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# Patient Registries, Real World Evidence and HEOR

Improve Outcomes through Innovative Analysis and Application of Patient Data

JANUARY 27-28, 2020 • MIAMI MARRIOTT BISCAYNE BAY • MIAMI, FL

Customize Your Conference Experience by Choosing from Three Comprehensive Tracks

## TRACK 1

### REGISTRY DEVELOPMENT AND ADVANCEMENT

TRACK CHAIR:



W. Benjamin Nowell, Ph.D.,  
Director, Patient-Centered Research,  
Global Healthy Living Foundation

## TRACK 2

### REAL WORLD EVIDENCE UTILIZATION

TRACK CHAIR:



Charles Makin, BS Pharm, MS, MBA, MM,  
Global Head, Real World Evidence Strategy,  
Biogen

## TRACK 3

### HEOR AND VALUE DEMONSTRATION

TRACK CHAIR:



Rami Ben-Joseph, Ph.D.,  
Global Value Leader,  
Jazz Pharmaceuticals

Dynamic, Multi-Stakeholder Perspectives from Key Thought-Leaders, Including:

## CONFERENCE CHAIR



J. Alexander Cole, DSc, MPH  
Executive Director and Global Head,  
Epidemiology, **Alexion Pharmaceuticals**



Athula Herath,  
Global Head Real World Evidence  
Epidemiology, **Novartis**



Terrie Livingston, PharmD, Head of  
Patient Outcomes and Solutions, North  
America Medical Affairs, **EMD Serono**



Cristina Masseria,  
Methods and Capabilities Lead, PHI,  
**Pfizer**



Jefferson Tea, Vice President,  
Medical & Scientific Affairs,  
**Takeda Canada**



Randel Plant,  
Director of Research Administration,  
**Alpha-1**



Boxiong Tang, M.D., Ph.D.,  
Senior Director, Health Economics and  
Outcomes Research (HEOR), **BeiGene**



Monica Weldon, Founder/CEO,  
**Bridge the Gap — SYNGAP Education**  
and Research Foundation

Additional Perspectives from:

NORD • Global Genes • HealthEconomics.com • Takeda Canada • Duke University Medical Center • Geisinger



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Informa Connect-CBI's **Patient Registries, Real World Evidence and HEOR** is the industry's premier forum for navigating complexities and optimize strategies relating to the collection and utilization of patient data. Diving deep into case studies and conversations across three tracks dedicated to registry advancement, RWE interpretation and value demonstration with HEOR, this program provides a unique opportunity to benchmark with peers and gain best practices for improving quality of treatments and outcomes for patients. Benefit from critical discussions on the evolving regulatory landscape and novel methods for data collection and interpretation, as well as strategies for ensuring patient involvement across the lifecycle.

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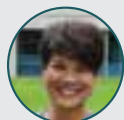
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Cristina Masseria, Methods and Capabilities Lead, PHI, **Pfizer**



Charles Makin, BS Pharm, MS, MBA, MM, Global Head, Real World Evidence Strategy, **Biogen**



Terrie Livingston, PharmD, Head of Patient Outcomes and Solutions, North America Medical Affairs, **EMD Serono**



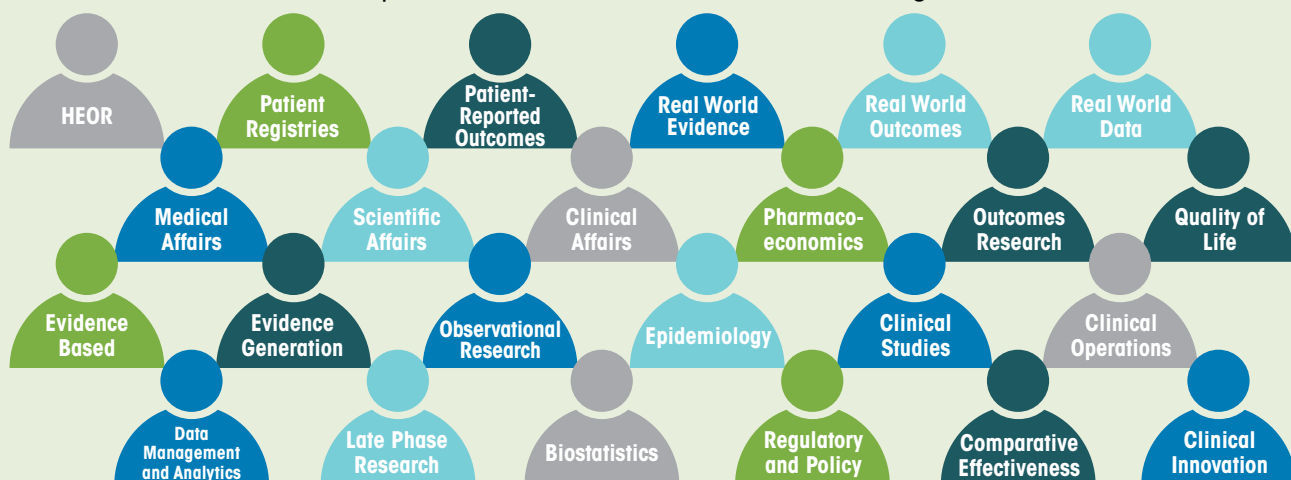
Pat Furlong, Founding President and CEO, **Parent Project Muscular Dystrophy (PPMD)**



James Patrick, PharmD, MS, MPA, Sr. Regional MSL, HEOR Lead West — Rare Disease, **Strongbridge Biopharma plc**

## WHO SHOULD ATTEND:

You will benefit from attending this event if you are from a pharmaceutical, biotechnology or medical device company, patient advocacy organization, foundation or specialty association with responsibilities or involvement in the following areas:



# DAY ONE

MONDAY, JANUARY 27, 2020

7:00 *Registration and Continental Breakfast*

8:00 *Chairperson's Welcome and Opening Remarks*

*J. Alexander Cole, DSc, MPH, Executive Director and Global Head, Epidemiology, Alexion Pharmaceuticals*

8:15 **KEYNOTE ADDRESS**

## Real World Data is Not a Dartboard

- The emphasis on RWE has resulted in a proliferation of data sources across the globe
- This has encouraged end users and data enthusiasts to mine RWD for informational nuggets
- However, RWD will lead to meaningful business solutions only by first formulating value statements and identifying attendant data gaps

*Charles Makin, BS Pharm, MS, MBA, MM, Global Head, Real World Evidence Strategy, Biogen*

9:00 **Getting to High-Quality Real-World Data and Applying it to RWE**

- Getting to the data that matters
- Making RWD research grade
- Applying it effectively across the product lifecycle

*Richard Gliklich, M.D., CEO, OM1*

9:45 *Networking and Refreshment Break*

10:15 **Virtual Research — What It Is and What It's Doing in the Real-World Setting**

- Virtual research is the subject of intense discussion, but consensus has yet to be reached on precisely what it is and how it is to be implemented
- Surveys of biopharmaceutical companies reveal a reluctance to implement virtual designs in their clinical trial programs, viewing the real-world setting as an alternative to test out innovative approaches to data capture
- Clarify what virtual research is, what kinds of virtual designs are being implemented in the real-world setting and what all this means for those interested in real-world evidence generation

*David Thompson, Ph.D., Senior Vice President, Real World and Late Phase, Syneos Health*



## Data Governance and Sharing Opportunities for Stakeholders

11:00 **Navigate Health Data Governance to Improve Treatments and Outcomes**



**PANEL**

- Identify silos in the data ecosystem and their implications on clinical outcomes
- Assess priorities of different industry stakeholders including pharma, patients, payers and regulators
- Evaluate challenges and opportunities for collaborative data sharing

### **MODERATOR:**

*Donovan Quill, President and CEO, OptimeCare*

### **PANELISTS:**

*Candace Lerman, Esq., Attorney/Patient Advocate, Lerman Law Firm*

*Randel Plant, Director of Research Administration, Alpha-1*

*Christian Rubio, Vice President of Strategic Advancement, Community Development and Engagement, Global Genes*

12:00 *Networking Luncheon*



## Navigate the Evolving Regulatory Landscape of Data Collection and Application

1:00 **Global Perspective and Outlook on Registries and RWE**



**Case Studies**

- Compare the regulatory and clinical landscapes of the US, Canada, EU and Asia regarding RWE and registry use
- Evaluate the emergence of common standards for data privacy
- Consider the future of RWE on a global scale

*Jefferson Tea, Vice President, Medical & Scientific Affairs, Takeda Canada*

1:45 **Scientific Registries as a Validated Methodology and Source for Regulatory Safety Studies**

This session will highlight the use of registries for regulatory purposes and will focus on the following areas:

- The spectrum of registries and the varying challenges and benefits
- Leveraging and analyzing existing, heterogeneous registry data
- Establishing regulatory grade registries using unique prospective approaches

*Michael R. Fronstin, Global Head of Innovation, RWE, Kantar*

2:45 *Networking and Refreshment Break*

## 3:15 CHOOSE FROM 3 CONCURRENT TRACKS (1-3)

## TRACK 1

## REGISTRY DEVELOPMENT AND ADVANCEMENT

### *Building and Maintaining Patient Registries*

3:15 *Track Chair's Opening Remarks*

W. Benjamin Nowell, Ph.D., Director,  
Patient-Centered Research,  
Global Healthy Living Foundation

### 3:30 **From Competition to Collaboration — Improving Industry Habits for Funding and Sustaining Registries**

- Outline financial demands and challenges of registry launch and maintenance
- Assess the fragmented state of industry and the resulting challenges for patients and the broader community
- Highlight more creative and efficient strategies for registry sustainability, including community participation and more

Monica Weldon, Founder/CEO,  
Bridge the Gap – SYNGAP  
Education and Research  
Foundation

### 4:15 **Strategies for Data Sharing Patient Registries**

- Identify shortcomings of registries relating to inaccessible data
- Evaluate the challenges of collecting, utilizing and sharing data
- Examine the need for enhanced data sharing practices
- Discuss GenomeConnect, the ClinGen patient registry, as an example of a registry engaged in data sharing

Juliann Savatt, Genetic Counselor,  
Geisinger

## TRACK 2

## REAL WORLD EVIDENCE UTILIZATION

### *Collecting and Interpreting Clinical Data*

3:15 *Track Chair's Opening Remarks*

Charles Makin, BS Pharm, MS, MBA, MM, Global  
Head, Real World Evidence Strategy, Biogen

### 3:30 **Advancements in Rare Disease Epidemiology Using Real World Data**

- Identify current challenges for epidemiology and critical opportunities for use of RWE
- Assess recent successes for incorporating RWE in rare disease studies
- Deep dive into case examples

J. Alexander Cole, DSc, MPH, Executive Director  
and Global Head, Epidemiology,  
Alexion Pharmaceuticals

### 4:15 **Leverage Machine Learning and New Technologies to Enhance RWE Generation and Outcomes Research**

- Uncover how AI platforms can be utilized to integrate data, synthesize evidence and generate meaningful RWE insights
- Compare end-to-end efficiencies of traditional data collection and analysis to automated processes
- Review examples of how implementation of AI, natural language processing and machine learning across the lifecycle can improve outcomes for patients, life sciences, payers and physicians

Athula Herath, Global Head Real World  
Evidence Epidemiology, Novartis

## TRACK 3

## HEOR AND VALUE DEMONSTRATION

### *Initiatives and Innovations in Economic Modeling and Analyses*

3:15 *Track Chair's Opening Remarks*

Rami Ben-Joseph, Ph.D., Global Value Leader,  
Jazz Pharmaceuticals

### 3:30 **Advancing Data-Driven Decision-Making**

- Review evolving trends in the use of real world data for coverage and treatment decisions
- Leverage clinical and health economic insights to identify market gaps and revenue opportunities, and drive development of evidence-based care pathways
- Innovate in bringing disparate data sources together to glean deeper insight
- Implement strategies for co-collection of retrospective and prospective data among healthcare stakeholders — Life sciences, payers, and providers

John E. Linnehan, MPH, MBA, Practice Director, Health  
Economics & Advanced Analytics, Avalere Health

Kristi Mitchell, MPH, AB, Practice Director,  
Avalere Health

### 4:15 **Moving from BIG Data to ACTIONABLE Data — Designing, Implementing and Measuring RWE Partnerships**

- If It's NOT Measurable, It's NOT Meaningful
- Co-Creation — Who's involved and what we aim to achieve
- Adherence isn't just a Patient Problem
- Process for Success — How to produce actionable data

Jake Caines, Chief Revenue Officer, Curant Health

Marc O'Connor, Principal/ Chief Business Officer,  
Curant Health

5:00 Close of Day One



## NETWORKING, WINE AND CHEESE RECEPTION

immediately following the final session on day one



# DAY TWO TUESDAY, JANUARY 28, 2020

8:00 *Networking Breakfast*

8:30 **CHOOSE FROM 3 CONCURRENT TRACKS (1-3)**

## TRACK 1

### REGISTRY DEVELOPMENT AND ADVANCEMENT

#### *Building and Maintaining Patient Registries*

8:30 *Track Chair's Review of Day One*

W. Benjamin Nowell, Ph.D., Director,  
Patient-Centered Research,  
Global Healthy Living Foundation

#### 8:45 **NORD-FDA Project Highlight — A Standardized Approach to Natural History Study Development for Rare Diseases**

- Unpack the need for a generalized and standardized approach to data collection in natural history studies
- Evaluate successes, thus far, in establishing baselines and common data elements
- Highlight opportunities to use higher quality, regulatory-grade data across clinical trial design and drug development
- Review case studies of use of registry data as confirmatory for regulatory review

Patricia Vanderwolf, PMP, Associate Director of Research Programs, **National Organization for Rare Disorders (NORD)**

#### 9:30 **Engaging Patients in the Registry Lifecycle**

- Highlight the importance of involving patients in studies and registry use
- Discuss strategies for collaboration with patient advisors and boards
- Assess effectiveness of different patient engagement strategies relating to recruitment, transparency and communication

W. Benjamin Nowell, Ph.D.,  
Director, Patient-Centered Research,  
Global Healthy Living Foundation

## TRACK 2

### REAL WORLD EVIDENCE UTILIZATION

#### *Collecting and Interpreting Clinical Data*

8:30 *Track Chair's Review of Day One*

Charles Makin, BS Pharm, MS, MBA, MM, Global Head, Real World Evidence Strategy, **Biogen**

#### 8:45 **Best Practices for Development and Utilization of Patient-Reported Outcomes (PRO)**

- Assess how EHR and other methods can be utilized to acquire patient-reported data
- Highlight the importance of patient centricity in ensuring key outcomes measured are valuable to patients
- Develop strategies for implementing appropriate and impactful PROs

Terrie Livingston, PharmD, Head of Patient Outcomes and Solutions, North America Medical Affairs, **EMD Serono**

#### 9:30 **Obtaining Patient-Generated Data from Social Media, Mobile Devices and Other Digital Sources**

- Map out the new digital landscape for generating sources of data
- Evaluate strategies for collecting and utilizing data
- Discuss regulatory considerations and privacy concerns for using mobile technology data

Candace Lerman, Esq.,  
Attorney/Patient Advocate,  
**Lerman Law Firm**

## TRACK 3

### HEOR AND VALUE DEMONSTRATION

#### *Initiatives and Innovations in Economic Modeling and Analyses*

8:30 *Track Chair's Review of Day One*

Rami Ben-Joseph, Ph.D., Global Value Leader,  
**Jazz Pharmaceuticals**

#### 8:45 **Strategies for Optimizing Economic Modelling and Value Demonstration**

- Accelerate value demonstration and decision-making with improved utilization of valuation tools
- Define common issues for modelling relating to transparency, sharing, updating and policy
- Explore how open source modelling can be implemented for cost-effectiveness and comparative effectiveness models

Boxiong Tang, M.D., Ph.D., Senior Director, Health Economics and Outcomes Research (HEOR), **BeiGene**

#### 9:30 **Analysis of Current Reimbursement Trends and New Developments in Market Access**

- Assess the changing landscape of patient access and reimbursement, and the evolving roles of economic stakeholders
- Outline the latest industry trends affecting the ability to define and communicate the value of drugs to different stakeholders
- Underline how proposed changes to reimbursement programs should be accounted for in economic modelling
- Discuss strategic methods for collaboration for accelerated value-based decision-making
- Utilize a comprehensive approach to clinical, economic and pragmatic trends to develop more robust value propositions

#### **MODERATOR:**

Patti Peeples, RPh, Ph.D., Founder and CEO,  
**HealthEconomics.com**; Principal Researcher,  
**HE Institute**

#### **PANELISTS:**

Cristina Masseria, Methods and Capabilities Lead, **PHI, Pfizer**  
Nanxin (Nick) Li, PhD, MBA, Senior Director, Health Economics and Outcomes Research (HEOR), **uniQure**  
Rachel Cunningham, Director, Health Outcomes and Payer Policy, **Foundation Medicine**



## Not Just A Buzzword – Achieving Patient-Centricity for Improved Outcomes

### 10:45 Harmonization of Outcomes Measures for More Patient-Centric Care

- Discuss challenges for registry utilization and validity related to lack of standard measures
- Evaluate the necessity of standardized measurements and the multi-stakeholder efforts to deliver these outcomes
- Highlight how standardization begins with, and enables, patient-centricity

*Evan R. Myers, M.D., MPH, Walter L. Thomas Professor,  
Department of Obstetrics & Gynecology,  
Duke University Medical Center*

### 11:30 Emerging Ethical and Compliance Issues in RWD-Driven Research

- Outline the most critical factors of the current legal/regulatory landscape, including the 21st Century Cures Act, FDA's 2018 Framework, CDC's Framework for Patient-Centered Outcomes Research, the Common Rule, HIPAA and more
- Consider what constitutes an effective compliance program for RWE usage in an uncertain and ever-changing space
- Discuss ethical considerations on a domestic and global scale, and how to account for principles of autonomy, justice, beneficence and non-maleficence
- Evaluate implications for different stakeholders and critical actions for future collaboration

*Renee Pierre-Louis, Senior Research Associate, Ph.D., MBA, MA,  
ACRP-CP, Stamford Health*

### 12:15 Networking Luncheon

1:15

### Bringing Data Back to Patients – Empowering Patients through Data Sharing

- Identify industry-wide issues relating to gaps in patient data collection and use
- Review case studies of successful data sharing and opportunities for stakeholders when giving data back to patients
- Outline opportunities to improve patient engagement and involvement
- Assess how patient registries can support longitudinal data

*Christian Rubio, Vice President of Strategic Advancement, Community Development and Engagement, Global Genes*



## The Future of Patient Data – Opportunities, Challenges and Innovations Disrupting the Space

2:00

### Achieving a Future of Improved Health Care Decision-Making – Overcoming Obstacles to Standardize Use of Registries, RWE and HEOR

- Discuss key challenges affecting the use of RWE including blurred endpoint definitions and lack of uniform standards
- Outline possibilities to improve utilization of RWE
- Review ongoing efforts for standardization and advancement

#### **MODERATORS:**

*J. Alexander Cole, DSc, MPH, Executive Director and Global Head,  
Epidemiology, Alexion Pharmaceuticals*

*Renee Pierre-Louis, Senior Research Associate, Ph.D., MBA, MA,  
ACRP-CP, Stamford Health*

*Rebekah Angove, Ph.D., Vice President, Patient Experience and  
Program Evaluation, Patient Advocate Foundation*

2:45

### Close of Conference



Case  
Studies



ROUNDTABLES

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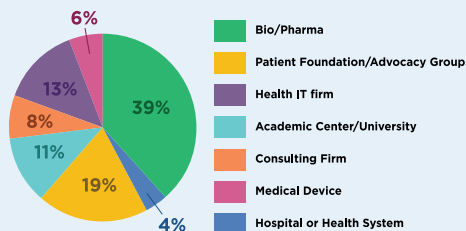


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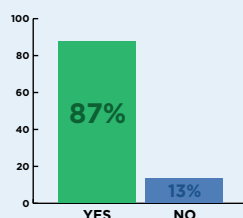
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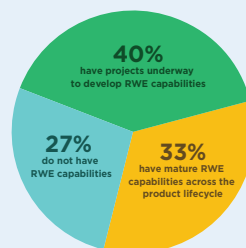
Attendee Breakdown



Percent of Organizations Utilizing Patient Registry Data



Maturity Level of Real World Evidence (RWE) Capabilities



### DID YOU KNOW?

- Over **80%** of organizations that use registry data create and maintain their own registries
- 60%** of those that use registries do so to determine clinical effectiveness and track natural history of diseases
- 70%** of executive leadership consider utilization of RWE a top priority
- Over **80%** anticipate an increase in the use of artificial intelligence (AI) and machine learning (ML) for real world data analysis in the future

### A HISTORY OF CONFERENCE PARTICIPANTS FROM ESTEEMED ORGANIZATIONS, INCLUDING:

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"High quality content and excellent speakers. Great attendee engagement and networking. Professionally organized and executed. All in all, well worth it."

"This was an excellent conference... it enabled me to network and meet great colleagues all looking to augment clinical trial research with RWE! I made some great connections that I will leverage for common goals."

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Improve Outcomes through Innovative Analysis and Application of Patient Data

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## Patient Registries, Real World Evidence and HEOR

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