



MICROB·AI·OME

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

Midterm recruitment report - Ireland

September 30th, 2024

Microb-AI-ome - Public deliverable report **D2.3**

©Microb-AI-ome consortium

This report is published on the Microb-AI-ome website www.microbaiome.net



Table of content

1	Microb-AI-ome as a whole	3
2	Midterm recruitment report - Ireland	3
2.1	Rational	3
2.2	Description of work performed	3
2.3	Microb-AI-ome partners involved	3
3	Conclusion, next steps	4

1. Microb-AI-ome as a whole

Current colorectal cancer (CRC) screening tools including the fecal immunochemical test (FIT), lack sensitivity and specificity. The microbiome has been shown to be altered in colorectal neoplasia. The Microb-AI-ome project evaluates the hypothesis that artificial intelligence (AI)-supported stool microbiome analysis may provide a more accurate, non-invasive and cost-effective tool for first-line population-based CRC screening. To test this hypothesis, patients from France and Ireland undergoing CRC screening colonoscopy, will provide stool sample for microbiome analysis via privacy-preserving federated AI. The study exploits the clinical, laboratory, computation and legal expertise of project partners in Ireland, France, Germany, Austria and Romania.

2. Midterm recruitment report - Ireland

2.1 Rationale

Irish clinical sites were recruited based on their formal relationship with Bowelscreen, the Irish National CRC screening service (under the governance of the Health Service Executive (HSE) and Irish Department of Health). Patients have been enrolled from the cohort undergoing screening colonoscopy (following a FIT-positive result) to provide a stool sample for subsequent microbiome analysis. Since this cohort comprises patients with CRC, pre-malignant polyps and normal colons, the correlation between clinical phenotype and microbiome signal may provide an enhanced non-invasive alternative to FIT for population screening.

2.2 Description of work performed

1. The challenges inherent in complex clinical studies including ethics, General Data Protection Regulation (GDPR) governance and study nurse recruitment have been addressed.
2. Patient selection and recruitment following informed consent has commenced.
3. Clinical, endoscopic and pathological datasets have been agreed upon and are being collated by the study nurse.
4. Comprehensive dietary/nutritional evaluation is being performed by study nurse.
5. Stool sample collection, transport from clinical sites and initial processing by partner UCC has commenced.
6. To date MMUH has recruited 56 patients with 42 meeting full inclusion criteria.
7. MUH (to be added as affiliated partner through an amendment to the grant agreement) recruitment has commenced in September with initial numbers of 2-3/week being enrolled

2.3 Microb-AI-ome partners involved

MMUH (Mater Misericordiae University Hospital): This is the major coordinating centre and clinical site. The Pillar Centre for Education and Research within the MMUH is the administrative centre for the Irish partners. MMUH's clinical site has designated a clinical lead (Prof. Jan Leyden) and nursing staff dedicated to the study.

MUH (Mercy University Hospital): is a clinical site to be added as an affiliated partner through an amendment to the grant agreement with dedicated clinical leads (Prof. Micheal O'Riordán, Dr. Donal Sheehan) and nursing staff for patient recruitment and stool sample collection.

SJH (St James Hospital): is a second clinical site that is to be added as an affiliated partner through an amendment to the grant agreement and is progressing through local ethics submission and associated documentation involved data control, governance and control.

UCC (University College Cork): is the Irish-based laboratory for stool processing and microbiome analysis under the supervision of the local PI, Prof. Paul O Toole.

SVUH (St Vincents University Hospital): is listed in the original grant agreement as one of the clinical sites for patient recruitment, but it has withdrawn from study.

3. Conclusion, next steps

1. Experience has been gained in patient recruitment protocols involving
 - a. direct contact with potential patients including in-person review of consent and information sheets with study nurse,
 - b. the anonymisation process
 - c. addressing stool collection challenges and dataset completion
2. We plan to significantly enhance patient enrolment following full time study nurse recruitment.
3. We aim to minimise patient exclusion by increasing direct patient contact by study nurse to optimise stool collection and reduce non-attendance for colonoscopy.
4. The clinical, colonoscopic and pathological datasets together with the comprehensive dietary/nutritional datasets will be registered in the federated database network to be made available for federated training of AI models to correlate clinical-pathological phenotypes with stool microbiome compositions.

Microb-AI-ome consortium partners

- Universitaet Hamburg (UHAM), DE
- University College Cork – National University Of Ireland, Cork (UCC), IE
- GNOME Design SRL (GND), RO
- 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



The Microb-AI-ome project has received funding from the European Union's Horizon Europe research and innovation programme under the grant agreement Nr. 101079777.

Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.