Summit on Translational Pathways for Cardiovascular Devices

ISCTR - TCT
September 25, 2019
at
Moscone Center
Room 151-153, Moscone South, Upper Mezzanine
747 Howard St., San Francisco, CA 94103
8:00am – 5:00pm

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

Objective:
To Present and Discuss the Translational Pathways for Cardiovascular Diagnostic and Therapeutic Devices that Incorporates Input from Academia, Industry, FDA, and Payers.

Introduction:
8:00 – 8:05 Welcome Statement – Anthony DeMaria
8:05 – 8:15 ISCTR Mission and Statement of Meeting Purpose – Nabil Dib
8:15 – 8:20 Presentation of the ISCTR-Nelson Award Presented by David Holmes and Diana Nelson to Spencer King

Keynote Address - Spencer King
8:20 – 8:35 “Education and Implementation of the Translational Pathways Document”

Session I: Device Development: Essential Concepts
Moderators: David Holmes and Anthony DeMaria

8:35 – 8:42 Choosing an Innovative Concept – Todd Brinton
8:42 – 8:49 Intellectual Property – James Inskeep
8:49 – 8:56 Business Plan, Development, and Fundraising – Stanton Rowe
8:56 – 9:03 Conflict of Interest and Product Development – Anthony DeMaria
9:03 – 9:10 Adoption of Technology – Ian Meredith
9:10 – 9:30  Panel Discussion: Todd Brinton, Peter Fitzgerald, James Inskeep, Stanton, Rowe, Ian Meredith, David Reuter, Jianhua Sun, Andrew Farb, Tonya Dowd, Gary Roubin

9:30 – 9:45  BREAK

Session II: Device Development: Focus on Diagnostic Devices
Moderators: Bram Zuckerman and Mitchell Krucoff

9:45 – 10:00  Advanced Cardiac Anatomy – Application in Translational Research Tailored to Current and Future Technology – Renu Virmani

10:00 – 10:15  Advanced Cardiac Imaging- Application in Translational Research Tailored to Current and Future Technology - Jeroen Bax

10:15 – 10:30  Statistics for Evaluation of Cardiovascular Diagnostic Devices – Chris Mullin

10:30 – 10:45  Regulatory Review of Cardiovascular Diagnostic Devices: FDA Perspective – Marco Cannella

10:45 – 11:00  Regulatory Review of Cardiovascular Devices: European Regulatory Perspective – Robert Byrne

11:00 – 11:15  Guideline Requirement for Diagnostic Devices – Roxana Mehran

11:15 – 11:30  Reimbursement for Diagnostic Devices – Lori Ashby


11:50 – 12:15  Lunch

Session III: Advances in the Assessment of High Risk Coronary Lesions
Moderators: Robert Bonow and Campbell Rogers

12:15 – 12:22  Unmet Clinical Needs, Value Added and Future Direction in CT Lesion Assessment – James Min

12:36 – 12:43  Regulatory Perspectives – Shawn Forrest
12:43 - 12:58  **Panel Discussion:** James Min, Morton Kern, Jeroen Bax, Adrian Magee, Shawn Forrest, Daniel Berman, Paul Yock, Carlos Collet, Manesh Patel, James Muller, Jaime Murillo,

**Session IV: Translational Pathways for Structural Heart Intervention Imaging**
**Moderators:** Rebecca Hahn and Dee Dee Wang

12:58 – 1:05  Unmet Clinical Needs for Tricuspid Valve Interventions – Carlos Sanchez
1:05 – 1:12  Current Imaging Limitations for Advancement Tricuspid Valve Interventions – Rebecca Hahn
1:12 – 1:19  Tricuspid Valve Interventions Challenges Regulatory Perspective – Changfu Wu
1:19 – 1:34  **Panel Discussion:** Steven Yakubov, Rebecca Hahn, Changfu Wu, Carlos Sanchez, Tobias Bohling, Andrew Farb, Tonya Dowd, Christopher Panarites, Steve Goldberg

1:34 – 1:45  **BREAK**

**Session V: Translational Pathways for Left Appendage Closure Devices**
**Moderators:** Ian Meredith and David Holmes

1:45 – 1:52  Unmet Clinical Needs and Future Directions – Brian Whisenant
1:52 – 1:59  Current and Future LAA Imaging Modalities to Optimize LAA Closure – Dee Dee Wang
1:59 – 2:06  Translational-Pathways Left-Appendage Closure-Devices FDA-Perspective – Rachel Neubrander
2:06 – 2:26  **Panel Discussion:** Brian Whisenant, Louis Jacques, Dee Dee Wang, Rachel Neubrander, Rebecca Hahn, Andrew Farb, Tonya Dowd, Kris Shah, Mark Reisman, Horst Sievert, Chris Mullin, Renu Virmani

**Session VI: Translational Pathway for Interventional Devices for Heart Failure**
**Moderators:** William O’Neill and Nicole Ibrahim

2:26 – 2:33  Overview Interventional Devices for Heart Failure – William Abraham

2:40 – 2:47  Current Landscape and Future Direction of Neuromodulation Therapies – Horst Sievert

2:47 – 2:54  Current Landscape and Future Directions: Intracardiac Shunts, Ventricular Remodeling Therapies - Gregg Stone

2:54 – 3:01  Clinical Preclinical Excellence Driving Innovation in Mechanical Circulatory Support - Navin Kapur

3:01 – 3:08  Translational-Pathway Interventional Devices for Heart Failure - FDA-CDRH-Perspective- Ileana Piña


3:28 – 3:40  BREAK

Session VII: Revascularization and Devices for Complex Coronary Lesions - Calcified, Total Occlusion

Moderators: Gregg Stone and Charles Simonton

3:40 – 3:47  Calcified Lesions Chronic Total Occlusions – Ajay Kirtane

3:47 – 3:54  Revascularization Devices for Complex Coronary Lesions Calcified, Total Occlusion– Kevin Croce

3:54 – 4:01  Devices for Complex Coronary Lesions FDA-Perspective– Lydia Glaw

4:01 – 4:21  Panel Discussion: Kevin Croce, Louis Jacques, Ryan Egeland, Richard Shlafmitz, Ajay Kirtane, Adrian Magee Lydia Glaw, Renu Virmani

Session VIII: Meet the Legends of Innovation – Challenges in Cardiovascular Device Development

Moderators: Martin Leon and Paul Yock

4:21 – 4:55  Round Table Discussion:
  John Simpson, Gary Roubin, Richard Schatz, Julio Palmaz, David Reuter, Gregg Sutton, Bram Zuckerman, Gregg Stone, Spencer King, Magdi Yacoub, Louis Jacques, James Muller, David Holmes, Charles Simonton, Neal Fearnott, Stanton Rowe

Closing Remarks

Nabil Dib