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September 18-19, 2019 | Boston, MA

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7th IMPACCT REAL WORLD EVIDENCE

Advancing the Use & Generation of RWE Across Drug Life Cycle for Patient-Centric Innovation

Expert Speakers include:

Tony Hebden
VP, HEOR
AbbVie

Javier Jimenez
VP & Global Head of RWE & Clinical Outcomes
Sanofi

Melvin Olson
Global Head of RWD Strategy & Innovation
Novartis

Cathy Critchlow
VP, Center for Observational Research
Amgen

John Graham
SVP, Medical Engagement & Value Evidence & Outcomes
GlaxoSmithKline

Partners: Clarify Health Solutions · Deloitte. · OM1 · PREMIER · Syneos Health

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hansonwade

Welcome to the 7th *IMPACCT: RWE*

Supporting & Enhancing Product Life Cycle from Clinical R&D to Commercial with Real-World Evidence

Real-world evidence generation and utilization in the healthcare context continues to undergo huge growth and development, driven by an underlying maturity, increased regulatory acceptance and growing innovation.

This is revolutionizing medical care, and driving clinical and commercial transformation across the drug life-cycle by enhancing patient-facing outcomes.

IMPACCT: RWE provides leading innovators and experts in the RWE space with a comprehensive, industry-focused forum dedicated to **supporting and advancing the generation and utilization of RWE across drug life cycle, from clinical development to commercialization**.

Join your peers for a collaborative discussion platform that aims to overcome key challenges to **define and implement a meaningful evidence generation plan that can effectively enhance patient-centric clinical R&D, support regulatory submission and decision-making, and ultimately drive commercial success**.

Hear what previous attendees have to say

"Amazing set-up with a very talented line-up of speakers and content. Best experience ever!"
Amgen, Past Attendee

"Excellent line-up of topics and great gathering of true experts in the field of RWE. Well done Hanson Wade"
QuintilesIMS, Past Attendee

"This is a great event! Something that provides a much needed direction to this community"
Sanofi, Past Attendee

5 Highlights You Cannot Miss

Sanofi, **Bristol-Myers Squibb** and **Alkermes** discuss how real-world data is helping improve clinical outcomes and supporting clinical research programs.

Harvard Medical School share considerations and guidelines around the FDA's RWE framework and how RWE can best support regulatory submissions.

AbbVie, **Pfizer** and **Bristol-Myers Squibb** explore how to tackle implementation challenges and data strategy.

Novartis, **Paratek Pharmaceuticals** and **Teva Pharmaceuticals** delve into how to rethink the strategic use and generation of evidence across the product life cycle.

UniQure and (former) **AstraZeneca** share examples of what it takes to demonstrate product value and how evidence can play a key role in this.

"Very engaging, productive conversations. There were some very important takeaways from the conference" **Takeda, Past Attendee**

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YOUR EXPERT SPEAKERS

Cathy Critchlow
VP, Center for Observational Research
Amgen

CJ Hameed
Senior Director, Real World Data & Analytics, Chief Digital Office
Pfizer

Danny Wiederkehr
Senior Director, Global HEOR Team Lead
Pfizer

David Anstatt
Executive Director, Observational Research & Data Sciences
Bristol-Myers Squibb

David Thompson
SVP, RWE Advisory
Syneos Health

Dongmu Zhang
Director & Head of Epidemiology Data Analytics
AbbVie

Frank Zhang
VP, Head, Market Access
UniQure

Javier Jimenez
VP & Global Head of RWE & Clinical Outcomes
Sanofi

John Graham
SVP, Medical Engagement & Value Evidence & Outcomes
GlaxoSmithKline

Judy Kando
VP, Head of Medical Affairs
Tris Pharma

Kara Dennis
SVP & General Manager, Life Sciences
Clarify Health Solutions

Keith Friend
Global Medical Director, Cardiovascular
Bristol-Myers Squibb

Leona Bessonova
Director – HEOR
Alkermes

Marla Curran
Executive Director, Head of Biometrics & Medical Writing
Paratek Pharmaceuticals

Mandeep Kaur
VP, Head of North America Medical Affairs
Immunology Sanofi

Melvin Olson
Global Head of RWD Strategy & Innovation
Novartis

Michael Lees
Head of Value, Evidence & Portfolio Strategy
Takeda

Ravi Iyer
Director, Global HEOR
Teva Pharmaceuticals

Richard Gliklich
CEO
OM1

Sandy Leonard
Former VP, Medical Evidence & Observational Research
AstraZeneca

Sebastian Schneeweiss
Professor of Medicine & Epidemiology
Harvard Medical School

Tony Hebden
VP – HEOR
AbbVie

Deloitte
Speaker to be Announced Soon

CONFERENCE DAY ONE
WEDNESDAY, SEPTEMBER 18, 2019

	8.15	**Chair's Opening Remarks**

Javier Jimenez
Sanofi
 	
Melvin Olson
Novartis
 	
Michael Lees
Takeda
 	
Kara Dennis
Clarify Health Solutions
	8.30	**'IMPACCT' Panel Discussion: Advancing the Generation & Utilization of RWE to Drive Patient-Centricity & Better Outcomes**
		• Focusing on patient-centered drug development – what is the role of RWE?
		• Defining and establishing clinically meaningful evidence to support R&D
		• How to bring RWE-enhanced drug development one step forward?
		  • Where does the biggest opportunity for next steps in this space lie?
		  • Discussing the current regulatory climate in RWE
		  • Analyzing the rise of AI and Machine Learning capabilities and its impact in RWE-driven patient-centric clinical innovation and outcomes

Supporting Clinical R&D with Real-World Evidence

Javier Jimenez VP & Global Head of RWE & Clinical Outcomes **Sanofi**	9.15	**Advancing the Use of Advanced Analytics in RWE** • More information coming soon
Deloitte **Speaker to be Announced Soon**	9.45	**Session Reserved for Deloitte** • More information coming soon
	10.15	**Speed Networking Session**
	10.45	**Morning Refreshments**
Keith Friend Global Medical Director, Cardiovascular **Bristol-Myers Squibb**	11.15	**Using RWD to Augment the Cardiovascular Drug Development Process** • Exploring the use of RWD in early development • Using RWD in full development • Discussing how to support registration, launch and market access activities with real-world data
Dongmu Zhang Director & Head of Epidemiology Data Analytics **AbbVie**	11.45	**Using NLP to Improve Identification of Patients of Interest & Safety Events** • Discussing EHR data vs. claims data • Exploring the use of NLP to identify and segment patients of interest • Developing NLP-based algorithm in safety events identification
Leona Bessonova Director – HEOR **Alkermes**	12.15	**Patient Perspective of Disease Burden & Prevailing Unmet Need in Serious Mental Illness Treatment Landscape** • Overviewing of study types to collect patient perspective data • Choosing appropriate instruments with study objectives in mind • Exploring examples of qualitative and quantitative patient perspective research to highlight disease burden & unmet need
	12.45	**Lunch & Networking**

Sebastian Schneeweiss Professor of Medicine & Epidemiology **Harvard Medical School**	1.45	**Real World Evidence to Support Regulatory Submissions** • Exploring the FDA's RWE framework • When and how can RWE best augment RCTs? • Discussing the FDA's demonstration projects
Tackling Implementation & Data Challenges		
Tony Hebden VP – HEOR **AbbVie**	2.15	**Lesson Learned from The Development & Implementation of an Integrated Data & Evidence Strategy at AbbVie** • Developing and implementing an original data and evidence strategy from first principles – delving into the experience at AbbVie, a new large cap biopharmaceutical company • Exploring the continuous implementation process over the last five years – identifying several key learnings that have led to modifications and additions to the ongoing roll out • Focusing on some of those key learnings and their impact on implementation of the data and evidence strategy at AbbVie
David Thompson SVP, RWE Advisory **Syneos Health**	2.45	**Biopharmaceutical Acceleration Model for Product Development & Commercialization** • Discussion how, historically, product development has largely been disengaged from commercialization. • Exploring how, in the current environment, health system stakeholders demand both clinical and real-world evidence to inform decisions regarding product use and reimbursement • Describing (and illustrating with a case study) the benefits of a Biopharmaceutical Acceleration Model approach to product development and commercialization, involving comprehensive evidence development to meet clinical, regulatory, and commercial needs
	3.15	**Afternoon Refreshments & Networking**
David Anstatt Executive Director, Observational Research & Data Sciences **Bristol-Myers Squibb**	3.45	**Advanced Analytics in Clinical & Observational Research** • The Data Story: evolving and expanding to meet research demands (social media, genomics as RWD, unstructured to structured, data provenance, sensors, privacy, PRO, study metadata) • The Methods Story: exploring the advances in research, grounded in FDA/EMA guidelines (boost techniques, NLP, prediction, optimization) • The Impact Story: working across the development and commercialization process (discovery and development predictive analytics, study optimization, patient journey/treatment analytics, regulatory use of RWD) • Exploring Social Media Data in Pharmacovigilance
Danny Wiederkehr Senior Director, Global HEOR Team Lead **Pfizer**	4.15	**Evolving Real World Evidence Strategy Across Lifecycle – Improving Evidence for Patient Care** • Identifying gaps is easy, addressing them requires a deep understanding of data sources available, including strengths, limitations, and accessibility • Generating relevant RWE requires understanding of key audience needs, their understanding of RWE, and credible methods and data sources • Successful RWE programs reflect cross-functional expertise and collaboration across internal and external stakeholders with disciplined approach to evidence generation
CJ Hameed Senior Director, Real World Data & Analytics, Chief Digital Office **Pfizer**	4.45	**What's Driving Real World Data Utilization from Early to Late Phase Development** • Reviewing the current landscape, identify gaps and opportunities for RWD utilizing in drug development • Discussing RWE Methodologies, Data management for RWD Assets and advance analytics • How to effectively engage the stakeholders in RWD use and evidence generation and where to go next?
	5.15	**Chair's Closing Remarks**

CONFERENCE DAY TWO
THURSDAY, SEPTEMBER 19, 2019

8.50 **Chair's Opening Remarks**

Rethinking RWE Strategy

Judy Kando
Tris Pharma

John Graham
GlaxoSmithKline

Tony Hebden
AbbVie

9.00 **'IMPACCT' Panel Discussion: Value Generation, RWE & Life Cycle Management – Distilling Strategy for Innovation**

- In what stages of the drug life cycle does RWE have greatest impact?
- Establishing the right evidence generation plan that meets clinical, regulatory and commercial needs of a product:
  - How to?
  - Does it differ between big and small pharma?
  - What's the ROI vs. value generation?
- Driving internal collaboration for value-based evidence generation

Melvin Olson
Global Head of RWD Strategy & Innovation
Novartis

9.45 **Can Pharma Save $1 Billion Through the Strategic Use of RWE?**

- Reviewing current evidence needs and trends
- Introducing a framework for integrated evidence generation
- Revisiting IMSHealth (now IQVIA) claims that Pharma can save $1 billion through real-world evidence

10.15 **Morning Refreshments & Networking**

Cathy Critchlow
VP, Center for Observational Research
Amgen

10.45 **The Role of RWE in a Comprehensive Product Evidence Generation Plan**

- Key questions across the product lifecycle that can be addressed through RWE
- Creating the necessary synergies across the organization to fully leverage the strengths of RWE
- Deriving critical insights from RWD to facilitate successful drug development and commercialization

Marla Curran
Executive Director, Head of Biometrics & Medical Writing
Paratek Pharmaceuticals

11.15 **RWE Across the LifeCycle – Strategy Before Tactical Solutions**

- Synthesizing information and alignment: key data gaps, SWOT, function-specific needs
  - Discussing big pharma vs. small pharma
- Strategic planning framework: Challenges → Resolutions → Tactical Plan
- Exploring stakeholder engagement and prioritization
- The strength of evidence spectrum and optimizing trial/study designs

11.45 **Mastermind Session: Supporting & Enhancing Product Life Cycle with Innovative Evidence Strategies**

This session facilitates in-depth discussions among participants in an informal environment. After splitting into groups, participants will discuss key challenges and opportunities regarding the current RWE landscape in regards to its utilization across product life-cycle to drive innovation and more patient-facing outcomes.

12.30 **Lunch & Networking**

Michael Lees
Head of Value, Evidence & Portfolio Strategy
Takeda

1.30 Making Choices in Evidence Development: Using Local Insights to Drive a Truly Global Evidence Base

- Generating a comprehensive evidence base for new medicines by using RCT and RWE in an integrated way
- Establishing trade-offs needed between competing needs of different country decision makers, when developing a truly global evidence base
- Effectively managing these trade-offs where strong local input, internal and external to the developer of the medicine, is provided early and systematically into the evidence team

Ravi Iyer
Director, Global HEOR
Teva Pharmaceuticals

2.00 Use of RWD Outside of Traditional Comparative Effectiveness Research

- Using RWD in early phase of life-cycle development
- Presenting a case study in the use of real world data to support payer discussions
- Exploring opportunities and challenges associated with use of RWD in early phase of asset development and payer discussions

2.30 Afternoon Refreshments & Networking

Driving Commercial Success & Supporting the Bringing of New Therapeutic Options to Market

Sandy Leonard
Former VP, Medical Evidence & Observational Research
AstraZeneca

3.00 Evidence Planning: Leveraging Innovation for Impact

- Understanding evidence needs early in the product lifecycle
- Identifying opportunities to invest in innovative evidence to address gaps
- Leveraging evidence with key medical and payer audiences

Frank Zhang
VP, Head, Market Access
UniQure

3.30 What Does it Take to Substantiate a Million-Dollar Price Tag in Gene Therapy?

- Exploring the challenges with gene therapy market access
- Discussing how evidence requirements are more rigorous in gene therapy
- Establishing a very different business model for gene therapies

Frank Zhang
UniQure

Mandeep Kaur
Sanofi

Sandy Leonard
AstraZeneca

4.00 'IMPACCT' Panel Discussion: Looking Outwards – Demonstrating Product Value & Improved Care Delivery with RWE

- Developing a suitable evidence framework to demonstrate product value and differentiation
- Addressing external stakeholders' (payors, providers and patients) concerns as they increasingly seek to understand the effects of new products in the real-world setting
- Supporting decision-makers and payors with evidence that is better tailored to help them determine reimbursement policies and insurance coverage for new therapeutic options

4.45 Chair's Closing Remarks

"Well organized event with a focused audience. The organizers were able to bring together individuals from different industries who despite their diverse backgrounds had a deep, shared interest in the topic"

RXDX, Past Attendee

PARTNER WITH US

Hosting Partner

Clarify Health delivers advanced analytics that empower provider, payer and life science organizations to optimize patient care and clinical trials. Our platform seamlessly integrates clinical, medical, prescription, social determinants of health and lab data on more than 200 million lives. Leveraging powerful, financial-grade technology, Clarify's solutions generates actionable insights designed to accelerate clinical trial site selection, define the clinical and economic benefits of therapies at scale, and enhance decision making across product portfolios.ata-driven, evidence-based transformation of health care.

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Truly actionable insights are hard to come by. They're derived from a combination of real-world information, evidence, and experience—not just data. Deloitte's ConvergeHEALTH suite of software solutions brings together all of these. Our tools reflect the conviction that every patient encounter presents a learning opportunity that can lead to greater efficiency, more patient engagement, and higher-quality care. Informed by our vast experience helping clients transform their enterprises, our applied analytics solutions are developed by, with, and for life science and health care innovators who are leading the data-driven, evidence-based transformation of health care.

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www.om1.com

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www.SyneosHealth.com

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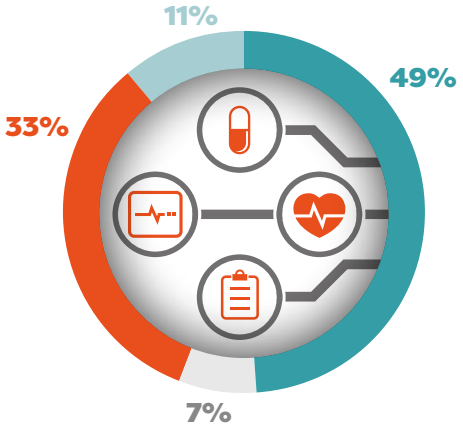

* Based on 2018's attendance statistics

FOR MORE INFORMATION ABOUT PARTNERING PLEASE CONTACT:

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1. Plan the evidence generation to effectively support drug development & commercialization success
2. Enhance decision-making across drug life-cycle for patient-facing outcomes
3. Establish yourself as a value-generating organization

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