



**Cardiac Safety Committee
Workshop
May 15-16, 2018
Boston, Massachusetts, USA
Langham Boston Hotel**

Agenda

(Available presentations are linked next to the corresponding talk)

Day 1, May 15, 2017

8:30 a.m. – 10:30 a.m.

Meeting Goals & Intro to Failure Modes:

- Building on our successes: Pushing the CV window – **Brian Berridge – NTP, [available online here](#)**
- Scoping/failure modes – to setup topics for the rest of the day – **Jean-Pierre Valentin – UCB, [available online here](#)**
- Overview – what does a high-throughput screen look like? – **Norman Stockbridge – US FDA**
- Systems Biology – how do we integrate and translate to arrive at meaningful understanding of results? – **Matthew White – US FDA**
- From in vitro cardiotoxicity screens to human population risk predictions: A case study of hazard, concentration-response, and population variability in the effects of 13 drugs – **Ivan Rusyn – Texas A&M University (Slides available upon request, email [Jennifer Pierson](#) for details)**

10:45 a.m. – 2:00 p.m.

Exploring possible solutions

- Brief overview of the existing Committee portfolio. – **Brian Berridge – NTP, [available online here](#)**
- Using Networks to Link Genotype to Phenotype- **John Quackenbush – Harvard University, [available online here](#)**
- One Cell to Bind Them All: Bridging Functional and Structural Cardiotoxicity Assays for a More Comprehensive Risk Assessment – **Mike Clements – Axion Biosystems, [available online here](#)**
- Engineered 3D cardiac tissue platforms to assess contractility – **Anant Chopra – Boston University, [available online here](#).**



- A view from the CRACK-IT consortium: Integration of hiPSC-cardiomyocytes into drug screening and disease modelling – **Chris Denning – University of Nottingham**
- Using human cardiomyocytes and bright-field imaging to finger-print different inotropic mechanisms of action – **Najah AbiGerges – Anabios, [available online here](#)**
- Heart-on-Chip Technologies for *in vitro* Cardiomyocyte Assessment Studies - **Herdeline Ardoña - Wyss Institute, [available online here](#)**

3:00 p.m. – 5:00 p.m.

Afternoon Discussion Groups:

- Breakout into groups to ID gaps related to failure modes

Day 2, May 16, 2017

9:00 a.m. – 9:30 a.m.

Review day 1 – what are the failure modes we want to consider, where are the gaps ID'ed from day 1 breakouts?

9:30 a.m. – 12:00 p.m.

Review of existing projects that fit into this scheme

- Cellular Systems – **Alexandre Ribeiro, [available online here](#)**
- Biomarkers – **Eric Schultze and Marjory Brooks, [available online here](#)**
- Math modeling – **Esther Bonetluz, [available online here](#)**
- Stem Cell – **Gary Gintant, [available online here](#)**
- Bridging Ion Channel and Myocyte Data – **Tim Strassmaier, [available online here](#)**

10:45 a.m. – 11:00 a.m.

Cardiac Safety Committee Working Groups Breakouts

1:00 p.m. – 2:00 p.m.

Report back from breakouts and discussion session

2:30 p.m. – 4:00 p.m.

- What it means to have an effective in-vitro assay strategy? Which assays can be implemented for early CV de-risking and later stages of development? Perspectives on new Merck & Co.'s strategies including CiPA paradigm. – **Dr. Frederick Sannajust– Executive Director of Safety & Exploratory Pharmacology, Merck Research Laboratories**



- CRACK -IT – NC3Rs – implementation of these efforts – **Anthony Holmes – NC3RS, [available online here.](#)**

 - Panel Discussion:
 - What additional partnerships or opportunities exist that can help us move in this direction?
 - Exploration of resourcing these efforts
- Invited panelists: Frederick Sannajust – Merck, Anthony Holmes – NC3RS, Malar Pannirselvam – Vertex, Brian Berridge – NTP, Norman Stockbridge – FDA, Jean-Pierre Valentin – UCB***

4:00 p.m.

Wrap-Up, Brian Berridge, [available online here](#)

5:00 p.m.

Adjourn