



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 2 hrs)*

- 1) **Welcome from the Course Directors (View for free online)**
 - Nabil Dib, MD, ISCTR *(42 mins 42 secs)*
 - Spencer King, MD, Emory University *(5 mins 50 secs)*
 - Anthony DeMaria, MD, University of California San Diego *(5 mins)*

 - 2) **Course Description (4 mins 45 secs)**

 - 3) **The Translational Pathway to Expedite Scientific Discovery to Patients**
 - Robert Califf, MD, FDA **(View for free online)** *(23 mins 45 secs)*

 - 4) **Meet the Legends of Innovation Panel Discussion (View for free online) (39 mins)**

<ul style="list-style-type: none">• John Simpson, MD, Avinger• Alain Cribier, MD, University of Rouen• Gary Roubin, MD, Brookwood Baptist Health• Richard Schatz, MD, Scripps Clinic• Julio Palmaz, MD, San Francisco• David Reuter, MD, PhD, Seattle Children's• Gregg Sutton, Surmodics, Inc.• Bram Zuckerman, MD, FDA	<ul style="list-style-type: none">• Gregg Stone, MD, Mt. Sinai• Spencer King, MD, Emory University• Magdi Yacoub, MD, Imperial College• James Muller, MD, InfraReDx• Charles Simonton, MD, Abbott Vascular• Neal Fearnot, PhD, Cook Group• Stan Rowe, NXT Biomedical
---	--
-

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 10 secs)*
-

Topic 2: Intellectual Property (Total = 5 mins)

2) **Intellectual Property**

- James Inskeep, Inskeep Intellectual Property Group (4 mins 45 secs)
-

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

3) **Business Plan, Product Development, and Fundraising**

- Stan Rowe, NXT Biomedical (6 mins)
-

Topic 4: Product Manufacturing (Total = 24 mins)

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

- Brad Quinn, FDA (9 mins 35 secs)

5) **Requirements for Medical Device Manufacturing & Iteration - Industry Point of View**

- Richard Rapoza, PhD, Abbott Vascular (14 mins 35 secs)
-

Topic 5: Preclinical Evaluation/Animal Model (Total = 1 hr 50 mins)

6) **Advanced Cardiac Anatomy – Application in Translational Research Tailored to Current and Future Technology**

- Renu Virmani, MD, CV Path Institute (14 mins 10 secs)

7) **Introduction to the Cardiac Cath Lab**

- Morton Kern, MD, University of California Irvine & Long Beach Veterans Administration Medical Center (52 mins 10 secs)

8) **Large Animal Model for Heart Failure, Valvular Disease, Coronary Artery Disease, and Device Testing**

- Daniel Burkhoff, MD, Columbia University (15 mins 50 secs)

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 (12 mins 40 secs)
-

Topic 6: Early Feasibility (Total = 31 mins)

11) **Early Feasibility Studies for Device Evaluation**

- Andrew Farb, MD, FDA (14 mins 50 secs)

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 35 secs)
-

Topic 7: Biostatistics (Total = 2 hrs 22 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 25 secs)

15) **Sample Size and Power**

- Chris Mullin, PhD, NAMSA (22 mins 30 secs)
-

- 16) **Sensitivity and Specificity**
- Chris Mullin, PhD, NAMSA (9 mins 15 secs)
- 17) **Common Study Design**
- Chris Mullin, PhD, NAMSA (22 mins 50 secs)
- 18) **Phases of Translational Research**
- Chris Mullin, PhD, NAMSA (4 mins 15 secs)
- 19) **Statistics for Evaluation of Cardiovascular Diagnostic Devices**
- Chris Mullin, PhD, NAMSA (12 mins 40 secs)
- 20) **Pre-Clinical & Clinical Trial Design & Endpoints of Fast Track to Device Approval**
- Roseann White, PhD, Duke Research Institute (14 mins 45 secs)
- 21) **Advanced Statistical Methods for Translational Research**
- Chris Mullin, PhD, NAMSA (13 mins 45 secs)
- 22) **Clinical Endpoints/Surrogate Endpoints**
- Roseann White, PhD, Duke Research Institute (6 mins 15 secs)
-

Topic 8: Regulatory Approval (Total = 39 mins)

- 23) **Regulatory Requirement for Marketing Approval**
- Bram Zuckerman, MD, FDA (**View for free online**) (15 mins 20 secs)
- 24) **Regulatory Review of Cardiovascular Diagnostic Devices – FDA Perspective**
- Marco Cannella, PhD, FDA (9 mins 45 secs)
- 25) **Regulatory Review of Cardiovascular Devices – European Regulatory Perspective**
- Robert Byrne, MD, Heart Center, Germany (**View for free online**) (14 mins 10 secs)
-

Topic 9: Reimbursement (Total = 24 mins)

- 26) **CMS Criteria for Reimbursement for Cardiovascular Innovation**
- Joseph Chin, MD, Centers for Medicare and Medicaid Services (CMS) (13 mins 25 secs)
- 27) **Reimbursement for Diagnostic Devices**
- Lori Ashby, Centers for Medicare and Medicaid Services (CMS) (10 mins 35 secs)
-

Topic 10: Practice Guideline (Total = 32 mins)

- 28) **Practice Guideline Requirement for New Technology**
- Alice Jacobs, MD, Boston University (16 mins 20 secs)
- 29) **Guideline Requirements for Diagnostic Devices**
- Roxana Mehran, MD, Icahn School of Medicine, Mount Sinai (16 mins)
-

Topic 11: Technology Adoption (Total = 37 mins)

- 30) **Adoption of Technology**
- Ian Meredith, MD, Boston Scientific (7 mins 10 secs)
- 31) **Global Heart Health, Implications for Translational Research**
- Salim Yusuf, MD, World Federation of Cardiology (29 mins 25 secs)
-

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

- 32) **Conflict of Interest and Product Development**
- Anthony DeMaria, MD, University of California San Diego (7 mins 45 secs)

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

33) *The Patients Voice*

- Mark Mercola, PhD, Stanford Cardiovascular Institute *(7 mins 35 secs)*
-

Panel Discussions *(Total = 2 hrs 3 mins)*

- 2019 Diagnostic Devices Development *(32 mins)*
 - 2019 Device Development: Essential Concepts *(21 mins)*
 - 2018 Requirements for CV Devices Approval *(36 mins 25 secs)*
 - 2017 Clinical Endpoints & Biostatistics *(19 mins 30 secs)*
 - 2016 Preclinical, Early Feasibility, and Safety Study for Device Development *(14 mins 20 secs)*
-

Session II: Translational Pathway for Transcatheter Aortic Valve Replacement

(Total = 2 hrs 30 mins)

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

- Martin Leon, MD, Columbia University *(17 mins 10 secs)*

2) *The Methods for TAVR Development*

- Stan Rowe, Edwards Lifesciences *(10 mins 30 secs)*

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 30 secs)*

5) *Current Challenges & Future Direction for AV Development & Iteration – Industry Point of View*

- Stan Rowe, Edwards Lifesciences *(9 mins 15 secs)*

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)*

- 2017 Valve Disease/TAVR *(29 mins)*
 - 2016 Aortic Valve Development *(16 mins 40 secs)*
-

Session III: Translational Pathway for Transcatheter Mitral/Tricuspid Valve Devices *(Total = 2 hrs 38 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 Mitral/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 *(12 mins 40 secs)*
-

- 4) **Current Challenges & Future Direction for Mitral/Tricuspid Valve Device Development & Iteration FDA Point of View**
 - John Laschinger, MD, FDA (14 mins 45 secs)
- 5) **Current Challenges & Future Direction for Mitral/Tricuspid Valve Device Development & Iteration Industry Point of View**
 - Patricia Todd, Edwards Lifesciences (14 mins 15 secs)
- 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 4 mins)

- 2019 Structural Heart Intervention Imaging (15 mins 15 secs)
 - 2017 MV/TV Transcatheter Repair/Replacement (35 mins 25 secs)
 - 2016 MV/TV Development (13 mins 20 secs)
-

Session IV: Translational Pathway for Coronary Stent (Total = 3 hrs 25 mins)

- 1) **The Clinical Need for Innovative Coronary Stent**
 - Gregg Stone, MD, Icahn School of Medicine, Mount Sinai (16 mins 40 secs)
- 2) **The Methods for Coronary Stent Development**
 - Chuck Simonton, MD, Abbott Vascular (24 mins)
- 3) **The Endpoints for Coronary Stent Development**
 - Donald Cutlip, MD, Beth Israel-Deaconess Medical Center (10 mins 20 secs)
- 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, Abbott Vascular (15 mins 30 secs)
- 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 20 secs)
- 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 30 secs)
- 9) **Advances in the Assessment of High-Risk Coronary Lesions – FDA Perspective**
 - Shawn Forrest, FDA (6 mins 45 secs)

- 10) **Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions - Unmet Clinical Needs/Future Directions**
 - Ajay Kirtane, MD, Columbia University Medical Center (6 mins 50 secs)
- 11) **Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions - Non-Clinical Evaluation**
 - Kevin Croce, MD, PhD, Harvard Medical School (7 min 40 secs)
- 12) **Revascularization & Devices for Complex Coronary Lesions – Calcified & Total Occlusions - FDA Perspective**
 - Lydia Glaw, PhD, FDA (6 min 15 secs)

Panel Discussions (Total = 1 hr 15 mins)

- 2019 Devices for Complex Coronary Lesions (17 mins 15 secs)
 - 2019 Advances in the Assessment of High Risk Coronary Lesions (17 mins 40 secs)
 - 2017 CAD/Coronary Stent (27 mins)
 - 2016 Coronary Stent Development (15 mins 35 secs)
-

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 (16 min 40 secs)
 - 2) **Methods for Catheter Ablation Development**
 - Douglas Packer, MD, Mayo Clinic (17 mins 50 secs)
 - 3) **The Endpoints for Catheter Ablation Development**
 - Marco Cannella, PhD, FDA (6 mins 45 secs)
 - 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, Biosense Webster at Johnson & Johnson (14 mins)
-

Panel Discussions (Total = 52 mins)

- 2017 Arrhythmia/Catheter Ablation (29 mins)
 - 2016 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 25 secs)

Panel Discussions (Total = 58 mins)

- 2018 Translational Pathway for LV Assist Devices (43 mins 45 secs)
- 2017 CHF/Ventricular Assist Devices (14 min 10 secs)

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 25 secs)
- 3) **Current Landscape & Future Direction of Neuromodulation Heart Failure Therapies**
 - Horst Sievert, MD, CardioVascular Center, Germany (6 mins 40 secs)
- 4) **Current Landscape & Future Direction – Intracardiac Shunts & Ventricular Remodeling Therapies**
 - Gregg Stone, MD, Icahn School of Medicine, Mount Sinai (7 mins 15 secs)
- 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, Montefiore Einstein Center (7 mins)

Panel Discussion (Total = 11 mins)

- 2019 Interventional Devices for Heart Failure (11 mins)

Session VIII: Translational Pathway for Left Atrial Appendage Closure Devices

(Total = 43 mins)

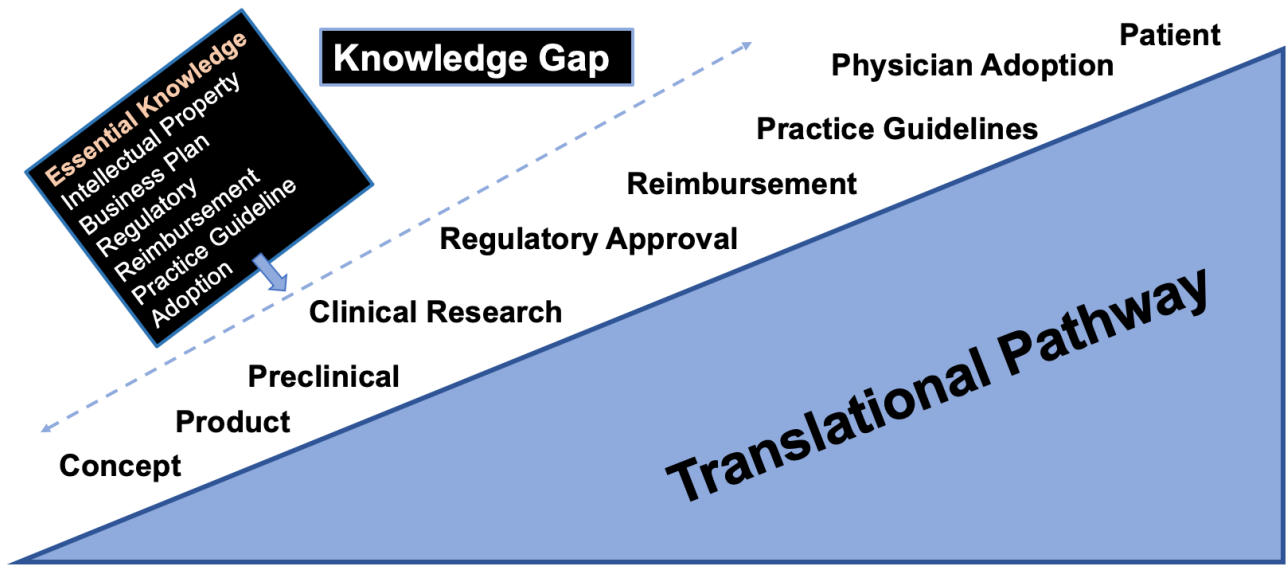
- 1) **Unmet Clinical Needs/Current and Future Direction**
 - Brian Whisenant, MD, University of Utah (7 mins)
- 2) **Current & Future Left Atrial Appendage Imaging Modalities to Optimize LAA Closure**
 - Dee Dee Wang, MD, Henry Ford Hospital (6 mins 45 secs)
- 3) **Left Atrial Appendage Closure Devices – FDA Perspective**
 - Rachel Neubrandner, PhD, FDA (6 mins 25 secs)

Panel Discussion (Total = 23 mins)

- 2019 Left Atrial Appendage Closure Devices (22 mins 35 secs)

Total Course Hours = 26 hours

Translational Pathways for Cardiovascular Devices



Translational Pathways for Cardiovascular Devices

Multi-disciplinary

