Yale UCL
COLLABORATIVE

London Cardiovascular Device Innovation Summit
January 9th and 10th, 2014

presented by

Yale University School of Medicine and
University College London

Program Chairs

Andreas Baumbach – Alexandra Lansky
John Martin – Anthony Mathur – Michael Mullen

Program Co-Chairs

Michael Cleman – Aroon Hingorani – Pascal Meier
Michael Simons – Bryan Williams – Carlos Mena

UCLPartners Academic Health Science Partnership
Yale University School of Medicine
UCL
NHS National Institute for Health Research

Thursday January 9th, 2014

8:00 am **Check-In and Breakfast, Royal College of Physicians**

9:00 am **Welcome and Introduction: Alexandra Lansky**

SESSION I **BRITISH HEALTHCARE POLICY AND FUNDING FOR MEDTECH**

Session Goals:

- *CV innovation as a major goal of British National interest*
- *Goals of MedTech in the EU/US trade and investment partnership*
- *Academic and private sector incentives and goals for innovation*

9:05 am Session Introduction
Moderators: **John Martin and Bryan Williams**

9:10 am The Yale-UCL Research and Device Evaluation Program: A Trans Atlantic Academic Initiative
Alexandra Lansky

9:20 am Keynote Address: Overview of the UK Health Care System: Health and Wealth Agenda
Bryan Williams
Director of the NIHR UCL Hospitals Biomedical Research Centre

9:40 am British Health Care Policy in a Global Landscape: Vision for Invigorating Academic Innovation and Entrepreneurship
TBD
Title

9:55 am Can the UK gain a competitive edge in BioTech? Role, Goals and Challenges of NIHR Office for Clinical Research Infrastructure (NOCRI)
Mark Samuels
Managing Director, NIHR Office for Clinical Research Infrastructure

10:15 am Discussion
John Martin and Bryan Williams

10:45 am Coffee Break

SESSION II **REGULATORY REFORM IN A GLOBAL LANDSCAPE**

Session Goals:

- *EU/US regulatory reform for faster device innovation*
- *Use of external data for pre-market submission*
- *EU/US regulatory harmonization initiatives for FIM*
- *Global trials for global approval*

Moderators: Alexandra Lansky and Bart Segers
Panel: Andy Farb, Pauliina Margolis, Michael Mullen, Ian Hudson, Robert Van Boxtel, Andreas Baumbach, Martin Rothman, Carlos Mena

11:00 am Medicines and Healthcare Products Regulatory Agency (MHRA): Can Regulators Facilitate Innovation while Balancing Responsibilities for Patient Safety
Ian Hudson
Chief Executive Medicines and Healthcare Product Regulatory Agency

11:15 am Is Early Feasibility in the US Really Feasible? Opportunities and Challenges

Session Goals:

- *US feasibility program need and requirements*
- *Practical implementation of US feasibility studies*
- *Implications of US feasibility on device innovation and iteration*

10" US Feasibility Program
Andy Farb
Senior Reviewer, Center for Devices and Radiological Health
US Food and Drug Administration

5" Case Example: My Experience with our Neuro-Protection Device
Pauliina Margolis

10" Discussion

11:40 am Disparities in Premarket requirements for CE Marking: From DES, biodegradable Scaffolds to TAVR

Session Goals:

- *Guidance process: who makes the guidelines, who implements them?*
- *Variation in clinical evidence required for different devices*
- *What are the differences between EU and US*

10" Role of the European Medicine Agency, Notified Body and Competent Authority: Who sets the standards for device approval?

Robert Van Boxtel

5" Case Example: Requirements for TAVI approval: Are they sufficient?
Mike Mullen

10" Discussion

12:05 pm Implementing EMA guidelines for DES CE Approval- Can I get my DES approved on the basis of Non-EU clinical data?

Session Goals:

- *2008 EMA DES guidance requirements and implications*
- *Considerations for EU approval on basis of external data*
- *Practical implications of new DES guidance on innovation in EU*

10" Understanding the 2008 EMA DES guidance and updates
Bart Segers

5" Case Example: Making the Case for CE Mark Approval on the basis of non-EU clinical data with a new DES
Christine Shan

10" Discussion

12:30 pm **Lunch**

SESSION III **INNOVATION HOT TOPICS: LESSONS LEARNED AND MISTAKES TO AVOID**

Session Goals:

- Practical experience of device innovation from concept to market
- Patent and intellectual property management dos and don'ts
- Challenges of device iteration and what to plan for
- Funding strategies in the early stages of device development
- Regulatory considerations in new therapeutic areas

Moderator: Andreas Baumbach

1:30 pm Intellectual Property: Disasters I have lived through and you should avoid
Maurice Buchbinder

1:50 pm 10" Case Example: Mitral Devices Challenges and Successes
Niel Starksen
20" Discussion

Session Moderator: Maurice Buchbinder
Panel: Rick Geoffrion, Mike Cleman, Andrew Farb, John Forrest, Michael Mullen, Michael Joner, Gopal Muppirala, Niel Starksen

2:20 pm 10" Case Example: Renal Denervation from Concept to Adoption
Mano Iyer

20" Discussion
Session Moderator: Mark Caulfield
Panel: Vincent Cabane, Martin Rothman, Bryan Williams, Jeanette Bankes, Andy Farb, Michael Joner, Mano Iyer, Helen, Reeve-Stoffer, Tami Abudi, Bart Segers

2:50 pm 10" Case Example: Bioreabsorbable Scaffolds from Design to Market
Jeff Anderson

20" Discussion
Session Moderator: Anthony Mathur
Panel: Krishna Sudhir, Andy Farb, Michael Joner, Pascal Meier, Robert Van Boxtel, Maurice Buchbinder, Carlos Mena

3:20 pm 10" Case Example: Drug Eluting Balloons from Design to Market
John Van Vleet

20" Discussion
Session Moderator: Carlos Mena
Panel: Jeanette Bankes, Martin Rothman, Mark Turco, Beaux Alexandre, Pascal Meier, Robert Van Boxtel, Andy Farb, Michael Joner

3:50 PM **BREAK**

SESSION IV **INNOVATION: PRECLINICAL AND IMAGING IN DEVICE ITERATION**
Moderators: Al Sinusas and Pascal Meier

4:10 pm Preclinical Evaluation Case Examples: How the Pathologist can Streamline Device Development
Michael Joner

4:30 pm Imaging in Device Evaluation
Al Sinusas

4:50 pm Discussion

SESSION V **BRINGING IT ALL TOGETHER: A COMPLEX BIODEGREDABLE MAGNETIZABLE BIOLOGICS RELEASING STENT PLATFORM: IMPLICATION ON PRECLINICAL AND CLINICAL TESTING AND APPROVAL PATHWAY**

Session Goal:

- To critically discuss the strategy and challenges including engineering, funding, testing, regulatory, and needs assessment for the development of a complex Biologics Releasing Stent

Moderators: John Martin and Carlos Mena
Panel: Michael Joner, Andy Farb, Al Sinusas, Mark Turco, Robert Van Boxtel, Bart Segers, Quentin Pankhurst, Lew Pell, Michael Cleman, John Forrest

5:00 pm 10" Case Example: Biomagscar
Anthony Mathur
20" Discussion

5:30 pm Adjourn

Friday January 10th, 2014

8:00 am **Breakfast**

SESSION VI **FUNDING OPTIONS FOR EARLY STAGE MED TECH IN 2014**

Session Goals:

- US and UK government opportunities for early stage device funding
- Program grant funding for National Center of device development
- Options and costs for private funding

Moderators: Bryan Williams and Peter Weissberg

9:00 am **Keynote Lecture:**
NIH Initiatives - Early Stage Funding Opportunities for Device Innovation
Jodi Black
Deputy Director, Office of Translational Alliances and Coordination
National Institutes of Health

9:15 am NIHR Funding Landscape in the Med-Tech Arena
Martin Hunt
Director, National Institute for Health Research, Invention for Innovation Program, United Kingdom

9:30 am British Heart Foundation – Funding Options from the British Heart Foundation
Peter Weissberg
Medical Director, British Heart Foundation

9:45 am Private Equity Funding in Med-Tech: What are the considerations for Investment in 2014
Rick Geoffrion

10:00 am Discussion

10:15 am Coffee Break

SESSION VI **INNOVATION: NEW FRONTIERS IN IMPLANTABLE THERAPIES: CLINICAL NEED, REGULATORY CHALLENGES, AND MARKET OPPORTUNITIES - CASE EXAMPLES WITH CRITIQUE**

Session Goal:

- To critically discuss the strategy and challenges including engineering, funding, testing, regulatory, and needs assessment for the development of novel devices

Moderators: John Forrest and Carlos Mena
Panel: Perry Bridger, Andy Farb, Pascal Meier, Michael Joner, Robert Van Boxtel, Anthony Mathur, Rick Geoffrion

10:30 am Next Generation Nanocomposite Polymeric Valve Leaflets: Design and Durability Features
5" Presenter: **Alex Seifalian**
Commentary: **Rick Geoffrion**

10:45 am Genetically Modified Porcine Pericardium in Valve Design: Rational and Initial Outcome
5" Presenter: **Chris McGregor**
Commentary: **Michael Joner**

11:00 am Tissue Engineered Vascular Endograft
5" Presenter: **George Hamilton**
Commentary: **Carlos Mena**

SESSION VI **NEW TECHNOLOGY APPRAISAL AND COMMISSIONING: IMPACT ON INNOVATION AND PATIENT CARE**

Session Goals:

- Mechanisms and considerations in new technology appraisal and commissioning
- Implications of appraisal and commissioning in UK and EU on trial design
- Efficient technology evaluation from pre market to post market evaluation to meet global approval and reimbursement requirements

Moderators: Mark De Belder and Perry Bridger
Panel: Mark Caulfield, Adam Timmis, Andreas Baumbach, Wayne Bartlett-Syree, Anthony Mathur, Michael Simons, Michael Mullen, Mirella Marlow

11:15 am Inside the National Institute for Health and Care Excellence: Defining Cost Effectiveness and Technology Assessment-Should it Impact my Clinical Trial Design?
Mirella Marlow

11:30 am Commissioning Through Evaluation: A Case for Funding New Technologies
Case Examples: TAVI and Renal Denervation
Wayne Bartlett-Syree

11:45 am Streamlining the Commissioning process: Aiming for an Early and Efficient Integrated Clinical, Regulatory and Reimbursement Pathway
Mark De Belder

12:05 pm	**Keynote Address** Tackling Global Reimbursement Considerations: How Does this Impact Trial Design? **Perry Bridger**
12:30 pm	Discussion
1:00 pm	Summit Summary and Concluding Remarks **John Martin and Michael Simons**
1:15 pm	Adjourn