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Response to Letter by Proctor and Tamborello
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Response to Letter by Proctor and Tamborello

Response

It is premature to comment on SAINT II before any manuscript is published. However, the suggestion that different products were used for the 2 SAINT trials can be discounted. Relevant knowledge contained in the patent application was applied identically to the study drug supplied for SAINT I and II. The patent application for test article preparation was filed in Sweden in May 2000 and filed internationally in May 2001. SAINT I commenced in April 2003. The suggestion that the SAINT I trial may have been delayed pending animal toxicity tests is also untrue. Appropriate testing was completed before early phase trials. The SAINT I protocol was finalized in December 2002, after the last of the preclinical efficacy studies advised by STAIR guidelines had concluded.^{1,2} Recruitment to SAINT I started promptly after Institutional Review Board and regulatory approvals, in April 2003, and completed ahead of schedule.^{3,4} Recruitment into SAINT II was impaired for a while in the US because of an interim restriction on the protocol barring concomitant treatment with rt-PA pending completion of the FDA requested interaction data.

Disclosures

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