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Translational Pathway for Medical Devices - Online Course -

**29 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**

Total Course \approx 9 Hours

Introduction (Total 13 mins)

Welcome from the Course Directors (View for free online)

- Spencer King, MD, Emory University (6 mins)
 - Anthony DeMaria, MD, University of California San Diego (5 mins)
 - Nabil Dib, MD, ISCTR (2 mins)
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Topics in Medical Device Development (Total \approx 6 hrs)

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

- 1) **Choosing an Innovative Concept**
 - Todd Brinton, MD, Edwards Lifesciences (7 mins)
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Topic 2: Intellectual Property (Total = 27 mins)

- 2) **Intellectual Property**
 - James Inskeep, Inskeep Intellectual Property Group (5 mins)
 - 3) **Overview of the Patent Process**
 - Jason Gilbert, Inskeep Intellectual Property Group (22 mins)
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Topic 3: Business Plan, Product Development, and Fundraising (Total = 6 mins)

- 4) **Business Plan, Product Development, and Fundraising**
 - Stan Rowe, NXT Biomedical (6 mins)
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Topic 4: Product Manufacturing (Total = 10 mins)

- 5) **Requirements for Medical Device Manufacturing & Iteration - FDA Point of View**
 - Brad Quinn, FDA (10 mins)
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Topic 5: Preclinical Evaluation/Animal Model (Total = 16 mins)

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

- Judith Davis, DVM, MS, FDA (16 mins)
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Topic 6: Early Feasibility (Total = 30 mins)

7) Early Feasibility Studies for Device Evaluation

- Andrew Farb, MD, FDA (15 mins)

8) 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)
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Topic 7: Biostatistics (Total = 2 hrs 24 mins)

9) Basic in Statistics – Clinical Study Design for Translational Research

- Chris Mullin, PhD, NAMSA (16 mins)

10) Basic Statistical Concepts

- Chris Mullin, PhD, NAMSA (22 mins)

11) Sample Size and Power

- Chris Mullin, PhD, NAMSA (22 mins)

12) Sensitivity and Specificity

- Chris Mullin, PhD, NAMSA (9 mins)

13) Common Study Design

- Chris Mullin, PhD, NAMSA (23 mins)

14) Phases of Translational Research

- Chris Mullin, PhD, NAMSA (4 mins)

15) Statistics for Evaluation of Cardiovascular Diagnostic Devices

- Chris Mullin, PhD, NAMSA (13 mins)

16) Pre-Clinical & Clinical Trial Design & Endpoints of Fast Track to Device Approval

- Roseann White, PhD, Duke Research Institute (15 mins)

17) Advanced Statistical Methods for Translational Research

- Chris Mullin, PhD, NAMSA (14 mins)

18) Clinical Endpoints/Surrogate Endpoints

- Roseann White, PhD, Duke Research Institute (6 mins)
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Topic 8: Regulatory Approval (Total = 48 mins)

19) Regulatory Requirement for Marketing Approval

- Bram Zuckerman, MD, FDA (**View for free online**) (15 mins)

20) FDA Perspective on Transformative Regulatory Pathways & Device Innovation

- Bram Zuckerman, MD, FDA (9 mins)

21) Regulatory Review of Cardiovascular Diagnostic Devices – FDA Perspective

- Marco Cannella, PhD, FDA (10 mins)

22) Regulatory Review of Cardiovascular Devices – European Regulatory Perspective

- Robert Byrne, MD, Heart Center, Germany (14 mins)
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Topic 9: Reimbursement *(Total = 24 mins)*

23) **CMS Criteria for Reimbursement for Cardiovascular Innovation**

- Joseph Chin, MD, Centers for Medicare and Medicaid Services (CMS) *(13 mins)*

24) **Reimbursement for Diagnostic Devices**

- Lori Ashby, Centers for Medicare and Medicaid Services (CMS) *(11 mins)*
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Topic 10: Practice Guideline *(Total = 32 mins)*

25) **Practice Guideline Requirement for New Technology**

- Alice Jacobs, MD, Boston University *(16 mins)*

26) **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 = 7 mins)*

27) **Adoption of Technology**

- Ian Meredith, MD, Formerly of Boston Scientific *(7 mins)*
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Topic 12: Conflict of Interest *(Total = 8 mins)*

28) **Conflict of Interest and Product Development**

- Anthony DeMaria, MD, University of California San Diego *(8 mins)*
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Topic 13: Patients *(Total = 8 mins)*

29) **The Patients Voice**

- Mark Mercola, PhD, Stanford Cardiovascular Institute *(8 mins)*
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Panel Discussions *(Total = 2 hrs 2 mins)*

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