Managing Late Stage Research and Observational Studies: Strategies and Technologies to Enable Non-Interventional Studies

Conference Highlights
- Enhance product development by creating synergy between observational and clinical trials
- Build customer engagement models that address needs of payers, health care providers and patients
- Overcome the challenges of building value propositions with RWD for a value-focused healthcare system

Leveraging Real World Data for Clinical and Observational Research: Integrating Evidence Generation with RWD

Conference Highlights
- Digital healthcare to impact pharmaceutical development
- Utilize EHRs and digital data capture to optimize peri-approval studies
- Real world evidence generation case studies from top pharma companies

Featured Speakers
- Cathy Critchlow, Ph.D., Executive Director, Amgen Center for Observational Research
- Riad Dirani, Ph.D., Vice President, Global Health Economics and Outcomes Research (GHEOR), Teva Pharmaceuticals
- Sean Zhao, M.D., Head, US Patient Safety Surveillance, AstraZeneca
- Andrew Roddam, Ph.D., Vice President & Head, Real World Evidence and Epidemiology, R&D Projects, Clinical Platforms & Sciences, GSK
- Hui Cao, M.D., Ph.D., Executive Director, Real-World Evidence for Respiratory, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation
- Usman Iqbal, M.D., Senior Medical Affairs Leader, Neuroscience, Global Medical Affairs, AstraZeneca

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January 24-25

January 25-26

Part of SCOPEsummit.com

January 24-26, 2017
Hyatt Regency Miami
Miami, FL
Event At-a-Glance

Monday, January 23
PM
Pre-Conference Short Courses (Optional, Separate Registration Required)
2:00 pm – 6:00 pm

SC1: Social Media, Digital Marketing, and Technology Growth Hacks to Enroll Patients Faster

SC2: How to Implement Risk-Based Monitoring on a Budget

SC3: Clinical Trial Protocol Optimization

SC4: Managing Clinical Trials in Oncology and Immuno-Oncology

SC5: Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract

SC6: How to Accelerate Digital Health Innovation in Your Company

Welcome and Networking Happy Hour on the Patio
6:30 pm - 8:30 pm
Hyatt Regency Miami’s Riverwalk Terrace

Tuesday, January 24
AM & PM

Conference 1A
Protocol Development, Global Site Selection, Feasibility, and Site Management

Conference 2A
Enrollment Planning and Patient Recruitment

Conference 3A
Clinical Trial Forecasting and Budgeting

Conference 4A
Establishing an Outsourcing Strategy

Conference 5A
Implementing Risk-Based Monitoring (Part 1)

Conference 6A
Clinical Data Strategy and Analytics

Conference 7A
Managing Late Stage Research and Observational Studies

Symposium 8A
Managing Precision Medicine Trials: Biomarker and Genomics Considerations

Wednesday, January 25
AM

Conference 1B
Improving Site-Study Activation and Performance

Conference 2B
Patient Engagement, Enrollment and Retention through Communities and Tech

Conference 3B
Managing Outsourced Clinical Trials

Conference 5B
Implementing Risk-Based Monitoring (Part 2)

Conference 6B
Clinical Technology and Innovation

Conference 7B
Leveraging Real World Data for Clinical and Observational Research

Symposium 8B
Sample, Lab and Diagnostics Services in Clinical Trials

Thursday, January 26
AM & PM

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Non-interventional studies are an integral part of product development plans. Product safety profiles, comparative effectiveness data as well as health economic evidence obtained from non-interventional studies, are essential for multiple stakeholders. These stakeholders include but are not limited to regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, healthcare professionals, and patients. Cambridge Healthtech Institute's Sixth Annual Managing Late Stage Research and Observational Studies conference is designed to facilitate knowledge exchange around all aspects of observational research from the designing and managing of post-approval studies, to applying the obtained data to pivotal business and medical decisions. Similarities and differences between clinical and observational studies will be addressed by the top industry experts.

Monday, January 23

1:00 pm Short Course Registration

Recommended Short Course*

2:00 – 6:00 pm Implementing Social Media, Digital Marketing, and Other New Strategies for Patient Recruitment

* Separate registration required; visit our website for full details

2:00 – 6:45 pm Main Conference Registration

6:30 – 8:30 pm Welcome and Networking Happy Hour on the Patio hosted by CHI, Drug Dev, INC Research and Praxis

Tuesday, January 24

7:30 am Registration and Morning Coffee

8:20 Opening Plenary Keynotes

9:45 Grand Opening Coffee Break in the Exhibit Hall

Why and How of Observational Research

10:45 Chairperson’s Remarks

Rachel Edwards, Ph.D., Executive Director, Global Clinical Program Management, Amgen US

10:50 keynote: Synergy between Observational and Clinical Studies

Cathy Critchlow, Ph.D., Vice President, Amgen Center for Observational Research

To fully capitalize on the value and efficiencies created by an optimal portfolio of observational and clinical studies, organizational challenges due to processes associated with study design, execution and reporting that were originally created to support randomized clinical trials must be recognized and resolved. Organizational opportunities resulting from the synergies between observational and clinical studies will be discussed.

11:15 Generating Value for All Key Stakeholder: Defining Value for Patients, Assessors, Payers & Providers

Julie C. Locklear, PharmD, MBA, Vice President & Head, Health Economics & Outcomes Research, EMD Serono

11:40 Monitoring Post-Marketing Studies: Specific Features and Requirements

Rachel Edwards, Ph.D., Executive Director, Global Clinical Program Management, Amgen US

Variability in data quality and standard of evidence required drive decisions regarding the type of study monitoring needed to assure study validity, for example, fully monitored versus another model such as risk-based monitoring or real life data review. The challenges associated with trying to assure ‘fit-for-purpose’ study design and execution, including monitoring to best support study and organizational objectives, will be discussed.

12:05 pm Harnessing the Power of Real-World Data for Enhanced Real-World Study Design and Delivery

Louise Parmenter, Vice President, Epidemiology, Real World Insights, QuintilesIMS

Using real-world insights can improve study design and impact the execution and outcomes of real-world observational studies and pragmatic clinical trials. Real-world data enables optimizing the study protocol by quantifying the number of patients who meet the inclusion/exclusion criteria, ensuring that required metrics are being captured during routine care and identifying areas of risk due to under-reporting/capture of key clinical measures. Insights from RWD allow for a more accurate forecast of time to recruit, using information on patient density at physician sites and the frequency of visits, which ensures greater precision over investigator estimates. Using a data driven approach during the study planning process can improve clinical research efficiency.

12:40 Luncheon Presentation: Managed Access Programs: Design and Operational Considerations to Maximize Value

Peggy Schrammel, Vice President, APAC and Scientific Affairs, PAREXEL ACCESS, PAREXEL

Managed Access Programs (MAPs), also known as Compassionate Use, Named Patient Programs or Expanded Access, are growing in popularity, not only as a means of providing life-saving investigational therapies to needy patient populations, but also as a vital piece of the commercialization strategy. As these programs are not mandated, knowing how to design and effectively execute these programs to bring maximum value to a variety of stakeholders is key. This session will explore elements of successful design, key operational strategies that minimize cost while providing a positive investigator and patient experience, and how small additions to a core MAP strategy can be useful in supporting upcoming product commercialization goals.

1:20 Coffee and Dessert in the Exhibit Hall

Strategizing Peri-Approval Research

2:00 Chairperson’s Remarks

Melva Covington, Ph.D., Senior Director, Strategy Lead, Sanofi Field Medical

2:05 Synergies in the Operationalization of Clinical and Observational Studies

Mark A. Price, MA, MEd, Senior Director, Surveys and Observational Studies, RTI Health Solutions

Lynne Hamm, Senior Director, Clinical & Medical Services, RTI Health Solutions

While randomized controlled trials are the gold standard for evaluating drug safety and efficacy, observational studies have become increasingly important in recent years to generate real world data on burden of illness, treatment patterns, health care resource utilization, safety outcomes, treatment effectiveness, adherence, and health-related quality of life among other things. This presentation will explore these differences as well as synergies and lessons learned that could benefit scientists engaged in both clinical and observational research.

2:30 Strategic Approaches to Building Customer Engagement Models: Creating Synergizes in Real World Outcomes and Clinical Trial Evidence for Value

Melva Covington, Ph.D., Senior Director, Strategy Lead, Sanofi Field Medical

This presentation will cover several key topics such as approaches to strategic planning and environment assessment to build customer engagement models that address scientific needs of payors, health care providers and patients, understanding how to navigate the risks and uncertainties to maximize engagement outcomes, leverage scientific information for alignment in a matrix environment and with external stakeholders; and build effective performance standards to evaluate impact and measure success of models.

SCOPE Summit for Clinical Ops Executives
Managing Late Stage Research and Observational Studies: Strategies and Technologies to Enable Non-Interventional Studies

January 24-25, 2017

2:55 PANEL DISCUSSION: Meeting the Evidentiary Needs of Multiple Stakeholders by Better Non-Interventional Studies
Moderator: Cathy Critchlow, Ph.D., Vice President, Amgen Center for Observational Research

Topics to be discussed include but are not limited to the following:

- What are key considerations and approaches to balance scientific and commercial values of non-interventional studies?
- What are common utilization of non-interventional studies in supporting clinical development programs?
- How can evidences generated from non-interventional studies be used in discussions with regulatory agencies during product development and post-marketing in support of establishing product benefit risk profile, continual safety monitoring, and risk management and mitigation activities, as well as fulfilling regulatory post-marketing safety requirement (PMRs and FUMs)?

3:20 Managing Late Stage Research, Observation Studies & Registries
Christina Fawcett, PMP, Director of US Operations, Late Phase Services, PRA Health Sciences

The heterogeneity of late-phase study designs, combined with an increased use of alternative monitoring strategies and an evolving regulatory framework collectively warrants careful operational planning. Early consultation and alignment of stakeholder groups to define protocol-specific study goals and data use, the regulatory strategy to be employed, and clinical rigor to be implemented under ICH/GxP guidances are key considerations. Increasingly, innovative patient-facing technologies are being integrated into global late-phase study designs to support streamlined data capture, reduce stakeholder burden, and increase value creation. The intersection of these operational parameters will be discussed.

3:55 Find Your Table and Meet Your Moderator

4:00 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and format please come prepared to share examples from your work, yet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation: eConsent: Put “Informed” Back in Informed Patient Consent
Eric Delente, President, Patient Solutions, DrugDev; Co-founder of SecureConsent (Part of DrugDev)

Electronic informed consent makes the consenting process more efficient and effective for staff, sponsors, monitors, and most importantly patients by presenting the information in formats and language in which patients are comfortable. Join us for breakfast to learn the best practices, latest technological advances, and proven benefits of deploying an eConsent solution - including the impact it has on improving patient satisfaction and retention and help us put “informed” back in patient consent process.

RWD IN OBSERVATIONAL STUDIES

8:25 Chairperson's Remarks
William Spalding, Ph.D., Director, Epidemiology Lead in Global Health Economics and Outcomes Research and Epidemiology, Shire

8:30 Building Differentiated Value Propositions in an Evolving Environment
Riad Dirani, Ph.D., Vice President, Global Health Economics and Outcomes Research (GHEOR), Teva Pharmaceuticals

With the continued shift towards a value-focused healthcare system, it has become even more critical for pharma companies to build solid value propositions for their products and offerings. An important component of this approach is developing a sound, scientifically robust research program utilizing real-world evidence (RWE) as well as P4 planning in the peri-launch phase. This presentation will provide an overview of this approach and examples of its application.

8:55 Opportunities and Challenges in the Use of RWE to Support Product Value Propositions
William Spalding, Ph.D., Director, Epidemiology Lead in Global Health Economics and Outcomes Research and Epidemiology, Shire

Data sources for RWE studies have evolved from use of administrative claims databases to assess disease burden and treatment outcomes, to use of de-identified electronic health records that include contextualized physician notes. While EHR provides a robust data source that goes beyond what is available via administrative claims, there are their own unique methodological challenges. This talk will focus on some of these challenges, and explore potential next-step evolution in RWE originating out of EHR studies.

9:20 Patient Access and Outreach: The Role of Disease Foundations to Secure and Manage Real World Data
Ginger Spitz, Executive Director, Foundation of Sarcoidosis Research

This presentation will focus on the valuable role of non-profit disease research foundations in securing and managing real world data through patient registries, clinical trial network, and recruitment. Given the “neutral third party” status of these non-profit organizations, issues in compliance and logistics can be navigated more easily. In addition, unlike CROs, foundations are more likely to provide viable and applicable patient information and outreach. This presentation will discuss registries, patient member databases, networks, social media outreach, and other techniques for securing and managing data.

9:45 Optimizing Operations in Post-Approval Research Requires a New Way of Thinking
Kirsten Colling, Senior Director Global Operations, Post-Approval Research, Bioclinica

Post-approval research studies are becoming increasingly large and complex in the post-approval clinical research landscape. With the pressing need to obtain real-world data, assess product safety profiles, and support the full span of a product's lifecycle, the ability to conduct efficient, cost-effective post approval studies is more important than ever. It's time to bring post-approval operational strategies into the 21st century.

10:10 Coffee Break in the Exhibit Hall

CONTINUITY OF PHARMACOVIGILANCE EFFORTS IN CLINICAL AND OBSERVATIONAL STUDIES

11:10 Chairperson's Remarks
Sean Zhao, M.D., Head, US Patient Safety Surveillance, AstraZeneca
11:15 Strategic and Practical Considerations in Combining Clinical Trials and Observational Studies for Product Safety Profile Assessment
Sean Zhao, M.D., Head, US Patient Safety Surveillance, AstraZeneca
By combining clinical trials and observational studies, pharmaceutical companies may be able to overcome above limitations and challenges, to effectively and efficiently assess product safety profile and to fulfill regulatory post-marketing safety requirements in the early phase of product marketing. This presentation will discuss strategic thinking and practical considerations in how to combine clinical trials and observational studies to assess product risk profile during early phase of product marketing.

11:40 Leveraging Real-World Observational Data for Safety Contextualization throughout a Product’s Life Cycle: A Case Study
Jamie Geier, Ph.D., Epidemiology, Pfizer
While many randomized clinical trials include at least one control group, the size of the control groups and duration of treatment may not permit precise comparative assessments for adverse events with low frequency or long latency. The use of indirect comparative methods can provide such context, but must take into account potential differences in the populations compared whose characteristics may vary. Data from observational sources can be used to provide these comparisons. This discussion will highlight approaches to address the strengths and weaknesses of observational data sources via a case study.

12:10 pm Bridging Luncheon Co-Presentation: Leveraging Educational Materials in the Site and Patient Engagement for Observational Research
Heather Gartman, Regional Managing Director, Public Relations Group, inVentiv Health
Julie Randolph, Ph.D., Project Director, Phase IV Operations, inVentiv Health
Researchers must be highly attuned to an increasingly engaged, well-informed, and metric savvy patient population. Developing meaningful research relationships with patients drives successful real-world evidence generation.
- Spark patient interest in observational research opportunities by demonstrating participation value
- Explore physician-patient connectivity strategies driving ongoing engagement
- Strengthen patient-site relationships via multiple points-of-contact
- Analyze patient feedback from recent clinical research experience

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference
Stay on and attend Part 2: Leveraging Real World Data for Clinical and Observational Research. See page 7 for details.
The abundance of data generated during routine health care is growing in significance and should be re-used for clinical and observational research. Patient electronic records, registries, insurance claims, data from pharmacy and social media, and electronic patient-reported outcomes have become increasingly used as eSources. This process requires strategizing, utilizing novel data technologies, as well as close collaboration between pharmaceutical companies and organizations that possess the data. CHI’s 2nd Annual Leveraging Real World Data for Clinical and Observational Research will discuss challenges and solutions with secondary use of existing healthcare data for assessing the effectiveness and safety of medical products. 

Arrive early and attend Part 1: Managing Late Stage Research and Observational Studies. See page 4 for details.

**WEDNESDAY, JANUARY 25**

12:10 pm **Bridging Luncheon Co-Presentation: Leveraging Educational Materials in the Site and Patient Engagement for Observational Research**

Heather Gartman, Regional Managing Director, Public Relations Group, inVentiv Health

Lisa Mummert, Senior Director, Program Delivery, inVentiv Health

Researchers must be highly attuned to an increasingly engaged, well-informed, and metric savvy patient population. Developing meaningful research relationships with patients drives successful real-world evidence generation.

- Spark patient interest in observational research opportunities by demonstrating participation value
- Explore physician-patient connectivity strategies driving ongoing engagement
- Strengthen patient-site relationships via multiple points-of-contact
- Analyze patient feedback from recent clinical research experience

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

**RWD TO INFORM TRIAL DESIGN**

4:00 **Chairperson’s Remarks**

Hui Cao, M.D., Ph.D., Executive Director, Real World Evidence for Respiratory, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation

4:05 **Systematic Approach to Use RWD to Inform Trial Design: Going beyond Simple Feasibility**

Hui Cao, M.D., Ph.D., Executive Director, Real-World Evidence for Respiratory, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation

The use of Real World Data (RWD) to optimize trial design has been widely recognized. However, the majority of work in this area has been providing simply trial feasibility, i.e., patient counts based on the inclusion and exclusion criteria. We will present our ground-breaking pilot work that goes beyond the feasibility and applies a structured, systematic approach to assess the impact of each item in the trial criteria on recruitability, efficacy endpoints and risk. The combined insights will allow the trial team to design a clinical trial that could include most real-world patients without compromising the efficacy and increasing the potential risks.

4:30 **Impact of ICD-10 Transition on Conducting Retrospective Observational Database Studies and Pragmatic Clinical Trials**

Rebecca Levin, MPH, Senior Research Scientist, UBC

U.S. healthcare providers are now required to use the ICD-10-CM version of the WHO’s disease classification which offers a substantial increase in the number and specificity of disease and procedure codes over ICD-9-CM. Our presentation will explain significant enhancements with ICD-10 and describe the strengths and limitations of available mapping tools to translate between ICD-9 and ICD-10 codes.

4:55 **Empowered Patients + Electronic Health Records + Data Access = Transformational Opportunity for Research**

Craig Lipset, Head of Clinical Innovation, Pfizer

The White House Precision Medicine Initiative provided funding for Sync for Science, with commitments from the largest EHR vendors to support such patient-centered data movement for research. Even the most recent iOS update from Apple is creating enabling opportunities, as HealthKit can now enable consumers to load and share their EHR data. Enabling this future state brings benefits for all stakeholders in the research ecosystem, from research sponsors to the patients looking to participate in finding new cures.

5:30 **INTERACTIVE PANEL: RWD to Inform Trial Design**

Moderator: Jane Fang, M.D., Head, Research & Development Information and Analytics for Clinical Biologics, AstraZeneca/Immunimmune

Panelists:

Hui Cao, M.D., Ph.D., Executive Director, Real-World Evidence for Respiratory, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation

Kyle Flickinger, Vice President, Clinical Markets, HealthVerity

Qin Ye, M.D., MS, Associate Principle, R&D Excellence, ZS Associates

5:45 Reception hosted by Exostar

**THURSDAY, JANUARY 26**

7:30 am **Registration**

7:45 Breakfast Co-Presentation: The Inspiring Hope Ideathon: Solving the Clinical Trial Awareness Gap

Christine Phillips, Senior Director, Site & Patient Access, INC Research

Angela Radcliffe, Executive Vice President, Senior Leadership, FCBVIO

To advance society’s ability to respond to future healthcare challenges and advance medical innovation we must increase awareness of clinical research and study participation. Clinical research is vital to the development of new drugs and treatments but is dependent on patient participation. The “Inspiring Hope Ideathon” was the first initiative of its kind designed to generate new and unique ideas. The participation and results were groundbreaking and will be shared here!

**INTEGRATING EVIDENCE GENERATION WITH RWD**

8:35 **Chairperson’s Remarks**

Jyotsna Mehta, MS, B.Pharm., Director, Economics Value Evidence and Outcomes, Alkermes, Inc.

8:40 **From Efficacy to Effectiveness: Studying the Effects of Medicines in Usual Care Settings**

Andrew Roddam, Ph.D., Vice President & Head, Real World Evidence and Epidemiology, R&D Projects, Clinical Platforms & Sciences, GSK

This talk will discuss the opportunities available to study the effects of medicines in more usual care settings than is typical in controlled clinical trials. We will discuss the challenges encountered in trying to design and operationalise such studies as well as discussing the opportunities presented by the ability to utilise technologies such as EHRs and digital data capture to make the experience more real-life for patients and physicians.

9:05 **Expanding Insight into Real World Oncology Practice through Linked Datasets**

Elizabeth MacLean, Pharm.D., Director, Global Health and Value/Outcomes & Evidence, Pfizer

Prescription records alone provide limited information on patient characteristics and other treatment experience. However, linking datasets can...
broaden insight into patient, provider and reimbursement characteristics. This presentation will discuss the experience of linking a de-identified specialty pharmacy database with de-identified medical and pharmacy databases to examine real world use of axitinib in patients with renal cell carcinoma.

9:30 Leverage RWE Data in Clinical Trial Protocol Design and Site/PI Selection
Jane Fang, M.D., Head, R&D Information and Analytics for Clinical Biologies, AstraZeneca/Medimmune
This presentation will provide use case examples on how to use real world evidence data and trial competition analytics to optimize clinical trial protocol development, patient population identification, patient recruitment and site/PI selection. The talk will also cover the strategy and business adoption to use RWE and trial competition information in today’s drug clinical pipeline development.

9:55 The “How” and “Why” of Leveraging Real World Data for Clinical and Observational Research
Amy Ryan, M.S., Director of Biostatistics, Phase IV Operations, inVentiv Health
Data from the real world shows what is actually going on in regular clinical practice. Some would say this data, often “messy”, and offers no real value in health outcomes research. This is not the case. The usefulness of the data is that it reflects our uncontrolled real world experiences. Knowing when to use this data is very important, but also knowing how to use this data is the true key to its value.

10:20 Coffee Break

INTEGRATING EVIDENCE GENERATION WITH RWD (CONT.)

10:35 Chairperson’s Remarks
Kelly Zou, Ph.D., PStat®, Senior Director and Analytic Science Lead, Real World Data & Analytics (RWDnA), Global Health & Value (GH&V), Pfizer, Inc.

10:40 Approaches and Methodologies to Develop High Quality Databases and Real World Evidence (RWE) Ecosystem for Observational Research
Jyotsna Mehta, MS, B.Pharm., Director, Economics Value Evidence and Outcomes, Alkermes, Inc.
Building a powerful platform of real-world data (RWD) is essential to providing leading-edge clinical, medical and commercial insights to the entire organization. However, developing meaningful and high quality databases warrants application of intricate data science that entails the ability to link detailed patient characteristics and information flows across different data sets to create a singular de-identified architecture, and provide a complete 360 degree view of the health care ecosystem.

11:05 Applying the OMOP Data Model & OHDSI Software to National European Health Data Registries: The IMI EMIF Project
Kees Van Bochove, MSc, CEO, The Hyve
A large open source initiative for standardisation and epidemiological analysis for real world data is OHDSI: Observational Health Data Sciences and Informatics. OHDSI leverages the OMOP common data model for observational data, and provides data analysis tools for a broad range of use cases. This talk will explain OMOP and OHDSI with case study IMI EMIF, in which health data from over 30 million patients from 13 national and regional European registries is brought together.

11:35 Accessing and Generating Real-World Evidence via DataMart and Distributed Research Network
Kelly Zou, Ph.D., PStat®, Senior Director and Analytic Science Lead, Real World Data & Analytics (RWDnA), Global Health & Value (GH&V), Pfizer, Inc.
A Real-World DataMart contains claims and transactions for healthcare resource utilization, electronic health records, surveys, linked datasets and other digital data collected outside a traditional clinical trial. To enhance the effectiveness and efficiency of health care delivery, it is important to understand risk factors for disease progression, treatment patterns, and utilization. Fruitful collaborative research opportunities exist across different healthcare stakeholders including academia, industry and government. A distributed research network is useful for generating real-world evidence. Examples on collaborative observational studies are illustrated.

12:00 pm Extracting Additional Value from Clinical Data
Edward Bowen, Head, Data Science and Solutions, GSK
TransCelerate is leading a collaboration across 12 companies to share placebo and standard-of-care (PSOC) clinical data for secondary research. Realized use cases include developing a standing safety cohort for providing context around SAEs observed in ongoing trials, and using data from prior trials to reduce the number of patients in new proof-of-concept trials. This discussion will discuss use cases for PSOC data, challenges around data sharing, successes to date, and important patient benefits.

12:25 Addressing the Critical Pieces in Utilizing Real World Patient Data, Key Success Factors of Evidence Generation
Kyle Flickinger, Vice President, Clinical Markets, HealthVerity
Tim McGarty, MBA, Global Category Manager, Digital Development, eCOA, PR&I, Novartis
Dave Billiter, MBA, Director-Data Strategy & Product Development, Specialty Solutions, Cardinal Health
Qin Ye, M.D., MS, Associate Principle, R&D Excellence, ZS Associates
This presentation will focus on the key aspects of RWD evidence generation and how both clinical and observational can utilize the same patient

Attention Pharma! 25 for 25 Special Offer
If you are an employee of the following TOP 25 Pharmaceutical companies as cited by Contract Pharma*, you may attend this meeting at a 25% discount off the current rate.

Group registrations are encouraged and we suggest calling:

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14 Bristol-Myers Squibb
15 Boehringer Ingelheim
16 Takeda
17 Novo Nordisk
18 Allergan
19 Bayer
20 Merck KGaA
21 Otsuka
22 Biogen
23 Mylan
24 Celgene
25 Daiichi Sankyo

* http://www.contractpharma.com/heaps/view/26071/
population. In the absence of a persistent common patient identifier, data linkage, and data discovery, has become one of the rate limiting steps in both de-identifiable and identifiable RWE use cases. Early data linkage directly from the data source at the patient level can provide a more complete view of a patient’s medical information and allow researchers the transparency to target the specific patient population & data required for a RWD analytics.

12:50 Closing Remarks

12:55 SCOPE 2017 Conference Adjourns (see you in Orlando for 2018!)
## Pricing and Registration Information

### CONFERENCE PRICING

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
<th>Academic, Government, Hospital-affiliated</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BEST VALUE!</strong> (Does not include access to pre-conference short courses)</td>
<td>$2,849</td>
<td>$1,349</td>
</tr>
<tr>
<td>Registration after December 23, 2016, and on-site</td>
<td>$2,849</td>
<td>$1,349</td>
</tr>
<tr>
<td><strong>BASIC CONFERENCE PRICING</strong> (Does not include access to pre-conference short courses)</td>
<td>$1,899</td>
<td>$1,025</td>
</tr>
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</tr>
</tbody>
</table>

### ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/Cancellations Policy, go to healthtech.com/regdetails

Video and or audio recording of any kind is prohibited onsite at all CHI events.

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### CONFERENCE DISCOUNTS

**Alumni Discount - SAVE 20%**: CHI appreciates your past participation at Summit for Clinical Ops Executives (SCOPE). As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

- **Alumni Discount**
  - 20% Off
- **SAFE BioPharma Association membership discount**
  - 10% Off

**REGISTER 3 - 4th IS FREE**: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

**Group Discounts**: Discounts are available for multiple attendees from the same organization. For more information on group rates contact Melissa Dolen at 781-972-5418.

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If you are unable to attend but would like to purchase the Summit for Clinical Ops Executives (SCOPE) CD for $750 (plus shipping), please visit SCOPEsummit.com. Massachusetts delivery will include sales tax.

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How to Register: **SCOPEsummit.com**

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please refer to the Registration Code below: