



Platform for Innovation of Procurement  
and Procurement of Innovation

## **D5.4 A core set of outcomes indicators**

# **PIPPI**

**GA No 826157**

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## Executive Summary

The Platform for Innovation of Procurement and Procurement of Innovation (PIPPI) project is creating a cross-border Community of Practice and bringing together experts from the demand side to identify common clinical needs that could be addressed using digital healthcare solutions. Based on these identified unmet needs, the Community of Practice will prepare a cross-border pre-commercial procurement (PCP/PPI) for a selected clinical need. The PIPPI consortium consists of seven leading European university hospitals (K, EMC, HUVH, HUS, MUW, OSR, KCH FT) and AQuAS, a relevant player in the adoption of PCP/PPI procurement instruments, including their affiliated academic institutions and the European University Hospital Alliance - EUHA ([www.euhalliance.net](http://www.euhalliance.net)), an organization that identifies and collaboratively tackles issues that impede the optimal functioning of healthcare delivery. This document responds to part of T5.1 'Identify clinical and patient needs and demand' of WP5 'Preparation for execution of a cross-border PCP' and aims to define, based on literature review, experiences in PCP and PPI, knowledge and understanding from PiPPI partners and their external stakeholders, a set of challenge-neutral results (outputs, outcomes and impact) to be adopted when evaluating the feasibility, planning and monitoring of performed value-based procurement activities. During the gray literature review ten seminal documents and six PCPs/PPIs were analyzed. From there a total number of 108 results (outputs, outcomes and impact) were identified and divided in five categories. Four of them are named accordingly to the main four identified stakeholders of generic PCPs/PPIs (patient, healthcare professional, healthcare provider, health system) to make explicit the stakeholder interest and point of view on the desired effects and impacts. Later the identified elements went through prioritization process thanks to the CARE selection criteria: by mean of a first survey, PiPPI internal and external stakeholders were requested to assess the Clearness and Exemplarity of each of the element and propose changes if applicable; later, by mean of a second survey, PiPPI internal and external stakeholders were requested to assess the Relevance and Availability of each of the element. Thanks to this process this deliverable establishes a challenge-neutral core set of 25 results (outputs, outcomes and impact) to provide valuable information when identifying ANY digital challenge, determining the interest and opportunities in industry and payers, projecting a plan of a cross-border PCP/PPI and finally completing its feasibility study. All the remaining identified elements are divided in two additional sets to be added to the analysis in case considered appropriate.



## List of Abbreviations

D - Deliverable

FP7 – Seventh Framework Programme

GA – Grant Agreement

H2020 – Horizon 2020

OECD - Organization for Economic Co-operation and Development

QOL – Quality of Life

PCP- Pre-Commercial Procurement

PIPPI – Platform for Innovation of Procurement and Procurement of Innovation

PPI - Public Procurement of Innovation

T - Task

WHO – World Health Organization

WP - Work Package



## Glossary

**Award criteria:** Economically most advantageous tender (MEAT) is the only award criterion mentioned in the modernised directive. MEAT criteria consist of *Price* (the purchase value of the supplies, services or works (regardless of the payment modalities)), *Cost* (monetary value of the production, acquisition, use, consumption, maintenance, interconnecting, recycling and/or disposal of the subject matter of the public contract), *Quality* (quality criteria may include qualitative, environmental, social or innovative aspects of products, services or works)<sup>1</sup>

**Contract performance:** Contract performance clauses should have at least the following aspects: (1) Contract performance criteria, measurable indicators of quality and performance targets; (2) Exit clauses in case of underperformance or in case that the market brings even more suitable solution than the one currently under development; (3) Contract modification clauses, due to volatility and high potential of further innovation ascertained during the contract performance<sup>1</sup>

**Functional requirements and specifications:** technical specifications set in terms of functional requirements shift the responsibility for achieving better results to the market. The public buyer sets minimum requirements in order to avoid an abusively low-performing tender, but is not overly prescriptive as regards the means of achieving a desired outcome. Economic operators enjoy openness and flexibility to reach the optimal performance.<sup>1</sup>

**Pre-Commercial Procurement (PCP):** it 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.<sup>2</sup>

**Public Procurement of Innovative solutions (PPI):** it 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.<sup>3</sup>

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<sup>1</sup> EUROPEAN COMMISSION (2018), Commission notice: Guidance on Innovation Procurement, EUROPEAN COMMISSION (last time accessed 23/11/2020: <https://ec.europa.eu/transparency/regdoc/rep/3/2018/EN/C-2018-3051-F1-EN-MAIN-PART-1.PDF> )

<sup>2</sup> <https://ec.europa.eu/digital-single-market/en/pre-commercial-procurement>

<sup>3</sup> <https://ec.europa.eu/digital-single-market/en/public-procurement-innovative-solutions>



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## Purpose of document

This document responds to part of T5.1 'Identify clinical and patient needs and demand' of WP5 'Preparation for execution of a cross-border PCP' and aims to define, based on literature review, experiences in PCP and PPI, knowledge and understanding from PiPPi partners and their external stakeholders, a set of challenge-neutral results (outputs, outcomes and impact) to be adopted when evaluating the feasibility, planning and monitoring of performed value-based procurement activities.

## Introduction

The main tasks of WP5 'Preparation for execution of a cross-border PCP' are to:

- identify clinical and patient needs and demands, which involve the participation and experience from patients;
- define interest and opportunities with supply-side and healthcare payers, and fit the needs from patients to the opportunities that market and insurance can provide;
- and do a feasibility study and preparation of a cross-border PCP (or PPI), taking into account the opinion and needs from all different actors in establishing unmet needs.

The present deliverable establishes a challenge-neutral core set of results (outputs, outcomes and impact) to provide valuable information when identifying a digital challenge (T5.1), determining the interest and opportunities in industry and payers (T5.2), projecting a plan of a cross-border PCP/PPI and finally completing its feasibility study (T5.3).

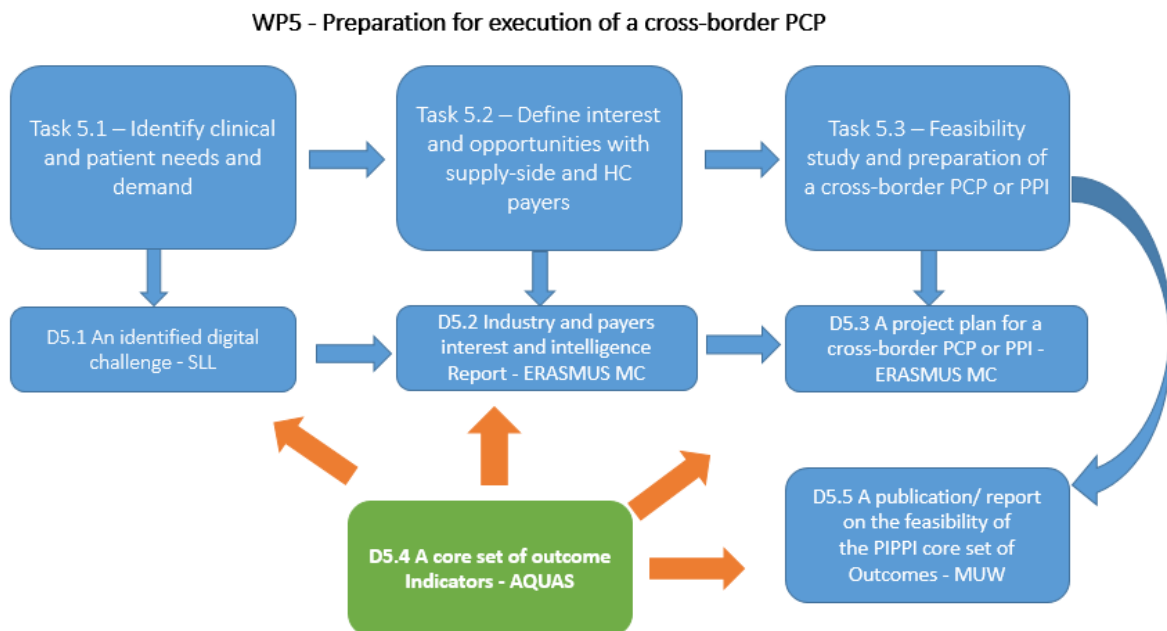


Figure 1 - Structure of WP5 tasks and deliverables



WHO reminds us that “(...) the use of digital technologies offers new opportunities to improve people’s health (...) But the evidence also highlights challenges in the impact of some interventions (...) If digital technologies are to be sustained and integrated into health systems, they must be able to demonstrate long-term improvements over the traditional ways of delivering health services.”<sup>4</sup>

Theory of Change framework is the framework proposed to support PiPPi project to conceptualize the relationship between the activities of the digital health intervention to be carried out through the PCPs/PPIs to address the identified unmet needs and their results and the demonstration of the long-term improvements over the traditional ways of delivering health services.

Consequently the demonstration of the evidence of the impact of the digital health intervention passes through the definition of an appropriate ‘Results Chain’<sup>5</sup>, the linear representation on the Theory of Change framework:



Figure 2 - Results chain

- **Inputs:** the financial, human, and material resources used for the development of the digital health intervention.
- **Activities:** actions taken or work performed through which inputs, such as the PCP or the PPI procurement procedures prepared along the PiPPi project, funds, technical assistance and other types of resources are mobilized to produce specific outputs.
- **Outputs:** immediate results, like the products, capital goods and services fruit of the development of the intervention; may also include changes resulting from the intervention which are relevant to the achievement of outcomes (e.g.: healthcare professional training, new healthcare protocols in place).
- **Outcomes:** The likely or achieved medium-term and long-term effects of an intervention’s outputs. In case of PiPPi we can refer to both non health-related outcomes (e.g.: increase guidelines adherence or healthcare worker performance) and health-related outcomes. WHO defines health outcomes<sup>6</sup> as a change in the health status of an individual, group or population

<sup>4</sup> WHO (2016) Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment. Geneva: World Health Organization; 2016. Licence: CC BY-NC-SA 3.0 IGO (last time accessed 16/11/2020: <https://www.who.int/news/item/17-04-2019-who-releases-first-guideline-on-digital-health-interventions> )

<sup>5</sup> OECD - (2010): Glossary of Key Terms in Evaluation and Results Based Management (last time accessed 16/11/2020: <https://europa.eu/capacity4dev/iesf/documents/glossary-key-terms-evaluation-and-results-based-management-oecd-2010> )

<sup>6</sup> WHO (1998) Health Promotion Glossary (last time accessed 16/11/2020: <https://www.who.int/healthpromotion/about/HPR%20Glossary%201998.pdf> )

[10]

which is attributable to a planned intervention or series of interventions, regardless of whether such an intervention was intended to change health status”.

- *Impacts*: effects on root causes and sustained significant changes<sup>7</sup> produced by a development intervention, directly or indirectly, intended or unintended (e.g.: sustained drop in the incidence of a given disease)
- *Results*: the whole outputs, outcomes and impacts of a development intervention.
- *Results Chain*: the causal sequence for a development intervention that stipulates the necessary sequence to achieve desired objectives-beginning with inputs, moving through activities and outputs, and culminating in outcomes, impacts, and feedback.

To complete the description a Results Chain and its elements, also the following items are to be defined:

- *Indicator*: Quantitative or qualitative factor or variable that provides a simple and reliable means to measure an achievement, a result, to reflect the changes connected to an intervention, or to help assess the performance of a development actor
- *Goals*: the higher-order objectives to which a development intervention is intended to contribute, the satisfaction of the identified unmet needs and that justifies the preparation of either the PCP or the PPI along PiPPI project

In the present document, a set of 109 of challenge-neutral results (outputs, outcomes and impact) have been defined by both internal and external stakeholders, according to their knowledge and experience on the field.

Divided in five categories, this set of elements aims to answer two specific questions:

1. *How are the new digital services, acquired through PiPPI activities, increasing value in health system?*
2. *To what extent is PiPPI succeeding in their PCP/PPI procedures according to both internal and external stakeholders?*

The two questions have been posed at a generic level independently of the intervention maturity life cycle: results like long-term outcomes and impacts will influence the go-no go decisions related to pursue a PCP or a PPI but cannot make part of the intervention monitoring since the number of users will be in the range of less than 10000 and it will be not possible to evaluate the overall effectiveness and the health impact of the intervention.

In the case of a PCP (precommercial technologies piloted with no more than 1000 patients) it will be possible to assess no more than outputs (like feasibility and usability), while, in the case of PPI, mid-term outcomes like the efficacy could make part of the intervention assessment.

In any case, by answering these both questions, PiPPI will comprehensively understand the extent to which their activities are contributing to increase the value in European health-care system. In accordance with the other deliverables, the potential conclusions of the challenge-neutral set of results (outputs, outcomes and impact) will be validated and tested in further steps throughout WP5,

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<sup>7</sup> Ebrahim A. and Kasturi Rangan V. (2010) The Limits of Nonprofit Impact: A Contingency Framework for Measuring Social Performance, Harvard Business School (last time accessed 16/11/2020: [https://www.hbs.edu/faculty/Publication%20Files/10-099\\_0b80d379-8e88-4992-9e8f-4b79596b1ff9.pdf](https://www.hbs.edu/faculty/Publication%20Files/10-099_0b80d379-8e88-4992-9e8f-4b79596b1ff9.pdf) )



and all the rest of deliverables: D5.1 'An identified digital challenge', D5.2 'Industry and payors interest and intelligence report', D5.3 'A project plan for a cross-border PCP or PPI' and D5.5 'A publication/report on the feasibility of the PIPPI core set of outcomes'

## Methodology

A variety of methods was employed during the identification and definition of the challenge neutral set of results:

- Gray literature review to identify a first bucket of results categories, levels and sublevels
- Elements prioritization process through CARE selection criteria. First, through a first survey, PiPPi internal and external stakeholders were requested to assess the Clearness and Exemplarity of each of the element and propose changes if applicable. Then, through a second survey, PiPPi internal and external stakeholders were requested to assess the Relevance and Availability of each of the element

### Gray literature review

Firstly, a literature review was performed in order to identify an initial list of challenge-neutral results (outputs, outcomes and impact) that could contribute to answer two key questions previously defined. Although a same methodology was employed in both cases, different literature was searched according to each question:

- How are the new digital services, acquired through PiPPi activities, increasing value in health system?*

With the objective to answer this first question, a set of seminal documents were identified for review according to the Consortium members knowledge and due to their in-depth focus on digital health interventions results and health outcomes identification and/or because the reporting entity (author or organization) is a recognized expert in the field. Reviewed documents included both grey literature and peer reviewed reports, which provided information on the generalizability of ultimate applicable outcome measures, as well as examples of their use in practical applications.

(Hyperlinks available for each of the items below and the whole lists of reference links available in section References)

- [ICHOM web](#) [1]
- [PROMS-PREMS \(ACI Wales\)](#) [2]
- [MAST Manual](#) [3]
- [CAHS Framework](#) [4]
- [NICE digital evidence standards framework](#) [5]
- [European Commission - Digital Transformation](#) [6]
- [MEAT Framework](#) [7]
- [Observatori del Sistema de Salut de Catalunya](#) [14]
- [COSMIN](#) [15]
- Impact Evaluation framework – HUS Virtual Hospital [16]<sup>8</sup>

<sup>8</sup> Arvonen, S., Lehto-Trapnowski, P. (ed.) 2019. We are getting there – Virtual Hospital 2.0 project summary. Published by: Hospital District of Helsinki and Uusimaa Helsinki. Copyright: The authors and Helsinki and Uusimaa Hospital District (HUS), Pirkanmaa Hospital District, Northern Ostro bothnia Hospital District, the Hospital District of Northern Savo and the Hospital District of South-west Finland.

- ii. *To what extent is PiPPi succeeding in their PCP/PPI procedures according to both internal and external stakeholders?*

Experiences in six PCP-PPI were revised in order to identify the challenge-neutral set of challenge-neutral results (outputs, outcomes and impact) from their evaluation frameworks, long-term health impacts and effects on root causes, as well as tenders' awarding criteria, that could contribute to answer the second question.

*(Hyperlinks available for each of the items below and the whole lists of reference links available in section References)*

- [RITMOCORE-PPI \(H2020 GA 727796\) \[8\]](#)
- [ANTISUPERBUGS-PCP \(H2020 GA 688878\) \[9\]](#)
- [STOPandGO-PPI \(FP7 GA 621013\) \[10\]](#)
- [LIVEINCITE-PCP \(H2020 GA 727558\) \[11\]](#)
- [DECIPHER-PCP \(FP7 GA 288028\) \[12\]](#)
- [STARS \(H2020 GA 727585\) \[13\]](#)

A total number of 108 results (outputs, outcomes and impact) were identified and divided in five categories depending on the stakeholder level, as observed in Annex I:

1. Patient-level outcome
2. Healthcare professional-level outcome
3. Healthcare provider-level outcome
4. Health system-level outcome
5. Socio-economic-level outcome

Four of them are named accordingly to the main four identified stakeholders of a generic digital health intervention, pre-commercial procurement and public procurement of innovation (patient, healthcare professional, healthcare provider, health system) to make explicit the stakeholder interest and point of view on the desired effects and impacts.

Additionally, each category was also divided in levels and sub-levels.

- 1- Patient-level results: A list of questions related to patients experiences and results which are patient-centered, focused on their experiences and relevant results of the iteration with the health system.
  - a. Patient-Reported Outcome Measures
  - b. Patient-Reported Experience Measures
  - c. Determinants of Health
  - d. Long-Term treatment improvement
- 2- Healthcare professional-level results: a set of results regarding the culture of the organization and the healthcare professionals skills.
  - a. Benefits for the healthcare professional
  - b. Workplace environment/culture results
- 3- Healthcare provider-level results: those that can measure the activity and performance of the health service.
  - a. Organizational aspects
  - b. Costs
  - c. Process
  - d. Technological Aspects

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- 4- Health system-level results: those that can measure the activity of the system providing quality, efficiency and accessibility.
  - a. Economic Sustainability
  - b. Safety and Sustainability
  - c. Long-Term treatment improvement
  
- 5- Socio-economic-level results: those that can measure other factors, which can significantly affect health status.
  - a. Social determinants
  - b. Economic Evaluation and HTA

## Elements prioritization process

For a successful identification of the set of challenge-neutral results (outputs, outcomes and impact), it is key to bring together the experiences and knowledge of patients, professionals, industry, academia, healthcare payers, decision makers and other relevant actors of the healthcare system. After compiling and categorizing the identified results, a two-round iteration exercise was performed in order to assess their applicability for PiPPi's potential use. To do so, **CARE selection criteria** were applied to each identified result by both internal and external stakeholder.

The **CARE selection criteria** consist of:

- Cleanness** - The meaning of the result sublevel is clear and easy to be understood.
- Availability** - The quantifiability of the data makes the result sublevel available.
- Relevance** - The result sublevel is relevant for the PiPPi CoP.
- Exemplarity** - The result sublevel is sufficiently representative of the level and/or the sublevel is intending to assess.

### First-round iteration: Cleanness and Exemplarity assessment

In the first iterative process, a questionnaire –available in Annex II - was sent to the PiPPi consortium to assess the **Cleanness** and **Exemplarity** of the results with the aim to properly define and categories each element. With the objective to gather an overall innovation ecosystem view, different categories of stakeholders were reached in this iteration process. Our main objective was to establish a professional and geographical representation of the PiPPi consortium members.

The output of the first iteration process was a validated set of defined and categorized outputs, outcomes and indicators elements.

Five PiPPi consortium members responded to this first survey: two from Spain and one from Sweden, Italy and Austria. These five respondents have two clear backgrounds: three Innovation Project Managers and two Academia/Researchers, who are familiarized with guidelines and outcomes identification. Survey was made available during 15 days in SurveyMonkey platform during the month of March 2020.



Regarding the **Clearness** of the elements:

- 17 results were clarified/re-defined.
- 20 results were included.
- 6 results were directly excluded.

Regarding the **Exemplarity** and categorization of the elements:

- 5 results were moved to other level/sub-levels.
- 1 sub-level was modified.
- 1 sub-level was created.

Finally, 122 elements got defined and categorized to make part of a validated set.

### Second-round iteration: Relevance and Availability assessment

A second questionnaire – available in Annex III- was sent to the PiPPi consortium in order to assess both the Relevance and Availability of the elements outlined after the first iteration process. The respondents scored from 0 to 5 points each element's relevance and availability. The **Relevance** weight was of **70%**, while **Availability's** was of **30%**.

This second questionnaire was required to be responded by one member per PiPPi consortium partner and from one to three external stakeholders, including patients, identified by each PiPPi consortium partner.

With the objective to gather an overall innovation ecosystem view, different group of stakeholders took part in this iteration process. To ensure the diversity of innovation ecosystem stakeholder, several internal and external stakeholders responded the questionnaire.

In total, 22 internal and external stakeholders from 6 different countries responded the questionnaire. Participants come from different EU countries: Spain (6), Italy (5), Austria (3), Sweden (3), Netherlands (3) and UK (2). Respondents work in different fields such as: Innovation Project Management (5), Industry (5), Academia (4), Hospital Management (5), Consultant (1) and Patient (1). Patient required to participate did only respond the patient-level outcomes.

From this group of respondents, 10 were internal stakeholders from PiPPi consortium and 12 were external stakeholders. Survey was made available during 15 days in SurveyMonkey platform during the month of October 2020.

Participants were asked to rate from 0 (less) to 5 (most) regarding their Relevance and Availability. Of the 122 elements validated in first iteration, none of them was rated negatively (<3). The core of the elements results were rated 3 and 4.

### Limitations on the methodology

As main limitation, due to COVID 19 pandemic outbreak during the deliverable development, partners found it difficult to engage specific stakeholders such as healthcare professionals (e.g., clinicians and nurses) and/or hospital unit managers that could respond to the questionnaires. Given the complexity, each of the PiPPi partners took upon themselves the responsibility to assess what stakeholder profiles



could be appropriate and reachable. Profiles with experience in ecosystems/CoPs/working groups/clusters were considered suitable to participate in the questionnaire (e.g., innovation managers, procurement managers, R&D managers, researchers and/or academics).

## Conclusions

Thanks to this methodology, PiPPi CoP has now available **three sets of challenge-neutral results**:

- **The first set** should be taken into consideration and make part of **ANY CHALLENGE PiPPi CoP will pursue**. It should bring relevant elements when prioritizing a digital challenge, determining the interest and opportunities in industry and payers and projecting a plan of a cross-border PCP/PPI and finally completing its feasibility study. This set comprises all the elements the the 2<sup>nd</sup> questionnaire respondents rated over 4 in terms of Relevance and Availability
- The **second set** should be considered as **additional to the first one** when tackling a new challenge and willing to take additional elements into consideration when prioritizing a digital challenge, determining the interest and opportunities in industry and payers and projecting a plan of a cross-border PCP/PPI and finally completing its feasibility study. This set comprises all the elements the 2<sup>nd</sup> questionnaire respondents rated between 3 and 4 in terms of Relevance and Availability
- The **third set** should be considered only if the PiPPi CoP users feel that still they need additional elements to take into consideration when prioritizing a digital challenge, determining the interest and opportunities in industry and payers and projecting a plan of a cross-border PCP/PPI and finally completing its feasibility study. This set comprises all the elements the 2<sup>nd</sup> questionnaire respondents rated lower than 3 in terms of Relevance and Availability



### Results core set to be analyzed for any challenge

At least 25 elements out of 122 are important, regarding the respondents, in terms of relevance and availability.

| Level                    | Sub-level                            | Results   |
|--------------------------|--------------------------------------|---|
| Patient                  | Patient-Reported Outcome Measures    | Health-related Quality of Life (QoL)                          |
|                          |                                      | Acceptability of the solution                                 |
|                          | Patient-Reported Experience Measures | Overall Satisfaction with care given                          |
|                          |                                      | Understanding of care plan/treatment/pathways                 |
|                          |                                      | Support to manage long-term condition                         |
|                          | Determinants of health               | Hospital acquired infections                                  |
|                          |                                      | Diagnostic accuracy   |
|                          |                                      | Quality Adjusted Life Years (QALY)                            |
|                          | Long-Term treatment improvement      | Reduced clinical errors                                       |
|                          |                                      | Mortality   |
|                          |                                      | Disability  |
| Healthcare professionals | Benefits for the HCP                 | Proportion of professionals' adherence to clinical guidelines |
| Healthcare provider      | Organizational aspects               | Number of hospitalizations                                    |
|                          |                                      | Waiting time  |
|                          |                                      | Number of re-hospitalizations/readmissions rates              |
|                          |                                      | Number of bed days for hospitalized patients                  |
|                          | Costs                                | Maintenance costs   |
|                          | Process                              | Work flow   |
|                          | Technological Aspects                | Production efficiency   |
| Data security            |                                      |   |
| Health system            | Safety and sustainability            | Data safety   |
|                          |                                      | Safety environment  |
|                          | Long-Term treatment improvement      | Mortality   |
|                          |                                      | Morbidity   |
|                          |                                      | Disability  |
| Socio-economic impact    | Economic Evaluation and HTA          | Cost Utility Analysis; Cost Effectiveness Analysis            |

Table 1 – Results CORE SET to be analysed for any challenge



**Example of digital challenge and the application of CORE set**

**Challenge description:** *‘Flexible visualization of aggregated diagnostic patient data’*. At this moment in clinical practice, the amount of data present for a single patient is becoming more and more cognitively problematic to digest for clinicians. In order to visualize all this different data (clinical, PROMS, wearables, imaging, laboratory, pathology, genetic, social, environmental,...) not only cross-sectional, but also longitudinal. We need to be able to display patient data in a flexible way that allows different views of a patients data dependent on in what context it is used. The contexts could vary from a 1:1 meeting with a patient to a multidisciplinary conference to information displayed during a surgical operation and depend on what information is available in that particular organization. It should be possible to choose what information is included in a view/dashboard by selecting different visualization modules.

We need different expertise to develop such a visualization to be of use in daily clinical practice. Besides the input of clinicians, patients and IT, we need digital transformation, (service) design, human–screen interaction, and visualization experts from for example the gaming industry and aviation.

**Champion/Owner of need:**

Contact at Erasmus: Jan Hazelzet

At Erasmus there is a project together with the Technical University Delft which is called “Consultation Room in 2030” which express interest in this.

**Target stakeholder / beneficiary**

Clinicians, Patients, HC and society

| Level   | Sub-level                         | Results                              | Results aimed to be achieved through this challenge   |
|---------|-----------------------------------|--------------------------------------|---|
| Patient | Patient-Reported Outcome Measures | Health-related Quality of Life (QoL) | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the long term view of the buyer |
|         | Patient-Reported Experience       | Acceptability of the solution        | Short term Output – to be detailed in the functional requirement to satisfy and awarding criteria + Short term Output – to be defined with quantitative   |

[18]

|  |                                 |   |   |
|--|---------------------------------|---|---|
|  | Measures                        |   | indicator as contract performance monitoring  |
|  |                                 | Overall Satisfaction with care given          | Short term Output – to be detailed in the functional requirement to satisfy and awarding criteria + Short term Output – to be defined with quantitative indicator as contract performance monitoring                            |
|  |                                 | Understanding of care plan/treatment/pathways | Short term Output – to be detailed in the functional requirement to satisfy and awarding criteria + Short term Output – to be defined with quantitative indicator as contract performance monitoring                            |
|  |                                 | Support to manage long-term condition         | Short term Output – to be detailed in the functional requirement to satisfy and awarding criteria + Short term Output – to be defined with quantitative indicator as contract performance monitoring                            |
|  | Determinants of health          | Hospital acquired infections                  | N/A (it is not clear whether this challenge can have an impact on this element)   |
|  |                                 | Diagnostic accuracy                           | Mid-term Outcome - to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the Mid-term view of the buyer          |
|  |                                 | Quality Adjusted Life Years (QALY)            | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the long term view of the buyer |
|  |                                 | Reduced clinical errors                       | Mid-term Outcome - to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the Mid-term view of the buyer          |
|  | Long-Term treatment improvement | Mortality                                     | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the long term view of the buyer |
|  |                                 | Disability                                    | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be  |



|                          |                           |   |   |
|--------------------------|---------------------------|---|---|
|                          |                           |   | shared with market to make them understand the long term view of the buyer  |
| Healthcare professionals | Benefits for the HCP      | Proportion of professionals' adherence to clinical guidelines | Mid-term Outcome - to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the Mid-term view of the buyer          |
| Healthcare provider      | Organizational aspects    | Number of hospitalizations                                    | N/A (it is not clear whether this challenge can have an impact on this element)   |
|                          |                           | Waiting time  | N/A (it is not clear whether this challenge can have an impact on this element)   |
|                          |                           | Number of re-hospitalizations/readmissions rates              | Mid-term Outcome - to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the Mid-term view of the buyer          |
|                          |                           | Number of bed days for hospitalized patients                  | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the long term view of the buyer |
|                          | Costs                     | Maintenance costs   | Short term Output – to be detailed in the functional requirement to satisfy and awarding criteria + Short term Output – to be defined with quantitative indicator as contract performance monitoring                            |
|                          | Process                   | Work flow   | Short term Output – to be detailed in the functional requirement to satisfy and awarding criteria   |
|                          | Technological Aspects     | Production efficiency   | Short term Output – to be defined with quantitative indicator as contract performance monitoring  |
|                          |                           | Data security   | Short term Output – to be detailed in the functional requirement to satisfy and awarding criteria   |
| Health system            | Safety and sustainability | Data safety   | Short term Output – to be detailed in the functional requirement to satisfy and awarding criteria   |
|                          |                           | Safety environment  | Short term Output – to be detailed in the functional requirement to satisfy   |

[20]

|                       |                                 |  |   |
|-----------------------|---------------------------------|--|---|
|                       |                                 |  | and awarding criteria   |
|                       | Long-Term treatment improvement | Mortality  | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the long term view of the buyer |
|                       |                                 | Morbidity  | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the long term view of the buyer |
|                       |                                 | Disability   | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the long term view of the buyer |
| Socio-economic impact | Economic Evaluation and HTA     | Cost Utility Analysis; Cost Effectiveness Analysis | Long term outcome/impact – to be defined with quantitative/qualitative indicators if intervention will scale up to more than 10.000 patients – to be shared with market to make them understand the long term view of the buyer |

*Table 2 - Example of application of CORE set*

**Additional results set**

|                             |   |  |
|-----------------------------|---|--|
| <b>Patient</b>              | <b>Patient-Reported Outcome Measures</b>    | Self-reported health status                        |
|                             |   | Improving Behaviour Outcome                        |
|                             |   | Bio-psycho-social functioning                      |
|                             |   | Autonomy   |
|                             |   | Symptom severity                                   |
|                             |   | Ability to work                                    |
|                             |   | Pain assessment                                    |
|                             |   | Exercise Tolerance                                 |
|                             | <b>Patient-Reported Experience Measures</b> | Acceptability in the co-creation process           |
|                             |   | Easy to use and user experience                    |
|                             |   | Bedroom comfortability                             |
|                             |   | Satisfaction with hospital food                    |
|                             |   | Professional's use of time                         |
|                             |   | Waiting time                                       |
|                             |   | % Reduction of patients and relatives' use of time |
| Confidence in the treatment |   |  |

[22]

|  |  |   |
|--|--|---|
|  | <b>Determinants of Health</b>          | Would they recommend the service to family and friends? |
|  |  | Adherence to clinical guidelines                        |
|  |  | Adherence to intervention/treatment                     |
|  |  | Adverse drug effects                                    |
|  |  | Adverse events  |
|  |  | Beneficence   |
|  |  | Proportionality   |
|  |  | Less surgery complications                              |
|  |  | Overtreatment cases identification                      |
|  | <b>Long-Term treatment improvement</b> | Morbidity   |
|  |  | Prevalence  |
|  |  | Incidence   |
|  |  | % of Relapse  |

*Table 3 - Additional results set – sub-table 1*

|                                 |                             |  |
|---------------------------------|-----------------------------|--|
| <b>Healthcare Professionals</b> | <b>Benefits for the HCP</b> | Trust in health and social care professionals  |
|                                 |                             | Proportion of professional with access to medical Evidence-Based information, and training to benefit from their use |
|                                 |                             | Level of involvement in design process   |
|                                 |                             | Electronic medical records adequately performed  |
|                                 |                             | (Regular) doctor spending enough time with patients during the consultation  |
|                                 |                             | Usability of the solution  |
|                                 |                             | Acceptability of the solution  |
|                                 | <b>Workplace</b>            | Training effectiveness for HCP   |

|  |                                     |                           |
|--|-------------------------------------|---------------------------|
|  | <b>environment/culture outcomes</b> | Safety environment        |
|  |                                     | Team/organization culture |

*Table 4 - Additional results set - sub-table 2*

|                            |                               |  |
|----------------------------|-------------------------------|--|
| <b>Healthcare provider</b> | <b>Organisational aspects</b> | Appointment statistics   |
|                            |                               | Number of primary clinic visits  |
|                            |                               | Number of urgent visits  |
|                            |                               | Number of specialist visits  |
|                            |                               | Actual vs. Expected hospital stay  |
|                            |                               | Applicability or external validity of the studies in the national/European health and social care system                                 |
|                            |                               | Proportion of centres/professionals that adhere to appropriate clinical guidelines (up-to-date evidence based)                           |
|                            |                               | Reduction in medication consumption  |
|                            |                               | Evidence-based guidelines  |
|                            | <b>Costs</b>                  | Approximated total income loss per year related to impact on potential admissions  |
|                            |                               | Total costs per year of the no. of extension of the LOS compared to average LOS/patient  |
|                            |                               | Total costs per year of the no. of cases that represent a significant extension of the LOS compared to the LOS reimbursed by the insurer |
|                            |                               | Medical device costs   |
|                            |                               | Training Costs   |
|                            |                               | Implementation costs   |
|                            |                               | Dispensing medications at the hospital   |
|                            |                               | Dispensing medications at the hospital per patient   |
|                            | <b>Process</b>                | Reduction of process complexity  |
|                            |                               | Training and resources   |
|                            |                               | Senior leadership performance  |
| <b>Technological</b>       | Interaction and communication |  |

[24]

|  |                |                             |
|--|----------------|-----------------------------|
|  | <b>Aspects</b> | Interoperability concerns   |
|  |                | Interoperability barriers   |
|  |                | Interoperability approaches |
|  |                | Connectivity                |

*Table 5 - Additional results set – sub-table 3*

|  |                                  |   |
|--|----------------------------------|---|
| <b>Health System</b>                   | <b>Economic Sustainability</b>   | Investments in equipment                              |
|  |                                  | Investment in hardware and software/digital services  |
|  |                                  | Training of staff                                     |
|  |                                  | Maintenance   |
|  |                                  | Use of staff (for each of the relevant type of staff) |
|  |                                  | Medication / Treatments - Therapy / Protesis          |
|  |                                  | Utensils  |
|  |                                  | Patients' use of time                                 |
|  |                                  | Transportation  |
|  |                                  | Scalability   |
|  |                                  | Replicability   |
|  |                                  | Reproducibility                                       |
|  | <b>Safety and Sustainability</b> | Air Quality   |
|  |                                  | Waste management                                      |
|  |                                  | The solution can evolve and be sustained over time    |
| <b>Long-Term treatment improvement</b> | Prevalence                       |   |
|  | Incidence                        |   |
|  | % of Relapse                     |   |

*Table 6 - Additional results set – sub-table 4*



[25]

|                              |                                    |  |
|------------------------------|------------------------------------|--|
| <b>Socio-economic impact</b> | <b>Social determinants</b>         | Level of social isolation                      |
|                              |                                    | Socioeconomic status                           |
|                              | <b>Economic Evaluation and HTA</b> | Equalities considerations                      |
|                              |                                    | Cost Benefit analysis                          |
|                              |                                    | Cost minimization analysis                     |
|                              |                                    | Health benefit in PROMs per health care dollar |

Table 7 - Additional results set – sub-table 5

Set to be analyzed if previous results sets do not provide enough elements

| Level                 | Sub-level                            | Result                         |
|-----------------------|--------------------------------------|--------------------------------|
| Patient               | Patient-Reported Experience Measures | Involvement in decision-making |
| Healthcare provider   | Process                              | Attitude and Culture           |
|                       | Technological Aspects                | Human Agency and Control       |
| Health system         | Economic Sustainability              | Relatives' use of time         |
| Socio-economic impact | Social determinants                  | Education levels               |
|                       |                                      | Social cohesion                |
|                       |                                      | Social happiness               |

Table 8 - Set to be analysed if previous results do not provide enough elements

## Annex I – Identified Outcome Measures

| Level              | Sublevel   | Output / Outcome   | Description   | Metric      | Method              | Recommended/Used by                 |                      |
|--------------------|--|--|---|-------------|---------------------|-------------------------------------|----------------------|
| Patient            | Patient-Reported Outcome Measures                          | Health-related Quality of life (QoL)                               | Multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning                | EQ-5D, AQoL | Survey              | [1], [2], [4], [5], [13]            |                      |
|                    |  | QALYs  | Provides a value between 1 (perfect health) and 0 (death) of quality of life for each year lived after an intervention        |             |                     | [4], [5]                            |                      |
|                    |  | Self-reported health status  |   | SF-36       | Survey              | [2], [4], [5], [12], [13]           |                      |
|                    |  | Self-efficacy  | individual's belief in his or her capacity to execute behaviors necessary to produce specific performance attainments         | GSE         | Survey              | [2], [4], [5]                       |                      |
|                    |  | Functioning (Physical, Emotional & Cognitive)                      |   |             | Survey or Interview | [1],[2], [4], [5], [8], [11], [13]  |                      |
|                    |  | Symptom severity   |   |             | Interview or Survey | [1], [4], [5]                       |                      |
|                    |  | Improving Behaviour Outcome  | Current smoking, Diet, Physical inactivity and Alcohol  |             |                     | [5], [11]                           |                      |
|                    |  | Ability to work  |   |             | Interview           | [1], [4], [5]                       |                      |
|                    |  | Pain reduction   | The visual analogue scale (VAS) and numeric rating scale (NRS)  |             | Interview           | [1], [4], [5], [13]                 |                      |
|                    | Exercise Tolerance   | exercise capacity of an individual as measured by their ability to |   |             | [1], [4], [5]       |                                     |                      |
|                    | Patient-Reported Experience Measures                       | Acceptability with users   | Be able to show that representatives from intended user groups were involved in the design, development or testing of the DHT |             |                     |                                     | [5], [8]             |
|                    |  | Overall Satisfaction   |   |             | Surveys, Interviews | [2], [4], [5], [6], [8], [13], [14] |                      |
|                    |  | Access to and ability to navigate services                         |   |             |                     | [1], [4], [6], [12]                 |                      |
|                    |  | Involvement in decision-making                                     |   |             |                     | [1], [4], [6], [13]                 |                      |
|                    |  | Bedroom comfort  |   |             |                     | [14]                                |                      |
|                    |  | Hospital food  |   |             |                     | [14]                                |                      |
|                    |  | Confidence (in the treatment)                                      |   |             |                     | [3], [6], [12]                      |                      |
|                    |  | Understanding of care plan/treatment/pathways                      |   |             |                     | [1], [4], [6], [8], [11], [12]      |                      |
|                    |  | Would they recommend the service to family and friends?            |   |             |                     | [1], [4], [6]                       |                      |
|                    | Waiting time   | Wait times for specific conditions and/or interventions            |   |             | [1], [4], [8], [14] |                                     |                      |
|                    | Support to manage long-term condition                      |  |   |             | [1], [4], [6], [12] |                                     |                      |
|                    | Determinants of Health                                     | Autonomy   | Measures of autonomy  |             |                     |                                     | [8], [11]            |
|                    |  | Adherence to clinical guidelines                                   | Identifying whether practice conforms to the most up-to-date evidence base  |             |                     |                                     | [4], [6], [11], [12] |
|                    |  | Adverse drug effects   | Numbers of adverse drug effects; year-on-year change  |             |                     |                                     | [4]                  |
|                    |  | Hospital acquired infections                                       | Levels of HAI; year-on-year change  |             |                     |                                     | [4]                  |
|                    |  | Diagnostic accuracy  | Not fixed indicators of a test performance, some are very   |             |                     |                                     | [5]                  |
|                    |  | % Reduction of patients and relatives' use of time                 |   |             |                     |                                     | [8]                  |
|                    |  | Less surgery complications   |   |             |                     |                                     | [1], [11]            |
|                    |  | Beneficence  | Beneficence involves balancing the benefits of treatment  |             |                     |                                     | [8]                  |
|                    | Proportionality  | In medical ethics, commensurate, that is, acceptably balanced      |   |             |                     | [8], [11]                           |                      |
|                    | Solution efficiency in the reduced clinical errors         | Reduced clinical errors  |   |             |                     | [8], [11]                           |                      |
|                    | Long-Term treatment improvement                            | Mortality  |   |             |                     | Systematic lit                      | [1], [2], [9], [14]  |
|                    |  | Morbidity  |   |             |                     | Systematic lit                      | [2], [11]            |
| % of relapse cases |  |  |   |             |                     | [15]                                |                      |
| Disability         |  |  |   |             |                     | [1]                                 |                      |
| Prevalence         |  | Number of cases for a condition in a population (shown as a        |   |             |                     | [4], [9]                            |                      |
| Incidence          | Number of new cases for a condition per 100,000 population |  |   |             | [4], [14]           |                                     |                      |

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[27]

|                          |                                |  |  |  |      |                          |                      |
|--------------------------|--------------------------------|--|--|--|------|--------------------------|----------------------|
| Healthcare Professionals | Benefits for the HCP           |  | Be able to show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field |  |      | [5]                      |                      |
|                          |                                |  | Credibility with health and social care professionals  |  |      |                          |                      |
|                          |                                |  | Proportion of professional with access to medical Evidence-Based information, and training to benefit from their use   |  |      |                          | [6], [12]            |
|                          |                                |  | Proportion of professionals that use appropriate clinical guidelines   |  |      |                          | [4], [6]             |
|                          |                                |  | Electronic medical records adequately performed  |  |      |                          | [6], [12]            |
|                          |                                |  | (Regular) doctor spending enough time with patients during the Usability of the solution   |  |      |                          | [6], [11], [12]      |
|                          |                                |  | Training   |  |      |                          | [11], [12]           |
|                          | Interoperability solution      |  |  |  | [11] |                          |                      |
|                          |                                |  |  |  |      | [9],[10],[11],[12], [14] |                      |
| Healthcare provider      | Utilization of health services |  | Number of hospitalizations   | Actual vs. past situation in a specific timeframe  |      | [3]                      |                      |
|                          |                                |  | Waiting list time  | Overall reduction on waiting list time or by condition   |      |                          | [1], [4], [8]        |
|                          |                                |  | Appointment statistics   | Actual vs. past situation in a specific timeframe  |      |                          | [4]                  |
|                          |                                |  | Number of rehospitalisations/readmissions rates  | Numbers of re-admissions by condition over a set time period; year-on-year change  |      |                          | [3], [4], [13], [14] |
|                          |                                |  | Number of bed days for hospitalised patients   | Overall or by condition over a set time period   |      |                          | [3], [8]             |
|                          |                                |  | Number of primary clinic visits  | Overall or by condition over a set time period   |      |                          | [3], [8], [13]       |
|                          |                                |  | Number of urgent visits  | Overall or by condition over a set time period   |      |                          | [3], [8]             |
|                          |                                |  | Number of specialist visits  | Overall or by condition over a set time period   |      |                          | [14]                 |
|                          |                                |  | Actual vs. Expected hospital stay  | the condition  |      |                          | [8], [13]            |
|                          |                                |  | Average stay hospitalized  | Overall or by condition over a set time period   |      |                          | [14]                 |
|                          |                                |  | Relevance to current care pathways in the national/European health and social care system  | Evidence to show that the DHT has been necessary protection the national/European health and social care system                          |      |                          | [5]                  |
|                          |                                |  | Proportion of centres/professionals that adhere to appropriate clinical  |  |      |                          | [5]                  |
|                          |                                |  | Reduction in medication consumption  |  |      |                          | [13]                 |
|                          |                                | Number of visits at emergency department |  |  |      | [3]                      |                      |
|                          |                                | Evidence-based guidelines                | Number per hospital  |  |      |                          |                      |
|                          |                                | Costs                                    |  | Approximated total income loss per year related to impact on potential admissions  |      |                          | [9]                  |
|                          |                                |  |  | Total costs per year of the no. of extension of the LOS compared to average LOS/patient  |      |                          | [9]                  |
|                          |                                |  |  | Total costs per year of the no. of cases that represent a significant extension of the LOS compared to the LOS reimbursed by the insurer |      |                          | [9]                  |
|                          |                                |  |  | Dispensing medications at the hospital   |      |                          | [14]                 |
|                          |                                |  | Dispensing medications at the hospital per patient   |  |      | [14]                     |                      |
|                          | Process                        |  | Work flow  | Time reduction (past vs. present) in the treatment delivery  |      | [3]                      |                      |
|                          |                                |  | Training and resources   | Existing training resources for hospital staff   |      | [3], [11]                |                      |
|                          |                                |  | Interaction and communication  | Hospital website and social media analytics  |      | [3]                      |                      |
|                          |                                |  | Attitude and Culture   | Change of processes in a year timeframe period   |      | [3]                      |                      |
|                          |                                |  | Interoperability concerns  | content (or aspect) of interoperation that may take place at   |      | [9],[10],[11],[12]       |                      |
|                          |                                |  | Interoperability barriers  | obstacles to interoperability in three categories (conceptual,   |      | [9],[10],[11],[12]       |                      |
|                          |                                |  | Interoperability approaches  | represents the different ways in which barriers can be removed   |      | [9],[10],[11],[12]       |                      |
|                          |                                | Changes in managers' span of control     | Evidences on micromanagement fostering   |  | [3]  |                          |                      |



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[28]

|                                    |                                 |  |   |  |                                    |
|------------------------------------|---------------------------------|--|---|--|------------------------------------|
| Health System                      | Economic Sustainability         | Investments in equipment   | Unit costs or prices for each resource used   |  | [3]                                |
|                                    |                                 | Training of staff  | Unit costs or prices for each resource used   |  | [3]                                |
|                                    |                                 | Maintenance  | Unit costs or prices for each resource used   |  | [3]                                |
|                                    |                                 | Use of staff (for each of the relevant type of staff)  | Unit costs or prices for each resource used   |  | [3]                                |
|                                    |                                 | Medication / Treatments - Teraphy / Prothesis  | Unit costs or prices for each resource used   |  | [3], [8], [10]                     |
|                                    |                                 | Utensils   | Unit costs or prices for each resource used   |  | [3]                                |
|                                    |                                 | Patients' use of time  | Unit costs or prices for each resource used   |  | [3]                                |
|                                    |                                 | Relatives' use of time   | Unit costs or prices for each resource used   |  | [3]                                |
|                                    |                                 | Transportation   | Unit costs or prices for each resource used   |  | [3]                                |
|                                    |                                 | Scalability  | Ability of a health intervention shown to be efficacious on a   |  | [12], [13]                         |
|                                    |                                 | Replicability  | Performing the same study protocol with new, independent data   |  | [9]                                |
|                                    |                                 | Reproducibility  | Closeness of the agreement between the results of   |  | [9]                                |
|                                    |                                 | Environmental  | Air pollution levels  | Level of known toxic pollutants in the air (parts per million) |                                    |
|                                    | Safety and health at work       | Data safety  | protecting data against loss by ensuring safe storage and making  |  | [9], [11], [12]                    |
|                                    |                                 | The solution can evolve and be sustained over time   |   |  | [11]                               |
|                                    | Long-Term treatment improvement | Mortality  |   |  | Systematic lit [1], [2], [9], [14] |
|                                    |                                 | Morbidity  |   |  | Systematic lit [2], [11]           |
|                                    |                                 | Less surgery complications   |   |  | [1], [11]                          |
|                                    |                                 | Disability   |   |  | [1]                                |
|                                    |                                 | Prevalence   | Number of cases for a condition in a population (shown as a   |  | [4], [9]                           |
| Incidence                          |                                 | Number of new cases for a condition per 100,000 population   |   | [4], [14]  |                                    |
| Improving Behaviour Outcome        |                                 |  |   | [5], [11]  |                                    |
| Modifiable risk factors            |                                 | Measures of prevalence of specific factors; e.g. For obesity, prevalence of BMI>30 for different population groups |   | [4], [5], [11]   |                                    |
| No. of patients with X diagnostics |                                 |  | [9]   |  |                                    |
| Socio-economic impact              | Social determinants             | Education levels   | Measures must be specific for the determinant; e.g. Literacy levels for education                         |  | [4]                                |
|                                    |                                 | Social cohesion  | Measures must be specific for the determinant; e.g. Literacy levels for education                         |  | [4]                                |
|                                    |                                 | Social happiness   | As measured using established survey techniques for happiness-depression                                  |  | [4]                                |
|                                    |                                 | Level of social isolation  | Loneliness scales for measuring social isolation of individuals   |  | [4]                                |
|                                    |                                 | Socioeconomic status   | Identifying socio-economic status of individuals in Europe  |  | [4]                                |
|                                    |                                 | Equalities considerations  | Evidence, if relevant, that the DHT contributes to challenge  |  | [5]                                |
|                                    | Economic Evaluation             | Cost Utility Analysis  | Form of CEA where consequence is measured in QUALYs or DALYs  |  | [4], [6]                           |
|                                    |                                 | Cost Effectiveness Analysis  | Comparison of two alternatives where consequences of the intervention are measured in natural units       |  | [5], [6]                           |
|                                    |                                 | Cost Benefit analysis  | Comparison of two alternatives where consequences of the intervention are measured in monetary units      |  | [5],[6]                            |
|                                    |                                 | Cost minimization analysis   | Comparison of relative costs of interventions with equivalent results                                     |  | [6]                                |
|                                    |                                 | Health benefit in PROMs per health care dollar   | Improvement in health measured through PROMs gained and divided by the cost of achieving that health gain |  | [4]                                |



## Annex II – First-round iteration: Clearness and Exemplarity assessment questionnaire

### BACKGROUND INFORMATION

#### QUESTIONNAIRE PURPOSE

An initial list of outcomes was identified from a set of seminal **documents** outlined: *ICHOM, PROMs-PREMs (ACI Wales), MAST Manual, CAHS Framework, NICE, European Commission and MEAT Framework*.

In addition, **experiences in five PCP-PPI** were also revised in order to identify outcomes from their evaluation frameworks as well as tenders' awarding criteria: *ANTISUPERBUGS-PCP, LIVEINCITE-PCP, DECIPHER-PCP, STOP'n'GO-PPI, RITMOCORE-PPI, STARS-PCP*.

After compiling the outcomes metrics, the objective of the present questionnaire is to, based on your knowledge and lived experiences, reach to a consensus by prioritising a core set of outputs/outcomes that will enable de consortium to measure the **impact of PiPPi activities**.

These will be divided in seven categories depending on the stakeholder level:

1. Patient-level outcome
2. Healthcare professional-level outcome
3. Healthcare provider-level outcome
4. Health system-level outcome
5. Socio-economic-level outcome

## QUESTIONNAIRE INSTRUCTIONS

Four selection criteria (CARE) will be applied to each metric in a two-round iteration exercise in order to assess an indicator's applicability for PiPPi's potential use.

- 1. Clearness** - The meaning of the indicator is clear and easy to be understood.
- 2. Availability** - The quantifiability of the data makes the metric available.
- 3. Relevance** - The indicator is relevant for the PiPPi CoP
- 4. Exemplarity**- The indicator is sufficiently representative of the results or the 'sublevel' is intending to assess.

In this first questionnaire, the Clearness and Exemplarity of the outcomes will be assessed in order to properly define and categorise each outcome indicator. Once the outcome indicators are clearly defined and categorized, a second iteration process will be performed in order to assess in 1-9 scale each outcome indicator's Relevance and Availability. The Relevance will have a weight of 80%, while the Availability's will be of 20%.

With the objective to gather an overall innovation ecosystem view, different groups of stakeholders will take part on this iteration process. To ensure the diversity of innovation ecosystem stakeholder, each consortium partner will be assigned with a specific type/profile of stakeholder.

For the First Questionnaire - **Clearness** and **Exemplarity** assessment

- A) 1 PiPPi Consortium member per partner.

For the Second Questionnaire - **Relevance** and **Availability** assessment

- A) 1 PiPPi Consortium member per partner (different from the first questionnaire)
- B) 3 Innovation ecosystem stakeholders identified by each PiPPi Consortium partner.

This first questionnaire will remain open until March 23rd.



## 1. PATIENT-LEVEL OUTCOME

Please, provide an answer on each box to assess each outcome indicator's **Clearness** and **Exemplarity** according to CARE criteria

- **Clearness:** The meaning of the indicator is clear and easy to be understood.

- **Exemplarity:** The indicator is sufficiently representative of the results or the sublevels intended to assess.

### Patient-Reported Outcome Measures (PROMs)

|  | Clearness            | Exemplarity          |
|--|----------------------|----------------------|
| <b>Health-related Quality of Life (QoL)</b> - Multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning | <input type="text"/> | <input type="text"/> |
| <b>QALY</b> - a generic measure of disease burden, including both the quality and the quantity of life lived   | <input type="text"/> | <input type="text"/> |
| <b>Self-reported health status</b>   | <input type="text"/> | <input type="text"/> |
| <b>Self-efficacy</b> - individual's belief in his or her capacity to execute behaviors necessary to produce specific performance attainments                 | <input type="text"/> | <input type="text"/> |
| <b>Functioning (Physical, Emotional &amp; Cognitive)</b>   | <input type="text"/> | <input type="text"/> |
| <b>Symptom Severity</b>  | <input type="text"/> | <input type="text"/> |

## Patient-Reported Experience Measures (PREMs)

|  | Clearness            | Exemplarity          |
|--|----------------------|----------------------|
| <b>Acceptability with users</b><br>- Be able to show that representatives from intended user groups were involved in the design, development or testing of the Digital Health Technology   | <input type="text"/> | <input type="text"/> |
| <b>Overall Satisfaction</b>  | <input type="text"/> | <input type="text"/> |
| <b>Access to and ability to navigate services</b>  | <input type="text"/> | <input type="text"/> |
| <b>Involvement in decision-making</b>  | <input type="text"/> | <input type="text"/> |
| <b>Bedroom comfort</b>   | <input type="text"/> | <input type="text"/> |
| <b>Hospital food</b>   | <input type="text"/> | <input type="text"/> |
| <b>Confidence (in the treatment)</b>   | <input type="text"/> | <input type="text"/> |
| <b>Understanding of care plan/treatment/pathways</b>   | <input type="text"/> | <input type="text"/> |
| <b>Would the patient recommend the service to family and friends?</b>  | <input type="text"/> | <input type="text"/> |
| <b>Support to manage long-term condition</b>   | <input type="text"/> | <input type="text"/> |
| <p>In case you consider there is any outcome indicator that <b>should be better defined</b> and/or <b>should be assigned to any other category</b>, please do specify here</p> <input style="width: 100%;" type="text"/>                 |                      |                      |
| <p>Based on your experience, would you <b>recommend any additional outcome</b> indicator in the present category? If so, please recommend it/them including a brief definition/description</p> <input style="width: 100%;" type="text"/> |                      |                      |

## Determinants of Health

|   | Clearness            | Exemplarity          |
|---|----------------------|----------------------|
| <b>Waiting time - Wait times for specific conditions and/or interventions</b> | <input type="text"/> | <input type="text"/> |
| <b>Appointment statistics</b>   | <input type="text"/> | <input type="text"/> |



|  | Cleaness             | Exemplarity          |
|--|----------------------|----------------------|
| <b>Adherence to clinical guidelines</b> - Identifying whether practice conforms to the most up-to-date evidence base   | <input type="text"/> | <input type="text"/> |
| <b>Adverse drug effects</b> - Numbers of adverse drug effects; year-on-year change   | <input type="text"/> | <input type="text"/> |
| <b>Hospital acquired Infections</b> - Levels of HAI cases; year-on-year change   | <input type="text"/> | <input type="text"/> |
| <b>Diagnostic accuracy</b> - Not fixed indicators of a test performance. Some are very sensitive to the disease prevalence, while others to the spectrum and definition of the disease               | <input type="text"/> | <input type="text"/> |
| <b>% Reduction of patients and relatives' use of time</b>  | <input type="text"/> | <input type="text"/> |
| <b>Non maleficence and beneficence</b> - Beneficence involves balancing the benefits of treatment against the risks and costs involved, whereas non-maleficence means avoiding the causation of harm | <input type="text"/> | <input type="text"/> |
| <b>Proportionality</b> - In medical ethics, commensurate, that is, acceptably balanced between the risk for harm and the likelihood of benefit   | <input type="text"/> | <input type="text"/> |
| <b>Autonomy</b> - Measures of autonomy   | <input type="text"/> | <input type="text"/> |
| <b>Solution efficiency</b> - Identify cases of overtreatment, Reduce clinical errors, Strengthen care coordination...  | <input type="text"/> | <input type="text"/> |
| <p>In case you consider there is any outcome indicator that <b>should be better defined</b> and/or <b>should be assigned to any other category</b>, please do specify here</p> <input type="text"/>  |                      |                      |

Based on your experience, would you recommend any additional outcome indicator in the present category? If so, please recommend it/them including a brief definition/description

### Long-Term treatment improvement

|   | Clearness            | Exemplarity          |
|---|----------------------|----------------------|
| Mortality   | <input type="text"/> | <input type="text"/> |
| Morbidity   | <input type="text"/> | <input type="text"/> |
| Less surgery complications  | <input type="text"/> | <input type="text"/> |
| Disability  | <input type="text"/> | <input type="text"/> |
| Prevalence  | <input type="text"/> | <input type="text"/> |
| Incidence   | <input type="text"/> | <input type="text"/> |
| Improving Behaviour<br>Outcome - Current smoking, Diet, Physical inactivity and Alcohol consumption | <input type="text"/> | <input type="text"/> |
| No. of patients with X diagnostics  | <input type="text"/> | <input type="text"/> |

In case you consider there is any outcome indicator that should be better defined and/or should be assigned to any other category, please do specify here

Based on your experience, would you recommend any additional outcome indicator in the present category? If so, please recommend it/them including a brief definition/description

## Annex III – Second-round iteration: Relevance and Availability assessment Questionnaire (Patient-level outcome)



PIPPi project - Defining a core set of outcomes (2/2)

### BACKGROUND INFORMATION

#### QUESTIONNAIRE PURPOSE

An initial list of outcomes/outputs was identified from a set of seminal **documents** outlined: *ICHOM, PROMs-PREMs (ACI Wales), MAST Manual, CAHS Framework, NICE, European Commission, Catalan Health System Observatory, COSMIN, MEAT Framework and the HUS Virtual Impact Evaluation Framework.*

In addition, **experiences in six PCP-PPI** were also revised in order to identify outcomes/outputs from their evaluation frameworks as well as tenders' awarding criteria: *ANTISUPERBUGS-PCP, LIVEINCITE-PCP, DECIPHER-PCP, STOP'n'GO-PPI, RITMOCORE-PPI, STARS-PCP.*

After compiling the outcomes/outputs metrics, the objective of the present questionnaire is to take advantage of your knowledge and lived experiences in order to reach a consensus by prioritising a core set of outputs/outcomes that will enable the consortium to measure the **impact of PIPPI activities**.

The identified outcomes/outputs are divided in seven categories depending on the stakeholder level:

1. Patient-level
2. Healthcare professional-level
3. Healthcare provider-level
4. Health system-level
5. Socio-economic-level



## QUESTIONNAIRE INSTRUCTIONS

Four selection criteria (CARE) will be applied to each identified outcome/output in a two-round iteration exercise in order to assess their applicability to PIPPI.

- 1. Clearness** - The meaning of the outcome/output is clear and easy to be understood.
- 2. Availability** - The quantifiability of the data makes the outcome/output available.
- 3. Relevance** - The outcome/output is relevant for the PIPPI CoP
- 4. Exemplarity**- The outcome/output is sufficiently representative of the level/sublevel is intending to assess.

In a prior questionnaire, the Clearness and Exemplarity of the outcomes/outputs was assessed in order to properly define them, as well as their level/sublevel category. Once the outcome/outputs were properly defined and categorized, a second iteration process is now performed in order to assess in 1-5 scale their Relevance and Availability. The weight of the Relevance will be 70%, while the one of the Availability will be 30%.

With the objective to gather an overall innovation ecosystem view, different groups of stakeholders will take part on this iteration process. To ensure the diversity of innovation ecosystem stakeholder, each consortium partner will be assigned with a specific type/profile of stakeholder.

For the First Questionnaire - **Clearness** and **Exemplarity** assessment

- A) 1 PIPPI Consortium member per partner.

For the Second Questionnaire - **Relevance** and **Availability** assessment

- A) 1 PIPPI Consortium member per partner (different from the first questionnaire)
- B) 1 to 3 Innovation ecosystem stakeholders identified by each PIPPI Consortium partner.

This second questionnaire (2/2) will remain open until [REDACTED]



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PIPPi project - Defining a core set of outcomes (2/2)

## 1. PATIENT-LEVEL OUTCOME













Please, provide an answer on each box to assess each outcome indicator's **Relevance** and **Availability** according to CARE criteria

- **Relevance:** The outcome/output is relevant for the PiPPi CoP
- **Availability:** The quantifiability of the data makes the outcome/output available.

### Patient-Reported Outcome Measures (PROMs)

|   | Relevance            | Availability         |
|---|----------------------|----------------------|
| Health-related Quality of Life (QoL) - Multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning | <input type="text"/> | <input type="text"/> |



|   | Relevance   | Availability  |
|---|---|---|
| <p><b>Self-reported health status</b> - Self-rated health (SRH) refers to a single-item health measure in which individuals rate the current status of their own health on a four- or five-point scale from excellent to poor. It is popular for its simplicity and has been extensively studied in Western populations</p> |    |    |
| <p><b>Bio-Psycho-Social Functioning</b> - The Functional Status Questionnaire can be used as a self-administered functional assessment for a patient seen in primary care. It provides information on the patient's physical, psychological, social and role functions</p>  |    |    |
| <p><b>Improving Behaviour Outcome</b> - Current smoking, Diet, Physical inactivity and Alcohol consumption</p>  |  |  |
| <p><b>Symptom Severity</b> - The SS scale quantifies symptom severity on a 0-12 scale by scoring problems with fatigue, cognitive dysfunction and unrefreshed sleep over the past week each on a scale from 0-3</p>   |  |  |
| <p><b>Autonomy</b> - Measures of autonomy</p>   |  |  |
| <p><b>Ability to work</b> - The Work Ability Index (WAI) is an instrument used in occupational health care and research to assess work ability of workers during health examinations and workplace surveys</p>  |  |  |

|  | Relevance                | Availability             |
|--|--------------------------|--------------------------|
| <b>Pain assessment-</b> The visual analogue scale (VAS) and numeric rating scale (NRS) are most commonly used to assess the present intensity of acute pain                    | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Exercise Tolerance</b> - exercise capacity of an individual as measured by their ability to endure exercise and/or the maximum workload achieved during the exercise period | <input type="checkbox"/> | <input type="checkbox"/> |

## Patient-Reported Experience Measures (PREMs)

|  | Relevance                | Availability             |
|--|--------------------------|--------------------------|
| <b>Acceptability of users within the co-creation process</b> - Be able to show that representatives from intended user groups were involved in the design, development or testing of the Digital Health Technology | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Acceptability of the solution</b> - Unrelated to whether there was enough SH involvement  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Easy to Use / User Experience</b>   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Overall Satisfaction with care given</b> - Measuring satisfaction with care given by a health professional or service   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Professional's use of time</b> in relation to performance.  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Involvement in decision-making</b>  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Waiting time</b> - Wait times for specific conditions and/or interventions  | <input type="checkbox"/> | <input type="checkbox"/> |

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|   | Relevance                | Availability             |
|---|--------------------------|--------------------------|
| <b>% Reduction of patients and relatives' use of time - Reduction in either patients and/or their relatives time in the care delivery/treatment</b> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Bedroom comfortability</b>   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Satisfaction with Hospital food</b>  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Confidence (in the treatment)</b>  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Understanding of care plan/treatment/pathways</b>  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Would the patient recommend the service to family and friends?</b>   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Support to manage long-term condition</b>  | <input type="checkbox"/> | <input type="checkbox"/> |

## Determinants of Health

|  | Relevance                | Availability             |
|--|--------------------------|--------------------------|
| <b>Adherence to clinical guidelines - Identifying whether practice conforms to the most up-to-date evidence base</b> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Adherence to Intervention/treatment</b>   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>QALY - a generic measure of disease burden, including both the quality and the quantity of life lived</b>         | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Adverse drug effects - Numbers of adverse drug effects; year-on-year change</b>                                   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Adverse events - Numbers of adverse events; year-on-year change</b>   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Hospital acquired infections - Levels of HAI cases; year-on-year change</b>                                       | <input type="checkbox"/> | <input type="checkbox"/> |





[41]

|   | Relevance                | Availability             |
|---|--------------------------|--------------------------|
| <b>Diagnostic accuracy</b><br>- Not fixed indicators of a test performance. Some are very sensitive to the disease prevalence, while others to the spectrum and definition of the disease               | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Non maleficence and beneficence</b><br>- Beneficence involves balancing the benefits of treatment against the risks and costs involved, whereas non-maleficence means avoiding the causation of harm | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Proportionality</b> - In medical ethics, commensurate, that is, acceptably balanced between the risk for harm and the likelihood of benefit  | <input type="checkbox"/> | <input type="checkbox"/> |
| Less surgery complications  | <input type="checkbox"/> | <input type="checkbox"/> |
| Overtreatment cases identification  | <input type="checkbox"/> | <input type="checkbox"/> |
| Reduced clinical errors   | <input type="checkbox"/> | <input type="checkbox"/> |

## Long-Term treatment improvement

|              | Relevance                | Availability             |
|--------------|--------------------------|--------------------------|
| Mortality    | <input type="checkbox"/> | <input type="checkbox"/> |
| Morbidity    | <input type="checkbox"/> | <input type="checkbox"/> |
| Disability   | <input type="checkbox"/> | <input type="checkbox"/> |
| Prevalence   | <input type="checkbox"/> | <input type="checkbox"/> |
| Incidence    | <input type="checkbox"/> | <input type="checkbox"/> |
| % of Relapse | <input type="checkbox"/> | <input type="checkbox"/> |

In case you want to express any **final comment** on the assessment of the present level, please specify

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