

Cardiac Safety Research Consortium

CSRC

Membership Committee Charter

19 January 2012

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1. Introduction

On 27 September 2006, the U.S. Food and Drug Administration (FDA) announced a partnership under the agency's Critical Path Initiative, with Duke University (Duke) to focus on cardiac safety and new medicinal product development. The Duke Clinical Research Institute (DCRI) will manage this Cardiac Safety Research Consortium (CSRC), which will involve industry, academics, and regulators. The FDA believes that this is an important effort and has involved senior representatives from the FDA Commissioner's Office, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and the Office of Women's Health.

Under the Memorandum of Understanding, signed between the FDA and Duke, the initial charge to the CSRC will include, but will not be limited to, the following:

1. To create an ECG library from clinical trials that could be used for identifying early predictors of cardiac risk (Cardiac Risk ECG Library);
2. To utilize the Cardiac Risk ECG Library to qualify new ECG biomarkers of cardiac risk;
3. To utilize the Cardiac Risk ECG Library to create a set of ECG reference standards;
4. To develop additional research and regulatory evaluation tools to facilitate clinical decision-making and future medical product development in the interest of public health; and
5. To develop nomenclature and tools to facilitate the development of standards that will provide the evidence base for new diagnostics and assessment tools, and to develop educational tools to make these research results widely available to researchers, clinicians and patients.

The CSRC represents a first step in bringing together key constituencies to focus on cardiac safety issues during the new medical product development process. By utilizing the principles of the Critical Path Initiative, the CSRC will focus on improving the evaluative sciences specifically in relation to cardiac safety.

2. Purpose of the Charter

The purpose of this charter is to describe the process by which individuals, companies, and organizations can apply to become members of the CSRC, as well as the terms, conditions, requirements, and benefits of CSRC membership. The CSRC Membership includes representatives from academia, the pharmaceutical industry, the biologics industry, the device industry, trade

organizations, contract research organizations, core laboratory organizations, patient advocate groups, and interested regulatory agencies. As well as maintaining strategic partnerships with professional societies. There are no geographic or regional restrictions on participation. Representation from all regions is encouraged.

The CSRC is governed by a number of committees that are described in detail in the Governance Charter; the Executive Committee has the final authority for decision making. The CSRC Executive Committee created the Membership Committee with a mandate to develop guidelines and implement processes related to nominated members to the CSRC. This Membership Charter outlines these guidelines and processes. The purpose of the CSRC Membership charter is:

- To outline the composition of membership
- To define the levels and benefits of membership
- To delineate the responsibilities and requirements of membership
- To define the Membership Committee nomination process

3. Composition of the Membership

The CSRC includes members from a variety of global constituencies including academia, government and regulatory agencies, drug and device companies, as well as the biotechnology industry. The CSRC seeks broad participation in its activities through participation in its membership. All members are expected to participate actively in the work of the consortium including participation in at least one face-to-face meeting each year. The criteria for membership in the Consortium are described in more detail below. All members are expected to make contributions-in-kind, including data, technology, manpower, or other resources.

The consortium considers its members as falling into three categories:

- Not-for-profit organizations
- For profit companies/organizations (pharmaceutical corporations, contract research organizations, core laboratories, and technology companies)
- Individuals (cardiac safety consultants, advisors, academics, individuals from regulatory agencies)

The CSRC recognizes that there are individuals who may work part-time for a larger company and work part-time as a consultant. In order to avoid ambiguity, the CSRC will define a potential individual member as:

- a person who has a full-time appointment at an academic institution;
- works for a regulatory agency, or

- provides consultative services on a fee-for-service basis as their sole source of income, and does not receive a significant source of income from another company including pharma, biotech, CRO, laboratory, etc

Part-time employees of a company are not eligible to become members of the CSRC as an individual, but can become involved in the activities of the CSRC if their employer becomes a member of the CSRC.

4. Levels of Membership

There are four levels of CSRC membership, which are described below. The levels of membership were designed to distinguish different levels of participation in the CSRC based on the level of commitment and contribution by the member. These four levels of membership apply to all three categories of members (for-profit companies, not-for-profit organizations, and individuals) although there are differences in the requirements associated with each level of membership based on the category of the member.

Founding Members

Founding Members are those companies, organizations, and individuals who were nominated by the CSRC as meeting the criteria for full membership in the CSRC as of June 30, 2010.

This level of membership is a retired category as of January 2012.

Sustaining Members

Sustaining Members are those members who meet the criteria as Principal Members (see below) and who have made, and will continue to make, a multi-year financial commitment to the CSRC.

Principal Members

Principal Members are defined as individuals, companies, and organizations who meet all of the requirements of CSRC membership as of July 1, 2010. These requirements are specific to the category of the member (Not-for-profit, for-profit, and individual membership). The requirements for CSRC membership are based on criteria (financial, contribution of data, contribution of manpower and expertise) that are outlined below. The consortium recognizes that the relative contribution in each of three areas will vary across different members.

Associate Members

Associate Members are defined as individuals, companies, and organizations who do not meet all of the requirements of CSRC membership but who make a meaningful commitment and contribution to the CSRC. Such commitments may include various combined contributions of financial, data, manpower and/or expertise as proposed by, and based on the resources of, the membership candidate, with review for approval by both the Membership Committee.

5. Requirements for Membership

In order to be granted membership to the CSRC, applicants must meet the membership requirements. These requirements differ based on the category of the member (Not-for-profit, for-profit, and individual membership) and the level of membership (full membership and associate membership – see below). All members are expected to make meaningful contributions to and actively participate in the work of the consortium. This participation may include committee meetings (face-to-face as well as by teleconference), document writing or review, and/or research projects and teams. The frequency of these activities will be specific to the committee/team.

The requirements of membership are based on three criteria:

- a financial contribution
- a contribution of data to be shared within the consortium,
- a contribution of manpower and expertise to support the consortium.

The consortium recognizes that the relative contribution in each of three areas will vary across different members.

Members from for-profit companies/organization are expected to make a financial contribution (a membership fee), an agreement to participate in consortium activities, and some type of contribution in-kind (e.g. technology, data, expertise, etc.). The CSRC recognizes the importance of the contributions of both large and small companies. The following guidance has been provided with regard to the financial contribution from for-profit companies/organizations:

Members who meet the criteria of founding/sustaining membership as well as individuals and regulatory agency representatives are eligible for positions on CSRC governance committees, including the Executive Committee, the Scientific Oversight Committee, the Membership Committee and the Strategic Relations Committee. The process for nomination and approval for a position on a CSRC governance committee is described in the CSRC governance charter.

	Founding Retired category no longer available	Sustaining	Principal	Associate
Large Companies - (market capitalization of > \$3 billion or yearly Gross Sales > \$1 billion)	\$50,000	\$25,000/year with a 3 year commitment	\$15,000 per year	\$8,000 per year
Medium Companies - \$25,000 (market capitalization of \$250 million - \$3 billion or yearly gross sales \$50 million - \$1 billion)	\$25,000	> \$10,000/year with a 3 year commitment	\$10,000 per year	\$4,000 per year
Small Companies - \$10,000 (market capitalization of < \$250 million or yearly revenue < \$50 million)	\$10,000	\$4,000/year with a 3 year commitment	\$4,000 per year	\$2,000 per year
Start-Up Companies (market capitalization - \$0 AND yearly gross sales - \$0)				\$1,000

Applications for Founding Members were closed on June 30, 2010.

Annual dues will be required for all membership levels in 2012. Founding Members will be considered as having paid their dues through 2011 and will be expected to begin paying annual dues in 2012. The Founding Member category is closed as of January 2012.

Potential members that anticipate difficulty in making the suggested financial contributions are encouraged to contact the CSRC membership committee at cardiacsafety@mc.duke.edu for a consultation. In rare circumstances, the CSRC will consider proposed alternatives from groups wishing to join the consortium although consideration will only be given to companies and organizations that are willing to provide a significant amount of data to the consortium or a significant amount of manpower relevant to the work of the CSRC. The final decision on level of membership will be based upon the financial contribution and its justification, the level of anticipated involvement, and the type of contribution-in-kind set forth in the application.

Individuals, and members from non-profit organizations are not expected to make a financial contribution but are expected to actively participate in consortium activities, and some type of contribution in-kind (e.g. technology, data, expertise, etc.). The membership level of individuals and non-profit organizations will be determined by the Membership committee based on their commitment and contributions to the work of the CSRC.

It is anticipated that the Membership Committee will review on an annual basis, the contributions and determine continued eligibility of each member. If during the course of participation on a major committee it is determined that the member is not fulfilling his/her obligations, the member may be asked to step down. If during the course of membership, it is determined that a CSRC member engages

in activities that the CSRC Executive Committee determines is detrimental to the consortium, the member will be asked to step down from any leadership position that they may hold, including seats on major committees, or research teams.

6. Benefits of Membership

The Benefits of Membership depend on the level of membership and include eligibility for leadership positions on CSRC committees, reduced registration fees for CSRC meetings, and eligibility for CSRC leadership meetings.

	Founding/Sustaining	Principal	Associate
Eligible for seat on Executive Committee and/or a Leadership Position of one of the CSRC Governing Committees	X		
Eligible for Leadership of Research Team	X*	X	X**
Eligible for participation in a Research Team	X	X	X
Registration fees for CSRC Think Tank and General Meetings ***			
Waived Fees	1	0	0
50% Discounted Fees	3	1	0
20% Discounted Fees	2	2	1
Access to Early Registration for CSRC Think Tank and General Meetings	X	X	X
Eligibility for CSRC Leadership Meetings**			
No fee	1	0	0
Fee	1	1	0

* Full membership is required to lead a research team

**An associate member may lead a research team only in association with a founding/sustaining/principal member

*** Numbers refer to number of participants eligible per meeting. [NOTE: The goals and structure of CSRC Leadership Meetings need to be delineated. These are meant to be meetings that include senior thought leaders from academia, industry, and regulatory agencies on a specific topic.]

Members who occupy seats on major CSRC committees, including the Executive Committee, Scientific Oversight Committee, Membership and Strategic Relations Committee, may retain their seats for the duration of the tenure specified for each committee, as long as the member's company continues to retain full or sustaining membership. However, if a committee member's tenure ends, it is not automatically assumed that a member from this person's organization will replace the member stepping down. As all founding/sustaining members are eligible for committee seats, the Membership Committee will work with the CSRC membership and Executive Committee to identify an appropriate replacement for the person stepping down. The CSRC governance charter will be used to consider the balance of members as outlined in the governance charter.

7. Membership Process

All potential members will complete a membership application (Appendix A) that the Membership Committee will use for evaluation and recommendation purposes to the Executive Committee.

8. Duration of Membership

CSRC membership requires annual renewal (based on meeting the requirements and expectations of membership as described above). All organizations are expected to renew their membership in 2012. All individuals and regulatory agencies will not be required to submit a renewal application but will be contacted annually to confirm continued participation in the CSRC.

As long as an organization or individual maintains an active status as a member of the CSRC, they may nominate persons to participate in the activities and the committees of the CSRC. Eligibility for participation in leadership positions is based on the level of membership as described above (See Section 6). However, it is important to recognize that persons participating in the CSRC as part of a company/organization lose their status within the CSRC if that person leaves the member company. When such a status change occurs, the person involved in the CSRC may apply to be granted Associate Member status for 1 year if other significant in-kind contributions continue, based on the assessment of the Membership Committee. After this 1 year grace period, that person must either re-apply to the CSRC as an individual (if they are no longer working for an organization), or their new organization must apply for membership in the CSRC in order for that person to continue their participation in the CSRC. The following examples are meant to illustrate a few examples of these potential situations.

- Dr. A has been a full time academic at a university and has been working with the CSRC for two years as a Founding/Sustaining Member and currently has a position on one of the CSRC Governance Committees (e.g., Executive Committee) and participates in a Research Team. Dr. A then leaves his post at the university and takes a job with NewDrugCo Inc. (which has previously not been involved with the CSRC). If NewDrugCo Inc. joins the CSRC as a Principal Member, then Dr. A can remain in his positions and involvement in the CSRC. In the event that NewDrugCo Inc. does not join the CSRC, Dr. A must step down from his position on Executive Committee immediately and can apply to the CSRC for a temporary status as an Associate Member which if granted allows him to continue participating on the Research Team.
- Dr. B works for BigDrugCo Inc, a Founding/Sustaining Member of the CSRC, has been working with the CSRC for two years and currently has a position on one of the CSRC Governance Committees (e.g., Membership Committee). Dr. B then leaves BigDrugCo Inc, and takes a job with NewDrugCo Inc. (which has previously not been involved with the CSRC). If NewDrugCo Inc. joins the CSRC as a Principal Member, then Dr. B can remain in his positions and involvement in the CSRC. In the event that

NewDrugCo Inc. does not join the CSRC, Dr. B must step down from his position on Executive Committee immediately and can apply to the CSRC for a temporary status as an Associate Member which if granted allows him to continue participating on the Research Team.

- Dr. C works for BigDrugCo Inc, a Founding/ Sustaining Member of the CSRC, has been working with the CSRC for two years, and currently has a position on one of the CSRC Governance Committees (e.g., Scientific Oversight Committee), and he chairs a Research Team. BigDrugCo Inc does not renew its membership with CSRC. Dr. B must step down from his position on Scientific Oversight Committee and must step down as chair of the Research Team immediately and can apply to the CSRC for a temporary status as an Associate Member for one year which if granted allows him to continue participating on the Research Team (although not as chair).

9. Nominations for Committee Participation and Leadership

It is expected that participation in all CSRC committees will rotate on a regular basis. The membership committee will be responsible for collecting nominations for the various committees and membership at large and for the formation of a nomination slate to be presented to the Executive Committee. Once approved by the Executive Committee, the nomination slate will be brought to the entire Membership Committee for approval. Further criteria will be specified in the CSRC Governance Charter.

APPENDIX A – Membership Application

Name of Applicant:

Organization:

Address:

E-mail:

Describe the category that best describes your organization or status as an individual:

- Not-for-profit organization
- For profit company/organization (pharmaceutical corporations, contract research organizations, core laboratories, and technology companies)
- Individual (cardiac safety consultants, advisors, academics, individuals from regulatory agencies)

Briefly describe your organization or your role as an individual interested in cardiac safety:

Briefly explain your interest in CSRC:

Briefly explain planned contribution to CSRC:

- Financial (indicate \$ amount of the contribution and justification for any variance with regard to the suggest contribution from Section 5)
- Data (Describe whether you have access to and permission to share data with the consortium)
- Expertise (Describe the expertise you plan to bring to the work of the consortium)
- Technology (Describe any technology you plan to bring to the work of the consortium)
- Other (Describe)

Please provide the names and CVs/Resumes of the individual who will be participating in the CSRC.