

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

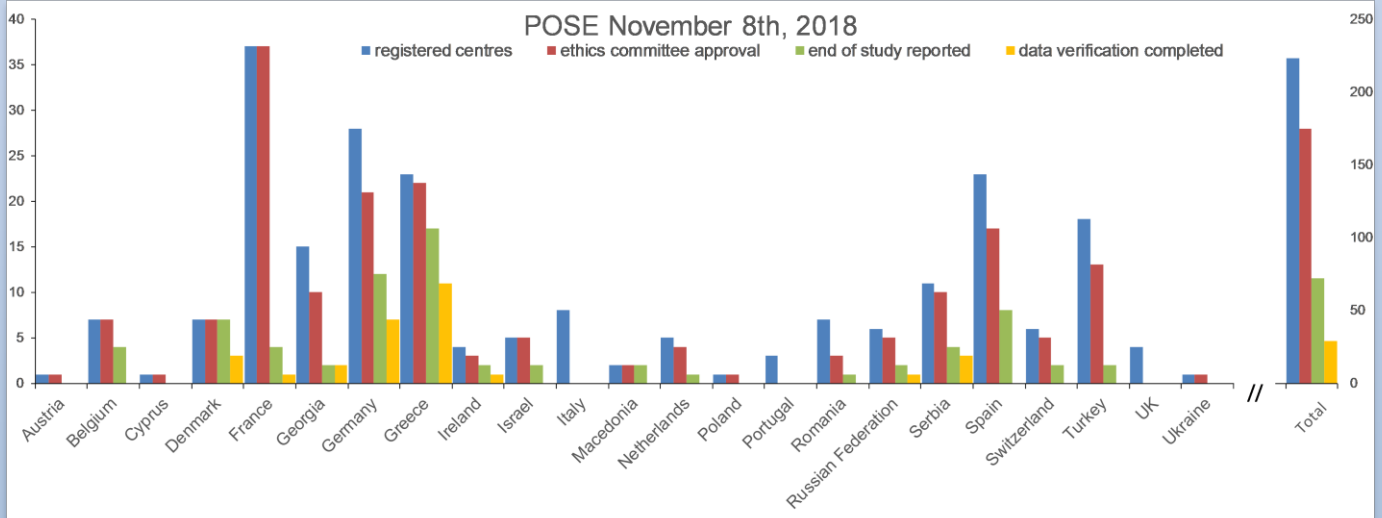
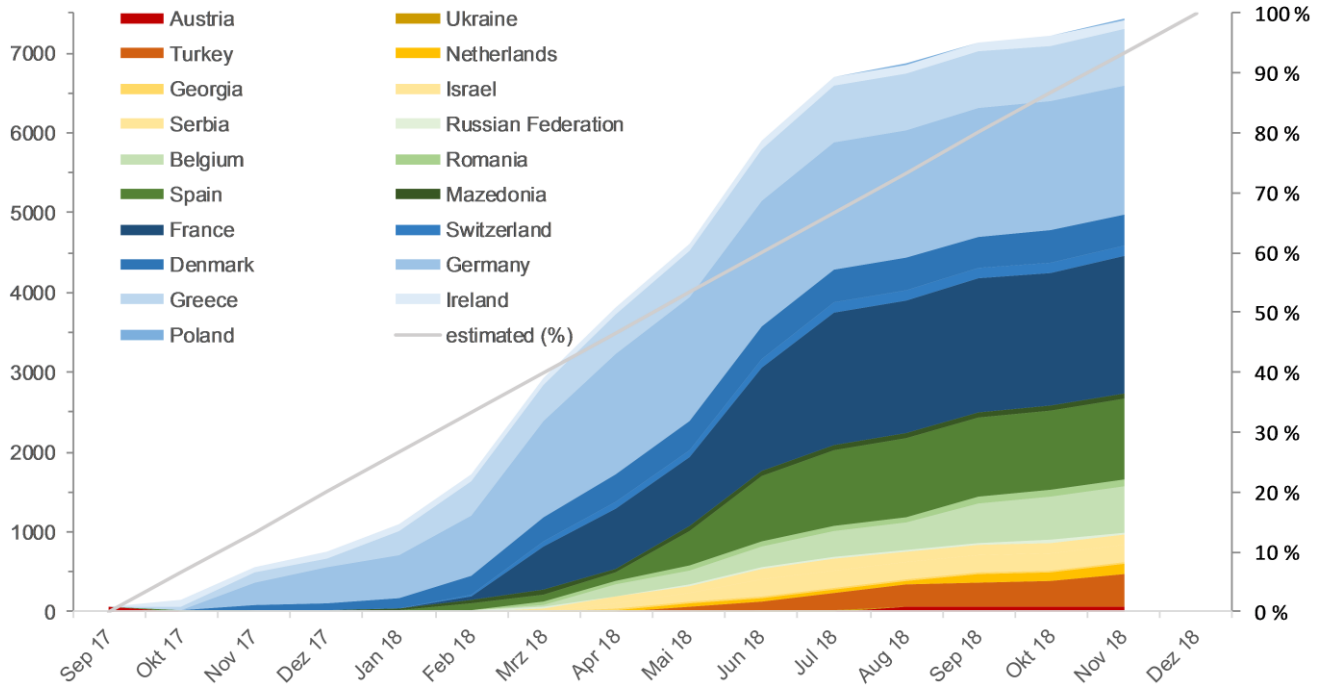
Highlights

- Until 8th November 7421/7500 (98,9%) patients were documented in 135 centres!
- We encourage all other centres to start the recruitment as soon as possible since we will not stop at 7500 patients. Our aim is to recruit as many patients as possible.
- Please make sure you do not miss the recruitment period! Last possible start date is 2nd December 2018 since recruitment ends 31st December 2018.
- 24 centres haven't entered any data in OpenClinica, even though they fulfil all requirements for recruitment. Please do not hesitate to contact us in case of difficulties.
- Data clearance is already in process. 29 centres have completed data verification and already received their certificates of participation.
- Completed data verification process is necessary for each centre, to be listed as co-author or collaborator in the POSE publications.
- Please read the important notices concerning **Classification of interventions as "Emergency case"** on page 3 of this newsletter.

Top 10 recruiters according to the OpenClinica database entries until 8th November 2018

	Site	Country	Enrolled patients
1.	Hospital de la Santa Creu i Sant Pau Barcelona	Spain	230
2.	LMU München	Germany	216
3.	CHU Toulouse	France	186
4.	Clinique de la Sauvegarde Lyon	France	177
5.	Hannover Medical School	Germany	167
6.	AZ Groeninge Hospital Kortrijk	Belgium	163
7.	Herlev Hospital	Denmark	147
8.	Hospital General Gregorio Maranon Madrid	Spain	146
9.	University Hospitals Leuven	Belgium	143
10.	Universitätsklinikum Schleswig-Holstein Campus Lübeck	Germany	141

7421 (98,9%) documented patients in 135 centres until November 8th, 2018



Important notices:

Classification of interventions as "Emergency case"

- If the question "Emergency case?" YES/NO in Visit 1 is ticked with YES, it has to be specified in Visit 2 in the question: "Urgency of surgery/intervention:" into
 - a) **Urgent** (that means: Intervention required within < 48 hrs) or
 - b) **Emergency** (that means: the patient's life or well-being is in direct jeopardy)
- That means: An intervention may be classified as Emergency case-YES in Visit 1 and only urgent in Visit 2!

Further tips for OpenClinica completion

- Visit 1: If you tick any "Chronic Medication", please make sure that you have also ticked any corresponding disease within the sections "Risk assessment" and/or "Medical History"
- If a patient takes "Antidepressants" or "Benzodiazepines" or "Z-drugs" due to e.g. a depression or an anxiety disorder, please make sure that you have ticked "Other cognitive complaints" and please specify it in the new opening field for free text.

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.

Please read and use the eCRF User Guide and the POSE Glossary from our website

- www.pose-trial.org => Tab: E-CRF (Electronic Case Report Form), for completion of the OpenClinica database. Particularly the subsection 10 a) in the eCRF user guide explains how to change your data after the CRF has already been marked as complete (green icon in the subject matrix)

Best wishes

Mark Coburn (Study Director)



Ana Kowark (Study Coordinator)

