

Topic idea submitted to IHI - Reference Number: TI_001160

Are you submitting the idea:

- in your personal capacity?
 on behalf of an organisation?

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:

Defining the temporal responsiveness of the gut microbiome to major diet and lifestyle interventions.

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field:

1. The gastrointestinal microbiome is intimately linked to diet and lifestyle and current health status. However, limitations in current evidence mean that defining microbial changes as cause or effect of health are not possible.
2. Further data from in-depth prospective sampling is required in order to start to unpick whether microbial changes precede or occur after measurable changes to health. Specifically, the level of stability and variability bowel movement by bowel movement has not been tested in response to major diet and lifestyle interventions
3. Whole diet and largescale lifestyle changes have been consistently evidenced to result in significant benefit to cognitive, cardiometabolic and gut health parameters. However, many Europeans do not adhere closely to food- or nutrient-based (inter)national dietary guidelines and the prevalence of excess body weight and metabolic disease is high across the region.
4. Tracking responsiveness (or lack thereof) of the gut microbiome from a composition and functional perspective to diet and lifestyle challenges will provide: a) additional understanding of the rate of change of the microbiome b) a temporal relationship between change in diet and lifestyle, expected improvement in health parameters and potential change in microbiome composition and function and c) to better contextualise the wider meaning of "change" in gut microbial outcomes measured across multiple other observational and interventional studies.
5. Previous studies suggest that the gut microbiome differs by location among other factors. There is a need to carry out research like this across a geographically and socio-economically diverse region like the EU (and associated countries) in order to ensure the meaningfulness of these findings, be that from a research, industry or public stakeholder perspective.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

["SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users"]

"SO5: enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions"]

Please select the keywords that are most relevant to your idea:

["Non-communicable diseases"]

"Health technology"

"Cardiovascular diseases"

"Metabolic diseases"

"Neurodegenerative diseases"

"Mental health"

"Digital health"

"Prevention"]

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

To track day-by-day change through faecal (and possibly other) microbiome sampling during major diet and/or lifestyle interventions. To ensure the work is best targeted at a population that stands to benefit the most from these findings, individuals will be recruited who a) do not meet (single-targeted or multiple) dietary or physical activity guidelines and b) who have measurable parameters of a pre-clinical health issues (e.g. moderately high blood pressure, mild cognitive impairment or similar).

3 **Expected impacts to be achieved by your idea**

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific objectives, as described in the IHI SRIA:

Impacts are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

IHI general objectives: 1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

From a research perspective, programmes of work like this would help direct currently speculative and unfocused research efforts into the relationship between diet/lifestyle, the gut microbiome and human health (be that cardiometabolic, gastrointestinal or mental health, or indeed reduction in cancer risk). Such work also provides foundational benefits to inform public health approaches, members of the public make choices around how they manage their health and multiple industries (e.g. food, nutrition, biotechnology) better consider their approaches and offerings aimed at meeting public demand.

Specifically this aligns both with IHI General Objective 1 (in relation to launching large-scale, complex cross-sectional projects) and 2 (by providing better context to the meaning of gut microbiome testing in relation to health outcomes and possibly providing biomarkers that could predict responsiveness to different types of diet and lifestyle-based intervention).

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners (e.g. academia, healthcare practitioners, patients, regulators)?

1. The gastrointestinal microbiome is intimately linked to diet and lifestyle and current health status. However, limitations in current evidence mean that defining microbial changes as cause or effect of health are not possible.
2. Further data from in-depth prospective sampling is required in order to start to unpick whether microbial changes precede or occur after measurable changes to health. Specifically, the level of stability and variability bowel movement by bowel movement has not been tested in response to major diet and lifestyle interventions
3. Whole diet and largescale lifestyle changes have been consistently evidenced to result in significant benefit to cognitive, cardiometabolic and gut health parameters. However, many Europeans do not adhere closely to food- or nutrient-based (inter)national dietary guidelines and the prevalence of excess body weight and metabolic disease is high across the region.
4. Tracking responsiveness (or lack thereof) of the gut microbiome from a composition and functional perspective to diet and lifestyle challenges will provide: a) additional understanding of the rate of change of the microbiome b) a temporal relationship between change in diet and lifestyle, expected improvement in health parameters and potential change in microbiome composition and function and c) to better contextualise the wider meaning of "change" in gut microbial outcomes measured across multiple other observational and interventional studies.
5. Previous studies suggest that the gut microbiome differs by location among other factors. There is a need to carry out research like this across a geographically and socio-economically diverse region like the EU (and associated countries) in order to ensure the meaningfulness of these findings, be that from a research, industry or public stakeholder perspective.

Why is the contribution of industry needed to achieve the expected impacts?

Contribution of industry: Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.

Expertise in remote data collection and analysis, as well as novel and feasible microbiome sampling approaches are under continuous development from industry partners. Their involvement is crucial to the effective delivery of the study and would also maximise the economic benefit of the findings of this programme of work.