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Translational Research

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ISCTR - TCT 2017 Consensus Summit International Society for Cardiovascular Translational Research

10/29/17

8:30 am – 5:00 pm

Colorado Convention Center
700 14th Street, Denver, CO 80202
Four Seasons Ballroom 4

Consensus Summit on Clinical Endpoints/Surrogates and Effect Size for Approval of Cardiovascular Devices (Academia, Industry, Regulatory, Reimbursement, Guideline, and Patients)

**Objective: Standardization of the Clinical/Surrogate Endpoints for
Cardiovascular Devices Evaluation**

**Course Directors: Nabil Dib, Bram Zuckerman, Spencer King, Martin
Leon**

8:30 – 8:33 Welcome Statement – Spencer King

8:33 – 8:40 ISCTR Mission Statement and Introduction – Nabil Dib

8:40 – 9:10 Session I

Clinical Endpoints & Biostatistics

Moderators: Anthony DeMaria and Chris Mullin

8:40 – 8:50 Clinical Endpoints/Surrogate & Biostatistics – Roseann White

**8:50 – 9:00 Endpoints for Clinical Trials for Cardiovascular Devices:
Challenges and Solutions - Ori Ben-Yehuda**

**9:00 – 9:15 – Panel Discussion: Bram Zuckerman, Roseann White, Ori Ben-
Yehuda, Stan Rowe, Chuck Simonton, Blasé Carabello, Ileana Piña, Douglas
Packer, Ian Meredith, Andrew Farb, Mitchell Krucoff**

9:15 – 10:25 Session II

Valve Disease/Transcatheter Aortic Valve Replacement

Moderators: Martin Leon, Bram Zuckerman

Clinical Scientist Point of View - Martin Leon

Industry Point of View - Stanton Rowe

Regulatory Point of View – Jaime Raben

Payor Point of View – Wade Aubry



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Practice Guideline Point of View – Robert Bonow
Patient Point of View - Susan Strong (patient)

9:45 – 10:25 *Panel Discussion/Questions lead by Jaime Raben (FDA)*
Discussants: Stanton Rowe, Wade Aubry, Robert Bonow, Susan Strong, Alan Balch, Kathleen Gallagher, Jeroen Bax, John Webb

10:25 – 10:30 - Break

10:30 – 11:40 Session III

**Valve Disease/Transcatheter Mitral/Tricuspid Valve
Repair/Replacement**

Moderators: Robert Bonow, Jeroen Bax

Clinical Scientist Point of View – John Webb
Industry Point of View – Patrick Verta
Regulatory Point of View - John Laschinger
Payor Point of View – Daniel Caños
Practice Guideline Point of View - Blasé Carabello
Patient Point of View – Sharon Saeger (patient)

11:00 – 11:40 *Panel Discussion/Questions lead by John Laschinger*
Discussants: John Webb, Patrick Verta, Daniel Canos, Blasé Carabello, Steve Goldberg, David Reuter, Vinayak Bapat, Mark Toland, Craig Thompson, Ori Ben-Yehuda, Sharon Saeger

11:40 – 12:10 Lunch

12:10 – 12:20

***Presentation of the Glen and Marilyn Nelson Award for Innovation and
Translation in Cardiovascular Medicine***

Presented by: Marilyn Nelson and Spencer King

Video presentation

Recipient: Sir Prof Magdi Yacoub

12:20 – 12:40

**Keynote Speaker – Sir Prof Magdi Yacoub “Ventricular Assist Devices,
the Windy Road to Recovery”**



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12:40 – 1:55 Session IV

CHF/Ventricular Assist Devices

Moderators: Ileana Piña, Magdi Yacoub

Clinical Scientist Point of View – Keith Aaronson
Industry Point of View (surgical) – Mark Carlson
Regulatory Point of View – Jaime Raben
Payor Point of View – Daniel Canos
Practice Guideline Point of View – Ileana Piña
Patient Point of View – Neil Argo (patient)

1:10 – 1:55 Panel Discussion/Questions lead by Jaime Raben (FDA)

Discussants: Keith Aaronson, Daniel Canos, Alan Fraser, Phil Adamson, Ileana Piña, Neil Argo, Mark Carlson, Michael Minogue

1:55 – 3:10 Session V

CAD/Coronary Stent

Moderators: David Holmes and Gregg Stone

Clinical Scientist Point of View – Gregg Stone
Industry Point of View - Charles Simonton
Regulatory Point of View – Andrew Farb
Payor Point of View – Jack Lewin
Practice Guideline Point of View - Alice Jacobs
Patient Point of View – John Dominguez (patient)

2:25 – 3:10 Panel Discussion/Questions lead by Gregg Stone

Discussants: Charles Simonton, Andrew Farb, Jack Lewin, Alice Jacobs, Ori Ben-Yehuda, Kathleen Gallagher, Mitchell Krucoff, Donald Cutlip, Neal Fearnot, John Dominguez

3:10 – 3:25 Break

3:25 – 4:30 Session VI

Arrhythmia/Catheter Ablation

Moderators: Marco Cannella, Douglas Packer

Clinical Scientist Point of View – Douglas Packer
Industry Point of View – Anthony Hong
Regulatory Point of View – Marco Cannella
Payor Point of View – Wade Aubry
Practice Guideline Point of View - Vivek Reddy
Patient Point of View – Larry Haffner (patient)

3:55 – 4:30 Panel Discussion/Questions lead by Marco Cannella (FDA)

Discussants: Anthony Hong, Wade Aubry, Vivek Reddy, Larry Haffner, Kathleen Gallagher, Alan Balch



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4:30 – 5:00 Session VII

Consensus on Clinical Endpoints Discussion and Action Items

Moderators: Bram Zuckerman and Nabil Dib

Discussants: Anthony DeMaria, David Holmes, Alan Fraser, Charles Simonton, Stan Rowe, Douglas Packer, Andrew Farb, Ileana Piña, Mark Toland, Patrick Verta, Jack Lewin, Alan Balch, Jeroen Bax, Spencer King, Wade Aubry, Robert Roberts

Adjourn