



MICROB·AI·OME

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

Training Plan for the Clinical Users of the CRC Stratifier

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Table of content

1	Microb-AI-ome as a whole	4
2	Training Plan for the Clinical Users of the CRC Stratifier	5
2.1	Rationale	5
2.2	Methods	5
2.2.1	Workshop	5
2.2.2	Questionnaire	6
2.3	Results	6
2.4	Training Plan.....	8
2.4.1	Module 0: Introduction to the CRC Stratifier (Approx. 5-10 minutes).....	8
2.4.2	Module 1.1: How to install the Microbiome Profile Extractor (Approx. 60 minutes)	9
2.4.3	Module 1.2 How to install the CRC Stratifier (Approx. 60 minutes)	9
2.4.4	Module 2.1: How to operate the Microbiome Profile Extractor (Approx. 90 minutes).....	9
2.4.5	Module 2.2: How to operate the CRC Stratifier (Approx. 15 minutes)	10
2.4.6	Module 3: Interpreting the Risk Report (Approx. 60 minutes)	10
2.4.7	Module 4: Limitations and Best Practices (Approx. 60 minutes)	10
2.4.8	Module 5: Practical Case Studies / Interactive Simulations (Optional, 30-60 minutes) ...	11
2.4.9	Delivery Approach	11
2.4.10	Module recommendations	11
2.5	Microb-AI-ome partners involved.....	11
3	Conclusion, next steps.....	12
4	Annexes.....	13
4.1	Questionnaire.....	13

History of changes

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0.4	Niklas Probul	2026/04/10	Reviewed by TP21, Revised by UHAM
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0.7	Marta Ferrandis Vila	2026/04/27	Final formatting
1.0	Christina Saak	2026/04/27	Submission

Table of acronyms and definitions

Acronym/Abbreviation	Full name/Description
APHP	Assistance Publique Hôpitaux De Paris, Hôpital Avicenne Service de Gastroentérologie
CRC	Colorectal cancer
CRCDC-IDF	Le Centre Régional de Coordination des. Dépistages des cancers d'Ile-de-France.
GND	Egnosis
INRAE	Institut national de recherche pour l'agriculture, l'alimentation et l'environnement
MMUH	Mater Misericordiae University Hospital and National Cancer Screening Service, Department of Gastroenterology
RI	Research Institute AG & Co KG
SC	Steering Committee
TP21	tp21 GmbH
UCC	University College Cork – National University Of Ireland, Cork
UHAM	Universitaet Hamburg

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 addition to national CRC screening programmes. In this project, federated AI will be used to facilitate international collaboration while improving data security and privacy. Patients in France and Ireland undergoing colonoscopy will be invited to contribute stool samples and relevant clinical and nutritional information. These data will be analysed through federated AI to develop and test improved screening approaches.

2 Training Plan for the Clinical Users of the CRC Stratifier

2.1 Rationale

This report presents the training approach developed for the CRC Stratifier: the CRC Stratifier is one of the end-products of the Microb-AI-ome project, a tool for calculating a CRC risk score that can be used in screening to help decide whether a colonoscopy is required.

As the project moves towards testing and real-world use of the tool, it is necessary to ensure that healthcare professionals and other users understand how to use it correctly as well as how to correctly interpret its results. This document therefore focuses on defining a clear and practical training plan to support its safe and effective use in clinical settings.

2.2 Methods

To ensure a meaningful training plan focused on the actual users of the CRC Stratifier, clinical partners of the project were invited to participate in a workshop presenting the CRC Stratifier rationale and an initial training plan for its usage.

Following the workshop, a questionnaire was developed and shared with the clinical partners to get even further detailed feedback.

Based on the workshop and questionnaire results, the initial training plan was further developed.

2.2.1 Workshop

Two tandem workshops were conducted to minimize scheduling conflicts. Feedback was collected from clinical and research partners involved in the project to ensure that the training plan reflects real-world needs.

The first session was conducted on 2026-03-09 at 12 CET.

The second session was conducted on 2026-03-12 at 15 CET

The following partners participated:

Table 1. Attendance to the CRC Stratifier workshop

Participants	
1.	UHAM
2.	TP21
3.	MMUH
4.	CRCDC-IDF
5.	St. James Hospital (subcontracted site)

In both workshops, the project itself was introduced as well as the concept of the CRC Stratifier.

Then, the following topics were discussed:

- The logistics of the CRC Stratifier deployment, considering possible deployments scenarios including in sequencing laboratories and hospitals as well as potential usage by laboratory staff, nurses, doctors or even patients.
- The data entry scenarios and validation of data input for a risk score calculation by the CRC Stratifier
- How the calculated risk should be displayed in the final result and what additional information would be useful to display.
- The training plan itself in terms of content, time and kind of training.
- The handling of updates to the CRC Stratifier and therefore also to the training plan

2.2.2 Questionnaire

An extensive questionnaire was developed based on the workshop using a GDPR-compliant survey tool provided by UHAM. The questionnaire was split into thematic groups, similarly to the workshop:

- Introduction and role assignment (nurse, doctor, laboratory staff, ...)
- Logistics of stool sample sequencing, microbiome profile extraction and risk score calculation
- Data entry and validation
- Generated risk report
- The training itself

Furthermore, a final free-form answer box was added to allow for any feedback not yet captured.

The full questionnaire can be found in the appendix [4.1 Questionnaire](#)

2.3 Results

The workshop was successfully concluded and the questionnaire was sent around for additional feedback.

Based on the combined feedback, a deployment plan with CRC Stratifier requirements as well as the training plan could be developed.

The following section summarizes the findings from the clinical workshops and the practitioner questionnaire, discussing deployment, the CRC Stratifier itself as well as training.

The consensus points to a two-stage deployment strategy. An initial pilot phase will involve localized deployment at partner hospitals for clinical validation and technical refinement, supported by UHAM. This phase serves as the prerequisite for a potential subsequent national-level screening roll-out.

Two general stakeholders are relevant for this initial pilot phase:

1. The hospitals themselves
2. The (sequencing) laboratories

While some clinics may have their own laboratories capable of sequencing the stool samples, this is not always the case. A key outcome of the workshops was the agreement to treat the full process, from sample preparation and microbiome sequencing to the generation of the microbiome profiles, as one continuous workflow, helping to ensure clarity and consistency across different settings. This entire process should then be performed by the sequencing laboratory, no matter whether the laboratory is internal to the hospital or an external service provider. It follows that a software to extract the microbiome profiles,

hereafter called the Microbiome Profile Extractor, should be developed for usage specifically in laboratories.

When giving out the CRC stool sample kit, the clinical providers should include a questionnaire for the required patient meta information, e.g. age, smoking status, etc. This questionnaire can either be a simple paper questionnaire or a more sophisticated website that is accessible via a QR code included in the CRC Stratifier kit.

Independent of the questionnaire format, the questions should be self-explanatory, giving guidance wherever necessary. In the paper format this can be extra information accompanying each question, in the online format there could be info boxes for each question. Appropriate warnings regarding the applicability of the CRC Stratifier to a specific person should also be included. In the paper format, this could be in the form of warnings as additional information for the relevant questions, e.g. “If your age is below 50, you are not suitable for this test, please talk with your doctor to make sure whether this test suits you”. For the online format this could be shown as a warning when selecting certain answers.

Depending on the specific logistics of the clinic and/or laboratory, it may be that the laboratories will receive all required data (the microbiome profiles extracted from the stool sample and the questionnaire of the meta data) and run the CRC Stratifier. The results of the CRC Stratifier will then be relayed to the clinical care provider who informs the patient. Alternatively, clinics may receive the microbiome profiles from the laboratory and input it into the CRC Stratifier together with the metadata.

The deployed CRC Stratifier should be password protected. A specific super user role should be available that allows seeing all CRC Stratifier runs of all users. In addition, a standard user system with a username and password is planned that allows the operation of the CRC Stratifier for a specific patient.

Regarding the CRC Stratifier output, it was concluded that there should be two separate risk reports, one for the clinical staff with more details and one for the patient with fewer, more condensed information. This will be clarified in the initial phase based on feedback from patients and clinical staff. Generally, the risk report should contain a percentage score (regression) as the CRC risk score. Alternatively, this might be a score between 0 and 1, depending on feedback in the initial phase. Additionally, the most relevant factors contributing to the result of the CRC Stratifier should be part of the risk report. Lastly, if the patient was not eligible for the CRC Stratifier, this should be mentioned again in the risk report.

Concerning the training itself, not one specific format of training was identified as the generally preferred one and a mix of in-person, online and video tutorial-based training is envisioned. In general, the CRC Stratifier should be thoroughly documented in an extensive documentation page including video tutorials.

Furthermore, an online sandbox version of the CRC Stratifier should be deployed to be used strictly with synthetic data that only serves for testing/training purposes. The training itself and therefore also the documentation should be split into multiple categories:

- A tutorial on how to use the CRC Stratifier
- A tutorial on how to interpret the risk report
- A tutorial on the limitations of the CRC Stratifier

Any training should take a maximum of up to 3 hours if done in person/online.

Lastly concerning updates that change how the CRC Stratifier is used or how results are interpreted: Updates that significantly change how the tool is used will be carefully managed and accompanied by appropriated training, in order to ensure safe and consistent use. Therefore, in the initial phase, the training plan will be updated multiple times, iteratively improving and making the CRC Stratifier ready for an up to nationwide deployment, with no further required training plan or usage updates after the initial phase.

Finally, in case of administrative or other issues with using the CRC Stratifier in the hospitals, a risk mitigation strategy was developed to use the CRC Stratifier as an educative tool. Purely based on the meta information, the CRC Stratifier can output information on which factors potentially contribute to a CRC risk, giving further information, e.g. linking the smoking status to CRC risk and how smoking contributes to CRC.

2.4 Training Plan

The training plan is split into modules which can be taken individually or together.

The modules are generally independent of each other, however two special modules exist:

- Module 0 serves to introduce the CRC Stratifier generally and should always be taken
- Module 5 is a practical module to try out the CRC Stratifier and analyze some demo results based on synthetic data. This module is meant as a follow up module after the other modules and the content can be adjusted depending on which aspect the focus is on, e.g. focusing on the data input into the CRC Stratifier or focusing on the results and their interpretation.

Other than these special modules, module 1 is for the installation of the Microbiome Profile Extractor and CRC Stratifier, while module 2 focuses on their usage. Module 3 then trains the interpretation of the resulting risk report, while Module 4 informs about the limitations and best practices.

2.4.1 Module 0: Introduction to the CRC Stratifier (Approx. 5-10 minutes)

This is a special module meant to introduce the CRC Stratifier before taking the other modules.

Target Audience:

- Patients
- Clinical and laboratory staff
- IT staff

Objectives:

- Teach the purpose, functionality and intended usage of the CRC Stratifier
- Communicate why and when to use the CRC Stratifier

2.4.2 Module 1.1: How to install the Microbiome Profile Extractor (Approx. 60 minutes)

Target Audience:

- IT personal of the laboratories

Objectives:

- Communicate hardware and time requirements of the Microbiome Profile Extractor. The sample processing can take up to hours of computation time and is not possible on normal desktop computers due to high computational and RAM requirements.
- Show the different available installation types either as a containerized sandbox or natively and help trainees on which option to choose
- Teach the access and users management of the Microbiome Profile Extractor
- Guide trainees on where to find help in troubleshooting if issues arise

2.4.3 Module 1.2 How to install the CRC Stratifier (Approx. 60 minutes)

Target Audience:

- IT personal of the laboratories or clinics

Objectives:

- Communicate hardware and time requirements of the CRC Stratifier. Depending on the finally chosen Microb-AI, the CRC Stratifier might require a computation server to run on.
- Show the different available installation types either as a containerized sandbox or natively
- Teach the access and users management of the CRC Stratifier
- Guide trainees on where to find help in troubleshooting if issues arise

2.4.4 Module 2.1: How to operate the Microbiome Profile Extractor (Approx. 90 minutes)

Target Audience

- Laboratory staff

Objectives

- Explain the final taxa abundance report conceptually as well as what the Microbiome Profile Extractor is doing.
- Communicate time requirements of the Microbiome Profile Extractor. The sample processing can take up to hours of computation time.
- Discuss the complete protocol from the sample arrival to the final taxa abundance report to help the trainees:
 - Understand the sample extraction protocol
 - Understand which sequencing methods and protocols are compatible and which ones are preferred with the Microbiome Profile Extractor
 - Understand how to use the Microbiome Profile Extractor with the sequences received from the chosen sequencing method and protocol.
 - Understand how to interpret the quality control report of the Microbiome Profile Extractor. Furthermore, understand how to manage insufficient quality

2.4.5 Module 2.2: How to operate the CRC Stratifier (Approx. 15 minutes)

Target Audience:

- Laboratory personnel responsible for generating the risk report
- Nurses, medical doctors and clinicians involved in generating the risk report

Objectives:

- Demonstrate the user interface and user system
- Guide trainees on what data needs to be input where and how to manage if certain data of a patient is unknown or in another format as the required format

2.4.6 Module 3: Interpreting the Risk Report (Approx. 60 minutes)

Target Audience:

- Nurses, medical doctors and clinicians involved in patient communication of results

Objectives:

- Explain the CRC risk scores produced by the CRC Stratifier:
 - What the score means
 - What concrete steps to take depending on the score
- Teach the meaning of contributing factors presented in the risk report
 - What does it mean if a factor is ranked as highly contributing
 - How to understand how exactly the patient's status of the factor is contributing, e.g. whether a elevated or lowered value of the patient for this factor is contributing to CRC risk.
 - Concrete suggestions that can be drawn from the results to give to the patients
 - How to find information if more abstract factors such as specific taxa are elevated or lowered
- Explain procedures when the patient is deemed ineligible or when results are uncertain.

2.4.7 Module 4: Limitations and Best Practices (Approx. 60 minutes)

Target Audience:

- Nurses, medical doctors and clinicians involved in patient care and communication of results

Objectives:

- Communicate the biases of the training data used for the Microb-AI in the CRC Stratifier
- Clarify limitations of the CRC Stratifier resulting from these biases, e.g. with data of young patients.
- Teach best practices on how to correctly identify and handle patients incompatible with the CRC Stratifier

2.4.8 Module 5: Practical Case Studies / Interactive Simulations (Optional, 30-60 minutes)

This module is a special, more flexible module. It offers multiple case studies to allow for a practical simulation of the previous modules 2 to 4. Therefore, depending on which module this module supplements, this module then should fulfil the same target audience and objectives as the relevant other module, teaching content in a more practical manner.

2.4.9 Delivery Approach

Each module will be available as video tutorials and textual documentation as well as in person or online workshops. Apart from the online textual documentation and video tutorials, an online sandbox will be made available for usage with synthetic data and is actively used in Module 5.

2.4.10 Module recommendations

Finally, we recommend the following modules:

- Patients
 - Module 0
- Clinical staff in charge of choosing people for the CRC Stratifier based screening program
 - Module 0, 4 and 5
- Clinical staff in charge of communication the risk report with the patient
 - Module 0, 3, 4 and 5
- Laboratory staff in charge of the sequencing and taxa abundance report creation
 - Module 0, 2.1 and 5
- Clinical or laboratory staff in charge of inputting patient data into the CRC Stratifier
 - Module 0, 2.2 and 5
- IT Staff in charge of installation of the Microbiome Profile Extractor or CRC Stratifier
 - Module 0, Module 1.1 or 1.2 respectively

2.5 Microb-AI-ome partners involved

Microb-AI-ome partners:

- University of Hamburg (Germany)
- tp21 GmbH (Germany)
- Assistance Publique Hôpitaux de Paris (France)
- Mater Misericordiae University Hospital (Ireland)

Non-Microb-AI-ome entities involved:

- St James Hospital (Ireland)
- Le Centre Régional de Coordination des Dépistages des cancers d'Ile-de-France (France)

3 Conclusion, next steps

The CRC Stratifier requirements were identified, including deployment conditions in clinics and laboratories, data input, practical usage considerations and result interpretation. Furthermore, the required forms and extent of documentation as well as personas interacting with the CRC Stratifier were identified. Lastly, the format of the training was defined. Based on this feedback, a structured and practical training plan was developed, containing modules to cater to the different roles involved in the CRC Stratifier usage process.

The requirements will be considered in the further CRC Stratifier development moving forward and the relevant trainings will be prepared to accompany the CRC Stratifier.

4 Annexes

4.1 Questionnaire

The following is the questionnaire that was shared with the clinical partners. This is the text form of the questionnaire. The questionnaire was created using limesurvey, but is given here as pure text for convenience.

Introduction to the CRC Stratifier (and questionnaire)

Welcome and thanks a lot for filling in the Microb-AI-ome CRC Stratifier Training Plan questionnaire! **This questionnaire should take 5 to 10 minutes to fill**

The colorectal cancer (CRC) Stratifier is being developed as part of the Horizon Europe project Microb-AI-ome (grant agreement number 101079777) which aims at providing privacy-preserving AI tools for the early detection of CRC (<https://microbaio.me.net/home>)

The CRC Stratifier is a screening tool aimed at predicting the risk for CRC and the need for a follow-up colonoscopy. It predicts a personalized risk score based on a laboratory test producing a taxa abundance report from stool samples as well as patient meta- information (e.g. age, BMI, smoking status, ...).

As an add-on package to the CRC Stratifier, we will provide a software package intended to be used by the laboratories carrying out the sequencing of the stool microbiomes, hereafter called the Microbiome Profile Extractor. After following the CRC Stratifier approved sequencing protocol, this software is used to produce the taxa abundance report of the sequenced stool microbiomes.

About you

What role would you consider the most fitting for you?

- IT staff
- Nurse
- Study Nurse
- Doctor
- Other (Please specify)

If IT staff is chosen:

- Please specify which of these dependencies would be problematic on one of your servers. Not all of them are used by us, so this is preliminary to make sure we don't add dependencies you cannot fulfil.
 - All services:
 - Kubernetes

- The Stratifier model
 - Docker
 - Python packages (e.g. via python venv/conda/poetry,...)
 - Python
- The backend managing the model
 - Docker
 - JVM (Java)
- The frontend shown to the clinical staff
 - Docker
 - NGINX/Apache
 - Any static website hosting

Software usage scenarios

Important comment: For initial validation and during project runtime, the CRC Stratifier is planned to be deployed in individual (partnering) hospitals. After this phase, a nation-, and even EU wide deployment is envisioned. The following questions only refer to the initial deployment in the individual hospitals.

- Based on your experience with similar software, which scenarios are the most probable? (Please note that the extracted DNA sent to the laboratory is considered sensitive health data)
 - A (to the hospital) external laboratory sequences the stool microbiome and deploys the Microbiome Profile Extractor and CRC Stratifier. The hospital or patient sends the stool sample and a filled-out questionnaire with the meta-information to the laboratory to be used as input for the CRC Stratifier.
 - The hospital's internal laboratory sequences the stool microbiome and deploys the Microbiome Profile Extractor and CRC Stratifier.
 - The hospital's internal laboratory sequences the stool microbiome and deploys the Microbiome Profile Extractor. The hospital's clinical staff deploys the CRC Stratifier.
 - An external laboratory sequences the stool microbiome and deploys the Microbiome Profile Extractor. The hospital's clinical staff deploys the CRC Stratifier.
 - An external laboratory sequences the stool microbiome and sends the raw sequences to the hospital. The hospital's clinical staff deploys the Microbiome Profile Extractor and CRC Stratifier.
 - Other

Data Entry

Conceptually, the CRC Stratifier requires patient information as well as the taxa abundance report based on the stool microbiome sequencing.

You can therefore imagine input in a form similar to this one:



The report from the laboratory would have to be added here, e.g. through a simple drag and drop of the report file into the software.

- What is the most likely scenario for collecting the patient metadata and stool sample?
 - The CRC Stratifier kit contains a paper questionnaire and a stool sample kit.
 - The patient uses this kit at home and fills in the questionnaire themselves.
 - The patient only gets the stool sample kit and the clinical staff fills in the patient meta-information.
 - The CRC Stratifier kit contains a QR code to an online questionnaire and a stool sample kit.
 - The patient used the kit at home and completes the questionnaire online.
 - The patient only gets the stool sample kit and the clinical staff fill in the electronic questionnaire.
 - Other (Please specify)

- How much time per patient do you think is reasonable for filling out the patient information, such as patient age, BMI, etc.
 - Up to 5 min
 - Up to 10 min
 - Up to 15 min
 - Up to 30 min
 - Up to 60 min

- Please check which form of supporting information concerning data entry you would find most useful.
 - Having additional info for each entry item (e.g. there is a small (i) besides cardiovascular disease that opens a small box that specifies what is considered a cardiovascular disease and why this matters)
 - A PDF document specifying usage, including example inputs
 - A website specifying usage, including example inputs
 - Video tutorials
 - Other (please specify)

Output of the CRC Stratifier

- How should the CRC Stratifier inform about the estimated risk and the need for a colonoscopy?
 - A traffic light with concrete suggestion, e.g. suggesting a colonoscopy, an additional test or nothing
 - A percentage score with concrete suggestion based on the percentage (e.g. >90% colonoscopy)
 - Just a positive/negative results with concrete suggestions (positive > perform another FIT-test/perform a colonoscopy)
- What additional information should the final report of the CRC Stratifier contain? You may tick multiple boxes.
 - Confidence of the CRC Stratifier in the prediction
 - Which factors were the most relevant for the prediction (e.g. heavy smoker and a certain bacteria is out of normal range)
 - Concrete suggestions on factors patients could improve to reduce the risk (less smoking, more sport, ...)
 - Other (please specify)
- Should the same report be interpretable by clinical staff and the patient or should there be separate reports?
 - Separate reports. One for the patient, one for clinical staff
 - One report meant for interpretation by clinical staff
 - One report meant for interpretation by both patients and clinical staff

- The risk prediction for some subsets of patients, e.g. very young patients, might not be very reliable. How should the CRC Stratifier inform about its confidence in the prediction?
 - On data entry, if e.g. a very young age is given, a warning appears but you can proceed with calculating a risk.
 - On showing the estimated risk, a confidence percentage is shown. A concrete suggestion which confidence level is necessary before rejecting a risk is shown.
 - On showing the estimated risk, if the model has too low confidence, no risk is shown but a relevant warning, e.g. the patient is too young to provide a relevant risk score
- Should there be auditing in place about which clinical user input which data and received which score from the AI? You may tick multiple boxes.
 - Auditing who calculated a risk score
 - Auditing of which patient data was input and which score was calculated
 - Other (please specify)
- Could the CRC Stratifier also serve for educational purposes, where a patient inputs their meta-information and the CRC Stratifier simply reports what patients should improve on to reduce the CRC risk (independent of information about the stool microbiome)?
 - Yes
 - No

If the CRC Stratifier might be used for educational purposes, what special considerations might apply?

The training itself

- What trainings would you consider taking? You may tick multiple boxes.
 - Installation tutorial
 - Simple usage tutorial
 - Extended usage tutorial including why certain variables are asked for (e.g. Why does the BMI matter)
 - Tutorial on how to interpret results
 - Tutorial on limitations of the CRC Stratifier (e.g. the CRC Stratifier will most likely not work well for young patients)
 - Technical explanation of the CRC Stratifier

- How much time do you realistically have to dedicate to a training?
 - Up to 15 min
 - Up to 1h
 - Up to 3h
 - Up to 7h
- How should this time be distributed?
 - One long session
 - Multiple smaller sessions
- What format do you prefer for a training?
 - Live online training
 - In person training
 - Manual-like documentation (e.g. a PDF file) for self study
 - Video tutorials
- Where would you watch tutorial videos
 - On the computer running the software
 - On your own devices, e.g. your phone. (For context, if you tick this this we would add a QR code to the software so you can access the tutorials also from your phone.)
- Would you like an online version of the CRC Stratifier for training with synthetic data? (This would mean a website you could visit that exactly resembles the CRC Stratifier interface and should be used only with synthetic data for training and trying out the tool).
 - Yes
 - No

Final free form feedback

- Do you have any other recommendations/requirements for the CRC Stratifier?
- Do you have any other recommendations/requirements for the training plan?

Microb-AI-ome consortium partners

- Universitaet Hamburg (UHAM), DE
- University College Cork – National University Of Ireland, Cork (UCC), IE
- Egnosis 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



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