

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



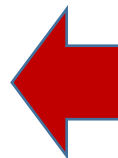
2. Determine number of patients/procedures or duration of surveillance and follow-up needed

- 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



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



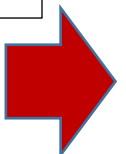
3. Determine if data beyond current VQI data forms are required

- 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)



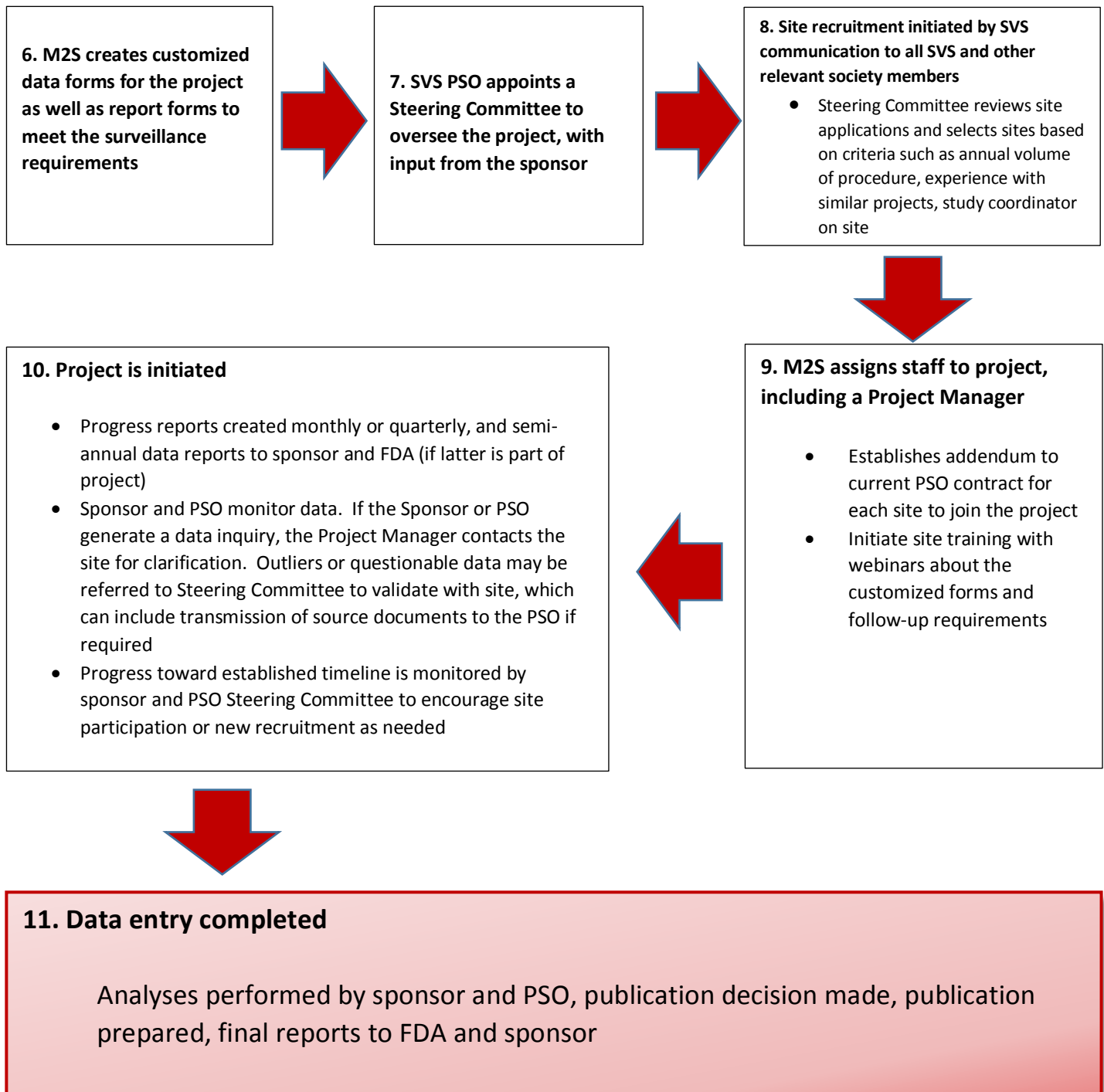
5. Develop 3-way contract between industry, SVS PSO and M2S

- 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



Vascular Quality Initiative®

vascularqualityinitiative.org



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