PASS Progress Report

Study ID: NN7008-3553

A Multi-centre Non-interventional Study of Safety and Efficacy of turoctocog alfa (rFVIII) during Long-Term Treatment of Severe and Moderately Severe Haemophilia A (FVIII ≤2%)

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Title page

Study ID	NN7008-3553
ClinicalTrials.gov identifier	NCT02035384
EU PAS register number	ENCEPP/SDPP/5501
EU PAS register link	http://www.encepp.eu/encepp/viewResource.htm?id=12316
Study initiated	Actual FPFV: 05-Jun-2014
Sponsor	Novo Nordisk A/S Novo Allé 1, 2880 Bagsværd, Danmark
Data cut-off date	04-May-2016

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1 Background

This progress report number 1 of 1 is related to the Post Authorisation Safety Study (PASS) (NN 7008-3553), which is conducted in accordance with the marketing authorisation for NovoEight® (EMEA/H/C/002719) granted by the Commission Decision in Nov. 2013.
This progress report will be provided to relevant competent authorities 24 months after first patient data entry.

The cut-off for the data presented in the report is 04-May-2016.

2 Study progress

2.1 Study Schedule

- Planned LPLV: Q2 2018
- Planned final study report: Q3 2018

The planned timelines may be adjusted during the course of the trial.

2.2 Enrolling countries

The following countries are actively participating in the study: Austria, France, Germany, Hungary, The Netherlands, Slovenia and Switzerland

The following countries are participating but have not started enrolment yet: Belgium, Greece, Italy, Spain, Sweden and United States.

2.3 Study Progress

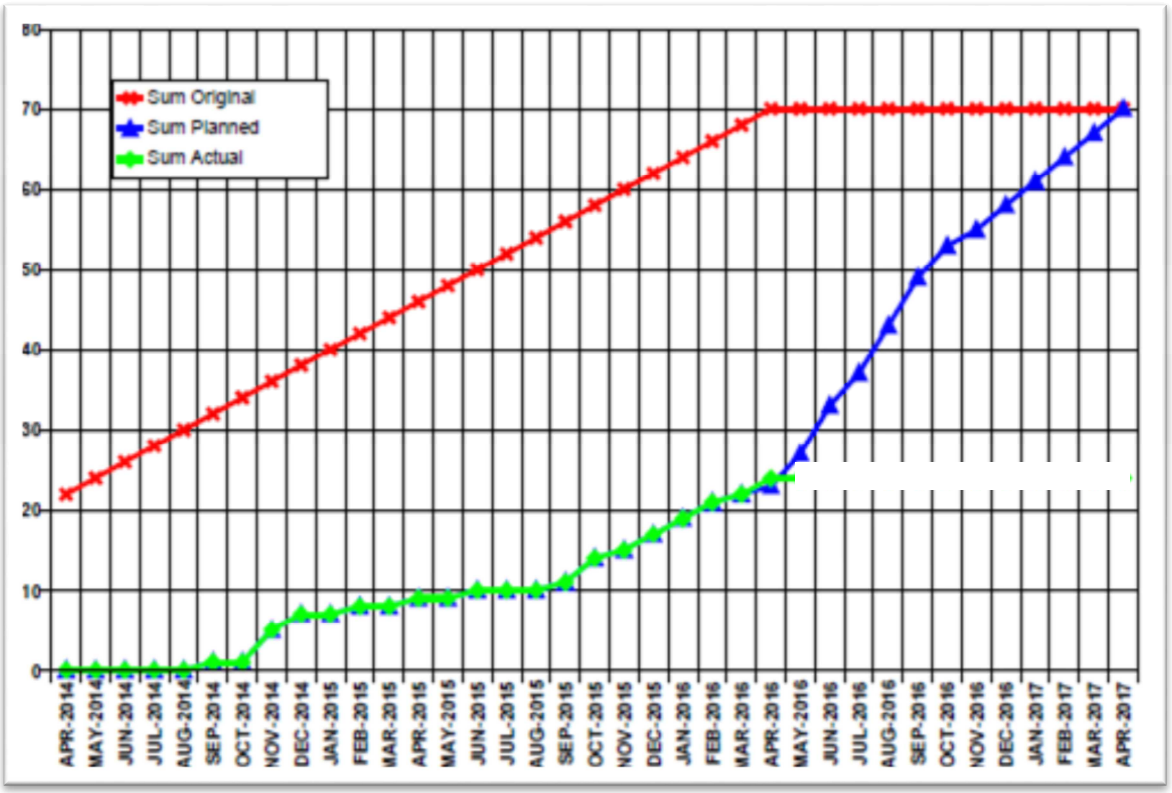

Figure 2-1 Actual versus planned enrolment during the review period
status :04-May-2016

Table 2–1 Number of patients screened, treated and completed (planned and actual)

	Planned in Trial	Actual in Trial	Planned Treated	Actual Treated	Planned Completed	Actual Completed
Total	80	24	70	24	50	5

status :04-May-2016

2.4 Status

Currently the enrolment of the study NN7008-3553 is behind the scheduled plan.