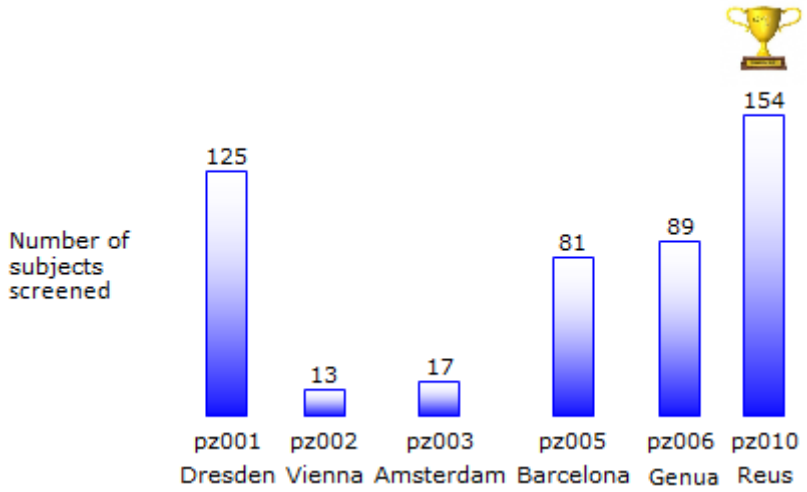
Steering Committee News Letter 3

Dresden, December 15, 2014

Dear members of the steering committee,
Dear friends,

1. Trial Status



In total, 95 Patients have been included in the ViPS Trial (228 Patients are needed!). The following table shows you the recruited patients per center (effective 15.12.2014):

Center	screened	randomized
Dresden	125	34
Vienna	13	6
Amsterdam	17	0
Barcelona	81	10
Genua	89	27
Reus	154	18
Total	479	**95**

Congratulations go to Reus for the highest number of screened patients, good work Immaculada & Hernan!

Please don't forget to screen all patients that are on controlled mechanical ventilation for more than 24 hours in your ICU – journals require namely CONSORT diagrams showing the number of screened patients with reason for non-enclosure. For further details, please have a look in Newsletter Nr. 1!

2. New center will join the trial !

I am happy to inform you that the university hospital of Kiel, Germany will soon join our trial. Dirk Schädler, MD, is the local investigator and very experienced in clinical studies. Together with his team they will recruit additional patients for our study. Welcome!

3. Adverse Events

Our drug safety monitoring board (DSMB) is composed of our SAE manager Sabrine Hemmes, Amsterdam and two DSMB members (Rupert Pearse, London & Rolf Rossaint, Aachen). Sabrine will assess all events and will report them if necessary to the DSMB for review. Please enter your adverse events in the database, especially if they are life threatening, lead to death or prolong hospitalization. All study-related or possibly related events should be reported within 24 hours to Sabrine (s.hemmes@amc.uva.nl). Below you will find two pictures on how to enter Adverse Events in the database.

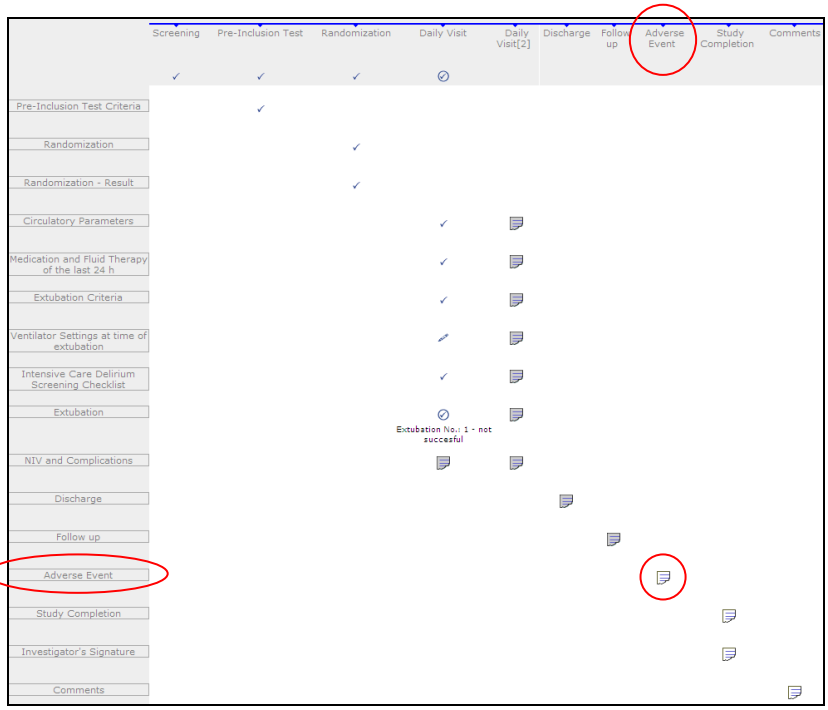
Please let me know if you have any addition questions or suggestions.

Thank you for your good work so far!

Best wishes from Dresden & Merry Christmas!

Thomas Kiss

Standard subject overview:



The Adverse Event mask: