DIA

Biosimilars Conference

Conference: September 23-24
DoubleTree Bethesdan | Bethesda, MD

PROGRAM CHAIR

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

PROGRAM COMMITTEE

Mary Jo Carden, BSN, JD, LLM, RPh
President, Carden Associates

Julie Marechal-Jamil, MSc
Director, Biosimilar Policy & Science
Medicines For Europe, Belgium

Laura McKinley, PhD
Director, Global Regulatory Policy & Intelligence
Pfizer, Inc.

Cecil Nick, MS
FTOPRA, Vice President (Technical)
PAREXEL Consulting, United Kingdom

Mark Stewart, PhD
Vice President, Science Policy
Friends of Cancer Research

Jian Wang, MD, PhD
Division Manager, Clinical Review Division
Heamatology/Oncology
Health Canada

Anna Welch, MA
Chief Editor, Biosimilar Development
Life Science Connect

Sarah Yim, MD
Acting Director for Therapeutic Biologics, OND, CDER
FDA

Overview

The Biosimilars Price Competition and Innovation Act (BCPIA) of 2009 created a biosimilars approval pathway in the US with the goal of increasing access safe and effective biological treatment options that are more cost effective than standard biologics. Since then, significant progress has been made in the science and regulation of biosimilar development and approval, and cooperative efforts among global regions is leading to better alignment on these issues.

These challenges are complex, interrelated, and best addressed by stakeholder collaboration. At the DIA 2019 Biosimilars Conference, manufacturers, regulators, payers, prescribers, and patients will come together to apply current biosimilar developments, experience, and the newest thinking to analyze strategies and next steps for improving biosimilar access and uptake.

Who Should Attend

Professionals involved in:

- Biosimilar/Biologic Pharmaceutical Executives
- Biomedical Product Developers and Manufacturers
- Regulatory Affairs Professionals
- Clinical and Nonclinical Researchers
- Biostatisticians and Data Managers
- Business Development Executives
- Marketing and Commercialization Staff involved with biosimilars
- Medical Communications/MSLs
- Patient Advocacy/Patient Support Programs
- Physicians including specialists across therapeutic disciplines
- Pharmacists and pharmacy professionals
- Payors, pharmacy benefit managers, insurers, health plans

Schedule At-A-Glance

DAY ONE | MONDAY, SEPTEMBER 23		ROOM
7:00AM–5:00PM	Registration	Bethesdan Foyer (Second Floor)
7:00–8:00AM	Networking Breakfast	Bethesdan CD
8:00–8:15AM	**Welcome and Opening Remarks**	Bethesdan AB
8:15–8:45AM	**Session 1:** Keynote Address	Bethesdan AB
8:45–10:00AM	**Session 2:** The Pitfalls and Promises of Real World Evidence in Evolving the Biosimilar Industry	Bethesdan AB
10:00–10:15AM	Refreshment and Networking Break	Bethesdan Foyer
10:15–11:30AM	**Session 3:** New Paths to Biosimilar Access: How These Stakeholders Can Promote Uptake	Bethesdan AB
11:30AM–12:30PM	Networking Luncheon	Bethesdan CD
12:30–1:45PM	**Session 4:** Overcoming Barriers-knowledge/perception	Bethesdan AB
1:45–2:15PM	Refreshment and Networking Break	Bethesdan Foyer
2:15–3:45PM	**Session 5:** Biosimilars in Practice-Critical Market Opportunities Awaiting to be Seized	Bethesdan AB
3:45–5:00PM	**Session 6:** Value to Patients	Bethesdan AB
5:00–6:00PM	Networking Reception	Bethesdan CD

DAY TWO | TUESDAY, SEPTEMBER 24		ROOM
7:00AM–3:30PM	Registration	Bethesdan Foyer (Second Floor)
7:00–8:00AM	Networking Breakfast	Bethesdan CD
8:00–8:05AM	**Opening Remarks**	Bethesdan AB
8:05–9:20AM	**Session 7:** Substitution of Biological Products	Bethesdan AB
9:20–9:45AM	Refreshment and Networking Break	Bethesdan Foyer
9:45AM–12:00PM	**Session 8:** Streamlining and Harmonizing Biosimilar Development	Bethesdan AB
12:00–1:00PM	Networking Luncheon	Bethesdan CD
1:00–2:15PM	**Session 9**: Transition Biologics	Bethesdan AB
2:15–3:30PM	**Session 10:** Regulatory Developments/Ask the Regulator	Bethesdan AB
3:30–3:45PM	Closing Remarks	Bethesdan AB
3:45PM	Conference Adjourns	

Learning Objectives

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

- Identify the current barriers to access and uptake facing biosimilars in the US
- Describe the US reimbursement and pricing landscape and its impact on market uptake and sustainability of biosimilars and interchangeable biological products
- Discuss educational needs of health care providers and patients around biosimilars/interchangeable biologicals and current strategies for increasing literacy on these products
- Explain the role of legal challenges such as patent litigation in influencing access to biosimilars
- Discuss current developments in regulatory and scientific issues and their impact on access and uptake of biosimilars and interchangeable products
- Discuss strategies and stakeholder-specific next steps to address these challenges

Continuing Education Credits

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, NOVEMBER 8, 2019

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 13 contact hours or 1.3 continuing education units (CEU's). Type of Activity: Knowledge

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by Friday, November 8, 2019, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 1.3 CEUs for this program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must sign in each day at the DIA registration desk upon arrival and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Tuesday, October 8**.

To view DIA's Grievance Policy, visit **DIAglobal.org/CE**

Continuing Education Credit Allocation

Day One: 7 Contact Hours .7 CEUs 0286-0000-19-067-L04-P

Day Two: 6 Contact Hours .6 CEUs 0286-0000-19-068-L04-P

TO ACCESS MY TRANSCRIPT

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

ACCESS PRESENTATIONS

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Choose **My Presentation**

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

DAY ONE | MONDAY, SEPTEMBER 23

7:00AM–5:00PM — **Registration**

7:00–8:00AM — **Networking Breakfast**

8:00–8:15AM — **Welcome and Opening Remarks**

Sudip Parikh, PhD, Senior Vice President and Managing Director, DIA Americas

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

8:15–8:45AM — **Session 1:** Keynote Address

Janet Woodcock, MD, Director, Center for Drug Evaluation and Research (CDER), FDA

8:45–10:00AM — **Session 2:** The Pitfalls and Promises of Real World Evidence in Evolving the Biosimilar Industry

Session Chairs
Mark Stewart, PhD, Vice President, Science Policy, Friends of Cancer Research

Anna Rose Welch, MA, Chief Editor, Biosimilar Development, Life Science Connect

Real world evidence has been a critical tool for reassuring stakeholders of the long-term safety and efficacy of biosimilars. But how else can RWE shape the evolving use of biologics and biosimilars? This panel will discuss the challenges of collecting and using RWE today to improve biosimilar understanding. It will also identify other areas of inquiry that can be addressed with RWE and the existing potential of RWE to evolve regulatory requirements and clinical treatment pathways.

Jaclyn Bosco, PhD, Global Scientific Head, Epidemiology and Biostatistics, IQVIA

Nancy Lin, DrSc, MS, Senior Scientist, Epidemiology, Optum

Edward Li MPH, PharmD, Associate Director, HEOR & RWE, Sandoz

Gianluca Trifirò, MD, PhD, Associate Professor of Pharmacology - Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina, Italy *(Presenting Remotely)*

10:00–10:15AM — **Refreshment and Networking Break**

10:15–11:30AM — **Session 3**: New Paths to Biosimilar Access: How These Stakeholders Can Promote Uptake

Session Chair
Anna Rose Welch, MA, Chief Editor, Biosimilar Development, Life Science Connect

Pharmacy benefits managers, patients, and physicians are credited with having the most influence in terms of U.S. biosimilar market access. While these stakeholders are critical pieces of the puzzle, the employer, health system, and GPO are often overlooked influencers in educating about biosimilars and improving uptake. This session will examine the tools each of these stakeholders have at their disposal to overcome systemic barriers individually and collectively to promote greater biosimilar access.

Lauren Vela, Senior Director, Pacific Business Group on Health

Ned Pojskic, Leader, Pharmacy & Health Provider Relations, Green Shield Canada

Sameer Awsare, MD, FACP, Associate Executive Director, Permanente Medicine, The Permanente Medical Group

11:30AM–12:30PM — **Networking Luncheon**

12:30–1:45PM

Session 4: Overcoming Barriers-knowledge/perception

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

This session will provide insights into the current knowledge and perception of different stakeholders about biosimilars, including patients and their healthcare providers. The FDA, a patient advocacy group and a physician group, will discuss targeted educational initiatives that are being undertaken to educate different stakeholders about key concepts of biosimilarity to address topics and issues that are often misunderstood. The session will consist of brief presentations, followed by a panel discussion that will provide the audience with the opportunity to pose questions to the panelists to initiate further discussion.

Sarah Ikenberry, MA, Senior Communication Advisor, OTBB, OND, CDER, FDA

Cheryl Koehn, Founder and President, Arthritis Consumer Experts, Canada

Angus Worthing, MD, Chair of the Government Affairs Committee, American College of Rheumatology

1:45–2:15PM

Refreshment and Networking Break

2:15–3:45PM

Session 5: Biosimilars in Practice-Critical Market Opportunities Awaiting to be Seized

Session Chair
Erika Satterwhite, Head of Global Biosimilars Policy-Mylan and Chair of the IGBA Biosimilars Committee

The U.S. biologic payer and reimbursement framework has revealed unfit for a biologic multi-source market, with a number of barriers blocking meaningful utilization and update. This session focuses on identifying mechanisms to overcome market access barriers in the U.S. and build a suitable environment to release the untapped potential of biosimilar medicines competition.

US Biosimilar Industry Perspective
Juliana Reed, MS, Vice President, Corporate Affairs, Global I & I and Biosimilars Lead, Pfizer, Inc.

Global Perspective 2030 on Biosimilars
Murray Aitken, Senior Vice President and Executive Director, IQVIA

Elizabeth Jex, Attorney Advisor, Office of Policy Planning at Federal Trade Commission

3:45–5:00PM

Session 6: Value to Patients

Session Chair
Mary Jo Carden, RPh, JD, Vice President, Government and Pharmacy Affairs

Biosimilars offer safe, effective, and more affordable alternatives to patients who use biologic medications for managing chronic conditions. To date, biosimilars have not necessarily achieved the expected goals of allowing patients to have access to more affordable biologic medications. This session will enable participates to hear the patient perspective on biosimilars and recommendations for overcoming current challenges and barriers. Issues considered will include potential cost savings of biosimilars to patients and the health care system, the implications of how access to biosimilars may improve adherence to biologics, and ways that savings from biosimilars may improve patient care through better access to services and patient support.

Implications to Biosimilar Access for Patients with Arthritis
Benjamin Chandhok, Senior Director, State Legislative Affairs, Arthritis Foundation

How Can Biosimilars Benefit Patients with Cancer and What Are Challenges to Access?
Laura Lasiter, Science Policy Analyst, Friends of Cancer Research

5:00–6:00PM

Networking Reception

DAY TWO | TUESDAY, SEPTEMBER 24, 2019

7:00AM–3:30PM — **Registration**

7:00–8:00AM — **Networking Breakfast**

8:00–8:05AM — **Opening Remarks**

8:05–9:20AM — **Session 7:** Substitution of Biological Products

Session Chair
Laura McKinley, PhD, Director, Global Regulatory Policy & Intelligence, Pfizer, Inc.

The term interchangeable has different meanings in different parts of the world. The session will begin with a brief review of terminology, including differences in US and EU definitions of interchangeability, and what has changed in the US with the finalization of guidance. The session will go beyond discussing the regulatory frameworks that support switching and substitution of biological products. The session will discuss the science supporting switching and substitution of biological products, experience to date with a focus on the US marketplace, and the anticipated value and impact of the interchangeability designation in the US.

The Current State of Affairs–Switching, Substitution, and Interchangeability
Laura McKinley, PhD, Director, Global Regulatory Policy & Intelligence, Pfizer, Inc.

The Science of Substitution
Hans Ebbers, PhD, International Scientific Affairs, Biogen Netherlands B.V., Netherlands

US Experience to Date
Sameer Awsare, MD, FACP Associate Executive Director, Permanente Medicine, The Permanente Medical Group

9:20–9:45AM — **Refreshment and Networking Break**

9:45AM–12:00PM — **Session 8:** Streamlining and Harmonizing Biosimilar Development

Session Chair
Christopher Webster, BVM&S, MSc, PhD, Principal, BioApprovals

Vast experience has been gained in the development of biosimilars over the past decade, which can enable the streamlining of biosimilar developments by allowing specific reductions of regulatory requirements without compromising the quality or safety of the product. Moreover, there is a broad interest of patients that such opportunities are pursued vigorously, as the elimination of unnecessary regulatory requirements contributes to competition within the biosimilars' market and the eventual affordability of, and access to, biosimilars. This session will examine new proposals for streamlining the development of biosimilars and consider the circumstances under which such new approaches might be introduced and the issues to be confronted in harmonizing these approaches across the world.

Efficient Development of Biosimilars: A Rumsfeldian Approach
Christopher Webster, BVM&S, MSc, PhD, Principal, BioApprovals

Tailored Clinical Biosimilar Development
Martin Schiestl, PhD, Global Head Regulatory Affairs Policy, Sandoz GmbH, Austria

Update on the WHO Pilot Procedure for Prequalification of BTPs: rituximab and trastuzumab
Guido Pante, PhD, Technical Officer, Italian Medicines Agency, World Health Organization, Italy

Panel Discussion: Streamlining Global Biosimilar Development
Guido Pante, PhD, Technical Officer, Italian Medicines Agency, World Health Organization, Italy

Martin Schiestl, PhD, Global Head Regulatory Affairs Policy, Sandoz GmbH, Austria

Christopher Webster, BVM&S, MSc, PhD, Principal, BioApprovals

Elena Wolff-Holz, Chair, Biosimilar Medicinal Products Working Party (BMWP) of CHMP, EMA

Sarah Yim, Acting Director for Therapeutic Biologics, OND, CDER, FDA

12:00–1:00PM **Networking Luncheon**

1:00–2:15PM **Session 9:** Transition Biologics

Session Chair
Gillian Woollett, MA, DPhil, Senior Vice President, Avalere Health

Title VII of Biosimilars Price Competition and Innovation Act (BCPIA) of 2009 include provisions that require FDA to transition those drugs that are biologics in science and have been regulated under the FD&C Act to become biologics regulated under the PHS Act on 23rd March 2020 (10 years after enactment of BPCIA). These include a number of products, principally hormones. The transition product that will impact most patients are the insulins. FDA has determined that all of the "transition" (also called "rollover") products will become standalone biologics regulated according to 351(a), and that none will become biosimilars under 351(k). This session will discuss the implications for stakeholders, especially patients, of this change.

Eva Temkin, JD, Acting Director of Policy, Office of Therapeutic Biologics and Biosimilars, CDER, FDA

Marjana Marinac, PharmD, Senior Director, Regulatory Affairs Drugs & Biologics, JDRF

Sundar Ramanan, Vice President, Global Regulatory Affairs, Biocon Research Limited-SEZ Unit, India

2:15–3:30PM **Session 10:** Regulatory Developments/Ask the Regulator

Session Chair
Sarah Yim, Acting Director for Therapeutic Biologics, OND, CDER, FDA

This session focuses on the regulator's perspective and provides an opportunity for interactive Q&A. The session will begin with brief presentations of the highlights of recent regulatory developments from the mentioned regulators, followed by a panel Q&A session.

The Regulatory Situation of Biosimilars in the EU
Elena Wolff-Holz, Chair, Biosimilar Medicinal Products Working Party (BMWP) of CHMP, EMA

Emily Griffiths, PhD, Subject Matter / Technical Specialist, Office of Policy and International Collaboration, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada

Guido Pante, PhD, Technical Officer, Italian Medicines Agency, World Health Organization, Italy

Sarah Yim, Acting Director for Therapeutic Biologics, OND, CDER, FDA

3:30–3:45PM **Closing Remarks**

3:45PM **Conference Adjourns**