Translational Pathways for Cardiovascular Devices
- Online Course -
55 Multidisciplinary Lectures presented by Innovators, Industry, Regulatory (FDA & EU), Reimbursement, Practice Guideline, and Patients

Target Audience:
Inventors, Clinical and Basic Scientists, Interventional Cardiologists, Medical Students, Engineers, Industry, Regulators, Payers, and Investors

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 (Preview free lecture online)

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

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

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

4) Current Challenges & Future Direction for Mitral/Tricuspid Valve Device Development & Iteration – FDA Point of View
   • John Laschinger, MD, FDA

5) Current Challenges & Future Direction for Mitral/Tricuspid Valve Device Development & Iteration – Industry Point of View
   • Patricia Todd, Edward’s Lifesciences
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

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

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
Translational Pathways for Cardiovascular Devices

Translational Pathway

Concept
Preclinical
Clinical Research

Knowledge Gap
Essential Knowledge
Intellectual Property
Business Plan
Regulatory
Reimbursement
Practice Guideline
Adoption

Physician Adoption
Practice Guidelines
Reimbursement
Regulatory Approval
Clinical Research

Patient

Multi-disciplinary
Collaboration
Commitment

Academia
Industry
Guideline
Regulatory
Reimbursement
Patients