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REMINDER: please use study settings!

Enrolment

As already indicated in the news letter, enrolment this quarter was recordbreaking as **109** patient were enrolled!!

The top enrolling centers of this quarter are:

- Na Homolce Hospital, Prague (CZ) - 15 enrolments
- Emory University Hospital, Atlanta (USA) - 12 enrolments
- Herzzentrum Leipzig (DE) - 9 enrolments
- Universitätsklinikum Schleswig Holstein, Kiel (DE) - 9 enrolments

With 16 enrolments so far in July, currently **792** patients are enrolled.

For practical reasons, we can only count patients that are randomised through the randomisation application. It is therefore important to randomise shortly after consenting.

Investigator Meeting HRS 2016



On May 5th the annual Investigator was held during the HRS in San Francisco. As we are aware that not everybody could attend, we are very pleased that 17 participating centers were represented. During the meeting the following topics were discussed:

- *Trial expansion* PRAETORIAN is further expanded since last HRS. Ultimately 40 sites will be participating.
- *Enrolment rate* Enrolment is peaking, amongst others due to the addition of more sites. With current enrolment, we expect to enroll the 850th patient in September 2016.
- *Enrolment opportunities* Possible pitfalls are discussed. It is indicated that in some centers it helps when the physician counsils the patient himself. Also it is emphasized that it is important that all the physicians in the team are onboard.
- *EMBLEM MRI* As all commercially available ICDs are allowed in the trial, the newest model S-ICD, EMBLEM MRI, can be used in the trial as well.
- *Software update S-ICD* A new software update for previously implanted EMBLEM S-ICD systems is released. This software update will automatically be performed when the S-ICD is connected with a programmer. Please make sure to document this software update in the eCRF on a new S-ICD programming page.
- *Baseline Characteristics* Last year during the Investigator Meeting it was asked to give an overview of the baseline characteristics, to assure there is no unknown enrolment bias. The baseline characteristics were analysed and are comparable to recent other ICD trials (SIMPLE, PREPARE, MADIT-RIT). Therefore it is not necessary to adjust enrolment strategies.

After the presentations there was of course also time for some drinks and snacks.

Adjustment Publication Policy

The publication policy was written in 2013, when participation of approximately 20 sites was anticipated. However, since then PRAETORIAN further expanded and currently 40 sites are participating.

To do more justice to the efforts of all centers, the Steering committee has decided in their meeting in July to adjust the credit grading. All adjustments were made such that a) no center will receive less credits than in the original policy and b) the original principles (enrolment and data quality determine the number of credits) are hold on to.

Interim analysis and sample size calculations

According to the protocol, the DSMB performs a conditional sample size calculation when 750 patients have been included. The DSMB is entitled to recommend an increase in sample size if the observed rates of the primary endpoint are substantially lower than anticipated. This calculation will be added to the DSMB report which will be discussed this month.

Furthermore, the protocol prescribes an interim analysis for superiority when the median follow-up of the complete cohort is 1 year. As more than half of the patients already has a follow up of more than 1 year, this analysis can be performed after the last patient is implanted.

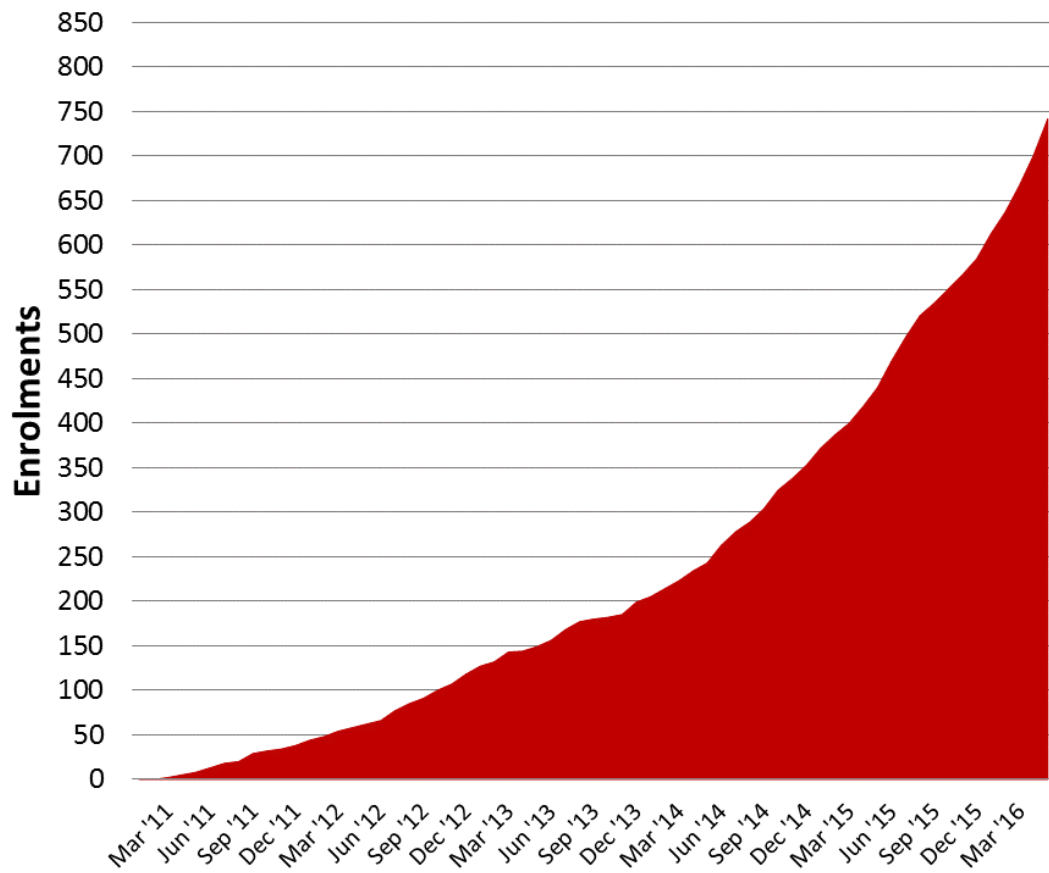
For this interim analysis it is very important that all data are complete and up-to-date in the eCRF. We will not be able to perform this analysis if data are incomplete!

Enrolments per center

AMC - Amsterdam,NL	161
Isala - Zwolle, NL	93
Flevoziekenhuis - Almere, NL	49
Universitätsklinikum Schleswig Holstein - Kiel, DE	45
Universitätsklinikum - Mannheim, DE	41
St. Antonius Hospital - Nieuwegein, NL	41
Herzzentrum Leipzig - Leipzig, DE	37
MUMC - Maastricht, NL	28
Catharina Hospital - Eindhoven, NL	25
RadboudUMC - Nijmegen, NL	23
Amphia Hospital - Breda, NL	22
John Radcliffe Hospital - Oxford, UK	21
OLVG - Amsterdam, NL	21
Heart and Chest Hospital - Liverpool, UK	21
Emory University Hospital - Atlanta, US	18
Herzzentrum Dresden - Dresden, DE	17

Rigshospital - Copenhagen, DK	16
Na Homolce Hospital - Prague, CZ	15
MST Twente - Enschede, NL	13
Hammersmith Hospital - London, UK	12
VU Medical Center - Amsterdam, NL	8
Barts Hospital - London, UK	7
Northwestern University, Chicago, US	7
Mount Sinaï Hospital - New York, US	7
Universitätsklinikum Würzburg - Würzburg, DE	7
University of Chicago - Chicago, US	6
LMU - Munich, DE	6
Medisch Centrum Leeuwarden - Leeuwarden, NL	5
Universitätsklinikum Jena - Jena, DE	5
Englewood Hospital - Englewood, US	3
Valley Health Hospital - Ridgewood, US	3
Columbia University - New York, US	3
Saint Georges - London, UK	2
Queen Elizabeth Hospital - Birmingham, UK	2
ErasmusMC - Rotterdam, NL	1
Weill-Cornell University - New York, US	1
Ohio State University Hospital - Columbus, US	0
Maimonides Hospital - Brooklyn, US	0
Yale University Hospital - New Haven, US	0
Beth Israel Hospital - New York, US	0
Medisch Centrum Alkmaar - Alkmaar, NL	0

PRAETORIAN Enrolment



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