Newsletter

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1000th participant randomized!

In October we have reached the major milestone of **randomizing** the **1000th** participant in the Renal Lifecycle trial! A BIG thank you to all involved Renal Lifecycle study team members. We acknowledge the dedication and hard work of all study team members. Keep up the excellent work and let's continue together to make this trial a success! Moreover, Belgium has finally been approved by the CTIS procedure. We would like to thank prof. dr. Dirk Kuypers and the participating sites for their patience and good luck with the start of the trial!

Focus on dialysis and transplant

The largest subgroup in the trial remains the CKD participants. We kindly request to keep focusing on enrolling dialysis participants (with and without residual diuresis) and transplant recipients. For transplant participants, please keep an eye on those patients with an eGFR <45 ml/min/1.73m^3 and higher albuminuria (i.e. >30 mg/24hr or > 3mg/mmol). Because these are the patients with progressive kidney disease.

Study progress — endpoints

As the follow-up period for participants is becoming longer, we are starting to collect more and more endpoints. The first potential endpoints for heart failure have been discussed in the Clinical Adjudication Committee as well. We kindly request all sites to ensure that all potential endpoints are reported within REDCap. Thank you!

REDCap topics of the month

Registration co-medication

This months topic is about the registration of co-medication in REDCap. We want to highlight the importance of verifying co-medication changes at every study visit and record changes in REDCap .

MEDDRA coding

Within the AEoSI, DAE and/or SAE CRF page, a change will be made to the MEDDRA field. It has been decided to change this field from 'mandatory' to 'read-only'. Please ensure that the description of the Adverse Event is as complete as possible and matches with the SAE form (if applicable). MEDDRA coding will be completed for future cases by the Data Management team.

Drug accountability forms

The central monitoring team noticed that drug accountability is not always completed the way it is described in the protocol. Please make sure that drug accountability forms are filled in and reported in REDCap. In case of questions or remarks you can reach out to the UMCG team, we are happy to help!

Inclusion champions — region Rotterdam

In this newsletter we would like to take a moment of appreciation for the participating centres in the Rotterdam region! The regional coordinator is Jeroen van der Net, nephrologist at the Albert Schweitzer hospital. During the trial the inclusion rate in his region has been very high and participating sites keep randomizing new participants. The Albert Schweitzer hospital randomized 39 participants until now!

Dr. Jeroen van der Net

We would like to thank Jeroen and the local study teams for their great contribution!