IRT

OCTOBER 19TH – 21ST 2021
Delivered as a 100% virtual conference

DISCOVER GROUND-BREAKING ADVANCEMENTS IN IRT, IXRS & RTSM TECHNOLOGY AND PROCESSES IN CLINICAL TRIALS

Drive Clinical Trial and Supply Chain Excellence Through Operational Best Practices and Interactive Response Technology Strategies

For more information visit:
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CONNECT WITH THE IRT CLINICAL COMMUNITY THIS OCTOBER AT A VIRTUAL EVENT LIKE NO OTHER!

A NETWORKING OPTION FOR EVERYONE:

ONLINE CHAT FUNCTIONALITY

Catch-up, connect, and discuss what you've learnt at the event via our chat functionality on the platform. A chance for more informal networking, you will be able to cultivate new lasting relationships with peers in the industry or discuss the conference with existing colleagues throughout the event.

1-1 VIDEO CALLS

Looking to grab a speaker for a more focused discussion on an issue directly relevant to your role? Hoping to connect with another attendee?

Our 1-1 video call option allows you to set up personal meetings in-platform, so you don't have to navigate multiple screens.

EXHIBITION BOOTHS

Seeking insights from key IRT vendors on their cutting-edge technology and solutions?

This is your opportunity to make the most of your time with them! Jump into an exhibitor booth to see what's on offer, and begin a discussion with a representative to obtain expert answers to your time-critical questions.

Q&A: PUT YOUR BURNING QUESTIONS TO THE EXPERTS

Have you got a question directly relevant to something a speaker mentioned on a live session?

Our Q&A function allows you to put your questions to speakers during live discussions, allowing you to obtain real-time answers from clinical pioneers who are leading the way for the future of IRT, data management and clinical trials.

INTERESTED IN SPONSORSHIP OPPORTUNITIES?

Please reach out to John Egan to discuss what options we have available for you:
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DAY 1 – TUESDAY 19TH OCTOBER

All times listed are EST time zone.

8:00 – 8:10 **Chair's Opening Remarks**

Simi Nischal, Head of Core Technologies- Clinical Supply Chain Product Development and Supply R&D Medicinal Science & Technology, GSK

8:15 – 9:10 **KEYNOTE PANEL: STATE OF THE INDUSTRY Part I: Emerging Trends Impacting IRT: COVID-19, Accelerated Innovation and Changing Trial Design**

- Lessons learned from COVID-19 and how the industry are converting them into "fit for innovation" changes
- Which new initiatives will be embedded into business as usual for clinical trials?
- Lessons learnt from rapid innovation and the impact on trials for the next 2 – 3 years
- What aspects of trials are shifting that IRT professionals can affect?
- Responding to change: increasing flexibility, evolving methodologies, and enhancing capabilities
- New innovation to improve the IRT site user experience
- Driving efficiency for operational data: manual data entry, APIs, and warehousing data lakes

Kyle Rader, Principal IXRS Analyst, Vertex Pharmaceuticals
Amy Sonderman, IRT Expert, Clinical Trial Supplies Unit (CTSU), Boehringer Ingelheim
Tom Nelson, Project Management Consultant, Cenduit, an IQVIA business
Helen Greta, Associate Director of Project Management, Cenduit, an IQVIA business

9:15 – 9:45 **CASE STUDY: Role of IRT in Decentralized Clinical Trials**

- Case study insight into the inner workings of the decentralized trial
- Details from sponsor perspective on practicalities, challenges of the trial
- Practical insight into how IRT helped the sponsor hold their study and provide flexibility

Mike Hutton, Head of Strategic Relationship Management EU, Almac
Jennifer Price, Executive Director, Data & Analytics, THREAD

9:50 – 10:20 **CASE STUDY: IRT and Direct to Patient Trials**

- Sharing experience of direct to patient clinical trials and challenges faced
- How was IRT leveraged for decentralized trials?
- Future plans and next steps for decentralized trials

Chris Driver, Associate Director, Solution Architecture, Cenduit IRT, and IQVIA business

10:25 – 10:55 **CASE STUDY Lessons Learned from a Mega COVID-19 Trial**

- Evaluate challenges of a fast-moving, high-enrolling mega COVID-19 trial
- Navigate "on-the-fly" changes of rapidly changing trial designs
- Understand the role of RTSM in enabling adaptive, flexible trials
- Hear lessons learned being utilized to inform future trial designs

Courtney Bortz, Client Services Lead, 4G Clinical
Thomas DeLiso, Associate Director, RTSM, Janssen

10:55 - Live Virtual Hub Networking and Solution Summit

12:15 – 12:45 **Tackling the drug ordering challenges of Investigator Sponsored Studies (ISS) using IRT**

- Problems with replacing manual drug ordering processes with system-based approach
- Addressing challenges of user access and ERP system integration for ISS
- Regulatory issues with trying to apply this system design outside of ISS
- Working solution developed to support ISS at Amgen without dependence on manual processes

Alastair Irving, IRT Manager – Clinical Systems and Analytical Reporting, Amgen
Derek Thornton, IRT Senior Manager – Clinical Systems and Analytical Reporting, Amgen

12:50 – 1:20 **CASE STUDY: Further Integration of IRT into your Enterprise Supply Chain Platform; the Benefits of Centralized Inventory, Kit Lists and a Free Picking Approach as we Enter a DCT Revolution**

Bart Nicholson, Director Product Management, RTSM, Signant Health
Roberto Rivera, Senior Director Logistic and Clinical Supply, AstraZeneca

DAY 1 – TUESDAY 19TH OCTOBER

All times listed are EST time zone.

1:25 - 1:55 **Unpacking Patient Centricity: How an Automated Patient Journey Makes Decentralized Trials Easier**

- What do we mean by patient centricity and how it can impact your trials
- Why decentralization and automation can improve the patient journey and enable more successful trials
- How Direct-to-Patient functionalities in IRT have evolved and what lessons were learned from COVID-19
- How to seamlessly manage patient workflows with eConsent & IRT
- Creating ease and efficiency for patients, sites and your study team

John Ristuccia, SVP Global Client Services, **Suvoda**
Andrés Escallón, eClinical Innovation, **Suvoda**

2:00 – 2:30 **CASE STUDY: Innovation and Efficiency in your Clinical Supply Chain Strategy**

- Vision for the future of trials: adaptive and flexible delivery models
- Leveraging the momentum for change to embed greater flexibility
- Practical experience of maintaining chain of custody using IRT to track drug touchpoints
- Sharing IRT clinical trial supply strategy updates to better manage cost, risk and effort

Paul Hughes, Director, Randomization and Trial Supply Management, **Janssen**

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DAY 2 – WEDNESDAY 20TH OCTOBER

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8:15 – 8:25 **Chair's Opening Address**

Tom Schiavon, Manager, Clinical Systems, Ultragenyx Pharmaceutical Inc.

8:30 – 9:00 **Improving Patient-Centricity with an IRT and Temperature Monitoring Integration**

In any clinical trial, the patient's wellbeing is the central point of concern. With the rise of temperature-sensitive drugs, the risk of administering drugs with an unknown state of temperature stability is therefore increasing. The integration of IRT and temperature monitoring provides a complete digitalized method of tracking the IMP, allowing for increased patient safety. During this presentation, Suvoda and Berlinger will present how IRT and temperature monitoring is applied in-practice with the associated operational benefits in your clinical trials.

Harald van Weeren, Segment Manager Clinical Trial Team Lead, Berlinger & Co Ag.
Henk Dieteren, Clinical Supply Chain Solutions Consultant, Suvoda

9:05 – 9:35 **CASE STUDY: Applying Fractional Prediction to Drive Clinical Supply Efficiency**

- Case study where usual site stock management is not efficient enough
- Understand how fractional prediction works and how it can be applied
- Insight into how it addresses protocol-specific challenges, resulting in a more efficient clinical supply chain

Sylvain Berthelot, Global Head, IRT and EDC Technical Solutions, Calyx

9:40 – 10:20 **Best Practice and New Models for IRT User Acceptance Testing (UAT)**

- Case study insight into the clinical trial and new models of UAT deployed
- Details on practicalities, challenges of the trial
- Insight into how IRT was leveraged to hold the study

Kate Chapman, Director, Clinical Technology Consultants Ltd

10:25 – 11:10 **PANEL DISCUSSION Vendor Selection and IRT System Implementation Best Practice**

- Sponsor considerations for vendor evaluation, selection and on-boarding
- Best practice lessons learned in IRT design
- Insight into managing the implementation of study specific IRT solutions from requirements through user acceptance testing (UAT)

Sarosh Anjum, Senior Manager - Information & Systems Strategy, Astellas Pharma US
Elisa Holzbaur, IRT Manager – Clinical Systems and Analytical Reporting, Amgen
Carol Lee, Director, Senior Director, Clinical Program Management, Ascentage Pharma
Patrick Nelligan, Associate Director, Interactive Response Technology (IRT), Bristol Myers Squibb

11:10 - Live Virtual Hub Networking and Roundtable Sessions

12:25– 12:30 **Chair's Opening Remarks**

Amy Rupp, Associate Director IRT, CSL Behring

12:35 – 1:05 **CASE STUDY: Innovation to Improve the IRT Site User Experience**

- Case study insight into the clinical trial and innovation deployed
- Details on practicalities, challenges of the trial
- Insight into how IRT was leveraged to hold the study

Sean Roy, Senior Director NA Services, Oracle Health Sciences
Michele Taylor-Scott, Director of Data Management, Health Decisions, Inc

1:10 – 1:40 **Take Confidence: Ensuring IRT Remain Compliant in Global Trials**

- Analysis of common IRT findings and system change requirements by regulatory authorities
- Improving awareness of different clinical trials regulatory requirements in key territories
- Essential privacy and data transfer challenges: European GDPR, invalidation of Privacy Shield and international data transfer
- Practical international compliance and regulatory challenges impacting IRT

Gayle Flynn, Engagement Delivery Partner - Life Sciences, Cognizant

1:45 – 2:15 **CASE STUDY NEW FDA REQUIRMENTS: Moving from Software Validation to Computer Software Assurance**

- Where to begin when creating a 'validation masterplan'
- Leveraging vendor documentation on the core systems to streamline your approach
- Practical guidance on translating your core IRT system documentation and transposing this for your protocols
- Developing a risk-based approach for your UAT system testing

Tom Schiavon, Manager, Clinical Systems, Ultragenyx Pharmaceuticals

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DAY 3 – THURSDAY 21ST OCTOBER

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8:15 – 8:25

Chair's Opening Remarks

Kate Chapman, Director, Clinical Technology Consultants Ltd

8:25 – 9:25

INDUSTRY BENCHMARKING SESSION Part I: Panel of IRT professionals from different size pharma and different stakeholders to work through practical scenarios, share different approaches and best practice advice

- Randomization and stratification cohorts: what do you do if you find this has gone wrong with the randomisation, how do you troubleshoot this and what steps can be put into place to avoid future randomization issues
- No drug at site today: how do you interact with the site? EG if it is placebo you can't tell the site it is placebo you are short of as you will unblind the site so how do you deal with it?

Maria Napoliello Humagain, Senior Manager, IRT Systems, Beigene
Dawn Sorenson, Associate Director, Clinical Systems, Theravance Biopharma US
David Morin, Director of Research, Holston Medical Group
Carol Lee, Director, Senior Director, Clinical Program Management, Ascentage Pharma

9:50 - Virtual Hub Networking

10:10 – 11:10

INDUSTRY BENCHMARKING SESSION Part II: Panel of IRT professionals from different size pharma and different stakeholders to work through practical scenarios, share different approaches and best practice advice

- **Data changes:** troubleshooting data changes and tools you have at your disposal
- **Decommissioning best practice:** practical challenges when closing out a study, how do you close IRT, what are you expecting from vendor? What do you need to keep available for audit?

David Morin, Director of Research, Holston Medical Group
Carol Lee, Director, Senior Director, Clinical Program Management, Ascentage Pharma
Sydney McElroy, Senior Project Manager, IRT, CSL Behring
Dawn Sorenson, Associate Director, Clinical Systems, Theravance Biopharma US

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SPONSORSHIP ENGAGEMENT OPPORTUNITIES

WHAT YOU SHOULD EXPECT

Hosted on a fully-interactive platform, the full scope of content will be covered while encouraging structured and unstructured networking and interaction between delegates, sponsors, and speakers.

Engage with highly influential clinical operations, clinical supply chain and clinical systems professionals with the budget and authority to recommend, specify and approve the purchase of products and services to enhance IRT systems and advance their clinical research, discovery efforts and clinical programs – all from the comfort of your seat!

Our Thought Leadership led sponsor packages offer:

Lead Generation

Our sponsor packages are geared around providing you concrete sales leads and lead prospects reports. We accomplish this by building your presentation right into the live agenda of the event.

Global Reach

Your brand and content are front and center, ensuring your direct engagement with a global audience.

Summary of Meetings and Engagement

See everyone who has viewed your profile, expressed interest in your products/services, and who has requested meetings with you and your colleagues.

Qualified Engagement

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If this sounds like you, and you're interested in participating at this years Interactive Response Technologies virtual event, please contact John Egan who can provide you some insights into the sponsorship and exhibition opportunities available and tailor a solution to fit your needs:

E. John.Egan@informa.com
T. +13392982205

SUPPLIER/VENDOR/CRO/TECHNOLOGY PROVIDER/CONSULTANT PRICING:

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