



# LAAO Registry<sup>™</sup>

## Frequently Asked Questions

### 1. What is the LAAO Registry<sup>™</sup>?

The LAAO (Left Atrial Appendage Occlusion) Registry is designed to assess the prevalence, demographics, management and outcomes of patients undergoing percutaneous and epicardial based left atrial appendage occlusion procedures to reduce the risk of stroke. Patient-level data will be submitted by participating hospitals on a quarterly basis to the American College of Cardiology's National Cardiovascular Data Registry (NCDR).

The primary goals of the LAAO Registry are to optimize the outcomes and management of patients through the implementation of evidence-based guideline recommendations in clinical practice, facilitate efforts to improve the quality and safety for patients undergoing percutaneous and epicardial based left atrial appendage procedures, investigate novel quality improvement methods and provide risk-adjusted assessments of patients for comparison with nationwide NCDR data. The secondary purpose of the LAAO Registry is to serve as a rich source of clinical data to support assessments of short- and long-term safety, comparative and cost effectiveness research, and as a scalable data infrastructure for post market studies.

### 2. Why the need for an LAAO Registry?

As new technologies develop, there is a need to understand the selection of patients and longitudinal outcomes for these procedures in contemporary clinical practice. A national registry will support the collection and analysis of data for patients with non-valvular atrial fibrillation (AFib) undergoing these therapies as new treatment options become available. The registry can serve to assist institutions in assessing the quality of care delivered for quality improvement/assurance purposes. Surveillance of device performance, monitoring of long-term outcomes, and comparative and cost effectiveness research are some of the proposed secondary uses of the registry.

The LAAO Registry is considered an observational registry which can quickly accumulate large amounts of data on real-world practice and effectiveness of new left atrial appendage occlusion procedures. Physicians and hospitals can use these data to support quality improvement efforts locally, monitor patterns of care, and assess procedure utilization and variability. Registry data will be used to help develop clinical guidelines leading to improved patient care. Ultimately, the registry will provide a better understanding of this population and emerging treatment options.

### 3. What will I receive in return for joining the LAAO Registry?

Participants will receive quarterly outcome reports providing:

- Executive summary benchmarked metrics
- Institutional performance in a rolling 4 quarter summary
- National aggregate data

An online dashboard will allow patient level metric drilldowns. Participants will also have access to a repository of their own data. The online tool will allow participants to evaluate their local practice and conduct user-specified queries of local data.

Once adequate data have been gathered, there will be opportunities to use LAAO Registry information to conduct formal research projects. A process will be available so that interested centers can present research proposals to a committee for consideration.

**4. Will participating in the LAAO Registry meet the registry requirement for Medicare coverage?**

On February 8, 2016, the Centers for Medicare and Medicaid Services (CMS) issued the final decision memo that supports a national coverage determination (NCD) for Medicare patients undergoing percutaneous left atrial appendage closure. [View the coverage decision memo on CMS.gov.](#)

The American College of Cardiology is pleased to announce the Centers for Medicare and Medicaid Services (CMS) has identified the LAAO Registry™ as an approved registry to meet the requirements of the national coverage determination (NCD) for Medicare patients undergoing percutaneous left atrial appendage closure.

CMS's registry approval is posted on the CMS website. [View Coverage with Evidence Development webpage on CMS.gov.](#)

**5. If my hospital is not yet enrolled in the LAAO Registry, how should my hospital capture the essential data fields for the left atrial appendage closure procedures that are included in the registry?**

Hospitals are encouraged to enroll in the LAAO Registry by contacting NCDR at [ncdr@acc.org](mailto:ncdr@acc.org) or 800-257-4737. If the hospital chooses to delay enrolling until after CMS has certified the registry, it's beneficial for hospitals to download the data collection form and ensure they are capturing all the data needed so they can easily enter the information once they enroll. [Click here to access the LAAO Registry data collection form.](#) Once the hospital is enrolled and actively ready to enter and submit data, the hospital will be able to retrospectively enter and submit cases.

**6. Where can I find more information about the LAAO Registry?**

Information about the LAAO Registry can be found at [ACC.org/LAAORegistry](http://ACC.org/LAAORegistry). There are several public web pages that provide information about the registry, data collection, and resources for how to join the registry. There is additional content on password protected web pages that can be accessed once you are an LAAO Registry participant.

**7. How do I join the LAAO Registry?**

Visit [ACC.org/LAAORegistry](http://ACC.org/LAAORegistry) and complete the Contact Form on the "Request for Information" web page to access the enrollment packet. The enrollment packet includes all the materials you need to enroll in the registry.

**8. How much does it cost to join the LAAO Registry?**

The fee to participate in the LAAO Registry is \$15,000. The fee is paid on an annual basis and is not prorated. The annual fee is based on expenses required to develop and operate the LAAO Registry. The NCDR has developed the LAAO Registry to provide a world-class product that will serve as the critical tool ensuring a rational dispersion of left atrial appendage occlusion technology within the U.S. It will provide an invaluable service to participants, FDA, CMS, and most importantly, our patients.

Considerable time, effort, and expense have been invested to create the registry. Experience with national databases has shown that maintaining a registry like the LAAO Registry will continue to

require significant resources in future years. Below are additional considerations that are factored into determining the LAAO Registry fee structure:

- Similar to the STS/ACC TVT Registry, the LAAO Registry represents the next generation of registries and will provide in-hospital adverse event adjudication as well as long-term follow-up out through 2 years, including activities of daily living, adverse event reporting and adverse event adjudication.
- Participants will receive information not otherwise available, such as risk-adjusted benchmarks and reports showing how local outcomes compare to national benchmarks. In the future, participants will be able to see international comparisons, and have the ability to conduct local analyses using their local data.
- An extensive registry support structure is available to provide prompt assistance.
- The total number of sites performing left atrial appendage occlusions procedures is far fewer than other national registries, where costs to operate the registry can be spread across many more hospitals.
- It is anticipated, given the nature of new commercial LAAO technologies, the LAAO Registry will require more frequent updates. These updates require additional resources throughout the year compared to traditional registries that are not tied to CMS reimbursement, include patient follow-up, or event adjudication.

**9. Is my hospital eligible to be an LAAO Registry participant?**

All hospitals are eligible to join the registry. Device-specific clinical training may be required by a device manufacturer prior to utilizing a specific device. This clinical training is separate from the LAAO Registry training on data collection and submission.

**10. Does my facility need proof of clinical training prior to joining the LAAO Registry?**

The registry does not require proof of clinical training prior to joining the LAAO Registry. A facility may join at any time by completing and returning the contract and payment for the registry.

**11. Will individual participants be able to query their own data?**

Yes, the LAAO Registry offers a feature to download a copy of your data into an Excel spreadsheet. This feature is accessed via the private, password protected section on the NCDR website.

**12. Why are there so many data elements and do all of them need to be answered?**

All the data elements are very important to the rigor of the data collected for the LAAO Registry. Participants should provide responses for all of the data elements and no sampling of patients or data elements is permitted in the registry.

These data elements were vetted with input from a panel of expert physician electrophysiologists and cardiologists as well as representatives from industry, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and other research-related groups. Based on input from these various sources, the current list of data elements was reviewed and approved.

**13. What is required of participants once they join the LAAO Registry?**

Each facility is required to identify an LAAO Registry Site Manager who will be responsible for ensuring the facility captures quality data and who will review outcome reports for quality improvement opportunities. Often, information technology skills as well as clinical expertise are desired qualifications for Registry Site Managers.

Staff resources will be required to collect, enter and submit the data. Hospitals may approach this in a variety of ways. Participants will be required to submit all data on consecutive patients, 18 years or older at time of admission, who have undergone an LAAO catheter-based procedure using any non-investigational approved closure device. Complete data will be required to pass Data Quality Checks built into the software.

**14. Who will own the LAAO Registry data?**

The LAAO Registry, including all aggregated data obtained from hospitals, health care providers and others and residing in the LAAO Registry is the property of the American College of Cardiology (ACC). ACC recognizes and understands that all data submitted to the LAAO Registry by hospitals, physicians, or others, including protected health information (PHI), are owned by the individual and/or the entity providing the data.

**15. Who will have access to the LAAO Registry data for research and other purposes?**

ACC will have access to and can use data in the LAAO Registry for research and publication purposes contingent on consent of the Research and Publication Subcommittee. Other parties may submit proposals for research based upon and using data from the LAAO Registry subject to approval by the Research and Publication Subcommittee and an IRB if applicable.

**16. Are there plans to certify software vendors to capture LAAO Registry data?**

At present, the LAAO Registry NCDR online data collection tool will be the sole source for data capture. Future integration with software vendors will be evaluated at a later time.

**17. Do we need local IRB approval to participate in the LAAO Registry?**

The NCDR does not require local Institutional Review Board (IRB) approval; however, your hospital policy may require the LAAO Registry protocol be reviewed by your local IRB. The LAAO Registry has been approved by Chesapeake Research Review, Inc., an independent IRB, and in accordance with 45 CFR 46.116(d) of the federal regulations Chesapeake's IRB has waived the requirement for obtaining informed patient consent for the registry. The IRB has also waived HIPAA Authorization in accordance with 45 CFR 164.512(i)(2). The approval document is available to assist with your local IRB application upon request from the NCDR via [ncdr@acc.org](mailto:ncdr@acc.org). Your local IRB may require other documents be submitted, such as the LAAO Registry Data Collection Form and Coder's Data Dictionary. [Click here to view these documents.](#)