

CSRC Membership: Who Are We and How Do We Grow?

Theresa J. Wright, MD
Chairperson
CSRC Membership Committee

CSRC Annual Meeting
December 9, 2010
White Oak Facility, FDA Headquarters
Silver Spring, Maryland



CSRC Membership: Who Are We?

- The CSRC is organized into a number of committees drawn from members of the CSRC and the FDA.
- 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 Membership Committee

- **Theresa Wright, MD**
(Chairperson)
Senior Director, Global Patient Safety,
Co-Chair, CV Safety Advisory
Committee
Eli Lilly and Company
- **Lawrence I. Deckelbaum, M.D.**
Vice President, Cardiovascular
Medicine
J&J Pharmaceutical Research &
Development
- **Corina Dana Dota, MD**
AstraZeneca ECG Centre Director,
Co-chair, AZ Cardiac QT/Arrhythmia
Safety Knowledge Group
- **Valarie Morrow**
Project Leader
Duke Clinical Research Institute
- **Adel Nada, MD, MS**
Director, Clinical Pharmacology
Medical Department
CPPM
Global Pharmaceutical R & D
Abbott Laboratories
- **Lawrence Satin, MD, FACC**
Chief Medical Officer
Cardiocore, Inc.

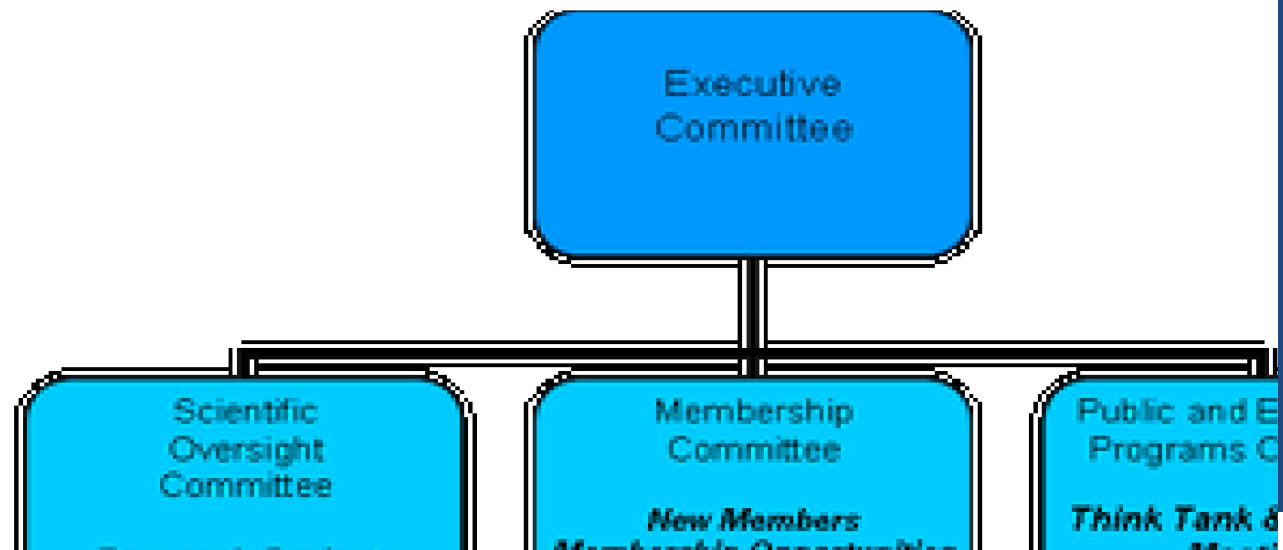


CSRC Membership Activities

- 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 Organization/Committees



How (or Why) Do We Grow?

- Sustain vitality of CSRC by recruiting new members and ensuring members have opportunities to participate and contribute to organization at every level.
- Serves as organizational center for determination of membership status of new applicants according to stipulations of membership charter.
- Provides means for replacement of committee leadership positions through formation of ad hoc nominations processes as needed.



Membership/Collaborations



■ Industry (55%)

■ Academic/Individual (20%)

■ Societies (21%)

■ Regulatory (4%)



Members: Industry

- Abbott
- Amgen
- AMPS
- Anilab
- AztraZeneca
- Biogen Idec
- Cardiocore
- Cardionet
- Daiichi
- Duck Flats
- Duke Clinical Research Institute
- Eli Lilly
- eResearch
- GE Healthcare
- GSK
- J&J
- Medifacts International
- Medpace
- Merck
- Monebo Tech
- Mortara
- NewCardio
- NISS
- NourHeart
- OBS Medical
- Pfizer
- Quintiles
- Roche
- Sanofi Aventis
- Singulex



Members: Academic/Individual

Cornell Medical College

Duke Medical Center

Harvard

Univ. Penn

Private individuals (6)



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**), are welcome to participate as members of the CSRC.



Collaborators: Professional Society or Academic Organization

- 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)
- Heart Rhythm Society (HRS)
- European Society of Cardiology (ESC)
- 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 ?

- 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 **you!**

Good for **science!**

Good for **patients !**





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

THANK YOU!