



MISTRAL Newsletter

November 2023

Dear MISTRAL colleagues,

Enrolment of participants is moving forward, thank you for all your hard work. As you will see below in more detail, we still have a ways to go before reaching our goal of 1,000 enrolments. To get there, an increase in our overall monthly recruitment is needed. If there is anything we can do to help ease this process, please let us know.

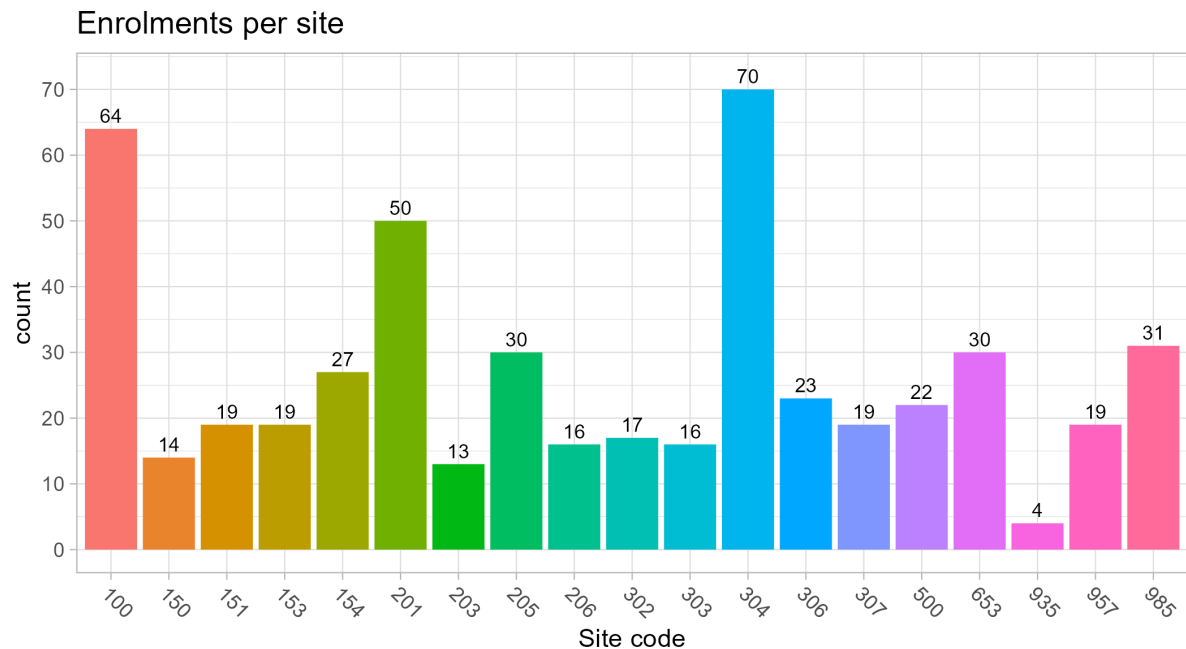
In this third MISTRAL study newsletter, we have gathered updates on the study, insights from the data collected so far, and some reminders to your sites. If you have any additional experiences or good ideas to share, feel free to contact us so we can share it with the other sites.

Lastly, as we are approaching December, we would like to start wishing you a lovely Christmas!

\MISTRAL team at CHIP

Site and enrolment status

There are now 21 sites open for enrolment in our MISTRAL work package. So far 504 participants have been enrolled and of these 213 were already part of EuroSIDA.



Cohort characteristics

Having just reached the half-way milestone, we can start exploring the main characteristics of the MISTRAL cohort. The group consists predominantly of white men who have sex with men (MSM). Their diet is mainly omnivorous, and the stool samples collected have mostly been of Type 4 of the Bristol Stool Chart.

We may not have yet reached full enrolment, but we can already see that we have a richly characterised cohort in relation to factors that may influence the

microbiome and the risk of serious non-AIDS events. Preliminary assessments also highlight the need to treat these variables carefully given the observed correlations and small numbers of certain subgroups (e.g., women and non-white ethnicities).

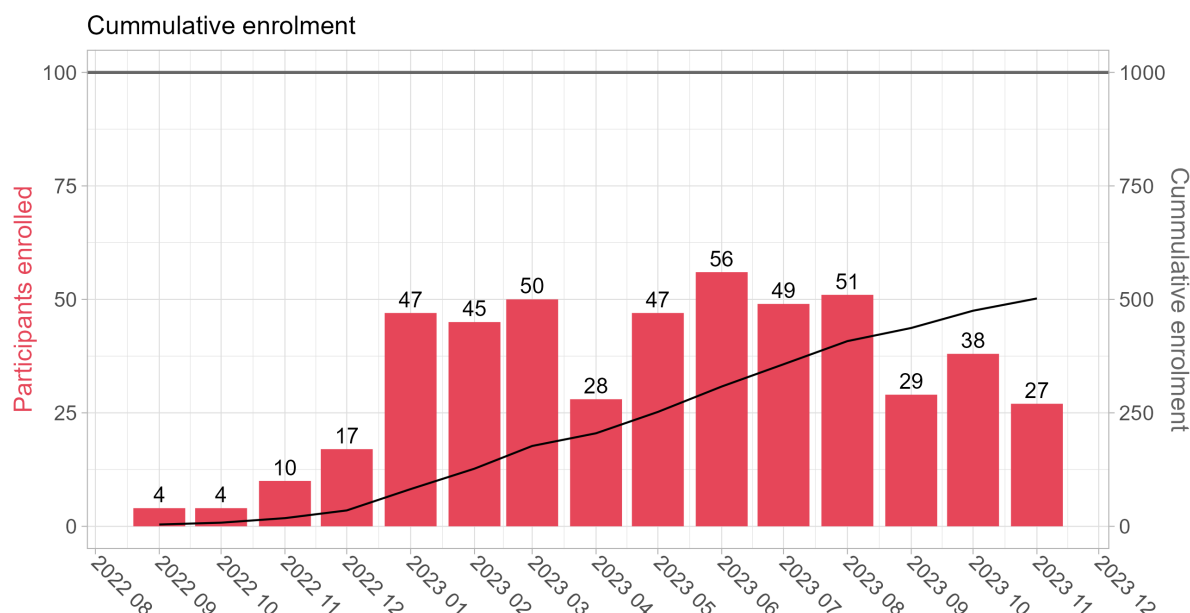
Total participants, n (%)	504 (100)
EuroSIDA, n (%)	213 (42)
Age, median [min, max]	59 [50, 86]
Male, n (%)	403 (80)
Consented to genomics analysis, n (%)	465 (92)
Country of recruitment, n (%)	
	Belgium 64 (13)
	Croatia 31 (6)
	Czechia 4 (1)
	Denmark 79 (16)
	Germany 145 (29)
	Luxemburg 22 (4)
	Poland 19 (4)
	Spain 30 (6)
	United Kingdom 109 (22)
Ethnicity, n (%)*	
	White 247 (49)
	Black 22 (4)
	Other 7 (1)
	Unknown 15 (3)
Mode of HIV infection	
	MSM 299 (59)
	Heterosexual contact 95 (19)
	Injecting drug user 15 (3)
	Sexual contact + injecting drug user 6 (1)
	Other 8 (2)
	Unknown 80 (16)
Diet preference, n (%)	
	Omnivore 452 (90)
	Pescetarian 9 (2)
	Vegetarian/vegan 15 (3)
	Unknown 27 (5)
* Data only available for non-EuroSIDA patients	

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 samples for 1,000 participants within the EU reporting period. However, given how recruitment of participants has been proceeding, we will not be able to complete the

recruitment by this year. We have therefore decided to extend the deadline for recruitment of new participants to the first quarter of 2024. This still requires recruitment to increase to around 100 per month across all open sites. As you can see in the figure below, we are quite far from this number.

If we need to close for new enrolments prior to full enrolment, the power for associations with clinical events will be reduced. We would of course like to avoid doing this.



MISTRAL Update at 19th European AIDS Conference (EACS), Warsaw, Poland. 18-21 October 2023

On Wednesday, 18th October 2023, in connection with the EACS Conference, we held a MISTRAL update meeting. Thank you to those who attended the (early morning) meeting, it was great to meet you in person. We very much appreciated the interest shown in the study, and the interesting questions and discussions.

Reminders and updates

MISTRAL Follow-up (FU1 Autumn 2023)

For those sites that have had enrolment forms checked and locked (validated) in REDCap before 1st July 2023, this is a kind reminder to complete MISTRAL Follow-Up (FU1 Autumn 2023) in REDCap by **1st December 2023**. Should you

encounter any challenges, please inform us promptly. We are happy to assist you with any support to facilitate the process.

Finalising forms before April 2024

All REDCap enrolment forms with a completed and locked (validated) status will be downloaded in April 2024. In order to include 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.

Plan for Visit 2

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

Frequently asked questions (FAQ)

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](#).

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.

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.

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, and in the meantime, MERRY CHRISTMAS!

Sincerely,

The MISTRAL staff at CHIP



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