Newsletter

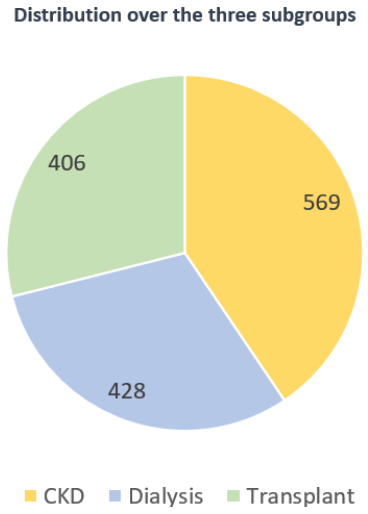
Issue 19· April 2025

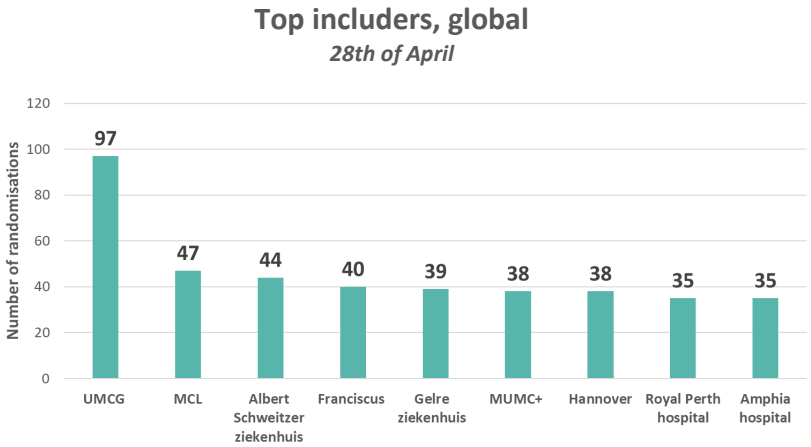
Recruitment

The current number of randomized participants has now reached **1325** in the overall trial. Thank you all for your efforts!

With the recruitment goal of 1750 participants, this means 425 new participants have to be randomized in the next few months.

Please find some key graphs the trial below.





First inclusion Belgium!

We are happy to see that the trial is still expanding to other countries. Last month Belgium had their first inclusion. Congratulations to the national leader Dirk Kuypers (UZ Leuven) and the study teams! At the moment the UZ Leuven, AZ Groeninge (PI : Gert Meeus) and AZ Glorieux (PI: Elien Mahieu) are activated.

Regulations (temporarily) stop medication

Clarifications regarding the discontinuation of study medication:

- **Temporary interruption of study medication exceeding 28 days** must be reported to the Sponsor via email. When the participant resumes the study medication, this should also be communicated to the Sponsor by email. Participants should restart the medication as soon as their treating physician considers it medically appropriate. Sponsor approval is not required to resume treatment.
- **Adverse Events leading to Discontinuation of study medication (DAE)** must be reported on the (S)AEoI page in REDCap. We emphasize the importance of accurately reporting these events.
- As highlighted in the February newsletter, **SGLT-2 inhibitors should not be initiated outside the trial** to avoid contamination of the placebo group. If discontinuation of an SGLT-2 inhibitor is not feasible, the participant should discontinue the trial medication but continue attending follow-up visits. In such cases, it is crucial to document the SGLT-2 inhibitor use on the co-medication page in REDCap to ensure clarity during later analyses regarding SGLT-2 exposure.

Patient representative committee going global

We are excited to announce the international expansion of the Renal Lifecycle's trial patient representative committee. Until now, we have been supported by the Dutch patient advisory board of the trial who's valuable input helped to optimize the design, conduct and communication of the trial from a patient's perspective. A current topic is developing a questionnaire about participant's experiences with the trial. From this month on the meeting will be joined by patient representatives from Australia, Belgium and Spain. We look forward to learning from their insights to further enhance the trial experiences and improve future trials.