SCMR Registry Request for Proposal
13 June 2018

Summary:
The Society for Cardiovascular Magnetic Resonance (SCMR) is the principal international, independent organization committed to the further development of cardiovascular magnetic resonance (CMR) through education, quality assurance, research, and training. The mission of SCMR is to improve cardiovascular health by advancing the field of CMR. Over 2,600 SCMR members represent approximately 950 CMR centers worldwide. The SCMR has developed and owns a Registry and database containing de-identified patient data relating CMR results to patient treatment and the practice of medicine. This registry currently contains CMR report data from ~65,000 cardiac MRI studies contributed from 17 international centers. The main goals of this registry are:

1. Promote evidence-based utilization of CMR through a collaborative global effort.
2. Provide a web mechanism for CMR centers to upload de-identified patient data, CMR indications, and images.
3. Provide a mechanism of tracking patient outcomes (death, events).
4. Support data access globally to make registry data available to the wider CMR research community.
5. Support the mission of the SCMR.

With the recent completion of enrollment for the SPINS SCMR Registry Trial with a focus on CMR stress perfusion, an important milestone in the history of the registry has been reached and related findings will be reported later this year. The success of SPINS clearly documents both the current power of this registry, and more importantly the ability of the SCMR to gather top CMR sites to participate in such an endeavor. The SCMR now seeks to identify an industry collaborator to accommodate future growth and to continue harvesting the full potential of the registry consistent with the above goals. With the right collaborator, the SCMR anticipates that hundreds of CMR centers worldwide will seek participation in the Registry for a variety of reasons including: contributing data to prove the benefits of CMR to advance the field, and using the registry as a means to verify to payers that CMR is used appropriately and meets quality standards at their institution. Collection and storage of CMR reports and image data on a larger scale, as well as a more in-depth investigation of CMR findings and their link with outcomes are on the roadmap. This collaboration will encompass public health benefit activities as well as dedicated research activities.

Therefore, this Request for Proposals (RFP) aims to identify a corporate collaborator with the full capability and capacity to provide the necessary services, and a solid track record of experience and success in managing patient and medical image data. Respondents to this RFP should describe their capabilities to provide the support, development, and maintenance of the Registry as necessary, consistent with the five goals listed above. The response should include a description of the manpower and services that can be brought to bear to support the infrastructure development and maintenance of a CMR Registry that could potentially include CMR reports and DICOM image data from hundreds of thousands of cases contributed by hundreds of centers worldwide. This RFP is unusual in that the SCMR does not anticipate paying a fee for this service; rather the SCMR is seeking a commercial collaborator that will derive benefit from the Registry by mechanisms other than direct remuneration for services rendered.

Description of the Current SCMR Registry

SCMR registry currently contains CMR report data from ~65,000 cardiac MRI studies contributed from 17 international centers.

- 10 centers from the United States
- 2 centers from China
- 2 centers from the United Kingdom
- 1 center from South Korea
- 1 center from Spain
- 1 center from South Africa

In general, data elements collected at the time of the CMR study include:

- Patient demographics,
- Detailed cardiac and other medical histories,
- Symptoms and clinical indications to performing CMR study,
- List of medications,
- CMR imaging pulse sequence protocols,
- Basic cardiac measurements of left ventricular structures and function,
- Findings of contrast enhancement of the heart,
- Clinical outcomes including mortality were collected in a minority of the patients.

DICOM images are currently included only with a small fraction of the reports. One of the goals of the SCMR is to greatly expand the inclusion of image data within the registry. Appendix A includes an article that describes in detail the goals and content of the SCMR Registry.

Instructions to Applicants

Proposals should address as many of the following points as possible. This list is not exhaustive and all items may not be relevant to all vendors.

Collaboration

1. Describe the vision of your organization for its collaboration with the SCMR on the development and sustainability of the Registry.
    a. Describe the experience and expertise of your company relevant to the SCMR Registry.
    b. In what ways do you anticipate the Registry will help to advance the field of CMR?
    c. What roles do you envision for your organization and for the SCMR in managing the Registry?
    d. What is the prime motivation for your organization to collaborate with SCMR?
        i. What benefits do you expect your organization to derive from the collaboration?
        ii. How will these benefits differ from those derived by competitive organizations who may also have access to Registry data?
    e. How do you anticipate your company will make it attractive for sites to participate in the Registry? For example, will CMR reporting tools be provided to registry participants? Will data access be easier for registry participants?

Financial sustainability

1. The registry must be sustainable and financially self-sufficient. The SCMR estimates the following annual personnel costs are necessary to sustain and grow the registry:
    a. Part-time PI salary support
        i. Scientific oversight
        ii. Fundraising
        Est. $250,000 salary, 30% benefits, 20% effort
        $65,000 estimated annual cost
    b. Full-time, permanent manager
        i. Database skills
        ii. Harmonize data from different software reporting tools
        iii. Connect with sites to train and troubleshoot
        iv. Create and update training materials
        v. Assist with registry trials
        Est. $80,000 salary, 30% benefits, 100% effort
        $104,000 estimated annual cost
    c. Statistical Analysis support (part-time)
        i. Statistical data analysis support
        ii. Assist with registry research studies
        Est. $80,000 salary, 30% benefits, 50% effort
        $52,000 estimated annual cost
    d. SCMR HQ support
        i. Contracts
        ii. Fundraising
        iii. Bookkeeping
        iv. CEO + support staff
        v. Legal fees
        $25,000 estimated annual costs

    Total approximate annual personnel costs: $246,000

    The respondent should outline a plan for the financial sustainability of the Registry.
    e. What financial resources do you estimate are required to sustain the Registry?
        i. Infrastructure costs
        ii. Personnel costs
        iii. Data collection costs (clinical, image, follow-up).
    f. What sources of revenue, internal and external to the respondent organization, do you propose to utilize to cover the costs of the Registry? Revenue could be derived, for example, by monetizing the registry data or charging a participation fee.
    g. Beyond mere sustainability, financial support of registry-based research is desirable. Explain how your company can facilitate and financially support registry-based research projects designed to prove the value of CMR.

Data Ownership and accessibility

1. Currently, SCMR retains ownership of all data. The respondent should outline their plans for honoring SCMR ownership of the data and for maintaining data security and patient privacy, while making the data accessible to researchers from both academic and commercial organizations.
    a. Describe the technical infrastructure that you would provide to meet these requirements, including details regarding image and report de-identification, tracking outcomes, and data security.

    b. Demonstrate an understanding of the global regulations on data ownership and privacy by including scenarios in which data ownership is retained by the participating centers or patients.
    c. Describe the personnel support provided to meet these requirements.
2. Appendix B includes the legal agreement signed by sites currently participating in the SCMR Registry. It is anticipated that a similar agreement would be used going forward, although not necessarily identical.
3. The winning bidder will be required to execute a legal agreement mutually agreeable to both parties that would detail the parties' duties, intellectual property rights, term and termination provisions, confidentiality, indemnification, and several other pertinent issues. Bidders may propose suggested contract terms.

Reporting: The respondent should describe their strategies to meet the following criteria.

1. Ability to provide a summary of quality of services for each site,
2. Provide detailed and graphic reports in a standardized format for comparing quality,
3. Enable examination of specific areas of improvement,
4. Provide customizable reports of site CMR utilization patterns,
5. Provide the ability for each site to track their own individual patients, including longitudinal follow-ups. This will require a mechanism to link the de-identified registry data back to the specific patient at the site for follow-up,
6. Provide the ability to measure the impact of changes in practice,
7. Provide the ability to implement a data-driven quality improvement program,
8. Enable researchers to access data for approved research projects.

Database: The respondent should describe their strategies to meet the following criteria.

1. Secure authentication with access privileges based on user need.
    a. Password protection.
    b. Individual site control of user privileges.
    c. Different roles for different users (Guest, Administrator, Clerical).
2. Automated de-identification at contributing site.
    a. HIPAA and international privacy law (EU General Data Protection Regulation) compliance.
    b. Client side encryption.
3. Vendor-neutral upload of results.
4. Automated follow-up of events (mortality, etc.) wherever possible.
5. Ability to store images (DICOM, vendor neutral).
    a. DICOM node support.
6. Web access or client access on variety of systems (Mac, Windows, browsers)
7. Backup and disaster recovery plans (no cost to SCMR or users for disaster recovery).
    a. E.g. upstream provider's SLA, redundancy, failover.
8. Optimized searching mechanisms and generation of reports.
9. Robust and simple data upload and download mechanisms/interface.
10. Support of access for artificial intelligence algorithm training.
11. Guaranteed server up time.
12. Maintenance and updates over time (system and antivirus).

Technical: The respondent should describe their strategies for compliance with security and privacy requirements:

1. Privacy law compliance (USA and international).
2. Unicode support.
3. Independent security assessment report.
4. Appropriate security controls.
5. Industry standards used in security and software development.
6. Authentication mechanism.
7. Remote access VPN and authentication.

Best Practice Software Development: The respondent should describe their software development and quality control processes, including the following:

1. Software development lifecycle (e.g., IEC 62304),
2. Change control process,
3. Testing and release process,
4. Certifications: ISO, FDA, CE mark,
5. Hazard analysis.

Term of the project: While the expectation is that the SCMR Registry will be sustainable for the foreseeable future, it is anticipated that the term of this collaboration will be for five years, renewable by mutual agreement. The registry infrastructure must be developed in such a way that it is reasonably feasible and affordable to transfer the data to another system should the collaboration end.

Anticipated RFP Response Timeline:

RFP issue date	13 June 2018
Letter of intent deadline	27 June 2018
Information TCON	2 July 2018
Written questions accepted	28 June - 20 Aug
Proposal submission deadline	24 Aug 2018
Three finalists announced	7 Sept 2018
Finalist interviews	20 - 21 Sept
Decision announced	28 Sept 2018

This timetable may be subject to change at the discretion of SCMR. All respondents will be notified of any changes to the timetable by the SCMR authorised representative.

All information must be submitted by email to the SCMR authorised representative (HQ@SCMR.org).

All proposals and all information contained therein will be treated as confidential by the SCMR. Only the Review Committee members will be allowed to view the proposals or have knowledge of the information contained within.

All potential members of the review committee will be screened for conflicts of interest before they have access to proposals or any confidential information. No one employed by or owning an equity interest in a respondent company, or in any potential competitor of any respondent company, will be permitted to serve on the review committee.

Letter of intent (Deadline 27 June 2018)

A letter (email to HQ@SCMR.org) from your company representative to the SCMR indicating your interest in responding to the RFP must be received by 11:59pm on 27 June 2018 to qualify your

company to participate in the Information TCON and to submit a response. The letter (email is sufficient) needs only to express your company's interest in potentially responding to the RFP and is not binding in any way.

Information TCON (2 July 2018, 12 noon EDT)
This TCON will provide a forum for the SCMR to present the motivation for the RFP and expectations of a commercial collaborator in the SCMR Registry. Questions from the participants will be fielded and the questions and answers posted on the RFP website. Questions submitted in writing prior to the TCON will also be addressed. Participants may be required to execute a non-disclosure agreement prior to the TCON.

Open question period (28 June to 20 August 2018)
Those companies which have submitted letters of intent will be allowed to submit written questions to the SCMR (HQ@SCMR.org). The written questions and answers will be posted on the Registry RFP website for all respondents to view.

Written proposals (Deadline 24 August 2018)
Proposals will be accepted via email (HQ@SCMR.org) up until 11:59PM on 24 August 2018. SCMR reserves the right to receive and consider a late response to this RFP. However, as a general rule, any response received after closing time will not be considered.

Proposals must include the following items and meet the following page limits:

- Executive Summary. **1 page limit**.
- Written response to the six categories listed above. **6 total page limit**; page allocation per section is left up to the applicant.
- Appendix including relevant information about the company (history, organizational structure, size, business performance, etc.). **3 page limit**.
- Minimum one-half inch margins on all sides; Arial 11 point font (or larger).

Page limits will be strictly enforced. Any pages exceeding these limits will be discarded before the proposals are forwarded to the review committee.

Written Proposal Evaluation (25 August – 6 September 2018)

- Written proposals will be scored by a review committee appointed by the SCMR Executive Committee.
    - Each committee member will score every proposal.
    - Applications will be scored based on the following point system:
        - Collaboration 150 points
        - Financial Sustainability 75 points
        - Data ownership & accessibility 50 points
        - Technical 50 points
        - Reporting 25 points
        - Database 25 points
        - Best Practice Development 25 points
        - **Total possible** **400 points**
    - Evaluation of proposals also will take into account the quality of services proposed; the proven reliability of the bidder to produce high quality work product; references documenting outstanding customer service; responsiveness and professionalism of the proposer; and the ability to meet the criteria and objectives as outlined in this RPF.

- Summary scores will be provided to all applications after completion of the entire review process and selection of the final awardee.
- Three finalists will be selected based on written proposals and announced on 7 September 2018.

Oral presentation and Q&A (20 - 21 September 2018)

- The three finalists will be invited to give a 15 minute oral presentation of their proposal followed by up to 30 minutes of questioning by the review committee via teleconference.

Final decision announcement (28 September 2018)

- A single winning proposal will be selected by the committee and recommended to the SCMR Board of Trustees for approval.
- All finalists will be notified of the outcome on 28 September 2018.

All communication between a respondent and SCMR will be conducted in writing (including electronic) through the SCMR authorised representative, apart from the TCON and interviews. The authorised representative is the only person authorised to make representations or offer explanations about this RFP.

This RFP is not an offer to contract. All proposals become the sole property of SCMR and will not be returned. Any costs incurred by bidders in the preparation, presentation, demonstration, or any other aspect in the process of proposal, evaluation, and contract negotiation is the responsibility of the bidder. Notwithstanding anything in this RFP to the contrary, we reserve the right to reject any and all proposals received for any reason.

All questions from respondents relating to this RFP should be emailed to the SCMR contact (HQ@SCMR.org). Questions from respondents and subsequent replies will be copied to all parties who have submitted a letter of intent. This process will also be used to communicate any errors and omissions identified and any new information obtained.

APPENDIX A: JCMR 2017 article describing the SCMR Registry
Journal of Cardiovascular Magnetic Resonance 2017 19:23

APPENDIX B: Current Registry template site agreement

THE SOCIETY FOR CARDIOVASCULAR MAGNETIC RESONANCE REGISTRY
PARTICIPATION AGREEMENT

THIS AGREEMENT is entered into and made effective the ___ day of _____, 2017 ("Effective Date"), by and between (a) the Society for Cardiovascular Magnetic Resonance (SCMR) and b) _____, "Participant").

WHEREAS, SCMR (with the assistance of a third party contractor) has developed and owns certain computerized databases containing information relating to patient treatment, the practice of medicine, and third party patient data submitted to these databases pursuant to rules developed by SCMR and its Global Cardiovascular Magnetic Resonance Registry (GCMR) Steering Committee (said databases collectively referred to herein as the "the Registry" and said Steering Committee referred to herein as the "SC"); and

WHEREAS, Participant has expressed an interest in participating in the Registry in accordance with this Agreement and SC requirements;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants contained herein, and for other good and valuable consideration, the parties hereto agree as follows:

1. Participation in the GCMR Registry.

1.1 Participant will participate in the data collection conducted by the Registry by submitting Participant's data to the SCMR through the web-based portal, and otherwise complying with the rules and collection schedules reasonably established by SCMR in connection therewith. Participant shall provide SCMR or its SC with only De-identified Data in accordance with its obligations under HIPAA. Participant may hold the key to re-identify any such De-identified Data in accordance with applicable law, including 45 C.F.R. §164.514(c).

1.1.1 Participant hereby states that to the best of its knowledge, all data submitted for inclusion in the Registry will be accurate and complete. Participant will use reasonable efforts to address any data or related deficiencies identified by SCMR or its SC. Upon request from the SC, Participant agrees to provide de-identified data at reasonable periods and subsequently on a regular interval requested by the SC (expected to be approximately every 6 months). SCMR will work with its third party contractor to convert the Partipant's data to the data format of GCMR. Participant agrees to inform the SC with any change to its data format.

1.1.2 Participant further promises to take all reasonable steps to avoid the submission of duplicative data for inclusion in the Registry, and agrees to assist and cooperate with SCMR in its efforts to conduct the Registry.

1.1.3 Participant shall be responsible for the negligent acts and omissions of its employees and agents in submitting data to the Registry.

1.1.4. Participant understands that SCMR provides the Registry "as is" and makes no warranties regarding the Registry, either express or implied, including no warranty of merchantibility or fitness for a particular purpose.

1.2 Participant agrees and acknowledges that its failure to submit data to the Registry, or its submission of data to the Registry that does not comply with SCMR requirements, may result in

Participant's failure to receive reports (if any) generated by the Registry and may result in Participant and its employees being excluded from access to the Registry for research purposes.

1.3 Participant agrees and represents that the data it submits to the Registry will be de-identified and shall not include protected health information ("**PHI**"). Participant agrees that it is Participant's responsibility to obtain any permissions from its institutional review board ("**IRB**") or other relevant regulators that may be required in order to submit such data for inclusion in the Registry

2. Participant Ad Hoc Queries. Participant may submit to the SC for analysis such requests for ad hoc queries (requiring access to and analysis of aggregate data from the Registry) as Participant may desire. All such requests for ad hoc queries shall be subject to prior approval by the SC, in accordance with such procedures and other requirements as it may reasonably establish, before efforts are undertaken to respond thereto. In its response to each of Participant's ad hoc queries, the SC shall give due consideration to scientific merit, the funds and other resources available to address ad hoc queries, qualifications of the participant to address the specific scientific question, and other pertinent factors.

3. Registry Funding. Participant acknowledges that SCMR and the SC may from time to time seek sponsorships or other forms of commercial funding to help sustain the Registry, which funding opportunities may include allowing commercial access to de-identified Registry data submitted by all participants.

4. Compliance with Laws. The parties hereby agree to comply with all applicable statutes and regulations, under federal and state laws, including but not limited to the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and any other applicable statutes or regulations concerning patient privacy and data security.

5. Intellectual Property; Benefits to Participants.

5.1 It is agreed and acknowledged that all data submitted for inclusion in the Registry by or on behalf of Participant are and shall remain Participant's proprietary information, but with a perpetual royalty-free license to SCMR to use and allow the SC and other third party researchers approved by the SC to use the data for research purposes.

5.2. Participants will receive the following benefits from submitting data to the Registry:

a. Each Participant will be informed in writing by the SC of any research project that will involve usage of that particular Participant's data and that has been approved by the SC.

b. Such notified Participants will then have the option, and on terms mutually agreeable to the parties, to a level of participation, recognition and/or authorship after due consideration by the SC of the scientific merits, potential authorships, time and effort provided to the research, available funding in support of the project, and such other factors as may be determined by the SC from time to time.

5.3 Participant acknowledges that SCMR is and shall be deemed the owner of all rights to the Registry (including the aggregate data contained therein and subsets thereof), and all trademarks associated with SCMR or the Registry (including, without limitation, "SCMR", "Society for Cardiovascular Magnetic Resonance", and the "GCMR Registry" and all variations thereon and

graphic representations thereof), (collectively, "SCMR Intellectual Property") with the exception of Participant's data.

5.4 Neither party shall use the name, trademark, or logo of the other party or its employees for promotional purposes without prior written consent of the other party.

6. Limitation of Liability. Each party to this Agreement agrees that it will be responsible for its own acts and omissions and the results thereof; and, shall not be responsible for the acts and omissions of the other party and the results thereof. Each party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees under this Agreement. Under no circumstances will either party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

7. Term and Termination.

7.1 Subject to the terms of Section 7.2 and 7.3, this Agreement shall be effective for a period of one year and shall be automatically renewed on an annual basis thereafter unless any party provides the other(s) with a written notice of termination at least 30 days prior to the expiration of any term.

7.2 This Agreement may be terminated upon any party's material breach of this Agreement, provided, however, that if said breach is cured to the non-breaching party's satisfaction within thirty (30) days after the provision of such notice, said termination notice shall of no further force or effect and this Agreement shall be fully reinstated.

7.3 Additionally, this Agreement may be terminated by either party without cause upon thirty (30) days written notice to the other Party.

7.4. Upon termination of this Agreement, Participant shall have the option of asking that its data in the Registry be removed at the later of the date of termination or the conclusion of any pending research projects using the data.

8. Equitable Relief. The parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this Agreement, and that each party shall be entitled to seek emergency injunctive relief as a remedy for any such breach by any other party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this Agreement, but shall be in addition to all other remedies at law or in equity to the non-breaching party.

9. Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors, and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.

10. Notices. All notices and demands of any kind or nature which any party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States mail, by facsimile transmission, by overnight courier or by electronic mail to the following addressees:

If to Participant: _____

_____

_____

_____

Email:_____

(fax #) _____

Attn:_____

If to SCMR:

Society for Cardiovascular Magnetic Resonance
19 Mantua Rd
Mt. Royal, NJ 08061
Email: hq@scmr.org
(fax #) 856-423-3420
Attn: Pete Pomilio

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any party hereto may, from time to time, by notice in writing served upon the other party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

11. Assignment. This Agreement may not be assigned by either party without the prior express written approval of the other party.

12. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument. Electronic signatures shall have the same effect as originals.

13. Waiver. A waiver by any party to this Agreement of any of its terms or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.

14. Severability. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

15. Entire Agreement. This Agreement (a) constitutes the entire agreement between the parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the party against whom enforcement is sought.

17. Confidentiality. SCMR acknowledges that, in the course of providing services to Participant and/or in the course of Participant utililizng Registry, that SCMR may become aware of or come into possession of certain Confidential Information. "Confidential Information" means all written and oral information, documents and data previously or hereafter obtained by SCMR from Participant in connection with this Agreement, including negotiated contract rates, technical data, programs, marketing plans, operating procedures and confidential medical information. SCMR agrees to hold all Confidential Information in confidence and, at the expiration or termination of this Agreement, return and/or destroy all Confidential Information as specified by Participant. This provision shall survive the termination or expiration of this Agreement.

Participant acknowledges that, in the course of providing services to SCMR and/or in the course of SCMR utililizng Registry, that Participant may become aware of or come into possession of certain Confidential Information. "Confidential Information" means all written and oral information, documents and data previously or hereafter obtained by Participant from SCMR in connection with this Agreement, including negotiated contract rates, technical data, programs, marketing plans, operating procedures and confidential medical information. Participant agrees to hold all Confidential Information in confidence and, at the expiration or termination of this Agreement, return and/or destroy all Confidential Information as specified by SCMR. This provision shall survive the termination or expiration of this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement, as of the Effective Date first written above.

SOCIETY FOR CARDIOVASCULAR MAGNETIC RESONANCE	PARTICIPANT
By:_____	By:_____
Its:_____	Its:_____
Date:_____	Date: _____