## Library of FAQs from Sites

**Q. What should we tell subjects still in the study?**

A. Tell them that new enrollment has stopped but the study and follow-up otherwise continues as planned.

**Q. When will participants be told to which arm they were randomized?**

A. This information will be provided to each site as soon as possible after the primary paper is published.

**Q. Do subjects need to stop study drug?**

A. Those subjects who have not completed the study should continue study drug and follow-up for the full 90-day follow-up period as planned.

**Q. Are there any concerns with additional use of anticoagulants?**

A. Anticoagulants have always been, and continue to be, prohibited concomitant medications in POINT.

**Q. Do the findings increase the risk to subjects?**

A. The answer is known to only the independent DSMB, the unblinded statisticians and the NINDS, but POINT has been assured that the study should continue, and that all subjects still on study drug should continue on it for the full 90-day follow-up period.

**Q. Are there required changes to the consent documents?**

A. Since all active subjects are already in the trial, and the DSMB and NINDS have recommended that they continue the study for their full 90 days, no changes to consent documents are necessary.

**Q. When will the results be available?**

A. Follow-up will continue for 90+14 days from the date enrollment ceased (i.e., Dec 18, 2017), and for a period after that as the close out process proceeds (late outcomes are reported, translations of source documents are completed for adjudication, data are cleaned, the database is locked, the primary publication is generated, etc.). This means several months from now.

It is expected the top line results will be provided to the investigators immediately prior to release of the published full results.

**Q. Which publication will publish the results?**

A. It is expected to be a top line journal, but is unknown at this time.

**Q. When will the results be presented at a conference?**

A. This is uncertain and will be until the likely date of the database lock becomes clearer.

**Q. Why did it take so long for this issue to become apparent?**

A. The DSMB monitored POINT for efficacy, safety and futility in the manner proscribed in the Study Protocol, and in the more detailed Statistical Analysis Plan which included formal stopping rules. The DSMB applied its judgment, based on regular assessments of the accumulating data. DSMB recommendations to stop a trial, stop enrollment but continue a trial, or other modifications, can occur at any time based on the observed data.

**Q. Why wasn't the trial stopped sooner?**

A. New enrollment has been stopped, but follow-up of already enrolled participants should continue. We must assume that the DSMB's assessment and judgment did not warrant an earlier intervention, as we all remain blinded.

**Q. Was there a safety concern?**

A. The DSMB has recommended that new enrollment be stopped, but that follow-up of already enrolled participants should continue. We will learn the reason for this recommendation after the trial results are published.

**Q. Is it unusual to stop a trial so close to the end of enrollment?**

A. Trials have been modified at every stage, and POINT still had 16% of its planned enrollment to complete.

**Q. Can I get a copy of the meeting minutes?**

A. The DSMB/NINDS provides only the IRB letter referred to above. No minutes or reports are provided to the study team until the primary results are published.

The IRB letter from NINDS, Open DSMB Report for POINT IRBs, version 6.0 of the Study Protocol and version 8.0 of the Statistical Analysis Plan are available in the POINT Toolbox on the NETT website: https://nett.umich.edu/clinical-trials/point/toolbox.

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