Session I: Basic Knowledge for CV Devices Development

**Topic 1: Concept/Innovation**

1) *Choosing an Innovative Concept*
   - Todd Brinton, MD, Edward’s Lifesciences

**Topic 2: Intellectual Property**

2) *Intellectual Property*
   - James Inskeep, Patent Attorney

**Topic 3: Business Plan, Product Development, and Fundraising**

3) *Business Plan, Product Development, and Fundraising*
   - Stan Rowe, Edward’s Lifesciences

**Topic 4: Product Manufacturing**

4) *Requirements for Medical Device Manufacturing & Iteration - FDA Point of View*
   - Brad Quinn, FDA

5) *Requirements for Medical Device Manufacturing & Iteration - Industry Point of View*
   - Richard Rapoza, PhD, Abbott Vascular

**Topic 5: Preclinical Evaluation/Animal Model**

6) *Advanced Cardiac Anatomy – Application in Translational Research Tailored to Current and Future Technology*
   - Renu Virmani, MD, CV Path Institute

7) *Large Animal Model for Heart Failure, Valvular Disease, Coronary Artery Disease, and Device Testing*
   - Daniel Burkhoff, MD, Colombia University

8) *Pre-Clinical Study Design & Endpoints for Device Evaluation – FDA Point of View*
   - Judith Davis, DVM, MS, FDA

9) *Pre-Clinical Study Design & Endpoints for Device Evaluation – Investigator Point of View*
   - Renu Virmani, MD, CV Path Institute

**Topic 6: Early Feasibility**

10) *Early Feasibility Studies for Device Evaluation*
    - Andrew Farb, MD, FDA
   • David Reuter, MD, Seattle Children’s Hospital

### Topic 7: Biostatistics

12) Basic in Statistics – Clinical Study Design for Translational Research
   • Chris Mullin, PhD, NAMSA

13) Basic Statistical Concepts
   • Chris Mullin, PhD, NAMSA

14) Sample Size and Power
   • Chris Mullin, PhD, NAMSA

15) Sensitivity and Specificity
   • Chris Mullin, PhD, NAMSA

16) Common Study Designs
   • Chris Mullin, PhD, NAMSA

17) Phases of Translational Research
   • Chris Mullin, PhD, NAMSA

18) Statistics for Evaluation of Cardiovascular Diagnostic Devices
   • Chris Mullin, PhD, NAMSA

19) Pre-Clinical & Clinical Trial Design & Endpoints of Fast Track to Device Approval
   • Roseann White, PhD, Duke Research Institute

20) Advanced Statistical Methods for Translational Research
   • Chris Mullin, PhD, NAMSA

21) Clinical Endpoints/Surrogate Endpoints
   • Roseann White, PhD, Duke Research Institute

### Topic 8: Regulatory Approval

22) Regulatory Requirement for Marketing Approval
   • Bram Zuckerman, MD, FDA [View free lecture online]

23) Regulatory Review of Cardiovascular Devices – European Regulatory Perspective
   • Robert Byrne, MD, Heart Centre, Germany [View free lecture online]

### Topic 9: Reimbursement

24) CMS Criteria for Reimbursement for Cardiovascular Innovation
   • Joseph Chin, MD, CMS

### Topic 10: Practice Guideline

   • Alice Jacobs, MD, Boston University

### Topic 11: Technology Adoption

26) Adoption of Technology
   • Ian Meredith, MD, Boston Scientific
27) Global Heart Health, Implications for Translational Research
   • Salim Yusuf, D. Phil, World Federation of Cardiology

Topic 12: Patients
28) The Patients Voice
   • Mark Mercola, PhD, Stanford Cardiovascular Institute

Panel Discussions

- 2019 Diagnostic Devices Development
- 2019 Device Development: Essential Concepts
- 2018 Requirements for CV Devices Approval
- 2017 Clinical Endpoints & Biostatistics
- 2016 Preclinical, Early Feasibility, and Safety Study for Device Development

Session II: Translational Pathway for TAVR

1) The Clinical Need for Innovative Treatment for AV Disease
   • Martin Leon, MD, Columbia University

2) The Methods for TAVR Development
   • Stan Rowe, Edwards’s Lifesciences

3) The Endpoints for TAVR Development
   • Ori Ben-Yehuda, MD, Cardiovascular Research Foundation

4) Current Challenges & Future Direction for AV Development & Iteration – FDA Point of View
   • Nicole Ibrahim, PhD, FDA

5) Current Challenges & Future Direction for AV Development & Iteration – Industry Point of View
   • Stan Rowe, Edward’s Lifesciences

6) TAVR Development from Concept to First In Man
   • Alain Cribier, MD, University of Rouen, France (View free lecture online)

7) TAVR Development from First In Man to Phase 3 & Beyond
   • Martin Leon, MD, Columbia University (View free lecture online)

Panel Discussions

- 2017 Valve Disease/TAVR
- 2016 Aortic Valve Development

Session III: Translational Pathway for Transcatheter Mitral/Tricuspid Valve Devices

1) The Clinical Need for Innovative Treatment for Mitral/Tricuspid Valve Disease
   • Michael Mack, MD, Baylor Scott & White Health

2) The Methods for Translational Mitra/Tricuspid Valve Device Development
   • Michael Mack, MD, Baylor Scott & White Health

3) The Endpoints for Transcatheter Mitral/Tricuspid Valve Device Development
   • Blasé Carabello, MD, East Carolina University
Panel Discussions

- 2019 Structural Heart Intervention Imaging
- 2017 MV/TV Transcatheter Repair/Replacement
- 2016 MV/TV Development

Session IV: Translational Pathway for Coronary Stent

1) The Clinical Need for Innovative Coronary Stent
   - Gregg Stone, MD, Columbia University

2) The Methods for Coronary Stent Development
   - Charles Simonton, MD, Abbott Vascular

3) The Endpoints for Coronary Stent Development
   - Donald Cutlip, MD, Beth Israel-Deaconess

4) Current Challenges & Future Direction for Coronary Stent Development & Iteration – FDA Point of View
   - Michael John, MPH, FDA

5) Current Challenges & Future Direction for Coronary Stent Development & Iteration – Industry Point of View
   - Charles Simonton, MD, Abbott Vascular

Panel Discussions

- 2019 Devices for Complex Coronary Lesions
- 2019 Advances in the Assessment of High Risk Coronary Lesions
- 2017 CAD/Coronary Stent
- 2016 Coronary Stent Development

Session V: Translational Pathway for Catheter Ablation

1) The Clinical Need for the Treatment of Arrhythmia Innovative Catheter Ablation
   - Douglas Packer, MD, Mayo Clinic

2) Methods for Catheter Ablation Development
   - Douglas Packer, MD, Mayo Clinic

3) The Endpoints for Catheter Ablation Development
   - Marco Cannella, PhD, FDA

4) Current Challenges & Future Direction for Catheter Ablation Development & Iteration – FDA Point of View
   - Mark Fellman, MS, FDA
5) **Current Challenges & Future Direction for Catheter Ablation Development & Iteration – Industry Point of View**
   - Uri Yaron, PhD, Johnson & Johnson

### Panel Discussions

- 2017 Arrhythmia/Catheter Ablation
- 2016 Catheter Ablation Development

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### Session VI: Translational Pathway for Ventricular Assist Devices

1) **Ventricular Assist Devices, the Windy Road to Recovery**
   - Sr. Magdi Yacoub, MD, Aswan Heart Center, London

2) **The Methods for Left Ventricular Assist Devices Development**
   - Francis Pagani, MD, University of Michigan

3) **The Endpoints for Left Ventricular Device Evaluation**
   - Keith Aaronson, MD, University of Michigan

### Panel Discussions

- 2018 Translational Pathway for LV Assist Devices
- 2017 CHF/Ventricular Assist Devices
Translational Pathways for Cardiovascular Devices

Multi-disciplinary

Collaboration

Academia

Industry

Regulatory

Guideline

Patients

Reimbursement

Translational Pathway for Cardiovascular Devices