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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
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Topic 2: Intellectual Property

- 2) *Intellectual Property*
 - James Inskeep, Patent Attorney
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Topic 3: Business Plan, Product Development, and Fundraising

- 3) *Business Plan, Product Development, and Fundraising*
 - Stan Rowe, Edward's Lifesciences
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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
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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, Columbia 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
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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
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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
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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**)
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Topic 9: Reimbursement

- 24) *CMS Criteria for Reimbursement for Cardiovascular Innovation*
- Joseph Chin, MD, CMS
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Topic 10: Practice Guideline

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

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

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](#))

Panel Discussions

- 2017 Valve Disease/TAVR
- 2016 Aortic Valve Development

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

Panel Discussions

- 2019 Structural Heart Intervention Imaging
- 2017 MV/TV Transcatheter Repair/Replacement
- 2016 MV/TV Development

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

Panel Discussions

- 2019 Devices for Complex Coronary Lesions
- 2019 Advances in the Assessment of High Risk Coronary Lesions
- 2017 CAD/Coronary Stent
- 2016 Coronary Stent Development

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

Panel Discussions

- 2017 Arrhythmia/Catheter Ablation
- 2016 Catheter Ablation Development

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

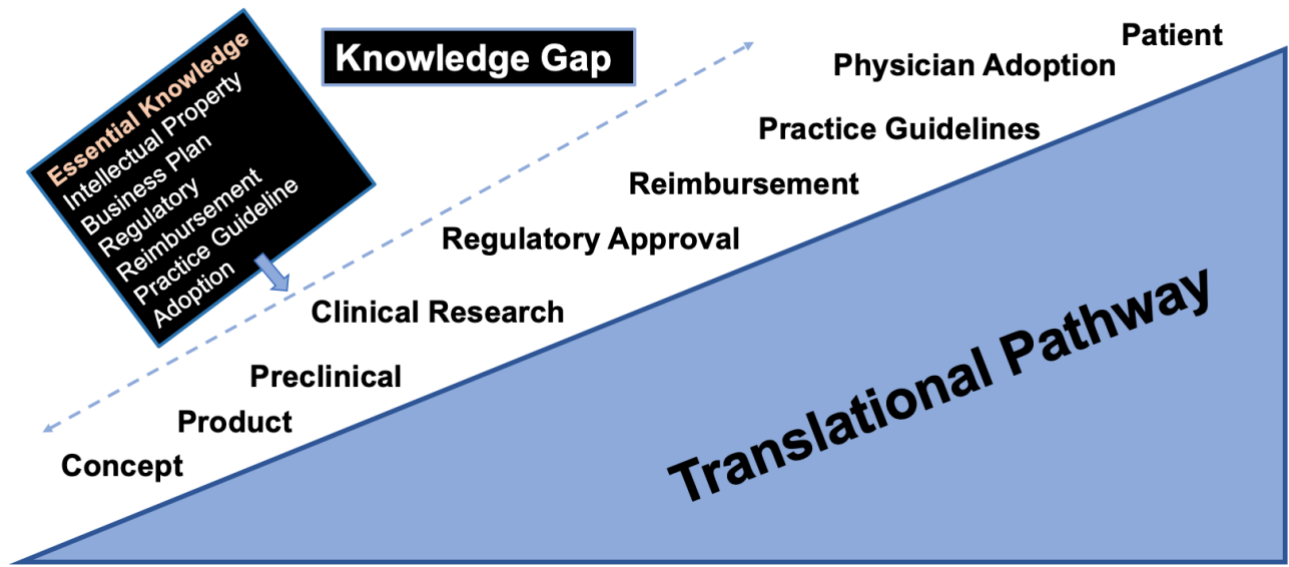
3) *The Endpoints for Left Ventricular Device Evaluation*

- Keith Aaronson, MD, University of Michigan

Panel Discussions

- 2018 Translational Pathway for LV Assist Devices
- 2017 CHF/Ventricular Assist Devices

Translational Pathways for Cardiovascular Devices



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Multi-disciplinary

