

Biosimilar User Fee Act (BsUFA) Regulatory Science Accelerator

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BsUFA III Regulatory Science Pilot Program: Progress Update –
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About the Foundation



- Independent non-profit organization created by Congress to help the FDA “do more” to protect and promote the public’s health
- As a working Foundation, we manage a suite of programs that help FDA engage with external stakeholders and that facilitate evidence generation, improve public understanding of the Agency and the products it regulates, and deliver more accessible health information to the public

Convene a Conversation Series with Biosimilar Developers: A Regulatory Science Accelerator...



- Goal: Explore emerging areas of regulatory science with a small group of biosimilar developers
- Timeframe: Convene 5 virtual conversations over the course of 3 months



Recruiting Participants

- Issued an “open ask” for participation and conducted targeted outreach
- Target participants: Biosimilar developers who may have had limited engagement with FDA
- Foundation chose participants from interested companies, ensuring presence of a wide representation of biosimilar development experience
 - Ten companies joined 1 or more of the conversations in the series

Roundtable Discussion Topics

Roundtable 1: Achieving Analytical Similarity

Roundtable 2: Leveraging Analytics to Inform Remainder of Biosimilar Development

Roundtable 3: Achieving Pharmacokinetic (PK) Similarity

Roundtable 4: Leveraging Pharmacokinetics and/or Pharmacodynamics to Inform Remainder of Biosimilar Development

Roundtable 5: Conducting Immunogenicity Risk Assessments and Evaluation

Insights Shared...

- **Critical Quality Attributes (CQAs)**
 - Developers sought clarity on CQAs, acceptable variability, and essential tests identified as a top priority
- **Analytical and Reference Product Challenges**
 - Variability and availability of reference product lots can be a significant barrier

Insights Shared...

- **Inefficiencies in Pharmacokinetic Studies**
 - High patient drop-out rate and increased complexity of using patients instead of healthy volunteers
- **Immunogenicity**
 - Uncertainty in reliable surrogacy of non-clinical in vitro assays for immunogenicity

Insights Shared...



- **Bias in Modeling and Simulation**

- Modeling reduces sampling needs but may introduce bias

Accelerator Output



- FDA gained insights into the challenges faced by biosimilar developers, particularly smaller companies
- Accelerator participants outlined the obstacles they face and shared suggestions on how the FDA BsUFA III Regulatory Science Pilot Program could support their development programs
- Watch for report publication later this year



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<https://reaganudall.org/news-and-events/events/biosimilar-roundtables>