



## **CARDIAC SAFETY RESEARCH CONSORTIUM**

### **CSRC Prevention of Sudden Cardiac Death in the Young: National Cardiac Screening Warehouse Pilot Study**

#### **Specific Aims**

Sudden Cardiac Death in young individuals (SCDY) occurs throughout the US. The sudden death of a young person who was apparently healthy is a tragic event that has substantial impact on families and communities. Current public efforts revolve around cardiac screening programs through which data, including individual and family history, limited physical exam findings, and cardiac test results – typically the electrocardiogram (ECG) – are evaluated to assess the risk of a person having diseases known to cause SCDY. The groups leading these programs often operate with limited resources. While there is some synergy of effort between these organizations, current practices vary significantly, preventing effective data analysis to measure the efficacy of screening and allow improvement of efforts.

Prevention of SCDY is an issue of cardiac safety and an initiative of the CSRC. A CSRC working group is active in developing a national screening data warehouse. The purpose of the warehouse is to accumulate screening information across the diverse US population in order to: (1) determine normal ECG values as a function age, gender, race/ethnicity, weight/BMI, activity level, and other metrics, given that such values do not exist; (2) determine SCDY screening efficacy and subsequently guide improvements in screening tools and practices; and (3) improve pediatric cardiac drug safety evaluation and pediatric cardiac device diagnostic efficacy given new population-based data.

The effective implementation of a national screening warehouse is dependent upon a unique multidisciplinary partnership between public screening groups and academic, government regulatory, and medical industry members of the CSRC. Each member of this partnership brings essential skills, experience, and oversight to this program. Each member is a stakeholder in the program who would benefit from its success. Public screening groups would benefit by being “at the table” to strengthen screening methods, organization, and potentially the efficacy of screening to reduce SCDY. Industry members would benefit dependent on their respective sectors. Relevant medical device companies – such as ECG machine manufacturers – would have access to data that could help improve diagnosis of SCDY-related diseases. Relevant pharmaceutical companies would have access to data needed to determine the risk of cardiac side effects (such as arrhythmias) in children, particularly in those who have a disease that increases the risk of SCDY.

To achieve these goals, the CSRC working group has determined that the following components are essential: (1) a core set of data needs to be collected uniformly across efforts and (2) data collection and storage methods need standardization to optimize data consistency and quality and to provide a platform for future research.

The CSRC working group is proposing a prospective pilot study to help overcome these obstacles and to achieve the following specific aims:



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1. Develop and implement uniform collection of a core screening dataset

*CSRC will work directly with public group partners to educate and enable consistent, high-quality data collection*

2. Demonstrate feasibility of data collection comparing paper and electronic methods

*Paper data-collection forms will be created to mirror electronic data elements. Partnering groups will be educated and equipped to use either form of data collection. Quality analysis will be performed comparing the data collection methods.*

3. Demonstrate feasibility of long-term outcome data collection and analysis

*Methods of unique identification will be used to link history, physical, and demographic data elements with collected digital ECG data across partnering groups.*

Screening groups are invited to partner in this pilot study. While it is not a goal to disrupt current methods of screening in these groups, it is expected that groups will work closely with the project team and fully participate in the collection of the relevant data. Given the nature of this work, quality improvement methods will be used and include cycles of data collection, process evaluation, and method adjustment followed by repeat data collection.

It is fully recognized that many screening groups have amassed large amounts of information from years of effort. The value of this information is not discounted. However, for the purpose of this study, data will be collected prospectively with emphasis on obtaining uniform, complete, digital data. This is critical to the success of this study, the data warehouse, and the quality of data analysis in the future.

In alignment with the mission of the CSRC, the stored data will be managed under customary CSRC agreements and operating procedures and be available to CSRC members, including those in this study, for collaborative data analysis. There are numerous examples of ongoing success of CSRC initiatives using this model.

The completion of the pilot study will demonstrate feasibility of establishing a scalable, reliable, national warehouse of cardiac screening information in the young. The warehouse will enable short and long-term outcomes research in the public, private, and regulatory sectors and enable critical partnerships to improve prevention of SCDY as well as partnerships to improve cardiac safety in the young.