Newsletter

Issue 23· September– October 2025

Study progress

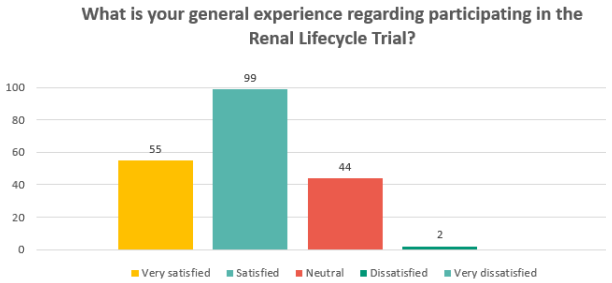
As of now, **1474** participants have been successfully randomized. This indicates that we have met our primary target of enrolling 1440 participants. We did so on schedule, which is a great accomplishment for an investigator initiated trial. We are also pleased to announce that **Spain** has included their first participant this month. Well done to everyone involved!

Please note that this is an endpoint-driven trial. For the CKD as well as the dialysis subgroups, the incidence of endpoints occurs largely in line with initial expectations. However, the kidney transplantation group has yielded fewer endpoints than anticipated. To enhance statistical power, we have therefore submitted a request to extend the **total number of participants to 1750**, which has recently been approved by the Medical Ethical Committee.

Lastly, we would like to share that the **DSMB** concluded in their recent meeting that there are **no safety concerns**, and the trial can continue without modification.

Results survey on participants' experiences in the trial

We recently conducted a **survey among Dutch participants** in the Renal Lifecycle trial, in collaboration with the Dutch Patient Federation. The survey focused on participants' experiences with the trial and a total of **200 participants responded**. Overall, participants reported high levels of satisfaction with their involvement in the trial (see graph). They felt well-supported throughout the study, reported a low burden of participation, and were satisfied with the information provided.



One key takeaway from this survey is the importance of improving how we communicate to ensure that participants feel to be participants, and not to be subjects. Participants had several **suggestions for the newsletter**, including overviews of updates per country, sharing experiences of trial participants, insight in side effects and information about initial results. We will include these topics in the coming newsletters for participants. Moreover, for future trials it would be beneficial to include consent for direct (email) communication from the sponsor or the patient advisory board in the informed consent form. This would allow us to share important updates—such as newsletters– directly with participants, enhancing patient engagement while also reducing the administrative burden for local study staff.

Update Orikami app for the Cognition Test

The Orikami app **measures cognition** of participants in the Renal Lifecycle Trial and is of crucial importance as previous studies showed an effect on SGLT-2 inhibitors on cognition in early-stage CKD. We want to test whether this is also the case **in late stage CKD**. The Orikami team informed us that an **update of the Orikami app** is available. Although many devices automatically update their app some may not. If there are problems with the app, please check for updates in the App store or Play Store.

Key data entry clarifications

Adverse events of Special Interest

Please ensure that you **correctly report** the following **AEoSI's** on the SAE form in REDCap: **urinary tract infection, genital infection, significant hypoglycemia and diabetic ketoacidosis**. We noticed that this is not always the case.

REDCap stop study medication pages

- Use the **temporarily stop medication page** when a participant pauses study medication temporarily.
- If a participant permanently discontinues medication, this must also be reported on the **medication termination page.**