

SVS PSO Policy on RAC data requests related to ongoing Industry Studies

Goal:

The safety and effectiveness of devices, medications and products (herein referred to as “Products”) are critical for excellent outcomes of a vascular procedure. As such, the SVS PSO collects data to allow precise identification of Products and works with Government Agencies (e.g. FDA and CMS) and Industry to look at Product performance in a “real world” setting, via VQI Industry Studies. Each Industry Study has an established charter and Steering Committee. The Steering Committee is responsible for monitoring of the study and the analysis and dissemination of information related to the stated research goals of its study.

This policy is designed to govern access to datasets related to ongoing Industry Studies in a manner that protects the integrity of the work of an Industry Study Steering Committee, while providing the full-VQI membership the ability to submit RAC proposals on studies outside of the Industry Study’s stated research goals.

Policy:

- 1) All Industry Projects must have a Charter, which clearly outlines the project’s primary study objectives, methodology and statistical methods which will be employed. These charters will be made available to all VQI members, via the VQI website, to ensure that the topics that are under the purview of an existing Industry Study Steering Committee are publicly available.
- 2) Any study proposals submitted to a VQI Regional RAC, related to an Industry Study or requesting Product/device identification, will be declined due to limited sample size and redirected to the national RAC.
- 3) The National RAC will be responsible for the initial review of all requests for VQI blinded data sets. For proposals related to ongoing Industry Studies, the SVS PSO staff will advise the National RAC if the submission is related to the primary goals of an existing Industry Study.
- 4) If the RAC deems that the proposal is related to the stated goals of Industry Study, the proposal will be denied, but the submitting investigator will be referred to the Chair of the respective Steering Committee to be considered for invitation to the Steering Committee writing group.
- 5) Every VQI member, regardless of their position on an Industry Steering Committee, must submit a RAC request for a proposal outside of the stated goals of an Industry Study.
- 6) Any RAC proposal requesting device-specific information or having a study objective that will lead to device identification will be subject to the PSO’s RAC Device Identification policy (attached).

Disclosures:

Each involved party in the Product-specific proposals must complete a disclosure form in keeping with the SVS Conflict of Interest standards. This will outline all potential conflicts for the investigators, as well as the Clinical and Statistical Advisors.

Industry Payments:

Any party wishing to act as the Principal Investigator, Clinical Advisor or Statistical Advisor for a Product-specific analysis must have not received any payments for industry-related activities for a 1-year period prior to receiving the datasets. These fees include, but are not limited to: speaker’s bureaus, device proctoring, scientific advisory boards, consulting payments, laboratory support or other indirect support. The Principal Investigator must also receive no industry-related payments during the analysis period.

SVS PSO Policy Regarding Device Identification in Research Projects

Goal:

Device safety and effectiveness are important for excellent outcome of vascular procedure. As such, the SVS PSO collects data to allow precise identification of devices so that comparative effectiveness analyses can be performed. Given the importance and sensitivity of such analyses to patients, industry and the VQI, special requirements have been established to ensure that research projects involving device identification are performed at the highest level of scientific validity.

Policy:

The SVS PSO Research Advisory Committee (RAC) will identify any research proposal in which device identification has been requested. After making an initial decision that the project has scientific merit, the RAC may appoint Project Advisors to provide ongoing oversight and specific review of the project, and to warrant the validity of any device-specific comparisons.

Two Project Advisors may be appointed for each project, with different roles. A Clinical Project Advisor will monitor the clinical interpretation of the analyses. A Statistical Project Advisor will monitor the analytic techniques, including data structure, cleanliness, exposures, outcomes, missing data elements, outcome assessment, modeling, validation, calibration, fit and power analysis. Both Advisors will have confirmed no conflict of interest related to the industry whose products are being analyzed.

The Clinical Project Advisor will be an active VQI participant in the VQI Registry being studied who has served as primary or senior author on at least 4 publications using VQI (national or regional) data. The Statistical Project Advisor will be one of the statistical consultants used by the Journal of Vascular Surgery or a similar vascular related journal who has extensive statistical experience with the type of project being conducted.

A dataset with device identities blinded will be initially used for all analyses. The Project Advisors will participate in meetings or conference calls during the design, execution, interpretation, presentation, and publication of the study, as appropriate, to provide guidance to the investigators. At the conclusion of the analysis, they will make a recommendation to the RAC as to whether the analyses have sufficient power and validity to justify publication of the device identities. Based on this recommendation, the RAC will vote to allow identification of the devices in the project, with a two-thirds vote required for such release. If a decision is made not to release identified data, and the investigators disagree, they may appeal to the SVS PSO Executive Committee for a final decision, also based on a two-thirds majority.

Following a decision to identify devices, a summary of the analysis will be shared with the relevant manufacturers at least 2 weeks prior to presentation or publication so that their input can be considered.

For projects approved by the RAC, related to current VQI Industry Studies which involve identified devices, the Principal Investigator must have their presentation/publication reviewed by the RAC and the respective Industry Study Steering Committee. The Chair or Vice-Chair of the RAC and Industry Study Steering Committee will be responsible for conducting the review. This review must be completed prior to sharing a summary of the analytics with the relevant manufacturer. If believed

necessary by the RAC either a Clinical Project Advisor or Statistical Project Advisor or both may be utilized as described above. A summary of the analysis will be shared with the relevant manufacturers at least 2 weeks prior to presentation or publication so that their input can be considered.

The above policy applies to research projects using national VQI data. Regional group research projects will be blinded to device identities to avoid low-powered analyses that do not take advantage of the full extent of available national data.

Public Comment Period:

When the SVS PSO RAC approves any Product-specific analyses, the Principal Investigator will be responsible for the preparation of a detailed analytic plan, including mechanisms to best understand Product-specific effects (including adjusting for measurable and unmeasurable confounders). This analytic plan will be shared with Product manufacturers during the analyses, and at least 30 days before any planned presentation if release of Product-identified data is approved. Product manufacturers will be invited to share publicly available comments with the investigative team. These comments and suggestions will be considered by the investigators and advisors during the project.

Disclosures:

Each involved party in the Product-specific proposals must complete a disclosure form in keeping with the SVS PSO Conflict of Interest standards. This will outline all potential conflicts for the investigators, as well as the Clinical and Statistical Advisors.

Industry payments:

Any party wishing to act as the Principal Investigator, Clinical Advisor or Statistical Advisor for a Product-specific analysis must have not received any payments for industry-related activities for a 1-year period prior to receiving the datasets. These fees include, but are not limited to: speaker's bureaus, device proctoring, scientific advisory boards, or other consulting payments. The Principal Investigator must also receive no industry-related payments during the analysis period.