



Biosimilars: A Decade of Experience and Future Directions
Strategies for Improving Biosimilar Adoption and the Potential Role of Clinical Pharmacology

Welcome and Opening Remarks

<https://cersi.umd.edu/>

University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)

- M-CERSI is an FDA-sponsored center at the Baltimore and College Park campuses of the University of Maryland.
- The mission of the Center is to foster the development of regulatory science – the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.



M-CERSI workshop website

- Agenda
- Biographies

Within ~2-3 weeks, speaker presentations will be available, along with the recordings from the workshop

<https://www.pharmacy.umaryland.edu/centers/cersievents/biosimilars2022/>



CERSI
University of Maryland

- Please use the Chat box for asking questions to the speakers & panelists; please select “Everyone” when asking your questions so everyone can see them
- There may be ~5 min after each presentation for the speaker to address any questions. Additional questions will be addressed during the panel discussion.

Agenda

1:00 pm – 1:05 pm

Welcome: Maureen Kane, PhD University of Maryland

1:05 pm – 1:10 pm

Opening Remarks: Yow-Ming Wang, PhD Food and Drug Administration

1:10 pm – 1:35 pm

Biosimilars in Oncology

Gary Lyman, MD, MPH, FACP, FRCP (Edin), FASCO University of Washington

1:35 pm – 2:00 pm

Biosimilars in Rheumatology (and Immune Mediated Inflammatory Diseases)

Allan Gibofsky, MD, JD, MACR, FACP, FCLM Weill Cornell Medical College

2:00 pm – 2:25 pm

Biosimilars in IBD: Real World Evidence

Gary Lichtenstein, MD, FACP, FACG, AGAF University of Pennsylvania

2:25 pm – 2:50 pm

Biosimilar Insulin Concepts

Zachary Bloomgarden, MD, MACE, FASPC Icahn School of Medicine at Mount Sinai

2:50 pm – 3:30 pm

Panel Discussion

Moderator

Raymond Cross, MD University of Maryland

Panelists

Yow-Ming Wang, PhD Food and Drug Administration

Sarah Yim, MD Food and Drug Administration

Zachary Bloomgarden, MD, MACE, FASPC Icahn School of Medicine at Mount Sinai

Allan Gibofsky, MD, JD, MACR, FACP, FCLM Weill Cornell Medical College

Gary Lichtenstein, MD, FACP, FACG, AGAF University of Pennsylvania

Gary Lyman, MD, MPH, FACP, FRCP (Edin), FASCO University of Washington