



## **PROGRAM ANNOUNCEMENT**

**Wednesday, March 15, 2017**

### **Monthly Program:**

### **Trend of Big Data in Healthcare for Therapeutics and Regulations**

Program Speaker:

Penny Randall, MD

VP and Global Therapeutic Head of CNS

QuintilesIMS

### **Event Agenda:**

Date: Wednesday, March 15, 2017

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

**NEW LOCATION:** BD (former CareFusion) (directions on last page of this flyer)  
6055 Lusk Blvd  
San Diego, CA 92121

Program Speaker: Penny Randall, MD

### **Program Topic:**

For years the biopharmaceutical industry has struggled with efficiency and productivity challenges in clinical development. Real world evidence and big data have a significant role to play in improving trial design, site identification, and patient recruitment. Dr. Penny Randall will discuss an approach for harnessing global data and overcoming historic challenges in clinical research. In addition, regulatory applications and landscape for big data as it applies to the legal standard for drug reviews will also be presented.

### **Program Summary:**

Biopharmaceutical and Contract Research Organizations (CROs) bring a wide array of medical products to market in ever more sophisticated and innovative ways. The increase in specificity and complexity of modern clinical development continuously challenges our ability to enable it. This is exemplified by the fact that 60% of clinical trials have protocol amendments, nearly 80% of trials are delayed by enrollment, patient dropout

remains very high, and almost half of trial sites are not able to reach enrollment targets.

New and innovative clinical development offerings are now emerging at a rapid rate that leverage Real World Data on a global scale to better understand the risks and influence clinical program decisions, predict success, and identify avenues to control time and cost. Enabling and embracing the complex world of healthcare data creates opportunities to bring new insights to improve a traditional clinical development and operations process that still heavily relies on Key Opinion Leaders (KOLs), historical experience, and assumptions. Applications of real world data can be used to validate or refute these assumptions with real evidence about patient journeys, standards of care, disease progression, and drug access that can bolster understanding and reduce risk that protocols emerge with inherent flaws.

In this presentation, we will look at areas where the applications of real world data coupled with experiential data can change the nature of clinical development. We will also discuss the regulatory applications and landscape for big data and real world data as it applies to the legal standard for drug reviews and the requirements for adequate and well controlled studies. We look to big data frameworks to build the concept of the learning healthcare system and how this information can be used to streamline clinical trials, satisfy post marketing commitments and requirements, and support applications of drugs into new indications.

### **Speaker Biography:**

Dr. Randall is Vice President and Global Therapeutic Head of the Central Nervous System (CNS) at QuintilesIMS. She oversees the clinical development programs for CNS biopharmaceutical customers, providing therapeutic and scientific leadership across all phases of clinical development.

Since joining QuintilesIMS in 2003, Dr. Randall has worked on numerous development programs, which resulted in several successful approvals for CNS drugs. She is also interested in leveraging disruptive technologies to modernize and accelerate clinical drug development, bringing new important therapies to the market more rapidly.

Board certified in psychiatry, Dr. Randall completed her psychiatry residency at Georgetown University School of Medicine, and a research fellowship in psychopharmacology at Yale University School of Medicine. Dr. Randall received her medical degree from the University of Louisville School of Medicine and a graduate business degree from the University of California at Irvine, concentrating in healthcare management.

**To register for the meeting, click on the link below to access the SDRAN registration system (123Signup) for this event:**

<https://www.123signup.com/register?id=nnksj>

**The above registration link can also be accessed on the SDRAN website Events page at:**

<http://www.sdran.org/#!/events-and-seminars>

**or via the SDRAN mobile site URL at:** <http://sdran1.wix.com/mobile>

**Please make your reservation early. The pre-registration due date is Monday March 13, 2017. Credit Cards are accepted on-line only. Cash and Check are accepted at the door.**

**On-line Pre-registration (through Monday March 13, 2017):**

\$15 SDRAN Member

\$30 Non-Member

**Late Online Registration (Tuesday March 14, 2017):**

\$25 SDRAN Member

\$40 Non-Member

**On-site Registration:**

\$25 SDRAN Member

\$40 Non-Member

**For Questions Email: [jodysuro@hotmail.com](mailto:jodysuro@hotmail.com)**

**Directions to BD (former CareFusion):**

**❖ NOTE — NEW LOCATION UNTIL FURTHER NOTICE**

**From the North 5:**

- I-5 South toward San Diego
- Keep left and continue on I-805 South
- Take exit 27 toward Mira Mesa Blvd
- Take Mira Mesa Blvd to Lusk Blvd
- Turn left on to Sorrento Valley Road
- Stay on the road until it turns into Mira Mesa Blvd
- Move to the left-hand lane
- At the light - On the left (notice Holiday Inn Express & Chili's)
- Turn left on to Lusk Blvd
- Turn at the first right hand
- Turn at the first left hand (opposite Chili's)
- BD, Bldg. "C" is straight ahead

**From the South 5**

- I-5 North
- From the right hand lane, take Exit 27A for Mira Mesa Blvd
- From the right hand lanes, turn right on to Mira Mesa Blvd
- Move to the left-hand lane
- At the light - On the left you will notice:
  - Holiday Inn Express / Chili's
- Turn left on to Lusk Blvd
- Turn at the first right hand
- Turn at the first left hand (opposite Chili's)
- BD, Bldg. "C" is straight ahead