Thursday, May 4th
7:30 AM: REGISTRATIONS OPEN

8:30 AM - 12:30 PM
Training Courses and Symposia

<table>
<thead>
<tr>
<th>Educational workshop: Critical appraisal using IDEAL</th>
<th>IDEAL for devices: regulation and innovation</th>
<th>Robotic surgery symposium in context</th>
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<tr>
<td>Speakers: Peter McCulloch, Oxford Joshua Feinberg, Oxford Chris Pennell, Maimonides Joel Horovitz, Maimonides</td>
<td><strong>Regulation of devices</strong> (8:30-10:30 AM)</td>
<td><strong>Robotic symposium</strong> (10:30 AM-12:30 PM)</td>
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<td>Facilitators: Art Sedrakyan, Weill Cornell Murray Sheldon, FDA</td>
<td><strong>Facilitators:</strong></td>
<td>Moderators: Jeffrey Levy, Institute for Surgical Excellence Martin Martino, ISE, Lehigh Valley Health Network Art Sedrakyan, Weill Cornell</td>
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<td><strong>Speakers:</strong> Binita Ashar, FDA Danica Marinac-Dabic, FDA Bruce Campbell, MHRA, UK Myoung Kim, Johnson &amp; Johnson Nobuhiro Handa, PMDA, Japan</td>
<td><strong>Speakers:</strong></td>
<td><strong>10:30 – 10:45 AM:</strong> Opening remarks on training, assessment and surveillance, update from first consensus meeting</td>
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<td>The speakers will discuss device regulation in USA, Europe and Japan and focus on recent developments. Important focus will be the lifecycle approach to device evaluation and current frameworks: reflections on IDEAL framework for devices and future advancement needs.</td>
<td><strong>10:45 – 11:25 AM:</strong> Surgical Specialties in Robotic Surgery: Panel presentations and discussion about the different stages of IDEAL in robotics. Faculty from the following specialties: 1. Urology &amp; Gynecology (stage 4) 2. Colorectal (stage 2a-2b) 3. Cardio-Thoracic (stage 1)</td>
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<td><strong>11:25 am – 12:00 PM:</strong> Robotic Device Manufacturers Panel: Robotic Registry</td>
<td><strong>11:00 PM:</strong></td>
<td>12:00 – 12:30 PM: Registry of the Future: Panel presentation and discussion of technology enhancements (IBM Watson, technologies and registries)</td>
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<td>1:00 PM: Welcome and Opening Remarks, Recognitions, Goals for the Day, Art Sedrakyan, Weill Cornell</td>
<td><strong>1:10 PM:</strong> Patient and Policy Perspective</td>
<td>TBD</td>
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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

1:20 – 3:00 PM: Plenary Session 1 - IDEAL Surgical Innovation/Evaluation: current developments
Moderator: Binita Ashar, FDA

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<tr>
<th>Time</th>
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| 1:20-1:40 | IDEAL: IDEAL Template and specific opportunities  
Peter McCulloch, Oxford |
| 1:20-2:00 | Introduction to IDEAL-D  
Art Sedrakyan, Weill Cornell Medical College |
| 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: Message from Peter McCulloch, Oxford University
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.

IDEAL Urology
Room TBD

**Faculty:**
- Vipul Patel, Global Robotics
- Binita Ashar, FDA
- Peter Schlegel, WCM
- Art Sedrakyan, WCM
- Mani Menon, Vattikuti Institute (TBC)
- Jim Hu, WCM

**Discussion:**
1. Robotic comparative effectiveness trial for prostatectomy  
   (Lead: Vipul Patel)
2. Developing HIFU evidence and registry  
   (Lead: Jim Hu)
3. Oral presentation of submitted abstracts

IDEAL CT/Vascular Surgery
Room TBD

**Faculty:**
- Murray Sheldon, FDA
- Grace Wang, University of Pennsylvania
- Phil Goodney, Dartmouth
- Bruce Campbell, MHRA, UK
- Greg Ribakove, Maimonides
- Darren Schneider, WCM
- Pablo Morales, FDA
- John Laschinger, FDA
- Robert Rhee, Maimonides
- Paul Saunders, Maimonides
- Jon Boyle, Cambridge
- Aresh Salemi, WCM
- Ajay Kirtane, Columbia

**Discussion:**
1. TAVR  
   (Lead: John Laschinger)
2. ECMO  
   (Lead: Paul Saunders)
3. TEVAR  
   (Lead: Grace Wang)
4. Oral presentation of submitted abstracts

IDEAL Abdominal/Ob-Gyn Surgery
Room TBD

**Faculty:**
- Cynthia Long, FDA
- Mitchell Roslin, Lenox Hill
- Peter McCulloch, Oxford University
- Jeffrey Milsom, WCM
- Martin Martino, LVHN
- Joel Horovitz, Maimonides
- Roberto Bergamaschi, Stony Brook
- Xin Sun, Sichuan University
- Jason Wright, Columbia
- Lewis Teperman, Northwell
- Takeshi Sano, Cancer Institute Hospital, Tokyo

**Discussion:**
1. Bariatric surgery/devices  
   (Lead: Mitchell Roslin)
2. Endoluminal surgery  
   (Lead: Jeffrey Milsom)
3. Robotic surgery examples  
   (Leads: Roberto Bergamaschi & Jason Wright)
4. Oral presentation of submitted abstracts

IDEAL Orthopedic Surgery
Room TBD

**Faculty:**
- Andrew Carr, Oxford University
- Steven Graves, Australian National Joint Replacement Registry
- Liz Paxton, Kaiser Permanente registries
- Steering Committee leads: American Joint Replacement Registries
- Jeff Dunkel, Titan Spine
- David Beard, Oxford
- Ron Navarro, Kaiser Permanente

**Discussion:**
1. Ceramic hip devices  
   (modular hips: Steven Graves)
2. Bioactive implant first in man (lead: Andrew Carr)
3. Innovative spine devices  
   (lead: Jeff Dunkel)
4. Oral presentation of submitted abstracts

5:30 – 5:45 PM: Summary of the day & agenda for next day
Organizers
### Friday, May 5th

**7:30 AM: REGISTRATION OPEN**

**8:00 – 9:00 AM: Summary from Day 1 Clinical Think-Tanks**
- **IDEAL presenters**

**9:00 – 10:15 AM: Plenary Session 2 - IDEAL Stakeholder Engagement in Education**
- **Moderators: Peter McCulloch, Oxford and Art Sedrakyan, Weill Cornell**

**Education perspective & current surgical research training**
- *Ajit Sachdeva, American College of Surgeons*
  - Commentary: *Binita Ashar, FDA*

  - **UK perspective: NICE, the MHRA and IDEAL**
    - *Bruce Campbell, MHRA*
    - Commentary: *Kazuhiro Sase, PMDA, Japan*

  - **Industry exposure to IDEAL: education and outreach**
    - *Jesse Berlin, Johnson & Johnson*
    - Commentary: *Theodore Lystig, Medtronic*

**10:15 – 10:30 AM: Coffee Break**

**10:30 – 11:00 AM: Publishing IDEAL – A Conversation with Journal Editors**
- **Moderators: Adil Haider, JAMA Surgery and Jose Merino, BMJ**

  - **Panel:**
    - *Riaz Agha, International Journal of Surgery*
    - *Elizabeth Loder, BMJ*

**11:00 AM – 12:15 PM: Plenary Session 3 – Health Technology Assessment**
- **Health technology assessment and IDEAL**

  - **Moderator:**
    - *Sean Tunis, CMTIP*
  
  - **Panel:**
    - *Murray Sheldon, FDA*
    - *Tammy Clifford, CADTH*

  - **Panel (con’t):**
    - *Suzanne Belinson, Blue Cross Blue Shield*
    - *Bruce Gingles, ISPOR, Cook Medical*
    - *Bruce Campbell, MHRA*
    - *Louis Jacques, ADVI*
    - *Perry Bridger, Edwards Lifesciences*

**12:15 – 1:15 PM: Lunch served, review posters**

**1:15 – 3:15 PM: MDEpiNet Update for IDEAL**

- **The history of MDEpiNet as an engine for device life cycle evaluations**
  - *Danica Marinac-Dabic, FDA*

- **Creating coordinated registry networks & utilizing routinely available data for device research**
  - *Art Sedrakyan, Weill Cornell*

- **Methodological approaches using registries: Bayesian and patient preference designs for registry trials**
  - *Marion Campbell, University of Aberdeen*

- **The UDI rule in the USA and its implementation: enhancing life cycle research capability**
  - *Terrie Reed, FDA (TBC)*

- **UDI database interoperability with registries: illustrative example with vascular devices**
  - *M2S presenter (TBC)*

- **Public-private partnerships within MDEpiNet: PASSION examples**

Medical Device Innovation Consortium (MDIC) think-tank with MDEpiNet
Planned efforts and possible IDEAL contribution

Moderator: Greg Pappas, FDA

Panel: Dawn Bardot, MDIC
Cynthia Long, FDA

Presentation by Bill Murray, MDIC

Panel: Myoung Kim, Johnson & Johnson
Danica Marinac-Dabic, FDA
Art Sedrakyan, Weill Cornell
Jeff Dunkel, Titan Spine

Paper Posters can be viewed during lunch time

Notes:
TBC, To Be Confirmed
TBD, To Be Determined