

TACIT

Executive Committee Outstanding Action Items

From the May 18, 2005 meeting

- Concentrate on EU funding efforts at the Paris meeting.
- Discuss with Dr. Mehran the impact of changing the primary endpoint on sample size.
- Have Dr. Mehran review the sample size calculations and sample size calculation documentation.
- Need to develop a list of data elements that are going to be considered standard of care and those that will not be considered standard of care.
- Dr. Katzen asked the executive committee to think about possible writers for the missing sections on pages 14 and 15 and bring those ideas to the Paris meeting.

From the May 4, 2005 meeting

- Need to develop a subcommittee for economics and quality of life.
- Review all tertiary endpoints listed in the protocol.
- The executive committee is to revise sections 1.1-1.7 on their own and submit their edits for discussion by the executive committee.
- Finalize a definition for MI.
- Dr. Mehran to provide definitions from ongoing relevant studies at CRF.
- Develop and send a questionnaire to all potential sites to ensure that the site will be able to be compliant with all protocol methodologies.
- Subcommittee groups need to organize and begin holding regular conference calls.
- Dr. Roubin will work on the inclusion and exclusion criteria for asymptomatic carotid stenting.

From the April 20, 2005 meeting

- Identify and submit a list of all people that should be involved with the development or implementation of the TACIT trial for both the US and Europe.
- Explore the need for IDEs in the US for off label use.
- The CIRSE office will begin the process of identifying and understanding the requirements and steps for pursuing EU funding.
- The SIR Foundation will work closely with CIRSE on the legal issues dealing with multi-national trials including information and requirements for the conformity statement.
- CIRSE office explore with Dr. Brown options for obtaining funding in the EU.
- Drs. Gaines, Sapoval and Lammer will work with CIRSE to develop a TACIT European Funding subcommittee.
- Consider strategy of obtaining pharmaceutical funding for TACIT. Identify and initiate dialogue with senior research managers from Bristol-Meyers (Plavix), Sanofi-Synthelabo (Plavix), and Pfizer (Lipitor).
- CIRSE to follow-up with European company counterparts who have already provided support for the development of TACIT from their US office.

From the November 19, 2005 meeting

- Commission a grant writer to assist in R01 preparation.
- Dr. Mehran will draft the statistical analysis section of the protocol.
- Develop a project funding plan to include options from NIH, EU countries, and device and pharmaceutical companies.
- Initiate talks with the FDA CDRH about a study IDE.
- Consider site/investigator enrollment strategies – need to examine site funding/payment, investigator funding/payment.