Newsletter - December 2024

Dear investigators,

Thanks to all your continued efforts, we have now reached **362 inclusions**!
We are very pleased with the progress so far and would like to encourage you to continue including patients in the trial.

We are delighted to announce that **Femke Roelofs** has joined the CASES team. She has started as a PhD candidate in Amsterdam UMC and will focus on the long-term follow-up of patients included in the CASES trial, working closely with the rehabilitation work package of CONTRAST.

The **DSMB** has met again on December 2nd for the third safety analysis and recommends continuing the trial as planned. As we approach our **efficacy interim analysis** (which will be conducted after 300 patients have reached their 90-day follow-up) at the end of January, we would like to highlight some important points:

- We would like to remind you that crossovers without valid reasons are major protocol violations and are strongly discouraged.
- **Missing data in Castor**: We kindly ask your team to complete the eCRF in Castor as thoroughly as possible. If it is difficult to retrieve all required information from the patient's electronic health record, **worksheets are available on our website** and can be used as source data. If certain data are missing, you can use the **'user missing' option.** This can be done by clicking on the small gear icon next to a question or form. For example, if a patient dies before the 3-month unblinded follow-up visit, the entire form can be marked as 'missing.' This ensures that all questions are marked as 'green' and that the progress bar for the eCRF reflects full completeness.
- **Discharge form**: The clinical endpoint is evaluated through centralized follow-up, so it is crucial to **complete the discharge** form. This can be done via the CASES website: https://cases-trial.eu/CASES/ontslag.php.
- **(S)AEs**: Please ensure that the **outcome status** of Serious Adverse Events (SAEs) is updated accordingly. Change the status from **'ongoing' to either 'resolved with/without sequelae' or 'death'**, as appropriate.

We appreciate your attention to these important points.

We wish you all a Merry Christmas and Happy New Year!
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The CASES coordinating team
Dora, Louise, Femke, Anne, Nynke, Annemie, Robin, Paul and Maarten

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My name is Femke Roelofs, and I have been part of the CASES team since December 1st. I completed the double master's degree SUMMA as a physician and clinical researcher in Utrecht. After that, I worked for a year as an ANIOS neurology in a peripheral hospital, and 4 months as an ANIOS in geriatric rehabilitation. I will be working on the new CASES inclusions in the Amsterdam UMC, and will be involved in setting up CASES-EXTENDED, in which we will follow up the CASES patients in the long term. I am very much looking forward to it, and I am very enthusiastic about the collaboration with the CASES team.

Deferred Informed Consent

Informed Consent Reminder for Investigators and Study Coordinators

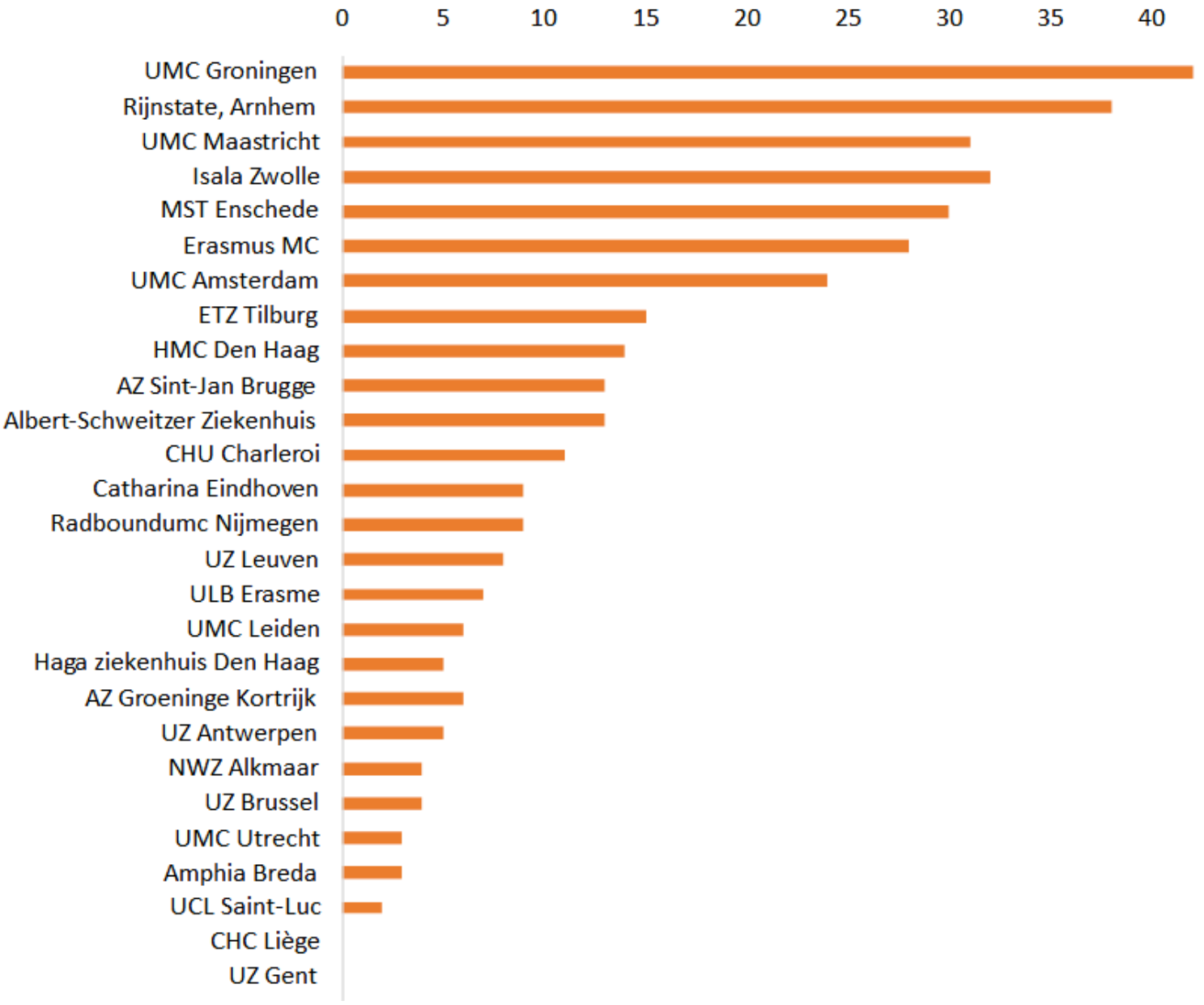
We would like to remind all investigators and study coordinators of the following important procedure:

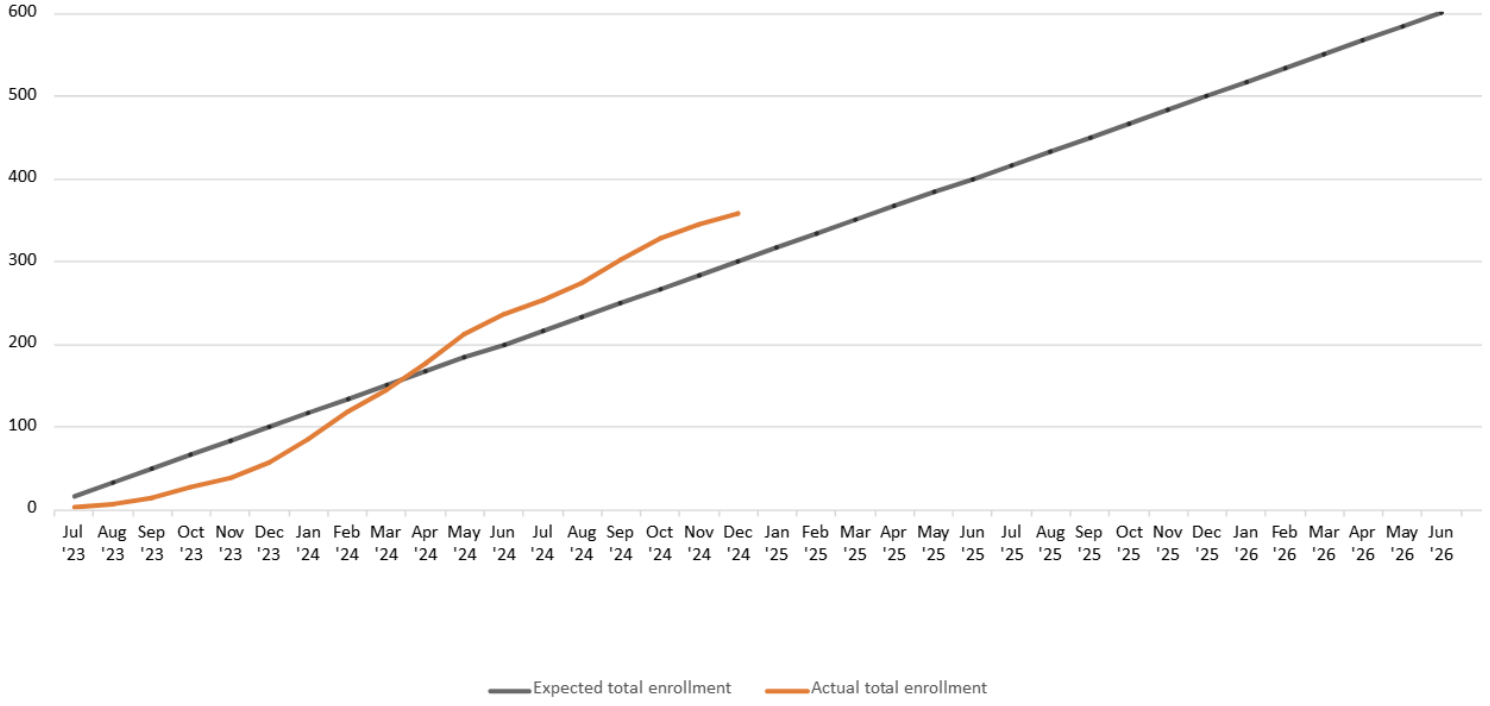
When initial deferred consent has been obtained from a participant's legal representative, it is crucial to also seek consent from the participant directly once their mental competence is restored. This may be at various stages of recovery, such as a few days before discharge, during rehabilitation, or at the 90-day follow-up consultation. If obtaining consent from the participant is not possible (e.g. poor functional recovery, loss-to-follow-up), it is essential to document this on the informed consent log.

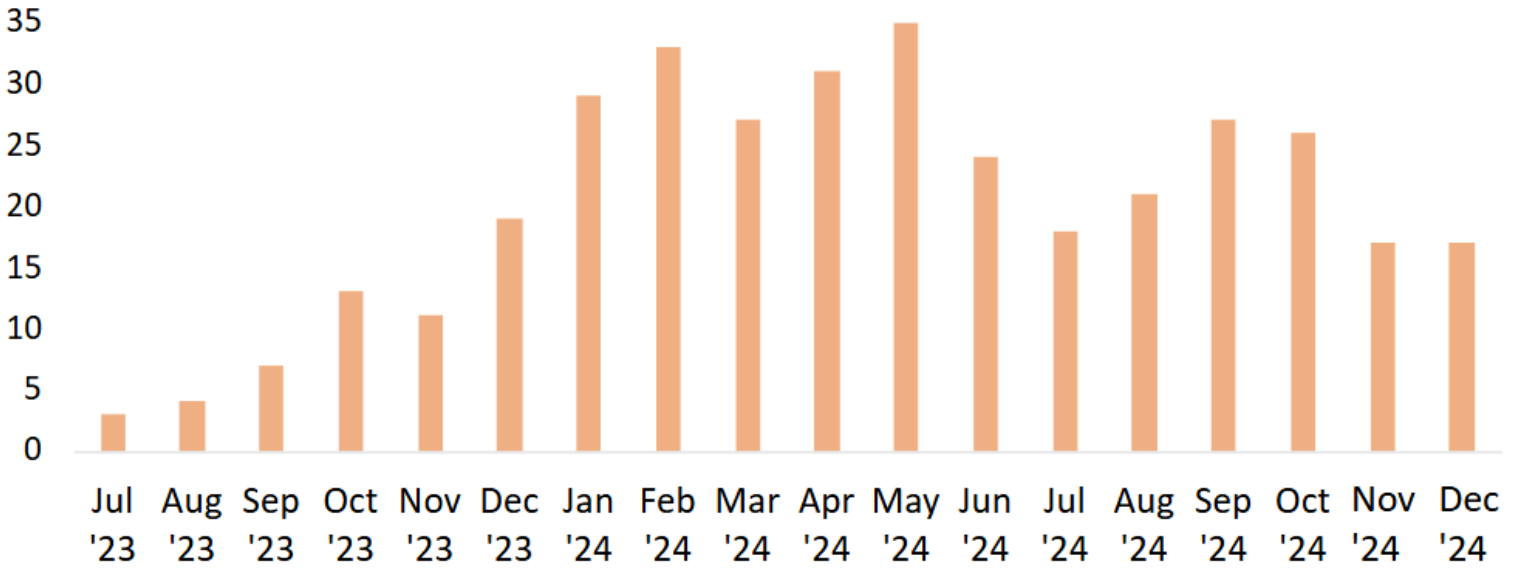
For investigators in Belgium, you may continue using the existing "Information and Consent Form Participant/Legal Representative," with the participant now adding their signature.
For those in the Netherlands, please use the "Informatiebrief en toestemmingsformulier tweede instantie" to fulfill this requirement.

For more information regarding deferred informed consent and some helpful tips please visit:
https://cases-trial.eu/DOC/SOP%20patient%20information%20and%20deferred%20consent%20(CASES).pdf

CASES inclusion progress







Documents such as the study protocol, information letters/informed consent forms and paper CRF worksheets can be found on the CASES website: www.cases-trial.eu/
If you have any questions don't hesitate to contact us via cases-trial@umcg.nl or +31 6 5272 4593.

Discharge form

Please remember to fill in the discharge form via the website: https://cases-trial.eu/CASES/ontslag.php

Please inform us in case of:

- SAE's
- Crossover (with and without valid reason)
- Non-compliance with inclusion/exclusion criteria
- Failing to obtain or withdrawal of informed consent
- Protocol deviations regarding used stents/EVT devices, imaging not done in time window

For items listed above and any questions please contact us at: cases-trial@umcg.nl
or via telephone +31 6 5272 4593

Frequently Asked Questions

Q: What if a patient is discharged to the referring center before the 5-7 days follow-up visit?

A: In case of transfer, the referring hospital is requested to provide the NIHSS score at 5-7 days (or discharge). Ask the referral center to provide the patient's discharge letter and any information regarding the deferred treatment (if applicable) to complete the visits 'discharge second hospital transfer, part 1 & 2', and 'deferred treatment'. The 90-day duplex ultrasound should be planned in the intervention center.

Information to complete the '90-day follow up (unblinded)' visit can be requested from the referral center.

Q: What if the interventional radiologist used a device that is not approved according to trial protocol?

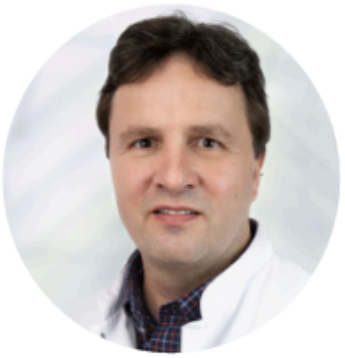
A: This is considered a 'minor deviation'. Please complete a deviation form and report it to the sponsor. We plan to add some devices, such as the Aperio Hybrid stent retriever, in our next protocol amendment.

Q: How do we have to follow-up on (S)AE's?

A: As long as an AE or SAE is ongoing, you must continue to follow-up until the patient has reached the 90 day follow up (+-14 days). You can update (S)AE's in Castor and complete a new paper form (as source) when additional information is available.

Other Frequently Asked Questions can be found on our website: https://cases-trial.eu/faq.html

The CASES study team



Paul Nederkoorn
Principal Investigator

Maarten Uyttenboogaart
Principal Investigator

Robin Lemmens
Principal Investigator

Femke Roelofs
CASES EXTENDED

Theodora van Elk
Trial Coordinator

Louise Maes
Trial Coordinator

Anne van der Meij
Fellow Neurology

Nynke Nicolaij
Research Nurse

Annemie Devroye
Research Nurse

E-mail
cases-trial@umcg.nl

Phone number
+31 6 5272 4593

Website
www.cases-trial.eu/