Vascular Quality Initiative®

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Using VQI for FDA-required Post Approval Surveillance Projects

1. Identify needed data elements, endpoints and expected event rates, with their respective definitions

- Guided by IDE study (primary, secondary endpoints and rates)
- May require input from multi-specialty physician experts
- Joint discussion by FDA, industry and VQI members

2. Determine number of patients/procedures or duration of surveillance and follow-up needed

- Identify the expected event rates that determine project size
- FDA Epidemiology group calculates number of procedures required or duration of surveillance based on desired confidence level
- Specify the number of patients required or the duration of surveillance over which index procedures are captured and required follow-up interval for each patient

3. Determine if data beyond current VQI data forms are required

- Map all endpoints to specific VQI variables and definitions
- Identify any variables that must be added to customize the standard VQI data form
- Determine whether any core lab (vs. site) measurements are required
- Determine how such data will be transmitted to SVS PSO (such as M2S core lab)

4. Determine format and schedule for data reporting to industry and FDA

- PSO can report non-identifiable data (patient, provider, hospital de-identified) without obtaining patient consent or IRB approval for standard of practice care
- PSO can report line by line non-identifiable data to industry and FDA; or only aggregate summary data to FDA; or report only to industry who prepares report for FDA

5. Develop 3-way contract between industry, SVS PSO and M2S

- Defines role of M2S to prepare customized data form and follow-up forms, data reports, progress tracking reports, and interactions with sites, including instruction, monitoring and data queries, and any required data audits, all supervised and on behalf of SVS PSO
- Defines role of SVS PSO to provide non-identifiable data, to recruit sites that volunteer to participate, and to provide scientific oversight for the project, including scientific publications after consulting the industry sponsor
- The contract includes detailed charge delineation, including reimbursement to sites for entering additional data and follow-ups, completion of which is required before payment
- If M2S (or another company) is being used as a core lab for image measurements, a contract is created to allow transmission of these data to the PSO where they are matched with the other clinical data for the specific patient/procedure

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6. M2S creates customized data forms for the project as well as report forms to meet the surveillance requirements

7. SVS PSO appoints a Steering Committee to oversee the project, with input from the sponsor

8. Site recruitment initiated by SVS communication to all SVS and other relevant society members

- Steering Committee reviews site applications and selects sites based on criteria such as annual volume of procedure, experience with similar projects, study coordinator on site

9. M2S assigns staff to project, including a Project Manager

- Establishes addendum to current PSO contract for each site to join the project
- Initiate site training with webinars about the customized forms and follow-up requirements

10. Project is initiated

- Progress reports created monthly or quarterly, and semi-annual data reports to sponsor and FDA (if latter is part of project)
- Sponsor and PSO monitor data. If the Sponsor or PSO generate a data inquiry, the Project Manager contacts the site for clarification. Outliers or questionable data may be referred to Steering Committee to validate with site, which can include transmission of source documents to the PSO if required
- Progress toward established timeline is monitored by sponsor and PSO Steering Committee to encourage site participation or new recruitment as needed

11. Data entry completed

Analyses performed by sponsor and PSO, publication decision made, publication prepared, final reports to FDA and sponsor

For more information, please contact Meridith Mitchell at 603.738.0066 or email mitchell@m2s.com

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