

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

We hope everyone had great summer holidays!

We are entering the final phase of POSE:

Patient recruitment is only possible until 31.12.2018!!

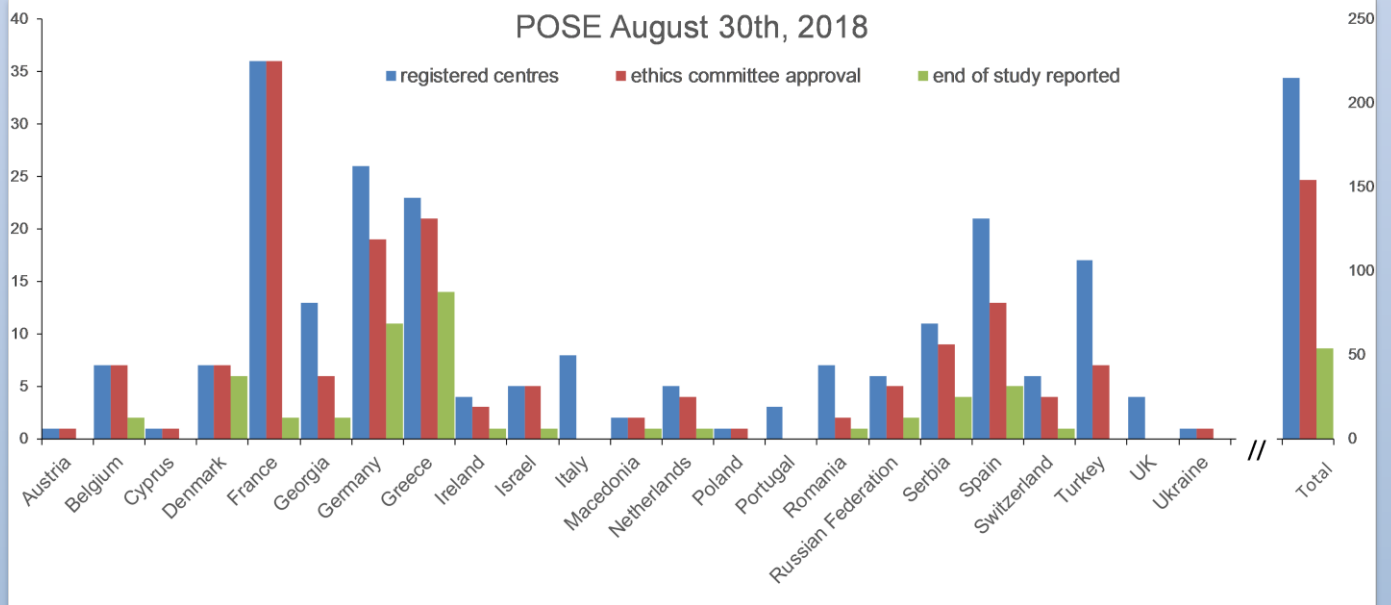
- Until 30th August 6426/7500 (85,7%) patients were documented in 112 centres!
- 217 Centres have registered to participate
- The last possible start of the recruitment phase is the 2nd December 2018. The last follow up day is expected to be the 30th January 2019

POSE to do list

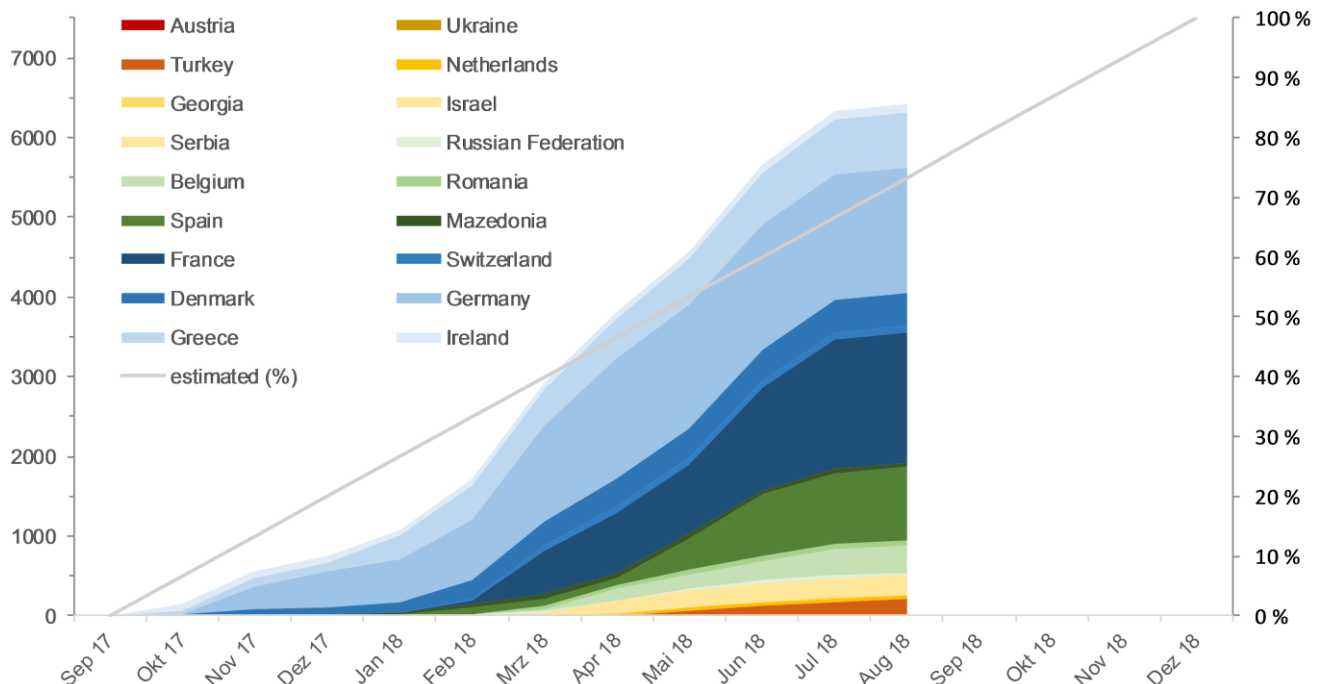
- We have obtained 150 IRB approvals so far. Please make sure you get your approval in time.
- Please chose your recruitment phase keeping in mind that patient recruitment ends on 31st of December. 105 centres need to recruit their patients
- Please inform the POSE study team, when you have entered all your data into the OpenClinica database and send them your completed end of study reporting form, POSE task delegation form and Screening list, see <https://pose-trial.org/study-documents/>

Top 10 recruiters according to the OpenClinica database entries until 30th August

	Site	Country	Enrolled patients
1.	LMU München	Germany	216
2.	Hospital de la Santa Creu i Sant Pau Barcelona	Spain	200
3.	CHU Toulouse	France	186
4.	Clinique de la Sauvegarde Lyon	France	177
5.	Hannover Medical School	Germany	167
6.	AZ Groeninge	Netherlands	163
7.	Hospital General Gregorio Maranon Madrid	Spain	150
8.	Herlev Hospital	Denmark	147
9.	University Hospitals Leuven	Belgium	143
10.	Universitätsklinikum Schleswig-Holstein Campus Lübeck	Germany	141



6426 (85,7%) documented patients in 112 centres until August 30th, 2018



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?

- All centres in the EU have to inform (e.g. via mail/e-mail/personally) the patients who have already received an old version of patient information (without new GDPR) and/ or have additionally signed old version of consent form (without new GDPR) 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.
- Please confirm, that your patient information has already included the new GDPR on the second page of the "New Data Protection Info for Investigators" (you find it on our website).

Mark Coburn (Study Director)



Ana Kowark (Study Coordinator)

