

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
1216 5th Avenue, New York, NY 10029

| | | |
|--|--|--|
| Thursday, May 4th | | |
| 7:30 AM: REGISTRATIONS OPEN | | |
| 8:30 AM - 12:30 PM | | |
| Training Courses and Symposia | | |
| Educational workshop: Critical appraisal using IDEAL | IDEAL for devices: regulation and innovation Robotic surgery symposium in context | |
| <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>Myoung Kim, Johnson & Johnson</i> <i>Nobuhiro Handa, PMDA, Japan</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, Institute for Surgical Excellence</i> <i>Martin Martino, ISE, Lehigh Valley Health Network</i> <i>Art Sedrakyan, Weill Cornell</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"> 1. Urology & Gynecology (stage 4) 2. Colorectal (stage 2a-2b) 3. Cardio-Thoracic (stage 1) <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> |
| 1:00 PM: Welcome and Opening Remarks, Recognitions, Goals for the Day, Art Sedrakyan, Weill Cornell | | |
| 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

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 <i>Room TBD</i> | IDEAL CT/Vascular Surgery <i>Room TBD</i> | IDEAL Abdominal/Ob-Gyn Surgery <i>Room TBD</i> | IDEAL Orthopedic Surgery <i>Room TBD</i> |
|--|---|---|--|
| <p>Faculty:</p> <ul style="list-style-type: none"> • Vipul Patel, Global Robotics • Binita Ashar, FDA • Peter Schlegel, WCM • Art Sedrakyan, WCM • Mani Menon, Vattikuti Institute (TBC) • Jim Hu, WCM <p>Discussion:</p> <ol style="list-style-type: none"> 1. Robotic comparative effectiveness trial for prostatectomy (Lead: Vipul Patel) 2. Developing HIFU evidence and registry (Lead: Jim Hu) <p>Oral presentation of submitted abstracts</p> | <p>Faculty:</p> <ul style="list-style-type: none"> • 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 <p>Discussion:</p> <ol style="list-style-type: none"> 1. TAVR (Lead: John Laschinger) 2. ECMO (Lead: Paul Saunders) 3. TEVAR (Lead: Grace Wang) <p>Oral presentation of submitted abstracts</p> | <p>Faculty:</p> <ul style="list-style-type: none"> • 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 <p>Discussion:</p> <ol style="list-style-type: none"> 1. Bariatric surgery/devices (Lead: Mitchell Roslin) 2. Endoluminal surgery (Lead: Jeffrey Milsom) 3. Robotic surgery examples (Leads: Roberto Bergamaschi & Jason Wright) <p>Oral presentation of submitted abstracts</p> | <p>Faculty:</p> <ul style="list-style-type: none"> • 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 <p>Discussion:</p> <ol style="list-style-type: none"> 1. Ceramic hip devices (modular hips: Steven Graves) 2. Bioactive implant first in man (lead: Andrew Carr) 3. Innovative spine devices (lead: Jeff Dunkel) <p>Oral presentation of submitted abstracts</p> |

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

Organizers

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

| | |
|--|--|
| Friday, May 5th | |
| 7:30 AM: REGISTRATION OPEN | |
| 8:00 – 9:00 AM: Summary from Day 1 Clinical Think-Tanks <i>IDEAL presenters</i> | |
| 9:00 – 10:15 AM: Plenary Session 2 - IDEAL Stakeholder Engagement in Education <i>Moderators: Peter McCulloch, Oxford and Art Sedrakyan, Weill Cornell</i> | |
| <u>Education perspective & current surgical research training</u> <i>Ajit Sachdeva, American College of Surgeons</i> Commentary: <i>Binita Ashar, FDA</i> UK perspective: NICE, the MHRA and IDEAL <i>Bruce Campbell, MHRA</i> Commentary: <i>Kazuhiro Sase, PMDA, Japan</i> Industry exposure to IDEAL: education and outreach <i>Jesse Berlin, Johnson & Johnson</i> Commentary: <i>Theodore Lystig, Medtronic</i> | |
| 10:15 – 10:30 AM: Coffee Break | |
| 10:30 – 11:00 AM: Publishing IDEAL – A Conversation with Journal Editors <i>Moderators: Adil Haider, JAMA Surgery and Jose Merino, BMJ</i> | |
| <u>Panel:</u> <i>Riaz Agha, International Journal of Surgery</i> <i>Elizabeth Loder, BMJ</i> | |
| 11:00 AM – 12:15 PM: Plenary Session 3 – Health Technology Assessment Health technology assessment and IDEAL | |
| <u>Moderator:</u> <i>Sean Tunis, CMTA</i> | <u>Panel (con't):</u> <i>Suzanne Belinson, Blue Cross Blue Shield</i> <i>Bruce Gingles, ISPOR, Cook Medical</i> <i>Bruce Campbell, MHRA</i> <i>Louis Jacques, ADVI</i> <i>Perry Bridger, Edwards Lifesciences</i> |
| <u>Panel:</u> <i>Murray Sheldon, FDA</i> <i>Tammy Clifford, CADTH</i> | |
| 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 <i>Danica Marinac-Dabic, FDA</i> Creating coordinated registry networks & utilizing routinely available data for device research <i>Art Sedrakyan, Weill Cornell</i> Methodological approaches using registries: Bayesian and patient preference designs for registry trials <i>Marion Campbell, University of Aberdeen</i> The UDI rule in the USA and its implementation: enhancing life cycle research capability <i>Terrie Reed, FDA (TBC)</i> UDI database interoperability with registries: illustrative example with vascular devices <i>M2S presenter (TBC)</i> Public-private partnerships within MDEpiNet: PASSION examples | |

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

Mitch Krucoff/Britt Barham, Duke (TBC)

Discussion with audience

3:15 – 4:15 PM: Introduction to National Evaluation System for Devices – IDEAL Opportunity

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

Planned efforts and possible IDEAL contribution

Moderator:

Greg Pappas, FDA

Presentation by *Bill Murray, MDIC*

Panel:

Dawn Bardot, MDIC

Cynthia Long, FDA

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

DRAFT