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
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


9:45 – 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
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
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


3:25 – 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