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Translational Pathways for Cardiovascular Devices
- Online Course -

55 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

Session I: Basic Knowledge for CV Devices Development

Topic 1: Concept/Innovation

1) *Choosing an Innovative Concept*
   - Todd Brinton, MD, Edward's Lifesciences

Topic 2: Intellectual Property

2) *Intellectual Property*
   - James Inskeep, Patent Attorney

Topic 3: Business Plan, Product Development, and Fundraising

3) *Business Plan, Product Development, and Fundraising*
   - Stan Rowe, Edward's Lifesciences

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

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

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

Topic 6: Early Feasibility

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

11) *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

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

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

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

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

16) *Common Study Designs*
- Chris Mullin, PhD, NAMSA

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

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

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

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

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

Topic 8: Regulatory Approval

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

23) *Regulatory Review of Cardiovascular Devices – European Regulatory Perspective*
- Robert Byrne, MD, Heart Centre, Germany **(View free lecture online)**

Topic 9: Reimbursement

24) *CMS Criteria for Reimbursement for Cardiovascular Innovation*
- Joseph Chin, MD, CMS

Topic 10: Practice Guideline

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

Topic 11: Technology Adoption

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

27) *Global Heart Health, Implications for Translational Research*
- Salim Yusuf, D. Phil, World Federation of Cardiology

Topic 12: Patients

28) *The Patients Voice*
- Mark Mercola, PhD, Stanford Cardiovascular Institute

Session II: Translational Pathway for TAVR

1) *The Clinical Need for Innovative Treatment for AV Disease*
- Martin Leon, MD, Columbia University

2) *The Methods for TAVR Development*
- Stan Rowe, Edwards's Lifesciences

3) *The Endpoints for TAVR Development*
- Ori Ben-Yehuda, MD, Cardiovascular Research Foundation

4) *Current Challenges & Future Direction for AV Development & Iteration – FDA Point of View*
- Nicole Ibrahim, PhD, FDA

5) *Current Challenges & Future Direction for AV Development & Iteration – Industry Point of View*
- Stan Rowe, Edward's Lifesciences

6) *TAVR Development from Concept to First In Man*
- Alain Cribier, MD, University of Rouen, France **(View free lecture online)**

7) *TAVR Development from First In Man to Phase 3 & Beyond*
- Martin Leon, MD, Columbia University **(View free lecture online)**

Session III: Translational Pathway for Transcatheter Mitral/Tricuspid Valve Devices

1) *The Clinical Need for Innovative Treatment for Mitral/Tricuspid Valve Disease*
- Michael Mack, MD, Baylor Scott & White Health

2) *The Methods for Translational Mitra/Tricuspid Valve Device Development*
- Michael Mack, MD, Baylor Scott & White Health

3) *The Endpoints for Transcatheter Mitral/Tricuspid Valve Device Development*
- Blasé Carabello, MD, East Carolina University

4) *Current Challenges & Future Direction for Mitral/Tricuspid Valve Device Development & Iteration – FDA Point of View*
- John Laschinger, MD, FDA

5) *Current Challenges & Future Direction for Mitral/Tricuspid Valve Device Development & Iteration – Industry Point of View*
- Patricia Todd, Edward's Lifesciences

Session IV: Translational Pathway for Coronary Stent

1) *The Clinical Need for Innovative Coronary Stent*
   - Gregg Stone, MD, Columbia University
2) *The Methods for Coronary Stent Development*
   - Charles Simonton, MD, Abbott Vascular
3) *The Endpoints for Coronary Stent Development*
   - Donald Cutlip, MD, Beth Israel-Deaconess
4) *Current Challenges & Future Direction for Coronary Stent Development & Iteration – FDA Point of View*
   - Michael John, MPH, FDA
5) *Current Challenges & Future Direction for Coronary Stent Development & Iteration – Industry Point of View*
   - Charles Simonton, MD, Abbott Vascular

Session V: Translational Pathway for Catheter Ablation

1) *The Clinical Need for the Treatment of Arrhythmia Innovative Catheter Ablation*
   - Douglas Packer, MD, Mayo Clinic
2) *Methods for Catheter Ablation Development*
   - Douglas Packer, MD, Mayo Clinic
3) *The Endpoints for Catheter Ablation Development*
   - Marco Cannella, PhD, FDA
4) *Current Challenges & Future Direction for Catheter Ablation Development & Iteration – FDA Point of View*
   - Mark Fellman, MS, FDA
5) *Current Challenges & Future Direction for Catheter Ablation Development & Iteration – Industry Point of View*
   - Uri Yaron, PhD, Johnson & Johnson

Session VI: Translational Pathway for Ventricular Assist Devices

1) *Ventricular Assist Devices, the Windy Road to Recovery*
   - Sr. Magdi Yacoub, MD, Aswan Heart Center, London
2) *The Methods for Left Ventricular Assist Devices Development*
   - Francis Pagani, MD, University of Michigan
3) *The Endpoints for Left Ventricular Device Evaluation*
   - Keith Aaronson, MD, University of Michigan

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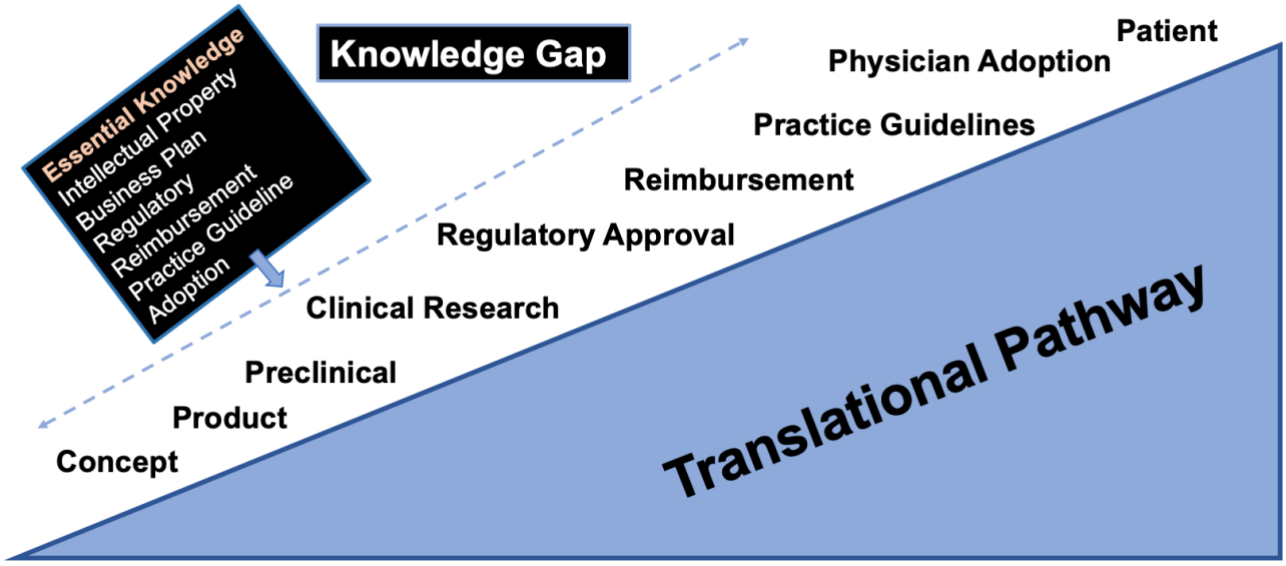

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Multi-disciplinary