EuroSIDA Newsletter

December 2024

Dear EuroSIDA Study Investigators,

The EuroSIDA Coordinating Centre sends many holiday greetings to all our worldwide collaborators. We deeply appreciate your ongoing commitment to the study. We are excited to share the latest updates from the EuroSIDA study.

30th Anniversary!

First, we would like to thank and congratulate everyone in the EuroSIDA network, colleagues, sites, partners, collaborators, funders, and last but not least participants, for an incredible 30-year journey!

EuroSIDA has come a long way since Jens Lundgren and Andrew Phillips started the study in 1994, with the purpose of studying the long-term clinical prognosis of the general population of HIV-infected individuals living in Europe.

Since then, EuroSIDA has published over 340 publications in peer-reviewed journals as well as more than two hundred oral and poster presentations at scientific conferences, contributing to improved treatment and quality of life for people living with HIV.

We encourage you to go to **EuroSIDA Presentations from 2019** and revisit the celebratory presentations from the 2025 years anniversary symposium at EACS Basel in 2019.

In early 2025 we will draft a patient leaflet for you to share with your EuroSIDA participants, with further information about this great achievement and how their data has helped change guidelines and improve outcomes for people with HIV.

Study Updates

Dataset 51 has been successfully cleaned and exported for analysis!

Dataset 52 opened on October 18, 2024. More than 6,800 follow-up forms have been collected in REDCap and follow-up data received via the REST submission system from 11 sites! We look forward to sites submitting and completing the remaining follow-up data before the holidays.

Submission deadline is **December 20, 2024**.

New Cohort investigating long-acting cabotegravir + rilpivirine

EuroSIDA is currently conducting a 5-year post-authorization safety study of long-acting cabotegravir and rilpivirine (LA CAB+RPV). The uptake of LA CAB+RPV in EuroSIDA has been slower than anticipated. To address this, and with the support of ViiV Healthcare and the EuroSIDA Steering Committee, we are including an additional cohort of 500-750 non-EuroSIDA patients from existing EuroSIDA clinics who have initiated LAI CAB + RPV since its approval by the EMA on December 17, 2020. This is an important step in being at the forefront of researching the new long-acting regimens in EuroSIDA.

Enrolment will continue **until December 2025**. If your site is interested in participating in this substudy, please don't hesitate to contact the EuroSIDA Coordinating Centre.

We kindly remind all sites to ensure that all injection dates are updated in the short REDCap form. To date, we have received data on **213 treatments**. We encourage sites to complete the forms in real-time.

MISTRAL

The MISTRAL study has reached the target of enrolling 1,000 participants in July. Big congrats to all involved! 380 participants have already completed their second visit. All visit-one samples (stool, plasma and whole blood) have been shipped from CHIP to IrsiCaixa in Spain. We are currently analysing the baseline samples for IL-6, D-Dimer and C-Reactive Protein for all baseline samples, and the results will be available soon. We will then carry out the analyses associating the microbiome composition with these biomarkers at the beginning of next year. In addition to this, we are running fecal proteome, metagenomic, and metabolome analyses. Results from the latter should be expected during February 2025.

For more information on the MISTRAL study **click here**.

RESPOND

The collection of RESPOND Dataset 7 began on 1st September 2024, and a data quality assessment is currently underway for sites to resubmit the data. EuroSIDA remains the largest contributor of participants in RESPOND with 15,000 participants.

RESPOND presentations and publications can be found **here**.

EuroSIDA Investigator Meeting in Glasgow, November 2024

Our traditional annual EuroSIDA investigator meeting was dedicated to updates on EuroSIDA, MISTRAL and RESPOND. We were very happy to see more than 30 investigators at the meeting. We hope you found the meetings informative!

We touched upon the past year and future plans for EuroSIDA and study updates including the new cohort investigation uptake, adherence, durability and effectiveness of long-acting cabotegravir and rilpivirine in EuroSIDA. There were good discussions on potential EuroSIDA studies using stored plasma samples. An overview was presented giving insights into various events including those with any prior sample. EuroSIDA investigators were encouraged to explore new **project proposals** based on these clinical events with stored plasma. Please reach out to the Coordinating Centre with any suggestions or inquiries.

Clinical events with stored plasma

	Events		With any prior sample		With sample within 12 months prior to event	
	n	%	*n*	%	*n*	%
Death	3074	14.3%	1885	61.3%	727	23.6%
CVD	1195	5.6%	848	71.0%	425	35.6%
ESLD	424	2.0%	220	51.9%	107	25.2%
ESRD	143	0.7%	103	72.0%	49	34.3%
NADM	1371	6.4%	926	67.5%	418	30.5%
Anal	248	1.2%	170	68.5%	75	30.2%
Bladder	64	0.3%	48	75.0%	20	31.3%
Breast	73	0.3%	50	68.5%	17	23.3%
Colon	59	0.3%	33	55.9%	10	16.9%
Head and neck	59	0.3%	34	57.6%	11	18.6%
Liver	141	0.7%	80	56.7%	31	22.0%
Lung	198	0.9%	131	66.2%	64	32.3%
Malignant melanoma	59	0.3%	47	79.7%	18	30.5%
Prostate	138	0.6%	97	70.3%	38	27.5%

Updated as of January 2024. All numbers are estimates and exact events/ samples would depend on inclusion and exclusion criteria and study design. *n* should be considered maximum. Individual NADM are displayed if *n*>50.

Glasgow poster presentations

1. **Mortality using raltegravir versus other integrase inhibitors in people with HIV in Europe and Australia** presented by Erich Tusch on behalf of the RESPOND study group.
2. **Outcomes after the most common cancers in people with HIV** presented by Alisa Timiryasova on behalf of the RESPOND and D:A:D study groups.

Reminders

Reimbursement

Please complete all event forms in REDCap (CoDe, Cabotegravir forms, RESPOND event forms) by **1 April 2025** to receive compensation for them in 2025.

Data Processing Agreement (DPA)

We have collected **21 DPAs** from all the sites that supply plasma samples to EuroSIDA. If your site has received a DPA template and **supplying plasma samples**, kindly fill out and return the DPA.

Regulatory Approvals

Sites have received reminders concerning the submission and approval status of regulatory documents. We kindly urge you to **keep us informed of any updates** or progress from your respective ethics committees to facilitate the progress.

Staff Changes

Please notify us if there are any changes in staff or principal investigators at your site. It will allow us to update our study group, and the database accordingly.

Query Form in REDCap

Last year, a REDCap project called ‘Query Form’ was added to your REDCap project list. This form is designed to consolidate all unresolved queries related to Event and CoDe forms, to centralize communication between sites and coordinating staff. Minor queries will be handled via email. All remaining unresolved queries from last upload will be included in the next query upload. Sites will be notified if an upload occurs, and sites must address and resolve these queries promptly. Working instruction for the query form can be found **here**.

EuroSIDA Publications

The EuroSIDA study has reached **343 publications**! Six manuscripts have been published since our last newsletter. Details of the latest publications are listed below::

Latest Publications in 2024

1. **Associations between change in BMI and the risk of hypertension and dyslipidaemia in people receiving integrase strand-transfer inhibitors, tenofovir alafenamide, or both compared with other contemporary antiretroviral regimens: a multicentre, prospective observational study from the RESPOND consortium cohorts.** Byonanebye DM, Polizzotto MN, Maltez F, Rauch A, Grabmeier-Pfistershammer K, Wit F, De Wit S, Castagna A, d'Arminio Monforte A, Mussini C, Wasmuth JC, Fontas E, Abela I, Sarcletti M, Bansi-Matharu L, Jaschinski N, Peters L, Hosein SR, Vannappagari V, Cohen C, Bissio E, Mocroft A, Law M, Ryom L, Petoumenos K; RESPOND study group.
   Lancet HIV. 2024;11(5):e321-e332.
2. **Trends in mortality in people with HIV from 1999 to 2020: a multi-cohort collaboration.** Tusch E, Ryom L, Pelchen-Matthews A, Mocroft A, Elbirt D, Oprea C, Günthard HF, Staehelin C, Zangerle R, Suarez I, Vehreschild JJ, Wit F, Menozzi M, d'Arminio Monforte A, Spagnuolo V, Pradier C, Carlander C, Suanzes P, Wasmuth JC, Carr A, Petoumenos K, Borgans F, Bonnet F, De Wit S, El-Sadr W, Neesgaard B, Jaschinski N, Greenberg L, Hosein SR, Gallant J, Vannappagari V, Young L, Sabin C, Lundgren J, Peters L, Reekie J; D:A:D cohort study; RESPOND cohort study.
   ClinInfectDis.2024:ciae228.
3. **All-cause and AIDS-related mortality among people with HIV across Europe from 2001–2020: impact of antiretroviral therapy, and regional differences in a multicentre cohort study.** Kraef C, Tusch E, Singh S, Østergaard L, Fätkenheuer G, Castagna A, Moreno S, Kusejko K, Szetela B, Kuznetsova A, Tomažič J, Ranin J, Zangerle R, Mansson F, Marchetti G, De Wit S, Clarke A, Gerstoft J, Podlekareva D, Peters L, Reekie J, Kirk O, and the EuroSIDA Study Group. The Lancet Regional Health - Europe 2024;44: 100989
4. **Chronic liver enzyme elevation and use of contemporary ARVs among people with HIV.** Roen AO, Peters L, Wandeler G, van der Valk M, Zangerle R, Günthard HF, Wit F, Mussini C, De Wit S, d'Arminio Monforte A, Vehreschild JJ, Castagna A, Jaschinski NJ, Vannappagari V, Chen L, Tallada J, C'mar J, Mocroft A, Ryom L.
   Open Forum Infectious Diseases, 2024.
5. **Integrase strand transfer inhibitor (INSTI) related changes in BMI and risk of diabetes: a prospective study from the RESPOND cohort consortium.** Rupasinghe D, Bansi-Matharu L, Law M, Zangerle R, Rauch A, Tarr PE, Greenberg L, Neesgaard B, Jaschinski NJ, De Wit S, Wit F, d'Arminio Monforte A, Fontas E, Castagna A, Stecher M,

Brandes V, Florence E, Begovac J, Mussini C, Sönnerborg A, Abutidze A, Groh A, Vannappagari V, Cohen C, Young L, Hosein S, Ryom L, Petoumenos K.
Clin Infect Dis.2024:ciae406.

6. **Risk of tuberculosis after initiation of antiretroviral therapy among persons with HIV in Europe.** Johansen IS, Roen A, Kraef C, Martín-Iguacel R, Nemeth J, Fenner L, Zangerle R, Llibre JM, Miller RF, Suarez I, de Wit S, Wit F, Mussini C, Saracino A, Canetti D, Volny-Anne A, Jaschinski NJ, Neesgaard B, Ryom L, Peters L, Garges HP, Rooney JF, Podlekareva D, Mocroft A, Kirk O; RESPOND Study group.
Int J Infect Dis.2024.

All EuroSIDA publications can be found **here**.

We wish everyone in the EuroSIDA study a joyful holiday season and a Happy New Year!
Thank you for a continuous rewarding successful collaboration.