

**SCMR**

*Society for Cardiovascular  
Magnetic Resonance*

# **SCMR Registry RFP**

**July 2, 2018**

# SCMR Mission, Vision, and Strategic Goals

- **Vision**

- The expanded recognition and utilization of CMR will improve cardiovascular health and outcomes.

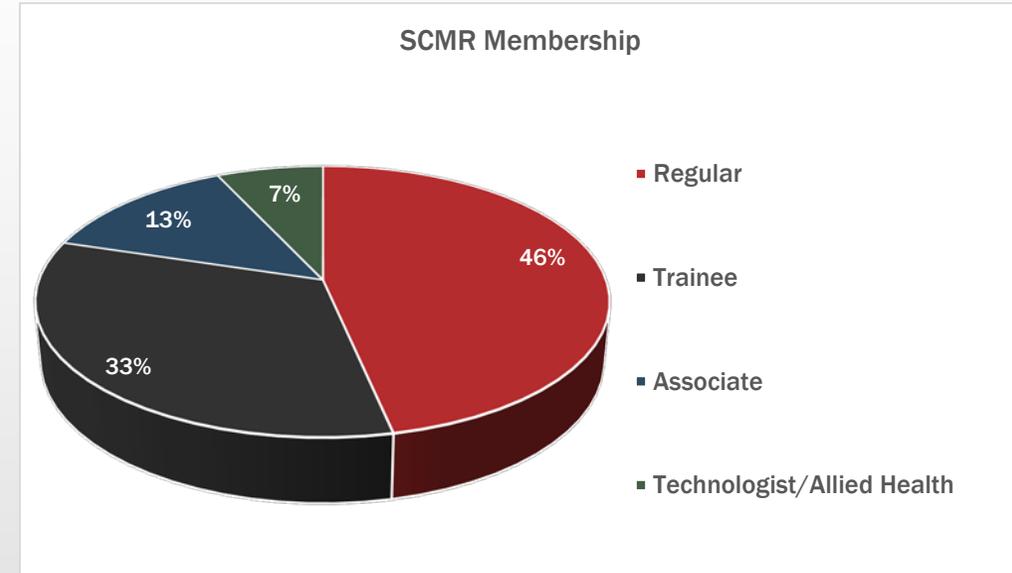
- **Mission**

- To improve cardiovascular health by advancing the field of CMR.

- **Strategic Goals**

1. Increase the Visibility and Acceptance of CMR.
2. Secure and maintain adequate reimbursement.
3. Provide a platform to maintain and expand CMR research that generates evidence for greater clinical effectiveness, cost effectiveness, and value.
4. Increase availability of education for CMR practitioners and referring physicians.
5. Standardization of acquisition, analysis, and reporting.

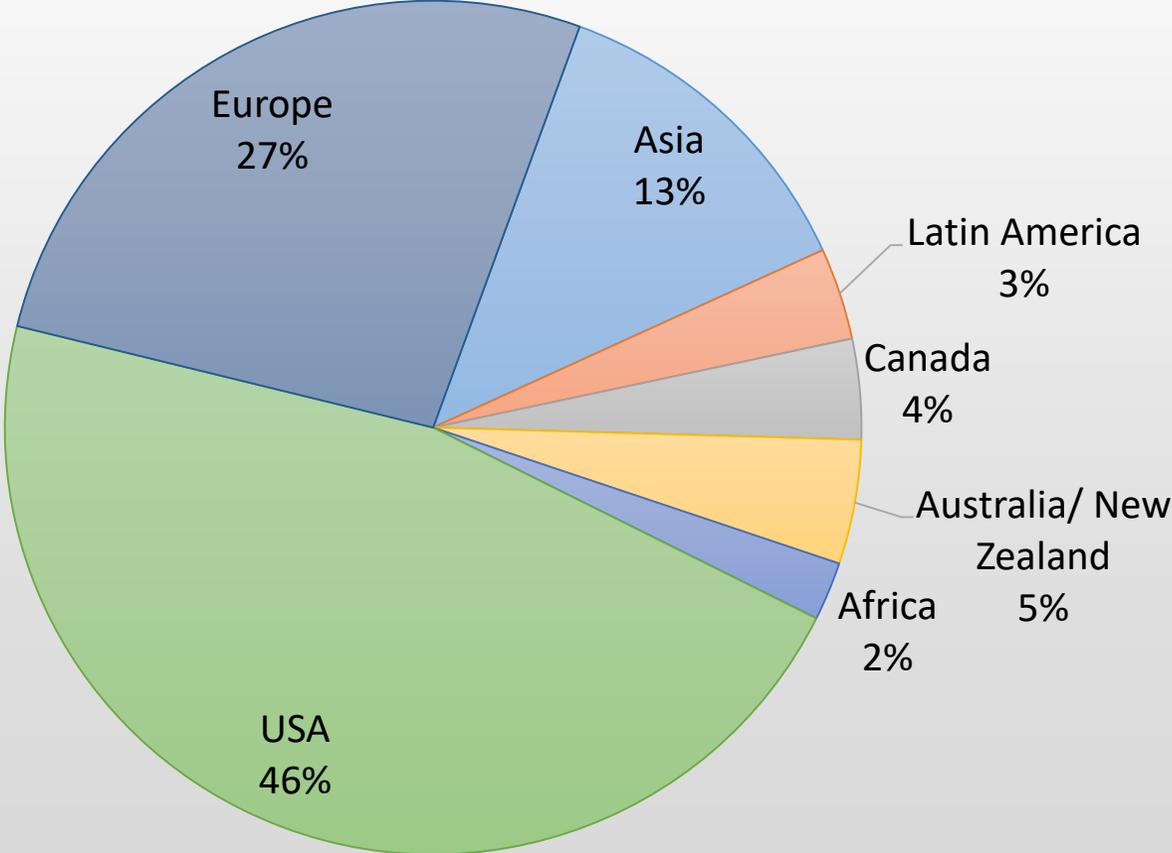
# SCMR Membership



- **2600 members**
- **>1400 conference attendees 2017 Washington, D.C.**
  - Largest US meeting ever
- **> 1900 attendees 2018 Joint EuroCMR/SCMR Barcelona**
  - Record attendance for a CMR conference

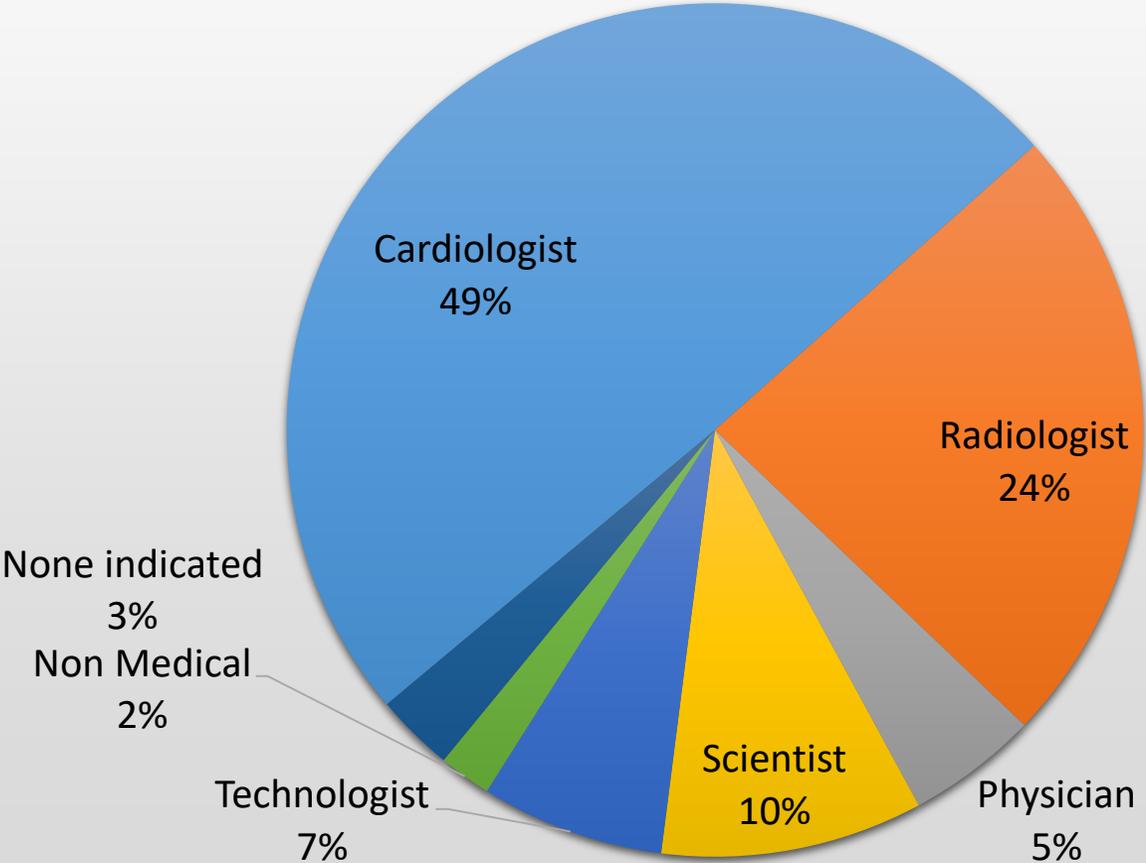
# SCMR Membership Geographic Breakdown

## Global Membership



# SCMR Membership by Specialty

## Primary Specialty



# SCMR Governance

## ▪ Executive Committee

- |                          |                        |                          |
|--------------------------|------------------------|--------------------------|
| ▪ Matthias Stuber, PhD   | Physicist              | President                |
| ▪ Andrew Powell, MD      | Pediatric Cardiologist | Vice President           |
| ▪ James Carr, MD         | Radiologist            | Treasurer                |
| ▪ Subha V. Raman, MD     | Cardiologist           | Vice Secretary-Treasurer |
| ▪ Matthias Friedrich, MD | Cardiologist           | Immediate Past Pres.     |

## ▪ Board of Trustees

- 12 elected members on 3-year rotation
- Cardiologists, radiologists, physicists, technologists from around the world
- Full board roster here: <http://scmr.org/?page=BoardTrustees>

# SCMR Staff

- **Chief Executive Officer**
  - Lon Simonetti, PhD                      employed by the SCMR
- **Chief Operating Officer**
  - Pete Pomolio, MBA
- **SCMR HQ Staff**
  - Ashley Duffy                      Conference and Events Manager
  - Shaunna Lee                      Programs Manager
  - Lisa Colangelo                      Membership Services
- **Additional HQ support**
  - HR, Accounting, Legal

# SCMR Standing Committees

- **Advocacy**
- **Annual Scientific Program**
- **Certification**
- **Clinical Practice**
- **Clinical Trials**
- **Communication**
- **Education**
- **Finance**
- **Global SCMR Registry**
- **International Outreach**
- **Membership**
- **Publications**
- **Public Relations**
- **Science**
- **Translations**

Committee chairs and rosters listed here: <http://scmr.org/?page=SCMRCommittees>

# SCMR Sections, Working Groups, Interest Groups

- **Sections**
  - Early Career
  - Pediatric and Congenital
  - Technologists
  - Women in CMR
- **Special Interest Groups**
  - Cardio-Oncology
  - Diffusion CMR
  - Interventional CMR
  - Parameter Mapping
  - Valvular Disease
- **Regional Working Groups**
  - Canada
  - China
  - Japan
  - Latin America
  - USA



# SCMR Registry



- **Why did the SCMR create a registry?**
  - Promote evidence-based utilization of CMR through global collaboration and impactful research.
    - Provide a web mechanism for CMR centers to upload de-identified patient data, CMR indications, and images.
    - Provide a mechanism of tracking patient outcomes (death, events).
    - Verify to payers that CMR is used appropriately and meets quality standards.
    - Support global availability of data to the wider CMR research community.

# SCMR Registry

- **21 Participating Centers**

- San Antonio Military
- Utah Revere Clinic
- Radiology Associates of Florida
- Brigham and Women's Hospital
- National Institutes of Health
- Cleveland Clinic
- Seoul St. Mary's Hospital
- Guangdong General Hospital
- Oregon Health Sciences University
- Royal Brompton Hospital

**Total CMR reports: ~65,000**

- Hospital San Pedro, Spain
- Oklahoma Heart Institute
- Oxford, England
- The Ohio State University
- University of Auckland
- Iowa Heart Center
- West China Hospital
- Capetown, South Africa
- St. Francis, Long Island
- Campinas, Sao Paulo
- Jankharia Imaging Center, Mumbai

**CMRLOOP web-based database developed by Dr. Raymond Kwong serves as the backbone of the existing SCMR registry.**

# SCMR Registry SPINS Trial

Retrospective, industry-supported, registry-based study led by Dr. Raymond Kwong to assess the impact of stress CMR perfusion guided therapy on 4-year patient outcomes in a multi-center cohort of 2,200 patients referred for assessment of myocardial ischemia in the USA.

- **Participating centers (USA only)**

- San Antonio Military
- Utah Revere Health
- University of Chicago
- Brigham and Women's Hospital
- National Institutes of Health
- University of Kentucky
- New York Presbyterian
- The Ohio State University
- Houston Methodist
- Sharon Regional, PA
- University of Minnesota
- University of Illinois Chicago
- San Diego Scripps Clinic

- 2,200 patient enrollment and 4-year follow-up recently completed *on schedule*.
- Initial results accepted for presentation in Late-Breaking Clinical Trials session at ESC 2018
- Manuscripts in preparation to be submitted this year.

# SCMR Registry RFP

- The SCMR seeks to identify an industry collaborator to accommodate future growth and to continue harvesting the full potential of the Registry.
- Collection and storage of CMR reports and image data on a larger scale of potentially hundreds of thousands of reports and image datasets from hundreds of centers around the globe.
  - SCMR members represent over 900 CMR centers worldwide.
- A robust system to support in-depth investigation of CMR findings and their link with outcomes and downstream costs.
- A system to support machine learning development based on real-world image and report data and patient outcomes.

# SCMR Registry RFP

- This RFP is unusual in that the SCMR does not anticipate paying a fee for this service.
- The SCMR is seeking a commercial collaborator that will derive benefit from the Registry by mechanisms other than direct remuneration for services rendered.
- **Proposals from multi-company consortiums are acceptable.**
  - **Companies that did not submit LOI are permitted to join a consortium led by a company that did submit an LOI.**
  - **The SCMR must be notified in writing by Friday 20 July if any company that did not submit a LOI will be participating in a consortium.**

# SCMR Registry RFP Categories



- **Collaboration (150 points)**
  - Your vision for the SCMR-Company Collaboration.
  - Your company's motivation to collaborate with SCMR on this project.
  - The roles you envision for your company and the SCMR in managing the Registry.
  - Your strategy to make it attractive for sites to participate.

# SCMR Registry RFP Categories



- **Financial Sustainability (75 points)**
  - The SCMR estimates annual personnel costs of approximately \$250,000 to support and grow the Registry
    - PI (20%), manager (100%), Stats (50%), admin (25%).
  - What financial resources do you estimate are required?
  - What sources of revenue do you propose to cover costs?
  - How can your company facilitate and financially support registry-based research?

# SCMR Registry RFP Categories



- **Data ownership and accessibility (50 points)**

- Your plan 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.
  - 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.
  - 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.
  - **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.**

# SCMR Registry RFP Categories



- **Technical (50 points)**

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

- Privacy law compliance (USA and international).
- Unicode support.
- Independent security assessment report.
- Appropriate security controls.
- Industry standards used in security and software development.
- Authentication mechanism.
- Remote access VPN and authentication.

# SCMR Registry RFP Categories



- **Reporting (25 points)**

- Ability to provide a summary of quality of services for each site,
- Provide detailed and graphic reports in a standardized format for comparing quality,
- Enable examination of specific areas of improvement,
- Provide customizable reports of site CMR utilization patterns,
- 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,
- Provide the ability to measure the impact of changes in practice,
- Provide the ability to implement a data-driven quality improvement program,
- Enable researchers to access data for approved research projects.

# SCMR Registry RFP Categories



- **Database (25 points)**

- Secure authentication with access privileges based on user need.
- Automated de-identification at contributing site.
- Vendor-neutral upload of results.
- Automated follow-up of events (mortality, etc.) wherever possible.
- Ability to store images (DICOM, vendor neutral).
- Web access or client access on variety of systems (Mac, Windows, browsers)
- Backup and disaster recovery plans (no cost to SCMR or users for disaster recovery).
- Optimized searching mechanisms and generation of reports.
- Robust and simple data upload and download mechanisms/interface.
- Support of access for artificial intelligence algorithm training.
- Guaranteed server up time.
- Maintenance and updates over time (system and antivirus).

# SCMR Registry RFP Categories



- **Best Practice Development (25 points)**

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

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

# SCMR Registry RFP



**SCMR**

Society for Cardiovascular  
Magnetic Resonance

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

# SCMR Registry RFP



- **Participants will be required to execute a mutual non-disclosure agreement with the SCMR.**
  - Agreement will be distributed today to those on the call.
  - Signed agreement must be received prior to proposal submission.
  
- **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.

# SCMR Registry RFP



- **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 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.**
    - **Supplemental Materials**
      - **May include only copies of existing related materials such as letters from customers and copies of company SOPs in support of items requested by the RFP. No 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.

# SCMR Registry RFP



- **Written Proposal Evaluation (25 August – 6 September 2018)**
  - Written proposals will be scored by a review committee appointed by the SCMR Executive Committee.
  - **Committee members will be strictly screened for Conflicts of Interest**
    - **No personal consulting agreements, equity ownership, employment, or any other forms of direct compensation will be allowed. This includes companies submitting proposals, as well as companies in related fields.**
  - 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

# SCMR Registry RFP



- 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;
  - 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)**
  - Up to 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.

# SCMR Registry RFP



- **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.
  
- Legal terms will be negotiated between the winning company/consortium and the SCMR.
  
- 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.