

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 comparing devices are performed at the highest level of scientific validity.

Policy:

Blinded datasets released for research by VQI will be blinded as to the specific identify of devices. Investigators who wish to identify manufacturer or device sub-type, either prospectively, or after having performed an analysis with blinded data, will request permission from the SVS PSO Research Advisory Committee (RAC) to conduct a device-identified project. After making an initial decision that the project has scientific merit, the RAC will appoint Project Advisors to provide ongoing oversight and specific review of the project, and to warrant the validity of any device-specific comparisons that are reached.

Two Project Advisors will 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 as defined by the SVS conflict of interest policy document.

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 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, analysis and interpretation of the study, to provide guidance to the investigators. At the conclusion of the analysis, the 2 advisors 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 unanimous vote required for such release. If a decision is made not to release identified device data, and the investigators disagree, they may appeal to the SVS PSO Executive Committee for a final decision, also based on a unanimous vote.

Following a decision to identify devices, a summary of the analysis will be shared with the relevant manufacturers at least 2 weeks prior to submission for 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 device-specific analyses, the Principal Investigator will be responsible for the preparation of a detailed analytic plan, including mechanisms to best understand device-specific effects (including adjusting for measurable and unmeasurable confounders). This analytic plan will be shared with device manufacturers during the analyses, and at least 30 days before any planned presentation if release of device-identified data is approved. Device 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 device-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 Analytic Advisors.

Industry payments:

Any party wishing to act as the Principal Investigator for a device-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.