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CONTACT INFORMATION

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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 – <i>Spencer King</i> |
| 8:05 – 8:20am | ISCTR Mission and Statement of Meeting Purpose – <i>Nabil Dib</i> |
| 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 – <i>Bram Zuckerman</i> |
| 8:35 – 8:50am | CMS Requirement for Reimbursement for Innovation – <i>Lori Ashby</i> |
| 8:50 – 9:05am | Practice Guideline Requirement for New Technology – <i>Alice Jacobs</i> |
| 9:05 – 9:20am | Pre-Clinical and Clinical Trial Design and Endpoints for Device Approval – <i>Roseann White and Chris Mullin</i> |
| 9:20 – 9:35am | Early Feasibility Studies for Device Evaluation – <i>Andrew Farb</i> |
| 9:35 – 9:45am | The Patients Voice – <i>Mark Mercola</i> |



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9:45 – 10:15am Panel Discussion: *Lori Ashby, Alice Jacobs, Roseann White, Chris Mullin, Andrew Farb, Mitchell Krucoff, Stan Rowe, Charles Simonton, 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 – 12:50pm 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



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– Michael Mack

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 Fearnot,
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



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4:25 – 5:00pm

Panel Discussion: *Lori Ashby, Andrew Farb, Stan Rowe, Alice Jacobs, Charles Simonton, Roseann White, Chris Mullin, Blasé Carabello, Douglas Packer, Keith Aaronson, Jeroen Bax*