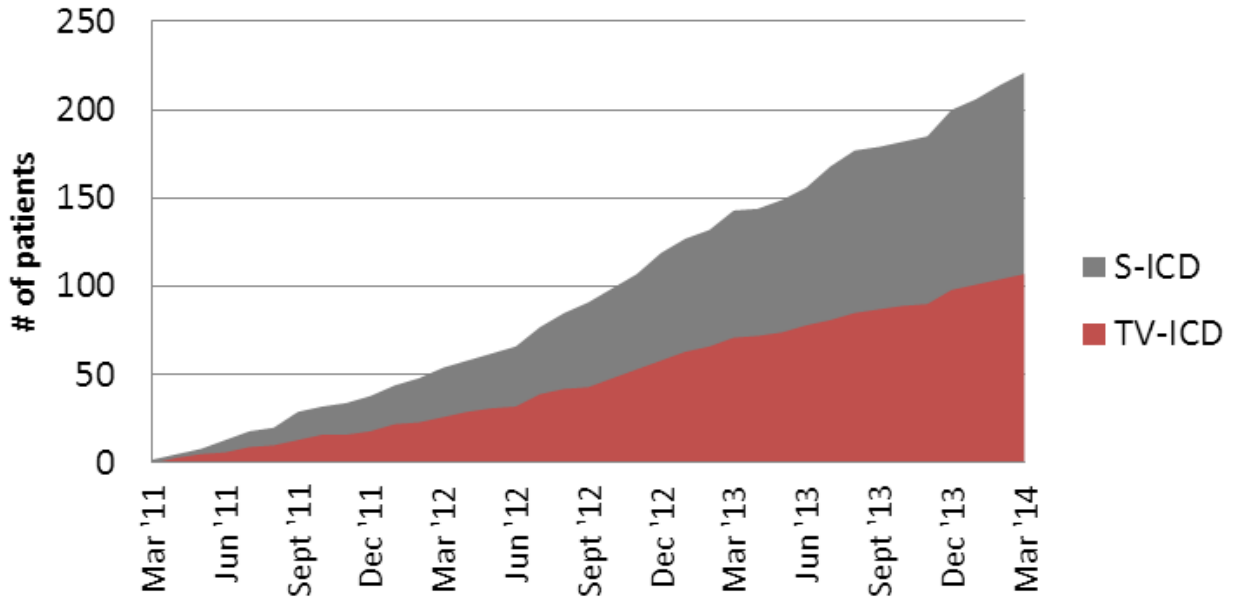




### Current inclusion (n=221)



Academic Medical Center - Amsterdam, The Netherlands	107
Isala Klinieken - Zwolle, The Netherlands	48
Flevoziekenhuis - Almere, The Netherlands	24
St. Antonius Hospital - Nieuwegein, The Netherlands	13
Maastricht UMC – Maastricht, The Netherlands	8
Amphia Hospital Breda, The Netherlands	7
Medisch Spectrum Twente Enschede, The Netherlands	4
Radboudumc - Nijmegen, the Netherlands	3
Catharina Ziekenhuis - Eindhoven, The Netherlands	3
OLVG - Amsterdam, The Netherlands	2
Rigshospitalet - Copenhagen, Denmark	1
ErasmusMC - Rotterdam, The Netherlands	1
St. Georges University of London - London, United Kingdom	0
LMU Munich University Hospital - Munich, Germany	0
UMC Groningen - Groningen, The Netherlands	0

**We thank all recruiting centers for their efforts!**



# PRAETORIAN

## S-ICD vs TV-ICD

Newsletter d.d. 26 March 2014

### **International participation**

In February we have welcomed three international sites; Rigshospitalet in Copenhagen, LMU Munich University Hospital in Munich and Saint George's Hospital in London started recruiting. We are very excited to have started Praetorian outside the Netherlands.

### **First international patient is recruited!**

Shortly after opening the Rigshospitalet as Praetorian site, the first international patient was recruited by Dr. Høgh Petersen in Denmark.

### **eCRF temporary offline**

Our eCRF will be temporary offline from Monday 31 March until Wednesday 2 April due to maintenance. ALEA will remain online, such that patients can still be randomized. Furthermore, several small changes will be made in the eCRF. New books can be found online.

### **Retrieving ICD after death**

After the death of a patient it is mandatory to retrieve the ICD. The patient may have had an arrhythmia episode prior to his/her death, which may potentially have caused the death. Therefore, all efforts must be made to return the ICD to the hospital to obtain read-outs.

### **Investigators meeting at HRS**

During HRS, an investigators meeting will be held on Thursday May 8 2014 from 17.30-19.00. The meeting will take place at Restaurant Lulu, 816 Folsom Street, San Francisco, CA 94107. A more detailed invitation will follow.

### **New monitor**

Recently, Annelies Vinken started as the new monitor started for Praetorian. In the last few weeks she has been trained in the Praetorian protocol. She will soon start the monitor visits to the sites.

### **Praetorian and Effortless**

We would like to emphasize that Praetorian patients cannot be included in the Effortless registry. S-ICD implants outside Praetorian can be included in Effortless. Please keep a list of all S-ICDs implants outside Praetorian.

### **SOP adverse event reporting**

We have updated our SOP on Adverse Event Reporting. In the new version it is more clearly described when to notify the Praetorian Trial Bureau and which source documents need to be sent. The new SOP is sent along this newsletter. The new flow chart can also be found in this newsletter. Please check if all source documents from currently known events are sent to the Praetorian Trial Bureau!

### **Contact**

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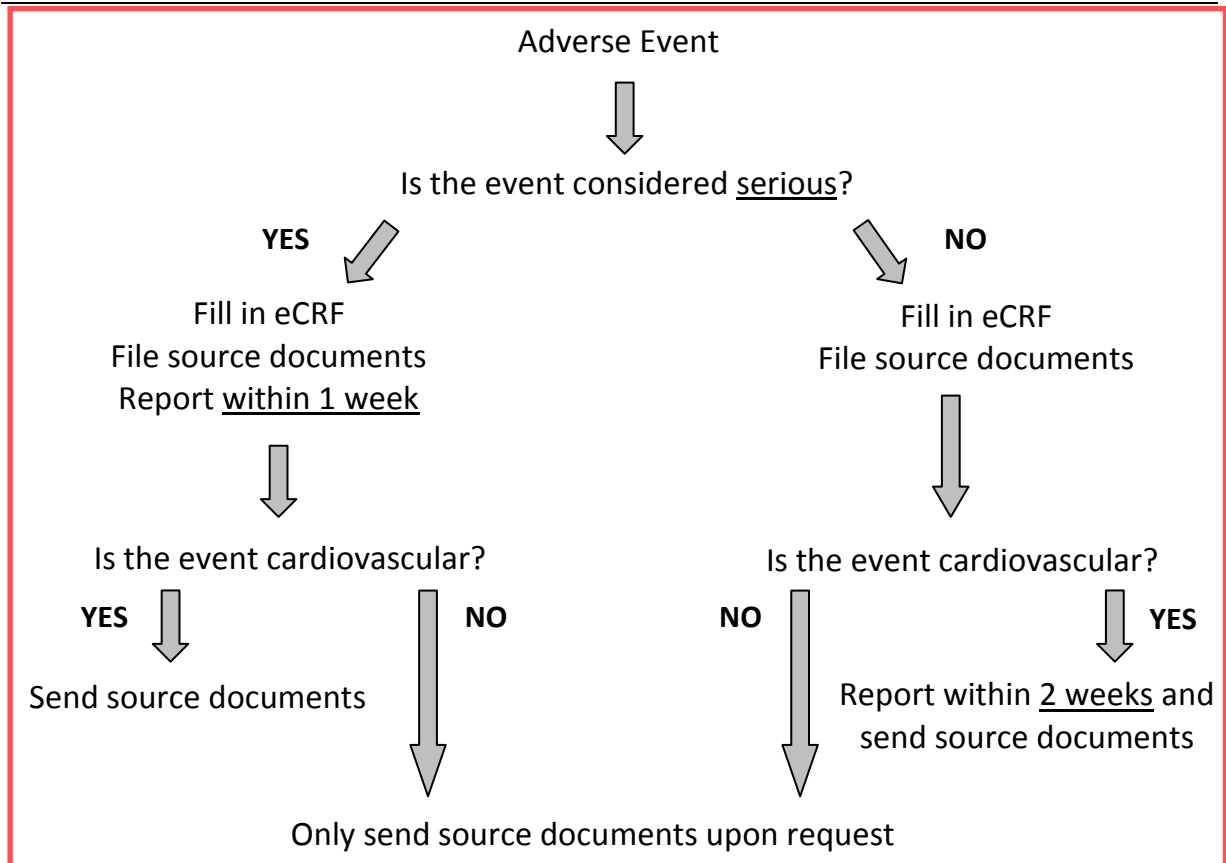
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### Flow chart Adverse Events and Arrhythmia Episodes



### Arrhythmia episodes

In case of:

- Shocks (both appropriate and inappropriate)
- ATP treatment (both appropriate and inappropriate)

Send notification and source documentation to Praetorian Trial Bureau.

Notifications and source documents can be sent to:

- E-mail: [l.smeding@amc.uva.nl](mailto:l.smeding@amc.uva.nl)  
[i.k.schon@amc.uva.nl](mailto:i.k.schon@amc.uva.nl)
- Fax: + 31 20 56 69784