

## First patient randomized!

SENATOR has overcome many challenges and we are delighted to announce the commencement of phase 2 of the trial. Congratulations to the Cork site on randomizing the first patient yesterday!



It will be important to hit recruitment targets due to the delay in starting the trial. Weekly updates will be circulated with recruitment progress and targets.



The Cork site will continue to recruit for the next few weeks to ensure smooth running and we will be touch to give the green light to start at your site.

In addition to liaising with your competent authorities for written confirmation the SENATOR trial is not a regulated study in your country, please use this time to continue to raise awareness of the SENATOR trial in your hospital, distribute your clinician information sheets and ensure clinicians are supportive of the trial.

## Workpackage 05

Workpackage 05 (Pilot testing and scientific validation of the SENATOR software) was recently completed which means we have a fully functioning software. After validation, the SENATOR software in comparison to the gold standard (two experienced clinical physicians) had a kappa coefficient of 0.8)

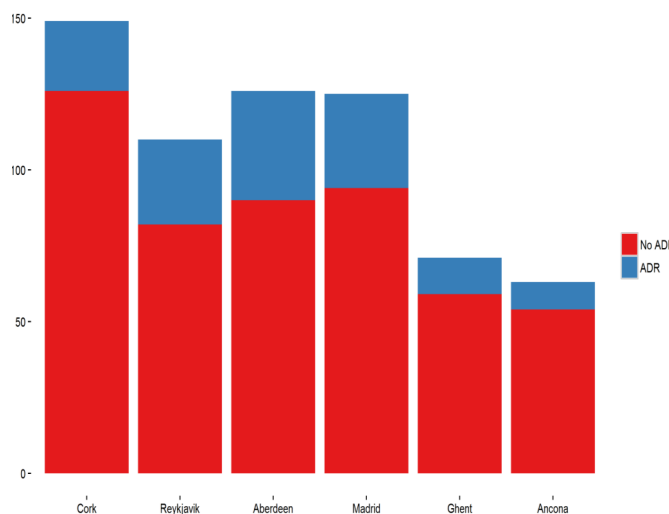
## Phase 1 Data

Data cleaning and adjudication of phase 1 data is complete. We would like to take this opportunity to thank all of our Primary Investigators and Primary Researchers for their hard work during the data cleaning and adjudication process. Your continued support and efficiency is greatly appreciated.

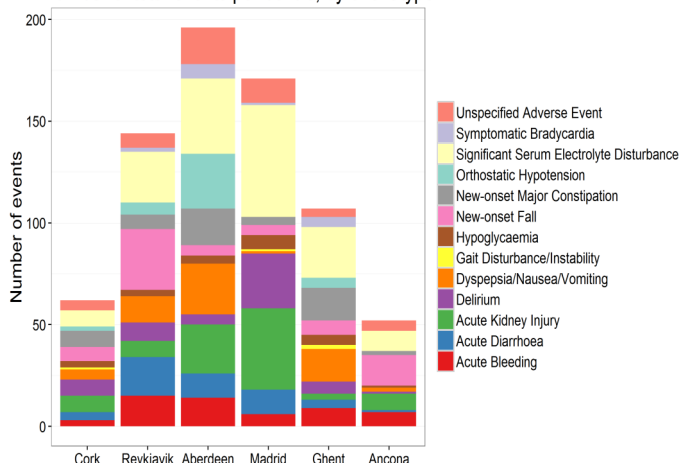
Darren Dahly, our statistician has analyzed the data and the overall incident ADR rate was 21-22%. Some results are shown below but you will see full details in the final Trial Progress Report which will be circulated shortly.



Absolute number of ADRs per centre



Number of total events per centre, by event type



## Version Control Check

Please make sure you are using the most up to versions of forms and older versions have been marked as superseded.

Document	Version	Date
Protocol	V7.0	21 Oct 15
CRF	V3.0	11 Jul 16
Evidence forms	V4.0	11 Jul 16
Manual of operations	V1.0	31 Mar 16
SOP 01—Reporting prevalent and Incident Adverse Events	V1.0	31 Mar 16
eCRF Completion guidelines	V1.0	11 Jul 16
Patient ID log	V2.0	23 Mar 16
Trial Deleterious Event form	V1.0	April 14

## Dates for your Diary

Date	Event	Location
17th Aug 16 13:00-14:00 CET (to be confirmed)	PR monthly Telco	Telco
7th Sept 16	Primary Researcher Training	Ghent
8-9th Sept 16	Annual General Assembly Meeting	Ghent
29th Sept-1st Oct	IGS	Killarney
7th Oct 2016	EUGMS	Lisbon
6-9th Oct	EACPT	Croatia
23-25th Nov	BGS	Glasgow



SENATOR team at the annual General Assembly meeting in Ancona—Sept 2015

## Welcome new members to the SENATOR Team



Dr Sandra Nelson  
Primary researcher  
Aberdeen



Dr. María Soledad Ferreiro Cotorruelo  
Primary Researcher  
Ancona



Védís Húnbogadóttir  
Primary Researcher  
Reykjavik



Kieran Dalton  
Primary Researcher  
Cork



Denis Curtin  
Primary Researcher  
Cork



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