eyeforpharma

Data Quality & Technology In Clinical Trials 2016

Philadelphia / 18-19 April 2016

SAVE $300

if you register before February 26th

#DQTCT

Deliver quality and slash timelines with new technology and analytics

Julian Jenkins, Vice President, Innovation Performance & Technology, **GSK**

Joe Camardo, Senior Vice President, **Celgene**

Immo Zadezensky, Clinical Pharmacologist, Professional Affairs and Stakeholders Engagement, **FDA**

Alan Wright, Chief Medical Officer, **Roche**

Anthony G. Johnson, Vice President, Head Early Clinical Development, **AstraZeneca**

Barbara Tardiff, Vice President, Global Head Clinical Informatics and Innovation **Pfizer**

- **Maximize data quality:** Enhance your trial rate of success with the perfect protocol design
- **Leverage the Digital Clinical Study:** Become an expert in understand, handle and validate wearable generated data
- **Overcome regulatory obstacle:** Hear directly from FDA representatives on how to validate patient generated data
- **Focus on what matters:** Achieve a structured risk identification, analysis, and measurement and successful transition to Risk Based Monitoring
- **Align your objectives with your sites:** Collaborate with key stakeholders and optimize the information exchange

8+ HOURS OF FACE-TO-FACE NETWORKING

FAST TRACK KNOWLEDGE FROM EXECUTIVE PANELS AND CASE STUDIES

2 DAYS WITH 100+ LEADING CLINICAL EXPERTS

RESEARCH-LED AGENDA SHAPED BY INDUSTRY THOUGHT-LEADERS

Sponsors: Clinical ink, SHYFT ANALYTICS, INTENT SOLUTIONS, AiCure

Partnering with: TransCelerate BIOPHARMA INC., ACRES, SCDM Society for Clinical Data Management, CISCRP, SCRS Our Voice. Our Community. Society for Clinical Research Sites

Reserve your place at www.eyeforpharma.com/data-clinical

Welcome to Data Quality & Technology in Clinical Trials

Dear Colleague,

It is my distinct honor to invite you to our inaugural annual Data Quality and Technology in Clinical Trials Summit for Pharmaceutical companies, Biotech, CROs, IT innovators, clinical trial sites, associations, patient organizations, and regulatory bodies.

Currently, the biggest challenges we face as an industry involve enhancing data quality through technology to achieve study endpoints more efficiently, and improving the chances of not only regulator, but, also payer approvals.

The advent of the internet, bringing along with it mobile health, social media, and advanced technologies that integrate risk analytics into decision making have allowed us to access larger amounts of relevant data, a trend that we can leverage to solve challenges within our clinical studies. However, without the appropriate technology and analytics to capture, link, aggregate, and distill this data - in addition to pharma's hesitancy to accept novel technology - we have been struggling to take full advantage of the available capabilities.

As part of our clinical trial infinitive Data Quality and Technology in Clinical Trials, we will present the solutions to these challenges through in depth analysis and industry case studies enabling you to integrate the right technology and analytics when designing and conducting clinical trials. Pharma attendees can expect to join key stakeholders involved in the clinical trial process, and together, drive the strategy shift and take full advantage of innovative technological advancement capabilities.

I sincerely hope you can join us for this important gathering, and I look forward to meeting you in Philadelphia.

NASSIM AZZI
Global Project Director
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AGENDA AT A GLANCE

DATA QUALITY

Hear about real benefits of data generated in digital study, measure the risk of compromising study end-point, and learn from the FDA when this data cross the regulatory lines.

Utilize Quality by Design principles to avoid data point overload and reduce the number of protocol amendments.

Establish a standard database design and decrease review and aggregation time.

Get the expertise on using big data analytics to competitively position medical products during trial design.

TECHNOLOGY

Get a full view of available technology that will give you the ability to get key insights faster and at lower costs.

Elaborate your optimal RBM planning strategy by understanding the most critical factors to base it on.

Learn about how to program the EDC to limit the monitoring to specific and targeted set of data.

Use analytics and statistical analysis to make your data speak to you.

STAKEHOLDER COLLABORATION

Learn how eSource is being used to enhance data quality and improve operational productivity at sites.

Hear how Industry aims to standardize approaches to quality management.

Learn how to get the data transferred electronically from the site to the sponsor reducing your queries.

Don't just take our word for it!

Here's what attendees have said about previous commercial and market access events...

"This event was extremely valuable for anyone who is involved in clinical research trial. The importance of the patient perspective and the growth of patient-centric trials make this conference a must attend for many in the pharma industry..."

Bristol-Myers Squibb

"The event sparked many great ideas that we can immediately implement. The sessions on technology and social media trends were some of the best forward thinking presentations I've heard".

AstraZeneca

" I came away from the conference feeling like I had some useful insights to share with my colleagues and ideas that could be implemented easily to further enhance our strategy"

Roche

"It was a great collaboration of professionals, experts and patients to discuss issues around engagement in research"

SANOFI

Industry Experts Include:

Julian Jenkins,
Vice President, Innovation Performance & Technology,
GSK

Johann Proeve,
Global Development and Strategy Advisor,
Bayer HealthCare

Immo Zadezensky,
Clinical Pharmacologist, Professional Affairs and Stakeholders Engagement, **FDA**

Alan Wright,
Chief Medical Officer,
Roche

Barbara Tardiff,
Vice President, Global Head Clinical Informatics and Innovation, **Pfizer**

Ann Meeker-O'Connell,
Head, Risk Management and External Engagement,
Johnson & Johnson

Jonathan Helfgott,
Professor, Johns Hopkins, Former Associate Director for Risk Science, Intelligence & Prioritization, **FDA**

Christine Pierre,
President,
Society of Clinical Research Sites (SCRS)

Rob DiCicco
Vice President, Clinical Pharmacology Sciences and Study Operations, **GSK**

Anthony G. Johnson,
Vice President, Head, Early Clinical Development,
AstraZeneca

Balazs Flink,
Clinical Trial Analytics Lead,
Bristol-Myers Squibb

Wendy Snyder,
Director, Clinical Development,
Amgen

Brian Nugent,
Associate Director, Clin Ops, Process,
Gilead Sciences

Gati Dharani,
Senior Associate Director,
Boehringer Ingelheim

Henrik Finnern,
Head of Global Patient Advocacy Relations,
Boehringer Ingelheim

Joe Camardo,
Senior Vice President,
Celgene

Matt Austin,
Director Development Data & Analytics, Development Design Center, **Amgen**

Mike Hale,
Global Head of Biometrics,
Baxalta

Vera Pomerantseva,
Clinical Data Management, Reporting and Analytics,
Daiichi-Sankyo

Mark Wiener,
Chief Medical Information Officer, **Temple University Health System**

Greg Koski,
President Alliance for Clinical Research Excellence and Safety,
ACRES

Ashish Cowlagi,
Product Management & Strategy, Watson Health,
IBM

Mollie Shields Uehling,
President & CEO,
SAFE-BioPharma

Jason Paragus,
Deputy Program Director, Biosecurity,
Lawrence Livermore National Laboratory

Do you have a speaker recommendation or topic we should discuss?

PLEASE GET IN TOUCH!

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SESSION 1:
Are Pharma companies transitioning from drug makers to data companies?

KEYNOTE

Driving the Strategy Shift and unlock to value in your clinical data

Having data that is consistent, clean, and reliable has become one of the biggest challenges facing pharmaceutical R&D. Hear from the industry's, top C level executives and the FDA how to:

- Use technology combined with clinical expertise to unlock the value behind the data, i.e. getting a clear view on the data, permitting to understand the data better and thus facilitating earlier intervention
- Navigate the challenges of adopting and applying technological innovations in data aggregation for pharma companies. In addition to hearing directly from the FDA when the regulatory line is crossed and learn how to overcome this challenge
- Break internal and external silos to create a more seamless network of data sources, and analytical approaches.
- Combine the knowledge captured from large available data set, Implement the right behavioral change, and ultimately improve patient's health.

Klaus Dugi,
Chief Medical Officer,
Boehringer Ingelheim

Boehringer Ingelheim

Mark Wiener,
Chief Medical Information Officer,
Temple University Health System

Temple University Health System

Immo Zadezensky,
Clinical Pharmacologist, Professional Affairs and Stakeholders Engagement,
FDA

FDA

KEYNOTE

A brand new source: Patient generated data

Wearable, mobile technology and e-pros have generated a new type of patient-generated data. More are on the horizon, including home-based blood sampling, eInformed consent and gamification. The pharma industry has quickly seen the potential in these new sources and started to look at it.

- Hear about how to leverage wearable devices' and other patient generated data, to improve and enhance the clinical trial enterprise in general and protocol design especially
- Define which data are useful and which ones are just going to add background noise and not adding value
- Hear from the FDA how regulators feels about patient's generated data, and overcome the regulatory challenges associated
- Leverage new technologies to turn clinical data into evidence and shorten the timelines and improve the quality of the trials

Martin Ho
Acting Branch Chief, Biostatistics
CDRH/FDA

FDA

Better understand your patient populations and the effect of your drugs far earlier in the process with smart use of technology

- Determine if technology provides everything you need to understand the data
- Get a full view of what kind of technology is available to help you to grasp what is going on in your trials
- Prepare all what you need to facilitate a holistic overview of your data across studies
- What kind of data do you need to look at to fully understand your trials? Patient data only?

Julian Jenkins, *Vice President, Innovation Performance & Technology,* **GSK**

gsk

PANEL DISCUSSION

Data driven decision making case study

- Discover this exclusive case study where BMS' clinical team utilized internal and external data and turned it to evidence on killing a development program early
- Hear about the type of insight behind this decision
- Understand why safety and efficacy are not the only parameters to take in consideration

Balazs Flink, *Clinical Trial Analytics Lead,*
Bristol-Myers Squibb

Bristol-Myers Squibb

SESSION 2:
Apply 'Quality by Design' principles to optimize trial design and reduce the number of protocol amendments

Designing protocols while planning for future commercialization

Strategically designing protocols while planning for future commercialization potential requires significant collaborations with post-marketing and commercial personnel.

- Listen to from Celgene's top management's perspectives about how commercial entities use clinical data to operate in a post-marketing environment
- Maximize your organization's success by collecting the right clinical data, and providing it to your commercial peers

Joe Camardo,
Senior Vice President, **Celgene**

Celgene

Examine the value proposition's implication on trial design

A case for action starts with a clear understanding of the quality of the data and the analytics supporting it. Appreciate the importance a value proposition plays in:

- Streamlining the activities of your clinical trial
- Utilizing Quality by Design principles to avoid data point overload
- Reducing the number of protocol amendments

Ann Meeker-O'Connell,
Head, Risk Management and External Engagement,
Johnson & Johnson

Monitoring patients for trials and post-market drugs with tracker technologies

- Discover evolving pharma best practices towards innovative solutions
- Hear from Boehringer Ingelheim executive on how to incorporate technology across the pharma value-chain.

Gati Dharani,
Senior Associate Director,
Boehringer Ingelheim

Reducing experience bias and encourage innovation

Many Biopharmaceutical enterprises are launching innovation initiatives, however, face cultural challenges in adopting novel directives.

- Hear from Amgen's top innovators on how to foster an environment that promotes cultural change, and encourages innovation
- Learn how to correctly use data systems to avoid experience bias for successfully designed protocols and reduce extra amendments

Wendy Snyder,
Director, Clinical Development,
Amgen

CASE STUDY

Description of the IMI EHR4CR project efforts on how to re-use electronic health records for various purposes of the clinical trial conduct

Description of the IMI EHR4CR project efforts on how to re-use electronic health records for various purposes of the clinical trial conduct:

- How to use the EHRs for the improvement of clinical trial protocols and what steps need to be undertaken by the data owners and the sponsor companies to make this process work?
- How can the information available in the EHRs be used to identify the best clinical trial sites and even find the right patients for the studies?
- May it be possible to conduct clinical trials based on EHRs and what are the challenges?
- Which functions in Pharma may benefit from the access to the EHRs

Johann Proeve,
Global Development and Strategy Advisor,
Bayer HealthCare

Use and reuse electronic health record data during the planning phase for better upfront protocol planning and review

- Enhance protocol feasibility to reduce protocol amendment, improve planning, and maximize your chances for achieving your trial objectives
- Acquire the knowledge needed for faster patient identification and recruitment with population targeting leading to shorter timelines
- See the direct impact of the using electronic health records on the efficiency of study conduct and reporting serious adverse events

Anthony G. Johnson,
Vice President, Head, Early Clinical Development,
AstraZeneca

Strategies on collecting data and generating evidence

- Leverage your past clinical data to strategically design your study to optimize the collection of new data
- Transform the insight generated by this data to evidence to enhance the chances of success of your study

Barbara Tardiff,
Vice President, Global Head Clinical Informatics and Innovation, **Pfizer**

SESSION 3:

Risk based monitoring: Pave the way for clean and reliable data

CASE STUDY

Risk Based monitoring vs 100% source data verification

Real life example on how offsite monitoring more effectively detects issues and trends that would otherwise not been spotted with traditional methods

Determine the most critical angle for each study (end-point)

- Learn about how to program the EDC to limit the monitoring to specific and targeted set of data
- Hear specific example on how the cost and time of monitoring of the trial has been reduced by only focusing on data related to efficacy endpoints reducing time needed for SDV and thus number of visit required (MVRs)
- Understand the risks of putting the focus on only the efficacy endpoints, ignoring the other important that have the potential to kill your study if not looked at carefully as well

Conference Agenda

Understand what makes successful risk based monitoring

In order to perform a successful risk mitigation model, especially when it comes to transitioning to Risk Based monitoring, a structured risk identification, analysis, and measurement is essential.

- Understand the construction of a structured model; with emphasis on the residual risk
- Case study on how Quality by Design can be integrated into the risk mitigation management model
- Create a robust risk training and manifest a culture change to deliver a structured risk approach

Brian Nugent,
Associate Director, Clin Ops, Process,
Gilead Sciences

Precision Medicine: The Biomarker Meets Predictive Analytics

Today, technology is enabling the healthcare system to shift from the universal to the individual.

- Hear about the tools available that are enabling this shift.
- Understand how a biomarker fits into the healthcare delivery system
- See practical examples from other industries' best practices that reflect the methodology

Mike Hale,
Global Head of Biometrics,
Baxalta

SESSION 4:

What is your data telling you?

Making your data speak to you

- Use statistical methodology to check the quality of the different types of data collected, and analyze them
- Understand how reliable the data are, and explore various types of data issues such as missing data, outliers and inconsistent data
- Explore the use of machine learning to leverage historical databases to explore patterns in new datasets
- Understand how to arrive at signals that are truly signals and not artefacts

A former FDA Investigator's perspective in quality risk management and technology implementation in clinical trials

Hear about the activities associated with the FDA's review of clinical trial data used to support marketing applications

- Learn about the direct implications on selecting clinical investigator sites for inspection, conducting inspections, and evaluating inspection results
- Discover the previous use of the Risk Based Site Selection Tool and Technology will be shared during this presentation

Jonathan Helfgott,
Professor, **Johns Hopkins,** *Former Associate Director for Risk Science, Intelligence & Prioritization,* **FDA**

SESSION 5:

Optimize your information exchange

Reducing your Queries

- Learn how to get the data transferred electronically from the site to the sponsor
- Best practices to estimate the number of edit checks needed before starting the study
- Integration of technology system to make the site/ sponsor exchange of data more efficient and reduce the layers (Pharma ->CRA->Site-> Monitors->CRA->Pharma)

Christine Pierre,
President, **Society of Clinical Research Sites (SCRS)**

Panel Discussion: Leveraging an all-stakeholder technology platform for clinical trials

- Sense the power and innovative capabilities of multi-stakeholder connectivity, inter-operability, and security.
- Understand the role of a collaborative IT Platform in a System for conducting clinical research that does not currently exist
- Hear about the value for data storage and exchange, as well as performance, regulatory and ethical analytic capability
- Discover The "Apollo" Model

Panel organizer
Scott Lowry,
CEO, **HealthIDx**

TransCelerate BioPharma: Transformation of Protocols from Paper to a Digital Platform

- Learn about TransCelerate's Common Protocol Template Initiative is working with industry stakeholders and regulators to create a model clinical trial protocol template containing a common structure and model language.
- Hear about how the model utilize libraries to facilitate common language in areas specific to patient population and therapeutic areas.
- Discover the common protocol template is a foundational element in the longer-term movement towards an electronic protocol.
- Find out how this industry-changing effort will benefit sponsors, sites, regulators and patients.

Rob DiCicco,
Vice President, Clinical Innovation & Digital Platform Performance Unit, **GSK**

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Registration: choose your pass type

SAVE $300

if you register before February 26th

GOLD PASS

- Exclusive Access to the PDF files of speakers' presentations
- Receive complete audio recordings of the entire conference
- Including 4 week premium subscription to eyeforpharma On Demand with access to recordings for all our events in 2013, 2014 and 2015 plus exclusive Premium Reports. More info: www.eyeforpharma.com/subscription
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STANDARD PRICE	$2195	$1995

FOR SOLUTION PROVIDERS & CONSULTANTS		
SUPER EARLY BIRD **SAVE $500** (exp. Jan 29th)	$1995	$1795
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Opportunities for solution providers

BUSINESS OPPORTUNITIES INCLUDE:

- 1-to-1 meetings with key decision makers
- Demonstrate thought leadership to a room of senior level executives
- Show off your latest products and services in our exhibition hall
- Build your brand with exclusive promotional opportunities
- Host interactive workshops with core clients and prospects...

and much more!

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Roche, the FDA, GSK, and others are joining their forces to **Revolutionize Clinical Trials**

Exclusively at Data Quality & Technology in Clinical Trials 2016

Philadelphia / 18 - 19 April 2016

Visit us on: **www.eyeforpharma.com/data-clinical**

Overcome regulatory Burden

Be a part of the first clinical summit where the FDA will share their views on new type of patient data and when the insight generated cross regulatory lines

Immo Zadezensky,
Clinical Pharmacologist, Professional Affairs and Stakeholders Engagement,
FDA

Redefine your culture

Hear from a unique C level keynote panel about how to best use your data on implement strategic decision on designing and managing your trials

Alan Wright,
Chief Medical Officer,
Roche

Collaborate with your peers and stakeholders

Pioneer the industry movement toward a collaborative mindset and exclusively hear from **TransCelerate** and **ACRES,** about the brand new platforms that will change the face for the clinical trial enterprise

Robert DiCicco,
Vice President, Clinical Innovation & Digital Platform Performance Unit,
GSK

Visit us on: www.eyeforpharma.com/data-clinical