

Cardiac Safety Research Consortium (CSRC)

 consortiapedia.fastercures.org/consortia/csrc/

Research Areas



Biomarker Research

Safety

At a Glance

- Status: **Active Consortium**
- Year Launched: **2006**
- Initiating Organization: **Duke University**
- Initiator Type: **Academia**
- Location: **International**

Abstract

The Cardiac Safety Research Consortium (CSRC) supports research by engaging stakeholders from industry, academia, and government to share data and expertise. CSRC outputs include research projects taking advantage of waveforms released from the U.S. Food and Drug Administration (FDA) electrocardiogram (ECG) warehouse, Think Tank Incubator programs, and consensus white papers. Additional work is under way to expand the portfolio of research projects beyond the ECG data into other areas of cardiac safety evaluation from the preclinical through the postmarket periods.

Mission

CSRC's mission is to advance regulatory science specifically related to precompetitive cardiac safety issues through the collaborative means of a public-private partnership across interested stakeholders. CSRC stands fully ready to encourage, contribute to, embrace, and support elements of clinical science such as good scientific design, data analysis, interpretation, and dissemination to the public domain within the construct of the resources and committee structure of the public-private partnership forum.

Consortium History

Accomplishments in 2012 include the following:

- Published six white papers
- Presented at American Heart Association on CardiOncology; co-sponsored session with International CardiOncology Society
- Represented at Drug Information Association (DIA) Japan, which resulted in Pharmaceuticals and Medical Devices Agency joining CSRC
- Co-sponsored four meetings with Center for Business Intelligence (CBI), DIA, and American College of Toxicology
- Launched three think tank meetings on QT assessment, blood pressure, and transradial approach for percutaneous coronary intervention (PCI) and bleeding
- Conducted open forum meeting on cardiac imaging and cardiotoxicity in conjunction with the FDA face-to-face meeting to launch the Diabetes Warehouse Project
- Initiated the case report forms for the Non-Cardiovascular Studies Project

The first annual meeting took place in 2008 and remains an annual event.

Structure & Governance

CSRC is governed by an Executive Committee, which oversees three separate committees: Scientific Oversight Committee, Membership Committee, and Public and Education Programs Committee. The Scientific Oversight Committee includes a White Papers and Publications Committee as well as research teams.

Detailed governance structure can be found here: <http://www.cardiac-safety.org/wp-content/uploads/2014/11/CSRC-Governance-Charter-05.13.2010-Final.pdf>

Financing

CSRC is funded through membership opportunities for both founding members and associate members. Full membership in the consortium for for-profit organizations requires monetary contributions.

Data Sharing

CSRC maintains a database of ECF data in the ECG warehouse that is owned by the entities (generally pharmaceutical company sponsors).

Links/Social Media Feed

Homepage

<http://www.cardiac-safety.org/>

Points of Contact

cardiacsafety@dm.duke.edu

Sponsors & Partners

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