



PRAETORIAN-DFT

Newsletter March 2019

Enrolments and site openings

Since PRAETORIAN DFT was first approved in May 2018, 7 sites are opened and **45** participants are enrolled. In 3 additional sites enrolment is pending the PI completing the PRAETORIAN Score eLearning. We are anticipating the start of 2 more sites this month and are working on study start up with additional sites in the UK, France, Germany, the Netherlands and the US.

Investigator meetings

There will be no PRAETORIAN DFT Study meetings at EHRA or HRS this year. Members of the AMC PRAETORIAN team will be present at the conferences, so there will be the opportunity to meet and discuss any queries.

DSMB review

The first DSMB review was performed 6 months after first enrolment, as indicated in the protocol. The review did not raise safety concerns and the study can continue according to its original plan.

Enrolling centers / Enrolments

Emory University Hospital, Atlanta GE (USA)	19
AMC, Amsterdam (NL)	17
Mount Sinai Hospital, New York, NY (USA)	7
John Radcliffe Hospital, Oxford (UK)	2
Flevoziekenhuis, Almere (NL)	-
OLVG, Amsterdam (NL)	-
Universitätsklinikum Mannheim (DE)	-

Enrolment pending

St. Antoniusziekenhuis, Nieuwegein (NL)
Universitätsklinikum Schleswig-Holstein, Kiel (DE)
Medisch Centrum Leeuwarden (NL)

New SOPs

The following SOPs have been updated and are attached to this newsletter. Please store these in the Investigator File (or thumb drive) at tab 5.4 'Study Specific Standard Operating Procedures (SOPs)'.

- SOP Addition of implanting physician
- SOP Protocol Training
- SOP Protocol deviations

Contact information

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