement eCTD v4.0.

Background Documents:

- *M8 EWG/IWG Work Plan, dated 2 August 2019.*

15.11. M9 EWG: Biopharmaceutics Classification System-based Biowaivers (Rapporteur: Dr. Welink – EC, Europe; Regulatory Chair: Dr. Seo – FDA, United States)

The M9 EWG continues its work on finalisation of the M9 Guideline and the Q&As document.

Steps 3 and 4 for the M9 Guideline and the Q&As document are expected in November 2019.

Background Document:

- *M9 EWG Work Plan, dated 30 July 2019.*

15.12. Q3C(R8) Maintenance EWG: Maintenance of the Guideline for Residual Solvents (Rapporteur: Dr. McGovern – FDA, United States)

The Q3C(R6) Guideline was published on the ICH website, effectively reinstating the PDE for ethyleneglycol to 6.2 mg/day (620 ppm), along with a cover statement to explain the reason for the reversion.

The revised monograph to Q3C(R6) for the PDE of ethyleneglycol is also planned for publication on the ICH website as a support document.

The Q3C(R8) Maintenance EWG continues its work on the development of Permitted Daily Exposure (PDE) levels for the solvents 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol.

Steps 1 and 2a/b are expected by October/November 2019.

Background Document:

- *Q3C(R8) EWG Work Plan, dated 9 August 2019.*

15.13. Q3D(R2) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities (Rapporteur: Dr. Hirose – MHLW/PMDA, Japan)

The Q3D(R2) Maintenance EWG continues its work on the draft Addendum on cutaneous and transdermal routes of administration.

Steps 1 and 2a/b of the Q3D(R2) revision for the cutaneous and transdermal products are expected by January 2020.

Background Document:

- *Q3D(R2) EWG Work Plan, dated 9 August 2019.*

15.14. S1(R1) EWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline (Rapporteur: Dr. Sistare – PhRMA; Regulatory Chair: Dr. Van der Laan – EC, Europe)

The third S1 Status Report was published on the ICH website in September 2019.

The S1(R1) EWG continues its work on the review of confidential Carcinogenicity Assessment Documents (CADs) and Final Study Reports (FSRs) and the revisions to the S1B Guideline.

Steps 1 and 2a/b are expected by May 2020.

Background Document:

- *S1(R1) EWG Work Plan, dated 13 August 2019.*

15.15. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals (Rapporteur: Dr. Waxenecker – EC, Europe)

The S5(R3) EWG continues its work on the finalisation of the S5(R3) Guideline.

Steps 3 and 4 are expected by November 2019.

Background Document:

- *S5(R3) EWG Work Plan, dated 5 August 2019.*

15.16. S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines (Rapporteur: Dr. Brown –FDA, United States; Regulatory Chair: Dr. van der Laan – EC, Europe)

The S11 EWG continues its work on the finalisation of the S11 Guideline.

Steps 3 and 4 are expected by November 2019.

The S11 training materials are expected by June 2020.

Background Document:

- *S11 EWG Work Plan, dated 2 August 2019.*

15.17. Informal Generic drug Discussion Group (IGDG) (Rapporteur: Dr. Tampal – FDA, United States; Regulatory Chair: Welink – EC, Europe)

The IGDG continues its work on: 1) finalisation of the review of the topic proposal on *Bioequivalence for Immediate-Release Solid Oral Dosage Forms*; 2) the identification of additional bioequivalence topics for harmonisation and communication with the BEWGG (Bioequivalence WG for Generics) of the IPRP (International Pharmaceutical Regulators programme); and 3) review of ICH Efficacy and Multidisciplinary Guidelines, with consultation with the IQDG.

Background Document:

- *IGDG Work Plan, dated 8 July 2019.*

15.18. Informal Quality Discussion Group (IQDG) (Rapporteur: Mr. Nosal – PhRMA; Regulatory Chair: Ms. Kruse – EC, Europe)

The IQDG continues its work on the review of the ICH Quality and Multidisciplinary Guidelines.

Background Document:

- *IQDG Work Plan, dated 8 April 2019.*

15.19. Pharmacoepidemiology Discussion Group (PEpiDG) (Rapporteur: Dr. Uyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Ball – FDA, United States)

The PEpiDG continues its work, including on its Work Plan.

16. Election of Assembly Chair and Vice-Chair

The Assembly will note the nominations received for Chair and Vice-Chair.

- The Assembly Members will be invited to **vote** via secret ballot on the appointment for a 2-year term of the new Assembly Chair and Vice-Chair from amongst the eligible applicants in line with the Assembly Rules of Procedure Section 3.1.

17. Organisation of Next Meetings

The Assembly will receive an update on the organisation of next ICH meetings.

Any Other Business

- The Assembly is invited to raise any other business for discussion.

Summary of Assembly Decisions

The ICH Secretariat will provide a summary of Assembly decisions taken during the meeting in Singapore.

- The Assembly is invited to provide any comments on the summary of Assembly decisions.

Press Release

The Assembly will be informed on the development and publication of the ICH Press Release for the meeting.

Agenda Item 14

WGs Meeting in Singapore

ICH E11A EWG/IWG Work Plan
August 06, 2019

Topic Adoption date: *June 2017*

Rapporteur: *Dr. Lynne Yao, FDA, United States*

Regulatory Chair: *N/A*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Oct. 2017	*Concept Paper endorsed by Management Committee*
Oct. 2017	*Business Plan endorsed by Management Committee*
Jun. 2018	*Completed review of global literature on pediatric extrapolation*
Jun. 2018	*Completed review of pediatric extrapolation issues from E11(A) public comments*
Nov. 2018	*Completed draft Table of Contents Outline of Guideline*
Jun. 2019	*Completed Detailed Outline of Guideline*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Nov. 2020	*Step 1 Consensus Building, Drafting of Technical Document*
Nov. 2020	*Step 2 ICH Parties Consensus on Technical Document*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2018	***Ongoing***	*Continued work of EWG Subgroups*	*Three subgroups were created to lead specific topics within the ICH guideline: Disease Similarity Sub-group; Modeling and Simulation Subgroup; Statistics Subgroup*
Jun. 2019	***Nov. 2019***	*Drafting of guideline from detailed outline*	*Each subgroup will work on writing of initial first draft of the document*
Jun. 2019	***Nov. 2019***	*Each subgroup will meet via conference call to review progress*	*Each subgroup will meet via conference call to review progress on initial drafting*
Jun. 2019	***Nov. 2019***	*EWG will meet via conference call to review progress*	*EWG will meet at least monthly to reivew progress on initial draft*
Jun. 2019	***Nov. 2019***	*Work on initial first draft of guideline*	*Goal is to have initial first draft of guideline by Nov 2019 for discussion and review*

ICH E14/S7B IWG Work Plan
July 31, 2019

Topic Adoption date: *November 2018*

Rapporteur: *Dr. David Strauss, FDA, United States*

Regulatory Chair: *Dr. Kaori Shinagawa, MHLW/PMDA, Japan*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Dec. 2015	*Finalized E14 Q&A regarding concentration-QTc analysis as an alternative analysis endpoint for QTc evaluation.*
Dec. 2017	*Publication of a white paper article to describe in more detail the steps involved in appropriate concentration-QTc analysis.* *(https://doi.org/10.1007/s10928-017-9558-5)*
June 2018	*A recommendation (a concept paper proposed through FDA) to ICH Assembly to reconstitute a WG at this time for the ICH E14 / S7B topic for clarification of the ICH S7B guideline through Q&As.*
Aug. 2018	*Revised concept paper for submission to the MC.*
Nov. 2018	*E14/S7B Discussion Group (DG) met in person and revised the concept paper to develop Q&As to both ICH S7B and E14. The concept paper describes a two-stage approach where Q&As will be written for both S7B and E14 in each stage. The concept paper was endorsed by the ICH Assembly and an Implementation Working Group (IWG) was formed.*
June 2019	*E14/S7B IWG met in person and discussed draft Q&As for stage 1. The draft Q&As for best practice for in vitro and in vivo studies and principles for proarrhythmia models reached general consensus. A decision was made to split the integrated risk assessment Q&A into two parts, one for S7B and one for E14. The discussion of stage 2 Q&A was also started.*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
June 2020	*Steps 3 and 4 for first stage Q&As for ICH S7B and E14*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2018	*Nov. 2018*	*Create Concept Paper for MC and Assembly*	*Create Concept Paper regarding updating ICH E14 and S7B with Q&As. Develop work plan.*
Nov. 2018	*Nov. 2018*	*Finalize Concept Paper and work plan for IWG*	*Finalize a detailed plan on the timelines to write the proposed Q&As for S7B and E14.*
Dec. 2018	*June 2019*	*Scope first stage Q&As for S7B and E14 and develop draft text*	*In regular teleconferences discuss scope and detail of potential Q&As for ICH S7B and E14.*
Dec. 2018	*Jan. 2019*	*Establish six sub-groups to discuss specific topics and draft Q&As*	*Establish four sub-groups to draft stage 1 Q&As (Best practices for in vitro assay; Considerations for S7B in vivo core battery assay; Principles for proarrhythmia models; Integrated risk assessment that combines S7B & E14). Establish two sub-groups to discuss related topics (Additional drugs/data required for advancing Stage 2; Large molecule threshold)*
June 2019	*June 2019*	*Meet face-to-face at ICH Meeting*	*Discuss the potential Q&As on best practices for ICH S7B assays, and criteria for robust proarrhythmia prediction model. Discuss the potential Q&As for E14 in clinical implementation scenarios.*
June 2019	*November 2019*		• *Reach agreement on best practice and proarrhythmia models stage 1 Q&As for regions to seek internal feedback from constituencies*

			• *Incorporate constituency feedback to finalize Q&As* • *Draft Integrated Risk Assessment Q&A for S7B and revisions to E14 Q&As*
November 2019	*November 2019*	*Meet face-to-face at ICH Meeting*	• *Meet face-to-face to finalize in vitro & in vivo best practice and proarrhythmia models Q&As* • *Seek consensus on Integrated Risk Assessment Q&A for S7B and revisions to E14 Q&As* • *Discuss second stage Q&As*
November 2019	*June 2020*	*Incorporate constituency feedback on stage 1 Q&As*	*Incorporate constituency feedback on Integrated Risk Assessment Q&A for S7B and revisions to E14 Q&As*
June 2020	*June 2020*	*Stage 1 Q&A sign off and discuss stage 2 Q&A*	• *Meet face-to-face for step 1 sign-off of first stage Q&As* • *Discuss second stage Q&As and finalize timeline*
Jan. 2019	*June 2020*	*Discuss potential second stage Q&As for S7B and E14 and generate any data needed*	*In regular teleconferences discuss the potential second stage Q&As focusing on data needs and gaps. In face-to-face meetings discuss data needs and timelines. A detailed timeline to finalize Q&As will be developed.*

ICH E19 EWG Work Plan

July 29, 2019

Topic Adoption date: *November 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
Jul. 2017	*Final concept paper endorsed by ICH Management Committee*
Apr. 2019	*Finalise the technical document and Step 1 Experts sign-off*
Apr. 2019	*Step 2a/b Endorsement of the Draft Guideline*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jun. 2021	*Finalise Step 3/Step 4 Adoption of the Final Guideline*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Apr. 2019	*Oct. 2019*	*End of regional public comment period*	➢ *Receive public comments from all regions* ➢ *Review regional public comments* *Deadline for public comments:* • *HSA, Singapore - 31 Jul.* • *TFDA, Chinese Taipei - 31 Jul.* • *MHLW/PMDA, Japan- 18 Aug.* • *NMPA, China- 20 Aug.* • *Health Canada, Canada- 13 Sept.* • *ANVISA, Brazil- 19 Sept.* • *FDA, United States - 25 Sept.* • *EC, Europe- 29 Sept.*
Nov. 2019	*Nov. 2019*	*Face-to-face meeting (Singapore)*	➢ *Revise technical document to address public comments*
Jun. 2020	*Jun. 2020*	*Face-to-face meeting (Vancouver)*	➢ *Revise technical document to address public comments*
Nov. 2020	*Nov. 2020*	*Face-to-face meeting (TBD)*	➢ *Revise technical document to address public comments*
Jun. 2021	*Jun. 2021*	*Face-to-face meeting (TBD)*	➢ *Finalise Step 3/Step 4 Adoption*

ICH M10 EWG Work Plan
August 01, 2019

Topic Adoption date: *June 2016*

Rapporteur: *Dr. Akiko Ishii-Watabe - MHLW/PMDA, Japan*

Regulatory Chair: *Dr. Brian Booth - FDA, United States*

Last Face-to-Face Meeting: *Charlotte, US, November 2018*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Oct. 2016	*Concept Paper endorsement*
Oct. 2016	*Business Plan endorsement*
Jan. 23, 2019	*Step1 sign-off*
Feb. 26, 2019	*Step 2b endorsement*
Mar - Sept, 2019	*Step 3 public consultation*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Sep. 2019	*Closing public consultation*
Nov. 2019	*Face-to-Face meeting for updating the draft guideline*
May. 2020	*Face-to-Face meeting for updating the draft guideline*
Nov. 2020	*Face-to-Face meeting for finalising the guideline* *Step 3 sign-off and Step 4 adoption*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Mar. 2019	*Sep. 2019*	*Public consultation period*	*Regional regulatory consultation of M10 draft guideline is conducted in each Regulatory Member* *(Closing date is Sept 25)*
Sep. 2019	*Oct. 2019*	*E mail consultations*	*Comments obtained through the public consultation in each Regulatory Member are collated, triaged, and shared within EWG.*
Oct. 2019	*Nov. 2019*	*Teleconferences*	*Topics to be discussed in face-to-face meeting are selected and discussed.*
Nov. 2019	*Nov. 2019*	*Face-to-Face meeting*	*The draft guideline is revised by reflecting the comments obtained via public consultation.*

ICH M11 EWG Work Plan
August 06, 2019

Topic Adoption date: *June 2018*

Rapporteur: *Ms. Vivian Combs, PhRMA*

Regulatory Chair: *Dr. Ron Fitzmartin, FDA, United States*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2018	*Concept Paper Outline endorsed at Kobe meeting*
Sep. 2018	*Establishment of Informal Working Group*
Nov. 2018	*Endorsement of Final Concept Paper, Business Plan, and Work Plan*
Nov. 2018	*Establishment of formal Expert Working Group (EWG)*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jun. 2020	*Step 1 Sign-off of Technical Document (guideline, template, technical specification)*
Jul. 2020	*Step 2a / 2b endorsement of Technical Document*
Jul. 2021	*Step 3 End of Public Consultation Period*
Nov. 2021	*Step 3 Signoff of Technical Document*
Nov. 2021	*Step 4 Adoption of Technical Document*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jul. 2019	*Aug. 2019*	*Establish ongoing collaboration with M2 EWG*	*Identify formal liaisons from M2 if needed* *Establish technical subteam from M2 and M11 Working Group Members; identify subteam leader, meeting schedule, project plan and strategy for development of technical specification, and schedule through year-end*
Aug. 2019	*Nov. 2019*	*Develop Business Requirements to Inform Technical Specification*	*Technical subteam to deliver business requirements for exchange of structured protocol information*
Aug. 2019	*Nov. 2019*	*Coordinate with other ICH Working Groups*	*Maintain established contact (E8, E9, M2) with ICH EWGs as previously agreed.* *Establish contact with additional EWGs/IWGs per Coordination Strategy and as needs emerge.*
Jun. 2019	*Nov. 2019*	*Complete Content Development of template and draft Guideline*	*Complete draft of template content and M11 Guideline. Circulate for SME review within ICH parties.*
Jul. 2019	*Sep. 2019*	*Develop Stakeholder Engagement Plan*	*Consult with ICH Management Committee on strategy and tactical plan for socializing the design concepts shaping the M11 template and specifications with important key stakeholders*

ICH Q2(R2)Q14 EWG Work Plan
August 21, 2019

Topic Adoption date: *June 2018*

Rapporteur: *Dr. Yukio Hiyama - MHLW/PMDA, Japan*

Regulatory Chair: *Dr. David Keire - FDA, United States*

Last Face-to-Face Meeting: *Amsterdam, Netherland, June 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
November 2018	*Concept Paper and Business Plan endorsements*
June 2019	*Structured texts for Q2(R2) and Q14*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
November 2019	*Drafts of Q2(R2) and Q14 for intra party consultation*
May 2020	*Step 1 sign-off, Step2a/b endorsement*
June-December 2020	*Public Consultation Period*
June 2021	*Step 4 adoption*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
June 2019	*October 2019*	*A series of sub team Web/telephone conferences*	*Complete texts for Q2(R2) and Q14* *Identify responses to the survey relative to the current version of Q2*

ICH Q12 EWG Work Plan
August 12, 2019

Topic Adoption date: September 2014

Rapporteur: Ms. Ashley Boam, FDA, United States

Regulatory Chair: Ms. Nanna Abby Kruse, 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
Sep. 2014	*Concept Paper endorsement*
Jun. 2017	*Step 1 for Q12 Technical Document, consisting of Core Guideline and associated Annex*
Nov. 2017	*Steps 2a and 2b reached*
Dec. 2018	*End of public consultation period*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Nov. 2019	*Step 3 Experts Sign-off*
Nov. 2019	*Step 4 adoption*
Spring 2020	*Initiation of training activities*

2. Timeline for specific tasks

Beginning date	End Date	Task / Activity	Details
Jun. 2019	***Jun. 2019***	*EWG meeting via teleconference and exchange of proposed text revisions via email*	*Continue discussion of any outstanding text from June 2019 meeting; discuss plans for training.*
Jul. 2019	***Jul. 2019***	*EWG meeting via teleconference and exchange of proposed text revisions via email*	*Discussion of proposed revised text for Chapter 1.*
Sep. 2019	***Sep. 2019***	*EWG meeting via teleconference to discuss proposed text revisions*	*Example and training sub-teams to report out. Continue discussion of examples (ECs for analytical methods, ECs for manufacturing process, PLCM) and plans for training.*
Oct. 2019	***Oct. 2019***	*EWG meeting via teleconference to discuss proposed text revisions and plan agenda for November F2F meeting*	*Continue discussion plan to development of training materials. Finalize agenda for Nov 2019 meeting.*

ICH Q13 EWG Work Plan
August 02, 2019

Topic Adoption date: *June 2018*

Rapporteur: *Dr. Sau (Larry) Lee – FDA, United States*

Regulatory Chair: *Dr. Yoshihiro Matsuda - MHLW/PMDA, Japan*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2018	*Concept Paper and Business Plan Endorsement*
Nov. 2018	*Initiation of consensus building*
May. 2019	*Outline for technical document developed*
Jun. 2019	*Face-to-Face Meeting in support of consensus building, outline finalization, and technical document drafting*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Nov. 2019	*Face to Face Meeting to develop the technical document*
Jun. 2020	*Face to Face Meeting to continue development of the technical document and Step 1 sign-off and Step 2 a/b endorsement, and initiate public consultation*
Nov. 2021	*Step 3 sign-off and Step 4 adoption of final guideline*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2019	*Nov. 2019*	*Multiple EWG Meetings via Teleconference*	*Share and revise draft text for the technical document; sub-team reports, if appropriate; discuss plans for next face-to-face meeting*
Nov. 2019	*Nov. 2019*	*Face-to-Face EWG Meeting*	*Continue progress on drafting of the technical document and consensus building; discuss potential regional and/or technical concerns identified between face-to-face meetings*

Agenda Item 15

WGs Not Meeting in Singapore

ICH E2B(R3) EWG/IWG Work Plan
August 09, 2019

Topic Adoption date: *July 2013*

Rapporteur: *Dr. Takashi Misu, MHLW/PMDA, Japan*

Regulatory Chair: *Mr. Ta-Jen Chen, FDA, United States*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2019	*Complete the Route of Administration (RoA) term mapping table between the ICH E2B code list and EDQM standard terms*
Jun. 2019	*Step 4 sign-off of the revised E2B(R3) Q&A document*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Sep. 2019	*Finalise revision of the EDQM User Guide incorporating the mapping table for RoA between ICH and EDQM terms*
Sep. 2019	*Finalise contents of the Training Material Module II*
Dec. 2019	*Finalise contents of the Training Material Module III*
Dec. 2019	*Finalise the Service Level Understanding (SLU) document with M2*
Mar. 2020	*Finalise the "voice over" presentation for Module I*
Jun. 2020	*Process and update Q&As as needed*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2019	*Sep. 2019*	*Finalise revision of the EDQM User Guide incorporating the mapping table for RoA between ICH and EDQM terms*	➢ *Revise the EDQM User Guide to reflect the results of the discussion in the Amsterdam meeting* ➢ *Incorporate the mapping table for RoA between ICH and EDQM terms*
Jun. 2019	*Sep. 2019*	*Finalise contents of the Training Material Module II*	➢ *Review the contents of the Module II discussed in the Amsterdam meeting* ➢ *Edit the contents appropriately* ➢ *Assess the necessity of the voice over presentation*
Jun. 2019	*Dec. 2019*	*Finalise contents of the Training Material Module III*	➢ *Create contents by each subsection: Regulatory section, Industry section and Technical section* ➢ *Finalise the subsections*
Jun. 2019	*Dec. 2019*	*Finalise the SLU document with M2*	*Review the SLU document drafted by M2 and provide feedback to M2*
Sep. 2019	*Mar. 2020*	*Finalise the "voice over" presentation for Module I*	*Add scripts and restructure the contents of Module I*
Jun. 2019	*Jun. 2020*	*Process and update Q&As as needed*	➢ *Monitor and discuss any comments submitted to the ICH mail box and/or from E2B experts* ➢ *Add new Q&As to the document if applicable*

ICH E8(R1) EWG Work Plan
August 09, 2019

Topic Adoption date: *June 2017*

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

Regulatory Chair: *Dr. Fergus Sweeney, 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
Nov. 2017	*Concept Paper endorsement, Business Plan endorsement*
May. 2019	*Draft Guideline Endorsement by the Members of the ICH Assembly under Step 2 and released for public consultation*
Jun. 2019	*Step 2 Presentation posted to ICH site*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Oct. 2019	*End of Public Consultation Period*
Oct. 2019	*ICH E8(R1) public stakeholder meeting targeted at global stakeholders to be held*
Jun. 2020	*Step 4: Adoption of an ICH Harmonised Guideline*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Aug. 2019	*Aug. 2019*	*EWG teleconference*	*Planning for upcoming ICH E8(R1) public stakeholder meeting.*
Sep. 2019	*Sep. 2019*	*EWG teleconference*	*Planning for upcoming ICH E8(R1) public stakeholder meeting.*
Oct. 2019	*Oct. 2019*	*EWG teleconference*	*Planning for upcoming ICH E8(R1) public stakeholder meeting.*
Nov. 2019	*Nov. 2019*	*EWG teleconference*	*Initial review of public feedback received during public consultation period*
Dec. 2019	*Dec. 2019*	*EWG teleconference*	*Initial review of public feedback received during public consultation period*
Jan. 2020	*Jan. 2020*	*EWG teleconference*	*Initial review of public feedback received during public consultation period*
Feb. 2020	*Feb. 2020*	*EWG teleconference*	*Initial review of public feedback received during public consultation period*

ICH E9(R1) EWG Work Plan
14 August 2019

Topic Adoption date: October 2014

Rapporteur: Mr. Franck Petavy, EC, Europe *(Acting Rapporteur)*

Regulatory Chair: Dr. Yuki Ando, MHLW/PMDA, Japan

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Oct. 2014	Concept Paper endorsement by the ICH Steering Committee.
2017	*Step 1 and Step 2a/b* - Finalisation of the Technical Document (draft addendum), sign-off by Topic Leaders and adoption by Assembly Members and by Assembly Regulatory Members.
Aug. 2017	*Step 3* - Draft addendum published.
Apr. 2018	*Step 3* - Public comments received in all ICH regions.
Aug. 2018	Publication of *Step 2b* training material slide decks on the ICH website

1.b. Future anticipated key milestones

Expected future completion date	Milestone
2019	*Step 3* - Discuss comments received during the public consultation period and consolidate the draft addendum.
2019	Organise and participate to trainings and scientific meetings, within ICH parties and at international congresses.
2019	*Step 3 and Step 4* - Finalisation of the addendum and sign-off by topic leaders of the ICH Regulatory Parties and by the ICH Regulatory Parties.

2. Timeline for specific tasks

Beginning date	End Date	Task / Activity	Details
Dec. 2017	**Early 2019**	Step 3	Organise or participate at meetings at a global or regional level to promote awareness and comments on the addendum. Discuss regional consultation comments and modify the addendum and accompanying documents, based on comments received. Outline plans for further progress towards finalisation.
Jan. 2018	**Early 2019**	In parallel with Step 3	Discuss methodological issues related with estimands and sensitivity analysis in clinical trials. Consider the relationship of ICH E9(R1) with other ICH documents.
Jun. 2019	**Sep. 2019**	Step 3 and Step 4	Finalise the addendum and any accompanying documents. Once all documents are finalised, engage the sign-off process. Step 3: Sign-off by topics leaders of Regulatory ICH Parties. Step 4: Adoption by ICH Assembly Regulatory Members. Plan for training and implementation activities, including the update of E9(R1) Step 2 slides.

ICH M1 PtC WG Work Plan
18 October 2019

Topic Adoption date: *1999 approximately*

This working group develops and maintains the MedDRA Points to consider (PtC) documents. As new areas of MedDRA are developed, the documents require refinement and updating twice a year in line with new MedDRA versions. This working group has also developed a Companion Document. The first version, released in June 2018, provides additional guidance on high level topics pertaining to the use of MedDRA (e.g. data quality issues and detailed examples for medication errors). Examples for product quality issues are planned for a later version. This WG also provides guidance on ICH MedDRA initiatives when requested by the MedDRA Management Committee.

Rapporteur: *Christina Winter, EFPIA*

Regulatory Chair: *Sonja Brajovic, FDA, United States*

Last Face-to-Face Meeting: *Geneva, Switzerland, November 2017*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2018	First release of the 'MedDRA Points to Consider, **Companion Document**'
Nov. 2018	Release of **Condensed Versions** of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" into all MedDRA languages (except English and Japanese)
Sep. 2019	Release of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (updated for MedDRA Version 22.1) in English and Japanese.

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Dec. 2019	Collation of user comments on the 'Companion document' and discussion of potential changes.
Mar. 2020	Release of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (updated for MedDRA Version 23.0) in English and Japanese. Conversion from six monthly to annual release.
Apr. 2020	Release of second edition of the 'Companion document', incorporating changes.
Sep. 2020	Release of Chinese, Korean, and Spanish translations of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (based on MedDRA Version 23.0)
Mar. 2021	Release of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (MedDRA Version 24.0) in English, Japanese, Chinese, Korean and Spanish.

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jul. 2018	*Dec. 2019*	"MedDRA Points to Consider, Companion document"	Collation of user comments, discussion of potential changes to the 'Companion document'.
Aug. 2019	*Apr. 2020*	"MedDRA Points to Consider, Companion document"	Release of second edition of 'Companion document' to incorporate changes.
Sep. 2019	*Feb. 2020*	"MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents in English and Japanese.	Discuss user feedback and update both documents for MedDRA version 23.0 (planned release 01Mar2020). [Change frequency of release from 6 monthly to annual.]

Oct. 2019	*Mar. 2021*	"MedDRA Points to Consider, Companion document"	Discuss new section of 'Companion document' on product quality issues
Dec. 2019	*Sep. 2020*	"MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents translated into Chinese, Korean and Spanish	Translation and release of both documents (Based on MedDRA version 23.0, 01Mar2020) in Chinese, Korean and Spanish.
Mar. 2020	*Mar. 2021*	"MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (English, Japanese, Chinese, Korean and Spanish)	Annual release of both documents (MedDRA version 24.0, 01Mar2021) in English, Japanese, Chinese, Korean and Spanish.

ICH M2 EWG Work Plan
August 06, 2019

Topic Adoption date: *June 1994*

Rapporteur: *Ms. Mary Ann Slack - FDA, United States; and Dr. Mihoko Okada - MHLW/PMDA, Japan (Co-Rapporteurs)*

Regulatory Chair: *Dr. Stephan Jaermann - Swissmedic, Switzerland*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Apr.-May 2019	*Revised draft white paper on the potential impacts and benefits of the HL7 FHIR standard for ICH initiatives*
Jun. 2019	*Face to Face working meeting with HL7 CTO on plan for ICH-adopted HL7 V3 standards and transition to HL7 FHIR*
Jun. 2019	*Report to the MC regarding considerations on existing ICH adopted HL7 v3 standards*
Jun. 2019	*Presented a project opportunity proposal on structured quality data to the MC and Assembly*
Jun. 2019	*Joint meeting with E2B to confirm jointly developed Service Level Understanding (SLU) for terminology list management*
Jun. 2019	*Joint meeting with M11 to discuss questions raised regarding M11 Technical Specification to be developed*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Aug. 2019	*Confirmation of SLU (Service Level Understanding) with E2B for terminology list management*
Aug. 2019	*Refined white paper on HL7 FHIR for ICH implications*
Oct. 2019	*Deliverables from M8-M2 joint activities (refer the joint M8-M2 workplan for any details)*
Nov. 2019	*Refined project opportunity proposal on standardized quality data for presentation to the MC*

2. Timeline for specific tasks

(note – periodic administrative activities such as SDO liaison activities are not included)

Beginning date	End date	Task / Activity	Details
Project Opportunity Proposal			
Oct. 2018	*Aug. 2019*	*Revise FHIR White Paper*	*Based on knowledge gained to date from face to face interactions with HL7, available material and experiences, refine white paper on HL7 FHIR for ICH implications.*
Apr. 2018	*Nov. 2019*	*Develop opportunity proposal on quality data*	*Further develop a project opportunity proposal on standardized quality data for internal discussion and presentation to the MC.*
Aug. 2019	*Nov. 2019*	*Evaluate new ICH topics for technical risks and opportunities – stage 1*	*Talk with topic experts in each EWG at Step 1 to explore potential technological risks or opportunities*
Aug. 2019	*Nov. 2019*	*Evaluate ICH topics for technical risks and opportunities – stage 2*	*Review Step 3-4 documents for technical risks and opportunities; aggregate and discuss at next F2F meeting; discuss findings with EWG Rapporteurs*
Supportive Activities			

Sep. 2018	*July 2019*	*Implement SLU with E2B*	*Confirm jointly developed Service Level Understanding (SLU) with E2B for terminology list management.*
Jun. 2019	*Oct. 2019*	*M8-M2 joint activities for eCTD*	*Refer to the M8-M2 joint eCTD workplan for any details*
	Oct. 2019	*M8-M2 joint interim meeting*	*Necessity of an interim meeting is under discussion and depends on the work progress*
Jun. 2019	*Nov. 2019*	*Discuss technical specification development with M11*	*Discuss working arrangements and plan for the development of a technical specification with M11*
Aug. 2018	*TBD*	*Standard practice for technical artefacts used*	*Develop a standard practice for managing and maintaining technical artifacts used to support standards, such as EDQM controlled vocabulary extraction script for E2B(r3)* *Deferred until EMA transition is competed*

ICH M7(R2) Maintenance EWG/IWG Work Plan
August 02, 2019

Topic Adoption date: *June 2014*

Rapporteur: *Dr. Roland Froetschl - EC, Europe*

Regulatory Chair: *N/A*

Last Face-to-Face Meeting: *Amsterdam, June. 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2014	*ICH-M7 was issued as Step4.*
Mar. 2017	*ICH-M7 (R1) was issued as Step 4. It contains Appendix 3 (Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes).*
Jul. 2018	*The concept paper of ICH-M7 (R2) is proposed; Maintenance of ICH-M7 with the 2nd addendum (application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes) and Q&A topics proposed based on experience through implementation of ICH-M7.*
Nov. 2018	*The first Face-to Face meeting of ICH-M7 (R2) was held in Charlotte.*
June 2019	*The second Face-to-Face meeting of ICH-M7 (R2) was held in Amsterdam.*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Dec. 2019	*revision of M7 main document and draft version of addendum and draft version of Q&A, finalizing step 1 document for sign off*
Jan. 2020	*Step 2a/b, revised M7 document, draft addendum and Q&A*
Jun. 2020	*Step 3 Public Consultation period*
Nov 2020	*Discussions of public comments, if feasible, reach Step 4*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2019	***Aug. 2019***	*Preparation of draft Q&A. Review one monograph for 2nd addendum. Work to be done via webex meetings and email*	*Discussion of outstanding Q and A topics. Agree on draft Q and A in preparation to disseminate for internal feedback from constituents.* *Review and finalize first draft of one compound monograph.*
Aug. 2019	***Sep. 2019***	*Finalize draft Q&A for internal constituent feedback.* *Review a second monograph for the addendum.*	*Finalize first draft of Q&As to get internal feedback from constituents* *Review and finalize first two compound monographs*
Sep. 2019	***Oct. 2019***	*Collect internal feedback from constituents on Q&As* *EWG to discuss comments.* *Review third and fourth monographs.*	*EWG to discuss feedback from constituents on points needing consideration to modify draft Q&As* *Review and finalize first four compound monographs*
Oct. 2019	***Nov. 2019***	*Finalize draft Q&As* *Review fifth and sixth monographs*	*Implement comments of constituents as appropriate and finalize the draft Q&A.* *Review and finalize first 6 compound monographs*
Nov. 2019	***Dec. 2019***	*Review seventh monograph* *Last review of Q and A and monographs. Agree final Step 1 for sign off*	*Complete Step 1: revised M7 guideline text, Q&A document and 2nd addendum*

ICH M8 EWG/IWG Work Plan
August 02, 2019

Topic Adoption date: *November 2010*

Rapporteur: *Mr. Mark Gray – FDA, United States*

Regulatory Chair: *Ms. 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
Jun. 2018	*Step 4 eCTD v3 Questions and Answers and Specification Change Request Document v1.31*
Jun. 2018	*Step 4 eCTD v4 Implementation Package v1.3*
Jun. 2018	*Step 4 Specification for Submission Formats for CTD v1.2*
Jun. 2018	*Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.2*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Nov. 2019	*Step 4 eCTD v3 Questions and Answers and Specification Change Request Document v1.32 (if Change Requests are received)*
Nov. 2019	*Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.3 (if Change Requests are received)*
Oct. 2019	*M8 Recommendation on eCTD v4.0 Implementation Strategy*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jul. 2019	*Nov. 2019*	*Update v3.2.2 v1.32 and v4.0 Q&A to v1.3*	• *Discuss change requests (if any)* • *Update and agree to the Q&As (if needed)*
Jul. 2019	*Oct. 2019*	*Discuss eCTD v4.0 Implementation Strategy*	• *Review eCTD v4.0 Requirements* • *Discuss Risks and Benefits* • *Determine ROI of eCTD v4.0 implementation* • *FHIR Mapping Exercise/Gap Analysis* • *Assess eCTD v3.2.2 longevity and/or feasibility of eCTD v3.X* • *Vendor Readiness Survey*

ICH M9 EWG Work Plan
July 30, 2019

Topic Adoption date: *June 2016*

Rapporteur: *Dr. Jan Welink – EC, Europe*

Regulatory Chair: *Dr. Paul Seo - FDA, United States*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2016	*Concept Paper endorsement*
Nov. 2016	*Business Plan endorsement*
Jun. 2018	*Reaching Step 1 on document*
Jun. 2018	*Reaching Step 2a/b on document*
Jul. 2018	*Public consultation period*
Feb. 2019	*Ending public consultation period*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Oct. 2019	*Step 4 adoption of the Final Guideline*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Sep. 2019	*Oct. 2019*	*Teleconferences*	*Completing Q&A document*
Oct. 2019	*Nov. 2019*	*Teleconference*	*Finalising guideline by including the Q&A document.*

ICH Q3C(R8) Maintenance EWG Work Plan
9 August 2019

Topic Adoption date: *November 2016*

Rapporteur: *Dr. Timothy McGovern - FDA, United States*

Regulatory Chair: *N/A*

Last Face-to-Face Meeting: *none (written procedure)*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
May 2017	*Achieved consensus on three solvents develop PDEs to include tert-butanol, 2-methyltetrahydrofuran, cyclopentylmethylether.*
November 2018	*Finalisation of Q3C(R7) – error correction for ethylene glycol PDE.*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Q4 2019	*Step 2a/b* Endorsement of the Draft Guideline
Q2 2020	*Step 4* Adoption of the final Guideline

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Oct. 2019		Approval by the Assembly under *Step 2*	➢ Release for public consultation
Oct. 2019	*Mar. 2020*	*Step 3*	➢ Internal/external consultation in ICH regions

Mar. 2020	*May. 2020*	EWG telecon/e-mail consultation	➢ Reviewing and resolving comments received from consultation process; preparing *Step 3/4* document
Q2 2020		*Step 3* signoff	➢ Postal signoff *Step 3* by the Regulatory Experts.
May. 2020		*Step 4*	➢ Adoption by the Regulatory Members of the Assembly.

ICH Q3D(R2) Maintenance EWG Work Plan
9 August 2019

Topic Adoption date: *October 2009 (Maintenance for Cutaneous and Transdermal Routes approved September 2016)*

Rapporteur: *Dr. Akihiko Hirose, MHLW/PMDA, Japan*

Regulatory Chair: *N/A*

Last Face-to-Face Meeting: *Amsterdam, Netherland - June 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Q1 2018	Achieve consensus on revision to Cadmium Inhalation PDE
Q3 2018	Publish Step 2 version for public comment on Cadmium Inhalation PDE
Q1 2019	Finalize Step 3/4 revision to Cadmium Inhalation PDE following review of public comments

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Dec. 2019	Step 1 sign-off of cutaneous PDEs document
Jan. 2020	Step 2a/b endorsement of cutaneous PDEs document
Q1-Q2 2020	Publish for public comment Step 2 cutaneous PDEs document
Sep. 2020	Step 3 document for cutaneous PDEs
Nov. 2020	Step 4 document for cutaneous PDEs

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Apr. 2017		Initiate development of permitted daily exposures for the cutaneous and transdermal routes of administration. Define whether cutaneous and transdermal PDEs are necessary for all or some of the 24 elements in the ICH Q3D Guideline.	➢ Schedule teleconferences ➢ Develop work plan and delegate work
August 2017		Initiate discussions regarding error in calculation for Cadmium Inhalation PDE	➢ Schedule teleconferences to discuss proposed revision
Nov. 2017		EWG meets for F2F meeting Review PDE revision to Cadmium Inhalation PDE	➢ Review progress on cutaneous and transdermal PDE development ➢ Achieve agreement on revision to text regarding PDE. Forward revision for public comment.
Nov. 2017	*Nov 2018*	EWG holds monthly teleconferences; subgroups work on key action items identified at 2017 F2F meeting	➢ Sub-groups address key issues including bioavailability assumptions; potential skin toxicity; applicability of limit for nickel; treatment of platinoids. Report back on progress at monthly calls. Initiate drafting of document.
Jun. 2018		Finalize PDE revision to Cadmium Inhalation PDE	➢ Sign off on *Step 2* document; prepare for release for public comment
Sep. 2018	*Nov. 2018*	Review public comments on Cadmium PDE revision	➢ Achieve agreement on final text for revision.

February 2019	*March 2019*	Finalize Cadmium Inhalation PDE revision	➢ Gain agreement on *Step 3/4* version
Jun. 2019		EWG meets for F2F meeting	➢ Conduct a detailed review of each section of the Addendum and updated text of cutaneous PDE development
Jun. 2019	*Nov. 2019*	EWG holds monthly teleconferences; work on finalizing of the sections identified at the 2019 F2F meeting as sections requiring further explanation	➢ Achieve agreement on the Addendum document for cutaneous PDEs.
December 2019		Step 1 sign-off	
January 2020		Finalize Step 2 PDEs for cutaneous and transdermal route of administration. Publish for public comment.	➢ Cutaneous PDEs to be published for public comment.
January 2020	*May 2020*	Review public comments on cutaneous PDEs	➢ Internal/external consultation in ICH regions for cutaneous and transdermal route of administration
Jun. 2019	*Sep. 2019*	EWG telecon/e-mail consultation	➢ Reviewing and resolving comments received from consultation process; preparing *Step 3/4* document
September 2020		*Step 3* signoff	➢ Postal signoff *Step 3* by the Regulatory Experts.
November 2020		*Step 4*	➢ Adoption by the Regulatory Members of the Assembly.

ICH S1(R1) EWG Work Plan
13 August 2019

Topic Adoption date: *April 2012*

Rapporteur: *Dr. Frank D. Sistare (PhRMA)*

Regulatory Chair: *Dr. Jan Willem van der Laan (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
Aug. 2013	*Regulatory Notice Document (RND) posted to ICH Website, formally launching the Prospective Evaluation Period (PEP) and calling upon the pharmaceutical industry to submit 50 Carcinogenicity Assessment Documents (CADs) and Final Study Reports (FSRs).*
Jan. 2016	*Substantially revised RND posted to ICH Website that redefined the target to 20 Category 3 CADs/FSRs, and extending the PEP for 2 yrs and setting a milestone of Dec 2017 for the 20 Category 3 CADs*
Jun. 2017	*Alignment reached on interpretation of 14 FSRs/CADs and the favorable results supported initiating the drafting of an ICHS1B Addendum*
Dec. 2017	*48 CADs total with 24 Category 3 received, so PEP agreed to be successfully terminated. Status Report posted to the ICH Website in Feb 2018 providing a public view to the strong progress.*
Nov. 2018	*With 14 additional to reach a total set of 28 matching FSRs/CADs we have confirmation of favorable results, and several additional topics have been raised for discussion in anticipation of preparing for step 1 in Nov 2019, pending receipt of additional favorable outcome Cat. 3 FSRs to total 20.*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
May 2020	*Step 1* "Signature Ready" Draft Guideline
June 2021	*Step 4* Guideline

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2018	*Jun. 2020*	EWG members to meet every other month by telecon. DRA members to meet separately to review all new CADs and FSRs. DRAs to draft updated PEP Status Report to ICH Website disseminating insights to evaluations of summary reports (Done Aug 2019). Drafting of modifications to S1B to continue.	EWG to review progress, feedback, on CAD submissions and align on plans for meeting face-to-face in May 2020 to review regulatory member conclusions from all FSRs received and reviewed; and to continue drafting revisions to S1B and review and align on new proposed guidance that reflects the experience and value of the CADs/ FSRs during the prospective evaluation.

ICH S5(R3) EWG Work Plan
August 05, 2019

Topic Adoption date: *November 2013*

Rapporteur: *Dr. Günter Waxenecker - EC, Europe*

Regulatory Chair: -

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2014	*ICH S5 Informal WG meeting in Minneapolis, US; Discussion on the topic and endorsement of Concept Paper within IWG. Post-hoc discussion about the further process.*
Nov. 2014	*ICH S5 Informal WG meeting in Lisbon, Portugal; Re-discussion on the topic and endorsement of revised Concept Paper within EWG. Definition of work packages for revision ICH S5(R2).*
Mar. 2015	*Topic endorsed by the ICH Steering Committee.*
Apr. 2015	*ICH S5(R3) EWG Telecons; Initiation of work on ICH S5(R3) in line with the identified work packages.*
Jul. 2017	*Step 1 sign-off; Experts sign-off to confirm all Members agreement with the document.*
Aug. 2017	*Step 2a/b document sign-off; Plan for a ≤ 6-month public review*
Oct. 2017	*Explanatory slides agreed by EWG members went online*
March 2018	*Public comment period closed*
June 2018	*EWG met in Kobe Japan. EWG came to consensus on how to resolve major issues identified during the public comment period and developed work packages for revision of the step 2a/b document.*
November 2018	*EWG met in Charlotte USA. There was an intial review of the revised document and agreement on reorganization. EWG completed line by line editing of the revised step 2a/b document.*
June 2019	*EWG met in Amsterdam Netherlands. The EWG did line by line editing to incorporate comments from internal stakeholder review. The EWG has continued agreement on the need for the maintenance procedure. EWG also made sure to align with S11. The document is in near final version.*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Prior to Nov. 2019	*Step 3 experts sign-off / Step 4 adoption: Face-to-face meeting in Singapore was not requested.*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jul. 2019	*Nov. 2019*	*ICH S5(R3) EWG Teleconferences*	*Final edits to the document will be made via monthly teleconferences.*

ICH S11 EWG Work Plan
August 02, 2019

Topic Adoption date: *November 2013*

Rapporteur: *Dr. Paul C. Brown, FDA, United States*

Regulatory Chair: *Dr. Jan Willem van der Laan, 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
Jun. 2018	*EWG agreement on Step 1 document*
Sep. 2018	*Endorsement by the Members of the ICH Assembly under Step 2 and release for public consultation*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jun. – Nov. 2019	*Regular TCs to discuss comments and revise guidance*
Nov. 2019	*Finalize Step 4 document*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2019	*Nov. 2019*	*Revise guidance sections and figures*	*Subgroups will work on specific parts of the document to revise wording, tables and/or figures. TCs of the entire EWG will occur regularly during this time to continue editing the document in response to comments received.*
Nov. 2019	*Nov. 2019*	*Finalize guidance*	*EWG will review guidance line-by-line by TCs/web to finalize wording.*

ICH Informal Generic Drug Discussion Group (IGDG) Work Plan
July 08, 2019

Topic Adoption date: N/A

Rapporteur: Dr. Nilufer Tampal, FDA, United States

Regulatory Chair: Dr. Jan Welink, EC, Europe

Last Face-to-Face Meeting: N/A

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
November 2018	ICH Reflection Paper on "Further Opportunities for Harmonization of Standards for Generic Drugs" endorsed by ICH Assembly
January 2019	IGDG remit endorsed by ICH Management Committee (MC)
April 2019	IGDG established
May 2019	Review of new topic proposal on "Bioequivalence for Immediate-Release Solid Oral Dosage Forms" and submit initial IGDG recommendations to the ICH MC for an amended scope

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jun. 2019	Finalize IGDG Workplan for submission to ICH MC for endorsement
By end of October 2019	**Continued Review and Consideration of Topic Proposal on "BE for IR Solid Oral Dosage Forms" (first priority)** • Information sharing regarding practices on bioequivalence study design (including review of WHO and regional guidances, as appropriate) • Revision of IGDG recommendation on the scope for initial BE guideline effort to reach consensus on a revised new topic proposal for ICH adoption in November 2019
By end of December 2019 (tentative)	**Establishment of two task groups to complete the below tasks, in parallel:** **Task 1: Continued information sharing, as needed, with a goal to identify additional BE topics for harmonization or BE guideline series (second priority)** • Review and discuss relevant portions from existing WHO and

	regional guidelines (as appropriate) • Review relevant publications from IPRP and GBHI related to standards for generic drugs to identify gaps and prior work to be leveraged in developing new ICH guidelines **Task 2: Review of existing ICH Guidelines (third priority)** • Review existing ICH Efficacy and Multidisciplinary Guidelines to assess a need for revision for additional guidance and considerations for generic drug standards
October 2019 (Tentative)	Interim review of progress of task groups; Draft recommendations on priority guideline(s) or guideline series for harmonisation of standards for demonstrating bioequivalence and consider possible new topic proposal(s) for ICH adoption in Jun. 2020
November 2019 (Tentative)	Teleconference with the ICH Informal Quality Discussion Group (IQDG) to gather input for generic drug considerations for ICH Quality Guidelines and determine follow-up actions (TBC)
November 2019	IGDG status update to ICH MC
December 2019	Interim review of outcomes and recommendations from Task 1, Task 2 and follow-up actions with IQDG;
February 2020	Finalize recommendations on priority guidelines or guideline series for harmonisation of standards for demonstrating bioequivalence (Task 1)
March 2020	Finalize IGDG recommendations on any proposed revisions to ICH Guidelines (Task 2)
April 2020	Finalize overall recommendations and prioritize work areas; Make recommendation on future plans
April/May 2020	IGDG status update to ICH MC

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Apr. 2019	Apr. 2019	Inaugural teleconference to discuss remit of the discussion group, workplan and new topic proposal "Bioequivalence for Immediate-Release Solid Oral Dosage Forms"	• Review IGDG's responsibilities and tasks specified in the Reflection Paper and Remit • Discuss workplan, sequencing of tasks, and timeline for deliverables • Initial discussion of topic proposal "Bioequivalence for Immediate-Release Solid Oral Dosage Forms" and request from MC for an amended scope
May. 2019	May. 2019	Teleconference to align on a workplan and continue discussion of new topic proposal	• Discuss revised workplan and finalize as needed • Finalize IGDG's initial recommendations for the ICH MC on an amended scope for the topic proposal on "Bioequivalence for Immediate-Release Solid Oral Dosage Forms"
Jun. 2019	Oct. 2019	**Continued Review and Consideration of Topic Proposal on "BE for IR Solid Oral Dosage Forms" (first priority)** • Information sharing regarding practices on bioequivalence study design (including review of WHO and regional guidances, as appropriate) • IGDG revised recommendation on scope for initial BE guideline effort to reach consensus on revised new topic proposal for ICH adoption in November 2019	• IGDG to consider feedback from ICH MC regarding a need to further refine scope for proposed options for the first guideline effort on BE • IGDG to share information on regional and international practices with respect to BE study design for IR solid oral dosage forms to help inform areas where harmonization is possible and necessary and better define scope for potential harmonization project. This includes consideration of WHO and regional guidelines, and other relevant reference materials.

			• IGDG to discuss options and work towards consensus on a recommendation for an initial BE guideline.
Jun. 2019	Dec. 2019	**Establishment of Task Group 1** **Task 1:** Review and discuss WHO guidelines and regional guidelines (as appropriate) and review prior work of IPRP and GBHI achieved through international collaboration efforts to identify gaps and prior work to be leveraged in developing new ICH guidelines (second priority)	• Review existing WHO guidelines and publications related to standards for generic drugs by IPRP and GBHI • Identify relevant portions of these documents to facilitate development of new ICH guidelines and avoid duplication of efforts
Jun. 2019	Dec. 2019	**Establishment of Task Group 2** **Task 2:** Review existing ICH Efficacy and Multidisciplinary Guidelines (third priority)	• IGDG will examine existing ICH Efficacy and Multidisciplinary guidelines to assess a need for revision for additional guidance for considerations for generic drug standards
Nov. 2019	Nov. 2019	T-con with the ICH Informal Quality Discussion Group (IQDG) to discuss generic drug considerations for ICH Quality Guidelines	• Teleconference with the ICH IQDG to discuss generic drug considerations for ICH Quality Guidelines and any revisions that may be needed. o Explore the need for additional guidance regarding generic drugs, currently not already addressed by the existing guidelines
Jun. 2019	Apr. 2020	Finalize recommendations on priority guidelines or guideline series of topics for harmonisation of standards for demonstrating bioequivalence	• The IGDG will work together to identify potential topics for harmonization under ICH • IGDG will identify a proposed sequencing and timing for any topics identified

ICH IQDG Work Plan
April 08, 2019

Topic Adoption date: November 2018

Rapporteur: Mr. Roger Nosal - PhRMA

Regulatory Chair: Ms. Nanna Abby Kruse - EC, Europe

Last Face-to-Face Meeting: NA

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Oct. 2018	*Remit of the Informal Quality Discussion Group (IQDG)*
Nov. 2018	*IQDG Remit endorsement by Management Committee*
Mar. 2019	*First IQDG telecon*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Mar. 2019	*IQDG draft Workplan*
Apr. 2019	*IQDG prioritization and recommendations for new ICH Guideline topic proposals (i.e. Q5A, Extractables and Leachables (E&L), Q9, Oligonucleotides...)*
Apr. 2019	*IQDG Work Plan for MC consideration*
Jun. 2019	*Agree IQDG Assessment Process establishing criteria to review/triage existing ICH Q & relevant M Guidelines, ICH Guidelines in progress (Steps 1-3) & newly proposed ICH Q topics/Guidelines.*
Jun. 2019	*Preliminary report to MC on:* • *IQDG future vision for integration & scope ICH Quality Guidelines* • *Plans for assessment & prioritization of existing ICH Quality Guidelines that warrant possible revision, updates, annexures, clarifications, Q & A, a potential new guideline, implementation plans &/or training in accordance with the ICH Quality Vision.*
Oct. 2019	*Assessment of any other new/revised ICH Quality topic proposals & priority recommendations to the MC for consideration & disposition.*

Nov. 2019	*IQDG Status report to MC on assessment & prioritization of existing ICH Quality guidelines that warrant possible revision, updates, annexures, clarifications, Q & A, a potential new guideline, implementation plans &/or training in accordance with the ICH Quality Vision*
Jun. 2020	*IQDG Status report to MC on assessment & prioritization of existing ICH Quality guidelines that warrant possible revision, updates, annexures, clarifications, Q & A, a potential new guideline, implementation plans &/or training in accordance with the ICH Quality Vision*
Nov. 2020	*IQDG Recommendation & Prioritization Report on assessment of ICH Q & relevant M Guidelines that warrant revision, updates, annexures, clarifications, Q & A, a new potential guideline, implementation plans &/or training in accordance with the ICH Quality Vision.*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Feb. 2019	*Feb. 2019*	*Inaugural Meeting*	• *Review of Reflection Paper and Remit* • *Assess & prioritize proposals for new ICH Q topics* • *Develop list of priorities for subsequent IQDG assessment*
Feb. 2019	*Mar. 2019*	*Draft workplan. Teleconference to meet and align on workplan*	*Align on tasks necessary to meet milestone activities.*
Mar. 2019	*Apr. 2019*	*Submit workplan to MC for consideration*	*NA*
Mar. 2019	*Apr. 2019*	*Teleconferences –* • *Agree to Process* • *Advise on the newly proposed ICH quality topics* *(Q5A, Oligonucleotide, E&L, Q9, M4Q(R1), BE for IR dosage forms)*	• *Develop process / develop criteria to review/triage the existing ICH Q and M Guidelines, new guidelines under review and newly proposed topics/guidelines* • *Consider new ICH Quality Topic proposals envisioned under the*

			ICH Quality Vision that have not been endorsed by the ICH with the goal of assessing how the proposal could be strengthened for reconsideration. • *Prioritize and understand linkages/relationships to existing ICH Guidelines.*
Apr. 2019	*Apr. 2019*	*Provide final recommendations for newly proposed ICH quality Topics*	*Provide the IQDG's final recommendations to ICH MC on the assessment and prioritisation of newly proposed 2018/2019 Quality topics (Q5A, Oligonucleotide, E&L, Q9, M4Q(R1), BE for IR dosage forms)*
Apr. 2019	*Jul. 2019*	*Teleconferences –* *Assessment of ongoing ICH quality Topics* *In Step 2: M9, Q3D(R1),* *In step 4: Q12, M7(R2), Q3C(R8), Q3D(R2)* *Other :* *M4Q(R1), Q13-, Q2(R2)/Q14*	• *Assess impact of <u>ongoing ICH Quality Topics</u> on future ICH Quality harmonization work envisioned under the ICH Quality Vision.* • *Identify gaps: what guidelines require further evaluation /updating and why?* • *Understand linkages/ relationships to other ICH Guidelines.* • *If relevant, suggest procedure /mechanism to update, i.e. Maintenance procedure (preferred as allows opening single chapters), Q&A, additional training* • *Update and compare activities, prioritizations, and progress with guideline evaluations.*
Jun. 2019	*Jun. 2019*	*Discuss proposal for ICH new topics process for 2019/2020 with MC*	• *Discuss ICH new topics process with MC for 2019/2020, i.e. all new Q topics should be progressed via the mechanism of the IQDG.*
Jul. 2019	*Nov. 2019*	*Monthly Teleconferences* *Evaluate current ICH Quality and Multidisciplinary Guidelines* *ICH Q1 – Q11*	• *Assess impact of <u>current ICH Quality Guidelines</u> on future ICH Quality harmonization work (I.e. Q12) envisioned under the ICH Quality Vision.* • *Identify gaps: what guidelines require further evaluation /updating and why?*

			• *Understand linkages/ relationships to other ICH Guidelines.* • *If relevant, suggest procedure /mechanism to update, i.e. Maintenance procedure, Q&A, additional training* • *Update and compare activities, prioritizations, and progress with guideline evaluations*
Nov. 2019	*Nov. 2019*	*Teleconference with Informal Generic Drug Discussion Group*	• *Provide feedback on the Informal Generics Drug Discussion group plan.*
Nov. 2019	*Nov. 2019*	*If requested and approved, attend F2F ICH meeting.*	• *Provide update of IQDG activities and progress to ICH MC and ICH Assembly at f2f meeting:* o *Update ICH Quality vision* o *Propose prioritised list of new guidelines and guideline updates* o *Provide recommendation to the training subcommittee*
Nov. 2019	*Nov. 2020*	*Monthly Teleconferences* *Continue tasks to complete assessment and attend f2f ICH meetings to present final recommendations on any proposed revisions to ICH Guidelines.*	• *Assess impact of <u>all ICH Quality Guidelines</u> on future ICH Quality harmonization work envisioned under the ICH Quality Vision.* • *Identify gaps: what guidelines require further evaluation /updating and why?* • *Understand linkages/ relationships to other ICH Guidelines.* • *If relevant, suggest procedure /mechanism to update, i.e. Maintenance procedure, Q&A, additional training*

			• *Prioritize and triage recommendations.* • *Provide update of IQDG activities and final recommendations to ICH MC and ICH Assembly at f2f meeting*