Newsletter

Issue 24· January 2026

Study progress

We are pleased to share that, as of today, a total of **1,584** participants have been randomized in our trial. We are excited to highlight that **Spain** has now contributed its first enrolled participants, and **Singapore** will follow per this week. **Many thanks** for your continued commitment!

Stop Study Medication & End of Study

It is now essential for the success of the study that patients remain on study medication. Please keep the medication discontinuation rate as low as possible. For instance, when a participant has CKD, and starts dialysis, medication can be stopped temporarily, but this participant should restart study medication after start of dialysis.

We will analyze the trial as intention-to-treat. This has consequences. If medication is discontinued but the participant stays in the study, all follow-up visits should continue as planned, ideally on site. If not possible, follow-up by phone and use of available clinical data are allowed. If a participant wishes to withdraw entirely, arrange an Early End of Study visit and ask for consent to vital status collection at study end.

REDCap Forms – Which form to use when?

- End of Study (EOS): Complete when a participant fully withdraws from study participation (e.g., withdrawal of consent or death).
- Study Medication Termination: Complete at any time study medication is definitively stopped.
- Study Close-Out Visit: Complete for both End of Study (EOS) and Early End of Treatment (EET).

If only study medication is discontinued and the participant remains in the study, only the Study Medication Termination form needs to be completed. All remaining visits should be performed according to schedule.

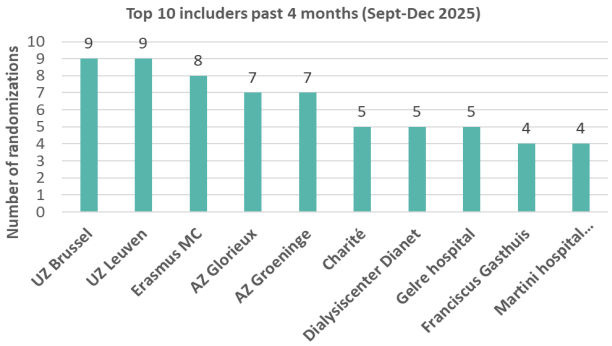
Practical reminders

We would like to highlight several important aspects:

- **Kit number verification**: Please double-check the kit before dispensing to avoid errors.
- **Restarting study medication**: **If study medication is temporarily interrupted, please discuss potential restart with participants.**
- **Open Open-label dapagliflozin**: We are seeing more SAEs reported in participants receiving open-label dapagliflozin while in the hospital. Please remind participants to always carry their study card and to show it if they are admitted. Also, please make sure that participants do not start open-label dapagliflozin.
- **Participant retention:** Please encourage patients to stay engaged and remain on study medication throughout the study as this is key for reliable data and study progress.

Top includers (Sep-Dec 2025)

Below you will find an overview of the centers with the highest number of randomizations over the past four months. Congratulations and thanks to everyone involved!



Follow-up cognition test

For participants enrolled in the Netherlands, Belgium, Singapore and selected sites in Australia, please check whether all new patients have a baseline cognition test been performed and that results are entered in REDCap. Only participants with a baseline test can complete follow-up tests. The app sends out a reminder to do the test at home, but please also remind participants during study visits to do the follow-up tests. If the test is performed on a device at your center, **make sure that follow-up tests are conducted**. Keep an up-to-date overview of which participants use your device and set a reminder for yourself to administer the test during visits. For example, you can use an Excel sheet, an Outlook reminder, or the 'plaknotitie' (sticky note) feature in EPIC. In case of a site switch also remind the new site of need for cognition tests for this participant. If the test is done on a device of the site the participant can be newly entered to the dashboard of the new site and execute the follow-up test on the device of the site. If no device is available on the new site it is possible to let the participant receive a welcome e-mail to do the test at home (if the participant agrees).

www.renal-lifecycle.com

renal.lifecycle.trial@umcg.nl

rlt.monitoring@umcg.nl