

## DEAR ALL,

This is part 6 of the GLORIA newsletter, to inform you about the news around the GLORIA trial. Recruitment progresses too slow. This is a major concern since we have to include 747 patients more patients in the coming 9 months (and now we included 53 in the past 9 months)... So we need 'all hands on deck' to fulfil our milestones!



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## RECRUITMENT AND INCLUSIONS

At the moment, GLORIA is ready to include patients in 25 of the 30 sites. We would like to congratulate: Prof. Van Laar, prof. Boonen, Dr. Kok, Dr. Klaasen and Dr. Bos from the Netherlands, Prof. Da Silva and Dr. Micaelo from Portugal, Prof. Cutolo from Italy, and Dr. Opris from Romania included their first patient(s). Since we still need 747 patients to include, extensive attention for recruitment is needed. In the Netherlands, last three months we organized two investigator recruitment meetings: one face-to-face meeting and two telephone meetings. During these meetings, the following interesting points were discussed:

Inclusion criteria:

- RA according 1987 criteria is also OK!
- DAS28 $\geq$ 3.2, NB no other disease activity criteria, so e.g. also patients without swollen joints can enter (but try to avoid fibromyalgia patients in remission)
- Age  $\geq$  65 years, birthday on date of inclusion is OK!

Exclusion criteria:

- Change, stop or start of antirheumatics in the past 3 months.  
HOWEVER, start or change of medication at baseline (right away after inclusion) is OK!  
**This includes giving an im or ia injection with glucocorticoids**, as the protocol allows a total of 2 im injections and 4 ia injections in the 2-year study period.

Recruitment:

- Attendees indicated that pre-screening the patients statuses is very useful. If this is done during for example the preparations of the visits for clinical care, than this is not that much work.

## STUDY MEDICATION

- When using the pill bottle for the first time and you remove the sticker, please look carefully if the little red lamp beneath it is burning for 3 times. This indicates the bottle is activated.
- Please do not forget to enter the current RA medication EVERY visit into the eCRF, since RA medication is a very important outcome of the trial.

## ECRF

- We know it is quite some work to enter all study data during the first visit. But please do not be discouraged, the follow-up visits are much less work.
- When laboratory analyses have not yet been completed at the time of the GLORIA visit, you can tick these as missing in the eCRF. In that case, please open an unscheduled visit in the eCRF when the data is available for you to enter. Of course it is not a real visit, the patient need not be present for this.

## TIPS & TRICKS

- **GOOD CLINICAL PRACTICE:**

Personnel involved in clinical research needs to be GCP certified. This is the responsibility of the PI. Below some links where you can find some free, online GCP training.

<https://gcp.nidatraining.org/>

<https://www.acrpnet.org/courses/introduction-clinical-trials>

## BEST REGARDS,

Prof. Maarten Boers, scientific lead  
Leonie Middelinck, MSc., project lead  
Linda Hartman, MSc., PhD candidate  
Linda Rasch, MSc., support manager

## UPDATE

SITE / INVESTIGATOR	PLANNED # PATIENTS	STATUS
<b>NETHERLANDS</b>		
101 Lems	40	<b>10 patients included</b>
102 Van Laar	15	<b>1 patient included</b>
103 Meek	15	Ready to start recruitment
104 Allaart	15	Ready to start recruitment
105 Starmans	15	Ready to start recruitment
106 Boonen	20	<b>1 patient included</b>
107 Griep	15	<b>8 patients included</b>
108 Kok	15	<b>1 patient included</b>
109 Klaasen	15	<b>1 patient included</b>
110 Van Woerkom	15	Ready to start recruitment
111 Ruiterman	15	Ready to start recruitment
112 Bos	15	<b>3 patients included</b>
113 Bruyn	15	Ready to start recruitment
114 Jansen	20	Approval pending
115 Spoorenberg	10	Approval pending
<b>GERMANY</b>		
201 Buttgereit	20	<b>1 patient included</b>
202 Aries	20	Ready to start recruitment
204 Sieburg	20	<b>1 patient included</b>
205 Prothmann	15	Ready to start recruitment
<b>PORTUGAL</b>		
301 Da Silva	15	<b>4 patients included</b>
302 Branco	10	Approval pending
303 Saavedra	10	Ready to start recruitment
304 Micaelo	10	<b>2 patients included</b>
305 Do Carmo Alfonso	15	Approval pending
<b>SLOVAKIA</b>		
401 Rovenský	70	<b>1 patient included</b>
<b>ITALY</b>		
501 Cutolo	100	<b>12 patients included</b>
<b>HUNGARY</b>		
601 Szekanecz	100	<b>3 patients included</b>
<b>ROMANIA</b>		
701 Opris	100	<b>4 patients included</b>
<b>FINLAND</b>		
801 Tuulikki	20	Approval pending
804 Puolakka	20	Ready to start recruitment
<b>Total # of patients included: 53</b>		

