CHERRIES
RESPONSIBLE HEALTHCARE ECOSYSTEMS

Adapted territorial methodology for the experimentation per territory. Phase III

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Table 1: Terminologies and Definitions used in CHERRIES

APPLICATION	Innovation solution proposal answering the call for solutions or all for needs. Consists of the following items: 1/ The Proposal has to follow the templates provided for this purpose; 2/ Declaration of honour duly signed, stating that this very same project proposal does not receive funds elsewhere.
CALL FOR NEEDS	Publication of an announcement inviting either organizations or individuals and generally stakeholders from the 4P model as defined in the project to submit a "need" as also defined in the project. CHERRIES methodology is a demand driven approach on healthcare innovation and the first and most important step is to properly identify and define a solid need. To define the need, the applicant has to complete the application form as designed by the consortium and adjusted accordingly in the territorial conditions. In CHERRIES, the current call is hosted in 3 different regions with different geographical, socioeconomical and healthcare characteristics.
CALL FOR SOLUTIONS	Publication of an announcement inviting innovative Start-ups, SMEs and other organizations to provide a solution addressing the unmet need that has been defined in the call for needs. To provide a solution, the applicant has to complete the application form as designed by the consortium and adjusted accordingly in the territorial conditions.
CHALLENGE PROPOSER (CP)	The organization/entity or group of organizations that propose the unmet need and frame it in the form of a challenge. The CP also works in close collaboration with the solution provider to co-create a solution. The Challenge Proposer is directly in collaboration with the territorial partners of CHERRIES.
EVALUATION SELECTION OF THE NEEDS	Group of stakeholders who are responsible for selecting the need among all proposals submitted. The Evaluation Selection Committee (ESC) is composed by the territorial partners as well as with the experts, professionals, and civil society in the field of the Need and Solution under examination
SELECTION COMMITTEE OF CHALLENGES	Group of stakeholders who are responsible for selecting the challenge among all proposals submitted. The SC (selection committee) is composed by the territorial partners as well as by the experts and committees in the field of the seed and solution under examination
EVALUATION PROCESS	The call for solution evaluation process is structured in three steps: 1- Eligibility Check. A first review performed by the local partners. 2-Proposal evaluation. A SC evaluates all eligible proposals, 3- Solution Provider selection. The selected local beneficiary solution providers and their solutions' proposals are published & notified.
FUNDING/CONTRACTING BODY	Funding/Contracting organization that launches a competitive call to select the best solution provider for each territorial challenge. It also provides the economic support to the Solution Provider to carry out the development of the solution. In CHERRIES project, the funding/contracting body is the regional partner that has received the funding (through the project) and will provide it to the solution provider following the sub-agreement regulation.
SOLUTION PROVIDER	Organization that, once selected, becomes the solution provider and starts co-creation with territorial team, supporter and challenge owner.
SUBGRANT AGREEMENT	Selected Solution Providers are requested to sign a covenant document which main objective is to validate the administrative, financial and technical operational capacity and to establish some minimum ground rules for receiving support from the CHERRIES project.
THEME	A Theme is a large Healthcare area where there are needs that can be addressed by an innovative solution. The Theme is defined by the call for needs and its purpose is to identify unmet need to be solved in relevant healthcare areas.

1 Introduction

CHERRIES engages health ecosystems in South-West Europe (**Murcia ES**), Northern Europe (**Örebro SE**) and South-East Europe (**Republic of Cyprus CY**), in which the territorial preconditions and development paths are varying. CHERRIES project is developing an adapted territorial methodology for the experimentation pilots in each territory. The demand driven innovation processes for co-creation and reflection to mirror territories implemented throughout the project are elaborated in the current document presenting the unique CHERRIES approach. By applying Responsible Research and Innovation tools and principles and adapting them to territorial preconditions in order to collect and identify the needs; the CHERRIES methodology is designed to adopt to regional challenges and to support co-creation solutions in the healthcare ecosystem whilst engaging all relevant stakeholders of the 4P model which are Patients, Professionals, Policymakers and Payors

CHERRIES Methodology has been designed to reflected the live progress and activities of the territorial experimentation process in the three different regions and as a result, it is able to provide any user and reader that potentially would apply the CHERRIES methodology in a mirror territory with all the necessary step-by-step guidance as well as the documentation to be used during its adoption. The unique value of CHERRIES methodology is that it provides the potential adopter with flexibility and agility to adjust and apply the core methodology based on its unique territorial preconditions.

2 Setting up the experimentation in the territories: The CHERRIES experimentation: a 5-step approach

The CHERRIES project set up its territorial experimentiatons following a carefully designed methodology (see chapter 3) that was set up in co-creative process with the key stakeholders in the terrirtories. It gives coherence to the experimentation process and facilitates its design based on territorial preconditions and the stakeholder landscape, allowing for regional adaptations where needed. In general, the CHERRIES approach to RRI-based policy and innovation experimentation in the healthcare sector can be broken down into five steps.

Step 1: Analysis of the regional context and potential for innovation

In order to properly set up the framework for the tailored experimentation processes in the three territories, a comprehensive analysis of the specific regional backgounds was implemented at the beginning of the project. The methodlogy developed for this “mapping exercise”[1] was based on the theoretical interface of innovation policy, RIS3, RRI, and the healthcare sector. The framework consists of mapping exercises within the territories. It covers the identification and classification of stakeholder involvement, the policy ecosystem, provids insights into the current policy mix in the context of RRI, and the innovation support ecosystem and was mapped according to the RIS3 principles.

The territorial mapping exercise encloses - as one of the main steps, the definition of the territorial priorities of the regions. In order to achieve this goal, the methodological approach follows the Research and Innovation Strategies for Smart Specialisation method (RIS3 Guide) from the European Commission (2012). The process entailed the adaptation of the steps and actions considered to provide a more specific input required in the context of the CHERRIES project. This version of the strategy established a special focus on Healthcare and Innovation sector. Additionally, the methodology considers using more recent data and information available, if compared with the previous Regional Smart Specialization Strategies.

The steps to describe the territorial context of the regions are as follows:

a. Analysis of regional economic specialisation: We assessed this task using sources such as; EUROSTATS at regional level and R&I Observatory, which contains the country reports from 2017,

[1] REFERENCE TO DELIVERABLE FROM WP2

providing a brief analysis of the R&I system covering the economic context, main actors, funding trends & human resources, policies to address R&I challenges.

b. Analysis of innovative behaviour: An examination of the regional innovative behaviour, capabilities, priorities, needs, and observable trends from the country and regional perspective. The sources used for this activity included the Smart specialisation platform – EU, European Observatory for Clusters and Industrial Change Mapping Tool, European innovation scoreboard, and the regional innovation scoreboard (RIS).
c. Defining type of health care system: The health care system was assessed on its public or private nature and the level of health care provided. We took as a source the Country Health profiles developed by the European Observatory on Health Systems and Policies and the Organisation for Economic Co-operation and Development (OECD).[2]

Step 1: Analysis of Scientific and Technological specialisation

Analysis of the regional knowledge production data based on publications and patent applications. In this section, we communicate the main strengths and capabilities already present in the region from the scientific perspective. Leiden University measured scientometric indicators based on CWTS internal database (Web of Science's (WoS) produced by Clarivate Analytics.

The type of analyses performed considered the following characteristics and sources of data, to build a profile of the current knowledge production in the regions:

- **Societal Grand Challenges:** Knowledge production associated with the SGC. We assessed the average number of publications (normalized by population) of each SGCs category associated with "Health" for the period 2012- 2016. This, characterizing the relationship between Health categories from SGC and the World Health Organization (WHO) priorities (Data source: Knowmak project).
- **Complexity and diversity indicators:** It refer to the variety of knowledge and is measured by the number of scientific subfields with revealed comparative advantage (RCA). Diversity matters because regions are more likely to expand and diversify into new topics and fields that are closely related to their existing activities. The complexity measure looks to explain the knowledge produced in a region combining metrics of the diversity of regions and the ubiquity of the fields to create measures of the relative complexity of a region's scientific portfolio. Hausmann and Hidalgo (2009)[3]. For further details of the methodology applied, please refer to Heimeriks *et al.* (2019)[4].
- **Relatedness:** The relatedness indicator measures the Revealed comparative advantage (RCA) by analysing the fields in which the region has an above-average concentration of publications. Likewise identify which scientific subfields are often found together in the same region, as a representation of the ability of the territory to diversify into related subfields. This analysis was performed for publications in the year 2018.
- **Analysis and characterization of priorities at micro-fields level**: The outcomes from this analysis provide a more detailed characterization of the fields already prioritized in the Relatedness analysis. It provides complementary information in respect to the level of specialization and knowledge production in the territory. We considered the absolute number of publication output and the Relative number of publications to specify the level of specialization in each field. For further details please refer to Waltman & Van Eck (2012)[5]. The sample for each region considers not only scientific articles but also reviews and conference proceedings published from 2014-2018

[2] https://www.euro.who.int/en/about-us/partners/observatory/publications/country-health-profiles
[3] Hausmann, R., & Hidalgo, C. A. (2009). The building blocks of economic complexity. Proceedings of the National Academy of Sciences of the United States of America, 106(26), 10570–10575. doi:10. 1073/pnas.0900943106
[4] Heimeriks, G., Deyu, Li, Wout, L., Meijer, I. & Yegros, A. (2019) Scientific knowledge production in European regions: patterns of growth, diversity and complexity. European Planning Studies 27(11):1-21.
[5] Waltman, L., & Van Eck, N.J. (2012). A new methodology for constructing a publication-level classification system of science. Journal of the American Society for Information Science and Technology, 63(12), 2378–2392. (paper, preprint)

- **Characterization of the most relevant fields from Biomedical and Health Science:** Using the same methodology as for the micro-level fields. This analysis involves only the key subjects developed in the Biomedical and Health Science field.

Step 2: Governance - Ensuring participation and ownership

After setting up the regional frame through step 1, the next step focused on getting governance strucutures in place that allowed creating an inclusive and participative environment for the key stakeholder, ensuring ownership of the process beyond the project consortium. In terms of process, this meant aiming for a wide participation of actors and experts from within region. The most important types of organizations that have been involved are public authorities, universities, and other knowledge-based institutions, investors and enterprises, civil society actors, and Healthcare organizations.

This step has been conducted in accordance with the territorial mapping of the Stakeholders. The process consisted of the following 4 steps: 1) identification of stakeholders from current regional network 2) addition of potential new partners from datasets 3) selection criteria for stakeholders 4) categorize stakeholders regarding their degree of involvement in the project.

Step 3: Elaboration of an overall vision for the future of the region

This is a highly political step. Its value mainly rests on getting the political endorsement for the subsequent steps, particularly for the implementation of the prioritized areas. The vision should also include justifications for its relevance in terms of meeting societal challenges, such as providing more healthy living conditions for its citizens, providing new employment opportunities for specific categories of the population, combating social divide, environmentally responsible, etc.

Step 4: Identification of territorial priorities

This step addresses the results of the analysis performed in Step 1, 2 and 3 and likewise the territorial priorities raised by the regions, as a result of the engagement process with the groups of local actors and stakeholders. It comes up with clearly defined regional needs (through a call for needs as described above) and launches a call for solutions addressing this regional priority per territory.

Ideally, both priorities should be aligned. If the assessment of the regional capabilities and skills present in the region (Step 1) are connected to the priorities defined by each territory as part of the “entrepreneurial discovery” process, the region has a better chance to succeed in that area.

Some of the requisites filled by the current priorities defined in each territory are:

a. Priority level should be smaller than whole sectors, but bigger than single activities for maximal effectiveness.
b. Priorities do not have to fit in one particular sector and can be connected to multiple sectors. This is important because often innovative concepts are formed from a diverse set of capabilities.
c. Concerning the importance of RRI and SDGs in today’s society these priorities do not have to carry an economic value only.
d. Stakeholders can formulate their societal visions for the future and collectively integrate these into their smart specialization priorities.

Step 5: Definition of coherent policy mix, roadmaps, and action plan

This step is being addressed through the Policy mapping activity. The mapping exercise follows the methodological approach developed within the consortium and aims in the design of territorial RRI-compliant innovation policy mix and the evidence based RRI -compliant development strategies

As already considered under the CHERRIES project framework, it is advised by the EU guidelines to test the new concepts in practice by setting up pilot projects in which can experiment with policy mixes before applying policies on the larger scale. For effective use of these pilot projects, a well-constructed evaluation mechanism should be in place to effectively assess which policy mixes are favourable.

The following chapters present the nature of the CHERRIES experimentation cases in the three pilot territories, describing their key characteristics, set up and implementation status (as of May 2021) according to the outlined 5 step approach.

3 The CHERRIES methodology

The engagement of societal actors, with central roles or knowledge about the healthcare and innovation ecosystem in the territories as well as citizens, all kind of citizens, irrespective of their age, gender, ethnicity and socio-economic background, is a central aim and methodological cornerstone of CHERRIES. The need articulation processes as well as the co-creation phase of the experiments guarantee that developed solutions are aligned with the values, needs and expectations of society[6].
The CHERRIES methodology presents a clear pathway towards RRI in the healthcare sector and offers innovation actors the tools and processes aimed at facilitating multi-stakeholders approaches to innovate in healthcare. It does so in order to address societal challenges in an adequate way through various aspects of a multi-stakeholder's dialogue:

- Broader vision/Long term vision.
- Increased and improved relationship between customers and users.
- New resources of creativity and innovation.
- Increased awareness about upcoming regulatory regimes.
- Reconsideration of business processes focusing on customers rather than competitors.
- Obtain competitive advantages and benefits by including RRI in their processes and products (cost reduction, risk reduction, better supply chain engagement, reputation, innovation capabilities, increased attractiveness of the employer, new opportunities).
- Increase the capacity of health entities to systematically identify and solve their needs while creating opportunities for private companies.
- Digital solutions with a high success rate -in terms of their application in practice/market uptake- because they have been developed side by side with the client.

RRI can help healthcare actors in their decision making taking into account a long-term vision, an inclusive attitude and a societally oriented approach.

CHERRIES experimentation process is therefore permeated by a RRI approach, from needs' identification to solutions' definition and co-creation. Through the proposed methodology and throughout the different pilot phases, CHERRIES will help healthcare innovation players act according to RRI process dimensions such as diversity and inclusion, openness and transparency, anticipation and reflection, responsiveness, and adaptability.

Moreover, wherever relevant, the 2 regional calls (call for needs and call for solutions) will refer to some specific RRI-driven criteria (such as open access, gender equality, public engagement, governance, ethics and science education) forcing healthcare innovation players working together towards ethically acceptable, socially desirable and environmentally sustainable products and services.

In the following paragraphs, where each phase of the experimentation is described in more detail, CHERRIES will suggest practices and tools that will help regional actors shaping responsible healthcare ecosystems.

[6] CHERRIES (G.A no.872873) Annex I to the Grant Agreement

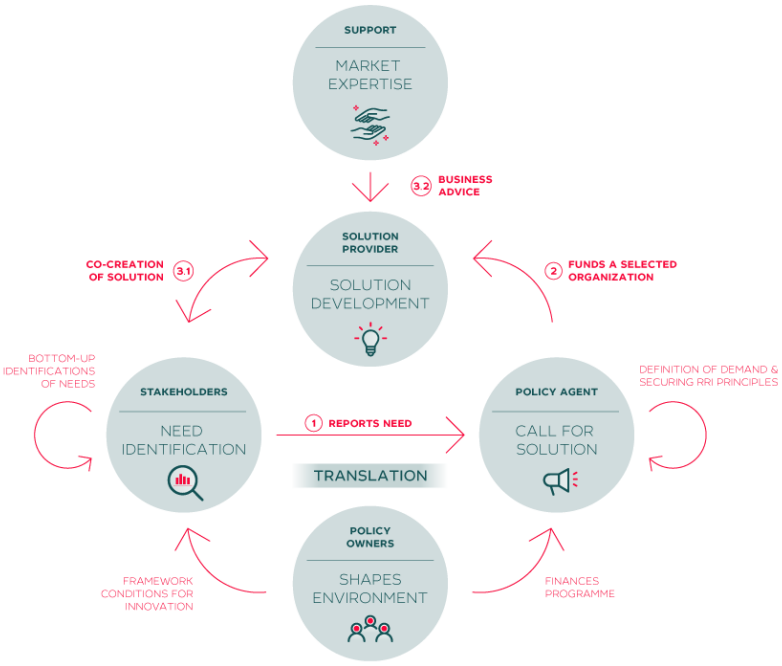

Figure 1: Schematic representation of the CHERRIES experimentation approach.

Introduction to the Phases of the Methodology

As mentioned above the CHERRIES methodology suggests a standard process that enables each region to tailor and adjust to its specific territorial context. Flexibility and adaptability are two key assets of CHERRIES approach.

The representation of the four phases in Figure 2, reflects the process and presents the method to be used by the partners responsible for the implementation of the CHERRIES pilots per territory. To propose a very practical and operational framework, the document is structured along these four phases which each region needs to implement on the regional level.

Phase 1 focuses on the need identification. In order to achieve this objective, stakeholders launch a call for needs to identify the unmet need in the social healthcare arena and, through a process of evaluation and selection, a regional need will be selected in each region.
Phase 2 aims to the translation of the selected need to be shaped into a call for solutions. The call for solutions is also divided into five micro-processes that are presented in Figure 3.
Phase 3 refers to the Co-Creation of Pilots in the territories within a duration of 9 months as well as to the contractual and managerial aspects of the activity.
Phase 4 aims to present the lessons learned during the adoption of the Methodology in the mirror territories as well as the adoption of RRI principles and tools in the healthcare ecosystem.

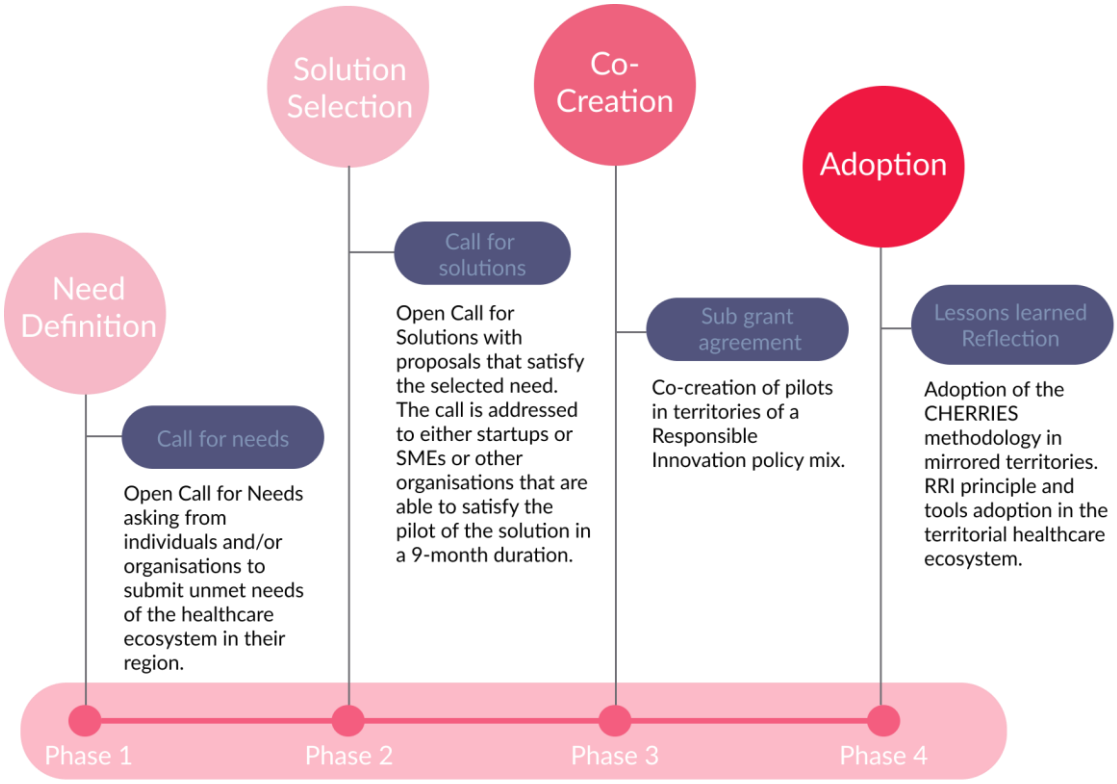

Figure 2: Cherries Methodology divided in phases

4 PHASE 2: The co-creation of solutions

4.1.1 Contractual and management aspects

In order to guarantee that the developed solutions are aligned with the values, needs and expectations of society, CHERRIES fosters the engagement of societal actors, professionals and patients. Therefore, the development of the solution needs to include interactions with all the actors (healthcare, professionals and patients) including mainly those involved in the definition of the need. The whole co-creation programme will last a maximum of 10th months, from June 2021 to March 2022 and a Sub-Grant Agreement (SGA) will be signed among the funding partner of the project CHERRIES, the solution provider and a representative of the team that defined the need to be solved. The solution provider will also receive business support by the CHERRIES consortium. The project will consult in questions of business modelling, access to private investors and commercialisation. At pilot end, each solution provider will deliver the solution and deliverables as defined in the sub-Grant Agreement. A local “review committee”.

Contractual and Management aspects start with the solution ranked in the first position with a view to open the pilot phase.

Selected solution providers are requested to sign a Sub-Grant Agreement (SGA) whose main objective is to validate financial and technical operational capacity from the SMEs teams, and to establish some minimum ground rules for receiving support from the CHERRIES project. Acting as a Memorandum of Understanding between the three parties, the SGA settles the specific conditions, rights and obligations for the concession of a grant to the beneficiary for the co-creation phase. Thus, for each solution, such a SGA will be signed between the funding/contracting body and the solution provider.

4.1.2 Contract regarding cascade funding

The beneficiary solution provider is requested to provide to the funding/contracting body two signed SGA within 15- calendar days after receiving it. A range of complementary documents are also requested:

- Legal existence: Deed or Articles of Association (corporate statutes)
- Legal representative: Copy of Power of attorney document (if applicable), National Identity Card
- Tax Agency Documentation to evidence the fulfilment of tax obligations.
- Certificate of up-to-date Social Security payments to evidence the fulfilment of obligations.
- Financial statements: P&L, Balance sheets (from previous year). In the case that it is the first year of activity, it will not be asked any further information.
- Bank Account information: IBAN & SWIFT code (if applicable)
- A valid Bank Guarantee (if Solution Provider is willing to access to the advance payment of the Grant)

The provision of the sub-grant agreement duly signed and the above-mentioned documents to the Funding/Contracting body duly constitutes proof of acceptance of the Grant by the Solution Provider.

Once completed the signature process of the Sub-Grant Agreement, the Funding/Contracting Body sends one copy back to the Solution Provider by email. The day of the last signature formally opens the co-creation phase.

Amendment of the SGA is possible during the implementation of the project. In such cases, the request for amendment must be formally issued from the interested parties to the other two parties in written form before the conclusion of the project, by including more precisely:

- Issue to be amended
- Reasons for such an amendment
- Contingency plan with detailed info on the measures to be implemented in order to assure the completion of the envisaged objectives of the project.
- Envisaged date of deliverance of the reporting evidence

Such a request is to be managed by the Funding/Contracting Body who will prepare a formal amendment of the SGA which will be circulated to the other two parties for signature. The flow of signatures will be: Solution Provider– Challenge Proposer – Funding/Contracting Body. In case of need, both Challenge Proposer and/or Funding/Contracting Body may request the Supporter for advice-support.

4.1.3 Contract for co-creation

General Planning & Minimum Requirements

The General Planning and Minimum Requirements are presented below in the order sequence that need to be taken:

- Initiate discussion with each company on the business model approach to identify the specific needs.
- Set a personalized framework including planning for the co-creation period with the following information: team, calendar, milestones, deliverables, description of the interactions.
- All materials will be prepared in English (to ensure knowledge transfer).
- The implementation may be completed in a local language (Challenge Proposer organisations' requirements for the co-creation language may differ).
- There will be at least 3 support face-to-face interactions coordinated with the co-creation interactions.
- Based on the needs of the sub-granted projects, the Supporter will assist companies to access services provided by consortium partners, such as coaching by experienced and qualified coachers,

validation with Business plan experts, support in the definition of a market development strategy and business scaling for target markets, and targeted support to access private capital market.

- Follow-up of the implementation
- When a milestone is reached, a joint assessment will take place and corrective measures, if necessary, are put in place. It is important to discuss these needed measures with all relevant stakeholders.
- Reporting of the co-creation results
- At the end of co-creation, Solution Provider and Challenge Proposer interact to discuss the targets vs results of co-creation.
- At the end of co-creation, Solution Provider and Supporter interact to discuss the potential continuation of the pilot.
- Solution Provider needs to report to the Funder the results and provides those in the set format.

Regional Adaptation

The pilot regions adapt the defined Minimum Requirements according to regional resources in creating own regional approach for the experiment implementation. The Regional Approach is required to ensure coordinated actions among Challenge owner, Solution Provider, Supporter and Funding/Contracting body organizations. In the regional approach, the most important activities will be defined (i.e., Project kick-off day for the Solution Provider, Co-creation with users, Group Sessions, One-to-One meetings, Test Trial Period, and the Co-creation Final Event). These Regional Approaches are shared with the rest of the Consortium Partners for feedback, and knowledge transfer.

CHERRIES Partners

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement nº 872873. This document reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains.