D4.2 Report on focus groups and interviews

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Deliverable description

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0.2	28/06/2024	BIOCAT	Second draft, submitted to the coordinator for revision
0.3	30/06/24	BIOCAT	Final version, with changes requested by coordinator

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1. Executive summary

One of the lessons learnt from the COVID-19 pandemic is the importance of flexibility in funding and organization of health systems. European countries responded to this extreme event by expanding the amount of financial resources available for health care and reallocating financial and human resources. However, there are several other challenges for health care systems that require efficient and flexible financing mechanisms to be successfully addressed. FLASH (Flexible Approaches to Support Health through financing), led by UVRN, undertakes a comprehensive analysis of health care financing mechanisms in Europe, by focusing on the two key stages of the process: budget allocation and financing of health services within a specific budget. The consortium identifies and examines the most prominent mechanisms underlying the relationship between the main challenges faced by health care systems (demand shocks, ageing, budget pressure) and their financing. By employing different methodological approaches, FLASH partners provide evidence on the ability of existing financing mechanisms and contracts to address such challenges and study new solutions to achieve more effective, efficient and equitable health care systems.

WP4, led by Biocat, intends to develop new tools to address the relevant financial challenges related to the adoption of innovative technologies, in two different phases: 1) before the technology reaches the market, and 2) at the time of adoption.

In the first deliverable of WP4, *Methodological description of the forecasting model and the model of decision*, a novel methodology was described, based on horizon scanning foresight analysis (PESTLE) with different dimensions of interest (political, economic, sociological, technological, regulatory and environmental). To validate and practice the described methodology, a group of 25 experts, were consulted using focus groups (15 individuals), interviews (4 individuals) and a questionnaire (22 individuals).

D4.2 reports this consultation and cocreation process to key opinion leaders. It is the second deliverable of FLASH WP4 and the seed of the third deliverable of this work package, which will be focused on developing the specific guidelines for policymakers.

2. Introduction to D4.2

Advancing towards more effective, efficient and equitable health care systems requires the definition of innovative, more flexible approaches to health financing, considering the role of technological innovation and how it drives transformation. The project **FLASH** (Flexible Approaches to Support Health through financing), coordinated by UVRN (University of Verona), undertakes a comprehensive analysis of health care financing mechanisms in Europe. **WP4**, led by Biocat, focuses on the development of new tools for decision making, assessing the relevance of drivers, barriers and enablers, and addressing the financial challenges related to the adoption of innovative technologies. The work in this WP tackles in different phases: 1) before the technology reaches the market, and 2) at the time of adoption.

In the first deliverable of WP4, *Methodological description of the forecasting model and the model of decision*, a novel methodology was described, based on horizon scanning foresight analysis (PESTLE). As defined some years ago by Gutiérrez-Ibarluzea et al (2009)[1] "early awareness and alert systems (EAASs) are also known as early warning systems or horizon scanning systems", which we implement here with different dimensions of interest (political, economic, sociological, technological, regulatory and environmental), in which key stakeholders have been consulted and requested to provide their viewpoints. The methodology is implemented in 4 modules:

1) A technology radar providing awareness and understanding on technologies being developed within an innovation ecosystem.
2) A consultation protocol designed to gather experts' advice on barriers and enablers on the adoption of early-stage health technologies.
3) A list of indicators to support policymakers in their decision-making process.
4) A decision matrix based on those indicators, to be used to measure both the value (clinical, social, and environmental) and the economic and organizational impact of technologies under development.

The consultation had 2 main objectives:

[1] https://www.researchgate.net/publication/280877428_A_toolkit_for_the_identification_and_assessment_of_new_and_emerging_health_technologies

1) To validate and test the methodology developed in task 4.1a and described in deliverable D4.1, leading to the development of the new decision-making methodology.
2) To generate, in cocreation of the experts, a list of indicators identifying key gaps in evidence and weight their relevance to be used in a decision matrix available to decision-makers to support them in their process of assessing the early-stage technologies for adoption as a response to the system's needs.

This document reports this consultation and cocreation process to key opinion leaders. It is the second deliverable of FLASH WP4 and the seed of the third deliverable of this work package, which will be focused on developing the specific guidelines for policymakers to help them early in the product life cycle, improving their performance regarding the transformative value of the early-stage technologies and their impact in system, from efficiency, accessibility, and cost-effectiveness perspectives, among others. Additionally, the ultimate objective of the guidelines is to be transferred across ecosystems and regions, for which the whole decision-making project will consider the specificities of the system.

3. Methodology

3.1. Design of consultations

3.1.1 Selection of experts

Expert opinion is a frequent resource to create or validate assumptions. This is the case with the methodology developed in WP4 Task 4.1a to, on one side, forecast the financial impact of adopting technologies that have yet to reach the market, and on the other, explore enablers and barriers for the adoption of an early-stage health technology.

The analysis of social, economic, technological, sociological environmental and political factors that can influence the process required the selection of a wide range of stakeholders considering expertise, the role, workplace, and context, to make sure that we identify properly the technologies that will contribute to a more efficient and sustainable healthcare system.

With a selected group of 25 experts, Biocat conducted 3 types of research methods to validate and test the methodology:

- **Focus groups** bringing together a small group of 15 experts to answer questions in a moderated setting. The components of the groups were chosen according to predefined demographic traits (at least one representative of each stakeholder

group in the BioRegion stakeholder map, from national and international spheres). The questions were designed to shed light on the methodology developed and the indicators to be implemented in a decision matrix for decision-makers.

- **Interviews**: in 4 cases, one-to-one interviews were conducted by Biocat to key opinion leaders. The criteria for selection were related either to these experts' availability or to the singularity of their roles.
- **Questionnaire**: 42 forms sent on a later stage to the focus groups members, to interviewed experts, and to additional representatives of other stakeholders to complete, validate and improve, on a second iteration (DELPHI), the outputs of the first 2 processes. From these 42 sent forms, Biocat obtained 22 answers (52%) that served to confirm and improve the findings.

3.1.2 Focus groups

1. The authors of this report worked with the Members of the Subcommittee for the Adoption of Innovation in the Health System of the Catalan Government[2]. On behalf of the Catalan Ministry of Health, Biocat coordinates since 2022 a group of local experts responsible of drafting an action plan to streamline innovation adoption in the healthcare system. Biocat considered it to be the most suitable group of experts to be part of the first focus group. Based on the agenda and their availability, we selected 7 local experts for a first meeting.

2. Biocat joined the Smart health Pilot[3] of Vanguard initiative in 2024. In brief, Vanguard gathers 39 of the most advanced industrial regions in Europe leading by example in delivering growth and jobs through industry-led interregional cooperation, co-creation, and co-investment. The core activity of the Vanguard Initiative is the implementation of Pilot Projects developed through the active participation of clusters, science parks, research institutes and universities in the member regions. Pilots focus on applications at post-prototyping level (> TRL5), with the potential for full market deployment in a time span of 3 to 5 years. This was, for Biocat as member of Smart health Pilot, the perfect setting for an international focus group implemented in Ghent on 23/04/2024[4] (Figure 2). Thanks to the

[2] https://www.biocat.cat/en/current-news/news/presentation-road-map-accelerate-adoption-innovation-catalan-health-system

[3] https://www.s3vanguardinitiative.eu/pilots/smart-health-personalised-medicine

[4] https://www.linkedin.com/posts/vanguard-initiative-smart-health-pilot_personalized-medicine-activity-7188450823188742144-LRzz/

international perspective of 8 experts, with whom we could assess the proposed methodology and explore if it could apply for other environments other than the BioRegion of Catalonia.

Figure 1 *– Kick-off in 2022 of the Subcommittee for the Adoption of Innovation in the Health System of the Catalan Government, from where 7 experts were selected for the Focus Group.*

Figure 2 *– Focus group developed in Ghent (Belgium) in the framework of the Vanguard Initiative Smart health Pilot plenary meeting. 2 people, experts on Pharma technologies, attended the Focus Group without participating in it.*

3.1.3 Interviews

Interviews give the opportunity of deepening in topics and questions in a more from focus groups. Apart from focus groups, we developed three interviews to prepare and validate the approach of the focus groups.

3.1.4 Questionnaire

When it comes to collecting reliable and accurate data, the capabilities of survey research are higher than focus groups or interviews, these latter designed to generate ideas or gather feedback. These is the reason behind the questionnaire intended to confirm the outputs related to the list of indicators and the preliminary design of a decision matrix, obtained from the previous consultations. The survey was sent to all the expert of the Subcommittee for the Adoption of Innovation in the Health System of the Catalan Government and to all the members the Smart Health Pilot group. The survey was replied by 22 experts.

3.2. Key questions

Both focus groups and interviews had three main sections:

3.2.1 Validation of the methodology

The first part of every session was dedicated to introducing FLASH PROJECT and the main objective of the methodology defined in D4.1, aimed to forecast the financial impact of adopting technologies that have yet to reach the market. Let's recall that this methodology is intended for the timely forecasting of the financial impact of adoption of technologies that have yet to reach the market. Additionally, it is intended to identify mechanisms that facilitate the sustainable financing and adoption of these key technologies, which might ultimately be adopted.

Hence, the experts were initially requested to provide feedback on the following aspects:

- How should healthcare system needs be defined?
- How can innovative ideas be more aligned to clinical needs and priorities?
- Who should participate on the decision-making process for the identification of health needs and for the allocation of financial resources?
- To which extent the decision-making process regarding adoption of innovation by a healthcare system can be translated internationally to other systems?

3.2.2 Dimensions, from a PESTLE perspective

The second part of the session was focused on addressing what kind of topics needed to be considered to make a transparent and informed assessment of a technology under development, at its different stages of development, and for different healthcare systems, and from the point of view of different stakeholders. A PESTLE analysis approach was used, in order to discuss key factors both in Health Systems' resilience and financial sustainability when considering the adoption of early technologies.

Participants were asked to discuss and prioritise which of the PESTLE dimensions (Political, Economic, Sociological, Technological, Legal and Environmental) are more relevant as enablers and barriers regarding adoption of a new technology.

3.2.3 Indicators for the decision matrix

Finally, we asked the participants to brainstorm which indicators they considered relevant to be to part of a support tool for early technology assessment considering each PESTLE dimensions (Political, Economic, Social, Technological, Legal and Environmental). Indicators with the most consensus were listed and weighted according to the relevance of the dimension of which they were part.

3.3. Design of the matrix

The indicators identified as most relevant by the experts consulted, with the weighed relevance assigned to each dimension, we propose a decision matrix in which the first dimension (lines) corresponds to the PSTLE (Political, Social, Technological, Legal and Environmental) indicators, and columns to E (Economic) indicators. Experts would assign a value to each dimension, which would finally be gathered in a scoring table (see Figure 7). The weigh of each dimension has been empirically assigned according to the relevance perceived by the experts (see Fig. 6). This methodology will be tested in real environments for different technologies in the framework of the Subcommittee for the Adoption of Innovation in the Health system of the Catalan Government prior to assess the feasibility of implementation in other systems. The matrix confronts the economic factors in decision making to other factors perceived as transformative of health systems.

4. Participant profile

4.1 Overall participant landscape

The decision-making process in health technology assessment involves various stakeholders, such as physicians, payers, patients, and health economists, making it a multi-disciplinary process.[5]

The stakeholders consulted were representative of the whole life sciences and health innovation ecosystem in Catalonia, used as a pilot case study to be further translated to other ecosystems (see figure 3).

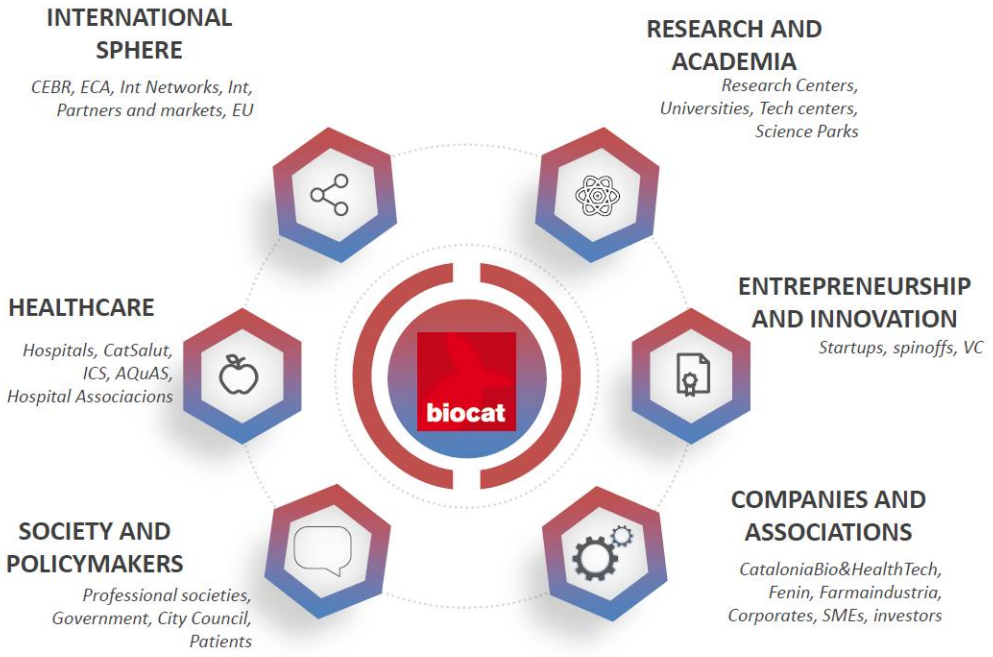

Figure 3 *– Stakeholders map of Biocat, partner in FLASH and organisation connecting and promoting the BioRegion of Catalonia, the Lifesciences and health innovation ecosystem in Catalonia, Spain.*

The following 4 tables display information on the profiles of participants in focus groups and interviews, and respondents to questionnaires in an anonymized mode: gender, position and role in the system.[6]

[5] https://www.mdpi.com/1660-4601/17/10/3608

[6] The participants in the 2 focus groups and the interviews, as well as respondents to the questionnaires, have been requested for their agreement to be mentioned. Upon reception of all agreements, the authors of this deliverable will provide further information for a better understanding of their profiles and roles. These details might be updated in D4.3 and/or the technical report at the end of the project.

4.1.1 Local focus groups (Catalan context)

Gender	Job position	Role
Female	Head of the Division of Projects and Care Quality of the Management of Comprehensive Health Processes, Catalan Service of the Health	Policymaker
Female	General Manager Iberia Amgen	Technology developer (Startup/Corporate)
Male	General Director of Innovation and Entrepreneurship of the Department of Business and Work (Catalan Government)	Policymaker
Female	Director of Health Innovation Technology Transfer	Consulting firm
Male	CEO of Tech Barcelona	Tech Startup & corporate Association
Male	Chief Medical Officer of the Barcelona Health Hub	Non-profit association
Female	Innovation Director at Fenin, Federación Española de Empresas de Tecnología Sanitaria	Non-profit association

4.1.2 International focus groups

Name	Job position	Role
Male	Project Manager	Regional Development Agency
Female	Project manager	Development agency
Male	Medical Scientific Director	Public private platform in Netherlands/Flanders
Female	Programme Manager/ EU liaison	Regional Development Agency
Male	Cluster Manager & Research Director	Research Centre

Female	Innovation and Cluster Manager	Cluster and scientific park
Male	Policy Advisor Innovation (Lifesciences & Health)	Policymaker
Female	Healthcare Innovation Manager	Policymaker

4.1.3 Interviews

Name	Job position	Role
Male	Partner consulting at Alira Health	Market Access Consulting firm
Male	Professor in Health Economics	University
Female	Knowledge Transfer Director General (Catalan Government)	Policymaker
Male	CEO of Patient Organizations Platform, member of the European Patients Forum	Patients

4.1.4 Questionnaire

Name	Job position	Role
Male	Project Manager	Regional Development Agency
Male	Director of Innovation and Partnership of the Catalan Health and Social Care Consortium	Healthcare Provider
Female	Project manager	Development agency
Male	Partner consulting at Alira Health	Consulting firm
Female	Head of the Division of Projects and Care Quality of the Management of Comprehensive Health Processes, Care Area, Catalan Service of the Health	Policymaker
Female	Healthcare Innovation Manager	Policymaker
Female	General Manager Iberia Amgen	Technology developer (Startup/Corporate)

Male	Head of the Innovation and Research Support Office	Healthcare Provider
Male	Medical Scientific Director	Public private platform in Netherlands/Flanders
Male	Professor in Health Economics	University
Female	Programme Manager/ EU liaison	Regional Development Agency
Female	Knowledge Transfer Director General (Catalan Government)	Policymaker
Female	Deputy Director Innovation and Head of Assessment of innovations and new technologies	Healthcare Provider
Male	General Director of Innovation and Entrepreneurship of the Department of Business and Work (Catalan Government)	Policymaker
Male	Senior Vice President	Technology developer (Startup/Corporate)
Male	Cluster Manager & Research Director	Research Centre
Female	Director of Health Innovation Technology Transfer	Consulting firm
Female	Director	Technology developer (Startup/Corporate)
Male	CEO of Tech Barcelona	Tech Startup & corporate Association
Male	Chief Medical Officer of the Barcelona Health Hub	Non-profit association
Male	CEO of Patient Organizations Platform	Patients
Female	Innovation Director at Fenin, Federación Española de Empresas de Tecnología Sanitaria	Non-profit association
Female	CEO	Health Technology Assessment Agency

Female	Innovation and Cluster Manager	Cluster and scientific park
Male	Policy Advisor Innovation (Lifesciences & Health)	Policymaker

4.2 Profiles

25 experts were consulted, either in focus groups, interviews or questionnaire (regarding gender distribution, 14 were women and 11 men, see figure 4). In relation to their job

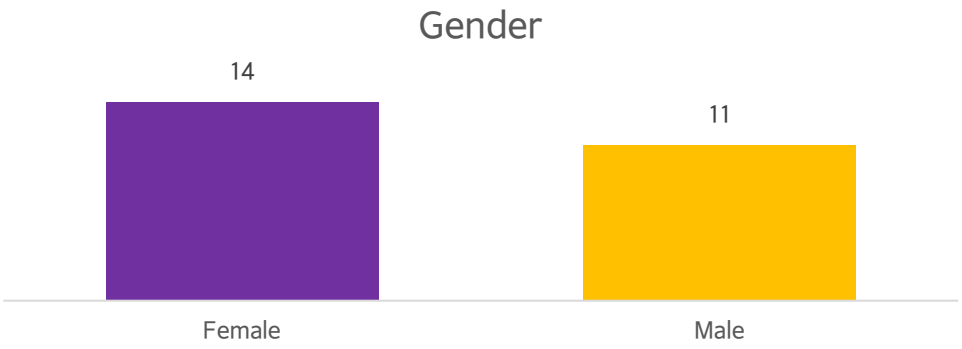

Figure 4 *– Number of people consulted, by gender.*

position, the vast majority occupied directive positions (66%), while management staff (5 people), consultant profiles (3 people) and one patient were also represented (Figure 5).

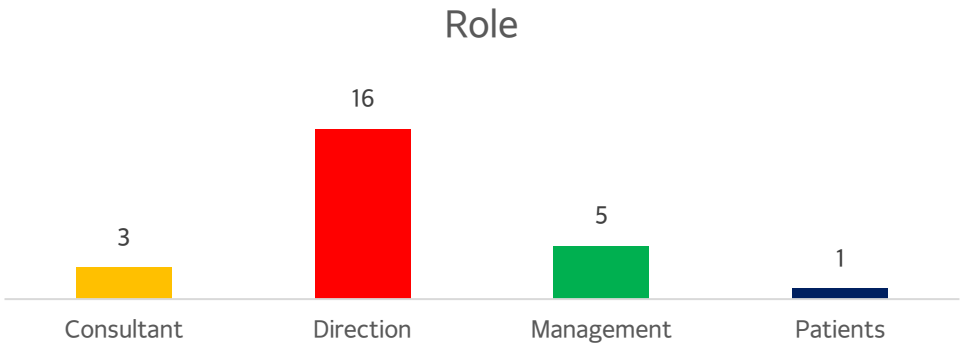

Figure 5 *– Number of people consulted, by job position.*

5. Findings

The following radar graph (see figure 6) summarises the main findings regarding the relevance perceived by the experts for the factors analysed in the PESTLE forecasting methodology, when answering to the following question:

Decision-makers need instruments and tools to enhance their ability to forecast the financial and organizational impact of the new technologies to improve their decision-making in terms of budget allocation. When planning the adoption of a new technology, decision-makers need to consider several factors in different dimensions. How far do you agree on the relevance of the following dimensions?

PESTLE GLOBAL					
	Totally agree	Agree	Neutral	Disagree	Totally disagr
Political factors	2	12	5	3	0
Economical factors	9	11	2	0	0
Social factors	4	12	6	0	0
Technological factors	7	12	3	0	0
Legal factors	7	13	2	0	0
Environmental factors	3	13	6	0	0

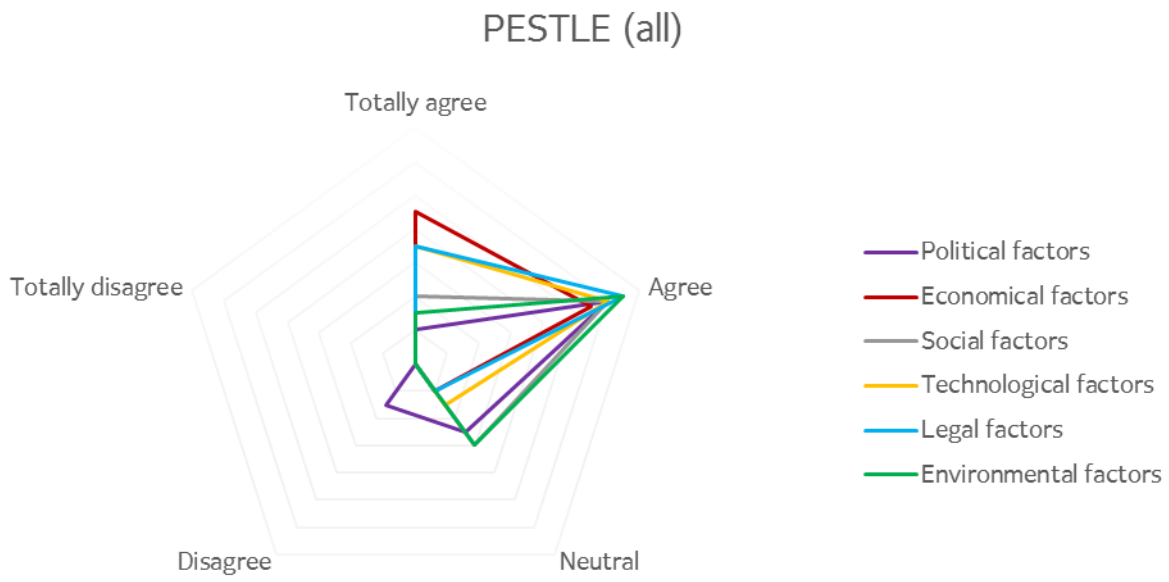

Figure 6 *–Distribution of answers and Radar Graph displaying the perceived relevance of political, economic, sociological, technological, legal (regulatory) and environmental factors.*

Most experts agree that enabling or hampering factors in all these dimensions are relevant. There is a slightly higher agreement among the experts that economic factors are relevant, in line with the objectives of this project. Conversely, political factors seem to be identified as less relevant by the experts. This will require an iteration in the next months, with regards to the guidelines for policymakers, as the new EU Health Technology Assessment (HTA) Regulation[7], that entered into force in January 2022 and applies as of January 2025, marks a significant shift in healthcare evaluation within the European Union. This regulation aims to streamline collaboration on health technology assessments across EU member states, fostering a more unified approach to evaluating medical technologies and therapies. This EU policy will become especially relevant when transferring the methodology to other regions. By harmonizing the assessment process, the regulation aims to reduce duplication of efforts and streamline access to innovative health technologies for patients across member states. The table below disaggregates the different factors analysed in these 6 dimensions of the PESTLE, identified as potential indicators for a decision matrix. Note the weight of the context in these indicators, which is relevant for the translational purposes of this methodology.

Note the indicators in bold and in a blue shadowed cell. Those are the factors considered more relevant by experts, in each dimension. Those for PSTLE (Political, Social, Technological, Legal and Environmental) have been used to be confronted to economic factors.

Indicator	Measure
Political indicators	
Degree of alignment with healthcare system priorities and strategies	**1-5 scale**
Degree of alignment with providers' and professionals' needs	1-5 scale
Degree of involvement of country's innovation	1-5 scale
Degree of involvement of the European MedTech industry	1-5 scale
Coverage of healthcare system unmet needs (orphan area)	Yes/No
Economic indicators	
Indicators of efficiency	

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282

% of reduction of waiting lists	%
Number of visits reduced	N
Number of beds reduced	N
Degree of process optimization/automation	1-5 scale
Cost analysis	
Cost-effectiveness analysis result	
Cost-benefit analysis result	
Cost-utility analysis result	
Cost-savings analysis result	
Evidence of cost reduction	Yes/No
Indicators of solvency	
Existence of economic impact study	Yes/No
Result of the economic impact study	
Degree of financial solvency of the startup/company delivering the innovation	1-5 scale
Indicators of procurement	
Acquisition of new/smart purchasing methods	Yes/No
% of co-funding when access to public system	%
Degree of Ability to fit financially in the healthcare market (e.g. potential profitability)	1-5 scale
Degree of return-on-investment to payers	1-5 scale
Indicators of market growth	
Number of workplaces generated in the country	N
Social indicators	
Evidence of quality-of-life improvement	1-5 scale
Evidence of patient's and professionals' preferences (better clinical adherence)	1-5 scale
Involvement of patients (and key stakeholders) in the innovation's design	Yes/No
Degree of evidence of increasing equity in health (reduction of access barriers, usability)	1-5 scale

PREMs (Patient-Reported Experience Measures)	
PROMs (Patient-Reported Outcome Measures)	
Degree of improvement of the clinical practise	1-5 scale
Technological indicators	
Level of product development/readiness (TRL)	1-9 scale
Degree of feasibility of arriving to market	1-5 scale
Capacity to remove obsolete tech/processes in place	Yes/No
Degree of uncertainty	1-5 scale
Level of evidence and promising evidence	1-5 scale
Presence of similar technologies/products	Yes/No
Degree of integration with current procedures and technologies	1-5 scale
Legal indicators	
Degree of regulatory compliance (national and international)	1-5 scale
Existence of legal advice or consultancy study	Yes/No
Existence of data/AI use management plan	Yes/No
Approval Data Privacy Policies	Yes/No
Degree of consideration of legal limitations	1-5 scale
Existence of a regulatory planning	Yes/No
Existence of certification & ethical committee	Yes/No
Degree of ability to execute with current legislation	1-5 scale
FDA /CE Approval status	Yes/No
Existence of patent protection	Yes/No
Number of notified bodies	N
Environmental indicators	
Ecological footprint of the biomanufacturing process	
Product's lifecycle	
Degree of commitment with the OPS/OMS	1-5 scale
Waste Management Compliance	Yes/No
Existence of a solution for reduction of use of (critical) raw material	Yes/No
Level of circularity	1-5 scale

Energy consumption	
Existence of Sustainability Certifications	Yes/No
Existence of Environmental Impact Assessments	Yes/No

Upon detailed analysis of the list of indicators above, we consider worth highlighting the most relevant economic indicators, which have been used for the decision matrix:

- Efficiency: description
- Cost-effectiveness
- Solvency
- Procurement
- Market growth

Nonetheless the importance of economic factors, the experts highlighted relevant factors in all dimensions. The authors of this report propose using these factors as grounds for the definition of indicators to be included in the decision matrix for policymakers in Fig 7, to be used by policymakers to enhance their ability to forecast the financial and organizational impact of these new technologies in terms of budget allocation.

	TECHNOLOGY REFERENCE		Efficiency			Cost-effectiveness			Financial capacity of the technology provider			Potential profitabilityof the technology			Market growth		
			High	Medium	Low	High	Medium	Low	High	Medium	Low	High	Medium	Low	High	Medium	Low
Political (13%)	Degree of alignment with healthcare system priorities and strategies	High	100	75	25	100	75	25	100	75	25	100	75	25	100	75	25
		Medium	75	50	10	75	50	10	75	50	10	75	50	10	75	50	10
		Low	25	10	0	25	10	0	25	10	0	25	10	0	25	10	0
Social (26% 13% each dimension)	Degree of quality-of-life improvement	High	100	75	25	100	75	25	100	75	25	100	75	25	100	75	25
		Medium	75	50	10	75	50	10	75	50	10	75	50	10	75	50	10
		Low	25	10	0	25	10	0	25	10	0	25	10	0	25	10	0
	Evidence of patient's and professionals' preferences	High	100	75	25	100	75	25	100	75	25	100	75	25	100	75	25
		Medium	75	50	10	75	50	10	75	50	10	75	50	10	75	50	10
		Low	25	10	0	25	10	0	25	10	0	25	10	0	25	10	0
Technological (32% 16% each dimension)	Level of product development/readiness (TRL)	High	100	75	25	100	75	25	100	75	25	100	75	25	100	75	25
		Medium	75	50	10	75	50	10	75	50	10	75	50	10	75	50	10
		Low	25	10	0	25	10	0	25	10	0	25	10	0	25	10	0
	Degree of feasibility of arriving to market	High	100	75	25	100	75	25	100	75	25	100	75	25	100	75	25
		Medium	75	50	10	75	50	10	75	50	10	75	50	10	75	50	10
		Low	25	10	0	25	10	0	25	10	0	25	10	0	25	10	0
Legal (16%)	Degree of regulatory compliance	High	100	75	25	100	75	25	100	75	25	100	75	25	100	75	25
		Medium	75	50	10	75	50	10	75	50	10	75	50	10	75	50	10
		Low	25	10	0	25	10	0	25	10	0	25	10	0	25	10	0
Environmental (13%)	Ecological footprint of the biomanufacturing process	High	100	75	25	100	75	25	100	75	25	100	75	25	100	75	25
		Medium	75	50	10	75	50	10	75	50	10	75	50	10	75	50	10
		Low	25	10	0	25	10	0	25	10	0	25	10	0	25	10	0

	Efficiency	Cost-effectiveness	Financial capacity of the technology provider	Potential profitabilityof the technology	Market growth	TOTAL
Degree of alignment with healthcare system priorities and	a	b	c	d	e	(a+b+c+d+e)* 13/100
Degree of quality-of-life improvement	a	b	c	d	e	(a+b+c+d+e)* 13/100
Evidence of patient's and professionals' preferences	a	b	c	d	e	(a+b+c+d+e)* 13/100
Level of product development/readiness (TRL)	a	b	c	d	e	(a+b+c+d+e)* 16/100
Degree of feasibility of arriving to market	a	b	c	d	e	(a+b+c+d+e)* 16/100
Degree of regulatory compliance	a	b	c	d	e	(a+b+c+d+e)* 16/100
Ecological footprint of the biomanufacturing process	a	b	c	d	e	(a+b+c+d+e)* 13/100
TOTAL						

Figure 7 *– Above: Decision matrix with the 2 dimensions: Lines refer to the PSTLE (Political, Social, Technological, Legal and Environmental) indicators and columns to E (Economic) indicators weighed as most relevant by the experts for the decision making process for the adoption of early technologies in their path to healthcare systems. Right: Table to gather the scores for decision making.*

6. Conclusions

From the activities developed in Task 4.1a, the authors of this deliverable extract the following list of conclusions:

1. It is recommended to include representatives of all stakeholders of an health innovation ecosystem in order to obtain a diverse set of indicators as the ones proposed in this report
2. The methodology developed in D4.1 has been validated and improved
3. Economic factors are considered more relevant than the other PESTLE dimensions, but these are not the unique relevant dimensions.
4. Political factors are considered less relevant by the experts. We cannot but mention here the new EU Health Technology Assessment (HTA) Regulation[8], relevant in the harmonization of the assessment process across member states.
5. As economic factors, Efficiency, Cost-effectiveness, Solvency, Procurement and Market growth are aspects to be considered in the decision.
6. The economic factors confronted to the other PESTLE dimensions provide a valuable matrix for decision making in early HTA.
7. The translational approach of the methodology might be guaranteed by the context indicators of the tool, though they might need further development.
8. The Ecological footprint of the biomanufacturing process being highlighted by some experts indicates an interesting approach that opens opportunity window for sustainability approaches in adoption of new technologies.
9. The information from this deliverable provides sound basis for the development of good practices and guidelines for policymakers (D4.3).
10. Catalonia Health system is a good case study for the definition of this tool, as the Subcommittee for the Adoption of Innovation in the Health System already gathers the main experts in the region willing to provide ideas for a transformative HTA.
11. The relevant role of the European dimension of health innovation is emphasized by the interest of the members of Vanguard Smart health Pilot and therefore further efforts should be devoted to connect this project and the process described in this deliverable to other EU initiatives, projects, networks and programs.

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282