A REGULATORY SUBMISSION CROSS-FUNCTIONAL WALK-THROUGH

WELCOME!

PhUSE Single Day Event

September 26, 2019

A Regulatory Submission Cross-functional Walk-through

Morning Agenda

Time	Presentation	Speaker(s)
08:30-09:15	Registration & Breakfast	
09:15-09:30	Welcome & Thank you to our SDE Chairs: **Changhong Shi (Merck) & Hima Bhatia (ICON)**	Amy Gillespie, *Merck*
09:30–10:00	Analysis Package e-Submission – Planning and Execution	Saigovind Chenna, *Merck*
10:00–10:30	Metadata-driven Automation for Standard Safety Analysis	Beilei Xu, *Sanofi*
10:30-11:00	Coffee Break	
11:00–11:30	Technical Rejection Criteria for Study Data	Heather Crandall, *FDA* Via video conference
11:30–12:00	Industry Experiences Submitting Standardized Study Data to Regulatory Authorities	Janet Low and Kiran Kundarapu, *Merck*
12:00–12:10	Poster Introduction	Various
12:10-1:00	Lunch Break	

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Afternoon Agenda

Time	Presentation	Speaker(s)
1:00–1:15	PhUSE Updates	Chris Hurley, *PhUSE Americas Director*
1:15–1:45	RTOR Pilot	Ketan Durve, *Janssen Research & Development*
1:45–2:15	The Drive to Incorporate Standardized nonclinical Data into Regulatory Submissions Through Collaboration	Catherine Roy, Matthew Bendekovits and Janessa Pierce, *Merck*
2:15-2:45	Coffee Break	
2:45–3:15	Value-added Validation: Regulatory Review of Data Submission Packages	Mary Anne Potok, *MMS*
3:15–3:45	Why Should We Care About the eCTD (electronic Common Technical Document) in the Submission Process?	Kevin Lee, *Clindata Insight*
3:45–4:00	Q&A and Closing Remarks	All presenters

MERCK
INVENTING FOR LIFE

A Regulatory Submission Cross-functional Walk-through
Housekeeping Items

Breakfast & Lunch: Skylight Café - make sure you have a wrist band

AM & PM Coffee Breaks: Located outside of auditorium on first floor; no food or drinks permitted in the auditorium; please return on time due to our tight schedule

Restrooms: Located outside of auditorium on first floor

Evacuation: Persons visiting the facility should be accompanied at all times by their Merck host. If, for any reason, visitors find themselves alone, they are to immediately stop what they are doing, leave the area, and follow signs to the nearest building exit to evacuate the building. Once outside the building they should proceed to an assembly area for accountability

Security: When a condition or situation exists that may pose an imminent threat to any person(s) or property:

1. Call Security at 5-5555.

2. State your name, nature of the incident, and specific location, etc.

3. Arrange to meet the emergency responders to provide further information or follow the instructions of Security personnel

A Regulatory Submission Cross-functional Walk-through
Focus of Today's Event

The delivery of a successful NDA submission requires a great deal of cross-functional effort. It is critical that the deliverables from this process conform to industry standards and regulatory requirements. It is also critical that submission teams work efficiently and effectively to meet the timelines while delivering a quality submission. A walk-through of the submission from different perspectives including data management, biostatistics & programming, medical writing, pharmacovigilance and regulatory operations at this SDE will produce profound insights. Participants and attendees of this SDE will walk away with a better understanding of where they fit into the overall submission process. Hearing others' perspectives will give attendees ideas to improve this collaborative effort for the next submission, or at the very least, give them a better understanding of the process in general.

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A Regulatory Submission Cross-functional Walk-through
When Working Cross-functionally…

- Build upon each other's strengths
- Recognize that an individual skill reaches its potential when combined with other skills
- Value all team members; support people are crucial members of a team
  - None of us is as smart as all of us
- All good teams have the following:
  - Purpose
  - Skills
  - Synergy
  - Recognition

Blanchard, Ken, and Sheldon Bowles. *High Five! The Magic of Working Together*. HarperCollins Publishers, 2001.

A Regulatory Submission Cross-functional Walk-through
A Good Team?

- Does the following team possess the following?
  - Purpose
  - Skills
  - Synergy
  - Recognition

Teamwork Video

A Regulatory Submission Cross-functional Walk-through
Today, Tomorrow, and the Future

Today: Connect, share and advance ideas around regulatory submissions

Recognize that no one person in today's audience is more knowledgeable than all of us as a group

Tomorrow: Share your learnings with your cross functional colleagues

Educate those who may not understand and appreciate the attributes of a high quality regulatory submission as well as the operational processes required. Leverage team skills and different perspectives for success.

Future: Innovate and invent

Question: What is the next step to advance the efficiency and quality of our regulatory submissions? Are there opportunities to transform? Can we "move the needle" by leveraging technology?

Have a great conference today!