



The Cardiac Safety Research Consortium Announces Prospective Collection of Pediatric Cardiac Screening Data for the National Pediatric Cardiac Screening Data Warehouse to Inform Prevention of Sudden Cardiac Death in the Young and Pediatric Product Development

Multi-Stakeholder Project Aims to Improve Pediatric Cardiac Safety

Durham, NC, March 2, 2022 – The Cardiac Safety Research Consortium (CSRC) announced that the Prevention of Sudden Cardiac Death in the Young (SCDY) National Cardiac Screening Warehouse Pilot Study continues to advance with prospective screening data collection having started in 2021. The first-of-kind national pediatric cardiac screening data warehouse is being created through a collaboration with the U.S. Food and Drug Administration (FDA), Duke University and multiple public screening groups from across the country. Over 40,000 high quality digital electrocardiograms (ECGs) recorded during community screenings dating from 2015 to 2021 have been added to the warehouse. However, starting in May 2021, prospective data are being acquired which, in addition to the ECG, include screened individual’s demographics (race, ethnicity, and other variables) as well cardiac screening history and physical information. The national data warehouse may offer significant public health benefits not only in assessing SCDY risk in children, but also in establishing better guidelines for pre- and post-market cardiac safety evaluation, as well as the development of biomarkers for use in pediatric clinical trials. Currently the FDA uses an ECG data warehouse to support cardiac safety review in adults, but until now, there has been no equivalent for children.

“This warehouse has the potential to address two major unmet public health needs – identification of children at risk for SCDY and enhanced cardiac safety in pediatric drug development,” said the project’s principal investigator, Salim F. Idriss, MD, PhD, executive co-director of the Duke Pediatric and Congenital Heart Center and director of pediatric electrophysiology at Duke University Medical Center. “Thanks to the support of our industry and academic partners and especially our collaborating public screening groups, many of whom are parent-led foundations with limited funding, we have improved the efficiency and quality of ECG data collection, leading to an unprecedented volume of reliable real-world data,” he added. “We now have the ability to begin establishing pediatric ECG interpretation normal values based on sex, race, and ethnicity, in addition to the current values used for age, based on these data alone.”

Data collection and data warehouse refinement is ongoing, and the next major step is the addition of collecting long-term data on individuals who had a cardiac screening. The CSRC pilot program will be rolling-out a feasibility study in early 2022 which enables recurrent electronic follow-up months after a screening to determine if a screened individual has a change in cardiac health status. Follow-up data are essential in determination of screening efficacy and establishment of screening best practices.

“The potential impact of this project demonstrates the power of multi-stakeholder teams working together to solve a problem facing the medical community,” said Jonathan Seltzer, MD, MBA, FACC, executive director of the CSRC. “We’re proud to be able to bring these groups together as part of our mission to improve cardiac safety and look forward to the possibility of future collaborations that will come out of this project.”

The identification of children at risk for SCDY may allow for early initiation of medical interventions to reduce the risk. SCDY can occur in healthy-appearing children without symptoms. Since many of the diseases known to cause SCDY are genetic, the identification of children at risk may help in determining if other members of the family are also at risk.

Dedicated to protecting youth from SCDY, over ten community screening organizations from across the country are working as partners to help establish the national data warehouse. The organizations were recruited through national project partner, [Parent Heart Watch](#), whose prevention-driven initiatives include cultivating local champions who create community programs focused on the prevention of SCDY.

In addition to Parent Heart Watch, current partners include:

- Community screening organizations including: [Championship Hearts Foundation](#) (Texas), [Cody Stephens Go Big or Go Home Memorial Foundation](#) (Texas), [Saving Hearts Foundation](#) (California), [Eric Paredes Save A Life Foundation](#) (California), [Screening America](#) (South Dakota), [Heart Screen New York](#) (New York), [Peyton Walker Foundation](#) (Pennsylvania), [Hearts for Athletes](#) (Alabama), [Thomas Smith Memorial Foundation](#) (Michigan), [Play for Jake Foundation](#) (Indiana), [Zac Mago Foundation](#) (Indiana), [Kyle J. Taylor Foundation](#) (California)
- Academic leaders from [Children’s Hospital of Philadelphia](#), [Lurie Children’s Hospital](#), [Baylor College of Medicine](#), [St. Luke’s Health System](#) (Idaho and Oregon), and [The Pediatric and Congenital Electrophysiology Society](#)
- Industry partners including: [AMPS LLC](#) (Analyzing Medical Parameters for Solutions), [AstraZeneca](#), [Cardiac Insight Inc.](#), [Eli Lilly](#), and [Clario \(formerly ERT\)](#).

The study is ongoing, and anyone interested in supporting the initiative is encouraged to contact CSRC about how to get involved. “This project is a success because of the collaborative nature of the CSRC and could not have happened without our partnerships with the public groups. We would love to have others join in supporting to establish this important national public health resource.” Dr. Idriss added.

About Cardiac Safety Research Consortium

The Cardiac Safety Research Consortium (CSRC) provides leadership and guidance for regulators, public and private clinical researchers, and industry through an open, interactive forum to collectively address cardiovascular related issues in clinical trials for both new and existing products. The organization offers unique resources and a collaborative structure that allows for valuable contributions to scientific study design, data analysis and interpretation, and dissemination to the public. CSRC’s non-competitive environment allows for experts to engage in a rigorous, transparent process to define an optimal path forward in the advancement of cardiac safety research, knowledge, and excellence. The impact of CSRC and the thought leadership of its members on key cardiac safety research issues has a proven track record of benefiting the global scientific and regulatory community. For more information about CSRC, visit their website or email info@cardiac-safety.org.

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