

Drug Discovery & Development Symposium

10-11 July 2023

10 July Day 1 Session 1

08:25 - 13:00

Welcome
Kurt Stenmark, PVRI President 2023 08:25 - 08:30

Digital Health Technology (DHT) Advancements & Implementation at the FDA, Foundation for the National Institutes of Health (FNIH) & Pharma to Optimise Clinical Trial Designs & Endpoints in PH

Chairs: Christine Garnett & Peter Fernandes
Panellists: Veronica Franco & Harry Rowland

FDA Center for Devices & Radiological Health (CDRH) DHT Center of Excellence; an overview
Troy Tazbaz & Matt Diamond 08:30 - 08:50

FDA Center for Drug Evaluation & Research (CDER) Division of Cardiology & Nephrology (DCN)
DHT initiatives: adults & paediatrics
Christine Garnett 08:50 - 09:10

Panel & delegate discussion 09:10 - 09:30

FNIH, Pharma & Academia Pioneering of Digital Endpoints

FNIH initiative to further the Clinical Outcome Assessment (COA) development of DHT endpoints
Josh Fessel & Jessilyn Dunn 09:30 - 09:45

Taking the plunge with actigraphy: USA & China (lessons learnt)
Peter Fernandes 09:45 - 10:00

Application of the CardioMEMS in the artisan trial
Yan Liu 10:00 - 10:15

Panel & delegate discussion 10:15 - 10:40

Break 10:40 - 11:00

Novel Trial Designs

The Decentralised Trial Design: Overcoming the Hidden Obstacles

FIT-PH/ UK Cohort study - Deciphering The Rosetta Stone of digital endpoints
Mark Toshner, Alexander Rothman & Martin Wilkins 11:00 - 11:15

Panel & delegate discussion 11:15 - 11:40

Stratified & adaptive trial designs
Mardi Gomberg-Maitland 11:40 - 11:55

Bayesian approaches
Sofia Villar 11:55 - 12:10

Putting the physician in the corner: the patient-centred trial
Joanna Pepke-Zaba 12:10 - 12:25

Panel & delegate discussion 12:25 - 13:00

Lunch 13:00 - 14:00



10 July Day 1 Session 2

14:00 - 17:00

Lessons Learned from Clinical Trials in PH Groups 2 & 3: What are the Similarities & Differences in Pathogenesis & Pathophysiology?

Chairs: Mardi Gomberg-Maitland & Steven Nathan
Panellists: Jordan E. Pomeroy & Sylvia Nikkho

Pulmonary Hypertension Group 2

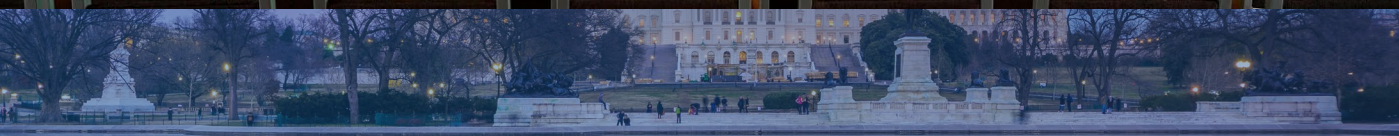
Pathophysiology & pathogenesis Raymond Benza	14:00 - 14:20
In adults Raymond Benza	14:20 - 14:40
In paediatrics Rachel Hopper	14:40 - 15:00
Panel discussion & debate	15:00 - 15:30

Pulmonary Hypertension Group 3

Pathophysiology & pathogenesis Paul Hassoun	15:30 - 15:50
In adults Steven Nathan	15:50 - 16:10
In paediatrics Steven Abman	16:10 - 16:30
Panel discussion & debate	16:30 - 17:00

Drinks Reception

17:00 19:00





11 July Day 2 Session 3

08:30 - 13:30

Novel Drug & Device Therapies

Chairs: Anna Hemnes & Raymond Benza

Panellists: Stephanie Hopley, Carol Satler & Hunter Gillies

Novel compliance enhancing device therapy: initial data from 28 implanted patients in WHO groups 1, 2 & 3 in PH
John Scandurra 08:30 - 08:40

Targeting Histone Deacetylase (HDAC) inhibition for pulmonary hypertension
Björn Dahlöf 08:40 - 08:55

Panel & delegate discussion 08:55 - 09:05

TGF- β ligands for pulmonary arterial hypertension 09:05 - 09:20

Simon Cooper

Discussion 09:20 - 09:25

Targeting the zinc transporter, ZIP12, with a monoclonal antibody 09:25 - 09:40

Lan Zhao

Discussion 09:40 - 09:45

Panel & delegate discussion 09:45 - 10:00

Mechanism of action in inhaled therapies: why do they work & how do we design the trials? 10:00 - 10:45

Nicholas Hill

Break

10:45 - 11:10

Disruptive Technologies in Novel Drug Discovery

Using large data aggregates 11:10 - 11:30
Steven Kawut

Molecular clustering 11:30 - 11:50
Allan Lawrie

Imaging & the lung 11:50 - 12:10
Alex Dusek & Benjamin Lavon

Panel & delegate discussion 12:10 - 12:30

Roundtable: Practical Solutions to Challenges in Drug Development 12:30 - 13:30

Chairs: Mark Toshner, Sylvia Nikkho, Raymond Benza & Peter Fernandes

Highlight 10 challenges in drug development, vote on the top 3 & solve them

End of Meeting

