MISTRAL Newsletter

November 2022

Dear sites involved in MISTRAL,

This is the first newsletter we send out for the EuroSIDA MISTRAL study, and we are very excited to share it with you. First, we would like to say thank you all for being part of the MISTRAL project. The study would not be possible without your or your patients' effort.

In this newsletter you can read about the status of the study, progress at the sites, frequently asked questions and general tips / information regarding study procedures. If you have any experiences or good ideas to share, feel free to contact us so we can share it with the other sites.

The MISTRAL consortium

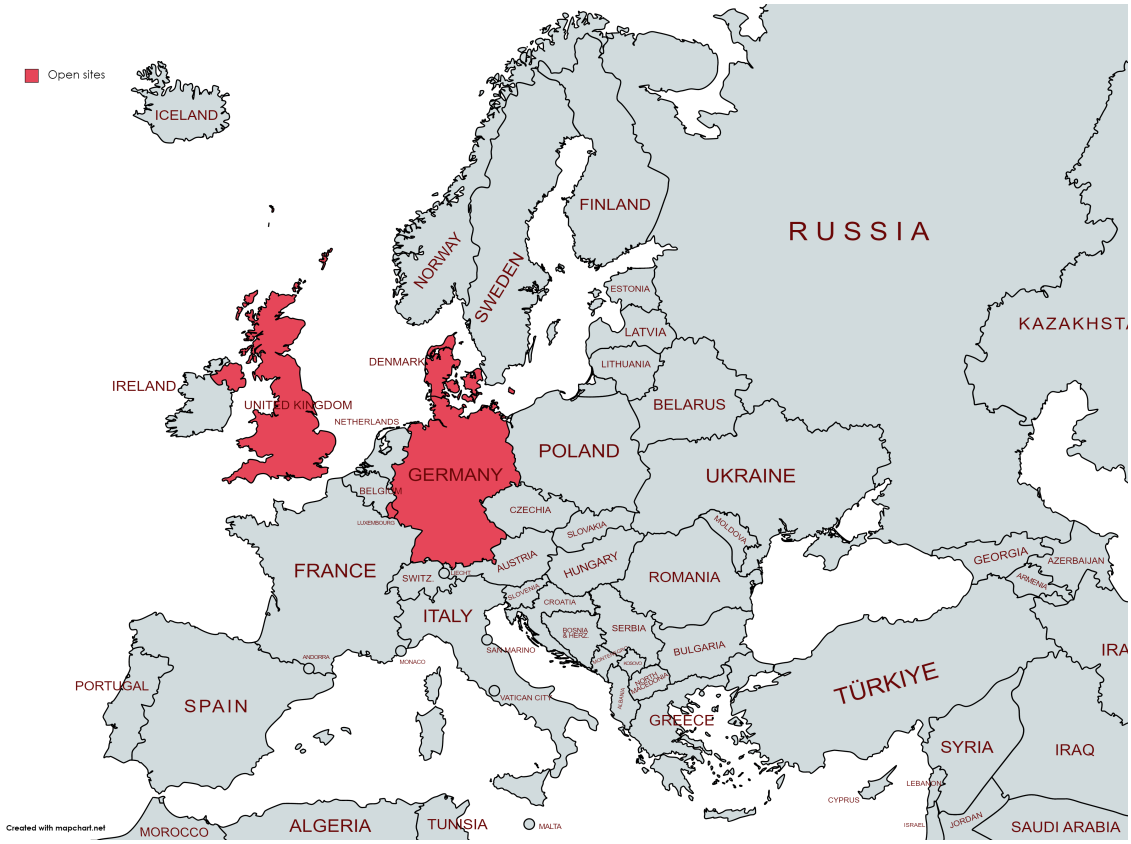
MISTRAL is a large international consortium funded by EU. Research groups from all over Europe are engaged in the work, which has been split into several work packages each with their own aim.

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.

On 20-21 October 2022 the MISTRAL investigators met in Barcelona to discuss the progress of the MISTRAL consortium. Although delayed by the COVID-19 pandemic, the work is progressing and the first results showing associations between HIV-1 viral replication and the gut microbiome are already published (paper).

Site and enrolment status

We are happy to announce that there are now 8 sites open for enrolment in our MISTRAL work package. On 29 September 2022, the first participant was enrolled by Hvidovre Hospital, Copenhagen, Denmark. This enrolment was closely followed by enrolments at University College London, United Kingdom, and now counts 8 participants in total. More sites are close to opening and we look forward to seeing many more participant enrolments across Europe.



Virtual training sessions

Three virtual training sessions have been held in September where 14 sites were trained. Two more sessions are planned for 8 November from 10-11 am CET and 9 November from 13-14 pm CET. If you would like to participate in one of the training sessions, please send an e-mail to the MISTRAL Secretariat mistral.rigshospitalet@regionh.dk. More online training sessions will be planned at a later time.

Frequently asked questions (FAQ)

Q: Does the creatinine clearance measurement have to be taken within

the last 3 months?
A: Previously, this was a requirement in REDCap, however this has now been changed to the last measurement taken.

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 form contains critical information on eligibility criteria and informed concent, 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.

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 defacation and blood samples can be taken after the stool sample has been returned.

Q: Must the patient take home the stool kit and do the stool sample at home?
A: Not necessarily. If possible, the stool sample can be taken the day of the visit, as long as the patient has given consent to participate in the study beforehand.

Q: A participant consents and takes the stool sample collection kit home with them, when do they have to return?
A: The participant has to return to the clinic with their stool sample within 48 hours of defacation. This should occur as early as possible to the consent, to ensure eligibility criteria are still met at time of sample collection. However, we allow up to 3 months from date of concent for the participant to collect the stool and return the sample to the clinic.

Issues with aliquoting stool into cryovials
We have also been made aware that the refrigerated stool sample can be

difficult to break up using the sterile inoculating loops provided in the study kit. The stool becomes hardened when cold and the plastic inoculating loops are too flexible to break it up into the required lentil sized pieces. We apologise for this inconvenience and we will look at obtaining different loops to overcome this. In the meantime, one suggestion to overcome this is to use sterile pipette tips to break up the stool and transfer the lentil sized aliquots into the storage tubes using the loop.

If you have any questions not answered above, other solutions to the problems, or any general tips for participant recruitment/engagement, feel free to contact us at mistral.rigshospitalet@regionh.dk.

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

Finally, you can follow the MISTRAL consortium on Twitter https://twitter.com/mistralhiv

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

Sincerely,
The MISTRAL staff at CHIP

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

Our mailing address is:
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