# Deliverable D2.1

## Overview of the legal and political framework at EU level

*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 689476*

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## Abstract:

**The RELIEF project searches for new technologies to assist chronic patients to self-manage their pain. The new technologies and solutions are sought by using a Pre-Commercial Procurement (PCP) process. An initial step for launching the PCP call is to acquire an insight in the political and legal framework and to identify potential barriers and opportunities for implementation of the PCP process in the involved countries. A review was performed in all three countries.**

**Legal and political framework**

**The PCP process is governed by the EU public procurement directives 2004/18/EC, 2004/17/EC and 2009/81/EC. The legal basis for PCP in procurement law are the exemptions in Article 16.F of public procurement Directive 2004/18/EC and Article 24.E of public procurement Directive 2004/17/EC.**

- **The review of the national plans and the legal framework in the countries involved in the RELIEF project shows support for the PCP process from both a legal and a political point of view.**

**Potential Barriers for a smooth PCP process**

**Following analysis and discussions at a technical meeting in Cordoba, May 17-18, 2016 some potential barriers to the implementation of the PCP process were identified;**

- **The EU General Data Protection Regulation (Regulation 2016/679 may have impact in the different countries. Mitigation: to assure that legal aspects are identified and addressed in the project it was decided to create a legal group with one representative from each of the different countries.**
- **Potential language barriers may have impact on the project. Mitigation: Translation into the main languages within the consortium was highlighted and should at least include important**

summaries.

- Dissemination of knowledge around the project itself and the PCP process in specific. Mitigation: Produce easy-to-understand information material that can be used in the communication around the project.

No specific barrier of show-stopping potential was identified. In conclusion, all the identified barriers for a smooth PCP process may be addressed by specific mitigations.

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## 1. Executive Summary

The RELIEF project searches for new technologies to assist chronic patients to self-manage their pain. The new technologies and solutions are sought by using a Pre-Commercial Procurement (PCP) process. An initial step for launching the PCP call is to acquire an insight in the political and legal framework and to identify potential barriers and opportunities for implementation of the PCP process in the involved countries.

The main conclusions acquired by the review performed in all three countries: Spain, France and Sweden are gathered in this report.

According to the legal and political framework, the PCP process is governed by the **EU public procurement directives 2004/18/EC, 2004/17/EC and 2009/81/EC.** The legal basis for PCP in procurement law are the exemptions in Article 16.F of public procurement Directive 2004/18/EC and Article 24.E of public procurement Directive 2004/17/EC.

The review of the national plans and the legal framework in the countries involved in the RELIEF project shows support for the PCP process from both a legal and a political point of view.

Concerning the potential barriers for a smooth PCP process, following analysis developed in Task 2.1 and discussions at a technical meeting in Cordoba, May 17-18, 2016 between involved partners, some potential barriers to the implementation of the PCP process were identified and mitigation plans were established so as to tackle minor incidences:

- The **EU General Data Protection Regulation** (Regulation 2016/679 may have impact in the different countries. Mitigation action: to assure that legal aspects are identified and addressed in the project it was decided to create a legal group with one representative from each of the different countries.
- **Potential language barriers** may have impact on the project. Mitigation action: Translation into the main languages within the consortium was highlighted and should at least include important summaries.
- **Dissemination of knowledge** around the project itself and the PCP process in specific. Mitigation action: Produce easy-to-understand information material that can be used in the communication around the project.

**No specific barrier of show-stopping potential was identified**. In conclusion, all the identified barriers for a smooth PCP process may be addressed by specific mitigation actions.

## 2. Introduction

Chronic pain is a major health problem amongst the adult population in Europe. It is estimated that around **95 million Europeans** suffer from different kinds of chronic pain and the annual cost for the health care system is over €300bn in Europe.

Since chronic pain is associated with many different diagnostic entities ranging from diseases like e.g. osteoarthritis, low-back pain and other muscular-skeletal conditions to neuropathic pain conditions like painful diabetic polyneuropathy and pain following stroke or multiple sclerosis. Due to this, treatment also varies from patient to patient and may include e.g. pharmacological treatments, neuromodulation, physiotherapy, multimodal rehabilitation. Chronic pain may, in many instances, be a complex syndrome of pain, disability, fatigue and often further complicated by psycho-social impact.

To improve chronic pain management in this large patient population, with limited resources, it is necessary to develop tools for self-management, therapeutic control, documentation of effects that enables the patient to take an active part in the treatment and to facilitate for the care provider to assist the patient in a cost-effective manner.

**The project searches for new technologies to assist chronic patients to self-manage their pain. The new technologies and solutions are sought by using a Pre-Commercial Procurement (PCP) process.**

The European Commission is reinforcing the policy framework in Europe for procurers to use pre-commercial-procurement and Public Procurement of Innovative Solutions as instruments to promote innovation from demand side.

In this regard, several EU policy initiatives on Innovation Procurement have been developed, such as the European Assistance on Innovation Procurement (EAFIP)[1], New 2014 EU State aid framework on R&D&I (Research, Development and Innovation)[2] or New 2014 EU public procurement directives in which it is maintained the exemption for R&D services that is used by PCP (Public procurers can thus continue to carry out PCP procurements based on exemption for R&D services in the new articles 14 in directive 2014/24/EC[3] and article 32 in directive 2014/25/EC[4]).

In addition, the PCP process is described in COM (2007)799 final.[5] PCP is the procurement of research and development of new innovative solutions before they are commercially available. Pre-Commercial Procurement is a method for procuring R&D services, or of the result of R&D services, with the purpose of developing a new product or solution.

In the following table it is shown the general process of a PCP:

[1] http://eafip.eu/
[2] C(2014) 3282
[3] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0024&from=EN
[4] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0025&from=EN
[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0799:FIN:EN:PDF

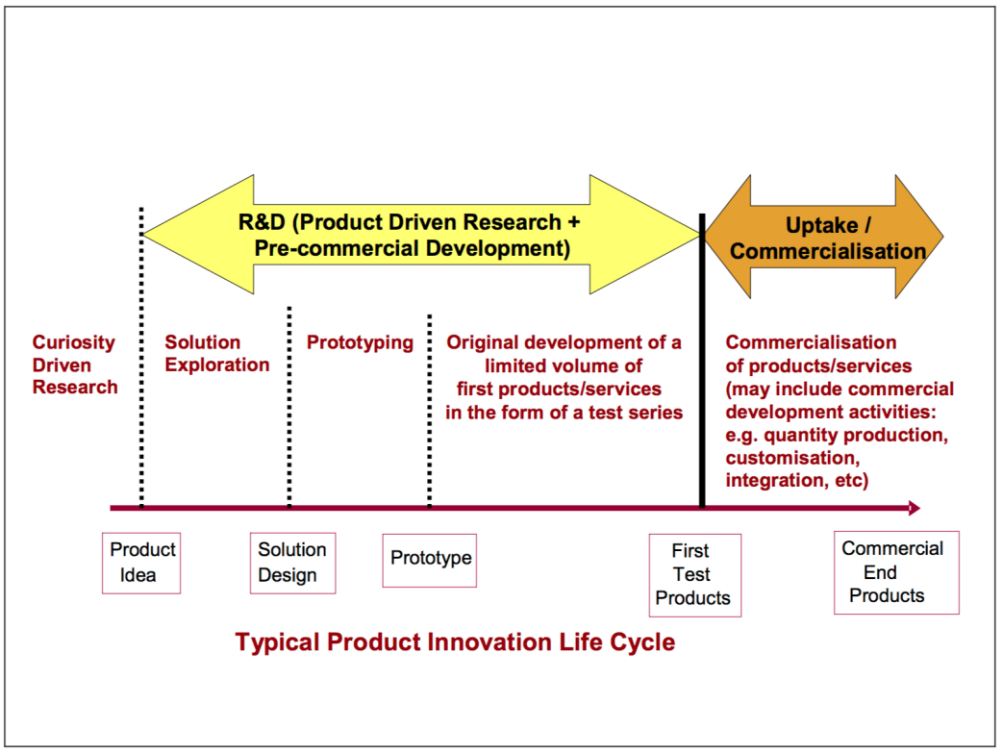


**Figure 1: R&D versus commercialization phase (from COM (2007) 799 final)**

**PCP is exempted from the EU public procurement directives** because procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors). It is also exempted from the **WTO Government Procurement Agreement (GPA)**[6] because this Agreement does not cover R&D services (the PCP being limited to such services — and any subsequent PPI procurements relating to commercial-scale supply of such solutions not being part of the PCP procurement). The procurement does not constitute state aid under the EU state aid rules because it **follows an open, transparent, competitive procedure with risk- and benefit-sharing at market price**. The division of all rights and obligations (including IPRs) and all selection and award criteria for all phases are published at the outset; the PCP is limited to R&D services and clearly separated from any potential follow-up PPI procurements; PCP contractors are not given any preferential treatment in a subsequent procurement for provision of the final products or services on a commercial scale.

In Europe, the PCP has so far been an under-utilized tool for promoting innovation. Although PCP is a very important vehicle for encouraging innovation in companies, little procurement in Europe is aimed to innovation. This means that Europe has an enormous opportunity to spur innovation using procurement because of the large financial volumes involve[7]. One of the aims of this project is to demonstrate the effectiveness of this approach to address societal and governmental needs.

The first objective of the project is **to establish, and execute, an agreed PCP process to run a cross-border PCP call for tender**. The aim is that in the future public organizations in

[6] https://www.wto.org/english/tratop_e/gproc_e/gpa_1994_e.htm
[7] http://data.consilium.europa.eu/doc/document/ST-1209-2015-INIT/en/pdf

the participating countries and in the EU become familiar with the PCP process and tools and use them to meet their needs.

An initial step for launching the PCP call in the RELIEF project is to get an **insight in the political and legal framework** and to **identify potential barriers and opportunities for implementation of the process in the involved countries**. To perform a review of the most critical aspects related to PCP in the procurer's countries an internal questionnaire was elaborated and distributed among public procurers.

Based on the general bibliography gathered of EU policy directives and also by conducting the internal review of the legal framework in each specific country (Spain, France and Sweden) we analyzed all gathered information and we synthesized them into an agreed process that fits the involved countries.

Mitigations actions have been established to tackle identified potential barriers to deploy the PCP process attending to the particularities of the involved countries.

# 3. Methods

## 3.1. EU directives on PCP

The PCP process is governed by the EU public procurement directives 2004/18/EC[1], 2004/17/EC[2] and 2009/81/EC[3]. PCP is exempted from the EU public procurement directives because procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors). The legal basis for PCP in procurement law are the exemptions in Article 16.F of public procurement Directive 2004/18/EC and Article 24.E of public procurement Directive 2004/17/EC[4].

## 3.2. National legal framework countries involved

The national plans and legal framework for development of PCP was analyzed based on country specific legislation and previous experiences of PCP in the three countries by legal and procurer experts. Information was gathered by inclusion in the questionnaire developed as a working document as described below.

Development of a questionnaire

Even if there are existing EU-directives on the PCP process (2004/18/EC[8], 2004/17/EC [9]and 2009/81/EC[10]), countries differ and there may be barriers and opportunities that need to be addressed in order to efficiently progress a PCP process involving several different countries. These barriers may be e.g. cultural, legal or political and analyzing these potential barriers is of outmost importance in order to, if necessary, find ways to address and overcome them. To review the most critical aspects related to the PCP process in the procurer's countries an internal questionnaire was developed as a working document and answers were provided by the public procurers and legal experts among the partners in the RELIEF project.

The questionnaire was designed by SAS partners with the support of all partners involved. The contents of the questionnaire are:

- What are the national plans and legal framework for development of pre - commercial procurement?
- Basing on available secondary data *(e.g. national reports, projects, etc.)* what are the most important:
  a) barriers
  b) opportunities
  for development of **innovation procurement** in your country?
- To what extent and in what way below factors influence development of **innovation procurement** in your country?
  - European targets
  - National policy targets
- Which **procurement methods** are allowed by the national regulation? *(e. g. open, restricted, negotiated, accelerated)*. List them.
  *Open contest, restricted contest, negotiated with publication, negotiated without publication, competitive dialogue.*

[8] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004L0018&from=en
[9] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:134:0001:0113:en:PDF
[10] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0081&from=ES

- What is the share of **dialogue-based / outcome-based procurement methods** *(e.g. technical dialogue, competitive dialogue)* in the overall amount of procurements in your country annually in last three years (*possible source of information: public procurement office)*?

# 4. Results

## 4.1 National plans and legal framework for development of PCP

SPAIN

In Spain (SAS) PCP is supported by the legal framework as stated in the Restated text of the Public Sector Procurement Law, approved by Royal Legislative Decree 3/2011, 14th November 2011[11].

On this law there are some articles supporting innovative public procurement as the following:

- Article 22.2. In this article, it is described the commitment of the public contractors with the innovation and the incorporation of high-tech in the public sector.
- Article 4.1.r: In this article, it is described the procurement contracts excluded from the considerations under the standard public procurement law. They speak about R&D contracts (innovation procurement), whenever in the procurement the risks and benefits of the scientific and technical research needed to develop innovative solutions overcome the ones available in the market.
- Article 11.1.: the collaboration contracts between public sector and private sector are defined, where the innovation procurement is described.
- Final fifth provision: It defines that public authorities will boost the pre-commercial procurement by setting apart some specific budget.

Further support is found in 14/2011 Law of Science, Technology and Innovation, 1st of June 2011[12].

*Article 44.3: approval and publication of Ministerial Departments of their Innovation Procurement Plan*.

The Spanish Science, Technology and Innovation Strategy 2013-2020 (http://www.idi.mineco.gob.es/stfls/MICINN/Investigacion/FICHEROS/Estrategia_espanola_ciencia_tecnologia_Innovacion.pdf) describes the capacity of the administration to act as an engine for business innovation managing their demand for products and services through innovative public procurement initiatives. It makes emphasis in the importance of the development of new networks between the public and private sector to boost innovation as pre-commercial procurement. It also remarks that it is necessary some changes in the legal public procurement framework in order to evaluate positively innovative aspects so the Public

[11] https://www.boe.es/buscar/act.php?id=BOE-A-2011-17887
[12] https://www.boe.es/boe/dias/2011/06/02/pdfs/BOE-A-2011-9617.pdf

authorities act as an innovation engine for the companies, managing their demanding of products and services.

The Sustainable Economy Law boosts particularly the innovation procurement, as for innovation procurement, general regimen of Public Sector Procurement Law is not applicable. Furthermore, it plans to put aside a budgetary reserve for funding this kind of public innovation procurement within the scope of State General Administration.

Through the Agreement of the Council of Ministers E2I(2nd July 2010) Public Innovation Procurement was supported and promotion of innovative markets via innovation procurement on different areas.

(http://www.idi.mineco.gob.es/stfls/MICINN/Innovacion/FICHEROS/Politicas_Fomento_Innv./Acuerdo_Consejo_Ministros_8-7-11_CPI.pdf).

Moreover, some of the key points defined in the Agreement of the Council Ministers- CPI, 8th October 2010) were the following (https://www.boe.es/buscar/act.php?id=BOE-A-2011-4117):

- Good and services were determined and offers criteria.
- Instruments for successful innovation procurement were defined.
- Roadmap of innovation procurement to be published with the suppliers as targets.
- Yearly Public Innovation Procurement proposal to be approved by Council of Ministers.
- Legal instruments to be defined by the Finance and Public Administrations Ministry.

FRANCE

In France (RESAH) **Article 14-3° of the ministerial order of July 23rd, 2015, Ministerial order No. 2015-899 on public procurement** (https://www.legifrance.gouv.fr/eli/ordonnance/2015/7/23/EINM1506103R/jo/texte**)** describes that the concept of "pre-commercial procurement" is based on the research and development (R&D) process before commercial development activities.

PCP thus takes the form of a single public procurement contract for R&D services managed in three stages. The first stage involves a solution exploration phase, followed by a prototyping phase and finally a test series where the R&D service covers the development of a first batch of pre-commercial volume pre-products, validated via field tests.

Article 14-3° of the ministerial order specifies that research and development service contracts are exempted from the scope of application of the public procurement regulation. However, this article does not specify the definition of a research and development service contract and whether the concept of R&D services in French law covers all three stages of PCP. The administrative judge may control these elements.

**National Pact for Growth, Competitiveness and Employment**, Ministry of Economy and Finance (2013) (http://www.economie.gouv.fr/files/PR-competitiveness.pdf) intends to use public procurement as a leverage to support business innovation capacity. Proposal No. 32 of the national pact requires that at least 2% of the public order of the State, its operators and

hospitals are made to innovative small and medium enterprises (SMEs ) and middle sized companies (ETI) in the Horizon 2020.

This requirement is reiterated by the Prime Minister's circular of September 23rd, 2013 on support for innovation through public procurement.

SWEDEN

In Sweden (CCU) no specific strategy for PCP has been identified, although the Government (SOU 2010:56 and SOU 2013:12, appendix 5) (www.regeringen.se) has supported the concept of PCP (www.regeringen.se).

These documents emphasises that PCP creates new opportunities for innovative companies and that public procurement of innovations can create conditions for expansion and export.

There are PCP projects on-going e.g. the **Silver project by VINNOVA**, developing robotics for elderly[13]. Vinnova is a Swedish government agency working under the Ministry of Enterprise. The concept of PCP is supported by VINNOVA (www.vinnova.se). VINNOVA manages programs for strengthening Sweden's innovativeness. The programs have different specialisms and cover several areas of society and industries.

The ability to perform a PCP is based on the EU Directive exemption from procurement obligation for the purchase of research and development services contracts. The exception has been implemented in Swedish law (**LOU 1 kap. 6§ p.6 and LUF 1 kap. 19§ p.5**) (www.riksdagen.se).

### 4.2 Barriers and opportunities based on the questionnaire

Based on the answers on the questionnaire several factors that could be **potential barriers and opportunities for the implementation of the PCP process in general were identified**. At a technical meeting in Cordoba, Spain, the involved partners discussed the potential impact of these factors and a consensus was reached.

The identified barriers and opportunities that could have impact are presented in Table 1.

Some other potential barriers were included in the answers of the questionnaire but after internal discussions they were not considered to have significant impact and are therefore excluded.

The mitigation actions to address the identified potential barriers for the PCP process are presented in Table 1:

[13] https://ec.europa.eu/digital-single-market/en/news/innovation-procurement-initiatives-around-europe

| Country | Identified barriers | Identified opportunities | Mitigation Action |
|---|---|---|---|
| Spain | Knowledge level/awareness of performing PCP – lack of training of the public managers about innovation procurement. It is commonly happening that managers are doing innovation procurement without knowing it, if so they do not take all the advantages that PCP can add to the purchasing process. (www.mineco.es) | | Produce information material understandable by layman report, factsheet dedicated to suppliers; training courses to procurers |
| | | Support for providing innovative solutions to unmet needs, improve efficiency and the quality of public services (www.mineco.es) | |
| | | PCP could help to encourage enterprises to consolidate research and innovation departments to build a corporate dynamic model (www.mineco.es) | |
| France | Knowledge level/awareness of performing PCP - the knowledge level and practically oriented interest and resources directed towards PCP/PPI are currently not very high among public authorities such as hospitals and municipalities in France. (INSPIRE D 2.5 – Gap Analysis and Recommendations on PCP & PPI implementation) | | Produce information material understandable by layman report, factsheet dedicated to suppliers; training courses to procurers |
| | Language barrier - One of the main obstacles to be part of a European Project for the French organisations is related to the language barrier. Indeed, many of them do not have a project manager dedicated to the management of European Project and often their employees do not speak English. This creates an obstacle for the public organisations to be involved at European level in the procurement of innovative solutions. (INSPIRE D 2.5 – Gap Analysis and Recommendations | | Translation to main languages, at least summaries in French and Spanish. Dissemination of tender also in national platforms. |

| | | | |
|---|---|---|---|
| | on PCP & PPI implementation) | | |
| | The possibility to assign/award a procured contract to a company that have previous knowledge from the PCP (http://www.economie.gouv.fr/files/files/directions_services/daj/marches_publics/actualites/projet-guide-achat-public-innovant.pdf) | | Transparency and sharing the results in public |
| | | Extensive communication around previous projects have risen the interest around PPI and PCP (INSPIRE project) (INSPIRE D 2.5 – Gap Analysis and Recommendations on PCP & PPI implementation) | |
| **Sweden** | Very strict legislation around data protection and patient privacy (patientdatalagen 2008:355) ( www.riksdagen.se) | | During the project, the EU general Protection Regulation will be in place and applied in EU |
| | | High level of acceptance for technical solutions and innovations (www.vinnova.se) | |
| | The EU General Data Protection Regulation (Regulation 2016/679) will replace the existing EU directive on data protection (www.ec.europa.eu/justice/data-protection) | | Create a legal group with representatives from each country. Evaluate the implications in the different countries |

**Table1. Identified barriers and opportunities for the smooth conduction of a PCP process in general**

## 5. Conclusions

The PCP process is governed by the EU public procurement directives 2004/18/EC, 2004/17/EC and 2009/81/EC. The legal basis for PCP in procurement law are the exemptions in Article 16.F of public procurement Directive 2004/18/EC and Article 24.E of public procurement Directive 2004/17/EC.

In Spain, PCP is supported by the legal framework as stated in the Restated text of the Public Sector Procurement Law, approved by Royal Legislative Decree 3/2011, 14th November 2011. Further support is found in 14/2011 Law of Science, Technology and Innovation, 1st of June 2011. From a political point support for the PCP process in Spain can be found in The Spanish Science, Technology and Innovation Strategy 2013-2020. It makes emphasis in the importance of the development of new networks between the public and private sector to boost innovation as pre-commercial procurement. It also remarks that it is necessary some changes in the legal public procurement framework in order to evaluate positively innovative aspects so the Public authorities act as an innovation engine for the companies, managing their demanding of products and services. Through the Agreement of the Council of Ministers E2I(2nd July 2010) Public Innovation Procurement was supported and promotion of innovative markets via innovation procurement on different areas.

In France, Article 14-3° of the ministerial order of July 23rd, 2015, Ministerial order No. 2015-899 on public procurement describes that the concept of "pre-commercial procurement" is based on the research and development (R&D) process before commercial development activities. It specifies that research and development service contracts are exempted from the scope of application of the public procurement regulation. However, this article does not specify the definition of a research and development service contract and whether the concept of R&D services in French law covers all three stages of PCP. The administrative judge may control these elements. National Pact for Growth, Competitiveness and Employment, Ministry of Economy and Finance (2013) intends to use public procurement as a leverage to support business innovation capacity. Proposal No. 32 of the national pact requires that at least 2% of the public order of the State, its operators and hospitals are made to innovative small and medium enterprises (SMEs ) and middle sized companies (ETI) in the horizon 2020. This requirement is reiterated by the Prime Minister's circular of September 23rd, 2013 on support for innovation through public procurement.

In Sweden the Government (SOU 2010) has supported the concept of PCP. The ability to perform a PCP is based on the EU Directive exemption from procurement obligation for the purchase of research and development services contracts. The exception has been implemented in Swedish law. Vinnova is a Swedish government agency working under the Ministry of Enterprise. VINNOVA manages programs for strengthening Sweden's innovativeness. The concept of PCP is supported by VINNOVA (www.vinnova.se).

**Overall, the review of the national plans and the legal framework in the countries involved in the RELIEF project shows support for the PCP process from both a legal and a political point of view.**

Based on the internal questionnaire and discussions at the technical meeting in Córdoba, May 17-18 2016 some barriers for the smooth conduction of the PCP process were

identified. Probably the most important is the EU General Data Protection Regulation (Regulation 2016/679).
Today, healthcare organizations are facing major challenges when it comes to reduce costs and complexity, while innovation and cooperation with the private market should be promoted. They must deliver high quality healthcare, holding down costs while working preventive with patients to promote public health. Software providers that target the health care often want to offer products that increase complexity rather than incrementally building on the existing one. There are many health care providers who want to expand their services to reach a wider market, which are daunted by the cost and resources required to create and manage the IT-infrastructure their growth ambitions require.

The above mentioned challenges are made even greater by the requirement to observe the regulations concerning the safety and integrity in the handling of confidential healthcare information. The responsibility for that the rules relating to confidential patient healthcare information is handled properly lies on the healthcare organizations, as well as the vendors/suppliers that come in contact with such information. In the current situation, all health actors has to relate to the existing EU Directive on Data Protection (European Parliament and Council Directive 95/46/EC of 24 October 1995), which is replaced in about two years by the GDPR.

Obviously GDRP is not a real barrier, but the potential impact in the different countries needs to be analyzed to identify implications for the project. It was decided to create a legal group, the first step will be to assign one representative from each of the different countries.

The possibility to assign/award a procurer contract to a company that has previous knowledge from the PCP is mitigated by complete transparency and sharing of the results within the project with the public domain.

To address potential language barriers the possibility to translate into the main languages within the consortium was highlighted and at least should include important summaries.

Another important aspect is the dissemination of knowledge around the project itself and the PCP process in specific. An important mitigation is to produce easy-to-understand information material that can be used in the communication around the project.

The most important opportunity identified was the **potential to increase awareness around PCP and boost the interest around innovation and technical development.**

**No specific barrier of show-stopping potential was identified**. In conclusion, all the identified barriers for a smooth PCP process may be addressed by specific mitigations.

The main conclusions gathered have been used to prepare Deliverable D2.2 PCP template.