MISTRAL Update

Wednesday, 18th October 2023

Platinium I room, Warsaw, Poland

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chip
Centre of Excellence for
Health, Immunity and Infections

EuroSIDA

This project has received funding from the European Union's Horizon 2020 Research and Innovation programme under Grant Agreement No 847943

Agenda

- Welcome and introduction
- Recruitment update + projections
- Frequently Asked Questions (FAQs)
- What's next?
- Q&A

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Background

- Gut microbial dysbiosis has been linked with increased immune activation and various inflammatory markers – and may be a risk factor for serious non-AIDS events
- To date, many studies into the gut microbiome of people with HIV are limited by
  - Sample size
  - A lack of control for key confounders (particularly diet and sexual practice)
  - Lack of association with hard clinical endpoints
  - Cross sectional study designs
- In order to inform future interventional strategies, larger, well characterised cohorts with adequate follow-up are needed
- The EuroSIDA / MISTRAL protocol was therefore designed in order to address this need

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Study Design

- Observational study
- Aim to recruit up to 1,000 participants from established EuroSIDA sites.
- Participants can be existing EuroSIDA participants or new persons followed at a EuroSIDA site
- Blood and stool collection and MISTRAL questionnaire will occur at baseline and one follow-up visit
- Follow-up clinical data collection will occur during yearly EuroSIDA data collection (Oct-Dec) for all MISTRAL participants – hoping to find funding to continue FU post-MISTRAL
- Asides from the additional sample collection and questionnaire, all other data collection and study procedures are the same as EuroSIDA

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Study objectives

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Primary objective

- 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

Secondary objectives

- To evaluate the associations between the gut microbiome composition and function and pathologic increases in inflammation and coagulation mediators in PLWH

- To develop a risk score which makes use of information in the gut microbiome as well as other risk factors separately for the different endpoints.

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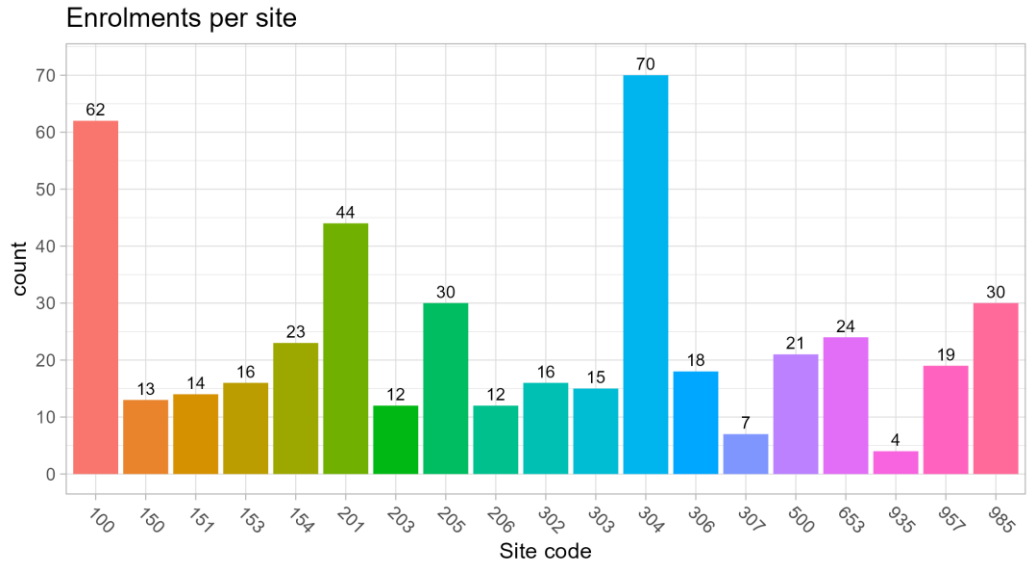
Recruitment update (as of 17.10.2023)

- 21 open sites, from 11 countries
- 19 sites have recruited at least one participant
- 450 enrollments, 259 of which are non-EuroSIDA participants



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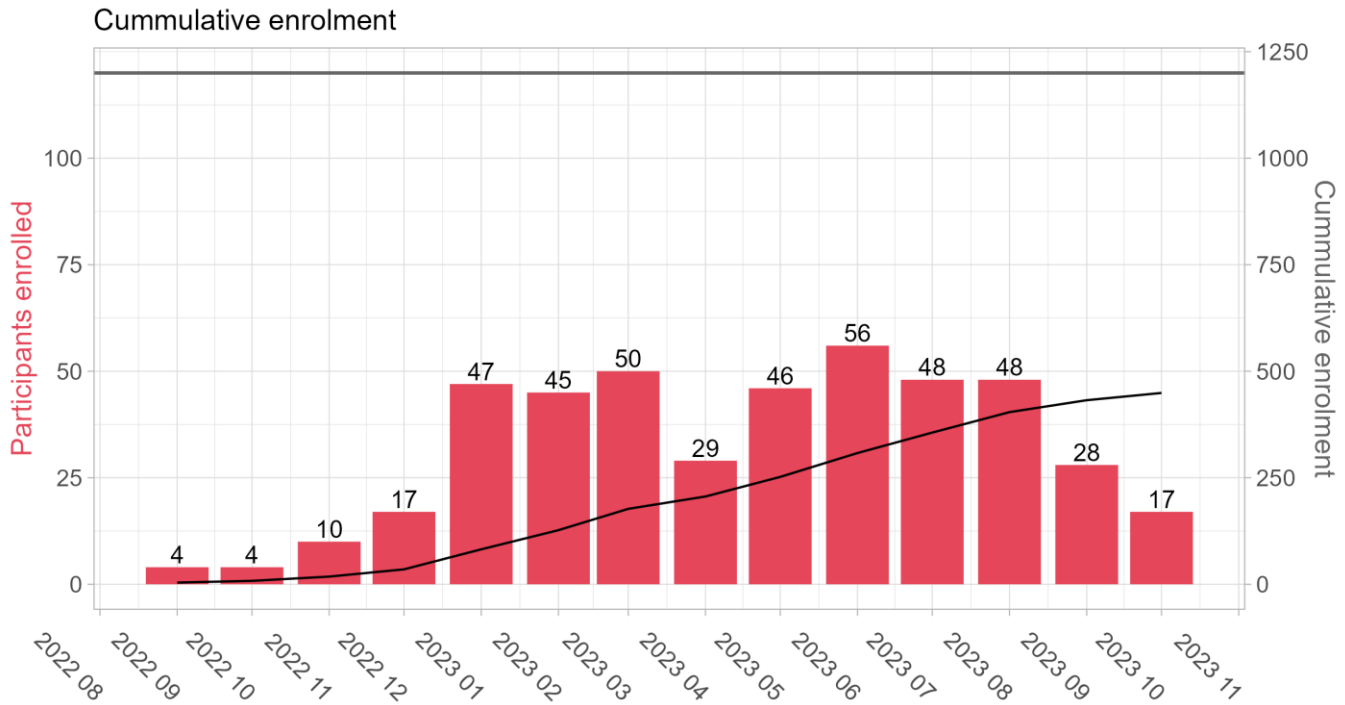
Recruitment projections

- Our original aim was to complete recruitment of 1,000 persons by December of this year to ensure adequate time for collection of follow-up sample for 1,000 participants within the EU reporting period
- We would like to complete enrolment by first quarter 2024 – but this requires recruitment to increase to 100 per month
- This new closing date will open the possibility of second samples being collected outside the Horizon2020 reporting period, which we hope to support, but we will likely close new enrolments by mid 2024
- If we need to close new enrolments prior to full enrolment, this will reduce power for associations with clinical events



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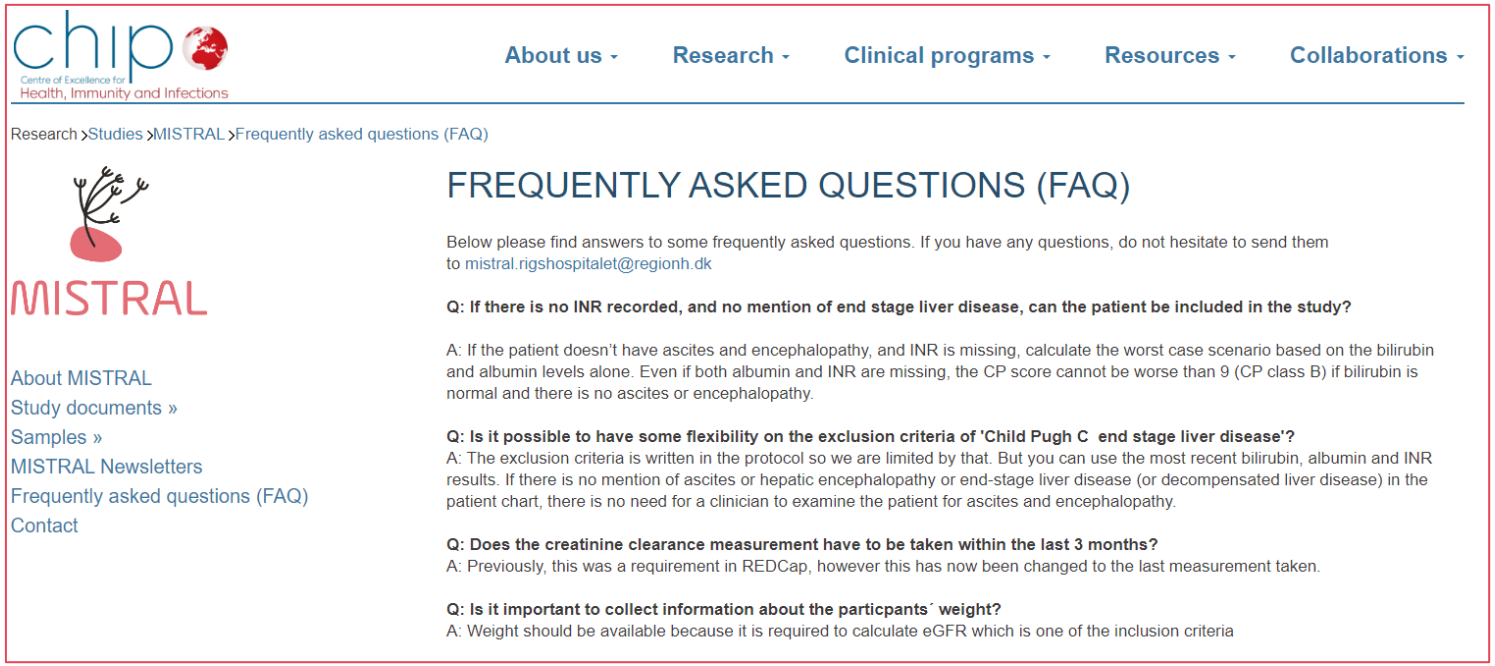
Frequently Asked Questions (FAQs)

- FAQs on our website.



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Frequently Asked Questions (FAQs)

Most frequent issues

E.g.

Q: Should the study staff or the patient complete the questionnaire?
A: The questionnaire should be completed by the study staff.

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

Q: Do the sample labels match, in any way, with the participants' PID numbers?
A: No, you should use one set of labels per participant per visit in the order that you receive the samples. The labels will then be linked to the correct participant and visit when they are scanned into REDCap. You will also need to record which label IDs belong to which patient on the site List of Stored Samples. For more information see slides 43-48 in the Training slides.

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What's next?

- Continue to support participant enrolment
- Plan for the first round of studies using the clinical samples
- The success of this study relies heavily on both site staff and participant interest and engagement
- We plan regular newsletters and investigator meetings to keep everyone updated
- Scientific manuscripts completed as part of this study will be made available to all through the CHIP and MISTRAL website
- We predict there will be a number of publications resulting from the samples and data collected as part of this protocol – as is standard in EuroSIDA, each manuscript will include MISTRAL site investigators as part of the writing group and each manuscript will acknowledge all site staff and participants for their contribution
- Investigators are also able to submit proposals to utilise these samples and data – in line with standard EuroSIDA and MISTRAL policies

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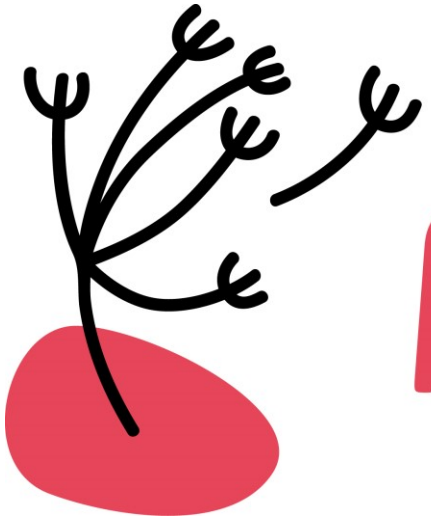
Questions?



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