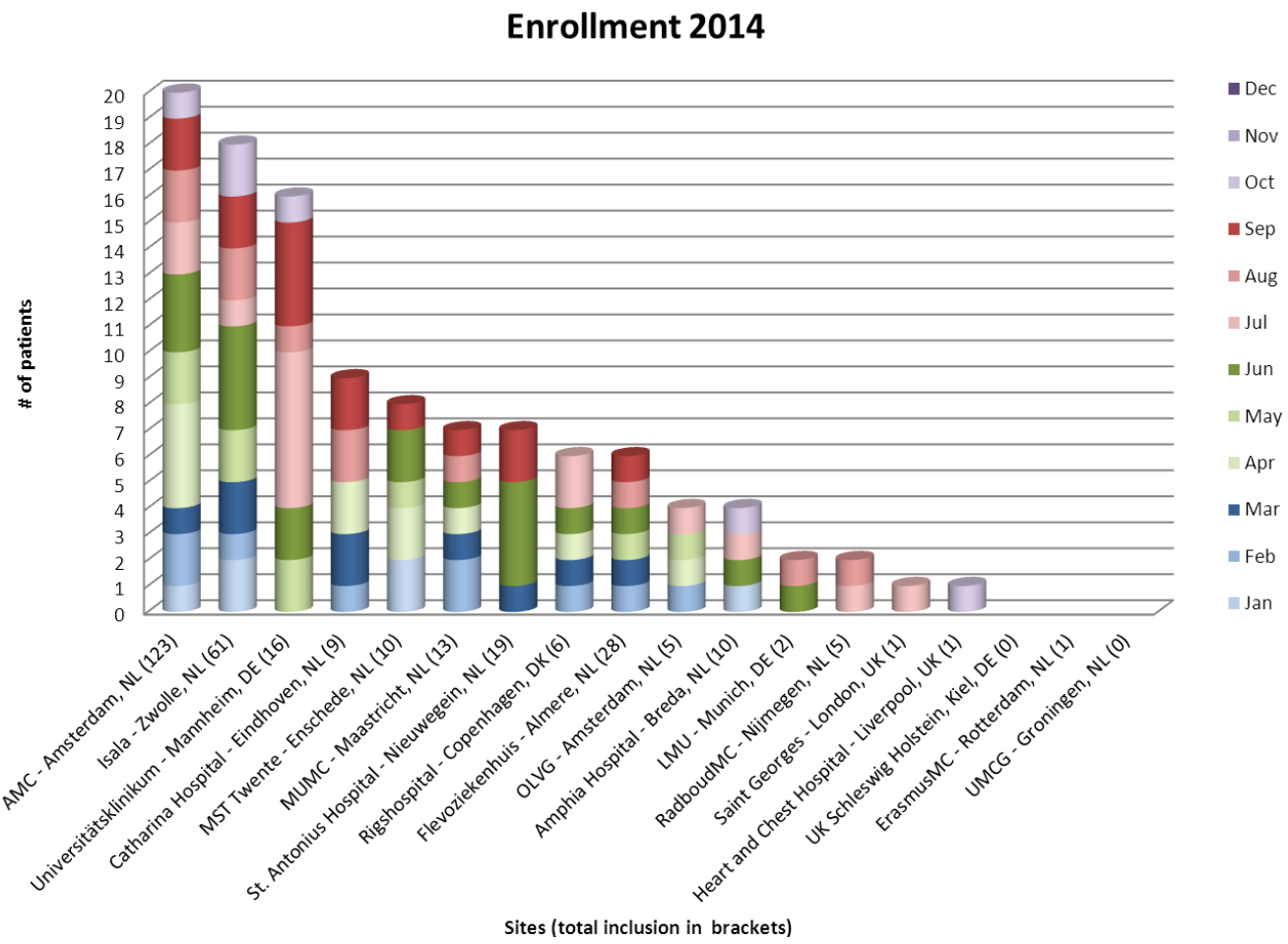
PRAETORIAN
S-ICD vs TV-ICD

Newsletter d.d. 03 October 2014

In this newsletter
We hope everyone had a nice summer and is fully recharged!
We would like to specifically bring your attention to some changes in the eCRF; an overview and manual regarding these changes is attached to this e-mail.

Enrollment

At this moment 310 patients are enrolled. Enrollment has slowed down somewhat during the summer months, but we got almost back to speed in September. Hopefully we will be at full speed again in October! An overview of enrollments in 2014 can be found below. The total number of enrollments per site is shown in brackets.
We would like to thank all participating centers for their efforts and enrollments.



Enrollment 300th patient
The 300th patient was enrolled by the Universitätsklinikum Mannheim in Germany. Congratulations!

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Initiation new sites

In the past three months 3 new sites were opened; The Heart and Chest Hospital in Liverpool UK, Queen Elizabeth Hospital, Birmingham UK and the Heart Centre in Leipzig, Germany. The Heart and Chest Hospital in Liverpool has already enrolled their first patient. We look forward to more enrollments in these sites!

In the upcoming months Hammersmith Hospital in London, UK, John Radcliffe Hospital in Oxford, UK, Herzzentrum Dresden in Germany and VU Medical Centre in Amsterdam, NL will also be initiated.

Expansion to the US

The participating sites are working on their IRB submissions, which are expected to be finished in October / November. At this moment we are working at the contract negotiations. We aim have all sites open at the beginning of 2015.

Protocol version 6.0

An amendment to the protocol was made, including the addition of the exclusion criteria which were mentioned in the previous newsletter. The protocol was sent to the Country PIs to be submitted the respective Ethical Committees. In the Netherlands the amendment was approved, and this was sent to all Dutch sites. Once approval in the other countries is obtained, the amendment and approval will be forwarded to all sites.

Changes in eCRF; please check data for your patients!

As previously announced, several new variables were added to the eCRF. This concerns parameters in baseline characteristics, arrhythmia episodes and S-ICD programming and follow-up. Furthermore two new options were added to the adverse event page. A manual regarding these changes is attached to this newsletter.

DSMB review

The Data and Safety Monitoring Board has conducted their bi-annual review. The review did not raise specific safety concerns, and therefore, Praetorian can proceed according to the original plan.

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