# Generating Evidence for Successful Market Access

## Discussion Topic | Speaker | Time
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REGISTRATION, COFFEE, PASTRIES | | 9:30—10:00
INTRODUCTIONS AND OPENING COMMENTS | Leanne Larson | 10:00—10:30
UNDERSTANDING DIFFERENT STAKEHOLDER REQUIREMENTS THROUGHOUT COMMERCIALIZATION | Richard Macaulay | 10:30—11:15
- The differences between payers and regulators, why payers view new regulatory approaches with caution
- Conflicting requirements with multiple stakeholders
OPTIMIZING YOUR EVIDENCE GENERATION PLAN | Leanne Larson, Janet Johnson, Colette Andrea | 11:15—11:45
- Comparing essentials and nice to haves
- Considerations for inclusion (RCT, databases, observational studies, modeling and analytics)
- Optimizing communications
DEVELOPING REAL-WORLD EVIDENCE TO DRIVE PRODUCT SUCCESS | Leanne Larson | 11:45—12:30
- Current RWE strategies and approaches
- Choosing the right study design to meet your clinical and commercial objectives
- Key success factors in implementing a RWE study
LUNCH & ASSESSMENT TOOL | | 12:30—13:15
Lunch location: Salon Durieux  (Buffet: Beletage Restaurant)
REAL-WORLD DATA: ACCESSING EXISTING DATA TO DRIVE EVIDENCE GENERATION | Michelle Hoiseth, Camie Britton, Aaron Kamauu (Anolinx) | 13:15—14:00
- Identifying and evaluating existing data sources for evidence-generation
- Challenges and opportunities in applying RWD in decision-making
BRINGING THEORY TO REALITY | Richard Macaulay, Leanne Larson | 14:00—14:30
- Creating an optimal model for your product
- Key success stories
WRAP-UP AND Q&A | Leanne Larson | 14:30—15:00
SYMPOSIUM CONCLUDES | | 15:00
**Colette Andrea**  
**Vice President of Client Services**

Colette is an accomplished leader with more than 20 years of sales, pharmaceutical, diagnostic marketing and agency experience including significant launch experience. Currently, she manages a diverse team of medical communications experts in the US and Europe. Colette has an extensive clinical background including experience as a hospital based medical technologist along with diverse therapeutic area experience in women’s health, asthma/allergy, antibiotics, men’s health, CNS, pain, anti-viral, cardiovascular, GI and diagnostic products. Her strong strategic skills provide a powerful foundation for innovative, solution-oriented recommendations. Colette has a MBA in Pharmaceutical Marketing from Saint Joseph's University and a BS in Medical Technology and MT (ASCP Certification) from Rutgers University.

**Camie Britton**  
**Senior Director, Real-World Data Services**

Camie has more than 20 years of pharmaceutical industry experience with roles of increasing responsibility within Project Management, Clinical Operations and Data Operations, including several years as a project and senior operations manager in the peri/post-approval space. She has a highly technical and analytical background gained from the many of years working in tandem with PAREXEL's Informatics business, where she held global operational responsibility for developing and implementing PAREXEL's risk-based monitoring solutions. Camie presently leads the teams responsible for real-world data-oriented process and technology development at PAREXEL. Her Real-World Evidence expertise is highlighted through successful experimentation and innovation in delivering novel real-world evidence strategies and solutions for many of the world’s leading biopharmaceutical companies.

**Michelle Hoiseth**  
**Corporate Vice President**

Michelle has been working in the drug and medical device development industry for 29 years, through a variety of positions that allowed her to create complete product development plans, design novel regulatory pathways to approval, write both strategic and tactical business development plans, and support product commercialization objectives and life cycle management. Michelle presently leads the development of PAREXEL’s real world data capability, working closely with her colleagues in a multi-disciplinary environment to solve the challenges using real world data in clinical research. Michelle is committed to leading inclusive, invested, innovative teams to move our industry into the future of clinical product development.
Janet Johnson, BSc  
**Vice President, Customer Strategy**

Janet has more than 20 years’ experience in health care supporting product and portfolio pre, launch and lifecycle management programs for major and niche brands across therapy areas. She has managed programs to drive the strategic development and implementation of international and regional integrated programs that support outcomes research initiatives, external expert identification and engagement, physician and patient engagement, publication planning strategy and implementation, and internal engagement. Janet has held a variety of roles at PAREXEL, including sales, marketing, and account management in medical and market access communications. Her strong leadership and a customer-centric, results-oriented approach enable her to develop the right strategy and messages for clients. Her career has also focused on regulatory affairs in the pharmaceutical industry as well as academic research in cellular biology and biotechnology. She holds a BSc (Hons) in Applied Biology, Marketing Diploma (Chartered Institute of Marketing) and is an active member of the International Society of Publication Professionals (ISMPP).

Aaron Kamauu, MD MS MPH  
**Vice President, Real World Data Services**

Dr. Aaron Kamauu leads innovation in leveraging healthcare data to support clinical research, informatics, clinical trials and drug development activities including pharmacoepidemiology, outcomes research, protocol design, site identification and data-driven patient recruitment. Prior to joining PAREXEL, Dr. Kamauu was the President and CEO of Anolinx LLC, Head of Healthcare Data Strategy at Roche Pharmaceuticals & Genentech Inc. He also worked in software development managing the underlying coding schemes for an outpatient electronic health record (EHR) system. Dr. Kamauu is a member of several medical societies where he has presented innovative research in radiology/imaging informatics, public health informatics and clinical research informatics. Dr. Kamauu brings a unique combination of clinical, biomedical informatics, drug development, and public health training and experience in innovative biomedical informatics methodologies to support projects based on individual patient care as well as population-based observations.

Leanne Larson  
**Corporate Vice President & WW Head, Real-World Evidence Strategy**

Leanne Larson has over twenty-five years’ experience in healthcare, featuring extensive work in pharmaceutical product development and marketing, and in healthcare technology and operational consulting. She is an industry leader in developing and leading patient registries and other outcomes research programs, and in advancing the science and application of outcomes research throughout the pharmaceutical, biotech, and medical device industries.

Richard Macaulay, PhD  
**Principal Consultant, Pricing and Market Access**

Richard Macaulay, Ph.D., is a Principal Consultant with PAREXEL Access in London. Richard has specialized for seven years’ in regulatory and market access strategy, in particular helping obtain regulatory and payer approval for treatments lacking Phase III trial data, with a specialist expertise in oncology treatments and rare diseases. He has completed over 40 research presentations in his field, including posters, webinars, conference presentations, and manuscripts. Richard has a PhD from University College London, and a BA (Hons) in Medicine from the University of Cambridge.