www.isctr.org

Translational Pathways for Cardiovascular Devices
- Online Course -

80 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

Introduction *(Total 13 mins)*

Welcome from the Course Directors **(View for free online)**

- Spencer King, MD, Emory University *(6 mins)*
- Anthony DeMaria, MD, University of California San Diego *(5 mins)*
- Nabil Dib, MD, ISCTR *(2 min)*

Session I: Basic Knowledge for CV Devices Development *(Total ≈ 10 hrs)*

Topic 1: Concept/Innovation *(Total = 7 mins)*

1) ***Choosing an Innovative Concept***
   - Todd Brinton, MD, Edwards Lifesciences *(7 mins)*

Topic 2: Intellectual Property *(Total = 27 mins)*

2) ***Intellectual Property***
   - James Inskeep, Inskeep Intellectual Property Group *(5 mins)*

3) ***Overview of the Patent Process***
   - Jason Gilbert, Inskeep Intellectual Property Group *(22 mins)*

Topic 3: Business Plan, Product Development, and Fundraising *(Total = 6 mins)*

4) ***Business Plan, Product Development, and Fundraising***
   - Stan Rowe, NXT Biomedical *(6 mins)*

Topic 4: Product Manufacturing *(Total = 25 mins)*

5) ***Requirements for Medical Device Manufacturing & Iteration - FDA Point of View***
   - Brad Quinn, FDA *(10 mins)*

6) ***Requirements for Medical Device Manufacturing & Iteration - Industry Point of View***
   - Richard Rapoza, PhD, Abbott Vascular *(15 mins)*

Topic 5: Preclinical Evaluation/Animal Model *(Total = 1 hr)*

7) ***Advanced Cardiac Anatomy – Application in Translational Research Tailored to Current and Future Technology***
   - Renu Virmani, MD, CV Path Institute *(14 mins)*

8) ***Large Animal Model for Heart Failure, Valvular Disease, Coronary Artery Disease, and Device Testing***
   - Daniel Burkhoff, MD, Columbia University *(16 mins)*

9) ***Pre-Clinical Study Design & Endpoints for Device Evaluation – FDA Point of View***
   - Judith Davis, DVM, MS, FDA *(16 mins)*

10) ***Pre-Clinical Study Design & Endpoints for Device Evaluation – Investigator Point of View***
   - Renu Virmani, MD, CV Path Institute *(13 mins)*

Topic 6: Early Feasibility *(Total = 30 mins)*

11) ***Early Feasibility Studies for Device Evaluation***
   - Andrew Farb, MD, FDA *(15 mins)*

12) ***Current Challenges & Future Direction for Human Early Feasibility Study for Device Evaluation – Industry Point of View***
   - David Reuter, MD, Seattle Children's Hospital *(15 mins)*

Topic 7: Biostatistics *(Total = 2 hrs 24 mins)*

13) ***Basic in Statistics – Clinical Study Design for Translational Research***
   - Chris Mullin, PhD, NAMSA *(16 mins)*

14) ***Basic Statistical Concepts***
   - Chris Mullin, PhD, NAMSA *(22 mins)*

15) ***Sample Size and Power***
   - Chris Mullin, PhD, NAMSA *(22 mins)*

16) ***Sensitivity and Specificity***
   - Chris Mullin, PhD, NAMSA *(9 mins)*

17) ***Common Study Design***
   - Chris Mullin, PhD, NAMSA *(23 mins)*

18) ***Phases of Translational Research***
   - Chris Mullin, PhD, NAMSA *(4 mins)*

19) ***Statistics for Evaluation of Cardiovascular Diagnostic Devices***
   - Chris Mullin, PhD, NAMSA *(13 mins)*

20) ***Pre-Clinical & Clinical Trial Design & Endpoints of Fast Track to Device Approval***
   - Roseann White, PhD, Duke Research Institute *(15 mins)*

21) ***Advanced Statistical Methods for Translational Research***
   - Chris Mullin, PhD, NAMSA *(14 mins)*

22) ***Clinical Endpoints/Surrogate Endpoints***
   - Roseann White, PhD, Duke Research Institute *(6 mins)*

Topic 8: Regulatory Approval *(Total = 48 mins)*

23) ***Regulatory Requirement for Marketing Approval***
- Bram Zuckerman, MD, FDA **(View for free online)** *(15 mins)*

24) ***FDA Perspective on Transformative Regulatory Pathways & Device Innovation***
- Bram Zuckerman, MD, FDA *(9 mins)*

25) ***Regulatory Review of Cardiovascular Diagnostic Devices – FDA Perspective***
- Marco Cannella, PhD, FDA *(10 mins)*

26) ***Regulatory Review of Cardiovascular Devices – European Regulatory Perspective***
- Robert Byrne, MD, Heart Center, Germany *(14 mins)*

Topic 9: Reimbursement *(Total = 24 mins)*

27) ***CMS Criteria for Reimbursement for Cardiovascular Innovation***
- Joseph Chin, MD, Centers for Medicare and Medicaid Services (CMS) *(13 mins)*

28) ***Reimbursement for Diagnostic Devices***
- Lori Ashby, Centers for Medicare and Medicaid Services (CMS) *(11 mins)*

Topic 10: Practice Guideline *(Total = 32 mins)*

29) ***Practice Guideline Requirement for New Technology***
- Alice Jacobs, MD, Boston University *(16 mins)*

30) ***Guideline Requirements for Diagnostic Devices***
- Roxana Mehran, MD, Icahn School of Medicine, Mount Sinai *(16 mins)*

Topic 11: Technology Adoption *(Total = 7 mins)*

31) ***Adoption of Technology***
- Ian Meredith, MD, Formerly of Boston Scientific *(7 mins)*

Topic 12: Conflict of Interest *(Total = 8 mins)*

32) ***Conflict of Interest and Product Development***
- Anthony DeMaria, MD, University of California San Diego *(8 mins)*

Topic 13: Patients *(Total = 8 mins)*

33) ***The Patients Voice***
- Mark Mercola, PhD, Stanford Cardiovascular Institute *(8 mins)*

Panel Discussions *(Total = 2 hrs 2 mins)*

- Diagnostic Devices Development *(32 mins)*
- Device Development: Essential Concepts *(21 mins)*
- Requirements for CV Devices Approval *(36 mins)*
- Clinical Endpoints & Biostatistics *(19 mins)*
- Preclinical, Early Feasibility, and Safety Study for Device Development *(14 mins)*

Session II: Translational Pathway for Transcatheter Aortic Valve Replacement
(Total = 2 hrs 29 mins)

1) ***The Clinical Need for Innovative Treatment for Aortic Valve Disease***
   - Martin Leon, MD, Columbia University *(17 mins)*
2) ***The Methods for TAVR Development***
   - Stan Rowe, NXT Biomedical *(10 mins)*
3) ***The Endpoints for TAVR Development***
   - Ori Ben-Yehuda, MD, Cardiovascular Research Foundation *(14 mins)*
4) ***Current Challenges & Future Direction for AV Development & Iteration – FDA Point of View***
   - Nicole Ibrahim, PhD, FDA *(11 mins)*
5) ***Current Challenges & Future Direction for AV Development & Iteration – Industry Point of View***
   - Stan Rowe, NXT Biomedical *(9 mins)*
6) ***TAVR Development from Concept to First In Man***
   - Alain Cribier, MD, University of Rouen, France **(View for free online)** *(18 mins)*
7) ***TAVR Development from First In Man to Phase 3 and Beyond***
   - Martin Leon, MD, Columbia University **(View for free online)** *(24 mins)*

Panel Discussions *(Total = 46 mins)*

- Valve Disease/TAVR *(29 mins)*
- Aortic Valve Development *(17 mins)*

Session III: Translational Pathway for Transcatheter Mitral/Tricuspid Valve Devices *(Total = 2 hrs 37 mins)*

1) ***The Clinical Need for Innovative Treatment for Mitral/Tricuspid Valve Disease***
   - Michael Mack, MD, Baylor Scott & White Health *(15 mins)*
2) ***The Methods for Translational Mitra/Tricuspid Valve Device Development***
   - Michael Mack, MD, Baylor Scott & White Health *(15 mins)*
3) ***The Endpoints for Transcatheter Mitral/Tricuspid Valve Device Development***
   - Blasé Carabello, MD, East Carolina University *(13 mins)*
4) ***Current Challenges & Future Direction for Mitral/Tricuspid Valve Device Development & Iteration FDA Point of View***
   - John Laschinger, MD, Edwards Lifesciences *(15 mins)*
5) ***Current Challenges & Future Direction for Mitral/Tricuspid Valve Device Development & Iteration Industry Point of View***
   - Patricia Todd, Edwards Lifesciences *(14 mins)*
6) ***Unmet Clinical Needs for Tricuspid Valve Interventions***
   - Carlos Sanchez, MD, Ohio Health-Riverside Methodist Hospital *(7 mins)*
7) ***Current Imaging Limitations for the Advancement of Tricuspid Valve Interventions***
   - Rebecca Hahn, MD, Columbia University Medical Center *(8 mins)*
8) ***Tricuspid Valve Interventions: Challenges from the Regulatory Perspective***
   - Changfu Wu, PhD, FDA *(7 mins)*

Panel Discussions *(Total = 1 hr 3 mins)*

- Structural Heart Intervention Imaging *(15 mins)*
- MV/TV Transcatheter Repair/Replacement *(35 mins)*
- MV/TV Development *(13 mins)*

Session IV: Translational Pathway for Coronary Stent *(Total ≈ 3.5 hrs)*

1) ***The Clinical Need for Innovative Coronary Stent***
   - Gregg Stone, MD, Icahn School of Medicine, Mount Sinai *(17 mins)*
2) ***The Methods for Coronary Stent Development***
   - Chuck Simonton, MD, Abiomed *(24 mins)*
3) ***The Endpoints for Coronary Stent Development***
   - Donald Cutlip, MD, Beth Israel-Deaconess Medical Center *(10 mins)*
4) ***Current Challenges & Future Direction for Coronary Stent Development & Iteration – FDA Point of View***
   - Michael John, MPH, FDA *(10 mins)*
5) ***Current Challenges & Future Direction for Coronary Stent Development & Iteration – Industry Point of View***
   - Chuck Simonton, MD, Abiomed J&J MedTech *(15 mins)*
6) ***Unmet Clinical Needs, Value Added & Future Direction in CT Lesion Assessment***
   - James Min, MD, Weill Cornell Medicine *(7 mins)*
7) ***Unmet Clinical Needs, Current & Future Direction in Intracoronary Physiology & Imaging Assessment***
   - Morton Kern, MD, University of California Irvine & Long Beach Veterans Administration Medical Center *(8 mins)*
8) ***Advances in the Assessment of High-Risk Coronary Lesions – Non-Clinical Evaluation***
   - Robert Safian, MD, Center for Innovation & Research in CV Diseases (CIRC) *(7 mins)*
9) ***Advances in the Assessment of High-Risk Coronary Lesions – FDA Perspective***
   - Shawn Forrest, FDA *(7 mins)*
10) ***Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions - Unmet Clinical Needs/Future Directions***
   - Ajay Kirtane, MD, Columbia University Medical Center *(7 mins)*
11) ***Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions - Non-Clinical Evaluation***
   - Kevin Croce, MD, PhD, Harvard Medical School *(8 mins)*
12) ***Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions - FDA Perspective***
   - Lydia Glaw, PhD, FDA *(6 mins)*

Panel Discussions *(Total = 1 hr 18 mins)*

- Devices for Complex Coronary Lesions *(17 mins)*
- Advances in the Assessment of High Risk Coronary Lesions *(18 mins)*
- CAD/Coronary Stent *(27 mins)*

- Coronary Stent Development *(16 mins)*

Session V: Translational Pathway for Catheter Ablation *(Total = 2 hrs)*

1) ***The Clinical Need for the Treatment of Arrhythmia Innovative Catheter Ablation***
   - Douglas Packer, MD, Mayo Clinic *(17 mins)*
2) ***Methods for Catheter Ablation Development***
   - Douglas Packer, MD, Mayo Clinic *(18 mins)*
3) ***The Endpoints for Catheter Ablation Development***
   - Marco Cannella, PhD, FDA *(7 mins)*
4) ***Current Challenges & Future Direction for Catheter Ablation Development & Iteration - FDA Point of View***
   - Mark Fellman, MS, FDA *(14 mins)*
5) ***Current Challenges & Future Direction for Catheter Ablation Development & Iteration – Industry Point of View***
   - Uri Yaron, PhD, Abbott *(14 mins)*

Panel Discussions *(Total = 52 mins)*

- Arrhythmia/Catheter Ablation *(29 mins)*
- Catheter Ablation Development *(23 mins)*

Session VI: Translational Pathway for Ventricular Assist Devices *(Total = 1 hr 42 mins)*

1) ***Ventricular Assist Devices, the Windy Road to Recovery***
   - Sir Magdi Yacoub, MD, Imperial College, England *(17 mins)*
2) ***The Methods for Left Ventricular Assist Devices Development***
   - Francis Pagani, MD, PhD, University of Michigan *(19 mins)*
3) ***The Endpoints for Left Ventricular Device Evaluation***
   - Keith Aaronson, MD, University of Michigan *(8 mins)*

Panel Discussions (Total = 58 mins)

- Translational Pathway for LV Assist Devices *(44 mins)*
- CHF/Ventricular Assist Devices *(14 mins)*

Session VII: Translational Pathway for Interventional Devices for Heart Failure *(Total = 53 mins)*

1) ***Overview of Interventional Devices for Heart Failure***
   - William Abraham, MD, Ohio State University *(7 mins)*
2) ***Current Landscape & Future Direction – Percutaneous Ventricular Assist Devices***
   - William O'Neill, MD, Henry Ford Hospital *(7 mins)*
3) ***Current Landscape & Future Direction of Neuromodulation Heart Failure Therapies***
   - Horst Sievert, MD, CardioVascular Center, Germany *(7 mins)*

4) ***Current Landscape & Future Direction – Intracardiac Shunts & Ventricular Remodeling Therapies***
   - Gregg Stone, MD, Icahn School of Medicine, Mount Sinai *(7 mins)*

5) ***Interventional Devices for Heart Failure – Non-Clinical Evaluation***
   - Navin Kapur, MD, Tufts Medical Center *(7 mins)*

6) ***Interventional Devices for Heart Failure – FDA Perspective***
   - Ileana Piña, MD, Central Michigan University *(7 mins)*

Panel Discussion *(Total = 11 mins)*

- Interventional Devices for Heart Failure *(11 mins)*

Session VIII: Translational Pathway for Left Atrial Appendage Closure Devices
(Total = 43 mins)

1) ***Unmet Clinical Needs/Current and Future Direction***
   - Brian Whisenant, MD, University of Utah *(7 mins)*

2) ***Current & Future Left Atrial Appendage Imaging Modalities to Optimize LAA Closure***
   - Dee Dee Wang, MD, Henry Ford Hospital *(7 mins)*

3) ***Left Atrial Appendage Closure Devices – FDA Perspective***
   - Rachel Neubrander, PhD, FDA *(6 mins)*

Panel Discussion *(Total = 23 mins)*

- Left Atrial Appendage Closure Devices *(23 mins)*

Total Course Hours = approx. 24 hours of lectures

Supplemental Lectures in Cardiovascular Medicine *(Total = 1 hr 38 mins)*

1) ***Introduction to the Cardiac Cath Lab***
   - Morton Kern, MD, University of California Irvine & Long Beach Veterans Administration Medical Center *(52 mins)*

2) ***Cardiac Imaging: The Right Test for the Right Patient***
   - Anthony DeMaria, MD, University of California San Diego *(46 mins)*