



Advanced Analytics for Clinical Data 2017

Data-Driven Decision Making for Drug Development

What's the one breakthrough you want to see regarding data analytics in clinical research over the next 5 years?



There will not be one breakthrough – no one big volcanic eruption – but rather a series of smaller quakes and rumblings. The tools will continue to evolve, the algorithms will continue to be refined, and some companies will be bold enough to apply learnings and alter their path forward, but in small, measured steps. Small insights will be gleaned, some processes altered and hopefully, some attitudes can change. A change I hope to see is the willingness and acceptance to act boldly and take quick action in this highly regulated environment.

Tony Cavaliere, Global Head of Data Sciences & Standards, Novartis

Tony will be chairing our meeting next February, and will be present on both days to moderate all interactions and provide his guidance and input to discussion.

Several of the data analytic solutions that are available and applied outside of regulated industry and the clinical enterprise already function at an extremely high level. The adoption of patient-driven initiatives that increase the quality, quantity and accessibility of rich, patient-level clinical data would be an extremely valuable breakthrough for the entire industry.

Todd Townsend, PhD., Commissioner's Fellow, United States Food and Drug Administration (FDA)

Todd will be addressing a talk on "Can Data Collection & Reporting from Wearable Devices Cloud, Supplement or Replace Standard Measures in Clinical Trial Reporting? – A Regulatory Perspective", and leading a round table discussion on "Regulation and Guidance for the Future of Data in Clinical Innovation: Wearables, RWE and Adaptive Trials".



A clinical development guided by 100% data-driven decision making.

Ray Liu, Senior Director & Head of Statistical Innovation & Consultation, Takeda Pharmaceuticals Inc.

Ray will be addressing a talk on "Joint Analysis – Statistical Innovation to Maximize the Insights from Big Data Integration", and joining a panel discussion on "Big data in Clinical Trials – Leveraging Data to Retrieve Meaningful Action".

In the coming years: Analytics will be the primary solution for the biggest challenges around patient safety, data quality and cost of clinical research.

Rajneesh Patil, Senior Director, Clinical Development, Quintiles

Rajneesh will be addressing a talk on "Advanced & Predictive Analytics – Implementation aspects in Risk Based Monitoring" and joining a panel discussion on "The Paradigm Shift of Clinical Data Management – From Support to Driver in Clinical R&D".



For what it is worth, I don't envision a specific breakthrough, although there may be several. There has been very rapid convergence of data records that are relevant to the business processes in clinical research. The most direct is solving the technical and regulatory barriers to moving data between medical records and study records. There have been a number of early efforts and conceptualizations (e.g., CDISC single-source and eSDI efforts) but we are now very close. Creating EMRs that are forward compatible with FDA-regulated EDC systems will become increasingly commoditized. However, creating continuity between medical records and post-approval study records is nearly as important and less innovation has focused on optimizing those records for clinical research. Importantly, the U.S. Congress and FDA are looking at the potential for observational studies, registries, and therapeutic treatment data to streamline the critical path to drug approval. So, the area is deserving of more attention and not just technology to address the inherent difficulties but also data standards and prospective design.

David S. Reasner, PhD., Vice President, Data Science & Head, Study Endpoints, Ironwood Pharmaceuticals

David will be joining a panel discussion on "Big data in Clinical Trials – Leveraging Data to Retrieve Meaningful Action".

Join the conversation with top experts in clinical data science, clinical innovation and clinical data management at **Advanced Analytics for Clinical Data 2017**, to focus on the practical implementation of big data analytics and data-driven methodologies for improved outcomes in clinical trials.