



Issues Panel: Opportunities and Challenges for Comparative Effectiveness Pragmatic Clinical Trials in Europe

- **Moderator :**
 - Marc L. Berger, M.D., Executive Vice President and Senior Scientist, OptumInsight Life Sciences
- **Panelists:**
 - Donna Messner, Ph.D., Senior Project Manager, Center for Medical Technology Policy (Baltimore, MD)
 - David Price, M.D., Primary Care Respiratory Society UK, Professor of Primary Care Respiratory Medicine University of Aberdeen
 - Finn Borlum Kristensen, M.D., Ph.D., Chairman, European network for HTA (EunetHTA)

Methods to Study Relative Effectiveness / Comparative Effectiveness:

- **Observational Studies**
 - Retrospective
 - Prospective (studies, registries)
- **Pragmatic Clinical Trials**
- **Head-to-head Post-marketing Randomized Controlled Clinical Trials**

The pragmatic-explanatory continuum indicator summary (PRECIS) tool.



Thorpe K E et al. CMAJ 2009;180:E47-E57



Efforts in the UK

- **GPRD**

- Randomized Evaluation of Accepted Choices in Treatment (REACT)
 - Large scale pragmatic trials within databases of routinely collected clinical data
- Feasibility Projects
 - » Antibiotics in Non-prurulent COPD Exacerbations
 - » Retro-Pro: Effectiveness of simvastatin compared to atorvastatin

- **UK Technology Assessment Programme**

- Two separate 2-year PCTs designed to evaluate the effectiveness of LTRA for primary care patients receiving asthma therapy under real-world conditions. (NEJM, May 5, 2011, volume 364, pp.1695-1707).
 - » LTRA and Inhaled Glucocorticoids
 - » LTRA and LABA as add-on therapy for for patients with uncontrolled asthma



- Donna Messner
 - Why haven't there been more PCTs?
 - What are the unique challenges for Europe?
- David Price, M.D.
 - Case Study of 2 PCTs in UK
 - How did it come about? What obstacles had to be overcome? How has it been received? What are the lessons learned?
- Finn Borlum Kristensen, M.D., Ph.D.
 - What is the status across the rest of Europe? What does the future hold?
- Q & A / Discussion