# 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**

### Thursday, May 4th

<table>
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<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>7:30 AM</td>
<td>REGISTRATIONS OPEN</td>
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<tr>
<td>8:30 AM - 12:30 PM</td>
<td>Training Courses and Symposia</td>
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<tr>
<td><strong>IDEAL surgery: stages and methodologies</strong></td>
<td><strong>IDEAL for devices: regulation and innovation</strong></td>
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<tr>
<td>Speakers:</td>
<td>Facilitators:</td>
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<tr>
<td>Peter McCulloch, Oxford</td>
<td>Art Sedrakyan, Weill Cornell</td>
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<td>Joshua Feinberg, Oxford</td>
<td>Murray Sheldon, FDA</td>
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<td>Chris Pennell, Maimonides</td>
<td>Danica Marinac-Dabic, FDA</td>
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<td>Joel Horovitz, Maimonides</td>
<td>Bruce Campbell, MHRA, UK</td>
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<td>Nobuhiro Handa, PMDA, Japan (TBC)</td>
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1. What is IDEAL? How it came about and what it is useful for.

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).

3. Disseminating IDEAL: How to present IDEAL studies to journals, funders, and others.

### Regulation of devices

(8:30-10:30 AM)

Speakers:
- Binita Ashar, FDA
- Danica Marinac-Dabic, FDA
- Bruce Campbell, MHRA, UK
- Jesse Berlin, Johnson & Johnson
- Nobuhiro Handa, PMDA, Japan (TBC)

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.

### Robotic symposium

(10:30 AM-12:30 PM)

Moderators:
- Jeffrey Levy & Martin Martino, Institute for Surgical Excellence

10:30 – 10:45 AM:
Opening remarks on training, assessment and surveillance, update from first consensus meeting

10:45 – 11:25 AM:
Surgical Specialties in Robotic Surgery: Panel presentations and discussion about the different stages of IDEAL in robotics. Faculty from the following specialties:
1. Urology & Gynecology (stage 4)
2. Colorectal (stage 2a-2b)
3. Cardio-Thoracic (stage 1)

11:25 am – 12:00 PM:
Robotic Device Manufacturers Panel:
Robotic Registry

12:00 – 12:30 PM:
Registry of the Future: Panel presentation and discussion of technology enhancements (IBM Watson, technologies and registries)

### 1:00 PM: Welcome & Introductions, Goals for the Day, Recognitions

*Art Sedrakyan, Weill Cornell Medicine and Peter McCulloch, Oxford University*

### 1:10 PM: Patient and Policy Perspective

*TBD*
# 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>IDEAL Urology</th>
<th>Room TBD</th>
<th>IDEAL CT/Vascular Surgery</th>
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<th>IDEAL Abdominal Surgery</th>
<th>Room TBD</th>
<th>IDEAL Orthopedic Surgery</th>
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<tr>
<td>• Vipul Patel, Global Robotics</td>
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<td>• Murray Sheldon, FDA</td>
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<td>• Benjamin Fisher, FDA (TBC)</td>
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<td>• Andrew Carr, Oxford</td>
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<td>• Binita Ashar, FDA</td>
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<td>• Jack Cronenwett, Dartmouth</td>
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<td>• Justin Dimick, U Michigan (TBC)</td>
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<td>• Steven Graves, Australian National Joint Replacement Registry</td>
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<td>• Mani Menon, Vattikuti Institute (TBC)</td>
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<td>• Phil Goodney, Dartmouth</td>
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<td>• Mitchell Roslin, Lenox Hill</td>
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<td>• Jim Hu, Weill Cornell</td>
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<td>• Martin Björck, Uppsala, Sweden</td>
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<td>• Peter McCulloch, Oxford</td>
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<td>• Steering Committee leads: American Joint Replacement Registries</td>
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<td>• Phil Dahm, U Minnesota</td>
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<td>• Bruce Campbell, MHRA, UK</td>
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<td>• Jeffrey Milsom, Weill Cornell</td>
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<td>• Jeff Dunkel, Titan Spine</td>
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<td>• Peter Schlegel, Weill Cornell (TBC)</td>
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<td>• Greg Ribakove, Maimonides</td>
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<td>• Martin Martino, Institute for Surgical Excellence</td>
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<td>• David Beard, Oxford</td>
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**Discussion:**

1. Robotic comparative effectiveness trial for prostatectomy (Lead: Vipul Patel)
2. Developing HIFU evidence and registry (Lead: Jim Hu)

**Oral presentation of submitted abstracts**

### 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.

**IDEAL Urology**

**Room TBD**

**Faculty:**

• Binita Ashar, FDA
• Peter McCulloch, Oxford University
• Art Sedrakyan, Weill Cornell Medicine
• Murray Sheldon, FDA

**Discussion:**

1. TAVR (Lead: Murray Sheldon)
2. ECMO (Lead: Paul Saunders)
3. TEVAR (Lead: Jack Cronenwett)

**Oral presentation of submitted abstracts**

**IDEAL CT/Vascular Surgery**

**Room TBD**

**Faculty:**

• Murray Sheldon, FDA
• Jack Cronenwett, Dartmouth
• Phil Goodney, Dartmouth
• Martin Björck, Uppsala, Sweden
• Bruce Campbell, MHRA, UK
• Greg Ribakove, Maimonides
• Darren Schneider, Weill Cornell
• Robert Rhee, Maimonides
• Paul Saunders, Maimonides

**Discussion:**

1. TAVR (Lead: Murray Sheldon)
2. ECMO (Lead: Paul Saunders)
3. TEVAR (Lead: Jack Cronenwett)

**Oral presentation of submitted abstracts**

**IDEAL Abdominal Surgery**

**Room TBD**

**Faculty:**

• Ben Fisher, FDA (TBC)
• Justin Dimick, U Michigan (TBC)
• Mitchell Roslin, Lenox Hill
• Peter McCulloch, Oxford

**Discussion:**

1. Bariatric surgery/devices (Lead: Mitchell Roslin)
2. Endoluminal surgery (Lead: Jeffrey Milsom)
3. Robotic surgery (Lead: Roberto Bergamaschi)

**Oral presentation of submitted abstracts**

**IDEAL Orthopedic Surgery**

**Room TBD**

**Faculty:**

• Andrew Carr, Oxford
• Steven Graves, Australian National Joint Replacement Registry
• Liz Paxton, Kaiser registries
• Steering Committee leads: American Joint Replacement Registries
• Jeff Dunkel, Titan Spine
• David Beard, Oxford

**Discussion:**

1. Ceramic hip devices (Lead: TBD)
2. Bioactive implant first in man (Lead: Andrew Carr)
3. Innovative spine devices (Lead: Jeff Dunkel)

**Oral presentation of submitted abstracts**

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

**Organizers**

1/26/2017
### Friday, May 5th

**7:30 AM: Registration Open**

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

**9:00 – 12:15 AM: Plenary Session 2 - IDEAL Education, Regulation and Reimbursement**
*Moderators: Peter McCulloch, Oxford and Art Sedrakyan, Weill Cornell*

- Education perspective & current surgical research training (robotic example)
  - Ajit Sachdeva, American College of Surgeons
  - Commentary: Binita Ashar, FDA
- Device epidemiology perspective
  - Danica Marinac-Dabic, FDA
  - Commentary: Theodore Lystig, Medtronic
- UK perspective: NICE, the MHRA and IDEAL
  - Bruce Campbell, MHRA
  - Commentary: Kazuhiro Sase, PMDA, Japan
- Industry exposure to IDEAL and attractiveness
  - Jesse Berlin, Johnson & Johnson
  - Commentary: Jeffrey Dunkel, Titan Spine

**10:30 AM – 10:45 AM: Coffee Break**

- IDEAL in reimbursement
  - Sean Tunis, CMTP
  - Commentary: Murray Sheldon, FDA
- Health Technology Assessment
  - Tammy Clifford, CADTH
  - Commentary: Centers for Medicare and Medicaid *(TBD)*
- Evidence use in reimbursement
  - Rita Redberg, UC San Francisco
  - Commentary: Philipp Dahm, University of Minnesota and GRADE
  - Moderator Discussion and Q&A

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


*Medical Device Innovation Consortium (MDIC) think-tank with MDEpiNet*

Planned efforts and possible IDEAL contribution

**Moderator:**
*Greg Pappas, FDA*

**Panel:**
*Dawn Bardot, MDIC*
*Ben Fisher, FDA *(TBD)*

Presentation by *Bill Murray, MDIC*
*Myoung Kim, Johnson & Johnson *(TBC)*
*Danica Marinac-Dabic, FDA*
*Art Sedrakyan, Weill Cornell*

**2:15 – 3:15 PM: Publishers Session**

*Moderators: Rita Redberg, JAMA Internal Medicine and Jose Merino, BMJ*

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

**3:00pm – 3:30 PM: Advancing the IDEAL Collaboration, Best Abstract Award, and Closing Remarks**
*Art Sedrakyan, Weill Cornell and Peter McCulloch, Oxford*
Paper Posters can be viewed during lunch time

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