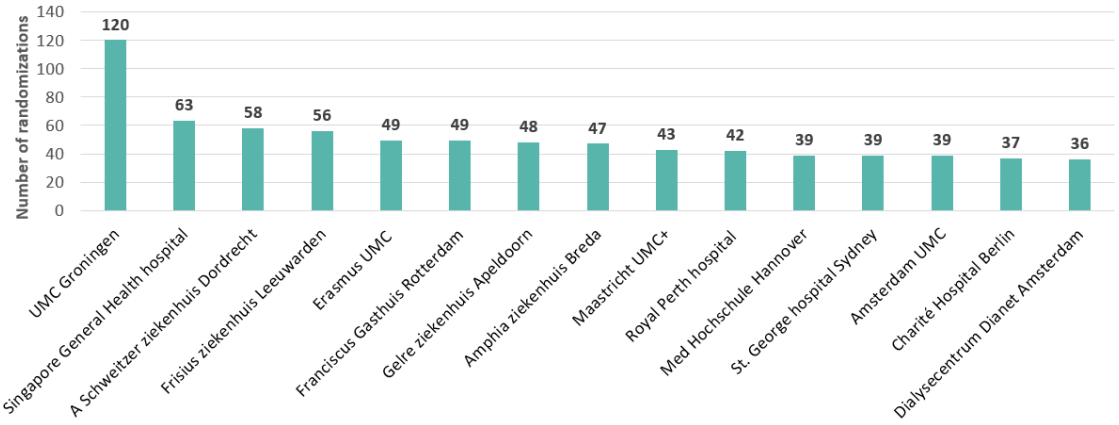
Newsletter

Issue 27· September 2026

Study progress

As of today, a total of 1,826 participants have been randomized in our trial. An important milestone has recently been reached as **randomization will stop on October 1, 2026**! We would like to thank you all for your dedication and hard work. As this is an endpoint-driven trial, participants will continue in the trial until **468 endpoints** have been reached (now we have 305 endpoints). Consequently, the exact trial end date is not known yet. Below you will find an updated overview of the **top recruiting centers worldwide**. Singapore deserves special mentioning. Opened less than 6 months ago they now have included already more than 60 participants. Hurah to Angela Wang and her team. And one additional, very important point: **Please keep patients on study medication!!** This is absolutely key to the success of the trial.



REDCap reporting

CV events

During each study visit, the Endpoint Assessment page in REDCap requires documentation of events that have occurred during the study. This includes recording primary endpoint information as well as any cardiovascular (CV) events or interventions, regardless of whether these were planned or unplanned. Please also add these to the SAE and AEoSI page and verify whether all cardiovascular events/interventions since the date of randomization have been reported. During recent data checks at several centers, we identified cases where CV events had not been accurately or completely reported. Therefore, please review the records carefully to confirm that all CV events and interventions are documented in REDCap. If any events are missing, please add them retrospectively. For more guidance on how to report those events we refer to the e-mail sent on the 1st of July 2026.

SAE's and endpoints

The event team has observed that SAEs reported on paper forms are often not entered into REDCap in a timely manner. Please make sure that, after submitting an SAE, the event is promptly completed in REDCap as well. Since this is an event-driven trial, timely **reporting of SAEs and endpoints is crucial** and directly affects how long the study has to continue.

Complete baseline data

As inclusion will soon be completed, the baseline data will undergo a full review, as these data will be described in an upcoming article. Please ensure that **all queries, particularly those related to baseline data, are resolved as soon as possible.**

Study Medication Expiry

For some sites, part of the study medication stock has an expiry date in October or December 2026. As ALEA calculates dispensing based on 28 days per month, these kits will no longer be dispensed for visits with a 6-month interval (so from visit 5 and later). However, these kits may still be dispensed at Baseline and Month 3 visits. Please ensure that the follow-up visit will be scheduled before the expiry date of the dispensed kits. In general, please ensure that expiring medication is not re-dispensed to participants. Site pharmacists will receive further instructions shortly to invalidate these kits in ALEA.