

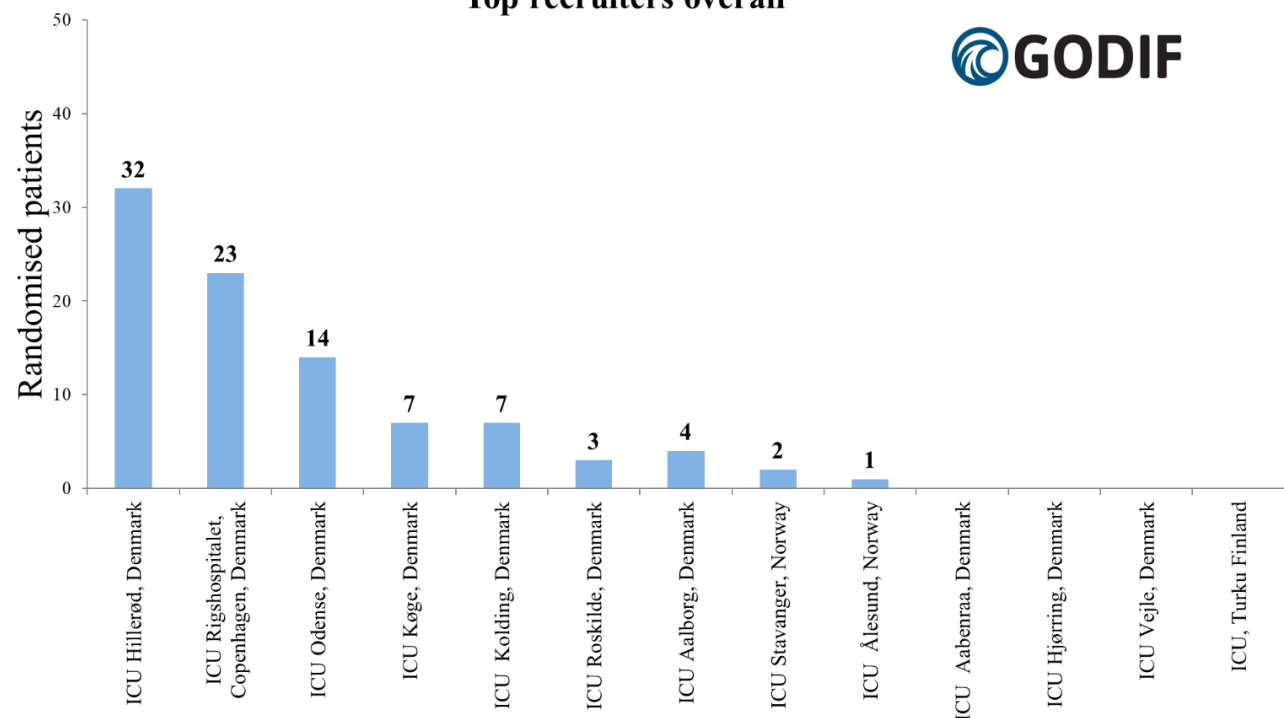
## GODIF Newsletter March to May 2022

### Thank you for committing to the GODIF trial!

Dear friends and colleagues,

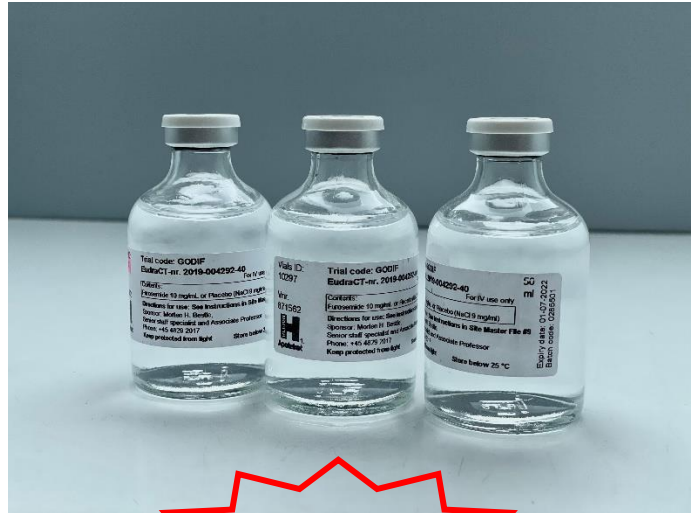
We are happy to inform you that we are now 13 active sites in Denmark, Norway and Finland. Welcome to Sygehus Sønderjylland Aabenraa, Regionshospitalet Nordjylland Hjørring, and Turku University hospital in Finland. We have now included 93 participants.

#### Top recruiters overall



## Expiry of trial drug

Expiring date on the GODIF trial drug is coming up on the 1<sup>st</sup> of July 2022 for medicine on the following 10 sites: Rigshospitalet, Køge, Roskilde, Hillerød, Odense, Vejle, Kolding, Aalborg, Stavanger and Ålesund. When an investigational medicinal product (IMP) for clinical trials is produced, the labeled expiry date is 2 years. When expiry is near it is possible to test the stability of the drug and if it is satisfying the expiry can be extended for one year according to guidelines. The GODIF trial drug has been tested and the new expiry date is the 1<sup>st</sup> September 2023. In June the 10 mentioned sites will need relabeling of their stored medicine. All will receive a plan for this shortly in their email.



**NEW EXPIRY DATE**

## One-year follow-up

One-year follow-up is approaching. Rigshospitalet will begin in June and Odense in September and more sites will follow later. Please read the SOP for 1-year follow-up. It is placed in your site master files chapter 17, but also attached to this newsletter.

We are using the new MoCA mini. Some of you might have worked with the former version. Please read the instructions for the MoCA mini and look at the test before you start the interviews. If none at your site is certified for performing the MoCA mini test, please get in touch with the coordinating center when your 1-year follow-up is coming near.

The 1-year follow-up consist of MoCA mini, health related quality of life questionnaire (EQ-5D-5L and EQ-VAS) and a question how they find their quality of life (acceptable/neutral/unacceptable).

**New documents for your site master file.**

New EudraCT file updated with new Danish sites and principal investigators, and the algorithms. New documents are always announced under trial documents on the page for site mater file (<http://www.cric.nu/godif-log-of-changes/>). New documents will always be attached to the newsletter send out four times a year.

The Coordinating Center is always available on the  
GODIF hotline: +45 48 29 67 73

Mail: [godif@cric.nu](mailto:godif@cric.nu)

[www.cric.nu/godif/](http://www.cric.nu/godif/)

Kind Regards form the GODIF team  
Morten (Sponsor) and Sine (Coordinating Investigator)

All the best,

Morten and Sine

