

Minutes
TACIT Executive Investigators Meeting
Wednesday, May 18, 2005
12:00pmET

I. TACIT Executive Investigators Present

Martin Brown, MD
Barry Katzen, MD
Johannes Lammer, MD
J.P. Mohr, MD
Gary Roubin, MD
Marc Sapoval, MD

II. SIR Foundation Staff Present

Jennifer Gajewski
Keith Hume

III. TACIT Article Discussion

Keith Hume brought up the issue of the TACIT article that is being written. He wanted to get a group consensus on the article, especially since it mentioned possible NIH and EU funding.

ACTION: Keith will send the article to Dr. Katzen for review before the article is sent to print.

IV. US and EU Government Funding Discussion

From the US side, the group discussed whether funding will be secured from the NIH. Dr. Mohr noted that NINDS would be more likely to fund this trial than NHLBI, but he also noted that the CREST trial is currently being funded by NINDS (with approval of an additional asymptomatic arm). Keith reported that Dr. Rundback had spoken with NHLBI and they indicated that their institute would not likely fund TACIT. Dr. Rundback has also spoken with representatives of NINDS, and reported that there is interest, regardless of the CREST trial. Dr. Mohr indicated the importance of showing how this trial is going to be different than CREST.

Dr. Brown reported that government funding from the EU side is very difficult, as they do not fund research, but rather “collaborations”. These collaborations could still pertain to TACIT (i.e., meeting funding, data collection funding, etc.), but would require someone with strong knowledge of the EU application process.

ACTION: Concentrate on EU funding efforts at the Paris meeting.

V. Protocol Review

Dr. Katzen led the group through the protocol review, beginning on page 8. Concerns of the group included:

- Should the primary endpoint be changed?
 - Possibilities were to change to change “all deaths” to “cardiovascular deaths”
 - It was noted that IH might like to see all deaths
 - Consensus was reached on the call to change the primary endpoint to, “3 year adjudicated ipsilateral strokes/neurological death in asymptomatic all risk patients with ICA stenosis $\geq 70\%$ ” on page 8.

ACTION ITEM: Discuss with Dr. Merhan the impact of changing the primary endpoint on sample size.

ACTION ITEM: Have Dr. Merhan review the sample size calculations and sample size calculation documentation.

- By changing the primary endpoint the following changes would also result:
 - Change the first secondary endpoint to, “30-day all stroke, all death, MI (q-wave and enzymes – CK-MB $> 2x$ nl)” and move the sequential secondary endpoints up in numerical order on page 9.
- Move the issue of gender up to a secondary endpoint.
- Consider changing some of the first tertiary endpoint subgroups on page 10.
 - Change “African American vs non-African American” to “Ethnic Groups”. In the summary statement a comment saying that the study is committed to recruiting a diverse range of participants to include gender and racial/ethnic diversity.
 - Eliminate “Prior CEA”
- Eliminate tertiary endpoints #3, #4, and possibly #6 on page 10.

ACTION ITEM: 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.

- Add Martin Brown, MD as the EU Neurology Study Chair to page 11.
- Eliminate “Diagnostic Angiography” from the “Angiographic Evaluation” on page 36 because you would not want to do an angiogram in all cases. Replace it with “Duplex”.

VI. Other Business

ACTION: Dr. Katzen asked the group to think about possible writers for the missing sections on pages 14 and 15 and bring those ideas to the Paris meeting.

XI. Adjournment

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

Respectfully Submitted,

Barry Katzen, MD