Newsletter

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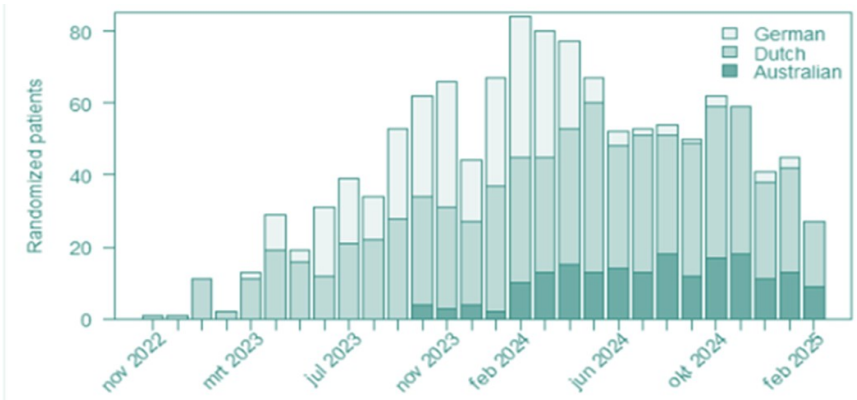
RENAL LIFECYCLE TRIAL

Please stay focused on our recruitment goal !

The first two months of the year have flown by. As always, we monitor recruitment progress. Since December 2024, we've noticed a slight decline in recruitment numbers. Overall number of randomized subjects is now 1250. From November 2023 to November 2024, we were consistently randomizing around 50 to 80 new participants per month. However, since December, this number has dropped to approximately 40 participants per month. While we're excited to see new sites joining the trial, it's important that we all remain focused on enrolling participants to reach our goal of 1,750 randomized participants by the end of 2025. Recruitment is challenging, but with everyone's continued dedication, we are sure that we will be able to achieve this target. Thank you for your ongoing commitment our study. Let's keep up the momentum to ensure success !



No SGLT2-inhibitors in standard care

Upon participant enrollment, it is vital to inform other treating specialists about the trial participation. This can be done by sending a letter or adding the trial medication to the participant's medication list. This is crucial, as SGLT-2 inhibitors should not be initiated outside the trial to avoid "contaminating" the placebo group. As you know, there is insufficient evidence for the efficacy of SGLT-2 inhibitors in this population in routine care. To collect evidence about the efficacy-to-safety ratio is therefore the rationale for the Renal Lifecycle trial. In case an SGLT-2 inhibitor is prescribed in routine practice, consider consulting the prescribing doctor to discontinue it. If discontinuation is not possible, the participant should stop using trial medication but continue follow-up visits.

Any medication discontinuation must be documented in REDcap, and the SGLT-2 inhibitor should be recorded as a concomitant medication.

Collecting endpoints and retention

There are two other aspects of large scale trials that merit your attention: endpoint collection and participant retention. The Renal Lifecycle trial is endpoint driven, with a goal of collecting 468 confirmed endpoints. We are still in the early phase of the trial. So far we have collected around 70 endpoints. As participants remain in the trial longer, this number will grow. Completing recruitment sooner will help accelerate endpoint collection. And please do not forget to report these endpoints in the eCRF. Retention is also critical. The first participant was randomized in November 2022. As the trial continues, participant drop-out rate tends to increase. This will lead to underestimation of the treatment effect. Retaining participants in the study for the entire duration of the trial will therefore be essential for the success of the study.

New study medication delivered to all sites

As previously announced, we are approaching the expiration date for part of the study medication (end of July 2025). New medication with extended expiration dates have been sent and are now delivered to all centers. Please ensure that the pharmacy registers the medication before it can be prescribed in ALEA. If the pharmacy has not completed this step, you will receive a notification stating "read-only: insufficient inventory". If you encounter this issue, please contact your local pharmacy first. In the coming months, you will receive further instructions regarding the destruction of expired medication.