



CARDIAC SAFETY RESEARCH CONSORTIUM

Scientific Oversight Committee (SOC)

■ What Does the SOC Do?

- Solicits and reviews scientific projects and programs
 - Projects typically yield a White paper
- Develops and facilitates research teams dedicated to each approved project
 - Team has a project lead (full CSRC member or employed by a company that is a CSRC member)
 - Teams may include members from industry, academia and regulatory authorities



Have a Proposal

Form available at: <http://cardiac-safety.org/projects/>
Submit to: cardiacsafety@dm.duke.edu

Ongoing CSRC Projects

Project	Team Leader	Purpose
Restricted Mean Survival Time (RMST) statistical analysis approach for analyzing Cardiovascular Outcomes Trials	David Manner, PhD (Eli Lilly)	To evaluate the utility of the RMST method (vs traditional HR) in diabetes CVOTs as RMST considers both events and exposure
Arrhythmia Normal Limits Combined Holter/12 Lead ECG Analysis	Polina Voloshko, MD (BioTelemetry Research)	To determine the incidence and variability of various arrhythmias during continuous ECG recordings in healthy adult clinical research volunteers
Prevention of Sudden Cardiac Death in the Young: National Cardiac Screening Warehouse Pilot Study	Salim Idriss, MD (Duke) & Theresa Wright, MD (CSRC; Lilly)	<ul style="list-style-type: none"> To develop and implement uniform collection of a core screening dataset To demonstrate feasibility of data collection comparing paper and electronic methods and feasibility of long term outcome collection
Regenerative Medicine Working Group Development		
CSRC/DIA Collaboration: Real World Evidence & CV Safety Educational Curriculum	Brian Bradbury, PhD (Amgen) Raleigh Malik (DIA) & Mary Jane Geiger, MD, PhD (CSRC; ICON)	To education physicians with regards to key design elements and critical interpretation of real world evidence studies

For more information:

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www.Cardiac-Safety.org
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