

Vascular Quality Initiative®

vascularqualityinitiative.org

VQI®

The Vascular Quality Initiative is a distributed network of regional quality improvement groups that use a Patient Safety Organization and the M2S cloud-based system to collect and analyze data to improve the quality of vascular health care.

REGIONAL QUALITY GROUPS

Through regional quality group meetings, VQI participants share data to develop quality improvement projects designed to standardize processes, improve outcomes, and reduce complications and costs.

SVS PSO

The Society for Vascular Surgery Patient Safety Organization houses the data registry used by VQI and collaborates with the FDA and medical device companies to evaluate the safety and effectiveness of vascular devices.

M2S, INC.

M2S is the technology partner for the SVS PSO, providing the M2S PATHWAYS cloud-based platform for the collection and analysis of clinical quality improvement data.

Prospective Data Collection

Benefits of VQI data collection

- ✓ **Elimination of site contracting**, training, monitoring and IRB approval costs, due to existing SVS PSO contract with sites and existing system for data entry at VQI sites
- ✓ Ability to **specify your own custom variables** and time points
- ✓ More **rapid, consecutive patient accrual**, since consent is not required to collect data for quality improvement projects within the SVS PSO
- ✓ Efficient and **low-cost data capture** since the majority of data are already collected in VQI
- ✓ Real-world data from multiple sized centers across the U.S. supports the potential to **broaden indications for use**
- ✓ **Evaluate the real-world application of devices** beyond the scope of expert centers
- ✓ Registry data from the SVS PSO is accepted by the FDA as **high quality for required post approval studies**
- ✓ Potential to **reduce requisite number of patients** due to availability of control group within VQI

OVERVIEW

Because of its collection of real world data involving implantable devices for vascular treatment, the **VQI** is uniquely positioned to provide valuable information to your vascular device R&D, marketing and project teams.

Data Sharing through the VQI offers you an opportunity to **understand device performance** in specific patient groups based on key demographics, procedure outcomes and follow up. Outcome data can be risk-adjusted by the SVS PSO when needed.

Pricing is based on volume of data shared. All data are de-identified for patient, hospital and provider.

THE VQI PROGRAM

Governed by the SVS PSO, the Data Sharing program is designed to provide industry partners with information to better design and improve vascular devices while ensuring appropriate protection of the data.

Data are validated, benchmarked, and provided as de-identified, blinded data sets, and available **for both venous and arterial procedures**

New data are available each month for all procedures.

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Scope of Project

Industry sponsors may submit specific and customized data collection requests for studies including:

- ✓ **Prospective observational studies of device performance**
- ✓ **Randomized controlled trials of new devices**
- ✓ **FDA required post approval studies of recently approved devices**
- ✓ **Potential for investigational device exemption studies of new devices**

PROCEDURE DATA

- Carotid Artery Stent
- Carotid Endarterectomy
- Endovascular AAA Repair
- Open AAA Repair
- Hemodialysis Access
- Inferior Vena Cava Filter
- Infra-Inguinal Bypass
- Supra-Inguinal Bypass
- Lower Extremity Amputation
- Peripheral Vascular Intervention
- Thoracic and Complex EVAR
- Varicose Vein

ADDED DATA FOR ANALYSIS

Retrospective Data Sharing

- ✓ **Retrospective data analysis to improve product**
- ✓ **Market research to define patient selection in current practice**
- ✓ **Real world outcomes to validate performance and aid development**

SERVICES AVAILABLE

- Data Sharing
- Custom Reports
- Custom Variables
- Data for Post-Approval Studies
- Data for Pre-Market Studies

CONTACT

For more information on our Data Sharing portfolio, please contact Meridith Mitchell at 603.738.0066 or email mitchell@m2s.com