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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*



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9:10 – 9:30 Panel Discussion: *Todd Brinton, Peter Fitzgerald, James Inskip, 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*

11:30 – 11:50 **Panel Discussion:** *Renu Virmani, Jeroen Bax, Avi Fischer, Roxana Mehran, Lori Ashby, Louis Jacques, Seth Clancy, Chris Mullin, Marco Cannella, Robert Byrne, Anthony DeMaria, Robert Roberts, Jaime Murillo*

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*

12:22 – 12:29 Unmet Clinical Needs, Value Added and Future Direction in Intracoronary Lesion Assessment (FFR, IVUS, OCT, Infrared) – *Morton Kern*



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12:29 – 12:36 Non-Clinical Evaluation – *Robert Safian*

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 Neubrandner*

2:06 – 2:26 **Panel Discussion:** *Brian Whisenant, Louis Jacques, Dee Dee Wang, Rachel Neubrandner, 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*



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2:33 – 2:40 Current Landscape and Future Directions – Percutaneous Ventricular Assist Devices – *William O’Neill*

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 Interventinal Devices for Heart Failure - FDA-CDRH-Perspective- *Ileana Piña*

3:08 – 3:28 **Panel Discussion:** *William Abraham, Gregg Stone, Horst Sievert, Navin Kapur, Seth Clancy, Rhonda Robb, Seth Bilazarian, Morton Kern, Ileana Piña, Fernando Aguel, Chris Mullin, Magdi Yacoub*

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 Shlofmitz, 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 Fearnot, Stanton Rowe

Closing Remarks

Nabil Dib