EuroSIDA Newsletter

November 2015



ANNOUNCEMENTS

Dear EuroSIDA Study Investigators,

The staff at the EuroSIDA coordinating centre sends you many greetings and we kindly thank you for your continued excellent work and continued contribution to the EuroSIDA study. Below, please find an update on the EuroSIDA study.

EACS 2015

We were happy to see many of you at the investigator meeting at EACS 2015 and we hope you found the meeting informative. The minutes from the meeting will be posted on our website soon.

The future of EuroSIDA was discussed at EACS. As EuroCoord funding expires 31st December 2015, we are working hard to secure new funding. However, EuroSIDA will continue unchanged in 2016.

We are very proud that EuroSIDA was represented at EACS with an impressive 9 presentations, 3 oral and 6 posters. This achievement would not be possible without the continued support from all of you! Please find the presentations <u>HERE</u>.

EuroSIDA Protocol 3.0 covers all patients until 31st December 2019

EuroSIDA Protocol 2.0 expires 31st December 2015, and we would like to inform you that EuroSIDA 2014-2019 Protocol, version 3.0, dated 16 April 2014, which was prepared for cohort 10, also covers patients from all cohorts preceding cohort 10.

If your centre has obtained an ethics approval for protocol 3.0 in connection with cohort 10, all your patients are covered until 31st December 2019. If your centre is not participating in cohort 10, you should have received an E-mail explaining that you need to apply for ethics approval for Protocol 3.0. Please contact the coordinating centre if you have not received this E-mail, or if you have any questions to this process.

EuroSIDA presents a new sub-study

The EuroSIDA steering committee has approved a five year-long cohort study, nested within the EuroSIDA study, looking at hypersensitivity reactions, hepatotoxicity and rash in patients who discontinue Dolutegravir (as Tivicay or Triumeq), or any other integrase inhibitor (elvitegravir or raltegravir) as monotherapy or combination therapy.

Many centres have already been asked to complete a new hypersensitivity form in REDCap, as part of a **retrospective** analysis looking at all reasons for treatment discontinuation since January 2014. **Prospectively**, we will

Dataset 43

Dataset 43 will be sent to sites in early December. Data entry in REDCap will remain open for enrolment, HCV treatment forms and the new hypersensitivity forms, whereas follow-up forms will re-open in December.

EuroSIDA reimbursements

The annual reimbursement to EuroSIDA sites was made in November 2015.

Due to a fault in our database, centres were not reimbursed for D:A:D and CoDe forms for cohort 9 patients and for CoDe forms for cohort 10 patients. We sincerely apologize for this inconvenience and all centres will of course be paid for these forms in 2016.

EuroSIDA and D:A:D

Please be reminded again that patients enrolled EuroSIDA cohort 10 are not included in the D:A:D study. D:A:D event forms should therefore not be completed for cohort 10 patients. For patients enrolled in earlier EuroSIDA cohorts there are no changes with regards to D:A:D.

REDCap

We have had a number of questions from investigators concerning how to enter the REDCap system. Please be aware that CHIP is working with more than one REDCap ask all centers to complete this form in connection with the usual biannual follow-up, **only** if treatment was discontinued due to hypersensitivity/rash/hepatotoxicity. We hope you all will support this important sub-study.

We would in this regard like to commend our collaborating sites for completing almost 250 hypersensitivity forms within a three week deadline. We are very impressed and pleased with your dedication.

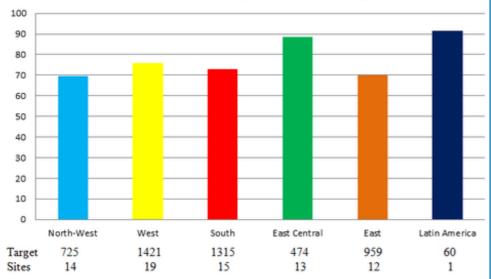
Enrolment status for the new EuroSIDA cohort

Enrolment in the new cohort 10 ends 31st December 2015 so we strongly urge centres who have not yet reached their target to **please continue** to enroll patients in REDCap as fast as possible.

Furthermore, we urge centres to please complete all enrolment forms in REDCap. Of the 3,688 enrolled patients, there are still 445 enrolment forms that have not yet been completed in REDCap.

So far 3,688 patients, **74% of the target of 5,000, have been enrolled.** 74 centres from 31 countries are contributing to the cohort and 42 centres have reached their enrolment target. The EuroSIDA team would like to thank these sites for their professional work done to complete the enrolment process.





PUBLICATIONS

Total number of publications in 2015: 14 Publications since last newsletter August 2015:

Liver-related death among HIV/HCV coinfected individuals, implications for the era of directly acting antivirals. D Grint, L Peters, JK Rockstroh, A Rakmanova, T Trofimova, K Lacombe, I Karpov, M Galli, P Domingo, O Kirk, JD Lundgren, A. Mocroft for EuroSIDA in EuroCoord. AIDS. 2015 Jun 19;29(10):1205-15. doi: 10.1097/QAD.00000000000000674. (IF: 6.348)

Hepatitis C seroconversions in HIV infection across Europe: which regions and patient groups are affected? C. Boesecke, D. Grint, V.

system and for EuroSIDA the link to be used is THIS.

HCV Treatment forms in REDCap

Please remember to follow the criteria for completing HCV Treatment forms in REDCap:

- For patients enrolled in cohort 10, the HCV Treatment form should be completed if HCV treatment was ongoing during enrolment or has commenced after enrolment (baseline).
- For patients enrolled in EuroSIDA before cohort 10, the HCV Treatment form should be completed if HCV treatment was ongoing 1 June 2014 or has commenced after 1 June 2014.

HCV Treatment Adverse Event forms forms in REDCap

The HCV Treatment Adverse Event form should be completed if HCV treatment is stopped early due to toxicity or intolerance.

Centres who deliver data in an electronic file will be reminded to complete this form in REDCap for relevant patients.

Testing Week 2015

recommend EuroSIDA investigators to sign up for European Testing Week. coordinated by HIV in Europe. The European HIV-Hepatitis Testing Week takes place from 20-27 November 2015. Policy makers, healthcare professionals and civil society organisations all across the WHO European Region unite for this one week to help more people to become aware of their HIV and/or hepatitis

Soriano, J.D. Lundgren, A. d'Arminio Monforte, V.M. Mitsura, N. Chentsova, V. Hadziosmanovic, O. Kirk, A. Mocroft, L. Peters, J. Rockstroh for EuroSIDA in EuroCoord. Liver Int. 2015 Nov;35(11):2384-91. doi: 10.1111/liv.12848. Epub 2015 Apr 29. (IF: 4.41)

All publications may be found **HERE**

Thank you for a continuous rewarding and successfull collaboration!

status. Join us HERE.



Update from EuroCoord

Please find the latest news from EuroCoord at: newsletter at

www.eurocoord.net





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This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under EuroCoord grant agreement n° 260694.