Biosimilars 2015

Tutorial: October 18 | Workshop: October 19-20

Hyatt Regency Bethesda | Bethesda, MD

As of September 18, 2015

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Chair of the European Biopharmaceuticals Group (EBG)
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OVERVIEW:

With the approval of the first biosimilars in the US and potentially more to follow, and with the expiration of patents for originator biologicals, the market for biosimilars is poised to grow at a rapid pace. These biosimilars and follow-on biologics have garnered great interest presenting new market opportunities for industry and greater potential for cost-effective benefits in patient care.

As biosimilars become more available to patients, there are important factors for patients and health care providers that must be addressed. This meeting will focus on the innovations, technologies, and regulatory information surrounding biosimilars. This is an exciting time in our industry.

FEATURED TOPICS:

- Interchangeability
- Quality Considerations
- Biosimilars in Oncology
- Updates from US and Global Regulators

LEARNING OBJECTIVES:

At the conclusion of this meeting, participants should be able to:

- Identify the unique challenges and complexities associated with demonstrating biosimilarity to a reference product
- Examine the implications for patients and health care professionals as biosimilars and (potentially) interchangeable biologics are introduced into the market

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Tutorial:

• Achieving Biosimilarity Through Matching of Critical Attributes to Reference Products: IACET: .3 CEUs

Meeting:

IACET: 1.3 CEUs

Pharmacy:

• Day 1: 6 contact hours or .6 CEUs, 0286-0000-15-109-L04-P

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SUNDAY, OCTOBER 18

12:45–1:00PM **REGISTRATION**

**Please note: Lunch is not provided by DIA during this tutorial.

1:30–5:00PM **TUTORIAL: ACHIEVING BIOSIMILARITY THROUGH MATCHING OF CRITICAL QUALITY ATTRIBUTES TO REFERENCE PRODUCTS**

INSTRUCTORS:

Michele Dougherty, PhD
Product Quality Reviewer, Monoclonal Antibodies
FDA

Niklas Ekman, PhD, MSc
Senior Researcher
Finnish Medicines Agency

Cecil Nick, BSc (Hons.), FTOPRA
Vice President (Technical)
PAREXEL Consulting

Emily Shacter, PhD
Independent Consultant
ThinkFDA, LLC

The first step in achieving biosimilarity is to ensure that the critical quality attributes (CQAs) of the biosimilar closely align to those of the reference product. To address this, there is a need to understand the importance of different attributes in terms of achieving biosimilarity. FDA has introduced a system for ranking of CQAs and the setting of equivalence criteria. But this approach raises many questions, such as:

1. What factors need to be considered in such ranking of CQAs?
2. How many batches should be compared?
3. Is it reasonable to establish equivalence margins?
4. If so, how tight should these margins be?

These questions are of profound importance as setting criteria unnecessarily tight would limit the potential for development of approvable biosimilars and thereby limit the availability of affordable biological medicines. On the other hand, allowing too much latitude could introduce uncertainty with potential impact on safety and potency of biosimilar medicines. This tutorial will debate these issues considering the importance of CQAs based on their impact on structure, function and therapeutic relevance and how close a match ought to be achieved to the reference product.

LEARNING OBJECTIVES:

At the conclusion of this tutorial, participants should be able to:

- Assess the importance of various CQAs
- Discuss what factors need to be considered in justifying the ranking of CQAs
- Discuss the importance in setting criteria for establishing similarity
- Explain the regulatory expectations for the degree of CQA similarity between the biosimilar and reference product

Please note: registration for this tutorial is separate from the meeting. You may register online at DIAglobal.org/Biosimilars

MONDAY, OCTOBER 19

7:30AM-4:30PM **REGISTRATION**

7:30-8:30AM **CONTINENTAL BREAKFAST**

8:30-9:00AM WELCOME AND OPENING REMARKS

Cecil Nick, BSc (Hons.), FTOPRA
Vice President (Technical)
PAREXEL Consulting

9:00-10:45AM SESSION 1: BIOSIMILARS IN THE US AND EUROPE

SESSION CHAIR:

Mark McCamish, MD, PhD
Global Head Biopharm & Oncology Injectables Development
Sandoz International GmbH

In this session we will review the latest scientific and regulatory developments in the US and Europe. Leading FDA and EMA regulators will provide their perspective on the approval of the first biosimilars in the US, biosimilar monoclonal antibodies, the development and revision of guidelines and efforts to achieve convergence of requirements between the US and Europe. We will also hear the stories of the approvals of the first two biosimilars in the US, a cytokine and a monoclonal antibody, directly from industry leaders who were closely involved with this work. Overall, this session will provide a comprehensive overview of where the cutting edge of the science and regulations for biosimilars stands today.

Keynote: Beyond the Finish Line: Biosimilars in the US

Steven Kozlowski, MD
Director, Office of Biotechnology Products
Office of Pharmaceutical Quality
CDER, FDA

Biosimilars 2.0 in the EU: Learnings, Challenges, and External Perceptions

Niklas Ekman, PhD, MSc
Senior Researcher
Finnish Medicines Agency

The First Biosimilar in the US – The Company Perspective

Mark McCamish, MD, PhD
Global Head Biopharm & Oncology Injectables Development
Sandoz International GmbH

10:45–11:15AM **REFRESHMENT AND NETWORKING BREAK**

11:15AM-12:30PM SESSION 2: QUALITY CONSIDERATIONS – PART ONE

SESSION CHAIR:

Sundar Ramanan, PhD
Director, Global Biosimilars R&D Policy
Amgen Inc.

CMC forms the foundation for Biosimilar development. Topics will focus on the nature biosimilar profile in comparison with the reference product and what highly similar means; the nature of tools and techniques used to describe “finger printing”; equivalence acceptance criteria; role of analytical similarity in extrapolation and how does one go about addressing attributes that are outside the equivalence window.

FDA Address

Steven Kozlowski, MD
Director, Office of Biotechnology Products
Office of Pharmaceutical Quality
CDER, FDA

Challenges and Approaches in Demonstrating Biosimilarity and How to Move Toward Fingerprint-Like Equivalence

Joseph Glajch
Director, Analytical Development
Momenta Pharmaceuticals

Defining the Requisite Components of Interchangeability

Paul Tebbey, PhD, MBA
Senior Scientific Director, Blotherapeutics
AbbVie, Inc.

PROFILE-NMR: Assessing Higher Order Structure of Formulated Protein Therapeutics

Brad Jordan, PhD
Senior Scientist – Molecular Structure and Biophysics
Amgen, Inc

12:30–1:45PM **LUNCHEON AND NETWORKING**

1:45-3:00PM SESSION 2: QUALITY CONSIDERATIONS – PART TWO, A PANEL DISCUSSION

SESSION CHAIR:

Sundar Ramanan, PhD
Director, Global Biosimilars R&D Policy
Amgen Inc.

CMC forms the foundation for Biosimilar development. Topics will focus on the nature biosimilar profile in comparison with the reference product and what highly similar means; the nature of tools and techniques used to describe "finger printing"; equivalence acceptance criteria; role of analytical similarity in extrapolation and how does one go about addressing attributes that are outside the equivalence window.

PANELISTS:

Joseph Glajch
Director, Analytical Development
Momenta Pharmaceuticals

Steven Kozlowski, MD
Director, Office of Biotechnology Products
Office of Pharmaceutical Quality
CDER, FDA

Paul Tebbey, PhD, MBA
Senior Scientific Director, Biotherapeutics
AbbVie, Inc.

Brad Jordan, PhD
Senior Scientist – Molecular Structure and Biophysics
Amgen, Inc

3:00–3:30PM REFRESHMENT AND NETWORKING BREAK

3:30–4:45PM SESSION 3: CLINICAL AND PHARMACOLOGY CONSIDERATIONS

SESSION CHAIR:

Cecil Nick, BSc (Hons.), FTOPRA
Vice President (Technical)
PAREXEL Consulting

The role of clinical data in the development of biosimilars is to address any residual uncertainty following the generation of extensive structural and biological comparative data against the reference product, as well as some limited nonclinical data. In this respect, PK/PD and immunogenicity data could be sufficient, while in other circumstances, limited therapeutic data generated in an adequately sensitive patient population may be needed. There are numerous challenges in designing and conducting therapeutic equivalence trials, and their importance in establishing biosimilarity is sometimes overplayed. This session will consider when therapeutic trials may be needed and what value they play as part of the total biosimilarity data package.

Maximizing the Value of PK/PD in the Development of Biosimilarity

Jan Hillson, MD
Senior Director, Clinical and Research
Momenta Pharmaceuticals, Inc.

The Role of Pharmacology Data in Establishing Biosimilarity

Darrell Abernethy, MD, PhD
Associate Director for Drug Safety
Office of Clinical Pharmacology
CDER, FDA

The Importance of Immunogenicity Data

Meena Subramanyam, PhD
Vice President, Translational Sciences and Technology
Biogen Idec, Inc.

Extrapolation Across Indications

Bernd Liedert
Boehringer Ingelheim Pharma GmbH & Co. KG Medicine

Panel Discussion

4:45–5:45PM NETWORKING RECEPTION

TUESDAY, OCTOBER 20

7:30AM-12:15PM **REGISTRATION**

7:30-8:30AM **CONTINENTAL BREAKFAST**

8:30 – 10:00AM SESSION 4: UNIQUE FEATURES OF DEVELOPING BIOSIMILARS IN ONCOLOGY

SESSION CHAIR:

Julie Ann Rosenberg, MD
Senior Director, Asset Lead, Biosimilars
Pfizer Worldwide Research and Development

Despite availability and known effectiveness of biologic therapies, limited patient access may affect overall patient outcomes. The global cost of cancer care continues to rise, and some health care systems ration high-cost treatments. Worldwide access to effective cancer treatments remains an unmet medical need in many countries.

This session will review:

- The evolving therapeutic landscape of oncology and the integration of biosimilars
- Key considerations in clinical trials of biosimilars in oncology
- Extrapolation of indications in oncology
- Patient views on biosimilars and access to cancer care
- US regulatory considerations for oncology biosimilars

Oncology Biosimilars: A Patient Perspective

Kimberly Wright, Advocate
Embryologist
Susan G. Komen AIS

US Regulatory Considerations for Oncology Biosimilars

Steven Lemery, MD, MHS
Lead Medical Officer
Division of Oncology Products 2
Office of New Drugs
CDER, FDA

Smart Extrapolation Strategy for Biosimilar Rituximab in Oncology

Bernd Liedert
Boehringer Ingelheim Pharma GmbH & Co. KG Medicine

Biosimilars: An Oncologist's Perspective

Robert Rifkin, MD, FACP
Medical Oncologist
Rocky Mountain Cancer Centers

10:00–10:15AM **REFRESHMENT AND NETWORKING BREAK**

10:15AM–12:15PM SESSION 5: GLOBAL REGULATORY POLICIES

SESSION CHAIR:

David Gaugh, RPh
Senior Vice President for Sciences and Regulatory Affairs
Generic Pharmaceutical Association (GPhA)

The market for biosimilars is predicted to rise rapidly as patents expire for blockbuster biologics. The approval and regulation of biosimilars are areas of notable regulatory innovation for now and for the foreseeable future. In order to have an efficient mechanism for initial approval and ongoing oversight with a country-specific focus, reaching convergence and/or harmonization among international regulatory authorities is essential. Speakers from different regions will provide updates and commentary on approvals and regulatory requirements for biosimilars.

Local Analytical and Clinical Studies for Biosimilars: Global Overview, Necessity and Consequences

Thomas Kirchlechner, PhD, MsC
Head, Regulatory Emerging Markets Group
Global Regulatory Affairs Biopharmaceuticals
Sandoz GmbH, Austria

US FDA Engagement in the Global Development of Biosimilars

Leah Christl, PhD
Associate Director for Therapeutic Biologics
OND Therapeutic Biologics and Biosimilars Staff (TBBS)
Office of New Drugs
CDER, FDA

Harmonization of Regulatory Expectations for Biosimilar Development, an Industry Perspective

Laura McKinley, PhD
Director, Worldwide Research and Development – Regulatory
Worldwide Safety and Regulatory
Pfizer, Inc.

Biosimilar Regulation in Japan – An Update

Daisaku Sato, PhD
Director, Office of Cellular and Tissue-based Products
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Standards for Regulatory Evaluation of Biotherapeutics Including Biosimilars: WHO Approach

Ivana Knezevic
Quality, Safety & Standards Team
Department of Immunization Vaccines and Biologicals
World Health Organization, Switzerland

Panel Discussion

Niklas Ekman, PhD, MSc
Senior Researcher
Finnish Medicines Agency, Finland

Session Speakers

12:15–1:15PM **LUNCHEON AMD NETWORKING**

1:15–2:45PM SESSION 6: PUSHING WELL FORWARD – COMMERCIALIZATION OF BIOSIMILARS POST-2020

SESSION CHAIR

Geoffrey Eich, MBA
Executive Director, External Affairs
Amgen Biosimilars

This panel discussion will focus on the post-2020 US biosimilars market and considerations for sustained biosimilars development of increasingly complex and/or rare disease biologic reference products. Topics will include implications of innovation in biosimilar markets (e.g. treatment of breast and colorectal cancers) and selection of viable reference products for biosimilars development. Panelists will be asked to address important policies and considerations related to the approval, post-market maintenance, health care community acceptance and reimbursement of highly complex and/or rare disease biosimilar medicines post-2020.

PANELISTS:

Aharon Gal, PhD
Senior Research Analyst
Sanford C. Bernstein

Leah Christl, PhD
Associate Director for Therapeutic Biologics
OND Therapeutics Biologics and Biosimilars Team (TBBS)
CDER, FDA

Steven Kozlowski, MD
Director, Office of Biotechnology Products Office of Pharmaceutical Quality
CDER, FDA

2:45–4:15PM SESSION 7: INTERCHANGEABILITY

SESSION CHAIR:

Cecil Nick, BSc (Hons.), FTOPRA
Vice President (Technical)
PAREXEL Consulting

Biosimilar access and adoption is dependent on biosimilars being available in the market place. A wide variety of commercial models exist varying from national tendering to individual commercial plan acceptance. These models will be variously impacted by or will impact the concepts of interchangeability, switching, and substitution. This session will also address the practical differences between each of these terms. It will specifically address regulatory considerations/ expectations related to interchangeability and the impact of such designation on the future market place dynamics and adoption. Scientific concepts and their application to achieve interchangeability designation will be discussed.

The Science of Interchangeability

Hillel Cohen, PhD
Executive Director, Scientific Affairs
Sandoz, Inc.

The Payer's Perspective

Tom B. Snyder
Senior Project Manager
PAREXEL International

Interchangeability: Is it Achievable? Will it Matter?

Jim Roach MD, FACP, FCCP
Senior Vice President
Development and Chief Medical Officer
Momenta Pharmaceuticals, Inc.

Panel Discussion

Leah Christl
Associate Director for Therapeutic Biologics
OND Therapeutic Biologics and Biosimilars Staff (TBBS)
Office of New Drugs
CDER, FDA

Session Speakers

4:15-4:30PM FINAL Q&A AND CLOSING REMARKS

Cecil Nick, BSc (Hons.), FTOPRA
Vice President (Technical)
PAREXEL Consulting

4:30PM MEETING ADJOURNED

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