

Deliverable

D6.4: Buyers group proposed model of governance

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Deliverable abstract

The form under which the procurement will be designed is relevant and has implications depending on the different cross-border collaboration models the buyer group decide to take. The present deliverable aims to serve as a guideline for the buyers' group to define the best model of governance on the tender preparation stage.

Deliverable Review

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the Description of Action?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a
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* Type of comments: M = Major comment; m = minor comment; a = advice

Abbreviations and Acronyms

BAFO	Best And Final Offer
BGA	Buyer Group Agreement
BGSC	Buyer Group Steering Committee
CA	Contracting Authority
CPA	Collaborative Procurement Agreement
CSA	Coordinating and Supporting Action
EURIPHI	European Innovative Procurement of Health Innovation
FA	Framework Agreement
JPA	Joint Procurement Agreement
PCP	Pre-Commercial Procurement of Innovation
PPI	Public Procurement of Innovation
VBP	Value-Based Procurement

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Executive Summary

The work undertaken in EURIPHI-CSA project has increased procurers' capacity in Value-Based Procurement (VBP) activities along all the preparatory pre-Tender key phases in both Rapid Diagnosis and Integrated Care fields. Starting from the assessment of care delivery shortcomings, going through the definition of procurement objectives and along an Open market Consultation (Market Readiness Analysis) - two in the case of Rapid Diagnosis- and with the eventual definition of a procurement case, as well as future tender specifications and the awarding criteria.

Prior to get into the procurement tender execution phase, the Buyer Group need to define the form under which the procurement will be designed. This decision is relevant and has implications depending on the different cross-border collaboration model the buyer group decide to go through.

The present document will provide assistance on the definition of model of governance for the buyers group, being this key to ensure the best common decisions during the tender execution phase. Among these decisions, a well-structured model of governance will enable Buyer Group to decide the extent to which they will collaborate with each other (external with other buying groups and internal taking an multidisciplinary approach) and during both the tender preparatory and execution stages, based on their political, economic and institutional contexts.

In conclusion, the present deliverable D6.4 aims to serve as a guideline for the buyers group involved in public procurement of innovative solutions to best define the governance and model of cooperation on the tender preparatory and execution stages.

Introduction

Technological innovation is one of the main drivers for change in the health sector and for improving its effectiveness in tackling diseases. At the same time, the increasing prices charged for new technologies are putting pressure on health budgets, which are already suffering from fiscal constraints. Thus, in order to ensure availability to patients of personalized quality care, address individual health systems and health care professionals' need to meet the challenge of anticipating and managing the impact of technological innovation by engaging in horizon scanning and early value analysis, mobilizing capacity to assess the value of new technology and their ability to address the cost of care, ability to keep people in good health, costly inefficiencies, waste in the health systems (estimated to about 20% of health care spending), ability to avoid costs, negotiate prices and terms of value based agreements will need to be established to innovate the delivery of care in economic most advantageous ways .

While these innovations may contribute to achieving better outcomes and, in some cases, even mitigating costs, the added value may either be uncertain or are not considered to justify a different price or rewarding compared to existing alternatives. Consequently, there is an increasing need for countries to assess information on the Value of a new technology or proposition (innovative solutions) taken a multidisciplinary view of what is of valued. The new technology's effectiveness, safety, quality, and price are part of these consideration and we advocate for a multi criteria analysis decision selecting economic most advantageous proposition. Furthermore, public purchasers often have relatively low bargaining power when confronted with the introduction of new, patent-protected health technologies, so we advocate for models fostering competition and mechanism rewarding effective value delivered as part of the agreement⁴.

This is particularly relevant when they are purchasing for smaller populations, either because the country itself is small; or we seek to more personalize treatment and care and advance to a value based health care, with an urgent need to innovate the delivery of care and introduce innovative, fit for purpose solutions. In these cases, it may be helpful for countries to join forces in public procurement processes and to establish forms of collaboration across borders to ensure access to health technology and opportunities to transform health care introducing innovative solutions.

There is no single term to cover the act of several buyers collaborating and pooling resources to negotiate or to buy medical goods and supplies at more favourable conditions. In the EU setting, joint procurement is a commonly used term. It is used in the EU Public Procurement Directives to denote the situation where **several buyers from different Member States and/or health and social care regions come together**, in a single process, to get increased volume and better prices or access. At the international level, pooled procurement or volume-based procurement is also a commonly used term for the same concept. However, joint procurement is only one form of collaborative procurement, which can take various formats. The operational definition for collaborative procurement used in this brief encompasses different possible levels of collaboration, as further elaborated in following sections.^[1]

A starting point for a collaborative procurement is often by an increase in volume and opportunity for better price, however this often limit the real opportunities to introduce innovative solutions of high value resulting in health economic and financial most advantageous outcomes and at high risk to be associated with unintended consequences. We therefore advocated for a Cross-border Value Based Innovation Procurement cooperation model, financially, socio-economically of highest interest.

⁴ **Health technology** is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. In procurement this most often refers to innovative medicines and/or other forms of technology (devices, equipment and health information technology (IT) systems).

To ensure a correct cross-border tendering process, it is key to, based on the procurement context, ensure that a proper model of governance is defined in order to make best and efficient decisions during the tendering execution phase following a well-established preparatory phase. This applicable independent on the procurement procedure planned, fostering effective cross-border cooperation while responding to the specific needs and respecting subsidiarity principles

What is a model of governance?

The word 'governance' is associated with words like government, governing and control (Klakegg & Williams, 2009). Control here means being able to decide, define limitations or delegate authority. Governance is a term that carries different meanings. Rhodes (1997) defined governance as a "non-hierarchical form of steering, where state and nonstate actors participate in the formulation and implementation of public policy". This means that both **accountability and transparency** should be implemented so that each stakeholder could participate in the formulation of the policies (Aliza, Stephen, & Bambang, 2011). It is good to understand governance from the definition by OECD (2005), who described public governance as the formal and informal arrangements that determine how public decisions are made and how public actions are carried out, from the perspective of maintaining a country's constitutional values in the face of changing problems, actors and environments.

The term "governance" has migrated to the centre of an overlapping set of concepts deployed across a broad range of settings, from academic theories, to advocates for change, to practitioners (Ramesh & Fritzen, 2009). Most discussions of governance can be conceptualized in terms of how authority, resources, and power are distributed among the public, private and "people" sectors, and across various levels of government. The concept of governance is so multifaceted for **three reasons**: it rose to prominence against a backdrop of myriad contemporary political and ideological changes and pressure; it has been substantively deployed and defined in a number of contradictory ways, and in support of varied agendas; and the study of its "transformation" is associated with a broad array of methods that do not necessarily generate coherent findings^[2]. Viewing governance in these three cross-sectional views allows discussing the governance in the public procurement sector, and the importance of such governance framework to support the successful implementation of a cross-border procurement procedure.

Principles of procurement are inherent to the governance framework for the implementation of a cross-border procurement. Governance framework should be designed without having to confront the difficult questions of how the principles are interrelated and whether there are any trade-offs among them that must be weighed.

The governance in public procurement with its instruments like public procurement acts, rules, and regulations influence the governance in the bidding community as well. Policy makers should take public sector transparency into consideration when designing and implementing public procurement reforms aimed at the procurement sector keeping the relationship between stakeholders including bidders and buyers, ignoring such interrelationships between public and private sector governance may reduce the relevancy of reform policies. Another important factor in public procurement governance is the institutional structure of the Contracting Authorities (CAs). The institutional patterns and structure, such as the degree of decentralization or centralization of the state structure, or funding and resource utilization authority in the procurement sector and readiness to evolve to innovation procurement to transform and innovate healthcare delivery matter to the success of a cross-border innovation procurement.

The Practices for Public Procurement are founded upon the Values of Public Procurement necessary to preserve the public trust, protect the public interest, and ensure fairness for the public good. Those Values are: Accountability, Ethics, Impartiality, Professionalism, Service, and Transparency. According to Aliza, Stephen and Bambang (2011) the governance framework should ensure the accountability

and transparency of the decisions made in awarding the right contract to the best contractor. Public procurement governance framework is often a subset of state governance focusing on the public procurement, but also applicable for private procurement.

Governance arrangements in cross-border procurement

Cross-border public procurement is a concept that has been gaining traction in recent years and could be considered at the spearhead of public procurement reform and innovation. The 2014 reform of the EU public procurement rules (mainly Directive 2014/24) expanded the toolkit available to contracting authorities (CAs) willing to engage in collaborative or centralised procurement activities, and in particular in cross-border procurement collaboration^[3]. To optimize the activities undertaken along the tendering process of a cross-border public procurement, it is needed to define a proper governance model according to procurers' context and needs.

Cross-border procurement entails the combining of procurement actions of two or more public procurers from different countries.

Objectives of putting in place governance arrangements

A proper definition of the model of governance will be needed in order to achieve a successful cross-border procurement. In the procurement of health technologies, the rationale for increased voluntary cross-border models of governance between countries aims to:

- **Join skills and expertise, understanding of the market readiness**– the participating procurers share knowledge, expertise and skills; for example, one of the procurers could bring significant economic expertise, while another could provide extensive legal expertise or expertise in undertaking innovation procurements; This enables procurers to learn on innovation procurement from other more experienced procurers and gain a better understanding of the market readiness.
- **Foster standardization** – collaborative / coordinated procurement (agreeing on collaborative requirements for solving common problems) can foster the creation of de facto and de jure standards and increase interoperability between the systems of participating public procurers; this is thus particularly interesting when coherence, interoperability, interchangeability or interconnectivity is required. Key functional requirement and mechanism to award criteria based upon the value created will become a common good and foster to use a value-based procurement. The enabling a change and adopt the best price/quality ratio method for most economic advantageous tendering in healthcare across Europe.
- **Deliver better value for money solutions** – the buying power and knowledge base is greater than the purchasing by individual procurers, which can enable economic operators to deliver better value for money solutions (e.g. economies of scale of production because of the larger potential market / higher value with more specific lots for more targeted, personalized treatment, ability to identify and address cost drivers, best practice exchange,...). This is thus particularly interesting when the identified need is likely to be faced also by other procurers at local/regional/national or European level and when the market for the solutions is very fragmented (joint signal from demand side is needed).
- **Reduce costs of procurement** – the costs for preparing and/or carrying out of the procurement (administrative costs to prepare the procurement, run the procedure and the non-administrative costs e.g. costs for the testing and acquisition of solutions) can be substantially reduced / split among the participating procurers. In particular collaborative procurement can thus enable procurers to tackle needs for which individual procurers lack sufficient financial resources to procure alone; These benefits need however to be balanced by possible increased cost due to adaptation needed towards national requirements, language and timeliness of action.

In addition to the above, transnational procurement enhances cohesion and cooperation on public sector challenges across borders by fostering cooperation between procurers and suppliers from more and less developed regions in Europe on common challenges (e.g. environmental protection, economic growth, fighting climate change etc.)⁵. It will also enable to capitalize on best practices to integrate primary and other health and social care and strive for information enabled value-based health and social care.

Key elements that all governance arrangements need to cover

Although there is a lack of conclusive evidence, it remains clear that both within and across borders, successful cross-border procurement depends on a **number of essential preconditions** to be fulfilled by the purchasers and their defined model of governance:

- Readiness to advance to an procurement toward innovation, integrated and value based procurement at local level
- Strong political support and committed investment in resources to introduce innovative solutions.
- trust between collaborating parties
- Cost of care transparency.
- Value based agreement model
- market analysis
- effective communication between internal and external stakeholders
- efficient financial management, including prompt payment of purchases made
- continuity through multi-year contracting that enables stable supply sources and fosters closer ties between participants
- clarity on management responsibilities for the collaborative procurement process and their remuneration
- sharing of information and good practices
- ongoing commitment to honour the conditions of the procurement agreement.

A basis of political will and mutual trust among the partners are obvious conditions for any form of cross-border collaboration. Mutual confidence and trust can be progressively built by countries starting with less intensive and demanding collaboration approaches, e.g. those implying only the exchange of information and experiences, time-limited collaborations, initiatives limited to one single technology or disease, etc. The longevity of such arrangements also seems to influence their effectiveness.

In all cases the starting point to ensure decision making is the prerogative of each contracting authority or procurement organization in response to the specific needs and values.

Putting in place a governance framework in cross-border innovation procurement

Best practice establishes public innovation procurement in terms of the application of methods and resources that produce the best health, social and economic outcomes from public financial resources, within a value framework that is ethical, non-discriminatory and transparent. These should be also the objectives for the cross-border procurement of innovation, independently of the chosen model. ^[2]

It should be noted that these objectives are focused on measurable outputs and results rather than technical characteristic and/or process or procedures indicators. To give operational effect to these

⁵ <https://eafip.eu/toolkit/module-2/>

procurement objectives through a cross-border procurement, a governance framework is required and should include:

1. Procurement Framework – Establishment of a framework of objectives, principles of cooperation in preparatory and execution phase, procedures, accountabilities, legislation and guidelines in order to go through a value-based procurement and select the most economic advantageous tender;
2. Procurement Planning - A procurement plan methodology;
3. Risk Management - Establishment of a risk management framework;
4. Procurement Evaluation - Performance monitoring and evaluation framework;
5. Procurement Institutional Roles and Individual Competency – Professionalization and accreditation for governance and performance.

1. Procurement Framework

The accountabilities under the procurement procedure must be aligned with good practice. The procurement procedure should unambiguously establish the higher authorities to be the accountable authorities in relation to the application of government procurement policies and legislation, and the regulations should require them to ensure compliance with the Rules and related government policies when engaged in duties related to procurement. Accountability means that officials are responsible and for the actions and decisions that they take in relation to procurement and for the resulting outcomes, and secondly that their actions and decisions are transparent. Accountability should be cascaded through the procurement organisations in order to enable a **value-based procurement** through a cross-border model, being able to respond to the identified specific needs. Last, but not least, accountability includes the achievement of results.

2. Procurement Planning

Comprehensive annual procurement plans are the foundation of the procurement framework. It is considered normal governance practice for an organisation's procurement framework to require procurement plans to be developed for each case of significant procurement.

3. Procurement Risk Management

Central to the governance, planning and management of public procurement is the concept of risk management. As seen in following section, public procurement is risk management in many ways. There is a requirement for the governance framework to have a risk management approach.

4. Procurement Evaluation

Evaluation is a process that applies at all levels of a project or contract, as well as the legislation itself. It would be beneficial for reporting to, inter alia, include comprehensive spend analysis, and indicators that assess the performance of the legislation itself.

5. Procurement Institutional Roles and Individual Competencies

The roles and responsibilities of procurement institutions should be defined and reflected in the procurement framework. Individual competency is extremely important in the success of cross border innovative procurement. The roles of the institutions and individual competency are assessed in terms of their alignment with best practice accountability in the eventually obtained innovative solution.

In the case several procurers carry out together not only the preparation but also the execution of the procurement procedure a cross-border **Collaborative Procurement Agreement (CPA)** needs to be

established to formally determining the practical arrangements governing that procedure⁶. And consequently agree on how the different procurers will cooperate to execute the Collaborative procurement:

For example, the CPA could be used to:

- determine the type of procedure used;
- identify the lead procurer that acts in the name and on behalf of the buyers group and what tasks this entails;
- decide who contributes to the drafting of the tender documentation and other aspects of preparing and/or managing the procurement (e.g. which procurer(s) provides test environments, who participates in monitoring of suppliers, who pays the suppliers etc.);
- agree on decision making procedures (e.g. for evaluation of offers, usage of results of the procurement, distribution of IPR related rights among procurers etc.);
- decide who is responsible for handling litigation (is the lead procurer the only legal contact towards vendors for legal action/counter claim or not, how are litigation costs shared between participating procurers).

Procurement Organisation roles will therefore vary depending on the selected cross-border collaborative model. For the mentioned models, the Cross-Border Collaborative Procurement Agreement^[4] template provided by the European Commission can serve as a **guideline to understand** how five mentioned steps can be integrated in an agreement to ensure a proper model of governance and, consequently, a proper procurement process.

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https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_explanatory_en.pdf

Main risks to be considered in cross-border procurement

'**Risk**' is defined as 'the possibility of something bad happening' (Cambridge Dictionary⁷, 2018) but it can also be considered as 'an uncertain event or set of events - positive or negative - that, should it occur, will have an effect on the achievement of project objectives.' (CoEPM², EC 2016)⁸. Within the scope of this Deliverable, only risks with a potential negative impact in the EURIPHI-PPI procedure are considered, and it will not develop further on risks considered as opportunities nor on Project issues.

Risk management entails a systematic process to identify, assess and develop a risk mitigation/response strategy. Risk assessment determines the likelihood of each risk to happen and the severity of its impact on project objectives.

Following the EUR 24229 report, five **types of risks** are taken into account:

- **Technological risks:** risks leading to non-completion, underperformance, or false performance of the procured good, service or solution. Due to its more innovative nature, the risk lies in the use in innovating care delivery and the use in practice associated with learning curve.
- **Organisational and societal risks:** risks of the procurement failing or under-delivering for reasons within the procurer(s) organisation(s) or related to a lack of acceptance and uptake by the users, respectively, buying/awarding a solution not meeting the exact needs adapted to the local requirements and specificities.
- **Market risks**, either from the *demand or supply* sides: related, for example, to the interest, responsiveness and/or investment capacity of potential private markets; potential competition; political strategies and instability or insufficient quality.
- **Financial risks:** related to uncertainty in meeting target costs and the ability to secure the funds needed.
- **Turbulence risks:** uncertainties hard to predict and measure, associated with a range of unforeseen events that might lead project actors to reassess their priorities and/or expectations.

Also, in line with the mapping depicted in the EUR 24229 report for the identification of the risks, different **risk sources** were also considered:

- Risks from the **demand side** (consortium) vs. risks from the **supply side** (bidders), and
- Risks due to the **procurement cycle** vs. due to the **innovation cycle**.

A mitigation of the risk and to incentivize partnerships to collaboratively address risks can be established by the use of the EURIPHI legal guidance and use of value based procurement and value based (partnership) agreements for which an overview is provide in EURIPHI D2.1. To address the risk due to procurement cycle vs innovation cycle can be addressed also by Value based agreement.

The **consortium** – supported by the **Project governance bodies** - is committed to perform a regular risk management exercise, so the set of identified risks will be updated as the project evolves and the proposed risk-mitigation measures will be revised to ensure their application and efficiency⁹.

Additionally, the Buyer Group may count on the **services of legal advisors** to minimize the risks related to legal and contractual implementation of the procurement procedure.

⁷ 'Risk' definition by Cambridge Dictionary (<https://dictionary.cambridge.org/dictionary/english/risk>)

⁸ Directorate-General for Informatics (European Commission); PM² project management methodology guide - Open edition; EU publications; 2016; doi: 10.2799/957700

⁹ INSPIRE Project, 'D2.4 Tool-kit; GA: 611714.

Source type	Institutional/ societal	Financial	Market	Technological	Other	Source type	
Stages in the Procurement cycle Planning and preparation Notification and pre-qualification Tendering Evaluation Contract Award Contract Management Evaluation	Definition risk Failure to define needs & communicate to market	Financial planning risk Innovation far beyond initial budget	Supplier market risk Not enough capable bidders	Technical risk Solution not feasible or suboptimal	Turbulence risk Unforeseen events mainly associated with large scale-projects	Stages in the Innovation cycle R&D stage Adoption by public client Diffusion in Public Realm Diffusion in Private Markets Maintenance and updating New cycle	
	Legal/regulatory Changes in regulations, misalignment with & proc. objectives	Financial market risk Failure to secure funding	Supply chain risk Supplier taking hidden risks Supply chain deficient	Contract design/award/evaluation proc. not adequate for technology			
	Adaptation risks Internal Integration/external acceptance		Market spillover risk No spill over to private markets	Lack of complementarities with networks/standards			
	Policy spill over No adoption/use by other services/policies	Cost monitoring Poor cost controlling, and choice of payment modalities	Market competition risk Dependency on few suppliers/ Distorsion of competition	High cost of upgrade and maintenance			Technological Lock-in
	Procurement Risks		Innovation Risks				

Figure 1. The Risk Map in Public Procurement for Innovation (Source: EUR 24229 — Risk management in the procurement of innovation - Concepts and empirical evidence in the European Union"; 2010

Considering the premises above, and based on experiences of previous processes, a set of risks have been listed in Annex I adapted to the PPI procedure defined in WP6 on **Rapid Diagnosis tool for antibiotic stewardship of VAP**.

Models of cross-border collaboration

A joint or cross-border collaboration in the field of public procurement is often put forward as a promising strategy to address some of the existing imbalances and challenges of the health technologies and innovative solutions market described above. In the procurement of health technologies, the rationale for increased voluntary collaboration between countries is to:

- share experience, pool skills and capacity and become aware of the market readiness
- enhance transparency and enable cross-country learning
- shape the market through information sharing to avoid asymmetries of information and joint negotiation
- tackling disproportionate high prices through economies of scale, building market power to apply value based and economic most advantageous procurement and partnerships
- tackle high transaction costs by pooling resources.

Cross-border collaboration in procurement can take different forms, with varying intensity and scope of activities that will have a direct impact on procurement entities' role and the common governance framework. According to the work performed in WP5, three different models of collaboration are highlighted in the execution of the following collaborative full tender process, consisting of a preparatory and execution phase.

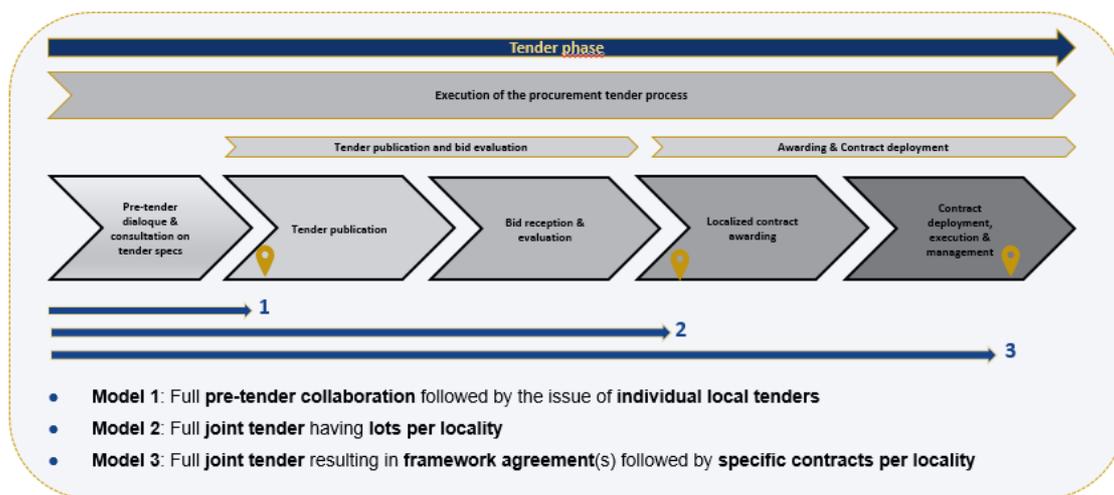
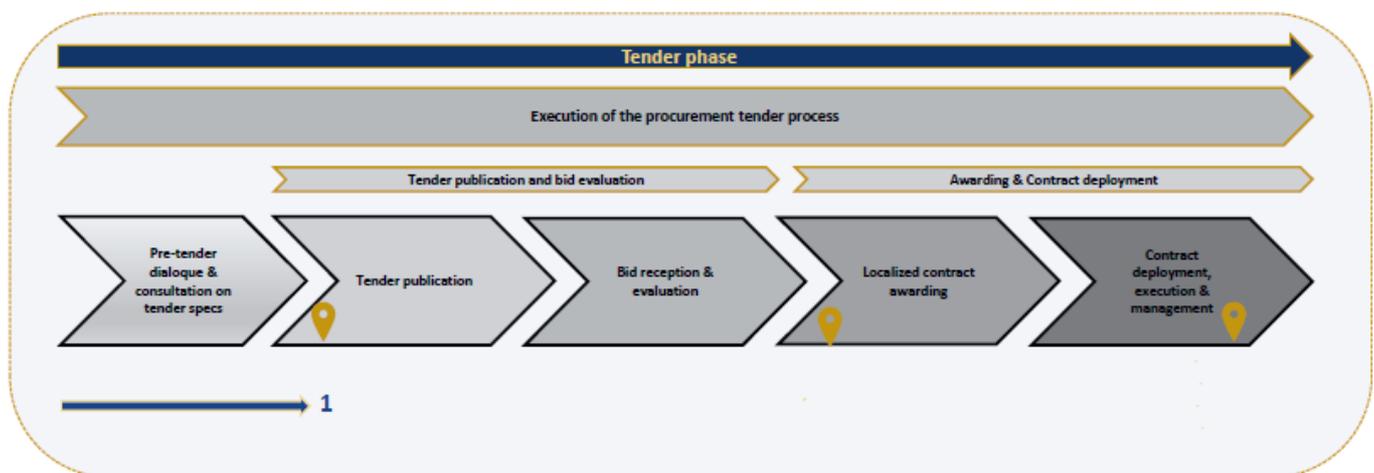


Figure 2. Cross-border collaborative procurement models enabling local decision making

Cross-border Model 1 - Full collaboration in the preparatory phase followed by the issue of individual public tenders by the participating organizations/partners

This first model implies collaboration between two or more public procurers with similar needs and structure during the pre-tender phase (assessment of care delivery shortcomings, market analysis, definition of the procurement strategy, etc...). After an effective collaboration during the preparatory phase, knowledge and procurement good practices are exchanged. Although actions like the publication of the prior information notice (PIN) and contract notice might be co-ordinately performed, public procurer gets ready afterwards to launch **its own individual tender**, taking in consideration its own national, regional or local specificities. Lastly, for a complete collaboration, public procurers are required to exchange their experiences at the end of the tendering process to share their results and



main lessons learnt.



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Figure 3. Cross-border Collaborative Procurement - Model 1

Going through a Collaborative Procurement has some implications regarding governance arrangements and considerations in cross-border procurement. On the objective's perspective, it enables cross-country learning by sharing experience and transparency through information sharing.

On the other hand, the present Model does not need the totality of key elements to successfully proceed with the procurement process. Given that no awarding or contracting collaboration will happen (beyond a possible use of consideration of evaluation metrics, collaboration in on pre-tender dialogue as part of the tender procedure,...) between Buyer Group during tendering execution phase, a detailed **Collaborative Procurement Agreement** is not needed. However, a commonly defined **principles of cooperation for cross-border Collaborative Procurement** is recommended to be defined/signed by the Buyer Group in order to regulate the relationship between them during the preparatory and tender preparation phase; regarding the publication of the Prior Information Notice (PIN) and the Invitation to Tender (ITT).

For the reasons exposed, trust between collaborating parties and ongoing commitment to honour the conditions of the procurement agreement are needed at a lower level than in the rest of Models, reducing in this manner the risks to be considered along the tendering execution process (i.e., failure

of procurers' commitment or project partners do not share common understanding of PPI and innovation development).

Based on experiences from EURIPHI partners, such as RESAH, coordinator and Lead Procurer in [HAPPI project](#) (where the first transnational joint tender in the healthcare sector was launched), as well as [INNOCAT PPI](#) and [RELIEF PCP](#) project, some considerations were made concerning situations when this type of cross-border procurement model might be interesting to be adopted as it was encountered that :

- 1. Language difference is a real barrier**, and getting to closer collaboration (as in cross-border Model 2 and 3) between Member States with different languages might require additional resources (both financial and human) in order to face the translation of the tender documents, translation of the offers and/or translation of the contract(s).
- 2. Differences between national laws:** Despite the fact that European Directive 2014/24/EU aimed to harmonize the different national public procurement laws among the member states, some legislations still respond to each country's national laws, which might differ and affect procurement entities from a Buyer Group. In these cases, cross-border Model 1 would be recommended instead of moving to closer models of collaboration.
- 3.** Getting to further collaborative models of cross-border procurement might imply the **consumption of additional resources:** Conduct and participate in several joint meetings, legal research and harmonization, answer the different questions received from suppliers during the tendering phase, the evaluation of tenders, etc... For these reasons, it is crucial to estimate the potential added value of doing a joint tender and compare it to the amount of additional resources to take the decision.
- 4.** Given the different contexts of procurement entities, the preparatory phase might show **low consensus among procurement entities** when identifying the needs and defining the functional requirements and most valued criteria. Collaborative Procurement allows independent local tenders adapted to its specific procurer's context instead of making concessions that might end up in solutions that do not entirely satisfy procurers' needs of lower value and not leading to economic most advantageous solutions.
- 5.** Local tenders are more likely to better contribute to **foster growth of local SMEs and start-ups** rather than large demand volume tenders, where access to these economic operators might be more complicated, given their lower capacity.

Cross-border Model 2 – Full collaborative tender having lots per buyer

Full collaboration in the preparatory phase followed by the issue of a (single) collaborative public tender in which every participating organization/partner holds its dedicated lot or lots. This lot is tailored to the specific needs of the organization and is awarded separately.

Cross-border Model 2 implies not only a collaborative preparation of the pre-tender phase, but also during the tender execution phase. In the present joint tender, a Lead Procurer is designated and empowered to make the needed actions for running the procurement process. This further level of collaboration has important implications, as the local law of the lead procurer will be respected by all the procuring entities participating in the tendering process. However, having lots per contracts per procuring entity makes them still responsible of defining their own awarding criteria on each lot and ability to enter into specific Value-Based Partnership Agreement.

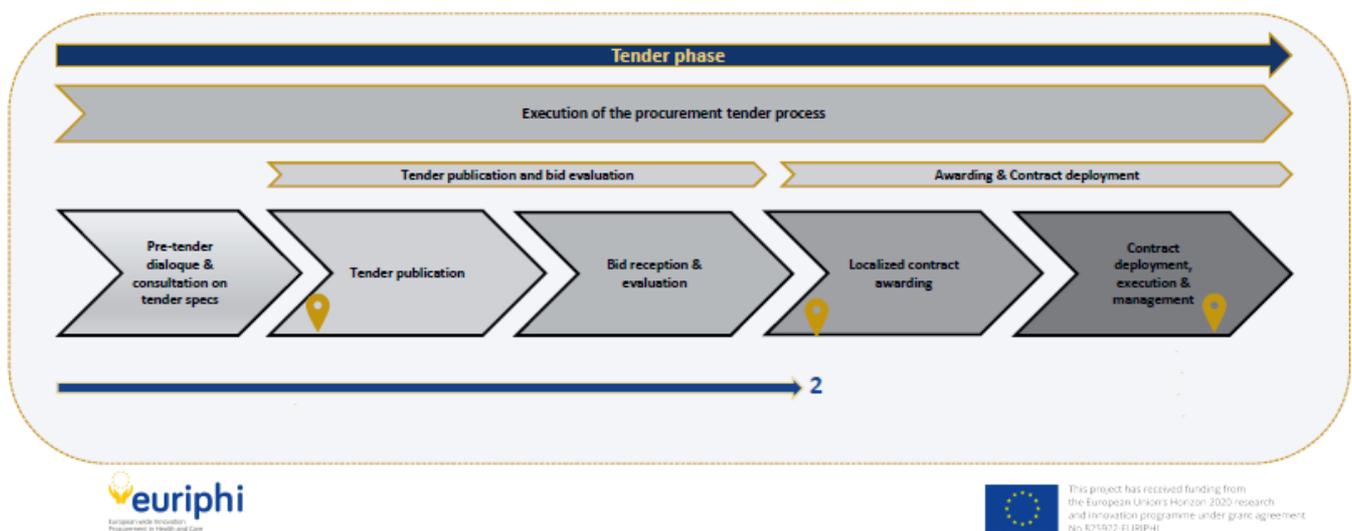


Figure 4. Cross-border Collaborative Procurement - Model 2

Given the legal implications of performing a joint tender per lots, the governance framework for the procurement will be provided by the following agreements:

- **The Collaborative Procurement Agreement (CPA):** which provides the formal approval by the Buyers Group to the Request for Tender documents issued by the Lead Procurer; and to the responsibilities arising from those documents for each signatory party, with regards to the execution of the tender procedure.
- **The Contracts for the provision of services corresponding to each lot,** that regulate the relationship between buyers and contractors in relation to the execution of procurement contracts. While the tender procedure is governed by the Lead Procurer country's Legislation; once awarded, the Contracts will be subject to the legislation of the corresponding Procurer of each Lot.

Model 2 level of collaboration implies a further cross-country learning and skills sharing than Collaborative procurement framework model (Model 1), as information sharing also pursues at a high level during the tender execution phase.

In the same way, additional key elements are needed comparing to Model 1 to successfully proceed with the totality of the procurement process. Trust between parties, as well as ongoing commitment to honour conditions of the procurement signed agreements are now necessary.

As a result, more risks will have also to be taken into account, as Lead Procurer will be legally empowered to make the needed actions for running the procurement process

As an example of Model 2, RITMOCORE¹⁰ is a Public Procurement of Innovation (PPI) project, funded by the European Union under Horizon2020, addressing the evolution in the treatment and management of patients using or in need of an implantable pacemaker (PM). Moving from a conventional purchasing of devices to an innovative service provision through a full joint tender having lots per locality. It is our understanding that also THALEA applies this approach for a cross-border innovation procurement and is seen as an excellent way forward the procurement of innovative solutions within an EU supported projects.

Cross-border Model 3 - Full Collaborative Tender resulting in one common framework contract

Full collaboration in the preparatory phase followed by the issue of a (single) joint public tender resulting in the awarding of a framework agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period. The overall term of the framework is not to legally exceed four years. Next, the local implementation of the framework agreement is executed by having specific contracts concluded between the individual contracting authorities/partners and the economic operator(s) under local law.

The full collaborative tender resulting in a common framework contract implies the highest level of collaboration model from the cross-border procurement models. Procurement organisations work together from the assessment of care delivery shortcomings to a common awarding criteria definition to eventually procure one innovative solution through a common localized contract awarding. Independently of the deployment volume, which can vary and will depend on the amount of money that each procurement organization is willing to invest, the final solution will be common for the participating procurement entities.

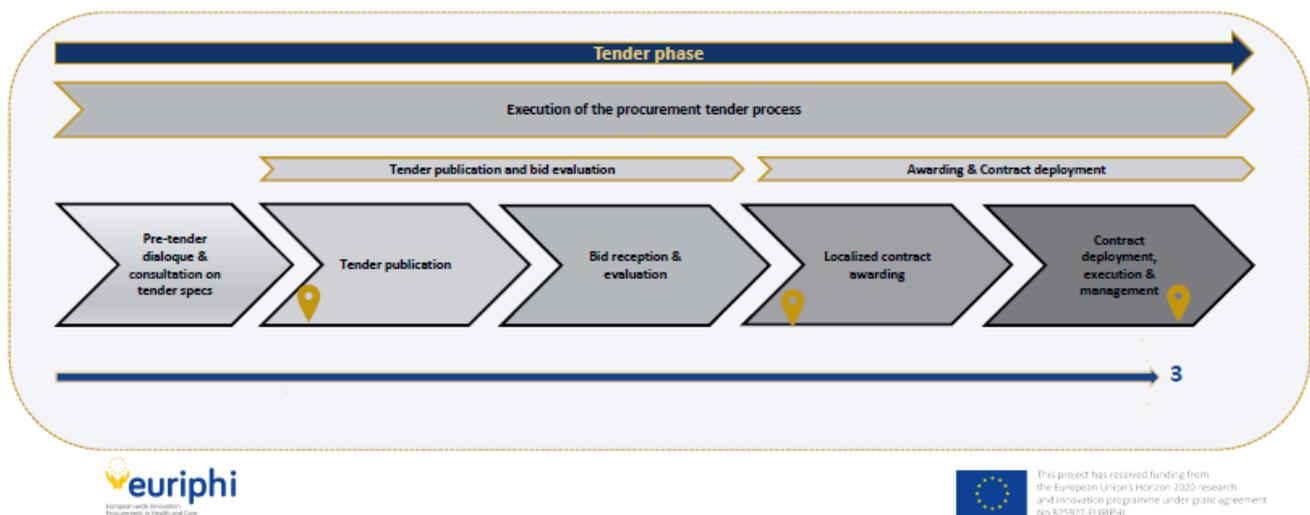


Figure 5. Cross-boarder Collaborative Procurement - Model 3

¹⁰ RITMOCORE-PPI project (GA : 727796) - <http://www.ritmocore-ppi.eu/>

Model 3 differentiates from Model 2 by eliminating the contracts corresponding to each contracting authority. The CPA framework will in this case define all the key actions of the contract execution during the tendering phase: Buyer Group's model of governance, evaluation procedures, type of procurement procedure, type and terms of contract, allocation criteria among procurers, awarding criteria, award and signature of specific contracts based on framework contracts, etc.

Referring to Framework Agreement, the FA can be concluded by the consortium with one supplier, followed by individual, specific contracts by the partners. However, FA may conclude with multiple suppliers, followed by local mini competitions in order to award the final specific contract to 1 or multiple of the selected supplier. In this case, the awarded suppliers may differ across the participating partners/countries.

Proceeding with a full Collaborative procurement tender resulting in a framework agreement with a common framework contract has important implications comparing to Model 1 and Model 2. On the one, all the objectives defined intended with cross-border procurement are achieved. High-level Cross-country learning and information sharing is gained, as well as the achievement of sustainable prices through economies of scale as a greater volume of same innovative solutions will be procured. It will be critical to assess if this common solution will lead to economic most advantageous solutions and responds to the specific needs and value criteria of interest

Accomplishing these objectives will require of a number of essential preconditions to be fulfilled by the purchasers and their defined model of governance:

- strong political commitment
- trust between collaborating parties
- price transparency
- market analysis
- effective communication between internal and external stakeholders
- efficient financial management, including prompt payment of purchases made
- continuity through multi-year contracting that enables stable supply sources and fosters closer ties between participants
- clarity on management responsibilities for the collaborative procurement process and their remuneration
- sharing of information and good practices
- Ongoing commitment to honour the conditions of the procurement agreement.

Not only these key elements will need to be considered but also the totality of the risks identified in Annex I, representing the totality of risks that can be faced by the Buyer Group during both the preparatory and execution phase of a tender procedure in a full joint tender.

The model 3 reflects closely the joint procurement agreement – JPA the EC has put in place.

ANTISUPERBUGS-PCP^{11[6]} project can serve as an example of Model 3 cross-border procedure, where six procuring entities went through a full joint PCP tender resulting in a common contract. To do so, a well-structured Joint Procurement Agreement was signed where, among other issues, model of governance was properly and strictly defined. The model might be best suited for procurement of research outside of national procurement legislation.

¹¹ ANTISUPERBUGS-PCP Project (GA: 688878) - <http://antisuperbugs.eu/>

Governance's elements to consider according to the procurement procedure

Public procurement rules are no longer only concerned with 'how to buy'; now they also provide more incentives to focus on **'what to buy'**, without prescribing it. Today, spending taxpayers' money is seen in a wider dimension than merely satisfying the primary supply of public entities. With each public purchase, the public opinion is rightly interested to know whether the procured solution is not only formally compliant but also whether it brings the best value in terms of cost-efficiency, quality of care, environmental and social impact and whether it opens opportunities for the suppliers' market¹².

Given the work undertaken on Task 2.1 by CMS (BE) and CMS UK, we have current knowledge that the chosen legal procedure will depend on the answer to 'what to buy' question.

- Already existing product/solution → open/restricted procedure
- Product/solution to be adapted/developed (without R&D phase) → Competitive procedure with negotiation
- Impossible to describe the product aimed to achieve the objective → Competitive dialogue
- Product/solution to be developed (R&D phase) → innovation partnership

Governance arrangements will need to be adjusted according to the different type of procedure used in the procurement process, based on the level of workload for CAs as well as the additional risks that each procedure comprises¹³ and the best suited cross-border cooperation model to use will also be impacted, the legal guidance (D2.1) provide an overview of the specificities of the different procedures as well as advantages and disadvantages. Complementing to these, we elaborated consideration related to the consequences for the governance:

Open procedure

Open procedure is an ordinary procedure that can be used for any public procurement contract. As specified in Article 127(2) of the Rules of Application "procurement procedures are open where all interested economic operators may submit a tender"

Three models of cross-border collaboration can be used in the Open procedure. In case Model 1 is adopted, each procuring entity will publish its own tender according to their local legislation. On the other hand, in Model 2 and 3, a CPA will be signed and where a Lead Procurer is designated and empowered to make the needed actions for running the procurement process according to its local legislation.

Workload for contracting authorities: **HIGH**

All compliant tenders must be examined by the CAs and this can delay the award. Resource intensive for both the CAs and the candidates who have to prepare a complete tender.

Risk of complaints, remedies or regulatory: **LOW**

Decision made with a straightforward focus on the award. Limited transparency risks as an open, transparent, competitive procedure

¹² <https://ec.europa.eu/docsroom/documents/25724/attachments/1/translations/en/renditions/native>

¹³

https://ec.europa.eu/regional_policy/sources/docgener/guides/public_procurement/2018/guidance_public_procurement_2018_en.pdf

Restricted procedure

As an alternative to the open procedure, the restricted procedure can be used for any public contract.

The main difference with an open procedure is that in a restricted procedure all interested economic operators may ask to participate nevertheless, only the economic operators fulfilling the selection criteria and invited may submit a tender for evaluation.

In the same way as in the Open Procedure, three models of cross-border collaboration can be considered in the restricted procedure. Under model 2 and 3, selection criteria to participate in the later tender needs to be agreed by the Buyer Group.

Workload for contracting authorities: **MEDIUM**

Limited number of tenders to evaluate and therefore less resource intensive for the evaluation committee/ BG. Two-stage procedures might be longer in order to respect the required time limits.

Risk of complaints, remedies or regulatories : **MEDIUM**

Greater potential for collusion/corruption due to the increased exercise of discretion by the CAs.

Competitive procedure with negotiation

The purpose of the competitive procedure with negotiation is to provide public procurers with more flexibility in awarding contracts where readymade solutions are not available on the market but a relatively straightforward, transparent and documented negotiation may enable the adaptation of existing elements or the development of an innovative solution that will meet the needs of the public procurer described in the technical specifications.

According to the D2.1 scheme, cross-border models 1 and 2 are recommended to be used in the Competitive procedure with negotiation.

After approval by the Buyer Group (just one in Model 1) of the shortlist of candidates drafted by the Lead Procurer, only these shortlisted candidates will be invited to negotiate. The negotiations shall be carried out, on the basis of preannounced criteria provided for in the tender specifications.

Workload for contracting authorities: **HIGH**

The burden of proof for the circumstances allowing for the use of the procedure rests with the CAs. The CAs are highly involved in the negotiation/dialogue with tenderers. Limited number of tenders to evaluate and therefore less resource intensive for the evaluation committee/ CAs. Two-stage or threestage procedures might be longer in order to respect the required time limits.

Risk of complaints, remedies or regulatories : **MEDIUM**

Greater potential for collusion/corruption due to the increased exercise of discretion by the CA.

Competitive dialogue

The competitive dialogue is a two-round procedure. The public procurer, first, describes its needs in a descriptive document or contract notice, sets the minimum requirements for candidates and defines the contract award criteria based on Best Price Quality Ratio (BPQR).

Typically, this type of the procedure is used in exceptional circumstances of the particularly complex contracts. "A contract is considered to be particularly complex where the CA is not objectively able to define the technical means capable of satisfying the needs or objectives or able to specify the legal or financial make-up of the project" (Article 132 of the Rules of Application¹⁴).

According to the D2.1 scheme, cross-border models 1 and 2 are recommended to be used in the Competitive procedure with negotiation.

Workload for contracting authorities: **HIGH**

The burden of proof for the circumstances allowing for the use of the procedure rests with the CAs. The CAs are highly involved in the negotiation/dialogue with tenderers. Limited number of tenders to evaluate and therefore less resource intensive for the evaluation committee/ CAs. Two-stage or three stage procedures might be longer in order to respect the required time limits.

Risk of complaints, remedies or regulatories : **HIGH**

Greater potential for collusion/corruption due to the increased exercise of discretion by the CAs. Transparency requirements are particularly challenging during the dialogue.

Innovation partnership

Innovation partnership has been established as a new type of procedure for cases where neither of the traditional procedures was adapted to the circumstances of the public procurer or the type of action to be performed.

The main feature of the innovative partnership is that the innovation occurs during the contractual phase once the innovation partner(s) is (are) selected and awarded the contract. In other procedures, innovation typically occurs in the pre-contracting phase and at the moment of the conclusion of the contract; the public procurer already knows what type of solution it is buying.

In simplified terms, innovation partnership can be understood as a restricted procedure followed by a contract containing several milestones comprising the research and development part (creating innovative solution) and the supply of the newly found solution (supplying the innovative solution adapted to the specific needs of the public procurer).

Given this fact, innovation partnership can follow each three mentioned cross-border collaborative models. However, according to the D2.1 scheme, the Innovation Partnership is most suitable to cross-border model 1

Workload for contracting authorities: **HIGH**

The burden of proof for the circumstances allowing for the use of the procedure rests with the CA. The CA is highly involved in the contract execution since it procures and monitors both the research and development and the delivery/deployment of a non-existing new product or service. Potentially, limited number of tenders to evaluate and therefore less resource intensive for the evaluation committee/CA. Three-stage procedures might be longer in order to respect the required time limits.

Risk of complaints, remedies or regulatories : **HIGH**

Greater potential for collusion/corruption due to the increased exercise of discretion by the CA. Transparency requirements are particularly challenging during the negotiation and the contract implementation. Risk of crowding out of other R&D investments and foreclosing of competition for the

¹⁴ Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

delivery/deployment stage (2014 R&D&I State aid rules consider there is no risk of State aid only when the procedure is limited to the purchase of unique/ specialised products or services for which there are no other potential suppliers on the market).

Pre-Commercial Procurement (PCP)

Pre-commercial procurement consists in procuring research and development services, under advantageous conditions, from several economic operators. The research would usually focus on the final stage of development of an innovative solution, just before its commercial deployment.

Pre-commercial procurement is an approach that has been proposed since 2007¹⁵. It puts in practice an exemption from the public procurement directive for research and development services **where the public procurer does not reserve all the benefits** from the research and development service contract exclusively to itself, but **shares them with the economic operators** under market conditions, thus ensuring that there is no State aid¹⁶.

Although three collaborative models are also possible, in the same way as in the Innovation partnership, makes more sense to join efforts among the Buyer Group in order to achieve a one common better technology that individually would not be possible to obtain. Therefore, Model 3 would be recommended in this procedure.

Examples of collaborative procurement having lots have been published (e.g., the tender published General Directorate of Roads in Spain)¹⁷. However, these are no lots per country/buyer but independent and different items where the Buyer Group want to develop technologies.

Workload for contracting authorities: **MEDIUM**

The burden of proof for the circumstances allowing for the use of the procedure rests with the CA. However, the burden of proof is lower compared to innovation partnerships (no crowding out of R&D investments or foreclosing of competition for final delivery of solutions).

Risk of complaints, remedies or regulatory: **LOW**

Decision made with a straightforward focus on the award. Limited transparency risks as an open, transparent, competitive procedure.

¹⁵ Article 25 of Directive 2014/23/EU, Article 14 of Directive 2014/24/EU and Article 32 of Directive 2014/25/EU.

¹⁶ Definition of the pre-commercial procurement in the Communication from the Commission C(2014) 3282, 'Framework for state aid for research and development and innovation', http://ec.europa.eu/competition/state_aid/modernisation/rdi_framework_en.pdf

¹⁷ https://contrataciondelestado.es/wps/wcm/connect/6a734f6d-c2ae-4fe4-b048-fd4057fb5db0/DOC_CD2018-075637.pdf?MOD=AJPERES

Conclusions

While actual initiatives on cross-border collaboration in procurement in Europe are few, there is increasing interest in exploring the potential of this option and a growing body of legislative work that is intended to provide the basis for collaborative initiatives. The international experience provides a few examples of collaborative purchasing of health technologies that have been running for more than two decades. While some are led by a group of countries and others by an international organization, it can be confirmed that there is insufficient evidence to recommend one model over another. However the specificities of how health and social care is organized and financed and given the subsidiarity it will be important to take the consideration of the value to innovate the specific delivery of care over the volume and preferable take a lot based approach unless the challenges to overcome are too high. For the Innovation partnership and especially when limited to a research as part of Pre-Commercial Procurement procedures, it seems more logic to collaborative forces so as to develop more ambitious technologies responsive to the specific needs. The challenge to ensure the development of innovative solutions will then be given to the life science industry and in future tenders the economic most advantageous to respond to the specific needs selected.

The balance between the potential benefits and costs of the different cross-border collaboration models undoubtedly depend on the characteristics of the activities, technologies and countries involved:

In all case, there is a clear cooperation in the preparatory phase. Further collaboration during the pre-tender phase of the execution in the collaborative models (Models 1, 2 and 3). Given the less elements and risks that will need to be considered (e.g., total consensus among on the procurers is not needed and/or less commitment is demanded), coordinated contract notice followed by the issue of individual tenders per Buyer permits a less demanding cross-border model of governance and permits, to adapt preparation phase's common learnings to procurement entities' local contexts.

A collaborative tender having lots/contracts per buyer entails a further level collaboration, and consequently, a more demanding model of governance through BGA and CPA agreement signatures to ensure Buyer Group commitments and to designate a Lead Procurer that will be empowered to make the needed actions for running the procurement process. This model can be recommendable when procuring entities want to foster cross-country learning while still having the capacity to adapt the commonly identified needs to their own specifications and awarding criteria for their individual lots.

Lastly, going through a full collaborative tender resulting in a common contract will require the most challenging and demanded model of governance with a CPA that should guide Buyer Group along the totality of the tender execution phase (also a common awarding criteria) in order to procure a common innovative solution to all the members of the Buyer Group. Additionally, Buyer Group will gain a meaningful learning of a total cross-border procurement experience.

Independently of the chosen cross-border model and procurement procedure, the Buyer Group will be responsible to commonly define a model of governance framework that must ensure an ethical, non-discriminatory and transparent procurement process that considers potential risks and, at the same time, satisfies each member's procurement demands. Evolving from the current joint procurement agreement with a focus on the volume and price to foster access to a selected collaborative procurement agreement driven by value to respond to the specific needs and obtain the economic most advantage way to innovate the specific delivery of care will be critical for a successful adoption of innovative solution by means of cross-border innovation procurement across Europe. An increased readiness of countries and regions to use innovation procurement as a way to transform health care and advancing value-based health care will be fostered by an opportunity to select the most appropriate collaborative model considering the multiple factors highlighted.

References

- [1] Espin, J. Rovira, J. Calleja, A. Azzopardi-Muscat, N. et al. How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe? Health systems and policy analysis. Policy Brief 21.
- [2] Kumar Shakya, R. Procurement governance framework: success to e-government procurement (e-gp) system implementation
- [3] Sanchez-Graells, A. Collaborative Cross-border Procurement in the EU: Future or Utopia? Reprint from procurement law journal. 2016 no 1.
- [4] EU Joint Procurement Agreement on medical countermeasures:
https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_agreement_medical_countermeasures_en.pdf

Annex I. Identified Risks on the PPI procedure on Rapid Diagnosis tool for antibiotic stewardship of VAP

ID	Risk	Likelihood	Impact	Possible Contingency
01	Project partners do not engage with procurement plan		High	Establish an agreed framework for Procurement Governance with the Buyers Group.
02	Failure of procurers' commitment		High	Monitor the commitment of the involved procurers and make sure it is always high. In case it decreases, Lead Procurer should secure the support of high level authorities. Procurers to sign the certification of commitment along with the Procurement Agreement.
03	Project Partners do not share common understanding of PPI and innovation development		High	Provide training on PPI, project and programme management. Hold on-line and/or face-to-face meetings as needed to provide specific clarifications to the procuring authorities. Development of the agreed PPI Procurement framework to ensure common understanding.

ID	Risk	Likelihood	Impact	Possible Contingency
04	Political changes in the procuring authorities regions could modify their commitment to the project or operational capacity		High	Lead Procurer will need to keep monitoring the political scenario of each of the participating regions.
05	Procurement Teams not updating progress of the procurement development		High	<p>Provide training on use of the selected PPI Tool.</p> <p>Hold web and face-to-face meetings.</p> <p>Clear definition of roles and responsibilities according to the Grant Agreement, the Consortium Agreement and/or the PPI Framework; including the creation of the Tendering Board and the Experts Board to support the implementation and evaluation of the procedure.</p>
06	Procurement Teams having difficulties in managing competitions and projects		Medium	Provide training on how to manage competitions and projects using the selected online tool.
07	PPI challenge is not realistically achievable given time, cost and technology limitations		High	Implementation of a detailed State of the art assessment and Technical Surveillance, completed with the open dialogue with the industry through Open Market Consultation (OMC) to understand the Technology Readiness level.

ID	Risk	Likelihood	Impact	Possible Contingency
08	Use Cases not defined		Very High	Scientific coordinator will work closely with the procurers on use case definition for the EURIPHI-VAP solution. Whenever feasible, internal stakeholders from procuring entities will be involved in the validation of the Use Cases.
09	Use Cases defined at project level not full in line with regional priorities		High	Scientific coordinator will work closely on the definition of common areas of interest of all the procurers, leaving space for adaptation of use cases according regional needs
10	Incoherent message to key stakeholders about the key EURIPHI –VAP requirements specified for a call for tender.		High	Make sure with partners that all presentations provide coherent message and communicate not only about their own organisations needs but also on common EURIPHI-VAP requirements.
11	Uncontrolled communications between partners and potential bidders during PPI preparation.		Medium	Ensure the compliance with procurement principles during OMC phase. Lead Procurer has subcontracted the provision of legal services to support the design and implementation of the procurement procedure. One of the requirement the selected legal firm needed to comply is the experience in PPI and in the appropriate legal and contractual implementation.

ID	Risk	Likelihood	Impact	Possible Contingency
12	Suppliers not joining competition		High	Promote the PPI via Member State networks covering academy, research centres and industry, related EU projects and procurement networks. Definition of the Project. Dissemination and Exploitation plan considering this risk. Specific meet-the-market events to be implemented during the OMC phase of the project to increase market engagement.
13	Low engagement of SMEs		Medium	Define and deploy efficient and direct dissemination tactics. Dissemination and Exploitation plan considering this risk.
14	Bias on the bidders participation due to geographical market price differences from South of Europe to North of Europe and from SMEs to large enterprises		Very High	EURIPHI consortium need to work very closely with industry players to understand better market conditions and make sure all kind of players are clear on the benefits and market potentials if joining the call
15	Awarded company go bankrupt while expected to produce their deliveries		High (one = Medium; more = high)	Criteria of selection will include the review of the accountancy books and the delivery of the commercialization plan. In the call definition it will be made clear that the payment will be phased according to the progress of the delivered work and specific clauses will be introduced (e.g.: in case an awarded SME cannot complete the delivery, the money will be re-assigned to the next bidder in the ranking list or re-distributed between the remaining bidders).

ID	Risk	Likelihood	Impact	Possible Contingency
16	Supplier does not deliver against agreed milestones		High	<p>Ensure a coherent definition of the evaluation procedure in order to select a supplier who are likely to delivery what they claim.</p> <p>Ensure Expert Board Panel and Tendering board manage the implementation of the contracts using PMPT and offline communications</p>
17	Claims received from bidder generating delay on the implementation of the procurement		Medium	<p>Ensure a clear definition of the evaluation criteria and tender requirements to ensure the consideration of the public procurement principles, as part of the PPI Procurement platform.</p> <p>The provision of legal services to support the design and implementation of the procurement procedure might be subcontracted. One of the requirement the selected legal firm needed to comply is the experience in PPI and in the appropriate legal and contractual implementation of the evaluation criteria.</p>
18	Complexity to define common needs due to diversity of Procuring entities		High	<p>Needs elicitation methodology and tools developed to ensure representation of all procurers and to facilitate the prioritization of needs. Going through a Collaborative Procurement with individual tenders can be a solution</p>

ID	Risk	Likelihood	Impact	Possible Contingency
19	The Initiative does not engage with other related EU programmes		Medium	Attend conferences and EU dissemination events to disseminate progress and to network.
20	Creation of excessive workload at the Microbiology labs due to increase in sample collection.		High	Ensure assessment of performance indicators, including economic indicators and data activity
21	Change in MDRO priorities due to specific infection outbreak (epidemic cycles) along entire project life-time		Medium	Inclusion of specific functional requirements regarding flexibility of the solution to include new detection capabilities.
22	Emergence of new relevant MDRO in VAP		Medium	Inclusion of specific functional requirements regarding flexibility of the solution to include new detection capabilities.

Annex II. Specific provisions applicable in the case of a negotiated procedure in Joint Procurement

1. Where the joint procurement is pursued through a negotiated procedure, paragraphs 2 to 8 shall apply to:

- (a) the invitation to submit offers for negotiation;
- (b) the negotiations with tenderers or their representatives;
- (c) the evaluation of the tenders.

2. In negotiated procedures without prior publication of a contract notice in the Official Journal of the European Union, the Lead Procurer shall submit a draft shortlist of candidates that it proposes to invite to negotiate, for approval by the Buyer Group Steering Committee, in accordance with Article 7.

3. Following the approval referred to in paragraph 2, the Lead Procurer shall, on behalf of the participating Contracting Parties, invite the shortlisted candidates to negotiate.

4. In negotiated procedures, following publication of a contract notice in the Official Journal of the European Union, the procedure may take place in stages by applying the award criteria set out in the tender specifications to reduce the number of tenders to be negotiated. If so, the tender specifications shall stipulate that this option is to be used and shall indicate how it shall be used. If the option envisaged under the first subparagraph is used, an evaluation committee set up in accordance with Articles 8 and 9 shall submit an evaluation report, for approval by the Buyer Group Steering Committee (BGSC) in accordance with Article 7, with a list of tenderers to be eliminated from participating in further stages of the joint procurement procedure based on application of the award criteria.

5. Following approval as referred to in [the second subparagraph of] paragraph 4, the Lead Procurer, acting on behalf of the participating Contracting Parties, shall notify each excluded tenderer of the reasons for its exclusion from further stages of the joint procurement procedure. The notification shall be made in accordance with Article 161(3) of the Rules of Application. Such notification shall be made as soon as practicable following the approval by the BGSC.

6. The negotiations shall be conducted by (an) evaluation committee(s) set up in accordance with Articles 8 and 9 with tenderers that have not been excluded or declared unsuccessful in accordance with Article 20(2) or through the application of the option envisaged under paragraph 4 of this Article.

7. The negotiations shall be carried out in accordance with Article 129 of the Rules of Application and on the basis of pre-announced criteria provided for in the tender specifications.

Where the negotiations are conducted orally, a written record of the negotiations shall be drawn up by the evaluation committee(s) referred to in paragraph 6. It shall be sent to the tenderer concerned, indicating a time limit for communicating any proposed addition or correction. During meetings with tenderers, the evaluation committee(s) shall be represented by at least two members, one of whom is designated by the Lead Procurer and another nominated by a BGSC. Oral negotiations may only be conducted where there is only one candidate, due to a monopoly situation, pursuant to Article 134(1)(b) or if the negotiations take place with a tenderer awarded the initial contract, in situations referred to in Article 134(1)(e) or (f) of the Rules of Application. Unless otherwise specified in the tender documents, the negotiations shall be strictly limited to the content of the tender and shall not modify initial terms of the technical specifications and/or contractual provisions.

8. During the negotiations, tenderers may be requested by the evaluation committee(s) to modify their tenders, in which case their offers shall be evaluated on the basis of their modified tenders.

Annex III. Specific provisions applicable in the case of a competitive dialogue in Joint Procurement

1. Where the joint procurement is pursued through a competitive dialogue procedure, paragraphs 2 to 7 shall apply to dialogues with candidates and their representatives that have not been excluded or declared unsuccessful in accordance with Article 20(2) or through the application of the option envisaged in paragraph 3 of this Article.
2. The dialogues shall be conducted by (an) evaluation committee(s) set up in accordance with Articles 8 and 9, in conformity with Article 132 of the Rules of Application. A written record of the dialogues shall be drawn up by the evaluation committee(s) referred to in the first subparagraph. It shall be sent to the candidate concerned, indicating a time limit for communicating any proposed addition or correction. The evaluation committee(s) shall also draw up a report setting out its overall assessment of and recommendations on the results of the dialogues, in particular on whether or not the dialogues should be concluded. The dialogues shall not concern the contract notice or descriptive document referred to in Article 132 of the Rules of Application.
3. The dialogues may take place in successive stages in order to reduce the number of solutions to be discussed by applying criteria set out in the descriptive document accompanying the contract notice. Where that is the case, the descriptive document shall stipulate that this option is to be used and indicate how it shall be used. If the option envisaged under the first subparagraph is used, an evaluation committee set up in accordance with Articles 8 and 9 shall submit an evaluation report, for approval by the BGSC in accordance with Article 7, with a list of candidates to be excluded from participating in further stages of the joint procurement procedure based on application of the criteria set out in the descriptive document.
4. Following approval as referred to in [the second subparagraph of] paragraph 3, the Lead Procurer acting on behalf of the participating Contracting Parties shall notify each candidate that has been so excluded of the reasons for their exclusion from further stages of the joint procurement procedure. The notification shall be made in accordance with Article 161(3) of the Rules of Application. Such notification shall be made as soon as practicable following the approval by the BGSC.
5. Before concluding the dialogues, a proposal informing candidates that the dialogues are concluded and inviting them to submit their final tenders on the basis of solutions presented and specified during the dialogues, shall be submitted by the Lead Procurer for the approval by the BGSC in accordance with Article 7.
6. Following approval as referred to in paragraph 5, the Lead Procurer, acting on behalf of the concerned Contracting Parties, shall notify each participant in the dialogues that has not been eliminated under paragraph 4 of the conclusion of the dialogues and shall invite them to submit their final tenders on the basis of solutions presented and specified during the dialogue. The notification shall be made in accordance with Article 113(2) of the Financial Regulation and Article 161(3) of the Rules of Application. Such notification shall be made as soon as practicable following the approval by the BGSC.
7. The tenders submitted shall be evaluated by the evaluation committee(s) referred to in paragraph 2, in conformity with the second and third subparagraphs of Article 132(4) of the Rules of Application.