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

Past 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	IPRP BWG Regulatory Information Sharing Platform

	sharing experiences between regulators on NRA's activities in order to enhance transparency and provide information to the members and the public	
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

1.2. Future anticipated key milestones

Expected future completion date	**Objective**	**Key Milestone or Deliverable**
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 Antibody for Regulatory Reviewers

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	**End date**	**Task / Activity**	**Details**
Mar. 2020	Nov. 2020	Teleconference - 1st TC (3/25/2020) - 2nd TC (June) - 3rd TC (Sept-Oct) No face to face meeting will be held in 2020.	1. Input from various agencies on content of training manual was discussed and clarified at 1st t-con and high-level outline of content areas discussed. 2. 4/14/2020: e-mail with meeting minutes, updated draft manual, request for member edits and additions 3. 2nd t-con: TBD, June
Mar. 2020	Dec. 2020	Drafting of training manual continues, with pre-tcon editing, t-con discussion/clarification, post-t-con draft and action items e-mailed. Post 3rd t-con follow-up should be a draft that has only a few final action items and final edits.	4. Post June t-con follow-up e-mail and assignments 5. 3rd T-con (Sept/Oct) 6. Post t-con follow-up with draft for final edits. Finalization will be done by e-mail if further discussion not needed.

		Finalization of training manual and submission to MC (Nov.)	7. Development of Training Manual for Regulatory Reviewers : The Basics of Clinical Comparability of Biosimilar Monoclonal Antibody for Regulatory Reviewers
		Publication at IPRP's homepage (Dec.)	