DIA

Biosimilars Conference

September 20-21 | Arlington, VA

Who Should Attend

Professionals involved in:

- Biosimilar/Biologic/Biomedical R&D
- Chemistry, Manufacturing and Controls
- Regulatory Affairs
- (Non)Clinical Research
- Business & Data Development
- Marketing/Medical Communications
- Patient Advocacy/Patient Support Programs
- Health Education & Provision
- Quality Analysis & Management

PROGRAM CO-CHAIRS

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

Tiffany Fletcher, MA
Head of Global Access Policy
Viatris

PROGRAM COMMITTEE

Denis Arsenault, MA
Manager, Policy Development
Health Canada

Mauricio Ede, MD, PhD
Chief Medical and Scientific Officer
Sandoz Canada Inc.

Stanton Mehr
Director of Content
Biosimilars Review and Report

Juliana Reed, MS
Executive Director
The Biosimilars Forum

Stacey Ricci, DrSc
Director, Scientific Review Staff, OTBB, OND, CDER
FDA

PROGRAM ADVISOR

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

Overview

At the DIA Biosimilars Conference 2022, manufacturers, regulators, payers, prescribers, and patients will convene to discuss factors that influence biosimilar access and development and share perspectives on what success and progress looks like to provide cost-saving options for providers and patients in need.

Attendees will apply practical solutions and forward-thinking learnings from around the world, to help build strategies for growth of the biosimilar's market.

Event Goals and Offerings

- Increase understanding of access to safe, effective, and cost-effective biological treatment options
- Collaborate with professionals in science, regulation, R&D, and more, to address barriers in biosimilar development
- Eliminate misinformation that delays policies to increase patient access
- Streamline global and regional goals with all stakeholder perspectives

Why You Can't Miss It

- **Increase potential** of and access to the biosimilar's market
- **Meet and network** with professionals involved in ongoing regulatory, manufacturing, pricing, and educational challenges
- **Discuss influencing** factors of biosimilar development by including stakeholders embedded in this space
- **Apply the newest thinking** and global learnings for strategic growth in biosimilar product development
- **Incorporate viewpoints** of manufacturers, regulators, payers, prescribers, and patients altogether

Thank you to our 2022 media partner:

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GaBi GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

Schedule At-A-Glance

All times listed are in EST

DAY ONE | TUESDAY, SEPTEMBER 20

7:00AM-5:35PM	Conference Registration	Gallery Ballroom Foyer
7:00-8:00AM	Networking Breakfast	Gallery Ballroom III
8:00-8:10AM	Opening Remarks	Gallery Ballroom I&II
8:10-8:45AM	**Session 1:** Keynote Address by **Jacqueline Corrigan-Curray, JD, MD**, Principal Deputy Center Director, Center for Drug Evaluation and Research (CDER), FDA	Gallery Ballroom I&II
8:50-10:05AM	**Session 2a:** So You Want to Develop a Biosimilar - Defining the Pipeline	Gallery Ballroom I&II
10:05-10:35AM	Refreshment and Networking Break	Gallery Ballroom III
10:35-11:55AM	**Session 2b:** Product Development Considerations: Regulatory	Gallery Ballroom I&II
11:55AM-1:00PM	Networking Luncheon	Gallery Ballroom III
1:00-2:15PM	**Session 3a:** Roadblocks and Disparities in Access of Biologics	Gallery Ballroom I&II
2:15-3:00PM	Refreshment and Networking Break	Gallery Ballroom III
2:30-3:00PM	**SPONSORED SESSION:** Case Study Spotlight hosted by Similis Bio: A Distributed Innovator Data Collection Approach to Expedite Biosimilar Development *Please note that this is an exhibitor sponsored event and is not eligible for CE credit. Separate RSVP is requested – click here or sign up on the Mobile App.*	Masters Room
3:00-4:15PM	**Session 3b:** Policy Solutions to Improve Access to Biosimilars	Gallery Ballroom I&II
4:20-5:35PM	**Session 4:** Payers as the Lever to Biosimilars' Success	Gallery Ballroom I&II
5:35-6:35PM	Networking Reception	Gallery Ballroom III

DAY TWO | WEDNESDAY, SEPTEMBER 21

7:00AM-3:00PM	Conference Registration	
7:00-8:00AM	Networking Breakfast	Gallery Ballroom III
8:00-9:15AM	**Opening Remarks and Session 5:** Biosimilar Regulatory Developments: Stay in the Loop!	Gallery Ballroom I&II
9:20-10:35AM	**Session 6:** Global Perspectives: Impact of Biosimilars Around the World – What Have we Learned so Far?	Gallery Ballroom I&II
10:35-11:05AM	Refreshment and Networking Break	Gallery Ballroom III
11:05AM-12:20PM	**Session 7:** Flipping the Switch: Building Confidence About Biosimilar Transitions and Substitutions	Gallery Ballroom I&II
12:20-1:30PM	Networking Luncheon	Gallery Ballroom III
1:30-2:45PM	**Session 8:** Now What? What Type of Evidence Will be Needed for Registering Biosimilars in the Future?	Gallery Ballroom I&II
2:45-3:00PM	Closing Remarks	
3:00PM	Conference Adjourns	

Learning Objectives

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

- Describe key biosimilar-related regulatory developments and initiatives in participating jurisdictions
- Describe the future market for biosimilar development
- Prepare and adjust product development plans in light of the evolving regulatory landscape
- Assess the impact of biosimilars in conquering disparities in access to medicines
- Identify the differences in patient access to biologics/biosimilars by region
- Describe the policy solutions needed to improve access to biosimilars
- Evaluate and understand the power of payers' formulary positioning in encouraging biosimilar use
- Devise plans for implementation while leveraging clinical experience obtained in markets similar to the US
- Identify the tendencies and different perspectives on the evolution of data requirements for licensing of biosimilars from regulators, HCPs, industry, and patient association representatives.

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 12 contact hours or 1.2 continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, NOVEMBER 4, 2022

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 4, 2022, 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

September 20 Day 1: Biosimilars Conference: 6.75 contact hours or .675 CEUs Type of Activity: Knowledge, 0286-0000-22-079-L04-P

September 21 Day 2: Biosimilars Conference: 5.25 contact hours or .525 CEUs Type of Activity: Knowledge, 0286-0000-22-080-L04-P

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the conference, you must attend one or both days of the conference (in their entirety), sign-in each day at the Registration Desk, 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 Tuesday, October 4, 2022.

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

1. Attend each day of the conference in its entirety
2. Sign-in at the Registration Desk both days of the conference upon arrival
3. Access your DIA account and select My Transcript to claim your ACPE credit, available on Tuesday, October 4, 2022

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DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

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https://crowd.cc/s/4rsdu

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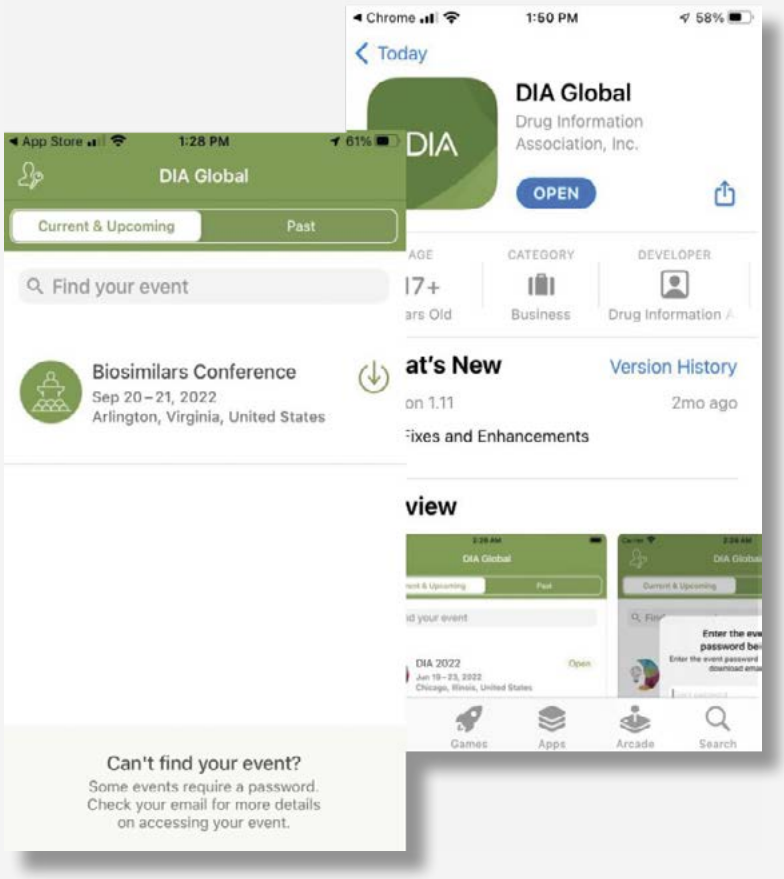

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Event Password: biosimilars22

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Thanks to our Exhibitor

similisbio

1280 N Mathilda AveSunnyvale, CA 94089
Contact: Dayn Sommer
Phone: 602-486-5115
Email: partner@similis.bio
Website: www.similis.bio

Similis Bio is leveraging a unique biosimilar development model to provide a combination of customized and off-the-shelf solutions to meet the needs of companies interested in developing biosimilars. Leveraging our strategic partnership with leading cell line developers and contract manufacturers, we provide tailored solutions to meet your needs: immediate initiation of cell line development, accelerated analytical and process development, and program selection flexibility through opt-in provisions.