SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Wednesday, 21 August 2019

Monthly Program

Evidence in the "Real World": reboot or old school?

Program Speakers:

Kristi Miller, PhD, Head of Regulatory Affairs, RPI, A Division of Premier Research
Nach Davé, Vice President, Development Strategy, Premier Research

Event Agenda:

Date: **Wednesday, 21 August 2019**

Time*:
5:15 – 6:00 PM Registration, Snacks, & Speed Networking
5:30 – 5:55 PM Speed Networking
6:00 – 6:05 PM Welcome and Announcements
6:05 – 7:05 PM Program Presentation
7:05 – 7:30 PM Q & A

*Times are approximate.

Program Topic:

Real-world evidence (RWE) is clinical evidence regarding the use and potential benefits and risk of a drug or medical device generated from real world data (RWD). Examples of RWD include electronic health records, administrative claims data, patient-reported data, and genomics/biomarker data when collected in the routine provision of care. The U.S. Food and Drug Administration (FDA) has acknowledged that RWE could be used to demonstrate compliance with regulatory requirements. To fulfill the mandate to further advance RWE, the U.S. FDA recently released the "Framework for FDA's Real-World Evidence Program" in December 2018.

This presentation will explore recent developments in RWE, including an overview of new guidance documents from FDA on drug[1] and device[2] products. Using case studies, we will look at how the Agency has used RWE. Through these examples, regulatory professionals will learn how to guide their teams to successfully implement RWD for FDA submissions.

[1] Draft FDA Guidance: Submitting Documents Utilizing Real-World Data and Real-World Evidence to FDA for Drugs and Biologics (May 2019).
[2] Final FDA Guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (August 2017).

Speaker Biography:

Kristi Miller has over 15 years of experience in the pharmaceutical industry in delivering both regional and international regulatory strategy for pharmaceutical and biotech drug development teams. Her experience encompasses providing regulatory leadership and execution of strategy for products across development (pre-IND through post marketing) in multiple therapeutic areas of immunology/inflammation, ophthalmology, oncology and other rare diseases. Her accomplishments include leading teams to successful global health authority interactions, INDs, orphan drug applications, fast track applications, pediatric strategies, and marketing applications.

Currently, Kristi leads a diverse, cross-functional team of regulatory affairs professionals at RPI in developing and implementing global regulatory strategy in conjunction with clients across all stages of development and diverse therapeutic areas, including neurology, immunology, and oncology. Kristi holds a B.S. degree in Genetic Engineering from Cedar Crest College and a Ph.D. in Tumor Cell Biology from Northwestern University.

Nach Davé oversees Premier Research's regulatory affairs service offerings across its broad range of therapeutic focus areas. Nach has over 20 years of experience in the pharmaceutical and contract research industries. He also led clinical and regulatory affairs at Maxx Orthopedics, a developer of orthopedic medical devices, and has held roles in clinical operations, business development, strategic consulting, and medical affairs at companies such as Merck, Bristol-Myers Squibb, Aventis Pharmaceuticals, and Mitsubishi Pharma America.

Nach holds a master's degree in drug regulatory affairs from Long Island University and a bachelor's degree in pharmacy from the Philadelphia College of Pharmacy and Sciences. He is a registered pharmacist in the state of New Jersey.

Location: Hologic Inc.
10210 Genetic Center Drive
San Diego, CA 92121

To register for the meeting, click here to access the SDRAN registration system (123Signup) for this event.

* **Please make your reservation early. The pre-registration due date is *Monday, 19 August 2019*. Advanced registration is appreciated to assist in event planning.**

** ***Space is limited for our monthly programs. Registration is capped at 100 participants. Register today to ensure your seat. Once our limit is reached, registration will close. Events with closed registration will not allow walk-ins.***

Online registration (through Monday 19 August 2019):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

For Questions Email: programs@SDRAN.org

Directions to Hologic:

From the North I-5 and I-805

I-5 South toward San Diego
Exit toward I-805 S
Exit toward Mira Mesa Blvd
Turn left onto Sequence Dr
Turn right to the facility

From the South I-805

I-805 North toward Sorrento Valley
Exit toward Mira Mesa Blvd
Turn left onto Sequence Dr
Turn right to the facility