



# Clinical Data Analytics



Virtual Education and Networking Event

LEVERAGE DATA TO DRIVE DECISIONS THAT STREAMLINE  
PROCESSES AND OPTIMIZE EFFICIENCIES IN CLINICAL OPERATIONS

## SPEAKER HIGHLIGHTS



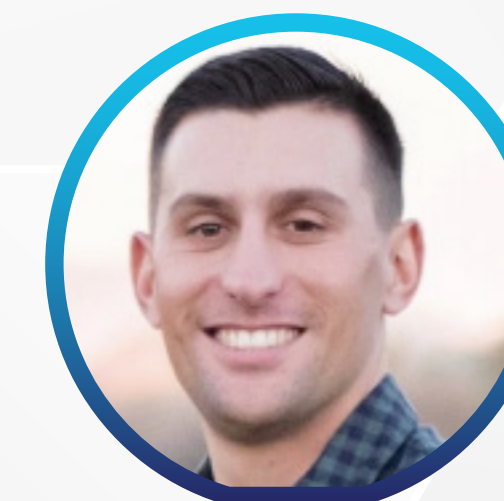
**Kevin Richards**  
Director, Analytics and Insights,  
Quality Investigation and Analytics  
**ASTRAZENECA**



**Lisa Bennett**  
Principal GCP Quality Lead  
**ROCHE**



**Ronojit Adyanthaya**  
Senior Director, Data Analytics  
**MERCK**



**Jeremy Jones**  
Strategic Planning & Operations  
Associate Director, R&D Quality  
**AMGEN**



**Leslie Sam**  
President  
**LESLIE SAM AND  
ASSOCIATES**



**Niloy N. Shah,  
M.S.**  
Senior Director,  
Clinical Quality Operations  
**HUTCHMED**



**Michael Torok,  
Ph.D.**  
Vice President, Global Head  
of Quality Assurance Programs  
**GENENTECH, A MEMBER  
OF THE ROCHE GROUP**



**Misha Abraham**  
Head of Clinical Risk Management  
Strategy, Innovative Medicine  
and MedTech  
**JOHNSON & JOHNSON**

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MPALA

FEBRUARY 15, 2024 | VIRTUAL EVENT

[www.clinicaldataanalytic.com](http://www.clinicaldataanalytic.com)





# TOP REASONS TO ATTEND

- 1.** Embrace the Industry's Shift towards Increased Transparency, Cultures of Quality, and Data-Informed Decision Making in Clinical Trials
- 2.** Recognize the Undeniable Benefits of Leveraging Analytics to Optimize Clinical Quality
- 3.** As Resources Remain Tight, Understand how to Accomplish More with Less through Simple Applications of Analytics
- 4.** No Need to Reinvent the Wheel, Evaluate Available Tools and Infrastructure to Expedite and Streamline your Company's Adoption of Clinical Data Analytics
- 5.** Streamline Clinical Operations and Gain the Competitive Advantage through Data Analytics



**IMPALA**

The Inter coMPany quALity Analytics (IMPALA) Consortium was initially established in July 2019 as an informal group of biopharmaceutical organizations with the common goal to share knowledge and better understand opportunities in applying advanced analytics for QA.

IMPALA's mission is to transform the Biopharmaceutical Clinical Quality Assurance process in the Good Clinical Practice and Good Pharmacovigilance Practice areas, by using advanced analytics and promoting the adoption of this new approach and associated methodologies by key industry stakeholders (e.g. pharma quality professionals, Health Authorities) to assure safe use therefore building patient trust, accelerating approvals and ultimately benefiting patients globally.

[Click here fore more information](#)

**REGISTER TODAY**





# AGENDA FEBRUARY 15, 2024



All sessions are in Eastern Time

## 10:00 AM WELCOME AND INTRODUCTION

### 10:15 AM THE POWER OF ANALYTICS

**Recognize the Industry's Shift Towards Increased Transparency, Culture of Quality, and Data-Informed Decision-Making**

- Why are clinical data analytics important and why now?
- Demonstrate the big-picture view of how data analytics can assess risks and catch issues early, therefore expediting more effective treatments to patients
- Examine the role of health authorities in driving the adoption of analytics
- Discuss why this is not just a big pharma issue, smaller companies need to learn and adapt to gain meaningful advantage in this competitive market



**Michael Torok, Ph.D.**  
Vice President, Global Head of Quality Assurance Programs  
GENENTECH, A MEMBER OF THE ROCHE GROUP

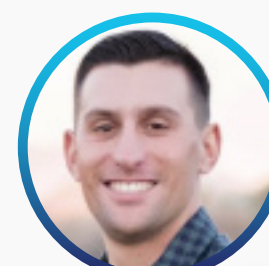
### 10:45 AM WHERE TO START?

**Recognize the Industry's Shift Towards Increased Transparency, Culture of Quality, and Data-Informed Decision-Making**

- Discuss the role of the IMPALA Consortium in catalyzing industry adoption of analytics
- Evaluate strategies for leveraging information from IMPALA to gain leadership buy-in
- Outline tools currently available to anyone via IMPALA website
- Recognize that these tools can be scaled to companies of any size



**Ronojit Adyanthaya**  
Senior Director, Data Analytics  
MERCCK



**Jeremy Jones**  
Strategic Planning & Operations  
Associate Director, R&D Quality  
AMGEN

### 11:15 AM SPEAKER Q&A - FACE-TO-FACE ENGAGEMENT VIA ZOOM

**Save your burning questions for this dedicated time to discuss with the previous speakers in an interactive face-to-face setting using Zoom.**

## 11:30 AM 15-MINUTE BREAK

### 11:30 AM ANALYTICS-BASED AUDITING

**Outline Implementation Steps to Integrate Analytics Into Routine Audit Practice and Drive Evidence-Based Conclusions from Large Volumes of Data Quickly**

- Discuss tools for calculating probability of AE under reporting
- Outline IMPALA's open source RAPID (Real-Time Audit Package Informed by Data) Audits
- Audits based on data analytics
- Follow a pre-defined methodology
- Compare RAPID audits to traditional audits to showcase increase in effectiveness with less resources



**Lisa Bennet**  
Principal GCP Quality Lead  
ROCHE

### 12:15 PM OPERATIONAL AND COST BENEFITS

**Accomplish More with Less, Minimize Inefficiencies, and Focus on High Value Work with Clinical Data Analytics**

- Structure and categorize data from various sources to draw actionable insights to prioritize high risk tasks
- Improve process flow and realize operational efficiencies to free up time for strategy and critical thinking
- Insert automation of noncritical tasks to shift focus to strategic efforts

### 12:45 PM SPEAKER Q&A - FACE-TO-FACE ENGAGEMENT VIA ZOOM

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## 1:00 PM 30-MINUTE BREAK

### 1:30 PM CASE STUDY: COMPANY IMPLEMENTATION

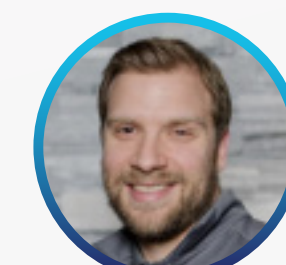
**Learn How a Medium-Sized Company is Leveraging Analytics to Optimize Clinical Quality**

- Discuss the start of the analytics journey and how to get internal buy-in
- Understand how implementation barriers were overcome Outline realized benefits and plans for the future

### 2:00 PM CASE STUDY: ANALYTICS DRIVEN OVERSIGHT

**Understand AZ's Journey to Design and Build a Clinical Data Analytics System that Fuels Inspection Readiness Activities by Prioritizing Risks**

- Identify where the drive and need for a system such as this originated and how it developed
- Examine the information collection process to identify everything related to inspection readiness that can be measured and how this was broken down into modules
- Discuss resistance and how education on the need for transparency actually builds the foundation for a culture of quality
- Evaluate progress to date and feedback from study and site teams



**Kevin Richards**  
Director, Analytics and Insights,  
Quality Investigation and Analytics  
ASTRAZENECA

### 2:30 PM SPEAKER Q&A - FACE-TO-FACE ENGAGEMENT VIA ZOOM

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### 3:15 PM CONCLUDING PANEL: REALIZED BENEFITS AND LESSONS LEARNED

**Discuss Where Different Companies Are on the Clinical Data Analytics Implementation Journey, What was Learned, and the Already Realized Efficiencies**

- Share implementation challenges and how they were overcome
- Understand how privacy and data security concerns were addressed
- Outline realized benefits and future plans



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## 4:00 PM EVENT CONCLUDES

**REGISTER TODAY**





## WHO SHOULD ATTEND

This conference is designed for professionals from pharmaceutical, biotechnology and device companies whose responsibilities include one of the below:

- Analytics/ Clinical Analytics/ Data Analytics/ Advanced Analytics
- Data Monitoring/ Clinical Data Monitoring
- Data Management/ Clinical Data Management
- Data Integration/ Clinical Data Integration
- Digital Innovation
- Digital Operations
- Digital Health
- Real World Evidence
- Clinical Quality/ Quality
- AI and Machine Learning
- Data Sciences/ Clinical Data Science/ Data Science Solutions
- Data Governance
- Technology Optimization/ Technology Innovation
- Clinical Operations
- Statistical Programming/ Statistics/ Biostatistics

## PRICING

PHARMA/BIOTECH/MEDICAL DEVICE COMPANIES

**ADVANCED RATE**

**\$795**

Register by 02/2/2024

**EARLY BIRD**

**\$895**

Register after 02/2/2024

**REGISTER TODAY**

SERVICE PROVIDERS/VENDORS

**ADVANCED RATE**

**\$1,095**

Register by 02/2/2024

**EARLY BIRD**

**\$1,195**

Register after 02/2/2024

**REGISTER TODAY**

**SPONSORSHIP OPPORTUNITIES ARE STILL AVAILABLE!**

**Learn More!**

**Email Meg Larson at**  
[meg@momentumevents.com](mailto:meg@momentumevents.com)

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**Clinical  
Quality  
Oversight**

**MAY 21-23, 2024**  
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**Click here for more information**