2018 REPORT CARD

The CSRC would like to thank you for your financial contribution. Below is a report card of accomplishments and involvement for your industry for the year 2018. Please feel free to contact us if you would like to be more involved. We welcome new ideas.

New Members

- Richmond Pharmacology
- CSL Behring
- Welch Allyn

CSRC MEMBERS LIST

New Collaborators

- Cardiology Today
  Published First Article (February 2018): “Stem cell therapy for CVDs: Advances persist, challenges remain” Jonathan Seltzer, MD on behalf of CSRC.

- Journal of Clinical Trials Collaboration
  Published First Article (August 2018): “The Comprehensive In Vitro Proarrhythmia Assay: An Update” Rick Turner, PhD, DSc on behalf of CSRC

We’re Getting Social!

- Follow us on our new social media pages and view our updated website.
  @CardiacSafety www.cardiac-safety.org

Cardiac Safety Research Consortium

CSRC Members Spotlight

Duke / Stanford CEC Summit
Chicago, IL
September 2018
Jonathan Seltzer, MD participated as speaker for session to discuss regulatory, industry and academic perspectives on CEC Review implementation of current standardized definitions.

Over the Edge
Durham, NC
October 2018
Salim Idriss, MD and Clare Matti went Over the Edge on behalf of CSRC. They raised $14,420 for the Duke Pediatric and Congenital Heart Center! They rappelled 17 stories on the outside of the 21c Hotel Building in downtown Durham, North Carolina.

Regenerative Medicine Texas Heart Meeting
October 2018
Tom Povsic, MD, PhD and Mitch Krucoff participated in the symposium to discuss findings, current research and debate the state of the field of clinical regenerative medicine and stem cell therapy.

Comprehensive In Vitro Proarrhythmia Assay (CiPA) Updates

As part of the Comprehensive In Vitro Proarrhythmia Assay (CiPA) Steering Team, representatives from CSRC attend team meetings to discuss project milestones and serve as liaisons between work streams and stakeholders. See below for recent updates from the team.

- Comprehensive In Vitro Proarrhythmia Assay (CiPA) Update from a Cardiac Safety Research Consortium / Health and Environmental Sciences Institute / FDA Meeting.
- Assessment of an In Silico Mechanistic Model for Proarrhythmia Risk Prediction Under the CiPA Initiative.
- International Multisite Study of Human Induced Pluripotent Stem Cell Derived Cardiomyocytes for Drug Proarrhythmic Potential Assessment.

VIEW ALL CiPA UPDATES
2018 REPORT CARD

Scientific Papers

• “The 2nd annual think tank on prevention of sudden cardiac death in the young: Developing a rational, reliable and sustainable National Health Care Resource. A report from the cardiac safety research consortium.”

• “Comparison of automated interval measurements by widely used algorithms in digital electrocardiographs.”

READ PUBLISHED PAPERS

Scientific Meetings

THINK TANKS

• “New Advances in the Assessment of Drug-Induced Arrhythmias and the Comprehensive In Vitro Proarrhythmia Assay (CiPA)”

• “Defining the Clinical and Regulatory Landscape for Cardiogenic Shock”

PILOT PROJECT MEETING

• “CSRC Prevention of Sudden Cardiac Death in the Young Pilot Study Training session at the 13th Annual Heart-to-Heart Meeting”

SCIENTIFIC MEETING DETAILS

Projects

• Restricted Mean Survival Time (RMST) statistical analysis approach for analyzing Cardiovascular Outcomes Trials

• Prevention of Sudden Cardiac Death in the Young: National Cardiac Screening Warehouse Pilot Study

• CSRC/DIA Collaboration: Real World Evidence & CV Safety Educational Curriculum

PROJECT SUBMISSION FORM

Collaborations

• Participation in DIA Annual Meeting

• Development of DIA Real World Evidence Educational Curriculum

• Participation in ACCP Global Conference

• DIA Real World Evidence Short Course

REQUEST NEW COLLABORATION

ON THE HORIZON FOR 2019

THINK TANKS

• “Driving Efficiencies in Clinical Trials through the use of Cardiac Biomarkers”

• “Clinical and Regulatory Landscape for Cardiogenic Shock”

• “NOAC Use in Pediatric Trials”

• “Use of Mobile Technologies in Clinical Trials for Assessment of Cardiovascular Endpoints”

• “Evaluation of Heart Failure as an Off-target Event in Development of Diabetes and other Non-cardiac Drugs”

PAPERS IN PROGRESS

• “CSRC Meeting & CSRC Think Tank: Detection, Assessment and Risk Mitigation of Cardiac Safety Signals in Oncology Drug Development”

• “CSRC Think Tank: Real World Data to Assess Cardiovascular Safety – Can We Improve Efficiencies in Phase 3 Development?”

• “Restricted Mean Survival Time for the Analysis of Diabetes Cardiovascular Outcome Trials Assessing Non-inferiority”