



# Real-World Evidence:

*Practical Strategies for Addressing the Needs of Multiple Stakeholders*

*December 11th, 2014. 8am - 5pm ET*

## VIRTUAL SUMMIT AGENDA

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Evidence of product performance in actual practice settings is of paramount importance. However, when it comes to developing, communicating, and implementing RWE, there are a variety of perspectives --- sometimes conflicting --- that need to be accommodated. This first-of-its-kind “virtual” conference will provide practical and progressive insights into maximizing the value of RWE for all stakeholders.

At this cutting-edge Virtual Summit, we will bring together Pharma, Payers, Providers, Patients, Policy Makers, and Researchers. You will hear actual case studies and examples of:

- **LIFE CYCLE MANAGEMENT OF RWE:** How to avoid the 8-ball problem to get your RWE study results earlier so they are more actionable
- **PARTNERS MATTER – SUCCESS STORIES:** How to identify the right partners from Payers, to Providers, to Patient populations so your results are actionable and drive market access
- **STRETCHING BOUNDARIES BEYOND USUAL STAKEHOLDERS:** Which stakeholders should you consider, but haven't? Expand your RWE study to other groups to drive recruitment, adaptation, and improve outcomes.
- **INNOVATION FORUM:** Which innovations exist that can take your RWE study designs and results to the next level? We'll discuss data sources, patient recruitment tools, communication methods, and more.

At the end of this VIRTUAL SUMMIT, you will be equipped with the knowledge to develop a RWE Checklist to help you execute your next study efficiently, effectively, and with maximum impact to meet your objectives.



**Patti Peeples**



**David Haddad**



**Jeff Trotter**



**Amy Smalarz**



**Mark Cziraky**



**John Glasspool**

# AGENDA:

**8:00 AM**

## **Welcome / Introduction**

**Patti Peeples, RPh, PhD.** CEO of HealthEconomics.Com.

**8:15 AM**

## **Keynote Address: Unlocking Potential of Health Data**

Real-time integration of patient-reported data into ongoing medical treatment is the future of evaluating and improving health outcomes. David will kick-off this meeting with inspiring ideas and insights into how we can develop real world evidence that matters.

**David Haddad.** Executive Director of Open mHealth.

**8:45 AM**

## **The Strategic Imperative of RWE for Pharma/Device Companies**

For product developers and marketers, the "real world" can be an unfamiliar place in which traditional approaches to research and commercialization don't apply. This session will address issues of particular strategic relevance to pharma/device companies striving to develop actionable RWE, both organizationally and operationally. A RWE Checklist will be presented as a mechanism for optimizing the development and communication of RWE over a product's life-cycle.

**Jeff Trotter.** President, Continuum Clinical.

**Amy Smalarz, PhD.** President, Strategic Market Insight.

**9:30 AM**

## **Session I: RWE: Needs, Expectations and Impact**

What exactly is the promise of RWE? This session will explore the various issues and perspectives involved, with a particular focus on the needs of the users of RWE and the resulting impact of RWE developers.

**Mark Cziraky, PharmD.** Vice President for Research, HealthCore.

### **a. 9:55 AM: What is at stake? Who are the stakeholders?**

Different stakeholders (payers, providers, patients, etc.) have different expectations for RWE. This session will highlight and contrast those differences.

**John Glasspool.** VP New Therapies and Marketing Development, Baxter Bioscience.





**Linda Abetz-Webb**



**Phillip Cyr**



**Allan M. Korn**



**Nathan White**



**Emily Freeman**



**Catherine Price**



**Donney John**

**b. 10:15 AM: Where is the field going in terms of PRO needs and imperatives?**

Where should the field be going in terms of including and requiring PROs and their links to health outcomes? How can we get to a place where patient centricity is not just a buzz word or something we talk about and move toward something we do?

**Linda Abetz-Webb. CEO, Patient-Centred Outcomes Assessment.**

**10:35 AM**

**Q&A RWE Needs, Expectations, Impact.**

**10:45 AM**

**BREAK**

**11:00 AM**

**Session II: Voices of the Stakeholders**

RWE holds a different promise depending on one's perspective. Session II speaks directly to these issues by going into additional depth on the perspectives of the stakeholders most impacted by RWE.

**a. 11:00 AM: Pharma and Stakeholders**

**Real World Evidence Strategy to Address Multiple Stakeholder's Evidence Requirements: A Case Study**

New products and technologies will impact multiple stakeholders including payers, hospital purchasers and free-standing infusion clinics, in many different ways. This session will present a case study of one product's targeted, specific real world evidence strategy in order to address these multiple stakeholder evidence desires.

**Phillip Cyr, MPH. Senior Director, ICON Health Economics.**

**b. 11:25 AM: Payers and Payer Partnerships**

Is RWE sufficient for influencing coverage and reimbursement decisions, and are the results actionable by the payer audience? Why or why not?

**Allan M. Korn, MD, FACP. Chief Medical Officer Emeritus, Blue Cross and Blue Shield Association (BCBSA), Chicago, IL, USA.**

**Nathan White, CPC. Director NucleusX Market Access.**

**c. 12:00 PM: Patients**

What role can patients play in the development of RWE, or – conversely – what role can RWE play in improving a patient's management of their disease? Is there adequate awareness of the value of RWE (in contrast to data from RCTs or other sources)?

**Emily Freeman, PhD. Director, Health Behavior & Program Evaluation, Pfizer.**

**Catherine Price. Journalist, ePatient, and Consultant, ASweetLife.org and Diabetes, Etc.**

**Dr. Donney John. Founder and CEO of Urban Medical Solutions and Chairman of the Board of Directors for NovaScripts Central.**



**Jack Kelly**



**Peter J. Neumann**



**Amy Smalarz**



**Katie Deering**



**Amanda Bruno**

**d. 12:45 PM: The Emerging Role of the Pharmacist: Real World Evidence Opportunities**

Hear a case study exhibiting successful patient engagement by leveraging resources through the lens of a multi-stakeholder approach.

**Jack Kelly, RPh. Chief Business Officer Pharmacist Partners.**

**e. 1:10 PM: RWE Data, Regulators, and Payers**

What changes are needed to improve communication and use of non-randomized evidence?

**Peter J. Neumann, Sc.D. Dir. of the Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, and Professor of Medicine at Tufts University School of Medicine, Boston, MA.**

**1:30 PM**

**Q&A**

**1:50 PM**

**BREAK**

**2:00 PM**

**Session III: Lifecycle Management of RWE**

RWE has different implications in the pre- versus post-approval timeframes, and even more subtle differences exist along the way. Session III will consider the “traditional” operational and organizational approaches employed by pharma/device companies in exploring whether RWE merits an unconventional approach.

**Amy Smalarz, PhD. President, Strategic Market Insight.**

**a. 2:15 PM: Leveraging RWE Across the Product Lifecycle**

Organizations often have a hard time making internal resources and processes designed for RCTs work for RWE. This session will present some of the critical success factors in effective and efficient RWE development, and will address the critical question of “when to start” in terms of developing RWE for the marketplace.

**Katie Deering, PharmD, BCPS. Vice-President, EPI-Q, Inc.**

**b. 2:35 PM: Using HEOR Field Teams Effectively**

Are you leveraging your HEOR Field Teams to best identify customer needs in outcomes research? Learn from 2 case study examples how you can garner valuable customer insights and discuss approaches for developing real world evidence that better meets your customer needs.

**Amanda Bruno. Group Director, Specialty Products, US Medical HEOR, Bristol-Myers Squibb Company.**



**Shontelle  
Dodson**



**Steve  
Chick**



**Joseph  
Jackson**



**Debra  
Patt**

**c. 2:55 PM: Successful partnerships (Pharma/ACOs/Vendors Payers)**

What Partnerships have worked and why? This session presents actual case studies on collaborative efforts with critical partners (ranging from data providers to investigators to payers) in the development, communication, and implementation of RWE.

**Shontelle Dodson.** Executive Director, Head of Outcomes Research and Managed Markets, Astellas.

**Steve Chick.** Market Vice President, Humana.

**3:20 PM**

**Q&A**

**3:35 PM**

**BREAK**

**3:45 PM**

**Session IV: Innovation and the Future: What's Next?**

What's the future of RWE, considering technological advances that may make information available at the touch of a finger? What new resources exist to assist in your next RWE study? This session will also explore the impact of recent regulation in terms of encouraging the proliferation of RWE, and also consider the underlying pros and cons.

**Joseph Jackson, PhD.** Program Director, Applied Health Economics and Outcomes Research, and Associate Professor, Jefferson School of Population Health.

**a. 3:45 PM: ACOs and Obamacare**

Recent legislation in the United States has had a dramatic impact on RWE, but where are we in terms of its acceptance? How are these new provider networks influencing the demand for RWE, and how it is implemented? Have we reached a "tipping point" from which there's no turning back on the importance of RWE.

**Joseph Jackson, PhD.** Program Director, Applied Health Economics and Outcomes Research, and Associate Professor, Jefferson School of Population Health.

**b. 4:10 PM: Underutilized data sources (EMRs)**

Medical record technology has advanced such that EMRs are becoming standard in medical practice; however, as a data source, EMRs may be underutilized. This session will explore the present and future of EMRs as a source for RWE.

**Debra Patt, MD, MPH, MBA.** Medical Director, Healthcare Informatics, McKesson Specialty Health and the US Oncology Network. Practicing Medical Oncologist and Hematologist with the Texas Oncology Cancer Center.

**4:30 PM**

**Q&A**





**Jeff  
Trotter**



**Amy  
Smalarz**



**Patti  
Peeples**

**4:45 PM**

**Session V: Strategic Summary and Checklist Review**

The virtual meeting concludes with a review of key issues and a reaffirmation of the importance of addressing the RWE imperative within a strategic context. A review of a RWE Checklist for implementation of your next RWE will be shared.

**Jeff Trotter.** President, Continuum Clinical.

**Amy Smalarz, PhD.** President, Strategic Market Insight.

**4:55 PM**

**Q&A / CLOSE**

**Patti Peeples, RPh, PhD.** CEO of HealthEconomics.Com