DIA
Biosimilars Conference

Short Course: October 5 | Conference: October 6-7 | Virtual Event

PROGRAM CHAIR

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

PROGRAM COMMITTEE

Leah Christl, PhD
Executive Director, Global Regulatory and R&D Policy
Amgen

Tiffany Fletcher, MA
Head of Global Biosimilar Policy and Access
Mylan

Julie Marechal-Jamil, MSc
Director, Biosimilars Policy and Science
Medicines for Europe, Belgium

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

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

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

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

Laura Wingate
Senior Vice President, Education, Support and Advocacy
Crohn's and Colitis Foundation

Sarah Yim, MD
Director for Therapeutic Biologics and Biosimilars, OND, CDER
FDA

Overview

This year marks the 10th Anniversary of the Biosimilars Price Competition and Innovation Act (BCPIA), which created a biosimilars approval pathway in the US with the goal of increasing access to safe, effective, and cost effective biological treatment options for patients. To date, significant progress has been made in the science and regulation of biosimilar development and approval, and awareness and educational efforts are increasing prescriber and patient confidence and uptake. The challenges have been and continue to be complex, interrelated, and best addressed by stakeholder collaboration, not only within the US but across global regions.

To sustain the momentum, stakeholders are now looking forward – to streamlining biosimilars development, meeting ongoing manufact uring challenges as well as those posed by the COVID-19 pandemic, addressing pricing issues, and to discovering new targets for biosimilar development. At the DIA 2020 *Biosimilars Conference*, manufacturers, regulators, payers, prescribers, and patients will come together to envision the biosimilars landscape of the next 5 years and to share perspectives on what success and equilibrium will look like. They'll apply the newest thinking and relevant learnings from global regions to build strategies for continuing the growth of the biosimilars market and bringing these important biologic therapies – and cost savings - to patients.

Who Should Attend

Professionals involved in:

- Biosimilar/Biologic Pharmaceutical Research
- Biomedical Product Development and Manufacturing
- Regulatory Affairs
- Clinical and Nonclinical Research
- Biostatistics and Data Management
- Business Development
- Marketing and Commercialization for biosimilars
- Medical Communications/MSLs
- Patient Advocacy/Patient Support Programs
- Health and medical care across therapeutic disciplines
- Health Education
- Provision of prescription products
- Development and management of prescription product formularies
- Development and management of prescription benefit plans

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Schedule At-A-Glance

All times listed are Eastern Time

DAY ONE | MONDAY, OCTOBER 5

12:00–3:30PM	**Short Course:** Current Biosimilar Policies: An Interactive Boot Camp for US Market Success **Short Courses require an additional registration fee. You do not need to be registered for the full conference to attend this course.*

DAY TWO | TUESDAY, OCTOBER 6

10:00-10:10AM	**Welcome and Opening Remarks**
10:10-10:40AM	**Session 1:** Keynote Address
10:40-10:55AM	Break
10:55AM-12:10PM	**Session 2:** Biosimilars During a Pandemic
12:10-12:40PM	Break
12:40-1:55PM	**Session 3:** Streamlining Biosimilar Clinical Development
1:55-2:20PM	Break
2:20-3:35PM	**Session 4:** A Success of Our Own: How Do We Define the U.S.' Biosimilar Success Story?
3:35-4:05PM	Break
4:05-5:20PM	**Session 5:** What Will Biosimilars Look Like in Five Years?
5:30-6:15PM	**Reception Round Tables – Round 1**

DAY THREE | WEDNESDAY, OCTOBER 7

10:00-11:15AM	**Session 6:** Growing Clinical Use and Experience: What Can be Learned from Key International Initiatives?
11:25AM-12:40PM	**Session 7:** Prescriber and Patient Confidence with Biosimilar Use
12:40-1:10PM	Break
1:10-2:40PM	**Session 8:** Stakeholder Voice: Biosimilar Decision Making
2:40-3:00PM	Break
3:00-4:15PM	**Session 9:** Regulatory Landscape – Ask the Regulators
4:15-4:30PM	Closing Remarks
4:40-5:25PM	**Reception Round Tables – Round 2**
5:25PM	Conference Adjourns

Learning Objectives

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

- Discuss current developments in regulatory and scientific issues and their impact on development, manufacturing, access, and uptake of biosimilars and interchangeable products
- Discuss imperative and progress in streamlining biosimilar development
- Describe the US reimbursement and pricing landscape and its impact on market uptake and sustainability of biosimilars and interchangeable biological products
- Examine current prescriber and patient confidence and patterns of biosimilar use, and education efforts that have been successful in increasing literacy on these products
- Describe relevant international developments influencing patterns of biosimilar uptake globally
- Discuss new product targets for biosimilar development
- Explore the nature of the US biosimilars landscape in the next 5 years, and how equilibrium will be defined
- Describe the status of biosimilar product development, availability, and uptake in the US

Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 14.25 contact hours or 1.425 continuing education units (CEU's). Type of Activity: Knowledge

Continuing Education Credit Allocation

ACPE credit is available if you attend the Biosimilars Conference live October 6-7, 2020. Credit will not be awarded for watching the sessions On Demand post-conference.

October 5 Short Course 1: Current Biosimilar Policies: An Interactive Boot Camp for US Market Success: 3.25 contact hours or .325 CEUs Type of Activity: Knowledge, 0286-0000-20-130-L04-P

October 6 Day 1: Biosimilars Conference: 5.5 contact hours or .55 CEUs Type of Activity: Knowledge, 0286-0000-20-131-L04-P

October 7 Day 2: Biosimilars Conference: 5.5 contact hours or .55 CEUs Type of Activity: Knowledge, 0286-0000-20-132-L04-P

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, NOVEMBER 20, 2020

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 20, 2020, 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**.

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual conference, you must virtually attend the entire short course one or both days of the conference, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation and request CE credit online through My Transcript (see instructions below). 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 Friday, October 23, 2020. To view DIA's Grievance Policy, visit **DIAglobal.org/CE**.

If you are claiming ACPE credit for this event you must:

1. Complete a Verification of Attendance Form

2. Send back to **CE@DIAglobal.org** by October 16, 2020

3. Access your DIA account and select My Transcript to claim your ACPE credit, available on Friday, October 23, 2020

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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.*

All times listed are Eastern Time

DAY ONE | MONDAY, OCTOBER 5

12:00-3:30PM

Short Course: Current Biosimilar Policies: An Interactive Boot Camp for US Market Success

**Short Courses require an additional registration fee. You do not need to be registered for the full conference to attend this course.*

Session Chair
Mary Jo Carden, RPh, JD, Head of Policy, Sandoz, Inc.

Federal and state biosimilar adoption policies impact stakeholders across the spectrum from research to commercialization to patients and their health care providers. An understanding of the complex policy environment, and how they interact, is necessary to ensure success of biosimilars' as part of a sustainable multisource market in the US.

This boot camp will provide a high-level overview of current and proposed biosimilar policies in the United States. This boot camp will also provide an opportunity for participants to engage with panelists and each other to have questions answered and provide feedback on the needs for further insight and education. It will be explicitly cross-disciplinary and integrate answers to questions from clinical, regulatory, legislative, and international perspectives. You should expect debate and discussion as we consider recent federal and state initiatives on misinformation in biosimilar communications, the potential for insulin biosimilars, the coming wave of pharmacy benefit biosimilars, and the consequences for critical classes of products that are front and central to the current discussion on access for affordable medications.

12:00-12:45PM

Key Policy Updates Impacting Biosimilars

John O'Brien, Former Senior Advisor to the Secretary, US Department of Health and Human Services

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12:45-1:45PM

The New Normal and Biosimilars' Policy: What is the Impact to

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

Panelists
William Kramer, Executive Director, Health Care Policy, Pacific Business Group on Health

Pam Traxel, Senior Vice President, American Cancer Society Cancer Action Network

Lisa LeGette, Director of Government Affairs, Express-Scripts

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1:45-2:00PM

Break

2:00-3:00PM

Other Key Policy Issues

What's Needed to Ensure Success in Insulin Biosimilars?
Gillian Woollett, MA, Senior Vice President, Avelere Health

DAY TWO | TUESDAY, OCTOBER 6

10:00-10:10AM

Welcome and Opening Remarks

Robin Weinick, PhD, Senior Vice President and Managing Director, Americas and Global Program Officer, DIA

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

10:10-10:40AM

Session 1: Keynote Address

Peter Stein, MD, Director, Office of New Drugs, CDER, FDA

10:40-10:55AM

Break

10:55AM-12:10PM **Session 2:** Biosimilars During a Pandemic

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

As the world continues to navigate the COVID-19 pandemic what will the impact be to biosimilars? This session will discuss the ways biosimilar stakeholders are adjusting to the COVID-19 pandemic to navigate and execute in the new normal. Panelists will present the regulatory perspectives, customer view, and potential impacts to access and uptake.

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

- Recognize the short and long-term regulatory impacts of COVID-19 on biosimilar development and approvals
- Discuss the customer perspective of pandemic implications to biosimilar use
- Debate the short and long-term impacts of COVID-19 on access and uptake

Speakers
Peter Stein, MD, Director, Office of New Drugs, CDER, FDA

Sean McGowan, MBA, Senior Director, Biosimilars, AmerisourceBergen

Juliana Reed, Vice President, Corporate Affairs Lead – I&I and Biosimilars, Pfizer, Inc.

12:10-12:40PM **Break**

12:40-1:55PM **Session 3:** Streamlining Biosimilar Clinical Development

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

This session addresses ways in which the clinical development of biosimilars can be streamlined exploring issues at to what extent current study designs contribute data that add value to the biosimilarity assessment. In particular is therapeutic equivalence adding value and to what extent CMC, PK and immunogenicity data can address therapeutic effect without the need for direct therapeutic equivalence trials.

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

- Appraise the clinical data requirements to support determination of biosimilarity
- Justify situations where therapeutic equivalence data may not be required
- Design and justify an optimal clinical development program to support determination of biosimliarity

The Path Towards a Tailored Clinical Biosimilar Development
Martin Schiestl, PhD, Global Head Regulatory Policy and Intelligence, Sandoz GmbH, Austria

Regulatory Expectations for Supporting Efficacy, Safety, and Immunogenicity of Biosimilars in the Clinic
Andrea Laslop, MD, Head of Scientific Office, Austrian Medicines and Medical Devices Agency (AGES), Austria

Applying Experiences with Udencya to Streamlining Future Biosimilar Clinical Development
Barbara Finck, MD, RN, Chief Medical Officer, Coherus

1:55-2:20PM ET **Break**

2:20-3:35PM **Session 4:** A Success of Our Own: How Do We Define the U.S.' Biosimilar Success Story?

Session Co-Chairs
Leah Christl, PhD, Executive Director, Global Regulatory and R&D Policy, Amgen

Tiffany Fletcher, MA, Head of Global Biosimilar Policy and Access, Mylan

The Biologics Price Competition and Innovation Act was signed into law on March 23, 2010 creating an abbreviated approval pathway for biosimilar medicines. The first biosimilar was approved in the US in 2015.

As of today, FDA has approved 26 biosimilars and 17 have launched into the US market. As we analyze how the market has developed over the last 10 years, it is important to understand the progression of the market and answer an important question: What does success look like for the biosimilars in the U.S.? We will discuss the following:

- What are the metrics of success?
- Does the measure of success differ between product types, sites of care, disease states, & stakeholder groups?
- What is the vision of success that is or is not being met today?
- What is the U.S.' definition of biosimilar market "equilibrium"? (i.e., the balance between success and failure)
- In what ways are biosimilars addressing health disparities and access to care, and should this factor into the evaluation of success?
- How are biosimilars laying the groundwork for the appropriate amount of reinvestment in innovation?

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

- Evaluate the current development of the biosimilar market in the US
- Define the appropriate metrics to measure the success/failure of the US biosimilars market
- Analyze the impact of biosimilar competition in the US on market access and healthcare economics
- Compare/contrast the differing levels of success for the different products and sites of care
- Create a framework for assessing the future success of biosimilars in the US

Speakers

Ronny Gal, PhD, Senior Research Analyst, AllianceBernstein, LP

Chad Pettit, MBA, Executive Director, Marketing, Global Biosimilars Commercial Lead

Chrys Kokino, Head of Global Biologics and Insulins Commercial, Mylan

Kevin Knopf, MD, MHP, Division Chief Hematology/Oncology, Highland Hospital

Mohannad Kusti, MD, MPH, Regional Medical Director, Pivot Onsite Innovations

3:35-4:05PM **Break**

4:05-5:20PM **Session 5:** What Will Biosimilars Look Like in Five Years?

Session Chair

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

As biosimilar stakeholders evaluate the appropriate metrics of success for the current wave of products, it's important to consider how the industry's market dynamics may shift in the future. Looking ahead, there are several critical questions to consider, including:

- Which company models will be best suited for the future market, and why?
- What types of products will be chosen as future biosimilar development candidates?
- What development challenges will these products pose for companies?
- How will companies strive to differentiate their biosimilar products or development process?

This session will visualize what the future biosimilar industry may look like. In doing so, stakeholders will better understand the challenges that must be addressed today to arrive at a sustainable and productive future.

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

- Evaluate the next wave of the biosimilar pipeline and the opportunities/challenges it will pose for the industry
- Understand best business practices (i.e., product selection and differentiation strategies) that can be employed to remain in the biosimilar market long-term
- Evaluate novel manufacturing and outsourcing strategies to reduce COGs

Speakers
Murray Aitken, MBA, Senior Vice President, IQVIA and Executive Director, IQVIA Institute for Human Data Science

Michiel Ultee, PhD, MS, Principal, Ulteemit BioConsulting

Alexandra Moulson, MBA, MS, VP Strategy, Programs and Portfolio, Polpharma Biologics Poland

George I'ons, Head of Product Strategy and Insights, Pharmaceutical Services, Owen Mumford, Ltd, United Kingdom

5:30-6:15PM

Reception Round Tables – Round 1

Join fellow attendees for a chance to network and have a discussion surrounding topics of common interest. The moderator will kick off the conversation then we welcome the attendees to engage in a dialogue exchange and share knowledge with one another. There are four round tables for you to choose from each day. Sign up here: **https://www.supersaas.com/schedule/DIA/Biosimilars_Round_Tables**.

1. Market challenges for Biosimilars

Moderated by
Tiffany Fletcher, MA, Head of Global Biosimilar Policy and Access, Mylan

2. How Can We Communicate New Data Methods to Build Public and Healthcare Provider Confidence in Biosimilars?

Moderated by
Laura Wingate, Senior Vice President, Education, Support, and Advocacy, Crohn's and Colitis Foundation

3. To Help Optimize Biosimilar Competitiveness in the Market, What Can Developers of Biosimilars do to Streamline Development and Manufacturing to Lower Development Costs and the Cost of Goods?

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

4. Interchangeability: Value and Outstanding Unknowns

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

DAY THREE | WEDNESDAY, OCTOBER 7

10:00-11:15AM

Session 6: Growing Clinical Use and Experience: What Can be Learned From Key International Initiatives?

Session Co-Chairs
Julie Marechal-Jamil, MSc, Director, Biosimilars Policy and Science, Medicines for Europe, Belgium

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

Biosimilar medicines have been available globally for nearly 14 years. As they entered various regions and countries, policy makers, healthcare community stakeholders have devised different ways to introduce these medicines in the medical practice, grow the use of biosimilar medicines, and enhance care for patients. The experience and confidence in biosimilar medicines keeps expanding, yet at different pace and rate depending on geographies. In this session, 3 initiatives (from outside the U.S.) supporting biosimilar uptake and clinical use will be presented followed by a discussion on the learnings, including key principles and key enablers.

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

- Share concrete examples of conducive biosimilar policy measures
- Inspire creative approaches to deliver broad healthcare benefits from biosimilar use
- Emulate experience sharing as driver towards policy implementation

The pan-Canadian Oncology Biosimilar Initiative: Building Confidence Through Engagement and Education
Scott Gavura, MBA, RPh, Director of Provincial Drug Reimbursement Programs, Cancer Care Ontario, Canada

UK Lessons Learned from Multi-winner Tenders
Blake Dark, Commercial Medicines Director, NHS, England

France National Health Strategy and Biosimilar Pilot Sharing Scheme
Etienne Nedellec, French National Health Care Directorate, Ministry of Social Affairs, and Health, France

11:25AM-12:40PM

Session 7: Prescriber and Patient Confidence with Biosimilar Use

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

In this session we will review how prescribers and pharmacists are integrating biosimilars into their practices and how biosimilars are being received by patients. We will also review awareness and education efforts that have been implemented, focusing on what has worked and what has not worked as expected.

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

- Identify programs implemented to educate healthcare professionals and their patients so that biosimilars are accepted and used
- Understand why some educational programs have been more successful than others
- Gain an appreciation for aspects of biosimilarity that are now well accepted as well as areas of residual concern

Best Practices for Biosimilar Integration into Routine Clinical Care
Shubha Bhat, PharmD, MS, BCACP, Ambulatory Care Clinical Pharmacy Specialist – Gastroenterology, Boston Medical Center, Center for Digestive Disorders and Crohn's and Colitis Program

Developing a Biosimilar Implementation Plan: Creating a toolkit for success
Ryan Haumschild, PharmD, MS, MBA, Director of Pharmaceutical Sciences, Emory Healthcare

Speaker
Ali McBride, MS, PharmD, MS. BCOP, FASHP, FAzPA, Clinical Coordinator, University of Arizona Cancer Center and President of the Association of Community Cancer Centers

12:40-1:10PM

Break

1:10-2:40PM

Session 8: Stakeholder Voice: Biosimilar Decision Making

Session Chair
Laura Wingate, Senior Vice President, Education, Support, and Advocacy, Crohn's and Colitis Foundation

Using moderated case presentation learners will explore the decision-making process between a physician and their patient as they determine the best course of biologic/biosimilar treatment. The session will feature three treatment scenarios and discussion:

- Shared decision-making process for a biologic naïve patient
- Discussion between a patient and provider when deciding to switch from an innovator to a biosimilar
- Discussion of the nocebo effect and its impact on decision making and switching behaviors
- Dialogue around multi-switch data and real world experience in practice

The session will explore the education provided, questions asked by the patient, whether insurance or patient assistance programs factored in the decision and what additional information might have improved or better informed the decision process.

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

- Understand the factors that influence patient and provider decision as it relates to biosimilars
- Articulate the barriers that are impacting the decision process between patient and provider
- Comprehend the need for to offer biosimilar educational resource for both patients and providers

Speakers
Frank Farraye, MD, MS, Director, Inflammatory Bowel Disease Center, Professor of Medicine, Mayo Clinic Jacksonville

Shubha Bhat, PharmD, MS, BCACP, Ambulatory Care Clinical Pharmacy Specialist – Gastroenterology, Boston Medical Center, Center for Digestive Disorders & Crohn's and Colitis Program

Shaila Abbott, Patient Advocate

Alex Hochstrasser, Patient Advocate

2:40-3:00PM — **Break**

3:00-4:15PM — **Session 9:** Regulatory Landscape – Ask the Regulators

Session Chair
Sarah Yim, MD, Director, Office of Therapeutic Biologics and Biosimilars, 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 question and answer session.

Speakers
Jian Wang, MD, PhD, Division Manager, Clinical Review Division-Hematology/Oncology, Health Canada, Canada

Andrea Laslop, MD, Head of Scientific Office, Austrian Medicines and Medical Devices Agency (AGES), Austria

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

Stacey Ricci, DrSc, Acting Director, Scientific Review Staff, Office of Therapeutic Biologics and Biosimilars, CDER, FDA

4:15-4:30PM — **Closing Remarks**

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

4:40-5:25PM — **Reception Round Tables – Round 2**

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4. Interchangeability: Value and Outstanding Unknowns

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

5:25PM — **Conference Adjourns**