Increasing the Efficiency of Biosimilar Development Programs — Reevaluating the Need for Comparative Clinical Efficacy Studies

Workshop Agenda

Session 1 (Public): ***Setting the stage—How have we been using comparative clinical efficacy studies (CES) in biosimilar development programs, and what have we learned?*** **Tuesday, September 12, 2023** **7:00 am – 10:00 am Eastern Time (US & Canada); 1300 – 1600 Central European Time (CET)**	
Welcome/Opening Remarks (10 min)	Carol Kim and Brooke DalSanto, FDA, United States
Regulatory Experience and Considerations to Date (110 min)	Regulatory Agency Speakers • Marie-Christine Bielsky, MHRA, UK • Hye-Na Kang, WHO • Rene Anour, EC, Europe • Bradley Scott, Health Canada, Canada • Ryosuke Kuribayashi, MHLW/PMDA, Japan • Woo-Yong Oh, MFDS, Republic of Korea • Stacey Ricci, FDA, United States
Panel, Q&A (50 min)	Moderator: Ali Al Homaidan, SFDA, Saudi Arabia
Closing Remarks (10 min)	Carol Kim, FDA, United States
Session 2 (Public): ***Stakeholder perspectives on the need for CES in biosimilar development programs*** **Wednesday, September 13, 2023** **7:00 am – 10:00 am Eastern Time (US & Canada); 1300 – 1600 Central European Time (CET)**	
Welcome Day 2 (5 min)	Brooke DalSanto, FDA, United States
Stakeholder Experience with and Perspectives on CES (120 min)	Stakeholder Representative Speakers • Martin Schiestl, Sandoz • Gillian Woollett, Samsung • Fabrice Romanet, Fresenius-Kabi • Keith Watson, KRW Bio Reg Solutions • Elena Wolff-Holz, Biocon • Elena Guillen, Hospital Clinic de Barcelona • Frank Schneider, Teva
Panel, Q&A (45 min)	Moderator: Steffen Thirstrup, EC, Europe
Closing Remarks (10 min)	Sarah Yim, FDA, United States

Session 3-5 (Regulators only): ***Regulatory considerations regarding efficient use of comparative clinical efficacy studies in biosimilar development programs*** **Tuesday-Thursday, September 19-21, 2023**

7:00 am-10:00 am Eastern Time (US & Canada); 1300 – 1600 Central European Time (CET)