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Translational Pathway for Medical Devices - Online Course -

**36 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 Farnot, PhD, Cook Group• Stan Rowe, NXT Biomedical
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Topics in Medical Device 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)*
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Topic 2: Intellectual Property (Total = 5 mins)

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)

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

- Stan Rowe, NXT Biomedical (6 mins)
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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)
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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)
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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)
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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)
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- 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)
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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)
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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)
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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)
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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)
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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

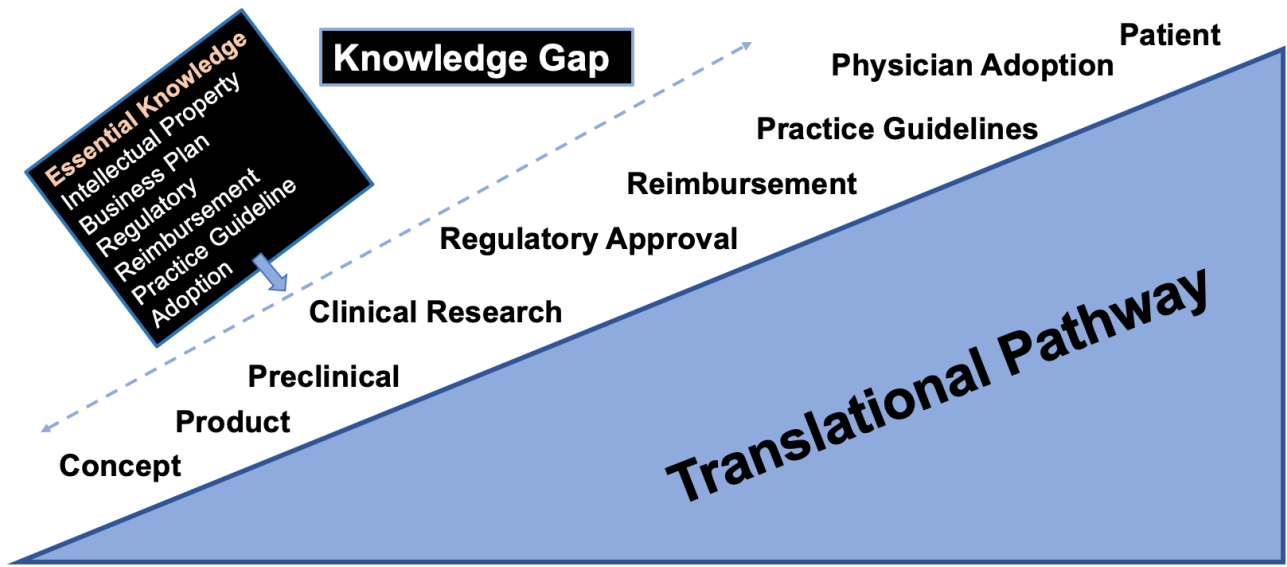
- Mark Mercola, PhD, Stanford Cardiovascular Institute *(7 mins 35 secs)*

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

- 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)*

Total Course Hours = 12 hours

Translational Pathways for Cardiovascular Devices



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Multi-disciplinary

