www.pose-trial.org

Register now!

UNIKLINIK
RWTH AACHEN

Ana Kowark POSE Study Coordinator

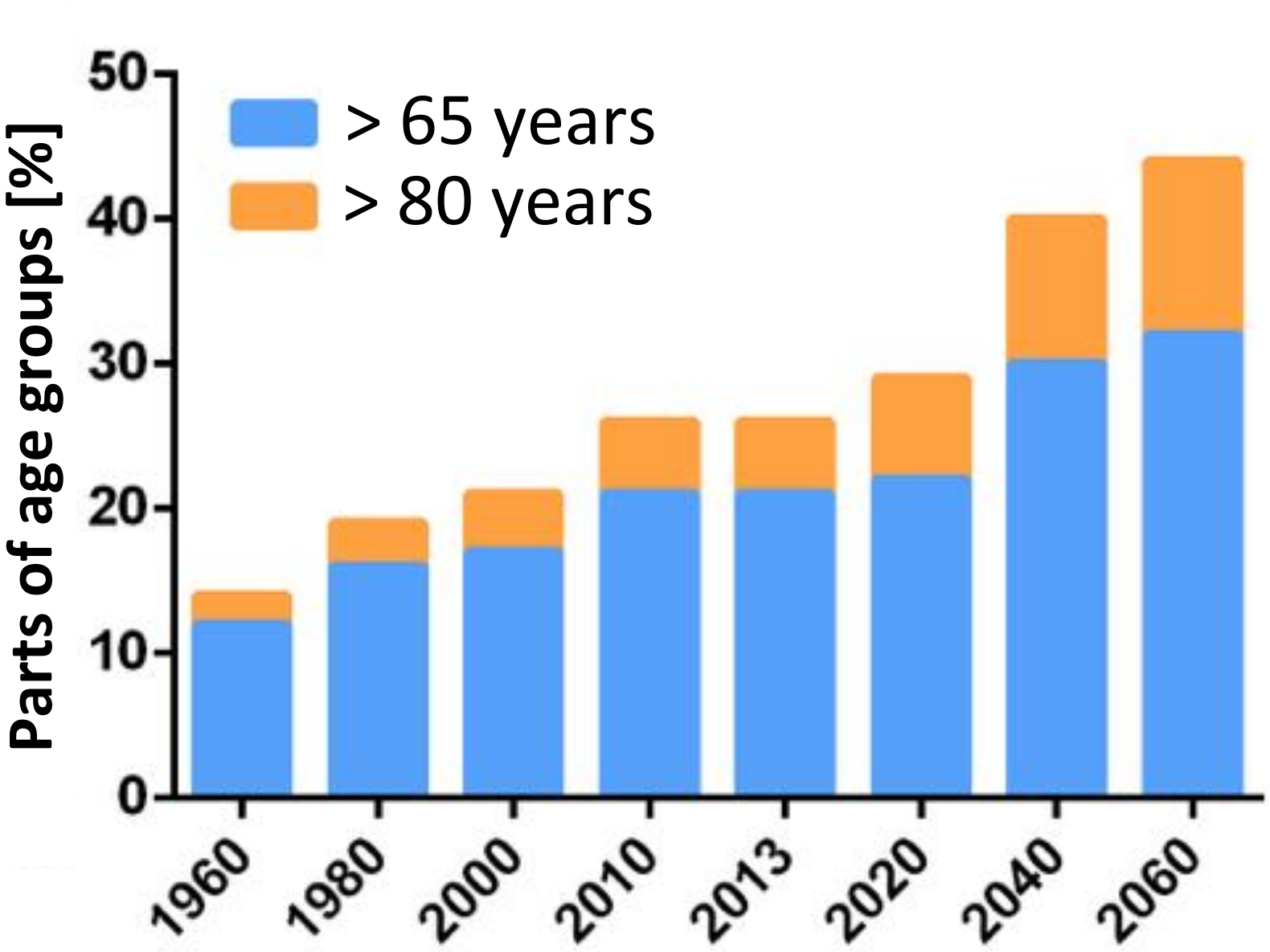
UNIKLINIK RWTH AACHEN

Background

„POS(S)E“

UNIKLINIK RWTH AACHEN

Background



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Statitisches Bundesamt, 2017; http://www.destatis.de

Background

University Hospital RWTH Aachen Procent of total 01.01-31.12.2016	Age [years] > 65	Age [years] > 80
AS (%)	30,0	6,0
VS (%)	51,3	9,3
Gyn (%)	9,7	1,3
CS (%)	50,1	6,9
HNE (%)	26,7	3,9
NS (%)	35,2	7,0
OR (%)	36,1	7,1
PC (%)	22,1	3,9
Trauma (%)	25,2	10,0
UR (%)	33,4	7,2
Total (%)	**32,0**	**6,3**

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Background

Surgical Outcomes for Patients Aged 80 and Older: Morbidity and Mortality from Major Noncardiac Surgery

Mary Beth Hamel, MD, MPH, William G. Henderson, PhD,†‡§ Shukri F. Khuri, MD,‖ and Jennifer Daley, MD¶*

30-Tage Letalität			
Eingriff	**Alter <80 Jahre (n=568,263)**	**Alter ≥ 80 Jahre (n=26,648)**	**P-Wert**
Alle Eingriffe	2.8%	8.2%	<0.001
Viszeralchirurgie	4.3%	11.4%	<0.001
Gefäßchirurgie	4.1%	9.4%	<0.001
Thoraxchirurgie	6.3%	13.5%	<0.001
Urologie	0.7%	1.9%	<0.001
Neurochirurgie	2.4%	8.6%	<0.001
HNO/MKG	2.5%	8.8%	<0.001
Orthopädie/UC	1.2%	8.3%	<0.001

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Hamel MB. J Am Geriatr Soc 2005; 53: 424-429

Study synopsis

Study title	Peri-interventional Outcome Study in the Elderly: European, multicentre, observational cohort study
Study registration	NCT03152734
Study objectives	POSE aims to be the first study to create evidence on peri-interventional mortality and outcome in the elderly population
Study duration	Study subject: 30 days Recruitment period per Center: 30 days Recruitment period: 01.10.2017-31.09.2018
Patients number	7500 patients
Number of centers	Approximately 100-200 centers
Inclusion criteria	1. Age ≥ 80 years 2. Written informed consent 3. All consecutive patients undergoing surgical and non-surgical interventions with anaesthesia care within the selected inclusion period of 30 days 4. Elective and emergency procedures
Exclusion criteria	1. People who are institutionalized by court or administrative order 2. Patients with re-intervention within the 30 days recruitment period

Study synopsis

Primary endpoint	Determine the peri-interventional all-cause mortality rate on day 30
Secondary endpoints	Major complications, functional and cognitive outcome until the post-interventional day 30
Visits	**Visit 1 (Baseline):** Patient demographics, functional and cognitive status, medical history, frailty and referring facility **Visit 2 (Intervention):** Intervention- and anaesthesia-related data and kind of post-interventional care **Visit 3 (Follow-up on day 30):** Medical record review/telephone interview: Mortality and serious cardiac/pulmonary complications, stroke and acute kidney injury after hospital discharge, if they led to hospital re-admission, patient´s functional and cognitive status

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POSE

2016	POSE idea
11/2016	Fokus-Meeting
05/2017	Launching POSE website
05/2017	Call for national coordinators
08/2017	60 Centers registered
09/2017	OpemClinica data base
09/2017	First Patient included
10/2017	100 centers registered
03/2018	25 % of Patients included
05/2018	50 % of patients included
05/2018	191 centers registred

www.pose-trial.org

POSE Peri-interventional Outcome Study in the Elderly
European Society of Anaesthesiology ESA Research Group

POSE Endorsement

Endorsed by

European Society of Anaesthesiology Research Group
https://www.esahq.org/research/research-groups/pose

SGAR (Suisse Society of Anaesthesiology and Reanimation)
http://www.sgar-ssar.ch

DGAI (German Society for Anaesthesiology and Intensive Care Medicine)
https://www.dgai.de/die-dgai/aufgaben-und-ziele/about-us

SFAR (French Society of Anesthesia & Intensive Care Medicine)
http://sfar.or

POSE

European Society of Anaesthesiology ESA Research Group
POSE
Peri-interventional Outcome Study in the Elderly

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POSE

Participating Centres

192 registered centres (04. June 2018)

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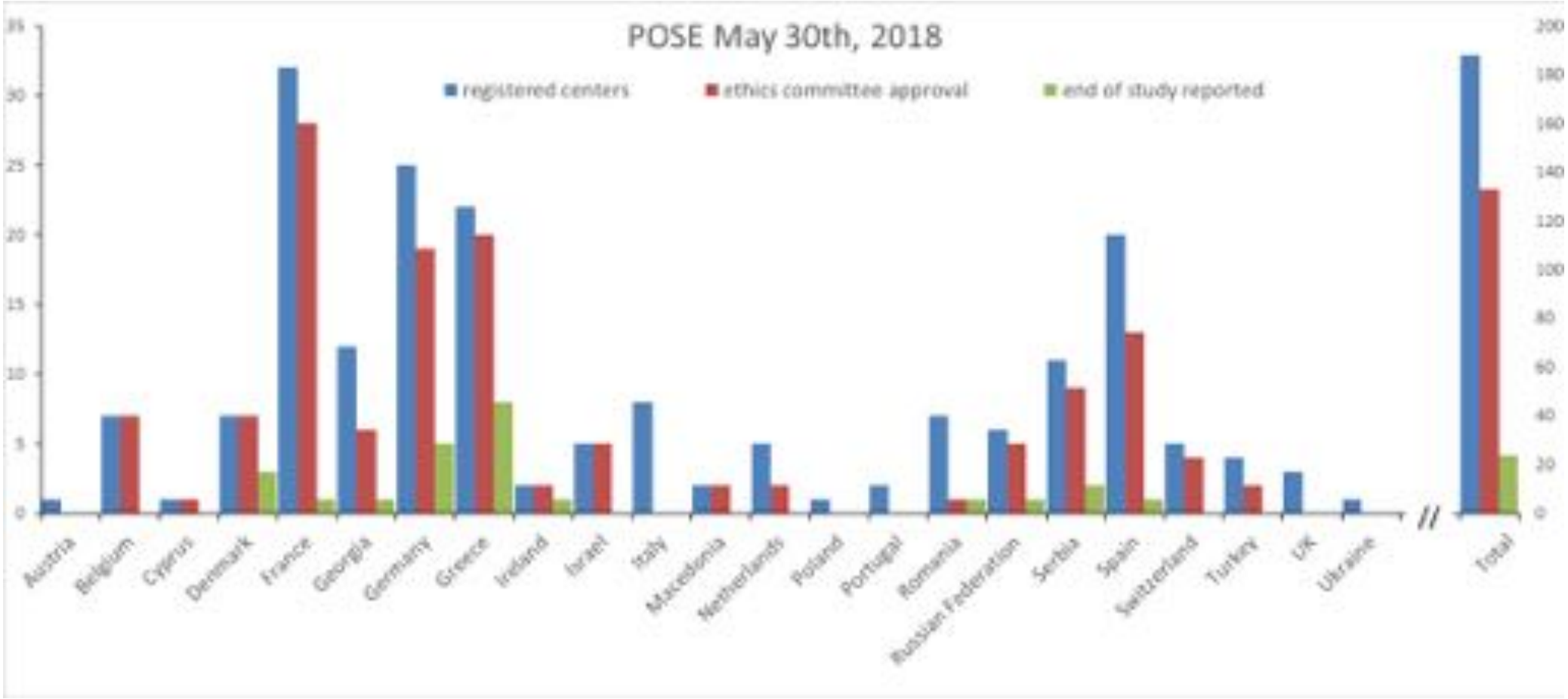
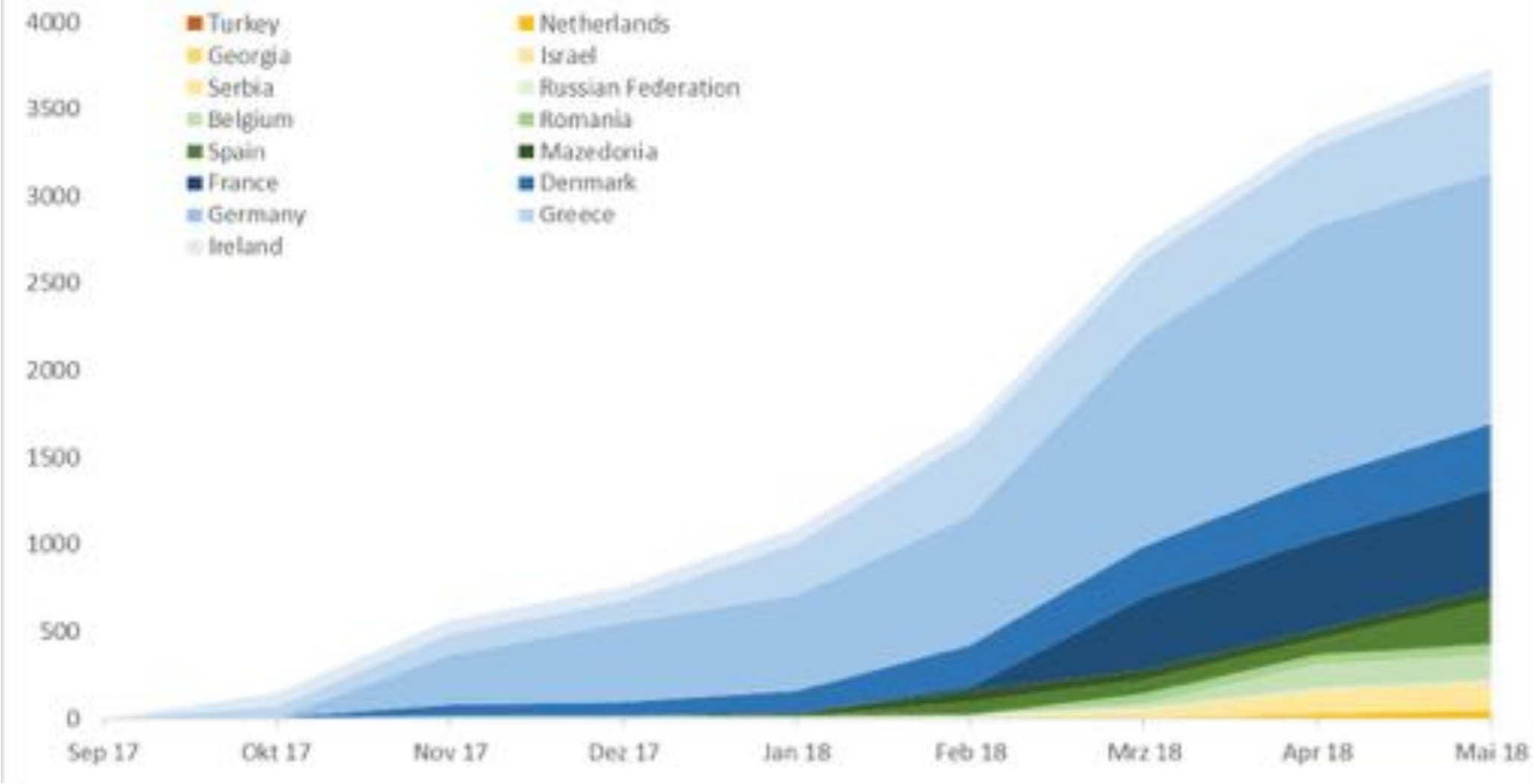
POSE


POSE May 30th, 2018
registered centers
ethics committee approval
end of study reported
Austria
Belgium
Cyprus
Denmark
France
Georgia
Germany
Greece
Ireland
Israel
Italy
Macedonia
Netherlands
Poland
Portugal
Romania
Russian Federation
Serbia
Spain
Switzerland
Turkey
UK
Ukraine
Total

POSE

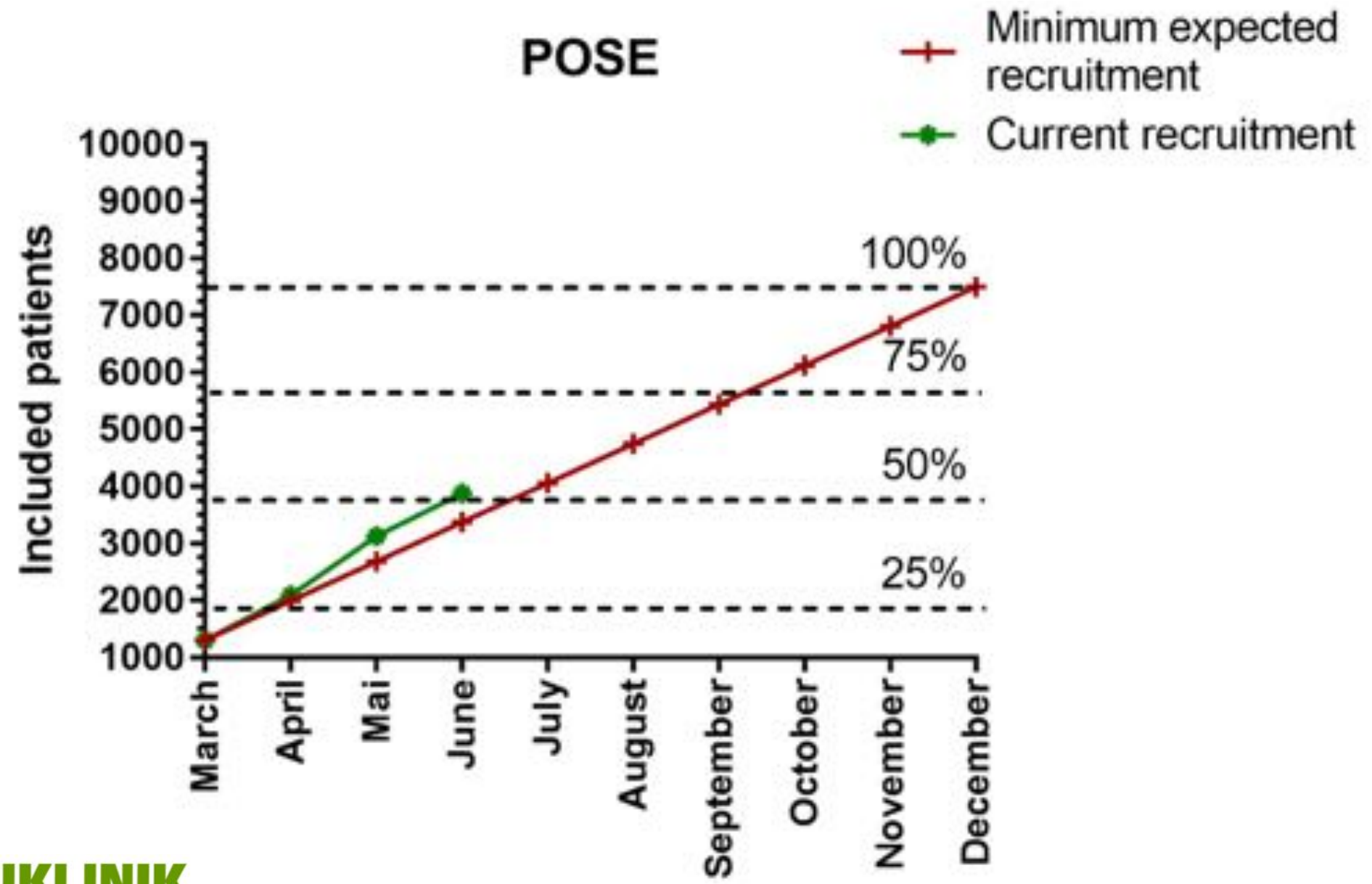
3895 (52%) documented patients in 71 centers until June 4th, 2018



Top 10 Recruiter

	Site	Country	Enroled patients
1.	LMU München	Germany	216
2.	Hannover Medical School	Germany	167
3.	Herlev Hospital	Denmark	148
4.	Universitätsklinikum Schleswig-Holstein Campus Lübeck	Germany	141
5.	University Hospitals Leuven	Belgium	136
6.	University Hospital Tübingen	Germany	135
7.	St. Franziskus-Hospital Münster	Germany	133
8.	CHU Toulouse	France	131
9.	Johannes Wesling Klinikum Minden	Germany	115
10.	University Hospital RWTH Aachen	Germany	112

POSE



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POSE end of recruitement now 31.12.2018

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POSE

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09/2017	First Patient included
10/2017	100 centers registered
03/2018	25 % of Patients included
05/2018	50 % of patients included
05/2018	191 centers registred
12/2018	End of recruitment
01/2018	End of follow-up
03/2018	Data base closed
06/2018	POSE Manuscript

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POSE Peri-interventional Outcome Study in the Elderly
European Society of Anaesthesiology ESA Research Group

GDPR

- Information letter for Investigators
  - Confirm receipt

- Information letter for participants (still recruiting or follow-up; Log remains in centre)
  - Patient information sheet log
  - No patient signature needed

GDPR

New Information About Your Data Privacy Rights

Principal Investigator	Site
XXX NAME XXX	Name of Hospital

- POSE-

Peri-interventional **O**utcome **S**tudy in the **E**lderly

EUROPEAN, MULTI-CENTRE, PROSPECTIVE OBSERVATIONAL COHORT STUDY

Dear Study Subject,

within the framework of the introduction of the new General Data Protection Regulation (GDPR) of the European Union, the Data Protection Law has been updated. The Data Protection Law covers the regulation of the secure handling of personal data and those affected are granted important rights with regard to their own data. The information that sponsors must provide to participants of clinical trials is subject to significant changes.

GDPR

Data Protection Information Sheet Issuing Log
-POSE study-

Principal Investigator	Site	Clinical Trials.gov
Name	Name of Hospital	NCT03152734

Data Protection Information Sheet Issuing Log

Subject ID	Date	Issuing of Data Protection Info Sheet		
		□ personally	□ e-mail	□ by post
		□ personally	□ e-mail	□ by post

GDPR

Changes to the European Data Protection Law
-Information for Investigators-

INFORMATION SHEET ON THE GDPR FOR STUDY SUBJECTS SIGNATURE PAGE FOR THE PRINCIPAL INVESTIGATOR

Study: Peri-interventional Outcome Study in the Elderly
SITE: XXX-XXX
PRINCIPAL INVESTIGATOR (First name, Last name): XXXXXXXXXXXX

Dear Sir or Madam,

I hereby confirm that I have handed over the attached information letter on the General Data Protection Regulation (GDPR) to all study subjects.

_____ _____

Name of the Principal Investigator Date

_____

Signature

Please place the original of this signature page in the investigator site file.

Please send a copy to the following fax number: +49-241-80-3335766

or

E-mail: akowark@ukaachen.de

Add Attachment: Information Sheet on the General Data Protection Regulation (GDPR) for study subjects.

POSE to do

- Call for National Cooridinators (Sweden, Finnland, Norway, Iceland)
- Reach out for further Centers!!
- Data Quality (primary outcome parameter)
- Data querries
- POSE Screeing List
- POSE End of Study Reporting Form
- GDPR Form Investigators

POSE and more

Research ideas may be submitted to the POSE ESA Research Group

mcoburn@ukaachen.de

www.pose-trial.org

Register now!

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