

Newsletter April 2016

Investigator Meeting at HRS

MAY 5th 2016

This year we will again meet for our annual investigators meeting during the HRS in San Francisco. The meeting will be held on **Thursday 5th of**May at 17:00 - 19:00 hours. We look forward to seeing many of you there!

Location will be communicated shortly.

CURRENT ENROLMENT

<u>671</u>

Enrolment is continuing at a steady pace. Keep up enroling at this speed! At the moment we have **79%** of the patients needed to finish PRAETORIAN enrolment!

NEW SITES OPENED - Q1 2016

We are very happy to introduce 6 new sites that have joined Praetorian in Q1 2016.

- Emory University Hospital Atlanta, GE, (US), PI: Dr. Mikhael el-Chami
- Maimonides Hospital, New York, NY (US), PI: <u>Dr. Yisachar Greenberg</u>
- Yale University Hospital, New Haven, CT (US), PI Dr. Jude Clancy
- Ohio State University Medical Center Columbus, OH (US), PI: <u>Dr. Raul</u>
 Weiss
- Universitätsklinikum Jena, Jena (DE), Pl: Dr. Dirk Prochnau
- Universitätsklinikum Wurzburg, Wurzburg (DE), <u>Dr. Peter Nordbeck</u>

All sites have shown great enthusiasm for the trial and some sites have started enroling their first patients only days after the initiation visit. Great work!

In Q2 we are happy to initiate Homolce Hospital in Prague with Prof. Petr Neuzil as PI.

Additionally we are working on 5 more hospitals in the US, France and the Netherlands to hopefully join us during Q2.

TOP 5 ENROLING SITES 2016

A special mention and congratulations to our top enrolling centres of 2016!

- 1. OLVG Amsterdam, The Netherlands (8)
- 2. Isala Zwolle, The Netherlands (7)
- 3. Herzzentrum Leipzig Leipzig, Germany (7)
- 4. UK Schleswig Holstein Kiel, Germany (7)
- **5.** Emory University Hospital Atlanta, United States **(6)**, MUMC Maastricht, The Netherlands **(6)** AND Hammersmith Hospital Londen, United Kingdom **(6)**

DATA AND SAFETY MONITORING BOARD

We have received notice from our DSMB stating that their review did not raise any specific safety concerns and the study should proceed according to it's original plan.

Keep the best possible TV- ICD settings in mind!

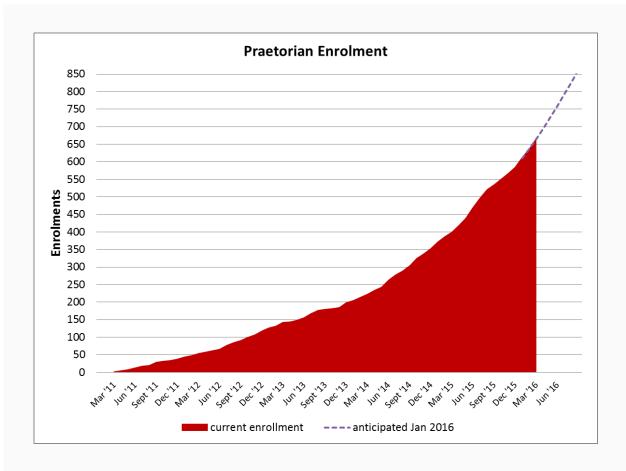
We have noticed that the best possible settings for the patients randomized to a transvenous ICD are a recurring issue raised at monitoring visits. Please make sure you use these settings unless there is an important clinical argument to deviate from these settings. As a reminder you can find the best possible settings below.

Study Settings

Best Possible:

	Monitor zone	(Fast) VT zone	VF zone
Protocol	167	182	250
Boston Scientific	160/165	180/185	250
SJM	166/168	181	250
Biotronik (Iperia)	167	182	231 (when using Morphmatch)

	ATP settings	Biotronik	Time to detect
Protocol	1 burst 88%	Lumax	25/31
Biotronik	85% of 90%	Ilesto	24/30
Sorin	12% (100-88%)	Iperia	30/40



As you can see in the graph above we will expect to finish enrolment this year if we continue at this speed.