

# COMET V

**Wednesday 20th and Thursday 21st May 2015**

**University of Calgary**

**Alberta, Canada**



*COMET Management Group: Professor Doug Altman, Professor Jane Blazeby, Professor Mike Clarke,  
Miss Elizabeth Gargon, Dr Sean Tunis, Professor Paula Williamson*

## COMET V Programme

### COMET V Programme

#### Day 1 – Wednesday 20th May 2015

<b>Time</b>	
<b>8.00-9.00</b>	<b>Registration and refreshments</b>
<b>8.30-8.50</b>	Nicola Harman (University of Liverpool) <b>Pre-meeting: Introductory session for newcomers</b>
<b>9.00-9.40</b>	<b>Meeting opening: Welcome and COMET update</b>
9.00-9.20	Theresa Radwell (Alberta Cancer Foundation) <b>Welcome and introduction</b>
9.20-9.40	Paula Williamson (University of Liverpool) <b>COMET – activities and update</b>
<b>9.40-10.40</b>	John Marshall (St. Michael's Hospital), Jonathan Craig and Allison Tong (University of Sydney), Amy Hoang-Kim (University of Toronto) <b>Core Outcome Set presentations</b>
<b>10.40-11.10</b>	<b>Refreshments and poster viewing</b>
<b>11.10-12.10</b>	<b>Panel discussion – Common ground for core outcome sets</b>
11.10-11.40	<b>Introducing the panel</b> CMAJ (John Fletcher), COMET (Mike Clarke), OMERACT (Peter Tugwell), Health Canada (Carole Légaré), Canadian Critical Care Trials Group (John Marshall)
11.40-12.10	<b>Questions to the panel</b>
<b>12.10-13.00</b>	<b>Lunch and poster viewing</b>
<b>13.00-13.30</b>	David Moher (Ottawa Hospital Research Institute) <b>EQUATOR</b>
<b>13.30-14.30</b>	Zafira Bhaloo (University of Alberta), Michele Hamm (University of Alberta), Mufiza Kapadia (The Hospital for Sick Children) <b>Outcomes for paediatric trials (Chair: Lisa Hartling, University of Alberta)</b>
<b>14.30-15.00</b>	<b>Refreshments and poster viewing</b>
<b>15:00-16:00</b>	Carina Benstöm (University Hospital RWTH Aachen), Chris Hylton (PaCER), Sally Crowe (Crowe Associates Ltd), Thomas Kelley (International Consortium for Health Outcomes Measurement) <b>Contributed talks</b>
<b>16.15-16.30</b>	Mike Clarke (Queen's University Belfast) <b>COMET in Canada</b>
<b>16.30</b>	<b>Meeting close – end of Day 1</b>
<b>19.30-22.00</b>	<b>COMET Dinner</b>

## Day 2- Thursday 21st May 2015 (shared with Cochrane Canada)

Time	
8.00-9.00	<b>Registration and refreshments; poster viewing</b>
9.00-10.30	Kay Dickersin (John Hopkins University), Mike Clarke (Queen's University Belfast), Holger Schunemann (McMaster University) <b>Opening, welcome remarks, and plenary speakers</b>  Paula Williamson (University of Liverpool) <b>Close of COMET V meeting</b>
10.30-11.00	<b>Refreshments and poster viewing</b>
11.00-12.30	<b>Parallel workshops</b>
	<b>Workshop 1 - Methods for determining what to measure in core outcome sets</b> Workshop lead: Paula Williamson (University of Liverpool)
	<b>Workshop 2 - Core outcome sets for randomised controlled trials and Cochrane reviews</b> Workshop lead: Mike Clarke (Queen's University Belfast)
	<b>Workshop 3 - Involving patients in core outcome set development: identifying the challenges and potential solutions</b> Workshop lead: Bridget Young (University of Liverpool)
12.30-13.30	<b>Lunch and poster viewing</b>

## Invited Speakers

### Day 1 AM speakers



**Nicola Harman**

University of Liverpool

Nicola Harman is a research associate at the North West Hub for Trials Methodology Research (NWHMTR). She has worked in the field of paediatric clinical trials since 2007 with special interest in recruitment and consent. She has also worked on the development of a core outcome set for the management of otitis media with effusion in children with cleft (the MOMENT study) with particular focus on how to involve all stakeholders, including parents and children in core outcome set development.



**Theresa Radwell**

Alberta Cancer Foundation

Theresa Radwell is the Vice President, Program Investment at the Alberta Cancer Foundation – the largest cancer fundraiser in Alberta, Canada and partner with the 17 cancer centres in the province. In this role, she is responsible for the strategic development, leadership and management of the Foundation's Program Investment portfolio which encompasses investments in cancer research, prevention, screening and enhanced care programs. Theresa joined the Foundation in January 2011 from her role as Associate Director in the Southern Alberta Cancer Research Institute overseeing the business and operational functions of cancer research in southern Alberta. Prior to working in cancer research environment, Theresa has accumulated over twenty years of experience in senior roles within the financial services sector in the United Kingdom, primarily in the areas of strategic marketing, customer and stakeholder relationship management and overseeing distribution channels of major organizations in this sector.



**Paula Williamson**

University of Liverpool

Paula's research has previously been focussed on the development and application of statistical methodology in medicine. Major contributions have been made in the fields of clinical trials methodology, meta-analysis, and in the treatment of epilepsy. More recently Paula has undertaken research around the selection of outcomes for clinical research. In 2002, she was appointed Director of a new Centre for Medical Statistics, now the Department of Biostatistics, since then developing a group of over 80 staff working in health research. She has been an Associate Director of the NIHR Medicines for Children Research Network and Director of the MCRN Clinical Trials Unit since inception in 2005. In 2007, Paula became Director of the Clinical Trials Research Centre (CTRC) and has been a member of the UK Clinical Research Collaboration Registered CTU Network Steering Group since its inception.

In 2008, Paula led a successful bid to create the MRC North West Hub for Trials Methodology Research (NWHTMR), a partnership between the Universities of Liverpool, Lancaster and Bangor. The recent extension bid, 2013-2018, including the University of Manchester, was successful. Paula has recently been appointed Chair of the MRC HTMR Network. She leads the Trials Feasibility Improvement Network theme within the MRC Health e-Research Centre North, and is responsible for liaison between these two MRC networks. Paula is the lead for the European Commission- and MRC-funded COMET (Core Outcome Measures in Effectiveness Trials) Initiative, endorsed by NIHR and now referred to in NIHR HTA Guidance for Applicants. Paula has recently been appointed as an NIHR Senior Investigator, 2014-2019.



**John Marshall**

St. Michael's Hospital

John Marshall is a Professor of Surgery at the University of Toronto, and a trauma surgeon and intensivist at St. Michael's Hospital in Toronto, Canada. His academic interests are sepsis, trauma, and the innate immune response. His laboratory studies the cellular mechanisms that prolong neutrophil survival in critical illness by preventing neutrophil programmed cell death, or apoptosis. Professor Marshall has an active clinical research interest in sepsis and ICU-acquired infection, and in the design of clinical trials and outcome measures. He has published 300 manuscripts, and 80 book chapters, and is the editor of 2 books. He is the founding chair of the International Forum of Acute Care Trialists (InFACT) – a global network of investigator-led critical care clinical research groups, Secretary-General of the World Federation of Societies of Intensive and Critical Care Medicine, and vice-chair of the International Severe Acute Respiratory Infections Consortium. He is past-chair of the International Sepsis Forum, past-President of the Surgical Infection Society, and past-chair of the Canadian Critical Care Trials Group. He has given invited lectures at more than 450 meetings around the world, and is a member of the editorial boards of seven journals.



**Jonathan Craig**

University of Sydney

Jonathan is a Senior Staff Specialist in Paediatric Nephrology at the Children's Hospital at Westmead, Associate Dean of Research for the Faculty of Medicine at the University of Sydney, and holds a personal Chair in Clinical Epidemiology in the School of Public Health. He has an interest in the development, synthesis, dissemination and implementation of research evidence to guide clinical decision-making, particularly in the area of kidney disease and child health. He is the author of about 500 peer-reviewed publications and is a past and present member of many editorial boards, including Journal of the American Society of Nephrology and the American Journal of Kidney Disease, and is Coordinating Editor of the Cochrane Kidney and Transplant Group. He is the immediate past Co-Chair of the Cochrane Collaboration, is on the board of Kidney Health Australia, and a member of the Medicare Services Advisory Committee.



**Allison Tong**

University of Sydney

Allison Tong is an Associate Professor at the Sydney School of Public Health, The University of Sydney. Her main interest is in using applied qualitative research methods to the area of chronic disease; to inform practice and policy for improved patient-centred outcomes. Allison developed the consolidated criteria for reporting qualitative health research (COREQ), and the enhancing transparency in reporting the synthesis of qualitative health research [ENTREQ]; which are both endorsed as key reporting guidelines by leading journals and by the international EQUATOR Network for promoting the transparency of health research. She runs training workshops in qualitative health research worldwide. Allison is conducting research on patient priorities for research questions and outcomes, experience of illness, treatment decision-making, quality of life, barriers and facilitators to implementing evidence, and process evaluations of healthcare interventions.



**Amy Hoang-Kim**

University of Toronto

Dr. Amy Hoang-Kim is a Young Investigator and recent Phd graduate scholar in the Department of Medical Sciences, Faculty of Medicine, at the University of Toronto. She received her bachelor's degree from Queen's University, and two master's degrees from University of Toronto. She is the executive director of the International Society for Fracture Repair. She has led expert panels on achieving consensus on minimal core sets of domains for clinical research and practice, especially in the treatment of distal radius in partnership with the International Osteoporosis Foundation. Other work has included standardizing outcomes for thumb CMC fractures and developing guidelines in fracture healing for geriatric programs dedicated to patients with osteoporosis. Her studies have included outcomes, prioritizing areas of health research investments for proximal humerus fractures, and use of qualitative frameworks to understand prognosis for patients with hip fracture, their caregivers, and providers both nationally and internationally.

## Introducing the panel



**John Fletcher**

CMAJ

John was born and brought up in England and studied medicine at the University of Cambridge. After 4 years of hospital medicine and some time in Zaire, Africa he completed training in general practice and moved to Oxford to work in the Department of Public Health and Primary Care. He obtained a Masters in Public Health at Harvard (the other Cambridge) in 1998 and later returned to Oxford. The following year he founded a medical knowledge company with Sir Muir Gray and Professor David Sackett. He was chairman of the board of two companies, the other providing buildings services and staff to the University of Oxford and Oxford Health Authority. In 2002 he resigned his business interests for a job at the British Medical Journal where he was Primary Care Editor and later Clinical Epidemiologist. He joined CMAJ in 2008 as Deputy Editor, Research. In January 2012, he was appointed Editor-in-Chief of CMAJ. He has an academic affiliation at the Department of Family Medicine at the University of Ottawa where he is an Assistant Professor.



**Mike Clarke**

COMET

Professor Mike Clarke is Director of the Northern Ireland Network for Trials Methodology Research, based at Queen's University in Belfast. He has spent more than 25 years working on systematic reviews and large randomised trials in a range of areas of health and social care. He has a strong interest in increasing capacity for the conduct of trials and reviews, and in improving accessibility to their findings. This includes his work on Evidence Aid, to make it easier for people and organisations planning for and responding to natural disasters to make well informed decisions. He is involved in the development of core outcome sets in maternity care and intensive care, and is a member of the COMET Management Group.



**Peter Tugwell**

OMERACT

Dr. Peter Tugwell is Professor of Medicine and Epidemiology & Community Medicine at the University of Ottawa and is a practicing rheumatologist at the Ottawa Hospital. In 2001, he became Director for the Centre for Global Health at the Institute of Population Health. He has built a research program and multidisciplinary team around his Canada Research Chair in Health Equity. Dr. Tugwell was Founding Director of the International Clinical Epidemiology Network Training Centre at McMaster University [1982-91] and currently serves as Secretary General to INCLEN's North American group (CanUSAClen). Dr. Tugwell is co-director of a WHO Collaborating Centre for Knowledge Translation & Health Technology Assessment in Equity. Dr. Tugwell is Coordinating Editor of the Cochrane Musculoskeletal Review Group and is Founding Co-convenor of the newly formed Cochrane Health Equity Field/Campbell Equity Methods Group and serves on the Steering Committee of the Campbell Collaboration. In 2002 he was appointed the North American Editor for the Journal of Clinical Epidemiology. He is also a Section Editor for UpToDate and a member of the Oversight committee of the Canadian Medical Association Journal. Dr. Tugwell's publication record includes over 600 journal articles, monographs, and book chapters.



**Carole Légaré**

Health Canada

Dr Carole Légaré completed her medical training at the University of Ottawa and holds a certificate in pharmacoepidemiology from the London School of Hygiene and Tropical Medicine. She has over 25 years of experience in various parts of the Canadian health care system, including clinical practice, public health, medical education and the federal drug regulatory system. She joined Health Canada in 2002 where she held positions as medical manager of post-market safety surveillance of biologic and biotechnology products and senior medical advisor for the Centre for Biologics Evaluation before joining the Therapeutic Products Directorate as director of the Office of Clinical Trials.



**John Marshall**

Canadian Critical Care Trials Group

John Marshall is a Professor of Surgery at the University of Toronto, and a trauma surgeon and intensivist at St. Michael's Hospital in Toronto, Canada. His academic interests are sepsis, trauma, and the innate immune response. His laboratory studies the cellular mechanisms that prolong neutrophil survival in critical illness by preventing neutrophil programmed cell death, or apoptosis. Professor Marshall has an active clinical research interest in sepsis and ICU-acquired infection, and in the design of clinical trials and outcome measures. He has published 300 manuscripts, and 80 book chapters, and is the editor of 2 books. He is the founding chair of the International Forum of Acute Care Trialists (InFACT) – a global network of investigator-led critical care clinical research groups, Secretary-General of the World Federation of Societies of Intensive and Critical Care Medicine, and vice-chair of the International Severe Acute Respiratory Infections Consortium. He is past-chair of the International Sepsis Forum, past-President of the Surgical Infection Society, and past-chair of the Canadian Critical Care Trials Group. He has given invited lectures at more than 450 meetings around the world, and is a member of the editorial boards of seven journals.

## Day 1 PM speakers



**David Moher**

Ottawa Hospital Research Institute

Dr. David Moher is a Senior Scientist in the Clinical Epidemiology Program, Ottawa Hospital Research Institute, and Associate Professor School of Epidemiology, Public Health and Preventive Medicine, Faculty of Medicine, University of Ottawa, where he holds a University Research Chair.

Dr. Moher has a special interest in the journalology (publication science) and ways to improve the quality of conducting and reporting health research. He spearheaded the development of several reporting guidelines including CONSORT, PRISMA and PRISMA-P. Dr. Moher is associated with many journals; founding editor-in-chief of Systematic Reviews; a member of the advisory board for the International Congress on Peer Review and Biomedical Publication, and a member of the EQUATOR Network's steering group.



**Zafira Bhaloo**

University of Alberta

Zafira holds a Bachelor of Science degree in Biological Sciences and French Language and Literature and a Master of Science degree from the University of Alberta. Her Master's thesis discusses the reporting and validation of measurement properties of primary outcome measures in pediatric RCTs. Zafira is currently completing her final year of medical school at the University of Calgary. She recently completed her term as President of the Calgary Healthcare Improvement Network (CHIN), a student group focused on quality improvement and patient safety.



**Michele Hamm**

University of Alberta

Michele Hamm is a Research Associate at the Alberta Research Centre for Health Evidence in the Department of Pediatrics at the University of Alberta. Her research is based on using knowledge translation to improve research in child health and she is involved in the evaluation of various methods to engage with different stakeholder groups. One stream of research has focused on understanding and improving the disconnect between the evidence on minimizing risk of bias in research and the actual conduct of randomized controlled trials in child health, and the other has been centred on novel methods of connecting with patients and parents, including through the use of social media.



**Mufiza Kapadia**

The Hospital for Sick Children

Mufiza Zia Kapadia is a physician with a PhD in Public Health. She is a postdoctoral research fellow at Child Health Evaluation Sciences, the Hospital for Sick Children, Toronto. She has extensive experience in statistical and epidemiological methodologies, including outcome selection for pediatric clinical trials, systematic reviews and meta-analyses. At the Hospital for Sick Children, she is involved in a series of research studies under TORCH (Toronto Outcome Research in Child Health) and pediatric clinical trial guideline development. Mufiza is currently developing guideline for the choice of outcomes for pediatric clinical trials and evidence synthesis. She is also developing pediatric extensions of Preferred Reporting Items for Systematic reviews and Meta-Analysis - Protocols for Children (PRISMA-PC) and Reporting (PRISMA-C).

## Day 2 speakers



**Kay Dickersin**

John Hopkins University

Kay Dickersin, M.A., Ph. D. is Professor of Epidemiology at the Johns Hopkins Bloomberg School of Public Health, where she serves as the Director for the Center for Clinical Trials. She is also Director of the U.S. Cochrane Center, one of 13 Centers worldwide participating in The Cochrane Collaboration. Kay's main research contributions have been in the area of clinical trials, systematic reviews and meta-analysis, reporting biases, trials registration, and the development and utilization of methods for the evaluation of health care interventions and their effectiveness. She has led and participated in research on reporting biases since the 1980s, most recently examining internal company documents related to the drug gabapentin and comparing the documents to the published record. Kay has also been actively engaged in teaching, including developing courses on evidence-based healthcare, epidemiology, peer review, clinical trials and systematic reviews. Among her honors, Kay is an elected member of the Institute of Medicine and received the 2014 Ingram Olkin Award from the Society for Research Synthesis Methods for lifetime contributions to the field. Kay received a Master's degree in zoology, specializing in cell biology, from the University of California, Berkeley, and a Ph.D. in epidemiology from Johns Hopkins University's School of Hygiene and Public Health.



**Mike Clarke**

Queen's University Belfast

Professor Mike Clarke is Director of the Northern Ireland Network for Trials Methodology Research, based at Queen's University in Belfast. He has spent more than 25 years working on systematic reviews and large randomised trials in a range of areas of health and social care. He has a strong interest in increasing capacity for the conduct of trials and reviews, and in improving accessibility to their findings. This includes his work on Evidence Aid, to make it easier for people and organisations planning for and responding to natural disasters to make well informed decisions. He is involved in the development of core outcome sets in maternity care and intensive care, and is a member of the COMET Management Group.



**Holger Schunemann**

McMaster University

### **GRADE Evidence to Decision Frameworks: Use and usefulness**

Succeeding eminent scientists including David Sackett, Mike Gent, Peter Tugwell, George Browman and Brian Haynes, Dr. Schünemann is chair of the Department of Clinical Epidemiology and Biostatistics at McMaster University, widely considered the birthplace of evidence-based medicine. He trained in internal medicine, epidemiology, preventive medicine and public health. Having contributed to over 400 peer-reviewed publications (across a broad area of health care questions) he is co-chair of the GRADE working group, co-director of the World Health Organization (WHO) collaborating center for evidence informed policy-making, a member of the Board of Trustees of the Guideline International Network, the Cochrane Collaboration Steering Group, and WHO committees. He led or participated in numerous guideline panels, including at the WHO, the American College of Physicians, American Thoracic Society, the World Allergy Organization and drafted the first version of the WHO's handbook on guideline development. Recently, he has focused on practical application of his work by researchers and clinicians through contributions to the guideline development tool ([www.gradepro.org](http://www.gradepro.org)), the guideline checklist ([cebgrade.mcmaster.ca/guidecheck.html](http://cebgrade.mcmaster.ca/guidecheck.html)) and GRADE evidence to decision frameworks ([www.decide-collaboration.eu](http://www.decide-collaboration.eu)). He enjoys his second home in Italy and long distance bike rides.



**Bridget Young**

University of Liverpool

### **Workshop 3 - Involving patients in core outcome set development: identifying the challenges and potential solutions**

Bridget Young is Professor of Psychology at University of Liverpool and co-lead for the Patient Perspectives Theme of the Northwest Hub for Trials Methodology Research. Her work focuses on psychosocial processes in healthcare and clinical research, with the ultimate aim of improving patient care. She specialises in the use of qualitative methods to investigate patient-practitioner communication in complex chronic illness and recruitment to clinical trials, and most recently, in the development of core outcome sets.

# Workshops

## **Workshop 1: Methods for determining what to measure in core outcome sets**

Selection of outcomes is crucial to trials designed to compare the effects of different interventions. For findings to influence policy and practice, chosen outcomes need to be relevant to patients, public, healthcare professionals and others making decisions about health care. Trials in a specific condition often report different outcomes, or address the same outcome in different ways. So much could be gained if an agreed core outcome set (COS) of a minimum number of appropriate and important outcomes was measured and reported in all clinical trials in a specific condition. There are, however, no agreed best methods for selection of outcomes for COSs. This workshop will comprise a mixture of presentations, exercises and participant discussion to consider the various methods that have been used to date for COS development. A presentation will introduce methodological issues and considerations involved in developing COS. This will be illustrated with examples of COS developed for different healthcare settings (e.g. primary, secondary care, acute and chronic illnesses). Participants will be given examples of existing work to design COS for clinical trials, and work in groups to discuss potential issues. Participants will also consider different methods and their role in COS development. The importance of including key stakeholders in establishing COS will be emphasised to ensure consideration of appropriate outcomes. The workshop will be suitable for participants who have no prior experience of COS development, as well as those who have some experience.

## **Workshop 2: Core outcome sets for randomised controlled trials and Cochrane reviews**

Ill health and treatments can affect people in different ways, making it difficult to select the most appropriate outcomes for research. The development of standardised core outcome sets for all trials of effectiveness in a particular condition would make this easier. This workshop will comprise a mixture of presentations and participant discussion. A presentation will set the scene for several key issues and the participants will then be given specific Cochrane reviews to look at. They will work in groups to identify examples of non-standardised selection, measurement and reporting of outcomes, and to discuss problems this may cause for authors of systematic reviews. Subsequent presentations and group discussion will focus on existing work to design core outcome sets for clinical trials, and to identify outcomes of most importance to patients, families and carers. Participants will discuss how similar research could identify appropriate outcomes for Cochrane reviews, and how core outcome sets can be used to help authors present their findings clearly and succinctly, such as within the Summary of Findings table.

## **Workshop 3: Involving patients in core outcome set development: identifying the challenges and potential solutions**

For a core outcome sets (COS) to have credibility, the chosen outcomes need to be relevant and meaningful to all stakeholders, including patients and carers. Participants in this interactive session will work together to identify the challenges that researchers may encounter when planning to involve patients and carers in COS development (such as how to access patients/carers, how to maintain their involvement over time and how to elicit their views on COS etc.) Participants will also exchange ideas about potential solutions to address these challenges in different contexts and with different stakeholder groups. After brief introductory presentations to set the scene, participants will join breakout groups to discuss the challenges and solutions. A plenary session at the end will provide the opportunity for groups to share their ideas and experiences. The workshop will be suitable for people who have no prior experience of working with patients/carers to develop COS, as well as those who have some experience. The aim of the workshop is not to teach people how to involve patients/carers in COS development, but rather to raise awareness of the challenges and to discuss some potential ways to tackle these challenges.

## COMET Management Group

**Doug Altman**



Doug Altman has been director of the Centre for Statistics in Medicine in Oxford since its inception in 1995. He has published over 400 peer reviewed articles, many aimed at clarifying statistical ideas for medical researchers. He is author of Practical Statistics for Medical Research. His varied research interests include the use and abuse of statistics in medical research, studies of prognosis, regression modelling, systematic reviews and meta-analysis, randomised trials, and studies of medical measurement. Doug is senior statistical editor at the BMJ and co-editor-in-chief of Trials. He is actively involved in developing guidelines for reporting research, including CONSORT, STROBE, and PRISMA, and in 2006 founded the EQUATOR Network which seeks to improve the quality of scientific publications by promoting transparent and accurate reporting of health research.

**Jane Blazeby**



Jane Blazeby is Professor of Surgery at the University of Bristol and an Honorary Consultant Surgeon at University Hospitals Bristol NHS Foundation Trust. She is Director of the MRC ConDuCT Hub (Collaboration and Innovation for Difficult and Complex Randomised Controlled Trials) for trials methodology research. ConDucT focuses on several themes including developing methods for integrating clinical and patient reported outcomes to influence clinical decision-making.

**Mike Clarke**



Professor Mike Clarke is Chair of Research Methodology at Queen's University in Belfast and Director of the all-Ireland Hub for Trials Methodology Research, since March 2011. He was Director of the UK Cochrane Centre from

2002 until then and has spent more than twenty years working on systematic reviews and large randomised trials in a range of areas. He has a strong interest in increasing capacity for the conduct of randomised trials and systematic reviews, and in improving accessibility to their findings, in particular in low and middle income countries. This includes his work on Evidence Aid, to make it easier for people and organisations planning for and responding to natural disasters to make well informed decisions about health care and other areas.

### **Elizabeth Gargon**



Elizabeth Gargon obtained a First class Bachelor of Science Degree in Psychology and Health Science from the University of Liverpool in 2007. She joined the University of Liverpool as a research assistant for a research programme funded by the National Institute of Health Research (NIHR), and worked in collaboration with Alder Hey Children's NHS Foundation Trust. She is now a member of the COMET (Core Outcome Measures in Effectiveness Trials) Initiative Management Group and the Project Coordinator, and is undertaking a part-time PhD in the Institute of Translational Medicine (Biostatistics) at the University of Liverpool.

### **Sean Tunis**



Sean Tunis, MD, MSc. is the Founder, President and Chief Executive Officer of the Center for Medical Technology Policy in Baltimore, Maryland. CMTF is an independent, non-profit organization that provides a neutral platform for multi-stakeholder collaborations that are focused on improving the quality, relevance, and efficiency of clinical research. His work currently focuses on expanding infrastructure for the conduct of pragmatic clinical trials within the health care delivery systems, developing condition-specific evidentiary standards for reimbursement, and promoting greater engagement of patients and consumers in clinical research. Dr. Tunis serves on the Board of Health Technology Assessment International, the Health Sciences Policy Council for ISPOR and a number of other advisory boards for public and private sector organizations focused on issues of comparative effectiveness, innovation, health technology assessment, evidence-based medicine, clinical research, and reimbursement.

**Paula Williamson**



Paula Williamson is Professor of Medical Statistics and Director of the Clinical Trials Research Centre (CTRC) at the University of Liverpool. She is an Associate Director of the NIHR Medicines for Children Research Network, and Director of the MCRN Clinical Trials Unit. In 2008 she led a successful bid to create the MRC North West Hub for Trials Methodology Research (NWHTMR), focussing on three themes (early phase trial design and analysis, later phase trial design and analysis, patients' perspectives), and developing methods for application across key clinical areas including paediatrics, drug safety, cancer and epilepsy. The MRC have recently funded NWHTMR for a further five years.

