SELECTION AND REPORTING OF OUTCOMES FOR INNOVATIVE SURGICAL DEVICES
A WORKSHOP

Wednesday 12 September 2018, 10:00 – 16:00; M Shed, Princes Wharf, Wapping Rd, Bristol BS1 4RN

Improving the evaluation of medical devices with development of a generic core outcome set (COS): a key stakeholder workshop for industry, innovators, clinicians, trialists, journal editors, health policy makers and patients

09:30 Registration (tea, coffee and refreshments will be available)

Chair of first session: Professor Robert Hinchliffe, Professor of Vascular Surgery, University of Bristol

10:00 Welcome and introduction
Professor Robert Hinchliffe, Professor of Vascular Surgery, University of Bristol

10:05 The challenges of outcome selection, measurement and reporting for devices
Dr Kerry Avery, Senior Lecturer in Health Services Research, University of Bristol

10:20 IDEAL-D: Evaluation of devices using an integrated pathway
Professor Peter McCulloch, Professor of Surgical Science and Practice, University of Oxford

10:40 Selection, measurement and reporting of outcomes from the SME / start-up innovator perspective
Professor Edward Draper, Chief Executive Officer, Ortheia Ltd

10:55 Selection, measurement and reporting of outcomes from the manufacturers’ perspective
Dr Ted Lystig, Director of Corporate Biostatistics, Medtronic

11:15 Coffee

Chair of second session: Professor Jane Blazeby, Professor of Surgery, University of Bristol

11:30 Clinical Investigations – A Regulatory perspective
Dr Camilla Fleetcroft, Unit Manager - Clinical Investigations and Evaluation, MHRA

11:50 Evaluating surgical innovation using real world evidence in the US
Professor Art Sedrakyan, Professor of Healthcare Policy and Research and Surgery, Weill Cornell Medical College

12:10 Taking a lifecycle approach to the evaluation of surgical devices: moving from Health Technology Assessment to Health Technology Monitoring
Dr Tammy Clifford, Chief Scientist and Vice President, Evidence Standards, Canadian Agency for Drugs and Technologies in Health

12:30 Lunch

Chair of third session: Professor Rob Hinchliffe, Professor of Vascular Surgery, University of Bristol

13:15 Clinical trial reporting and the recent scandals in surgical innovation
Professor Carl Heneghan, Director of the Centre for Evidence-Based Medicine and Director of Programs in Evidence-Based Healthcare, University of Oxford

13:40 Core Outcome Sets
Professor Paula Williamson, Professor of Medical Statistics, MRC North West Hub for Trials Methodology Research

14:00 Breakout groups (with afternoon refreshments available)
• Professor Jane Blazeby, Professor of Surgery, University of Bristol
• Professor Martin Elliott, Professor of Paediatric Cardiotoracic Surgery, University College London
• Professor Paula Williamson, Professor of Medical Statistics, MRC North West Hub for Trials Methodology Research
• Professor Jonathan Sterne, Professor of Medical Statistics and Epidemiology, University of Bristol

15:00 Living articles
Professor Richard Smith, former Editor, BMJ and Dr Michaela Torkar, Publishing Director, F1000 Platforms

15:30 Feedback from breakout group chairs

15:45 Conclusions / Day Summary
Professor Robert Hinchliffe, Professor of Vascular Surgery, University of Bristol

16:00 End