MISTRAL Newsletter

April 2023

Dear sites involved in MISTRAL,

Enrolment of participants is going well. Thank you for all your hard work! It is highly appreciated, and we look forward to analysing the many samples you collect.

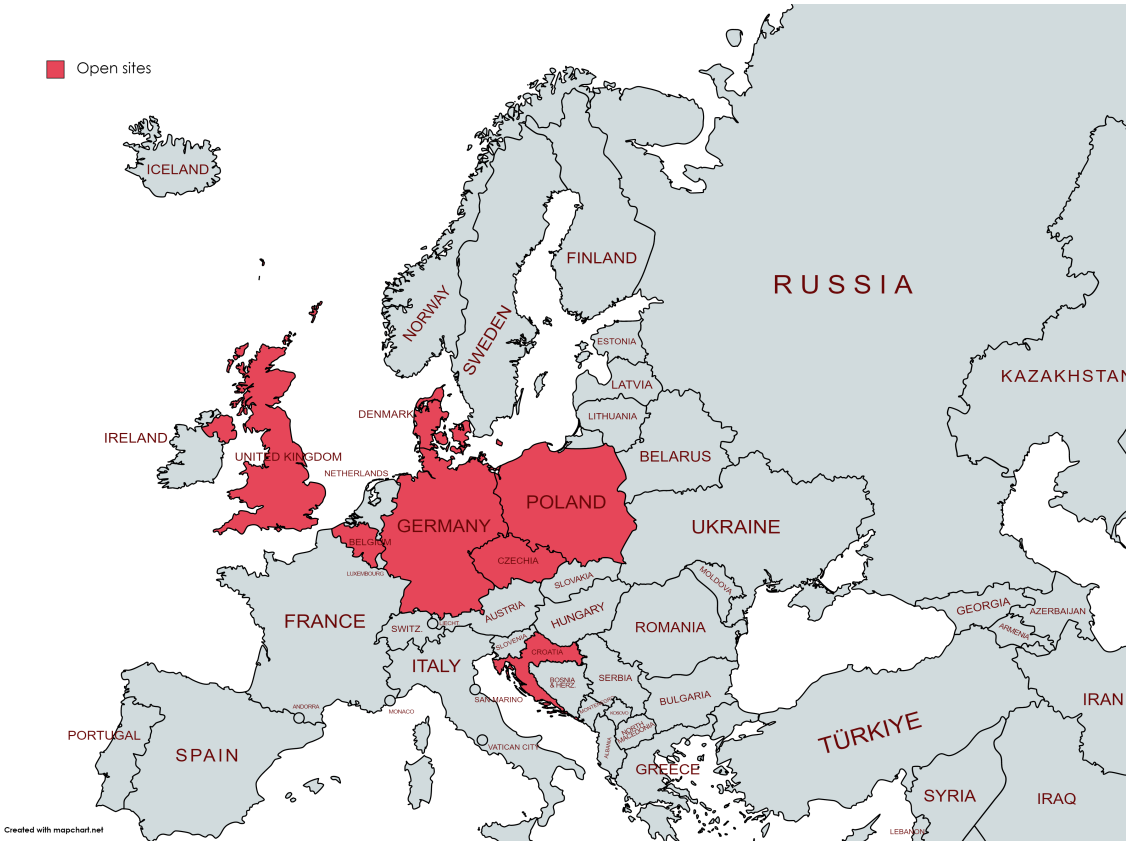
Please remember to plan the next patient visits keeping in mind that the follow-up sample should be collected within 10-24 months after their first MISTRAL visit.

In this second EuroSIDA MISTRAL study newsletter, we have gathered updates on the study, things to be aware of when filling out forms, and insights from the data collected so far. If you have any additional experiences or good ideas to share, feel free to contact us so we can share it with the other sites.

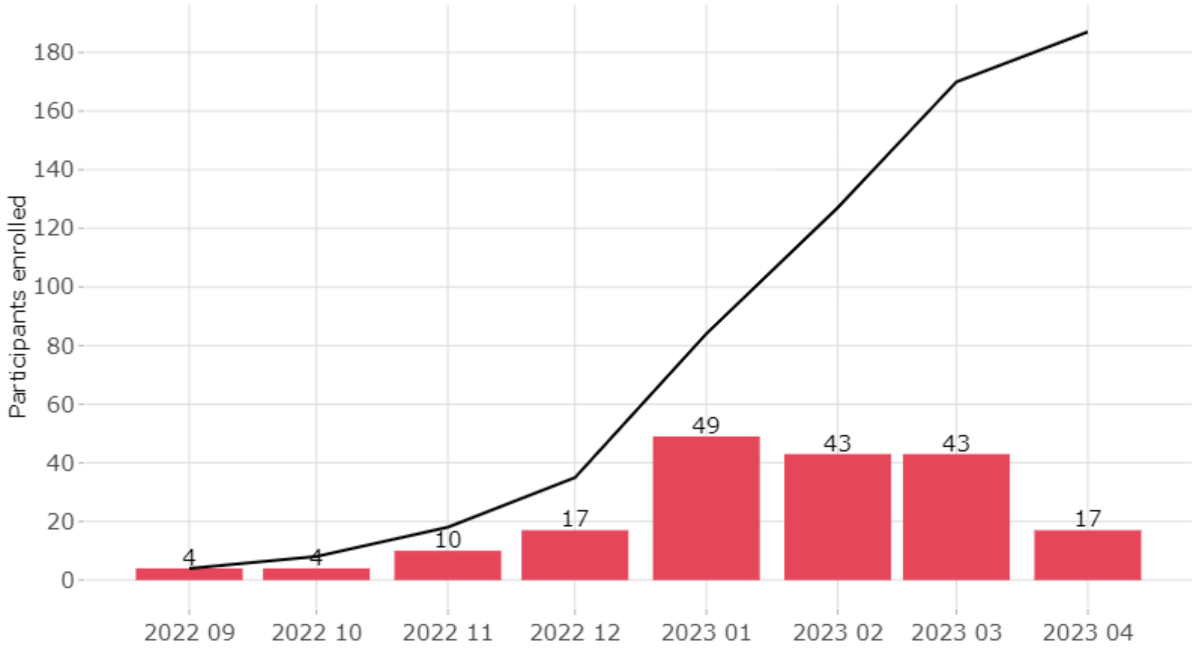
\MISTRAL team at CHIP

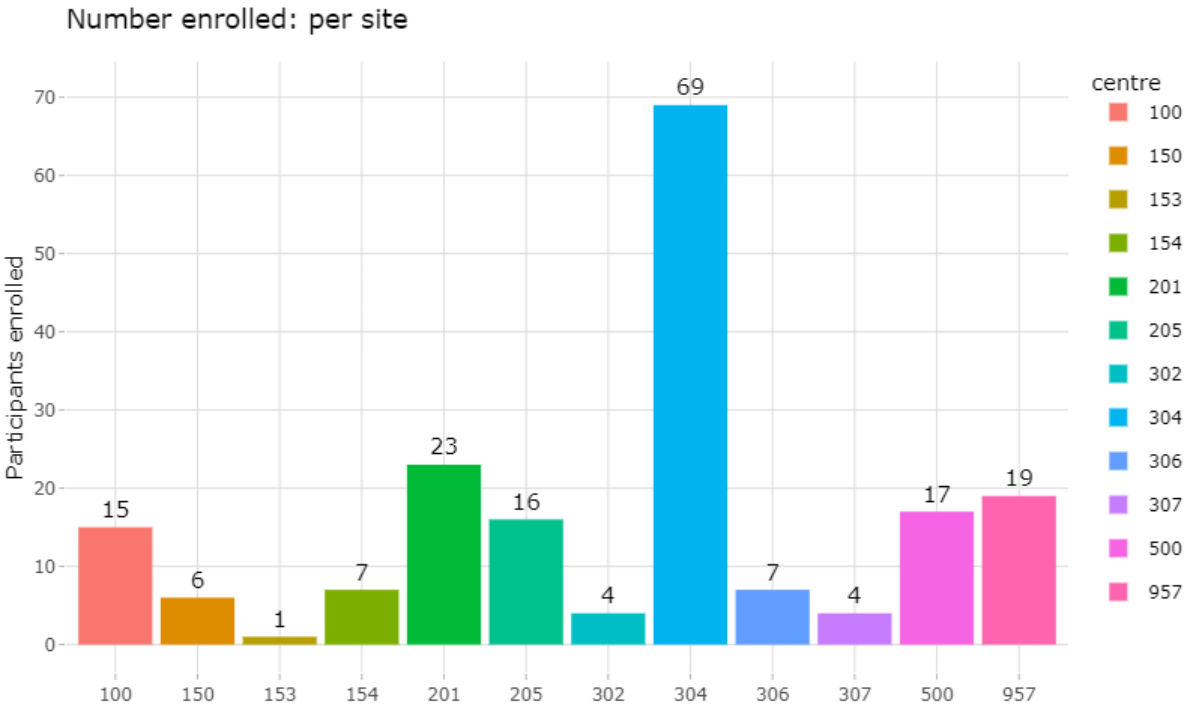
Site and enrolment status

We are happy to announce that there are now 17 sites open for enrolment in our MISTRAL study. So far 188 participants have been enrolled and of these, 54 were already part of EuroSIDA. The median age of the participants is 60 years, 90% are male, and 92% have agreed to genomics analysis. As you can see below, January of 2023 was our best enrolling month with 49 enrolled. This great work continued into the new year. We have tailed off a little in April, but as more new sites open, we hope to see this increase again. Our plan is to complete enrolment (n=1000) this year, so keep up the good work!



Number enrolled: per month and in total





Finalising forms before 1st June 2023

All REDCap enrolment forms with a completed and locked status will be downloaded on 1st June 2023. If you want to be able to include already enrolled participants for follow-up in the fall, you need to finalise their forms before this deadline. Do not hesitate to ask if this raises any questions on your end.

Notes for filling out forms

We have noticed some missing data for multiple participants. These particular variables are known to be correlated with the gut microbiome and cardiovascular events. We therefore urge you to gather information about the following variables when possible and update after the visit if you did not collect it.

- Height and weight
- Smoking and drug-use
- Lowest ever CD4 T cell count

ART drugs

Many ART drugs have more than one name. Please check the list of ART drugs on our website for common names if you are not able to find the drug in the list in the form. If a specific combination of drugs is not listed, please select the drugs individually. We do not need information regarding the doses so please keep to the list when possible.

Updated COVID-19 test questions
We have changed the questions in the enrolment form regarding COVID-19 PCR and antibody tests. Now, rather than having to note all tests, we ask only for the first positive test. We hope this will ease your work of filling out this section.

Marking forms as complete
Once you have marked a form as complete, we will go through it and check that everything is filled out properly. In these cases, we lock the forms so you cannot make further changes. Should something be missing or wrong with the form, we will contact you so we can achieve the best quality data possible. Therefore, please only mark forms as complete when you are completely done with them.

Frequently asked questions (FAQ)

Q: When should Patient Baseline Data be completed?
A: Patient Baseline Data should be completed immediately after the patient has consented to participate in the study. This section in the visit form contains critical information on eligibility criteria and informed consent, so we ask this is filled out as early as possible.

Q: Should the study staff or the patient complete the questionnaire?
A: The questionnaire should be completed by the study staff together with the participant. If time does not allow for an interview in conjunction with the patient visit, the interview can be done over the phone.

Q: Is a print version of the questionnaire available?
A: A print version of the questionnaire can be found at the website (https://chip.dk/Research/Studies/MISTRAL/Study-documents) together with many other study documents.

Q: Can blood samples be taken before the patient has given a stool sample?
A: No, the patient must deliver a stool sample before blood is taken. As the primary aim of this study is to investigate microbiome related factors associated with serious AIDS and non-AIDS events, collection of the faecal sample is of utmost importance. Stool samples should be returned to the lab within 48 hours of defecation and blood samples can be taken after the stool sample has been returned.

Q: The ART drug is not found in the list, do I use "other"?
A: Many ART drugs have more than one name. Please check the list of ART drugs on our website for common names. If the specific combination of drugs is not listed, please select the drugs individually. We do not need information regarding the doses.

All frequently asked questions are gathered on our website. If you have any questions not answered here, other solutions to the problems, or any general tips for participant recruitment/engagement, feel free to contact us at mistral.rigshospitalet@regionh.dk

---

Tips for enrolment

If you at your site has any tips or experiences to ease the enrolment process, please share with us so that other sites can benefit from them as well.

The MISTRAL consortium

MISTRAL is a large international consortium funded by EU. Research groups from all over Europe are engaged in the work, which has been split into several work packages each with their own aim.

The primary objective of the work led by CHIP is to strengthen and evaluate the understanding of the association between the gut microbiome composition and the risk of developing serious AIDS and non-AIDS events (SNAEs), including cardiovascular events. The progress report for the second reporting period (months 19-36) is currently under review with EU.

Other work packages within the MISTRAL consortium have recently published in the field of HIV and the microbiome. These works include an analysis of the gut microbiome in mice after vaccination with a HIV T-cell immunogen, and the impact of probiotics on immunological and gut microbiome factors in HIV discordant individuals. Links to these articles are provided below:

https://www.nature.com/articles/s41522-022-00368-y

https://www.frontiersin.org/articles/10.3389/fimmu.2022.1066036/full

---

Learn more about MISTRAL

You can find all the study documents related to this MISTRAL project at https://chip.dk/Research/Studies/MISTRAL/Study-documents

General information about MISTRAL can be found on this website https://chip.dk/Research/Studies/MISTRAL

Information about all the work packages included in MISTRAL can be found at www.mistral-hiv.eu

You can follow the MISTRAL consortium on Twitter https://twitter.com/mistralhiv

Finally, previous newsletters can be found at https://chip.dk/Research/Studies/MISTRAL/MISTRAL-Newsletters

This was all for now. We look forward to sharing more updates with you in half a year.

Sincerely,
The MISTRAL staff at CHIP

Daniel D. Murray
Scientific Lead

Lars Peters
Clinical Lead

Jakob F. Larsen
Project Manager

Karen S. Hansen
Project Coordinator

Francesca Roper
Project Coordinator

Kirstine Rasmussen
Bioinformatics

Emma E. Ilett
Scientific Collaborator

Sophia Hejndorf
Medical Student

You are receiving this letter because you are affiliated with the MISTRAL Study.

Our mailing address is:
mistral.rigshospitalet@regionh.dk

The MISTRAL study is funded under the European Commission's Research and Innovation Horizon 2020 Programme under Grant Agreement 847943.