Overview of VQI Data for Industry

The Vascular Quality Initiative® (VQI®) was launched in 2011 by the Society for Vascular Surgery (SVS) to improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information.

The VQI uses the structure of a Patient Safety Organization (PSO) to permit collection of patient-identified information for quality improvement and safety while protecting benchmarked comparisons from legal discovery.

Real-world data are collected to provide process and outcome analyses, benchmarked reports, and other aggregated information intended for quality improvement purposes – and creating a valuable resource for device development.

Regional Quality Improvement groups are another important component of the VQI. These groups have been established throughout the US to share and analyze the data collected by individual sites and to initiate regional quality improvement projects.

The VQI is now partnering with industry to improve the quality, safety, and effectiveness of devices used for vascular treatment, since this is an integral part of vascular health care, and thus central to the mission of the VQI.

PSO BENEFITS FOR DEVICE MANUFACTURERS

The key advantage for device manufacturers is that the PSO is allowed to collect patient-identified data for quality improvement purposes without requiring consent from individual patients or prior approval from an Institutional Review Board. The PSO can share non-identifiable data with industry for device evaluation based on real world practice.

VQI collects detailed clinical data including pre-operative, intra-operative, and post-operative variables. It contains over 191,000 procedures as of December 2014, and adds 7,500 per month, captured across 12 vascular procedure modules (see reverse for current procedure list).

THE VQI CENTERS

Over 320 centers participate in the VQI across the United States and Canada. Participation includes an even distribution of academic and community hospitals.

This network of sites already collects most of the data needed by industry so a device evaluation process is much more efficient.

Participation is also open to all specialties with 50% of board certified physicians in vascular surgery, 15% board certified in cardiology and 15% board certified in radiology.
Real World Device Use and Performance Data from an Existing Network of Sites

There are multiple opportunities for medical device manufacturers to partner with VQI to obtain data to drive new device development, pre-market and post-approval studies, labeling expansion of existing devices, and long-term evaluation of existing devices. Detailed information is available, including:

- Patient demographic, anatomic and pathology data
- Details of care, such as device type, lesion and procedure details
- Long term outcomes, assessed at one year follow-up
- Late survival and re-intervention rate from matched claims data

CUSTOMIZED DATA FIELDS CAN BE ADDED FOR PROSPECTIVE DATA

Prospective observational study of device performance
Use de-identified data from the PSO to understand device performance in standard practice

FDA required Post-Approval Studies using de-identified data from the SVS PSO
Use prospectively collected, supplemental data with the potential for long-term follow-up

IDE studies of new devices, expansion of current device indications for use or randomized controlled trials
Use VQI for electronic data capture and leverage the existing network of sites

ANALYSIS OF EXISTING VQI DATA

Non-identifiable data from the VQI are available to industry for device evaluation:

- Retrospective data analyses to improve product performance
- Market research to understand and improve patient selection
- Real-world outcomes to validate device performance and improve future devices