

## SELECTION AND REPORTING OF OUTCOMES FOR INNOVATIVE SURGICAL DEVICES A WORKSHOP

Wednesday 12 September 2018, 10:00 – 16:00; MShed, 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***

<b>09:30</b>	<b>Registration (tea, coffee and refreshments will be available)</b> <i>Chair of first session: Professor Robert Hinchliffe, Professor of Vascular Surgery, University of Bristol</i>
<b>10:00</b>	<b>Welcome and introduction</b> Professor Robert Hinchliffe, Professor of Vascular Surgery, University of Bristol
<b>10:05</b>	<b>The challenges of outcome selection, measurement and reporting for devices</b> Dr Kerry Avery, Senior Lecturer in Health Services Research, University of Bristol
<b>10:20</b>	<b>IDEAL-D: Evaluation of devices using an integrated pathway</b> Professor Peter McCulloch, Professor of Surgical Science and Practice, University of Oxford
<b>10:40</b>	<b>Selection, measurement and reporting of outcomes from the SME / start-up innovator perspective</b> Professor Edward Draper, Chief Executive Officer, Ortheia Ltd
<b>10:55</b>	<b>Selection, measurement and reporting of outcomes from the manufacturers' perspective</b> Dr Ted Lystig, Director of Corporate Biostatistics, Medtronic
<b>11:15</b>	<b>Coffee</b> <i>Chair of second session: Professor Jane Blazeby, Professor of Surgery, University of Bristol</i>
<b>11:30</b>	<b>Clinical Investigations – A Regulatory perspective</b> Dr Camilla Fleetcroft, Unit Manager - Clinical Investigations and Evaluation, MHRA
<b>11:50</b>	<b>Evaluating surgical innovation using real world evidence in the US</b> Professor Art Sedrakyan, Professor of Healthcare Policy and Research and Surgery, Weill Cornell Medical College
<b>12:10</b>	<b>Taking a lifecycle approach to the evaluation of surgical devices: moving from Health Technology Assessment to Health Technology Monitoring</b> Dr Tammy Clifford, Chief Scientist and Vice President, Evidence Standards, Canadian Agency for Drugs and Technologies in Health
<b>12:30</b>	<b>Lunch</b> <i>Chair of third session: Professor Rob Hinchliffe, Professor of Vascular Surgery, University of Bristol</i>
<b>13:15</b>	<b>Clinical trial reporting and the recent scandals in surgical innovation</b> Professor Carl Heneghan, Director of the Centre for Evidence-Based Medicine and Director of Programs in Evidence-Based Healthcare, University of Oxford
<b>13:40</b>	<b>Core Outcome Sets</b> Professor Paula Williamson, Professor of Medical Statistics, MRC North West Hub for Trials Methodology Research
<b>14:00</b>	<b>Breakout groups (with afternoon refreshments available)</b> <ul style="list-style-type: none"> <li>• Professor Jane Blazeby, Professor of Surgery, University of Bristol</li> <li>• Professor Martin Elliott, Professor of Paediatric Cardiothoracic Surgery, University College London</li> <li>• Professor Paula Williamson, Professor of Medical Statistics, MRC North West Hub for Trials Methodology Research</li> <li>• Professor Jonathan Sterne, Professor of Medical Statistics and Epidemiology, University of Bristol</li> </ul>
<b>15:00</b>	<b>Living articles</b> Professor Richard Smith, former Editor, BMJ and Dr Michaela Torkar, Publishing Director, F1000 Platforms
<b>15:30</b>	<b>Feedback from breakout group chairs</b>
<b>15:45</b>	<b>Conclusions / Day Summary</b> Professor Robert Hinchliffe, Professor of Vascular Surgery, University of Bristol
<b>16:00</b>	<b>End</b>