CVCT

December 9 -11, 2024
The Mayflower Hotel, Washington DC

SCIENTIFIC PROGRAM

21st Global Cardio Vascular Clinical Trialists Forum

FACULTY

ACADEMY

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174. Silvia Priori (Pavia, ITA)
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193. Clara Saldarriaga (Medelin, COL)
194. Rajiv Sankaranarayanan (Liverpool, UK)
195. Raul Santos (San Paolo, BR)
196. Naveed Sattar (Glasgow, UK)
197. Ruth Frikke Schmidt (Copenhagen, DEN)
198. Gregory Schwartz (Aurora, CO, USA)
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202. Mike Sharma (Hamilton, CAN)
203. Leslee Shaw (New York, NY, USA)
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206. Takeshi Shinkawa (Tokyo, JPN)
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209. Gérald Simonneau (Paris, FRA)
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217. Isaac Ssinabulya (Kampala, UGA)
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228. Katherine Tuttle (Spokane, WA, USA),
229. Jean-Luc Vachiéry (Brussels, BEL)
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251. Seppo Ylä-Herttuala (Kuopio, FIN)
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253. Faiez Zannad (Paris, FRA)
254. André Zimerman (Rio Grande do Sul, BRA)
255. Daniel Zimpfer (Vienna, AUT))

JOURNAL/MEDIA

256. Michael Basson (Nature Medicine, USA)
257. Robert Bonow (JAMA Cardiology, USA)
258. Gregory Curfman (JAMA, USA)
259. Flavia Geraldes (Lancet, UK)
260. Harlan Krumholz (JACC, USA)
261. Joe Hill (Circulation, USA)
262. Jane Leopold (NEJM, Boston, USA)
263. Chana Sacks (NEJM Evidence, USA)
264. Stuart Spencer (Lancet, UK)
265. Sami Viskin (Heart Rhythm, Tel Aviv, ISR)
266. Helena Wang (Lancet, CHN)
267. Chloe Wilson (Lancet, UK)

INDUSTRY

268. Cheryl Abbas (Novartis, USA)
269. Siddique Abbasi (Amgen, USA)
270. Philip Adamson (CVRx, USA)
271. Eva Adås (Johnson & Johnson, USA)
272. Eric Adler (Lexeo Therapeutics, USA)
273. Rahul Agrawal (Cereno, SWE),
274. Shazia Ali (Regeneron, USA)
275. Sangeetha Anand (CSL Behring, SWI)
276. Puja Banka (Merck, USA)
277. Lance Bates (Boston Scientific, USA)
278. Craig Basson (BitterrootBio, USA)
279. Arnaud Bastien (BMS, USA)
280. Nani Bhalla (BMS, USA)
281. Jenny Blau (AstraZeneca, USA)
282. Maria Borentain (Bayer, GER)
283. Pol Boudes (Galectin Tx, USA)
284. Brian Bradbury (Amgen, USA)
285. Todd Brinton (Edwards, USA),
286. Kristine Buchholtz (Novonordisk, DEN)

287. Mathijs Bunck (Eli Lilly, USA)
288. Jim Carr (Stealth, USA)
289. Adam Castano (BridgeBio, USA)
290. Sharon Chan (Johnson & Johnson, CHN)
291. Alan Cheng (Medtronic, USA)
292. Dan Chiche (35Pharma, USA)
293. Martine Clozel (Idorsia, CH)
294. Michael Cooreman (Inventiva, FRA)
295. Gad Cotter (Momentum LLC, USA)
296. Martin Cowie (AstraZeneca, UK)
297. Bjorn Dahlof (Cereno, SWE)
298. CQ Deng (United Therapeutics, USA)
299. Efthymios Deliargyris (Cytosorbent, USA)
300. DeAunne Denmark (Somalogic, USA)
301. Jodi Devlin (Altathera, USA)
302. Nancy Dreyer (Dreyer strategies, USA)
303. Eric Ducker (XyloCor, USA)
304. Richard Dujmovic (Boston Scientific, USA)
305. Jason Duran (CRISPR Therapeutics)
306. Zubin Eapen (Element Science, USA)
307. Sahar Ebrahim (IQVIA, EGY)
308. Jay Edelberg (Prolaio, USA)
309. Mathias Ekman (Microsoft, SWE)
310. Kevin Elgui (Owkin, FRA)
311. Perry Mark Elliott (London, UK)
312. Mads Engelmann (Novo Nordisk, DEN)
313. Joann Evangelista (Genentech, USA)
314. Michalis Fardis (Astra Zeneca, SWE)
315. Mackenzie Ford (Merck, USA)
316. Liming Gan (Ribocure Pharmaceuticals, CHN)
317. Leonard Ganz (Abbott, USA)
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319. Richard George (Regeneron, USA)
320. Sofia Gerward (NovoNordisk, DEN)
321. Al Gianchetti (Xylocor, USA)
322. Doug Godshall (Shockwave Medical, USA)
323. Christine Gouillard (US2AI, SIN)
324. Belinda Hardin (Lexicon, USA)
325. Jennifer Hellawell (Arrowhead Pharmaceuticals, USA)
326. James Hamilton (Arrowhead Pharmaceuticals, USA)
327. Scott Harris (Altimmune, USA)
328. Sibylle Hauske (Boehringer, GER)
329. Steve Heitner (Cytokinetics, USA)
330. Graeme Hickey (Medtronic, USA)
331. Robert Hillman (Celecor, USA)
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333. Udo Hoffmann (Cleerly, USA),
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335. Philip Janiak (Corteria, FRA)
336. Peter Kahr (Neurimmune, CH)
337. Takehiko Kaneko, (Heartseed, JPN)
338. John Kastelein (New Amsterdam Pharma, UK)
339. Trish Kay-Mugford (Novartis, USA)
340. Matthieu de Kelbermatten (Cellprothera, FRA)
341. Kirstie Keller (Additional Ventures, USA)
342. Amit Khera (Verve Therapeutics, USA)
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345. Robert Kormos (Abbott, USA)
346. Margaret Koziel (Axcella, USA)
347. Bettina Kraus (Boehringer, GER)
348. John Krege (Lilly, USA),
349. Emil Kuriakose (Terns, USA)
350. Alessandra Lafranconi (Boehringer, GER)
351. Andres Laguna (Novartis, ESP)
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358. nastasia Lesogor (Novartis, USA)
359. Hsiao Lieu (NGMBio, USA)
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361. Jennifer Linge (Amra Medical, SWE)
362. Dustin Little (AstraZeneca, USA)
363. Antonio Lopez (Amgen, USA)
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369. Serge Masson (Roche, CH)
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372. Laura Michael (Lilly, USA)
373. Marie Mide Michelsen (NovoNordisk, DEN)
374. Atif Mohammad (AsyraZeneca, USA)
375. Karina Morley (AstraZeneca, SWE)
376. James Moon (Myocardium AI Ltd, UK)
377. Eva Muehlhofer (Bayer, GER)
378. Masahiro Murakami (Eli Lilly, USA)
379. Gillian Murtagh (Abbott, UK)
380. Jens Naeumann (Initiative Herzklappe, GER)
381. Christie Nie (Prothena, USA)
382. Stefan Nilsson (Lipigon Pharmaceuticals, SWE)
383. Paul Nioi (Alnylam, UK)
384. Sarah Noonberg (Metagenomi, USA)
385. Janethe Pene de Oliveira (Oorja Bio, USA)
386. Shira Perl (AstraZeneca, USA)

387. Duane Pinto (JenaValve, USA)
388. Alexei Plotnikov (Janssen, USA)
389. Jeff Popma (Medtronic, USA)
390. Juergen Prochaska (Boehringer, GER)
391. Garg Pushkal (Alnylam, UK),
392. Curtis Rambaran (Silence Therapeutics, UK)
393. Jason Rashkin (Sanofi, FRA)
394. Robert Reynolds (GSK, USA)
395. Dan Riskin (Verantos, USA)
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413. Shanthi Sethuraman (Eli Lilly, USA)
414. Chuck Simonton (Abiomed, USA)
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416. Dorthe Charlotte Skovgaard (NovoNordisk, DEN)
417. Evan Stein (LIBTherapeutics, USA)
418. Kenneth Stein (Boston Scientific, USA)
419. Dominic Steubl (Boehringer, GER)
420. Michelle Stewart (Pfizer, USA)
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423. Mikhail Sumin (Boehringer Ingelheim, GER)
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429. Julie Tyler (Abbott, USA) Alessia Urbinati (Merck, USA)
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440. Larry Zisman (Gossamer, USA)

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480. Bindi Shah (FDA,USA)

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486. Norman Stockbridge (FDA, USA)
487. Mary Ross Southworth (FDA, USA)
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489. George van Hare (FDA, USA)
490. Patrick Vrijlandt (EMA, NED)
491. Janet Woodcock (FDA, USA)
492. Changfu Wu (FDA, USA)
493. Zaril Harza Zakaria (NPRA, MY)
494. Bram Zuckerman (FDA, USA)

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495. David Goff (NHLBI, NIH, USA)
496. Rebecca Gottesman (NHLBI, NINDS, USA)
497. Cara Lewis (NHLBI, NIH, USA)
498. George Mensah (NHLBI, NIH, USA)
499. Gail Pearson (NHLBI, NIH, USA)
500. Tiffany Powell-Wiley (NHLBI, NIH, USA)
501. Yves Rosenberg (NHLBI, NIH, USA)
502. Tomislav Sokol (European Parliament, CRO)
503. Rahul Thakar (NHLBI, NIH, USA)

PATIENTS/PATIENTS REPRESENTATIVES

504. Jacqueline Alikhaani (Los Angeles, USA)
505. Sadegh Alikhaani (Los Angeles, USA)
506. Alessia Argiro (Florence ITA)
507. Marc Bains (Vancouver, CAN)
508. Colleen Brunetti (Pulmonary Hypertension Association, USA)
509. Patrick Gee (Chesterfield, MO, USA)
510. Penilla Gunther (Stockholm, SWE)
511. Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK)
512. Anitha John (Washington DC, USA)
513. Trudie Lobban (Heart Rhythm Alliance, London, UK)
514. Isabelle Lousada (Amyloidosis Research Consortium, USA)
515. Steve Macari (Poitiers, FRA)
516. Maria Mavris (Patient Relations, EMA, NED)
517. Greg Merritt (Patient Is Partner, Brighton, USA)
518. Caius Ovidiu Merșa (Timișoara, ROM)
519. Rhonda Monroe (Baltimore, MD, USA)
520. Wanda Moore (CCHHE, USA)
521. Juddson Rupp (Charlotte, NC, USA)
522. Lisa Salberg (HCMA, USA)
523. Mellanie True Hills (Stop AFib, Greenwood, USA)
524. Mariette Verbakel (Nijmegen, NED)

PAYER / ECONOMISTS

525. Meindert Boysen (NICE, UK)
526. Aurelia Chaudhury (CMS, USA)
527. Joseph Chin (CMS, USA)
528. Jackie Fielding (NICE, UK)
529. Lee Fleisher (CMS, USA)
530. Gary Ford (NICE, UK)
531. Linda Gousis (CMS, USA)
532. Borislava Mihaylova (London, UK)
533. Jesse Roach (CMS, USA)
534. Shaun Rowark (NICE, UK)
535. Justin Whatling (NICE, UK)

MONDAY, DECEMBER 9TH

LUNCH SERVED AT THE MEETING VENUE

ROOM 1

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
REAL WORLD DATA view details >>		MASTER CLASS 1 view details >>		MASTER CLASS 2 view details >>		WIN RATIO view details >>

ROOM 2

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
NEUROCARDIOLOGY view details >>		GENE THERAPY view details >>		CELL THERAPY view details >>		ARTIFICIAL INTELLIGENCE view details >>

ROOM 3

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
WOMEN IN TRIALS view details >>		THROMBOSIS TRIALS CHALLENGING INDICATIONS view details >>		ATRIAL FIBRILLATION view details >>		HF-ELECTRO-PHYSIOLOGY view details >>

ROOM 4

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
HYPERTENSION view details >>		DIABETES – CKD 1 view details >>		DIABETES – CKD 2 view details >>		iCVCT THROMBOSIS FACTOR XI INHIBITORS view details >>

TUESDAY, DECEMBER 10TH

LUNCH SERVED AT THE MEETING VENUE

ROOM 1

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
CVCT GOING GLOBAL view details >>		PAH TRIALS 1 view details >>		PAH TRIALS 2 view details >>		PAH TRIALS 3 view details >>

ROOM 2

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
GLP1RA in CKM view details >>		PEDIATRIC TRIALS view details >>		PEDIATRIC DEVICES view details >>		BIOLOGICS view details >>

ROOM 3

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
CV SAFETY view details >>		POST MI DRUG THERAPY view details >>		CORONARY CT view details >>		IMPLEMENTATION TRIALS view details >>

ROOM 4

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
AMYLOIDOSIS view details >>		CARDIO-MYOPATHIES 1 view details >>		CARDIO-MYOPATHIES 2 view details >>		HFPEF TRIALS view details >>

19:00 - 19:30
PLENARY KEYNOTE

WEDNESDAY, DECEMBER 11TH

LUNCH SERVED AT THE MEETING VENUE

ROOM 1

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
OBESITY TRIALS 1 view details >>		HEART FAILURE 1 view details >>		OBESITY TRIALS 2 view details >>		HEART FAILURE 2 view details >>

ROOM 2

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
TRIGLYCERIDE view details >>		LIPOPROTEIN(A) view details >>		CHOLESTEROL view details >>		AORTIC STENOSIS view details >>

ROOM 3

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
iCVCT VALVE view details >>		iCVCT STRUCTURAL HEART view details >>		iCVCT SHOCK view details >>		iCVCT CORONARY view details >>

ROOM 4

8:00 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 19:00
GLOBAL REGULATORY SUMMIT view details >>		PATIENT TRIALISTS WHO OWNS THE DATA? view details >>		UNDIAGNOSED HEART FAILURE view details >>		BIOMARKER view details >>

Room 1
Monday, December 9, 2024
8:00 -10:30

Real-Worl Data (RWD) - WHAT IT IS, WHY IT'S USEFUL AND WHY CARDIOLOGISTS SHOULD CARE?
Chairpersons : Robert Califf (FDA, USA) & Mark McClellan (Durham, NC, USA)

«There are too many important questions to attempt to answer them all with RCTs, and too little funding» **(Rob Califf, FDA, USA)**

Quantifying/Optimizing RWD reliability.
Brian Bradbury (Amgen, USA)

Transparency and clarity of Real-World Evidence
Lars Hemkens (Basel, CH)

How often and in what contexts RWE do findings match RCTs'?
Emulating RCTs with non-randomized RWE Studies.
Shirley Wang (Los Angeles, CA, USA)

RWD and AI for patient finding for trial enrollment.
How RWD and AI may help trial design and trial results implementation
Ryan Ahern (Truveta, USA)

RWD for investigating patients and conditions not studied in clinical trials, such as studies of the elderly, youth, pregnancy and ethnic minorities.
Kelvin Yiu (Hong Kong, CHN)

Understanding the RW impact of surrogate endpoints from pivotal trials.
Robert Yeh (Boston, MA, USA)

Can RWD make drugs safer than simply using randomized clinical trials?
Alison Cave (MHRA, UK)

RW impact measuring patient-generated outcomes.
Robert Reynolds (GSK, USA)

RWD on STEMI management in Africa.
Habib Gamra (Sousse, TN)

Payer's viewpoint: Can RWD informing risk/benefit models for payers.
TBD (CMS, USA)
Shaun Rowark (NICE, UK)

Regulatory viewpoints.
Kenneth Quinto (FDA, USA)
Peter Arlett (EMA, NED)

Industry viewpoint.
Nancy Dreyer (Dreyer Strategies, USA)

The CVCT multi-stakeholder think tank moderated debate

RWD - WHAT IT IS, WHY IT'S USEFUL AND WHY CARDIOLOGISTS SHOULD CARE?
Chairpersons Robert Califf (FDA, USA) & Mark McClellan (Durham, NC, USA)

Panelists : Ryan Ahern (Truveta, USA), Peter Arlett (EMA, NED), Brian Bradbury (Amgen, USA),Robert Califf (FDA, USA), Alison Cave (MHRA, UK), Nancy Dreyer (Dreyer Strategies, USA), Habib Gamra (Sousse, TN), Lars Hemkens (Basel, CH), Graeme Hickey (Medtronic, USA), Ramesh Nadarajah (Leeds, UK), Shaun Rowark (NICE, UK), Robert Reynolds (GSK, USA), Thomas Senderovitz (Novo Nordisk, DEN) , Shirley Wang (Los Angeles, CA, USA), Robert Yeh (Boston, MA, USA)

Room 1
Monday, December 9, 2024
11:00 -13:00

CVCT STATISTICS MASTERCLASS - 1
KEY TYPES OF TRIAL DESIGN.
HOW TO BEST MEET THE NEEDS OF KEY STAKEHOLDERS?
Chairpersons : Gregg Stone (New York, NY, USA) & Jan Tijssen (Brussels, BEL)

Trial design requires both quality and creativity to achieve success. The aim of this MasterClass is to cover both current good practice and also strategic innovations to ensure that future trial designs best meet the challenges in advancing patient care. The speakers and discussants have a depth of experience in cardiovascular trials research and will relate the practical relevance of their insights to specific trial examples.

Pragmatic trials using patient health data: realities and myths.
Frank Rockhold (Durham, NC, USA)

Flexible trial designs: from frequentist multi-arm to bayesian platform trials.
Peter Juni (Oxford, UK)

Non-inferiority trials: when, why, how and choice of margin.
Stuart Pocock (London, UK)

The CVCT Multi-Stakeholder Think Tank Debate
WHICH TRIAL DESIGN TO MEET THE NEEDS OF KEY STAKEHOLDERS?
Chairpersons : Gregg Stone (New York, NY, USA) & Jan Tijssen (Brussels, BEL)

Panelists : Ali Abbasi (FDA, USA), Lesley Curtis (FDA, USA), Lars Hemkens (Basel, CH), Peter Juni (Oxford, UK), Stuart Pocock (London, UK), Frank Rockhold (Durham, NC, USA), Lei Shen (Madison, WI, USA), Gregg Stone (New York, NY, USA), Jan Tijssen (Brussels, BEL), Cindy Westerhout (Edmonton, CAN)

Room 1
Monday, December 9, 2024
14:00 -16:00

CVCT MASTERCLASS - 2
KEY ISSUES IN TRIAL PLANNING, DESIGN, SIZE AND ENDPOINTS
HOW TO BEST MEET THE NEEDS OF KEY STAKEHOLDERS?
Chairpersons : Peter Juni (Oxford, UK) & Stuart Pocock (London, UK)

Core challenges in trial design: patient enrichment, sham controls, choice of primary endpoint, including hierarchical composites.
Gregg Stone (New York, NY, USA)

Determining trial size, including sample size re-estimation.
Cindy Westerhout (Edmonton, CAN)

Testing primary and secondary endpoints with type i error control: how to best meet the needs of key stakeholders.
Lei Shen (Madison, WI, USA)

The CVCT Multi-Stakeholder Think Tank Debate
HOW STATISTICIANS MAY HELP MEET THE NEEDS OF KEY STAKEHOLDERS?
Chairpersons : Peter Juni (Oxford, UK) & Stuart Pocock (London, UK)

Panelists : Ali Abbasi (FDA, USA), Lesley Curtis (FDA, USA), Peter Juni (Oxford, UK), Stuart Pocock (London, UK), Frank Rockhold (Durham, NC, USA), Lei Shen (Madison, WI, USA), Gregg Stone (New York, NY, USA), Cindy Westerhout (Edmonton, CAN)

Room 1
Monday, December 9, 2024
16:30 -19:00

WIN RATIO AND HIERARCHICAL ENDPOINT ANALYSES IN CLINICAL TRIALS
Chairpersons : Joao Ferreira (Porto, POR) & Stuart Pocock (London, UK)

Systematic review of published win ratio trials during 2022-24.
Stuart Pocock (London, UK)

Use and misuse of the win ratio: when is clinical meaning lost?
Norman Stockbridge (FDA, USA)

A clinical perspective on the win ratio.
Gregg Stone (New York, NY, USA)

Win ratio and the Cox model: are results different?
Joao Ferreira (Porto, POR)

Determining trial size with primary hierarchical endpoints.
Huiman Barnhart (Durham, NC, USA)

Statistical challenges in using the win ratio.
John Gregson (London, UK)

The CVCT Multi-Stakeholder Think Tank Debate

WIN RATIO: ARE WE TO THROW THE BABY WITH THE BATH WATER?
Chairpersons : Joao Ferreira (Porto, POR) & Stuart Pocock (London, UK)

Panelists : Huiman Barnhart (Durham, NC, USA), Efthymios Deliargyris (Cytosorbent, USA),
Joao Ferreira (Porto, POR), John Gregson (London, UK), Stuart Pocock (London, UK), Chana Sacks (NEJM Evidence, USA),
Norman Stockbridge (FDA, USA), Gregg Stone (New York, NY, USA), Cordula Zeller (Boehringer, GER)

Room 2
Monday, December 9, 2024
08:00 -10:30

NEUROCARDIOLOGY: RUNNING MULTIDISCIPLINARY TRIALS IN AN EMERGING SPECIALTY
Chairpersons : Rebecca Gottesman (NHLBI, NIH, USA) & Edip Gurol (Boston, MA, USA)

What is neurocardiology? Ongoing trials relevant to neurocardiology.
Edip Gurol (Boston, MA, USA)

Cognition as an outcome measure in neurocardiology trials
Rebecca Gottesman (NHLBI, NIH, USA)

Heart failure and cognitive decline. Should we pay attention?
Pooja Dewan (Glasgow, UK)

Ischemic and hemorrhagic strokes: etiologies and their relevance to prevention.
Edip Gurol (Boston, MA, USA)

Extracranial large vessel disease: medical management vs surgery/stenting.
Seemant Chaturvedi (Baltimore, MA, USA)

Left atrial appendage closure for neurocardiology
Vivek Reddy (New York, NY, USA)

Large simple trials for vascular surgeons - lessons learned from randomising over 6000 patients in ACST-1 and ACST-2.
Richard Bulbulia (Oxford, UK)

Intracranial atherosclerosis: an understudied but major cause of stroke.
Shadi Yaghi (Providence, RI, USA)

Challenges in enrolling stroke patients to secondary prevention trials: post-stroke cognitive and motor impairments.
Michelle Johansen (Baltimore, MA, USA)

Regulatory viewpoints.
Kristina Dunder (EMA, SWE)
Paul Lee (FDA,USA)

Patient's viewpoint
Juddson Rupp (Charlotte, NC, USA)

The CVCT Multi-Stakeholder Think Tank Debate
NEUROCARDIOLOGY TRIALS. HAVING THE BRAIN AT HEART.
Chairpersons : Rebecca Gottesman (NHLBI, NIH, USA) & Edip Gurol (Boston, MA, USA)

Panelists : Richard Bulbulia (Oxford, UK), Seemant Chaturvedi (Baltimore, MA, USA), Kristina Dunder (EMA, SWE), Pooja Dewan (Glasgow, UK), Rebecca Gottesman (NHLBI, NIH,, USA), Edip Gurol (Boston, MA, USA), Michelle Johansen (Baltimore, MA, USA), Paul Lee (FDA,USA), Juddson Rupp (Charlotte, NC, USA), Bertram Pitt (Ann Arbor, USA), Vivek Reddy (New York, NY, USA), Shadi Yaghi (Providence, RI, USA), Faiez Zannad (Paris, FRA)

Room 2
Monday, December 9, 2024
11:00 -13:00

GENE THERAPY FOR GENETIC AND FOR COMMON HEART DISEASES PROGRESSING INTO CLINICAL STAGE

Chairpersons: Barry Greenberg (San Diego, CA, USA) & Silvia Priori (Pavia, ITA)

Mechanisms of in vivo gene editing using lipid nanoparticle delivery for cardiovascular disease.
Amit Khera (Verve Therapeutics, USA)

Targeting monogenetic disease.
Joseph Rossano (Philadelphia, PA, USA)

Targeting arrhythmogenic cardiomyopathies.
Silvia Priori (Pavia, ITA)

Targeting common heart diseases. Gene-PHIT in heart failure.
Tim Henry (Cincinnati, OH, USA)

Targeting coronary artery disease and refractory angina: lessons learned from the EXACT clinical program for trial design
Eric Ducker (XyloCor, USA)

Early assessment for efficacy and de-risking strategies. Trial design and endpoints.
Seppo Ylä-Herttuala (Kuopio, FIN)

Once for all (or once-in-a-while) administration therapy. Implementation, adherence, and pricing consequences.
Shaun Rowark (NICE, UK)

Regulatory viewpoint.
TBD (FDA, USA)
Claus Bolte (Ex-Swissmedic, Basel, CH)

Patient's preference. Pill burden vs once for all (or once-in-a-while) administration therapy?
Alessia Argiro (Florence ITA)

Payer's viewpoint
Aurelia Chaudhury (CMS, USA)

The CVCT Multi-Stakeholder Think Tank Debate

GENE THERAPY FOR GENETIC AND FOR COMMON DISEASES PROGRESSING INTO CLINICAL STAGE

Chairpersons: Barry Greenberg (San Diego, CA, USA) & Silvia Priori (Pavia, ITA)

Panelists: Eric Adler (Lexeo Therapeutics, USA), Alessia Argiro (Florence ITA), Claus Bolte (Ex-Swissmedic, Basel, CH), Aurelia Chaudhury (CMS, USA), Eric Ducker (XyloCor, USA), Jason Duran (CRISPR Therapeutics), Al Gianchetti (Xylocor, USA), Barry Greenberg (San Diego, CA, USA), Tim Henry (Cincinnatti, OH, USA), Amit Khera (Verve Therapeutics, USA), Marie Mide Michelsen (NovoNordisk, DEN), Silvia Priori (Pavia, ITA), Laura Robertson (Tenaya, USA), Joseph Rossano (Philadelphia, PA, USA), Shaun Rowark (NICE, UK), Jonathan Schwartz (RocketPharma, USA), Christine Seidman (Boston, MA, USA), Seppo Ylä-Herttuala (Kuopio, FIN)

Room 2
Monday, December 9, 2024
14:00 -16:00

CELL THERAPY TRIALS FOR HEART FAILURE.
RIGHT CELLS? RIGHT TARGET POPULATION? RIGHT DESIGN?
Chairpersons: Biykem Bozkurt (Houston, USA) & Philippe Ménasché (Paris, FRA)

What are the right cell products?

Stem cell derived products vs. Induced pleuripotent cell derived products.
Joshua Hare (Miami, FL, USA)

Exosomes and secretomes.
Philippe Ménasché (Paris, FRA)

What are the right cells?
Tissue engineering for cardiac repair.
Karen Christman (San Diego, CA, USA)

What is the right target population?
Chronic HFpEF, post myocardial infarction or chronic HFpEF.
Emerson Perin (Houston, TX, USA)

What post-MI patients are still at high risk?
Tabassome Simon (Paris, FRA)

What are the right endpoints.
Scott Solomon (Boston, MA, USA)

What is the right design?
Population, study design and controls or alternatively matching treatment to disease.
Barry Greenberg (San Diego, CA, USA)

Industry viewpoint
Takehiko Kaneko (Heartseed, JPN)

Regulatory viewpoints
TBD (FDA, USA)
Narumi Okura (PDMA, JPN)

Payer's viewpoint
Aurelia Chaudhury (CMS, USA)

The CVCT Multi-Stakeholder Think Tank Debate

CELL THERAPY TRIALS FOR HEART FAILURE.
RIGHT CELLS? RIGHT TARGET POPULATION? RIGHT DESIGN?
Chairpersons: Biykem Bozkurt (Houston, USA) & Philippe Ménasché (Paris, FRA)

Panelists : Aurelia Chaudhury (CMS, USA), Karen Christman (San Diego, CA, USA), Kieran Docherty (Glasgow, UK), Matthieu de Kelbermatten (Cellprothera, FRA), Barry Greenberg (San Diego, CA, USA), Joshua Hare (Miami, FL, USA), Takehiko Kaneko (Heartseed, JPN), Sanjay Kaushal (Chicago, IL, USA), Philippe Ménasché (Paris, FRA), Narumi Okura (PDMA, JPN), Emerson Perin (Houston, TX, USA), Lothar Roessig (AskBio-Bayer, GER), Tabassome Simon (Paris, FRA), Scott Solomon (Boston, MA, USA)

Room 2
Monday, December 9, 2024
16:30 -19:00

ARTIFICIAL INTELLIGENCE FOR TRIAL DESIGN, CONDUCT, ANALYSIS, & RESULT IMPLEMENTATION

Chairpersons: Jonathan Cunningham (Boston, MA, USA) & Harlan Krumholz (New Haven, USA)

The role of AI in large decentralized clinical trials.
Tor Biering-Sorenson (Copenhagen, DEN)

AI for clinical event adjudication.
Jonathan Cunningham (Boston, MA, USA)

AI for safety event monitoring.
Joann Evangelista (Genentech, USA)

AI for CV imaging core labs in trials.
Jose Rivero (Boston, MA, USA)

AI for dissemination & implementation of trial results.
Rohan Khera (JAMA, New Haven, CT, USA)

How should journals evaluate AI Tools & AI-generated results?
Harlan Krumholz (JACC, USA)

Statistical viewpoint.
Christopher Lindsell (Durham, NC, USA)

Industry viewpoints.
Shanthi Sethuraman (Eli Lilly, USA), TBD

Journal editor's viewpoint.
Stuart Spencer (Lancet, UK)

Regulatory viewpoints.
Anindita Saha (FDA, USA)
Justin Whatling (NICE, UK)

Patient's viewpoint
Caius Ovidiu Merșa (Timișoara, ROM)

The CVCT Multi-Stakeholder Think Tank Debate

ARTIFICIAL INTELLIGENCE FOR TRIAL DESIGN, CONDUCT, ANALYSIS, & RESULT IMPLEMENTATION

Chairpersons: Jonathan Cunningham (Boston, MA,USA) & Harlan Krumholz (New Haven, USA)

Panelists : Tor Biering-Sorenson (Copenhagen, DEN),Jonathan Cunningham (Boston, MA,USA); Joann Evangelista (Genentech, USA), Rohan Khera (JAMA, New Haven, CT, USA),Harlan Krumholz (JACC, USA) , Christopher Lindsell (Durham, NC, USA), Caius Ovidiu Merșa (Timișoara, ROM), Jose Rivero (Boston, MA, USA), Anindita Saha (FDA, USA),Shanthi Sethuraman (Eli Lilly, USA), Stuart Spencer (Lancet, UK), Justin Whatling (NICE, UK)

Room 3
Monday, December 9, 2024
08:00 -10:30

TRIALS IN WOMEN – WOMEN IN TRIALS: YES WE CAN!
CVCT-WomenAs1 joint session.
Chairpersons: Roxana Mehran (New York, NY, USA) & Stacey Rosen (Manhasset, NY, USA)

Regulatory tradewinds towards diversity.
Jaime Raben (FDA, USA)

The NHLBI's view on diversity in clinical trials.
Yves Rosenberg (NHLBI, NIH, USA)

The importance of Participation Prevalence Ratios (PPR)
Erin Bohula (Boston, MA, USA)

Case study: the SMART trial.
TBD

Enrollment caps: Yay or Nay?
Tabassome Simon (Paris, FRA)

Case study: LIFE BTK.
Sahil Parikh (Boston, MA, USA)

Case study: CLEAR outcomes.
Leslie Cho (Cleveland, OH, USA)

Women as trial leaders: challenges and opportunities.
Harriette Van Spall (Hamilton, Canada)

Global viewpoint: how to incorporate sex/gender in CV clinial trial design.
Carolyn Lam (Singapore, SIN)

How to overcome the under-representation of women from the middle East and Africa in clinical trials?
Mirvat Alasnag (Jedda, KSA)

Learned societies viewpoint.
Stacey Rosen (Manhasset, NY, USA)

Journal editor's viewpoint.
Flavia Geraldes (Lancet, UK)

The CVCT Multi-Stakeholder Think Tank Debate
TRIALS IN WOMEN – WOMEN IN TRIALS: YES WE CAN!
Chairpersons: Roxana Mehran (New York, NY, USA) & Stacey Rosen (Manhasset, NY, USA)

Panelists : Mirvat Alasnag (Jedda, KSA), Erin Bohula (Boston, MA, USA), Leslie Cho (Cleveland, OH, USA), Flavia Geraldes (Lancet, UK), Carolyn Lam (Singapore, SIN), Roxana Mehran (New York, NY, USA),Michelle Sahil Parikh (Boston, MA, USA), Jaime Raben (FDA, USA), Stacey Rosen (Manhasset, NY, USA), Yves Rosenberg (NHLBI, NIH, USA), Tabassome Simon (Paris, FRA), Harriette Van Spall (Hamilton, Canada)

Room 3
Monday, December 9, 2024
11:00 -13:00

THROMBOSIS TRIALS – NEW DRUGS – CHALLENGING INDICATIONS
Chairpersons: Renato Lopes (Durham, NC, USA) & Mpiko Ntsekhe (Cape Town, SA)

Prehospital anti-thrombotic therapy trials in STEMI.
Michael Gibson (Boston, MA, USA)

Industry viewpoints.
Robert Hillman (Celecor, USA), Sébastien Roux (Viatris, CH)

Anticoagulation of valvular atrial fibrillation: is the debate over after the INVICTUS trial?
Mpiko Ntsekhe (Cape Town, SA)

Anticoagulation versus left atrial appendage closure post AF ablation: the OPTION trial.
Oussama M Wazni (Cleveland, OH, USA)

Management of the atrial fibrillation patient unsuitable for anticoagulant drugs
Michael Gibson (Boston, MA, USA)

Left atrial appendage closure for patients unsuitable for anticoagulant for atrial fibrillation: do we need a stronger level of recommendation in the guidelines?
Habib Gamra (Sousse, TN)

Role of anticoagulation in the management of the dialysis patient.
Renato Lopes (Durham, NC, USA)

The antiplatelet and thrombotic effects of SGLT1/2 vs SGLT2i
Bertram Pitt (Ann Arbor, USA)

The CVCT Multi-Stakeholder Think Tank Debate

THROMBOSIS TRIALS – NEW DRUGS – CHALLENGING INDICATIONS
Chairpersons: Renato Lopes (Durham, NC, USA) & Mpiko Ntsekhe (Cape Town, SA)

Panelists: Habib Gamra (Sousse, TN), Michael Gibson (Boston, MA, USA), Robert Hillman (Celecor, USA), Carolyn Lam (Singapore, SIN), Renato Lopes (Durham, NC, USA), Mpiko Ntsekhe (Cape Town, SA), Bertram Pitt (Ann Arbor, USA), Sébastien Roux (Viatris, CH), Oussama M Wazni (Cleveland, OH, USA)

Room 3
Monday, December 9, 2024
14:00 -16:00

ATRIAL FIBRILLATION (AF) BURDEN AND TRIAL ENDPOINT CONSIDERATIONS. HOW TO CONVINCE THE RESPECTIVE STAKEHOLDERS?

Chairpersons: Paulus Kirchhof (Hambourg, GER) & Andrea Russo (Cooper Health, USA)

How much atrial fibrillation (AF) is dangerous? The risks associated with persistent AF, paroxysmal AF and device-detected AF. What are the respective unmet needs in each group?
John Camm (London, UK)

Most recent evidence-based technical developments in atrial fibrillation ablation.
Josef Kautzner (Prague, CZ)

How to evaluate incremental technologies. Pre-and post-approval requirements.
Andrea Russo (Cooper Health, USA)

Efficacy endpoints: atrial fibrillation burden. How to measure and how clinically meaningful?
Jason Andrade (Vancouver, CAN)

Maximizing efficacy, safety & operational outcome/ technical convenience endpoint.
Vivek Reddy (New York,NY, USA)

Consumer electronics.
Photoplethysmography-documented atrial fibrillation burden quantification?
Dominik Linz (Maastricht, NED)

Industry viewpoints.
Jodi Devlin (Altathera, USA), Leonard Ganz (Abbott, USA), Steven Lubitz (Novartis, USA)

Regulatory viewpoints.
Bindi Shah (FDA,USA)
Piotr Szymanski (EU, POL)

Sum up of outstading issues which this think tank may help progress.
John Camm (London, UK)

The CVCT Multi-Stakeholder Think Tank Debate

AF BURDEN AND OTHER TRIAL ENDPOINT CONSIDERATIONS. HOW TO CONVINCE THE RESPECTIVE STAKEHOLDERS?

Chairpersons : Paulus Kirchhof (Hambourg, GER) & Andrea Russo (Cooper Health, USA)

Panelists: Jason Andrade (Vancouver, CAN), John Camm (London, UK), Jodi Devlin (Altathera, USA), Leonard Ganz (Abbott, USA), Josef Kautzner (Prague, CZ) , Paulus Kirchhof (Hambourg, GER), Jane Leopold (NEJM, Boston, USA), Dominik Linz (Maastricht, NED), Steven Lubitz (Novartis, USA), Jason Rashkin (Sanofi, FRA), Vivek Reddy (New York,NY, USA), Andrea Russo (Cooper Health, USA), Bindi Shah (FDA,USA), Kenneth Stein (Boston Scientific, USA), Piotr Szymanski (EU, POL), Mellanie True Hills (Stop AFib, Greenwood, USA), Sami Viskin (Heart Rhythm, Tel Aviv, ISR)

Room 3
Monday, December 9, 2024
16:30 -19:00

TRIALS AT THE HEART FAILURE/ELECTROPHYSIOLOGY INTERSECTION
Chairpersons : Thomas Deering (Atlanta, GA, USA) & Mariell Jessup (Philadelphia, PA, USA)

Conduction system pacing or CRT? What additional studies do we need?

HF specialist 's viewpoint.
Mariell Jessup (Philadelphia, PA, USA)

EP's viewpoint.
Philip Sommer (Bad Oeynhausen, GER)

Tempo matters: what heart rate is best in HF.
Markus Meyer (Minneapolis, MN, USA)

Conduction system pacing or RV apical pacing to prevent heart failure – What trials are needed?
TBD

What role do CCM & barostim treatment options play – what trials are needed?
William Abraham (Columbus, USA)

ICD therapy in HF: quick pitches building the case for a retrial

HF doc viewpoint. do we have equipoise?
Javed Butler (Dallas, TX, USA)

EU-EP doc viewpoint. PROFID and CMR-ICD.
Gerd Hindricks (Leipzig, GER)

US-EP doc viewpoint. The CONTEMP-ICD trial.
Ilan Goldenberg (Rochester, MN, USA)

Is it time to look at DNA in heart failure? Sudden death prediction using genetic information.
Michael Ackerman (Rochester, MN, USA)

Timing matters: the value of extending time to decision for ICD implantation in patients with heart failure with reduced ejection fraction (HFrEF).
John Hummel (Columbus, OH, USA)

Industry viewpoints.
Alan Cheng (Medtronic, USA), Zubin Eapen (Element Science, USA), Kenneth Stein (Boston Scientific, USA)

Regulatory viewpoint.
Brian Lewis (FDA, USA)

Patient's viewpoint.
Trudie Lobban (Heart Rhythm Alliance, London, UK)

The CVCT Multi-Stakeholder Think Tank Debate

WHAT PACING IN HEART FAILURE?
The HEART FAILURE – EP DEBATE
Chairpersons : Thomas Deering (Atlanta, GA, USA) & Mariell Jessup (Philadelphia, PA, USA)

Panelists: William Abraham (Columbus, USA),Javed Butler (Dallas, TX, USA), Alan Cheng (Medtronic, USA), Thomas Deering (Atlanta, GA, USA), Zubin Eapen (Element Science, USA),Ilan Goldenberg (Rochester, MN, USA) , Gerd Hindricks (Leipzig, GER), John Hummel (Columbus, OH, USA), Mariell Jessup (Philadelphia, PA, USA), Brian Lewis (FDA, USA), Trudie Lobban (Heart Rhythm Alliance, London, UK), Markus Meyer (Minneapolis, MN, USA), Philip Sommer (Bad Oeynhausen, GER), Kenneth Stein (Boston Scientific, USA)

Room 4
Monday, December 9, 2024
08:00 -10:30

REVIVAL OF HYPERTENSION TRIALS.
ONE-SIZE-FITS-ALL VS. PATIENT STRATIFICATION STRATEGIES
Chairpersons: Rhian Touyz (Montreal, CAN) & Bryan Williams (London, UK)

Emerging targeted therapies and the importance of patient stratification

Endothelin antagonists.
Michael Weber (New York, NY, USA)

RNA interference therapeutic agents.
Christopher Granger (Durham, NC, USA)

New biologic therapy for hypertension - activating the natriuretic peptide receptor.
Bryan Williams (London, UK)

Aldosterone dysregulation in hypertension and aldosterone targeted drugs.
Michel Azizi (Paris, FRA)

What is the optimal timing of initiating a yearly dose of an SiRNA angiotensinogen? A mendelian randomization and causal AI algorithm investigation.
Brian Ference (Cambridge, UK)

New hypertension trial designs - unique challenges. Dose finding and how to evidence additional benefit, on top of background therapy.
Bryan Williams (London, UK)

Hypertension trial designs seamless phase II to phase III designs, non-traditional designs (e.g., historical placebo).
David Reboussin (Winston-Salem, NC, USA)

Beyond one-size-fits-all: how advanced patient phenotyping can revolutionize treatment approaches.
Christian Delles (Glagow, UK)

The virtues of one-size-fits-all anti-hypertensive polypill.
Antony Rodgers (Sydney, AUS)

Industry viewpoints.
Martine Clozel (Idorsia, CH), Jason Duran (CRISPR Therapeutics)

Regulatory viewpoints.
Rekha Kambhampati (FDA, USA), Heidi Janssen (EMA, NED)

Lifestyle and implementation issues. The role of digital therapeutics.
Kazuomi Kario (Tochigi, JPN)

Hypertension in Africa : do we need more trials for a better control?
Anastase Dzudie (Douala, CM)

The CVCT Multi-Stakeholder Think Tank Debate

ANTIHYPERTENSIVE THERAPY
HOW NEW DRUGS NEW TRIALS AND NEW STRATEGIES MAY ADDRESS THE MANY UNMET NEEDS
Chairpersons: Rhian Touyz (Montreal, CAN) & Bryan Williams (London, UK)

Panelists: Michel Azizi (Paris, FRA), Martine Clozel (Idorsia, CH), Christian Delles (Glagow, UK), Jason Duran (CRISPR Therapeutics), Anastase Dzudie (Douala, CM), Brian Ference (Cambridge, UK) , Christopher Granger (Durham, NC, USA), Heidi Janssen (EMA, NED), Rekha Kambhampati (FDA, USA), Kazuomi Kario (Tochigi, JPN), Marty Lefkowitz (Novartis, USA), Karthik Linganathan (AstraZeneca, SWE), Judy Meadows (Regeneron, USA), Shira Perl (AstraZeneca, USA), David Reboussin (Winston-Salem, NC, USA), Adel Rizkala (Novartis, USA), Antony Rodgers (Sydney, AUS), Rhian Touyz (Montreal, CAN), Sotirios Tsimikas (Ionis, USA), Michael Weber (New York, NY, USA), Bryan Williams (London, UK) , Fred Yang (KBP BioScience, USA), Dion Zappe (Alnylam, UK)

Room 4
Monday, December 9, 2024
11:00 -13:00

DIABETES AND CKD THERAPIES Part 1.
HOW TO IMPLEMENT THE FAST-GROWING EVIDENCE?
Chairpersons: Jennifer Green (Durham, NC, USA) & Peter Rossing (Copenhague, DEN)

The totality of available evidence

SGLT2i and GLP1RA
Hiddo Heerspink (Groningen, NED)

nsMRA
Peter Rossing (Copenhague, DEN)

Do we still need RASI in the mix
Matthew Weir (Baltimore, MA, USA)

Combining all of the above
Muthiah Vaduganathan, (Boston, MA, USA)

How to manage safety concerns as they should not harm implementation.
Brendon Neuen (Sydney, AUS)

How can we optimize implementation?
Guidelines, disease management programs and post approval studies.
Katherine Tuttle (Spokane, WA, USA)

Industry viewpoint.
Sibylle Hauske (Boehringer, GER)

Health economist / payer's viewpoints.
Joseph Chin (CMS, USA)
Borislava Mihaylova (London, UK)

Patient's viewpoint.
Patrick Gee (Chesterfield, MO, USA)

The CVCT Multi-Stakeholder Think Tank Debate

DIABETES AND CKD THERAPIES Part 1. HOW TO GET DIABETES AND CKD PATIENTS TO BENEFIT FROM THE EXPLOSION OF EVIDENE-BASED THERAPIES?
Chairpersons: Jennifer Green (Durham, NC, USA) & Peter Rossing (Copenhague, DEN)

Panelists: Maria Borentain (Bayer, GER), Kristine Buchholtz (NovoNordisk, DEN), Joseph Chin (CMS, USA), Jennifer Green (Durham, NC, USA), Hiddo Heerspink (Groningen, NED), Sibylle Hauske (Boehringer, GER), Patrick Gee (Chesterfield, MO, USA), Dustin Little (AstraZeneca, USA) Borislava Mihaylova (London, UK), Brendon Neuen (Sydney, AUS), Peter Rossing (Copenhague, DEN), Katherine Tuttle (Spokane, WA, USA), Muthiah Vaduganathan, (Boston, MA, USA), Matthew Weir (Baltimore, MA, USA), Fred Yang (KBP BioScience, USA)

Room 4
Monday, December 9, 2024
14:00 -16:00

DIABETES AND CKD THERAPIES Part 2.
GAPS IN EVIDENCE AND HOW TO ADDRESS.
NEW INVESTIGATIONAL DRUGS AND NEW TRIALS.
Chairpersons: Mansoor Husain (Toronto, CAN) & TBD

What additional/alternative agents are in the pipeline (NsMRA, Ziltivekimab, ASI, Cagrisema, dual/triple Incretins, etc...)?
Hiddo Heerspink (Groningen, NED)

What additional benefit should be investigated in future trials?

Stroke and cognition
Mansoor Husain (Toronto, CAN)

Retinopathy.
TBD

“An ounce of prevention...”. Evidence and trial opportunities in prediabetes.
Gregory Schwartz (Aurora, CO, USA)

What to do in Type 1 Diabetes?
Amy Mottl (Chapel Hill, NC, USA)

Industry viewpoint.
Sofia Gerward (NovoNordisk, DEN)

Regulatory viewpoints.
John Sharretts (FDA, USA)
TBD (EMA)

The CVCT Multi-Stakeholder Think Tank Debate

DIABETES AND CKD THERAPIES Part 2.
ADDRESSING THE GAPS. NEW INVESTIGATIONAL DRUGS AND NEW TRIALS.
Chairpersons: Mansoor Husain (Toronto, CAN) & TBD

Panelists: Maria Borentain (Bayer, GER), Patrick Gee (Chesterfield, MO, USA), Jyothis George (Amgen, USA), Sofia Gerward (NovoNordisk, DEN), Jennifer Green (Durham, NC, USA), Hiddo Heerspink (Groningen, NED), Mansoor Husain (Toronto, CAN), Amy Mottl (Chapel Hill, NC, USA), Masahiro Murakami (Eli Lilly, USA), Peter Rossing (Copenhague, DEN), Gregory Schwartz (Aurora, CO, USA),John Sharretts (FDA, USA), Dominic Steubl (Boehringer, GER), Fred Yang (KBP BioScience, USA)

Room 4
Monday, December 9, 2024
16:30 -19:00

iCVCT
THROMBOSIS TRIALS. WHAT IS HAPPENING WITH FACTOR XI INHIBITORS?
Chairpersons: Michael Gibson (Boston, USA) & Vijay Kunadian (Newcastle upon Tyne, UK)

Overview of factor XI/XIa inhibitors as a biological target.
Jeffrey Weitz (Hamilton, CAN)

The results of OCEANIC-AF
Manesh Patel (Durham, NC, USA)

Update On Ongoing Adjacent AF Trials Targeting FXI/XIa.
LIBREXIA-AF / LILAC-TIMI-76
Carolyn Lam (Singapore, SIN)

Oral Factor XIa Inhibitor Trials in Secondary Stroke Prevention
OCEANIC-STROKE / LIBREXIA-STROKE
Mike Sharma (Hamilton, CAN)

Oral Factor XIa Inhibitor Trial After Recent ACS
LIBREXIA- ACS
Michael Gibson (Boston, USA)

Methodology perspective – Trial population and dose finding issues .
Edip Gurol (Boston, MA, USA)

Alternative dose finding options
Marc Bonaca (Denver, CO, USA)

DSMB perspective – Stopping trials prematurely.
David Cohen (Boston, USA)

Industry viewpoints.
Eva Muehlhofer (Bayer, GER), Nani Bhalla (BMS, USA), Alessandro Maresta (Janssen, CH)

Regulatory viewpoints.
Jordan Pomeroy (FDA, USA)
TBD (EMA)

Payers viewpoints.
Gary Ford (NICE, UK)
Lee Fleisher (CMS, USA)

The CVCT Multi-Stakeholder Think Tank Debate
THROMBOSIS TRIALS. DOES DOSE MATTER?
Chairpersons: Michael Gibson (Boston, USA) & Vijay Kunadian (Newcastle upon Tyne, UK)

Panelists: Nani Bhalla (BMS, USA), Marc Bonaca (Denver, CO, USA), , Daniel Canos (FDA, USA), Davide Capodanno (Catania, ITA), Lee Fleisher (CMS, USA), Gary Ford (NICE, UK), Habib Gamra (Sousse, TN), Michael Gibson (Boston, USA), Edip Gurol (Boston, MA, USA), Robert Hillman (Celecor, USA), Aaron Kithcart (Regeneron, USA), Jay Kokar (London, UK), Vijay Kunadian (Newcastle upon Tyne, UK), Carolyn Lam (Singapore, SIN), Renato Lopes (Durham, NC, USA), Manesh Patel (Durham, NC, USA), Alessandro Maresta (Janssen, CH), Eva Muehlhofer (Bayer, GER), Mpiko Ntsekhe (Cape Town, SA), Alexei Plotnikov (Janssen, CH), Jordan Pomeroy (FDA, USA), Sébastien Roux (Viatris, CH), Mike Sharma (Hamilton, CAN), Jeffrey Weitz (Hamilton, CAN), So Young Kim (Bayer, GER)

Room 1
Tuesday, December 10, 2024
08:00 -10:30

CVCT GOING GLOBAL. CLINICAL TRIALS IN APAC – LATAM – AFRICA/ME
Chairpersons: David Goff (NHLBI, NIH, USA) & Carolyn Lam (Singapore, SIN)

Need for global approach to Cardio-Renal-Metabolism clinical trials.
TBD

The Global Cardiovascular Research Funders Forum viewpoints. Transational funding of institutional trials (2x5 mins)
David Goff (NHLBI, NIH, USA)
Brian Wiliams (British Heart Foundation, UK)

Traditional chinese medicine in Randomized Controlled Trials.
Xin Li (Nanjing ; CHN), Yuejin Yang (Beijing, CHN)

Drug development: local to global.
Liming Gan (Ribocure Pharmaceuticals, CHN)

ARO viewpoint.
Renato Lopes (Durham, NC, USA)

CRO viewpoint.
Sahar Ebrahim (IQVIA, EGY)

Ethnic differences in cardiovascular clinical trials.
Kazuomi Kario (Tochigi, JPN)

Investigator ‘s viewpoint.
Felipe Martinez (Cordoba, ARG)

Industry viewpoints.
Sangeetha Anand (CSL Behring, SWI), Kenneth Stein (Boston Scientific, USA), TBD (AMGEN, USA)

Industry viewpoint: harnessing innovation from Asia.
Sharon Chan (Johnson & Johnson, CHN)

Challenges and opportunities with conducting trials in Africa-middle East.
Faiez Zannad (Paris, FRA)

Regulatory viewpoints.
Agustina Bisio (ANMAT, ARG)
Manabu Minami (PMDA, JPN)

Journal editors’ viewpoints.
Harlan Krumholz (JACC, USA), Helena Wang (Lancet, CHN)

The CVCT Multi-Stakeholder Think Tank Debate
CLINICAL TRIALS IN APAC – LATAM – AFRICA/ME
What Would It Take for CV Clinical Trials to Go Global?
Chairpersons: David Goff (NHLBI, NIH, USA) & Carolyn Lam (Singapore, SIN)

Panelists : Sangeetha Anand (CSL Behring, SWI), Kenneth Cavanaugh (FDA, USA), Sharon Chan (Johnson & Johnson, CHN), Sahar Ebrahim (IQVIA, EGY), Habib Gamra (Sousse, TN), Liming Gan (Ribocure Pharmaceuticals, CHN), David Goff (NHLBI, NIH, USA), Kazuomi Kario (Tochigi, JPN), Harlan Krumholz (JACC, USA), Carolyn Lam (Singapore, SIN) , Renato Lopes (Durham, NC, USA), Felipe Martinez (Cordoba, ARG), Manabu Minami (PMDA, JPN), AUS), Xin Li (Nanjing, CHN), Kenneth Stein (Boston Scientific, USA), Helena Wang (Lancet, CHN), Brian Wiliams (British Heart Foundation, UK), Fred Yang (KBP BioScience, USA), Yuejin Yang (Beijing, CHN), Faiez Zannad (Paris, FRA), André Zimerman (Rio Grande do Sul, BRA)

Room 1
Tuesday, December 10, 2024
11:00 -13:00

PULMONARY ARTERIAL HYPERTENSION TRIALS. SHALL WE START THINKING OUT OF THE BOX? BACK FROM THE 7th WORLD PH SYMPOSIUM.

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

Trial fortune and misfortune of emerging therapies for PAH.

Activin signaling inhibitors updates.
Marius Hoeper (Hannover, GER)

Oral and inhaled tyrosine kinase inhibitors phase 2 and 3 RCT.
Olivier Sitbon (Paris, FRA)

Inhaled MK 5475. Insights from the INSIGNIA trial.
Guillermo Bortman (Buenos-Aires; ARG)

Synthetic external controls in PAH: Ready for prime time or yesterday's news
Steve Kawut (Philadelphia, PEN, USA)

Withdrawal trial designs in PAH.
Jason Weatherald (Edmonton, CA)

Drug replacement trials.
Rogério Souza (Sao Paulo, BRA)

The value of patient preference and Patient-Reported Outcomes
Jimmy Ford (Chapel Hill, NC, USA)

Investigator's viewpoint.
Corey Ventetuolo (Providence, RI, USA)

Patient viewpoint.
Colleen Brunetti (Pulmonary Hypertension Association, USA)

Industry viewpoint.
Larry Zisman (Gossamer, USA)

FDA/EMA viewpoints.
Mitch Psotka (FDA, USA)
TBD (EMA, NED)

Payer's viewpoint.
Linda Gousis (CMS, USA)

The CVCT Multi-Stakeholder Think Tank Debate

PULMONARY ARTERIAL HYPERTENSION INNOVATIVE DESIGNS

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

Panelists : Guillermo Bortman (Buenos-Aires; ARG), Colleen Brunetti (Pulmonary Hypertension Association, USA), Bjorn Dahlof (Cereno, SWE), CQ Deng (United Therapeutics, USA), Jimmy Ford (Chapel Hill, NC, USA), Linda Gousis (CMS, USA), Marius Hoeper (Hannover, GER), Marc Humbert (Paris, FRA), Steve Kawut (Philadelphia, PEN, USA), Brad Maron (Baltimore, MA,USA), Vallerie McLaughlin (Ann Arbor, MI, USA), Mitch Psotka (FDA, USA), Sandeep Sahay (Houston, TX,USA), Olivier Sitbon (Paris, FRA), Rogério Souza (Sao Paulo, BRA), Corey Ventetuolo (Providence, RI, USA), Jason Weatherald (Edmonton, CA), Larry Zisman (Gossamer, USA)

Room 1
Tuesday, December 10, 2024
14:00 -16:00

GROUP 2 PULMONARY HYPERTENSION TRIALS. INTERSECTIONS WITH HEART FAILURE
Chairpersons: Mardi Gomberg-Maitland (Washington, DC, USA) & Milton Packer (Dallas, TX, USA)

Endothelin antagonists. Failed borrowing from PAH to Heart Failure.
Sanjiv Shah (Chicago, IL, USA)

Epidemiology and unmet needs in Group 2 PH.
Brad Maron (Baltimore, MD, USA)

A critical analysis of currently available RCTs in Group 2 PH.
Jean-Luc Vachiéry (Brussels, BEL)

Sotatercept for Group 2 PH: CADENCE trial update.
Mardi Gomberg-Maitland (Washington, DC, USA)

A heart failure trialist critical appraisal of contemporary PAH trials.
Milton Packer (Dallas, TX, USA)

Can the heart failure outcome trial design model apply to PAH?
Faiez Zannad (Paris, FRA)

Industry viewpoint.
Alessia Urbinati (Merck, USA)

Regulatory viewpoints.
Peter Mol (EMA, NED)
Mitch Psotka (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

GROUP 2 PULMONARY HYPERTENSION TRIALS. INTERSECTIONS WITH HEART FAILURE
Chairpersons: Mardi Gomberg-Maitland (Washington, DC, USA) & Milton Packer (Dallas, TX, USA)

Panelists : Mardi Gomberg-Maitland (Washington, DC, USA), Brad Maron (Baltimore, MD, USA), Milton Packer (Dallas, TX, USA), Mitch Psotka (FDA, USA), Sanjiv Shah (Chicago, IL, USA), Alessia Urbinati (Merck, USA), Jean-Luc Vachiéry (Brussels, BEL), Faiez Zannad (Paris, FRA)

Room 1
Tuesday, December 10, 2024
16:30 -18:30

GROUP 3 PULMONARY HYPERTENSION TRIALS. INTERSECTIONS WITH RESPIRATORY DISEASES
Chairpersons: Kelly Chin (Dallas, TX, USA) & Gérald Simonneau (Paris, FRA)

Interstitial Lung Disease – PH.

A critical analysis of PDE5i RCTs for ILD-PH.
Fernando Martinez (Boston, MA, USA)

Inhaled Treprostinil for ILD-PH.
Oksana Shlobin (Washington, DC, USA)

Novel therapies for ILD-PH.
Rajan Saggar (UCLA, CA, USA)

Chronic Obstructive Pulmonary Hypertension

Inhaled Treprostinil for COPD-PH: PERFECT trial.
Steven Nathan (Washington, DC, USA)

Inhaled MK-5475 for COPD-PH.
Paul Hassoun (Baltimore, MA, USA)

Tadalafil for COPD-PH: ERASE PH-COPD trial update.
Marc Humbert (Paris, FRA)

Investigator's viewpoint.
Sandeep Sahay (Houston, TX, USA)

Industry viewpoints.
Mackenzie Ford (Merck, USA)

FDA/EMA viewpoints.
Mitch Psotka (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

GROUP 3 PULMONARY HYPERTENSION TRIALS. INTERSECTIONS WITH RESPIRATORY DISEASES
Chairpersons: Kelly Chin (Dallas, TX, USA) & Gérald Simonneau (Paris, FRA)

Panelists : Rahul Agrawal (Cereno, SWE), Kelly Chin (Dallas, TX, USA), Dan Chiche (35Pharma, USA), Mackenzie Ford (Merck, USA), Paul Hassoun (Baltimore, MA, USA), Marc Humbert (Paris, FRA), Steve Kawut (Philadelphia, PEN, USA), Brad Maron (Baltimore, MA, USA), Fernando Martinez (Boston, MA, USA), Steven Nathan (Washington, DC, USA), Janethe Pene de Oliveira (Oorja Bio, USA), Mitch Psotka (FDA, USA), Rajan Saggar (UCLA, CA, USA), Sandeep Sahay (Houston, TX, USA), Carlos Sanmarco (Roivant, USA), Oksana Shlobin (Washington, DC, USA), Gérald Simonneau (Paris, FRA), Corey Ventetuolo (Providence, RI, USA)

Tuesday, December 10, 2024
18:30 - 19:00

PLENARY KEYNOTE

Valentin Fuster (New York, NY and Madrid, ESP)

Past-editor-in-chief of the Journal of the American College of Cardiology (JACC), Past President of the American Heart Association, Past President of the World Heart Federation, Past member of the US National Academy of Medicine

Room 2
Tuesday, December 10, 2024
08:00 -10:30

GLP1 RA FOR CARDIO-KIDNEY-METABOLISM
DISSECTING THE INCREMENTAL EVIDENCE
Chairpersons: Joao Ferreira (Porto, POR) & Katherine Tuttle (Spokane, WA, USA)

FLOW trial main results.
Vlado Perkovic (Sydney, AUS)

Mechanistic insight and plausibility. Do we know how GLP1RA work?
Katherine Tuttle (Spokane, WA, USA)

Safety of GLP1RAs. Results from trials and from Real World.
David D'Alessio (Durham, NC, USA)

What do GLP1RAs add to other CKM therapies.
Ellen Apperloo (Groningen, NED)
Brendon Neuen (Sydney, AUS)

Heart failure patients and heart failure outcomes in GLP1RA trials.
Joao Ferreira (Porto, POR)

Statistical viewpoint. Stopping early and other considerations.
Jan Tijssen (Brussels, BEL)

Moving toward a 4-Pillar therapy? Issues relative to combination therapy.
Meg Jardine (Sydney, AUS)

Industry viewpoints.
Dorthe Charlotte Skovgaard (Novonordisk, DEN), Bettina Kraus (Boehringer, GER), TBD (Lilly, USA)

Regulatory viewpoints.
Rekha Kambhampati (FDA, USA)
TBD (EMA)

Patient's viewpoint.
Steve Macari (Poitiers, FRA)

Payer's viewpoint.
Jesse Roach (CMS, USA)

The CVCT Multi-Stakeholder Think Tank Debate
GLP1 RA FOR CARDIO-KIDNEY-METABOLISM
RESULTS AND PRACTICAL CONSEQUENCES OF ACCUMULATING EVIDENCE.
Chairpersons: Joao Ferreira (Porto, POR) & Katherine Tuttle (Spokane, WA, USA)

Panelists : Ellen Apperloo (Groningen, NED), David D'Alessio (Durham, NC, USA), Joao Ferreira (Porto, POR), Meg Jardine (Sydney, AUS), Rekha Kambhampati (FDA, USA), Bettina Kraus (Boehringer, GER), TBD (Lilly, USA), Steve Macari (Poitiers, FRA), Brendon Neuen (Sydney, AUS), Vlado Perkovic (Sydney, AUS), Jesse Roach (CMS, USA), Dorthe Charlotte Skovgaard (NovoNordisk, DEN), Jan Tijssen (Brussels, BEL), Katherine Tuttle (Spokane, WA, USA)

Room 2
Tuesday, December 10, 2024
11:00 -13:00

PEDIATRIC CARDIOLOGY SPECIFIC CLINICAL TRIAL CONSIDERATIONS
Chairpersons: Shelley Miyamoto (Denver, CO, USA) & Gail Pearson (NHLBI, USA)

What makes pediatric trials different?
Joseph Rossano (Philadelphia, PA, USA)

Children are not small adults! Rationale for pediatric drug development.
Jennifer Li (Durham, NC, USA)

Why bother labeling drugs/devices for children?
John Van Hare (FDA, USA)

Moving from adult to pediatric therapies in HF: VICTORIA & VALOR trials.
Mackenzie Ford (Merck, USA)

What are ideal drug candidates for study?
Donato Bonifazi (Pavia, ITA)

What endpoints are valid ?

Use of biomarkers in pediatric clinical trials.
Shelley Miyamoto (Denver, CO, USA)

Role of Patient Reported Outcomes. The PCORI CHI RON study.
Anitha John (Washington DC, USA)

Regulatory viewpoints.
Ann Punnoose (FDA, USA)
Claus Bolte (Swissmedic, CH)

Who funds clinical trials? Funders viewpoints (5 mins each).

NHLBI
Gail Pearson (NHLBI, USA)

Role of Foundations
Kirstie Keller (Additional Ventures, USA)

The CVCT Multi-Stakeholder Think Tank Debate
PEDIATRIC SPECIFIC CLINICAL TRIAL CONSIDERATIONS
Chairpersons: Shelley Miyamoto (Denver, CO, USA) & Gail Pearson (NHLBI, USA)

Panelists : Claus Bolte (Ex-Swissmedic, Basel, CH), Donato Bonifazi (Pavia, ITA), Mackenzie Ford (Merck, USA), Anitha John (Washington DC, USA), Kirstie Keller (Additional Ventures, USA),Jennifer Li (Durham, NC, USA), Shelley Miyamoto (Denver, CO, USA), Gail Pearson (NHLBI, USA), Ann Punnoose (FDA, USA), Joseph Rossano (Philadelphia, PA, USA)

Room 2
Tuesday, December 10, 2024
14:00 -16:00

GETTING A PEDIATRIC CARDIOLOGY DEVICE TO TRIAL
Chairpersons : Angela Lorts (Cincinatti, OH, USA) & Elfriede Pahl (Wilmette, IL, USA)

Experience with preclinical work on devices for children.
Beverly Tang (Berkeley, CA, USA)

New devices for supporting infants/children.
Takeshi Shinkawa (Tokyo, JPN)

Pediatric EP devices, why class III (CV) devices won't get through a pediatric device consortium.
Anne Dubin (Palo Alto, CA, USA)

Highlights of the PICCOLO PDA device - for preemies and PIVOTAL trial.
Thomas Forbes (Hollywood, FL, USA)

The European perspective on devices/VADs. What devices are preferred for MCS in children in 2024?
Daniel Zimpfer (Vienna, AUT)

Artificial Intelligence/Machine Learning and the use of digital twinning.
Alison Marsden (Stanford, CA, USA).

Real World Data and Registries– How do they inform clinical trials?

ACTION Registry & lessons learned from Berlin trial.
Angela Lorts (Cincinatti, OH, USA)

PHTS lessons learned.
Kevin Daly (Boston, MA, USA)

The stress trial. How to leverage existing resources from Society of Thoracic Surgery Registry.
Kevin Hill (Durham, NC, USA)

Industry viewpoint
Richard Dujmovic (Boston Scientific, USA)

FDA's perspectives on using of real world data in regulatory decision making
George Van Hare (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

GETTING A PEDIATRIC CARDIOLOGY DEVICE TO TRIAL
Chairpersons : Angela Lorts (Cincinatti, OH, USA) & Elfriede Pahl (Wilmette, IL, USA)

Panelists : Kevin Daly (Boston, MA, USA), Anne Dubin (Palo Alto, CA, USA), , Richard Dujmovic (Boston Scientific, USA), Kevin Hill (Emma Moran (Pediatric Device Consortium, USA), Kirstie Keller (Additional Ventures, USA), Elfriede Pahl (Wilmette, IL, USA), Martin Schweiger (Zurich, CH), Takeshi Shinkawa (Tokyo, JPN), Beverly Tang (Berkeley, CA, USA), Rahul Thakar (NHLBI, USA), George Van Hare (FDA, USA), Daniel Zimpfer (Vienna, AUT)

Room 2
Tuesday, December 10, 2024
16:30 -18:30

BIOLOGICS THERAPEUTICS MOVING TO CLINICAL STAGE
Chairpersons: Marianna Fontana (London, UK) & Thomas Thum (Hannover, GER)

Overview of novel and ongoing clinical trials.

siRNA and ASO therapeutics.
TBD

miRNA therapeutics.
Thomas Thum (Cardior, GER)

Antibody therapies .
Marianna Fontana (London, UK)

Targeting the heart and/or the kidney.

Seeking cardiovascular indications.
Mads Engelmann (Novo Nordisk, DEN)

Seeking kidney indications.
Christoph Wanner (Wursburg, GER)

Industry viewpoints.
Anders Himmelmann (Astrazeneca, UK), Andres Laguna (Novartis, ESP), Paul Nioi (Alnylam, UK), Christopher O'Donnell (Novartis, USA), Lothar Roessig (ASKBIO/Bayer, GER), Ricardo Rocha (Intellia Therapeutics, USA), Bryan Young (Regeneron, USA)

Journal editor's viewpoint.
TBD

Regulatory viewpoints.
TBD (FDA, USA), Maria Jesus Lamas (AEMPS, ESP)

Patient's viewpoint.
TBD

The CVCT Multi-Stakeholder Think Tank Debate
BIOLOGICS THERAPEUTICS MOVING TO CLINICAL STAGE
Chairpersons: Marianna Fontana (London, UK) & Thomas Thum (Hannover, GER)

Panelists: Mads Engelmann (Novo Nordisk, DEN), Marianna Fontana (London, UK), Anders Himmelmann (AstraZeneca, UK), Andres Laguna (Novartis, ESP), Maria Jesus Lamas (AEMPS, ESP) , Paul Nioi (Alnylam, UK), Lothar Roessig (Askbio/Bayer, GER), Ricardo Rocha (Intellia Therapeutics, USA), Thomas Thum (Cardior, GER), Christoph Wanner (Wursburg, GER)

Room 2
Monday, December 9, 2024
08:00 -10:30

SAFETY EVALUATION OF CARDIOVASCULAR DRUGS AND DEVICES
Chairpersons: Marc Pfeffer (Boston, MA, USA) & Nawab Qizilbash (Madrid, ESP)

The proper assessment of drug safety is a key requirement of successful drug and device development and consequent use. This session will bring leading experts in the field to present and debate what are the key issues in safety evaluation of both pre-licensing trials and post-approval studies.The combination of clinical, statistical, epidemiological, industry, regulatory and HTA perspectives should ensure a lively interactive session.

Part 1 EVALUATION OF SAFETY IN PIVOTAL PHASE 3 TRIALS (PRE-LICENSING)

Clinical perspective.
Marc Pfeffer (Boston, MA, USA)

Data Safety Monitoring Boards.
Barry Greenberg (San Diego, CA, USA)

Statistical perspective.
John Gregson (London, UK)

Industry perspective.
Anastasia Lesogor (Novartis, USA), TBD

Regulatory perspective.
Mary Ross Southworth (FDA, USA)
TBD (EMA, ...)

Patient's viewpoint.
Penilla Gunther (Stockholm, SWE)

The CVCT Multi-Stakeholder Think Tank Debate
Part 1: HOW TO PROGRESS EVALUATION IN PRE-APPROVAL TRIALS?
Chairpersons: Marc Pfeffer (Boston, MA, USA) & Nawab Qizilbash (Madrid, ESP)

Panelists : Peter Arlett (EMA, BEL), Richard Dujmovic (Boston Scientific, USA), Joann Evangelista (Genentech, USA), Barry Greenberg (San Diego, CA, USA), John Gregson (London, UK), Penilla Gunther (Stockholm, SWE) , Anastasia Lesogor (Novartis, USA), Marc Pfeffer (Boston, MA, USA), Nawab Qizilbash (Madrid, ESP), Frank Rockhold (Durham, NC, USA), Mary Ross Southworth (FDA, USA), Bram Zuckerman (FDA, USA)

Room 2
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SAFETY EVALUATION OF CARDIOVASCULAR DRUGS AND DEVICES
Chairpersons: Marc Pfeffer (Boston, MA, USA) & Nawab Qizilbash (Madrid, ESP)

Part 2: EVALUATION OF SAFETY POST-APPROVAL

Epidemiological/CRO perspective.
Nawab Qizilbash (Madrid, ESP)

Methodological perspective.
Frank Rockhold (Durham, NC, USA)

Industry perspective.
Richard Dujmovic (Boston Scientific, USA), Joann Evangelista (Genentech, USA)

Regulatory perspective.
Peter Arlett (EMA, NED)
Bram Zuckerman (FDA, USA)

HTA perspective.
TBD

The CVCT Multi-Stakeholder Think Tank Debate
Part 2: EVALUATION OF SAFETY POST-APPROVAL
Chairpersons: Marc Pfeffer (Boston, MA, USA) & Nawab Qizilbash (Madrid, ESP)

Panelists : Peter Arlett (EMA, BEL), Richard Dujmovic (Boston Scientific, USA), Joann Evangelista (Genentech, USA), John Gregson (London, UK), Anastasia Lesogor (Novartis, USA), Marc Pfeffer (Boston, MA, USA), Nawab Qizilbash (Madrid, ESP), Frank Rockhold (Durham, NC, USA), Norman Stockbridge (FDA, USA), Bram Zuckerman (FDA, USA)

Room 3
Tuesday, December 10, 2024
11:00 -13:00

THE FUTURE OF POST-MI DRUG THERAPY TRIALS
Chairpersons: Josephine Harrington (Durham, NC, USA) & Sanjit Jolly (Hamilton, CAN)

Trials in patients developing heart failure post-myocardial infarction

Main results of EMPACT MI.
Javed Butler (Dallas, TX, USA)

Statistical viewpoint. EMPACT MI and AEGIS II.
Stuart Pocock (London, UK)

Colchicine and Spironolactone in unselected post-MI population. CLEAR-SYNERGY main results, and meta-analysis.
Sanjit Jolly (Hamilton, CAN)

Mitigating the challenge of declining event rate. The value of win ratio and of ranking/ordinal endpoint in post-MI trials.
John Gregson (London, UK)

Putting the results of recent post-MI patients in the context of clinical practice.
Mariell Jessup (Philadelphia, Pa, USA)

The residual risk In post-MI patients. When enough is enough?
Marc Pfeffer (Boston, Ma, USA)

What opportunities are left? What future post-MI trial design should look like.
Faiez Zannad (Paris, FRA)

Industry viewpoints
Sébastien Roux (Viatris, CH), Mikhail Sumin (Boehringer, GER), Thomas Thum (Cardior, GER)

Regulatory viewpoint.
Charu Gandotra (Fda, USA)

The CVCT Multi-Stakeholder Think Tank Debate
THE FUTURE OF POST-MI TRIALS POST EMPACT-MI
Chairpersons: Josephine Harrington (Durham, NC, USA), Sanjit Jolly (Hamilton, CAN)

Panelists: Javed Butler (Dallas, TX, USA), Charu Gandotra (FDA, USA), John Gregson (London, UK), Josephine Harrington (Durham, NC, USA), Mariell Jessup (Philadelphia, PA, USA), Sanjit Jolly (Hamilton, CAN), Marc Pfeffer (Boston, MA, USA), Stuart Pocock (London, UK), Sébastien Roux (Idorsia, CH), Mikhail Sumin (Boehringer, GER), Thomas Thum (Cardior, GER), Faiez Zannad (Paris, FRA)

Room 3
Tuesday, December 10, 2024
14:00 -16:00

CORONARY CT ATHEROSCLEROSIS AS A PROGNOSTIC AND SURROGATE BIOMARKER IN CLINICAL TRIALS

Chairpersons: Kelley Branch (Seattle, WA, USA) & Pamela Douglas (Durham, NC, USA)

CAD imaging endpoints to accelerate drug development and translation.
Keith Channon (Oxford, UK)

Which coronary atherosclerosis imaging test(s) and metrics should be used as an enrichment biomarker to improve efficiency of CAD clinical trials?
Ron Blankstein (Boston, MA, USA)

Pragmatic considerations for CTCA, CAD and NCPV measures for enrichment in clinical trials.
Leslee Shaw (New York, NY, USA)

Coronary atherosclerosis CT imaging as a surrogate endpoint to accelerate CAD drug development.
Pamela Douglas (Durham, NC, USA)

Future Trialist viewpoint
Guiomar Mendieta (Madrid, ESP)

Industry viewpoints.
Craig Basson (Bitterrootbio, USA), Udo Hoffmann (Cleerly, USA), Denise Yates (Novartis, USA)

Regulatory viewpoints.
Jeff Siegel (FDA, USA)
Norm Stockbridge (FDA, USA)

Payer's viewpoint.
Jonathan Blum (USA)

Patient's viewpoint.
TBD

The CVCT Multi-Stakeholder Think Tank Debate

CAN OR WHEN COULD CT PLAQUE IMAGING REPLACE ADVERSE EVENTS ASSESSMENTS IN CLINICAL TRIALS

Chairpersons: Kelley Branch (Seattle, WA, USA) & Pamela Douglas (Durham, NC, USA)

Panelists: Craig Basson (BitterrootBio, USA), Ron Blankstein (Boston, MA, USA), Kelley Branch (Seattle, WA, USA), Daniel Canos (FDA, USA), Keith Channon (Oxford, UK), Pamela Douglas (Durham, NC, USA), Richard George (Regeneron, USA), Udo Hoffmann (Cleerly, USA), Guiomar Mendieta (Madrid, ESP), Leslee Shaw (New York, NY, USA), Jeff Siegel (FDA, USA), Norm Stockbridge (FDA, USA), Denise Yates (Novartis, USA)

Room 3
Tuesday, December 10, 2024
16:30 -18:30

IMPLEMENTATION TRIALS
CVCT-NHLBI joint session
GETTING PRACTICAL WITH DESIGNING FOR EFFECTIVENESS/IMPLEMENTATION
A SERIES OF CASE STUDIES
Chairpersons : Cara Lewis (NHLBI,USA) & George Mensah (NHLBI, USA)

Introduction: how trialists may ultimately increase the reach of their intervention by prospectively designing and simultaneously testing for effectiveness and implementation.
Cara Lewis (NHLBI,USA)

Case study 1. Implementation outcomes: the WHO Integration of hypertension management into HIV care in the Real-World setting.
Isaac Ssinabulya (Kampala, UGA)

Case study 2: determinant frameworks to inform intervention design and implementation readiness. The pre-implementation phase of a project seeking to deliver a community-based CVD prevention intervention (SPICES-Sussex).
Hilde Bastiaens (Antwerp, BEL)

Effectiveness-implementation hybrid study types

Type 1 case study: learning about clinical and implementation outcomes simultaneously.
Margrét Leósdóttir (Malmö, SWE)

Implementation trials in Asia.
Lijing Yan (Kunshan, CHN)

Challenges and opportunities to improve trial design and conduct to be most responsive to the needs of clinical practice. The JAMA initiative.
Gregory Curfman (JAMA, USA)

Editor's viewpoints
Michael Basson (Nature Medicine, USA)
Chloe Wilson (Lancet, UK)

The CVCT Multi-Stakeholder Think Tank Debate
CVCT-NHLBI joint session
DESIGNING TRIALS WITH IMPLEMENTATION IN MIND
Chairpersons : Cara Lewis (NHLBI, USA) & George Mensah (NHLBI, USA)

Panelists: Michael Basson (Nature Medicine, USA), Hilde Bastiaens (Antwerp, BEL), Gregory Curfman (JAMA, USA), Margrét Leósdóttir (Malmö, SWE), Cara Lewis (NHLBI, USA), George Mensah (NHLBI, USA), Isaac Ssinabulya (kampala, UGA), Chloe Wilson (Lancet, UK), Lijing Yan (Kunshan, CHN)

Room 4
Tuesday, December 10, 2024
08:00 -10:30

CARDIAC AMYLOIDOSIS.
HOW LATEST PROGRESS IN DETECTION, TREATMENT AND PREVENTION MAY AFFECT FUTURE TRIAL DESIGN.
Chairpersons: Marianna Fontana (London, UK) & Dan Judge (Charleston, SC, USA)

Gene-silencing, antibody therapy and new kids in the block: progress in ATTR stabilization and ATTR prevention drug therapy.
Pablo Garcia-Pavia (Madrid, ESP)

Lessons from science, biology, clinical medicine and clinical trials. The future of amyloidosis as a rare disease and consequences on new cardiac amyloidosis trials.
Julian Gilmore (London, UK)

Progress in cardiac amyloidosis diagnosis and AI tracking of cardiac amyloidosis
High-throughput identification of ATTR-CM at scale.
Rohan Khera (New Haven, CT, USA)
Venky Soundararajan (Anumana, USA)

Most recent clinical trials results and approvals.
Marianna Fontana (London, UK)

What should be the right background and control therapy in future amyloidosis trials?
TBD

How to define disease progression endpoints in prevention trials? Surrogates vs. symptoms vs. outcomes.
Dan Judge (Charleston, SC, USA)

Industry viewpoints.
Adam Castano (Bridebio, USA), Christie Nie (Prothena, USA), Garg Pushkal (Alnylam, UK), SotiriosTsimikas (Ionis,USA)

Patient ‘s viewpoint.
Isabelle Lousada (Amyloidosis Research Consortium, USA)

Regulatory viewpoint.
Rosalyn Adigun (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate
CARDIAC AMYLOIDOSIS.
SHAPING THE NEXT WAVE OF CLINICAL TRIALS.
Chairpersons: Marianna Fontana (London, UK) & Dan Judge (Charleston, SC, USA)

Panelists : Rosalyn Adigun (FDA, USA), Alberto Aimo (Pisa,ITA), Adam Castano (BridgeBio, USA), Marianna Fontana (London, UK), Pablo Garcia-Pavia (Madrid, ESP), Julian Gilmore (London, UK), Dan Judge (Charleston, SC, USA), Peter Kahr (Neurimmune, CH), Rohan Khera (New Haven, CT, USA), David Lebwohl (Intellia Therapeutics, USA), Isabelle Lousada (Amyloidosis Research Consortium, USA), Christie Nie (Prothena, USA), Garg Pushkal (Alnylam, UK), Maria Sejersten Ripa (Novo Nordisk, DEN), Sotirios Tsimikas (Ionis,USA), Venky Soundararajan (Anumana, USA), Michelle Stewart (Pfizer, USA)

Room 4
Tuesday, December 10, 2024
11:00 -13:00

HYPERTROPHIC CARDIOMYOPATHIES (HCM). Part 1
PROGRESS IN DETECTION AND CLINICAL MANAGEMENT LIKELY TO AFFECT FUTURE TRIALS
Chairpersons: Kimberly Hong (San Diego, CA, USA) & Martin Maron (Boston, MA, USA)

Most recent HCM clinical trials results and approvals.
Martin Maron (Boston, MA, USA)

Expected implementation of recent trials findings.

Updating the guidelines.
Elena Arbelo (Barcelona, ESP)

How recent findings may translate into daily practice.
TBD

The genetic/pediatric perspective.
Kimberly Hong (San Diego, CA, USA)

The consequences of the changing landscape on future HCM trials.

Patient identification for clinical trials progress in HCM diagnosis, genomics and imaging.
James Moon (Myocardium AI Ltd, UK)

How Ai may help understanding Early stage HCM
Maxime Touzot (Owkin, FRA)

Industry viewpoint.
Steve Heitner (Cytokinetics, USA)

Patient's viewpoint.
Lisa Salberg (HCMA, USA)

Payers' viewpoints.
Meindert Boysen (NICE, UK)
Joseph Chin (CMS, USA)

The CVCT Multi-Stakeholder Think Tank Debate
HYPERTROPHIC CARDIOMYOPATHIES. Part 1
HOW PROGRESS IN DISEASE DETECTION AND MANAGEMENT WILL AFFECT PATIENT SELECTION IN FUTURE TRIALS
Chairpersons: Kimberly Hong (San Diego, CA, USA) & Martin Maron (Boston, MA, USA)

Panelists: Eric Adler (Lexeo, USA), Elena Arbelo (Barcelona, ESP), Arnaud Bastien (BMS, USA), Meindert Boysen (NICE, UK), Jim Carr (StealthTx, USA), Joseph Chin (CMS, USA), Belinda Hardin (Lexicon, USA), Steve Heitner (Cytokinetics, USA), Kimberly Hong (San Diego, CA, USA), Matthew Lee (Glasgow, UK), Martin Maron (Boston, MA, USA), James Moon (Myocardium AI Ltd, UK), Lisa Salberg (HCMA, USA), Jonathan Schwartz (RocketPharma, USA), Laura Robertson (Tenaya, USA), Marc Semigran (Edgewise, USA), Maxime Touzot (Owkin, FRA)

Room 4
Tuesday, December 10, 2024
14:00 -16:00

HYPERTROPHIC CARDIOMYOPATHIES (HCM).
Part 2 NEW CHALLENGES FOR FUTURE TRIALS
Chairpersons: Carolyn Ho (Boston, MA, USA) & Juan Pablo Kaski (London, UK)

What is the right background therapy in future trials?
Perry Mark Elliott (London, UK)

What comparators in future trials. What will be standard of care: drug therapy, surgical myectomy and septal ablation?
Milind Desai (Cleveland, OH, USA)

How to assess disease modification? Upstream prevention of progression.
Ethan Rowin (Burlington, MA, USA)

Translating learnings from HCM to HFPEF (and vice versa).
Iacopo Olivotto (Trieste, ITA)

Targeting diastole. Splitting vs lumping hypercontractile states.
Ajay Shah (London, UK)

Pediatrician's viewpoint.
Juan Pablo Kaski (London, UK)

Industry viewpoint.
Marc Semigran (Edgewise, USA)

Patient's viewpoint.
Lisa Salberg (HCMA, USA)

Regulatory viewpoints.
Hylton Joffe (FDA, USA)
Claus Bolte (Ex-Swissmedic, Basel, CH)

The CVCT Multi-Stakeholder Think Tank Debate
HYPERTROPHIC CARDIOMYOPATHIES (HCM).
Part 2 DESIGNING FUTURE TRIALS
Chairpersons: Carolyn Ho (Boston, MA, USA) &, Juan Pablo Kaski (London, UK)

Panelists: Eric Adler (Lexeo, USA), Arnaud Bastien (BMS, USA), Claus Bolte (Ex-Swissmedic, Basel, CH), Jim Carr (StealthTx, USA), Milind Desai (Cleveland, OH, USA), Perry Mark Elliott (London, UK), Belinda Hardin (Lexicon, USA), Carolyn Ho (Boston, MA, USA), Hylton Joffe (FDA, USA), Juan Pablo Kaski (London, UK), Matthew Lee (Glasgow, UK),Iacopo Olivotto (Trieste, ITA), Laura Robertson (Tenaya, USA), Ethan Rowin (Burlington, MA, USA), Lisa Salberg (HCMA, USA), Jonathan Schwartz (RocketPharma, USA), Marc Semigran (Edgewise, USA), Ajay Shah (London, UK)

Room 4
Tuesday, December 10, 2024
16:30 -18:30

MINERALOCORTICOID RECEPTOR ANTAGONISTS (MRA) CARDIO-KIDNEY THERAPY
Chairpersons: Maria Rosa Costanzo (Naperville, IL, USA) & Jozine Ter Maaten (Groningen, NED)

FINEARTS main results.
Scott Solomon (Boston, MA, USA)
John Mcmurray (Glasgow, UK)

Mechanistic insight and plausibility.
Bertram Pitt (Ann Arbor, USA)

Kidney outcomes with MRA therapy. The totality of evidence .
Hiddo Heerspink (Groningen, NED)

Statistical viewpoint.
Frank Rockhold (Durham, NC, USA)

Cardiovascular outcomes with MRA therapy. The totality of evidence.
Faiez Zannad (Paris, FRA)

Industry viewpoints.
Maria Borentain (Bayer, GER), Martin Cowie (AstraZeneca, USA)

Regulatory viewpoints.
Charu Gandotra (FDA, USA)
Heidi Janssen (EMA, NED)

Patient's viewpoint.
Mariette Verbakel (Nijmegen, NED)

Payer's viewpoint.
Meindert Boysen (NICE, UK)

The CVCT Multi-Stakeholder Think Tank Debate

MINERALOCORTICOID RECEPTOR ANTAGONISTS (MRA) CARDIO-KIDNEY THERAPY
Chairpersons: Maria Rosa Costanzo (Naperville, IL, USA) & Jozine Ter Maaten (Groningen, NED)

Panelists : Maria Borentain (Bayer, GER), Meindert Boysen (NICE, UK), Maria Rosa Costanzo (Naperville, IL, USA), Martin Cowie (AstraZeneca, USA), Charu Gandotra (FDA, USA), Patrick Gee (Chesterfield, MO, USA), Hiddo Heerspink (Groningen, NED), Heidi Janssen (EMA, NED), John McMurray (Glasgow, UK), Bertram Pitt (Ann Arbor, USA), Juergen Prochaska (Boehringer, GER), Frank Rockhold (Durham, NC, USA), Scott Solomon (Boston, MA, USA), Jozine Ter Maaten (Groningen, NED), Mariette Verbakel (Nijmegen, NED), Faiez Zannad (Paris, FRA)

Room 1
Wednesday, December 11, 2024
08:00 -10:30

ANTI-OBESITY MEDICINES (AOMS) AND CV OUTCOME TRIALS PART 1 – RESULTS TO DATE AND IMPLICATIONS

Chairpersons: Naveed Sattar (Glasgow, UK) & TBD

Why obesity really matters to CV medicine.
Naveed Sattar (Glasgow, UK)

Benefit of lifestyle /surgical interventions weight loss for CV outcomes?
Ian Neeland (Dallas, TX, USA)

SELECT – Summary of all findings to date.
Carolyn Lam (Singapore, SIN)

STEP-HFpEF – SUMMIT and other obesity trials in HF..
Milton Packer (Dallas, TX, USA)

Any evidence for likely CV impacts of adding to GLP-1, RAS, GIP agonists /antagonists, Glucagon / Amylin agonists? Rationale for combination therapy?
David D'Alessio (Durham, NC, USA)

Weight loss, sleep apnea and other non-CV outcomes with potential CV consequences.
Atul Malhotra (San Diego, CA, USA)

Statistician's viewpoint.
Frank Rockhold (Durham, NC, USA)

Industry viewpoints: how industry is planning implementation strategies for AOMs?
Maria Sejersten Ripa (Novonordisk, DEN), Masahiro Murakami (Eli Lilly, USA)

Evidence based implementation of AOMs. Implications for guidelines and care.
TBD

What OMs in CV medicine exist?
Javed Butler (Dallas, TX, USA)

Health economist and payer's viewpoint: how are regulators responding to results so far.
Joseph Chin (CMS, USA)
Borislava Mihaylova (London, UK)

Patient's viewpoint.
Wanda Moore (CCHHE, USA)

The CVCT Multi-Stakeholder Think Tank Debate

ANTI-OBESITY MEDICINES (AOMS) AND CV OUTCOME TRIALS PART 1 – RESULTS TO DATE AND IMPLICATIONS

Chairpersons: Naveed Sattar (Glasgow, UK) & TBD

Panelists: Siddique Abbasi (Amgen, USA), Pol Boudes (Galectin Tx, USA), Javed Butler (Dallas, TX, USA), Joseph Chin (CMS, USA), Michael Cooreman (Inventiva, FRA), David D'Alessio (Durham, NC, USA), Scott Harris (Altimmune, USA), Margaret Koziel (Axcella, USA), Emil Kuriakose (Terns, USA), Alessandra Lafranconi (Boehringer, GER), Carolyn Lam (Singapore, SIN), Hsiao Lieu (NGMBio, USA), Leigh MacConell (Hightide, JPN), Atul Malhotra (San Diego, CA, USA), Joseph Meidling (CytoDyn,USA), Borislava Mihaylova (London, UK), Wanda Moore (CCHHE, USA), Masahiro Murakami (Eli Lilly, USA) , Ian Neeland (Dallas, TX, USA), Milton Packer (Dallas, TX, USA), Elke Platz (Boston, MA, USA), Maria Sejersten Ripa (NovoNordisk, DEN), Frank Rockhold (Durham, NC, USA), Naveed Sattar (Glasgow, UK), Sangeeta Sawhney (Intercept, USA), Pietro Scalfaro (Enyo, FRA), Julia Schoelermann (35Pharma, USA), Rebecca Taub (Madrigal, USA), TBD (Roche)

Room 1
Wednesday, December 11, 2024
11:00 -13:00

ACUTE DECOMPENSATED HEART FAILURE (ADHF) DRUG AND DEVICE TRIALS
Chairpersons: Daniel Burkhoff (New York, NY, USA) & Maria Rosa Costanzo (Naperville, IL, USA)

Which ADHF patients should be candidates for device therapy trials?
Maria Rosa Costanzo (Naperville, IL, USA)

What is the most relevant primary endpoint in ADHF trials?

Should endpoints in ADHF be specific for device therapies trials?
Javed Butler (Dallas, TX, USA)

ADHF trial: are in-hospital outcomes realistic?
Gad Cotter (Momentum LLC, USA)

Improved decongestion is all what matters!
Biykem Bozkurt (Houston, USA)

How to prevent positive phase 2 trials to lead to neutral phase 3 trials.
Christopher O'Connor (Washington, DC, USA)

Regulatory viewpoints.
Meir Shinnar (FDA, USA)
Ileana Pinea (FDA, USA)
Piotr Szymanski (EU, POL)

Industry viewpoints.
Philip Adamson (CVRx, USA), Francesca Lawson (Corteria, USA), Chuck Simonton (Abiomed, USA)

Patient's' viewpoint.
Rhonda Monroe (Baltimore, MD, USA)

Payer's viewpoint.
Alan Fraser (Cardiff, UK)

The CVCT Multi-Stakeholder Think Tank Debate

ACUTE DECOMPENSATED HEART FAILURE (ADHF) DRUG AND DEVICE TRIALS
Chairpersons: Daniel Burkhoff (New York, NY, USA) & Maria Rosa Costanzo (Naperville, IL, USA)

Panelists: Philip Adamson (CVRx, USA), Daniel Burkhoff (New York, NY, USA), Javed Butler (Dallas, TX, USA), Maria Rosa Costanzo (Naperville, IL, USA), Gad Cotter (Momentum LLC, USA), Alan Fraser (Cardiff, UK), Philip Janiak (Corteria, FRA), Francesca Lawson (Corteria, USA), Rhonda Monroe (Baltimore, MD, USA), Chris O'Connor (Washington, DC, USA), Joanna Osmanska (Glasgow, UK), Ileana Pinea (FDA, USA), Meir Shinnar (FDA, USA), Chuck Simonton (Abiomed, USA), Piotr Szymanski (EU, POL)

Room 1
Wednesday, December 11, 2024
14:00 -16:00

ANTI-OBESITY MEDICINES (AOMS) AND CV OUTCOMES TRIALS
PART 2– HOW ONGOING AND FUTURE TRIALS ARE ADAPTING TO THE NEW LANDSCAPE
Chairpersons: Donna Ryan (Baton Rouge, LA, USA) & TBD

Are AOMs combinatorial agents?
Proven benefits of AOMs: NASH, CKD, OA, Hypertension, Lipids, Diabetes, Others
Donna Ryan (Baton Rouge, LA, USA)

Summary of ongoing CVOTS to report in next 3-4 Years: SURPASS CVOT, SYNCHRONIZE, REDEFINE-3, SURMOUNT MMO, others.
Carolyn Lam (Singapore, SIN)

Mechanistic gaps in effects of AOMs on CV outcomes: weight loss vs other effects?
Naveed Sattar (Glasgow, UK)

Multi-organ imaging. Revealing the cardio-kidney-liver benefits of investigational drugs.
Tom Waddell (Pespectum, USA)

How to measure and what are the consequences of muscle loss relative to fat loss?
Jennifer Linge (Amra Medical, SWE)

For how long can placebo-controlled trials of AOMS continue? Time to move to active -control designs?
Jennifer Green (Durham, NC, USA)

Industry viewpoints.
Kristine Buchholtz (Novonordisk, DEN), Mathijs Bunck (Eli Lilly, USA), Elena Startseva (Boehringer, GER)

Regulatory viewpoints.
Alar Irs (EMA, EST)
TBD (FDA, USA)

NIH viewpoint.
Tiffany Powell-Wiley (NHLBI, NIH, USA)

The CVCT Multi-Stakeholder Think Tank Debate

ANTI-OBESITY MEDICINES (AOMS) AND CV OUTCOMES TRIALS
PART 2– HOW ONGOING AND FUTURE TRIALS ARE ADAPTING TO THE NEW LANDSCAPE
Chairpersons: Donna Ryan (Baton Rouge, LA, USA) & TBD

Panelists: Jenny Blau (AstraZeneca, USA) , Kristine Buchholtz (NovoNordisk, DEN), Mathijs Bunck (Eli Lilly, USA), Javed Butler (Dallas, TX, USA), Siddique Abbasi (Amgen, USA), Richard George (Regeneron, USA), Jennifer Green (Durham, NC, USA), Alar Irs (EMA, EST), Carolyn Lam (Singapore, SIN) , Jennifer Linge (Amra Medical, SWE), Wanda Moore (CCHHE, USA), Karina Morley (AstraZeneca, SWE), Elke Platz (Boston, MA, USA), Tiffany Powell-Wiley (NHLBI, NIH, USA), Donna Ryan (Baton Rouge, USA) , Naveed Sattar (Glasgow, UK), Elena Startseva (Boehringer, GER),, Tom Waddell (Pespectum, USA)

Room 1
Wednesday, December 11, 2024
16:30 -18:30

HEART FAILURE NOVEL THERAPIES AND TRIALS
Chairpersons: Mona Fiuzat (Washington, DC, USA) & Alexandre Mebazaa (Paris, FRA)

Soluble Guanylate Cyclase stimulator. VICTOR trial update.
Clara Saldarriaga (Medelin, COL)

New advenues with myosin activation.
Fady Malik (Cytokinetics, USA)

Prednisone – CORTAHF trial.
Gad Cotter (Momentum LLC, USA)

Colchicine update.
Jean Claude Tardif (Montreal, CAN)

Targeting systemic inflammation in patients with heart failure through leucocyte immuno-modulation.
Bertram Pitt (Ann Arbor, MI, USA)

The Mega-Elephant in the room in HF trials: should it be mandatory to enroll only patients on optimal evidence-based HF therapies?
Milton Packer (Dalla, TX, USA)

Using AI to improve HF trials and the management of the HF patient.
Arnaud Rosier (Paris, FRA)

Remote monitoring and AI prediction of HF worsening. How this may be useful for clinical trials.
Jay Edelberg (Prolaio, USA)

The CVCT Multi-Stakeholder Think Tank Debate

HEART FAILURE NOVEL THERAPIES AND TRIALS
Chairpersons : Mona Fiuzat (Washington, DC, USA) & Alexandre Mebazaa (Paris, FRA)

Panelists : Gad Cotter (Momentum LLC, USA), Jay Edelberg (Prolaio, USA), Mona Fiuzat (Washington, DC, USA), Fady Malik (Cytokinetics, USA), Alexandre Mebazaa (Paris, FRA),, Atif Mohammad (AstraZeneca, USA), Milton Packer (Dallas, TX, USA), Bertram Pitt (Ann Arbor, MI, USA), Arnaud Rosier (Paris, FRA), Clara Saldarriaga (Medelin, COL), Jean Claude Tardif (Montreal, CAN)

Room 2
Wednesday, December 11, 2024
08:00 -10:30

TRIGLYCERIDE RICH LIPOPROTEINS TRIALS
Chairpersons: Borge Nordestgaard (Copenhagen, DEN) & Ruth Frikke Schmidt (Copenhagen, DEN)

How to optimize population selection.

Genetic epidemiology.
Borge Nordestgaard (Copenhagen, DEN)

Machine learning identification of rare coding variants.
Ron Do (New York, NY, USA)

Obesity and hypertriglyceridemia: implementation of trial results in the middle-East.
TBD

Lipid profile of the African patient and need for specific clinical trials.
Abdoul Kane (Dakar, SN)

Apolipoprotein C3 inhibitors.
For chylomicronemia for prevention of acute pancreatitis.

Anti-sense obligonucleotides
Erik Stroes (Amsterdam, NED)

RNA inhibitors
Gerald Watts (Perth, AUS)

For mixed hyperlipidemia in the prevention of CVD.
Christie Ballantyne (Houston, TX, USA)

ANGPTL3 inhibitors. Versatility for the broad spectrum of dyslipidemia.
Robert Rosenson (New York, NY, USA)

Industry viewpoint.
Giacomo Ruotolo (Lilly, USA)

Regulatory viewpoint.
John Sharretts (FDA, USA)

Patient's viewpoint.
Jacqueline Alikhaani (Los Angeles, USA)

The CVCT Multi-Stakeholder Think Tank Debate
WHAT IS THE BEST TRIGLYCERIDE LOWERING THERAPY FOR THE PREVENTION OF CARDIOVASCULAR EVENTS?
Chairpersons: Borge Nordestgaard (Copenhagen, DEN) & Ruth Frikke Schmidt (Copenhagen, DEN)

Panelists : Jacqueline Alikhaani (Los Angeles, USA), Christie Ballantyne (Houston, TX, USA), Ron Do (New York, NY, USA), Jennifer Hellawell (Arrowhead Pharmaceuticals, USA), Abdoul Kane (Dakar, SN), Hank Mansbach (89bio, USA), Stefan Nilsson (Lipigon Pharmaceuticals, SWE), Borge Nordestgaard (Copenhagen, DEN) , Robert Rosenson (New York, NY, USA), Giacomo Ruotolo (Lilly, USA) , Ruth Frikke Schmidt (Copenhagen, DEN), John Sharretts (FDA, USA), Erik Stroes (Amsterdam, NED), Xue-Qiao Zhao (Regeneron, USA)

Room 2
Wednesday, December 11, 2024
11:00 -13:00

CLINICAL TRIALS TARGETING LIPOPROTEIN(a) FOR ATHEROSCLEROSIS THERAPY
Chairpersons : Pia Kamstrup (Herlev, DEN) & Robert Rosenson (New York, NY, USA)

Leveraging Lp(a) mechanisms for risk assessment.
Sascha Goonewardena (Ann Arbor, MI, USA)

Differences and similarities among major outcome trials design.

ACCLAIM (Lepodisiran).
Ann Marie Navar (Dallas, TX, USA)

HORIZON
Leslie Cho (Cleveland, OH, USA)

OCEAN(A) update.
Michelle O'Donoghue (Boston, MA, USA)

Promises of an oral inhibitor: Muvalaplin.
Laura Michael (Lilly, USA)

Opportunities with anti-inflammatory therapies.
Wolfgang Koenig (Munich, GER)

Lp(a) gene editing.
Jason Duran (CRISPR Therapeutics)

Regulatory viewpoints.
Rosalyn Adigun (FDA, USA)
Patrick Vrijlandt (EMA, NED)

Industry viewpoints.
Antonio Lopez (Amgen, USA)

The CVCT Multi-Stakeholder Think Tank Debate

THE CHALLENGES OF A PRIMARY PREVENTION TRIAL FOR LP(A) LOWERING
Chairpersons : Pia Kamstrup (Herlev, DEN) & Robert Rosenson (New York, NY, USA)

Panelists : Rosalyn Adigun (FDA, USA), Shazia Ali (Regeneron, USA), Leslie Cho (Cleveland, OH, USA), Jason Duran (CRISPR Therapeutics), Sascha Goonewardena (Ann Arbor, MI, USA), Pia Kamstrup (Herlev, DEN), Wolfgang Koenig (Munich, GER), Antonio Lopez (Amgen, USA), Guiomar Mendieta (Madrid, ESP), Laura Michael (Lilly, USA), Ann Marie Navar (Dallas, TX, USA), Michelle O'Donoghue (Boston, MA, USA), Curtis Rambaran (Silence therapeutics, UK), Robert Rosenson (New York, NY, USA), Patrick Vrijlandt (EMA, NED)

Room 2
Wednesday, December 11, 2024
14:00 -16:00

CHOLESTEROL LOWERING THERAPIES TRIALS
Chairpersons: Wolfgang Koenig (Munich, GER) & Gerald Watts (Perth, AUS)

ORION-4 and VICTORION-2 PREVENT.
Louise Bowman (Oxford, UK)

PCSK9 interference, progress beyond monoclonal antibodies and RNA inhibitors?
Eric Klug (Sandton, ZAF)

Single-course in vivo gene editing to inactivate PCSK9 and durably lower LDL-C.
Scott Vafai (Verve Therapeutics, USA)

LDL cholesterol lowering with CETP inhibition. Fulfilled expectations?
Anne Goldberg (St Louis, MO, USA)

How special are pediatric trials?

PCSK9
Raul Santos (San Paolo, BR)

ANGPTL3
Xue-Qiao Zhao (Regeneron, USA)

Industry viewpoint.
John Kastelein (New Amsterdam Pharma, UK)

Regulatory viewpoints.
John Sharretts (FDA, USA)
Patrick Vrijlandt (EMA, NED)

Patient's viewpoint.
Sadegh Alikhaani (Los Angeles, USA)

The CVCT Multi-Stakeholder Think Tank Debate
HOW DO WE SELECT THE RIGHT CHOLESTEROL LOWERING THERAPY AMONG ALL THE APPROACHES?
Chairpersons: Wolfgang Koenig (Munich, GER) & Gerald Watts (Perth, AUS)

Panelists : Sadegh Alikhaani (Los Angeles, USA), , Cheryl Abbas (Novartis, USA), Puja Banka (Merck, USA), Louise Bowman (Oxford, UK), James Hamilton (Arrowhead Pharmaceuticals, USA), John Kastelein (New Amsterdam Pharma, UK), Eric Klug (Sandton, ZAF), Wolfgang Koenig (Munich, GER) Sarah Noonberg (Metagenomi, USA), Raul Santos (San Paolo, BR), John Sharretts (FDA, USA), Evan Stein (LIB Therapeutics, USA), Scott Vafai (Verve Therapeutics, USA), Patrick Vrijlandt (EMA, NED), Gerald Watts (Perth, AUS), Xue-Qiao Zhao (Regeneron, USA)

Room 2
Wednesday, December 11, 2024
16:30 -18:30

DELIVERING THE FIRST EFFECTIVE MEDICAL THERAPY FOR AORTIC STENOSIS
Chairpersons: Martin Leon (New York, NY, USA) & TBD

Aortic stenosis and the need for an effective medical therapy.
Philippe Pibarot (Laval, CAN)

Need for a medical therapy in aortic stenosis- the patients view.
TBD

Potential treatment targets in the valve.
David Newby (Edinburgh, UK)

Targeting the valve- how to design the perfect RCT of a new therapy.
Andres Laguna (Novartis, ESP)

Potential treatment targets in the myocardium.
Paolo Springhetti (Laval, CAN)

Targeting the myocardium- what is the current standard of care & how to design the perfect RCT of a new therapy.
Marc Dweck (Edinburgh, UK)

Medical therapies in aortic stenosis- what the FDA might require for approval.
Charu Gandotra (FDA, USA)

Medical therapies in aortic stenosis- what the EMA might require for approval.
Clemens Mittman (EMA, NED)

The CVCT Multi-Stakeholder Think Tank Debate

ACCELERATING APPROVAL OF A FIRST EFFECTIVE MEDICAL THERAPY FOR AORTIC STENOSIS
Chairpersons: Martin Leon (New York, NY, USA) & TBD

Panelists : Robert Bonow (JAMA Cardiology, USA), Marc Dweck (Edinburgh, UK), Charu Gandotra (FDA, USA), John Krege (Lilly, USA), Andres Laguna (Novartis, ESP), Alexandra Lansky (New Haven, CT, USA), Martin Leon (New York, NY, USA), Clemens Mittman (EMA, NED), David Newby (Edinburgh, UK), Mark Petrie (Glasgow, UK) , Philippe Pibarot (Laval, CAN), Curtis Rambaran (Silence Therapeutics, UK), Paolo Springhetti (Laval, CAN), Sreekanth Vemulapalli (Durham, NC, USA)

Room 3
Wednesday, December 11, 2024
08:00 -10:30

iCVCT
HOW TO EVOLVE THE DESIGN OF VALVE TRIALS
Chairpersons: David Cohen (New York, NY, USA) & Stephan Windecker (Bern, CH)

Transcatheter or Surgical Treatment of Aortic-Valve Stenosis. Insight from DEDICTAE
Stefan Blankenberg (Hamburg, GER)

Transcatheter therapies for mitral annular calcification. Debate: do we need a definitive RCT?

Pro: Definitely — Follow the example of TAVR.
Sanjay Kaul (Los Angeles, CA, USA)

Con: are you kidding? All we need is safety data.
TBD

Transcatheter mitral valve trials with surgical comparators-
rationale, population, and endpoints.
Joanna Chikwe (Los Angeles, CA USA)

The second wave of transcatheter tricuspid valve trials – population, comparators, and endpoints.
Raul Moreno (Madrid, ESP)

Pre-emptive TAVR: ready for prime time! We have the data!
Marko Banovic (Belgrade, RS)

Pre-emptive TAVR: what's the rush?
Robert Bonow (JAMA Cardiology, USA)

What are the remaining clinical trial questions for TAVR in aortic stenosis?
Stephan Windecker (Bern, CH)

Design Of TAVR trials for aortic insufficiency.
Martin Leon (New York, NY, USA)

Industry viewpoints.
Todd Brinton (Edwards, USA), Duane Pinto (Jenavalve, USA), Daniel Wendt (Cytosorbent, USA)

Regulatory viewpoints.
Mauro Moscucci (FDA,USA), Changfu Wu (FDA, USA)

HTVA viewpoints.
TBD (CMS, USA)

The iCVCT Multi-Stakeholder Think Tank Debate
HOW TO EVOLVE THE DESIGN OF VALVE TRIALS
Chairpersons: David Cohen (New York, NY, USA) & Stephan Windecker (Bern, CH)

Panelists: Marko Banovic (Belgrade, RS), Stefan Blankenberg (Hamburg, GER), Robert Bonow (JAMA Cardiology, USA) , Todd Brinton (Edwards, USA), Daniel Canos (FDA, USA), Joanna Chikwe (Los Angeles, CA USA),David Cohen (New York, NY, USA), Marc Dweck (Edinburgh, UK), Hélène Eltchaninoff (Rouen, FRA), Aakriti Gupta (Los Angeles, CA, USA), Sanjay Kaul (Los Angeles, CA, USA), Martin Leon (New York, NY, USA), Raul Moreno (Madrid, ESP), Mauro Moscucci (FDA,USA), John Spertus (Kansas City, MO, USA), Martyn Thomas (Edwards, USA), Daniel Wendt (Cytosorbent, USA), Stephan Windecker (Bern, CH), Changfu Wu (FDA, USA)

Room 3
Wednesday, December 11, 2024
11:00 -13:00

iCVCT
EMERGING ISSUES AND THE FUTURE OF CLINICAL TRIALS IN STRUCTURAL HEART DISEASE
Chairpersons: Rasha al Lamee (London UK) & David Cohen (New York, NY, USA)

We need more sham/placebo-controlled trials in structural heart disease.

Pro
Rasha Al Lamee (London, UK)

Con
John Spertus (Kansas City, MO, USA)

Alternatives to Randomized Controlled Trials—When are they reasonable?

Instrumental variable analysis: the case of cerebral embolic protection.
Neel Butala (Denver, CO, USA)

How do we know when observational studies are futile? The case of impella in AMI/CS
TBD

The win ratio should be the preferred method for analyzing clinical trials in structural heart disease

Pro
David Cohen (Boston, MA, USA)

Con
Javed Butler (Dallas, TX, USA)

Industry viewpoint.
Sandra Lesenfants (Abbott, USA), Janarthanan Sathananthan (Boston Scientific, USA)

Regulatory viewpoints.
Alan Fraser (EU, Cardiff, UK)
Bram Zuckerman (FDA, USA)

HTA viewpoints.
TBD (CMS, USA)

The iCVCT Multi-Stakeholder Think Tank Debate
EMERGING ISSUES AND THE FUTURE OF CLINICAL TRIALS IN STRUCTURAL HEART DISEASE
Chairpersons: Rasha al Lamee (London UK) & David Cohen (New York, NY, USA)

Panelists: Rasha al Lamee (London, UK), Neel Butala (Denver, CO, USA), Javed Butler (Dallas, TX, USA), Daniel Canos (FDA, USA), David Cohen (New York, NY, USA), Alan Fraser (EU, Cardiff, UK), Ahmed Kolkailah (Dallas, TX, USA), John Laschinger (Edwards, USA), Sandra Lesenfants (Abbott, USA), Jeff Popma (Medtronic, USA), Janarthanan Sathananthan (Boston Scientific, USA), John Spertus (Kansas City, MO, USA), Karl von Mangoldt (Protembis, USA), Robert Yeh (Boston, MA, USA), Bram Zuckerman (FDA, USA)

Room 3
Wednesday, December 11, 2024
14:00 -16:00

iCVCT
SHOCK MECHANICAL CIRCULATORY SUPPORT TRIALS
Chairpersons: Holger Thiele (Leipzig, GER) & Robert Yeh (Boston, USA)

DANGER – generalizability of results in contemporary practice.
TBD

Design of future post-MI shock trials of mechanical support – exclusions, endpoints, control group.
Navin Kapur (Boston, MA, USA)

What is the regulatory pathway for mechanical circulatory support devices for cardiogenic shock after DANGER?
Changfu Wu (FDA, USA)

Real World Evidence to support mechanical circulatory support device evaluation.
Robert Yeh (Boston, MA, USA)

Industry vision for the future of mechanical circulatory support devices in cardiogenic shock.
Chuck Simonton (Abiomed, USA), Nitin Salunke (Supira Medical, USA), Janarthanan Sathananthan (Boston Scientific, USA)

HTA viewpoints.
Linda Gousis (CMS, USA)

Industry Viewpoint
Robert Kormos (Abbott, USA)

The iCVCT Multi-Stakeholder Think Tank Debate
SHOCK MECHANICAL CIRCULATORY SUPPORT TRIALS
Chairpersons: Holger Thiele (Leipzig, GER) & Robert Yeh (Boston, USA)

Panelists: Suzanne Baron (Boston, MA, USA), Daniel Burkhoff (New York, NY, USA), George Dangas (New York, USA), Michael Gibson (Boston, MA, USA), Linda Gousis (CMS, USA), Chuck Simonton (Abiomed, USA), Navin Kapur (Boston, MA, USA), Robert Kormos (Abbott, USA), Jaime Raben (FDA, USA), Sunil Rao (New York, NY, USA), Nitin Salunke (Supira Medical, USA), Janarthanan Sathananthan (Boston Scientific, USA), Holger Thiele (Leipzig, GER), Changfu Wu (FDA, USA), Robert Yeh (Boston, MA, USA)

Room 3
Wednesday, December 11, 2024
16:30 -18:30

iCVCT
CORONARY INTERVENTION TRIALS
PROMOTING INNOVATION AND IMPROVING PATIENTS ACCESS
Chairpersons: Don Cutlip (Boston, MA, USA) & Roxana Mehran (New York, NY, USA)

Review of clinical trial designs for intra-stent restenosis indication.
Robert Yeh (Boston, MA, USA)

Clinical trial designs for coronary drug-coated and eluting balloons de novo indications.
Ron Waksman (Washington, DC, USA)

Is it time to move to hierarchical composite?
Milton Packer (Dallas, TX, USA)

How should clinical trials assess PCI effectiveness?
Are peri-procedural MI and target lesion revascularization still the right metrics?
Lydia Glaw (FDA, USA)

Should angina based quality of life measures be included?
Rasha Al-Lamee (London, UK)

RWD on the use of drug-coated balloon in gulf states .
Abdullah Shehab (Al Ain, UAE)

How can we improve access for patients in a sustainable way?
Sunil Rao (New York, NY, USA)

How can we incentivize innovation?
Investigator's viewpoint.
TBD

Regulatory viewpoints.
Adrian Magee (FDA, USA)
Jackie Fielding (NICE, UK)

Industry viewpoints.
Lance Bates (Boston Scientific, USA), Julie Tyler (Abbott, USA)

The iCVCT Multi-Stakeholder Think Tank Debate
CORONARY INTERVENTION TRIALS
HOW CAN WE INCENTIVIZE INNOVATION AND IMPROVE SUSTAINABLE ACCESS FOR PATIENTS?
Chairpersons: Don Cutlip (Boston, MA, USA) & Roxana Mehran (New York, NY)

Panelists: Rasha Al-Lamee (London, UK), Lance Bates (Boston Scientific, USA), Don Cutlip (Boston, MA, USA), Andrew Farb (FDA, USA), Jackie Fielding (NICE, UK), Lydia Glaw (FDA, USA), Doug Godshall (Shockwave Medical, USA), Adrian Magee (FDA, USA), Roxana Mehran (New York, NY), Milton Packer (Dallas, TX, USA), Sunil Rao (New York, NY, USA), Abdullah Shehab (Al Ain, UAE), Julie Tyler (Abbott, USA), on Waksman (Washington, DC, USA), Robert Yeh (Boston, MA, USA)

Room 4
Wednesday, December 11, 2024
08:00 -10:30

GLOBAL REGULATORY SUMMIT
HOW TO PROMOTE INCLUSIVENESS AND ACCELERATE APPROVAL OF EVIDENCE BASED CARDIOVASCULAR THERAPY GLOBALLY
Chairpersons: Robert Califf (FDA, USA) & Faiez Zannad (Paris, FRA)

The ever rising global burden of CV disease.
Nawab Qizilbash (Madrid, ESP)

Is applying for approval of CV common diseases drugs declining globally?
Claus Bolte (Ex-Swissmedic, Basel, CH)

Issues with global generalizability of Western-generated evidence.
Salim Yusuf (Hamilton, CAN)

Industry viewpoints.
Jyothis George (Amgen, USA)
Trish Kay-Mugford (Novartis, USA)

Regional regulatory viewpoints.
Mirvat Alasnag (Saudi FDA, KSA)
Claudiosvam Alves De Sousa (ANVISA, BRA)
Yutaku Kaneta (PMDA, JPN)
Obakeng Khaole (SAHPRA, ZA)
Rana Malkawi (Jordan FDA, JOR)
Claudia Saidman (ANMAT, ARG)
Azza Saleh (MOH, EGY)
Zaril Harza Zakaria (NPRA, MY)
Fanpu Kong (Ex-CFDA, CN)

The CVCT Multi-Stakeholder Think Tank Debate

GLOBAL REGULATORY SUMMIT
HOW TO PROMOTE INCLUSIVENESS AND ACCELERATE APPROVAL OF EVIDENCE BASED CARDIOVASCULAR THERAPY GLOBALLY
Chairpersons: Robert Calif (FDA, USA), Faiez Zannad (Paris, FRA)

Panelists : Mirvat Alasnag (Saudi FDA, KSA), Claus Bolte (Ex-Swissmedic, Basel, CH), Robert Califf (FDA, USA), Claudiosvam Alves de Sousa (ANVISA, BRA, Jyothis George (Amgen, USA), Trish Kay-Mugford (Novartis, USA), Yutaku Kaneta (PMDA, JPN), Obakeng Khaole (SAHPRA, ZA), Fanpu Kong (Ex-CFDA, CN), Charles Lee (AstraZeneca, USA) , Rana Malkawi (Jordan FDA, JOR), Manabu Minami (PMDA, JPN), Nawab Qizilbash (Madrid, ESP), Claudia Saidman (ANMAT, ARG), Azza Saleh (MOH, EGY), Salim Yusuf (Hamilton, CAN), Zaril Harza Zakaria (NPRA, MY), Faiez Zannad (Paris, FRA)

Room 4
Wednesday, December 11, 2024
11:00 -13:00

PATIENT TRIALISTS MEET CLINICAL TRIALISTS.
"The impact of Health Data and Digital Tools from clinical trials to results in treatments"
Chairpersons: Penilla Gunther (FOKUS,Patient, Stockholm, SWE) & Greg Merritt (Patient Is Partner, Brighton, USA)

Welcome
Penilla Gunther (FOKUS Patient, Stockholm, SWE) & Greg Merritt (Patient Is Partner, Brighton, USA)

Introduction part 1
How to Build a Health System Powered by Data and Technology to Benefit Patients
Mathias Ekman (Microsoft, SWE)

The Importance of Understanding and Agreement for Usage of Health Data
The European Health Data Space
Tomislav Sokol (European Parliament, CRO)

Regulatory Viewpoints. Who Owns Patients' Data in Clinical Trials
Leonard Sacks (Office of Medical Policy – CDER, FDA, USA)
Maria Mavris (Patient Relations, EMA, NED)

Patient Panel Discussion – Response to Speakers
Jerker Liljestrand (Stockholm, SWE), Isabelle Lousada (Amyloidosis Research Consortium, USA), Jens Naeumann (Initiative Herzklappe, GER)

Introduction part 2
Do Digital Culture and Maturity Within Patient Groups Matters for Global Trials
Anne Snowdon (HMSS, CAN)

How Digital Tools May Help Enrolling More Patients
Michalis Fardis (Astra Zeneca, SWE)

Sharing Trial Results with Patient Participants. How is this Done Across The Globe?
Eva Adås (Johnson & Johnson, USA)

Patient panel discussion – response to speakers
Celina Gorre (Women at Heart, USA)
Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK)

Questions from the audience

Summary
Penilla Gunther (FOKUS Patient, Stockholm, SWE) & Greg Merritt, Patient is Partner

The CVCT Multi-Stakeholder Think Tank Debate

LISTEN TO PATIENT TRIALISTS VOICE
HOW TO FACILITATE PATIENT ACCEPTANCE TO BE ENROLLED IN TRIALS
ACCESS TO HEALTH DATA FROM CLINICAL TRIALS – WHO OWNS THE DATA?
Chairpersons: Penilla Gunther (FOKUS,Patient, Stockholm, SWE) & Greg Merritt (Patient Is Partner, Brighton, USA)

Panelists : Eva Adås (Johnson & Johnson, USA), Mathias Ekman (Microsoft, SWE), Michalis Fardis (AstraZeneca, SWE), Penilla Gunther (FOKUS,Patient, Stockholm, SWE), Celina Gorre (Women at Heart, USA), Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK) , Jerker Liljestrand (Stockholm, SWE), Isabelle Lousada (Amyloidosis Research Consortium, USA), Maria Mavris (Patient Relations, EMA, NED), Greg Merritt (Patient Is Partner, Brighton, USA); Jens Naeumann (Initiative Herzklappe, GER), Leonard Sacks (Office of Medical Policy – CDER, FDA, USA), Anne Snowdon (HMSS, CAN), Tomislav Sokol (European Parliament, CRO)

Room 4
Wednesday, December 11, 2024
14:00 -16:00

UNDIAGNOSED HEART FAILURE
WHY WE SHOULDN'T WAIT FOR PATIENTS TO COME TO US?
Chairpersons: Nick Hartshorne Evans (Preston, UK) & Rajiv Sankaranarayanan (Liverpool, UK)

BEAT HF disease awareness campaign reaching out. Why, how and what.
Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK)

Results from the national BEAT-HF screening campaign.
Rajiv Sankaranarayanan (Liverpool, UK)

Results from Everton one-stop breathlessness hu.
Rajiv Sankaranarayanan (Liverpool, UK)

Wait for Echo - Revolution HF.
Lisa Anderson (London, UK)

Quick AI Echo HF diagnosis in BEAT TO TREAT.
Christine Gouillard (US2AI, SIN)

Bridging the findings BEAT TO TREAT with the STRONG HF findings.
Start early and move fast?
Alexandre Mebazaa (Paris, FRA)

Is BEAT TO TREAT replicable in other health care systems?
Nicolas Girerd (Nancy, FRA), Ambarish Pandey (Dallas, TX, USA)

Industry viewpoints.
Martin Cowie (Astrazeneca, UK), Serge Masson (Roche, CH)

Patient's viewpoint.
Marc Bains (Vancouver, CAN)

The CVCT Multi-Stakeholder Think Tank Debate
PROACTIVE MANAGEMENT OF UNDIAGNOSED AMBULATORY HEART FAILURE.
Chairpersons: Nick Hartshorne Evans (Preston, UK) & Rajiv Sankaranarayanan (Liverpool, UK)

Panelists : Lisa Anderson (London, UK), Ankeet Bhatt (Boston, MA, USA), Marc Bains (Vancouver, CAN), Meindert Boysen (NICE,UK), Martin Cowie (AstraZeneca, UK), Nicolas Girerd (Nancy, FRA), Christine Gouillard (US2AI, SIN),Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK), Serge Masson (Roche, CH), Alexandre Mebazaa (Paris, FRA), Ambarish Pandey (Dallas, TX, USA),Rajiv Sankaranarayanan (Liverpool, UK)

Room 4
Wednesday, December 11, 2024
16:30 -18:30

BIOMARKER GUIDED DRUG DEVELOPMENT

Chairpersons : Kirkwood Adams (Chapel Hill, NC, USA) & Jim Januzzi (Boston, MA, USA)

How to make a good use of biobanks collected during clinical trials?
Faiez Zannad (Paris, FRA)

Proteomic studies for drug discovery using trial bio-samples.
Jasper Tromp (Singapore, SIN)

Biomarkers utilization in clinical trial for risk enrichment and/or enrollment of potential responders.
Paul Ridker (Boston, MA, USA)

Biomarker data from clinical trials for MOA investigation and potential label expansion;
Peter Liu (Toronto, CAN)

What will it take to bring natriuretic peptides to the level of regulatory tool?
Jim Januzzi (Boston, MA, USA)

Industry viewpoints.
Gillian Murtagh (Abbott, UK), Karsten Strauß (Olink, SWE)

Regulatory viewpoints.
Lars Hemkens (Basel, CH), Jeff Siegel (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

BIOMARKER GUIDED DRUG DEVELOPMENT

Chairpersons : Kirkwood Adams (Chapel Hill, NC, USA) & Jim Januzzi (Boston, MA, USA)

Panelists : DeAunne Denmark (Somalogic, USA), Lars Hemkens (Basel, CH), Jim Januzzi (Boston, MA, USA), Peter Liu (Toronto, CAN), Gillian Murtagh (Abbott, UK), Paul Ridker (Boston, MA, USA), Jeff Siegel (FDA, USA), Mikhail Sumin (Boehringer Ingelheim, GER), Karsten Strauß (Olink, SWE), Jasper Tromp (Singapore, SIN), TBD (FDA, USA), Faiez Zannad (Paris, FRA)