EuroSIDA Newsletter

June 2021

Dear EuroSIDA Study Investigators,

We hope you are all well. Due to the COVID-19 pandemic, the EuroSIDA Secretariat recognises that healthcare facilities and communities continue to be affected by closed, restricted and/or overloaded services.

Despite these challenges, EuroSIDA study activities progressed in 2020-2021 and we would like to provide you with an update. We would like to thank all of you for your tremendous support and contributions to the EuroSIDA study.

We wish you a relaxing and enjoyable summer and look forward to continued collaboration in the second half of 2021 and beyond.

Study updates

Dataset 48

Dataset 48, autumn 2020 was sent to almost 100 clinics in 35 countries. **Thank you** for submitting your data and for meeting the December 2020 deadline. We are deeply impressed about the level of engagement and commitment to EuroSIDA. Approximately 8,000 completed follow-up forms in the face of a pandemic which occupies us all.

Reimbursement 2021

We are working hard to clean and download Dataset 48 so we will be able to complete reimbursement before summer. It may be delayed, but we are pushing hard to complete it before the summer so you all will be compensated before long.

Leadership Changes

Amanda Mocroft retires after decades as EuroSIDA lead

As of January 2021, Amanda no longer works at University College London, but continues to contribute to EuroSIDA as a consultant employed by CHIP. After a lengthy tenure leading both EuroSIDA and RESPOND, Amanda will focus on the scientific work within the cohorts. The EuroSIDA Secretariat thanks Amanda for her tremendous leadership and contributions to the EuroSIDA study over the past 25 years and looks forward to continuing to collaborate with her in her new role.

Lars Peters is new study lead and Principal Investigator of EuroSIDA study

As of February 2021, Lars Peters is the new study lead and Principal Investigator of the EuroSIDA study. Lars has been involved in EuroSIDA since 2007 and looks forward to continuing the excellent collaboration with all of you as he assumes his new leadership role.

Cohort 11

In 2019, EuroSIDA identified a new cohort with the goal to enroll 2000 participants to ensure that the study is representative of the current HIV epidemic. The inclusion criteria are the same as for RESPOND to ensure that the new participants can be included in the RESPOND data lake, as RESPOND is now the main funder of EuroSIDA. As of June 2021, approximately 1400 participants have been enrolled and the cohort remains open for enrolment at least until the end of 2021. We will make sure to notify participating sites when enrolment concludes. Thank you immensely to all sites contributing to the cohort.

Clinical Reporting Form Updates

Cabotegravir

Two separate data collection forms for each of the protocols that include cabotegravir have been developed in REDCap (see below for more details about these prototocols).

COVID-19

The COVID-19 form was introduced with the dataset 48 collection in REDCap for participants who had a positive PCR test and have been admitted to hospital for treatment of COVID-19. The form includes information on symptoms, comorbidities, clinical and laboratory data and treatment. For each form completed, 50 Euro will be reimbursed. You can read more about this new form in the COVID-19 eCRF Manual of Operations here. As of May 2021, we have received 24 forms.

EuroSIDA in RESPOND

EuroSIDA is a founding partner and major stakeholder of the RESPOND International Cohort Consortium, which is an investigator-initiated multicenter collaboration launched in 2017.

EuroSIDA continues its activities as a separate cohort with its own research agenda and Steering Committee but contribute pseudonymized data to RESPOND.

The aim of RESPOND is to build an innovative, flexible and dynamic cohort consortium for the study of infectious diseases, including HIV, as a generic structure for facilitating multi-stakeholder involvement.

In RESPOND, all contributed data is part of a common data repository or ‘data lake’ which is stored in a central database. EuroSIDA is represented in the RESPOND Executive Committee as well as in the RESPOND Scientific Steering Committee and in the various Scientific Interest Groups (SIGs) for each study that EuroSIDA provides data. SIGs that focus on Outcomes with Antiretrovirals, Tuberculosis, Hepatitis and Public Health have been established.

If you have interest in joining a SIG, please contact:

- **Outcomes:** Nadine Jaschinski nadine.josephine.jaschinski@regionh.dk
- **Tuberculosis:** Christian Kraef christiankraef@googlemail.com
- **Hepatitis:** Lars Peters Lars.Peters@regionh.dk
- **Public Health:** Marie Louise Jakobsen marie.louise.jakobsen@regionh.dk

As of May 2021, seven RESPOND manuscripts have been published.

All data from EuroSIDA participants are shared with the RESPOND data lake. The EuroSIDA protocol v4 was shared with all EuroSIDA sites in late 2019 and the updated informed consent form includes patient consent to share data with RESPOND. It is the responsibility of the sites to make sure local regulatory requirements are met, but the Coordinating Centre is ready to assist with any needs.

New Sub-Studies

Cabotegravir

Two protocols have been finalized for the following studies funded by ViiV Healthcare:

a. A prospective observational cohort study to monitor for hepatotoxicity and regimen discontinuation due to liver related adverse events among patients initiating cabotegravir containing antiretroviral regimen
b. Drug Utilization, Adherence, Effectiveness and Resistance: A Prospective Observational Cohort Study in Patients initiating ARV regimen of CAB LA+RPV LA.

Data will be collected on two separate REDCap forms that will be reimbursed. Data collection in both studies is expected to begin with the collection of D49 (autumn 2021).

MISTRAL study

We are pleased to announce that the EuroSIDA microbiome project proposal was awarded a large grant from the European Union's Horizon 2020 Research and Innovation Programme.

The microbiome project (MISTRAL study) is part of a larger consortium called MISTRAL, which consists of 11 academic, private and public sector members. The total budget is 10 million Euro; one million Euro has been allocated to operationalizing the collection of 2000 stool and blood samples from a cohort of 1000 participants to investigate associations between the gut microbiome and

clinical outcomes of people living with HIV.

The project period is five years and we plan to begin enrolment in 2021. All participants will be recruited from existing EuroSIDA Centres and the project will be overseen by the EuroSIDA Steering Committee.

CHIP in Copenhagen is responsible for MISTRAL study operations. Roger Paredes from the IrsiCaixa AIDS Research Institute in Barcelona will lead the laboratory work.

Publications and Presentations

EuroSIDA reached 300 publications

As of February 2021, the EuroSIDA study group has issued 313 publications, 17 of which were published during 2020. This is an extremely impressive milestone and we want to thank you for your invaluable contributions to the EuroSIDA study and global community of people living with HIV.

All EuroSIDA publications can be found here: https://chip.dk/Research/Studies/EuroSIDA/Publications.

EuroSIDA study group celebrates 25 year anniversary at European AIDS Clinical Society (EACS) 2019

We celebrated 25 years of scientific achievements in EuroSIDA during EACS 2019.

All presentations can be viewed here: https://chip.dk/Research/Presentations/2019.

EuroSIDA Staff Updates

Sarah Amele, who has been a PhD student at EuroSIDA for four years has handed in her PhD dissertation that looked at hepatitis in EuroSIDA participants. Sarah passed her PhD viva in May and she has a new job in

Glasgow. We wish her well and thank her for her contributions to EuroSIDA over the past four years.

Meredith Sather joined CHIP in 2020 as the Project Coordinator on the MISTRAL study. Meredith is an experienced research project manager and has a master's degree in global health policy and management and she will be part of the cohort team moving forward.

Reminders

Protocol v4.0 Ethics Committee Approvals

EuroSIDA protocol v4.0 was approved on 5 July 2019. For the Centres that have received Ethics Committee approval, the EuroSIDA Coordinating Centre will be contacting you in 2021 to ensure all approvals are included in our regulatory files.

We thank you in advance for providing these approval documents and ensuring EuroSIDA study files are current.

Research Project Proposal Submissions

The EuroSIDA Steering Committee encourages the submission of concepts for new research projects. Once submitted, research concepts will be evaluated based on scientific relevance, design and feasibility, statistical power and feasibility and overlap with currently approved projects.

Upon completion of the review, feedback from the EuroSIDA Steering Committee will be provided to applicants. All members of the evaluation panel are bound by confidentiality.

If you are interested in submitting a research concept, the proposal template and corresponding information about the submission process can be found here, https://chip.dk/Research/Studies/EuroSIDA/Submit-proposal.

Deadline

Dataset 49: 1 December 2021

Please continue to complete CoDe forms and RESPOND Event forms when relevant. Please also include the COVID-19 form in this dataset submission.

Study Group Updates

We would like to keep the EuroSIDA study group list current. Please review the names and affiliations in the study group (https://chip.dk/Research/Studies/EuroSIDA/Study-group) and inform the Coordinating Centre of any changes.

Change in Centre Staff

Please remember to update the EuroSIDA Coordinating Centre if there are staff changes at your Centre. This allows all correspondence (newsletters, etc.) to be sent to the right contact person.

It also allows the EuroSIDA Coordinating Centre to maintain the study group and correctly award co-authorship.

Furthermore, if staff no longer work at your Centre or new staff members join your team, we will remove or assign REDCap access accordingly.

Plasma Sample Request

One plasma sample per participant per year is requested and reimbursed in the EuroSIDA study. Sample shipment instructions can be referenced here, https://chip.dk/Research/Studies/EuroSIDA/Samples

All EuroSIDA study documents can be found here

We hope to see you all at EACS in October 2021 either online or in London!

Why are you receiving this email?

You are receiving this email because you are affiliated with the EuroSIDA study. By providing your contact details to the EuroSIDA Coordinating Centre, you are included in the mailing list for the EuroSIDA study.

Contact

Please always feel free to contact the EuroSIDA coordinating centre at ***eurosida.rigshospitalet@regionh.dk***.
No question is too small or too big, we are happy to assist in all matters!

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