

Clarification of the Accuracy Study Plan 1/3

Aim of study:

To show the accuracy of the turoctocog alfa pegol (N8-GP)
Chromogenic assay by using the (b) (4) method One-stage clotting
assay

Clarification of the Accuracy Study Plan 2/3

| Parameter | Description |
|-------------------------------------|--|
| Assays | Chromogenic and One-stage clotting* |
| Samples | N8-GP drug product placebo + N8-GP reference material (b) (4) (same matrix) |
| (b) (4) | (b) (4) |
| (b) (4) potency | (b) (4) |
| Study design, both assays | (b) (4) |
| Acceptance criteria for recovery | (b) (4) |

(b) (4)

2 pages determined to be not releasable: (b)(4)