Co-funded by the European Union

SPECIFIC TECHNICAL CLAUSES FOR CONSULTANCY SERVICES FOR THE IMPLEMENTATION OF THE BEST PRACTICE "Reverse Diabetes 2 Now"

Ref.: CT2022-03

1. BACKGROUND

The European Commission launched a competition in 2021 for the selection of the most relevant Best Practices to be transferred from one Member State to others. One of the Best Practices selected was "Reverse diabetes 2 now", which main aim is to reduce the burden of type 2 diabetes and related risk factors, both socially and personally, through effective treatment, lifestyle choices and education programmes.

Afterwards, also in 2021, the European Commission launched a call for proposals (EU4H Call 2021 2nd Wave) with several topics, including the topic "EU4H-2021-JA-08.1: Direct grants to Member States' authorities: implementation of best practices and research results on prevention of non-communicable diseases and risk factors (AWP Ref.: DP-g-07.1.1)", which was addressed to the definition of a Joint Action to implement the best practice "Reverse Diabetes2 Now", previously selected because of its relevance in Diabetes.

The Regional Ministry of Health of Asturias (CSPA), in collaboration with the Healthcare Service of Asturias (SESPA) and the Foundation for the Promotion in Asturias of Applied Scientific Research and Technology (FICYT), built a consortium and wrote the project CARE4DIABETES - Reducing the burden of non-communicable diseases by providing a multi-disciplinary lifestyle treatment intervention for type 2 diabetes – which was submitted to the EU4Health funding program in February 2022.

The European Commission communicated on 5 July 2022 to CSPA, SESPA and FICYT, that the project was selected for funding. The main aim of the project is the implementation of the best practice "Reverse Diabetes2 now" in the participating countries and regions. The project CARE4DIABETES is a Joint Action that will be co-funded by the EU4Health program of the European Union. The consortium is made up of 31 entities from 13 countries (Spain, Belgium, Bulgaria, Finland, Greece, Hungary, Italy, Malta, the Netherlands, Poland, Portugal, Slovakia and Slovenia). FICYT participates as coordinator and beneficiary, and SESPA and CSPA as affiliated entities. The scientific coordination of the project will be led by CSPA and SESPA and the administrative and financial coordination will be led by FICYT.

For the implementation of the project, a contract with the European Commission or Grant Agreement (Annex II) (hereinafter GA, reference 101082427) and a Consortium Agreement between the project partners (hereinafter CA) will be signed, which will define the obligations and rights of the beneficiary entities and their affiliated entities. The project is scheduled to start on 1 February 2023 and its duration is 36 months unless a subsequent extension is required.

FICYT is a foundation of the public sector in Asturias, which has established a collaboration agreement with CSPA to provide advice to researchers of CSPA and the SESPA, on how to participate in European projects.

FICYT will coordinate the financial and administrative management of the project CARE4DIABETES and is the entity responsible for the hiring of the subcontracting costs indicated in the Annex I of the Grant Agreement signed with the European Commission, which is stated this way: “The JA will subcontract consulting and advising services from the best practice owner - Voeding Leeft. The contribution of Voeding Leeft is essential to guide partners in the thorough understanding of the best practice and to plan, execute, and monitor its adaptation and transfer at Member States level. Voeding Leeft’s consulting services will be subcontracted to support tasks under WP5, WP6, and WP7. The total expected budget for the contractor is € 291,680. Costs for subcontracting have been put under the budget of the Coordinator, FICYT”.

FICYT asked the project officer of the European Commission for advice on how to properly manage the tender to execute the subcontracting costs. The project officer has informed FICYT that: “For the Joint Action CARE4DIABETES (EU4H Call 2021 2nd Wave, JA 08.01), the consortium will roll out the best practice “Reverse diabetes now”. The owner of the BP is subcontracted for the use of the BP. It is a position of de facto monopoly”.

According to this, and following the National and European regulations on public contracts, FICYT is launching the tender under a Negotiated procedure without publication, complying with the following sections of the Law on Public Sector Contracts (Law 9/2017, 8 November) which states:

- Article 162,8, a), 2º: a Negotiated procedure without publication can be followed when there is no competition for technical reasons.
- First Additional Provision. Recruitment abroad. Point 5: Contracts formalised abroad which are to be executed in whole or in part in Spain and which are directly linked to the implementation of cooperation programmes or projects in the field of culture or research or development cooperation, may be awarded by negotiated procedure without advertising and subject to the conditions freely agreed by the Administration with the foreign contractor, when the latter's intervention is absolutely essential for the implementation of the project or programme, as required by the conditions of participation in the cooperation programmes or projects, and this is accredited in the file.

2. OBJECT

The object of the contract referred to in this document is the subcontracting of the consulting services of the owner of the best practice “Reverse Diabetes 2 Now” - to ensure good understanding of all methods, tools, and resources for the transfer and implementation of the best practice to other regions/countries, in the framework of the European project CARE4DIABETES.

3. TECHNICAL DESCRIPTION OF THE SERVICES

3.1. Objectives of the services

The services will consist of giving advice and guidelines and training on the methodology that the partners and the affiliated entities of the project should follow to

implement the best practice in their territories. For doing that, the bidder will actively participate in the following work packages (WP):

- WP5 – Preparatory actions. The main objectives of this WP are: 1) to perform all preparatory actions for the best practice's implementation; 2) to have a thorough understanding of the best practice features; 3) to establish a detailed plan for transferring in each relevant Member State; 4) to prepare the online community platform to complement patients' lifestyle training sessions on WP6 to produce an overall framework and guiding material for patients´ recruitment.

- WP6 - Phase I implementation (capacity building oriented). The main objectives of this WP are: 1) to implement the Phase I capacity building oriented part of the best practice applying PDSA framework; 2) to transfer, adapt, and translate materials for patients´ lifestyle treatment; 3) To train the healthcare professionals in charge of local pilot actions; 4) to conduct the first intensive care phase of the intervention in the 12 countries including two PDSA cycles; 5) to continuously monitor and evaluate the progress and interim results to correct potential bottlenecks.

- WP7 - Phase II implementation (after-care oriented). The main objectives of this WP are: 1) to prepare and execute the Phase II after-care implementation, with the two patients' intervention group and including one PDSA cycle; 2) to perform a close follow-up on patients after the intensive training programme of WP6; 3) to implement dedicated after-care activities including continuous tracking and support of enrolled patients; 4) to develop a health and socio-economic impact assessment about how transfer and implementation of the best practice was done.

3.2. Technical tasks to be developed

The tasks that will have to be developed by the bidder under this contract are:

WP5 - Preparatory actions
T5.1. In-depth review of the best practice, context analysis & stakeholder engagement (Month 1 - Month 5)
This first task will allow the consortium an in-depth understanding to describe the Dutch Reverse Diabetes2 Now best practice. In this task, there will be a key involvement of the bidder of this contract to set the ground for practice pilot replication of WP6. Partners will have the opportunity to know in-depth the original best practice during a dedicated workshop at the kick-off meeting. A detailed description on how it was implemented step-by-step (resources and capabilities required, barriers and facilitators, how problems were solved etc.) will follow. These explanations will help pilot partners to get a better understanding to meet the adopting requirements. Ad hoc follow-up online B2B meetings will be scheduled upon needs, to acquire deeper knowledge on specific aspects of the best practice, and further questions.

According to the previous description, the bidder will have to contribute to the activities detailed above and will have to: establish procedures for the management, internal coordination and communication with JA consortium that help with the set up and training of health professionals; give input on the best practice methodology for the in-depth analysis of the best practice; attend the kick-off meeting to explain the methodology for the partners of the project to get the scope definition and the practice core features implemented in The Netherlands.
T5.3. Coordination and development of the online portal/intervention system (M4-M11)
This task deals with the establishment of the needed online environments by local teams. On one side, partners that will implement the best practice either hybrid or fully digital. Under this task, they will take care of identifying or developing their online intervention system/platform for the intensive programme (T6.4). On the other side, all replicators will either establish or identify their (new/existing) online tool that will serve as the community platform for patients` interaction. Along with the sessions with the multidisciplinary team, patients will be invited to join an online peer-learning platform. This could be integrated into pre-existing online web pages or partners' platforms according to the number of patients involved and their needs, media platforms like Telegram or Facebook could be considered as media platforms by implementers, when applicable and in line with national data protection rules. Patients will be able to meet peers and interact with their local healthcare team. The platform will be used to share opinions and experiences, receipts, and suggestions to help with the adoption of healthier lifestyle by the pilot participants. Task leader, supported by the bidder of this contract, will provide a guidance document with all the tips and recommendations for the set-up and management of the online resources. Periodic B2B checks will be implemented by the task leader to ensure activities are implemented smoothly in each country. Partners will ensure compliance with their respective data protection laws. According to the previous description, the bidder will have to contribute to the activities detailed above and will offer input and support on the development of the online tool and will coordinate with the WP leader and the partners the best way and requirements needed for the successful implementation of the online platform/intervention system.
WP6 - Phase I implementation (capacity building oriented)
T6.1. Adaptation of intervention materials (M4-M11)
Based on WP5, pilot local teams will not just translate but to adapt original materials to their own health context along with social, cultural, nutritional, and geographical peculiarities. The material includes presentations and guidelines. Example recipe videos, podcasts, animations, etc will also be made available in English by the bidder of this contract, and individual countries can determine whether these are required in the local context. These resources will be used for the T6.4- intensive care training programme. The task leader, NLNA, will oversee the adaptation in all countries and perform regular checks to ensure the activities are performed smoothly on time. The bidder of this contract will also provide a help desk to the pilot countries to solve any doubts or questions on the adapted materials based on the initial provided guidelines.

According to the previous description, the bidder will have to contribute to the activities detailed above and will specifically have to carry out the following ones: the preparation and translation to English of the materials for the training days, of the e-modules and of the challenges; and development of the IT community, including translation to English and set up for trainees.
T6.2. Training the trainers (M1- M11)
The Regional Ministry of Health of Asturias (CSPA), supported by the bidder of this contract, will organise the "train-the-trainers" training of local healthcare staff that will be implementing the pilot actions. Each local team will be multidisciplinary, including programme coordinators, nutritionist/dietitians, GPs/internists, nurses, and, if applicable, coaches (or comparable figures). At the beginning of the task, up to 8-10 healthcare professionals per pilot country will be selected to receive the train-the-trainers action in English by the bidder of this contract. The training courses will be divided per country cluster. Following recommendations on the bidder of this contract, 4-5 countries will compose each cluster. The training will include transfer of knowledge by several experts´ presentations. Additionally, participants will practice by doing several exercises, have assignments, and conduct reflection assignments. The training will last ca. 3 months. When applicable, professionals trained by the bidder of this contract will become "replicators" by training further staff that might be needed to implement the action at national/regional level. During the whole task, the bidder of this contract will support CSPA coaching individual countries. T6.2 actions will be continuously monitored for improvement. Satisfaction & opinions for evaluation and fine-tuning purposes will be collected from healthcare participants. The assessment of the first cluster training will serve to correct any potential major bottlenecks and fine-tuning the next training. Healthcare professionals will receive a certificate upon completion of the training by the bidder of this contract, which will give them the capacity to train other health professionals in their country. According to the previous description, the bidder will have to contribute to the activities detailed above and will, specifically, have to carry out the following ones: the organization of 5 online training days and 3 online sessions; management and moderation of the training community & e-modules; sessions of reflection with local teams and of Questions & Answers to solve doubts; preparation of participant materials for local translation, and Certification of the health professionals that attended successfully the trainings.
T6.3. Intensive care implementation, monitoring, and reporting (Phase I) (M12-M27)
The Phase I implementation will be executed with the collaboration of the bidder of this contract. Each patient´s group will go through an intensive lifestyle training & coaching programme of 6 months. Intensive treatment will be focused on dealing with type 2 diabetes to achieve healthy blood glucose levels, less medication and better quality of life such as self-care, usual activities e.g., work, study, housework, family or leisure activities, mobility, pain / discomfort, anxiety / depression (using the internationally accepted tools and measures, based on e.g., EuroQol (5Q5D5L), PROMS, and PREMS). Patients will receive dedicated sessions by a multidisciplinary local healthcare team. They will work on medication adjustments, better sleep and relaxation techniques, nutrition recommendations, and physical exercise activities. They will set personal goals and will receive coaching to gain durable changes in their

lifestyle. Pilot Member State might implement the intensive programme fully online, in a hybrid format, or fully in-person. For the online modality, groups of patients may be reduced (15-20 people), while face-to-face format can sustain groups of ca. 20 people each. The in-person training will entail an initial 2-day kick-off staying overnight intervention, followed by sessions of three more days: 1, 3 and 6 months after initial kick-off intervention. In each face-to-face meeting, patients will be tested for glucose levels and other specific medical parameters. Online training will foresee more regular meetings: at least 6 online sessions including 4 full or half day sessions within a 6-month period as appropriate to local circumstances and participant demographics. In the remote intervention programme, during the first online meeting, how the glucose monitoring device works will be explained, so the participants will be able to manage their blood glucose regularly and report to the diabetic nurse. Based on this the medication can be adjusted, if required. The Deming-PDSA cycle will be in parallel to Phase I to facilitate monitoring, assessment, and improvement as long as activities progress. This methodology will be explained in a dedicated workshop at the 1st consortium meeting (kick off) by CSPA and NIJZ. Leveraging the PDSA framework, all implementing partners will initiate Phase I implementation at M12, which will run 6 months until M18 and will engage a restricted number of patients (total: 340). Upon this first intervention round’s completion, in parallel with first PDSA cycle, partners will comprehensively evaluate performance and outcomes (M19-M20) and, if needed, adjust the approach for the second intervention round (and second PDSA). This second round of Phase I pilot actions will involve a higher number of patients (total: 520) and will run from M21 until M27.
Each pilot local team will report the whole implementation experience using the SQUIRE 2.0 tool. In the annual consortium meeting (M24, approximately), pilot countries will share their experiences, lessons learned and general feedback. Healthcare professionals participating will provide opinions on strengths and weaknesses at local settings, making suggestions where to focus for improvements. Partners will also evaluate
results under participating patients considering key clinical and non-clinical KPIs. Along with intensive training on lifestyles, there will be the online community platform established in T5.3 and running in each pilot country for patients to seek information, supportive docs & guidelines, and where to share experiences and opinions with peers and experts. CSPA will schedule a bi-monthly teleconference with pilot local teams to closely monitor the progress and address any issues/delays. CSPA will provide continuous support to implementers, fully supported by the bidder of this contract.

According to the previous description, the bidder will have to contribute to the activities detailed above and will, specifically, have to carry out the following ones: give the consortium full support to the pilots during the phase of intensive implementation, providing coordination with all the partners of the consortium and for expert support.

WP7 - Phase II implementation (after-care oriented)

T7.1. After-care activities´ implementation (Phase II) (M19-M33)

Upon the completion of the intensive Phase I intervention in T6.4, this task will address the follow-up of patients in the so-called “Phase II after-care implementation”. The key objective of this phase is to ensure durable lifestyle changes and to offer additional support to patients that may need it. The Phase II after-care period will include continuous (but with time constraints) coaching, nutrition support, online communities support via the online platform, based on the needs and

requirements of each patient. Additional monthly follow up sessions for patients will be available. Coaching and behaviour change for pilot local teams' interventions will be ensured on a monthly basis. It will include principles of the intervention, nutrition recommendations and creating recipes.

Along with the lifestyle sessions, similar to Phase I, patients will be encouraged to take part in the online community platform. It will be available to share experiences among peers, to access extra supportive/background info and additional tips. Phase II after-care intervention will be conducted with total 860 patients, including one PDSA.

The first intervention round with first group of 340 patients will conduct Phase II between M19 and M24, in parallel with one PDSA cycle for evaluation purposes. The second intervention group of 520 patients will begin Phase II in M28 and finish in M33. The results of the second group of patients will not be considered for evaluation due to time constraints, as explained in the Methodology section.

According to the previous description, the bidder will have to contribute to the activities detailed above and will, specifically, have to carry out the following ones: give advice to the partners of the consortium for the pilot implementation of the after-care activities offering coordination with the partners and for expert support.

3.3. Content of the technical offer

The technical offer must include:

- A working plan that exhaustively sets out the methodology, a Gantt Chart or timeline of the activities and milestones that the tendering company proposes to follow in the development of the service, according to the Technical Specifications.
- A list of the staff that will carry out the tasks included in this contract, indicating the academic background and professional experience of each person on the tasks of the contract.