CLINICAL DATA MANAGEMENT INNOVATION 2023

13-14 September 2023

Princeton, **New Jersey**

SPEAKERS

Audrey Hill, Senior Director, Data Management, **Advaxis**

Madhu Kumar Komuravelli, Head of Data Management, **BlueRock Therapeutics**

Eric Nicolai, Associate Director, Clinical Data Management, **Bristol-Myers Squibb**

Sam Hume, Vice President, Data Science, **CDISC**

Guang-Liang Wang, Ph.D., Head of Data Management, **Cerevel Therapeutics**

Terry Katz, Senior Director, Biostatistics and Data Management Planning and Functional Excellence, **Daiichi Sankyo**

Mohammad Alajarmeh, Director, Clinical Operations, **Eunoia Health**

Keith Chiasson, Vice President, Drug Development, **Feldan Therapeutics**

William Newton, Senior Healthcare Reporter, Clinical Trials Arena, **GlobalData Healthcare**

Satish Dachepally, Executive Director, Clinical Database Programming, **Incyte Corporation**

Narayan Lebaka, Senior Director, Clinical Data Management, **Inspirna**

Joshua Cox, Vice President, Clinical Data Management, **Loxo at Lilly, Eli Lilly and Company**

Joe Shan, MPH, Executive Director, Clinical Development Operations, **MEI Pharma**

Rosanne Petros, Associate Director, Clinical Research, **Merck Research Laboratories**

Chris Natale, Director, Clinical Data Management, Oncology, **Moderna**

Devdatt (Dev) Patel, Director, Clinical Data Management, **Seagen**

Noopur Singh, Director, Medical Affairs, **Xentria**

CLINICAL DATA MANAGEMENT INNOVATION

13TH-14TH SEPTEMBER | PRINCETON, NJ

Clinical Data Management Innovation DAY 1 – Wednesday 13th September	
8:00am	**Registration and refreshments**
8:50am	**Chairperson's opening remarks** **William Newton,** Senior Healthcare Reporter, **Clinical Trials Arena/GlobalData Healthcare**
9:00am	**PANEL DISCUSSION: Innovating your clinical data management processes: what's new in 2023?** • How is data management and data capture evolving, and how can you make your processes most efficient? • Overcoming obstacles in order to ensure data is captured and processed in a timely manner • Choosing vendors for clinical data management: what new players are in the market? • Modernizing approaches to traditional data management: what new data engineering tools are available? • Using data management technology to reduce burden on short-staffed sites **PANELLISTS:** **Sam Hume,** Vice President, Data Science, **CDISC** **Chris Natale,** Director, Clinical Data Management, Oncology, **Moderna** **Devdatt (Dev) Patel,** Director, Clinical Data Management, **Seagen**
9:30am	**Session reserved for featured sponsor**
10:00am	**Opportunities created by incorporating real world evidence into clinical trials** • Tapping into the full potential of real world evidence and incorporating this into your trial • Barriers to adopting RWE: how to address and overcome these • Navigating regulations in the USA in relation to the use of real world evidence in clinical trials **Terry Katz**, Senior Director, Biostatistics and Data Management Planning and Functional Excellence, **Daiichi Sankyo**
10:30am	**Morning refreshments and networking**
11:15am	**Best practice in acquiring and reviewing external and biomarker data to reduce turnaround and improve quality** • How to ensure biomarker data is processed and reviewed in a timely manner and the benefits of this • Assessing different platforms and available technologies for handling biomarker data • Centralizing and aligning biomarker data in order to increase efficiency **Eric Nicolai,** Associate Director, Clinical Data Management, **Bristol-Myers Squibb**
11:45am	**Session reserved for sponsor**

CLINICAL DATA MANAGEMENT INNOVATION

13TH-14TH SEPTEMBER | PRINCETON, NJ

12:15pm	**The impact of high turnover of site staff on data collection and what sponsor companies can do to help** • How to deal with high turnover of staff as a sponsor company: what issues are caused by this? • Assessing available technology and processes to alleviate pressure and workload on site staff • The importance of maintaining a strong relationship with sites when it comes to data entry and collection **Rosanne Petros,** Associate Director, Clinical Research, **Merck Research Laboratories**
12:45pm	**TECHNOLOGY SPOTLIGHT: Reserved for eClinical Solutions**
1:00pm	**Lunch and networking**
2:00pm	**PANEL DISCUSSION: Optimizing data capture: new trends in data acquisition to ensure data benefits indication and treatment** • Ensuring no data that is collected goes to waste: where are biotech and pharma companies collecting unnecessary data? • Bringing down overall costs by eliminating collection of data which is not used as part of your trial • Regulatory guidance around data acquisition and choosing which data to collect • How minimizing the number of data points captured can ease burden on patients during site visits, increase retention, and speed up overall study timelines **MODERATOR:** **William Newton,** Senior Healthcare Reporter, **Clinical Trials Arena/GlobalData Healthcare** **PANELLISTS:** **Chris Natale,** Director, Clinical Data Management, Oncology, **Moderna** **Satish Dachepally,** Executive Director, Clinical Database Programming, **Incyte Corporation** **Audrey Hill,** Senior Director, Data Management, **Advaxis** **Joe Shan, MPH,** Executive Director, Clinical Development Operations, **MEI Pharma**
2:30pm	**Session reserved for Viedoc**
3:00pm	**High impact CDISC Open-Source Alliance (COSA) projects** • Highlights of some of the most important COSA projects and related standards development • Using the CDISC Open Rule Engine (CORE) for conformance checking • Piloting Dataset-JSON as a SAS v5 XPORT replacement • The OAK project: automated CDASH to SDTM transformations • Digital protocol and study design projects • Other COSA projects generating interest from industry **Sam Hume,** Vice President, Data Science, **CDISC**
3:30pm	**Afternoon refreshments and networking**

CLINICAL DATA MANAGEMENT INNOVATION

13TH-14TH SEPTEMBER | PRINCETON, NJ

4:15pm	**Data Management in oncology: the importance of using suitable technology in your clinical trial in order to create a manageable data structure** • Challenges in how we collect data: number of data forms and adverse effects in oncology • Using the right technology to maximize efficiency of data systems in oncology trials • Understanding how to use and analyze data effectively • Looking at how to manage your data structure **Narayan Lebaka,** Senior Director, Clinical Data Management, **Inspirna**
4:45pm	**Session reserved for sponsor**
5:15pm	**Choosing the right technology vendors for clinical data management** • Weighing up the cost and benefits of different providers for data collection and analysis • Striking the balance of outsourcing vs keeping data management in house: what can vendors offer? • What new innovations and technology are available in 2023: keeping ahead of the curve when selecting data vendors **Joshua Cox,** Vice President, Clinical Data Management, **Loxo at Lilly, Eli Lilly and Company**
5:45pm	**Chairperson's closing remarks** **William Newton,** Senior Healthcare Reporter, **Clinical Trials Arena/GlobalData Healthcare**

END OF DAY 1 AND NETWORKING DRINKS

Clinical Data Management Innovation

DAY 2 – Thursday 14th September

8:00am	**Registration and refreshments**
8:50am	**Chairperson's opening remarks** **William Newton,** Senior Healthcare Reporter, **Clinical Trials Arena/GlobalData Healthcare**
9:00am	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into four 'zones'. Delegates can choose which zone they would like to join. Each zone will be led by a table moderator and will focus on a different challenge within clinical data management. After 45 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	ROUNDTABLE 1: Building a strong relationship with sites to ensure data is collected and processed efficiently and in a timely manner **Devdatt (Dev) Patel,** Director, Clinical Data Management, **Seagen**

CLINICAL DATA MANAGEMENT INNOVATION

13TH-14TH SEPTEMBER | PRINCETON, NJ

	ROUNDTABLE 2: Getting the most out of limited data sets in rare disease clinical trials **Noopur Singh,** Director, Medical Affairs, **Xentria**
	ROUNDTABLE 3: Choosing technology and vendors to fit your needs for clinical data management **Keith Chiasson,** Vice President, Drug Development, **Feldan Therapeutics**
10:30am	**Morning refreshments and networking**
11:15am	**PANEL DISCUSSION: Fostering a strong relationship with sites in order to ensure data management is as streamlined and efficient as possible** • What more should clinical trial sponsors be doing in order to relieve burden on understaffed sites? • An overview of new technology and innovative processes available in order to increase efficiency around data collection and entry • How can having a good relationship with your site improve processes and reduce overall trial timelines? • Regulatory considerations around data collection and site processes • Managing expectations of site staff when it comes to data entry without damaging relationships • Training site staff on your technology and systems in order to avoid errors and ease burden on sites **PANELLISTS:** **Narayan Lebaka,** Senior Director, Clinical Data Management, **Inspirna** **Rosanne Petros,** Associate Director, Clinical Research, **Merck Research Laboratories** **Joshua Cox,** Vice President, Clinical Data Management, **Loxo at Lilly, Eli Lilly and Company**
11:45am	**Session reserved for sponsor**
12:15pm	**Strategies for data standardization and real-time data analytics** • Challenges and benefits of real-time data: what can this add to your trial, and what additional challenges are created? • Analyzing, sorting and handling large amounts of real-time data: understanding best practice • Choosing vendors and technologies to support real-time data collection and analytics: what should you consider? **Guang-Liang Wang, Ph.D.,** Head of Data Management, **Cerevel Therapeutics**
12:45pm	**Lunch, networking and prize draw!**
1:45pm	**Leveraging data and information from electronic medical records in order to shorten patient recruitment timelines** • What are the benefits of electronic medical records and how can they enhance patient recruitment processes? • Navigating challenges and overcoming hurdles when using electronic medical records • Using electronic medical records in conjunction with other methods of identifying and screening patients in order to shorten timelines and reduce overall costs **Madhu Kumar Komuravelli,** Head of Data Management, **BlueRock Therapeutics**
2:15pm	**Session reserved for sponsor**

2:45pm	**Weighing up statistical significance vs clinical meaningfulness when submitting a new drug for approval** • Ensuring data and results from your trial are meaningful to patients: is putting out your drug worthwhile to patients? • Meeting expectations from the FDA and regulatory bodies when it comes to clinical meaningfulness of your data • Considerations when preparing documents for submissions and proving clinical meaningfulness **Mohammad Alajarmeh,** Director, Clinical Operations, **Eunoia Health**
3:15pm	**Chairperson's closing remarks** **William Newton,** Senior Healthcare Reporter, **Clinical Trials Arena/GlobalData Healthcare**

END OF CONFERENCE

Additional topic suggestions:

Data management and rare diseases: how to make the most of limited data sets with rare disease and orphan drug trials

- Capturing and analyzing data effectively in studies with smaller numbers of patients
- Ensuring data is accurate and efficient in situations where only one attempt at a trial is possible
- Optimal ways to analyze data in order to ensure regulatory guidelines are met even with smaller sample numbers and in single arm studies

Designing an effective single arm study: what to do when your patient numbers are too small for control and placebo groups?

- Is it possible to do control comparison in rare and ultra-rare disease studies? What options are available?
- Making the most of data and evidence available in order to ensure regulatory requirements are met and to maximize the likelihood of gaining approval for your drug
- Real world evidence: using data collected by monitoring patients long term in chronic rare diseases

Decentralized clinical trials: adapting your data collection processes in remote and hybrid settings

- Handling data when there is a mix of electronic data and paper data when patients are not present at the clinic
- Collecting and analyzing data from wearables and remote monitoring devices
- Making the most of ePros and patient diaries as data capture tools when running a decentralized trial

CASE STUDY: Utilizing eCOA to improve clinical trial data quality

- Considerations for eCOA study data collection: developing trial objectives and design
- Choosing primary and secondary endpoints for your trial: which data is most important to collect?
- How using eCOA effectively and efficiently can minimize overall costs, increase data accuracy and improve patient retention for your clinical trial