



MICROB·AI·OME

Federated artificial intelligence for privacy-preserving international stratification of colorectal cancer patients

Midterm recruitment report - France

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History of Changes

Change			Description of Change	Approval of the Report
No.	Date	Version		
1	31/03/2025	1	First submitted version	Mathieu Almeida

Table of Acronyms and Definitions

CRC	Colorectal cancer
FIT	Fecal immunochemical test
CPP	Comité de Protection des Personnes (French Ethics Committee)
GDPR	General Data Protection Regulation
CNIL	Comission Nationale Informatique et Liberté (French National Protection Data Agency)

1 Microb-AI-ome as a whole

Colorectal cancer (CRC) is the second most common cancer worldwide, but early detection significantly improves outcomes. Current screening relies on the fecal immunochemical test (FIT) to determine the need for a colonoscopy. However, FIT has a high false-positive rate leading to unnecessary and costly procedures. It is known that the microbiome is altered in colorectal neoplasia. The *Microb-AI-ome* project explores whether AI-assisted stool microbiome analysis combined with clinical and nutritional data can offer a more accurate, non-invasive, and cost-effective alternative for CRC screening. In this project, federated AI will be used to facilitate international collaboration while improving data security and privacy. In this international collaboration and as a proof of concept of federated AI, patients in France and Ireland undergoing colonoscopy will provide stool samples, clinical and nutritional data and will be used for federated AI.

2 Midterm recruitment report – France

2.1 Rationale

In France, “Le French Gut-colo” study for Microb-AI-ome project is an observational study, sponsored by INRAE and coordinated by Pr Robert Benamouzig (AP-HP), designed to analyze the intestinal microbiota of individuals aged 50 to 75 undergoing routine colonoscopy. The research aims to identify microbiota signatures associated with colorectal features such as adenomas, advanced adenomas, and colorectal cancer (CRC). This study is an ancillary project of the broader “Le French Gut” study, which aims to collect 100,000 fecal samples along with associated nutritional and clinical data from French residents. The main aim of “Le French Gut” is to gain a better understanding of the diversity of intestinal microbiota as a function of lifestyle, state of health, physical activity and other parameters.

The recruitment of “Le French Gut-colo” study, taking place from 2024 to 2028, is supported by a collaboration between AP-HP, INRAE, and a network of expert centers specializing in colorectal cancer. Pr Robert Benamouzig is the investigator coordinator of “Le French Gut” and “Le French Gut-colo”.

2.2 Description

1. The study logistics, ethical and General Data Protection Regulation (GDPR) compliance procedures have been implemented (approval obtained from the ethics committee (CPP) on December 7, 2023 and from the national data protection agency (CNIL) on February 15, 2024).
2. We have developed and produced patient communication flyers to explain the purpose of the study and the steps to be taken to complete data collection. Here are the flyers used in the study:



Figure 1: Flyers of Le French Gut-colo study.

- To maximize inclusion, we have developed a colorectal cancer expert centers network and updated the ethical agreements to notify the ethics committee. Here is a map of the 27 expert centers included in the study:

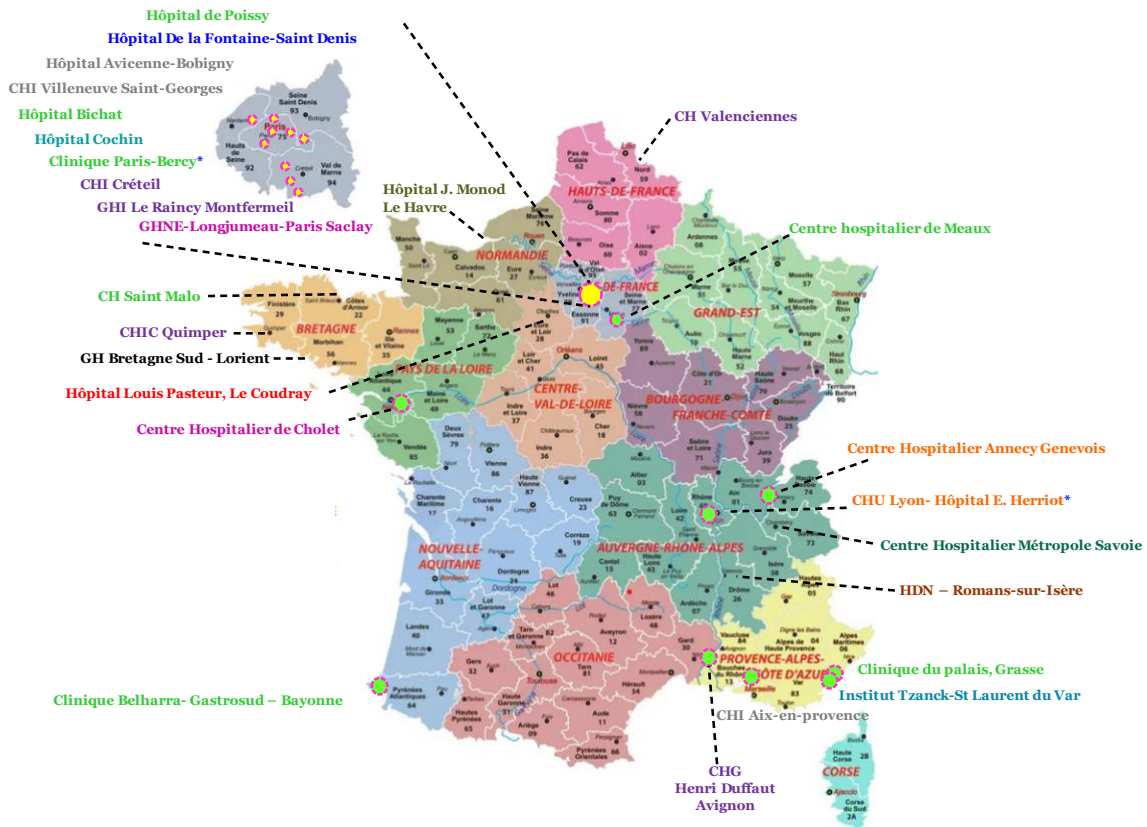
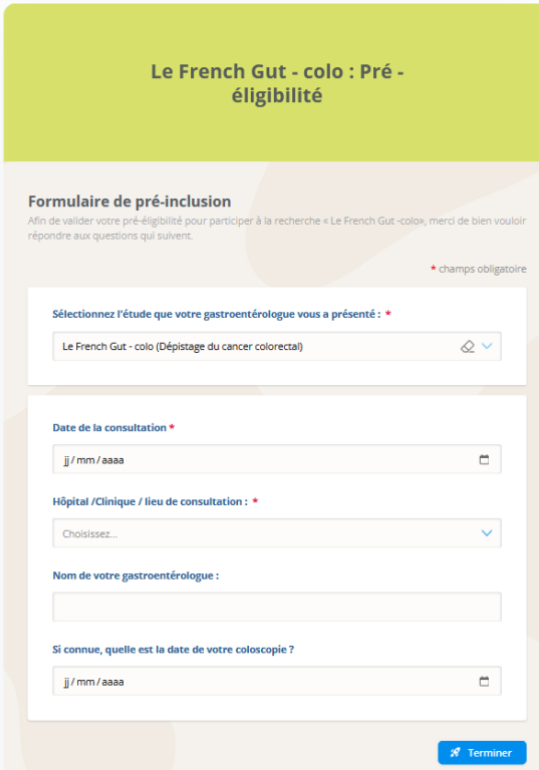


Figure 2: Map of Le French Gut-colo clinical expert center network

4. We have started the clinical phase of the study, with the presentation of the project to patients during consultation (flyer and FIT test distribution), pre-inclusion in the study, and return of the patient for colonoscopy performed by expert centers.
5. For data collection, the patients register on the web platform and provide information on nutrition, health, previous colonoscopies (if applicable), and cancer risk factors (either at home or with assistance from a clinical research associate). The FIT test (blood in stool) and colonoscopy results are also collected by the coordinating investigator.

Here is a view of the first questionnaire to complete by the patient on the web platform:



Le French Gut - colo : Pré-éligibilité

Formulaire de pré-inclusion
Afin de valider votre pré-éligibilité pour participer à la recherche « Le French Gut -colo», merci de bien vouloir répondre aux questions qui suivent.

* champs obligatoire

Sélectionnez l'étude que votre gastroentérologue vous a présenté : *

Le French Gut - colo (Dépistage du cancer colorectal)

Date de la consultation *

jj / mm / aaaa

Hôpital /Clinique / lieu de consultation : *

Choisissez...

Nom de votre gastroentérologue :

Si connue, quelle est la date de votre coloscopie ?

jj / mm / aaaa

Terminer

Figure 3: View of the first online questionnaire page for Le French Gut-colo study.

6. The stool samples are centralized at AP-HP Avicenne hospital with quality control assessment and pseudonimized.
7. Finally, the samples are received at INRAE-MetaGenoPolis for biobanking and microbiome analysis (fecal data collection). The samples are stored in our biobanking facility prior to processing, see below:

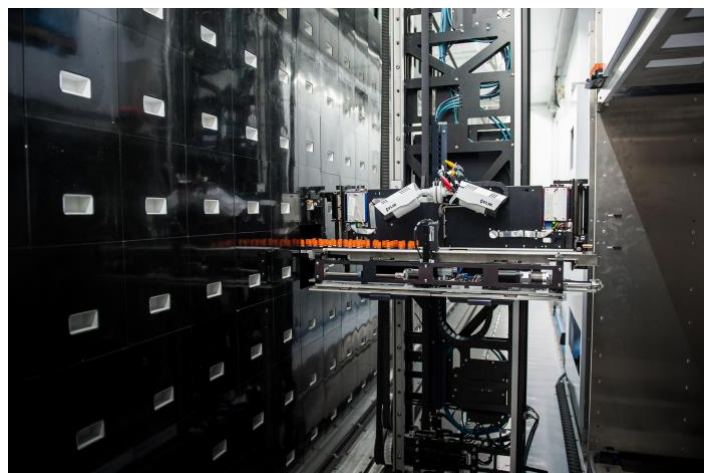


Figure 4: Picture of the INRAE MetaGenoPolis biobank, which can store up to 600,000 microbial samples.

2.3 Centers involved

The following centers are enrolled in France:

Table 1: List of the clinical centers, the inclusion date and the lead investigators. Pink, new centers included.

Investigator	Center	City	Launch meeting
Armand GARIOUD	CHI Villeneuve Saint-Georges	Villeneuve Saint Georges	15/05/2024
Edoardo POLI	Groupe Hospitalier Nord Essonne	Orsay	15/05/2024
You-Heng LAM	Centre Hospitalier de Cholet	Cholet	15/05/2024
Robert BENAMOUZIG	Hopital Avicenne	Bobigny	15/05/2024
Christophe LOCHER	Centre hospitalier de Meaux	Meaux	04/06/2024
Frédéric MORYOUSSEF	CH Poissy	Poissy	04/06/2024
Sabra GUELLOUZ	Centre hospitalier Saint Malo	Saint Malo	04/06/2024
Patrick DELASALLE	Clinique du palais	Grasse	04/06/2024
Mathias VIDON	CHI Créteil	Créteil	20/06/2024
Serge BELLON	CHG Henri Duffaut	Avignon	20/06/2024
Ambroise LALIEU	CH Valenciennes	Valenciennes	20/06/2024
Karine BIDEAU	CHIC QUIMPER	Quimper	20/06/2024
Guillaume ALLARD	CHI Aix en provence	Aix en Provence	20/06/2024
Gael GOUJON	Hôpital Bichat	Paris	20/06/2024
Razvana-Sorina MUNTEANU	Hôpital Louis Pasteur	Le Coudray	04/07/2024
Adrien SPORTES	Institut Arnault Tzanck	Saint-Laurent du Var	05/09/2024
Sylvain MERLE	Centre Hospitalier Annecy Genevois	Epagny	10/09/2024
Caroline LEMAITRE	Hopital Monod	Le Havre	01/10/2024
Mathieu PIOCHE	CHU Lyon-Hopital Edouard Hériot	Lyon	04/10/2024
Florence SKINAZI	Hôpital De la Fontaine-Saint Denis	Saint Denis	04/10/2024
Gilles MACAIGNE	GHI Le Raincy Montfermeil	Montfermeil	18/12/2024
Olivier BERTHELET	CH Chambéry	Chambéry	13/01/2025
David KARSENTI	Clinique de Bercy	Charenton le pont	20/06/2024 & 24/01/2025
Fabien DARFEUIL	Hopitaux Drome Nord	Romans sur Isère	04/02/2025
Maxime REMOND	Hôpital Cochin	Paris	14/02/2025
Florent EHRHARD	Hopital de Lorient	Lorient	27/02/2025
Christine LEFORT	Clinique Belharra	Bayonne	04/06/2024 & 24/02/2025

3 Conclusion, next steps

1. Patient enrollment is progressing across the country, with the first sample collections already being processed at INRAE-MetaGenoPolis. To date, 123 patients have been included.
2. The sample processing pipeline is efficient, benefiting from the expertise of the core French Gut project and the prioritization of samples upon reception.
3. Each expert center receives personalized support from the AP-HP team, working in collaboration with INRAE, to enhance patient enrollment.
4. Experience-sharing meetings were organized with all investigators to optimize and improve study procedures.
5. The network of expert centers is expanding, with four new centers having joined since 2025.
6. The French Gut-colo questionnaire will be distributed to participants of Le French Gut project who have consented to follow-up. This initiative could allow the inclusion of up to 2,000 additional participants who have previously undergone a colonoscopy and provided a stool sample.
7. Data from other ongoing studies analyzing the gut microbiome in colorectal cancer will be integrated, including the French “Lynch” project led by Prof. Robert Benamouzig. The *Lynch* study is a multicenter, double-blind, placebo-controlled trial designed to evaluate the preventive effects of low-dose aspirin on the development and recurrence of colorectal adenomas in patients with Lynch syndrome (a hereditary condition that significantly increases the risk of colorectal and other cancers). The collected data will be analyzed and integrated into the federated *microb-AI-ome* system to enhance the identification of predictive biomarkers for colorectal cancer risk.

Microb-AI-ome consortium partners

- Universitaet Hamburg (UHAM), DE
- University College Cork – National University Of Ireland, Cork (UCC), IE
- Egnosis SRL (Egnosis), RO (Formerly: GNOME Design SRL (GND))
- tp21 GmbH (TP21), DE
- Research Institute AG & CO KG (RI), AT
- Institut National De Recherche Pour l'Agriculture, l'Alimentation et l'Environnement (INRAE), FR
- Assistance Publique Hopitaux de Paris (APHP), FR
- Mater Misericordiae University Hospital (MMUH), IE



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