Translational Pathways for Cardiovascular Devices

ISCTR - TCT
September 21, 2018

San Diego Convention Center
111 West Harbor Drive
San Diego, CA 92101
8:00 am – 5:00 pm
Room 30A-C

Program Directors: Nabil Dib, Bram Zuckerman, Spencer King,
Martin Leon

Objective:
To Present and Discuss the Translational Pathway for Cardiovascular
Device Development and Iteration for Cardiovascular Diseases (Valvular
Disease, Coronary Artery Disease, Arrhythmia and Heart Failure) That
Incorporates Input from Academia, Industry, FDA, and Payers.

Introduction:
8:00 – 8:05am Welcome Statement – Spencer King
8:05 – 8:20am ISCTR Mission and Statement of Meeting Purpose – Nabil Dib

Session I: Requirements for CV Devices Approval; Regulatory,
Payers, and Practice Guidelines

Moderators: Bram Zuckerman, Spencer King

8:20 – 8:35am Regulatory Requirement for Marketing Approval
including the Parallel Review, NEST, and Beyond
– Bram Zuckerman

8:35 – 8:50am CMS Requirement for Reimbursement for Innovation
– Lori Ashby

8:50 – 9:05am Practice Guideline Requirement for New Technology
– Alice Jacobs

9:05 – 9:20am Pre-Clinical and Clinical Trial Design and Endpoints for
Device Approval
– Roseann White and Chris Mullin

9:20 – 9:35am Early Feasibility Studies for Device Evaluation
– Andrew Farb

9:35 – 9:45am The Patients Voice – Mark Mercola
9:45 – 10:15am Panel Discussion: Lori Ashby, Alice Jacobs, Roseann White, Chris Mullin, Andrew Farb, Mitchell Krueckoff, Stan Rowe, Charles Simonon, Robert Bonow, Louis Jacques, Phil Adamson, David Reuter

10:15 – 10:30am Break

Session II: ISCTR Award Presentation and Keynote Address
Moderators: Stan Rowe, Robert Bonow

Award Presentation:
10:30 – 10:40am Presentation of the Glen and Marilyn Nelson Award for Innovation and Translation in Cardiovascular Medicine to Alain Cribier and Martin Leon presented by Stan Rowe and Robert Bonow

10:40 – 10:45am Video Presentation of the Glen and Marilyn Nelson Award for Innovation and Translation in Cardiovascular Medicine

Keynote Address:
10:45 – 11:05am The TAVR Development from Concept to First in Man – Alain Cribier

11:05 – 11:25am The TAVR Development from First in Man to Phase 3 and Beyond – Martin Leon

11:25 – 12:00pm Lunch

Session III: Translational Pathway for Transcatheter Aortic Valves
Moderators: Martin Leon, Jeroen Bax

12:00 – 12:15pm The Methods for Transcatheter Aortic Valve Development – Stan Rowe

12:15 – 12:30pm The Endpoints for Transcatheter Aortic Valve Development – Ori Ben-Yehuda

12:30 – 1:05pm Panel Discussion: Stan Rowe, Jeroen Bax, Seth Clancy, Bernard Vassuer, Bram Zuckerman, Robert Bonow, Ian Meredith, Susan Strong

Session IV: Translational Pathway for Transcatheter Mitral/Tricuspid Valves
Moderators: Robert Bonow, John Laschinger

12:50 – 1:05pm The Methods for Transcatheter Mitral/Tricuspid Valve Development
1:05 – 1:20pm The Endpoints for Transcatheter Mitral/Tricuspid Valve Development
– Blasé Carabello

1:20 – 1:40pm Panel Discussion: Michael Mack, Blasé Carabello, Gregg Stone, Patrick Verta, Changfu Wu, Sharon Saeger, Robert Thatcher, Steve Goldberg, David Reuter, Wade Aubry

Session V: Translational Pathway for Coronary Stents
Moderators: Gregg Stone, Mitchell Krucoff

1:40 – 1:55pm The Methods for Coronary Stent Development – Charles Simonton

1:55 – 2:10pm The Endpoints for Coronary Stent Development – Donald Cutlip

2:10 – 2:30pm Panel Discussion: Donald Cutlip, Neal Farnout, Andrew Farb, Spencer King, Ian Meredith, Laura Perkins, Robert Benton

2:30 – 2:45pm Break

Session VI: Translational Pathway for Catheter Ablation
Moderators: Douglas Packer, Marco Cannella

2:45 – 3:00pm The Methods for Catheter Ablation Development – Douglas Packer

3:00 – 3:15pm The Endpoints for Catheter Ablation Development – Marco Cannella

3:15 – 3:35pm Panel Discussion: Wade Aubry, Tonya Dowd, Jun Dong, Timothy Laske, Larry Haffner, Amit Shanker

Session VII: Translational Pathway for Left Ventricular Assist Devices
Moderators: Ileana Piña, Magdi Yacoub

3:35 – 3:50pm The Methods for LVAD Development – Francis Pagani

3:50 – 4:05pm The Endpoints for LVAD Evaluation – Keith Aaronson

4:05 – 4:25pm Panel Discussion: Francis Pagani, Keith Aaronson, Phil Adamson, Changfu Wu, Michael Minogue, Bernard Vassuer

Session VIII: Application of the Translational Pathway for Cardiovascular Devices
Moderators: Bram Zuckerman, Spencer King
Panel Discussion: Lori Ashby, Andrew Farb, Stan Rowe, Alice Jacobs, Charles Simonton, Roseann White, Chris Mullin, Blasé Carabello, Douglas Packer, Keith Aaronson, Jeroen Bax