IPRP
International Pharmaceutical Regulators Programme

Work Plan

Biosimilar Working Group (BWG)

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1. Key Milestones and Deliverables

1.1. Current status of key milestones and deliverables

Completion date	Objective	Key Milestone or Deliverable
Aug. 2016	To provide a template to assist NRAs in making available a summary of the review of biosimilar applications in their country in a common language (English)	Public Assessment Summary Information for Biosimilar (PASIB)
Mar. 2017	To help train quality reviewers with experience in biotherapeutics to review the analytical comparability of biosimilar monoclonal antibodies	Training Manual for Regulatory Reviewers : The Basics of Analytical Comparability of Biosimilar Monoclonal Antibody for Regulatory Reviewers
Nov. 2017	To compile the common features of various biosimilar guidelines and to highlight to NRAs harmonized scientific considerations on the extrapolation of indication(s) for biosimilar products	Reflection Paper on Extrapolation of Indications in Authorization of Biosimilar products
Dec. 2018	To establish an IT platform for regulatory convergence on biosimilars by collecting regulatory information and sharing experiences between regulators on NRA's activities in order to enhance transparency and provide information to the members and the public	IPRP BWG Regulatory Information Sharing Platform

Dec. 2019	To help train reviewers with experience in biotherapeutics to review the nonclinical comparability of biosimilar monoclonal antibodies	Training Manual for Regulatory Reviewers: The Basics of Nonclinical Comparability of Biosimilar Monoclonal Antibody for Regulatory Reviewers
Dec. 2020	To help train reviewers with experience in biotherapeutics to review the clinical comparability of biosimilar monoclonal antibodies	Training Manual for Regulatory Reviewers: The Basics of Clinical Comparability of Biosimilar Monoclonal Antibodies for Regulatory Reviewers
Dec 2021	To educate regulatory reviewers about current approaches with respect to specific scenarios in the regulation of biosimilar biotherapeutic products	Primer on Biosimilar-Related Regulatory Topics for Regulatory Reviewers

1.2. Future anticipated key milestones

Expected future completion date	**Objective**	**Key Milestone or Deliverable**
Dec. 2022	To maintain applicability and utility of IPRP BWG published documents	Survey of current deliverables on the IPRP BWG website to determine any necessary updates Perform necessary updates and publish revised documents

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	**End date**	**Task / Activity**	**Details**
Feb. 2022	Oct. 2022	1. Review/identify documents needing update 2. Teleconferences - 1st TC (March) - 2nd TC (June) - 3rd TC (Sept-Oct) No face-to-face meeting currently planned	1. Pre-Tcon, Firm up work plan details with BWG, receive initial input regarding documents needing update. 2. March Tcon: discuss identified document update needs / assign task leads / next steps 3. Post-Tcon: Revise document(s) accordingly 4. June Tcon: discuss progress / concerns / next steps 5. Post-Tcon: Complete document revisions 6. Fall Tcon: discuss progress / clarifications / concerns / final edits

Nov. 2022	Dec. 2022	Finalization of updates and submission to MC (Nov.)	7. Nov 2022: Finalize documents and refer to IPRP MC 8. Dec 2022: Publish on IPRP website
		Publication of revised documents at IPRP's homepage (Dec.)	