

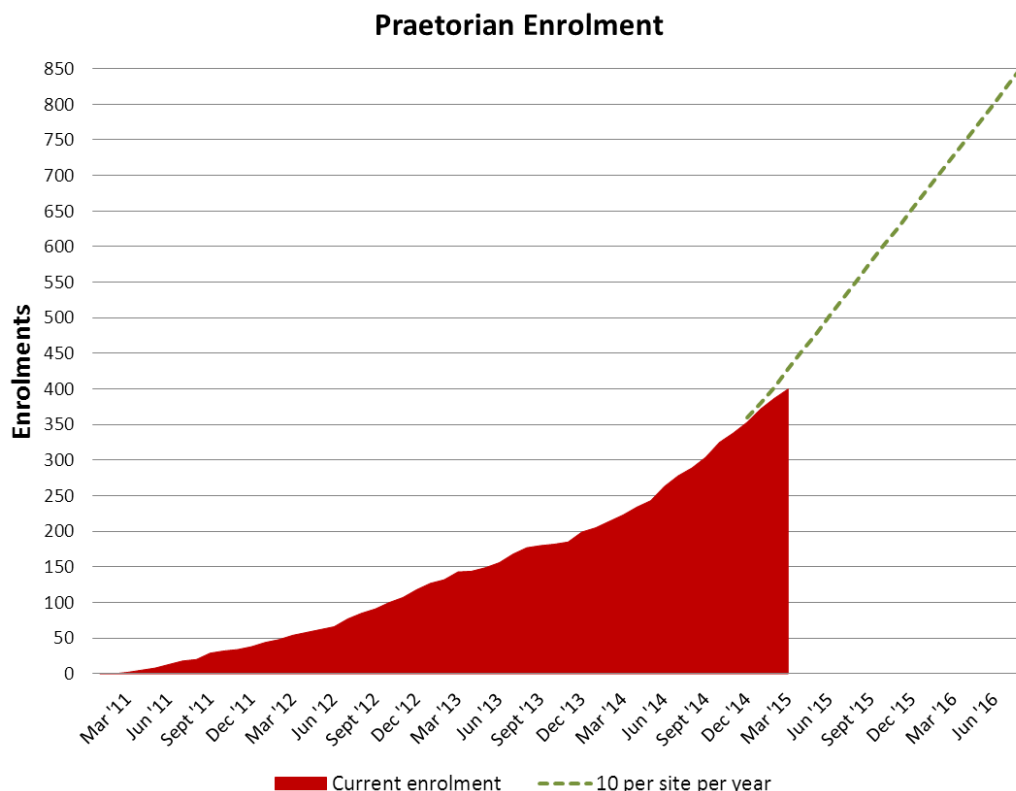


In this newsletter

- *Currently 408 patients are enrolled, please keep screening and enrolling*
- *Two centers in Chicago have started enrolment as of this month*
- *ICD settings, 'best possible' programming*
- *Please report the (serious) adverse events according to the SOP 'Adverse Event reporting'*
- *Praetorian Investigator meeting **Thursday May 14, 2015 17.30-19.30 (5.30pm-7.30pm)***

Enrolment

After a good start in 2015, enrolment has slightly dropped, from 19 enrolments in January, to 15 in February and 13 in March. So far, 8 patients were enrolled in April. Please keep screening and don't hesitate to contact us if you encounter any issues enrolling patients; we are happy to help. We thank all centers for their efforts.



400th patient enrolled

The 400th patient was enrolled on March 30th by Catharinahospital, Eindhoven, NL.

Top 6 enrolling centers Q1-2015

AMC Amsterdam, Amsterdam, NL	7
John Radcliffe Hospital, Oxford, UK	6
UK Schleswig Holstein, Kiel, DE	6
Herzzentrum Leipzig, Leipzig, DE	4
St. Antonius Hospital, Nieuwegein, NL	4
Radboudumc, Nijmegen, NL	4



Initiation new sites

PRAETORIAN has now also started in Chicago, IL, USA. The hospital of the University of Chicago with PI Dr. Martin Burke and Northwestern Memorial Hospital with PI Dr. Alex Chicos have started their enrolment as of this month.

EMBLEM in PRAETORIAN

The second generator S-ICD, named EMBLEM, has been approved in both Europe (CE) and the US (FDA) and is currently launched by Boston Scientific. Therefore, a parameter has been added to the eCRF (S-ICD implant page) to indicate whether the first (1010 SQ-RX) or second generation (EMBLEM) was implanted.

ICD settings

In some devices it is not possible to exactly program the study settings. In these cases we ask to program the closest possible, with emphasis on the FVT zone (182 bpm) and VF zone (250 bpm). Also, please remember to program only 1 episode of ATP (at 88% or closest possible).

Detection times were calculated for all manufacturers and are presented in the protocol and on the pocket cards. However, in case of Biotronik devices these settings can vary between the devices, and the calculated settings are not always possible. In the attachment you can find more details on best possible programming.

Adverse event reporting

Please remember to report your adverse event according to the SOP. We will need (blinded) source documents of cardiovascular events, as we will need to submit these to the critical event committee. You can send these either by fax (+ 31 20 56 69784) or by e-mail to L.Smeding@amc.nl and/or I.K.Schon@amc.nl



Investigator meeting Thursday May 14th 17.30, at HRS 2015, Boston

On Thursday May 14th, the yearly Investigator Meeting is scheduled at the Boston Park Plaza Hotel, 50 Park Plaza, Boston. All physicians and other trial staff is welcome to amongst others hear an update and discuss difficulties encountered in the trial. The meeting will be from 17.30-19.30 (5.30pm-7.30pm). Snacks and refreshments will be available.

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PRAETORIAN

Best possible settings

When programming the ICD according to the protocol is not possible, please program best possible, where it is of particular interest to program the FVT and VF zone as close to the prescribed settings.

For **Boston devices**, please program 160-180-250 or 165-185-250

For **St. Jude Medical Devices**, please program 166/168-181-250

- As shocks at max output is not possible, please enter programmed output

For **Biotronik devices**:

1. *Intervals to detect in the VF zone:*
 - a. Lumax: 25/31 NID (as mentioned in the Protocol)
 - b. Illesto 24/30 NID
 - c. Iperia 30/40 NID
2. *Redetection:* Make sure that, if possible, the redetection interval is NOT programmed similar to the initial detection interval. This to avoid very long redetection time!
Iperia redetection: 8/12 NID (*this is not entered in the eCRF*)
3. *Morphmatch:* In the latest Iperia platform there is a new SVT/VT morphology based discrimination algorithm called MorphMatch. When programmed 'ON' the highest programmable rate in the VF zone is 231.
When using this algorithm (MorphMatch) we request to program the VF zone to the highest possible setting, i.e 231 bpm. Please indicate at the comments field in the eCRF that 'MorphMatch is programmed 'on''