PROGRAM ANNOUNCEMENT

Wednesday, 16 September 2020

Monthly Program

Understanding SEND Requirements for Better Preparation and Timely Submission

Program Speaker:

Kamran Ghoreishi

Toxicologist, Head of *in vivo* group
Bristol Myers Squibb, San Diego

Event Agenda:

DATE: **Wednesday**, **16 September 2020**

TIME:
6:00 – 6:05 PM Welcome and Announcements (ONLINE)
6:05 – 7:05 PM Program Presentation (ONLINE)
7:05 – 7:30 PM Q & A (ONLINE)

LOCATION: Virtual platform-this is an ONLINE event

Click here to register for this event.

Program Topic:

The Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data (**SEND**) provides the structure and implementation rules for the submission of nonclinical study datasets to the U.S. Food and Drug Administration (FDA). As the result of collaboration between stakeholders, including FDA and Sponsors, SEND continues to evolve,

and implementation guides continue to add more domains to the standard. The implementation of SEND has a major impact on the industry, as these standards are required for all sponsors wishing to submit nonclinical data to the FDA. Failure to comply with SEND standards may result in rejection of the submission. Implementing SEND requires support from professionals in several disciplines including Toxicology, IT, Regulatory Affairs, and project team scientists.

Despite being a requirement for submission of IND and NDA, many Sponsors have limited knowledge and resources to prepare, complete, or verify the SEND datasets. This presentation is designed for a broad audience and covers: SEND history and timeline, basic understanding of SEND, what studies require SEND, SEND domains, current state of SEND implementation guide, most frequent issues with SEND data preparation, and the upcoming additions.

Speaker Biography:

Kamran Ghoreishi is a toxicologist with over 20 years of clinical and nonclinical research experience. His doctoral work at Medical College of Virginia campus of Virginal Commonwealth University was focused on the mechanism of hypocalcemia associated with parathyroid hormone deficiency. Prior to that, he received his master's degree in Toxicology from San Diego State University. He also received his master's degree in Regulatory Affairs from Center for Regulatory Sciences of SDSU. He is also a California licensed clinical toxicologist.

Kamran is currently a Sr. Scientist and head of the *in vivo* group in Discovery Toxicology at Bristol Myers Squibb (formerly Celgene Corporation), San Diego, CA. He established the SEND team within the Discovery Toxicology department and is a subject matter expert in SEND dataset preparation. During his tenure at Bristol Myers Squibb, he established the processes for electronic data capturing system, SEND dataset generation, data visualization, SEND dataset validation. Kamran is currently a volunteer and contributor to CDISC SEND sub-team that is working on a future SEND implementation guide to include new domains and nonclinical data in the SEND dataset.

Prior to that, Kamran was a scientist at Amylin pharmaceuticals and clinical toxicologist at Poisonlab.

Registration Information:

Online registration ends Tuesday, 15 September 2020.

$10.00 SDRAN Member $10.00 Non-Member

For Questions Email: Programs.committee@sdran.org