

2017 USER GROUP MEETING NEW ORLEANS

CONNECT, LEARN AND COLLABORATE

#endpointugm2017

Wednesday, September 13, 2017

8:15 AM – 9:00 AM: **CHECK-IN AND BREAKFAST**

9:00 AM – 9:30 AM: **WELCOME**

We'll take a look at how IRT® has been reinvented to accommodate more complex trials and the vision of how we see the clinical trial landscape evolving in the future.

9:30 AM – 10:30 AM: **CASE STUDY – OTSUKA: Integrating eSource and IRT®**

The workload on investigator sites has steadily increased over the years; each technology advancement requires the site to learn new tools, remember more usernames and passwords and work with yet another siloed dataset for reporting.

This session will discuss:

- A new approach by integrating eSource and IRT to simplify the site experience
- How this can improve the day-to-day operations and compliance of your clinical studies
- How this can accelerate the speed at which you can obtain insights into study data

10:30 AM – 10:45 AM: **NETWORKING BREAK: Innovation Café**

Topic: Drug Accountability>Returns

10:45 AM – 11:45 AM: **USER EXPERIENCE: Survey Results**

We will share results from our user experience surveys and provide a hands-on introduction to a new user experience.

11:45 AM – 1:00 PM: **LUNCH**

1:00 PM – 2:00 PM: **ENDPOINT ASKS**

A rapid-fire session where endpoint asks for feedback from our users on product, service, process and people. A great opportunity to help drive the future of endpoint!

2:00 PM – 2:45 PM: **CASE STUDY – PROTEOSTASIS: Managing Cohorts on the Fly**

A case study will be presented on how Cohort Management allows you to plan for the unknown when doses and CTM strengths are not known at the time of system development. The Cohort Management tool eliminates the need for system downtime to accommodate a dose selection or CTM strength update as it allows for advanced preparation of multiple possibilities.

2:45 PM – 3:00 PM: **NETWORKING BREAK: Innovation Café**

Topic: Dose and Cohort Manager for Dose Finding Studies

3:00 PM – 3:45 PM: **CASE STUDY – DRIVE: Managing Supply Beyond IRT**

We will present information on integrating supply forecasting and DRIVE through a case study example.

3:45 PM – 5:00 PM: **CONTEST**

An endpoint user group tradition where we break into teams and compete in an IRT-driven challenge. This is where it gets personal!

6:30 PM: **DEPART FOR EVENING EVENT**

Meet in Hilton Hotel lobby.

7:00 PM – 10:00 PM: **EVENING EVENT AT MURIEL'S JACKSON SQUARE**



endpoint's User Group Meeting 2017 will take place in the heart of the "Big Easy" — New Orleans. This informative and fun client-focused event combines opportunities to network and learn IRT® best practices from your peers while gaining insight into the evolving world of IRT and tapping the knowledge of endpoint's experts and executives.

Client Appreciation Event



An Unforgettable Evening

In the heart of Jackson Square, we'll gather together at Muriel's for an exclusive dining experience alongside spirits of the yesteryear. The finest Creole cuisine and culture of New Orleans will be shared for a night that is sure to be remembered for years to come.

Thursday, September 14, 2017

8:15 AM – 9:00 AM: **CHECK-IN AND BREAKFAST**

9:00 AM – 9:15 AM: **RECAP OF DAY ONE**

9:15 AM – 10:45 AM: **WHAT'S NEXT: Innovation from endpoint**

In this session, we will take a look at both the evolution of our product development over the years as well as the future innovation at endpoint.

10:45 AM – 11:00 AM: **NETWORKING BREAK: Innovation Café**

Topic: Non-IRT DRIVE (ISSR, early phase)

11:00 AM – 12:00 PM: **PANEL DISCUSSION: Recent ICH E6 changes – Guideline for Good Clinical Practice E6(R2)**

This session will discuss:

- Changing regulations from the sponsor perspective and how they apply to IRT
- Oversight of system validation
- UAT
- Human readable audit trails

12:00 PM – 1:15 PM: **LUNCH**

1:15 PM – 2:00 PM: **CASE STUDY – CELGENE: Risk-Based Approach to UAT**

Sponsors perform User Acceptance Testing in a variety of ways. This session will discuss:

- Celgene's current approach to UAT
- A new risk based approach being piloted, which uses a validated template and compares technology
- Expected time savings from risk based approach

2:00 PM: **WRAP UP**



"The endpoint user group meeting has been a great benefit to me as well as to my organization over the years. The meetings are always diverse in content, engaging and keep everyone at the forefront of what is going on in the IRT space." – Large Pharma

2017

endpoint