Platform for Innovation of Procurement
and Procurement of Innovation

**D2.4 · Report on procedures and criteria to
identify/recruit patient stakeholders**

PIPPI

GA No 826157

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History of changes

Change	Date/Beneficiary	Explanation
First preparation for submission deliverable 2.4	May 2019/ HUVH	First version of deliverable 2.4 was send to coordinator for submission
Submission deliverable 2.4	May 2019/ Karolinska	Coordinator upload first version of the deliverable
Revisions made based on reviewers' comments	December 2020 / HUVH	First draft of revisions according to the mid-project review, distributed to partners for review
Content adjusted based on comments from partners	December 2020 / HUVH	Revised document based on comments, sent to coordinator for submission
Revised Word and PDF versions	December 2020 / Karolinska	Upload to portal

This deliverable includes all information regarding the identification of the identity, role and criteria specifically of patient stakeholder group in PIPPI project. This explains the inclusion of a theoretical frame in the deliverable. This deliverable has been adjusted due to reviewers comments including new sections 5 and 6. Furthermore, the rest of the sections have been adapted in response to reviewer, and also including the learnings and previous experience and to adapt to the new situation due to Covid-outbreak.

Moreover, the identification and role of other stakeholders groups (policy makers, industry, healthcare providers, research & innovation community, payers and enablers) have been briefly described, together with the description of the presentation workshop in the annex, due to reviewer comments. However, an in deep description will be submitted in deliverable 2.1.

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List of abbreviations

CoP: Community of Practice
PCAG: Patient/Citizen Advisory Group
D: deliverable
T: task
EUHA: European University Hospital Alliance
PIPPI: Platform for Innovation of Procurement and Procurement of Innovation
HUVH - Hospital Universitari Vall d'Hebron
Karolinska - Karolinska University Hospital
HUS – Helsinki University Hospital
OSR – Ospital San Raffaelle
MUW – University of Medicine Wien
King's – King's College Hospital
Erasmus MC – Erasmus Medical Center
PCP- Pre-Commercial Procurement
PPI - Public Procurement of Innovation
WP - Work Package

Glossary

Community of Practice: gathering of individuals motivated by the desire to cross organizational boundaries, to relate to one another, and to build a body of actionable knowledge through coordination and collaboration. More colloquially, a CoP is a group of people who share a concern or passion for something they do, and learn how to do it better as they interact regularly.[1]

PCP: Pre-Commercial Procurement (PCP) challenges industry from the demand side to develop innovative solutions for public sector needs and it provides a first customer reference that enables companies to create competitive advantage on the market. PCP enables public procurers to compare alternative potential solution approaches and filter out the best possible solutions that the market can deliver to address the public need.[2]

PIPPI Platform: Technical enabler of PiPPI CoP functionalities

PPI: Public Procurement of Innovative solutions (PPI) facilitates wide diffusion of innovative solutions on the market. PPI provides a large enough demand to incentivise industry to invest in wide commercialisation to bring innovative solutions to the market with the quality and price needed for mass market deployment. This enables the public sector to modernize public services with better value for money solutions and provides growth opportunities for companies.[3]

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[1] http://documents1.worldbank.org/curated/en/188671504682900121/pdf/119411-REVISED-PUBLIC-Community-Primer-2018-Final-2-21-2018.pdf

[2] https://ec.europa.eu/digital-single-market/en/pre-commercial-procurement

[3] https://ec.europa.eu/digital-single-market/en/public-procurement-innovative-solutions

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1. Purpose of document

This document describes the procedures and criteria that will be used to identify, select and recruit patients/citizens throughout the PIPPI Project. These procedures and criteria are likely to be further developed during the development and following establishment of the Community of Practice (CoP).

This deliverable lies within the framework of Work Package 2, the aim of which is to identify all stakeholder clusters, including patients/citizens, and to analyse their contributions in terms of provided value and incentives as well as their involvement in the CoP, with an ultimate goal of ensuring sustainability of its value. Two different approaches of participation are defined according to two different objectives of their involvement: *1) To identify, formulate and prepare procurement for unmet needs*. In order to conduct task 2.1 (define and map the stakeholders [SH]) and task 2.2 (engagement and monitoring of SH), a clear strategy for the identification, engagement, enrolment and selection of patients/citizens has to be set on the organizational level (i.e. patient associations) and the individual level (i.e. expert patients); and *2) To provide input and get involved in the development of procedures and functionalities of the CoP*, a Patient/Citizen Advisory Group (PCAG) will be set up (task 2.3). The PCAG will offer insight on relevant issues, thus ensuring the stakeholder input for the development and future operation of the CoP.

This document also aims to set the basis for ensuring that the principles of inclusivity, representativeness and ethics are accomplished in the project by considering the specificities of the clusters of patients/citizens.

2. Background and introduction

Procedures and criteria defined in this document are based on the specific needs of the PIPPI project and have been defined on the basis of:

1) Input and current practices from the PiPPi Consortium partners (Annex 1)

2) The conceptual framework of the project, which include the Framework of Communities of Practice (Wenger, 1998)

3) Frameworks developed in the international context, including:
   a. The UN Framework aimed at guarantying the inclusivity of patients (UN Committee for Development Policy's pledge to leave no one behind and the UN's 2030 Sustainable Development Agenda (UN News Centre, 2015; Why leaving no one behind matters, 2018))
   b. The Engagement Framework proposed by the International Association for Public Participation (IAP2) (International Association for Public Participation, 2014)

2.1. PIPPI Project

The **digital transformation** of healthcare asks for the procurement of innovative solutions for which public-private collaborations are essential. These collaborations are often reactive and not fully connected with the real needs and specifications of the healthcare professionals and patients. To address this challenge, the demand side should be in the driver seat regarding innovation procurement in healthcare. Therefore, the PIPPI (platform for innovation procurement and procurement of innovation) project aims to create a cross-border CoP of European university hospitals that will bring together experts from the demand and supply side to identify common clinical needs for digital healthcare solutions and procurement of innovation.

The consortium includes **seven major European university hospitals** offering expertise on digital healthcare, patient-centred care and procurement with the ultimate aim to solve shared clinical challenges. The project will engage relevant stakeholders involved throughout the innovation procurement process at a regional, national and European level. The consortium with its network partners such as industry and payers of healthcare, will gather best practices, and develop structural capital and tools around procurement. These results will be shared through a knowledge platform on a European level by actors involved in, planning or interested in procurement of innovation. The consortium will identify major clinical needs from seven university hospitals spread around Europe and compile a short-list of challenges that are suitable to solve with digital solutions and for procurement of innovation. This shortlist will be the base for a feasibility study and preparation of a concrete cross-border PCP or PPI. To ensure the future use of project results, including long-term assessment and monitoring of outcomes, the PIPPI project will develop a business and implementation plan with the ultimate goal to make the platform sustainable and improve patient outcome, decrease healthcare costs, create growth for European life science industry and create new markets.

The PIPPI project consists of seven **Work Packages (WP)**, each with a set number of tasks, of which several are clearly linked with each other. WP2 aims to ensure that all relevant stakeholder groups must be analysed in terms of value provided, incentives, and involvement, to be able to build the planned CoP, and ensure that the principles of an open innovation ecosystem are applied and provide sustainable value.

Figure 1. WP2 structure and relationship between tasks and deliverables
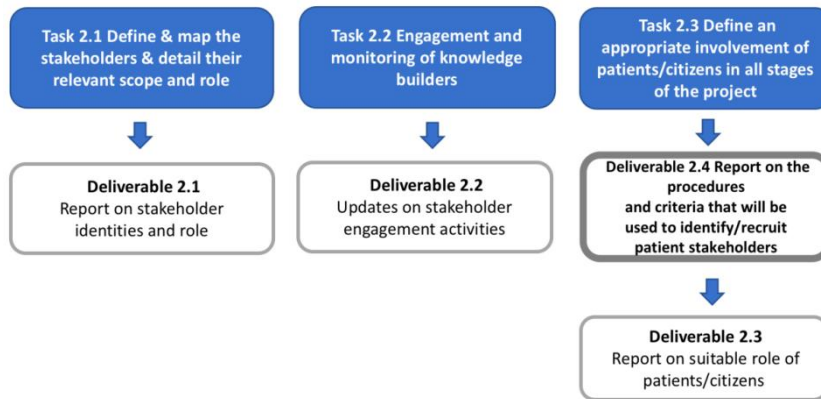
The PIPPI consortium has inventoried its network and will attract and enrol already identified, as well as, new stakeholders within the local ecosystems in all the relevant stakeholder groups to ensure that all steps of value-based innovation procurement are taken. The aim is to activate a strong and credible stakeholder network which can be scaled beyond the project scope and duration, establishing a sustainable and successful open innovation ecosystem centred on the CoP vision.

In this deliverable 2.4 we will discuss the identification of the identity, role and criteria specifically of patient stakeholder group. The identification and role of the other stakeholders groups (policy makers, industry, healthcare providers, research and innovation community, enablers and payers) (Figure 2) will be further developed and discussed in the frame of deliverable 2.1. but we have also reported briefly in Annex 3in this deliverable. As it can be seen in figure 1, and to avoid the overlap between deliverable 2.1 and 2.4, we will include in this deliverable all the information related to patients.

Figure 2. Stakeholder clusters identified to participate in PiPPI Community of Practice
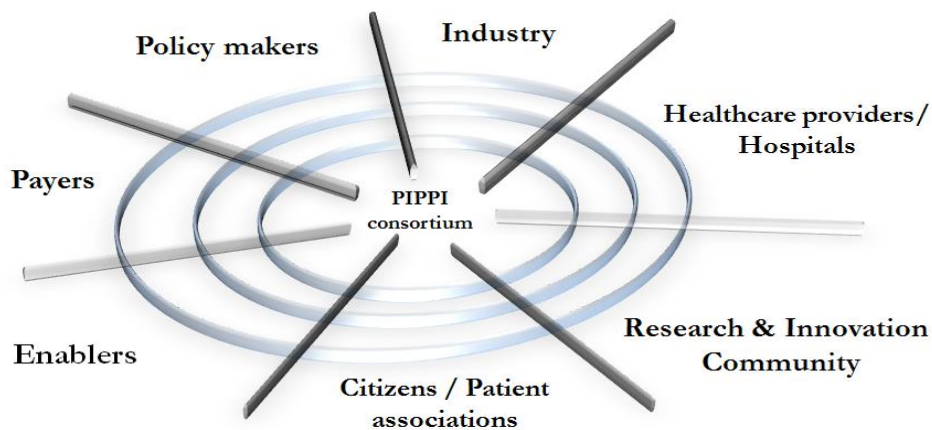
2.2. The role and scope of patient/citizens involvement in the PIPPI project

The engagement of patients and citizens is needed throughout the PiPPi project since they play an essential role as stakeholders at the point of service of the delivery of care. Patient involvement is central to the pursuit of sustainable allocation of financial resources in healthcare, as patients who know how to navigate through the healthcare system tend to use more efficiently resources available. Engaging patients both through the patient/citizen advisory group and other forms of participation enables for a better assessment of patients' needs, envisioned outcomes and expectations, all of which are key at different stages of the innovation procurement process.

Doing so ensures that resources are allocated where it matters most to patients and improve acceptance of the innovation, in line with the highlights of the 2017 OECD report on tackling wasteful spending on health (OECD, 2017).

Patient and citizen participation in the redesign of healthcare processes and services is central to the ideas of patient-centred care and patient empowerment. However, as several authors have noted, this process can sometimes be limited (Morrison & Dearden, 2013; Ocloo & Matthews, 2016). This is often the case when different stakeholder clusters hold asymmetric roles in a given process (Ansell & Gash, 2008). The characterization of patient engagement allows for a better understanding of patients' roles in the introduction and adoption of innovations in health services and aids in the design of strategies to maximize their involvement.

The course of the PIPPI Project aligns with the ongoing trend towards establishing patients and citizens at the centre of the delivery process to ensure they receive the care they need. All in all, there is vast potential for patient engagement throughout the innovation process using methods of co-creation, both at the level of identifying, formulating and preparing procurement for unmet needs and the level of participating in the development of procedures and functionalities of the CoP. A broader involvement of the patient stakeholder cluster is likely to place a spotlight on technology supported self-management and will thus boost and redirect innovation in the direction of patient empowerment.

Below is detailed the general framework employed to define the kind of participation sought thorough the PIPPI project, distinguishing between the two previously described objectives: to identify, formulate and prepare procurement for unmet needs (section 2.2.1) and to provide input and get involved in the development of procedures and functionalities of the CoP (section 2.2.2).

2.2.1 To identify, formulate and prepare procurement for unmet needs

Patient/citizen will be involved in the CoP functionality and, more specifically, in the identification, formulation and preparation of procurement for specific unmet needs/opportunities (see figure 1). They will provide insight and patient input on specific areas of unmet needs and/or opportunities; for

example they will be engaged in multi-competence team work for identifying challenges and/or opportunities.

Figure 3. The main process of the CoP both for the duration of the PIPPI project and the future CoP once established[4]
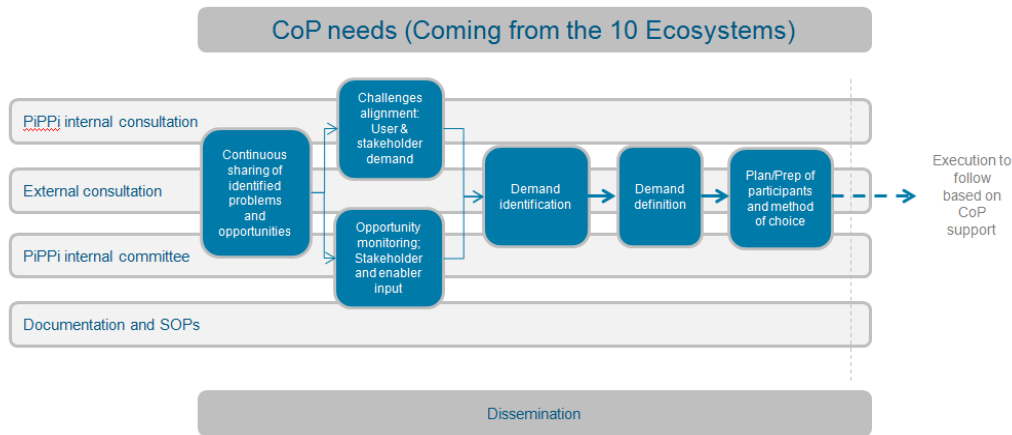
The engagement of patients will follow a dynamic process according to the stage of the CoP and the profile of patients (see Table 1). For this purpose, different levels of patient engagement are defined, following the classification proposed by the International Association for Public Participation (IAP2) Patient Participation Spectrum (International Association for Public Participation, 2014). Three different levels of engagement are considered relevant for our context.

1. Inform: patients will receive information to assist them in understanding problems, opportunities and/or solutions for unmet needs. Patients for example may receive the information through newsletters or the webpage. This is the lowest level of engagement in the project.
2. Participate: patients will provide specific feedback on analysis, alternatives and/or decisions related to unmet needs. Patient input may be obtained through quantitative or qualitative methods (such as focus groups or surveys).
3. Collaborate: patients will provide data and resources to obtain feedback as consultants in specific stages of the project through participative techniques such as working groups. Collaboration is the highest level of engagement.

Table 1 describes these three stages in combination with the different phases of patient participation in innovation and present some examples of possible strategies to engage patients/citizens.

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[4] Based on the main CoP process, three distinct phases can be identified in the project: **Phase 1** is the "continuous sharing of identified problems and opportunities" and works in a continuous loop, compartmentalized from the actual solution development process; **Phase 2** encompasses Challenge Alignment and Opportunity Monitoring, which has the development of draft proposals of specific needs and/or solutions as an outcome; **Phase 3** encompasses Demand Identification, Demand Definition and Plan / Preparation of Participants and represents a linear solution development process.

Table 1. Characterization of patient engagement[5]

STAGE	Level of engagement		
	Inform	**Participate**	**Collaborate**
Need assessment	Dissemination of information at the early stages of the process among patients and the opportunity to ask for further information *(i.e. newsletters, info on web page, provision of email address for inquiries…)*	Participation of patients as subjects in needs assessment research *(i.e. primarily through quantitative techniques such as questionnaires or qualitative techniques such as interviews)*	Participation of patients as consultants in needs assessment activities *(i.e. through requests for open feedback, participation in workshops, Delphi…)*
Solution	Dissemination of information at the early stages of the process among patients and the opportunity to ask for further information *(i.e. newsletters, info on web page, provision of email address for inquiries…)*	Surveying patients on their preferences regarding potential solutions and other parameters that affect viability *(i.e. primarily through quantitative techniques such as questionnaires or qualitative techniques such as interviews)*	Inquiring patients on their preferences regarding potential solutions and other parameters that affect viability *(i.e. through requests for open feedback, participation in workshops, Delphi…)*
Implementation	Dissemination of information of the solution among potential early adopters patients and the opportunity to inquire about purchase options *(i.e. newsletters, info on web page, provision of email address for inquiries…)*	Surveying patients on their preferences regarding different parameters of the solution *(i.e. primarily through quantitative techniques such as questionnaires or qualitative techniques such as interviews)*	Inquiring patients on the acceptance of the solution and other general feedback *(i.e. through requests for open feedback, participation in workshops, Delphi…)*

Following table 1 patient engagement levels different actions will be followed through PIPPI project CoP project to include patient and citizen participation to identify, formulate and prepare procurement for unmet needs.

- During all phases (need assessment, solution, implementation) patients, citizens and patient associations will be actively encouraged to become stakeholders of PIPPI project CoP through specific contacts, events and dissemination

Need assessment:
- Patients, citizens and patient associations will be encouraged to share their needs through PIPPI platform
- Patients, citizens and patient associations will be invited to participate in focus and working groups to validate the unmet needs/challenges proposed through PIPPI platform to

Solution:

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[5] Adapted from the IAP2's Framework (International Association for Public Participation, 2014)

- Patients, citizens and patient associations will be invited to participate in surveys, focus and working groups during the process of ideation to obtain solutions that coverts their demands, regarding values and outcomes.
- Patients, citizens and patient associations will be actively encouraged to become stakeholders of PIPPI project CoP through specific contacts, events and dissemination

Implementation:
- Patients, citizens and patient association's participation in looking for and development of the solution will be also complemented with their participation through the implementation phase of the procurement. They will be invited to participate to ensure that during the procurement process, their values or important outcomes for them are considered.

2.2.2 To provide input and get involved in the development of procedures and functionalities of the CoP

Patient and citizens will be involved to give input in developing the procedures and functionality of the CoP to ensure their concerns and aspirations are consistently understood and considered, providing feedback on the plan, performance and outputs of the PIPPI Project. For this purpose a patient/citizen advisory group (PCAG) will be created. Their involvement will lead to participate in consulting and in decision taking from PIPPI core. Its purpose is to offer insights on relevant issues by providing:

- Advice to ensure that the PIPPI project develops in accordance to patients' and citizens' needs, perspectives and expectations. Some of their functions are the provision of input, test and feedback in the development of processes, advice on incentives for patient participation, and identification and verification of focus areas, dissemination activities on the PIPPI project and engagement of stakeholders, and ensuring gender perspective is included during PIPPI process.
- Orientation and feedback on strategies of dissemination and exploitation of the results of the project. For example, dissemination activities on the PIPPI project and engagement of stakeholders.
- Co-creation of the training process (i.e. content, means and duration) of future PCAG members and informational package for individual patients who may be recruited as participants in specific activities related to the PIPPI project or future CoP.

3. Procedures and criteria to identify/recruit patient stakeholders

Procedures and criteria are described separately to reach the following two objectives:
.1. To establish a method for the identification and selection of patients and citizens at the different stages of the PIPPI Project, as an active part of the CoP,

in which they are expected to participate in the identification, formulation and preparation of procurement for unmet needs.

.2. To define the process of identification and selection of patient/citizens for the constitution of the patient advisory group, this is aimed at providing input and get involved in the development of procedures and functionalities of the CoP.

3.1 Identification and selection of patients and citizens at the different stages of the PIPPI Project

Associations of patients/citizens and individual patients/citizens will be identified, selected and recruited throughout the PIPPI project, following a dynamic, iterative process, in order to contribute to identify, formulate and prepare procurement for unmet needs. Patient associations will have an important role on advising how communication with patients should be done. When necessary, individual patients will be approached in the project.

3.1.1 Defining the source for patient/citizen identification

In principle, three main strategies could be used to identify and select patients. The strategy to use in each phase will be defined according to the characteristics of each organization, their previous experience working with expert patient and associations, the aim of patient/citizen selection and the required characteristics of patients/citizens. In both cases we will consider existing relationships between the PIPPI partners and the associations and expert patients.

i) The identification and selection of patients/citizens is led by patient associations, as representatives of the patient cluster. The selection of those patients will be made by associations following the selection criteria and support provided by the partners of the PIPPI Consortium. This will be the priority chosen method for identifying patient and citizens

Given the number, diversity and volatility of patient organizations, developing an **inventory** suppose a complex task. The initial method for the identification of patient associations by PIPPI partners will be as part of the stakeholder identification exercise, through the development of the stakeholder inventory (WP2 task 2.1). Gatekeepers, staff such as customer service managers, as well as clinicians who are in contact with collaborating patient associations, are vital for the adequate inclusion of patient associations in the stakeholder inventory and are therefore critical for identifying patient associations. If the associations listed in the inventory do not meet the ad-hoc criteria for the selection of patients or patient associations for a given project, partners will be in charge of the search and identification of additional suitable organizations and their addition to the inventory, ideally appointing gatekeepers within their institution to complete the task. All associations included in the inventory will be asked for a means of contact and also will be asked for some initial input related to concerns about the project scope and possible incentives for participation. Periodic updates on the stage of

the project and future CoP, as well as updates on meetings will be sent to associations for as long as they are included in the inventory.

ii) The identification and selection of patients/citizens is made through direct engagement between partners and individual patients or citizens. Partners may identify potential gatekeepers in their own organizations, defined as people who are in contact with patients who have some sort of participation within the institution (i.e., customer service managers, clinicians). Gatekeepers may be involved in the project in order to support in patient identification, selection and contact.

iii) The identification and selection of patients/citizens is made through PCAG. PCAG may be gatekeepers for identifying potential patients or citizens. Required patients and citizens can be recruited after an active call from the PCAG or may have been presented as volunteers themselves through PCAG email contact address.

In any case, PIPPI Consortium will keep or use information regarding patient pathology or health record, and gatekeeper will be the once responsible to recruit patient/citizens.

Independently of the identification process they follow, all patient associations' representatives and individual patients/citizens will be included in the inventory, and will convey for an informational meeting where a brief formation will be given regarding the following items:
- The EUHA
- The PIPPI project and future CoP
- Basics of innovation procurement processes
- Patient involvement and tasks in the project and future CoP

This formation template will be available in the platform for all partners and new recruited patients/citizens that may require to go through the formation process. Upon identification of, and regardless of the means chosen to establish contact with associations or individual patient/citizen, an official letter of invitation including a consent form will be sent on behalf of the PIPPI Consortium.

3.1.2 Inclusion criteria

Inclusion criteria refer to specific skills and characteristics that patients/citizens are required to meet to ensure that they are able to properly contribute to the project at the expected level. The main types of inclusion criteria that will be considered are:

- **Patient/Citizen characteristics.** The specific criteria for patient/citizen selection may vary from case to case and must therefore be tailored for each particular situation. These may include dimensions such as age, type of stakeholder, pathology or presence of disability among others.
- **Patient/Citizen skills** which may be required to collaborate or to be involved in the

project. These may include some of the following: appropriate communication skills, knowledge of regional languages, absence of relevant conflict of interest, previous experience in co-creation processes, and capacity and availability to travel (if activities demand travelling).

- **No relevant conflict of interest (CoI).** CoI will be defined case by case by all partners and no bias situation may occur during the engagement.

3.1.3 Variation criteria

The selection of patients/citizens aims for the maximum achievable level of inclusivity and representativeness of experiences, needs and expectations, and will be appropriate in tasks/activities with methodologies of **qualitative nature** such as working groups, focus groups and individual interviews. Maximum variability will be sought according to the following criteria:

- **Type of stakeholder**: different groups can be identified within the Patient & Citizen stakeholder cluster. Whereas these groups may find common ground in their needs and goals, each one may offer a unique insight at each stage of the innovation procurement process. Three different stakeholders are identified:
  - ✓ Patients: for the purpose of this project, a patient is a person that has become a user of the healthcare system in relation to an existing diagnosis. Certain types of former patients who have been declared disease free can be included in this category so as not to lose valuable insights (cancer survivors, congenital defects, etc.).
  - ✓ Family members & informal caregivers: are unquestionable components of the healthcare delivery ecosystem. As such, they have needs on their own and are able to provide unique views on the procurement of solutions for both patients' needs and their own. Relatives and caregivers are especially relevant for children and adolescents, older adults, people with cognitive impairments, etc.
  - ✓ Citizens: for the purpose of this project, a citizen is a person that it is or will be user of the healthcare system, without relation to a current existing diagnosis.
- **Gender:** We employed an inclusive perspective of gender that includes three categories[6]: 1) people who identify as female; 2) people who identify as male; and 3) people who identify themselves as either a combination of genders or neither gender.
- **Geographic area:** When applicable, samples of patients should include representatives from as many of the partner countries as possible.
- **Educational Level:** We will consider three categories of educational level, which are clusters of the categories described in the International Standard Classification of Education (ISCE 2011): 1) Less than primary, primary and lower secondary

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[6] In accordance to Resolution 2048 of 2015 on the discrimination against transgender people in Europe, gender rather than sex is the preferred variable for inclusive sampling.

education (ISCE levels 0-2); 2) Upper secondary and post-secondary non-tertiary education (ISCE levels 3-4); and 3) Tertiary education (ISCE levels 5-8). Partners will be encouraged to include representatives of all three educational levels.

Additional criteria may be used to further guarantee that no collective is underrepresented and according to the specific aim defined in each task/activity of a specific innovative procurement. These may include but are not limited to age, migration status, disability, religion or disease.

Upon identification and regardless of the means chosen to establish contact with the patient, an official letter of invitation will be sent on behalf of the PIPPI Consortium or project coordinator. Partners are free to establish contact with individual patients in whichever way they find most appropriate in order to produce the desired outcome and necessary documents (i.e. consent and participation forms) but PIPPI Consortium will not keep or use any information regarding patients pathology and health records. Collaboration with associations is strongly encouraged.

3.2 Construction of the patient citizen advisory group (PCAG)

In order to ensure the success of the PIPPI project it is necessary to ensure the participation of patients throughout the project. A specific group of patients and citizens (advisory group) will be recruited and selected in representation of this stakeholder cluster with the aim of providing feedback on the plan, performance and outputs of the PIPPI Project. The mission, vision and values of the PCAG are:

Mission: the PCAG has the mission to be the representative body of citizens and patients through the different stages of development of PIPPI project.

Vision: citizens and patients participation in PIPPI project together with other stakeholder, through patient association or individual patients/citizens is key to guarantee quality, transparency and efficiency of procurement processes, and therefore, the healthcare system.

Values:
Representativity: this body will compromise to represent patient and citizens perspective
Participation: the decisions of this body will be made after active participation of their members
Transparency: information shared between PIPPI project core and PCAG will follow transparency criteria.
Quality: PCAG will promote efficient, sustainable and quality processes
Corresponsability: PCAG will collaborate to guarantee the sustainability of procurement processes.

Some tasks –which may be update thorough the project– of the PCAG, are:

- Provision of input, test and feedback in the development of processes
- Gather inputs from citizen/patient group and ensure their voice it is listened
- Ensure participation of citizens and patients to identify, formulate and prepare procurement for unmet needs
- Facilitate and potentiate patient and citizen participation (individual or association) in PIPPI project related activities
- Identification and selection of citizens and patients in case recruitment it is not possible through patient association or through partners
- Advice on incentives for patient participation
- Identification and verification of focus areas, dissemination activities on the PIPPI project and engagement of stakeholders.
- Provide orientation and feedback on strategies of dissemination and exploitation of the results of the project
- Ensure transparent, concrete, accessible and comprehensible information of the project it is disseminated.
- Ensure active and transparent participation of patient and citizens group in all required CoP processes.
- Participation in the design of the training process (i.e. content, means and duration) for the patient/citizen group
- Work to keep gender perspective in PiPPI CoP processes

3.2.1 Composition

Adaptation to social distancing and also, prior actions to prepare the initiation of PCAG have made us realize that our initial number of PCAG members and the recruitment chosen method was not a viable option. In consequence, we propose a new model for PCAG, including changes in the composition, recruitment method and inclusion criteria. The PCAG will be composed by 3 to 12 patients/citizens (Figure 4). The minimum has been defined to permit variability and decision-taking, whereas the maximum it has been set to be able to do fruitful virtual meetings. The number of PCAG members may grow in a future once we have the infrastructure to canalize bigger groups.

PCAG members will be recruited through an open call through PIPPI webpage with the aforementioned specific inclusion criteria with the aim of recruiting members for the PCAG able to respond to the tasks they have been assigned. For this open call, PIPPI information and material will be shared and disseminated through PIPPI communication channels to introduce the project to the community of patients/citizens. This call will open in February 2021 and will be completed by April 2021. Submissions from candidates will be received through PIPPI mailbox using an online form created with this purpose that will be uploaded in PIPPI webpage.

Figure 4. Composition of the patient citizen advisory group
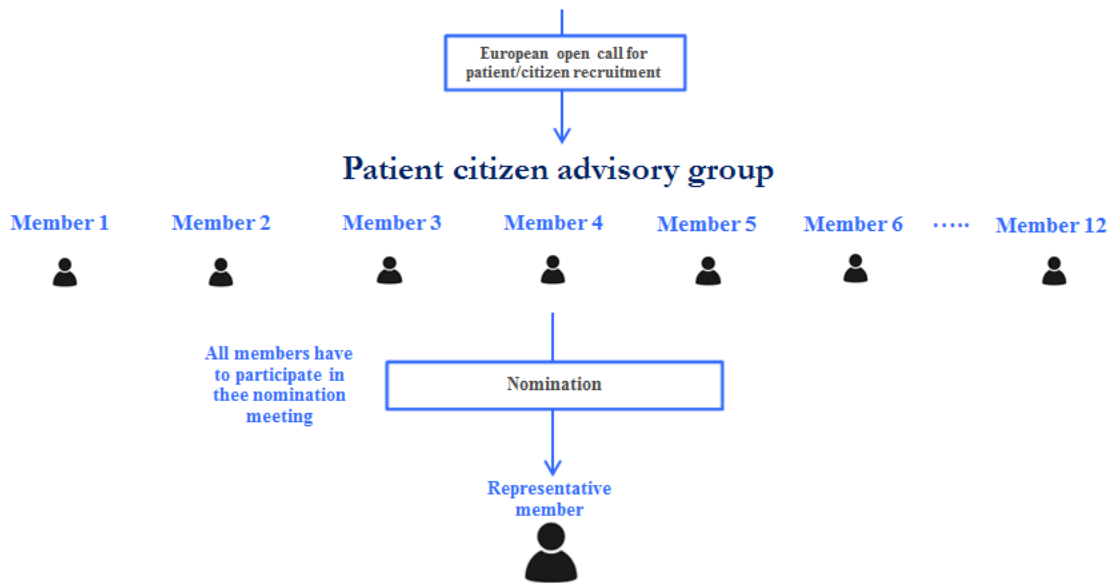
3.2.2 Selection of members

To select members, a set of in-/exclusion (required criteria to be met) and variation criteria (to obtain a richer perspective taking into account variability within the patient/citizen cluster) have been defined.

Inclusion Criteria

Inclusion criteria refer to the specific skills that patients/citizens are required to demonstrate to ensure that they are able to properly contribute to the project at the expected level. The following set of criteria must be met:

- Individuals included should belong to one of this groups previously defined:
  - a) Patients
  - b) Family members or informal caregivers of patients
  - c) Citizen

- Appropriate communication skills in English, both verbal and written. Working knowledge of English it is needed
- Be able to represent patient and citizen perspective, being able to transcend the problems with regard to their own clinical situation or to separate themselves from their own illness
- Be resident of one European and H2020 associated-countries.
- Have been involved in the care provided as patients or citizens
- Be able to cover and act at a transcending and administrative level
- Critical and constructive, able to communicate in a clear and pleasant way
- No relevant conflict of interest (CoI). CoI will be defined case by case by all partners and no bias situation may occur during the engagement

- Previous experience and knowledge in healthcare sector, innovation and public procurement

Variation Criteria

Maximum variability will be sought according to the following criteria:

- **Gender**: We employed an inclusive perspective of gender that includes three categories: 1) people who identify as female; 2) people who identify as male; and 3) people who do not identify themselves as either a combination of genders or neither gender. Partners must ensure that not all PCAG appointees share the same gender category. Each partner is encouraged that, in the case that four candidates are selected any category exceeds 50% of the total. Identification of non-binary and/or transgender candidates is encouraged but not mandatory.
- **Type of Stakeholder:** Partners should aim to include at least one appointee representing a patient family member / caregiver in their selection.
- **Educational Level**: We will consider three categories of the educational level, which are clusters of the categories described in the International Standard Classification of Education (ISCE 2011): 1) Less than primary, primary and lower secondary education (ISCE levels 0-2); 2) Upper secondary and post-secondary non-tertiary education (ISCE levels 3-4); and 3) Tertiary education (ISCE levels 5-8). Partners will be encouraged to include representatives of all three educational levels.
- **Regions and countries**: we will seek for variety on region and country of residency of all PCAG members.

In case more than 12 candidates submit their candidacy, after the deadline for a selection process will be initiated. A selection committee composed by at least 3 different partner institutions will propose PCAG members by using a quantitative method based on inclusion criteria and considering the established variation criteria.

Selected candidates will be contacted and officially invited to participate in PIPPI project. After the recruitment of PCAG members' specific informative material and an invitation will be created according to the communication plan and issued to candidates. Once patients/citizens have accepted the invitation to participate, they will once again be briefed on the project and their role and tasks in particular.

PCAG appointees will serve for three-year terms, at the end of which new members will be appointed. Whereas previous PCAG members are not excluded from future participation, no member will serve for two consecutive terms. Substitutes for former members will serve for the continuing mandate of their predecessors, if necessary.

Not selected candidates will be contacted and will be kept with their consent on PIPPI database for further actions that involve their participation, for future replacement of

PCAG members or when the PCAG will be able to grow because changes in the situation and better management of virtual meeting it is achieved. They will be kindly invited to continue involved in future activities and actions of PIPPI project event not being part of PCAG if they are interested.

3.2.3 Nomination of representatives

PCAG members will be asked to nominate one member to act as their representative. PCAG members will be informed of the nomination process and reminded in the first virtual meeting and will be encouraged to prepare their candidacy, during which the nomination will be conducted.

The representative member of the PCAG will be responsible of conveying and leading the meetings and acting as spokespersons for PCAG. He/she is expected to have leadership qualities, good communication skills and be a team builder.

3.2.4 Substitution of patients/citizens upon cessation of involvement

Patient/citizens participation may be terminated for a variety of reasons, ranging from conflicts of interest to health issues. Whatever the reason, upon a dropout scenario, a replacement matching its predecessor's characteristics will have to be sought by those initially appointed to the task. In case of dropout, firstly, not accepted candidates of the open call that have accepted to be part of PIPPI database, will be contacted in order of qualification and following the variation criteria for becoming PCAG member. In case, there are no candidates from the previous call, a new call looking for new members will be published to look for replacement.

4. Ensuring the continuity of patient participation beyond the project

Despite the continuity of activities, an important distinction must be made between the activities in the context of the PIPPI Project and those of the CoP. The completion of the solution development pilot constitutes a milestone separating the project from the fully established CoP.

As the PIPPI Project comes to an end, partners must ensure the correct functioning of the CoP through the assessment of the relevance of their roles in future activities.

5. Patient/citizen value and engagement with PiPPI CoP

Co-creation and collaboration with patient and citizens it is key to stablish patients at the center of the delivery process. Moreover, patients and citizens want to be more involved than currently in making decisions in their health and in the healthcare system.

The knowledge and understanding on patients or citizens needs during acute phase of treatment leads to a standard acute care process. A stronger connection with patients and citizens through all the process will lead to a better connection that will allow addressing medical issues beyond acute care and also, gaps and barriers within the

health and social system. Altogether, making patient and citizen participation a critical factor for success and sustainability.

Relationship with patient/citizen stakeholder group should be maintained through common sense of purpose and celebrated through recognition of individual efforts and collective success. Moreover, this relation have to be built over time through fostering trust, gaining self-awareness, acceptance of others and using tools of communication and education.

Trust

Patient and citizen participation should be always guided by trust. Trust should be build and grown through engagement processes by ensuring patient/citizen participation, their ability to impact in the CoP and in procurement processes by sharing their experience in order to facilitate, stablish and maintain trust and to foster better understanding of patient experience.

Alignment between patient/citizen stakeholder group and PIPPI project will potentiate and collaborate on building and growing trust. Moreover, they will have the support of PIPPI CoP, enabling engagement and proper development of their activities

Self-awareness and acceptance

PIPPI CoP members should understand barriers and challenges from citizens and patients accessing healthcare system. Moreover, healthcare providers should accept their bias and assumption to potentially be able to break new barriers. Healthcare providers and industry should understand that not active listening of patient and citizen voice lead to suboptimal procurement processes, therefore suboptimal care. Providers should recognize their own bias and assumptions and listen actively to patients to learn from their experience and optimize procurement and care processes.

PIPPI members should accept that our world it is in constant change and constant adaptation it is needed. Therefore, PIPPI CoP through the input of their stakeholders should be able to act and adapt. On that sense, patients/citizens stakeholder group are an important voice to take into account as they are the ones who are mainly affected.

Communication and education

The commitment to listen often to stakeholders, particularly patients and citizens in order to understand their experiences and perspectives should be done by PIPPI member to achieve patient/citizen engagement. Moreover, taking time and efforts to allow personal and professional development of patients and citizens will help to build a collective expertise and confidence in the CoP. Altogether obtaining best outcomes on CoP processes and procurements.

Relationships are strengthened through intentional process to understand where we are, our bias and assumptions and how we relate. Patient and citizen experience, together with other stakeholder experiences and perspectives, will be shaped through intersection of forces, and if we allow the proper communication it will rise a whole range of

opportunities through the CoP to improve the understanding of all stakeholders needs and procurement processes

The value of including patient and citizen stakeholder group in the CoP include their expertise on the disease, nobody knows better than them their experiences (Table 2). But also, it is very valuable for PIPPI CoP and process their social circumstances, their attitude to risk, their values and preferences. Their participation in the CoP and the procurement process will allow to include what it is important for them and really work on placing patient needs in the center.

Table 2. Value of involving patients/citizens for the CoP and value of the CoP for patients/citizens

PIPPI CoP expertise	Patients/citizen expertise
Rich pan-European ecosystem, need sharing and modulation of other needs, decision-taking influence, choose preferences	Experience of illness, social circumstances, attitude to risk, values and preferences Experience of wellness

To keep them engaged it is important that patient/citizen opinions and needs are respected and analyzed, instead of judged or misunderstood. Their perspectives are key to meet healthcare system and patient goals, and also, really valuable to help staff to handle complexity of care and procurement processes. This relationship should be based in a collaborative approach encouraging patients to take their own steps.

On the other side, PIPPI project will help patients/citizens group to participate in the development of PIPPI CoP, to be part of a rich pan-european ecosystem, to share their unmet needs, give their input and modulation needs already detected by other stakeholders groups, participate in the CoP processes and procurements, being able to influence decision-taking (Table 2). Altogether, will help to raise their voice and put their experience in the center of procurement processes.

6. Patient/citizen participation in procurement processes in university hospitals

As previously stated, patients/citizens are the main actor of healthcare processes, and their inclusion in procurement processes it is key for the sustainability of the system. It is important to remember that health do not start in healthcare system it is where it ends. Therefore, complexity and transversality of the unmet needs highlights the importance of involving all stakeholders in the processes to work together. One of the main challenges of healthcare system it is to involve patient and citizens to solve unmet needs and build the healthcare system of the future.

Managerial imperial activities sometimes lead to displace good intention about informing patients, listening to their needs and ensuring they are treated in a supportive manner. It was defined by Coutler as the essence of patient centered care. If healthcare system ignores patients/citizen needs, values and preferences, they may be treated in a way that does not fulfil their needs. Therefore, creating tools to help patients/citizen to participate in the co-creation of the system may be appropriate and cost-effective.

Therefore, patient/citizen involvement in procurement processes at University hospital should be encouraged. Previous experience in participation of patient/citizen in procurement processes have shown that their participation resulted in better outcomes and lower prices paid by procurer (O'Mahony et al 2015). This article analyses previous experience in 19 countries with different legal frameworks on procurement processes of coagulation concentrates, and also stated, that clinician participation on these processes resulted in lower prices. All countries that involved clinicians, also involved patient organization, so the inclusion of the latter showed a greater impact.

The involvement of clinicians and patients/citizen organizations have shown better outcomes in the procurement processes. Their knowledge and opinions leads to a better selection criteria and better knowledge-based analysis of these criteria. However, formal patient/citizen involvement in procurement processes it is not frequent.

It is important to mention that patient/citizen participation in this processes may be achieve following several methods. One or two patient representative may be included in public tenders committees together with clinicians, managers and other involved stakeholders. Another option to have a broader input from patients/citizens may be work on focus groups on procurement processes. The focus group will include between 3 and 12 patients/citizens representatives, and one will be nominated as the representative of the body. The institution looking for input from patients/citizens will prepare all information required for patients/citizens to be able to understand and decide. The group will debate and explore all required questions and it will help to raise unmet needs, values and preferences. Later on, this information will be shared to the public tender committee by the patient/citizen representative.

Independently of the chosen method, their involvement demands serious commitment and well-trained and knowledgeable patient/citizen representative. PIPPI CoP will allow to test this method for patient/citizens participation in procurement processes. The involvement of patient/citizen in identifying, formulating and prepared procurement of PIPPI CoP challenges will help to stablish a framework to future processes.

7. Patient training
7.1 Patients in the CoP

Patients/citizens/Participants will receive specific training for the purposes of their activities. The required information may be portrayed in a document and circulated prior to the beginning of the activity. These will be co-created by both partners and the

PCAG during the project. Online courses may be developed too for this purpose if resources are available and upon agreement of the consortium. These resources will be available and shared through PIPPI platform to future engagement and participation of new patients. It will include PIPPI project framework and ecosystem, basics of innovation procurement processes, importance and value of patient involvement and basic notions about confidentiality, responsibility, rights and obligations.

7.2 Patient citizen advisory group

Beyond the characteristics used as criteria for the selection of PCAG members, further training using the following resources will be required. The contents, means and duration of the training program will be assessed and improved during the project for future PCAG members.

Virtual presentation or electronic leaflet for patient participants
- The PIPPI Project framework and ecosystem: EUHA, Consortium partners
- The basics of the innovation procurement process
- The basics of CoP
- Basic notion about confidentiality, responsibility, rights and obligations
- Tasks and PCAG formulation process
- Importance of patient involvement
- PCAG information and formulation process
  Reimbursement instruction

Tutorials for patient participants
- Essential skills for project management: teleconference tools
- Bioethics Essentials

Finally, in order to co-create an improved training process, members will be asked to provide us feedback about the entire training program through:
1. A survey to assess satisfaction and quality of content of training program
2. Hot line for the petition of specific training materials that patients deem necessary for the correct execution of their tasks.

8. Financial Compensation

Best practices among partners are under review in order to define the best approach to financial compensation while also covering ethical concerns. However, the final decision on providing financial compensation, as well as the quantities, means and basis for compensation will be made by each partner considering the specific conditions in each country. Financial compensation practices we are currently discussing include:

- To reimburse PCAG members for their travelling expenses and issued a daily allowance during travel, adjusted for cost of living of country of destination

- To compensate PCAG representatives with an additional monthly allowance based on the cost of living in their country of residence.

Under certain circumstances, patients who are not part of the PCAG may be summoned by partners for specific tasks. Such patients may also be reimbursed accordingly. The conditions of this reimbursement must be discussed by partners taking each particular scenario into consideration and taking into account that the final decision will be made by each partner.

9. Ethical characteristics

Ethical principles will be guaranteed in accordance with national, Union and international legislations, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Particular attention will be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

Voluntary participation. Participation throughout the course of the PIPPI project is strictly voluntary and can be terminated at any point upon notification. The termination of the participation will be possible without any consequence for the participants. All participants will be informed about their voluntary participation in the informed consent to participate.

Contact with patients/citizen. First contact with patients or citizens will always be carried out by a designated gatekeeper of the association, the partner institution (personnel from a hospital's customer service unit or clinicians) or by the PCAG. All participants will be informed about project objectives, implications and their obligations and responsibilities.

Prior informed consent. Patients will be informed and asked for their consent upon first contact. Consent forms will be adapted for each nation's legal framework and each specific activity by a team of legal experts and at least will include the following items:
- Consent to have your contact details stored in the PIPPI CoP contacts directory
- Consent to be contacted with regards to specific activities of the PIPPI Project
- Consent to be informed of news, activities and events regarding the PIPPI Project
- Consent to have any anonymously collected data be used for the purposes of the PIPPI Project.

Participants will receive an informed consent form and a detailed information sheet in their national language. Annex 2 contains a preliminary template of the informed consent form.

Privacy, data protection and management. Data related with the health status of participants will not be asked, used or stored at any point of the project. PIPPI members will not have information regarding patient health status, as gatekeepers will be the ones contacting patients and citizens and for the open call this information will not be asked. The team of PIPPI project (as described in deliverable 1.9) will guarantee the compliance of national and Horizon 2020 ethics requirements, ensuring that any data collected is managed according to regulations and directives. The PCAG personal data will be protected in accordance to the General Data Protection Regulation (GDPR). All partner institutions involved in patient identification and selection will appoint a Data Protection Officer (DPO), the details of whom will be made available to all data subjects involved in any activities that require data process.

Furthermore, a Data Management plan is being drafted to describe how data generated by the project will be handled. It will also include the implementation of measures to meet the principles of data protection by design and by default, as well as appropriate technical and organizational measures (policies and procedures) to ensure and demonstrate compliance.

Gender issues. Patient selection will ensure the effective promotion of gender equality. Particular attention will be paid to ensure gender balance in all activities.

Disclaimer. We can confirm that no children or adults unable to give informed consent will be involved in any of the activities described in this document.

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Annex 1. Current practices from the PiPPi Consortium partners

WP2.3: Define an appropriate involvement of patients/citizens in all stages of the project
Purpose of the Survey
The purpose of this survey is to identify a set of best practices in the identification and recruitment of patients and patient associations in the PiPPi Ecosystem. Characterising these strategies is vital not only to ensure the adequacy of candidates to the participation in the PiPPi Project and ensuing CoP, but also to design a fit-for-all patient identification and selection strategy.

Some of these questions may not be applicable in the context of your institution. If this is the case please give a brief explanation of why it is so.

Identification of gatekeepers

For the purpose of this project we will define gatekeeper/s as the person or people who are in contact with patients who have some sort of participation within the institution. Gatekeepers engage in processes of identification and/or selection of patients for a variety of purposes, namely research, in healthcare. Examples of gatekeepers at the Vall d'Hebron Campus are customer service managers, who are in direct contact with both patients and associations and who engage in the identification of patients for diverse purposes with different sets of inclusion criteria.

> ➔ *Please state briefly whether or not you identify gatekeepers within your institutions, as well as their quantity and the positions these hold.*

Patient / Patient Association identification strategies / procedures
Patients may be needed for a variety of purposes, such as their participation in focus groups or trials. Patient associations may be sought as a means to identify individual patients or for other purposes such as dissemination of information. For both instances, gatekeepers may approach the identification process in different ways.

> ➔ *Please state briefly the strategies / procedures present in your institution for the identification of patients and particularly patient associations.*

Patient / Patient Association selection and recruitment strategies / procedures

Most institutions develop an inventory of patient associations with which they have collaborated. When this is the case, or when more patients and/or associations than required have been identified, gatekeepers or the staff in charge at this stage of the process may have to apply a strategy to select the most adequate candidate.

> ➔ *Please state briefly the strategies / procedures present in your institution for the selection and recruitment of patients and particularly patient associations.*

Patient / Patient Association engagement strategies / procedures

Institutions may develop and differ in strategies to ensure the participation of patients and patient associations. Examples of these types of strategies are cost reimbursement, access to information or project documentation, compensation and other incentives.

> ➔ *Please state briefly the strategies / procedures present in your institution for the engagement of patients and patient associations.*

Patient training strategies / procedures

Some project may require specific patient training to maximize their input. For instance, specific training in the use of tools used for data collection, handling of devices, etc.

> ➔ *Please state briefly the strategies / procedures present in your institution for the training of patients.*

Annex 2. Patient Citizen informed consent
Prior informed consent for the H2020-PIPPI Patient Citizen participation

Project: H2020 PIPPI (GA Nº826157)
Promotor: TBD

Aims
We request your participation in the project, which main goal is to develop a better way to work together on the digital transformation of healthcare, by incorporating patient participation. It is important to incorporate your opinion through the project, for example identifying and verifying new areas of improvement or studying the best way to contact and train patients with punctual participation during the project. Your participation in the project will involve your attendance to meetings to debate and interviews, but in any case it will not imply medical visits nor usage of medical data.

If you accept to participate in the project, you will be part of the patient advisory group of the H2020-PIPPI. You will have the opportunity to actively participate in meetings and other events to guarantee the success of the project. If you give your consent you will be part of a multidisciplinary team working in an European project to develop the hospitals of the future.

Benefits
It is possible that your participation in the project does not lead to direct benefits. However, patient involvement is central to enable better assessment of patients' needs, envisioned outcomes and expectations, all of which are key at different stages of the innovation process. Therefore, your participation will help to find adequate and better solutions to patient needs

Personal data protection
According to the European and national personal data protection law, personal data obtained will be the necessary for the purpose of the project. We inform you that the Foundation Hospital Universitari Vall d'Hebron -Institut de Recerca (VHIR), with NIF G-60594009, Barcelona - 08035- Passeig Vall d'Hebron 119-129, Edifici Mediterrània, 2a floor, it is responsible for the personal data and will process it in a transparent and loyal manner.

The purpose of the processing of the data is being able to participate in the project entitled: H2020-PIPPI.

The recipient of your data is VHIR, or other authorized personnel, and they will have to keep the confidentiality of the information according to the law. In any case your personal data will be transferred without your previous consent, with the exception of legal obligation according to (UE) 2016/679 to the people who can demand it. International transfers are not foreseen, however in some cases it could be done.

Personal information will be kept under secure conditions by: TBD[3]

The legal basis of the processing is your given consent, which can be revoked at any time. However, if you do not give your consent for process your data, you will not be able to participate in the project. Automatic decisions regarding personal data will not be taken, including profiling. Personal data will be processed during the time that they are useful and necessary for the purpose they have been taken, or until you revoke your consent or you ask for its   suppression.
but personal data can be kept for legitimate reasons or in the exercise or defense of possible claims.

_____

[3]TBD: to be determined

In any case you will be able to exert your right of access, modification, opposition, limitation, portability and suppression or cancelation of your consent.

According to the regulation (UE) 2016/679, VHIR has designed a delegate for data protection: dpd@ticsalutsocial.cat.

The legal unit of the Foundation we will solve all the doubts, complaints, clarifications, suggestions and we will attend to the exercise of the data subject's rights, through the electronic mail: lopd@vhir.org.

You can also do a claim to the Control Authority in data protection.

Voluntary participation and revoke right of the consent
Your participation in this project is voluntary and you can change your decision and revoke the consent any time.

If you need further information regarding this project contact with: TBD
Telephone: TBD

Informed consent

Title of the project: H2020-PIPPI.

I _____ (name and surname of the participant)

I read the information given by the professional that signs this consent regarding:
- ☐ The project
- ☐ Where personal data will be obtained, stored and processed,
- ☐ My participation in the project is voluntary
- ☐ I can revoke my consent in any moment, request the erasure of the persona, data and withdraw from the project without explanation.
- ☐ I have the right to access, rectify, restriction, portability and erasure of personal data.
- ☐ I understood the information and I have asked all questions that I considered to TBD

With my signature I confirm that:
- ☐ I give my consent that I will be able to revoke my consent in any moment, and I accept to participate in the project.
- ☐ I give my consent to the responsible of the project to contact me in the futur for specific activities regarding PIPPI project.
- ☐ I give my consent to the processing of my personal data according with the information read in the personal data protection section
- ☐ I give consent to have my contact details stored in the PIPPI CoP contacts directory.
- ☐ I give consent to be informed regarding news, activities and events related with PIPPI project.

Barcelona, _____de _____de 20_____

Participant:

Name of the participant (over 14 years old): _____

DNI: _____

Signature: _____

Tutor o legal representative _____

Name of the legal representative:_____

Identification number.: _____Relation: _____

Signature of the authorized person:_____

Declaration of the person who has informed to the participant:

Name of the authorized person: _____

Identification number: _____

Signature: _____

Annex 3. Stakeholder interaction summary

Purpose of the document

The purpose of this document is to present the mapping and the identification of stakeholders that have been already done and to inform the different stakeholder interaction actions that have been organized by PIPPI partners from the beginning of the project until December 2020.

1. Stakeholder mapping

PIPPI project aims to create a CoP in which information, skills and experience it is shared within groups to improve professional outcomes. It is about co-creating ideas and solutions that would rise thanks to CoP members participation from many point if view, field experience and studied expertise. The value of the CoP is to increase the effectiveness of its members, by allowing each member to deliver better against his or her own individual performance objectives, by giving them access to the knowledge base of the community.

Stakeholders of PIPPI Community of Practice have been mapped. There is a need to integrate different knowledge and find ways to collaborate with all relevant parties. Before starting the project PIPPI partners had already highlighted particular stakeholder clusters with which the communication it is important. Moreover, during the project these clusters have been better mapped and defined. This process has been done including partners and also including external stakeholders by analyzing PPI/PCP processes and PIPPI CoP processes. Several internal working meetings and external interaction with stakeholders (presentation workshops) have been needed to properly define stakeholders clusters involved in the CoP. This is an ongoing work, and further variations may be included in the future.

The current stakeholders clusters involved in the CoP are:
1. Industry: includes start-up, small, medium and large companies involved in the technology development.
2. Healthcare providers / Hospitals: includes all healthcare providers that offers healthcare services to citizens/patients.
3. Research and innovation community: includes universities, research and technological centers. It is an important cluster that includes basic and translational research but also technological development.
4. Citizens and patient associations: it includes citizens, patients and patient association involved in healthcare processes.
5. Enablers: it includes a variety of companies and members important for PIPPI CoP such as consulting firm, governmental agencies, investors,…
6. Payers: it includes the group of stakeholders that have to finance healthcare for society in different countries and regions.
7. Policy makers: it includes the group of stakeholders in charge of developing policy recommendation and rules for the society

Each cluster include different subclusters, that after the analysis done by partners and also by them in the presentation workshop different needs have been detected and communication and engagement pattern should be followed. In the following table the stakeholder clusters involved in PIPPI CoP are being described by their role and scope and their value and expertise, and also, the value that they offer to the CoP and the value the CoP offers to each group.

Table 3: PIPPI CoP stakeholder role, scope and value offered by them and for PIPPI CoP to them

| Stakeholder groups	Role	Scope	Value offered by the PIPPI CoP	Value offered by each agent to PIPPI CoP
Healthcare providers / Hospital	Share data and information to present unmet needs	Public Hospitals University Hospitals Public Health Institutions Primary care	Rich pan-European ecosystem, need sharing and aggregation to others needs, decision-taking influence, access to experience and expertise, education and previous cases	Experience in unmet needs and challenges. Previous experience in CPI/PPI processes.
Industry	Give input/get output, input on their needs regarding PCP/PPI process and PIPPI platform functionalities. In specific challenges they will give input to gain knowledge of details surrounding unmet needs and increased knowledge of opportunities	Large companies	Rich pan-European ecosystem, access to new needs of the healthcare system, new contacts to initiate new challenges. Access to experience and expertise, education and previous cases	Experience in technology and processes to solve challenges and unmet needs. Potential risk-sharing and new solutions for development of new solutions. Previous experience in CPI/PPI processes.
		SME Start-ups	Rich pan-European ecosystem, access to new needs of the healthcare system, new contacts to initiate new challenges. Access to potential investors. Access to experience and expertise, education and previous cases	Experience in technology and processes to solve challenges and unmet needs. Previous experience in CPI/PPI processes.
Research and Innovation Community	Give input/get output; share problem descriptions, opportunities to initiate awareness and interest. Deep in challenge unmet needs. Provides a horizon scan view of future directions of technology/innovation	Technological Centres Research Centres Academia	Rich pan-European ecosystem, access to new needs and challenges of the healthcare system, new contacts to initiate new challenges. Awareness to their experiences and R+D expertise. Access to funding and investors. Access to experience and expertise, education and previous cases	Experience in technology and processes to solve challenges and unmet needs. Previous experience in CPI/PPI processes.
Citizen / Patient association	Involvement in PIPPI CoP processes and sharing of new needs and challenges and definition of specific challenges (further detail in D2.4)	Citizens Patients Patients association	Rich pan-European ecosystem, need sharing and modulation of other needs, decision-taking influence, choose preferences	Experience of illness, social circumstances, attitude to risk, values and preferences Experience of wellness

Policy makers	Sharing data, information and analysing policies and regulations from different regions	Policy makers	Rich pan-European ecosystem, access to unmet needs and challenges of the system that may need for new regulations. Be up to date in the I+D and innovation sector	Experience in solving previous unmet needs with impact in society
Payers	Sharing data and information to present unmet needs from their perspective, sharing and analyzing procurement processes in different regions ie: sustainability of the system	Payers	Rich pan-European ecosystem, access to new needs and challenges of the healthcare system, access to others needs and challenges, looking actively for better solutions that can work on making more sustainable the system	Experience in unmet needs and challenges. Previous experience in CPI/PPI processes.
Enablers	Give input/get output, input on their needs regarding PCP/PPI process and PIPPI platform functionalities. In specific challenges they will give input to gain knowledge of details surrounding unmet needs and increased knowledge of opportunities	Governmental agencies	Rich pan-European ecosystem, access to unmet needs and challenges of the healthcare system	Experience in processes to solve challenges and unmet needs. Previous experience in CPI/PPI processes and digital solutions. Knowledge on the regional innovation ecosystem
		Consulting firms	Rich pan-European ecosystem, access to unmet needs and challenges of the healthcare system, new contacts to initiate new challenges. Access to experience, and expertise, education and previous cases	Experience in processes to solve challenges and unmet needs. Previous experience in CPI/PPI processes and digital solutions.
		Investors	Rich pan-European ecosystem, access to unmet needs and challenges of the healthcare system, new contacts to initiate new challenges. New trends.	Experience in processes to solve challenges and unmet needs. Access to funding.

Each stakeholder cluster, or each organization from a stakeholder cluster contain a variety of profiles and roles. The profile and role included in the interactions of each stakeholder cluster have been selected depending on the purpose and aim of the interaction. It will vary depending on the purpose and aim we want to achieve with the interaction and the process of the CoP they are involved (Figure 3), because of that, the CoP aims to include different profiles and roles of the institutions. Further details on specific roles for each step of the process will be detailed in D2.1. Moreover, this is an active process, so, it may be updated during the future and after new interactions with stakeholders

2. Stakeholder identification processes

Stakeholder identification process started by the identification of external stakeholders by each partner by using the following template (Figure 5).

Figure 5: Partner analysis of their ecosystem template
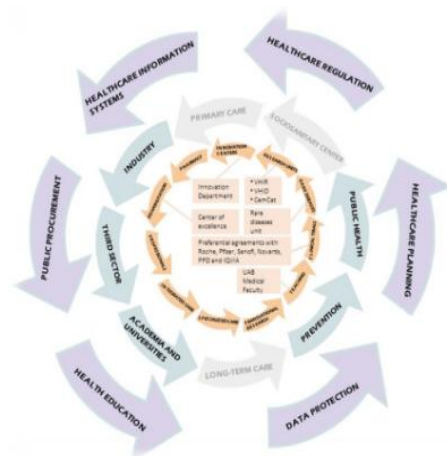
This process led to the identification of all partners external stakeholder and the generation of the inventory. This inventory can potentially make PIPPI CoP grow. For a homogenous generation of the inventory the following template was shared with all partners (Figure 6). This template was included in an excel file that was filled up containing specific information of each stakeholder cluster. Each stakeholder cluster has an adapted structure that can be consulted in the excel file (External SH inventory of each partner_allSH groups.xls). This inventory was not shared between partners because of privacy reasons but it has been used and will continue being used with the aim to lead the CoP to grow.

Figure 6: Inventory template for industry cluster

The inventory has been used by each partner to disseminate PIPPI events and workshops in the localizations where we were able to organize before Covid outbreak.

The inventory filled up in each site has been resumed in the following tables where you can find each partners numbers by stakeholders cluster. Importantly, these are all contacts from external organizations of the consortium.

Table 4. Total number of organization by stakeholder cluster by each partners and all consortium

All partners included:

Stakeholder cluster	Total n of org
Patients / Patients associations	58
Research community	101
Industry	355
Enablers	43
Policy makers	33
Healthcare providers	117
Payers	23
Total	730

HUVH

Stakeholder cluster	Total n of org
Citizens / Patients associations	12
Research community	20
Industry	160
Enablers	8
Policy makers	10
Healthcare providers	17
Payers	1
Total	227

AQuAS

Stakeholder cluster	Total n of org
Citizens / Patients associations	21
Research community	2
Industry	0
Enablers	1
Policy makers	0
Healthcare providers	16
Payers	1
Total	41

ERASMUS MC

Stakeholder cluster	Total n of org
Citizens / Patients associations	2
Research community	40
Industry	10
Enablers	3
Policy makers	3
Healthcare providers	40
Payers	2
Total	**60**

King's

Stakeholder cluster	Total n of org
Citizens / Patients associations	4
Research community	0
Industry	1
Enablers	17
Policy makers	1
Healthcare providers	11
Payers	0
Total	**34**

Karolinska

Stakeholder cluster	Total n of org
Citizens / Patients associations	7
Research community	16
Industry	27
Enablers	8
Policy makers	5
Healthcare providers	12
Payers	0
Total	**75**

MUW

Stakeholder cluster	Total n of org
Citizens / Patients associations	3
Research community	3
Industry	75
Enablers	9
Policy makers	3
Healthcare providers	5
Payers	13
Total	**111**

OSR

Stakeholder cluster	Total n of org
Citizens / Patients associations	6
Research community	12
Industry	17
Enablers	13
Policy makers	0
Healthcare providers	15
Payers	5
Total	**68**

HUS

Stakeholder cluster	Total n of org
Citizens / Patients associations	3
Research community	8
Industry	65
Enablers	0
Policy makers	9
Healthcare providers	24
Payers	1
Total	**110**

Early 2021 all partners will contact all the contacts from their inventory to inform about the project, to invite them to participate in dissemination events and to allow them to register and become a stakeholder of PIPPI CoP. Furthermore, the new dissemination plan and new events of the CoP will open new opportunities to go beyond known external stakeholders by partners and inform new stakeholders of the project.

3. Registration of new stakeholders to become CoP members and list of CoP members:

A temporal registration form to become member of the CoP has been made available through PIPPI webpage with the collaboration of WP7. This will allow to activate registration of new interested stakeholder following new stakeholders interactions or dissemination activities, and will allow the update of the first PIPPI CoP members created after the Presentation Workshop organized in Barcelona, Rotterdam, Wien and Milan. London event and the other localizations were stopped by Covid outbreak. This list also includes stakeholders that participated in business and operating model workshops.

The list of CoP members contains information from each stakeholder regarding:

1. Partners site / Event registered participant
2. Name and Surname
3. Organization
4. Role
5. Working country

6. Stakeholder cluster
7. Type of stakeholder: internal: contacts inside partners organizations / external: contacts from non-partners organizations
8. Status: active: have been actively participated in survey and workshops during last 12 months / Involved: have been participating events, workshop and surveys. Communicated*: have been informed of PIPPI project. This status will include stakeholders registered to PIPPI newletter and not to CoP, registered members of the CoP that have not been involved in surveys and workshops. There are part of communicated stakeholders through conferences and social network that we cannot directly register.

The CoP members list it is and will be continuously monitored and analyzed by WP2 and WP3, to study gaps in countries, stakeholder cluster, roles and status. The status it is and will be continuously monitored by WP2 and WP3 to keep the engagement and collaboration of all members, and keep the value of the CoP.

List of CoP members numbers by:

Table 5. List of CoP members by working country

By working country	Total n of org
Spain	42
Sweden	64
Italy	4
Austria	11
Netherlands	16
United Kingdom	4
Total	**141**

We have a clear gap on countries to the lack of workshops due to Covid outbreak. To work on this, as it was previously mentioned, early 2021 (January-February) all partners will contact their known stakeholders inventory to inform about the project and to allow them to register and become a stakeholder of the CoP. Furthermore, partners who organized an event have still potential stakeholders that have not been reached to increase CoP involvement. It will be complemented by new registrations due to communication events and also actions to potentiate stakeholder registration.

Table 6. List of CoP members by stakeholder cluster

Stakeholder cluster	Total n of org
Citizens / Patients associations	9
Research community	15
Industry (SME)	19
Industry (large)	18
Enablers	21
Policy makers	15
Healthcare providers	42
Payers	2
Total	**141**

Analysis of stakeholders groups already registered has showed the need to involve more payers and investors (included in enablers cluster). Specific strategies will be followed to grow and involve stakeholder cluster less involved until now. And this process will be continuously done during the project to ensure a proper and compensate ecosystem. These actions to involve and include specific stakeholder will be done in coordination with WP7 and will include direct contact with them and their associations, presentations in specific conferences, events on a specific target cluster…

Table 7. List of CoP members by type of stakeholder

By type of stakeholders	Total n of org
External	110
Internal	31
Total	**141**

Numbers probably underestimate both external and internal, and not all our interactions have lead to the involvement in the CoP. To include them in the list and share the contacts within the consortium they have had to sign the consent. Until now only stakeholders who have participated in events have signed the consent. This is an action that must be taken into account for the rest of the project. All interaction events (interviews, workshops, dissemination events) will require that partners ask first for registration in the CoP, and in case, stakeholders are not interested, we will share a minimum information including organization, working country, stakeholder cluster and type of stakeholder that would allow us to track in a better way all interactions.

Table 8. List of CoP members by status

By status	Total n of org
Active	137
Communicated	4
Involved	0
Total	**141**

This numbers show what it was previously explained. All CoP members have been involved in workshops during last year and signed the consent. The tracking of all other involved and communicated stakeholders have been not done properly. Therefore, during next period all stakeholders' interactions will use a new strategy that will include a new internal registration form for no CoP members.

Moreover, once the MVP platform and the CoP start validating specific challenge, the activity through the CoP will increase and the involvement and engagement different stakeholders cluster, and profiles included in each stakeholder cluster too.

4. Type of interaction

We can recognize three main types of interactions with stakeholders, that include different stakeholders clusters, with different aims.

1) Internal interactions: we define as internal when stakeholders are PIPPI core partners or members of their institutions. These type of interactions have included different methods as working meetings, focus groups, interviews…Examples of interactions done during first period are:

- Analysis of best practices in partner institutions (Karolinska, Wien, Barcelona,)
- Analysis of platform functionalities all partners included (Consortium meeting Barcelona-December 2019)
- Bi-weekly meetings and consortium meetings
- Internal dissemination of the project in our organization
- Questionnaire for preparing business model (Barcelona to all partners December 2020)

2) External interactions: we define as external interactions when most stakeholders involved are not members of PIPPI consortium. It include members of the seven stakeholder clusters defined (Industry, Policy makers, Patients/Patients association, Healthcare providers, Enablers, Payers and Research Community). This type of interactions has included different methods as surveys, face to face and virtual workshops, personal interviews and focus groups. Examples of external interactions done during first period are:

- Presentation workshop and surveys done in Barcelona, Rotterdam, Milan and Wien (January-March 2020)
- Workshops and interviews for preparing the business model and operating model workshops (Barcelona; July-October 2020)
- Interviews and questionnaires for preparing D3.4 and 5.1 (AQuAS March and October 2020).
-

3)Dissemination / Communication: explained in detail in D7.1, 7.2 and 7.3

5. Presentation workshop

The presentation workshop was held in five partner localization including Barcelona, Rotterdam as a pilots, and Stockholm, Milan and Wien with a total of 129 participants. Furthermore, London workshop was stopped by Covid outbreak.

5.1 Aims and framework
- Presentation of the project to the ecosystem of each partner site
- Obtain input from different stakeholder clusters to improve our knowledge of their needs in public procurement of innovation processes
- Obtain input from different stakeholder clusters to know the different point of view of the PiPPI project and the future platform

- Obtain input of participants to know and evaluate they interest in participating in the project

5.2 Agenda of the workshop

    9.00h Welcome - Briefing
    9.20h Survey I
    9.45h Project presentation
    10.00h Dynamic activity
    10.30h Coffee break
    11.00h Workshop
    13.00h Debriefing and survey II
    13.30h Final

5.3 Brief explanation of the workshop

After a brief welcome and presentation of all stakeholders invited, a first survey was answered: http://bit.ly/WSPIPPI1. This first survey was used to analyze general previous experience of all attendees in PCP/PPI processes. Followed by PIPPI project presentation information, including PCP/PPI introduction and the most important issues that the project will tacke. After that, a dynamic activity to break the ice helped to create good atmosphere to collaborate. It was followed by a brief coffee break before starting the proper workshop. After the coffee break PIPPI process was explained:

Figure 7: The main process of the CoP both for the duration of the PIPPI project and the future CoP once established
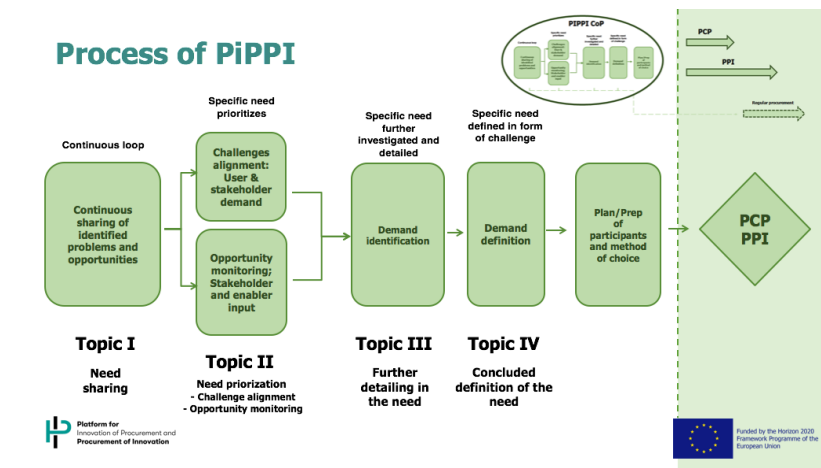
The workshop included work in groups composed by 5 to 7 stakeholder members from different clusters. Each site, adapted depending on the number of attendees and the stakeholder clusters, but the aim was to include several clusters in each group to open discussion on their different needs and problems in procurement processes and that PIPPI platform may help to improve. Each group had an external dinamizer and notekeeper to keep track of all conversation and discussions done during the workshop.

Each group discussed during 20 minutes each of the 4 topics already commented of PIPPI process: Need sharing, Need priorization, Further detailing in the need and demand definition. Their discussion was focus on enablers, stoppers and stakeholders cluster that may be included in each phase. We considered enablers, aspects that will help to PIPPI CoP/platform to achieve the aim of improving, potentiating and optimizing PCP/PPI processes. Furthermore, we considered stoppers, all aspects that could stop PIPPI CoP/platform to achieve its aim.

Figure 8: Templates for filling up per group and topic, including enablers, stoppers and stakeholder clusters
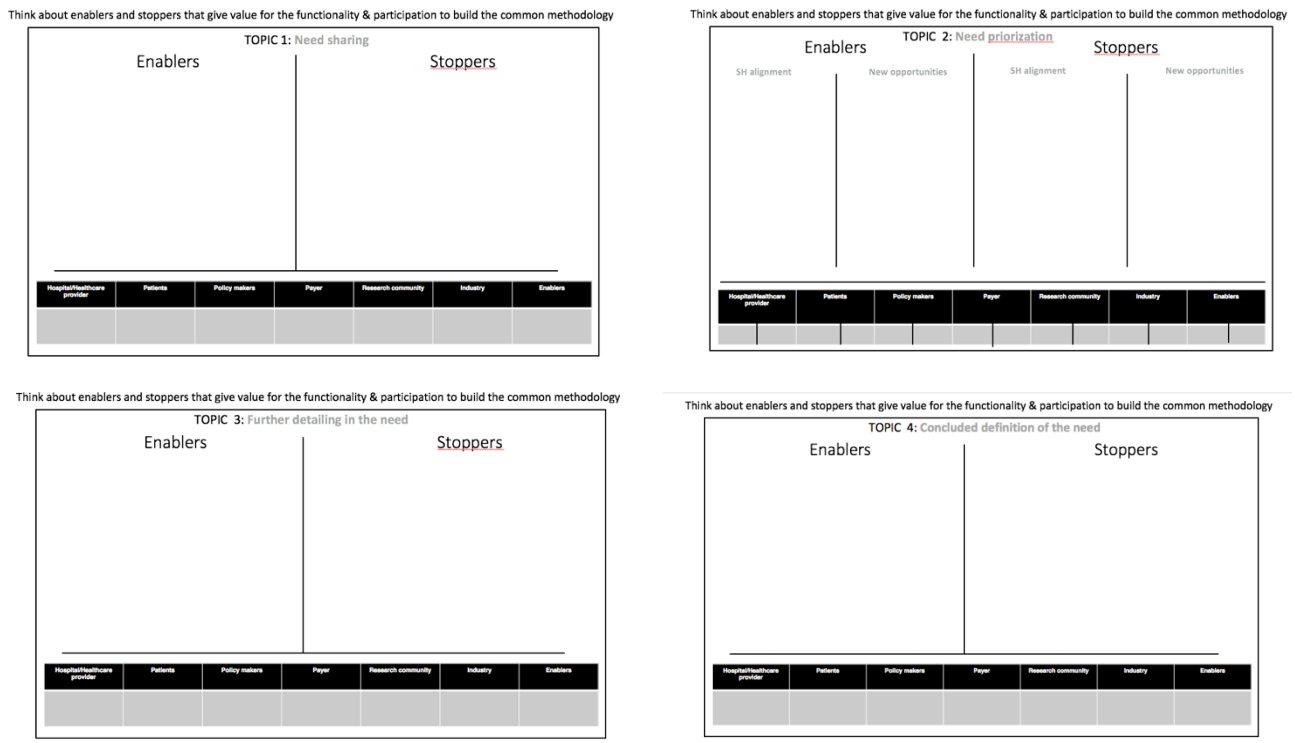
Here you can see the topics that were discussed by attendants in each phase, and the stakeholders clusters they think may be bring together in each phase to improve procurement processes in an example group.

Figure 9: Comments regarding need sharing in an example group of Barcelona Presentation Workshop
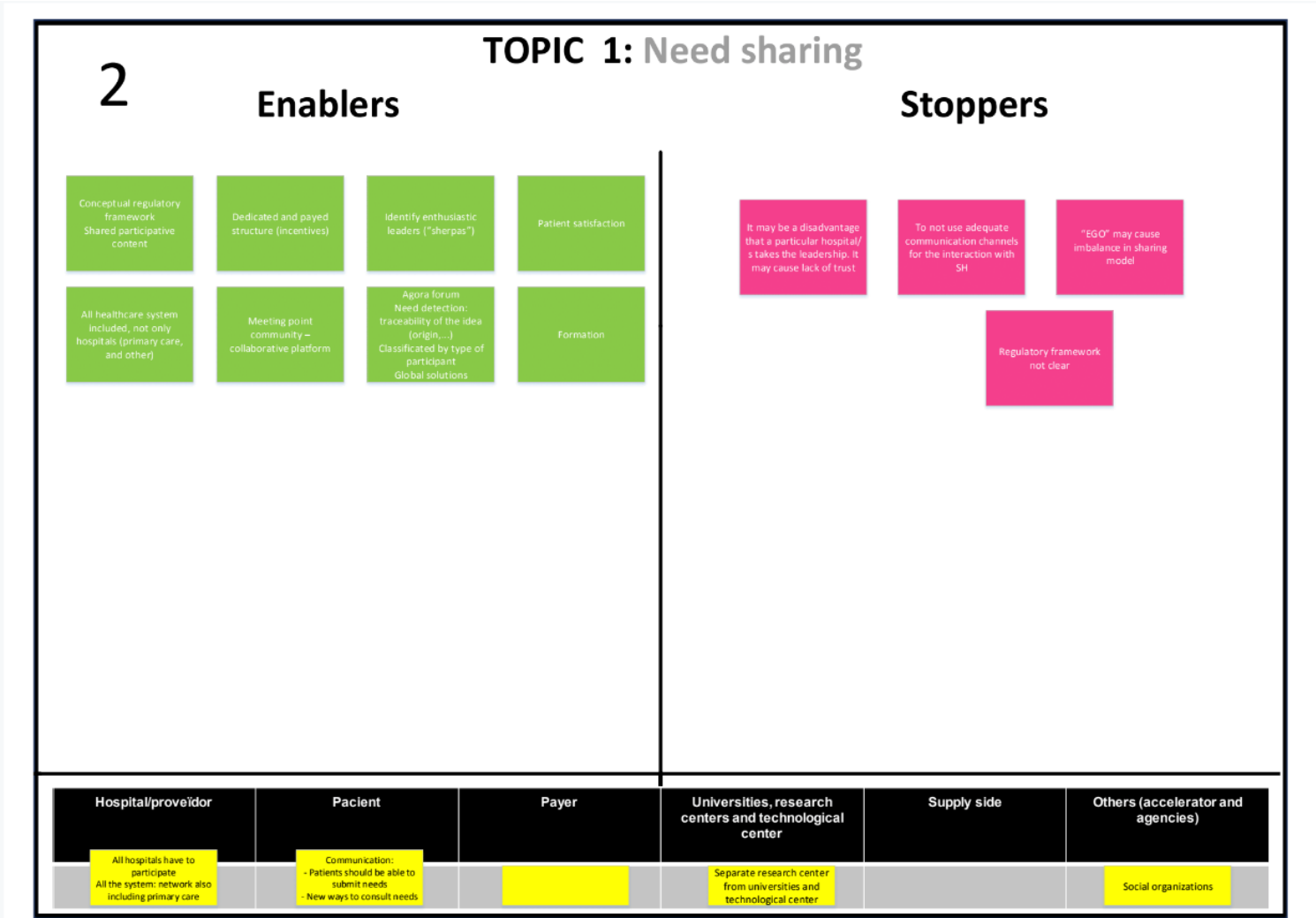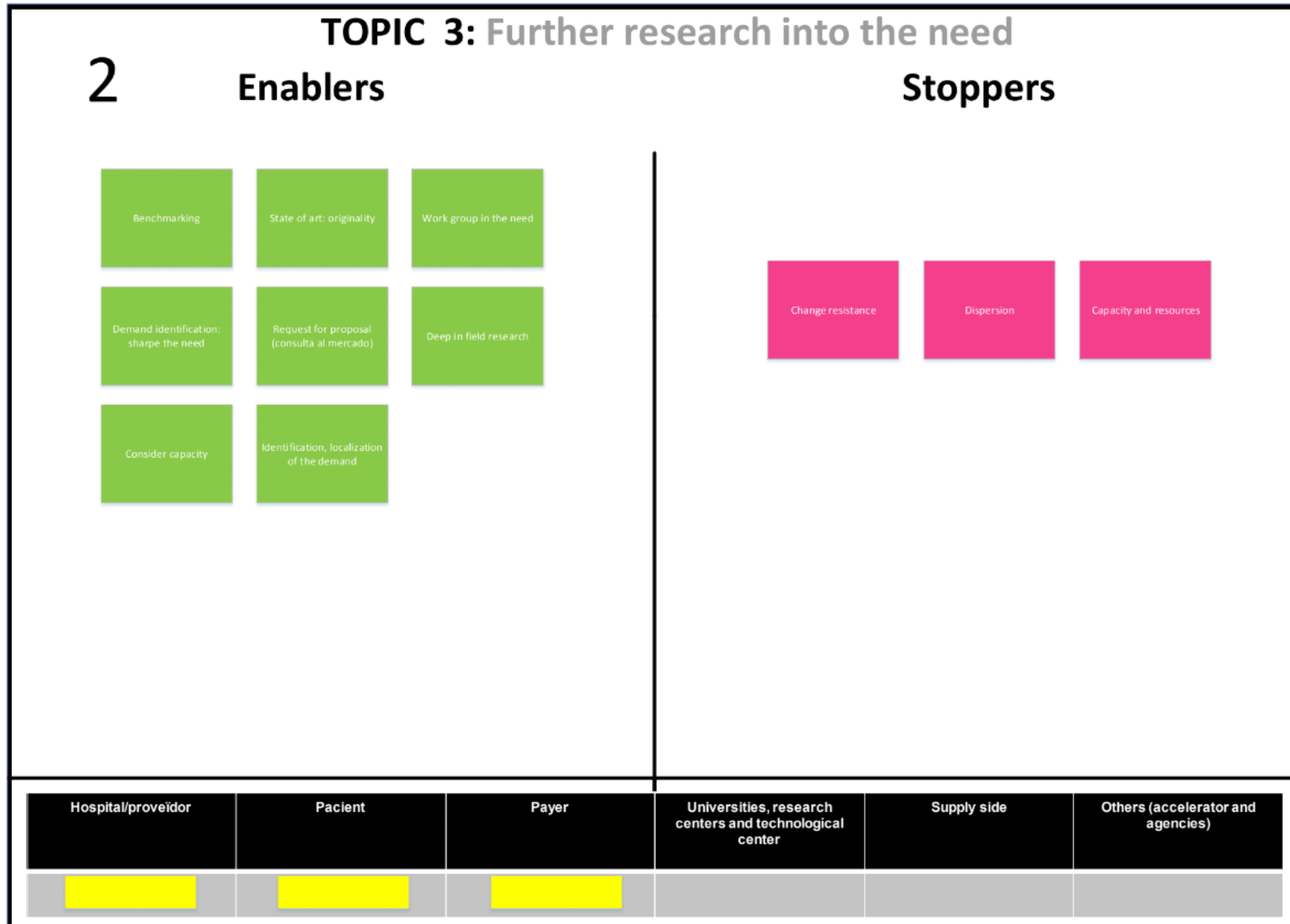
Figure 10: Comments regarding need priorization in an example group of Barcelona Presentation Workshop
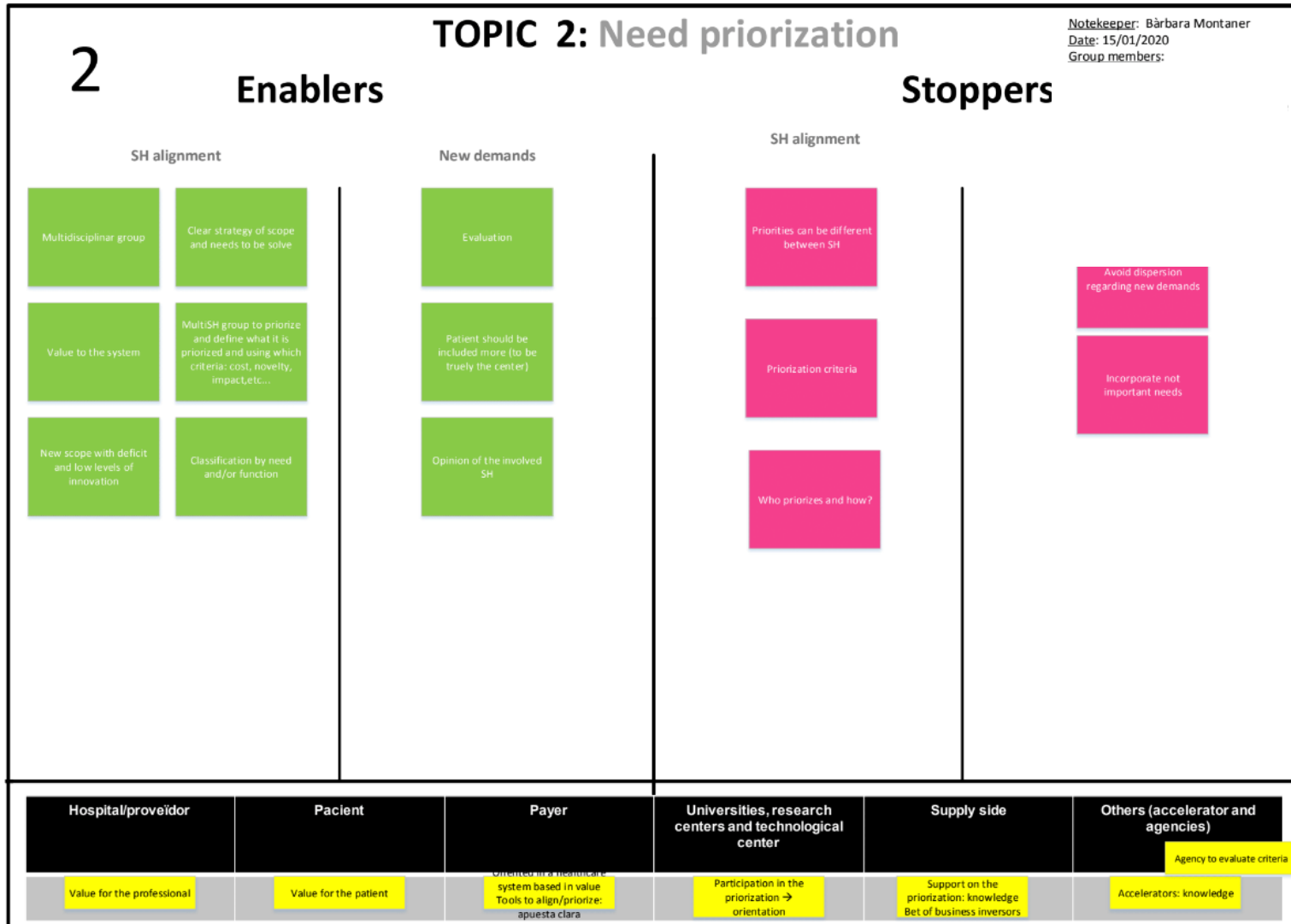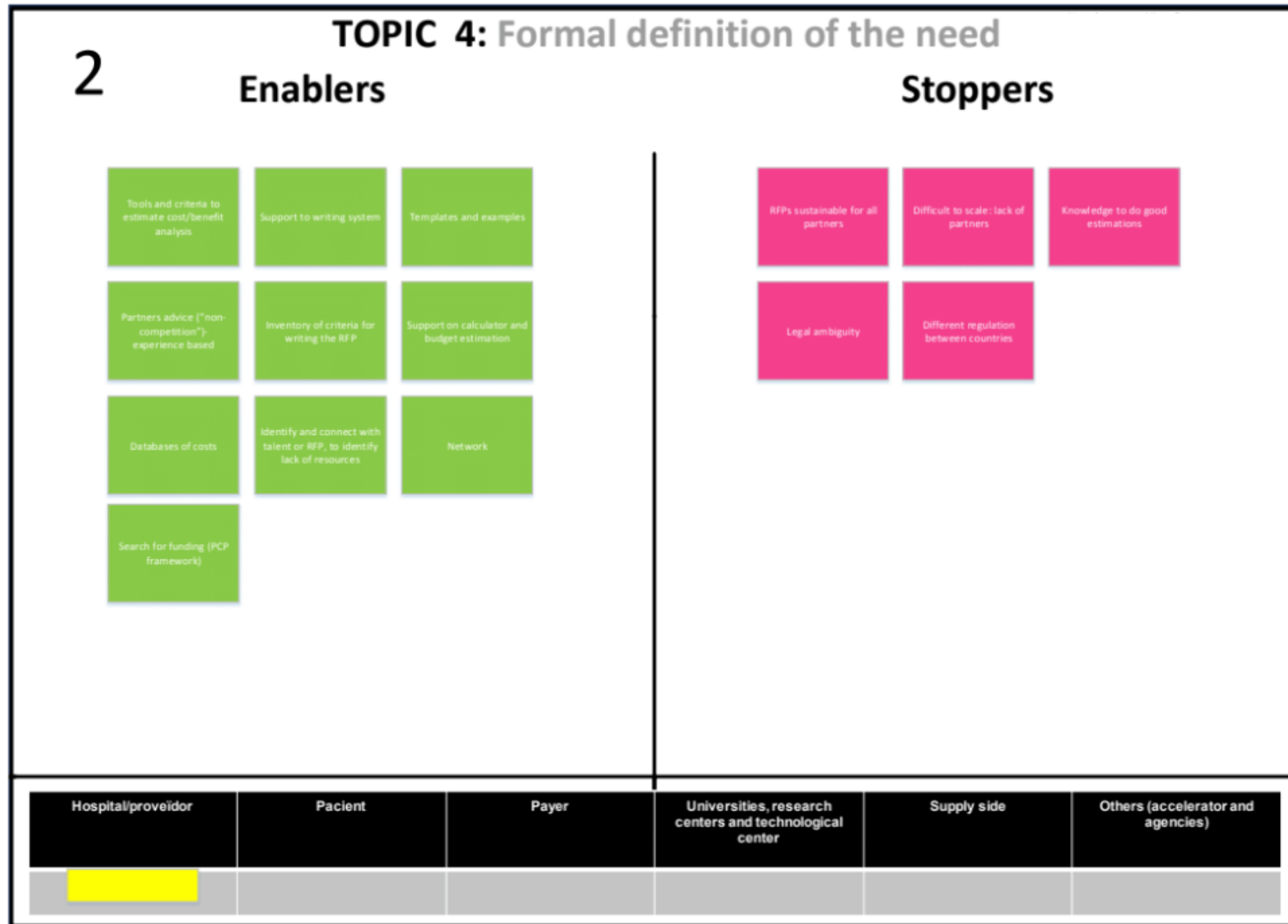
Figure 11: Comments regarding further detailing into the need in an example group of Barcelona Presentation

Figure 12: Comments regarding formal definition of the demand in an example group of Barcelona Presentation

Finally, after a brief debriefing and the second survey was answer by all participants to know they satisfaction rate and to analyze their participation on the project: http://bit.ly/WSPIPPI2

5.4 Information compilation from all stakeholder sites.

All the information gathered during the 4 stakeholder presentation events was compiled, as you can see in the following figure, by compiling and digitalising all posters and notes. Moreover, an excel file including all information clustered by topic and type of enabler/stopper and the suggested functionality was generated at each site.

Figure 13. Unified process of compilation of all information from presentation stakeholder workshop at each site

Group input
1 2 3 4
+
Notes by notekeepers
All sites compiled input for participants
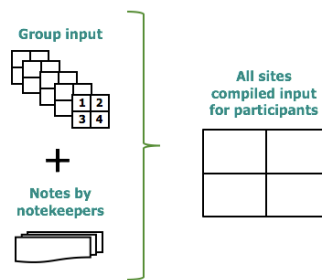
Cluster	Enablers/stoppers	TOTAL			Topic 1 Need sharing			Topic 2 Need priorization			Topic 3 Further detailing into the need			Topic 4 Concluded definition of the need			First suggested functionality	Other comments
		Total n° of citation	Total n° of citation as enabler	Total n° of citation as stopper	total n° citation	n° of citation enablers	n° of citations stoppers	total n° citation	n° of citation enablers	n° of citations stoppers	total n° citation	n° of citation enablers	n° of citations stoppers	total n° citation	n° of citation enablers	n° of citations stoppers		
Search	Time consuming	0	0	0	0			0			0			0				
	Expectation control	0	0	0	0			0			0			0				
	.....	0	0	0	0			0			0			0				
	.....	0	0	0	0			0			0			0				
		0	0	0	0			0			0			0				
		0	0	0	0			0			0			0				
Language		0	0	0	0			0			0			0				
		0	0	0	0			0			0			0				
		0	0	0	0			0			0			0				
		0	0	0	0			0			0			0				
...		0	0	0	0			0			0			0				

5.5 Analysis and conclusions of presentation workshop

In the following picture you can see clustered topics that at least appeared in 40% of groups in Barcelona workshop. Therefore, attendees mostly discussed about enablers visualization, language, business development, allowance of stakeholder interaction, priorization as enablers. In stoppers several legal and administrative issues appeared, efficiency and time use of the platform, the price of access and egos between different stakeholders and organization while sharing and working together. Futhermore, all stockholder clusters analysed their and others participation at each topic. Most of them were agree on participation of:

- **Healthcare providers in**: need sharing, need priorization, detailing the need and definition of the demand
- **Citizens / Patient association in**: need sharing, need priorization, detailing the need and definition of the demand
- **Policy makers in**: need sharing, need priorization and detailing the need
- **Payers in:** need sharing, need priorization, detailing the need and definition of the demand
- **Research community in**: need sharing and detailing the need

- **Industry in**: need sharing and detailing the need
- **Enablers in**: need sharing and detailing the need

A deep analysis on all the information gathered during the presentation workshop it is being done and it is still going on. The final analysis will be included in D2.1, that will be submitted during first term of 2021. Moreover, this information has been also used to start preparing the business and operating model (D6.1, D6.3 and 6.6) and in WP4.

Figure 14: Information clustered from 4 treated topics that were commented by 40% or more groups of Barcelona Presentation Workshop