



Food4Health - Call for Expressions of Interest 2020 Annex







Annex – Work package descriptions

In cooperation with EIT Food and EIT Health, these Food4Health projects have been developed to address two of the major challenges that we face in Europe today; providing European citizens with the tools and capacities to manage their own health in a smarter way as well as offering nutrition-based products and solutions for more effective treatment, and even prevention, of disease. These projects also highlight the interdependency of food and health and the need to work in a multi-disciplinary manner by bringing together actors from different sectors. In this respect, EIT, and in particular this cross-KIC collaboration between EIT Food and EIT Health, is in a unique position to drive innovation in the combined food, health and health care sectors across Europe.

In order to have a major impact on the health and wellbeing of citizens throughout Europe, Food4Health is focussed on delivering tangible, innovative outcomes that that can be brought to the market within 2 years upon completion of the projects. The project definitions below outline the entire work plan until 2021, to show the long-term objectives, project continuity and expected commercial outcomes, and have been included in this call to illustrate future activities.

Only the tasks that start in 2020 are applicable for this call. Those shown in grey were included in the 2019 call and those in red are expected to start in 2021.

Project A – Using indicators to influence consumer behaviour and prevent pre-disease through food and lifestyle-related interventions

The Food4Health project 'STOP MetSyn' (sustainable tackling of pre-metabolic syndrome) intends to deliver methods, tools and a strategy to tackle the pre-metabolic syndrome in Europe.

Non-communicable diseases (NCD) have become the major health hazard of the modern world. Though it started in the Western world, with the spread of the Western lifestyle across the globe, it has become now a truly global problem. The two basic forces spreading this condition are the increase in consumption of high calorie-low fibre fast food and the decrease in physical activity due to mechanized transportations and sedentary form of leisure time activities.

Metabolic syndrome (MetSyn) represents a clustering of different metabolic abnormalities. MetSyn is present in approximately 25% of all adults with increased prevalence in advanced ages. What many people do not realise is that having MetSyn increases the risk of developing other serious diseases, such as heart disease, stroke and type 2 diabetes. Perhaps what is more shocking is that most people are not even aware of MetSyn, with surveys showing that only between 12 and 29% of people have heard of MetSyn

¹ https://www.mayoclinic.org/diseases-conditions/metabolic-syndrome/symptoms-causes/syc-20351916





with fewer than 10% actually understanding what it is.² To underline the impact of MetSyn in society today, we have included the following facts and figures.

4.8–7% of **young adults**: Atherogenic dyslipidaemia defined as low high density lipoprotein (HDL) cholesterol was the most prevalent MetSyn component (26.9–41.2%), followed by elevated blood pressure (16.6–26.6%), abdominal obesity (6.8–23.6%), atherogenic dyslipidaemia defined as raised triglycerides (8.6–15.6%), and raised fasting glucose (2.8–15.4%).³

In subjects with MetSyn, the distribution of altered components differed between men and women and cross-country wise. Specifically, **elevated glucose** was highly prevalent in cohorts from Belgium, UK, Lithuania, Spain and Sardinia in Italy, whereas the lowest prevalence was observed in the Greek cohort. **Low HDL cholesterol** showed the highest prevalence in the cohorts from Sweden, USA, the Netherlands and the lowest in Italian Sardinia and in the UK. **Elevated triglycerides** were highly prevalent in the cohort from Germany, UK, and Lithuania and less prevalent in Spain and Sweden. **Elevated blood pressure** had a prevalence >90% in the cohorts from Sweden, Germany, and Greece with the lowest prevalence in the cohorts from USA and Lithuania. The prevalence of **abdominal obesity** showed a wide significant gender difference (75.6% in men and 90.6% % in women, p< 0.0001). Of note, waist circumference exceeded the cut-off values in more than 90% of women from USA, UK, and Mediterranean countries, whereas it was less frequently altered in the Swedish cohort.⁴

Given the high prevalence of MetSyn in association with the general lack of awareness of the disease, the goal of this project is to gain a better understanding of the indicators that are linked to MetSyn, and consequently develop effective strategies for reversing the disease. In particular, this project aims to:

- Establish a science-based methodology for measuring pre-metabolic syndrome in Europe.
- Develop a pre-disease prevention program for measuring pre-metabolic syndrome in the broader European community.
- Establish a strategy to engage the European population to adopt a healthier lifestyle by preventing and tackling pre-metabolic syndrome.
- Perform a real-life test in Europe combining measurement, tooling and strategies to engage and coach consumers towards a healthier lifestyle.

WP1 - Indicators of pre-metabolic syndrome

Objective: Understand the different indicators and lifestyle factors that lead to the pre-metabolic state

• All tasks were a part of the 2019 call

Tasks Skills/Expertise/Resources Deliverables Duration Indicative Budget

² https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6338970/

³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5540707/

⁴ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4544872/





WP2 – Design of diagnosis/intervention combinations

Objective: Deliver nutrition and lifestyle interventions to consumers with pre-metabolic syndrome

• All tasks were a part of the 2019 call

Tasks Skills/Expertise/Resources Deliverables & Duration Indicative Budget

WP3 – Co-creation consumer behaviour lab

Objective: Engage consumers in understanding their behaviour and strategies to change their habits

WP Leader

- Experience in behavioural science, marketing, psychology or social economy
- Experience in co-creation and/or living labs
- To be led by a research/university partner

Tasks	Skills/Expertise/Resources	Deliverables	Duration	Indicative Budget
T3.1 Market research on consumer behaviour and habits	 Insights in consumer behaviour, nudging, psychology In-depth knowledge of qualitative and quantitative market research Access to consumers 	D3.1 Report on consumer lifestyle behaviour and eating habits in different target groups from an industrial/retail and academic perspective	2019	-
T3.2 Map actual behaviour and habits related to food purchases and lifestyle choices Minimum partnership - 1 research/university partner - 1 industry partner	 D3.1 to be used as input for this task Expertise in behavioural science, marketing, psychology or social economy Access to platforms/ tools/surveys to engage ≥1000 consumers in >3 countries via online surveys Access to recent and actual consumer food purchasing data 	D3.2 Map of consumer behaviour, habits, food purchases and lifestyle choices	Feb – Sep 2020 8 months	80 k€
T3.3 Co-create and evaluate strategies to help people to change and	 D3.1 to be used as input for this task Expertise in behavioural science, marketing, 	D3.3 Overview of strategies to change consumers	Feb – Sep 2020	100 k€





monitor their habits with respect to nutrition and physical activity	psychology or social economy • Experience in co-creation methodologies	habits and monitor the changes	8 months	
Minimum partnership - 1 research/university partner - 1 industry partner	 and/or living labs Engage ≥100 consumers in roundtable discussions in 4-5 different countries 			

WP4 – Pilot study on food, lifestyle and behaviour interventions

Objective: Evaluate the intervention program in a real-life setting

WP Leader

- Experience in designing intervention studies for consumers in a non-clinical setting
- Experience in planning, executing, monitoring and reporting on pilot studies
- Experience in communicating to consumers
- Experience in nudging of consumers (behavioural science)
- To be led by an industry partner

Tasks	Skills/Expertise/Resources	Deliverables	Duration	Indicative Budget
T4.1 Use the outcomes from WP1-3 to design a self-prevention program to combat pre-metabolic syndrome combining measuring and monitoring. This task includes the strategy to reach consumers and convince them to adopt a healthier lifestyle Minimum partnership - 1 research/university partner - 1 industry partner	 Deliverables from WP1-3 to be used as input for this task State of the art knowledge and experience in the development of digital tools Experience in designing, executing, monitoring and disseminating outcomes from nutritional, lifestyle and behaviour intervention studies Expertise in behavioural science, marketing, psychology or social economy 	D4.1 (Digital) tools and/or APIs for measurement and monitoring, coaching and behaviour change to combat pre- MetSyn D4.2 Final protocol for the pilot study	Apr – Dec 2020 9 months	250 k€
T4.2 Engaging consumers for the program and β- testing of materials through marketing/	Deliverables from WP1- 3 to be used as input for this task	D4.3 A communication strategy Es,	May – Dec 2020 8 months (continues in 2021)	100 k€





communication strategy and materials Minimum partnership - 1 research/university	 Knowledge of consumer marketing Experience in communication to consumers (strategies, 	D4.4 Communication materials		
partner - 1 industry partner	design of materials supporting the launch on the market) • Access to platforms/ tools/services to engage consumers	D4.5 A marketing plan	2021	50 k€
T4.3	Deliverables from WP1-	D4.6 Interim	Oct – Dec	100 k€
Execution of the pilot study of the prevention	3 and T4.1 to be used as input for this task	report on the status of the	2020 3 months	
support program for	 Experience in planning, 	prevention	(continues	
consumers	executing, monitoring and reporting on pilot	program	in 2021)	
Minimum partnership	atualisa an facal and	D4.7	2021	250 k€
willing partiessing	studies on food and	D4.7	2021	230 KC
- 1 research/university	lifestyle interventions	Report on	2021	250 KC
- 1 research/university partner		Report on outcomes of the	2021	250 KC
- 1 research/university	lifestyle interventionsAccess to >300 consumers per country	Report on outcomes of the prevention	2021	250 KC
- 1 research/university partner	lifestyle interventions • Access to >300	Report on outcomes of the	2021	230 KC

WP5 – Implementation and scalability

Objective: Deliver a plan for the exploitation of the consumer behaviour support program to combat pre-metabolic syndrome

WP Leader

• Experience in the development of business models and business plans

Tasks	Skills/Expertise/Resources	Deliverables	Duration	Indicative Budget
T5.1 Scalability of the support program	 Experience in scale-up and scale-out of lifestyle interventions Experience in consumer communication Access to consumers/patients 	D5.1 Report on scaling strategy	2021	60 k€
T5.2 Business plan for the prevention support program	Experience in business case development	D5.2 Business plan	2021	60 k€





Definitions for Project A:

<u>Indicators</u>: Indicators are markers of health status, service performance or resource availability. They are used to diagnose the health status of a population and to plan, monitor and evaluate activities related to disease control efforts and/or health care delivery.⁵

<u>Metabolic syndrome</u>: MetSyn has been defined as the presence of three or more of the five risk factors established by the International Diabetes Federation (IDF) and the American Heart Association/National Heart, Lung, and Blood Institute (AHA/NHLBI): 1) abdominal obesity (WC \geq 90 cm in men and \geq 80 cm in women); 2) hypertriglyceridemia (triglycerides \geq 150 mg/dL or use of medications to lower triglycerides); 3) low HDL-c (<40 mg/dL in men and <50 mg/dL in women or use of medication to increase HDL-c); 4) high blood pressure (systolic blood pressure \geq 130 mmHg and or diastolic blood pressure \geq 85 mmHg or use of antihypertensive medication); 5) high fasting plasma glucose \geq 100 mg/dL or use of hypoglycemic medication.

<u>Pre-metabolic syndrome/state:</u> a cluster of pre-conditions that occurs together and increase the risk of some pre-disease. Pre-metabolic syndrome (pre-MetSyn) was defined as having no less than two components of MetSyn but did not meet the criteria for the diagnosis of MetSyn.⁷

<u>Assessment:</u> 1. Evaluation of the patient/consumer using selected skills of history-taking; physical examination, laboratory, imaging, and social evaluation, to achieve a specific goal. 2. Appraisal or analysis of conditions, disorders, data, or a patient's/consumer's overall state.⁸

<u>Monitoring</u>: Monitoring is the systematic process of collecting, analysing and using information to track a program's progress toward reaching its objectives and to guide management decisions. Monitoring usually focuses on processes, such as when and where activities occur, who delivers them and how many people or entities they reach. Monitoring is conducted after a program has begun and continues throughout the program implementation period. Monitoring is sometimes referred to as process, performance or formative evaluation.⁹

(<u>Disease</u>) <u>Prevention</u>: specific, population-based and individual-based interventions for primary and secondary (early detection) prevention, aiming to minimize the burden of diseases and associated risk factors.¹⁰

Project B – Tackling muscle loss in cancer patients through nutrition solutions and lifestyle interventions

Cancer-related malnutrition is highly prevalent in patients undergoing cancer treatment (30-85%), in particular in cancers of the gastrointestinal tract (esophagus, stomach, pancreas, small intestine, colorectal), head & neck, and lung. Cancer-related malnutrition results from reduced food intake due to a range of symptoms including psychological stress, pain, anorexia, physical obstruction, swallowing

⁵ https://apps.who.int/iris/bitstream/handle/10665/68467/WHO CDS TB 2001.289.pdf?sequence=1

⁶ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4339435/

⁷ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4339435/

⁸ https://www.medilexicon.com/dictionary/8003

⁹ Adapted from Gage and Dunn 2009, Frankel and Gage 2007, and PATH Monitoring and Evaluation Initiative - http://www.endvawnow.org/en/articles/330-what-is-monitoring-and-evaluation-.html

 $^{^{10}}$ http://www.emro.who.int/about-who/public-health-functions/health-promotion-disease-prevention.html





problems, etc. occurring in combination with catabolic factors such as increased energy expenditure, altered protein metabolism, systemic inflammation, dysbiosis and vitamin deficiencies. Anti-cancer treatment can in turn worsen the patient's ability to eat by inducing nausea, sickness, loss of appetite, taste alteration, mucositis. These leads to energy and protein imbalance and results in accelerated loss of body weight.

Involuntary body weight loss in cancer patients is prevalent and very specific, as it mainly consists of the wasting of muscle mass. Furthermore, evidence shows that having low or losing muscle mass has a negative impact on the prognosis and survival rate of cancer patients by increasing the occurrence of complications and dose-limiting toxicities, decreasing treatment adherence, and diminishing quality of life of patients. Thus, maintaining muscle mass and during treatment is of utmost importance to enable patients to fully benefit from their treatment.

Specific interventions through tailor-made nutrition or physical activity programs are hypothesized to prevent cancer-related muscle wasting. The maintenance of muscle mass may help patients adhere to their treatment plan, thus having a favourable clinical outcome with reduce (dose-limiting) toxicities while maintaining quality of life. Nowadays, neither physical nor nutritional interventions are routinely prescribed or in a too late stage of ongoing muscle wasting where the window of benefit has already passed. Providing evidence of the benefit of such interventions and defining the best conditions in which to implement them creates the opportunity of integrating them in standard cancer treatment enabling patients to benefit during treatment.

This program will address the need for knowledge, service and validation of solutions for muscle mass preservation. Outcomes for commercialization that this program will deliver, with the aim to preserve muscle mass are:

- Tool to dynamically measure muscle mass
- Tailormade medical nutritional solution
- Tailormade activity/exercise program
- Digital tools/services to enable and empower patients and HCPs

WP1 – Identify novel tools to dynamically measure muscle in cancer patients

Objective: to deliver a muscle mass quantification tool precise and easy to use in daily practice

WP Leader:

Experienced in device development and validation for biomarker quantification of muscle mass

Prerequisites:

- Selection of a suitable muscle mass measurement tool (T1.2) is a prerequisite for Task 1.3
- Selected tool must be available for the project
- Access to the suitable tool to be discussed with shortlisted partners before the final partner selection

Tasks	Ski	lls/Expertise/Resources	Deliverables	Duration	Indicative Budget
T1.1	•	Hardware and/or	D1.1	2019	-
Scout dynamic muscle		software development	Report on		
mass quantification		of (novel) tool(s)	intended use of		
methods/techniques and	•	HCP and patient	methods		
		contact to assess	/techniques with		





identify their intended use	intended use and feasibility	best suited (novel) solution to measure muscle mass		
T1.2 Select suitable method/technique for muscle mass quantification and investigate suitability method/technique for use in oncology patients	 Hardware and/or software development of (novel) tool HCP and patient contact to assess intended use and feasibility Market/clinical expertise to develop tool for patients 	D1.2 (Novel) muscle quantification tool (ready to test in pilot trial)	2019	-
T1.3 Validate tool in cancer patients Minimum partnership	Task lead* should have experience in: Designing, running and monitoring clinical trials in cancer patients	D1.3 Tool validated on user feasibility, intended use and sensitivity	Feb – Dec 2020 11 months	100 k€
- 1 hospital/clinic	 Validation of hardware/software And access to: Developed/selected tool of T1.2 Cancer patients receiving CT-scan for body composition analysis Study site* should have: Direct access to cancer 	(compared to body composition analysis by CT scan)		

^{*}Task lead and study site may be the same or different partners.

WP2 – Enable patients to follow nutrition and exercise to be in control during the disease journey and enable HCP to promote health

Objective: launch of app to support patients by empowering and educating both patients and HCP

WP Leader:

 Experienced in sensory and/or behaviour sciences, bringing innovation to the market and app development

Prerequisites:

• Outcomes from Task 2.1 to be used as input for Task 2.2

Tasks	Skills/Expertise/Resources	Deliverables	Duration	Indicative
				Budget





T2.1 Identify barriers related to food intake in cancer patients, such as choice, drivers of compliance (liking, external factors) and possible solutions	Experience with sensory alterations and behaviour studies	D2.1 Overview of barriers and solutions	2019	-
T2.2 Digital tools/services to empower patients for nutritional solution compliance in co-creation with patients, HCP and patient organizations Minimum partnership - 1 partner (any type of partner)	App development (with /without website); coding and/or visual/artistic communication design Sensory alterations and behaviour studies, familiar with T2.1 output Access to: Patients/HCP/patient association for co-building	D2.2 Finalized App with/ without a website comprising co- creation output with patients/ patient associations	Feb - Dec 2020 11 months	100 k€
T2.3 Integration of nutrition and exercise programs into daily life by co- creation with patients, HCP and patient organizations	 D2.1 and D2.2 output Access/collaboration with HCP, patients/ patient organizations Affinity with developing educational programs and/or awareness campaigns 	D2.3 Awareness campaign Cooking class Educational program	2021	100 k€

WP3 - Nutritional intervention in cancer patients

Objective: Deliver and generate evidence with a tailormade medical nutrition intervention to support muscle mass in cancer patients

WP Leader:

- Experienced and proven track record in designing, executing, monitoring, disseminating clinical trials with oncology patients in a multi-centre, multi-country setting
- Experienced in running nutritional intervention trials with medical nutritional supplements with cancer patients
- Resources for protocol writing, ethical submission, monitoring of clinical studies, logistics, data analysis, budget overview and overall study management
- Experienced in designing, prototyping, and producing medical nutritional supplements
- Experienced in bringing nutritional concepts towards marketed products
- Proven availability of a ready-to-be-used nutritional prototype for cancer patients with high quality and patient grade safety





Prerequisites:

- Outcomes from D3.1 and 3.2 to be used as input for Task 3.2
- Patient population not yet defined but highly likely to include patients with GI-related and/or Lung cancer
- Access to patient populations to be discussed with shortlisted partners before the final partner selection
- Budget will be allocated based on the number of patients that can be brought to the trial
- Selected partners will need to pass a feasibility report for conduct of the trial before the start
 of the trial

Tasks	Skills/Expertise/Resources	Deliverables	Duration	Indicative Budget
T3.1 Deliver a tailormade medical nutrition intervention to support muscle mass in cancer patients	 Experienced in designing, prototyping, producing and marketing of nutritional supplements. Production of high-quality nutritional solution prototypes Scientific record in nutritional research 	D3.1 Rationale for nutritional solution prototype with produced prototype (high quality and safety) to be used in an intervention trial in cancer patients	2019	
T3.2 Nutritional intervention study in cancer patients	Study lead* should have the experience and skills as indicated for the WP leader (see above).	D3.2 Study protocol finalization	2019	-
Minimum partnership - 1 study lead (research/university or hospital or industry partner) - 2-3 study sites (hospitals) in different	Study sites* should have experience in: Running nutritional intervention trials with medical nutritional supplements in cancer patients	D3.3EC approvalFirst patient inProgress report	Feb - Dec 2020 11 months	500 k€
countries	 Executing study procedures and data collection/entry required by intervention protocol And access to: Patient population defined in study protocol, ability to recruit patient population 	 D3.4 Continue patient recruitment Opening sites in multiple countries Last patient out Study report 	2021	1000 k€
T3.3 Dissemination of results to enrich value proposition and maximize commercial impact and easy of acceptance of	Experienced in scoping, executing, disseminating clinical trials in oncology patients	D3.5 Abstract submission to key congresses in the field. Published manuscript. Linked to task 3.2	2021	350 k€





nutritional interventions for cancer patients	 Collaborations with relevant medical societies Experienced in writing clinical study manuscripts To be in regular contact 	
	with partners involved in T3.2	

^{*}Study lead and study site may be the same or different partners.

WP4 – Physical program intervention

Objective: Deliver and generate evidence with a physical program to support muscle mass in cancer patients

WP Leader:

- Experience in designing, executing, and monitoring exercise programs for cancer patients
- Experienced scoping, executing, monitoring, disseminating studies in oncology patients
- · Experienced principal investigator and investigator/research nurse to conduct feasibility trial
- Access to patient populations defined in the study protocol
- Ability to implement the tailormade exercise program designed in T4.1

Prerequisites:

- Outcomes from Task 4.1 to be used as input for Task 4.2
- Patient population not yet defined but highly likely to include patients operated on for liver and/or pancreas tumours
- · Access to patient populations to be discussed with shortlisted partners prior to final selection

Tasks	Skills/Expertise/Resources	Deliverables	Duration	Indicative Budget
T4.1 Design optimal exercise program for cancer patients	 Experience with activity/movement/exercise program development Access to HCP and cancer patients Experience with exercise in cancer patients 	D4.1 Tailormade Exercise/activity program	2019	-
T4.2 Feasibility pilot study of exercise program in cancer patients	D4.1 to be used as input for this study Study lead* should have the experience and skills as indicated for the WP leader (see above).	D4.2 Study protocol finalization	Feb - Dec 2020 11 months	250 k€
Minimum partnership - 1 study lead (research/university or hospital partner)	Study sites* should have experience in: • Executing study procedures and data collection/entry required by intervention protocol	in Last patient out Study report		





- 1-2 study sites (hospitals) in different countries	Ability to implement the tailormade exercise program designed in T4.1 And access to:	
	 And access to: Patient population defined in study protocol, ability to recruit and select patient population with cardio pulmonary exercise test (CPET) Physiotherapists to train patients in home environment 	

^{*}Study lead and study site may be the same or different partners.

WP5 – Economic implications of muscle mass preservation on health care costs

Objective: Deliver evidence demonstrating economic implications of muscle mass loss and the associated benefit of muscle mass preservation on health care costs

WP Leader:

Experienced in conducting health economics studies

Tasks	Skills/Expertise/Resources	Deliverables	Duration	Indicative Budget
T5.1 Health economic analysis muscle mass loss and healthcare cost of cancer patients	 Experiences with health economics studies Access to database with analysed muscle mass of cancer patients during treatment combined with QoL (EORTC-QLQ-C30) and/or Health economics questionnaires (EQ-5D or equivalent) and access to patients medical records 	T5.1 Health economic analysis: Algorithm linking muscle mass loss to health care costs	Feb - Dec 2020 11 months	50 k€
Minimum partnership - 1 partner (any type of partner)	 Access to health care costs of patients in muscle mass database Skills to develop algorithms for muscle mass and health economics outcome 	Analysis of increased cost per amount (kg) of lost muscle mass in cancer patients		
T5.2 Business case to implement muscle mass preservation in clinical practice	 Knowledge of Health economic analysis output Skills to develop business models based on health economics 	T5.2 Business model linked to T5.1	2021	25 k€