

Establishment of Scientific Infrastructure for the International Consortium of Orthopaedic Registries (ICOR) to Support Regulatory Science

Meeting Agenda

Day 1, May 9th, 2011 – Public Meeting

7:00 am: Transportation from Courtyard Silver Spring North by Marriott to FDA Conference Center

7:45 am: Continental Breakfast at FDA Conference Center

8:15 am: Welcome, Introductions from Conference Co-Chairs

- Danica Marinac-Dabic, MD, PhD, (FDA, Division of Epidemiology, Office of Surveillance & Biometrics) Art Sedrakyan MD, PhD, (Hospital for Special Surgery, Weill Cornell Medical Center, FDA)
- Goals for the Day, Background of ICOR
- All briefly describe your registries: Year Established, Regions/Centers, and Goals.

8:30 am: Setting the Stage

Moderator: Danica Marinac-Dabic, MD, PhD

- Jeff Shuren, MD, JD, Director, Center for Devices and Radiological Health, FDA (5 min)
- William Maisel, MD, MPH, Deputy Director, Center for Devices and Radiological Health, FDA (5 min)
- Mark Melkerson, MS, Division of Surgical Orthopaedic and Reconstructive Devices (5 min)
- Danica Marinac-Dabic, MD, PhD, Division of Epidemiology, FDA (5 min)
- Thomas Gross, MD, MPH (Office of Surveillance & Biometrics, FDA) Sentinel Initiative (5 min)
- Jay Crowley, Unique Device Identification, FDA (5 min)
- Questions and Answers (20 min)

9:20 am: Goals of International Registries and the Potential of ICOR to Advance Collaborative Work Worldwide

Moderator: Ove Furnes, MD, PhD (Norwegian Arthroplasty Register)

- Göran Garellick, MD, PhD (Swedish Hip Arthroplasty Register): The NARA organisation (10 min)
- Leif Ivar Havelin, MD (Norwegian Arthroplasty Register): The NARA database, analysis and results (10 min)
- Elizabeth Paxton, PhD, Kaiser and Norwegian registry collaboration (10 min)
- Panel Discussion (20 min)
- Stephen Graves, MBBS D Phil FRACS FA OrthA, Australian National Joint Replacement Registry
- Henrik Malchau, MD, PhD, Massachusetts General Hospital Harris Joint Registry
- Göran Garellick MD, PhD, Swedish Hip Arthroplasty Register
- Gerold Labek, MD, EFORT European Arthroplasty Register
- Questions and answers (10 min)

Establishment of Scientific Infrastructure for the International Consortium of Orthopaedic Registries (ICOR) to Support Regulatory Science

Meeting Agenda

10:20 am: Break

10:35 am: Goals of U.S. Surgeons, Complementary Roles of AJRR / ICOR / Other US Registries

Moderators: Thomas Barber, MD (Kaiser Permanente) and Terence Gioe, MD (HealthEast Joint Registry) Panel Discussion

- Goals and Challenges of U.S. Orthopaedic Implant Registries:
 - Institutional level – Terence Gioe, MD, (HealthEast Joint Registry), Rafael Sierra, MD, (Mayo Clinic Total Joint Registry)
 - Multicenter/National level – Thomas Barber, MD, (Kaiser Permanente), David Ayers, MD, Patricia Franklin, MD, MBA, MPH (*FORCE-TJR*), David Lewallen, MD, (American Joint Replacement Registry), Kevin Bozic, MD, MBA (California Joint Replacement Registry)

11:25 am: Evidence Needs and Generation, U.S. Stakeholder Payer Perspectives and Potential for Public Private Partnership

Moderator: Ben Eloff, PhD (FDA, Public Private Partnerships) Panel Discussion

- Elise Berliner, PhD, Agency for Healthcare Research and Quality (AHRQ) (5 min)
- Jyme Schafer, MD, MPH, Centers for Medicare & Medicaid Services (CMS) (5 min)
- Randall Krakauer, MD, MBA, Aetna (5 min)
- Steven Stern, MD, UnitedHealthcare (5 min)
- Marcel Salive, MD, MPH, National Institute on Aging (NIA) (5 min)
- Shamiram Feinglass, MD, MPH and Cheryl Blanchard, PhD, Zimmer, Inc. (5 min)
- James Panagis, MD, MPH, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (5 min)
- Questions and Answers (10 min)

12:15 pm: Working Lunch

12:40 pm: Implant Safety and Effectiveness I, Metal on Metal Experience

Moderators: Stephen Graves, MBBS D Phil FRACS FA OrthA, (Australian Orthopaedic Association National Joint Replacement Registry) and Mark Melkerson, MS, (Center for Devices and Radiological Health, FDA)

- Ron Yustein, MD, (Center for Devices and Radiological Health, FDA) - Metal on Metal Workgroup Experience (7 min)
- Keith Tucker, MB, BS, FRCS (Eng.), England and Wales National Joint Registry – Overview of MHRA UK alert (7 min)
- Stephen Graves, MBBS D Phil FRACS FA OrthA, Australian Joint Replacement Registry (7 min)
- Alastair Rothwell, ONZM MB ChM FRACS, New Zealand Joint Replacement Registry (7 min)
- Robert Namba, MD, Kaiser Experience (7 min)
- Joshua Jacobs, MD, (*Rush University Medical Center Joint Registry*) - Metal Ion Measurement (7 min)
- Discussion (25 min)

Establishment of Scientific Infrastructure for the International Consortium of Orthopaedic Registries (ICOR) to Support Regulatory Science

Meeting Agenda

1:50 pm: Implant Safety and Effectiveness II

Moderators: Thomas Sculco, MD (Hospital for Special Surgery) and Henrik Malchau, MD, PhD (Massachusetts General Hospital)

- Stephen Graves, MBBS D Phil FRACS FA OrthA, Australian Orthopaedic Association National Joint Replacement Registry - How New Devices Perform Fixed vs. Mobile Bearing Knees, Cement, Exchangeable Femoral Neck Component (10 min)
- Robert Namba, MD - Kaiser Study Fixed vs. Mobile Bearing and Patella Resurfacing (8 min)
- Terence Gioe, MD (HealthEast Joint Registry) to respond about experience with all Polyethylene Tibial Components (8 min)
- Ove Furnes, MD, PhD, Norwegian Arthroplasty Register - Fixed vs. Mobile and Patella Resurfacing: The Norwegian Experience (8 min)
- Discussion (10 min)
- Susannah Stea, Dr., Register of Orthopaedic Prosthetic Implants - Italian Implant Safety Studies (8 min)
- Rob Nelissen, MD, PhD (Hip and Knee Prosthesis Registry of the Netherlands) will comment on importance of RSA in Device Safety Evaluation (5 min)
- Bryan Nestor, MD, will comment on importance of Additional Data Elements (i.e. Squeaking in Device Evaluation) (5 min)
- Discussion (10 min)
- Gerold Labek, MD, European Arthroplasty Register-Differences in Safety Published Literature vs. Registries (10 min)
- Discussion and Wrap-up (8 min)

3:20 pm: Break

3:35 pm: Methodology Session, Tools for Multinational Collaborations within ICOR

- Frederic Resnic, MD, MSc, FACC, FSCAI, Brigham and Women's Hospital - DELTA System for Distributed Data Analysis (20 min)
- Art Sedrakyan, MD, PhD, Hospital for Special Surgery/Weill Cornell Medical College/FDA - Cornell and Harvard Project on Harmonizing Analytic Methods (Advanced Meta-Analysis) (20 min)
- Discussion (10 min)

4:25 pm: Patient Reported Outcomes: Advancing Measurement and Harmonizing Data Collection within ICOR Registries

Moderator: Elizabeth Paxton, PhD, (Kaiser Permanente)

- Göran Garellick, MD, PhD, Swedish Hip Arthroplasty Register - Efforts to Collect Patient Reported Outcomes (15 min)
- Alastair Rothwell, ONZM MB ChM FRACS, The New Zealand Joint Registry - Oxford 12 Score at 5 years Post-op Predicts Early Revision (15 min)
- Eric Bohm, Eng MD, MSc, FRCSC, Winnipeg Regional Health Authority/Manitoba Orthopedic Society Joint Replacement Registry (15 min)
- Discussion (10 min)

5:20 - 6:30 pm: Adjourn (transportation to reception)

6:30 pm – 8:30 pm: Reception

Establishment of Scientific Infrastructure for the International Consortium of Orthopaedic Registries (ICOR) to Support Regulatory Science

Meeting Agenda

Day 2, May 10, 2011 (Closed to Public)

7:15 am: Transportation from Hotel to Meeting Venue

8:00 am: Continental Breakfast in Conference Room, Welcome Remarks for Day 2: Goals for the Day

8:15 am: Device Identification, Classification and Definition

Moderators: FDA

- Stan Mendenhall, Mendenhall Associates, Inc. - Problems with Implant Definitions in US and How to Overcome Them (10 min)
- Shamiram Feinglass, MD, MPH, Zimmer, Inc. - Role of Manufacturers in Harmonization Effort and Device Identification (e.g. Zimmer) (10 min)
- Otto Robertsson, MD, PhD, Swedish Knee Arthroplasty Register - Standard Classification for Implants; Identifying Implants with Different Part Numbers; Subcategories for Modularity (10 min)
- Discussion (15 min)

Project Review

- For each of the 5 projects, the moderators will present an outline (using template), discuss common data elements (and definitions) and harmonization. Discuss variables needed for the most comprehensive study and less robust study (Some registries will have all of the needed data and others will have some of the data).

9:00 am: Review Project 1 (Head size)

Moderators Henrik Malchau, MD, PhD (Massachusetts General Hospital Harris Joint Registry) and Stephen Graves MBBS D Phil FRACS FA OrthA (Australian Orthopaedic Association National Joint Replacement Registry)

10:15 am: Coffee break

10:30 am: Review Project 2 (Bearing Surface)

Moderators: Ove Furnes, MD, PhD (Norwegian Arthroplasty Register) and Leif Ivar Havelin, MD, (Norwegian Arthroplasty Register) and FDA (Danica Marinac-Dabic, MD, PhD and/or Art Sedrakyan, MD, PhD)

12:00 pm: Working Lunch

12:30 pm: Review Project 3 (Mobile vs. Fixed Bearing Knees) and 4 (Robertsson, Knee Topic with Kaiser)

Moderators: Robert Namba, MD, (Kaiser Permanente) Tad Funahashi, MD, (Kaiser Permanente) Thomas Barber, MD, (Kaiser Permanente) and Otto Robertson, MD, PhD (Swedish Knee Arthroplasty Register)

2:30 pm: Break

Establishment of Scientific Infrastructure for the International Consortium of Orthopaedic Registries (ICOR) to Support Regulatory Science

Meeting Agenda

2:45 pm: Review Project 5 (Cemented vs. Hybrid Hips)

Moderators: Douglas Padgett, MD, (Hospital for Special Surgery), Timothy Wright, PhD, (Hospital for Special Surgery) Art Sedrakyan, MD, PhD (Hospital for Special Surgery, Weill Cornell Medical College, FDA)

3:45 pm: Final Overview/Summary and the Outline of the Next Steps such as Governance and Leadership, Finance, Privacy

Moderators: Conference Organizing Team

4:45 pm: Closing Remarks

5:00 pm: Adjourn Meeting