Symposium 1: Real world evidence or clinical trials? Which should I believe?

Stella Blackburn, IQVIA, UK

Stella studied medicine at Cambridge and Guys and worked in hospital medicine before joining the pharmaceutical industry. She has worked in pharmacovigilance and pharmacoepidemiology for 30 years: in industry (11+ years) as a regulator (nearly 17 years) and CRO (3+ years). She has an MSc in Epidemiology from the London School of Hygiene and Tropical Medicine. In 1997 she joined the European Medicines Agency (EMA). Stella developed EU strategy and policy on risk management, writing the EU guidelines on this topic and was part of the core team implementing the 2010 PhV legislation. She was on original steering group developing ENCEPP and was the Alternate Co-ordinator, and a scientific work package leader, of IMI PROTECT.

Stella is a Fellow of the International Society of Pharmacoepidemiology, the Royal College of Physicians of Edinburgh and the Faculty of Pharmaceutical Medicine. She is a past President of ISPE and an Honorary Associate Professor at the LSHTM and Visiting Scientist at MIT.

Jeremy Rassen, Aetion Inc, USA

Jeremy A. Rassen, MS, ScD is a pharmacoepidemiologist and technologist with nearly 25 years of academic and industry experience. He is Co-Founder, President and Chief Science Officer at Aetion, Inc., a New York-based healthcare technology company that provides science-driven real-world evidence (RWE) solutions to healthcare companies, regulatory bodies and academic centers. Dr. Rassen leads Aetion's efforts to design, scale and communicate scientific products and methodologies for obtaining valid and timely medical evidence from real-world data.

Prior to Aetion, Dr. Rassen was Assistant Professor of Medicine at Harvard Medical School, where he focused on methods for improving the quality and validity of studies based on real-world data, including administrative claims and electronic health records. In peer-reviewed publications and invited talks in the United States, Europe and Asia, he has looked at how real-world data can be used to validly, transparently and reproducibly measure the safety, effectiveness and value of medications and other treatments. Before coming to Harvard, Dr. Rassen worked in Silicon Valley in a variety technology companies, including Hewlett-Packard and Epiphany, Inc. His focus was on high-performance software for the creation and analysis of large databases. Dr. Rassen received his bachelor's degree in Computer Science from Harvard College and his masters and doctorate degrees in Epidemiology from the Harvard T.H. Chan School of Public Health.

Debra Rowett, The University of South Australia, AUS

Professor Debra Rowett, School of Pharmacy and Medical Sciences University of South Australia, Director Drug and Therapeutics Information Service and past President of the Australian Pharmacy Council. Debra has worked extensively in the area of academic detailing, quality use of medicines, inter-professional practice and medicines policy. Debra is a member of the national Drug Utilisation SubCommittee of the Australian Pharmaceutical Benefits Advisory Committee.

Andrew Roddam, GlaxoSmithKline, UK

Andrew is currently Vice President and head of Epidemiology, RWE and Digital Clinical Platforms at GSK, and is a renowned expert in epidemiological research with specific interest in the utilisation of routine data for research purposes. Andrew obtained his DPhil in Statistics at the University of Oxford and completed a post-doc in Infectious Disease Epidemiology. He was a Senior Researcher at the CRUK Cancer Epidemiology Unit at the University of Oxford before taking up an appointment at Amgen where he was most recently Regional Head (EU, EEMEA) in the Center for Observational Research. In his current role, he oversees the teams responsible for the epidemiological input into the discovery and development of new medicines as well as the real-world data and analytics group and the team charged with delivering innovation in real-world study execution.

Andrew is a participant on several expert groups and advisory committees both in the UK and internationally where his expertise in epidemiological methods and health informatics are highly regarded.