European wide Innovation Procurement in Health and Care

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825922-EURIPHI

Deliverable

D5.1: Prioritization and Test Case Learnings

WP	**5**	Supportive Actions
Task	**5.2/5.4**	Test learning cases / Memorandum of Understanding

Dissemination level[1]	PU
Type[2]	R

Due delivery date	31/03/2020
Actual delivery date	31/07/2020

Lead beneficiary	MEDTECH
Contributing beneficiaries	IFIC, UniHA, RESAH, APHP, NHSCS, NWSSP, AQUAS, FCRB, FPT, ARreSS, SORESA, FDG, Goblirisch, HOPE, CMS, CMS-UK

Document Version	Date	Author	Comments[3]
v1	20/04/2020	Hans Bax / Isabella Notarangelo	Document creation
v2	04/05/2020	Hans Bax	Modification
v3	05/05/2020	Isabella Notarangelo	Modification
v4	26/06/2020	Hans Bax	Final draft based on input from WP partners

[1] Dissemination level: **PU**: Public; **CO**: Confidential, only for members of the consortium (including the Commission Services); **EU-RES**: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); **EU-CON**: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); **EU-SEC** Classified Information: SECRET UE (Commission Decision 2005/444/EC)
[2] Type of the deliverable: **R**: Document, report; **DEM**: Demonstrator, pilot, prototype; **DEC**: Websites, patent fillings, videos, etc.; **OTHER**; **ETHICS**: Ethics requirement; **ORDP**: Open Research Data Pilot
[3] Creation, modification, final version for evaluation, revised version following evaluation, final

Deliverable abstract

This deliverable provides an overview of the most important learnings collected from the partners in the EURIPHI project. The learnings, under the project, correspond with the main steps in the full procurement process as executed. Key learnings have been collected on e.g. the application of the VBP procurement approach and the associated MEAT-VBP framework. The learning are structured around the prioritization of common unmet needs, market readiness assessment using an Open Market Consultation and management of the challenges associated with cross-border procurement, including its legal issues, defining final procurement needs and overall consideration on the full procurement process. The learnings serve to draft the MoU Principles of Cooperation, writing of PPI in selected fields, to further finetune the supportive actions and support any future call writing in health and social care procurement. Specific consideration on prioritized procurement objective and learning from specific partners are provided within the annexes.

Deliverable Review

	Reviewer #1: .Yves Verboven			Reviewer #2: NA		
	Answer	Comments	Type*	Answer	Comments	Type*
Is the deliverable in accordance with						
the Description of Action?	☒ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
the international State of the Art?	☒ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
Is the quality of the deliverable in a status						
that allows it to be sent to European Commission?	☒ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
that needs improvement of the writing by the originator of the deliverable?	☐ Yes ☒ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
that needs further work by the Partners responsible for the deliverable?	☐ Yes ☒ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a

* Type of comments: M = Major comment; m = minor comment; a = advice

Abbreviations and Acronyms

CoP	Community of Practice
CSA	Coordinating and Supporting Action
IC	Integrated Care
ICPO	Integrated Care Procurement Objective
EURIPHI	European Innovative Procurement of Health Innovation
MEAT	Most Economically Advantageous Tender
OMC	Open Market Consultation
PCP	Pre-Commercial Procurement of Innovation
PIN	Prior Information Notice
PPI	Public Procurement of Innovation
RD	Rapid Diagnostics
SME	Small and Medium-sized Enterprise
TED	Tenders Electronic Daily
VBA	Value Based Agreement
VBP	Value Based Procurement
W2P	Willingness to Pay

Table of Content

Introduction

This deliverable provides an overview of the consolidated test case learnings collected from the partners in the EURIPHI project. The learnings, referring to the execution of the tasks performed under the project, correspond with the main process steps of the EURIPHI full procurement process as completed during the project. The learnings serve as an input to the writing of PPI/PCP in selected fields and to further finetune the supportive actions.

In order to provide the consolidated test case learnings under this deliverable, several sources of information have been consulted e.g.:

- Deliverables and Tasks performed under the EURIPHI project;
- Meetings minutes on various Working Group meetings, meetings of the Health Regions; Network and the International Round Table;
- Minutes and results of the Open Market Consultations on IC and RD;
- Individual feedback provided by EURIPHI partners.

The collected learnings on the execution of the tasks have first been grouped and subsequently been consolidated using the skeleton of the full procurement process as completed during the project. A detailed overview of the process can be found annex I and D3.3 (figure 2).

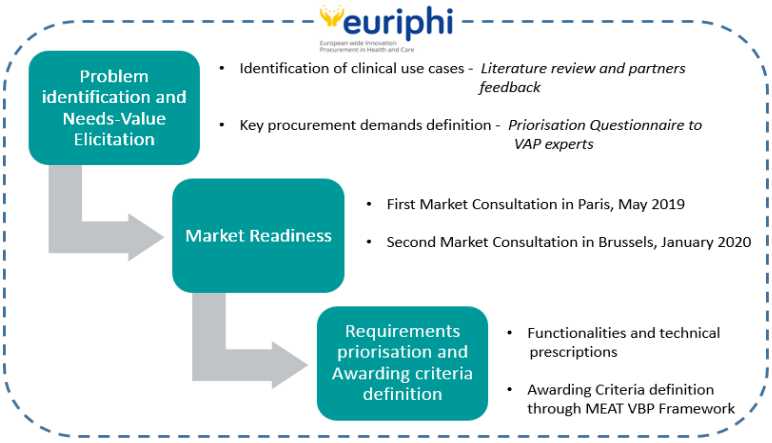
Figure 1: Full procurement process – 5 steps

General

The collected learnings on the execution of the tasks performed under the EURIPHI project resulted in some **general learnings** not to be directly connected to a specific phase in the procurement process.

1. The EURIPHI project has been supportive in exchanging good practises between the partners including a better understanding on the challenges involved in collaborative cross-border procurement of innovative solutions.
2. The exchange of good practices and innovative practises is key to foster the use of EU cross-border collaborative procurement and builds relations for future collaboration.
3. The procurement approach of Value Based Procurement (VBP) has proven instrumental to the procurement and uptake of innovative solution to improve health and innovate the delivery of care.
4. VBP can increase competitiveness and drive companies' motivation to develop and deliver solutions responding to the needs. It can also provide a niche in the market where SME can access the market with their value based innovative solution.
5. The EURIPHI project represented an opportunity to the participating partners to acquire knowledge and a good understanding of the Value Based Procurement approach and the associated Adapted MEAT VBP framework for Integrated Care and Rapid Diagnostics, including also those organizations not used to purchase through public procurement procedures (e.g. FDG).
6. The EURIPHI performed tasks and deliverables add value by supporting (regional) health care authorities to identify and prioritise care delivery common unmet needs. This is considered a priority and starting point for (any) cross-border value based procurement collaboration.
7. In order to address the (non-) clinical, social and public health unmet needs, health authorities and providers shall act together on the collaborative procurement of integrated, innovative solutions.
8. Information on regions readiness in applying innovation procurement in general is scarce. EURIPHI partners performed a mapping exercise on this as well as a mapping on the regions readiness for value-based PPI in integrated care (ref. D1.1) to provide additional information.
9. A continuous, structural dialogue between regional authorities, contracting authorities, health care providers and industry should be promoted, to raise ongoing awareness on health and social care delivery unmet needs, the financial burden of care service provision as well as innovative solutions available or to be developed.
10. Pooling demand for solutions to specific unmet needs, care delivery shortcoming and using value based collaborative procurement activities stimulate the development of innovative solutions and can offers increased market access opportunities for suppliers, including start- and scale-ups.

11. Execution of collaborative procurement activities needs a structured approach, starting with the identification and assessment of common problems/unmet needs, the assessment of the market readiness, prioritization of the identified needs and requirements and preparation of the procurement case, followed by the execution of



the procurement tender process.

Figure 2: EURIPHI Need Assessment Methodology

12. Cross-border collaborative procurement provides an efficient and effective means to address joint cross-border care delivery shortcomings. Both national and local demand/supply circumstances require the final purchase of solutions to be made on a regional or local level.
13. Performing procurement across borders could be a driver for local SMEs and start-ups to scale-up foreign markets. Condition to success, SMEs and start-ups need to be strongly supported on how to put in place international outreach strategies. If this happens, regions across Europe could leverage the positive effects of cross-border value-based innovation procurement for health systems and society.
14. An alternative to (full) cross-border *joint* procurement is cross-border *collaborative* procurement, in which two or more procurers having similar needs and structure collaborate and exchange good practices during the preparatory phase (unmet need definition, market readiness analysis, definition of the procurement strategy e.g.) enter the execution phase enabling local decision-making taking local specificities and requirements into consideration. To complete the collaborative project, procurers are recommended to exchange the results and main lessons learned when finishing the tender phase in order to 'close the loop'.
15. Contracting authorities organizing cross-border procurement should be attentive for the requirements laid down in the procurement documents; too strict requirements can have as a consequence that SME and start-up cannot meet such requirements.
16. As the start of the implementation of a cross-border collaborative procurement project and the application of VBP,, it is advised to be under the stewardship of a group of (external) experts on the matter to guide and help to overcome challenges in the process. The EURIPHI VBP Community of Practice is composed and equiped in order to succesfully fulfill this role.

17. The transformation from traditional procurement practice into Value Based innovation Procurement is vital towards meeting the unmet needs and demands of citizens in gaining better health outcomes, including those patients suffering from e.g. rare diseases or in case of a pandemic. Additionally, Value Based Procurement of innovations will bring long-term cost-effective benefits to health care systems across Europe.
18. Collaborative ecosystems, such as the Health Regions Network and EURIPHI VBP CoP, promise to be excellent platforms to jointly identify and prioritise shortcomings in healthcare delivery across Europe on a structural basis as well as to initiate a collaborative VBP procurement process, by those partners having the same unmet need, to support the adoption of innovative solutions and to allocate financial funding.
19. Membership to these ecosystems should be made widely available in order to allow for as many members as possible to collaborate on their specific unmet need(s) with other members having the same specific unmet need(s).

Assessment of care delivery shortcomings and unmet needs (step 1)

The aim of WP3 and WP4 was to gain insight in and to organise the demand side around a small set of identified integrated care and rapid diagnostics service delivery issues as well as to support EURIPHI care delivery organisations and Public Procurement Organisations in the related procurement process.

1. Participating in a joint cross-border project will foster mechanisms of identification and prioritisation of common unmet needs. Therefore, health authorities and health care providers are encouraged in defining the highest priorities in their agenda as well as the resources to invest in order to meet these priorities. If the organisations involved prioritise the same unmet need(s), cross-border collaboration could bring positive consequences to the health systems, including knowledge sharing and economy of scale.
2. The assesment of care delivery shortcomings is a challenging and complex process having multiple stakeholders involved, risking to 'think solution' instead of to 'think unmet needs'.
3. Given the identified unmet needs, prior to defining the subject matter ('what to buy') it is important to also determine '*are* we going to buy', e.g. to create a business case to which the (Adapted) MEAT-VBP Framework could act as a supportive tool.
4. Publication via notifications in the European Journal could be an additional mean of determining common unmet needs outside the scope of those already involved.
5. In order to initiate new joint projects on the basis of an existing structural partnership, such as the EURIPHI CoP, it is important to first identify the partners' individual care delivery shortcomings, next to identify those shortcomings in common and then to jointly prioritize.
6. Collecting multi-stakeholder structured feedback on a long-list of care delivery shortcomings from e.g. healthcare regions, care delivery organisations, procurement organisations and external advisors, proved another successful means in order to prioritise common shortcomings among those parties involved.
7. To address the end-users' (clinical and non-clinical) needs it is regarded essential to involve the end-users and patients in the procurement process, especially in the preparation phase in order to ensure a perfect understanding of the unmet needs; It is regarded impossible to continue having procurers executing the procurement process without consulting and deeply involving the end-users.
8. Starting from a systematic review of care delivery shortcomings, the application of a 'funnel approach' (ref. ICPO selection flow chart, fig.1, D3.4) proved to be successful in order to prioritize the most important care delivery shortcomings on dedicated disease areas.
9. The application of a funnel approach and collecting multi-stakeholder input strengthens the active cooperation and involvement of parties in the project.
10. It may be challenging to most organisations to exactly define and prioritise the same unmet need(s), requiring concessions to be made. Equal prioritisation will most likely

happen between partners have the same healthcare structure and/or from a contiguous geographical area.

11. Even though common care delivery shortcomings/unmet needs can be the same throughout regions, the prioritization and weighting of most relevant criteria to consider to meet these needs often differ, making it difficult for consensus on towards a joint solution and regions do not necessarily seek to collaborate with each other in the procurement and implementation of innovative solutions as the challenges outweigh the opportunities.
12. The mechanism to identify and prioritise unmet needs is not in place in most European regions. The procedures for doing so need to be developed and applied across all European regional/national borders.
13. As indicated by several EURIPHI partners, it could be beneficial to establish a network or (central) task force to align regional priorities for procurement of innovative solutions to ensure a more cost effective process.

Preliminary definition of procurement objectives (step 2)

The aim of the second step was to further elaborate the 'unmet needs' into preliminary solution requirements and procurement objectives, including identifying key functional requirement and the application of the VBP-approach and the associated MEAT-VBP framework.

1. The way the provision of health care services is organised differs between countries and even in some cases within the same country. This entails a tailored approach in the definition of what is required from the market and on the outcomes to achieve, having its impact on the tender specifications and award criteria.
2. Solutions on unmet needs in the continuum of integrated care delivery, including social care, typically transcend the borders of individual health care providers and payer organizations towards individual patients (cross-organizational).
3. When preparing the solution requirements and procurement objects the coalition should be composed of representatives from those who buy, pay and use the innovative solution across the full care pathway; these potentially being individual organizational entities.
4. A patient centered approach in integrated care does require patient's involvement in the full procurement process and the co-creation process of innovative solutions ('patient-empowerment').
5. The MEAT-VBP framework defines and categorizes the most relevant criteria from which a procurement project team can select and build on. The robust framework can first be used to define 'what matters to us' and subsequent to the initial identification and selection of the most important (value-based) award criteria.
6. The MEAT-VBP framework places the patient in the center and provides solutions to solve the patient's and health systems holistic problem instead of focusing on a specific product to be purchased.

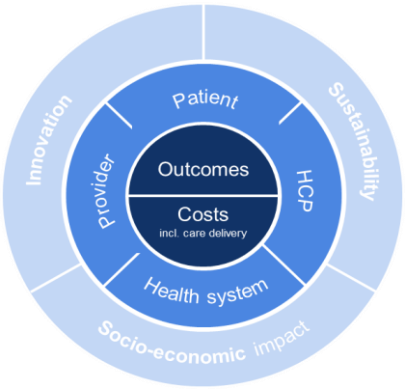


Figure 3: MEAT-VBP framework

7. Adaption of some existing criteria as well as generating additional criteria in the standard MEAT-VBP framework proved important in order to capture the specific characteristics of the care delivery shortcoming on integrated care and rapid diagnosis on VAP: resulting in the 'Adapted MEAT-VBP frameworks on IC and RD'.

8. Feedback provided by the EURIPHI partners validated the applicability of the MEAT-VBP framework. Feedback collected on the applicability will also be used to further develop the (standard) MEAT-VBP framework.
9. Award criteria enable contracting entities to evaluate and compare the different bids received. Award criteria shall be predetermined prior to the tender, set in advance, and linked to the subject matter of the contract to be awarded.
10. In addition to the application of the MEAT-VBP framework to identify tender award criteria, the framework also offers a wide variety of criteria to be used during innovative health tech product scouting. *For example as a supportive tool in the application of the 'Loop of Innovation' (iLoop): the EURIPHI partner FDG's methodology to make medtech companies collaborate with healthcare providers to increase the value of their solutions for an easier market access and to validate the iLoop action as a value enhancer afterwards.*
11. The availability of appropriate analysis is an important necessity to enable a broad shift towards value-based innovation procurement. The development of a common way to measure value is therefore encouraged e.g. by using standards and outcome in the scientific literature as well as available experimental data.
12. The Willingness to Pay (W2P) method allowed to assigns a monetary value to non-monetary criteria such as outcomes and other benefit criteria. Main advantage is the involvement of clinicians and other stakeholders in prioritizing and valuing the clinical and patient reported outcomes as well as helping to overcome limitations from traditional score-based approaches (e.g. 'rank-reversal').
13. As clinicians and health care practitioners may not be accustomed to assign a monetary value to specific criteria, there is a further need to support them on this method.
14. Value-Based Agreement (VBA) is a legal agreement to align the interests of both procurer and supplier to the impact a medical device or solution delivers in practice, based on criteria selected within the MEAT-VBP framework. VBA enables risk sharing when expected outcomes, benefits or the cost impact are less clear or lack detailed evidence.
15. The W2P method and VBA are supportive in the (wider) shift towards Vale Based Procurement of innovations and to give greater importance to the needs of patients.
16. On the basis of the foregoing assessment of shortcomings and the subsequent preliminary description of the procurement objectives, it is important for these to be tested and verified during an Open Market Consultation prior to finalizing the objectives, requirements and (technical) specifications in the tender documents.

Open Market Consultation (step 3)

The Public Procurement Directive 2014/24 clarifies that before launching a procurement procedure, contracting authorities may conduct market consultations with a view to preparing the procurement and informing economic operators of their procurement plans and requirements. During the EURIPHI project a total of 3 OMCs (2 on RD and 1 on IC) were executed in order to determine the market readiness on the prioritized unmet needs.

1. *General*: Contracting authorities should conduct these Open Market Consultations (OMC) carefully and bear in mind that the procurement process deriving from them should still be impartial and non-biased by these market consultations. An OMC should not restrict competition and therefore still allow for other economic operators to participate to the procurement process afterwards. In the event of such prior involvement, the contracting authority must take appropriate measures to ensure that competition is not distorted by the participation of that candidate or tenderer.
2. An OMC should be organised when advanced in the preparation phase and already having a good understanding of common interest on e.g. why, what and how to buy as well as reach out to any interested suppliers.
3. Publication of a Prior Information Notice (PIN) on Tenders Electronic Daily (TED), the Supplement to the Official journal of the EU, turned out to be an adequate starting points to inform and invite suppliers to participate in the OMC and formulate a common need.
4. Since not all suppliers across Europe are sufficiently affiliated to TED yet and in order to have an even greater number of participants, it important to also identify potential suppliers through a market study and using the participating partners' existing network and involve industry association networks) and to direct them to the PIN issued in order to participate in the OMC.
5. Participating in an OMC requires a very thorough preparation by both the procurement/contracting authority and supplier, including a guidance document on the contents, goals and use of the results.
6. The OMCs proved to be excellent opportunities for suppliers to better understand the challenges and care delivery shortcomings as well as to discuss the preliminary defined procurement objectives with the participating (EURIPHI) partners.
7. The OMCs proved to be excellent opportunities for the (EURIPHI) partners to asses the market readiness regarding the solutions readily available, innovative solutions under development or any interest in developing a dedicated solution. (possible adapted from other disease area's with common needs (horizontal challenges in care delivery)
8. The assessment of the market readiness appeared to be an important input for the final selection of the most appropriate procurement tender procedure.
9. In case of a long-list of unmet needs (jointly identified by the participating partners) has to be prioritised, the use of pre-, peri- and post-OMC data on the market readiness will be supportive.
10. In the event an OMC does not provide adequate outcomes, it is recommended to organise an additional OMC or to select a tender/procurement procedure allowing a dialogue with interested suppliers, such as the competitive dialogue.
11. For future OMCs it is recommended to design a (standard) methodology to be applied in order to further enhance the efficiency and effectivity for both procurers and suppliers.

12. The OMC's put forward the interest to engage in partnerships and co-creation of innovative solutions beyond to only supply technology. The market readiness varied from having available solution beyond initial expectation in some and advanced technological innovation but not responding to the basic needs.

Final definition of the procurement case (step 4)

Based on the results of the previous phases, the final definition of the procurement case (annex 2) consists of answering four basic questions: *what* are we going to buy (related to prioritised unmet needs, subject matter and functional requirements), *who* is going to buy (related to participating partners, principles of cooperation and internal stakeholder alignment), *what matters* to us (related to joint and any additional individual value-based award criteria) and *how* are we going to buy (related to procurement tender procedure and selected cross-border modality).

1. In case of (cross-border) procurement it is useful to follow an iterative process in order to achieve the final procurement case definitions and to also align the feedback from internal stakeholders not directly represented in the project team.
2. Feedback received from (potential) suppliers during the OMC needs to be taken in consideration in order to update the procurement case definition and associated tender documents.
3. The OMCs conducted and the resulting market readiness proved to be an efficient and effective way to identify the most appropriate tender/procurement procedure to be applied.
4. Although still rather uncommon in practice, (joint) cross-border procurement can have a positive impact on the professionalization of procurement, the efficiency of the tender process and ultimately on the conditions of the awarded solution.
5. The EURIPHI partners, however, identified constraints on both the supply and demand side having an impact on full joint procurement throughout the entire procurement and tendering process especially for PPI and effective buying decisions.
6. On the demand side, constraints in a cross-border project have been identified regarding disparities in:
    - specific needs and prioritization on a local/individual level requiring specific subject matter and context-applicable award criteria; (annex 3)
    - national transpositions of the European Directive, national judicial regulations and case law;
    - the structure of health care provision and organizational set-ups;
    - administrative burden and need of additional resources for e.g. communication, meetings, legal harmonization, translations;
    - health care payment- and reimbursement models;
    - language and business culture.
7. On the supply side, constraints have been identified regarding:
    - different local product- and solution and service offerings by medtech suppliers;

- limited and targeted supply and implementation capacity to support full scale cross-border projects;
- SMEs and start-ups often neither have the capacity and knowledge on how to access EU tenders, nor have the capacity to sell and supply their product and provide associated services across countries. This hinders SMEs and start-ups from participating in EU public procurement tenders and thus contributing to health and social care delivery problems;
- excessive demand volume only to be supplied by a limited number of suppliers, endangering competition and increasing the probability of single bid tenders.

8. Full joint procurement require additional resources and time compared to a localized tender and unwanted flexibility on the procurers' side since the selected solution may not perfectly address the unmet needs of all parties involved.
9. When organizing a cross-border procurement procedure it is necessary to clarify which (national) law is applicable for the organization of the procurement procedure and the implementation of the awarded contract.
10. The provision of solutions to the unmet need must be a collaboration between the demand and supply side prior to the final tender. In the procurement execution phase the demand side should be able to act individually in order to adapt to the conditions of each local market, the particular conditions of each organization and the legal conditions of each country.
11. Given the context of public procurement, the indicated constraints on the demand/supply side as well as the degree of specific needs on a local/individual level requiring specific award criteria applicable to the local context, partners have to decide to what point(s) in the full procurement process it is appropriate to closely cooperate and when to enable local decision making thereafter; as reflected in the Principles of Cooperation (annex 2).
12. As a result, the procurement organizations will be able to take the jointly defined procurement case and adapt them according to the local circumstances, specific needs, local legislation, specific award criteria and weights assignment.
13. The EURIPHI developed 'Cross-border collaborative procurement model' identifies three modalities enabling to maintain the ability for a local decision making by partners involved in a cross-border procurement project projects while benefitting of a valued cooperation.:
    - Full collaboration in the preparatory phase followed by the issue of individual public tenders by the participating organizations/partners (*model 1*);
    - Full collaboration in the preparatory phase followed by the issue of a (single) joint public tender in which every participating organization/partner holds its dedicated lot. This lot is tailored to the specific needs of the organization and is awarded separately (m*odel 2*);
    - Full collaboration in the preparatory phase followed by the issue of a (single) joint public tender resulting in the awarding of a framework agreement. Next, the local implementation of the framework agreement is executed by having specific contracts concluded between the individual participating organization/partner and the party to the framework agreement under local law (*model 3*).

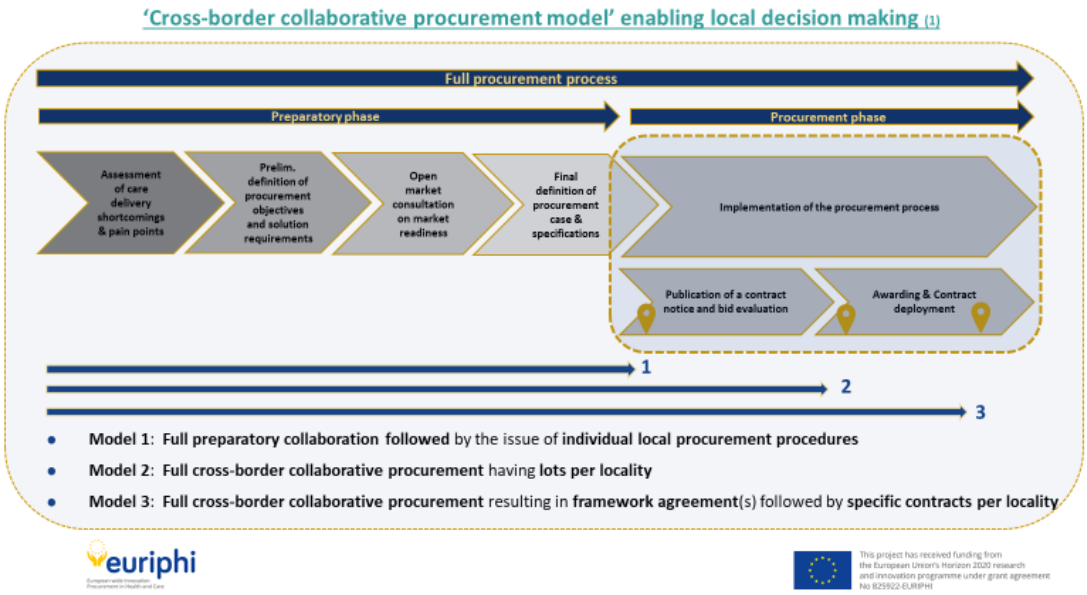
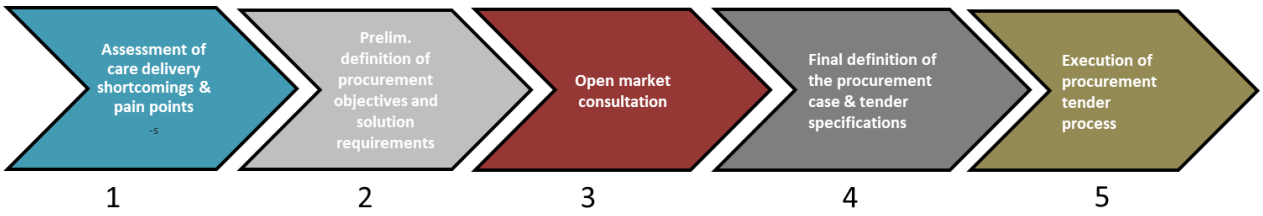


Figure 4 : EURIPHI Cross-border collaborative procurement model

14. Given the context of public procurement and demand/supply side constraints, has learned the partners to make a decision to what point in the full procurement process it is appropriate to cooperate and at what point they should continue on their own to safeguard efficient local processes and local decision making as laid down in the Principles of Cooperation (annex 3).
15. The extent of the constraints on the demand/supply side and the specific needs on a local/individual level, will largely define which cross-border procurement modality to apply.
16. Considering the distinctive advantages (and challenges) of specific European procurement procedures, the selection of the applicable procedure is largely influenced by the identified market readiness and selected cross-border procurement modality in any specific collaborative procurement project.
17. Full collaboration (including the information sharing and exchange of knowledge) in the preparatory phase, selecting one out of the three identified cross-border collaborative procurement modalities and applying the most appropriate procurement procedure, will bring positive consequences to both health systems and patients including the information sharing, knowledge exchange and optimal economies of scale resulting in economic most advantageous solutions for all participating partners.

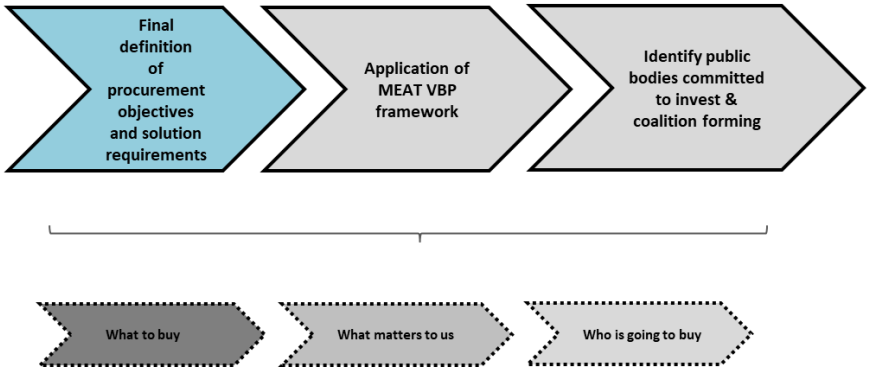
Annexes

Annex I - Skeleton EURIPHI full procurement process

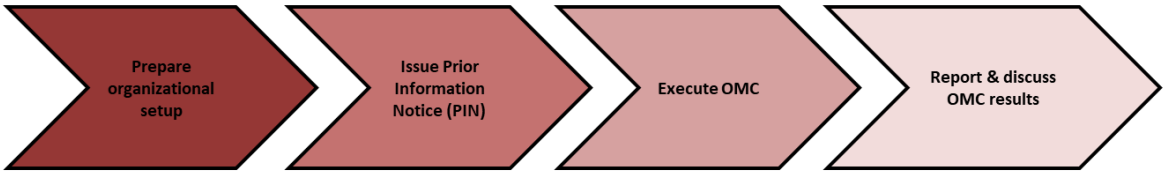


1. Assessment of care delivery shortcomings and unmet needs

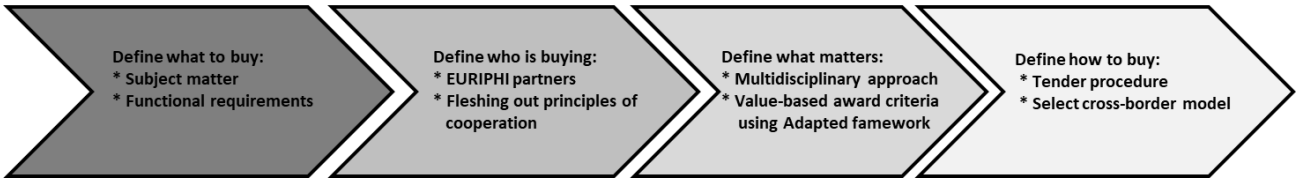
2. Preliminary definition of procurement objectives and solution requirements



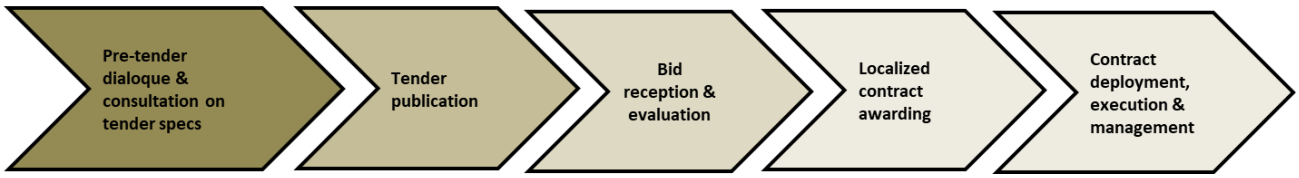
3. Open market consultation



4. Final definition of the procurement case and tender specifications



5. Execution of the procurement tender process



Annex II – EURIPHI ICPO test case descriptions and award criteria selection

ICPO #1: ICPO03 - Stroke

ICPO: Integrated risk assessment tools
➢ **Stroke** ICPO 03: Link stroke risk assessment results with an interface for care practitioners to ensure that the identified person with high risk of stroke can be monitored and followed up. Risk calculation and therapeutic recommendation tools should be personalised, addressing data sharing and infrastructure needs such as integrating highly heterogeneous multi-scale data sources, integrating omics data into clinical care or integrating imaging data. The provision of multiple channels to establish bi-directional communication of text, images, voices, video should be addressed as well. ➢ **Procurement procedure** PCP ➢ **EURIPHI Partners who expressed interest in contributing** NHS-CS, APHP, ARESS/InnovaPuglia, FCRB, FPT, NHS Wales, AQUAS, RSD

Subject of matter

Lifestyle is impacting on the risk of having a stroke. There is currently no device that can properly asses the risks of a stroke, taking into account all parameters. The issue is about (easy) integration of the different technologies/devices/apps rather than development of a new one.
The population scope are those persons with an identified high risk of stroke.

The new IT device should be a (cross-institutional) *communication IT platform integrating different 'platforms or data sources' connecting the different stakeholders* (patient, social care, clinicians, other health care practitioners). The tool must be an innovative technological solution empowering the patient.

It must bring both clinical and non-clinical data together and will provide data to both care practitioners and patients in order to manage stroke risk factors (e.g. blood testing, blood pressure, medication adherence) and to prevent from having a stroke. Also see (minimal) functional requirement listed below.

The tool should:

- Use life style data, patient tests and –data
- (Inter-) Connect the care practitioners team to the high-risk stroke patient
- Assure equality in the use and to avoid age and gender discrimination
- Monitoring stroke risk factors

- Analyse, asses and predict the risk of a stroke appearance (based on an intelligent algorithms and weighting risk factors)
- Send out alarms, alerts and signals to and from patients and care team

Regarding data attention should be given to:

- different data source(s)
- different data formats
- roles of data owner and -processor
- impact on GDPR and Information Governance
- current baseline data problems

Minimal functional requirements (ref. deliverable D3.3)

Risk assessment tools should be able to detect individuals and subgroups of the population at risk to allocate resources to create specific prevention plans, screening programmes and design the adequate care pathway.

- individual risk assessment results need to be made available to care practitioners in order for them to case find, monitor and follow-up individuals (with appropriate consent)

Risk calculation and therapeutic recommendation tools should be personalised, addressing data sharing and infrastructure needs such as integrating highly heterogeneous multi-scale data sources. The provision of multiple channels to establish bi-directional communication of text, images, voices, video should be addressed as well.

- integration functionalities towards EHRs or medical records (to draw risk parameters or to deliver assessment results back into the relevant systems)
- address limited accuracy of risk assessment tools (manual entries, only present "snap-shot" measurements of risk factors)
- more personalised risk calculation
- address lack of implemented standards for clinical and research data
- avoid algorithms that are not representative of real situations and do not allow flexibility

Risk assessment tools need to have a holistic approach beyond the disease-specific risk stratification tools. They should also include:

- variables relating to an individual's social connectedness
- capacity and capability of family carers to respond to the care burden
- cognitive and functional competencies
- self-awareness and self-management possibilities
- competencies in the use of digital solutions to communicate with care providers in case of an emergency or to design monitoring and self-management interventions and support

Risk assessment tools for secondary prevention need to assess people's situation in a more comprehensive way to foresee, plan and react in a proportionate way and avoid evitable relapses or reactivations, reduce the risk of unrecoverable disabilities or capacity reduction and avoid unnecessary hospitalisation. To do so they should be able to detect:

- the disease progression
- drug interaction risk
- changes in motivation and risk for mental health disorders
- treatment fatigue and the risk for treatment compliance reduction
- family and carers burnout and risk of social support reduction
- social isolation

- the risk of abuse and suspect possible abuses
- To be able to assess a secondary prevention, there is need to have access to the specific stroke etiologic information

In the procurement test case the (minimal) functional requirements will serve as a knock-out (does the product/solution has it or not?). In addition to these mandatory requirements, the tender documentation will also contain a number evaluation criteria in order to asses **which supplier has offered the best product (-solution) to the unmet need.** Evaluation criteria contain two types: declaration and assessment criteria. The bidder must respond electronically to all declaration criteria. The assessment criteria will be evaluated unanimously by representatives from the stakeholders.

Other functional requirements mentioned

- Ease of use
- Easy to install
- Easy to connect to different data sources
- Interoperability (including semantical interoperability across different countries)
- GDPR compliant and system security

ICPO #2: ICPO12 - Multimorbidity

ICPO: Integrated solutions to support information sharing and real-time communication within care provider organisations, among different care practitioners, people receiving care and their supporting community and social network

- **Multimorbidity**

ICPO 12: Develop strategies and tools to support care teams with specialists for complex case management. Centralised expert team directories and protocols to access (even remotely) should facilitate the care of patients and increase the confidence of the team.

- **Procurement procedure**

Competitive Dialogue / Negotiated Procedure involving buyers & (end) users

- **EURIPHI Partners who expressed interest in contributing**

ARESS/InnovaPuglia, FCRB, RESAH

Subject of matter

Main difficulty for integrated care solutions is on *managing the transitions* across different professionals, levels of care and jurisdictions. The *shared treatment plan* is still often paper based, however it is a fundamental piece in setting goals, deploying interventions and assessing impact of interventions/treatment.

Therefore a smart/intelligent IT product/solution is needed that *interacts and interconnects*, like an umbrella, with existing electronic medical/clinical records of health care practitioners and social workers, exchanging information as needed and displaying information when needed. The tool should collect information from current sources, but should also be able to allow for exchange of information and new ways of management not already available (e.g. virtual visits).

To be realised in *short term*:

The IT tool should serve and support two main objectives:

1. Health care: to allow to know (in real time) what the different health care professionals are doing with the patient, the tool needs to allow interaction and flow of information:
    - Among health care professionals of different clinical specialities and different health care levels (clinicians and nurses)
    - Between health care professionals and social care to allow the exchange of accurate information between types of care

- Between patients and health care professionals to allow patients to contact his/her clinician/nurse/social care when needed using different types of interaction (video, messaging e.g.)

2. Education: tools (video e.g.) to allow patients to get the needed information to properly manage their multimorbidity (patient empowerment)

To be realised in *mid/long term*:

A new technological system that we could call "Virtual Room" equipped with Augmented Reality hardware and Artificial Intelligence software able to support real-time and top-level medical and multi-specialists assistance in hospitals/care provider organisations for patients affected by different diseases (multiple, rare, chronic etc.).
The new technological system should support virtual visits, remote patient treatment, information sharing, real time communication, poly-specialists consultancy, and education/training facilities. It is expected that the new system is able to integrate or make it interoperable already existing IT platform, electronic medical records data, broadband infrastructure, clinician lab data outcomes, etc. Requiring a governance model across jurisdictions.

Such integrated hardware system and software solutions should easily and better support, with respect to the existing situation, care teams with specialists for complex case management (multi morbidity, rare disease etc.) increasing the confidence of the team, reducing inopportune patient transferring or extensive hospitalization while increasing value based quality of care and patient life.

Minimal functional requirements (ref. deliverable D3.3)
Develop strategies and tools to support care teams with specialists for complex case management. Centralised expert team directories and protocols to access (even remotely) should facilitate the care of patients and increase the confidence of the team.

- uniform coding of patients' health problems that should adapt easily to new care delivery models and be modifiable to new population's needs. Patient information should be accessible for all involved care practitioners
- information sharing systems need to be safe due to their sensitive information as well as accessible for all the care providers
- offer options to summarise patient's progression and status data effectively
- support Multidisciplinary, coordinated team processes and shared decision making

Address the lack of information integration among different stakeholders and different health and social care providers, resulting in information fragmentation and increase the risk of errors. This shall include the development of a summary of patient's information (e.g. needs, care plan, medication, care delivery schedule) with the content being subjected to local role-based access rules and made available to all care practitioners. The solution should also include the ability for the content to be coded in such a way that the patient's main health and care needs etc can be accurately mapped to the coding systems and documentation used by the care team.

- information sharing system should enable all stakeholders to receive the relevant information with appropriate consent
- address interoperability issues

- ensure systems developments comply with European initiatives to share information within and across regions and countries ensuring data safety and patients confidentiality but providing continuity of care to patients.

Address the need to include other stakeholders that have not been included in the classical care model but are recognised to be beneficial in a more comprehensive care provision. This would include a high variety of different roles from the pharmacist, care coordinators, community and social resources, voluntary sector, travel and leisure activities, and others.

- offer options to summarise patient's progression and status data effectively
- coding systems should reflect new care delivery models and be modifiable to new population's needs.

Improve transition from hospital to community setting- Innovative solutions should tackle the need of patients and family carers of receiving the necessary training to enable a successful transition to the home environment. Patients and family carers often receive insufficient information on the psychological and emotional impact of the conditions and how they can manage these complex feelings. Furthermore, it seems to be difficult to find and access information and assistance on care and support services after discharge from the hospital. Solutions should also enable a better addressing of the current lack of proactive follow-up either from primary care, the hospital, allied care practitioners, and/or social care services and the coordination of all the services included in the care of a person with multimorbidity.

- identify individual factors and therapy options to allow specifically tailored rehabilitation treatment
- improve shared decision making and goal setting
- meet patients and informal caregivers' information and communication needs
- support improved communication collaboration during the discharge planning process
- Integrated tools that empower the patients to identify co-morbidities (such as depression)
- address information needs to support self-care
- sensory and motor impairments, as well as limited vision and impaired speech, need to be taken into account when designing mHealth applications or any other end-user interfacing application
- transitions to community settings should promote and support self-management strategies tailored to each person's capacity and capabilities, as well as their values, desires, and expectations
- nutrition and physical activity advice and monitoring should be accessible in the patients' records to facilitate their follow-up

Information sharing systems need to guarantee security of the personal data of care receivers as well as of care practitioners accessing the system and be compliant with the existing GDPR.

- Sensitive data need to be protected and confidential
- Data access need to guarantee traceability
- Security systems that guarantee data breaches, their detection and rapid reaction strategies need to be in developed and in place
- Data breaches and avoid information breaches

In the procurement test case the (minimal) functional requirements will serve as a knock-out (does the product/solution has it or not?). In addition to these mandatory requirements, the tender documentation will also contain a number evaluation criteria in order to asses **which supplier has offered the best product (-solution) to the unmet need.** Evaluation criteria contain two types: declaration and assessment criteria. The bidder must respond electronically to all declaration criteria. The assessment criteria will be evaluated unanimously by representatives from the stakeholders.

Other (functional) requirements mentioned

A commitment to outcome advantages via risk-sharing agreements needs to be included in the tender and to be agreed with the contractor(s).

Change management

Developing and implementing a solution involves important change management activities to be executed. It is necessary to develop a comprehensive solution, but it is essential for the solution to be regularly used by the targeted users (e.g. multi-disciplinary healthcare professionals, patients, family. As this will impact on their habits, it is highly important to define the different types of user profiles and prepare a change management strategy for each of them. The bidding (and awarded) companies will have to take this crucial aspect into consideration from the beginning.

Preliminary value-based outcome criteria

- Improvement of QOL
- Mortality reduction
- Decrease in visis encounters (less readmissions, less visits, less contacts with nurse e.g.)

-

ICPO #3: ICPO15 - Multimorbidity

ICPO: Integrated (remote) monitoring solutions for people living with complex needs

- **Multimorbidity**

ICPO 15: Develop tools to help monitor patients with multimorbidity in real-life situations and share that information with the care team.

- **Procurement procedure**

Open procedure

(alternatively the Competitive Dialogue or Negotiated Procedure given the personalisation job depending on who will buy the solution)

- **PO EURIPHI Partners who expressed interest in contributing**

NHS-CS, FDG, RESAH

Subject of matter

IT communication platform; connecting several (existing) devices monitoring data and sharing information with care professionals. Also see minimal functional requirements listed below.

Note: European project 'Gatekeeper' (EU grant nr. 857223) has developed a platform with notably Samsung equipment and are currently performing 8 use cases in different regions. The main goal is to upscale existing procedures and market solutions.

Minimal functional requirements (ref. deliverable D3.3)

All devices and solutions need to be interoperable and easy to use.

Monitoring solutions shall:

- include a desktop and mobile application for care professionals
- include a desktop and mobile application for clients
- include a monitoring platform
- allow direct communication between patient and care providers
- include role-based access to data and information
- secure data sharing and storage
- devices, supportive aids, and health monitoring tools should be user-friendly
- enable prompt response and easy communication among all members of the care team
- include improved functions and formulas to balance the risk of missing a significant abnormality and the enormous workload
- include integration functionalities towards EHRs or medical records
- address accuracy necessary for medical decision making

- include algorithms that allow personalisation according to patient characteristics and shared decision making amongst the members of the care team
- allow mobile monitoring to the best possible extent
- address lack of integration of nutritional and physical information and advice needed for prevention purposes
- allow patients to track a range of parameters including blood pressure, weight, fluid intake, physical activity, stress levels etc.

Monitoring solutions need to be flexible and adapt to changing needs over time. ICT tools shall facilitate self-care during rehabilitation especially home-based rehabilitation and respect care receiver perspective.

Monitoring solutions should be able to detect difficulties for treatment compliance in long-term and complex situations with polypharmacy. ICT solutions should be able to detect drug intake, motivate and remind care receivers and inform care teams when difficulties, poor technique or treatment fatigue signs appear.
Self-monitoring solutions need to be user-friendly and adaptable to different capacities and capabilities. Capacity building in the use of the devices for users and information management for care providers should be guaranteed and included in the monitoring solution package.
Self-monitoring devices and solutions need to develop an easy-to-understand language that will be adapted to different capacities, local languages, contexts, and cultures and translate the results into a standardised language.
Self-monitoring solutions should be personalised and flexible to adapt to contextual changes (change in behaviours, lifestyle, health state, and knowledge) throughout life. They should also develop strategies to motivate care receivers and carers with strategies such as rewards for quick wins, celebrating the small successes, or gamification. The solutions should be able to acknowledge personal values, desires, goals, and priorities and assess the success based on each person's individual goals.

In the procurement test case the (minimal) functional requirements will serve as a knock-out (does the product/solution has it or not?). In addition to these mandatory requirements, the tender documentation will also contain a number evaluation criteria in order to asses **which supplier has offered the best product (-solution) to the unmet need.** Evaluation criteria contain two types: declaration and assessment criteria. The bidder must respond electronically to all declaration criteria. The assessment criteria will be evaluated unanimously by representatives from the stakeholders.

Other (functional) requirements mentioned
A commitment to outcome advantages via risk-sharing agreements needs to be included in the tender and to be agreed with the contractor(s).

Change management
Developing and implementing a solution involves important change management activities to be executed. It is necessary to develop a comprehensive solution, but it is essential for the solution to be regularly used by the targeted users (e.g. multi-disciplinary healthcare professionals, patients, family. As this will impact on their habits, it is highly important to define the different types of user profiles and prepare a change management strategy for

each of them. The bidding (and awarded) companies will have to take this crucial aspect into consideration from the beginning.

Common needs – specific value considerations

Value-based award criteria - ICPO12 (#2)			
EURIPHI partner	**Description**	**Weight (%)**	**Measurement**
RESAH	Maintenance or improvement of clinical outcomes due to prevention, acute therapy, rehab care and/or ongoing	30	One of the potential options is the definition of fictive uses cases (with different patient profiles and care plans) and asks the suppliers to concretely explain how their solutions will cover these different use cases, with a concrete focus on this criteria.
	Maintenance or improvement of patient reported health outcomes due to prevention, acute therapy, rehab care	30	One of the potential options is the definition of fictive uses cases (with different patient profiles and care plans) and asks the suppliers to concretely explain how their solutions will cover these different use cases, with a concrete focus on this criteria
	Purchase price of IC solution (for system or per patient)	15	define different scenarios and ask the suppliers to apply its prices to these scenarios. The offer with the lowest price is assigned the maximum number of points, and the other offers according to their respective price.
	Seamless integration with IT, data and workflow of different care providers and easy information exchange	15	ask the suppliers to provide their methodology to install their solutions as well as their interoperability level. The most convincing obtain the maximum point
	Introductory training by supplier - Added family and social carers and patient as those might need additional train	10	Request the change management strategy of the suppliers during and after the installation of the new solution. Important to have a clear understanding of their process to train the future users of the solution. The evaluation will be based on the quality of their proposals.
		100	
INNOVA-PUGLIA	Costs savings for patients and/or relatives	20	Comparison of out-of-pocket healthcare patient expenses before and after the introduction of the new system
	Training and access to education	20	Available quantity of GigaByte material for self-training and live training opportunities. Ranking of quality level for this material as a result of users expressed satisfaction
	Impact on social inequalities (technology neutrality can help in sharing information between patient and specialis	20	Patient/customer satisfaction measurement survey compared to a zero measurement
	Interoperability and data connectivity	25	Number of already existing information system and databases integrated in the new platform
	Support in measuring and reporting on outcomes	15	Using Natural Language Processing techniques on anonymized data log text conversation and real world evidence a diagram mapping of outcomes vs cost impact over time can be validated
		100	
FCRB	Patient reported outcome maintained or improved (personalised treatment)	30	QOL, ADL
	Interoperability and data connectivity	20	Compliance with providers' standards and norms on interoperability and data connectivity.
	Support in improving efficiency along patient care pathway	30	satisfaction by care professionals (indirect measure, very difficult measure the cost of process for each patient)
	Maintanability and technical service support	10	24/7 support, frequency of upgrades, minimal downtime for maintenance / upgrade
	Price of purchasing	10	costs
		100	

Value-based award criteria - ICPO15 #3			
EURIPHI partner	**Description**	**Weight (%)**	**Measurement**
APHP	Patient Reported Outcomes improvement	15	QOL questionnaire
	Clinical outcome improvement	25	set of defined indicators; individual selection for each patient dependent on which morbidities are combined ?
	Treatment adherence	15	-
	Cost per year using the service (including staff time)	25	-
	Reduced cost of social care required	20	
		100	
RESAH	Maintenance or improvement of clinical outcomes due to prevention, acute therapy, rehab care and/or ongoing	30	One of the potential options is the definition of fictive uses cases (with different patient profiles and care plans) and asks the suppliers to concretely explain how their solutions will cover these different use cases, with a concrete focus on this criteria
	Risk factors are detected as early as possible to enhance awareness and ability to adjust early on	30	One of the potential options is the definition of fictive uses cases (with different patient profiles and care plans) and asks the suppliers to concretely explain how their solutions will cover these different use cases, with a concrete focus on this criteria. If there is risk factor detection functionality in the solution, that mean there is an algorithm which analyse the data collected and translate it into risk prediction. If this is the case, important to ask to the suppliers all the available information on this algorithm, how it has been created, how it works concretely etc… The quality of the algorithm will determine the score obtained.
	Purchase price of IC solution (for system or per patient)	15	define different scenarios and ask the suppliers to apply its prices to these scenarios. The offer with the lowest price is assigned the maximum number of points, and the other offers according to their respective price.
	Seamless integration with IT, data and workflow of different care providers and easy information exchange	15	ask the suppliers to provide their methodology to install their solutions as well as their interoperability level. The most convincing obtain the maximum point.
	Supporting treatment adherence and monitoring (remote)	10	if the solution exists, request validated statistics which prove the added value on treatment adherence.
		100	
FDG	Clinical outcome maintenance or improvement	30	through validated clinical scales
	Interoperability and data connectivity	25	compliance with established communication standards and protocols. Availability of well-documented API (application protocol interface) for data exchange
	compliance with established communication standards and protocols. Availability of well-documented API (application protocol interface) for data exchange	20	comparing staff costs with and without the IC solution
	Support in measuring and reporting on outcomes	15	comparing the number of outcome measurements in the traditional way (periodic control) with the remote platform measurements. Devices must be able to measure and collect large quantity of data more frequently than the traditional way (as frequent as the clinician needs). Platform should be able to aggregate and update outcome measurements automatically. Platform should be able to generate clinical reports easily understandable by operators and clinicians.
	Patient and relatives' comfort and convenience	10	Measure usability and acceptability through validated scales. Measure the improvement of quality of life. Evaluate how much relatives and patient feel serene with the monitoring platform since it can predict an acute event and monitor the adherence to the treatment).
		100	
NHS-CS	Integration with existing systems and workflow	25	Ease of implementation and speed of implementation
	Seamless integration with IT data and workflow	25	Technology "agnostic" interface with existing platforms
	Personalised risk assessment and prevention and therapeutic Interventions	15	Ease of access to information, technology ease of use
	Care decision where most effective and efficient	25	Proximity to patients own home/locally versus requirement to attend outpatients or hospital
	Purchase price of IC solution for system or per patient	10	Cost/Benefit per patient as a service versus product purchase
		100	

Annex III – Memorandum of understanding on the principles of cooperation.

MEMORANDUM OF UNDERSTANDING ON THE PRINCIPLES OF COOPERATION REGARDING

MODELS OF ENABLING LOCAL DECISION MAKING WITHIN A CROSS-BORDER COLLABORATIVE PROCUREMENT PROJECT

This Memorandum of Understanding (MoU) on the Principles of Cooperation is a non legally binding expression of intend and enter into force on the [day] of [month], [year] by and between the following 'Parties':

[Name to be inserted at the moment of signature]
[Name to be inserted at the moment of signature]

For the procurement project :

[Name of project to be inserted at the moment of signature] :

For which (Please tick)

☐ there is a concrete interest to perform a buying decision at the given point in time *[date when the procurement is planned to take place]*

Or ☐ for which there is an interest to learn the opportunities of applying a cross-border cooperation

WHEREAS

1. The European Directive 2014/24/EU on public procurement governs the procurement and tender process of public authorities including (most) healthcare procurement organizations across Europe in order to award contracts for the purchase of public works, goods and services in accordance with the principles underlying the Treaties of the European Union;
2. Cross-border collaboration aims to support efficient and effective public procurement;
3. Parties wishing to ensure compliance with applicable procurement- and competition law legislation and be guided by EURIPHI Cross-Border Innovation-legal guidance as prepared by CMS supported by other EURIPHI partners.

https://www.euriphi.eu/virtual-library/guidance-on-economic-most-advantageous-procurement-of-innovative-solutions/

4. Parties having a common interest to procure innovative solutions responding to their specific unmet needs and to put a suitable testing environment in place, in order to cooperate in the preparatory phase and execute one of the proposed cross-border procurement model;
5. The specificities of the needs and practical and legal circumstances on both the supply and demand side impede full joint procurement throughout the entire procurement process resulting in a buying and contract;
6. On the demand side, bottlenecks and differences between participants in a cross-border project apply regarding:
    - exact common local requirements;
    - national transpositions of the European Directive and nation-based legal frameworks;
    - structuring of health care provision and organizational set-ups;
    - health care payment- and reimbursement models;
    - language and business culture.
7. On the supply side, bottlenecks apply regarding:
    - differences in local product- and solution offerings by medtech suppliers;
    - limited supply and implementation capacity to support full scale cross-border projects;
    - SMEs, having local development and offering of innovations, not covering on a European level thus hampering participation in EU-wide public procurement tenders;
    - excessive demand volume only to be supplied by a limited number of suppliers, endangering competition and increasing the probability of single bid tenders.

THE PARTIES INDICATE AND INTEREST AN AGREE TO SEEK COOPERATION ON THE FOLLOWING

Given the context of public procurement and issues on the demand/supply side, Parties indicate to what point(s) in the procurement process it is appropriate to closely cooperate and the modalities to safeguard local decision making thereafter (*annex 1*);
The full procurement process is divided in the preparatory phase and procurement phase;

1. For the preparatory phase, I agree in principle to cooperate in the following sub-phases:
(please tick all those of interest)

- Assessment of local care delivery shortcomings and common pain points;
- Preliminary definition of the procurement objectives and solution requirements;
- Execution of market analysis and open market consultation(s);
- Final definition of the procurement case, tender specifications and selection of the appropriate public procurement procedure.

2. The procurement phase comprises the actual execution of the tender process and, in order to safeguard local decision making and to manage local refinements, Euriphi parnters identified 3 applicable modalities. I agree in principle to cooperate in the following model and will engage in the discussion of the governance of buyers as expressed by Euriphi. https://www.euriphi.eu/virtual-library/buyers-group-proposed-model-of-governance/

   ☐ Given full pre-tender collaboration, subsequent issue of individual tenders (*model 1*);
   ☐ Given full pre-tender collaboration, subsequent issue of a joint tender having individual lots to be awarded by each participating party (*model 2*);
   ☐ Given full pre-tender collaboration, subsequent issue of a joint tender resulting in the awarding of a framework agreement to be implemented locally using specific contracts (call-offs) by each participating party (*model 3*);
   ☐ None of the above;

3. So for the procurement phase I agree in principle to cooperate in :
   - Pre-tender dialogue and consultation;
   - Tender publication;
   - Bid reception and evaluation;
   - Distributed contract awarding;
   - Local contract deployment and management.

Parties recognize the added value of cooperation in the identification and prioritization of common unmet needs, the allocation of resources to meet these unmet needs, the execution of joint open market consultations to assess market readiness and the joint drafting of solution requirements and procurement/tender specifications (defining 'who will participate/buy and what/how to buy');

Full cross-borde collaboration in the preparatory phase and applying one out of three cross-border collaborative procurement models safeguarding local decision

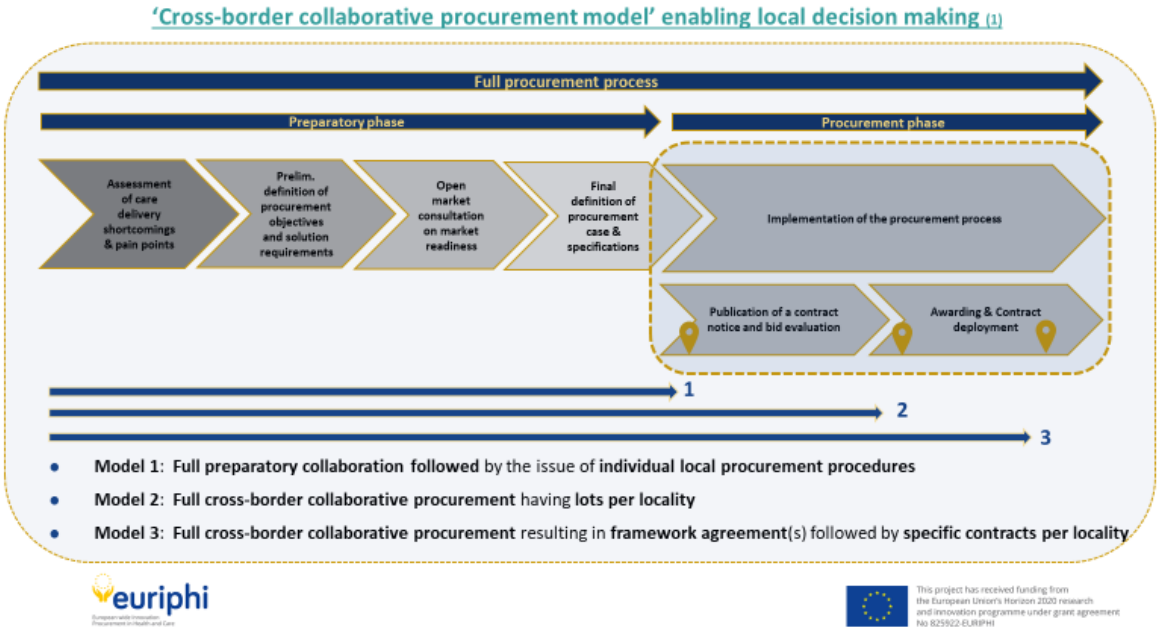
making, will have positive consequences to both health systems, including information sharing, knowledge exchange and economies of scale, as well as to patients, including those who e.g. suffer from rare diseases or in case of a pandemic.

IN WITNESS WHEREOF

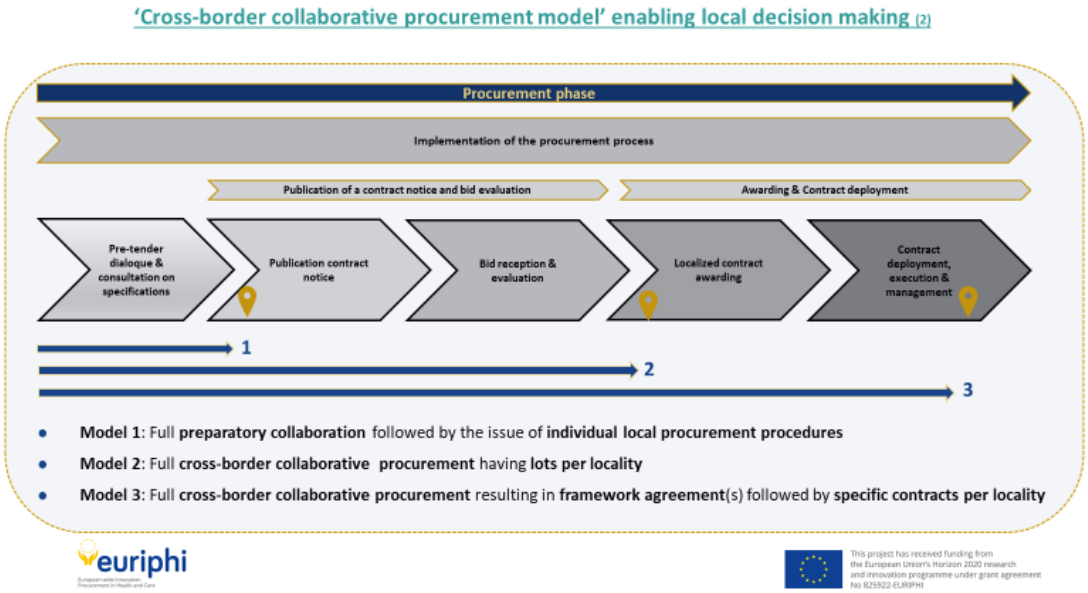
The undersigned expresses in personal name or in name of his organization for which he is being duly authorised, and have signed this MoU on principles of cooperation.

Signed [place], on [day] [month], [year]
Signed [place], on [day] [month], [year]

Annex 1: Cross-border collaborative procurement models enabling local decision making



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825922-EURIPHI


'Cross-border collaborative procurement model' enabling local decision making (2)
Procurement phase
Implementation of the procurement process
Publication of a contract notice and bid evaluation
Awarding & Contract deployment
Pre-tender dialoque & consultation on specifications
Publication contract notice
Bid reception & evaluation
Localized contract awarding
Contract deployment, execution & management
1
2
3
Model 1: Full preparatory collaboration followed by the issue of individual local procurement procedures
Model 2: Full cross-border collaborative procurement having lots per locality
Model 3: Full cross-border collaborative procurement resulting in framework agreement(s) followed by specific contracts per locality
euriphi
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825922 EURIPHI

Annex IV – Test case learnings selected EURIPHI partners

FCRB – Test case learnings; input and comments

1. Assessment of specific and in common care delivery shortcomings/unmet needs incl. its prioritization;

The approach taken is the right one. It is important to first identify the partners' individual care delivery shortcomings, next to identify those shortcomings in common and then to jointly prioritize these .
The exchange of knowledge and the economy of scale for the health systems that can be achieved is positive. Nevertheless, in the EURIPHI project, our main "need" was not prioritized as a topic to address, what would have been the impact in the real world of this? That would mean that countries/providers which their main topic is not prioritized should go out of the tender process? Probably, therefore, how to ensure to capture and put together in the real world the countries with the same uncovered need? This has not been addressed in the EURIPHI project, but is worth to mention. The CoP could be a solution only if all the U countries and providers are represented; otherwise a EU tool that arrives to all of them claiming the search for procurers to address an unmeet need of their interest should be promoted.

2. Preliminary definition of procurement objectives and solution requirements incl. the application of the MEAT-VBP framework in support of defining the objectives;

The knowledge acquired in this part is very important because It defines the objectives of the purchase and the implications of all the actors. Nevertheless, the exercise done in the EURIPHI project, although very well scientifically grounded, has been a little difficult; specially because some of the IPCO selected were not directly highlighting the real need of our specific context.

The willingness-to-pay (W2P) method that assigns a monetary value to non-monetary criteria, has some limitations to implement among health care professionals (please see our comments attached). The use of Value Based Contract (BVC) as a procedure to align the interests of both the buyer and the supplier to share risks giving a expected results (benefits or cost impact) are still less clear or lack detailed evidence; nevertheless they are very important for change of vision and is a way to give more importance to the needs of patients.

3. Open Market Consultation – market readiness evaluation incl. the preparation, execution and results/outcomes;

Obviously, market consultations are a great opportunity to publicize needs and find out if there is a solution to them. Also for providers it is an opportunity to participate from the beginning in the design of solutions.
It was a good experience to share with other colleagues their experiences and knowledge. Nevertheless, we have noticed the uneven preparation and knowledge of suppliers when

coming at the OMC during the EURIPHI project. In our real life, we have noticed a learning curve for some companies in the last years on understanding IPP and presenting information for tenders. Mainly for big companies, we think that still SMEs and start-ups lack of proper knowledge and capacity to do it.

4. Final definition of the procurement case & tender specifications, including definition of the subject matter;

We agree that cross-border purchases cannot yet be made easily to the end due to local needs and requirements. Regarding the challenges under the demand and supply side you mention in the reports, we completely agree, and it seems clear that the effect of full cross-border cooperation on competition is not yet defined or ready to "freely fly".

Additionally, like the report seems to point out, given the context of public procurement and demand / supply side issues, partners must decide at what point in the procurement process it is appropriate to cooperate and at what point they should continue on their own.

5. The experience with cross-border cooperation in general and the participation in this EU project (identifying the opportunities and your challenges);

The experience with cross-border cooperation in general, and the participation in this EU project, has been very satisfactory because it has allowed us to expand our knowledge in a new form of public procurement. It was positive to analyze the needs from another point of view, and to apply new methods to value the proposals, including to shared risk and the valuation of non-monetary criteria with monetary criteria.
It is evident that there are many opportunities to improve the current purchasing processes with this new approach, not only economic (for example, economies of scale) but also medical and social, since this change in the way of purchasing it makes the patient in the center and thinks more about a global solution to solve their problems, than focus on a specific product. Therefore, the purchase becomes patient-oriented.

Nevertheless, the challenges are also many, being most important from our point of view, that related to the provision of solution of the bottlenecks by the supply side. It should be a collaboration between the demand and supply side prior to the final tender, but afterwards each side must act separately in order to adapt to the conditions of each market, the particular conditions of each organization and the legal conditions of each country. If this separation is not possible, it is difficult for projects to go ahead and find good solutions for all members.

6. The proposed model on 'Cross-border collaborative procurement enabling local decision making';

It is clear from the work done at EURIPHI that it is essential at this time that decisions are allowed at the local level, so as not to harm local economies that cannot follow the overall process. At the meetings, there was already some discrepancy in the criteria when choosing some of the procedures to be tendered, so there will be even more related to supply and demand and how to facilitate participation when translated to local contexts.

FDG – Test case learnings; input and comments

The Euriphi project represented for FDG an opportunity to learn in deep and better understand the different approaches related to Value Based Procurement. In particular, throughout the project we had the opportunity to acquire knowledge on:

- the procedure which has to be done for choosing a product or solution, from "open/restricted procedure", "competitive one with negotiation" or "PCP / innovation partnership" to "competitive dialogue".

- how to contribute to fine tuning the MEAT approach, by integrating it with a post-acute value-based metrics. For instance, by adapting the VBP Framework for IC in FDG, where we defined some criteria and their relative importance, as well as the way to measure them.

- the cross-border procurement importance: we are willing to exchange good practices and build relations for future collaboration among partners. We are keen in defining what are the highest priorities in our agenda as well as the resources to invest, to foster mechanisms of identification and prioritization of common unmet needs. We have learnt some barriers for the Cross-border joint procurement, from the lessons that partners have experienced. The challenges such as the language difference, differences between national laws, requirement of additional resources, context and local needs and endangering competition.

Despite FDG, being a private entity, is not used to purchase through public procurement procedures, we tried to retrospectively apply to a couple of case studies of rehabilitation solutions some of the steps of "skeleton process" that was elaborated during the project. In particular, we tried to define the requirements and awarding criteria, to clarify the subject matter ('what to buy') and creating a business case for the solution. FInally, we applied the adapted MEAT-VBP Framework to the potential solutions.

We selected the most relevant items (based on the importance as voted by the project partners during EURIPHI Paris meeting, complemented with FDG strategic view of the Adapted VBP framework for Integrated Care:

INPUT: **Outcomes**
Outcomes and evidence:

- Risk factor maintenance or reduction
- Clinical outcome maintenance or improvement
- Patient reported outcome maintenance or improvement
- Existence of high quality of outcomes data
- Social care outcome maintenance or improvement

Outcomes focus:

- Support in measuring and reporting on outcomes
- Willingness to offer outcomes-dependent risk-sharing

INPUT: Total cost of care

Purchasing:

- Price of purchasing/renting IC product/solution
- Compatibility: upgrades to existing systems/infrastructure

- Adoption: medical staff, carers, patient training for IC solution

Maintenance:

- Spare parts
- Service contract

Operating cost in health and social care delivery:

- Own health and social care staff time using IC solution
- Cost of consumables
- Ongoing staff/carer/patient training
- Interoperability and data connectivity
- Care optimization across integrated clinical and social care pathway

INPUT: Other benefits to stakeholders

Patient's and relatives' secondary benefits:

- Personalized treatment
- Impact on patient behavioral change
- Patient and/or relative comfort and convenience
- Impact on treatment adherence
- Cost savings for patient and/or relatives

Health & social care professional benefits:

- Ease-of-use/handling & functionality of IC solution

Provider benefits:

- Alignment and support with reimbursement structure
- Maintainability & technical service support
- Strategic fit for provider and support of strategy

Health & social care system benefits:

- Reduced long term costs of treatment and social care
- Reduction of rehospitalization/# of treatments & care visits
- Care optimization across full clinical/social care pathway

INPUT: Broader benefits to society:

Innovation:

- Development of new, improved technologies/ care practices
- Contribution to development of health and social care

Sustainability:

Socio-economic impact:

- Burden carried by non professional care providers
- Societal health and social status

Although it was sometime difficult to retrieve accurate information for some of the criteria listed above, the MEAT methodology allowed to consider all the relevant characteristics of the solutions.

From FDG point of view, the most important lesson we learnt is that MEAT can help us as a companion tool for the application of the “Loop of Innovation” (iLoop), the FDG methodology

to make medtech companies collaborate with healthcare providers to increase the value of their solutions for an easier market access. In fact, MEAT offers a wide variety of criteria during health tech product scouting (the early phase of the iLoop), while the iLoop action as a value enhancer is afterwards validated through the MEAT criteria value-based innovation procurement process.

INNOVAPUGLIA + AReSS –; input and comments

1. Assessment of specific and in common care delivery shortcomings/unmet needs incl. its prioritization;

Shortcomings and unmet needs referred originally to procedures on Integrated solutions able to support information sharing by means of target technological system like "Virtual Room". Priorities of this virtual hub was a specific equipment with Augmented Reality hardware and Artificial Intelligence software able to support real-time and top-level medical and multy-specialists assistance in hospitals for patients affected by different diseases (multiple, rare, chronic, stroke, etc.). Part of this shortcomings have been addressed during the project lifecycle and imported on the three Integrated Care Procurement Objectives where the new technological system were intended to support virtual visits, remote patient treatment, information sharing, real time communication, poly-specialists consultancy, and education/training facilities. One specific learning point was on the emerging evidence of a common unmet needs among the different interested Procurement Organization related to the shortcomings of an already existing system able to integrate or make interoperable already existing IT platform, electronic medical records data, broadband infrastructure, clinician lab data outcomes, etc. This has driven our prioritization on the three main ICPO objectives as part of the project work and local discussion with stakeholders.

2. Preliminary definition of procurement objectives and solution requirements incl. the application of the MEAT-VBP framework in support of defining the objectives;

Procurement objectives and requirement was addressed according to the description agreed at partnership level, while more demanding effort was requested to define some of the procurement criteria. This last aspect in terms of lesson learned represented a deep investigation on the Value based award criteria from the 'Adapted VBP Framework for IC' developed within the project. In terms of procedural approach one of the proposed criteria has been e.g. "early detection of patient risk factors" to be measured as a perspective analysis on number of risk patients treated in secondary prevention or the "impact on social inequalities" with a measurement of patient satisfaction measurement survey compared to a zero measurement. On the other hand the technological approach was investigated and estimated in terms of criteria like "interoperability and data connectivity" with a measured number of already existing information system and databases integrated in the new platform or one more challenging criteria of "support in measuring and reporting on outcomes" to be verified by means of usage of Natural Language Processing techniques on anonymized data log text and real world evidence of a diagram mapping on outcomes vs cost impact over time. This to say that while using innovative procurement instruments, cases and specifications are not really a huge problem to be addressed while criteria for

booth selection and awarding actions need specific and deep learning mechanism in order to be able to favouring innovative solutions and higher technology readiness level

3. Open Market Consultation – market readiness evaluation incl. the preparation, execution and results/outcomes;

The preliminary open market consultation launched in October 2019 was also a high level learning milestone in the innovative procurement instruments implementation. With respect to some of our previous OMC conducted at regional/national level with the participation of a lower number of European and international enterprises, the EURIPHI OMC was reach in terms of internationalization level of the investigation although week in terms of number of companies participating at the one day workshop. Nevertheless this aspect was also addressed by the WP leader by means of some extra remote interview complementing the originally organized physical workshop.

During the OMC meeting the market side was correctly focused:

i) on solutions already available
ii) solution development in pipeline for future delivery
iii) on interest to develop a dedicated solution.

This approach has allowed a learning process from the point of view of the Procurement Organizations while enlarging our market knowledge on the delivery of care services to people living with health and/or social care needs across multiple countries in Europe. A complex multifactor comparison mechanism was developed in order to assess *i) population Health and Chronic Conditions Management*, *ii) whole care pathway including care transitions between care delivery settings* and *iii) home and community setting have been defined as the core focuses on the three identified Integrated Care Procurement Objectives (ICPO)*. The matching between "enterprise development priorities" and "already existing industrial innovative solution" collected for each procurement objective was helpful to understand the distance of procurer needs from the market deployment and was one of the main input in order to identify the right instrument suitable to be used among the different available PCP, PPI, IP, Open Procedure, Closed Procedure.

4. Final definition of the procurement case & tender specifications, including definition of the subject matter;

Procurement cases and tender specification was not finalized up to now due to the link of this issue with what described at point 6 in terms of a final choice on the best procurement model.

- Model 1: Full pre-tender collaboration followed by the issue of individual local tenders
- Model 2: Full cross border collaborative procurement having lots per locality
- Model 3: Full cross-border collaborative resulting in framework agreement(s) followed by specific contracts per locality.

Nevertheless two procurement subject cases were addressed. One on stroke issues where lifestyle is impacting on the risk of having a stroke and there is currently no device that can properly asses the risks of a stroke, taking into account all parameters. The issue is here an

easy integration of the different technologies, devices, apps rather than development of a new one being a cross-institutional communication IT platform integrating different 'platforms or data sources' connecting the different stakeholders as patient, social care, clinicians, other health care practitioners. A Second subject cases was also addressed on Multiborbidity issue where main difficulty for integrated care solutions is on managing the transitions across different professionals, levels of care and jurisdictions. The shared treatment plan is still often paper based, however it is a fundamental piece in setting goals, deploying interventions and assessing impact of interventions/treatment. Therefore a smart IT solution is needed with specific requirement of interconnecting with existing electronic medical and clinical records of health care practitioners and social workers, exchanging and displaying information when needed (e.g. virtual visits).

5. The experience with cross-border cooperation in general and the participation in this EU project (identifying the opportunities and your challenges);

Expectation on EURIPHI participation was mainly related to share long experience of the Puglia Region in using innovative procurement instrument at local level while gaining knowledge and opportunity to scale up to a joint/collaborative procurement pilot actions. At the moment the open European call on PCP and PPI offering the opportunity to exercise a procurement role and use the outcomes generated by extensive preliminary work addressed by this CSA (EURIPHI project) have been addressed separately. On the SC1-BHC-20A-2020 call for proposal directly linked with some of the outcomes of EURIPHI project, we are evaluating, together with the Lead Partner of the new proposal targeting heart failure issues, some specific involvement focusing on the answer to specific questions "According to the results of the design, implementation and exploitation phases of the hearth failure PCP, would you be interested to buy the product/solution which embed the outcomes of the financed PCP research? If yes why?" We all know that non all the PCP produce sufficient mature outcomes suitable to move forward with the following engineering and purchasing phases (somehow following PPI).This of course is not a problem and from a certain point of view is also normal because of the risk nature of the PCP instrument and the information asymmetry between PA (procurers) and supplier (market), but perhaps there is some room for further investigation. We could, for example, complement the standard multiphase model of PCP (design, prototype and testing) with an extra and following phase for the assessment of risk concerns and opportunities issues able to facilitate the transition from R&D procurement and pre-commercial procurement towards commercial procurement. This of course is not to be intended to work on a PPI which is not the purpose here and, of course, is not a goal of this "PCP" call, but it is to evaluate pro/cons if going in such direction. In other words to better understand how to evaluate the highest TRL (Technology Readiness Level) and preliminary IRL (Innovation Readiness Level) with some structured approach able to address impact on organization, usability and acceptance, sustainability in real settings, use in clinical practice. On the other call SC1-BHC-20B-2020 it is under investigation also with the lead partner of the new proposal targeting rapid detection and covid-19 impact a potential involvement according to the PPI requirement rules. Possible synergies between European structural and investment funds (ESIF) and horizon 2020 (h2020) in the programming period 2014-2020 is under investigation for the execution of one joint or several coordinated PPIs where a procurer from the less developed Region in Europe

purchases the innovative solution with the support of the ESIF in line with the objectives of the Regional Operational Programme and with a co-funding rate up to 85%. Finally as a result of the learning phase with cross-border cooperation and procurement issues is under assessment the Framework Agreement approach in a joint procurement actions and specifically the proposal described in the book "Joint Public Procurement and Innovation. Lesson across borders" edited by Racca and Yuklns 1re édition 2019.

6. The proposed model on 'Cross-border collaborative procurement enabling local decision making';

At Procurers Consortium Meetings a general model (Model 1, 2 and 3) on collaborative procurement was jointly set-up with the aim of considering all the possible implication in terms of national procurement interest, framework agreement, cross-border procurement experimentation, etc. It is clear that booth the Procurers advantages of having local level technical requirement specificity request from one side and European level multi stakeholder contractual power will be hard to be matched equally. A pre-tender collaboration (Model 1) is a must and agreed at all the levels of discussion. This has also been performed up to now among many procurers on the specific description of Integrated Care Procurements Objectives. Having, for the following steps, separate lots for locality (Model 2) can definitely help procurers while leaving freedom i) in using local applicable law to conduct the tender and ii) finalizing local specification character of the unmet needs for the subject matter, but on the contrary i) require multiple steering committee set-up with specific lots procedures and ii) generate different impact on European market while defining participation rules for enterprises in applying to different tender lots. Finally a completely joint tender resulting in framework agreement followed by specific contracts per locality (Model 3) has the benefit of i) having a single evaluation of tenders and awarding procedure at European level and ii) contractual power because of a synergies of procurers intent in terms of specs and formalization of common technical requests, but it can generate i) complexity in applicable law (generally the once of the lead procurer), ii) higher organization level demand to suppliers in delivering final products at multi member state level. As a result no specific decision has been taken so far for the implementation stage although some preliminary understandings are emerging especially linking procurement procedure offered by the European directives (DIRECTIVE 2014/24/EU on Public Procurements) and Joint Procurement Models defined at EURIPHI consortium level.

- Integrated care procurement objective (ICPO) targeting needs with potential solutions available on the market at TRL higher than 9 (TRL>9) could be procured with "open or closed procedures" easily applying joint procurement approach following the three defined Model.
- ICPOs addressing needs with potential solutions not completely available on the market with TRL between 3 and 8 (3≤TRL ≤8) could be treated for procurement purpose with a "competitive procedure with negotiation" or "competitive dialogue" applying for a joint procurement only Model 1 and Model 2.
- Procurement objectives and specifically ICPOs addressing shortcomings/unmet needs with potential solutions not completely available on the market and with TRL up to level 9 (3≤TRL≤9) that could be procured through the "innovation partnership"

instruments are reasonably targeted only with a joint procurement based only on Model 1

7. General learnings.

For many years, innovation policy has focused on supporting the generation of innovations. Recently, increasing attention has been paid to the demand conditions for innovation and consequently demand-side innovation policy. In addition to the support for private demand, public demand, i.e. public procurement, has gained significant attraction as innovation policy instrument due to the larger purchasing and signaling power that the government (National and Regional) has as a lead user. Policy makers have opened public procurement to innovation (2014/24/EU) to increase the impacts of public purchasing on innovation. Moving beyond improving public service provision, public procurement which stimulates the generation of new ideas and facilitates their translation into innovation has impacts at the firm level and subsequent macro-level benefits. We are convinced that performing innovative procurement actions also across borders is a driver for local SME and start-ups to scale-up local and foreign markets. SMEs and start-ups need also to be supported on how to put in place PCP, PPI and IP also at international outreach strategies. Innovative public demand, usage of new procurement instruments, engagement of SMEs and start-ups are three main pillars for regional policy makers to pave the way to a positive effects of value-based innovation procurement for health systems and society at local and cross-border level. While approaching the innovation goals Procuring organization, Contracting authorities and Buyers groups have the chance to use framework and local condition to adopt the right procedure and instrument. Timing constraint have often been raised as bottle neck of the procurement strategy although innovative procurement instruments can be adapted to the on the filed condition. The pandemic situation of Covid-19 is a clear example of potential exploitation of procurement directives for targeting the most suitable approach (Costs, solution, TRLs, MEAT, etc.) to the degree of importance (extremely-urgent, urgent, non-urgent) and to the right instrument (PCP, PPI, Negotiated procedure without prior notice, Accelerated procedure, Innovation Partnership, etc.). A multiple step process is the most suitable learning case: i) Identify needs; determine which are extremely urgent, urgent, or non-urgent (standard); ii) Understand the legal possibilities for procuring to meet these needs; iii) Draft a business case to justify the urgency of needs, identify cost-effectiveness, and inform the tender; iv) Find suppliers who could deliver supplies and services on short notice; v) Draft technical specifications and award criteria to reflect the business case; vi) draft contracts and property right implication.

RSD – Test case learnings; input and comments

On the process steps in the preparatory phase:

1. **Assessment of specific and in common care delivery shortcomings/unmet needs incl. its prioritization**

- Even though common care delivery shortcomings/unmet needs can be the same throughout regions, the prioritization of meeting these needs often differ, making it difficult for consensus on towards a collaborative solution.

- Also, regions don't necessarily collaborate with each other in the procurement and implementation of innovative solutions, meaning two regions can have carried out the same process resulting in a less efficient and cost effective process.

- For these two reasons, it could be beneficial to establish a central task force or national procurement body that could align regional priorities for procurement of innovative solutions to ensure a more cost effective process. Also a national body could be an advantage in identifying future health needs trends, increasing the possibilities for cross border collaborative procurement and in shifting towards and advancing value-based innovation procurement in health care systems.

2. **Preliminary definition of procurement objectives and solution requirements incl. the application of the MEAT-VBP framework in support of defining the objectives**

- VBC can increase competitiveness and drive companies' motivation to develop and deliver solutions with better health outcomes. It can also provide a niche in the market where SME can access the market with their value based innovative solution.

- A patient centered approach in integrated care requires patient's involvement in the co design and co creation processes of the innovative solution.

3. **Open Market Consultation – market readiness evaluation incl. the preparation, execution and results/outcomes**

- At the OMC, SMEs reflected how difficult it was to gain access to tender process within healthcare systems. To support SME throughout Europe, it is important to review present day practice and identify how these practices can evolve to benefit newly upstarted SMEs.

4. **Final definition of the procurement case & tender specifications, including definition of the subject matter**

- RSD has nothing further to add to this section.

On the (additional) experience by RSD:

5. **The experience with cross-border cooperation in general and the participation in this EU project (identifying the opportunities and your challenges)**
   Many of the partner countries have the same unmet needs but again prioritisation differs. However, this is not the main barrier to cross border collaborative procurement, the main barrier being the judicial regulations within each country. A common EU legal framework for cross border procurement is needed to overcome this barrier. The legal aspects barrier means there becomes limitations in a cross border procurement model, where there continues to be a need to complete the procurement process within individual country's jurisdiction.

6. **The proposed model on 'Cross-border collaborative procurement enabling local decision making'**

- The model is comprehensive and the table with procurement procedure and the three different models give a good overview.

7. **General learnings**

- The transformation towards value based innovation procurement is vital towards meeting the needs and demands of citizens in gaining better health outocmes. Additionally investments in value based innovation procurement will give long-term cost-effective benefits to health care systems.
- Although progress is been made in this area throughout Europe, the concept of value- based procurement is still a novel concept that needs to be promoted. EURIPHI project is paving the way with the establishment of the CoP forum.
- EU directives for procurement but the legal frameworks lack to support the directive.
- Health care needs evolve at a rapid pace, procurement frameworks need to be flexible to adapt to these changes.