

The logo for CVCT (Centre for Veterinary Clinical Trials) features the letters 'CVCT' in a bold, sans-serif font. The 'C' and 'T' are white, while the 'V' is a vibrant yellow. The letters are set against a solid blue background.

December 7 - 9, 2026
The Mayflower Hotel, Washington DC

SCIENTIFIC PROGRAM

23rd Global Cardio Vascular Clinical Trialists Forum

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270. Maria Borentain (Bayer, GER)
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284. Amy Crawford (Berry Consultants, USA)
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287. Alex DePaoli (Rona Therapeutics, CHN)

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290. Punag Divanji (Cytokinetics, USA)
291. Cord Dohrmann (Evotec, GER)
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293. Jennifer Hellawell (Arrowhead pharmaceuticals, USA)
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295. Odd Erik (Roche, CH)
296. Chris Farina (Abcentra, USA)
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298. Udi Fainberg (Novo Nordisk, DK)
299. Juan Camilo Arjona Ferreira (Organon, COL)
300. Tim Fischell (Ablative Solutions, USA)
301. Amy Ford (Lilly, USA)
302. Folke Folkvaljon (AstraZeneca, ESP)
303. Brandon Fornwalt (Tempus, USA)
304. Kristen Fortney (BioAge, USA)
305. Jonathan Fox (BridgeBio, USA)
306. Kevin Friedman (Kelonia, USA)
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308. Anders Gabrielsen (Ribocure, SWE),
309. Christine Garrett (Preload Therapeutics)
310. Nadim Geloo (Abbott, USA)
311. Federica Genovese (Nordic Bioscience, DNK)
312. Jyothis George (NodThera, GBR)
313. George Georges (38 Pharma/GSK, USA)
314. Saar Gill (Interius BioTherapeutics, USA)
315. Justin Godown (Cytokinetics, USA)
316. Alexandra Goncalves (BMS, USA),
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JOURNAL

- 492. Kirsten Bibbins-Domingo (JAMA, USA)
- 493. Barbara Casadei (JAMA Cardiology)
- 494. Filippo Crea (EHJ, ITA)
- 495. Flavia Geraldès (The Lancet, GBR)
- 496. Harlan Krumholz (JACC, USA)
- 497. Bonnie Ky (JACC Oncology, USA)
- 498. Jane Leopold (NEJM, USA)
- 499. Ji-Hyun Lee (Nature Medicine, USA)
- 500. Bradley Maron (Circulation, USA)

PATIENTS

- 501. Marc Bains (HeartLife, CAN)
- 502. Bray Patrick-Lake (Evidation, USA)
- 503. Coleen Brunetti (Pulmonary Hypertension Association, USA)
- 504. Magdalena Daccord (FH Europe Foundation, CHE)
- 505. Emma Doble (BMJ, GBR)
- 506. Hyvelle Ferguson-Davis (Heart Sistas, USA)
- 507. ShantaQuilette Carter (Pink Peppermint Project, USA)
- 508. Patrick Gee (iAdvocate, USA)
- 509. Pieter Glijnis (Phospholamban Foundation, NED)
- 510. Celina Gorre (WomenHeart, USA)
- 511. Corinne Hudson (Pumping Marvellous, GBR)
- 512. Trudie Lobban (London, GBR)
- 513. Steven Macari (AVEC, FRA),
- 514. Francesca Musso (HCM Patient, ITA)
- 515. Rhonda Monroe (Charlotte, NC, USA)
- 516. Joseph Nadglowski (Obesity Action Coalition, USA)
- 517. Lisa Salberg (HCMA, USA)
- 518. Ai Ling Sim-Devadas (Office of Patient Engagement, SIN),
- 519. Devin Verbueken (HCM Patient, NED)

MONDAY, DECEMBER 7TH

PALM COURT

8:30 - 10:30

AI MASTER CLASS 1

[view details >>](#)

10:30
11:00



11:00 - 13:00

AI MASTER CLASS 2

[view details >>](#)

13:00
14:00



14:00 - 16:00

AI MASTER CLASS 3

[view details >>](#)

16:00
16:30



16:30 - 19:30

CELL THERAPY

[view details >>](#)

EAST

8:30 - 10:30

AMYLOIDOSIS

[view details >>](#)

10:30
11:00



11:00 - 13:00

HYPERTROPHIC
CARDIOMYOPATHY

[view details >>](#)

13:00
14:00



14:00 - 16:00

PATIENT-REPORTED
OUTCOMES

[view details >>](#)

16:00
16:30



16:30 - 19:30

HYPERTENSION

[view details >>](#)

STATE

8:30 - 10:30

ALDOSTERONE IN
CKM

[view details >>](#)

10:30
11:00



11:00 - 13:00

CKM TRIALS

[view details >>](#)

13:00
14:00



14:00 - 16:00

WOMEN'S HEALTH

[view details >>](#)

16:00
16:30



16:30 - 19:30

RISK OF ASCVD

[view details >>](#)

CHINESE

16:30 - 19:30

PATIENT SESSION

[view details >>](#)

BALLROOM

8:30 - 10:30

LDL CHOLESTEROL

[view details >>](#)

10:30
11:00



11:00 - 13:00

LP (A) TRIALS

[view details >>](#)

13:00
14:00



14:00 - 16:00

iCVCT #5 MEDTECH
STARTUPS

[view details >>](#)

16:00
16:30



16:00 - 19:00

BIOTECH STARTUPS

[view details >>](#)

19:30 - 21:00: RECEPTION OR POSTER WINE AND CHEESE
OR AWARDS

TUESDAY, DECEMBER 8TH

PALM COURT

8:30 - 10:30

**STATS
MASTERCLASS # 1**

[view details >>](#)

10:30
11:00



11:00 - 13:00

**STATS
MASTERCLASS #2**

[view details >>](#)

13:00
14:00



14:30 - 16:30

**STATS
MASTERCLASS #3**

[view details >>](#)

16:30
17:00



17:00 - 19:00

**OBESITY: BODY
COMPOSITION**

[view details >>](#)

EAST

8:30 - 10:30

ZEUS DEEP DIVE

[view details >>](#)

10:30
11:00



11:00 - 13:00

**ANTI-
INFLAMMATORY &
ASCVD**

[view details >>](#)

13:00
14:00



14:30 - 16:30

PAH 1

[view details >>](#)

16:30
17:00



17:00 - 19:00

PAH 2

[view details >>](#)

STATE

8:30 - 10:30

**iCVCT #1
THROMBOSIS**

[view details >>](#)

10:30
11:00



11:00 - 13:00

**iCVCT #2
VENTRICULAR
ASSIST DEVICES**

[view details >>](#)

13:00
14:00



14:30 - 16:30

**iCVCT # 3
IMPLANTABLES FOR
DENOVO PCI**

[view details >>](#)

16:30
17:00



17:00 - 19:00

**iCVCT #4 VALVE
TRIALS**

[view details >>](#)

BALLROOM

8:30 - 10:30

AI MASTER CLASS 4

[view details >>](#)

10:30
11:00



11:00 - 13:00

**INDUSTRY-
ACADEMIA
INTERACTIONS**

[view details >>](#)

13:00
14:00



14:30 - 16:30

OBESITY NEW DATA

[view details >>](#)

16:30
17:00



17:00 - 19:00

GREAT DEBATES

[view details >>](#)

13.30 - 14.20: KEYNOTE LECTURE BY MARC PFEFFER (BOSTON, MA, USA) & VICTOR J. DZAU (BOSTON, MA, USA)
19.30 - 21.00: RECEPTION OR POSTER WINE AND CHEESE OR AWARDS

WEDNESDAY, DECEMBER 9TH

PALM COURT

8:00 - 10:00

LBCT 1

[view details >>](#)

10:00
10:30



10:30 - 12:30

GENE THERAPY

[view details >>](#)

12:30
13:30



13:30 - 16:30

GENETIC MEDICINE

[view details >>](#)

16:30
17:00



17:00 - 19:00

EP STROKE

[view details >>](#)

EAST

8:00 - 10:00

LBCT 2

[view details >>](#)

10:00
10:30



10:30 - 12:30

HF MEETS EP

[view details >>](#)

12:30
13:30



13:30 - 16:30

CHRONIC HEART
FAILURE DEVICES

[view details >>](#)

16:30
17:00



17:00 - 19:00

IMPLEMENTATION
SCIENCE AND
PAYMENT REFORM

[view details >>](#)

STATE

8:00 - 10:00

LBCT 3

[view details >>](#)

10:00
10:30



10:30 - 12:30

IMPLEMENTATION

[view details >>](#)

12:30
13:30



13:30 - 16:30

WEARABLES

[view details >>](#)

16:30
17:00



17:00 - 19:00

DRIVERS OF HEART
FAILURE

[view details >>](#)

CHINESE

8:00 - 10:00

LBCT 4

[view details >>](#)

BALLROOM

8:00 - 10:00

LBCT 5

[view details >>](#)

10:00
10:30



10:30 - 12:30

WHO IS IN THE
COMMAND ROOM?

[view details >>](#)

12:30
13:30



13:30 - 16:30

TRIALS'
PUBLISHING &
ADOPTION

[view details >>](#)

16:30
17:00



17:00 - 19:00

REGULATORY
HARMONIZATION

[view details >>](#)

**Palm court
Monday, December 7, 2026
08:30 -10:30**

**AI MASTER CLASS 1
AI IN CARDIOVASCULAR DEVICES AND HARDWARE
HOW SHOULD EVIDENCE STANDARDS FOR AI-ENABLED DEVICES ALIGN WITH TRADITIONAL DEVICE
EVALUATION?**

Chairpersons: Kirsten Bibbins-Domingo (JAMA, USA) & Harriette Van Spall (Hamilton, CAN)

AI in Devices and Hardware. What Evidence Do We Need? Defining future evaluation frameworks
Michelle Tarver (FDA, USA)

Planning an AI in Devices trial: regulatory pathways (510(k), De Novo, PMA) and what each demands
Stephen Browning (FDA, USA)

From bench to bedside: evaluating a locked algorithm across multiple clinical contexts
Udo Hoffmann (Cleerly / MGH, USA)

Prospective validation, real-world evidence, and pragmatic trial designs for device-AI
Milos Vukadinovic (Los Angeles, CA, USA)

Case study: AI-ECG - multiple products, heterogeneous validation, and no head-to-head data
Peter Noseworthy (Rochester, MN, USA)

Case study: AI-Echocardiography, Core lab automation and solving measurement variability
TBD

Wearables, arrhythmia algorithms, and post-market performance monitoring after clearance
Mintu Turakhia (Stanford, CA, USA)

Generalizability, dataset shift, and the demographic gap in device-AI validation
Nick Gossen (Dandelion, USA)

Industry viewpoints
David Albert (AliveCor, USA), Brandon Fornwalt (Tempus, USA), Campbell Rogers (Heartflow, USA)

Investor perspective: how capital is allocated and what signals matter for device-AI
Julie Yoo (a16z, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**AI IN CARDIOVASCULAR DEVICES AND HARDWARE: HOW SHOULD EVIDENCE STANDARDS FOR AI-
ENABLED DEVICES ALIGN WITH TRADITIONAL DEVICE EVALUATION?**

Chairpersons : Kirsten Bibbins-Domingo (JAMA, USA) & Harriette Van Spall (Hamilton, CAN)

Panelists: David Albert (AliveCor, USA), Kirsten Bibbins-Domingo (JAMA, USA), Stephen Browning (FDA, USA), Nick Gossen (Dandelion, USA), Brandon Fornwalt (Tempus, USA), Udo Hoffmann (Cleerly/MGH, USA), Peter Noseworthy (Rochester, MN, USA), Campbell Rogers (HeartFlow, USA), Michelle Tarver (FDA, USA), Mintu Turakhia (Stanford, CA, USA), Harriette Van Spall (Hamilton, CAN), Milos Vukadinovic (Los Angeles, CA, USA), Julie Yoo (Andreessen Horowitz (a16z), USA)

**Palm court
Monday, December 7, 2026
11:00 -13:00**

**AI MASTER CLASS 2
CLINICAL DECISION SOFTWARE: EVALUATING ADAPTIVE ALGORITHMS AND SaMD
FOR CARDIOVASCULAR RISK PREDICTION, IMAGING DIAGNOSTICS, TRIAGE, AND DECISION
SUPPORT: PREDETERMINED CHANGE CONTROL PLANS, CLINICAL UTILITY VS. ACCURACY, AND THE
SaMD FRAMEWORK**

Chairpersons : Carolyn Lam (Singapore, SGP) & Harlan Krumholz (JACC, USA)

The SaMD evidence framework. What Evidence Do We Need? Defining future evaluation frameworks
Bakul Patel (former FDA, USA)

From risk prediction to clinical action: when does AI improve cardiovascular prevention?
John Deanfield (London, GBR)

Why high AUC does not equal clinical value: decision-consequential endpoints
Ann Marie Navar (Dallas, TX, USA)

Predetermined Change Control Plans: enabling software updates without full re-review
Rob Kazmierski (ex FDA, USA)

Alert fatigue, workflow disruption, clinician trust: the implementation science of CDS
TBD

Can you run a traditional RCT on software that updates quarterly? Adaptive trial designs for SaMD
Harriette Van Spall (Hamilton, CAN)

The CDS exemption boundary: where does decision support end and regulated SaMD begin?
Michelle Tarver (FDA, USA)

What is the appropriate regulatory strategy for generative AI in medicine?
Evangelos K Oikonomou (New Haven, CT, USA)

Industry viewpoints
Shiv Rao (Abridge, USA)

Regulatory viewpoints
Jordan Pomeroy (FDA, USA)

Investor perspective: how capital is allocated and what signals matter for SaMD
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**ADAPTIVE CLINICAL DECISION SOFTWARE: WHAT LEVEL AND TYPE OF EVIDENCE SHOULD BE
REQUIRED FOR CLINICIANS TO TRUST AND ADOPT AI DIAGNOSTIC AND DECISION SUPPORT TOOLS?**

Moderators: Carolyn Lam (Singapore, SGP) & Harlan Krumholz (JACC, USA)

Panelists: Stephen Browning (FDA, USA), John Deanfield (London, GBR), Harlan Krumholz (JACC, USA), Carolyn Lam (Singapore, SGP), Ann Marie Navar (Dallas, TX, USA), Bakul Patel (former FDA, USA), Jordan Pomeroy (FDA, USA), Rob Kazmierski (ex FDA, USA), Evangelos K Oikonomou (New Haven, CT, USA), Shiv Rao (Abridge, USA), John Spertus (Kansas City, MO, USA), Michelle Tarver (FDA, USA), Harriette Van Spall (Hamilton, CAN)

**Palm court
Monday, December 7, 2026
14:00 -16:00**

AI MASTER CLASS 3
GENERATIVE AI AND AUTONOMOUS SYSTEMS: EVALUATING THE UNEVALUABLE
CAN EXISTING FRAMEWORKS ASSESS GENERATIVE AI - OR DO WE NEED TO BUILD FROM SCRATCH?
Chairpersons: Rohan Khera (Stanford, USA) & TBD

Unbiased Evaluation of Generative AI and Autonomous Systems
Emily Alsentzer (Stanford, CA, USA)

Generative AI deployment at the point of care: from accurate answers to adoption and workflow
Travis Zack (OpenEvidence / UCSF, USA)

Generative AI for Implementation of Evidence-Based Cardiovascular Therapies
Lovedeep Dhingra (New Haven, CT, USA)

Red-Teaming and Adversarial Testing AI Before Clinical Deployment
Isabella Wiest (Dresden, GER)

Guardrails and governance: deployment safety, liability frameworks, and institutional oversight
Suchi Saria (Baltimore, MD, USA)

Funder perspective: what should be funded for clinical agentic and autonomous systems?
Haider Warraich (ARPA-H, USA)

Regulatory Perspective
Aneesh Deoras(FDA, USA)

Digital Health Industry Perspectives
Ashwin Nayak (UpDoc, USA)

Investor Perspective
Julie Yoo (a16z, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate
GENERATIVE AI IN CLINICAL MEDICINE: CAN EXISTING FRAMEWORKS ASSESS GENERATIVE AI - OR
DO WE NEED TO BUILD FROM SCRATCH?
Chairpersons: Rohan Khera (Stanford, USA) & TBD

Panelists: Emily Alsentzer (Stanford, CA, USA), Aneesh Deoras (FDA, USA), Lovedeep Dhingra (New Haven, CT, USA), Rohan Khera (Stanford, CA, USA), Ashwin Nayak (UpDoc, USA), Suchi Saria (Baltimore, MD, USA), Isabella Wiest (Dresden, GER), Julie Yoo (Andreessen Horowitz (a16z), USA), Travis Zack (OpenEvidence, USA)

Palm court
Monday, December 7, 2026
16:30 -19:30

CARDIAC TARGETED BIOLOGICS, REGENERATION, REALITY, AND REINVENTION
Chairpersons : Stefanie Dimmeler (Frankfurt, GER) & Emerson Perin (Houston, TX, USA)

Issues related to routes of administration
Mapping-guided catheter delivery of iPSC-derived cardiomyocyte spheroids
Keiichi Fukuda (Heartseed, JAP)

Catheter-based delivery of iPSC-derived cardiomyocytes
Eugene Wang (HELP Therapeutics, CHN)

Regulatory viewpoint
Chinwe Okoro (FDA, USA)

Gene therapy for boosting cardiomyocyte proliferation: the SALVADOR-HF trial
Emerson Perin (Houston, TX, USA)

siRNA for the treatment of heart failure
Thomas Thum (Hannover, GER)

Secretome-based therapy.
Eduardo Marban (Capricor, USA), Ambarish Pandey (Dallas, TX, USA), Marshelle Smith Warren (Secretome Tx, USA)

Can digital twins help in cell therapy clinical trials
Sarah Zohar (Paris, FRA)

Developmental and regulatory enabling aspects of human cardiac organoid platform
Stanko Skrtic (HeartBeat.bio, AUT)

Industry briefings (2-3 slides, 5 minutes)
Peter Altman (BioCardia, USA), Cord Dohrmann (Evotec, GER), Stefan Irion (GC Therapeutics, GER), Silviu Itescu (Mesoblast, AUS),
Gavin Jeffries (Fluicell, SWE), Stanko Skrtic (HeartBeat.bio, AUT), Jordan Lancaster (Avery Therapeutics, USA), Marshelle Smith
(Secretome Therapeutics, USA), Eugene Wang (HELP Therapeutics, CHN), Fred Kamal (Medley Tx, USA)

Industry briefings: From in-vivo immune-cell engineering to myocardial precision delivery: can targeted vectors be redirected to the heart?
Kevin Friedman (Kelsonia, USA), Saar Gill (Interius BioTherapeutics, USA), Luke Walker (Umoja Biopharma, USA)

Investor viewpoint
Matthew Hammond (RA Capital's, USA)

Regulatory guidance
Wilson Bryan (CBER/FDA)

Patients viewpoints
Devin Verbueken (HCM Patient, NED)

Closing remarks: Philippe Menasche (Paris, FRA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

SHOULD CARDIOLOGY ADOPT ACCELERATED PATHWAYS FOR REGENERATIVE THERAPIES?
Chairpersons : Stefanie Dimmeler (Frankfurt, GER) & Emerson Perin (Houston, TX, USA)

Panelists: Peter Altman (BioCardia, USA), Cord Dohrmann (Evotec, GER), Stefanie Dimmeler (Frankfurt, GER), Kevin Friedman (Kelsonia, USA), Keiichi Fukuda (Heartseed, JPN), , Saar Gill (Interius BioTherapeutics, USA), Matthew Hammond (RA Capital's, USA), Stefan Irion (GC Therapeutics, GER), Silviu Itescu (Mesoblast, AUS), Gavin Jeffries (Fluicell, SWE), Fred Kamal (Medley Tx, USA), Stanko Skrtic (HeartBeat.bio, AUT), Jordan Lancaster (Avery Therapeutics, USA), Stephen Levine (Dassault Systèmes, FRA), Eduardo Marban (Capricor, USA), Philippe Menasché (Paris, FRA), Chinwe Okoro (FDA, USA), Emerson Perin (Houston, TX, USA), Stanko Skrtic (HeartBeat.bio, AUT), Marshelle Smith (Secretome Therapeutics, USA), Thomas Thum (Hannover, GER), Devin Verbueken (HCM Patient, NED), Luke Walker (Umoja Biopharma, USA), Eugene Wang (HELP Therapeutics, CHN), Marshelle Smith Warren (Secretome Tx, USA), Sarah Zohar (Paris, FRA)

East
Monday, December 7, 2026
08:30 -10:30

CARDIAC AMYLOIDOSIS TRIALS CHANGING LANDSCAPE AND IMPLEMENTATION ISSUES

Chairpersons: Mariana Fontana (London, GBR) and Iacopo Olivotto (Florence, ITA)

Diagnosis of cardiac amyloidosis—the tip of an iceberg?
Mariana Fontana (London, GBR)

Should we systematically screen for ATTR?
Francesco Cappelli (Florence, Italy)

What should future control groups in future trials look like in an era of acoramidis/tafamidis + silencers?
Ahmad Masri (Portland, USA)

Innovative trial design options.
Mariana Fontana (London, GBR)

What are my thoughts on the future treatment landscape including CRISPR based, other long term silencer– stabilizer therapies, and depleters
Isabella Cooper (Amyloidosis Research Consortium, USA)

What are the financial realities for ATTR management?
Dhruv Kazi (Boston, MA, USA)

What does holistic care look like for people with ATTR-CM?
Justin Grodin (Dallas, TX, USA)

Regulatory viewpoint: Approvability issues
Karim Mikhail (FDA, USA)

Industry Viewpoints
Sameer Bansilal (Alnylam, USA), Gillian Murtagh (Bridgebio, USA), Manju Revanna (NovoNordisk, DNK), Liron Walsh (Intellia, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

TAKING ATTR-CARDIOMYOPATHY TREATMENT TO THE NEXT LEVEL: IDENTIFYING PATIENTS, ASSESSING FRAILTY, INTEGRATING THERAPIES.

Chairpersons: Mariana Fontana (London, GBR) and Iacopo Olivotto (Florence, ITA)

Panelists: Alberto Aimò (Pisa, IT), Sameer Bansilal (Alnylam, USA), Francesco Cappelli (Florence, ITA), Isabella Cooper (Amyloidosis Research Consortium, Boston, MA, USA), Mariana Fontana (London, GBR), Justin Grodin (Dallas, TX, USA), Christophe Hotermans (Alexion, USA), Dhruv Kazi (Boston, MA, USA), Mori Krantz (FDA, USA), Ahmad Masri (Portland, USA), Karim Mikhail (FDA, USA), Gillian Murtagh (BridgeBio, Palo Alto, CA, USA), Iacopo Olivotto (Florence, ITA), Manju Revanna (NovoNordisk, DNK), Liron Walsh (Intellia, USA)

East
Monday, December 7, 2026
11:00 -13:00

THE END OF THE BEGINNING: WHAT NEXT FOR DRUG TRIALS IN HYPERTROPHIC CARDIOMYOPATHY?

Chairpersons: Perry Elliott (London, GBR) and Iacopo Olivotto (Florence, ITA)

Lessons from ODYSSEY and ACACIA -HCM.

Differences in molecule, design, execution, or chance in non-obstructive HCM?

Anjali Owens (Philadelphia, PA, USA)

Do we need 'next (third) generation' myosin modulators?

Martin Maron (Boston, MA, USA)

Metabolic modulators and mitotropes: We've been here before—so what is new this time?

Caroline Coats (Glasgow, GBR)

Is it possible to do hard end-point trials in hypertrophic cardiomyopathy?

Ahmad Masri (Portland, USA)

The case of pediatric trials

Joseph Rossano (Philadelphia, PA, USA)

Industry perspectives

Michael Ayers (Edgewise, USA), Arnaud Bastien (BMS, USA), Gabriel Brooks (Solid Biosciences, USA), Justin Godown (Cytokinetics, USA), Natasha Paterson (Tenaya Therapeutics, USA)

Regulatory viewpoints

Fortunato Senatore (FDA, USA)

Ann Punnoose (FDA, USA)

Patient viewpoints

Lisa Salberg (HCMA, USA)

Francesca Musso (HCM Patient, ITA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HYPERTROPHIC CARDIOMYOPATHY TRIALS. THE SURROGATE vs. HARD OUTCOME DILEMMA

Chairpersons: Perry Elliott (London, GBR) and Iacopo Olivotto (Florence, ITA)

Panelists: Michael Ayers (Edgewise, USA), Arnaud Bastien (BMS, USA), Gabriel Brooks (Solid Biosciences, USA), Caroline Coats (Glasgow, GBR), Perry Elliott (London, GBR), Justin Godown (Cytokinetic, USA), Martin Maron (Boston, MA, USA), Ahmad Masri (Portland, OR, USA), Francesca Musso (HCM Patient, ITA), Iacopo Olivotto (Florence, ITA), Anjali Owens (Philadelphia, PA, USA), Natasha Paterson (Tenaya Therapeutics, USA), Ann Punnoose (FDA, USA), Joseph Rossano (Philadelphia, PA, USA), Lisa Salberg (HCMA, Denville, NJ, USA), Fortunato Senatore (FDA, USA)

East
Monday, December 7, 2026
14:00 -16:00

**CVCT - HEART FAILURE Collaboratory joint session
PATIENT-REPORTED OUTCOMES – ESSENTIAL, BUT HOW?**

Chairpersons: Mona Fiuzat (Washington, DC, USA) & Chris O'Connor (Washington, DC, USA)

History And Challenges with Current PRO Endpoints
Javed Butler (Dallas, TX, USA)

What Is an Anchor and Minimally Clinically Important Difference, and How To Assess It?
Folke Folkvaljon (AstraZeneca, ESP)

Population Mean Difference and Responder Analysis
Mitch Psotka (FDA, USA)

Does Distribution-Based Analysis Solve the Problem?
Cordula Zeller (Boehringer Ingelheim, GER)

Do We Need Pros? NYHA Class as Endpoint? How to use Anchor?
Charu Gandotra (FDA, USA)

PROs in Win Ratio and in Open-Label Trials
Eric Leifer (NIH/NHLBI, USA)

NIH Viewpoint
Eric Leifer (NIH, USA)

Regulatory Viewpoint
Charu Gandotra (FDA, USA)
Lisa Plummer (FDA, USA)

Industry Viewpoints
Phillip Adamson (CVRx, USA), Lothar Roessig (AskBio, GER)

Patient viewpoints
Rhonda Monroe (Charlotte, NC, USA)
Steven Macari (AVEC, FRA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

REFINING PATIENT-REPORTED OUTCOMES USE IN CLINICAL TRIALS.

Chairpersons: Mona Fiuzat (Washington, DC, USA) & Chris O'Connor (Washington, DC, USA)

Panelists: Phillip Adamson (CVRx, USA), Martina Brueckmann (Roche, CH), Javed Butler (Dallas, TX, USA), Mona Fiuzat (Washington, DC, USA), Folke Folkvaljon (AstraZeneca, ESP), Charu Gandotra (FDA, USA), Eric Leifer (NIH, USA), Steven Macari (AVEC, FRA), Rhonda Monroe (Charlotte, NC, USA), Christopher O'Connor (Washington, DC, USA), Lisa Plummer (FDA, USA), Mitch Psotka (FDA, USA), Lothar Roessig (AskBio, GER), Frances Varian (Sheffield, GBR), Cordula Zeller (Boehringer Ingelheim, GER), Bram Zuckerman (FDA, USA)

East
Monday, December 7, 2026
16:30 -19:30

**HYPERTENSION TRIALS
PART I**

NOVEL TARGETED THERAPEUTICS —NAVIGATING THE OPPORTUNITIES AND OBSTACLES

Chairpersons: Jenifer Brown (Boston, MA, USA) & Neha Pagidipati (Durham, NC, USA)

Are all forms of difficult-to-control or resistant hypertension caused by aldosterone dysregulation?

Jenifer Brown (Boston, MA, USA)

Acute Severe Hypertension: Disease? Target? Bystander?

Jay Edelberg (Kardigan, USA)

Aldosterone Synthase Inhibitors (ASIs): Will they transform hypertension management?

Bryan Williams (London, GBR)

Small Interfering RNA (siRNA) Against Angiotensinogen: Going Beyond Conventional RAS Blockade for Hypertension Treatment and CVD Prevention?

Neha Pagidipati (Durham, NC, USA)

Have Endothelin Receptor Antagonists Finally Found Their Place in Resistant Hypertension?

Markus Schlaich (Perth, AUS)

Industry Viewpoints

Martine Clozel (Idorsia, CHE), Shira Perl (AstraZeneca, USA), David Rodman (Mineralys Therapeutics, USA)

Panel Discussion & Q&A

HAVE WE REACHED PEAK INNOVATION IN HYPERTENSION THERAPIES?

Chairpersons: Jenifer Brown (Boston, MA, USA) & Neha Pagidipati (Durham, NC, USA)

Panelists: Michel Azizi (Paris, FRA), Jenifer Brown (Boston, MA, USA), Martine Clozel (Idorsia, CHE), Jay Edelberg (Kardigan, USA), Tim Fischell (Ablative Solutions, USA), Naomi Fisher (Boston, MA, USA), William Herzog (FDA, USA), Neha Pagidipati (Durham, NC, USA), Shira Perl (AstraZeneca, USA), Garrett Pilcher (Medtronic, USA), David Rodman (Mineralys Therapeutics, USA), Anthony Rodgers (Sydney, AUS), Markus Schlaich (Perth, AUS), Roland Schmieder (Erlangen, GER), Laurence Tallon (MHRA, GBR), Noriko Tojo (Otsuka, JPN), Bryan Williams (London, GBR), Dion Zappe (Alnylam, USA)

East
Monday, December 7, 2026
16:00 -19:00

HYPERTENSION TRIALS PART II

ARE STANDARD RCT DESIGNS KILLING POTENTIALLY EFFECTIVE ANTI-HYPERTENSIVE DRUGS AND DEVICE-BASED THERAPY?

Chairpersons: Michel Azizi (Paris, FRA) & Bryan Williams (London, GBR)

Learning from Recent Failures of Novel Drug and Device Development for Hypertension. How would I design my next trial?

Drug Therapy
Michel Azizi (Paris, FRA)

Device-based therapy
Roland Schmieder (Erlangen, GER)

Navigating Regulatory Guidelines: Where Does RDN Stand in 2026 in an Era of Novel Approaches To Treatment?
Naomi Fisher (Boston, MA, USA)

Ubiquitous Single-Pill multidrug combination therapy for hypertension: Multiple drugs or better-targeted therapy?
Anthony Rodgers (Sydney, AUS)

Industry Viewpoints
Shon Chakrabarti (Recor Medical, USA), Tim Fischell (Ablative Solutions, USA), Amer Joseph (Idorsia, CHE), Noriko Tojo (Otsuka, JPN), Dion Zappe (Alnylam, USA)

Cheap daily generics versus one-shot or biannual injectable therapies?

Regulatory viewpoints
Laurence Tallon (MHRA, GBR), Aliza Thompson (FDA, USA)
William Herzog (FDA, USA)

Payers' viewpoint
Karine Chevreul (HAS, FRA)

The CVCT Multi-Stakeholder Think Tank Debate

BRIDGING THE GAP BETWEEN INNOVATION AND IMPLEMENTATION: CAN CHEAP, GENERIC POLYPILLS FOR THE MASSES COEXIST WITH INNOVATIVE TARGETED THERAPIES?

Chairpersons: Michel Azizi (Paris, FRA) & Bryan Williams (London, GBR)

Panelists: Michel Azizi (Paris, FRA), Jenifer Brown (Boston, MA, USA), Shon Chakrabarti (Recor Medical, USA), Karine Chevreul (HAS, FRA), Martine Clozel (Idorsia, CHE), Tim Fischell (Ablative Solutions, USA), Naomi Fisher (Boston, MA, USA), William Herzog (FDA, USA), Amer Joseph (Idorsia, CHE), Neha Pagidipati (Durham, NC, USA), Shira Perl (AstraZeneca, USA), Garrett Pilcher (Medtronic, USA), David Rodman (Mineralys Therapeutics, USA), Anthony Rodgers (Sydney, AUS), Markus Schlaich (Perth, AUS), Roland Schmieder (Erlangen, GER), Laurence Tallon (MHRA, GBR), Aliza Thompson (FDA, USA), Noriko Tojo (Otsuka, JPN), Bryan Williams (London, GBR), Dion Zappe (Alnylam, USA)

State
Monday, December 7, 2026
08:30 -10:30

**ALDOSTERONE IN CARDIOVASCULAR-KIDNEY-METABOLISM DISEASES
ENDURING AND EMERGING SCIENCE, NEW OPPORTUNITIES AND CLINICAL TRIALS LANDSCAPE**
Chairpersons: Bertram Pitt (Ann Arbor, MI, USA) & Faiez Zannad (Paris, FRA)

Prevalence and Clinical Impact of Hyperaldosteronism and Hypercortisolism in CKM disease
Irina Bancos (Rochester, MN, USA)

How far can we suppress maladaptive mineralocorticoid biology without toxicity. How translational science may inform clinical trials.

Jenifer Brown (Boston, USA)

Is aldosterone level the wrong target, and MR overactivation the real disease biology?
Bertram Pitt (Ann Arbor, MI, USA)

Do we need to measure aldosterone at all to identify patients who benefit from aldosterone-directed therapy?
Jordana Cohen (Philadelphia, PA, USA)

ASI trials update
Javed Butler (Dallas, TX, USA)

nsMRA trials update
Scott Solomon (Boston, MA, USA)

Primary care physician viewpoint. Why are we failing to detect hyperaldosteronism in routine CKM care?"
Javier Morales (New York, NY, USA)

Industry viewpoints
Alessandro Albuquerque (Recordati, ITA), Maria Borentain (Bayer, GER), Mikhail Kosiborod (AstraZeneca, USA), David Rodman (Mineralys Therapeutics, USA)

What level of incremental benefit justifies premium pricing?
Tamara Syrek Jensen (CMS, USA), Niklas Hedberg (TLV, SWE)

The CVCT Multi-Stakeholder Think Tank Debate

**ALDOSTERONE IN CARDIOVASCULAR-KIDNEY-METABOLISM DISEASES
ENDURING AND EMERGING SCIENCE, NEW OPPORTUNITIES AND CLINICAL TRIALS LANDSCAPE**
Chairpersons: Bertram Pitt (Ann Arbor, MI, USA) & Faiez Zannad (Paris, FRA)

Panelists: Alessandro Albuquerque (Recordati, ITA), Irina Bancos (Rochester, MN, USA), Maria Borentain (Bayer, GER), Javed Butler (Dallas, TX, USA), Jenifer Brown (Boston, MA, USA), Niklas Hedberg (TLV, SWE), Masatake Kobayashi (Tokyo, JPN), Mikhail Kosiborod (AstraZeneca, USA), Javier Morales (New York, NY, USA), Bertram Pitt (Ann Arbor, MI, USA), David Rodman (Mineralys Therapeutics, USA), Scott Solomon (Boston, MA, USA), Tamara Syrek Jensen (CMS, USA)

State
Monday, December 7, 2026
11:00 -13:00

CARDIO-KIDNEY-METABOLIC TRIALS. HOW TO COPE WITH MULTIPLE DRUGS, MULTI-ORGAN COMPOSITE ENDPOINTS AND MULTIPLE SOURCES OF EVIDENCE.

Chairpersons: Hidido L Heerspink (Groningen, NED) & Clare Arnott (Sydney, AU)

Targeting combined multiorgan cardiovascular and kidney benefits. Rationale and opportunities

Nephrologist viewpoint
Hidido L Heerspink (Groningen, NED)

Cardiologist viewpoint
Faiez Zannad (Paris, FRA)

Primary Care Physician viewpoint
Naresh Kanumilli (Manchester, GBR)

How to select the right patient population in multiorgan cardio-kidney-metabolic clinical trials?

Brendon Neuen (Sydney, AUS)

Hitting multiple birds with a single stone

Virtues and limitations of composite endpoints. Statistician viewpoints.
Heidi Christ (Basel, CHE)

Can dual indications be claimed with a single trial? Regulatory viewpoint.
Aliza Thompson (FDA, USA)

How may payers value single drug multi-organ benefits?
Rod Taylor (London, GBR), Karine Chevreul (HAS, FRA)

Trials investigating multidrug CKM stack. Add-on, vs. head-to-head, vs. non-inferiority trial designs.

Clinical viewpoint
Will Herrington (Oxford, GBR)

Statistical viewpoint
Brian Claggett (Boston, MA, USA)

Regulatory viewpoints
Aliza Thompson (FDA, USA), Alar Irs (EMA, EST), Milou Drici (EMA, FRA)

Industry viewpoints.
Meike Brinker (Bayer, GER), Martina Brueckmann (Roche, CH), Dustin Little (Astra Zeneca, USA), Peter Erland Marstrand (NovoNordisk, DNK)

Patient viewpoint.
Steven Macari (AVEC, FRA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

CARDIO-KIDNEY-METABOLIC TRIALS. HOW TO COPE WITH MULTIPLE DRUGS, MULTI-ORGAN COMPOSITE ENDPOINTS AND MULTIPLE SOURCES OF EVIDENCE

Chairpersons: Hidido Heerspink (Groningen, NED) & Clare Arnott (Sydney, AU)

Panelists: Clare Arnott (Sydney, AU), Martina Brueckmann (Roche, CH), Meike Brinker (Bayer, GER), Karine Chevreul (HAS, FRA), Heidi Christ (Basel, CHE), Brian Claggett (Boston, MA, USA), Milou Drici (EMA, FRA), Jennifer Green (Durham, NC, USA), Hidido L. Heerspink (Groningen, NED), Will Herrington (Oxford, GBR), Alar Irs (EMA, EST), Naresh Kanumilli (Manchester, GBR), Dustin Little (AstraZeneca, USA), Steven Macari (AVEC, FRA), Peter Erland Marstrand (NovoNordisk, DNK), Brendon Neuen (Sydney, AUS), Norman Stockbridge (S&S Consulting, USA), Rod Taylor (London, GBR), Aliza Thompson (FDA, USA), Faiez Zannad (Paris, FRA)

State
Monday, December 7, 2026
14:00 -16:00

CVCT-NIH-WOMEN AS ONE JOINT SESSION
BEYOND REPRESENTATION: DESIGNING CARDIOVASCULAR TRIALS AROUND WOMEN'S BIOLOGY AND LIFE COURSE

Chairpersons: Robert Califf (Durham, NC, USA) & Martha Gulati (Los Angeles, CA, USA)

Cardiovascular disease (CVD) in women evolves across the lifespan, shaped by reproductive biology, hormonal transitions, and social and environmental influences. A life-course framework highlights pregnancy and menopause as two critical points where cardiovascular risk is either revealed or accelerated. These windows provide important opportunities for early detection, targeted prevention, and improved clinical trial design. However, significant gaps persist, including the underrepresentation of pregnant and perimenopausal women in trials, limited randomized evidence, and a lack of longitudinal studies that track risk across decades.

Reframing lifespan transitions as strategic opportunities for detection and intervention can enable a proactive, lifespan-based approach to prevention and improve cardiovascular outcomes.

Current and future unmet needs in women's cardiovascular health research
Martha Gulati (Los Angeles, CA, USA)

Global priorities and funding opportunities for advancing women's cardiovascular research
Janine Clayton (NIH/ OWH, USA)

Pregnant and lactating individuals in clinical trials: ethical and clinical crossroads
Catherine Spong (Dallas, TX, USA)

Peripartum and Postpartum interventions to improve short- and long-term maternal and fetal cardiovascular health
Garima Arora (Birmingham, AL, USA)

Trials' opportunities in menopause as a vascular transition.
Chrisandra L. Shufelt (Jacksonville, FL, USA)

Ischemia with no obstructive coronary artery disease: A female-enriched phenotypes in HFpEF trials?
Odayme Quesada (Cincinnati, OH, USA)

Obesity-metabolic trials in women
Neha Pagidipati (Durham, NC, USA)

Regulatory expectations for sex-specific evidence
Kaveeta Vasisht (FDA, USA)

Industry viewpoints
Amy Ford (Lilly, USA), Luba Soskin (Bayer, CHE), Anna Windle (Novo Nordisk, USA)

Patient Viewpoints
Celina Gorre (WomenHeart, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

SETTING PRIORITIES FOR RESEARCH, POLICY, AND PRACTICE IN WOMEN'S HEALTH
Chairpersons: Robert Califf (Durham, NC, USA) & Martha Gulati (Los Angeles, CA, USA)

Panelists: Garima Arora (Birmingham, AL, USA), Juan Camilo Arjona Ferreira (Organon, COL), Robert Califf (Durham, NC, USA), Ediina Cenko (Bologna, IT), Janine Clayton (NIH/ OWH, USA), Amy Ford (Lilly, USA), Celina Gorre (WomenHeart, USA), Martha Gulati (Los Angeles, CA, USA), Neha Pagidipati (Durham, NC, USA), Odayme Quesada (Cincinnati, OH, USA), Luba Soskin (Bayer, CHE), Catherine Spong (Dallas, TX, USA), Chrisandra L. Shufelt (Jacksonville, FL, USA), Kaveeta Vasisht (FDA, USA), Anna Windle (Novo Nordisk, USA)

State
Monday, December 7, 2026
16:30 -19:30

STRATEGIES FOR CLINICAL TRIAL DESIGN IN - PATIENTS AT RISK OF ATHEROSCLEROTIC CARDIOVASCULAR DISEASE

Part 1

HOW BEST TO DEFINE TARGET POPULATIONS?

Chairpersons: Marc Sabatine (Boston, MA, USA) & Lale Tokgozoglu (Ankara, TUR)

Comparison of guideline recommendations: Sorting out the “at-risk” trial population
Lale Tokgozoglu (Ankara, TUR)

Guiding the next generation of trials in high-risk event-free patients
Erin Bohula (Boston, MA, USA)

Can blood pressure and LDL cholesterol be targeted at once with a single bullet?
Sergio Fazio (Corsera, USA)

Target patient population: Screening of atherosclerosis risk

3-dimensional ultrasonography of carotid and iliofemoral arteries
Valentin Fuster (New York, NY, USA)

CT angiography plaque volume and plaque characteristics
Gemma Figtree (Sydney, AUS)

Genetic instruments
Ron Do (New York, NY, USA)

Proteomic profiling
Sascha Goonewardena (Ann Arbor, MI, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HOW BEST TO DEFINE TARGET POPULATIONS?

Chairpersons: Marc Sabatine (Boston, MA, USA) & Lale Tokgozoglu (Ankara, TUR)

Panelists: Erin Bohula (Boston, MA, USA), Brian Claggett (Boston, MA, USA), Ron Do (New York, NY, USA), Sergio Fazio (Corsera, USA), Gemma Figtree (Sydney, AUS), Valentin Fuster (New York, NY, USA), Charu Gandotra (FDA, USA), Sascha Goonewardena (Ann Arbor, MI, USA), Adrian Hernandez (Durham, NC, USA), Paulus Kirchhof (Hamburg, GER), Darren McGuire (Dallas, TX, USA), Guiomar Mendieta-Badimon (Barcelona, ESP), Heng Tony Qian (Olink, USA), Marc Sabatine (Boston, MA, USA), Patrick Schlömer (BAYER, GER), Nishant Shah (Durham, NC, USA), John Sharretts (ex FDA, USA), Lale Tokgozoglu (Ankara, TUR), Raymond Soccio (FDA, USA), Aliza Thompson (FDA, USA), Muthiah Vaduganathan (Boston, MA, USA), Stephen Wiviott (AstraZeneca, USA)

State
Monday, December 7, 2026
16:00 -19:00

Part 2

CVCT-DCRI JOINT SESSION

ENDPOINT FOR PREVENTION BEYOND ASCVD

Chairpersons: Adrian Hernandez (Durham, NC, USA) & Guiomar Mendieta-Badimon (Barcelona, ESP)

Heart failure: Hospitalization or outpatient diagnosis?
Muthiah Vaduganathan (Boston, MA, USA)

Atrial fibrillation: Clinically relevant burden?
Paulus Kirchhof (Hamburg, GER)

Diabetes: The prevention vs. masking conundrum and does it matter?
Darren McGuire (Dallas, TX, USA)

Guiding the next generation of trials in high-risk event-free patients
Nishant Shah (Durham, NC, USA)

Statistical viewpoint
Brian Claggett (Boston, MA, USA)

Industry viewpoint
Stephen Wiviott (AstraZeneca, USA), Patrick Schlömer (BAYER, GER), Heng Tony Qian (Olink, USA)

Regulatory viewpoint
Charu Gandotra (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PREVENTION TRIALS IN AT RISK POPULATIONS – HOW TO ACCELERATE INNOVATION?

Chairpersons: Adrian Hernandez (Durham, NC, USA) & Guiomar Mendieta-Badimon (Barcelona, ESP)

Panelists: Erin Bohula (Boston, MA, USA), Brian Claggett (Boston, MA, USA), Ron Do (New York, NY, USA), Sergio Fazio (Corsera, USA), Gemma Figtree (Sydney, AUS), Valentin Fuster (New York, NY, USA), Charu Gandotra (FDA, USA), Sascha Goonewardena (Ann Arbor, MI, USA), Adrian Hernandez (Durham, NC, USA), Paulus Kirchhof (Hamburg, GER), Darren McGuire (Dallas, TX, USA), Guiomar Mendieta-Badimon (Barcelona, ESP), Heng Tony Qian (Olink, USA), Marc Sabatine (Boston, MA, USA), Patrick Schlömer (BAYER, GER), Nishant Shah (Durham, NC, USA), John Sharretts (ex FDA, USA), Lale Tokgozoglu (Ankara, TUR), Raymond Soccio (FDA, USA), Aliza Thompson (FDA, USA), Muthiah Vaduganathan (Boston, MA, USA), Stephen Wiviott (AstraZeneca, USA)

Chinese
Monday, December 7, 2026
16:30 -19:30

CVCT/PATIENT ADVOCACY CONSORTIUM JOINT SESSION
MAKING CLINICAL TRIAL EVIDENCE UNDERSTANDABLE TO PATIENTS —AND TO EVERYONE OUTSIDE
THE TRIALIST COMMUNITY?

PLAIN-LANGUAGE TRIAL SUMMARIES PUBLICATIONS.
Chairpersons : Marc Bains (HeartLife, CAN) & Faiez Zannad (Paris, FRA)

CVCT is to announce the important CVCT PLSP new initiative
With the participation of patient trialists and journal editors

Plain language summaries for patients sit at the intersection of three otherwise separate problems: widespread, often underestimated gaps in health literacy; a clinical encounter structurally too brief to transmit complex medical information; and the well-documented link between patient understanding and treatment adherence. None of these problems is fully solvable by better bedside manner alone. A well-constructed PLSP — tested for readability, free of unexplained jargon, and ideally reviewed by actual patients before publication — gives people durable, revisitable access to the information a rushed visit cannot fully deliver. As regulators, journals, funders, and pharmaceutical sponsors increasingly require these summaries as a condition of publication, the opportunity is not just to check a compliance box, but to meaningfully close the gap between what medical research knows and what the patients living with that research actually understand.

«Plain language» to change clinical actions and trial implementation in the real world.

The EU perspective
Carl Heneghan (Oxford, GBR)

The US perspective
Michael Wolf (Chicago, IL, USA)

No jargon, please. Just tell me what this trial means. What do non-trialists actually want to know?
Rhonda Monroe (Charlotte, NC, USA)
Frances Shiely (Cork, GBR)

Readable is not necessarily understandable: what health-literacy research teaches us
Kamlesh Khunti (Leicester, GBR)

What errors would make a PLS unacceptable—even if patients and non-trialists find it easy to read?
John Mandrola (Louisville, KY, USA)

The Human-AI loop. Responsible use of artificial intelligence in creating plain language summaries
Karen Gainey (Sydney, AUS)

The respective roles of regulatory lay summaries and of citable plain-language summary journal publications.
Emma Doble (BMJ, GBR)

The CVCT PLSP Initiative: From Trial Results to Non-Trialist Understanding
What minimum standard should CVCT adopt today?
Javed Butler (Dallas, TX, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

Making clinical trial evidence understandable for everyone.
Why and how should scientific publication no longer be the final stop?
Chairpersons : Marc Bains (HeartLife, CAN) & Faiez Zannad (Paris, FRA)

Panelists : Marc Bains (London, GBR), Javed Butler (Dallas, TX, USA), Emma Doble (BMJ, GBR), Karen Gainey (Sydney, AUS), Carl Heneghan (Oxford, GBR), Kamlesh Khunti (Leicester, GBR), Steven Macari (AVEC, FRA), John Mandrola (Louisville, KY, USA), Rhonda Monroe (Charlotte, NC, USA), Frances Shiely (Cork, IRE), Michael Wolf (Chicago, IL, USA), Faiez Zannad (Paris, FRA)

Ballroom
Monday, December 7, 2026
08:30 -10:30

STRATEGIES TO ACHIEVE LDL CHOLESTEROL GOALS MORE EFFECTIVELY AND MORE EFFICIENTLY
Chairpersons: Pamela Morris (Mount Pleasant, SC, USA) & Greg Schwartz (Denver, CO, USA)

Bivalent approaches to achieve LDL cholesterol goals. Building the platform on a PCSK9 inhibitor
Jie Zeng (Rona Therapeutics, CHN)

Oral combinations getting to goal more effectively – trial design considerations for dual targets
Neha Pagidipati (Durham, NC, USA)

Investigating durable solutions with gene/base editing
Sekar Kathiresan (Verve, USA)

Industry viewpoints
Puja Banka (Merck, USA), Alex DePaoli (Rona Therapeutics, CHN), Jason Duran (CRISPR Therapeutics, USA), Jennifer Hellowell (Arrowhead pharmaceuticals, USA), Per Johannsen (AstraZeneca, SWE), David Kallend (Lib Therapeutix, USA), John Kastelein (New Amsterdam, USA), Anastasia Lesogor (Novartis, CHE)

Regulatory viewpoint
Eileen Craig (FDA, USA)
Jacob George (MHRA, GBR)

Patient viewpoint
Magdalena Daccord (FH Europe Foundation, CHE)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

STRATEGIES TO ACHIEVE POWERFUL AND LONGER DURATION CHOLESTEROL LOWERING
Chairpersons: Pamela Morris (Mount Pleasant, SC, USA) & Greg Schwartz (Denver, CO, USA)

Panelists: Alex DePaoli (Rona Therapeutics, CHN), Puja Banka (Merck, USA), Eileen Craig (FDA, USA), Magdalena Daccord (FH Europe Foundation, CHE), Jason Duran (CRISPR Therapeutics, USA), Jacob George (MHRA, GBR), Jennifer Hellowell (Arrowhead pharmaceuticals, USA), Per Johannsen (AstraZeneca, SWE), David Kallend (Lib Therapeutix, USA), John Kastelein (New Amsterdam, USA), Sekar Kathiresan (Verve Therapeutics, USA), Anastasia Lesogor (Novartis, CHE), Michelle O'Donoghue (Boston, MA, USA), Pamela Morris (Mount Pleasant, SC, USA), Neha Pagidipati (Durham, NC, USA), Greg Schwartz (Denver, CO, USA), Jie Zeng (Rona Therapeutics, CHN)

Ballroom
Monday, December 7, 2026
11:00 -13:00

LP (a) TRIALS. HORIZON AND BEYOND THE HORIZON

Chairpersons: Leslie Cho (Cleveland, OH, USA) & Robert Rosenson (New York, NY, USA)

HORIZON – Main findings
Leslie Cho (Cleveland, OH, USA)

Epidemiologic and genetic/Mendelian randomization evidence: how well did it predict HORIZON, and what does that mean for OCEAN(a)-Outcomes, ACCLAIM-Lp(a), and MOVE-Lp(a)?
Borge Nordestgaard (Copenhagen, DNK)

Safety with different approaches to RNA inhibition, consequences on adherence and power size calculation in Lp(a) trials
Robert S. Rosenson (New York, NY, USA)

How HORIZON will frame the Lp(a) developments
Expanded use of pelacarsen beyond the very high-risk patient
Michelle O'Donoghue (Boston, MA, USA)

Role of biomarkers: why did Lp(a) reduction not predict benefit? What should the next biomarker strategy be, including OxPL and proteomics?
Sascha N. Goonewardena (Ann Arbor, MI, USA)

Which should be the preferred approach for patients with ASCVD and elevated Lp(a)? Targeted Lp(a) suppression or PCSK9 inhibition, or both?
Greg Schwartz (Denver, CO, USA)

Different patient populations: is calcific aortic valve stenosis (CAVS) the next test of the Lp(a) hypothesis?
George Thanassoulis (Montreal, CAN)

Industry viewpoints
Hui Cao (Novartis, USA), Amit Khera (Verve Therapeutics, USA), Sam Tsimikas (Ionis, USA).

Regulatory viewpoint
Jacob George (MHRA, GBR)
Brittany Schuck (FDA, USA)

Patient viewpoint
ShantaQuilette Carter (Pink Peppermint Project, USA)
Magdalena Daccord (FH Europe Foundation, CHE)
Hyvelle Ferguson-Davis (Heart Sistas, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

ADOPTION OF HORIZON RESULTS AND ADAPTION OF LP (a) TRIALS.

Chairpersons : Leslie Cho (Cleveland, OH, USA) & Robert Rosenson (New York, NY, USA)

Panelists: Hui Cao (Novartis, USA), ShantaQuilette Carter (Pink Peppermint Project, USA), Leslie Cho (Cleveland, OH, USA), Magdalena Daccord (FH Europe Foundation, CHE), Hyvelle Ferguson-Davis (Heart Sistas, USA), Charu Gandotra (FDA, USA), Jacob George (MHRA, GBR), Sascha N. Goonewardena (Ann Arbor, MI, USA), Amit Khera (Verve Therapeutics, USA), Børge G. Nordestgaard (Copenhagen, DNK), Michelle O'Donoghue (Boston, MA, USA), Robert Rosenson (New York, NY, USA), Greg Schwartz (Denver, CO, USA), Brittany Schuck (FDA, USA), Tabassome Simon (Paris, FRA), George Thanassoulis (Montreal, CAN), Sam Tsimikas (Ionis, USA)

Ballroom
Monday, December 7, 2026
14:00 -16:00

iCVCT # 5

STRATEGIZING ENTERING THE CLINICAL STAGE FOR HF MEDTECH STARTUPS

Chairpersons: Dan Burkhoff (New York, NY, USA) & Martin Leon (New York, NY, USA)

Overview. The innovation landscape of HF devices

Innovators' viewpoint
Howard Levin (Coridea, USA)

Investors' viewpoints
Josh Makower (Coravin, USA)
Antoine Papiernik (Sofinova Partners, FRA)
Hanson Gifford (The Foundry, USA)
Lisa Suennen (AHA Ventures, USA)

Regulatory viewpoint
Andrew Farb (FDA, USA)

Recent learnings from pilot studies

Devices to treat Heart Failure
Dan Burkhoff (New York, NY, USA)

Devices to treat Structural Heart Disease
Martin Leon (New York, NY, USA)

The competitive landscape. What is in the pipeline? Industry presentations (5min each)

Do we still need to test every device the same way? The role of virtual patients and in-silico trials
Simon Sonntag (Virtonomy, GER)

Industry viewpoint. Shifting from Feasibility to Pivotal Global Trials (Structural & Interatrial Shunts)
William Abraham (V-Wave, ISR), Jeff Closs (Ancora, USA), John Laschinger (Edwards, USA), Howard Levin (Coridea, USA), Kate Stohlman (Corvia, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

STRATEGIZING ENTERING THE CLINICAL STAGE FOR HF MEDTECH STARTUPS

Chairpersons: Dan Burkhoff (New York, NY, USA) & Martin Leon (New York, NY, USA)

Panelists: William Abraham (V-Wave, ISR), Dan Burkhoff (New York, NY, USA), Jeff Closs (Ancora, USA), Andrew Farb (FDA, USA), Hanson Gifford (The Foundry, USA), Howard Levin (Coridea, USA), Martin Leon (New York, NY, USA), Josh Makower (Coravin, USA), Antoine Papiernik (Sofinova Partners, FRA), Kate Stohlman (Corvia, USA), Lisa Suennen (AHA Ventures, USA)

Ballroom
Monday, December 7, 2026
16:30 -19:30

STRATEGIZING ENTERING THE CLINICAL STAGE FOR BIOTECH STARTUPS.

Part 1: HEART FAILURE

Chairpersons: Peter Libby (Boston, MA, USA) & Milton Packer (Dallas, TX, USA)

The innovation landscape: Regulatory viewpoints
Robert Califf (Durham, NC, USA)
Jacob George (MHRA, GBR)

The innovation landscape: Investors' viewpoints
Craig Gordon (GordonMD Global Investment LP, USA)

What de-risking do investors expect?
Daniel Becker (Access, USA), Julian Harris (Deerfield Management, USA)

Recent conceptual advances and Heart failure phase 2 trials
Milton Packer (Dallas, TX, USA)

The competitive landscape. What is in the heart failure pipeline? Industry presentations

Activin type II receptor antagonists-1
Dushyanth Srinivasan (Regeneron, USA)

Activin type II receptor antagonists-2
George Georges (38 Pharma/GSK, USA)

Activin signaling inhibitors
Alessia Urbinati (Merck, USA)

Endotrophin antagonists
Laurent Audoly (PriveBio, USA), Federica Genovese (Nordic Bioscience, DNK)

FGF21 Receptor Agonists
Christine Garrett (Preload Therapeutics, USA)

PDE9 inhibitors
Howard Surks (Cardurion, USA)

Actin-related antibodies
Mark DiNubile (BioAegis, USA)

Targeting Titin N2B
Richard Nkulikiyinka (GenKardia, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

Part 1: Heart Failure

Chairpersons: Peter Libby (Boston, MA, USA) & Milton Packer (Dallas, TX, USA)

Panelists: Hafid Ait-Oufella (Polygon, FRA), Laurent Audoly (PriveBio, USA), David Bauman (Schrödinger, USA), Daniel Becker (Access, USA), Brieana Buckley (Editas Medicine, USA), Robert Califf (Durham, NC, USA), Mark DiNubile (BioAegis, USA), Chris Farina (Abcentra, USA), Christine Garrett (Preload Therapeutics, USA), Federica Genovese (Nordic Bioscience, DNK), George Georges (38 Pharma/GSK, USA), Jacob George (MHRA, GBR), Craig Gordon (GordonMD Global Investment LP, USA), Julian Harris (Deerfield Management, USA), Filip Janku (Monterosa, USA), Peter Libby (Boston, MA, USA), Ciaran McMullan (Merck, USA), Richard Nkulikiyinka (GenKardia, USA), Milton Packer (Dallas, TX, USA), Dushyanth Srinivasan (Regeneron, USA), Howard Surks (Cardurion, USA), Alessia Urbinati (Merck, USA)

Ballroom
Monday, December 7, 2026
16:00 -19:00

STRATEGIZING ENTERING THE CLINICAL STAGE FOR BIOTECH STARTUPS.
Part 2: INFLAMMATION ATHEROSCLEROSIS
Chairpersons: Peter Libby (Boston, MA, USA) & Milton Packer (Dallas, TX, USA)

Recent conceptual advances and phase 2 inflammation Atherosclerosis Trials)
Peter Libby (Boston, MA, USA)

The competitive landscape. What is in the inflammation pipeline? Industry presentations

What is new in computational drug design
David Bauman (Schrodinger, USA)

Targeted Protein Degradation in Therapeutics
Filip Janku (Monterosa, USA)

A Novel Anti-inflammatory Approach with a Companion Diagnostic
TBD

Immunological Targets in Cardiac Disease
Hafid Ait Oufella (Polygon, FRA)

Plaque-targeted Anti-Inflammatory Therapy: Targeting Oxidized LDL
Chris Farina (Abcentra, USA)

Repairing Broken Genes with CRISPR
Brieana Buckley (Editas, Medicine, USA)

Oral NLRP3 inflammasome inhibition
Jyothis George (NodThera, GBR)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

Part 2: Inflammation and Atherosclerosis
Chairpersons: Peter Libby (Boston, MA, USA) & Milton Packer (Dallas, TX, USA)

Panelists: Hafid Ait-Oufella (Polygon, FRA), Laurent Audoly (PriveBio, USA), David Bauman (Schrödinger, USA), Daniel Becker (Access, USA), Brieana Buckley (Editas Medicine, USA), Robert Califf (Durham, NC, USA), Mark DiNubile (BioAegis, USA), Chris Farina (Abcentra, USA), Christine Garrett (Preload Therapeutics, USA), Federica Genovese (Nordic Bioscience, DNK), George Georges (38 Pharma/GSK, USA), Jacob George (MHRA, GBR), Craig Gordon (GordonMD Global Investment LP, USA), Julian Harris (Deerfield Management, USA), Filip Janku (Monterosa, USA), Peter Libby (Boston, MA, USA), Ciaran McMullan (Merck, USA), Richard Nkulikiyinka (GenKardia, USA), Milton Packer (Dallas, TX, USA), Dushyanth Srinivasan (Regeneron, USA), Howard Surks (Cardurion, USA), Alessia Urbinati (Merck, USA)

**Palm court
Tuesday, December 8, 2026
08:30 -10:30**

**Statistics Master Class # 1:
SOME PERENNIAL CHALLENGES IN TRIAL DESIGN AND ANALYSIS
Chairpersons: Frank Rockhold (Durham, NC, USA) & Gregg Stone (New York, NY, USA)**

In this session, we cover these topical themes:

Per protocol analyses, as usually done, are viewed skeptically as potentially biased, whereas the instrumental variable approach provides greater insight.

Randomized trials often lack power and generalizability, and incorporating external data can enhance both. The non-inferiority design remains common but can be a cumbersome, underpowered tool asking the wrong question. Is there a better way forward?

Instrumental Variables in Randomized Trials

Robert Yeh (Boston, MA, USA)

David Cohen (Boston, MA, USA)

Discussion

Augmenting Power in Randomized Trials Using External Data

Issa Dahabreh (Boston, MA, USA)

Gregory Alexander (FDA, USA)

Discussion

Non-inferiority trials: Their use, misuse, and possible alternatives.

Stuart Pocock (London, GBR)

Javed Butler (Dallas, TX, USA)

Discussion

**Palm court
Tuesday, December 8, 2026
11:00 -13:00**

Bayesian Statistics Masterclass #2

BAYESIAN STATISTICS IN CARDIOVASCULAR TRIALS: FOUNDATIONS, GUIDANCE, AND EVOLVING PERSPECTIVES

Chairpersons: Frank Harrell (Nashville, TN, USA) & Norman Stockbridge (S&S Consulting, USA)

Bayesian statistics is gaining renewed attention in cardiovascular trials, offering a framework for integrating prior knowledge, accumulating evidence, and supporting clinically meaningful decision-making. This masterclass will introduce Bayesian concepts for clinicians, explore how Bayesian thinking differs from traditional frequentist approaches, and examine how it reframes evidence thresholds, multiplicity, and interpretation of trial results. It will also review the draft Bayesian guidance and consider what doors it may open for trial design, regulatory considerations, and future cardiovascular evidence generation. The session will close with reflections on how views of Bayesian methods have evolved, from skepticism to recognition of their potential role in modernizing cardiovascular trials.

**A Primer on What Bayes Offers to Randomized Clinical Trials
Scott Berry (Berry Consultants, USA)**

Discussion

**The Essence of Bayesian Statistics
Frank Harrell (Nashville, TN, USA)**

Discussion

**A Review of the Draft Bayesian Guidance and its Impacts
James Travis (FDA, USA)**

Discussion

**Evolving Views on Bayes
Norman Stockbridge (S&S Consulting, USA)**

Discussion

The CVCT Multi-Stakeholder Think Tank Moderated Debate

UNDERSTANDING BAYESIAN STATISTICS

Chairpersons: Frank Harrell (Nashville, TN, USA) & Norman Stockbridge (S&S Consulting, USA)

**Panelists: Scott Berry (Berry Consultants, USA), Frank Harrell (Nashville, TN, USA), Norman Stockbridge (S&S Consulting, USA),
James Travis (FDA, USA)**

**Tuesday, December 8, 2026
13:30 - 14:20**

KEYNOTE LECTURE

Marc Pfeffer (Boston, MA, USA)
Victor J. Dzau (Boston, MA, USA)

**Palm court
Tuesday, December 8, 2026
14:30 -16:30**

**Statistics Masterclass #3
BAYESIAN DESIGNS IN ACTION: LEARNING, BORROWING, AND ADAPTING
Chairpersons: Scott Berry (Berry Consultants) & Stuart Pocock (London, GBR)**

Bayesian methods offer a flexible framework for clinical trial design, allowing studies to learn and adapt as evidence accumulates. Beyond familiar uses such as interim monitoring, early stopping, and sample size selection, Bayesian approaches can support borrowing from historical or external data, adaptive enrichment of trial populations, and more flexible approaches to complex or multiple endpoints, while also offering powerful tools for earlier-phase questions such as dose selection. Through real-world trial examples, this masterclass will illustrate how Bayesian designs can use accumulating evidence to guide trial decisions, focus enrollment on populations most likely to benefit, and create more flexible and efficient cardiovascular trials.

**ICONIC-HF: Dynamic Borrowing in Practice
TBD**

Discussion

**RESPONDER-HF: Fixed Borrowing with a Hierarchical Endpoint
Amy Crawford (Berry Consultants, USA)**

Discussion

**ENRICH: Adaptive Enrichment of the Trial Population
Ben Saville (Austin, TX, USA)**

Discussion

**CATALYST: Adaptive Sample Size and Follow-up with Multiple Endpoints
Shu Yu (Abbott, USA)**

Discussion

Palm court
Tuesday, December 8, 2026
17:00 -19:00

OBESITY MEDICINES: BODY COMPOSITION, ASSESSMENTS, TARGETS AND CONCERNS
Chairpersons: Pam Taub (San Diego, CA, USA) & Subodh Verma (Toronto, CAN)

How to assess body composition and muscle function before and after interventions
Roger A. Fielding (Boston, MA, USA)

Body composition changes in health and disease, and association with outcomes
Jason Gill (Glasgow, GBR)

Body composition changes with obesity medicines and surgery
Jennifer Linge (Linköping, SWE)

Beyond weight loss: Muscle and bone preservation with GLP-1 RAs, and will they translate into better functionality?
Jason Gill (Glasgow, GBR)

What target should we treat to: a certain weight, resolution of comorbidities, or both
Ildiko Lingvay (Dallas, TX, USA)

Weight loss concerns: potential for too much weight loss in some and rapid regain post cessation / weight cycling?
Naveed Sattar (Glasgow, GBR)

NHLBI viewpoint
Laurie Donze (NIH/NHLBI, USA)

Primary care physician viewpoint: What should tell my obese patients about their muscles?
Javier Morales (Bew York, NY, USA)

Industry talks
Yousuf Ali (Boehringer Ingelheim, GER)
Chad Grothen (Lilly, USA)

Regulatory Perspective : Reflections on muscle- building agents PLUS need for trials with weight loss targets
Raymond Soccio (FDA, USA)

Patient viewpoint
Joseph Nadglowski (Obesity Action Coalition, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HOW TO DESIGN OBESITY MEDICINES TRIALS BEYOND WEIGHT LOSS
Chairpersons: Pam Taub (San Diego, CA, USA) & Subodh Verma (Toronto, CAN)

Panelists: Yousuf Ali (Boehringer Ingelheim, GER), Laurie Donze (NIH, USA), Roger A. Fielding (Boston, MA, USA), Jason Gill (Glasgow, GBR), Chad Grothen (Lilly, USA), Jennifer Linge (Linköping, SWE), Ildiko Lingvay (Dallas, TX, USA), Steven Macari (AVEC, FRA), Javier Morales (Bew York, NY, USA), Joseph Nadglowski (Obesity Action Coalition, USA), , Naveed Sattar (Glasgow, GBR), Raymond Soccio (FDA, USA), Pam Taub (San Diego, CA, USA), Subodh Verma (Toronto, CAN), Shu Yu (Abbott, USA)

East
Tuesday, December 8, 2026
08:30 -10:30

ZEUS TRIAL DEEP DIVE : UNDERSTANDING AND INTERPRETING THE RESULTS OF ZEUS

Chairpersons: Paul Ridker (Boston, MA, USA) & Jean Claude Tardif (Montreal, CAN)

ZEUS rationale and primary results
Paul Ridker (Boston, MA, USA)

The consequence of ZEUS on the ongoing inflammation trials
Wolfgang Koenig (Munich, GER)

What populations are most appropriate targets in cardio-immunology trials:

Is CKD an appropriate target population.
Hiddo Heerspink (Groningen, NLD)

Post-MI inflammation-enriched patients
Adrian Hernandez (Durham, NC, USA)

Heart failure: ATHENA and HERMES
Guiomar Mendieta Badimon (Madrid, ESP)

Therapeutic window and safety issues in cardiovascular inflammation trials
Jean Claude Tardif (Montreal, Canada)

Industry viewpoint
Andres Hvelplund (NovoNordisk, DEN)

Regulatory viewpoints
Aliza Thompson (FDA, USA)

Clinical development learnings from ZEUS
Mads Engelmann (Copenhagen, DEN)

Patient viewpoint
Patrick Gee (iAdvocate, USA), Devin Verbueken (HCM Patient, NED)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

ZEUS TRIAL DEEP DIVE: IMPLICATIONS FOR CKM TRIALS

Chairpersons: Paul Ridker (Boston, MA, USA) & Jean Claude Tardif (Montreal, CAN)

Panelists: Mads Engelmann (Copenhagen, DEN), Patrick Gee (iAdvocate, USA), Hiddo Heerspink (Groningen, NED), Adrian Hernandez (Durham, NC, USA), Andres Hvelplund (NovoNordisk, DEN), Charles Kaplan (Bitterroot Bio, AUS), Wolfgang Koenig (Munich, GER), Guiomar Mendieta Badimon (Madrid, ESP), Paul Ridker (Boston, MA, USA), Jean Claude Tardif (Montreal, CAN), Aliza Thompson (FDA, USA), Devin Verbueken (HCM Patient, NED)

East
Tuesday, December 8, 2026
11:00 -13:00

ANTI-INFLAMMATORY TREATMENT OF ASCVD: BEYOND ZEUS, WHAT IS NEXT?
Chairpersons: Wolfgang Koenig (Munich, GER) & Giovanna Liuzzo (Rome, IT)

Reverse translation: What have we learned from completed trials?
Peter Libby (Boston, MA, USA)

Targeted immune modulation for atherosclerosis
Klaus Ley (Augusta, GA, USA)

Can proteomics/multiomics provide novel insights into the best targets?
Manuel Mayr (London, GBR)

Could trials investigating an anti-inflammatory transcriptome in T-cells mediated by EPA finally solve the controversy?
Preston Mason (Boston, MA, USA)

T reg cell-based therapies—how can we identify the immunotolerant patients with the best benefit/risk ratio
Rouchelle Sriranjana-Rothwell (Cambridge, GBR)

IL-1 β , direct NLRP3 inhibitors – Offsetting risk versus benefit.
Reginald McNulty (Irvine, USA)

Industry Viewpoints
Chris O'Donnell (Novartis, CH), Kristen Fortney (BioAge, USA), Jyothis George (Nodthera, GBR), Charles Kaplan (Bitterroot Bio, AUS), Maria Sejersten Ripa (Novo Nordisk, DNK), Marzia Rigolli (Eli Lilly, USA)

Regulatory Viewpoint
Mori Krantz (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

ANTI-INFLAMMATORY TREATMENT OF ASCVD: WHAT HAVE WE LEARNED FROM RECENT TRIALS? HOW TO TEST NEW TARGETS IN TRIALS?

Chairpersons: Wolfgang Koenig (Munich, GER) & Giovanna Liuzzo (Rome, ITA)

Panelists: Chris O'Donnell (Novartis, CH), Kristen Fortney (BioAge, USA), Jyothis George (Nodthera, GBR), Charles Kaplan (Bitterroot Bio, AUS), Wolfgang Koenig (Munich, GER), Mori Krantz (FDA, USA), Klaus Ley (Augusta, GA, USA), Peter Libby (Boston, MA, USA), Giovanna Liuzzo (Rome, ITA), Preston Mason (Boston, MA, USA), Manuel Mayr (London, GBR), Reginald McNulty (Irvine, CA, USA), Niek Baksh Mohammadnia (Nijmegen, NED), Jorge Plutzky (Boston, MA, USA), Marzia Rigolli (Eli Lilly, USA), Maria Sejersten Ripa (Novo Nordisk, DNK), Fortunato Senatore (FDA, USA), Rouchelle Sriranjana-Rothwell (Cambridge, GBR)

East
Tuesday, December 8, 2026
14:30 -16:30

**PULMONARY ARTERIAL HYPERTENSION
PULMONARY ARTERIAL HYPERTENSION INNOVATIVE TRIALS DESIGNS**

Chairpersons: Marc Humbert (Paris, FRA) & Vallerie McLaughlin (Ann Arbor, MI, USA)

PDGF as a target in PAH: lessons from IMPRESS, IMPAHCT and PROSERA
Olivier Sitbon (Paris, FRA)

PDGF as a target in PAH: design of IMPROVE-PAH
Kelly Chin (Dallas, TX, USA)

Sotatercept in PAH: central, hematologic, and peripheral mechanisms of benefit
Yogesh Reddy (Rochester, MN, USA)

Activin signaling inhibitors safety signals in PAH trials
Iona Preston (Boston, MA, USA)

Drug development on top of drugs targeting four pathways: how?
Anna Hemnes (Nashville, TN, USA)

Investigator Viewpoints
Nick Hill (Boston, MA, USA)
Anjali Vaidya (Philadelphia, PA, USA)

Patient Viewpoint
Coleen Brunetti (Pulmonary Hypertension Association, USA)

Industry Viewpoints
Chris Cabell (Inhibikase, USA)
Ciaran McMullan (Merck, USA)
Franck Rahaghi (United Therapeutics, USA)
Rainer Zimmermann (Gossamer, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PULMONARY ARTERIAL HYPERTENSION INNOVATIVE DESIGNS

Chairpersons: Marc Humbert (Paris, FRA) & Vallerie McLaughlin (Ann Arbor, MI)

Panelists: Coleen Brunetti (Pulmonary Hypertension Association), Kelly Chin (Dallas, TX, USA), Chris Cabel (Inhibikase, USA), Bjorn Dahlof (Cereno, SWE), Hap Farber (Boston, MA, USA), Mardi Gomberg-Maitland (Washington, DC, USA), Anna Hemnes (Nashville, TN), Nick Hill (Boston, MA, USA), Marc Humbert (Paris, FRA), Steve Kawut (Philadelphia, PA, USA), Bradley Maron (Circulation, USA), Vallerie McLaughlin (Ann Arbor, MI, USA), Ciaran McMullan (Merck, USA), Mahesh Patel (Merck, USA), Iona Preston (Boston, MA, USA), Mitch Psotka (FDA, USA), Franck Rahaghi (United Therapeutics, USA), Yogesh Reddy (Rochester, MN, USA), Carlos Sanmarco (Pulmovant, USA), Oksana Shlobin (Falls Church, VA, USA), Olivier Sitbon (Paris, FRA), Derek Solum (United Therapeutics, NC), Mark Toshner (Cambridge, GBR), Anjali Vaidya (Philadelphia, PA, USA), Jean-Luc Vachiéry (Brussels, BE), Corey Ventetuolo (Providence, RI), Jason Weatherald (Edmonton, CA), Rainer Zimmermann (Gossamer, USA)

East
Tuesday, December 8, 2026
17:00 -19:00

PULMONARY HYPERTENSION NEXT FRONTIERS

Chairpersons: Mardi Gomberg-Maitland (Washington, DC) & Bradley Maron (Circulation, USA)

Concept of urgency in treatment of patients with pulmonary hypertension
Mardi Gomberg-Maitland (Washington, DC, USA)

Survival discrepancy between PAH patients eligible for clinical trials and clinical reality
Mark Toshner (Cambridge, GBR)

Heterogeneity of treatment effect in patients with PAH and co-existing mild lung diseases participating in randomized clinical trials
Steve Kawut (Philadelphia, PA, USA)

Remission as a goal in PAH
Jason Weatherald (Edmonton, CA)

Predictors of pulmonary hypertension in patients with interstitial lung disease
Corey Ventetuolo (Providence, RI, USA)

Pulmonary hypertension associated with interstitial lung diseases: Is it time to consider a morbidity and mortality primary endpoint?
Oksana Shlobin (Falls Church, VA, USA)

Pulmonary hypertension associated with left heart disease: Is it time to consider a morbidity and mortality primary endpoint?
Jean-Luc Vachiéry (Brussels, BE)

Investigator Viewpoints
Hap Farber (Boston, MA, USA)
Sandeep Sahay (Houston, TX, USA)

Patient Viewpoint
Coleen Brunetti (Pulmonary Hypertension Association, USA)

Industry Viewpoints
Mahesh Patel (Merck, USA), Carlos Sanmarco (Pulmovant, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PULMONARY HYPERTENSION NEXT FRONTIERS

Chairpersons: Mardi Gomberg-Maitland (Washington, DC) & Bradley Maron (Circulation, USA)

Panelists: Coleen Brunetti (Pulmonary Hypertension Association), Kelly Chin (Dallas, TX, USA), Chris Cabel (Inhibikase, USA), Bjorn Dahlof (Cereno, SWE), Hap Farber (Boston, MA, USA), Mardi Gomberg-Maitland (Washington, DC), Anna Hemnes (Nashville, TN), Nick Hill (Boston, MA, USA), Marc Humbert (Paris, FRA), Steve Kawut (Philadelphia, PA, USA), Bradley Maron (Circulation, USA), Vallerie McLaughlin (Ann Arbor, MI, USA), Ciaran McMullan (Merck, USA), Mahesh Patel (Merck, USA), Iona Preston (Boston, MA, USA), Mitch Psotka (FDA, USA), Franck Rahaghi (United Therapeutics, USA), Yogesh Reddy (Rochester, MN, USA), Sandeep Sahay (Houston, TX, USA), Carlos Sanmarco (Pulmovant, USA), Oksana Shlobin (Falls Church, VA, USA), Olivier Sitbon (Paris, FRA), Derek Solum (United Therapeutics, NC), Mark Toshner (Cambridge, GBR), Anjali Vaidya (Philadelphia, PA, USA), Jean-Luc Vachiéry (Brussels, BE), Corey Ventetuolo (Providence, RI), Jason Weatherald (Edmonton, CA), Rainer Zimmermann (Gossamer, USA)

State
Tuesday, December 8, 2026
08:30 -10:30

iCVCT #1

THROMBOSIS TRIALS. CAN WE UNCOUPLE THROMBOSIS FROM BLEEDING? **Chairpersons: Michael Gibson (Boston, MA, USA) & Carolyn Lam (Singapore, SGP)**

From neutral OCEANIC AF to positive OCEANIC-Stroke trial. Clot mechanics, active drug comparator, and levels of target inhibition.

Mike Sharma (Hamilton, ON, CAN)

Regeneron FXI inhibition AF trials.

Understanding Cerebral Hemorrhage Risk and its Relevance to Stroke Prevention Treatment Choices
Edip Gurol (Boston, MA, USA)

What comparator(s) and what endpoints in FXI VAD trials?"
Mandeep Mehra (Boston, MA, USA)

Mechanistic insights from the ROXI-CATH tests REGN9933 and REGN7508 contact activation (pic lines and indwelling catheters) trials
Jeff Weitz (Hamilton, CAN)

Are current trial well designed to figure whether FXIa inhibition is a new anticoagulant class — or a precision antithrombotic for selected thrombo-inflammatory vascular beds
Ken Mahaffey (Stanford, CA, USA)

Speed versus diagnostic certainty — Add-on versus replacement strategies?
Michael Gibson (Boston, MA, USA)

Industry viewpoints
Carlos Cuevas (BMS/J&J, USA), Anders Gabrielsen (Ribocure, SWE), David Gutstein (Regeneron, USA), András Gruber (Aronora, USA), Eva Muehlhofer (Bayer, GER)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

THE FUTURE OF THROMBOSIS INNOVATION. LARGE TARGETS VS. PRECISION-BIOLOGY BIOTECH ECOSYSTEMS?"

Chairpersons: Michael Gibson (Boston, MA, USA) & Carolyn Lam (Singapore, SGP)

Panelists: Carlos Cuevas (BMS/J&J, USA), Anders Gabrielsen (Ribocure, SWE), Michael Gibson (Boston, MA, USA), András Gruber (Aronora, USA), Edip Gurol (Boston, MA, USA), David Gutstein (Regeneron, USA), Carolyn Lam (Singapore, SGP), Ken Mahaffey (Stanford, CA, USA), Mandeep Mehra (Boston, MA, USA), Eva Muehlhofer (Bayer, GER), Mike Sharma (Hamilton, ON, CAN), Jeffrey Weitz (Hamilton, CAN)

State
Tuesday, December 8, 2026
11:00 -13:00

iCVCT # 2

PERCUTANEOUS VENTRICULAR ASSIST DEVICES TRIALS.

HIGH-RISK PCI , CARADIOGENIC SHOCK AND UNANSWERED QUESTIONS

Part #1: Percutaneous Mechanical Circulatory Support Devices for High-Risk PCI

Chairpersons: Mitch Krucoff (Durham, NC, USA) & Marie-Claude Morice (Massy, FRA)

Randomized Evidence Evaluating Percutaneous MCS for High-Risk PCI
Divaka Perera (London, GBR)

MCS for High-Risk PCI – What the Evidence Tells Us
Suzanne Baron (Boston, MA, USA)

Regulatory viewpoint
William Herzog (FDA, USA)

Industry viewpoint
Devi Govender (Abiomed, USA)

Update on Percutaneous Ventricular Assist Devices Academic Research Consortium. Endpoint and other trial design issues.
Jeffrey Popma (CRF, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT DEVICES FOR HIGH-RISK PCI

Chairpersons: Mitch Krucoff (Durham, NC, USA) & Marie-Claude Morice (Massy, FRA)

Panelists: Suzanne Baron (Boston, MA, USA), Dan Burkhoff (New York, NY, USA), Rafael Cavalcante (Boston Scientific, USA) , Kathleen Fenton (NIH, USA), Philippe Garot (CERC, FRA), Devi Govender (Abiomed, USA), William Herzog (FDA, USA), Navin Kapur (Abiomed/JnJ, USA), Mitch Krucoff (Durham, NC, USA), Christina Lalani (Boston, MA, USA), Craig Markovitz (Magenta Medical, ISR), Roxana Mehran (New York, NY, USA) , Marie-Claude Morice (Massy, FRA), Mauro Moscucci (FDA, USA), Divaka Perera (London, GBR), Jeffrey Popma (CRF, USA), Jon Resar (FDA, USA), Nitin Salunke (Supira Medical, USA), Robert Yeh (Boston, MA, USA), Bram Zuckerman (FDA, USA)

State
Tuesday, December 8, 2026
11:00 -13:00

iCVCT # 2
PERCUTANEOUS VENTRICULAR ASSIST DEVICES TRIALS
Part #2. Mechanical Circulatory Support Devices for Cardiogenic Shock
Chairpersons: Roxana Mehran (New York, NY, USA) & Robert Yeh (Boston, MA, USA)

Benefit/Risk of MCS In Stable Patients: The Critical Difference Defining «High Risk PCI» vs.»SCAI A (Pre-shock) CAD Phenotype
Michell Krucoff (Durham, NC, USA)

Clinical Trial Designs to Support Approval of New Shock Devices
Christina Lalani (Boston, MA, USA)

Pumps and Pills in Parallel: The INTeGRATE Trial in HF-Cardiogenic Shock
Alexandre Mebazaa (Paris, FRA)

Regulatory viewpoint
Jon Resar (FDA, USA)

Industry viewpoints
Navin Kapur (Abiomed/JnJ, USA), Craig Markovitz (Magenta Medical, ISR), Nitin Salunke (Supira Medical, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate
HIGH-RISK PCI, CARDIOGENIC SHOCK AND UNANSWERED QUESTIONS
Chairpersons: Roxana Mehran (New York, NY, USA) & Robert Yeh (Boston, MA, USA)

Panelists: Suzanne Baron (Boston, MA, USA), Dan Burkhoff (New York, NY, USA), Rafael Cavalcante (Boston Scientific, USA), Kathleen Fenton (NIH, USA), Philippe Garot (CERC, FRA), Devi Govender (Abiomed, USA), William Herzog (FDA, USA), Navin Kapur (Abiomed/JnJ, USA), Tenley Kreter (Supira Medical, USA), Mitch Krucoff (Durham, NC, USA), Christina Lalani (Boston, MA, USA), Craig Markovitz (Magenta Medical, ISR), Alexandre Mebazaa (Paris, FRA), Roxana Mehran (New York, NY, USA), Marie-Claude Morice (Massy, FRA), Divaka Perera (London, GBR), Jeffrey Popma (CRF, USA), Jon Resar (FDA, USA), Nitin Salunke (Supira Medical, USA), Robert Yeh (Boston, MA, USA)

State
Tuesday, December 8, 2026
14:30 -16:30

iCVCT # 3

**PCI WITHOUT PERMANENT CAGING - NEW DEVICES FOR DE NOVO CORONARY ARTERY
REVASCLARIZATION**

**Part 1: WILL A LEAVE-NOTHING-BEHIND STRATEGY FOR DE NOVO PCI IMPROVE LATE OUTCOMES
AFTER FIRST DES?**

Chairpersons: Donald Cutlip (Boston, MA, USA) & Robert Yeh (Boston, MA, USA)

Coronary disease: have we finally learned whom to revascularize?
Bernard Gersh (Rochester, MN, USA)

Avoiding first DES in favor of a nothing-behind strategy will improve late outcomes after PCI.
Gregg Stone (New York, NY, USA)

Late outcomes after PCI are unlikely to improve with a leave nothing behind strategy.
Ziad Ali (New York, NY, USA)

FDA viewpoint
Lydia Glaw (FDA, USA)

Industry viewpoints
Rafael Cavalcante (Boston Scientific, USA) Christopher Buller (Teleflex/Biotronik, CAN), Laura Mauri (Medtronic, USA)

Patient viewpoint
Bray Patrick-Lake (Evidation, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

LEAVE-NOTHING-BEHIND STRATEGY

Chairpersons: Donald Cutlip (Boston, MA, USA) & Robert Yeh (Boston, MA, USA)

Panelists: Ziad Ali (New York, NY, USA), Dom Alloco (Shockwave, USA), Christopher Buller (Teleflex/Biotronik, CAN), Rafael Cavalcante (Boston Scientific, USA), David Cohen (Boston, MA, USA), Donald Cutlip (Boston, MA, USA), Simon Eccleshall (Norwich, GBR), Andrew Farb (FDA, USA), Philippe Garot (CERC, FRA), Lydia Glaw (FDA, USA), Atul Gupta (Philips, USA), Bernard Gersh (Rochester, MN, USA), Ethan Korngold (Abbott, USA), Margaret McEntegart (Glasgow, GBR), Laura Mauri (Medtronic, USA), Roxana Mehran (New York, NY, USA), Bray Patrick-Lake (Evidation, USA), Giovanni Occhipinti (Barcelona, ESP), Motasim Sirhan (Elixir Medical, USA), Gregg Stone (New York, NY, USA), Stefan Verheye (Brussels, BEL), Ron Waksman (Washington, DC, USA), Robert Yeh (Boston, MA, USA), Bram Zuckerman (FDA, USA)

State
Tuesday, December 8, 2026
14:30 -16:30

iCVCT # 3

**PCI WITHOUT PERMANENT CAGING - NEW DEVICES FOR DE NOVO CORONARY ARTERY
REVASCLARIZATION**

Part 2: LEAVE LESS BEHIND STRATEGIES: COST, BENEFIT, INNOVATION AND SUSTAINABILITY

Chairpersons: Donald Cutlip (Boston, MA, USA) & Robert Yeh (Boston, MA, USA)

Drug-coated balloons for de novo lesions. Review of current clinical trial designs and future utilization.
Simon Eccleshall (Norwich, GBR)

Beyond the permanent cage: Can “uncaging devices” overcome the late failure of DES without repeating the bioresorbable-
scaffold experience..
Stefan Verheye (Brussels, BEL)

Health system viewpoint – Why Should We Pay for New Balloons/Stents/Scaffolds When DES Are So Affordable
Ron Waksman (Washington, DC, USA)

Industry viewpoints

Dom Alloco (Shockwave, USA), Atul Gupta (Philips, USA), Ethan Korngold (Abbott, USA), Motasim Sirhan (Elixir Medical, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

LEAVE-NOTHING VS. LEAVE LESS BEHIND STRATEGIES

Chairpersons: Donald Cutlip (Boston, MA, USA) & Robert Yeh (Boston, MA, USA)

Panelists: Ziad Ali (New York, NY, USA), Dom Alloco (Shockwave, USA), Christopher Buller (Teleflex/Biotronik, CAN), Rafael Cavalcante (Boston Scientific, USA), David Cohen (Boston, MA, USA), Donald Cutlip (Boston, MA, USA), Simon Eccleshall (Norwich, GBR), Atul Gupta (Philips, USA), Andrew Farb (FDA, USA), Philippe Garot (CERC, FRA), Lydia Glaw (FDA, USA), Bernard Gersh (Rochester, MN, USA), Ethan Korngold (Abbott, USA), Margaret McEntegart (Glasgow, GBR), Laura Mauri (Medtronic, USA), Roxana Mehran (New York, NY, USA), Bray Patrick-Lake (Evidation, USA), Giovanni Occhipinti (Barcelona, ESP), Motasim Sirhan (Elixir Medical, USA), Gregg Stone (New York, NY, USA), Stefan Verheye (Brussels, BEL), Ron Waksman (Washington, DC, USA), Robert Yeh (Boston, MA, USA), Bram Zuckerman (FDA, USA)

State
Tuesday, December 8, 2026
17:00 -19:00

**iCVCT # 4
VALVE TRIALS**

Part #1 ARE OUR CURRENT TRIAL DESIGNS “FIT FOR PURPOSE”?

Chairpersons : David Cohen (Boston, MA, USA) & Vinod Thourani (Atlanta, GA, USA)

Device vs. device Trials: Considerations for endpoint selection
Chad Kliger (FDA, USA)

Quality of Life is the Main Benefit of TTVI—Why not Make it the Primary Endpoint of Device vs. Device Trials?
Suzanne Arnold (Kansas City, MO, USA)

Statistician viewpoint: Multiple Comparators, Crossover and Bayesian issues
Ben Saville (Austin, TX, USA)

Are Device vs. Device trials even Appropriate?
Juan Granada (New York, NY, USA)

Should Cardiac Surgery be in the Mix? The Case for Trials vs. Surgery
Gorav Ailawadi (Ann Arbor, MI, USA)

Panel Discussion

ARE OUR CURRENT TRIAL DESIGNS “FIT FOR PURPOSE”?

Chairpersons : David Cohen (Boston, MA, USA) & Vinod Thourani (Atlanta, GA, USA)

Panelists: Gorav Ailawadi (Ann Arbor, MI, USA), Suzanne Arnold (Kansas City, MO, USA), Suzanne Baron (Boston, MA, USA), Wayne Batchelor (Orlando, FL, USA), Rishi Chandiramani (Baltimore, MD, USA), David Cohen (Boston, MA, USA), Philippe Garot (CERC, FRA), Juan Granada (New York, NY, USA), Kendra Grubb (Medtronic, USA), Aakriti Gupta (New York, NY, USA), Sanjay Kaul (Los Angeles, CA, USA), Chad Kliger (FDA, USA), Michael Mack (Dallas, TX, USA), Roxana Mehran (New York, NY, USA), Marie-Claude Morice (Massy, FRA), Mark Reisman (Edwards, USA), Frederic Resnic (Burlington, MA, USA), Ben Saville (Austin, TX, USA), Sreek Vemulapalli (Durham, NC, USA), Vinod Thourani (Atlanta, GA, USA), Changfu Wu (FDA, USA)

State
Tuesday, December 8, 2026
17:00 -19:00

iCVCT # 4
TRICUSPID VALVE INNOVATION
Part #2 THE TVT REGISTRY AT THE CROSSROADS
Chairpersons : David Cohen (Boston, MA, USA) & Vinod Thourani (Atlanta, GA, USA)

The TVT Registry- Lessons from the First 15 Years.
Michael Mack (Dallas, TX, USA)

A View from the Trenches— What I Wish we Had Done Differently.
Sreek Vemulapalli (Durham, NC, USA)

Are EHR-Based Solutions a Viable Alternative?
Frederic Resnic (Burlington, MA, USA)

Industry viewpoints
Kendra Grubb (Medtronic, USA), Nadim Geloo (Abbott, USA)

Regulatory viewpoint
Changfu Wu (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate
TRICUSPID VALVE INNOVATION – LESSONS FROM TRIALS AND REGISTRIES
Chairpersons : David Cohen (Boston, MA, USA) & Vinod Thourani (Atlanta, GA, USA)

Panelists: Gorav Ailawadi (Ann Arbor, MI, USA), Suzanne Arnold (Kansas City, MO, USA), Suzanne Baron (Boston, MA, USA), Wayne Batchelor (Orlando, FL, USA), Rishi Chandiramani (Baltimore, MD, USA), David Cohen (Boston, MA, USA), Philippe Garot (CERC, FRA), Nadim Geloo (Abbott, USA), Juan Granada (New York, NY, USA), Kendra Grubb (Medtronic, USA), Aakriti Gupta (New York, NY, USA), Sanjay Kaul (Los Angeles, CA, USA), Chad Kliger (FDA, USA), Michael Mack (Dallas, TX, USA), Roxana Mehran (New York, NY, USA), Marie-Claude Morice (Massy, FRA), Mark Reisman (Edwards, USA), Frederic Resnic (Burlington, MA, USA), Ben Saville (Austin, TX, USA), Sreek Vemulapalli (Durham, NC, USA), Vinod Thourani (Atlanta, GA, USA), Changfu Wu (FDA, USA)

**Ballroom
Tuesday, December 8, 2026
08:30 -10:30**

**ACC-CVCT JOINT SESSION
AI MASTER CLASS 4**

**FROM BORROWED TO BUILT: HOW FAR CAN WE GO WITHOUT ENROLLING A PATIENT?
EMULATING, BORROWING, GENERATING AI AND SIMULATING TRIAL DATA
CAN REGULATORS AND CLINICIANS STILL TRUST IT?**

Chairpersons: Rohan Khera (New Haven, CT, USA) & Harlan Krumholz (JACC, USA)

Every control arm we randomize costs money, costs time, and exposes patients to a treatment we already believe is inferior. Four distinct technologies now propose to shrink or replace it: emulating trials from routinely collected data, borrowing control patients from completed trials, generating patients with AI, and simulating them from physiology. Each rests on a different assumption and each fails in a different way — exchangeability for the first two, model fidelity for the third, verification and validation for the fourth. This session climbs the four rungs in order and asks, at each one, what a regulator has actually accepted and what remains a promise.

Framework for Regulatory/Community Acceptance of AI-Generated Data: Context of Use, Model Influence, and Decision Consequence

Jonathan Cunningham (Boston, MA, USA)

From replicating trial findings with healthcare data to robust trial-anchored non-randomized evidence.

Sebastian Schneeweiss (Boston, MA, USA)

Real patients, borrowed: external and synthetic control arms

Stéphanie Allasonnière (Paris, FRA)

Digital Twins and In Silico Control Arms: When Are They Valid?

Blanca Rodriguez (Oxford, GBR)

Simulated patients: in silico clinical trials

Emmanuelle Pham (NovoInSilico, FRA)

EHR-based eligibility surveillance and automated patient recruitment

Michael Gibson (Boston, MA, USA)

AI-Assisted clinical trials screening

Alexander Blood (AlwithCare, USA)

Industry Perspective

Alexandra Goncalves (BMS, USA)

Regulatory Perspective

Marco Viceconti (Bologna, IT)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**WITHIN 10 YEARS, AI- AND MODEL-GENERATED EVIDENCE WILL BE ACCEPTED AS EQUIVALENT TO
TRADITIONAL TRIAL EVIDENCE — AND THIS IS A GOOD THING**

Chairpersons : Rohan Khera (New Haven, CT, USA) & Harlan Krumholz (JACC, USA)

Panelists: Stéphanie Allasonnière (Paris, FRA), Auriel August (Santé Ventures, USA), Alexander Blood (AlwithCare, USA), Jonathan Cunningham (Boston, MA, USA), Viral Gandhi (Aviga Health, USA), Michael Gibson (Boston, MA, USA), Alexandra Goncalves (BMS, USA), Rohan Khera (New Haven, CT, USA), Harlan Krumholz (JACC, USA), Emmanuelle Pham (NovoInSilico, FRA), Blanca Rodriguez (Oxford, GBR), Sebastian Schneeweiss (Boston, MA, USA), Marco Viceconti (Bologna, IT)

Ballroom
Tuesday, December 8, 2026
11:00 -13:00

INDUSTRY-ACADEMIA TRIALISTS' INTERACTIONS

Chairpersons: Biykem Bozkurt (Houston, TX, USA) & Scott Solomon (Boston, MA, USA)

Innovation and Excellence - The Importance of Industry-Academic Collaborations
Rob Califf (Durham, NC, USA)

Safeguarding the Industry-Academic Relationship
Marc Pfeffer (Boston, MA, USA)

Investigator Access to Data
Scott Solomon (Boston, MA, USA)

Use of biosamples and the Investigators' Access to biobanks
Faiez Zannad (Paris, FRA)

Journal Editors' Viewpoints
Barbara Casadei (JAMA Cardiology)
Filippo Crea (EHJ, IT)
Flavia Geraldes (The Lancet, GBR)
Harlan Krumholz (JACC, USA)
Jane Leopold (NEJM, USA)
Bradley Maron (Circulation, USA)

Ensuring Trust in Clinical Trials – Patient Perspective
Corinne Hudson (Pumping Marvellous, GBR)

Industry Viewpoints
Sameer Bansilal (Alnylam, USA), Antonieta Bomfim (Boehringer Ingelheim, GER), Steve Heitner (Cytokinetics, USA), Mahesh Patel (Merck, USA), Katja Rohwedder (Bayer, GER)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

INDUSTRY-ACADEMIA TRIALISTS' INTERACTIONS: SHARING IS TRUST!

Chairpersons: Biykem Bozkurt (Houston, TX, USA) & Scott D. Solomon (Boston, MA, USA)

Panelists: Sameer Bansilal (Alnylam, USA), (Bayer, GER), Antonieta Bomfim (Boehringer Ingelheim, GER), Biykem Bozkurt (Houston, TX, USA), Robert Califf (Durham, NC, USA), Barbara Casadei (JAMA Cardiology), Filippo Crea (EHJ, IT), Mariana Fontana (London, GBR), Flavia Geraldes (The Lancet, GBR), Steve Heitner (Cytokinetics, USA), Corinne Hudson (Pumping Marvellous, GBR), Harlan Krumholz (JACC, USA), Jane Leopold (NEJM, USA), Bradley Maron (Circulation, USA), Mahesh Patel (Merck, USA), Marc Pfeffer (Boston, MA, USA), Katja Rohwedder (Bayer, GER), Scott D. Solomon (Boston, MA, USA), Faiez Zannad (Paris, FRA)

Ballroom
Tuesday, December 8, 2026
14:30 -16:30

OBESITY MEDICINE: NEW DATA AND BIG QUESTIONS

Chairpersons: Ildi Lingvay (Dallas, TX, USA) & Naveed Sattar (Glasgow, GBR)

Known and recent cardiovascular outcome data from incretin-based CVOTs
Ildi Lingvay (Dallas, TX, USA)

Women's health, liver disease and cardiovascular prevention
Marat Fudim (Durham, NC, USA)

Ongoing CVOTs of obesity medicines: what gaps in knowledge will they fill?
Jennifer Green (Durham, NC, USA)

To what extent is weight loss the mechanism of CV and other benefits: what do we really know?
Naveed Sattar (Glasgow, GBR)

How to investigate the anti-inflammatory effects of GLP-1 agonists in clinical trials?
Jorge Plutzky (Boston, MA, USA)

Do incremental MOAs for weight loss really make a difference?
Javed Butler (Dallas, TX, USA)

The Death of the Pure Placebo? Navigating GLP-1 Cross-Over in Future Outcome Trials
Odd Erik (Roche, CH)

Industry viewpoints: What future CVOTs design would companies like FDA to consider
Filip Knop (NovoNordisk, DNK), Li Li (Innovent Biologics, CHN)

FDA/EMA: What future CVOTs design would regulator be willing to accept?
TBD (FDA, USA)
TBD (EMA)

Patient viewpoint: What do patients wish to see in future trials?
Joseph Nadglowski (Obesity Action Coalition, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

NEXT FRONTIERS FOR OBESITY TRIALS

Chairpersons: Ildi Lingvay (Dallas, TX, USA) & Naveed Sattar (Glasgow, GBR)

Panelists: Javed Butler (Dallas, TX, USA), Odd Erik (Roche, CH), Marat Fudim (Durham, NC, USA), Jennifer Green (Durham, NC, USA), Filip Knop (NovoNordisk, DNK), Ildiko Lingvay (Dallas, TX, USA), Li Li (Innovent Biologics, CHN), Joseph Nadglowski (Obesity Action Coalition, USA), Steven Nissen (Cleveland, OH, USA), Jorge Plutzky (Boston, MA, USA), Naveed Sattar (Glasgow, GBR), Raymond Soccio (FDA, USA), Faiez Zannad (Paris, FRA)

Ballroom
Tuesday, December 8, 2026
17:00 -19:00

CVCT GREAT DEBATES

Chairpersons: Barbara Casadei (JAMA Cardiology) & Jane Leopold (NEJM, USA)

Debate 1

Oral diuretic intensification should be included in the composite endpoint for HF failure

Pro: Harriette Van Spall (Hamilton, CAN)

Con: Javed Butler (Dallas, TX, USA)

Debate 2

It is time to have multi-organ multi-endpoint composites for cardiovascular trials

Pro: Faiez Zannad (Paris, FRA)

Con: Milton Packer (Dallas, TX, USA)

Debate 3

Device trials should be judged differently than drug trials due to size/design limitations

Pro: William Abraham (Columbus, OH, USA)

Con: Mark Petrie (Glasgow, GBR)

Debate 4

Coronary revascularization should be included in expanded MACE endpoint

Pro: Roxana Mehran (New York, NY, USA)

Con: Scott Solomon (Boston, MA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

CVCT GREAT DEBATES

Chairpersons: Barbara Casadei (JAMA Cardiology) & Jane Leopold (NEJM, USA)

Panelists: William Abraham (Columbus, OH, USA), Javed Butler (Dallas, TX, USA), Barbara Casadei (JAMA Cardiology), Maria Rosa Costanzo (Naperville, IL, USA), Jane Leopold (NEJM, USA), Steven Macari (AVEC, FRA), Roxana Mehran (New York, NY, USA), Milton Packer (Dallas, TX, USA), Mark Petrie (Glasgow, GBR), Scott D. Solomon (Boston, MA, USA), Harriette Van Spall (Hamilton, CAN), Faiez Zannad (Paris, FRA)

**Palm court
Wednesday, December 9, 2026
08:00 -10:00**

**ESC-CVCT JOINT SESSION
LBCT 1
Chairpersons: TBD**

Session under construction

**The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 1
Chairpersons: TBD**

Palm court
Wednesday, December 9, 2026
10:00 -12:00

CARDIOVASCULAR GENE THERAPY TRIALS: WHY IS TRANSLATION SO DIFFICULT?
Chairpersons : Deborah Ascheim (Boston, MA, USA) & Andrew Baker (Edinburgh, GBR)

Contrasting irreversible genomic intervention with the conservative cardiovascular outcomes trial culture.
Deborah Ascheim (Boston, MA, USA)

Target patient populations

Who should receive an irreversible therapy?
Jonathan Kimmelman (Montreal, CAN)

Gene therapy for prevention of vein graft failure
Andrew Baker (Edinburgh, GBR)

What duration is sufficient for approval in the context of durability—reversibility of expression?
Roger Hajjar (Boston, MA, USA)

How and how long to monitor the safety of irreversible overexpression and DSMB-related issues.
Marc Bonaca (Aurora, CO, USA)

Gene therapy for rare diseases (5min each)

Danon Disease and Rare Disease Clinical Translation
Barry Greenberg (San Diego, CA, USA)

Rare Cardio-Neuro Disorders and Precision Cardiomyopathies
Alessia Argirò (Florence, ITA)

LMNA Cardiomyopathy and Mechanobiology
Monica Shah (Nuevocor, Singapore, SGP)

Genetic Therapies for Inherited Life-Threatening Arrhythmias: From CPVT to LQT8
Silvia Priori (Pavia, ITA)

Duchenne muscular dystrophy
Gabriel Brooks (Solidbio, USA)

Statistical viewpoint. Challenges in Rare Cardiovascular Disease. How much evidence-flexibility is acceptable?
Janet Wittes (Wittes LLC, USA)

Patient Perspectives and Acceptance of an irreversible therapy.
Pieter Glijnis (Phospholamban Foundation, NED)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

CREATIVE CLINICAL TRIALS SOLUTIONS FOR ADVANCING GENE THERAPY
Chairpersons: Deborah Ascheim (Boston, MA, USA) & Andrew Baker (Edinburgh, GBR)

Panelists : Alessia Argirò (Florence, ITA), Deborah Ascheim (Boston, MA, USA), Andrew Baker (Edinburgh, GBR), Marc Bonaca (Aurora, CO, USA), Gabriel Brooks (Solidbio, USA), Barry Greenberg (San Diego, CA, USA), Pieter Glijnis (Phospholamban Foundation, NED), Roger Hajjar (Boston, MA, USA), Jonathan Kimmelman (Montreal, CAN), Monica Shah (Nuevocor, SGP), Silvia Priori (Pavia, ITA), Janet Wittes (Wittes LLC, USA)

**Palm court
Wednesday, December 9, 2026
13:30 -16:30**

THE NEXT GENERATION OF CARDIOVASCULAR GENETIC MEDICINE

Part 1

Chairpersons: Roger J. Hajjar (Boston, MA, USA) & Seppo Ylä-Herttuala (Kuopio, FIN)

Where Cardiovascular Gene Therapy Becomes Clinical Reality.

To this purpose, the CVCT Gene Therapy Trials sessions will explore the transition from first-generation AAV cardiac gene therapy toward scalable cardiovascular genetic medicine. This includes

- Convergence of gene therapy, gene editing, RNA therapeutics, and engineered delivery systems
- Rare monogenic cardiomyopathies versus broad, high-prevalence heart failure indications.
- Clinical trial design evolution in advanced therapeutics
- Regulatory acceleration pathways and “plausible mechanism” frameworks
- Cardiovascular inflammation, fibrosis, and precision endotyping
- Next-generation vector engineering and repeat dosing strategies
- Real-world translational lessons from active clinical programs
- The emergence of gene editing in cardiovascular disease

**Opening Perspective. Cardiovascular Genetic Medicine Has Entered Its Second Era
Roger Hajjar (Boston, MA, USA)**

**Disease Mechanisms and Precision Endotyping.
Victoria Parikh (Stanford, CA, USA)**

**Cardiac Angiogenesis and Therapeutic Vascular Gene Transfer
Seppo Ylä-Herttuala (Kuopio, FIN)**

**Cardiac Regeneration in the Clinic
James Martin (Dallas, TX, USA)**

PART 1 DISCUSSION

Panelists : Narinder Bhalla (Lexeo Therapeutics, USA), Gabriel Brooks (Solid Biosciences, USA), Roger Hajjar (Boston, MA, USA), Christophe Hotermans (Alexion, USA) Kiyotake Ishikawa (New York, NY, USA), James Kim (Medera, USA), Kevin Costa (Novoheart, CAN), James Martin (Dallas, TX, USA), Maritza McIntyre (Former CBER Director, FDA, USA), Victoria Parikh (Stanford, CA, USA), Luke Roberts (Bayer, GER), Lothar Roessig (AskBio, GER), Whit Tingley (Tenaya Therapeutics, USA), Seppo Ylä-Herttuala (Kuopio, FIN)

**Palm court
Wednesday, December 9, 2026
13:30 -16:30**

**THE NEXT GENERATION OF CARDIOVASCULAR GENETIC MEDICINE
PART 2 : DELIVERY: ARE WE TESTING THE GENE OR THE PROCEDURE? OUTCOMES MAY DEPEND MORE
ON DELIVERY SUCCESS THAN BIOLOGICAL CONSTRUCT QUALITY**

Chairpersons: Roger J. Hajjar (Boston, MA, USA) & Seppo Ylä-Herttuala (Kuopio, FIN)

Advanced Cardiac Gene Delivery Platforms
Kiyotake Ishikawa (New York, NY, USA)

Cardiac gene delivery and next-generation capsids.
Gabriel Brooks (Solid Bio, USA)

Precision cardiac gene delivery & Hemodynamic Endpoints in heart failure
James Kim (Medera, USA)

Human Engineered Tissue and IND-Enabling Translation
Kevin Costa (Novoheart, USA)

Neutralizing Antibodies and the GENEPHIT Experience
Luke Roberts (Bayer, GER)

Large-Scale Translation of Cardiovascular Gene Therapy
Lothar Roessig (Askbio, GER)

Hypertrophic Cardiomyopathy Programs
Whit Tingley (Tenaya Therapeutics, USA)

BAG3 Cardiomyopathy and the UPBEAT Trial
Christophe Hotermans (Alexion, USA)

Friedreich Ataxia Cardiomyopathy and Rare Disease Translation
Greg Aubert (Lexeo Therapeutics, USA)

Regulatory Viewpoints
Maritza McIntyre (Ex CBER director FDA, USA)
Jan Müller-Berghaus (EMA, GER)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

GENE THERAPY TRANSLATABILITY AND READINESS FOR CLINICAL STAGE

Chairpersons: Roger J. Hajjar (Boston, MA, USA) & Seppo Ylä-Herttuala (Kuopio, FIN)

Panelists : Greg Aubert (Lexeo Therapeutics, USA), Gabriel Brooks (Solid Biosciences, USA), Roger Hajjar (Boston, MA, USA), Christophe Hotermans (Alexion, USA), Kiyotake Ishikawa (New York, NY, USA), James Kim (Medera, USA), Kevin Costa (Novoheart, CAN), James Martin (Dallas, TX, USA), Maritza McIntyre (Former CBER Director, FDA, USA), Jan Müller-Berghaus (EMA, GER), Victoria Parikh (Stanford, CA, USA), Luke Roberts (Bayer, GER), Lothar Roessig (AskBio, GER), Whit Tingley (Tenaya Therapeutics, USA), Seppo Ylä-Herttuala (Kuopio, FIN)

Palm court
Wednesday, December 9, 2026
17:00 -19:00

ELECTROPHYSIOLOGY WILL BE PART OF STROKE PREVENTION IN 2030
Chairpersons: Paulus Kirchhof (Hamburg, GER) & Ken Mahaffey (Stanford, CA, USA)

PFA at Five: The Energy Source That Changed AF Ablation
Arian Sultan (Hamburg, GER)

AF Burden and Stroke Risk: Can we measure more to treat less?
Lindsay Rosman (Chapel Hill, NC, USA)

EAST-AFNET 4, OCEAN, ALONE, OPTION: Is rhythm control a stroke-prevention therapy?
Jason Andrade (Vancouver, CAN)

Debate: "Ready or Reckless: Are left atrial occluders a valid replacement for oral anticoagulation?"

PRO: Oussama Wazni (Cleveland, OH, USA)
CON: Atul Verma (Hamilton, CAN)

Better stroke prevention with novel drugs: Factor XI antagonists for stroke prevention
Ken Mahaffey (Stanford, CA, USA)

The 'EP Collaboratory' proposal: addressing systemic challenges in clinical trials
Paul Wang (Stanford, CA, USA)

NIH Viewpoint
Patrice Desvigne-Nickens (NIH/NHLBI, USA)

Industry Viewpoint: "Can Industry Build Comparative Evidence Without Killing Innovation?"
Greg Michaud (JnJ, USA)

Industry Viewpoint: "Anticoagulation in 2030: A Pharma Perspective on the Patients We Still Aren't Reaching"
Carlos Cuevas (BMS, USA)

Industry Viewpoint: "Beyond Anticoagulation: A Biotech Perspective on Residual Stroke Risk in AF"
David Gutstein (Regeneron, USA)

Industry Viewpoint: "Rhythm control and LAAO. A Medtech perspective on stroke prevention"
Kenneth Stein (Boston Scientific, USA)

Patient Viewpoint: "Stroke and bleeds: What matters for AF patients"
Trudie Lobban (London, GBR)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HOW ELECTROPHYSIOLOGY MAY BE PART OF STROKE PREVENTION IN 2030?
Chairpersons: Paulus Kirchhof (Hamburg, GER) & Ken Mahaffey (Stanford, CA, USA)

Panelists : Jason Andrade (Vancouver, BC, CAN), Carlos Cuevas (BMS, USA), Patrice Desvigne-Nickens (NIH/NHLBI, USA), David Gutstein (Regeneron, USA), Paulus Kirchhof (Hamburg, DEU), Trudie Lobban (London, GBR), Kenneth Mahaffey (Stanford, CA, USA), John Mandrola (Louisville, KY, USA), Greg Michaud (JnJ, USA), Puneet Mohan (BMS-Pfizer, USA), Yogesh Reddy (Rochester, MN, USA), Lindsay Rosman (Chapel Hill, NC, USA), Kimberly Selzman (FDA, USA), Kenneth Stein (Boston Scientific, USA), Arian Sultan (Hamburg, GER), Atul Verma (Hamilton, CAN), Oussama Wazni (Cleveland, OH, USA), Paul Wang (Stanford, CA, USA)

East
Wednesday, December 9, 2026
08:00 -10:00

ESC-CVCT JOINT SESSION
LBCT 2
Chairpersons: TBD

Session under construction

The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 2
Chairpersons: TBD

East
Wednesday, December 9, 2026
10:30 -12:30

HEART FAILURE MEETS ELECTROPHYSIOLOGY: THE QUESTIONS THAT WON'T GO AWAY **Chairpersons: Javed Butler (Dallas, TX, USA) & Tina Baykaner (Stanford, CA, USA)**

AF ablation outcome trials: The EP community is growing up
Emma Svennberg (Stockholm, SWE)

Debate: "AF ablation in HFrEF: The question is answered!"
PRO: Christian Sohns (Hannover, GER)
CON: Mark Petrie (Glasgow, GBR)

Bidirectional effects of cardiometabolic drugs on atrial and ventricular function.
Anne-Christine Ruwald (Copenhagen, DK)

Beyond the Primary Endpoint: Can Atrial Fibrillation Be Better Tracked in Heart Failure Trials?
Nicolas Girerd (Nancy, FRA)

AF burden and heart failure trajectories: Known unknowns.
Paulus Kirchhof (Hamburg, GER)

Industry Viewpoint: "Measuring More, Treating Smarter": Industry View of HF–EP Trial Design"
Nirav Patel (Medtronic, USA)

Industry Viewpoint: Entresto and Beyond: Reimagining Disease Modification Across the HF–AF Continuum
Steve Lubitz (Novartis, USA)

Industry Viewpoint: "Connecting HF and AF: A Pharma Perspective on Anticoagulation,
Cardiorenal Protection, and Trial Design"
Maria Borentain (Bayer, GER)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

ROADMAP FOR HEART FAILURE & ELECTROPHYSIOLOGY TRIALISTS COLLABORATIONS **Chairpersons: Javed Butler (Dallas, TX, USA) & Tina Baykaner (Stanford, CA, USA)**

Panelists :Tina Baykaner (Stanford, CA, USA), Maria Borentain (Bayer, GER), Javed Butler (Dallas, TX, USA), Kieran Docherty (Glasgow, GBR), Nicolas Girerd (Nancy, FRA), Paulus Kirchhof (Hamburg, GER), Steve Lubitz (Novartis, USA), John Mandrola (Louisville, KY, USA), Nirav Patel (Medtronic, USA), Mark Petrie (Glasgow, GBR), Anne-Christine Ruwald (Copenhagen, DNK), Christian Sohns (Hannover, GER), Emma Svennberg (Stockholm, SWE)

East
Wednesday, December 9, 2026
13:30 -16:30

**CVCT-THT JOINT SYMPOSIUM
DEVICE THERAPIES FOR HEART FAILURE
SLOW DEVELOPMENT AND SLOW ADOPTION
WHAT IS THE PROBLEM AND WHAT CAN WE DO?**

Chairpersons: Dan Burkhoff (New York, NY, USA) & Faiez Zannad (CVCT, Paris, FRA)

Should devices always follow failure of comprehensive drug therapy?
Finn Gustafsson (Abbott, USA)

What is the development and adoption landscape?
Marat Fudim (Durham, NC, USA)

Can In-Silico Evidence Address the Device Development Bottleneck
Simon Sonntag (Virtonomy, GER)

Impediments and solutions to more sham control trials
Rita Redberg (San Francisco, CA, USA)

Why not more event driven trials? When and how
Robert Mentz (Durham, NC, USA)

Maximizing follow-up, Open Label Extension, and Real World Evidence
Maria Rosa Costanzo (Naperville, IL, USA)

Diuretic intensification and GDMT change – endpoints?
Javed Butler (Dallas, TX, USA)

PRO assessment, sham, blinding and placebo adjustment
Gregg Stone (New York, NY, USA)

Endpoints – hierarchical, Bayesian – what will work and what will be believe in?
Graeme Hickey (Medtronic, USA)

What evidence is needed for payer?
JoAnna Baldwin (CMS, USA)
Sari Ormstad (EU JCA, NOR)

Industry Perspective
Philip Adamson (CVRx, USA), Navin Kapur (Abiomed/JnJ, USA), John Brumfield (Berlin Heals, GER)

FDA Perspective
Ileana Pinea (FDA, USA)

Patient viewpoint
Corinne Hudson (Pumping Marvellous, GBR)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**DEVICE THERAPIES FOR HEART FAILURE. SLOW DEVELOPMENT AND SLOW ADOPTION
WHAT IS THE PROBLEM AND WHAT CAN WE DO?**

Chairpersons: Dan Burkhoff (New York, NY, USA) & Faiez Zannad (CVCT, Paris, FRA)

Panelists : Philip Adamson (CVRx, USA), JoAnna Baldwin (CMS, USA), John Brumfield (Berlin Heals, GER), Dan Burkhoff (New York, NY, USA), Javed Butler (Dallas, TX, USA), Maria Rosa Costanzo (Naperville, IL, USA), Andrew Farb (FDA, USA), Marat Fudim (Durham, NC, USA), Finn Gustafsson (Abbott, USA), Graeme Hickey (Medtronic, USA), Corinne Hudson (Pumping Marvellous, GBR), Navin Kapur (Abiomed/JnJ, USA), Robert Mentz (Durham, NC, USA), Rhonda Monroe, (Charlotte, USA), Sari Ormstad (EU JCA, NOR), Ileana Pinea (FDA, USA), Rita Redberg (San Francisco, CA, USA), Simon Sonntag (Virtonomy, GER), Gregg Stone (New York, NY, USA), Faiez Zannad (CVCT, Paris, FRA).

East
Wednesday, December 9, 2026
17:00 -19:00

**FROM EVIDENCE GENERATION TO UPTAKE
IMPLEMENTATION SCIENCE AND PAYMENT REFORM IN CARDIOMETABOLIC MEDICINE**
Chairpersons: Ankeet S. Bhatt (San Francisco, CA, USA) and Neha Pagidipati (Durham, NC, USA)

Why positive CV trials still fail at uptake
Ankeet S. Bhatt (San Francisco, CA, USA)

Designing phase 3 trials for implementation from day 1
Harriette Van Spall (Hamilton, CAN)

Can pragmatic health-system trials help?
Tor Beiring Sorenson (Copenhagen, DEN)

FDA's Total Life Cycle Advisory Program (TAP)
April Marrone (FDA, USA)

Implementation of science for equity in HF and cardiometabolic care
Mariam Elmegaard (Herlev, DEN)

Financial Toxicity
Karen Joynt Maddox (St. Louis, MO, USA)

Payment reform and New Models
Rishi Wadhera (Boston, MA USA)

Payer/HTA perspective: coverage, affordability, and access after positive trials
Jaime Murillo (Bogotá, COL)

Industry Perspectives
Udi Fainberg (Novo Nordisk, DNK)

Patient Perspective
Steven Macari (AVEC, FRA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

IMPLEMENTATION-READY EVIDENCE GENERATION
Chairpersons: Ankeet S. Bhatt (San Francisco, CA, USA) & Neha Pagidipati (Durham, NC, USA)

Panelists : Ankeet S. Bhatt (San Francisco, CA, USA), Mariam Elmegaard (Herlev, DEN), Udi Fainberg (Novo Nordisk, DNK), Karen Joynt Maddox (St. Louis, MO, USA), Steven Macari (AVEC, FRA), April Marrone (FDA, USA), Jaime Murillo (Bogotá, COL), Neha Pagidipati (Durham, NC, USA), Tor Beiring Sørensen (Copenhagen, DNK), Harriette Van Spall (Hamilton, ON, CAN), Rishi Wadhera (Boston, MA, USA)

State
Wednesday, December 9, 2026
08:00 -10:00

ESC-CVCT JOINT SESSION
LBCT 3
Chairpersons: TBD

Session under construction

The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 3
Chairpersons: TBD

State
Wednesday, December 9, 2026
10:30 -12:30

CVCT-NIH/NHLBI joint session
THE TRIAL YOU DIDN'T KNOW YOU WERE RUNNING: IMPLEMENTATION PROBLEMS AS
CARDIOVASCULAR SCIENCE

Chairpersons: Cara Lewis (NIH/NHLBI, USA) & Harriette Van Spall (Hamilton, CAN)

Some of the most consequential cardiovascular research of the past two decades didn't start with a molecule or a device — it started with a clock. When door-to-balloon time got attention, something deceptively radical occurred: treating the process of care delivery as a scientific problem worthy of rigorous investigation. The result was a body of evidence that changed how hospitals are organized, not just what drugs or devices they use.

This session invites cardiovascular trialists to look at their own work through the same lens: within or alongside the trials you are already running, what are the implementation problems hiding in plain sight?

Welcome and framing: What the clock taught us — the door-to-balloon story as a model for cardiovascular science
George Mensah (NIH/NHLBI, USA)

From trialist to implementation scientist: Rethinking what counts as a research question
Muthiah Vaduganathan (Boston, MA, USA)

The evidence-practice gap: When the evidence is sufficient, but the system is not
Christopher Granger (Durham, NC, USA)

Delivery as intervention: Designing trials around the prevention gap
Clara Chow (Sydney, AUS)

Where the gap is widest: Implementation science in low- and middle-income country cardiovascular care
Mohan Sailesh (New Delhi, IND)

The methodological toolkit: How to turn a care delivery problem into a rigorous trial
Mark Huffman (St Louis, MO, USA)

Journal Editors' Viewpoint: What journals need to see — making implementation science publishable in high-impact cardiovascular medicine
Flavia Geraldès (The Lancet, GBR)

Should implementation outcomes be co-primary endpoints in phase 3 cardiovascular trials?
Harriette Van Spall (Hamilton, CAN)

Who is responsible for closing the evidence-to-practice gap — trialists, health systems, regulators, or journals?
Filippo Crea (ESC, London, GBR)

Global perspective and implementation a large scale.
Christina Mack (IQVIA, USA)
Vaseeharan Sathiyamoorthy (WHO, GBR)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

IF THE GAP BETWEEN EVIDENCE AND PRACTICE IS THE HIGHEST-YIELD TARGET IN CARDIOVASCULAR
MEDICINE, WHAT IS STOPPING US?

Chairpersons: Cara Lewis (NIH/NHLBI, USA) & Harriette Van Spall (Hamilton, CAN)

Panelists : Clara Chow (Sydney, AUS), Filippo Crea (ESC, London, UK), Anthony Etyang (Kilifi, KEN), Flavia Geraldès (The Lancet, GBR), Christopher Granger (Durham, NC, USA), Mark Huffman (St. Louis, MO, USA), Cara Lewis (NIH/NHLBI, USA), Steven Macari (AVEC, FRA), Christina Mack (IQVIA, USA), George Mensah (NIH/NHLBI, USA), Mohan Sailesh (New Delhi, IND), Vaseeharan Sathiyamoorthy (WHO, GBR), Muthiah Vaduganathan (Boston, MA, USA), Harriette van Spall (Hamilton, ON, CAN)

State
Wednesday, December 9, 2026
13:30 -16:30

WEARABLES IN CARDIOVASCULAR CLINICAL TRIALS: FROM SIGNAL TO ENDPOINT PART 1: FROM MEASURE TO ENDPOINT

Chairpersons: Jessilyn Dunn (Durham, NC, USA) & Abhinav Sharma (Montreal, CAN)

The 2025 CVCT wearables session ("Wearables for CV Trials") and AI Masterclass established that wearables are ready to participate in trials. The 2026 session advances the conversation by committing to a single, narrow question: how do we take a signal off a wrist and make it count as an endpoint. The structure is pipeline-based rather than stakeholder-based, and the case-study arc deliberately includes the one wearable-derived primary endpoint qualified anywhere in the world (SV95C in DMD) alongside a cardiovascular-adjacent pivotal trial that missed on a wearable endpoint (REBUILD). The cross-cutting payer and statistical perspectives are new.

Setting the frame: from signal to endpoint in cardiovascular trials
Abhinav Sharma (Montreal, CAN)

Analytical validation: turning sensor signals into trustworthy digital measures
Jessilyn Dunn (Durham, NC, USA)

Clinical validation case studies: from measure to endpoint

From implant to endpoint: making device telemetry research-ready
David Hayes (Biotronik, GER)

Wearable activity monitoring in HF rehabilitation trials (REHAB-HF and beyond)
Ambarish Pandey (Dallas, TX, USA)

AFib burden
Jason Andrade (Vancouver, CAN)

Ambulatory / nocturnal BP– Cuffless devices
Paul Muntner (Birmingham, AL, USA)

Novel biomarkers: sleep, HRV, respiratory rate
Mintu Turakhia (Stanford, CA, USA)

REBUILD MVPA endpoint: lessons from a negative trial
Steven Nathan (Falls Church, VA, USA)

Safety monitoring: wearables as pharmacovigilance tools

Remote detection of decompensation and SAEs
Michael Gibson (Boston, MA, USA)

US Regulatory qualification pathways
Stephen Browning (FDA, USA)

Part 1 DISCUSSION

Panelists : Gregory Alexander (FDA, USA), Tariq Ahmad (FDA, USA), Jason Andrade (Vancouver, BC, CAN), Marc Bains (HeartLife, CAN), JoAnna Baldwin (CMS, USA), Ami Bhatt (Boston, MA, USA), Juuso Blomster (CardioSignal, FIN), Stephen Browning (FDA, USA), Punag Divanji (Cytokinetics, USA), Jessilyn Dunn (Durham, NC, USA), Charu Gandotra (FDA, USA), Michael Gibson (Boston, MA, USA), Christine Guo (Ametris, USA), David Hayes (Biotronik, GER), Laura Higginbotham (IQVIA, USA), Steven Lubitz (Novartis, USA), Marco Marchetti (Agenas, IT), Paul Muntner (Birmingham, AL, USA), Steven Nathan (Falls Church, VA, USA), Sari Ormstad (EU JCA, NOR), Ambarish Pandey (Dallas, TX, USA), Abhinav Sharma (Montreal, CAN), Mintu Turakhia (Stanford, CA, USA)

State
Wednesday, December 9, 2026
13:30 -16:30

**WEARABLES IN CARDIOVASCULAR CLINICAL TRIALS: FROM SIGNAL TO ENDPOINT
PART 2: FROM DIGITAL ENDPOINTS TO ADOPTION**

Chairpersons: Jessilyn Dunn (Durham, NC, USA) & Abhinav Sharma (Montreal, CAN)

From trial to clinic: translating digital endpoints into practice
Ami Bhatt (Boston, MA, USA)

Statistician viewpoint. Digital endpoints.
Jennifer Clark (FDA, USA)

Industry and CROs viewpoints
Punag Divanji (Cytokinetics, USA), Christine Guo (Ametris, USA), Steven Lubitz (Novartis, USA), Laura Higginbotham (IQVIA, USA)

Regulatory viewpoint
Tariq Ahmad (FDA, USA)

Will Payers Trust Digitally Derived Endpoints? From Validation to Coverage and Reimbursement
JoAnna Baldwin (CMS, USA)
Sari Ormstad (EU JCA, NOR)
Marco Marchetti (Agenas, IT)

Patient viewpoint: adherence, burden, and equity
Marc Bains (HeartLife, CAN)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

WEARABLES IN CARDIOVASCULAR CLINICAL TRIALS. READY FOR MAINSTREAM?

Chairpersons: Jessilyn Dunn (Durham, NC, USA) & Abhinav Sharma (Montreal, CAN)

Panelists : Gregory Alexander (FDA, USA), Tariq Ahmad (FDA, USA), Jason Andrade (Vancouver, BC, CAN), Marc Bains (HeartLife, CAN), JoAnna Baldwin (CMS, USA), Ami Bhatt (Boston, MA, USA), Juuso Blomster (CardioSignal, FIN), Stephen Browning (FDA, USA), Jennifer Clark (FDA, USA), Punag Divanji (Cytokinetics, USA), Jessilyn Dunn (Durham, NC, USA), Charu Gandotra (FDA, USA), Michael Gibson (Boston, MA, USA), Christine Guo (Ametris, USA), David Hayes (Biotronik, GER), Laura Higginbotham (IQVIA, USA), Steven Lubitz (Novartis, USA), Marco Marchetti (Agenas, IT), Paul Muntner (Birmingham, AL, USA), Steven Nathan (Falls Church, VA, USA), Ambarish Pandey (Dallas, TX, USA), Abhinav Sharma (Montreal, CAN), Mintu Turakhia (Stanford, CA, USA), Sari Ormstad (EU JCA, NOR)

State
Wednesday, December 9, 2026
17:00 -19:00

DRIVERS OF HEART FAILURE: WHERE ARE WE?

Chairpersons: Lynne Warner Stevenson (Nashville, TN, USA) & Mark Petrie (Glasgow, GBR)

Overview of residual risk in heart failure.
Michele Senni (Bergamo, ITA)

Is pulmonary hypertension a treatment target in HFpEF?
Milton Packer (Dallas, TX, USA)

Hemodynamics as potential mechanistic target in pulmonary hypertension related heart failure
Stuart Rich (Chicago, IL, USA)

Device therapy trials in pulmonary hypertension associated with left heart disease
Gegg Stone (New York, NY, USA)

Decompensated Heart Failure Trials. Where are we?
Jan Biegus (Wrocław, POL)

Is there any value to singling out HFmrEF?
Gianluigi Savarese (Stockholm, SWE)

Racing the remodeling clock: Rapid fire communications

Ghrelin for fast remodeling/recovery:
Lars Lund (Stockholm, SWE)

Fast full GDMT for fast remodeling/recovery
Alexandre Mebazaa (Paris, FRA)

Industry viewpoints
Francis Duhay (Pulnovo, CHN), Mahesh Patel (Merck, USA), So Young Kim (Tenax, USA)

Regulatory viewpoints
Charu Gandotra (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

WHAT ARE THE NEXT HEART FAILURE TRIALS TARGET PATIENT POPULATIONS?

Chairpersons: Lynne Warner Stevenson (Nashville, TN, USA) & Mark Petrie (Glasgow, GBR)

Panelists: Jan Biegus (Wrocław, POL), Javed Butler (Dallas, TX, USA), Kieran Docherty (Glasgow, GBR), Francis Duhay (Pulnovo, CHN), Charu Gandotra (FDA, USA), Josephine Harrington (Denver, COL), Riccardo Inciardi (Brescia, IT), So Young Kim (Tenax, USA), Lars Lund (Stockholm, SWE), Alexandre Mebazaa (Paris, FRA), Rhonda Monroe, (Charlotte, USA), Rachel Neubrandner (FDA, USA), Milton Packer (Dallas, TX, USA), Mahesh Patel (Merck, USA), Mark Petrie (Glasgow, GBR), Stuart Rich (Chicago, IL, USA), Gianluigi Savarese (Stockholm, SWE), Michele Senni (Bergamo, ITA), Gregg Stone (New York, NY, USA), Rhian Touyz (Montreal, CAN), Lynne Warner Stevenson (Nashville, TN, USA)

Chinese
Wednesday, December 9, 2026
08:00 -10:00

ESC-CVCT JOINT SESSION
LBCT 4
Chairpersons: TBD

Session under construction

The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 4
Chairpersons: TBD

Ballroom
Wednesday, December 9, 2026
08:00 -10:00

ESC-CVCT JOINT SESSION
LBCT 5
Chairpersons: TBD

Session under construction

The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 5
Chairpersons: TBD

Ballroom
Wednesday, December 9, 2026
10:30 -12:30

WHO IS IN THE COMMAND ROOM?
HOW BIG PHARMA, CROs, AROs AND REGULATORY BODIES ARE RESHAPING THE FUTURE OF CV INNOVATION.

Chairpersons : Robert Califf (Durham, NC, USA) & Thomas Lüscher (London, GBR)

Oncology, Device and rare disease have become the prototype ecosystem for accelerated innovation (surrogate endpoints, precision medicine, adaptive approvals, companion diagnostics, payer tolerance for uncertainty), whereas cardiovascular medicine remains more conservative, outcomes-driven, reimbursement-constrained, and operationally expensive. Has cardiovascular innovation become economically unviable? Are regulators slowing innovation — or protecting science? Did oncology “win” because it accepted uncertainty? Are heavy mega-trials now unsustainable?

Why does cardiovascular medicine move slower than oncology?

Bishal Gyawali (Kingston, CAN)
Bonnie Ky (JACC Oncology, USA)
Norman Stockbridge (Stockbridge LLC)

Are rare diseases the oncology-ization of cardiovascular medicine?

Sanjay Kaul (Los Angeles, CA, USA)
Jonathan Fox (BridgeBio, USA)

Why do cardiovascular devices and drugs follow different evidence pathways?

Roxana Mehran (New York, NY, USA)
Robert Califf (Durham, NC, USA)

Are we spending billions measuring things that no longer matter?

Martin Landray (Oxford, GBR)

The adjudication ritual: When is it really needed?

Renato Lopes (Durham, NC, USA)
John Mandrola (Louisville, KY, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HOW CAN BIG PHARMA, CROs, AROs AND REGULATORY BODIES ALIGN TO IMPROVE THE RATE OF CV DRUG INNOVATION?

Chairpersons : Robert Califf (Durham, NC, USA) & Thomas Lüscher (London, GBR)

Panelists : Robert Califf (Durham, NC, USA), Jonathan Fox (BridgeBio, USA), Bishal Gyawali (Kingston, CAN), Sanjay Kaul (Los Angeles, CA, USA), Bonnie Ky (JACC Oncology, USA), Martin Landray (Oxford, GBR), Renato Lopes (Durham, NC, USA), Thomas Lüscher (London, GBR), John Mandrola (Louisville, KY, USA), Roxana Mehran (New York, NY, USA), Rita Redberg (San Francisco, CA, USA), Tabassome Simon (Paris, FRA), Norman Stockbridge (Stockbridge LLC)

Ballroom
Wednesday, December 9, 2026
13:30 -16:30

PUBLISHING TRIAL RESULTS AND ADOPTION BY GUIDELINES. WHAT WOULD IT TAKE FOR JOURNALS AND GUIDELINES COMMITTEES TO NOT GIVE TRIALISTS A HARD TIME?

Chairpersons: Filippo Crea (EHJ, ITA) & Bradley Maron (Circulation, USA)

Editorial difficulties do not usually arise because journals want to be obstructive. They often arise because authors and journals approach the trial report with different priorities. Authors want to communicate the importance of the study; journals need to protect interpretability, proportionality, and trust. Guidelines are not simply a pass-through mechanism for positive trials or regulatory approvals. Guideline committees need to judge certainty, applicability, clinical priority, feasibility, and how new evidence fits within an existing therapeutic landscape.

Before the results: trial design choices that later determine editorial scrutiny.

Stuart Pocock (London, GBR), Ji-Hyun Lee (Nature Medicine, USA)

Endpoint hierarchy, composite outcomes, estimands, multiplicity, non-inferiority margins, subgroup plans, missing data, interim analyses, external validity, and whether the trial can answer the clinical question it claims to address.

After the results: how to report positive, neutral, or mixed findings avoiding interpretive tensions.

Sanjay Kaul (Los Angeles, CA, USA), Flavia Geraldes (The Lancet, GBR)

Discordant components of composite outcomes, positive secondary outcomes after neutral primary outcomes, underpowered safety findings, subgroup "signals", effect sizes versus p values, and statistical versus clinical importance.

The editor/statistical reviewer perspective: what makes a trial paper easier or harder to accept?

Issa Dahabreh (JAMA, USA), Jane Leopold (NEJM, USA)

Protocol and SAP transparency, CONSORT adherence, completeness of reporting, sponsor role, data access, patient-relevant outcomes, and whether the interpretation is proportionate to the data.

Case Studies

- VICTOR a neutral primary outcome with an important mortality signal.

Faiez Zannad (Paris, FRA), Flavia Geraldes (The Lancet, GBR)

- SELECT a trial with a broad claim but narrow population

John Deanfield (London, GBR), Jane Leopold (NEJM, USA)

When is one positive trial enough? Ibrahim Halil Tanboga (Istanbul, TUR)

Strength of evidence, replication, internal validity, magnitude and consistency of benefit, patient-centred outcomes, safety, totality of evidence, and how committees think about class and level of recommendation.

From trial population to guideline population. Tomasz Guzik (Krakow, POL)

Heart Failure guidelines: Applicability across sex, age, geography, comorbidity, kidney function, frailty, background therapy, under-represented groups, and whether subgroup evidence should narrow or broaden recommendations

When evidence, approval, and guidelines move at different speeds. Rita Redberg, San Francisco, CA, USA)

Conflicting trials, rapid therapeutic innovation, surrogate versus clinical outcomes, neutral or mixed trials, changing standards of care, and whether guidelines should lead, follow, or wait.

Case Studies

- BAROSTIM and BEAT-HF: Approved interventions without formal guideline recommendations

William Abraham (Columbus, OH, USA), Bram Zuckerman (FDA, USA)

- PARTNER 3 plus NOTION-2. TAVR versus surgery: sequencing an irreversible intervention.

Michael Mack (Dallas, TX, USA), Andrew Farb (FDA)

A class-effect question; a positive trial with limited generalizability; or a treatment whose uptake depends on sequencing with existing therapies.

Patients viewpoints

Rhonda Monroe (Charlotte, NC, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PUBLISHING TRIAL RESULTS AND ADOPTION BY GUIDELINES. WHAT WOULD IT TAKE FOR JOURNALS AND GUIDELINES COMMITTEES TO NOT GIVE TRIALISTS A HARD TIME?

Chairpersons: Filippo Crea (EHJ, ITA) & Bradley Maron (Circulation, USA)

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Ballroom
Wednesday, December 9, 2026
17:00 -19:00

THE MULTI-REGION REGULATORY HARMONIZATION MATRIX: PRAGMATIC REALITIES OF GLOBAL EVIDENCE ACCEPTANCE

Chairpersons: Robert M. Califf (Durham, NC, USA) & Jian'an Wang (Hangzhou, CHN)

The MHRA's Innovative Licensing and Access Pathway (ILAP): Accelerating Multi-Agency Scientific Alignment
Jacob George (MHRA, GBR)

The Mathematical Reality of ICH E17: How the FDA Evaluates Multi-Regional Clinical Trials (MRCTs)
Tzu-Yun McDowell (FDA, USA)

Bridging the Atlantic: Friction and Successes within the EMA-FDA Parallel Scientific Advice Pipeline
Anabela Marçal (Amsterdam, NED)
Shannon Thor (FDA, USA)

Beyond Border Restrictions: The China's Evolution from Localized Phase 3 Trials to Global Multi-Center Trials
Xinyang Hu (Hangzhou, CHN)

One Global Trial, Multiple Regulatory Decisions: What Evidence Can Japan Accept—and What Still Needs to Be Local
Manabu Inoue (PDMA, JPN)

Erasing the «Drug Lag»: Operational Mechanics of Simultaneous Global Regulatory Submissions
Akihiro Ishiguro (PMDA, Tokyo, JPN)

Power in Numbers: Reliance-Based Reviews and Unified Decisions within the Access Consortium
Raymond Chua (HSA, Singapore, SIN)

Patient's viewpoint
Ai Ling Sim-Devadas (Office of Patient Engagement, SIN)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

«Friction & Alignment»: Navigating Conflicting Endpoint Requirements, Ethnic Sensitivity Bridging, and the Future of Sovereign Data Acceptance

Chairpersons: Robert M. Califf (Durham, NC, USA) & Jian'an Wang (Hangzhou, CHN)

Panelists: Gregory Alexander (FDA, USA), Stephen Browning (FDA, USA), Robert M. Califf (Durham, NC, USA), Raymond Chua (HSA, Singapore, SGP), Andrew Farb (FDA, USA), Charu Gandotra (FDA, USA), Jacob George (MHRA, GBR), Xinyang Hu (Hangzhou, CHN), Manabu Inoue (PDMA, JPN), Akihiro Ishiguro (PMDA, Tokyo, JPN), Rob Kazmierski (ex-FDA, USA), Ai Ling Sim-Devadas (Office of Patient Engagement, SIN), Tzu-Yun.McDowell (FDA, USA), Anabela Marçal (Amsterdam, NED), Karim Mikhail (FDA, USA), Chinwe Okoro (FDA, USA), Francesco Pignatti (EMA, NED), Mitch Psotka (FDA, USA), Jon Resar (FDA, USA), Christian Schneider (London, GBR), John Sharretts (ex FDA, USA), Jeff Shuren (FDA, USA), Laurence Tallon (MHRA, GBR), Aliza Thompson (FDA, USA), Shannon Thor (FDA, USA), James Travis (FDA, USA), Jian'an Wang (Hangzhou, CHN), Changfu Wu (FDA, USA)