IPRP
International Pharmaceutical Regulators Programme

Work Plan

Biosimilar Working Group (BWG)

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Chair: Sarah Yim, FDA, United States

Co-Chair: Ali Al Homaidan, SFDA, Saudi Arabia

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
September 2023	To discuss considerations and inputs into a risk-based framework for determining when CES may be useful and when they may not be needed.	Scientific Workshop: Increasing the Efficiency of Biosimilar Development Programs—Re-evaluating the Need for Comparative Clinical Efficacy Studies (CES).
July 2024	To educate regulatory staff and the public on the discussions held at the September 2023 scientific workshop.	Workshop Summary Report of September 2023 Workshop

1.2. Future anticipated key milestones

Expected future completion date	**Objective**	**Key Milestone or Deliverable**
4th QTR 2024	Alignment on the considerations to incorporate on a risk-based framework for determining when CES may be useful	White paper/concept paper

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	**End date**	**Task / Activity**	**Details**

4th QTR 2024	4th QTR 2025	1. Working Group t-con, 4th QTR 2024 2. Working Group t-con 1st QTR 2025 3. Working Group t-con 2nd QTR 2025 4. Concept Paper finalize and clear for publication, 3rd QTR 2025	1. Align on risk-based framework details and format 2. Further align on draft concept paper content 3. Continue work on Concept Paper 4. Concept paper finalize and clear for publication