



Cardiac Safety Research Consortium

CSRC Membership

Expanding to Meet Your Needs

CSRC/ICOS Annual Meeting(s)
October 5-6, 2011



CSRC Membership: Who Are We?

CSRC Mission: To advance scientific knowledge on cardiac safety for new and existing medical products by building a collaborative environment based upon the principles of the FDA's Critical Path Initiative as well as other public health priorities.

The CSRC is a first step in bringing together regulators, academicians, physicians, and scientists from industry to focus on cardiac safety issues during medical product development.

The spirit of this collaboration intends to create opportunities by sharing existing knowledge and data that will facilitate the process of enhancing, refining, and ultimately improving the process used to evaluate new medical products.

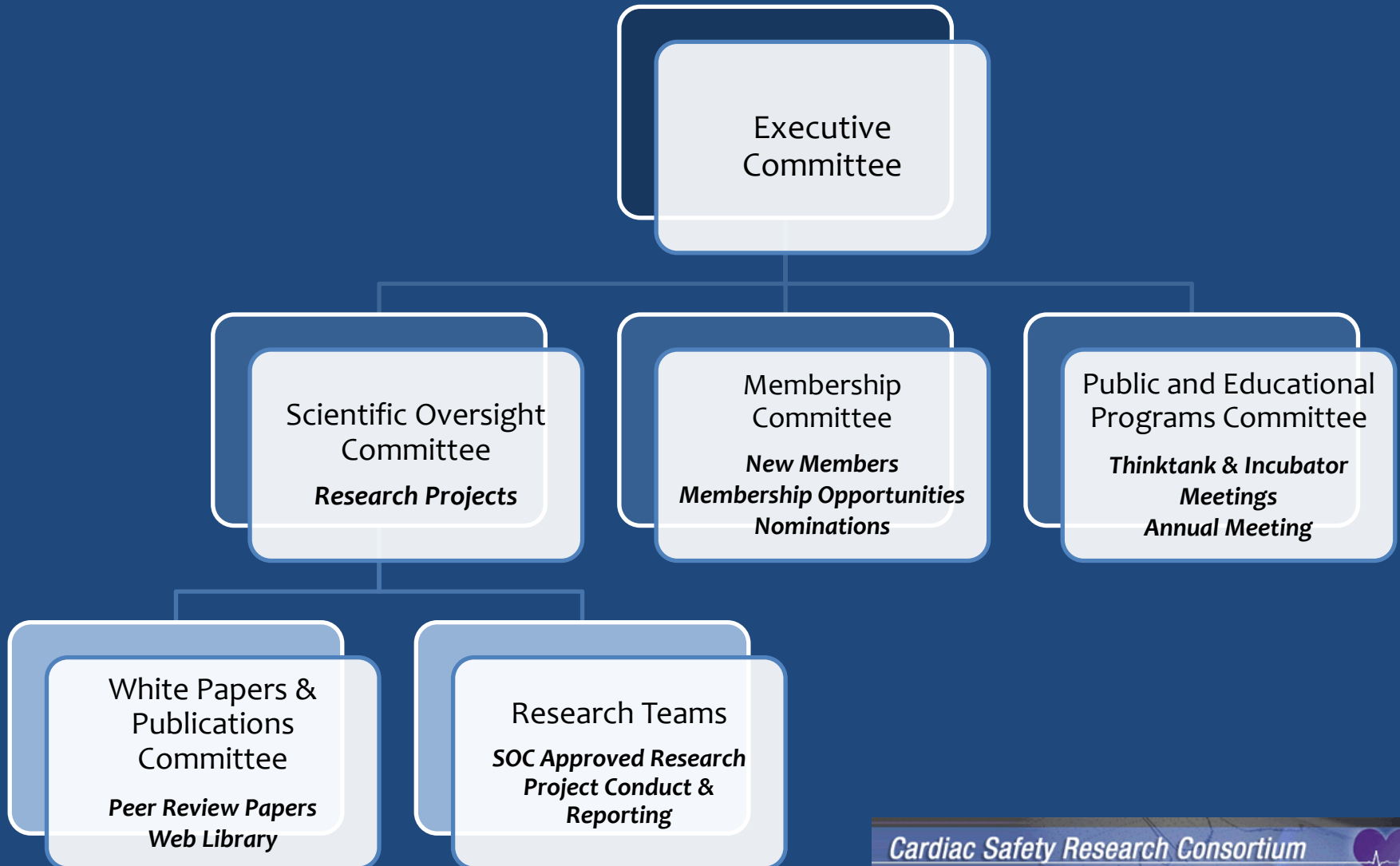


CSRC Membership: Who Are We?

- The CSRC is organized into a number of committees drawn from members of the CSRC , FDA, Health Canada and UK-MHRA.
- CSRC membership includes representatives from the major stakeholders including, but not limited to, academia, the pharmaceutical industry, biologics industry, device industry, professional societies, trade organizations, contract research organizations, core laboratory organizations, patient advocate groups, and interested regulatory agencies.
- These major stakeholders are not limited to United States representation. They may include participation from international groups.



CSRC Organization/Committees



Think Tanks, Research Projects, and White Papers

Think Tanks

The CSRC has hosted 6 of these collaborative incubator initiatives many at the FDA Headquarters. These meetings often produce White Papers or Research Projects and provide CSRC members with networking opportunities.

- Brief Provocative Presentations
- Focused on key issues and barriers
- No lectures
- 50% of meeting time is open discussion

CSRC Thinktanks

- CSRC/ HESI Thinktank- Focusing on Preclinical Issues
- SAFARI Thinktank I and II- Focusing on developing Atrial Fibrillation Registry
- Transradial Education and Therapy Initiative I and II- Focusing on the Transradial Approach to PCIs
- Pediatric Cardiac Safety- Focusing on Drug and Device Cardiac Safety Issues

Think Tanks, **Research Projects**, and White Papers

Research Projects

- Safety of Atrial Fibrillation Ablation Initiative (SAFARI)
- Dual Anti-Platelet Therapy (DAPT) Study
- Study of Access Site for Enhancement of PCI for Women (SAFE-PCI For Women)
- 10 "Thorough QT" studies (Placebo and Moxifloxacin control arms only) released from FDA ECG warehouse by data owners (Merck, GSK, Lilly) for use in CSRC-approved research projects. 4 studies currently available accounting for 25,000 individual records total.

Think Tanks, Research Projects, and **White Papers**

An output of the CSRC is the publication of consensus white papers with participation of experts from industry, academia, and regulatory agencies.

A white rounded rectangular box with a blue shadow, containing the text "White Papers" in blue.

White Papers

These position papers cover challenging areas of cardiovascular safety addressing

- What is known and unknown
- Propose paths forward to address such knowledge gaps
- Members of the CSRC are eligible for participation in writing groups, taking full advantage of the learning process and leadership opportunities involved in publications.

8 White Papers have been published to date in the American Heart Journal.
3 are currently in press.

CSRC Membership Committee

Theresa Wright, MD
(Chairperson)

Senior Director, Global Patient Safety,
Co-Chair, CV Safety Advisory Committee
Eli Lilly and Company

Valarie Morrow

Project Leader
Duke Clinical Research Institute

Lawrence I. Deckelbaum, MD

Vice President, CV Medicine
J&J Pharmaceutical Research & Development

Adel Nada, MD, MS

Director, Clinical Pharmacology
Medical Department CPPM
Global Pharmaceutical R & D
Abbott Laboratories

Corina Dana Dota, MD

AstraZeneca
ECG Centre Director
Co-chair, AZ Cardiac
QT/Arrhythmia Safety
Knowledge Group

Lawrence Satin, MD, FACC

Chief Medical Officer
Cardiocore, Inc.



CSRC Membership Activities

- The CSRC seeks broad participation in its activities through the participation of its members in the mission and activities of the organization.
- Criteria for membership require meaningful contribution although the specifics of the contribution of each member will vary, as detailed in the CSRC Membership Charter.
- Members from private industry are expected to make some financial contribution, as also described in the Membership Charter.
- All members are expected to make contributions-in-kind including data, technology, organizational and operational manpower, or other resources



CSRC Membership Activities, continued

- CSRC members are eligible to participate in the different committees of the CSRC as described below:
 - ECG Database Committee
 - Executive Committee
 - Meeting Planning & Public Forum Committee
 - Membership Committee
 - Scientific Oversight Committee
 - White Paper & Publications Committee



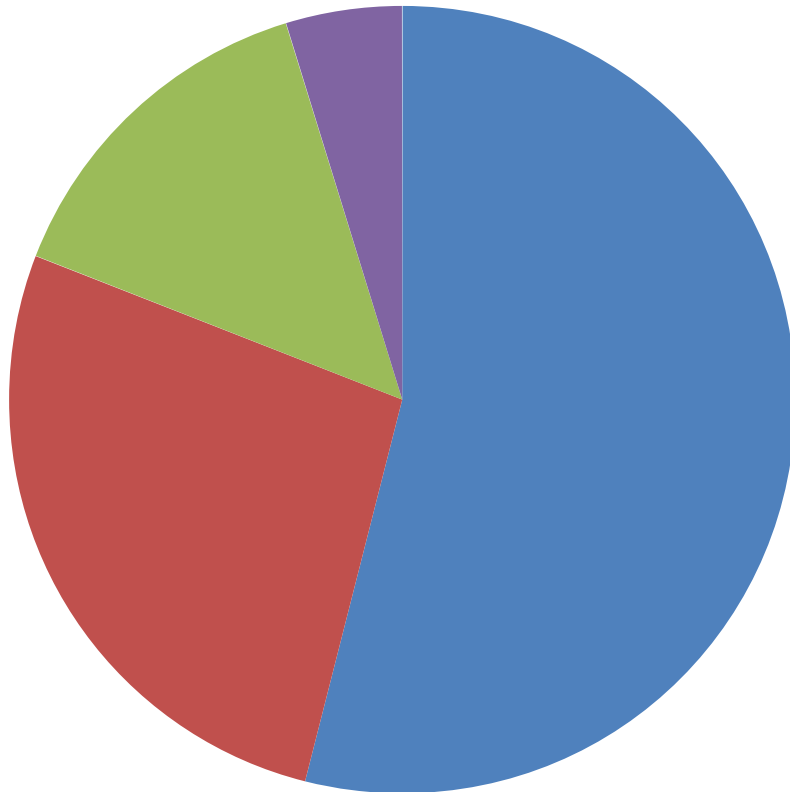
2010 Annual Meeting information

- Since 2007, approximately 6 new companies per year have joined CSRC.
- The largest portion of our membership come from Industry/Companies--Large (10), Medium (2), Small (7), Start Up (5), Over 30 Academic Members
- We are partnering with societies and consortiums such as ACC, ARC, HESI, HRS, DIA.

2011 Annual Meeting Information:

- Since last year, 5 new companies have joined CSRC: 3 Medium size, 2 Start up.
- We now have 37 Academic members representing 17 different institutions.
- We are working and/ developing relationships with more societies and consortiums , such as **International CardiOncology Society (ICOS)**

Membership/Collaborations



■ Industry (55%)

■ Academic/Individual (20%)

■ Societies (21%)

■ Regulatory (4%)



Members: Industry

Abbott	Duck Flats	Merck	OBS Medical
Amgen	Duke University	Merrimack Pharmaceuticals	Pfizer
AMPS	Eli Lilly	Medpace	Quintiles
Anilab	eResearch	Midas Mediscience	Roche
AstraZeneca	GE Healthcare	Monebo Tech	Sanofi Aventis
Biogen Idec	GlaxoSmithKline	Mortara Instruments	Singulex
Cardiocore	iCardiac	NewCardio	Theravance
Cardionet	Johnson & Johnson	NISS	
Daiichi	Medifacts International	NourHeart	

Members: Academic/Individuals

Cornell University	Non-Academic Affiliation— Members (Individuals)
Duke University Medical Center	Thomas Jefferson University
European Institute of Oncology	University of Pennsylvania
Harvard	University of Rochester Medical Center
Memorial Sloan-Kettering Cancer Center	Vanderbilt

Global Regulatory Representation

- The participation of the **FDA** is guided by the Memorandum of Understanding executed between the FDA and the DCRI (September, 2006).
 - The FDA appoint Federal liaisons to the Executive Committee of the CSRC and, as needed, to the other Committees, Advisory Boards and Research Teams.
 - Such Federal liaisons do not have any fiduciary roles in the CSRC and are non-voting
- Members of other Federal agencies (NIH, CMS, CDC etc.), as well as members of interested regulatory agencies from outside of the United States (i.e. **Health Canada, UK-MHRA**), are welcome to participate as members of the CSRC.



Collaborators: Professional Society or Academic Organization

- Academic Research Consortium (ARC)
- Advanced Medical Technology Association (AdvMed)
- Agency for Healthcare Research and Quality (AHRQ)
- American College of Cardiology (ACC)
- Canadian Heart Association (CHA)
- Center for Business Intelligence (CBI)
- Drug Information Association (DIA)
- European Society of Cardiology (ESC)
- Heart Rhythm Society (HRS)
- International Cardio-Oncology Society (ICOS)
- Latin American Society of Interventional Cardiology (SOLACI)
- National Institutes of Health (NIH)
- The Health and Environmental Services Institute (HESI)
- The Society for Cardiovascular Angiography and Interventions (SCAI)



Why Join CSRC ?

- For the patient
 - ❖ Address unmet medical needs in cardiac safety
 - ❖ Positive impact of development attrition & marketed compounds
- Network/Collaboration Opportunities
 - ❖ Share data and expertise in an Intellectual Protected environment
- Think Tanks, White Papers and other key publications above and beyond the theoretical level:
 - ❖ State of art science to enhance public health & patient safety
 - ❖ Hot topics focused on practical cardiac safety issues to promote the development of new innovative medicines, devices and tools of assessment
 - ❖ Rapid peer reviewed publications
 - collaboration agreement with American Heart Journal.



Why Join CSRC?, continued

Good for **patients!**

Good for **science!**

Good for **you!**



Cardiac Safety Research Consortium

Duke Clinical Research Institute (DCRI)



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

Thank You!

