



## Enrolment news

- As of 01 December 2020, **436** patients were enrolled
- Two centers have started since last news letter:
  - Centre Hospitalier Universitaire de Lille, Lille (FR) – 3 enrolments
  - Manchester University NHS Foundation Trust, Manchester (UK) – 1 enrolment

## S-ICD related procedures

Information about S-ICD repositioning or replacements *during follow up* needs to be collected. When in routine practice a DFT would have been performed, study patients will be treated according to the arm they are randomised to. When in routine care no DFT would be performed, no specific action is needed.

DFTs need to be done according to the procedure described in the protocol. In case of a DFT, the DFT worksheet and read out need to be collected. For patients that are randomised to the non-DFT arm, no DFT will be done, but instead the PRAETORIAN Score needs to be calculated. Please remember to use the work sheet. For the procedure itself no worksheet needs to be filled out.

### Data entry in the eCRF

The information can be entered in the step 'Procedures' under the tab 'Follow up'. Similar to other reports, you click 'add measurement' for each procedure.

Not Started  
Follow up  
Completed  
FU Visits including AE & ARR  
Not Started  
Pain Questionnaire 1-4 months post-implant  
Completed  
Procedures

Procedures

1 Type of procedure  
 Device reposition  
 Lead reposition  
 Lead replacement  
 Pulse generator change

2 Date of procedure  
[ ] [3] (dd-mm-yyyy)

3 Reason for Procedure  
 Device malfunction  
 Lead malfunction  
 Discomfort  
 ERI  
 Inappropriate shock  
 Infection  
 Lead migration  
 Device migration  
 Other

4.1 Date of event  
[ ] [3] (dd-mm-yyyy)

5 AP chest X-ray after procedure (if available) [i] [ ] Browse...

6 LAT chest X-ray after procedure (if available) [i] [ ] Browse...

Device malfunction is selected here as example. In such case, the "Date of event" needs to be entered.

If the procedure was the action on an adverse event or arrhythmia, the date of this event needs to be entered. If chest X-rays are made after the procedure, these need to be uploaded, irrespective of the treatment arm. Also programming parameters are collected. The eCRF will automatically show the relevant parameters per treatment arm.

## Thank you for your efforts!

### Top enrolling centers since last news letter

- UK Schleswig-Holstein, Lübeck, DE – 5 enrolments
- Victoria Hospital, Blackpool, UK – 4 enrolments
- John Radcliffe Hospital, Oxford, UK – 4 enrolments
- OLVG, Amsterdam, NL – 4 enrolments
- Papworth Hospital, Cambridge, UK – 4 enrolments
- AmsterdamUMC loc. AMC, Amsterdam, NL – 4 enrolments

### Top 10 enrolling centers

	Enrolments	New enrolments
1 Emory University Hospital, Atlanta, US	48	1
2 AmsterdamUMC loc. AMC, Amsterdam, NL	46	4
3 Victoria Hospital, Blackpool, UK	37	4
4 Barts Health, London, UK	33	2
5 UK Schleswig-Holstein, Lübeck, DE	31	5
6 Catharinaziekenhuis, Eindhoven, NL	22	2
7 Universitätsklinikum Würzburg, Würzburg, DE	22	1
8 UK Schleswig-Holstein, Kiel, DE	17	2
9 Erlanger Health System, Chattanooga, US	17	0
10 Basildon and Thurrock University, Basildon, UK	15	1



### Contact information

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