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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**

Welcome (Total = 12 mins 25 secs)

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

- Spencer King, MD, Emory University (5 mins 50 secs)
 - Anthony DeMaria, MD, University of California San Diego (5 mins)
 - Nabil Dib, MD, ISCTR (1 min 35 secs)
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Introduction (Total = 1 hr 10 mins)

1) *Mission Statement*

- Nabil Dib, MD, ISCTR (View for free online) (8 mins 15 secs)

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

- Robert Califf, MD, FDA (View for free online) (23 mins 45 secs)

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

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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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Topic 1: Concept/Innovation (Total = 7 mins 10 secs)

1) *Choosing an Innovative Concept*

- Todd Brinton, MD, Edwards Lifesciences (7 mins 10 secs)

Topic 2: Intellectual Property (Total = 4 mins 45 secs)

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 10 secs)

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 - Examples from the CV System (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 = 30 mins 25 secs)

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)
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- 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)
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Topic 8: Regulatory Approval (Total = 39 mins 15 secs)

- 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 20 secs)

- 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 = 36 mins 35 secs)

- 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 = 7 mins 45 secs)*

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 = 7 mins 35 secs)*

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)*

- 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 = 8 Hours