



## **In this newsletter:**

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## **Protocol amendment V3.0**

An amendment to the protocol was made. The most prominent change is a change in the ICD programming section. As a difference in programming between the arms can result in a difference in number of treated episodes and a difference in the primary endpoint, it is now indicated in the protocol that ICD programming must be similar in both arms. Programming is therefore no longer per physician’s discretion but per site discretion. We therefore ask all sites to decide on the programming strategy for all patients. As patients are randomised per center but not per physician or per indication, all patients in a center must be programmed similarly.

*Of note: As in protocol version 2.0 it is described that programming is per physician discretion, it is already possible to program according to the above-mentioned criteria.*

Other changes include the removal of parameters that turned out to be non-feasible (and were therefore not included in the eCRF) and a change in the AE-reporting section. The AE reporting remain the same, but the text in the protocol has been adjusted to more explicitly indicate which events are not reported.

The new protocol version is approved by the METC for all Dutch sites and submitted to all relevant EC’s/IRBs.

## **Site openings**

Since last newsletter the following sites were opened.

- UK Schleswig Holstein, Kiel (DE)
- St Antoniusziekenhuis, Nieuwegein (NL)
- Basildon and Thurrock University, (UK)
- Bart’s Health, London (UK)
- Corvita Science Foundation, Chicago (US)
- Victoria Hospital, Blackpool (UK)
- Medisch Centrum Leeuwarden, (NL)
- New Cross Hospital, Wolverhampton (UK)
- Isala Klinieken, Zwolle (NL)
- Catharinaziekenhuis, Eindhoven (NL)
- UK Schleswig Holstein, Lübeck (DE)

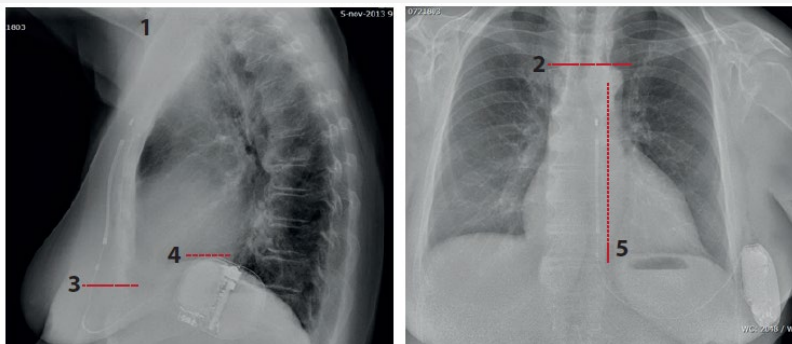
**We welcome the new sites and are looking forward to your enrolments!**

## **New Worksheet “Implant”**

The worksheet “Implant” has been updated to better match the eCRF. Please use this new worksheet, version 3.0 from now on. The new worksheet is attached to the mail with this newsletter.

## PRAETORIAN Score - Image requirements

We noticed that in several cases *participants have not lifted their arms properly* in the lateral image. Please note that if the arms are not lifted properly, it is not possible to calculate the PRAETORIAN Score. In addition, it is important *the participant should stand straight in the lateral view and not rotated*, as otherwise it is not possible to correctly draw a midline to check the generator position, necessary in Step 2 of the PRAETORIAN Score.



- 1) Arms should be elevated in a horizontal plane (lateral image)
- 2) The distal sensor of the lead should not be positioned higher than the clavicular bone
- 3) The proximal sensor of the lead should not be below the xiphoid
- 4) The upper side of the can should be projected over the heart
- 5) The coil should be projected over the spinal column

### Enrolments

Emory University Hospital, Atlanta, US	25	8.5
AmsterdamUMC AMC, Amsterdam, NL	22	13
Bart's Health, Londen, UK	7	2.5
The Mount Sinai Health, New York, US	7	10
John Radcliffe Hospital, Oxford, UK	5	5
Victoria Hospital, Blackpool, UK	4	1.5
Basildon and Thurrock University, Basildon, UK	3	2.5
Isala Klinieken, Zwolle, NL	2	1
New Cross Hospital, Wolverhampton, UK	2	1.5
St. Antoniusziekenhuis, Nieuwegein, NL	2	2.5
UK Mannheim, Mannheim, DE	2	4.5
Flevoziekenhuis, Almere, NL	2	5
UK Schleswig-Holstein, Lübeck, DE	1	0.5
Medisch Centrum Leeuwarden, NL	1	1.5
Catharinaziekenhuis, Eindhoven, NL	0	0.5
Corvita Science Foundation, Chicago, US	0	1.5
UK Schleswig-Holstein, Kiel DE	0	2.5
OLVG, Amsterdam, NL	0	4.5

### Enrolments

### Months open

## **Contact information**

*Please note the changed e-mail addresses*

### Trial Management

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