



Presentation Title

Date

Scientific Programs Planning Committee

Corina	Dota		AZ
Mary Jane	Geiger		ICON
Gretchen	Kimmick		Duke
Bob	Kleiman		Ert
Kenneth	Mahaffey		Stanford
Boaz	Mendzelevski		Cardiac Safety Consultants Ltd
Gail	Moreschi		FDA
Evelyn	Nunez		Bayer
Dakshesh	Patel		FDA
Philip	Sager		Consulting
Jonathan	Seltzer		ACI Clinicial
Shari	Targum		FDA

Thinktanks Completed since Annual Meeting

- Real World Data to Assess Cardiovascular Safety- Can We Improve Efficiencies in Phase 3 Development?
- Future of the Assessment of Drug-Induced Arrhythmias and the Comprehensive in Vitro Proarrhythmia Assay (CiPA)
- QTc Exposure-Response Modeling Workshop: What is Required?
- Endpoints When Treating VT/VF in Patients with ICDs
- CSRC Prevention of Sudden Cardiac Death in the Young: National Cardiac Screening Warehouse Pilot Study
- THI International Symposium on CV Regenerative Medicine Symposium

ThinkTanks Planned for next year

- **Detection, Assessment and Risk Mitigation of Cardiac Safety Signals in Oncology Drug Development**
- **With DIA: Evaluation of Mobile Technologies in CV Medicine**
- **Understanding cardiogenic shock and defining the concept of “Pre-shock”**
- **With THI: Cardiac Endpoints for Trials in Regenerative Medicine**
- **Using Cardiac Biomarkers to drive efficiencies in clinical trials**
- **Evaluation of Heart Failure as an off-target event in development of Diabetes and other Non-Cardiac Drugs**

Suggestions for Future Thinktanks

Assessment of NCE's for cardiotoxicity	TT Suggested
Best Practices for Cardiac Endpoint Committees	TT Suggested
Cardiac Safety Assessment for Orphan Drugs	TT Suggested
CIPA Update	TT Suggested
Design Issues for CVOTs for Non-CV drugs	TT Suggested
How to define risk benefit of SGLT2i in DM and CVOT	TT Suggested
Nutrition Assessment and Relation to Adverse Cardiac Safety Outcomes	TT Suggested
Patient engagement in research design and conduct – why, how, when	TT Suggested
Pediatric Cardiovascular Devices: Novel Considerations of Early and Long Term Safety	TT Suggested
Real World Evidence for Cardiac Safety II	TT Suggested
Risk Benefit Balance of Bleeding in CV therapies	TT Suggested
Use of Cardiac Imaging in Safety Evaluation	TT Suggested
Use of Left Atrial Appendage Occlusion Devices	TT Suggested
Use of Placebo Controls in Pediatric Cardiology Research	TT Suggested

CSRC THINKTANK: Project Submission Form

1. Title of Project Concept	
2. Submission Date	
3. Submitter name, title, email address, and phone number	
4. Name and address of submitting organization	
5. Name(s) of other partner organization(s), if Applicable	
6. What scientific gap/public health need is addressed by this project?	
7. What technologies are addressed by this project (ECG, imaging, molecular, genetic, etc.)?	
8. Briefly describe the proposed project, including any preliminary results and evidence concerning feasibility.	N/A
9: What is the proposed duration and format of the thinktank?	
10. Are you willing to take an active role in planning and leading? If not, can you suggest someone?	
11. Are there specific presenters who are already interested? If so, who?	
12. If this project is linked to commercial products(s), clearly state the scientific question which obviates any conflict of interest issues.	

Scientific Programs Committee 2017-2018

- **Please fill out Project Submission Form in order to suggest future programs**
- **We look forward to expanding partnerships with other organizations**
- **We will need your help in participating in**