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Translational Pathways for Cardiovascular Devices
Session I: Basic Knowledge for CV Devices Development

33 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

1) *Meet the Course Directors* **(View for free online)**
   - Spencer King, MD, Emory University
   - Anthony DeMaria, MD, University of California San Diego
   - Nabil Dib, MD, ISCTR

Introduction

1) *Mission Statement*
   - Nabil Dib, MD, ISCTR **(View for free online)**
2) *The Translational Pathway to Expedite Scientific Discovery to Patients*
   - Robert Califf, MD, FDA **(View for free online)**
3) *Meet the Legends of Innovation Panel Discussion* **(View for free online)**
   - 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

Session I: Basic Knowledge for CV Devices Development

Topic 1: Concept/Innovation

1) *Choosing an Innovative Concept*
   - Todd Brinton, MD, Edwards Lifesciences

Topic 2: Intellectual Property

2) *Intellectual Property*
   - James Inskeep, Inskeep Intellectual Property Group

Topic 3: Business Plan, Product Development, and Fundraising

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

Topic 4: Product Manufacturing

4) *Requirements for Medical Device Manufacturing & Iteration - FDA Point of View*
   - Brad Quinn, FDA

5) *Requirements for Medical Device Manufacturing & Iteration - Industry Point of View*
   - Richard Rapoza, PhD, Abbott Vascular

Topic 5: Preclinical Evaluation/Animal Model

6) *Advanced Cardiac Anatomy – Application in Translational Research Tailored to Current and Future Technology*
   - Renu Virmani, MD, CV Path Institute

7) *Introduction to the Cardiac Cath Lab*
   - Morton Kern, MD, University of California Irvine & Long Beach Veterans Administration Medical Center

8) *Large Animal Model for Heart Failure, Valvular Disease, Coronary Artery Disease, and Device Testing*
   - Daniel Burkhoff, MD, Columbia University

9) *Pre-Clinical Study Design & Endpoints for Device Evaluation – FDA Point of View*
   - Judith Davis, DVM, MS, FDA

10) *Pre-Clinical Study Design & Endpoints for Device Evaluation – Investigator Point of View*
   - Renu Virmani, MD, CV Path Institute

Topic 6: Early Feasibility

11) *Early Feasibility Studies for Device Evaluation*
   - Andrew Farb, MD, FDA

12) *Current Challenges & Future Direction for Human Early Feasibility Study for Device Evaluation – Industry Point of View*
   - David Reuter, MD, Seattle Children's Hospital

Topic 7: Biostatistics

13) *Basic in Statistics – Clinical Study Design for Translational Research*
   - Chris Mullin, PhD, NAMSA

14) *Basic Statistical Concepts*
   - Chris Mullin, PhD, NAMSA

15) *Sample Size and Power*
   - Chris Mullin, PhD, NAMSA

16) *Sensitivity and Specificity*
- Chris Mullin, PhD, NAMSA

17) *Common Study Design*
- Chris Mullin, PhD, NAMSA

18) *Phases of Translational Research*
- Chris Mullin, PhD, NAMSA

19) *Statistics for Evaluation of Cardiovascular Diagnostic Devices*
- Chris Mullin, PhD, NAMSA

20) *Pre-Clinical & Clinical Trial Design & Endpoints of Fast Track to Device Approval*
- Roseann White, PhD, Duke Research Institute

21) *Advanced Statistical Methods for Translational Research*
- Chris Mullin, PhD, NAMSA

22) *Clinical Endpoints/Surrogate Endpoints*
- Roseann White, PhD, Duke Research Institute

Topic 8: Regulatory Approval

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

24) *Regulatory Review of Cardiovascular Diagnostic Devices – FDA Perspective*
- Marco Cannella, PhD, FDA

25) *Regulatory Review of Cardiovascular Devices – European Regulatory Perspective*
- Robert Byrne, MD, Heart Center, Germany **(View for free online)**

Topic 9: Reimbursement

26) *CMS Criteria for Reimbursement for Cardiovascular Innovation*
- Joseph Chin, MD, Centers for Medicare and Medicaid Services (CMS)

27) *Reimbursement for Diagnostic Devices*
- Lori Ashby, Centers for Medicare and Medicaid Services (CMS)

Topic 10: Practice Guideline

28) *Practice Guideline Requirement for New Technology*
- Alice Jacobs, MD, Boston University

29) *Guideline Requirements for Diagnostic Devices*
- Roxana Mehran, MD, Icahn School of Medicine, Mount Sinai

Topic 11: Technology Adoption

30) *Adoption of Technology*
- Ian Meredith, MD, Boston Scientific

31) *Global Heart Health, Implications for Translational Research*
- Salim Yusuf, World Federation of Cardiology

Topic 12: Conflict of Interest

32) *Conflict of Interest and Product Development*
- Anthony DeMaria, MD, University of Southern California San Diego

Topic 13: Patients

33) *The Patients Voice*

- Mark Mercola, PhD, Stanford Cardiovascular Institute

Panel Discussions

- 2019 Diagnostic Devices Development
- 2019 Device Development: Essential Concepts
- 2018 Requirements for CV Devices Approval
- 2017 Clinical Endpoints & Biostatistics
- 2016 Preclinical, Early Feasibility, and Safety Study for Device Development