ISCTR

International Society
For Cardiovascular
Translational Research

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International Society for Cardiovascular Translational Research

The Translational Pathways for Cardiovascular Devices; Current and Future Direction

A Satellite Program at TCT

Consensus Summit
October 29, 2016
Walter E. Washington Convention Center
Washington, DC
7:00 am – 5:00 pm
Room 146 A

Objective:
To Develop a Consensus Document for Translational Pathway for Future Cardiovascular Device Development and Iteration for Cardiovascular Diseases (Valvular, Coronary Artery, and Arrhythmia) That Incorporates Input from Industry, FDA, and CMS.

Introduction:
7:00 – 7:05 Welcome Statement - *Nabil Dib, Spencer King*

7:05 – 7:20 ISCTR Mission And Statement of Meeting Purpose - *Nabil Dib*

Session I - Basic Process for Device Development
Moderators: Bram Zuckerman, Jack Lewin

7:20 – 7:35 Requirement for New Technology to be Included in the Guidelines, "The Ultimate Goal" - *Alice Jacobs*

7:35 – 7:50 CMS Criteria For Reimbursement of Cardiovascular Innovation – *Joseph Chin*

7:50 – 8:05 Regulatory Requirement for Marketing Approval - *Deborah Castillo*

8:05 – 8:20 Pre-Clinical and Clinical Trial Design and Endpoints of Fast Track to Device Approval - *Roseann White*

8:20 – 8:35 A Unified Approach for Clinical Trial Design That Meets The Requirement of Regulatory Approval, Reimbursement And The Clinical Practice Guideline - *Mitchell Krucoff*

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8:35 – 9:00 Panel Discussion: *Bram Zuckerman, Jack Lewin, Nabil Dib, Alice Jacobs, Joseph Chin, Deborah Castillo, Roseann White, Mitchell Krucoff, Robert Roberts, Anthony DeMaria, Stan Rowe, Charles Simonton, Spencer King, Ron Waksman*

9:00 – 9:15 ***Break***

Session II – Pre-Clinical, Early Feasibility, and Safety Study for Device Development
Moderators: Andrew Farb, David Reuter

9:15 – 9:30 Current Challenges and Future Direction for Feasibility and Early Human Study for Device Evaluation; FDA Point of View - *Andrew Farb*

9:30 – 9:45 Current Challenges and Future Direction for Feasibility and Early Human Study for Device Evaluation; Industry Point of View – *David Reuter*

9:45 – 10:00 Requirements for Medical Device Manufacturing And Iteration; Industry Point of View - *Richard Rapoza*

10:00 – 10:15 Requirements for Medical Device Manufacturing And Iteration; FDA Point of View - *Brad Quinn*

10:15 – 10:30 Optimal Pre-Clinical Study Design and Endpoints for Device Evaluation; Investigator Point Of View - *Renu Virmani*

10:30 – 10:45 Optimal Pre-Clinical Study Design and Endpoints for Device Evaluation; FDA Point Of View - *Judith Davis*

10:45 – 11:00 Panel Discussion: *Andrew Farb, David Reuter, Michael Minogue, Richard Rapoza, Brad Quinn, Renu Virmani, Judith Davis, Laura Perkins, Roseann White, James Muller, Patricia Todd, Robert Kohler*

11:00 – 11:20 Lunch

11:20 – 11:30 Presentation of the Glen and Marilyn Nelson Award for Innovation and Translation in Cardiovascular Medicine to Robert Califf - *Anthony DeMaria and Marilyn Nelson*

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Keynote Address

11:30 – 12:00 The Translational Pathway to Expedite Scientific Discovery to Patients - *Robert Califf*

Session III – Aortic Valve Development
Moderators: Spencer King, Stan Rowe

12:00 – 12:15 The Clinical Need for Innovative Treatment for Aortic Valve Disease - *Martin Leon*

12:15 – 12:30 Current Challenges and Future Direction for Aortic Valve Development and Iteration; Industry Point of View - *Stan Rowe*

12:30 – 12:45 Current Challenges and Future Direction for Aortic Valve Development and Iteration; FDA Point Of View - *Nicole Ibraham*

12:45 – 1:00 Panel Discussion: *Stan Rowe, Nicole Ibraham, Michael Mack, Renu Virmani, Patricia Todd, Bram Zuckerman, Spencer King*

Session IV – Mitral/Tricuspid Valve Development
Moderators: Gregg Stone, Changfu Wu

1:00 – 1:15 The Clinical Need for Innovative Treatment for Mitral/Tricuspid Valve Disease - *Michael Mack*

1:15 – 1:30 Current Challenges and Future Direction for Mitral/Tricuspid Valve Development And Iteration; Industry Point of View - *Patricia Todd*

1:30 – 1:45 Current Challenges and Future Direction for Mitral/Tricuspid Valve Development and Iteration; FDA Point of View - *John Laschinger*

1:45 – 2:00 Panel Discussion: *Gregg Stone,* Changfu Wu, *Patricia Todd, John Laschinger, Renu Virmani, Michael Mack*

Session V - Coronary Stent Development
Moderators: Neal Fearnot, Spencer King

2:00 – 2:15 The Clinical Need for Innovative Coronary Stent - *Gregg Stone*

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2:15 – 2:30 Current Challenges and Future Direction for Coronary Stent Development and Iteration; FDA Point of View
- *Michael John*

2:30 – 2:45 Current Challenges and Future Direction for Coronary Stent Development and Iteration; Industry Point of View
- *Charles Simonton*

2:45 – 3:00 Panel Discussion: *Spencer King, Michael John, Charles Simonton, Neal Fearnot, Mark Toland, Gregg Stone, Craig Thompson*

3:00 – 3:10 ***Break***

Session VI – Catheter Ablation Development
Moderators: Douglas Packer, Mark Fellman

3:10 – 3:25 The Clinical Need for the Treatment of Arrhythmia, Innovative Catheter Ablation - *Douglas Packer*

3:25 – 3:40 Current Challenges and Future Direction for Catheter Ablation Development and Iteration; Industry Point of View - *Uri Yaron*

3:40 – 3:55 Current Challenges and Future Direction for Catheter Ablation Development and Iteration; FDA Point of View
- *Mark Fellman*

3:55 – 4:15 Panel Discussion: *Douglas Packer, Uri Yaron, Jun Dong, Mark Fellman, Anthony DeMaria, Timothy Laske, Win-Kuang Shen, Mark Carlson*

Session VII – Consensus Document

4:15 – 4:30 Writing Consensus Document - *Anthony DeMaria*

4:30 – 5:00 Panel Discussion: *Anthony DeMaria, Spencer King, Bram Zuckerman, Jack Lewin, Robert Roberts, Andrew Farb, Stan Rowe, Charles Simonton, Rick McGuire, Roseann White, Nabil Dib, James Muller*