

Dear Investigators, we thank you all for your support and collaboration.
We are pleased to give you the latest news about the POSE Study!

Highlights

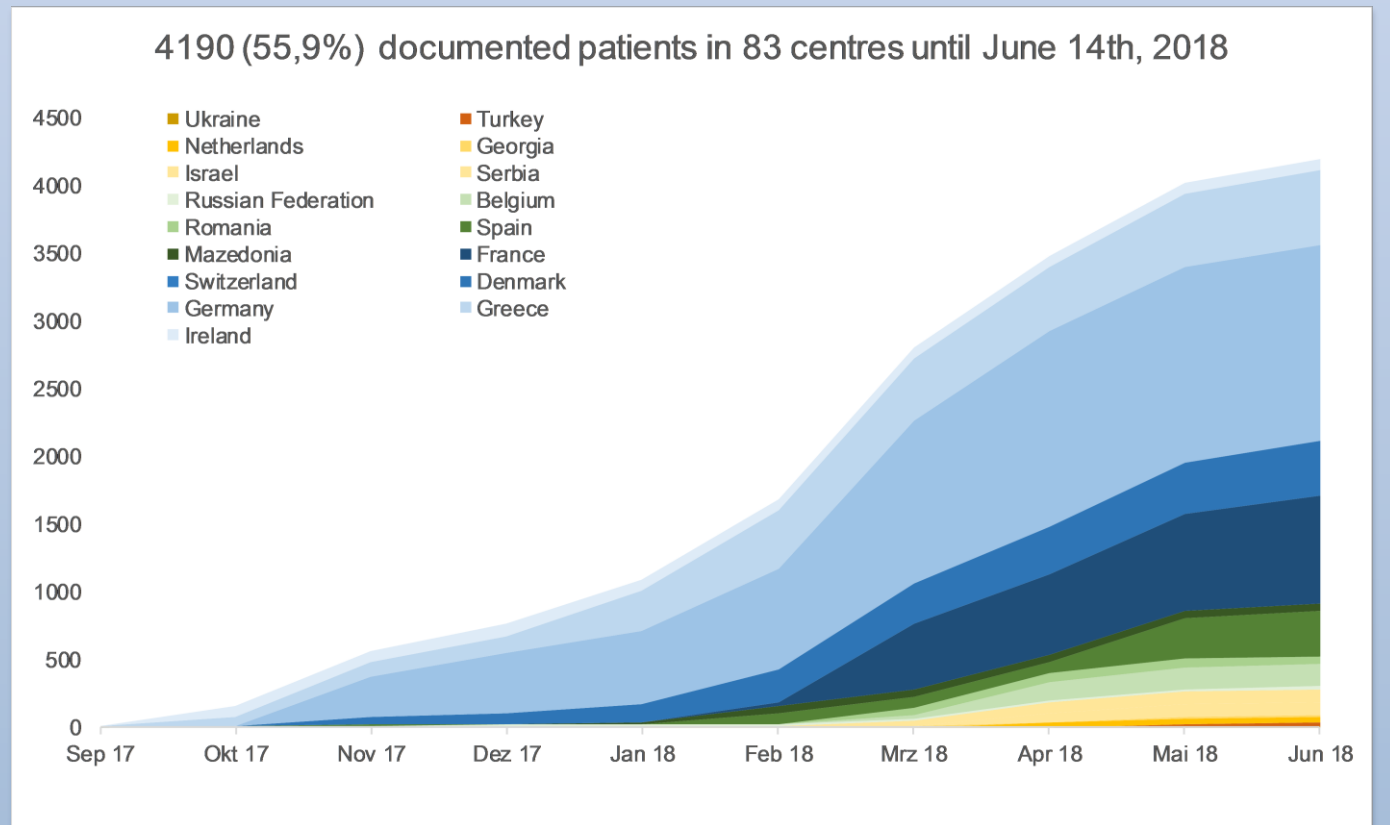
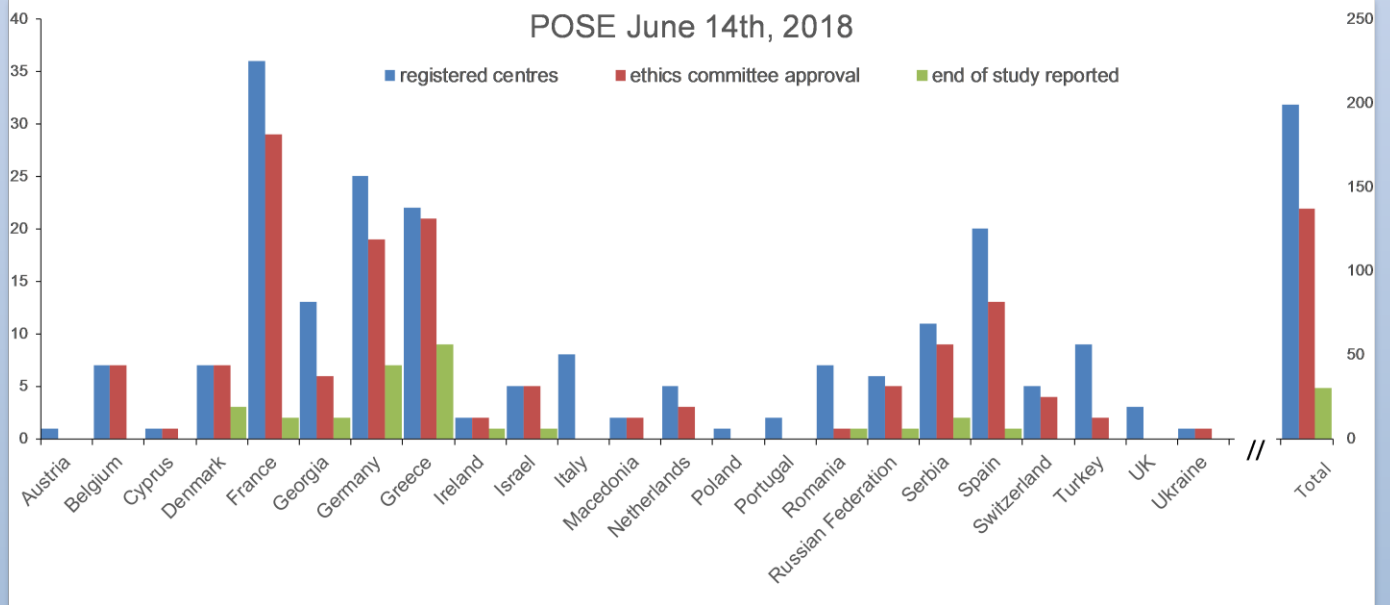
- The steering committee has decided to extend the recruitment period until the 31th December 2018, the amended Study protocol can be found on our website under "Study documents".
- We welcome Prof. Kudsioglu from the Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital, Istanbul, as 200th registered centre.
- Until 14th June 4190/7500 (55,9%) patients were documented in 83 centres!
- All centres located in the EU, please read the important notices concerning the **New General Data Protection Regulation (GDPR)** on page 3.
- Data clearance has already started

1st Investigator Meeting was held on 4th June 2018

We would like to thank all attendees of our first Investigator meeting during the ESA Euroanaesthesia Congress in Copenhagen! The presented Powerpoint presentation can be found on our website under the tab "Latest News".

Top 10 recruiters according to the OpenClinica database entries until 14th June

	Site	Country	Enrolled patients
1.	LMU München	Germany	216
2.	CHU Toulouse	France	186
3.	Hannover Medical School	Germany	167
4.	Herlev Hospital	Denmark	147
5.	University Hospitals Leuven	Belgium	145
6.	Universitätsklinikum Schleswig-Holstein Campus Lübeck	Germany	141
7.	University Hospital Tübingen	Germany	135
8.	St. Franziskus-Hospital Münster	Germany	133
9.	CHU Saint-Étienne Nord	France	116
10.	Johannes Wesling Klinikum Minden	Germany	115



Important notices:

New General Data Protection Regulation (GDPR)

- Became applicable on 25th May 2018 for all centres participating in POSE from the EU!
- Considering the updated data protection rights provided for patients in the GDPR, future patient information sheets and consent forms must be adapted to the requirements of the GDPR.

Who has to take into account the GDPR?

- All centres within the European Union, which were recruiting beyond 25th May 2018 or had patients in the follow up period beyond 25th May 2018.
- All centres, which have started or plan to start their recruitment after 25th May 2018.

What should these centres do?

- The centres have to inform (e.g. via mail/e-mail/personally) the patients who have already received a patient information and/ or have additionally signed consent form to participate in a clinical trial about the new subsidiary legal data protection regulations with the *Information sheet for study subjects* (you find a template on our website www.pose-trial.org => Ethics section). Please individualize this information sheet template according to your centre (i.e. please fill in and check all the yellow highlighted fields).
- Additionally, please confirm the delivery or dispatch of the information sheet to your study subjects on the signature page, which is enclosed to the New Data Protection Info sheet for Investigators (you find it also on our website www.pose-trial.org => Ethics section) and send a copy back to us.
- We have also placed a Data Protection Information Sheet Issuing Log on our website, which you can use for your documentation of dispatching of the additional patient information sheets.
- All centres, which are awaiting an ethical approval, or plan to submit an ethical application soon, should directly integrate the new GDPR information from our patient template into their patient information sheet.

Best wishes

Mark Coburn (Study Director)



Ana Kowark (Study Coordinator)

