www.isctr.org

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)*

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)*
   - 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
   - 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 Fearnot, PhD, Cook Group
   - Stan Rowe, NXT Biomedical

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)*

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

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

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)*

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)*

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)*

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 = 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)*

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)*

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)*

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)*

Topic 13: Patients *(Total = 7 mins 35 secs)*

33) *The Patients Voice*

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

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

- 2019 Diagnostic Devices Development *(32 mins)*
- 2019 Device Development: Essential Concepts *(21 mins)*
- 2018 Requirements for CV Devices Approval *(36 mins 25 secs)*
- 2017 Clinical Endpoints & Biostatistics *(19 mins 30 secs)*
- 2016 Preclinical, Early Feasibility, and Safety Study for Device Development *(14 mins 20 secs)*

Total Course = 8 Hours