

EuroSIDA Newsletter

November 2014

follow-up after the EuroSIDA investigator meeting in Glasgow



ANNOUNCEMENTS

EuroSIDA investigator meeting in Glasgow

Thank you to all investigators joining the EuroSIDA investigator meeting in Glasgow and for the great support to enrol the new cohort in the study.

During the investigator meeting a few key topics were discussed:

All future follow-up in REDCap

All future follow-up will be in the electronic CRF system REDCap. Our hope is that this will **ease the workload for EuroSIDA investigators**. We are aware that it can take some time in the beginning and the coordination secretariat is available to assist in all possible ways. The system is very simple and used in many other studies.

During the meeting, **investigators proposed the following, which we are working on:**

- that we make a REDCap training program/test CRF
- that it is possible to get an overview of entered data before final confirmation of the form
- that sites get feedback on the quality of entered data
- that it should be possible to delete forms
- that it should be possible to easily print forms that are filled in

We look forward to working with you in the new electronic system to ease data entry and transfer!

The new EuroSIDA cohort

Some investigators have made us aware that completing the enrolment form can be time consuming. Therefore, the steering committee decided to make some **amendments to the enrolment form:**

Instead of a complete ART history, we request:

- Start date and composition of 1st ART regimen
- All ARVs received in the last 12 months prior to enrolment

Instead of complete history of conditions requiring hospitalisation, we request:

Scientific presentations in Glasgow

EuroSIDA was well represented at the conference, and posters and presentations can be found at our website at:

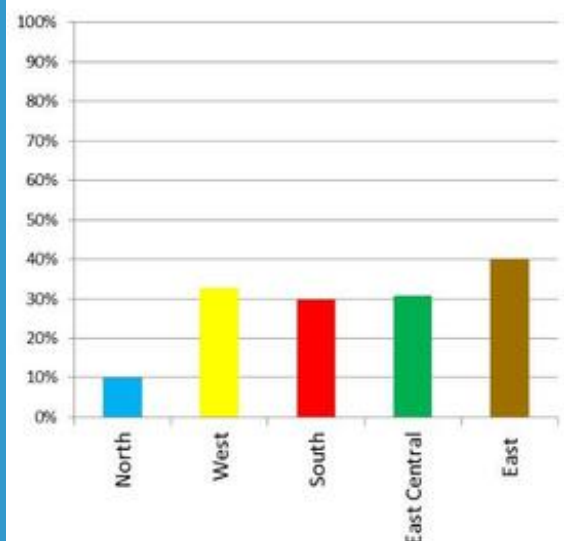
www.chip.dk/eurosidea/presentations

Enrolment status for the new EuroSIDA cohort

Enrolment in the new cohort is ongoing and is happening in a different pace at the sites. A total of **29% of the final goal** has been reached. The investigators were shown the enrolment status for each individual country. The enrolment status by region can be seen below.

We kindly ask you to **complete enrolment by 3 months** after you have your ethics approval.

Enrolment status by region as percent of target



- History restricted to the last 12 months up to enrolment into EuroSIDA

These changes to the enrolment form will be made as soon as possible!

There was some uncertainty about the new HCV Treatment Form and HCV Treatment Adverse Events form. Please note that we **request forms for all EuroSIDA patients** (in the new cohort as well as previously enrolled patients), when indicated:

HCV Treatment Form

The form should only be filled out if the patient is **undergoing HCV treatment at the time of enrolment in the new cohort, or if the patient starts HCV treatment after enrolment**. If HCV treatment was completed prior to enrolment, an HCV Treatment form should *not* be filled out. Information about prior HCV treatment is collected in the Enrolment Form.

For patients from the prior cohorts this HCV Treatment form should be completed only if the patient has started HCV treatment since last follow up

HCV Treatment Adverse Event Form

If a patient is receiving HCV treatment at the time of enrolment or during follow-up in the new cohort, but **stops HCV treatment before planned due to toxicity or intolerance**, the Adverse Event Form should be filled in. If the treatment was completed prior to enrolment in the new cohort, any information about treatment toxicity/intolerance is collected in the Enrolment Form.

For patients from the prior cohorts, the Adverse Event Form should be filled in if the patient has started HCV treatment and the patient then *stops* HCV Treatment before planned due to toxicity or intolerance.

Questions?

Please make sure to contact the coordinating center if you have any **problems, questions, or suggestions** about how to make the electronic enrolment- and follow-up forms better!

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