

SafeBoosC News

Dear SafeBoosC participant,

Welcome to the first SafeBoosC Newsletter. Our plan is to circulate a short update every month to keep you all informed about recent movements within the SafeBoosC trial.

Consortium Agreement:

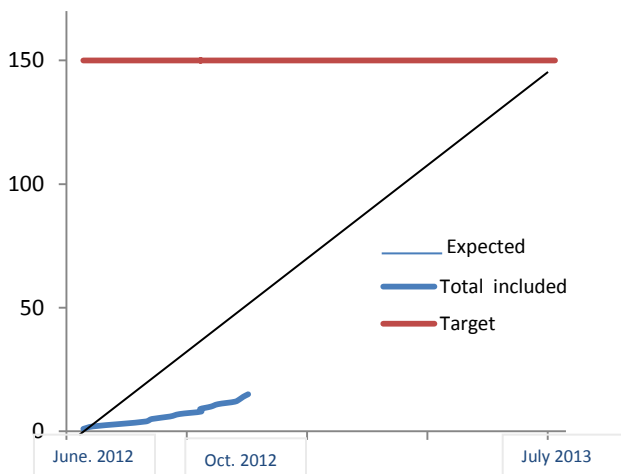
Axel Franz will be the PI for Tübingen. He will replace Claudia Roll who was not able to participate since the German Medicines Device Agency required 2 years of experience with device trials to be approved as a national PI.

Data Monitoring Safety Committee (DMSC):

First data-set was sent to DMSC in September and gave rise to no comments. Cuno Uiterwaal has withdrawn and Armin Koch has kindly accepted to take on the task as the DMSC biostatistician.

Status: Six sites have obtained full approval for the SafeBoosC trial. Five are now enrolling.

By 25 Oct, 16 participants have been enrolled. Is the 'growth curve' approaching catch up ☺?



Site	Recruiting	Screened	Included	Targeted
Graz	+	5	2	5
Leuven	-	0	0	5
Zurich	-	0	0	5
Tübingen	-	0	0	5
Copenhagen	+	22	8	20
Madrid	+	9	5	35
Lyon	+	1	1	20
Cork	+	0	0	25
Milan	-	0	0	5
Utrecht	-	0	0	15
Uppsala	-	0	0	5
Cambridge	-	0	0	5
Total		37	16	150

SOPs/eCRF:

Are currently being revised, latest version can always be found at the website

Clinical Investigational Plan (CIP):

When most countries have obtained full approval for trial initiation there will be an amendment: CIP v.4.0

Oxyprems: Those who are interested in testing these please contact Martin for organising this.

Calendar

SafeBoosC Annual F2F Meeting 2013, Dragør, Denmark:

A doodle has been sent out, please visit the link to give your vote for the date most convenient for you !

Best wishes,
Gorm & Berit