

**IDEAL 2017 Conference Program Draft**  
**Research, Regulation, and Reimbursement in Surgery and Technologies**  
**May 4-5, 2017, New York Academy of Medicine, New York City**

<b>Thursday, May 4<sup>th</sup></b>		
<b>7:30 AM: REGISTRATIONS OPEN</b>		
<b>8:30 AM - 12:30 PM</b>		
<b>Training Courses and Symposia</b>		
<b>IDEAL surgery: stages and methodologies</b>	<b>IDEAL for devices: regulation and innovation Robotic surgery symposium in context</b>	
<p>Speakers:  <i>Peter McCulloch, Oxford</i>  <i>Joshua Feinberg, Oxford</i>  <i>Chris Pennell, Maimonides</i>  <i>Joel Horovitz, Maimonides</i></p> <p>1. What is IDEAL? How it came about and what it is useful for.</p> <p>2. Using IDEAL: Explanation about (a) how to use it to understand the literature (b) how to use it to design research. Interactive discussions with examples for audience to try out (small group discussion to come up with a study design and study conduct plan, focusing on stage 1-3 of IDEAL).</p> <p>3. Disseminating IDEAL: How to present IDEAL studies to journals, funders, and others.</p>	<p><u>Regulation of devices</u> (8:30-10:30 AM)</p> <p>Facilitators:  <i>Art Sedrakyan, Weill Cornell</i>  <i>Murray Sheldon, FDA</i></p> <p>Speakers:  <i>Binita Ashar, FDA</i>  <i>Danica Marinac-Dabic, FDA</i>  <i>Bruce Campbell, MHRA, UK</i>  <i>Jesse Berlin, Johnson &amp; Johnson</i>  <i>Nobuhiro Handa, PMDA, Japan (TBC)</i></p> <p>The speakers will discuss device regulation in USA, Europe and Japan and focus on recent developments.</p> <p>Important focus will be the lifecycle approach to device evaluation and current frameworks: reflections on IDEAL framework for devices and future advancement needs.</p>	
	<p><u>Robotic symposium</u> (10:30 AM-12:30 PM)</p> <p>Moderators:  <i>Jeffrey Levy &amp; Martin Martino, Institute for Surgical Excellence</i></p> <p><u>10:30 – 10:45 AM:</u>  Opening remarks on training, assessment and surveillance, update from first consensus meeting</p> <p><u>10:45 – 11:25 AM:</u>  Surgical Specialties in Robotic Surgery: Panel presentations and discussion about the different stages of IDEAL in robotics. Faculty from the following specialties:</p> <ol style="list-style-type: none"> <li>1. Urology &amp; Gynecology (stage 4)</li> <li>2. Colorectal (stage 2a-2b)</li> <li>3. Cardio-Thoracic (stage 1)</li> </ol> <p><u>11:25 am – 12:00 PM:</u>  Robotic Device Manufacturers Panel:  Robotic Registry</p> <p><u>12:00 – 12:30 PM:</u>  Registry of the Future: Panel presentation and discussion of technology enhancements (IBM Watson, technologies and registries)</p>	
<b>1:00 PM: Welcome &amp; Introductions, Goals for the Day, Recognitions</b>		
<i>Art Sedrakyan, Weill Cornell Medicine and Peter McCulloch, Oxford University</i>		
<b>1:10 PM: Patient and Policy Perspective</b>		
<i>TBD</i>		

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**1:20 – 3:00 PM: Plenary Session 1 - IDEAL Surgical Innovation/Evaluation: current developments**

*Moderator: Binita Ashar, FDA*

**1:20-1:40** IDEAL: IDEAL Template and specific opportunities  
*Peter McCulloch, Oxford University*

**1:20-2:00** Introduction to IDEAL-D  
*Art Sedrakyan, Weill Cornell Medicine*

**2:00-2:20** IDEAL and Innovation at the FDA  
*Murray Sheldon, FDA*

**2:20-2:40** IDEAL is continuously improving work in progress  
*Jane Blazeby, University of Bristol*

**2:40-3:00** Moderator led discussion and Q&A

**3:00 – 5:30 PM: Parallel Tracks**

Clinical think-tanks and abstract presentations. Panel discussion using case studies and reflection on IDEAL and typically adopted approaches. Technology assessments (e.g. trials) nested within registries.

<b>IDEAL Urology</b> <i>Room TBD</i>	<b>IDEAL CT/Vascular Surgery</b> <i>Room TBD</i>	<b>IDEAL Abdominal Surgery</b> <i>Room TBD</i>	<b>IDEAL Orthopedic Surgery</b> <i>Room TBD</i>
<p><b>Faculty:</b></p> <ul style="list-style-type: none"> <li>• Vipul Patel, Global Robotics</li> <li>• Binita Ashar, FDA</li> <li>• Mani Menon, Vattikuti Institute (TBC)</li> <li>• Jim Hu, Weill Cornell</li> <li>• Phil Dahm, U Minnesota</li> <li>• Peter Schlegel, Weill Cornell (TBC)</li> </ul> <p><b>Discussion:</b></p> <ol style="list-style-type: none"> <li>1. Robotic comparative effectiveness trial for prostatectomy (Lead: Vipul Patel)</li> <li>2. Developing HIFU evidence and registry (Lead: Jim Hu)</li> </ol> <p><b>Oral presentation of submitted abstracts</b></p>	<p><b>Faculty:</b></p> <ul style="list-style-type: none"> <li>• Murray Sheldon, FDA</li> <li>• Jack Cronenwett, Dartmouth</li> <li>• Phil Goodney, Dartmouth</li> <li>• Martin Björck, Uppsala, Sweden</li> <li>• Bruce Campbell, MHRA, UK</li> <li>• Greg Ribakove, Maimonides</li> <li>• Darren Schneider, Weill Cornell</li> <li>• Robert Rhee, Maimonides</li> <li>• Paul Saunders, Maimonides</li> </ul> <p><b>Discussion:</b></p> <ol style="list-style-type: none"> <li>1. TAVR (Lead: Murray Sheldon)</li> <li>2. ECMO (Lead: Paul Saunders)</li> <li>3. TEVAR (Lead: Jack Cronenwett)</li> </ol> <p><b>Oral presentation of submitted abstracts</b></p>	<p><b>Faculty:</b></p> <ul style="list-style-type: none"> <li>• Benjamin Fisher, FDA (TBC)</li> <li>• Justin Dimick, U Michigan (TBC)</li> <li>• Mitchell Roslin, Lenox Hill</li> <li>• Peter McCulloch, Oxford</li> <li>• Jeffrey Milsom, Weill Cornell</li> <li>• Martin Martino, Institute for Surgical Excellence</li> <li>• Joel Horovitz, Maimonides</li> <li>• Roberto Bergamaschi, Stony Brook</li> </ul> <p><b>Discussion:</b></p> <ol style="list-style-type: none"> <li>1. Bariatric surgery/devices (Lead: Mitchell Roslin)</li> <li>2. Endoluminal surgery (Lead: Jeffrey Milsom)</li> <li>3. Robotic surgery (Lead: Roberto Bergamaschi)</li> </ol> <p><b>Oral presentation of submitted abstracts</b></p>	<p><b>Faculty:</b></p> <ul style="list-style-type: none"> <li>• Andrew Carr, Oxford</li> <li>• Steven Graves, Australian National Joint Replacement Registry</li> <li>• Liz Paxton, Kaiser registries</li> <li>• Steering Committee leads: American Joint Replacement Registries</li> <li>• Jeff Dunkel, Titan Spine</li> <li>• David Beard, Oxford</li> </ul> <p><b>Discussion:</b></p> <ol style="list-style-type: none"> <li>1. Ceramic hip devices (lead: TBD)</li> <li>2. Bioactive implant first in man (lead: Andrew Carr)</li> <li>3. Innovative spine devices (lead: Jeff Dunkel)</li> </ol> <p><b>Oral presentation of submitted abstracts</b></p>

**5:30 – 5:45 PM: Summary of the day & agenda for next day**

*Organizers*

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<b>Friday, May 5<sup>th</sup></b>		
<b>7:30 AM: REGISTRATION OPEN</b>		
<b>8:00 – 9:00 AM: Summary from Day 1 Clinical Think-Tanks</b> TBD		
<b>9:00 – 12:15 AM: Plenary Session 2 - IDEAL Education, Regulation and Reimbursement</b> <i>Moderators: Peter McCulloch, Oxford and Art Sedrakyan, Weill Cornell</i>		
<p>Education perspective &amp; current surgical research training (robotic example)  <i>Ajit Sachdeva, American College of Surgeons</i>            Commentary: <i>Binita Ashar, FDA</i></p> <p>Device epidemiology perspective  <i>Danica Marinac-Dabic, FDA</i>            Commentary: <i>Theodore Lystig, Medtronic</i></p> <p>UK perspective: NICE, the MHRA and IDEAL  <i>Bruce Campbell, MHRA</i>            Commentary: <i>Kazuhiro Sase, PMDA, Japan</i></p> <p>Industry exposure to IDEAL and attractiveness  <i>Jesse Berlin, Johnson &amp; Johnson</i>            Commentary: <i>Jeffrey Dunkel, Titan Spine</i></p>		
<b>10:30 AM – 10:45 AM: Coffee Break</b>		
<p>IDEAL in reimbursement  <i>Sean Tunis, CMTF</i>            Commentary: <i>Murray Sheldon, FDA</i></p> <p>Health Technology Assessment  <i>Tammy Clifford, CADTH</i>            Commentary: <i>Centers for Medicare and Medicaid (TBD)</i></p> <p>Evidence use in reimbursement  <i>Rita Redberg, UC San Francisco</i>            Commentary: <i>Philipp Dahm, University of Minnesota and GRADE</i></p> <p>Moderator Discussion and Q&amp;A</p>		
<b>12:15 – 1:15 PM: Lunch served, review posters</b>		
<b>1:15 – 2:15 PM: Introduction to National Evaluation System for Devices – IDEAL Opportunity</b>		
<p><u>Medical Device Innovation Consortium (MDIC) think-tank with MDEpiNet</u>            Planned efforts and possible IDEAL contribution</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>Moderator: <i>Greg Pappas, FDA</i></p> <p>Presentation by <i>Bill Murray, MDIC</i></p> </td> <td style="width: 50%; vertical-align: top;"> <p>Panel:                Dawn Bardot, MDIC  <i>Ben Fisher, FDA (TBC)</i>  <i>Myoung Kim, Johnson &amp; Johnson (TBC)</i>  <i>Danica Marinac-Dabic, FDA</i>  <i>Art Sedrakyan, Weill Cornell</i></p> </td> </tr> </table>	<p>Moderator: <i>Greg Pappas, FDA</i></p> <p>Presentation by <i>Bill Murray, MDIC</i></p>	<p>Panel:                Dawn Bardot, MDIC  <i>Ben Fisher, FDA (TBC)</i>  <i>Myoung Kim, Johnson &amp; Johnson (TBC)</i>  <i>Danica Marinac-Dabic, FDA</i>  <i>Art Sedrakyan, Weill Cornell</i></p>
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<b>2:15 – 3:15 PM: Publishers Session</b> Moderators: <i>Rita Redberg, JAMA Internal Medicine</i> and <i>Jose Merino, BMJ</i> Panel: <i>Riaz Agha, International Journal of Surgery</i> ; <i>Elizabeth Loder, BMJ</i>		
<b>3:00pm – 3:30 PM: Advancing the IDEAL Collaboration, Best Abstract Award, and Closing Remarks</b> <i>Art Sedrakyan, Weill Cornell and Peter McCulloch, Oxford</i>		

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**Paper Posters can be viewed during lunch time**

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Notes:

TBC, To Be Confirmed

TBD, To Be Determined

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