



Newsletter
20 October 2016

In this Newsletter:

- 850 patients enrolled!
- Interim analysis will be performed: Please enter all data promptly in the eCRF
- Please activate SMARTPASS on EMBLEM S-ICD
- DSMB review: no safety concerns

Enrolment

Currently the projected 850 patients are enrolled, no new enrolments are necessary at this time. Final end-of-enrolment will be announced when all enrolled patients have received their devices., which is expected in December. We will then send the final overview of enrolments per center.

Interim analysis

Per protocol, an interim analysis to test for S-ICD superiority will be performed when 850 patients have reached a median follow-up of 1 year. This follow up will be reached after the last patient received his/her device.

Please enter all data on implant, follow up, adverse events and arrhythmia promptly in the eCRF such that full data will be available for this analysis.

Activate SMART Pass on EMBLEM S-ICD

As indicated before, new firmware was introduced for the S-ICD last April. This firmware includes, amongst others, SMART Pass, a digital high pass filter that is expected to decrease the inappropriate shock rate for T-wave oversensing. The new firmware including SMART Pass is automatically installed on the EMBLEM S-ICD when connected to the programmer but needs to be activated *manually*. As inappropriate shocks are part of the primary endpoint, **it is important that SMART Pass is activated**. An extra box will be made available in the eCRF to indicate activation of SMART Pass.

DSMB review

The Data and Safety Monitoring Board has performed their semi-annual review. No safety concerns were found and the study can proceed according to the original plan.

BEDANKT – DANKE – THANK YOU – TAK – DĚKUJU
