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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**

Welcome

1) *Meet the Course Directors* (**View for free online**)

- Spencer King, MD, Emory University
 - Anthony DeMaria, MD, University of Southern California San Diego
 - Nabil Dib, MD, ISCTR
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Introduction

1) *Mission Statement*

- Nabil Dib, MD, ISCTR (**View for free online**)

2) *The Translational Pathway to Expedite Scientific Discovery to Patients*

- Robert Califf, MD, FDA (**View for free online**)

3) *Meet the Legends of Innovation Panel Discussion* (**View for free online**)

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| • John Simpson, MD, Avinger | • Gregg Stone, MD, Mt. Sinai |
| • Alain Cribier, MD, University of Rouen | • Spencer King, MD, Emory University |
| • Gary Roubin, MD, Brookwood Baptist Health | • Magdi Yacoub, MD, Imperial College |
| • Richard Schatz, MD, Scripps Clinic | • James Muller, MD, InfraRedx |
| • Julio Palmaz, MD, San Francisco | • Charles Simonton, MD, Abbott Vascular |
| • David Reuter, MD, PhD, Seattle Children's | • Neal Farnot, PhD, Cook Group |
| • Gregg Sutton, Surmodics, Inc. | • Stan Rowe, NXT Biomedical |
| • Bram Zuckerman, MD, FDA | |
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Session I: Basic Knowledge for CV Devices Development

Topic 1: Concept/Innovation

1) *Choosing an Innovative Concept*

- Todd Brinton, MD, Edwards Lifesciences
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Topic 2: Intellectual Property

- 2) *Intellectual Property*
- James Inskeep, Inskeep Intellectual Property Group

Topic 3: Business Plan, Product Development, and Fundraising

- 3) *Business Plan, Product Development, and Fundraising*
- Stan Rowe, NXT Biomedical

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) *Introduction to the Cardiac Cath Lab*
- Morton Kern, MD, University of California Irvine & Long Beach Veterans Administration Medical Center
- 8) *Large Animal Model for Heart Failure, Valvular Disease, Coronary Artery Disease, and Device Testing*
- Daniel Burkhoff, MD, Columbia University
- 9) *Pre-Clinical Study Design & Endpoints for Device Evaluation – FDA Point of View*
- Judith Davis, DVM, MS, FDA
- 10) *Pre-Clinical Study Design & Endpoints for Device Evaluation – Investigator Point of View*
- Renu Virmani, MD, CV Path Institute

Topic 6: Early Feasibility

- 11) *Early Feasibility Studies for Device Evaluation*
- Andrew Farb, MD, FDA
- 12) *Current Challenges & Future Direction for Human Early Feasibility Study for Device Evaluation – Industry Point of View*
- David Reuter, MD, Seattle Children's Hospital

Topic 7: Biostatistics

- 13) *Basic in Statistics – Clinical Study Design for Translational Research*
- Chris Mullin, PhD, NAMSA
- 14) *Basic Statistical Concepts*
- Chris Mullin, PhD, NAMSA
- 15) *Sample Size and Power*
- Chris Mullin, PhD, NAMSA

- 16) *Sensitivity and Specificity*
 - Chris Mullin, PhD, NAMSA
 - 17) *Common Study Design*
 - Chris Mullin, PhD, NAMSA
 - 18) *Phases of Translational Research*
 - Chris Mullin, PhD, NAMSA
 - 19) *Statistics for Evaluation of Cardiovascular Diagnostic Devices*
 - Chris Mullin, PhD, NAMSA
 - 20) *Pre-Clinical & Clinical Trial Design & Endpoints of Fast Track to Device Approval*
 - Roseann White, PhD, Duke Research Institute
 - 21) *Advanced Statistical Methods for Translational Research*
 - Chris Mullin, PhD, NAMSA
 - 22) *Clinical Endpoints/Surrogate Endpoints*
 - Roseann White, PhD, Duke Research Institute
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Topic 8: Regulatory Approval

- 23) *Regulatory Requirement for Marketing Approval*
 - Bram Zuckerman, MD, FDA ([View for free online](#))
 - 24) *Regulatory Review of Cardiovascular Diagnostic Devices – FDA Perspective*
 - Marco Cannella, PhD, FDA
 - 25) *Regulatory Review of Cardiovascular Devices – European Regulatory Perspective*
 - Robert Byrne, MD, Heart Center, Germany ([View for free online](#))
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Topic 9: Reimbursement

- 26) *CMS Criteria for Reimbursement for Cardiovascular Innovation*
 - Joseph Chin, MD, Centers for Medicare and Medicaid Services (CMS)
 - 27) *Reimbursement for Diagnostic Devices*
 - Lori Ashby, Centers for Medicare and Medicaid Services (CMS)
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Topic 10: Practice Guideline

- 28) *Practice Guideline Requirement for New Technology*
 - Alice Jacobs, MD, Boston University
 - 29) *Guideline Requirements for Diagnostic Devices*
 - Roxana Mehran, MD, Icahn School of Medicine, Mount Sinai
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Topic 11: Technology Adoption

- 30) *Adoption of Technology*
 - Ian Meredith, MD, Boston Scientific
 - 31) *Global Heart Health, Implications for Translational Research*
 - Salim Yusuf, World Federation of Cardiology
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Topic 12: Conflict of Interest

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

Topic 13: Patients

33) *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 Transcatheter Aortic Valve Replacement

1) *The Clinical Need for Innovative Treatment for Aortic Valve Disease*

- Martin Leon, MD, Columbia University

2) *The Methods for TAVR Development*

- Stan Rowe, Edwards 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, Edwards Lifesciences

6) *TAVR Development from Concept to First In Man*

- Alain Cribier, MD, University of Rouen, France ([View for free online](#))

7) *TAVR Development from First In Man to Phase 3 and Beyond*

- Martin Leon, MD, Columbia University ([View for free 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 Mitral/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, Edwards Lifesciences
- 6) *Unmet Clinical Needs for Tricuspid Valve Interventions*
 - Carlos Sanchez, MD, Ohio Health-Riverside Methodist Hospital
- 7) *Current Imaging Limitations for the Advancement of Tricuspid Valve Interventions*
 - Rebecca Hahn, MD, Columbia University Medical Center
- 8) *Tricuspid Valve Interventions: Challenges from the Regulatory Perspective*
 - Changfu Wu, PhD, FDA

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, Icahn School of Medicine, Mount Sinai
- 2) *The Methods for Coronary Stent Development*
 - Chuck Simonton, MD, Abbott Vascular
- 3) *The Endpoints for Coronary Stent Development*
 - Donald Cutlip, MD, Beth Israel-Deaconess Medical Center
- 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*
 - Chuck Simonton, MD, Abbott Vascular
- 6) *Unmet Clinical Needs, Value Added & Future Direction in CT Lesion Assessment*
 - James Min, MD, Weill Cornell Medicine
- 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) *Advances in the Assessment of High-Risk Coronary Lesions – Non-Clinical Evaluation*
 - Robert Safian, MD, Center for Innovation & Research in Cardiovascular Diseases (CIRC)
- 9) *Advances in the Assessment of High-Risk Coronary Lesions – FDA Perspective*
 - Shawn Forrest, FDA

- 10) *Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions - Unmet Clinical Needs/Future Directions*
 - Ajay Kirtane, MD, Columbia University Medical Center
- 11) *Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions – Non-Clinical Evaluation*
 - Kevin Croce, MD, PhD, Harvard Medical School
- 12) *Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions – FDA Perspective*
 - Lydia Glaw, PhD, FDA

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, Biosense Webster at Johnson & Johnson

Panel Discussions

- 2017 Arrhythmia/Catheter Ablation
- 2016 Catheter Ablation Development

Session VI: Translational Pathway for Ventricular Assist Devices

- 1) *Ventricular Assist Devices, the Windy Road to Recovery*
 - Sir Magdi Yacoub, MD, Imperial College, England
- 2) *The Methods for Left Ventricular Assist Devices Development*
 - Francis Pagani, MD, PhD, 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

Session VII: Translational Pathway for Interventional Devices for Heart Failure

- 1) *Overview of Interventional Devices for Heart Failure*
 - William Abraham, MD, Ohio State University
- 2) *Current Landscape & Future Direction – Percutaneous Ventricular Assist Devices*
 - William O’Neill, MD, Henry Ford Hospital
- 3) *Current Landscape & Future Direction of Neuromodulation Heart Failure Therapies*
 - Horst Sievert, MD, CardioVascular Center, Germany
- 4) *Current Landscape & Future Direction – Intracardiac Shunts & Ventricular Remodeling Therapies*
 - Gregg Stone, MD, Icahn School of Medicine, Mount Sinai
- 5) *Interventional Devices for Heart Failure – Non-Clinical Evaluation*
 - Navin Kapur, MD, Tufts Medical Center
- 6) *Interventional Devices for Heart Failure – FDA Perspective*
 - Ileana Piña, MD, Montefiore Einstein Center

Panel Discussion

- 2019 Interventional Devices for Heart Failure

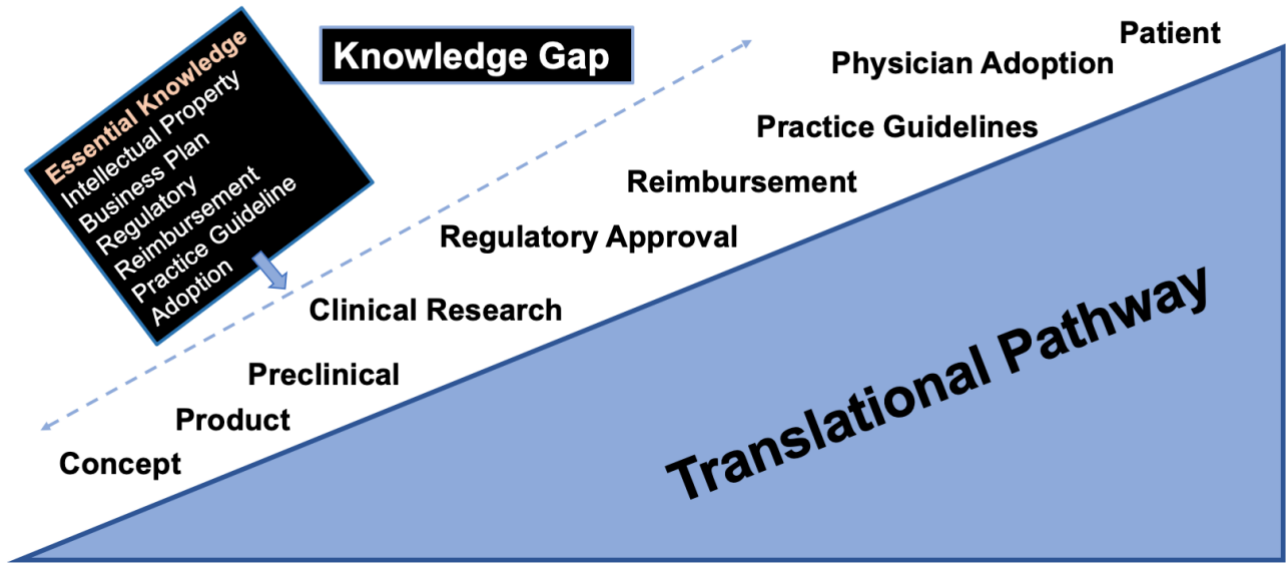
Session VIII: Translational Pathway for Left Atrial Appendage Closure Devices

- 1) *Unmet Clinical Needs/Current and Future Direction*
 - Brian Whisenant, MD, University of Utah
- 2) *Current & Future Left Atrial Appendage Imaging Modalities to Optimize LAA Closure*
 - Dee Dee Wang, MD, Henry Ford Hospital
- 3) *Left Atrial Appendage Closure Devices – FDA Perspective*
 - Rachel Neubrandner, PhD, FDA

Panel Discussion

- 2019 Left Atrial Appendage Closure Devices

Translational Pathways for Cardiovascular Devices



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Multi-disciplinary

