Over the course of the past several years, the Pharmaceutical industry has seen a tremendous increase in the prevalence and buzz surrounding comparative effectiveness research. While none could possibly deny the importance of providing CER data to healthcare practitioners, industry executives are unsure of the actual benefits, uses and integration of this type of research and fear that it may cause more problems than it solves. Through the development of a program that will incorporate perspectives from healthcare practitioners, government authorities, payers, and industry executives with real-time case studies showing firm benefits of comparative effectiveness, this program will provide participants with an illuminated view of the future of comparative effectiveness research.

Going beyond establishing what CER is comprised of, or how to design and conduct comparative effectiveness research, and focusing rather on how this data can be maximized will be the core differentiator of this conference program. With healthcare reforms continually validating that the future will include this type of assessment, and the global market already firmly embracing health assessment and impact, there is no better time than now to discuss and learn how to make an impact on the bottom line through the use and integration of comparative effectiveness research.

Program Overview

Distinguished Presenters Include:

- Louis B. Jacques, MD
- Martin Marciniak
- Clyde W. Yancy, MD
- Manu Sondhi, MD, MPH
- Dr. Melva Covington
- Dr. Douglas Levine
- Michael O. Montgomery, MD, CPI
- Sarah Garner, PhD, BPharm, MRPPharmS
- Amy Rudolph, PhD
- Jean R. Slutsky
- Dominick Esposito, PhD
- David H. Howard
- Sanjoy Roy
- Dr. Rajesh Balkrishnan
- Stephen Paul Mahinka
- Joseph D. Jackson, PhD

DAY ONE / MONDAY, DEC. 5 / INTEGRATING COMPARATIVE EFFECTIVENESS RESEARCH

7:00  REGISTRATION & CONTINENTAL BREAKFAST
7:45  OPENING REMARKS & CONFERENCE WELCOME
8:00  SCOPE OF CER AND ITS EVOLVING DEFINITION

Within the healthcare industry, there are various differing opinions on what comparative effectiveness research consists of and how to properly conduct the trials, read the findings, and implement changes of how a therapy is being used for a specific patient group. Harmonizing these differing theories of how to best define comparative effectiveness research is imperative for successfully understand and use the findings.

• Differing viewpoints of what CER is and how it should be used
• Real world application of CER
• Applying completed research to answer newer questions of therapies

Dominick Esposito, PhD
Sr. Economist, Assistant Director, Center on Health Care Effectiveness

MATHEMATICA POLICY RESEARCH, INC

9:00  IMPACT OF CER ON THE PHARMACEUTICAL INDUSTRY

Comparative effectiveness research has become a recent hot topic of interest in following the US Healthcare Reform, allocating $1.1 billion in federal funding for CER which has called for urgency in understanding what CER means for the pharmaceutical industry. Understanding the role CER will play in decision making for new therapies and how trials will be judged by government bodies, private payors & physicians will give guidance on the impact CER has on the pharmaceutical industry so companies can best position their drug and properly plan the development and commercialization of a therapy.

• When CER can best be positioned in the product life cycle
• CER effect on drug development & commercialization
• Understanding how CER will be graded by payors, government bodies

Amy Rudolph, PhD
Head, Comparative Effectiveness Research & Communications
NOVARTIS PHARMACEUTICALS CORPORATION, HE&OR

9:45  COFFEE & NETWORKING BREAK

10:15  THE ROLE OF AHRQ IN COMPARATIVE EFFECTIVENESS RESEARCH

The Agency of Healthcare Research & Quality supports research designed to improve healthcare for patients while reducing its costs and ensuring that the benefit of receiving treatment outweighs possible harm to the patient. New innovations within AHRQ include PROSPECT, which allows for comparison of tests and therapies through patient-specific electronic data, enhancing registries for quality improvement and comparative effectiveness research. Another current project by AHRQ, Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE) is the first coordinated national effort to establish a series of pragmatic clinical comparative effectiveness studies. By these developments, AHRQ is helping to ensure that the right treatment is given to the right patient at the right time.

• Structure for patient-centered healthcare
• Providing best outcomes at the lowest cost for the patient

Jean R. Slutsky, PA, MSPH
Director, Center for Outcomes & Evidence
AGENCY FOR HEALTHCARE RESEARCH & QUALITY

11:00  GLOBAL IMPACT OF COMPARATIVE EFFECTIVENESS RESEARCH

Realizing how countries around the world are currently integrating CER and firmly embracing health assessment will allow the US to gain perspective moving forward. This discussion will cover global perspectives from NICE on the implantation of CER and what this means to the pharmaceutical world. A case study will be discussed on the research NICE has been doing regarding CER and the impact it will make.

• Integration of CER in European countries
• Impact of CER on innovation within pharmaceutical companies
• Understanding the large perspective of CER
• Case Study: NICE research study of CER integration

Sarah Garner, PhD, BPharm, MRPharmS
Associate Director, Research and Development
NICE

12:00  LUNCHEON FOR ALL CONFERENCE GUESTS

1:30  METHODS & DATA NEEDED IN CER TO SUPPORT DRUG ACCEPTANCE

Varying definitions of what comparative effectiveness research means and how it will change the health care industry result in different ideas of which methods should be used to obtain the most appropriate data to compare therapies for a specific patient group. The larger the database of findings from various research studies, the more feasible and specific a targeted therapy can become for the patient. Using the most suitable method of research & understanding how to best translate the findings will help ensure the therapy performs well in the real world, resulting in better decision-making by stakeholders that will improve the care used.

• Debate of which research method is best used in CER
• Acceptance of observational research
• Proper evaluation of research findings
• Demonstrating the real world value of a drug

Manu Sondhi, MD, MPH
Head, Comparative Effectiveness & Health Outcomes
SANOFI

2:15  CER: RANDOMIZED TRIAL OR OBSERVATIONAL STUDIES

A current debate within the healthcare industry is agreeing on which clinical trial proves to be the best approach to conduct research for CER. There are different opinions on whether observational studies and randomized trials provide the same answer if they are designed and analyzed in similar ways. Each approach has different aspects of research providing evidence that best serves the specific patient group but there is not one approach to clinical research that is best in each individual therapy.

• Benefits of real world clinical practice found in observational studies
• Using data collected in insurance patient registries to conduct CER studies
• Role of methodologies for observational studies versus randomized trials

Sanjoy Roy
Associate Director, Health Economics and Reimbursement
ETHICON, A JOHNSON & JOHNSON COMPANY

3:00  COFFEE & NETWORKING BREAK

3:30  IMPACT OF FORMULARY RESTRICTIONS ON AVAILABLE TREATMENTS FOR THE PATIENT

The definitions of, methodologies for, and applications of comparative effectiveness research (CER) are evolving. Typically, the context for clinical applications of evidence derived from CER is at the level of individual patient treatment decisions. However, with the imperative to improve overall health care quality while reducing care costs in the US, CER can help define the value of treatments at the population level in health plans and health systems.

• Hierarchy of clinical evidence
• Prospective claims data analysis of total health care services utilization
• Cost impacts associated with a health plan formulary exclusion

Douglas Levine
Vice President, Medical Affairs
IRONWOOD PHARMACEUTICALS

4:15  COST EFFECTIVENESS RESEARCH: IMPACT ON PRICING & MARKETING

Understanding the difficulties of developing comparative effectiveness research acceptable to payors and regulators, and incorporating such research into strategic decisions on product selection, development, and testing; the potential effects of CER on biopharma pricing and reimbursement, both initially and over the product’s lifecycle; and the manner and degree to which CER can properly and effectively be incorporated into product marketing and promotion, all represent significant future challenges to product developers and marketers.

• Evaluating products for formulary & reimbursement acceptance
• Impact of CER on strategic decisions throughout lifecycle
• Assessing use of CER in marketing & promotion

Stephen Paul Mahinka
Chair, Life Sciences & Healthcare Interdisciplinary Group
MORGAN, LEWIS & BOCKIUS, LLP

5:00  DAY ONE CONFERENCE CONCLUSION
Aligning current CER methodologies into one specific analytical methodology model will assist in not only defining CER and how it can be used but will also give guidance to health care professionals on how to effectively implement CER findings. Developing synthesized guidelines of how to conduct CER trials will help in validating the research findings by defining the appropriate methods needed to accurately conduct research and understand the findings. Standardizing the methodology of CER will enable manufacturers to efficiently transfer these findings into the using the right drug for the right patient group.

- Implementation and use of different methods for CER
- Philosophies and mandates for differing CER methodology
- Designing homogenous trials in order to accurately compare to one another
- Adoption and uptake of research findings

Clyde W. Yancy, MD, MSc, FACC, FAHA, MACP
Magerstadt Professor of Medicine, Chief, Division of Cardiology
NORTHERN ILLINOIS UNIVERSITY, FEINBERG SCHOOL OF MEDICINE

8:45 CHALLENGES FOR PAYORS IN CONSIDERING COMPARATIVE EFFECTIVENESS

Comprehensive effectiveness research allows for health care providers to deliver treatments helping to improve patient health outcomes based on medical evidence. Within the decision process of choosing which outcomes are most relevant to the patients of a specific state, many questions arise of how to best evaluate the findings, determine which treatments provide the best patient health outcomes and engage patients & physicians into acceptance of treatments. This open discussion will allow for payors and policy makers to discuss how they have implemented CER findings and what CER means for the future of health care providers.

- Implementing policies encouraging the development of targeted therapies
- Evaluating clinical trial outcomes best for a patient
- Value seen in head-to-head trials

Louis B. Jacques, MD
Director, Coverage and Analysis Group
CENTERS FOR MEDICARE AND MEDICAID SERVICES

9:30 COFFEE & NETWORKING BREAK

10:00 CASE STUDY: REAL-WORLD IMPLEMENTATION & BENEFIT OF CER

In order to achieve the vision of the full integration of evidence based medicine and comparative effectiveness research in the healthcare setting: pharma companies will need to fully embrace this type of research. Unfortunately, at this time, securing funding and support for this type of a study is increasingly challenging, as the value proposition for many senior level executives is low, regardless of the ultimate benefit to patients. Through a series of short case-studies, the following presentations will provide attendees with examples where CER studies have been implemented into the healthcare setting, initiated change in standards of care and driven value to the corporation. Key points being addressed include:

- Study design considerations & publication strategies
- Dissemination of results
- Driving value to the manufacturer
- Real-time results & ROI

Russell L. Knott, PhD
Director, US Health Economics and Outcomes Research
EISAI, INC.

10:45 PANEL DISCUSSION: IMPACT OF CER ON CARDIOLOGY & ONCOLOGY

With the topic of healthcare reform on the rise, providers are trying to guarantee the best therapy at the lowest cost is administered to patients of prevalent diseases seen in areas of cardiology and oncology. Answering the question of how well the patient will benefit from a current therapy versus an older treatment on the market ensures the patient receives the right treatment at the right time. This open discussion will review recent clinical findings and how CER is changing treatment for cardiology and oncology to best treat the patient.

- New findings and developments that have improved quality of life for patients
- How CER will change the treatment of cardiology and oncology

David H. Howard
Associate Professor, Health Policy & Management
EMORY UNIVERSITY, ROLLINS SCHOOL OF PUBLIC HEALTH

12:00 LUNCHEON FOR ALL CONFERENCE ATTENDEES

1:30 IMPACT OF CER ON INDIVIDUAL PATIENTS

The promise of comparative effectiveness studies and analysis is improvements in the quality of care for patients while reducing costs by giving physicians and patients access to therapy options that will ensure better decisions are made for the healthcare of a specific patient. The obstacle seen here is understanding how to determine whether CER studies will help the general population or rather just a subpopulation with similar genetic traits towards a certain disease, and whether widespread distribution of findings can impact patient care.

- Physician and patient acceptability of CER findings
- Ensuring or promoting cost effectiveness to the patient
- Strategies of getting findings into decision makers hands in right format & time

Dr. Melva Covington
Director, Comparative Effectiveness & Health Outcomes
SANOFI

12:15 UNDERSTANDING TO WHOM CER RESULTS APPLY

The ultimate goal of comparative effectiveness research studies is to ensure that the best treatment is applied to specific patients at the best time, but an underlying challenge is found in testing various patient groups to confirm which patient groups are most applicable for a particular therapy. Within formal CER studies, some patients may be left without meeting standards to enter the study and receive treatment, further narrowing the number of potential subjects. For manufacturers, the selection process used in profiling the optimal patient groups for a specific product is essential in ultimately providing the best data to support product use.

- Benefit of smaller sub groups and populations in CER
- Criteria of how to decide which therapy will be tested
- Getting the best match of therapy to the patient at the right time

Joseph D. Jackson, PhD
Program Director, Applied HEOR
THOMAS JEFFERSON UNIVERSITY

12:45 UNDERSTANDING TO WHOM CER RESULTS APPLY

Understanding how to influence physicians to promote the new evidence supporting a more cost-effective therapy to the patient is an ongoing obstacle seen in CER. Patients are also making their own decisions based on how efficiently it improves the quality of life. Aligning financial incentives from payors is imperative to ensure the most cost-efficient treatment is being used.

- Incorporating CER findings into clinical practice
- Communicating findings to ensure most effective therapy is used
- Strategies of influencing providers to accept CE analysis

David H. Howard
Associate Professor, Health Policy & Management
Rollins School of Public Health, Emory University

1:45 GLOBAL COMPARATIVE EFFECTIVENESS EVALUATIONS

Pharmaceutical companies are continually looking for cost-effective methods to conduct comparative effectiveness research in multiple locations in order to generate optimal data and ultimately usable reports. Harmonizing databases and registries for CER around the world will be imperative for future users and researchers looking to impact health outcomes on a global level. Exploring CER in countries previously considered emerging markets but with booming populations such as India & China will help organizations present unified and comprehensive results.

- Developing standardized validated outcome measures across evaluations
- Global system for CER across all payer systems
- Developing methodologies for CER assessment globally

Dr. Rajesh Balkrishnan
Associate Director for Research and Education
University of Michigan
SPEAKER SPOTLIGHT:

CLYDE W. YANCY, MD, MSc, FAAC, FAHA, MACP
Magerstadt Professor, Chief of Cardiology
Northwestern Memorial Hospital

Clyde W. Yancy, MD, MSc, FACC, FAHA, MACP, is the Magerstadt Professor and Chief of Cardiology at Northwestern Memorial Hospital and Northwestern University Feinberg School of Medicine. He is also a current member of the PCORI Methodology Committee. Previously, he was Professor of Medicine and Associate Dean of Clinical Affairs at UT Southwestern Medical Center in Dallas. He was most recently the Medical Director for the Baylor Heart and Vascular Institute and Chief of Cardiothoracic Transplantation for Baylor University Medical Center in Dallas, and he is the immediate past president of the American Heart Association (AHA). Dr. Yancy’s current medical appointment also includes serving as Associate Director of Clinical Programs for the Bluhm Cardiovascular Institute.

His academic and research interests are in heart failure, hypertension, heart transplantation, prevention and disparate care. He has authored or co-authored over 200 peer reviewed contributions to the literature along with multiple book chapters, editorials and web-based educational initiatives.

In addition to his roles at Northwestern, Dr. Yancy formerly served on the executive committee for the Heart Failure Society of America, currently serves on the guidelines task force for the American College of Cardiology, and still holds numerous appointments for the AHA and the American College of Cardiology. He is chair of the Food and Drug Administration’s cardiovascular device panel; serves as an ad hoc Chair for the Agency for Health Care Research and Quality study sections; former member of several NIH study sections; and is an advisor to the Director of the NIH and a consultant for the National Institute of Medicine. He serves on multiple editorial boards and is the current Associate Editor of the American Journal of Cardiology.

ATTENDEE PROFILE:

Individuals that will find this program of greatest interest and applicability will be those responsible for the generation and dissemination of comparative effectiveness research. With presenters bringing decades of years of expertise to the program agenda, this conference program will be a must attend for those looking to remain up to date with recent and ongoing changes. Executives with the following job titles will find this program of the greatest applicability:

- Health Economics
- Outcomes Research
- Health Outcomes
- Pharmacoeconomics
- Medical Affairs
- Patient Reported Outcomes
- Health Technology Assessments
- Medical Data Analytics

SPONSORSHIP OPPORTUNITIES:

A number of sponsorship opportunities exist for organizations wishing to further promote their expertise in this evolving marketplace. From table-top exhibits to keynote presentation opportunities, Q1 is prepared to work with sponsor partners to ensure the appropriate match of sponsorship exposure. Products and services that attendees are currently seeking include:

- Health Economics & Outcomes Consultants
- Data Analytics Consulting Services
- Contract Research Organizations
- Electronic Data Capture Services
- Data Mining Service Providers
- Patient Reported Outcomes Systems
- Electronic Patient Reported Outcomes

PREVIOUS ATTENDEES INCLUDE:

- Director of Strategic Planning, ABBOTT
- Sr. Manager, EBM, ABBOTT
- Associate Dir, Reimbursement Planning, ABBOTT
- Sr. Director Government Policy, ASTELLAS
- Sr. Director Commercial Analytics, AVANIR
- Director, Government Affairs, BAYER
- Sr. Manager, US Reimbursement, BAXTER
- Director, Business Analysis, BIOVAIL
- Director of Trade, BIOVAIL
- VP Commercial Operations, BIOVAIL
- Dir, Reimbursement, BRISTOL MYERS SQUIBB
- Dir, US Reimbursement, EDWARDS LIFESCIENCES
- Director, Global HEOR, EISAI
- Sr. Outcomes Liaison, ELI LILLY
- Sr. Director Reimbursement Strategy, ENDO
- Director, Managed Care Operations, FERRING
- Global Reimbursement Mgr, GE HEALTHCARE
- Sr. Policy Analyst, Reimbursement, GENENTECH
- Dir, Managed Markets, INSPIRE PHARMA
- VP Managed HC Markets, KING PHARMA
- VP Health Outcomes, LEO PHARMA
- Head, Market Access & Pricing, LEO PHARMA
- Sr. Director Managed Markets, LUNDBECK
- VP Managed Healthcare, MEDA PHARMA
- Director Reimbursement, MILLENNIUM PHARMA
- Director, New Product Analysis, NOVARTIS
- Associate Director, Pricing, NOVARTIS
- Sr. Manager, Federal Programs, OTSUKA
- Director of Reimbursement, OTSUKA
- Sr. Dir Reimbursement, PHILLIPS HEALTHCARE
- Associate Director, Outcomes, PFIZER
- Director, Reimbursement, PFIZER
- Sr. Director, Oncology Outcomes, PFIZER
- Sr. Director, Ophthalmology, REGNERON
- VP Commercial Operations, REGENERON
- Sr. Manager, Marketing, ROXRO PHARMA
- Assistant General Counsel, SANOFI-AVENTIS
- Sr. Dir Pricing & Contracting, SANOFI-AVENTIS
- Sr. Director Reimbursement, SCHERING-PLUGH
- Director, Government Marketing, SHIRE
- Director, HEOR, SHIRE
- Director, Strategic Accounts, SIRION
- Managed Care Director, SMITH & NEPHEW
- Manager, Health Economics, SMITH & NEPHEW
- Manager, Health Policy, ST. JUDE MEDICAL
- Sr. Reimbursement Manager, THORATEC
- VP Health Policy, WRIGHT MEDICAL