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