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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**

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### Introduction *(Total 2 hrs)*

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- 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"><li>• John Simpson, MD, Avinger</li><li>• Alain Cribier, MD, University of Rouen</li><li>• Gary Roubin, MD, Brookwood Baptist Health</li><li>• Richard Schatz, MD, Scripps Clinic</li><li>• Julio Palmaz, MD, San Francisco</li><li>• David Reuter, MD, PhD, Seattle Children's</li><li>• Gregg Sutton, Surmodics, Inc.</li><li>• Bram Zuckerman, MD, FDA</li></ul>	<ul style="list-style-type: none"><li>• Gregg Stone, MD, Mt. Sinai</li><li>• Spencer King, MD, Emory University</li><li>• Magdi Yacoub, MD, Imperial College</li><li>• James Muller, MD, InfraRedx</li><li>• Charles Simonton, MD, Abbott Vascular</li><li>• Neal Farnot, PhD, Cook Group</li><li>• Stan Rowe, NXT Biomedical</li></ul>
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### Session I: Basic Knowledge for CV Devices Development *(Total = 12 hrs)*

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

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- 1) **Choosing an Innovative Concept**
    - Todd Brinton, MD, Edwards Lifesciences *(7 mins 10 secs)*
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## **Topic 2: Intellectual Property** (Total = 5 mins)

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### 2) **Intellectual Property**

- James Inskeep, Inskeep Intellectual Property Group (4 mins 45 secs)
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## **Topic 3: Business Plan, Product Development, and Fundraising** (Total = 6 mins)

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

- Stan Rowe, NXT Biomedical (6 mins)
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## **Topic 4: Product Manufacturing** (Total = 24 mins)

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

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

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

### 8) **Pre-Clinical Study Design & Endpoints for Device Evaluation – FDA Point of View**

- Judith Davis, DVM, MS, FDA (16 mins)

### 9) **Pre-Clinical Study Design & Endpoints for Device Evaluation – Investigator Point of View**

- Renu Virmani, MD, CV Path Institute (12 mins 40 secs)
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## **Topic 6: Early Feasibility** (Total = 31 mins)

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### 10) **Early Feasibility Studies for Device Evaluation**

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

### 11) **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)
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## **Topic 7: Biostatistics** (Total = 2 hrs 22 mins)

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### 12) **Basic in Statistics – Clinical Study Design for Translational Research**

- Chris Mullin, PhD, NAMSA (16 mins)

### 13) **Basic Statistical Concepts**

- Chris Mullin, PhD, NAMSA (22 mins 25 secs)

### 14) **Sample Size and Power**

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

### 15) **Sensitivity and Specificity**

- Chris Mullin, PhD, NAMSA (9 mins 15 secs)
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- 16) **Common Study Design**
    - Chris Mullin, PhD, NAMSA (22 mins 50 secs)
  - 17) **Phases of Translational Research**
    - Chris Mullin, PhD, NAMSA (4 mins 15 secs)
  - 18) **Statistics for Evaluation of Cardiovascular Diagnostic Devices**
    - Chris Mullin, PhD, NAMSA (12 mins 40 secs)
  - 19) **Pre-Clinical & Clinical Trial Design & Endpoints of Fast Track to Device Approval**
    - Roseann White, PhD, Duke Research Institute (14 mins 45 secs)
  - 20) **Advanced Statistical Methods for Translational Research**
    - Chris Mullin, PhD, NAMSA (13 mins 45 secs)
  - 21) **Clinical Endpoints/Surrogate Endpoints**
    - Roseann White, PhD, Duke Research Institute (6 mins 15 secs)
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### **Topic 8: Regulatory Approval (Total = 48 mins)**

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- 22) **Regulatory Requirement for Marketing Approval**
    - Bram Zuckerman, MD, FDA (**View for free online**) (15 mins 20 secs)
  - 23) **FDA Perspective on Transformative Regulatory Pathways & Device Innovation**
    - Bram Zuckerman, MD, FDA (9 mins 10 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)
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### **Topic 9: Reimbursement (Total = 24 mins)**

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

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- 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)
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### **Topic 11: Technology Adoption (Total = 37 mins)**

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

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## 32) **Conflict of Interest and Product Development**

- Anthony DeMaria, MD, University of California San Diego (7 mins 45 secs)

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

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### 33) **The Patients Voice**

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

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

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

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## **Session II: Translational Pathway for Transcatheter Aortic Valve Replacement** (Total = 2 hrs 30 mins)

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### 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)

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## **Panel Discussions** (Total = 46 mins)

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

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

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### 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)
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### **Panel Discussions** (Total = 1 hr 4 mins)

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- Structural Heart Intervention Imaging (15 mins 15 secs)
  - MV/TV Transcatheter Repair/Replacement (35 mins 25 secs)
  - MV/TV Development (13 mins 20 secs)
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### **Session IV: Translational Pathway for Coronary Stent** (Total = 3.5 hrs)

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- 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)

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### **Panel Discussions** (Total = 1 hr 15 mins)

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- Devices for Complex Coronary Lesions (17 mins 15 secs)
  - Advances in the Assessment of High Risk Coronary Lesions (17 mins 40 secs)
  - CAD/Coronary Stent (27 mins)
  - Coronary Stent Development (15 mins 35 secs)
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## **Session V: Translational Pathway for Catheter Ablation** (Total = 2 hrs)

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- 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)

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### **Panel Discussions** (Total = 52 mins)

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- Arrhythmia/Catheter Ablation (29 mins)
  - Catheter Ablation Development (23 mins)
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## **Session VI: Translational Pathway for Ventricular Assist Devices**

(Total = 1 hr 42 mins)

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- 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)

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### **Panel Discussions** (Total = 58 mins)

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

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

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- 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)

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### **Panel Discussion** (Total = 11 mins)

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- Interventional Devices for Heart Failure (11 mins)

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

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- 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)

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### **Panel Discussion** (Total = 23 mins)

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

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

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- 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)

**Total Course Hours = approx. 30 hours**