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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

Total Course = 10 Hours

Introduction *(Total 12.5 mins)*

Welcome from 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 40 secs)*

Topics in Medical Device Development *(Total = 9.75 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 = 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)*

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

4) ***Business Plan, Product Development, and Fundraising***
   - Stan Rowe, NXT Biomedical *(6 mins)*

Topic 4: Product Manufacturing *(Total = 24 mins)*

5) ***Requirements for Medical Device Manufacturing & Iteration - FDA Point of View***
   - Brad Quinn, FDA *(9 mins 35 secs)*
6) ***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)*

7) ***Advanced Cardiac Anatomy – Application in Translational Research Tailored to Current and Future Technology***
   - Renu Virmani, MD, CV Path Institute *(14 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 = 48 mins)*

23) ***Regulatory Requirement for Marketing Approval***
- Bram Zuckerman, MD, FDA **(View for free online)** *(15 mins 20 secs)*

24) ***FDA Perspective on Transformative Regulatory Pathways & Device Innovation***
- Bram Zuckerman, MD, FDA *(9 mins 10 secs)*

25) ***Regulatory Review of Cardiovascular Diagnostic Devices – FDA Perspective***
- Marco Cannella, PhD, FDA *(9 mins 45 secs)*

26) ***Regulatory Review of Cardiovascular Devices – European Regulatory Perspective***
- Robert Byrne, MD, Heart Center, Germany *(14 mins 10 secs)*

Topic 9: Reimbursement *(Total = 24 mins)*

27) ***CMS Criteria for Reimbursement for Cardiovascular Innovation***
- Joseph Chin, MD, Centers for Medicare and Medicaid Services (CMS) *(13 mins 25 secs)*

28) ***Reimbursement for Diagnostic Devices***
- Lori Ashby, Centers for Medicare and Medicaid Services (CMS) *(10 mins 35 secs)*

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

29) ***Practice Guideline Requirement for New Technology***
- Alice Jacobs, MD, Boston University *(16 mins 20 secs)*

30) ***Guideline Requirements for Diagnostic Devices***
- Roxana Mehran, MD, Icahn School of Medicine, Mount Sinai *(16 mins)*

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

31) ***Adoption of Technology***
- Ian Meredith, MD, Boston Scientific *(7 mins 10 secs)*

32) ***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)*

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

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

34) ***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)*