Cardiac Safety Research Consortium
Governance Structure

DATE: 21 May 2017

I. Scientific Rationale

Safety is a critical component of medical product[1] development and approval. In particular, cardiac safety has received intense focus with several high profile issues including market withdrawals. This has stimulated debate over the best way in which to measure efficacy while ensuring the protection of the public health. At the center of this debate is the balance between efficacy and safety. Importantly, rapid advances in therapeutic medical product development have yet to reach full potential, in part due to limits in our ability to understand and quantitate therapeutic balance.

Unfortunately, the evaluative sciences surrounding medical product approval have not kept pace with our fundamental understanding of disease. Societal investment in research and development to improve the approval process has been lacking in contrast to the large investment, both private and public, in basic research and specific product advances. In order to improve the ability of regulatory agencies to promote and protect the public health there needs to be a fundamental investment in the evaluative sciences. Specifically, the scientific basis of our understanding of medical product safety needs to be enhanced and integrated with refined measurements of efficacy. An investment in the evaluative sciences will provide more precise scientifically-based information enabling health care professionals and patients to appropriately assess risk and benefits.

The *Critical Path Initiative* has been developed by the FDA to address many of these issues by establishing greater collaboration between regulators, academics, physicians, and scientists from industry. The spirit of this collaboration is intended 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. A central tenet to *Critical Path* is a focus on the evaluative science of the approval process, including both efficacy and safety measures.

The Cardiac Safety Research Consortium (CSRC) brings together key constituencies to focus on cardiac safety issues during the medical product development process. By utilizing the principals of the *Critical Path Initiative*, the CSRC has focused on improving the evaluative sciences specifically in relation to cardiac safety.

II. Mission Statement

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.

III. Areas of Focus in Cardiac Safety

This consortium was created to address cardiac safety in cardiovascular and non-cardiovascular medical products. While the initial focus was on the proarrhythmic risk of products, the intent of this public-private partnership is to cultivate collaborations facilitating the development of clinical research strategies, evaluative tools, standards, validated tests and cardiovascular biomarkers across the broader spectrum of cardiac safety including, but not limited to arrhythmia, thrombosis, myocardial infarction, diabetes, heart failure, cardio oncology, and regenerative therapy.

[1] Medical Product = drugs, biologics, devices, and combination products

IV. Key Objectives

1. To facilitate focused pragmatic research that will inform regulatory processes with regard to cardiac safety
2. To develop expert consensus around common nomenclature, standards, and key definitions, and to draft white papers in challenging areas, describing what is known, unknown, and proposing paths forward to address such knowledge gaps
3. To develop knowledge and strategies intended to improve the evaluative sciences in relation to cardiac safety and product development
4. To coordinate "think tanks" and other programs and public forums for open discussion and updates on topics in cardiovascular safety pertaining to drug and device development
5. To establish infrastructure and operational processes with the following components:
    - Transparent processes that promote dialogue on cardiovascular safety
    - Assure input from all primary stakeholders (e.g. regulators, industry, academics, professional societies and other consortiums)
    - Involve all Consortium contributors in the decision-making and project development process
    - Leverage resources and expertise from multiple public and private partners
    - Create an open and efficient mechanism for submitting potential projects and their objective evaluation
    - Facilitate and, where appropriate, orchestrate mechanisms for the continuance of ongoing cardiac safety research programs
    - Involve broader public or patient groups in the process as appropriate
    - Encourage cross-sector interaction and problem solving
    - Leverage previously conducted and ongoing clinical studies, research infrastructure and databases
    - Preserve proprietary interests

V. Governance Structure

Consortium Membership

The CSRC will be organized into a number of committees drawn from members of the CSRC, the FDA, and other regulatory agencies. CSRC membership will include 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, payers and interested regulatory agencies. These major stakeholders will not be limited to United States representation, but may include participation from international groups.

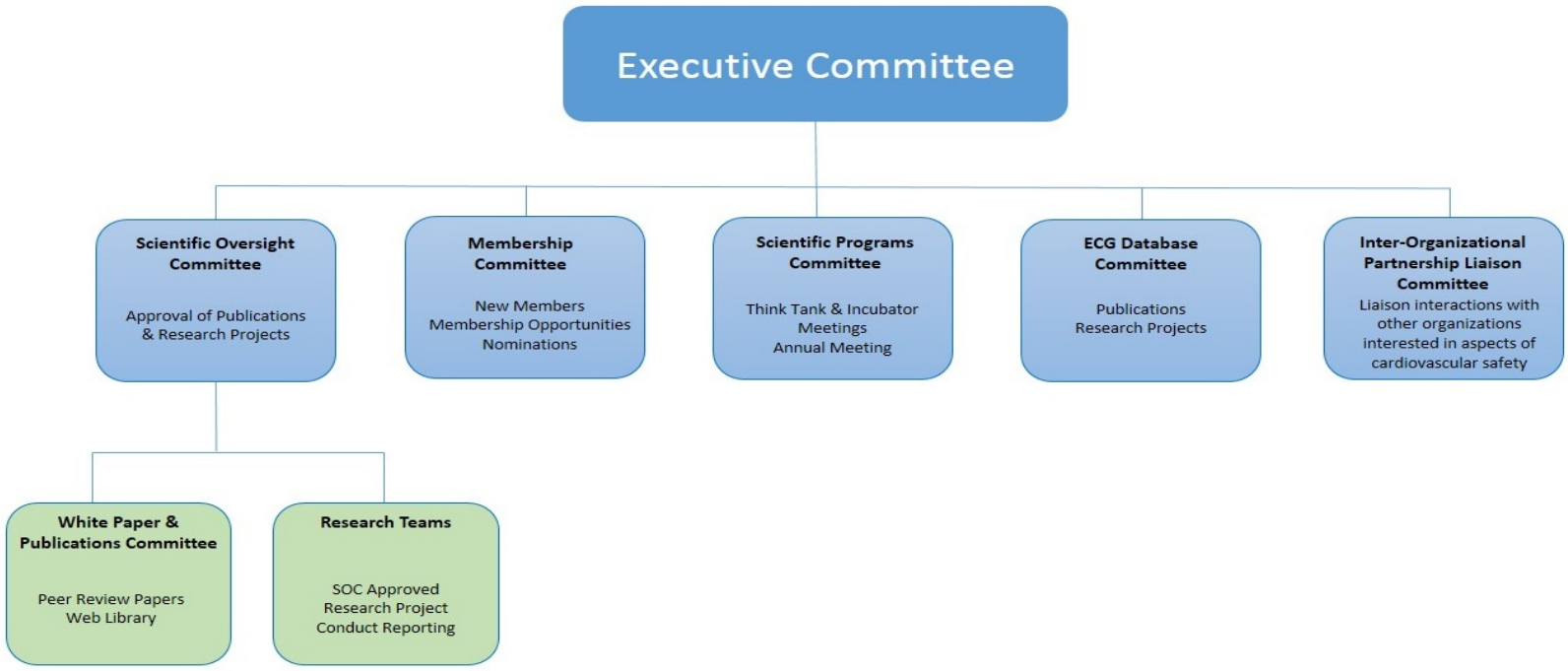
The CSRC seeks broad participation of its members in the mission and all activities of the organization. Criteria for membership require meaningful contribution (financial and/or in-kind) as detailed in the CSRC Membership Charter. The specifics of the contribution of each member will vary, but all members are expected to make contributions-in-kind including data, technology, organizational and operational manpower, or other resources. CSRC members are eligible to participate in the different committees of the CSRC as described below.

Representation from the FDA

The participation of the FDA is guided by the Memorandum of Understanding executed between the FDA and the DCRI (September, 2006). The FDA will appoint Federal liaisons to the Executive Committee of the CSRC and, as needed, to the other Committees and Research Teams. Such Federal liaisons will not have any fiduciary roles in the CSRC and will be non-voting in matters with potential financial implications (see Appendix A for roles and responsibilities of FDA representatives).

Members of other Federal agencies (NIH, CMS, CDC etc.), as well as members of interested regulatory agencies from outside of the United States, are welcome to participate as members of the CSRC.

Figure 1. Structure and Governance



Executive Committee (EC)

The Executive Committee will primarily maintain the CSRC organization in concert with its Charter mission. The Executive Committee will provide oversight of all CSRC Committee activities, based primarily through review of each Committee's recommendations to the Executive group. The Executive Committee will retain final decision making responsibility for all CSRC activities and processes. The Executive Committee will also retain final responsibility for providing all in-kind and fiscal resources, or strategies and support for obtaining such resources, needed to facilitate each Committee's activities on behalf of the CSRC.

Composition

- The Executive Committee will consist of a total of 10-18 voting members, including but not limited to:
  - EC Chair, Co-Chair
  - Chairs of each one of the other CSRC Committees
  - FDA representative (s)

  - Past chair of the EC
  - Three to five invited members considered valuable of the EC activities.
- The EC composition should ensure that all three key stakeholder categories are included (i.e. regulators, industry and academia)
- Co-Chairpersons will consist of one member from academia and one member from industry
- The EC Chair and Co-chair should have been part of the EC for at least one year, and will be elected by the whole EC. It is expected that the Co-Chairpersons are elected in different years, and serve in this role for 2 years with one potential re-election. Longer tenure represents an exception and will require consensus agreement by the EC members.
- FDA and other regulators will be encouraged to place at least one advisor on the Executive Committee, more if both parties agree. Regulators are also encouraged to participate in various working committees.
- The Executive Committee may modify its size or composition with 3 extra slots without the need to modify this charter. Any other changes beyond the above require formal modification of this Governance Charter
- EC seats occupied by non-Committee chairs will be filled through ad hoc nominations by any member of the EC, and will require unanimous approval by the EC.
- The Executive Committee may invite experts and advisors to Committee meetings as needed

<u>Responsibilities</u>

- Ensure that all activities are commensurate with the CSRC Mission through oversight of all committee activities
- Ensure development of operational infrastructure in order to orchestrate and facilitate CSRC activities and committees
- Form ad hoc advisory groups or committees as needed

<u>Eligibility and Expectations for Participation</u>

- Must be a Sustaining Member (as defined in the Membership Charter) and served as an active participant in CSRC activities for at least one year.
- Regular (>50%) participation in conference calls
- Attend at least 1 face-to-face meeting each year
- It is expected that EC members actively participate in at least one of the CSRC initiatives each year
- If Executive Committee member cannot fulfill these expectations then the member may be asked to step down by consensus of the co-chairs

Scientific Oversight Committee (SOC)

The SOC will provide the primary intellectual repository for the solicitation, review, and ongoing oversight of all CSRC scientific projects and programs, and will make recommendations on all such directly to the Executive Committee. To execute this mission, the SOC will develop and facilitate Research Teams specifically dedicated to each of the approved research programs.

<u>Composition</u>

- Chair: Must be a full member of CSRC with at least 2 years prior membership
- Co-chair: May be Advisory or Associate Member in select cases
- The SOC Chair and Co-chair should have been part of the SOC for at least one year, and will be approved by the EC. It is expected that the Co-Chairpersons are elected in different years, and serve in this role for 2 years with one potential re-election. Longer tenure represents an exception and will require consensus agreement by the EC members.
- Membership to include at least one academic, one member from industry, and one member from Regulatory
- Membership to include the Chairs of the White Papers and Scientific Programs Committees

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Responsibilities

- Solicit and review scientific project proposals
- Recommend project proposals to the Executive Committee for final approval
- Form and support Project Teams specific to implementation of approved projects. Project Team composition will be determined on a project-specific basis by soliciting interested individuals from the CSRC membership. A committee will be formed from the interested CSRC Members as well as non-member experts, if needed. The project proposer will serve as the Project Lead and at least one SOC member will participate per project, to be the liaison between the project and the SOC.
- Provide ongoing oversight and facilitation of Project Team activities, timelines and deliverables
- Support and facilitate leadership and activities of the White Paper Writing Committee
- Liaise with other CSRC Committees as needed to coordinate related efforts

Eligibility and Expectations for Participation

- Meetings as required primarily by teleconference, face-to-face if needed
- Regular participation in conference calls
- To be a Project Team leader, the individual(s) must be either 1) a full CSRC member or 2) employed by a company that is a full CSRC member, with at least 6 months membership in CSRC.

White Papers and Publications Committee

The White Papers and Publications Committee will organize and provide logistical support for all CSRC sponsored publications. Although this committee is separate from other committees, it is intended to work in an integrated fashion to ensure that appropriate topics are raised to the SOC for consideration from the various CSRC groups. This group functions as an oversight committee to review proposals for white papers or similar publications in which the CSRC is involved. Specifically, the committee focuses on topics which either emerge from or would likely catalyze other sustained efforts such as research projects or public meetings and programs. The White Papers and Publications Committee then assists in forming specific writing and reviewer groups as needed to provide direction, guidance, administrative support, communications, and involvement with other facets of the CSRC. Membership of this committee will consist of at least industry, academia and regulators. The White Papers and Publications Committee will report through the SOC.

Composition

- Chair: Must be a full member of CSRC with at least 2 years prior membership
- Co-chair: May be Advisory or Associate Member in select cases
- The Chair and Co-chair should have been part of the committee for at least one year. It is expected that the Co-Chairpersons are elected in different years, and serve in this role for 2 years with one potential re-election. Longer tenure represents an exception and will require consensus
- Membership to include at least one academic, one member from industry, and one member from Regulatory

Responsibilities

- To develop (and support) writing and reviewer groups, which will draft white papers in challenging areas describing what is known, unknown, and proposing paths forward to address such knowledge gaps

Eligibility and Expectations for Participation

- Regular (>50%) participation in conference calls
- If committee member cannot fulfill these expectations then the member will be asked to step down by the chair(s).

Membership Committee

The Membership Committee will be the primary center of activity to sustain the vitality of the CSRC through recruiting new members and through ensuring that members have opportunities to participate and contribute to the CSRC organization at every level. The Membership Committee will also serve as the organizational center for determination of membership status of new applicants (according to stipulations of the Membership Charter).

Composition

- Chair: Must be a full member of CSRC with at least 2 years prior membership
- Co-chair: May be Advisory or Associate Member in selected cases
- The Chair and Co-chair should have been part of the committee for at least one year. It is expected that the Co-Chairpersons are elected in different years, and serve in this role for 2 years with one potential re-election. Longer tenure represents an exception and will require consensus
- Membership to include at least one academic, one member from industry, and one member from Regulatory

Responsibilities

- Develop and maintain CSRC informational materials for potential new members
- Solicit, provide support and outreach for potential members
- Evaluate applications for CSRC membership, and present proposals to the EC
- Determine level of membership (Sustaining/Principal/Associate)
- Provide information on and facilitate new members opportunities within the CSRC
- Liaise with other CSRC Committees as needed to coordinate related efforts
- Periodic review of membership composition and participation

Eligibility and Expectations for Participation

- Regular (>50%) participation in conference calls
- If a Membership committee member cannot fulfill these expectations then the member will be asked to step down by the chair(s)

Scientific Programs Committee

The Scientific Programs Committee will organize and provide logistical support for all CSRC sponsored public meetings. Although this committee is separate from the SOC and other committees, it works in an integrated fashion to ensure that appropriate topics are raised to the Executive Committee for consideration from the various CSRC groups. This group functions as an oversight committee to review proposals for annual meetings, think tanks, or other public forums in which the CSRC is involved. Specifically, the committee focuses on meetings which would likely catalyze other sustained efforts such as white papers and research projects. The Scientific Oversight committee then assists in forming specific working groups as needed to provide direction, guidance, administrative support, communications, and involvement with other facets of the CSRC.

Composition

- Chair: Must be a full member of CSRC with at least one-year experience on the Program Committee and with active participation in setting up at least 2 meetings.
- Co-chair: May be Advisory or Associate Member in selected cases

- The Chair and Co-chair should have been part of the committee for at least one year. It is expected that the Co-Chairpersons are elected in different years, and serve in this role for 2 years with one potential re-election. Longer tenure represents an exception and will require consensus
- Membership to include at least one academic, one member from industry, and one member from Regulatory
- For specific topics (when available) patient advocacy groups will be invited to participate
- All program planning teams will include direct participation of CSRC project leadership from DCRI to ensure appropriate financial planning

Responsibilities

- Identify and prioritize topical themes for think-tank/incubator meetings, in addition to the Annual Meeting
- Ensure the Annual CSRC meeting
- Develop meeting planning teams for each specific meeting
- Provide oversight and facilitate the activities of each specific Meeting Planning Team
- Meeting Planning Teams will be chaired by a full member with at least 6 months membership in CSRC, along with a co-chair who may be an Associate member or Advisor in selected cases.
- Define the composition of each specific Meeting Planning Teams. It is expected that at least one Committee member will participate in each one of the specific Meeting Planning Teams
- Liaise with other CSRC Committees as needed to coordinate related efforts (e.g. white papers and/or proceedings from the meetings)

Eligibility and Expectations for Participation

- Regular (>50%) participation in conference calls
- If committee member cannot fulfill these expectations then the member will be asked to step down by the chair(s)

ECG Database Committee

ECG data in the ECG warehouse are owned by specific entities. Most typically these are pharmaceutical company sponsors that submit ECGs in the course of drug development or post-market surveillance. In other scenarios, they can be research organizations (public or private) that collaborate with CSRC for shared common scientific goals.

Release of these ECG data to the CSRC for additional analyses represents a collaborative effort of scientific good will on the part of the data owners. Within the CSRC, the ECG Database Committee covers all technical sides related to project proposals (before their submission) and subsequent data analysis (after the projects have been executed). Project proposals are formally evaluated by the Scientific Oversight Committee (SOC), which evaluates proposals for use of the released ECG data and fosters collaboration within the research community. Individual research protocols cleared by the SOC are then approved by the Executive Committee.

Composition

- Chair: Must be a full member of CSRC with at least 1 year prior membership
- Co-chair: May be Advisory or Associate Member in selected cases
- The Committee should include at least one member from the institution holding the data released to the CSRC ECG Warehouse and who is responsible for vetting and compiling the data
- Membership to include at least one academic, one member from industry, and one member from Regulatory
- All program planning teams will include direct participation of CSRC project leadership from DCRI to ensure appropriate financial planning

Responsibilities

- Identify and prioritize potential research projects and uses for the CSRC ECG Warehouse data
- Identify and solicit potential data that could be added to the CSRC ECG Warehouse
- Ensure fair access to the CSRC ECG Warehouse data, including methods for obtaining data
- Ensure statistical analysis requests can be fulfilled based on staff and budget
- Recommend project proposals to the SOC/Executive Committee for final approval
- Provide ongoing oversight and facilitation of research projects, including timelines and deliverables
- Support and facilitate leadership and activities of the ECG Database Committee
- Attend the Annual CSRC meeting (face-to-face)
- Attend other CSRC meetings as necessary
- Attend monthly committee meetings (conference calls) and help develop agenda items for each meeting
- Liaise with other CSRC Committees as needed to coordinate related efforts

Eligibility and Expectations for Participation

- Regular (>50%) participation in conference calls
- If committee member cannot fulfill these expectations then the member will be asked to step down by the chair(s)

Inter-Organizational Partnership Liaison Committee

Provides a 'single point of contact' at the CSRC for collaborative partner organizations. While these organizations are not members of the CSRC, they share the neutrality and patient-centered goals of the Consortium. Facilitates jointly-sponsored meetings and publications.

Composition

- Chair: Must be a full member of CSRC with at least 1 year prior membership
- The Chair should have been part of the committee for at least one year. It is expected that the Chairperson serve in this role for 2 years with one potential re-election. Longer tenure represents an exception and will require consensus
- Committee size not to exceed 10 voting members (not including non-voting Advisors)
- Ideally, membership, as for other committees, to include at least one academic, one member from industry, and one member from a regulatory agency. However, in this case it may not be appropriate to have a regulator interacting with individual organizations in 'preference' to others: this can be revisited on an ongoing basis.

Responsibilities

- Attend the Annual CSRC meeting.
- Members of this committee will focus on interactions with external organizations, and identify a 'single point of contact' liaison within each organization.
- Encourage participation by organizations in CSRC sponsored activities including our Annual Meeting, and discuss if/when/how CSCR can participate in organizations' Annual Meeting.
- Liaise with other CSRC Committees as needed to coordinate related efforts.

Eligibility and Expectations for Participation

- Regular (>50%) participation in conference calls
- If committee member cannot fulfill these expectations then the member will be asked to step down by the Chair.

Transition of Leadership

The Executive Committee will determine replacements for CSRC Leadership roles. These individuals will be selected based on their contributions to the CSRC. Desirable characteristics are demonstrated leadership in other roles (e.g., as a committee member leading projects under the direction of the Committee Chair), and demonstrated enthusiasm and commitment to the CSRC's endeavors. Individuals stepping down from leadership roles may continue to supply important institutional memory and leadership to the CSRC and there likely will be value on an individual basis in their remaining on the Committee. Incoming Committee Chairs will join the Executive Committee.

VI. Antitrust Guidelines

The consortium will handle all antitrust issues in compliance with federal standards (Sherman Act 15 U.S.C sect 1 *et seq).* Specifically, any indication of improper commercial bias or facilitation of collusion (directly or indirectly) associated with the legitimate scope of Consortium activities could expose its members to antitrust risk. Issues may arise that could have antitrust implications which include but are not limited to:

1. Use of Consortium unfairly to promote a particular technology or product or exclude another for commercial reasons
2. Inappropriate sharing of confidential/competitively sensitive information of competing companies including intellectual property, pricing, production or innovative plans

All members of the consortium will need to abide by guidelines based upon federal standards to prevent such risk.

Recommended Antitrust Guidelines

1. Private partners may freely conduct activities that do not infringe on intellectual property of other members or intellectual property generated by the Consortium (see section VIII Intellectual Property, data sharing guidelines)
2. No member shall take or seek action relating to Consortium for purposes of excluding products or technology of competitors from the market or impeding research and development
3. Executive Committee must review/approve all public communication and data sharing activities

Restricted Topics

1. Pricing, pricing policies, market shares, services of private partners
2. Intentions about commercial activities, including advertising, promotion, research and development outside the Consortium, or whether to deal with specific customers (including government programs)
3. Speculation or prediction about commercial activities of private partners in response to business or legislative developments
4. Discussion of any topic of commercial significance to competitors that may involve antitrust compliance

VII. Intellectual Property Guidelines

1. Except as authorized or required by law, no participant shall be required, by virtue of their participation in the Consortium, to grant exclusive licenses to any entity
2. Consortium participants, grantees, or contractors will not be forbidden to challenge patents or Intellectual Property of other Consortium participants, grantees or contractors including patents or Intellectual Property arising from the Consortium
3. Clear rules will govern whether, and under what circumstances, participants will be required to disclose the existence of Intellectual Property or patent applications regarding inventions relevant to Consortium activities

4. Any research data, results, or Intellectual Property collected or shared with the Consortium will be covered by written contract with the contributor in conformity with these guidelines

VIII. Data Sharing Guidelines

I. Sharing data from public and private partners is anticipated to expedite the work of the Consortium
II. Confidential scientific data may be shared by Consortium participants, subject to intellectual property, antitrust, data sharing and FDA confidentiality policies and other federal laws
III. Participants should not share data or other confidential information about commercial activities with each other, particularly restricted topics (see antitrust guidelines)
IV. Executive Committee and legal counsel of the participants should be consulted on the appropriateness of:
    a. Data sharing (FDA OCC must approve all activities associated with sponsor-data)
    b. Confidential and commercial information
    c. Subject to foregoing precautions, if unaggregated, confidential, and competitively sensitive information are collected under Consortium activities, such information should never be shared outside the project team and should be destroyed except where subject to federal regulation
V. Any data collection from private participants should include statements that info will be handled in conformity with final guidelines of the Consortium

IX. Funding

Financial operations will be the responsibility of, and managed through Duke in conjunction with the Duke-FDA Memorandum of Understanding to conduct the CSRC Public-Private Partnership.

Funding for CSRC will be derived primarily from membership dues per the Membership Charter. CSRC membership requires annual renewal (based on meeting the requirements and expectations of membership as described above).

Thinktank meetings will be run on a responsible "break even" fiscal plan which may involve registration fees. Any residual from thinktank meetings will be directly re-invested into CSRC activities. CSRC thinktank meetings will not provide honoraria or other personal revenue of any kind to participants. The management of participating faculty registration fees or related expenses will be individually managed by the specific program planning team.

Ad hoc efforts to apply for, receive and manage grants may be reasonably considered by the Executive Committee, with input from any and all relevant CSRC Committees.

Appendix A: Roles and Responsibilities for FDA Federal Liaison

The activities of all FDA representatives to the CSRC will abide by Title18 U.S.C, section 208, of the criminal conflict of interest statute, which prohibits federal employees from participating in an official matter that affects the financial interest of an outside organization in which the employee serves as officer, director or trustee. The Office of Government Ethics has opined a federal employee can violate section 208 by participating in an official matter that affects the financial interest of an outside organization in which the federal employee serves as officer, director or trustee, even where the federal employee serves as an official duty activity. Therefore, section 208 prohibits federal employees from serving in their official capacity as officer, director or trustee of an outside organization, unless one of the following options has been satisfied:

- An employee may be assigned as a "Federal Liaison" to the organization, which would not implicate section 208. As a Federal Liaison to the CSRC, the employee would be the DHHS/FDA representative to the organization, and would present and receive information and views on behalf of the Department and FDA; but would not direct the organizations internal operations, or
- An FDA employee may serve in an official capacity if a federal statute expressly authorizes such service with the organization; or
- An FDA employee may serve in an official capacity if the outside organization releases the individual from all fiduciary obligations. In order for such a release to be effective, it would have to be permitted under applicable state law; or
- An FDA employee may serve in an official capacity if the individual obtains a waiver of the conflict of interest statute under section 208 from the appropriate DHHS official (see link for sample waiver); or
- An FDA employee may serve an organization in a purely private capacity, as an outside activity. An employee who engages in an outside activity as officer, director or trustee of an organization would have to recuse himself from any official matter that affects the financial interest of the organization. The employee would have to avoid any appearance of using his public office for private gain, and proper clearance must be obtained on Form HHS-520, "Request for Approval of Outside Activity."

It is recommended that each component determine whether employees in their FDA Center/Office are serving outside organizations in their official capacity as an officer, director or trustee. If it is determined that an employee is serving an outside organization as part of his official duties, action should be taken on one of the options listed above.

Appendix B: SOC Project Clearance Criteria

A preliminary list of criteria for the clearance of project proposals (prior to project plan development) includes the following:

1. **Collaborative approach:** Are the goal(s) of the project attainable through a partnership clearance within the context of the Consortium?
2. **Scientific importance**: Will the proposed studies/projects promote the understanding of the underlying biology of disease or health?
3. **Clinical importance**: Will proposed studies/projects meet a clinical need to better understand, diagnose or manage potential clinical safety risks, and/or for diagnosis; assessment of disease activity, stage, severity, or outcomes; and/or provide useful information in the conduct of clinical trials?
4. What resources are already available to address the problem and does the project offer a **unique** solution(s)? How does the proposed project fill scientific gaps?
5. **Regulatory importance**: Will biomarker development and/or qualification facilitate drug development and/or approval?
6. **Feasibility**: Is the proposed studies/projects feasible operationally, technically and financially? Does the technical platform permit the accomplishment of the study's aims? Is there a potential for development and commercialization beyond research laboratory applications? What evidence is available that the biomarkers identified are likely to be a measure of pathologic disease?
7. Does the project foster and improve opportunities among industry competitors rather than relating specifically to a particular product in the competitive sphere?
8. Do the partners express a **willingness to share data** (if applicable to the project)?
9. Do the partners express a willingness to share the results of their analyses in the public domain?
10. Have Consortium partners agreed to the **rationale and intent of the project**?
11. Are partners available to **conduct and fund the project**?

Please note that every project is not required to meet all of the criteria outlined above; the weighting of the criteria will be determined by the CSRC Executive and Scientific Oversight Committees.

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The Cardiac Safety Research Consortium (CSRC)

Project Concept Submission Form

1. Submission Date		
2. Submitter name, title, email address, and phone number		
3. Name of Submitting Organization		
4. Name(s) of Other Partner Organization(s), If Applicable	Name of Organization	Organizational Contact
5. Title of Project Concept		
6. Scientific Gap/Public Health Need addressed		
7. Technologies addressed (imaging, molecular, genetic, etc.)		
8. Has the concept received any formal review? If so by whom?		
9. What is the estimated budget for the project?		
10. What is the estimated duration of the project?		

NOTE – ALL TABLES WILL EXPAND TO ACCOMMODATE TEXT AS ADDED.

11. In lay language, state the objective of the project and its relevance to patients. *Your answer should be limited to 50 words.*

12. Briefly describe the proposed project, including any preliminary results and evidence concerning feasibility. Provide up to 5 key literature references. *Your answer should be limited to 500 words (one page) not including references*.

13. How would the project benefit from a partnership under the CSRC? *Your answer should be limited to 150 words.*

14. How will this project promote the understanding of the underlying (patho)biology of disease or health, advance public health and further the mission of the CSRC? *Your answer should be limited to 150 words.*

15. What advantages does the project have with respect to other approaches? How does the proposed project fill scientific gaps and public health needs? *Your answer should be limited to 150 words.*

16. How would this project facilitate medical product development and/or regulatory approval? *Your answer should be limited to 150 words.*

17. Is sufficient technology and data available to carry out this project? Please explain. *Your answer should be limited to 150 words.*

18. What are the prospects for development and commercialization of technologies developed in this project? *Your answer should be limited to 150 words.*

19. Is the project linked to a particular commercial product? *Your answer should be limited to 150 words.*

22. Please identify known and potential funding partners (if possible).

22. If a specific investigator or group is proposed to do the work, please provide CVs.