

Minutes
TACIT Executive Investigators Meeting
Wednesday, May 4, 2005
12:00pmET

I. TACIT Executive Investigators Present

Peter Gaines, MD
Johannes Lammer, MD
Roxanna Mehran, MD
Rodney Raabe, MD
Gary Roubin, MD
John Rundback, MD
Marc Sapoval, MD

II. CIRSE, and SIR Foundation Staff Present

Jennifer Gajewski
Keith Hume
Daniel Waigl

III. Subcommittee and Chair Discussion

The group discussed possibilities for a Surgical European Committee Chair. Peter Gaines, MD suggested that the group contact Frans Moll, MD from Utrecht, The Netherlands and Domenico Biasi, MD from Milan, Italy. The European site selection committee was also discussed. It was noted that the aim is to eventually have 100 total U.S. and European sites, with current concentration on the primary sites.

ACTION: SIR Foundation and CIRSE Foundation staff will work with Dr. Gaines to make contact with Drs. Moll and Biasi regarding the Surgical European Committee Chair position.

ACTION: Need to develop a subcommittee for economics and quality of life

IV. Protocol Review

Dr. Rundback asked that the group review the first thirteen pages of the working draft protocol. The group went through each section and made edits, as appropriate, up to section 1.1. It was decided that the group would work on sections 1.1-1.7 and submit their revisions via email.

ACTION: The group worked through the protocol summary, up to section 1.1 of the draft. Revisions are noted in the attached protocol draft.

ACTION: Review all tertiary endpoints listed in the protocol draft.

ACTION: The group is to revise sections 1.1-1.7 on their own and submit their edits via email.

ACTION: Finalize a definition for MI.

ACTION: Dr. Mehran to provide definitions from ongoing relevant studies at CRF.

ACTION: Will need to develop and send a questionnaire to all potential sites to ensure that the site will be able to be compliant with all protocol methodologies.

V. Other Business

Dr. Rundback told the group that he recently spoke with NINDS and they were interested in the TACIT trial, but hinted funding from multiple sources would be an advantage.

ACTION: Subcommittee groups are to organize and have a conference call before the PCR meeting in Paris.

ACTION: Dr. Roubin will work on the inclusion and exclusion criteria for asymptomatic carotid stenting.

ACTION: Dr. Mehran will share with the group her endpoint definitions that she has used in other similar trials.

ACTION: Next call will be scheduled for Wednesday, May 18, 2005.

XI. Adjournment

With no other business, the meeting was adjourned at 1:00pmET.

Respectfully Submitted,

John Rundback, MD