

From: [Wood, Lorraine](#)
To: [Ammons, Stanley](#)
Subject: Information Request for BLA 125612: Response Requested by July 8, 2016
Date: Friday, July 01, 2016 2:24:00 PM
Importance: High

Dear Mr. Ammons,

- A. The Study Report for study FORMA-01 lists a protocol deviation as “Received $\geq 90\%$ of the planned total dose of Octafibrin and of Haemocomplettan® P/RiaSTAP”. Page 41 of the Study Report indicates that subject (b) (6) was excluded from the PP dataset as **he** received $< 90\%$ of the planned dose of Octafibrin and Haemocomplettan® P/RiaSTAP™ (also excluded from PK-PP dataset).
- i. Should the potential protocol deviation have been correctly written as $\leq 90\%$?
 - ii. The Demographic listing lists subject (b) (6) as a 13 year old Asian **female**. Please correct either the Study Report sentence or the demographic listing.
- B. The Area Under the Curve for Fibryna was greater than that for RiaSTAP in FORMA-01. Unaddressed was the higher actual dose of Fibryna that subjects received (see Tables 8 and 9, page 46 of the Final Study Report). Please explain this discrepancy in doses and address any impact the different doses would have had on the AUC conclusion.

Please respond to this request by Friday July 8, 2016.

Sincerely,

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