Call: HORIZON-HLTH-2022-IND-13

(A competitive health-related industry (2022))

Topic: HORIZON-HLTH-2022-IND-13-03

Type of Action: HORIZON-RIA

Proposal number: 101095593

Proposal acronym: HI-PRIX

Type of Model Grant Agreement: HORIZON Action Grant Budget-Based

Table of contents

Proposal ID **101095593**

Acronym **HI-PRIX**

1 - General information

Fields marked * are mandatory to fill.

Topic	HORIZON-HLTH-2022-IND-13-03	Type of Action	HORIZON-RIA
Call	HORIZON-HLTH-2022-IND-13	Type of Model Grant Agreement	HORIZON-AG

Acronym HI-PRIX

Proposal title Health Innovation Next Generation Payment & Pricing Models

Note that for technical reasons, the following characters are not accepted in the Proposal Title and will be removed: < > " &

Duration in months 36

Fixed keyword 1 Health care sciences and services (including hospital administration, heal

Free keywords *pricing models; payment schemes; innovation; affordable healthcare system; competitive life science industry*

Abstract *

The variety of innovative technologies with the potential to revolutionize the delivery of health care means that the policy toolbox will need several pricing and payment models, adapted in their design and implementation according to the specific situation. Although there are examples of novel pricing and payment models, the lack of appropriate data infrastructure, legal barriers and unwillingness to adapt current systems often prevent their use. Therefore, the overall objectives of the Health Innovation Next Generation Pricing Models (HI – PRIX) project are: i) to map and formulate new pricing and payment schemes that can be used across technology classes, therapeutic areas, setting and healthcare systems/geographies together with a related set of principles that may guide successful adjustment and flexible implementation to the context of use; ii) to investigate the impact on competitiveness, innovation, equity and affordability of a pipeline of contracting modalities for health innovations; iii) to address the challenges and concerns of payers, manufacturers, healthcare professionals, and patients about different models of pricing by sustaining an effective dialogue across stakeholders' groups about the trade-offs between affordability, innovation and patient access. Coordinated by Bocconi University, the HI-PRIX Consortium involves 18 partners from 10 European countries, including academic institutions, public authorities, healthcare providers, and independent research organizations. Through theoretical models, quantitative simulation, qualitative research work and case-studies, this three-year project structured around 10 WPs, will generate new evidence on the role of public sector in R&D and indirect medical and environmental costs in pricing and reimbursement determinations, on the pricing dynamics over pharmaceutical products' lifecycle, on the impact of policies and incentives on the competitiveness, innovativeness and equity in the healthcare system.

Remaining characters 5

Has this proposal (or a very similar one) been submitted in the past 2 years in response to a call for proposals under any EU programme, including the current call? ○ Yes ◉ No

Please give the proposal reference or contract number.

Administrative forms

Proposal ID **101095593**

Acronym **HI-PRIX**

Declarations

Field(s) marked * are mandatory to fill.

1) We declare to have the explicit consent of all applicants on their participation and on the content of this proposal. *	☒
2) We confirm that the information contained in this proposal is correct and complete and that none of the project activities have started before the proposal was submitted (unless explicitly authorised in the call conditions).	☒
3) We declare: - to be fully compliant with the eligibility criteria set out in the call - not to be subject to any exclusion grounds under the EU Financial Regulation 2018/1046 - to have the financial and operational capacity to carry out the proposed project.	☒
4) We acknowledge that all communication will be made through the Funding & Tenders Portal electronic exchange system and that access and use of this system is subject to the Funding & Tenders Portal Terms and Conditions.	☒
5) We have read, understood and accepted the Funding & Tenders Portal Terms & Conditions and Privacy Statement that set out the conditions of use of the Portal and the scope, purposes, retention periods, etc. for the processing of personal data of all data subjects whose data we communicate for the purpose of the application, evaluation, award and subsequent management of our grant, prizes and contracts (including financial transactions and audits).	☒
6) We declare that the proposal complies with ethical principles (including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity, as well as applicable international and national law, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Appropriate procedures, policies and structures are in place to foster responsible research practices, to prevent questionable research practices and research misconduct, and to handle allegations of breaches of the principles and standards in the Code of Conduct.	☒
7) We declare that the proposal has an exclusive focus on civil applications (activities intended to be used in military application or aiming to serve military purposes cannot be funded). If the project involves dual-use items in the sense of Regulation 2021/821, or other items for which authorisation is required, we confirm that we will comply with the applicable regulatory framework (e.g. obtain export/import licences before these items are used).	☒
8) We confirm that the activities proposed do not - aim at human cloning for reproductive purposes; - intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or - intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer. - lead to the destruction of human embryos (for example, for obtaining stem cells) These activities are excluded from funding.	☒
9) We confirm that for activities carried out outside the Union, the same activities would have been allowed in at least one EU Member State.	☒

The coordinator is only responsible for the information relating to their own organisation. Each applicant remains responsible for the information declared for their organisation. If the proposal is retained for EU funding, they will all be required to sign a declaration of honour.

False statements or incorrect information may lead to administrative sanctions under the EU Financial Regulation.

2 - Participants

List of participating organisations

#	Participating Organisation Legal Name	Country	Role	Action
1	UNIVERSITA COMMERCIALE LUIGI BOCCONI	IT	Coordinator	
2	UNIVERSITAET HAMBURG	DE	Partner	
3	HTA AUSTRIA - AUSTRIAN INSTITUTE FOR HEALTH TECHN	AT	Partner	
4	ESCUELA ANDALUZA DE SALUD PUBLICA SA	ES	Partner	
5	UNIVERSITE LIBRE DE BRUXELLES	BE	Partner	
6	Office of Health Economics	UK	Partner	
7	FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA	ES	Partner	
8	HOSPITAL CLINIC DE BARCELONA	ES	Affiliated	
9	IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDI	UK	Partner	
10	ERASMUS UNIVERSITEIT ROTTERDAM	NL	Partner	
11	UNIVERSIDADE NOVA DE LISBOA	PT	Partner	
12	ECOLE D'ECONOMIE DE PARIS	FR	Partner	
13	VILNIAUS UNIVERSITETAS	LT	Partner	
14	FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD	ES	Partner	
15	AGENZIA ITALIANA DEL FARMACO	IT	Associated	
16	INFARMED - AUTORIDADE NACIONAL DO MEDICAMENTO	PT	Associated	
17	LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIEN	UK	Partner	
18	SERVEI CATALA DE LA SALUT	ES	Associated	

Organisation data

PIC	Legal name
999838850	*UNIVERSITA COMMERCIALE LUIGI BOCCONI*

Short name: UB

Address

Street	VIA SARFATTI 25
Town	MILANO
Postcode	20136
Country	Italy
Webpage	www.unibocconi.it

Specific Legal Statuses

Legal person	yes
Public body	no
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	13/01/2022	- no
SME self-assessment	unknown	
SME validation	08/09/2008	- no

Departments carrying out the proposed work

Department 1

Department name: CERGAS ☐ not applicable

☐ Same as proposing organisation's address

Street: Via Sarfatti 10

Town: Milan

Postcode: 20136

Country: Italy

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Prof.

Gender (•) Woman ( ) Man ( ) Non Binary

First name* **Oriana**

Last name* **Ciani**

E-Mail* **oriana.ciani@unibocconi.it**

Position in org. Professor

Department CERGAS

☐ Same as organisation name

☐ Same as proposing organisation's address

Street Via Sarfatti 10

Town Milan

Post code 20136

Country Italy

Website https://www.sdabocconi.it/it/home

Phone *+xxx xxxxxxxxx*

Phone 2 *+xxx xxxxxxxxx*

Other contact persons

First Name	Last Name	E-mail	Phone
claudia	PICCIONI	claudia.piccioni@unibocconi.it	+xxx xxxxxxxxx

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Oriana	Ciani	Woman	Italy	oriana.ciani@unibocconi.it	Category B Senior resea	Leading	0000-0002-3607-0508	Orcid ID
Prof	Rosanna	Tarricone	Woman	Italy	rosanna.tarricone@unibocconi.it	Category B Senior resea	Team member	0000-0002-2009-9357	Orcid ID
Prof	Claudio	Jommi	Man	Italy	claudio.jommi@unibocconi.it	Category B Senior resea	Team member	0000-0003-0356-8710	Orcid ID
Prof	James	Robinson	Man	United States	james.robinson@berkeley.edu	Category A Top grade re	Team member	0000-0003-0056-3017	Orcid ID
Prof	Mike	Drummond	Man	United Kingdom	mike.drummond@york.ac.uk	Category A Top grade re	Team member	0000-0002-6126-0944	Orcid ID

Role of participating organisation in the project

Project management	☒
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Robinson JC, Brown TT, Whaley C. Reference Pricing Changes The 'Choice Architecture' Of Health Care For Consumers. Health Aff (Millwood). 2017 Mar 1;36(3):524-530. doi: 10.1377/hlthaff.2016.1256.*
Publication	*Callea G, Armeni P, Marsilio M, Jommi C, Tarricone R. The impact of HTA and procurement practices on the selection and prices of medical devices. Soc Sci Med. 2017 Feb;174:89-95. doi: 10.1016/j.socscimed.2016.11.038.*
Publication	*Villa F, Tutone M, Altamura G, Antignani S, Cangini A, Fortino I, Melazzini M, Trotta F, Tafuri G, Jommi C. Determinants of price negotiations for new drugs. The experience of the Italian Medicines Agency. Health Policy. 2019 Jun;123(6):595-600. doi: 10.1016/j.healthpol.2019.03.009.*
Publication	*Drummond MF, Neumann PJ, Sullivan SD, Fricke FU, Tunis S, Dabbous O, Toumi M. Analytic Considerations in Applying a General Economic Evaluation Reference Case to Gene Therapy. Value Health. 2019 Jun;22(6):661-668. doi: 10.1016/j.jval.2019.03.012. Epub 2019 May 17.*
Publication	*Jommi C, Listorti E, Villa F, Ghislandi S, Genazzani A, Cangini A, Trotta F. Variables affecting pricing of orphan drugs: the Italian case. Orphanet J Rare Dis. 2021 Oct 19;16(1):439. doi: 10.1186/s13023-021-02022-w.*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
COMED (GA:779306)	*CERGAS was project leader in COMED: Pushing the boundaries of Cost and Outcome analysis of Medical Technologies (H2020-funded: 3 years; EUR 3 million) www.comedh2020.eu*
IMPACT- HTA (GA:779312)	*CERGAS was co-leader in IMPACT- HTA: Improved Methods and Actionable Tools for Enhancing Health Technology Assessment (H2020-funded; 3 years; EUR 3,1 million) https://www.impact-hta.eu/*
MEDTECHTA (GA:305694)	*CERGAS was project leader in MEDTECHTA: Methods for Health technology assessment of medical devices: an European perspective (FP7 funded; 3 years; EUR 2,6 million). CERGAS coordinated research activities of seven partners from six European countries. http://www.medtechta.eu/*
CINDERELLA	*Test and validate the implementation in clinical practice of BreLO-AI (Breast Locoregional Outcome AI system for the aesthetic evaluation and prediction of breast cancer locoregional treatment) in a cloud-based healthcare platform (CANKADO, approved for medical use - EU reg. nr DE/CA59/11976/2017) to personalize the approach for breast cancer patients. With the CINDERELLA APProach, we'll improve the patient's and physician's understanding and choice of locoregional breast cancer treatment.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
999905101	*UNIVERSITAET HAMBURG*

Short name: UHAM

Address

Street	MITTELWEG 177
Town	HAMBURG
Postcode	20148
Country	Germany
Webpage	http://www.uni-hamburg.de/

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	26/01/2022 - no
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name	Hamburg Center for Health Economics	☐ not applicable
	☐ Same as proposing organisation's address	
Street	Esplanade 36	
Town	Hamburg	
Postcode	20354	
Country	Germany	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title: Prof.

Gender: ○ Woman ◉ Man ○ Non Binary

First name*: **Jonas**

Last name*: **Schreyoegg**

E-Mail*: **jonas.schreyoegg@uni-hamburg.de**

Position in org.: Director

Department: Hamburg Center for Health Economics

☐ Same as organisation name

☐ Same as proposing organisation's address

Street: Esplanade 36

Town: Hamburg

Post code: 20354

Country: Germany

Website: www.hche.uni-hamburg.de

Phone: +49 (40) 42838-8041

Phone 2: *+xxx xxxxxxxxx*

Other contact persons

First Name	Last Name	E-mail	Phone
Meilin	Moellenkamp	meilin.moellenkamp@uni-hamburg.de	+49 (40) 42838-4677
Katharina	Berghoefer	katharina.berghoefer@uni-hamburg.de	+49 (40) 42838-1813

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Jonas	Schreyoegg	Man	Germany	jonas.schreyoegg@uni-hamburg.de	Category A Top grade re	Leading	0000-0001-8030-2161	Orcid ID
	Meilin	Moellenkamp	Woman	Germany	meilin.moellenkamp@uni-hamburg.de	Category D First stage r	Team member	0000-0003-1831-6954	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☒
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☒
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Neumann-Böhme, S., Varghese, N. E., Sabat, I., Barros, P. P., Brouwer, W., van Exel, J., Schreyögg, J. & Stargardt, T. (2020). Once we have it, will we use it? A European survey on willingness to be vaccinated against COVID-19. The European Journal of Health Economics, 21, 977-982. https://doi.org/10.1007/s10198-020-01208-6*
Publication	*Frey, S., Stargardt, T., Schneider, U., & Schreyögg, J. (2019). The economic burden of cystic fibrosis in Germany from a payer perspective. Pharmacoeconomics, 37(8), 1029-1039. https://doi.org/10.1007/s40273-019-00797-2*
Publication	*Hatz, M., Schreyögg, J., Torbica, A., Boriani, G., Blankart, C. R. (2017) Adoption Decisions for Medical Devices in the Field of Cardiology: Results from a European Survey, Health Economics 22: 124-144. https://doi.org/10.1002/hec.3472*
Publication	*Blankart, C. R., Stargardt, T., & Schreyögg, J. (2011). Availability of and access to orphan drugs. An International Comparison of Pharmaceutical Treatments for Pulmonary Arterial Hypertension, Fabry Disease, Hereditary Angioedema and Chronic Myeloid Leukaemia. Pharmacoeconomics, 29(1), 63-82. https://doi.org/10.2165/11539190-000000000-00000*
Publication	*Stargardt, T., & Schreyögg, J. (2006). Impact of cross-reference pricing on pharmaceutical prices. Applied Health Economics and Health Policy, 5(4), 235-247. https://doi.org/10.2165/00148365-200605040-00005*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
European Training Network (ETN) IQCE (2017-2020)	*Consortium that set up a joint research and training programme for researchers at doctoral level aimed at improving the quality and performance of European health care systems. Funded by the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie (Grant agreement No 721402). (Coordinator)*
EU project COMED (2018-2020)	*International joint project with the overall aim of shifting the limits of existing methods for cost and outcome analysis of health technologies both within the framework of Health Technology Assessment (HTA) and Health System Performance (HSP) and developing instruments to promote economic evaluation in policy-making. Funded by the European Commission within the framework of Horizon2020 (Grant agreement No 779306). https://www.comedh2020.eu/*
EU project MedtecHTA (2012-2016)	*International joint project on improving the existing methods within the paradigm of Health Technology Assessment (HTA) for the assessment of medical devices in a European comparison. The project filled the gap on the research debate on the challenges to the available methodological framework for HTA when applied to medical devices. Funded by the European Union Seventh Framework Programme (Grant No. HEALTH-F3-2012-305694). https://www.medtechta.eu/*
German Innovation Fund (2020-2022)	*Harmonizing reimbursement across health care sectors – Funded by Innovation Fund of the German Government (Grant agreement No. 01VSF19040) (Coordinator)*
Major consortium project	*Self-governmental Organizations of German Health Care (2016-2020): Scientific Evaluation of the introduction of a Case Payment System (PEPP) for Psychiatric Care in Germany (Coordinator)*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Research facilities and equipment	*The Hamburg Center for Health Economics (HCHE) offers excellent research facilities and equipment including access to international economic and medical literature, office space for staff, experimental labs and – more generally – access to all necessary research resources.*
Institutional support	*The HCHE is part of the graduate school for Business, Economics and Social Sciences providing institutional support for doctoral students and post-graduate staff.*

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (●) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
897291323	*HTA AUSTRIA - AUSTRIAN INSTITUTE FOR HEALTH TECHNOLOGY ASSESSMENT GMBH*

Short name: AIHTA GMBH

Address

Street	GARNISONGASSE 7/20
Town	WIEN
Postcode	1090
Country	Austria
Webpage	

Specific Legal Statuses

Legal person	yes
Public body	no
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	no
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is no (small- and medium-sized enterprise) for the call.

SME self-declared status	unknown
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

No department involved

Department name *Name of the department/institute carrying out the work.*

☒ not applicable

☐ Same as proposing organisation's address

Street *Please enter street name and number.*

Town *Please enter the name of the town.*

Postcode *Area code.*

Country *Please select a country*

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Dr

Gender ◉ Woman ○ Man ○ Non Binary

First name* **Claudia**

Last name* **Wild**

E-Mail* **claudia.wild@aihta.at**

Position in org. Manager (CEO of AIHTA) and Scientific Director

Department AITHA

☐ Same as organisation name

☒ Same as proposing organisation's address

Street GARNISONGASSE 7/20

Town WIEN

Post code 1090

Country Austria

Website www.aihta.at

Phone +43 1 236 8119-0

Phone 2 +43 664 53 03 742

Other contact persons

First Name	Last Name	E-mail	Phone
Karin	Hutterer-Schubert	karin.hutterer-schubert@aihta.at	+43 1 236 8119-10

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Claudia	Wild	Woman	Austria	Claudia.wild@aihta.at	Category A Top grade re	Leading	0000-0003-1754-9422	Orcid ID
	Christoph	Strohmaier	Man	Austria	Christoph.Strohmaier@aihta.at	Category D First stage r	Team member		
	Ozren	Sehic	Man	Austria	Ozren.Sehic@aihta.at	Category D First stage r	Team member		

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☐
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☒

lead WP2

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Schmidt L, Sehic O, Wild C. Assessing the public and philanthropic financial contribution to the development of new drugs: a bibliographic analysis. Science, Technology & Public Policy (STPP). 2020;4 (1):8-14. https://www.sciencepublishinggroup.com/journal/paperinfo?journalid=518&doi=10.11648/j.stpp.20200401.12*
Publication	*Schmidt L, Sehic O, Wild C. EU FP7 research funding for an orphan drug (Orfadin®) and vaccine (Hep C) development: a success and a failure. J of Pharm Policy and Pract 2021;14:37. https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00317-8*
Other achievement	*Schmidt L, Wild C. Public & philanthropic financial contribution to the development of new drugs: Methodology and three Case Studies. LBI-HTA 120. Vienna: 2019. HTA-Projektbericht_Nr.120.pdf (lbg.ac.at)*
Publication	*Wild C. COVID-19 as Catalyst for Changing Orphan Drug Regulations. BioProcess International. March 2021 18(3): 61. https://bioprocessintl.com/business/regulatory-affairs/covid-19-as-a-catalyst-for-changing-orphan-drug-regulations/*
Other achievement	*Fischer S, Stanak M Social Return on Investment: Outcomes, Methods, and Economic Parameters. LBI-HTA 120. Vienna: 2017. https://eprints.aihta.at/1142/1/HTA-Projektbericht_Nr.96.pdf*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
Public contribution to development of new drugs	*The project was carried out in two stages: in Phase 1, a methodology was developed to systematically identify the contribution of public research funding to the development of new drugs. In Phase 2, the methodology of the Phase 1 analytical approach was piloted using three selected paediatric Orphan Drugs (Spinraza®, Brineura®, Crysvita®), approved by the European Medicines Agency (EMA) in 2017.*
EU FP7 research funding: a success and a failure	*Using the publicly available database of FP7-HEALTH funded projects, we identified awards relating to late-stage clinical development, classified them according to product type and clinical indication, and calculated total EC funding amounts. We then identified two case studies representing extreme outcomes: failure to proceed with the product (hepatitis C vaccine) and successful market authorisation (Orfadin® for alkaptonuria).*
Counting the cost of direct public R&D funding	*This project is ongoing: it applies the bibliographic methods developed in 2019 to PARP inhibitors for breast cancer. Olaparib was chosen as it was developed by a public sector research institute in the UK and is marketed by a British pharmaceutical company. Here we complement the bibliographic approach with administrative accounting information from the research centre behind its scientific development.*
Social RoI: Outcomes, Methods, …	*The main aim of this report was to give an overview of „social impact measurement" in the field of child and adolescence health. We focused on Social Return on Investment (SROI) analyses, and cost-benefit analyses as well.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? ○ Yes ◉ No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
999859996	*ESCUELA ANDALUZA DE SALUD PUBLICA SA*

Short name: EASP

Address

Street	CUESTA DEL OBSERVATORIO CAMPUS UNIVERSIT
Town	GRANADA
Postcode	18011
Country	Spain
Webpage	www.easp.es

Specific Legal Statuses

Legal person	yes
Public body	no
Non-profit	no
International organisation	no
Secondary or Higher education establishment	no
Research organisation	no

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	13/10/2008	- yes
SME self-assessment	unknown	
SME validation	13/10/2008	- no

Departments carrying out the proposed work

No department involved

Department name *Name of the department/institute carrying out the work.*

☒ not applicable

☐ Same as proposing organisation's address

Street *Please enter street name and number.*

Town *Please enter the name of the town.*

Postcode *Area code.*

Country *Please select a country*

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Mr

Gender ◯ Woman ◉ Man ◯ Non Binary

First name* **Victor**

Last name* **De Haro**

E-Mail* **victorjavier.haro.easp@juntadeandalucia.es**

Position in org. Assistant to the Director

Department ESCUELA ANDALUZA DE SALUD PUBLICA SA

☒ Same as organisation name

☒ Same as proposing organisation's address

Street CUESTA DEL OBSERVATORIO CAMPUS UNIVERSITARIO DE CARTUJA 4

Town GRANADA

Post code 18011

Country Spain

Website www.easp.es

Phone +34 958027401

Phone 2 +34 671591716

Other contact persons

First Name	Last Name	E-mail	Phone
Jaime	Espin Balbino	jaime.espin.easp@juntadeandalucia.es	+34 670944108

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Jaime	Espín-Balbino	Man	Spain	jaime.espin.easp@juntadeandalucia.es	Category A Top grade re	Leading	0000-0001-7299-6554	Orcid ID
Dr	Joan	Rovira-Forns	Man	Spain	elrovira@yahoo.com	Category B Senior resea	Team member	0000-0001-6552-7151	Orcid ID
Dr	David	Epstein	Man	Spain	davidepstein@go.ugr.es	Category B Senior resea	Team member	0000-0002-6300-2738	Orcid ID
Dr	Leticia	García-Mochón	Woman	Spain	leticia.garcia.easp@juntadeandalucia.es	Category C Recognised	Team member	0000-0002-6300-2738	Orcid ID
Dr	Zuzana	Špacírová	Woman	Slovakia	zuzana.spacirova.easp@juntadeandalucia.es	Category C Recognised	Team member	0000-0002-2905-2934	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☐
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*How innovation can be defined, evaluated and rewarded in health technology assessment. JC Rejon-Parrilla, J Espin, D Epstein Health economics review 12 (1), 1-11*
Publication	*Costing methodologies in European economic evaluation guidelines: commonalities and divergences. L García-Mochón, Z Špacírová, J Espín The European Journal of Health Economics, 1-13*
Publication	*A general framework for classifying costing methods for economic evaluation of health care. Z Spacirova, D Epstein, L Garcia-Mochon, J Rovira, A Olry de Labry Lima, ... EUROPEAN JOURNAL OF HEALTH ECONOMICS 22 (5)*
Publication	*Implementing outcomes-based managed entry agreements for rare disease treatments: nusinersen and tisagenlecleucel. KM Facey, J Espin, E Kent, A Link, E Nicod, A O'Leary, E Xoxi, ... Pharmacoeconomics 39 (9), 1021-1044*
Publication	*Analysis of differences and commonalities in pricing and reimbursement systems in Europe J Espin, J Rovira. Brussels: DG Enterprise and Industry of the European Commission 100*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
IMPACT_HTA	*Principal Investigator – Work Package 3 – IMPACT_HTA – Improved methods and actionable tools for enhancing HTA - European Union's Horizon 2020 grant agreement No 779312.*
Joint Action CANCON	*External expert to the Joint Action CANCON Work-package 5 (MS Platform), Topic "DISINVESTMENT IN CANCER CONTROL PLANNING", Co-author of the paper "Enhancing value of cancer care through a more appropriate use of health care interventions".*
FP7- HEALTH-2012.3.2-2	*Principal Investigator – Work Package 6 - FP7- HEALTH-2012.3.2-2 – New methodologies for health technology Assessment - Advancing and strengthening the methodological tools and practices relating to the application and implementation of Health Technology Assessment (HTA) (2013-2016).*
EU-WHO project	*Member of the Steering Committee. EU-WHO project - Research agenda for the EU on Health Economic Evaluation*
COST - IS0903	*Researcher and Member of the Management Committee - COST - IS0903: Enhancing the role of medicine in the management of European health (2009-2013)*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)
EASP headquarter	*EASP facilities comprises its own servers, 9 classrooms equipped with multimedia resources, computers and internet, online meeting apps and video conference system, an auditorium for 300 people and a library.*

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
999986290	*UNIVERSITE LIBRE DE BRUXELLES*

Short name: ULB

Address

Street	AVENUE FRANKLIN ROOSEVELT 50
Town	BRUXELLES
Postcode	1050
Country	Belgium
Webpage	www.ulb.be

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	23/02/2022 - no
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name	Institute fot Interdisciplinary Innovation in Healthcare (I3H)	☐ not applicable
	☒ Same as proposing organisation's address	
Street	AVENUE FRANKLIN ROOSEVELT 50	
Town	BRUXELLES	
Postcode	1050	
Country	Belgium	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title: Prof.

Gender: (•) Woman ( ) Man ( ) Non Binary

First name*: **Hilde**

Last name*: **Stevens**

E-Mail*: **hstevens@i3health.eu**

Position in org.: Professor / Co-director of I3H

Department: Institute fot Interdisciplinary Innovation in Healthcare (I3H)

☐ Same as organisation name

☐ Same as proposing organisation's address

Street: Campus Solbosch, CP135 - Avenue Paul Heger 6

Town: Brussels

Post code: 1050

Country: Belgium

Website: https://i3health.eu/

Phone: +32 2 650 21 05

Phone 2: *+xxx xxxxxxxxx*

Other contact persons

First Name	Last Name	E-mail	Phone
Palina	Shauchuk	palina.shauchuk@ulb.be	+32 494 779 136
Rachel	Leproult	ulb-europe@ulb.ac.be	+32 2 650 31 62

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Hilde	Stevens	Woman	Belgium	hstevens@i3health.eu	Category B Senior resea	Leading	0000-0002-7096-0467	Orcid ID
Prof	Mathias	Dewatripont	Man	Belgium	mathias.dewatripont@ulb.be	Category A Top grade re	Team member	0000-0002-8624-799X	Orcid ID
Ms	Shiri	Mermelstein	Woman	Israel	shiri.mermelstein@ulb.be	Category D First stage r	Team member	0000-0003-4183-6720	Orcid ID
Ms	Sanae	Akodad	Woman	Belgium	sakodad@i3health.eu	Category D First stage r	Team member		
Ms	Palina	Shauchuk	Woman	Belgium	palina.shauchuk@ulb.be	Category C Recognised	Team member	0000-0002-4803-3499	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☒
Prototyping and demonstration	☐
IPR management incl. technology transfer	☒
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Mermelstein S, Stevens H. TRIPS to Where? A Narrative Review of the Empirical Literature on Intellectual Property Licensing Models to Promote Global Diffusion of Essential Medicines. Pharmaceutics (2022), 14(1):48. https://doi.org/10.3390/pharmaceutics14010048*
Publication	*Stevens H and Huys I. Innovative Approaches to Increase Access to Medicines in Developing Countries. Frontiers in Medicine 2017, 4:218 doi: 10.3389/fmed.2017.00218*
Publication	*Stevens H, Van Overwalle G, Van Looy B, Huys I. Intellectual property policies in early-phase research Public-Private Partnerships. Nature Biotechnology 2016, 34(5), 504-10 doi:10.1038/ nbt.356*
Publication	*Stevens H, Debackere K, Goldman M, Mahoney RT, Stevens P, Huys I. Vaccines: Accelerating Innovation and Access. Global Challenges Report 2017, WIPO Geneva – Final report presented in November 2017 in Geneva, Switzerland at the World Intellectual Property Organization (WIPO) at the Global Challenges Seminar on Vaccines: Accelerating Innovation and Access.*
Publication	*van Overbeeke E, Michelsen S, Toumi M, Stevens H, Trusheim M, Meslin E, Huys I, Simoens S. Market access of gene therapies across Europe, USA and Canada: challenges, trends and solutions. Drug Discov Today (2020), https://doi. org/10.1016/j.drudis.2020.11.024*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
2019-1-NL01-KA203-060286	*Name: Educating the next generation of Advanced Therapy (ATMP) professionals and advancing ATMP development. ADVANCE is a 30-month EU training project, supported by Erasmus Plus with the objective to develop a 3-stage blended learning programme to support early-career biomedical scientists in developing currently missing scientific knowledge, transversal skills and competences to meet the key challenge areas existing in the ATMP development cycle.*
Project supported by the Fondation Roi Baudouin	*The project addresses a very important issue with a high potential to amplify treatment options for rare disease patients. It investigates how to improve the regulatory framework surrounding drug repurposing, identifies market incentive traps that prevent the pharmaceutical industry from investing in repurposing, and investigates solutions.*
Baillet-Latour grant	*Since 2016, the Baillet Latour Grant supports the I³h Institute for the development of the innovative training project "Healthcare Innovation". It consists of an interdisciplinary program (medicine, pharmacy, economics, management, applied sciences, ...) aiming at creating a state-of-the-art medical training with the objective of improving the performance - in the broadest sense - of patient care.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
951066183	*Office of Health Economics*

Short name: OHE

Address

Street	Empty
Town	Empty
Postcode	Empty
Country	United Kingdom
Webpage	www.ohe.org

Specific Legal Statuses

Legal person	yes
Public body	no
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	no
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is no (small- and medium-sized enterprise) for the call.

SME self-declared status	unknown
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

No department involved

Department name *Name of the department/institute carrying out the work.*

☒ not applicable

☐ Same as proposing organisation's address

Street *Please enter street name and number.*

Town *Please enter the name of the town.*

Postcode *Area code.*

Country *Please select a country*

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Dr

Gender ◉ Woman ○ Man ○ Non Binary

First name* **Amanda**

Last name* **Cole**

E-Mail* **acole@ohe.org**

Position in org. Senior Principal Economist

Department Office of Health Economics

☒ Same as organisation name

☒ Same as proposing organisation's address

Street Empty

Town Empty

Post code Empty

Country United Kingdom

Website www.ohe.org

Phone +442077478861

Phone 2 *+xxx xxxxxxxxx*

Other contact persons

First Name	Last Name	E-mail	Phone
Kerry	Sheppard	ksheppard@ohe.org	+442077471440
Mikel	Berdud	mberdud@ohe.org	+442077478859
Mireia	Jofre-Bonet	mjofre-bonet@ohe.org	+442077478864
Adrian	Towse	atowse@ohe.org	+442077471407
Graham	Cookson	gcookson@ohe.org	+442077471408

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Mireia	Jofre-Bonet	Woman	Spain	mjofre-bonet@ohe.org	Category A Top grade re	Leading	0000-0001-6168-0407	Orcid ID
Dr	Amanda	Cole	Woman	United Kingdom	acole@ohe.org	Category B Senior resea	Team member	0000-0001-6179-7752	Orcid ID
Dr	Mikel	Berdud	Man	Spain	mberdud@ohe.org	Category B Senior resea	Leading	0000-0002-4816-5272	Orcid ID
Prof	Adrian	Towse	Man	United Kingdom	atowse@ohe.org	Category A Top grade re	Leading	0000-0001-8874-2049	Orcid ID
Dr	Dimitros	Kourouklis	Man	Greece	dkouroulkis@ohe.org	Category B Senior resea	Team member	0000-0002-8068-4363	Orcid ID
Prof	Graham	Cookson	Man	United Kingdom	gcookson@ohe.org	Category A Top grade re	Team member	0000-0002-2547-7978	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☒
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☒
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Latimer, N.R., Pollard, D., Towse, A. et al. Challenges in valuing and paying for combination regimens in oncology: reporting the perspectives of a multi-stakeholder, international workshop. BMC Health Serv Res 21, 412 (2021). https://doi.org/10.1186/s12913-021-06425-0*
Publication	*Lorgelly, P., Pollard, J., Cubi-Molla, P., Cole, A., Sim, D. and Sussex, J., 2020. Outcome-Based Payment Schemes: What Outcomes Do Patients with Cancer Value?. The Patient-Patient-Centered Outcomes Research, pp.1-12. https://doi.org/10.1007/s40271-020-00430-x*
Publication	*Sachin Kamal-Bahl, Adrian Towse, Liz Spurgin, Patricia M. Danzon, 2019 Specific value assessment considerations. New approaches to value assessment: towards more informed pricing in healthcare, Value in Health, VOLUME 22, ISSUE 6, SUPPLEMENT , S24-S28, JUNE 01, 2019 DOI:https://doi.org/10.1016/j.jval.2019.04.1920*
Publication	*Berdud M, Drummond M, and Towse A., 2020. Establishing a reasonable price for an orphan drug. Cost Effectiveness and Resource Allocation. DOI: 10.1186/s12962-020-00223-x*
Publication	*Danzon, P., Towse, A., & Mestre-Ferrandiz, J. (2015). Value-based differential pricing: Efficient prices for drugs in a global context. Health economics, 24(3), 294-301. DOI: 10.1002/hec.3021*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
Legal Barriers to the Better Use of Health Data	*Involved engagement with experts in digital health policy, cybersecurity and health informatics, payers, industry, and European data protection authority. Recommended policy priorities on data subject rights, anonymisation, consent and GDPR. Influenced EFPIA advocacy of positive environment for pharmaceutical innovation, has been utilized and cited heavily by the EMA in their Discussion Paper on the GDPR, and by the European Commission in their groundwork report for European Health data space.*
Making outcome-based payment a reality in the NHS	*Phase 1 and Phase 2 research grant from Cancer Research UK, in collaboration with RAND Europe, UCL and University of Manchester investigating the potential and practical considerations for the use of outcome-based payment for innovative medicines in the NHS, involving interviews with clinicians, payers and data experts, focus groups with patients, and simulation modelling.*
Economics of innovative payment models	*Exploring the short term and long term dynamic impact of indication-based pricing, and the impact of competition in reducing prices below the value-based price. https://www.ohe.org/publications/economics-innovative-payment-models-compared-single-pricing-pharmaceuticals-0*
Procure, Pay, Distribute & Use vaccines for COVID	*The study analysed the need to incentivise vaccine developers to develop candidates, invest in their production capacity and keep in the race to the market even after the first candidates made it to licensing point. We introduced a vaccine classification system based on efficacy thresholds and quality bands according to predefined Target Product Profiles. We supported the concept of advanced purchase agreements to incentivise vaccines' production in the pipeline ex-ante regulatory approval.*
HTA and Payment Mechanisms for New Drugs	*'Public health effects' of antibiotics such as preventing infection transmission and slowing down resistance development are not captured in value assessment. Traditional pricing arrangements where revenues depend on volumes sold are unlikely to be profitable, as AMR stewardship will limit the use of antibiotics. We reviewed the current state of HTA and contracting for antibiotics in five European countries, providing policy recommendations for revising them.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? ○ Yes ◉ No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
999477525	*FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA*

Short name: FCRB-CERCA

Address

Street	CARRER ROSSELLO 149
Town	BARCELONA
Postcode	08036
Country	Spain
Webpage	https://www.clinicbarcelona.org/en

Specific Legal Statuses

Legal person	yes
Public body	no
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	no
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	17/06/2008 - no
SME self-assessment	unknown
SME validation	17/06/2008 - no

Departments carrying out the proposed work

Department 1

Department name	Innovation	☐ not applicable
	☐ Same as proposing organisation's address	
Street	C/Mallorca 183	
Town	Barcelona	
Postcode	08036	
Country	Spain	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Dr

Gender ◉ Woman ○ Man ○ Non Binary

First name* **Laura**

Last name* **Sampietro**

E-Mail* **lsampiet@clinic.cat**

Position in org. Deputy Director Innovation, Head Assessment Innovations

Department Innovation

☐ Same as organisation name

☐ Same as proposing organisation's address

Street C/Mallorca 183

Town Barcelona

Post code 08036

Country Spain

Website https://www.clinicbarcelona.org/en

Phone +34932271872

Phone 2 *+xxx xxxxxxxxx*

Other contact persons

First Name	Last Name	E-mail	Phone
Lidia	Castro	licastro@clinic.cat	+xxx xxxxxxxxx
FCRB	Management	eu.fcrb@clinic.cat	+xxx xxxxxxxxx

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Dr	Albert	Alonso	Man	Spain	aalonso@clinic.cat	Category B Senior resea	Team member	0000-0003-0921-8033	Orcid ID
Dr	Laura	Sampietro Colom	Woman	Spain	lsampiet@clinic.cat	Category A Top grade re	Leading	0000-0001-7182-0231	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☒
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Cash-Gibson L, Tigova O, Alonso A, Binkley G, Rosenmöller M. Project INTEGRATE: Developing a Framework to Guide Design, Implementation and Evaluation of People-centred Integrated Care Processes. Int J Integr Care [Internet]. 2019 Feb 1;19(1). DOI: 10.5334/ijic.4178* *A tool to support the development of patient-centric interventions, taking into account the views from different stakeholders.*
Publication	*Baltaxe E, Cano I, Herranz C, Barberan-Garcia A, Hernandez C, Alonso A, et al. Evaluation of integrated care services in Catalonia: population-based and service-based real-life deployment protocols. BMC Health Serv Res [Internet]. 2019 Jun;19(1):370. Available from: https://doi.org/10.1186/s12913-019-4174-2* *This manuscript contains methods to assess novel practices of care services at population level that will apply to the cost-utility analysis.*
Publication	*Mair A, Alonso A. Polypharmacy and Integrated Care. In: Amelung V, Stein V, Suter E, Goodwin N, Nolte E, Balicer R, editors. Handbook Integrated Care [Internet]. Second. Cham: Springer International Publishing; 2021. p. 453–77. Available from: https://link.springer.com/10.1007/978-3-030-69262-9_27* *Book Chapter looking into the specifics of adopting a polypharmacy strategy by incorporating the principles of integrated care.*
Publication	*Riese J, Hendry A, Alonso A, Mahtani Chugani V, Rodriguez L. Investigación (in Spanish). In: Hacia una Sociedad Cuidadora. Barcelona: Fundación Mémora; 2021. p. 250. Available from: https://fundacionmemora.org/proyecto/foro-de-debate-hacia-una-sociedad-cuidadora* *Book chapter that explores the specificities of research when focusing on old people, carers and communities.*
Publication	*McIntosh J, Alonso A, MacLure K, Stewart D, Kempen T, Mair A, et al. A case study of polypharmacy management in nine European countries: Implications for change management and implementation. PLoS One. 2018;13(4). DOI: 10.1371/journal.pone.0195232* *This article provides useful background on change management and theory-based implementation strategies.*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
Project Integrate	*This EU funded project looked at core components of integrated care: process design, service delivery, skill mix, patient involvement, financial flows, regulatory conditions, and enabling information technologies in order to create connectivity, alignment and collaboration within and between the cure and care sectors. The final product was a set of evidence based managerial and policy recommendations.*
Project Simpathy	*EU funded project that undertook case studies and benchmarked European strategies on polypharmacy management. The outcome of the project was a strategic guidance to deploy interventions in polypharmacy and adherence management.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

FCRB Facilities	*FCRB disposes of a large unit of project managers that are in charge of assisting the researchers with international projects issues. Moreover, full secretarial, management and financial support will be available for the researcher.*

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? ○ Yes ◉ No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

Administrative forms

PIC	Legal name
905096816	*HOSPITAL CLINIC DE BARCELONA*

Short name: HOSPITAL CLINIC DE BARCELONA

Address

Street	CALLE VILLARROEL 170
Town	BARCELONA
Postcode	08036
Country	Spain
Webpage	https://www.clinicbarcelona.org/en

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	no
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is no (small- and medium-sized enterprise) for the call.

SME self-declared status	unknown
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name	Innovation	☐ not applicable
	☐ Same as proposing organisation's address	
Street	C/Mallorca 183	
Town	Barcelona	
Postcode	080036	
Country	Spain	

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title _____ Gender ◯ Woman ◯ Man ◯ Non Binary

First name* Last name*

E-Mail*

Position in org. Please indicate the position of the person.

Department *Name of the department/institute carrying out the work.* ☐ Same as organisation name

☐ Same as proposing organisation's address

Street *Please enter street name and number.*

Town *Please enter the name of the town.* Post code *Area code.*

Country *Please select a country*

Website *Please enter website*

Phone *+xxx xxxxxxxxx* *Phone 2* *+xxx xxxxxxxxx*

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Dr	Laura	Sampietro	Woman	Spain	LSAMPIET@clinic.cat	Category A Top grade re	Leading	0000-0001-7182-0231	Orcid ID
Dr	Esmail	Abbas	Man	Spain	abbas@clinic.cat	Category B Senior resea	Team member	0000-0001-9172-9435	Orcid ID
Ms	Maria	Fernandez Albizuri	Woman	Spain	Fernandez13@clinic.cat	Category D First stage r	Team member		

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☒
Co-definition of research and market needs	☒
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☒
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☒
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Identification and selection of health technologies for assessment by agencies in support of reimbursement decisions in Latin America. The work was done with key policy makers of region and industry to know key criteria that innovation has to comply for their reimbursement. DOI: 10.1017/s0266462321000416*
Publication	*Lifecycle evidence requirements for high-risk implantable medical devices: a European perspective. The work aimed to develop a pathway of evidentiary requirements that innovations should fulfill to guaranty their access to market and coverage in EU. DOI: 10.1017/ s0266462320000756*
Publication	*Optimization of cardiac resynchronization therapy device selection guided by cardiac magnetic resonance imaging: Cost-effectiveness analysis. Research showing how an innovative software to diagnose the presence of myocardial scar after a myocardial infarction and, therefore, identify candidates to cardiac resynchronization device, decrease mortality, increase QOL and has a budget impact leading to huge savings in countries under the European Society of Cardiology. DOI: 10.1177/2047487319873149*
Publication	*Developments in Value frameworks to inform the allocation of health care resources. The work involved health authorities and industry from several EU countries and North America to analyze and state what would be the criteria to value when making decisions on coverage/ reimbursement of innovative technologies.DOI: 10.1017/s0266462317000502*
Publication	*Health Technology Assessment of a new water quality monitoring technology: impact of automation, digitalization and remoteness in dialysis units. The research, performed at the Hospital Clinic after the introduction of the first advanced innovation in water machine for dialysis unit, show the benefits in organizational impact and a positive impact in budget (savings) for a hospital. DOI: 10.1371/journal.pone.0247450*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
VALIDATE	*Values in Doing Assessment of Health Technologies:* *The goal of the VALIDATE project is to train and introduce the next generation of HTA experts to a novel, integrative approach to HTA, wherein the study of safety, clinical and cost-effectiveness of new healthcare technologies and their wider ethical, legal and social implications are closely integrated and stakeholders are involved in a more productive way throughout the process of HTA. URL: https://validatehta.eu/*
EURIPHI	*European wide innovation procurement in Health Care:* *The project aimed to build out a common vision on the use of Value Based Innovation Procurement as a strategic tool fostering innovation. Different tools and contractual arrangements where developed as a guidance for future in-country and cross-country innovation procurement, including proposals of procurement for integrated care. https:// www.euriphi.eu/*
AdHopHTA	*Adopting Hospital Based Health Technology Assessment in EU:* *The project analyzed how innovations are introduced in EU hospitals and proposed a set of principles that should guide a value-based and sustainable buying of innovative technologies considering hospital stakeholders values. https://www.adhophta.eu/*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? ○ Yes ◉ No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
999993468	*IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE*

Short name: Imperial

Address

Street	SOUTH KENSINGTON CAMPUS EXHIBITION ROAD
Town	LONDON
Postcode	SW7 2AZ
Country	United Kingdom
Webpage	www.imperial.ac.uk

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	08/07/1907 - no
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name	Department of Economics and Public Policy	☐ not applicable
	☐ Same as proposing organisation's address	
Street	Exhibition Road	
Town	London	
Postcode	SW72 AZ	
Country	United Kingdom	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Dr

Gender ○ Woman ◉ Man ○ Non Binary

First name* **David**

Last name* **Wilson**

E-Mail* **david.wilson@imperial.ac.uk**

Position in org. Head of Research Support

Department Imperial College Business School

☐ Same as organisation name

☒ Same as proposing organisation's address

Street SOUTH KENSINGTON CAMPUS EXHIBITION ROAD

Town LONDON

Post code SW7 2AZ

Country United Kingdom

Website *Please enter website*

Phone +4420 7594 5168

Phone 2 *+xxx xxxxxxxxx*

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Dr	Marisa	Miraldo	Woman	Portugal	m.miraldo@imperial.ac.uk	Category B Senior resea	Leading	0000-0002-5772-7740	Orcid ID

Role of participating organisation in the project

Project management	☒
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☒
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☒
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Simmons B, Ariyoshi K, Ohmagari N, et al. Progress towards antibiotic use targets in eight high-income countries. Bull World Health Organ. 2021;99(8):550-561. doi:10.2471/BLT.20.270934*
Publication	*Simmons B, Cooke GS, Miraldo M. Effect of voluntary licences for hepatitis C medicines on access to treatment: a difference-in-differences analysis. Lancet Glob Health. 2019 Sep;7(9):e1189-e1196. doi: 10.1016/S2214-109X(19)30266-9. Epub 2019 Jul 27. PMID: 31362914.*
Publication	*Crea G, Galizzi MM, Linnosmaa I, Miraldo M. Physician altruism and moral hazard: (no) Evidence from Finnish national prescriptions data. J Health Econ. 2019 May;65:153-169. doi: 10.1016/j.jhealeco.2019.03.006. Epub 2019 Mar 19. PMID: 31022628.*
Publication	*Barrenho E, Miraldo M, Smith PC. Does global drug innovation correspond to burden of disease? The neglected diseases in developed and developing countries. Health Econ. 2019 Jan;28(1):123-143. doi: 10.1002/hec.3833. Epub 2018 Nov 12. PMID: 30417950.*
Publication	*Barrenho, E. and Miraldo, M., 2018. R&D Success in Pharmaceutical Markets: A Duration Model Approach. In: Health Econometrics, Contributions to Economic Analysis. [online] Emerald Publishing Limited, pp.201–233. 10.1108/S0573-855520180000294010.*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
RARE2030 (https://www.rare2030.eu/)	*Foresight study that gathers the input of a large group of patients, practitioners and key opinion leaders to propose policy recommendations that will lead us to improved policy and a better future for people living with a rare disease in Europe. Led programme on pharmaceutical innovation for rare diseases.*
Research Project	*Research project that assessed inequalities in cancer drug development and market launch. The determinants of failure in anticancer drug development & the future anticancer pharmaceutical R&D landscape and product market launch. Project funded by the National Cancer Institute (INCA). Network effects in the diffusion of innovation*
Research Project	*Principal investigator of the Health Foundation funded research programme on the role of networks on adoption and diffusion of healthcare innovation*
Research Project	*Co-I on the Academy of Finland funded project on the Determinants of pharmaceuticals prescription behaviour.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)
Dataset	*Unique dataset (>215k obs, 1960-2019) merging R&D data at global level across all disease areas and ATCs, with health need data.*
Data Observatory	*Infrastructure to visualise data in a way that uncovers new insights, and promotes analyses of complex data sets and analysis in an immersive and multi-dimensional environment.*
Research Computing Service	*Supercomputing resource for innovation in the fields of science, engineering, medicine and business. The RCS allows researchers to securely store and process complex datasets and supports simulation, alongside theory and experimentation*
Big Data & Analytical Unit	*ISO27001 compliant secure compute environment for storing and processing highly sensitive personal data, including patient data from NHS Digital and associated healthcare data providers. BDAU users routinely explore big sensitive datasets and use cutting edge tools and analyses to guide research.*

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (●) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
999839335	*ERASMUS UNIVERSITEIT ROTTERDAM*

Short name: EUR

Address

Street	BURGEMEESTER OUDLAAN 50
Town	ROTTERDAM
Postcode	3062 PA
Country	Netherlands
Webpage	www.eur.nl

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	01/10/2008 - no
SME self-assessment	unknown
SME validation	01/10/2008 - no

Departments carrying out the proposed work

Department 1

Department name	Erasmus School of Health Policy & Management, section HE	☐ not applicable
	☒ Same as proposing organisation's address	
Street	BURGEMEESTER OUDLAAN 50	
Town	ROTTERDAM	
Postcode	3062 PA	
Country	Netherlands	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Prof.

Gender ◯ Woman ◉ Man ◯ Non Binary

First name* **Werner**

Last name* **Brouwer**

E-Mail* **brouwer@eshpm.eur.nl**

Position in org. Professor of Health Economics

Department ERASMUS UNIVERSITEIT ROTTERDAM

☒ Same as organisation name

☒ Same as proposing organisation's address

Street BURGEMEESTER OUDLAAN 50

Town ROTTERDAM

Post code 3062 PA

Country Netherlands

Website www.eur.nl/eshpm

Phone +31104088525

Phone 2 +31104088550

Other contact persons

First Name	Last Name	E-mail	Phone
Stanley	Blanco Carlos	blancocarlos@eshpm.eur.nl	+31104088525

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Pieter	Van Baal	Man	Netherlands	vanbaal@eshpm.eur.nl	Category A Top grade re	Team member	0000-0001-9913-2393	Orcid ID
Prof	Werner	Brouwer	Man	Netherlands	brouwer@eshpm.eur.nl	Category A Top grade re	Leading	0000-0002-0476-8397	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☒
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Software	*With the Practical Application to Include Disease cost (PAID) tools, one can estimate the additional costs incurred to the health care system due to improved longevity after treatment. There are tools available for the Netherlands and the UK, with the plan to add further country tools in the future. Find the free PAID tools here: www.imta.nl/tools/paid/*
Publication	*K Kellerborg, B Wouterse, WBF Brouwer, P van Baal. Distributional consequences of including survivor costs in economic evaluations. Health Economics 2021; 30(10): 2606–2613*
Publication	*L de Vries, Kellerborg K, Brouwer W, van Baal P. Don't Forget About the Future: The Impact of Including Future Costs on the Cost-Effectiveness of Adult Pneumococcal Conjugate Vaccination with PCV13 in the Netherlands. Vaccine 2021; 39(29): 3834-3843*
Publication	*M Perry-Duxbury, Lomas, J., Asaria, M. et al. The Relevance of Including Future Healthcare Costs in Cost-Effectiveness Threshold Calculations for the UK NHS. PharmacoEconomics 2022; 40: 233–239*
Publication	*WBF Brouwer, PHM van Baal, NJA van Exel, MM Versteegh. When is it too expensive? Cost-effectiveness thresholds and health care decision making. European Journal of Health Economics 2019; 20(2): 175-180*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
COMED project	*EU funded project. The overarching objective of the COMED project is to push the boundaries of existing methods for cost and outcome analysis of healthcare technologies, both within the Health Technology Assessment (HTA) and Health System Performance (HSP) frameworks and to develop tools to foster the use of economic evaluation in policy making. Dutch WorkPackage leader (on Coverage with Evidence Development schemes, related to cost-effectiveness).*
IQCE project	*EU funded project, European Training Network on the theme of 'Improving Quality of Care in Europe'. Funded by the EU programme Marie Skłodowska-Curie Actions (MSCA). It set up a joint research and training programme for researchers at doctoral level. The aim of the IQCE program was to improve the quality and performance of European health care systems. As Dutch project leader supervised two PhD projects, on efficiency and equity in economic evaluations.*
Smarter Choices for Better Health	*Large scale (about 7 million euros) program, called the Erasmus Initiative Smarter Choices for Better Health, funded by the Erasmus University Rotterdam. This program, of which Werner Brouwer was the Academic Lead, addressing the challenges many countries still face when it comes to funding and delivering high quality health care. It is fully multi-disciplinary in nature (https://www.eur.nl/en/research/erasmus-initiatives/smarter-choices-better-health)*
When is it too expensive?	*Funded by the Netherlands Organisation for Health and Research Development (ZonMW), the project 'When is it too expensive?' was conducted to further investigate the appropriate thresholds by which to judge incremental cost-effectiveness ratios (like the value of a QALY and the marginal cost-effectiveness of current spending).*
Academia project National Healthcare institute	*This project, funded by the Dutch national Healthcare Institute (Zorginstituut, €725K), led by Werner Brouwer, further developed methodology used, in practice, by the Dutch Healthcare Institute, for the delineation of the basic benefits package, which included cost-effectiveness analysis as well as equity considerations.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
960782479	*UNIVERSIDADE NOVA DE LISBOA*

Short name: UNL

Address

Street	CAMPUS DE CAMPOLIDE
Town	LISBOA
Postcode	1099 085
Country	Portugal
Webpage	

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	05/01/2022 - no
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name: Nova School of Business & Economics ☐ not applicable

☐ Same as proposing organisation's address

Street: Carcavelos Campus, Rua da Holanda, 1

Town: Carcavelos

Postcode: 2775-405

Country: Portugal

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Dr

Gender (•) Woman ( ) Man ( ) Non Binary

First name* **Alexandra**

Last name* **Veiga**

E-Mail* **alexandra.veiga@novasbe.pt**

Position in org. Head of Research & Innovation Funding

Department Nova School of Business & Economics

☐ Same as organisation name

☐ Same as proposing organisation's address

Street Carcavelos Campus, Rua da Holanda, 1

Town Carcavelos

Post code 2775-405

Country Portugal

Website https://www.novasbe.unl.pt/en/

Phone +351 213 801 640

Phone 2 *+xxx xxxxxxxxx*

Other contact persons

First Name	Last Name	E-mail	Phone
Sofia	Vala	research.office@novasbe.pt	+351 213 801 640
Pedro	Pita Barros	ppbarros@novasbe.pt	+xxx xxxxxxxxx
Teresa	Costa	research.innov.funding@novasbe.pt	+xxx xxxxxxxxx

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Pedro	Pita Barros	Man	Portugal	ppbarros@novasbe.pt	Category A Top grade re	Leading	0000-0002-0881-4928	Orcid ID
Prof	Steffen	Hoernig	Man	Germany	steffen.hoernig@novasbe.pt	Category A Top grade re	Team member	0000-0003-1461-0048	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☐
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Opinion on innovative payment models for high-cost innovative-medicines, Report of the EC Expert Panel on Effective Ways of Investing in Health, 2018, Rapporteur Pedro Pita Barros.*
Publication	*Moura, A., Barros, Pedro Pita, 2020, Entry and price competition in the over-the-counter drug market after deregulation: Evidence from Portugal, Health Economics (United Kingdom), 29 (8), pp. 865-877.*
Publication	*Neumann-Böhme, S., Varghese, N.E., Sabat, I., Barros, Pedro Pita, Brouwer, W., van Exel, J., Schreyögg, J., Stargardt, T., 2020, Once we have it, will we use it? A European survey on willingness to be vaccinated against COVID-19, European Journal of Health Economics, 21 (7), pp. 977-982*
Publication	*Barros, Pedro Pita, 2011, "The Simple Economics of Risk-Sharing Agreements between the NHS and the Pharmaceutical Industry". Health Economics. Volume 20, Issue 4, pages 461 – 470.*
Publication	*Barros, Pedro Pita 2003, "Cream-skimming, incentives for efficiency and payment system". Journal of Health Economics, 22: 419 – 443.*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
Limits and opportunities of patient empowerment in	*Provided analysis and econometric identification of vulnerable population in Portugal to pharmaceutical expenditure. The rational was that a) it is the European OECD country with the highest level of out-of-pocket payments; b) Most of the out-of-pocket payments result from pharmaceutical co-payments of NHS-covered prescriptions, c) Protection against catastrophic expenditures was increasing before the international financial rescue, and the elderly were the more vulnerable population.*
Health and health care under austerity	*Impacts of fiscal austerity in Portugal were addressed in three distinct areas: a) use of pharmaceutical products; b) use of hospital services; c) population ability to cope with rising health expenditures. Both demand side (patients) and supply side (NHS provision affected by financial constraints and use of arrears to not interrupt services) were identified. The impact on the health of the population from financial hardship, both at the individual and public sector level, were addressed.*
Improving Quality of Care in Europe (2017-2020)	*This European Training Network (ETN) brought together 6 European universities (U. of Hamburg, Erasmus U. Rotterdam, Bocconi, U. Nova de Lisboa, U. of Southern Denmark, U. of York) and the multinational health care company Abbott. Fifteen early-stage researchers from 11 countries were trained to be experts in the field of quality of care. The scientific evidence originated 63 research papers, contributing to national and European health care.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)
Social Sciences Data Lab (DataLab)	*Provides access to bibliographic and statistical databases for conducting advanced research in the Social Sciences (Economics, Finance & Management). It also offers access to unique large datasets with microdata. DataLab supports the Survey of Health, Ageing and Retirement in Europe (SHARE) project*

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
998940242	*ECOLE D'ECONOMIE DE PARIS*

Short name: PARIS SCHOOL OF ECONOMICS EEP PSE

Address

Street	BOULEVARD JOURDAN 48
Town	PARIS
Postcode	75014
Country	France
Webpage	https://www.parisschoolofeconomics.eu/fr/

Specific Legal Statuses

Legal person	yes
Public body	no
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	03/09/2008 - yes
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name	Hospinnomics	☐ not applicable
	☐ Same as proposing organisation's address	
Street	1 place du Parvis Notre-Dame	
Town	Paris	
Postcode	75004	
Country	France	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title: Prof.

Gender: (•) Woman ( ) Man ( ) Non Binary

First name*: **Lise**

Last name*: **Rochaix**

E-Mail*: **lise.rochaix@psemail.eu**

Position in org.: Scientific Director of Hospinnomics

Department: Hospinnomics

[ ] Same as organisation name

[ ] Same as proposing organisation's address

Street: 1 place du Parvis Notre-Dame

Town: Paris

Post code: 75004

Country: France

Website: https://www.hospinnomics.eu/

Phone: +33679346758

Phone 2: *+xxx xxxxxxxxx*

Other contact persons

First Name	Last Name	E-mail	Phone
Iris	Kerambrun	iris.kerambrun@psemail.eu	+xxx xxxxxxxxx
Hugo	Jacquin	hugo.jacquin@psemail.eu	+xxx xxxxxxxxx
Thomas	Pelloquin	thomas.pelloquin@psemail.eu	+33 663090010

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Lise	Rochaix	Woman	France	lise.rochaix@psemail.eu	Category A Top grade re	Leading	0000-0002-6467-0332	Orcid ID
Mr	Thomas	Pelloquin	Man	France	thomas.pelloquin@psemail.eu	Category D First stage r	Team member		
Ms	Isis Catalina	Paramo Herrera	Woman	Colombia	isis.paramo@psemail.eu	Category D First stage r	Team member		
Mr	Ivan	Tzintzun	Man	Mexico	ivantval@gmail.com	Category D First stage r	Team member	0000-0002-7388-5941	Orcid ID
Ms	Meng	Jiang	Woman	China (People's	meng.jiang@psemail.eu	Category D First stage r	Team member		
Prof	Lionel	Perrier	Man	France	lionel.perrier@lyon.unicancer.fr	Category A Top grade re	Team member	0000-0003-4487-8723	Orcid ID
Dr	Grégoire	Mercier	Man	France	g-mercier@chu-montpellier.fr	Category B Senior resea	Team member		
Prof	Rosella	Levaggi	Woman	Italy	rosella.levaggi@unibs.it	Category A Top grade re	Team member	0000-0002-6018-1283	Orcid ID
Prof	Zeynep	Or	Woman	France	or@irdes.fr	Category A Top grade re	Team member	0000-0002-6860-3735	Orcid ID
Prof	Pascal	Paubel	Man	France	pascal.paubel@u-paris.fr	Category B Senior resea	Team member	0000-0002-9301-7826	Orcid ID
Prof	Herr	Annika	Woman	Germany	annika.herrihe@uni-hannover.de	Category A Top grade re	Team member	0000-0001-5479-0093	Orcid ID
Dr	Albane	Degrassat Theas	Woman	France	albane.degrassat-theas@aphp.fr	Category B Senior resea	Team member	0000-0002-2866-332X	Orcid ID

Role of participating organisation in the project

Project management	☒
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☒
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Rachet-Jacquet, L., Toulemon, L., & Rochaix, L. (2021). Hospital payment schemes and high-priced drugs: Evidence from the French Add-on List. Health Policy, 125(7), 923–929. doi: 10.1016/j.healthpol.2021.04.012*
Publication	*Herrera-Araujo D, Rochaix L. Competition between Public and Private Maternity Care Providers in France: Evidence on Market Segmentation. Int J Environ Res Public Health. 2020 Oct 26;17(21):7846. doi: 10.3390/ijerph17217846. PMID: 33114744; PMCID: PMC7662386.*
Publication	*NACI H., SALCHER-KONRAD M., KESSELHEIM A.S., WIESELER B., ROCHAIX L., REDBERG R., SALANTI, G, JACKSON E., GARNER S., STROUP. S., CIPRIANI, A. (2020) "Generating comparative evidence on new drugs and devices before approval." The Lancet 395.10228: 986-997.*
Publication	*RAIMOND V., JOSSELIN J.M., ROCHAIX L., (2014), "HTA Agencies Facing Model Biases: The Case of type-2 diabetes", Pharmacoeconomics, 32: 825-39.*
Publication	*"Inequities In Cancer Drug Development in Terms of Unmet Medical Need" Social science and medicine, 2022, to be published*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
IMPACT HTA	*IMPACT HTA (779312). Improved Methods and Actionable Tools for Enhancing Health Technology Assessment (H2020, 2018-2020). Lise Rochaix is leader for Hospinnomics/PSE WP11: "From HTA results to guidance: Implementation: Paving the Way" https:// cordis.europa.eu/project/rcn/213045_en.html*
ADVANCE HTA	*ADVANCE-HTA. Funded by the European Commission's Research Framework Programme (FP7/2007-2013). Lise Rochaix was member of the Scientific Advisory Board.*
CBIG-SCREEN	*H2020-SC1-BHC-2018-2020. Working collaboratively with vulnerable women to identify the best implementation gains by screening cervical cancer more effectively in European countries. CBIG-SCREEN aims to tackle inequality in cervical cancer screening (CCS) continuum. Lise Rochaix is leader for Hospinnomics/PSE WP4 : "Behavioural determinants and societal issues in targeted CCS programmes"*
@Hotel-Dieu	*AMI Santé Numérique (i-Démo). Large Project led by the AP-HP on digital health innovations. The Project aims to develop digital innovations and enhance the research on such innovations. Lise Rochaix leads a work package on the impact of digital health technologies on heathcare systems and healthcare delivery, and the challenges of the economic evaluation of such innovations.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
999893170	*VILNIAUS UNIVERSITETAS*

Short name: Vilniaus universitetas

Address

Street	UNIVERSITETO G. 3
Town	VILNIUS
Postcode	01513
Country	Lithuania
Webpage	http://www.vu.lt

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	24/01/2022	- no
SME self-assessment	31/12/2015	- no
SME validation	unknown	

Departments carrying out the proposed work

Department 1

Department name	Faculty of Medicine	☐ not applicable
	☐ Same as proposing organisation's address	
Street	M. K. Ciurlionio str. 21/27	
Town	Vilnius	
Postcode	LT-03101	
Country	Lithuania	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title: Prof.

Gender: (•) Woman ( ) Man ( ) Non Binary

First name*: **Liubove**

Last name*: **Murauskiene**

E-Mail*: **murauskiene@mtvc.lt**

Position in org.: Professor

Department: VILNIAUS UNIVERSITETAS

☒ Same as organisation name

☒ Same as proposing organisation's address

Street: UNIVERSITETO G. 3

Town: VILNIUS

Post code: 01513

Country: Lithuania

Website: https://www.mf.vu.lt

Phone: +37068642592

Phone 2: *+xxx xxxxxxxxx*

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Prof	Liubove	Murauskiene	Woman	Lithuania	Liubove.murauskiene@mf.vu.lt	Category A Top grade re	Leading	0000-0002-6625-8843	Orcid ID
	Kristina	Garuoliene	Woman	Lithuania	Kristina.garuoliene@mf.vu.lt	Category B Senior resea	Team member	0000-0001-7910-0108	Orcid ID
	Indre	Treciokiene	Woman	Lithuania	indre.treciokiene@mf.vu.lt	Category C Recognised	Team member	0000-0001-6583-9999	Orcid ID
	Evelina Marija	Vaitėnienė	Woman	Lithuania	emblazyte@gmail.com	Category D First stage r	Team member		Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☐
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☒
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Godman B, et al. Are new models needed to optimize the utilization of new medicines to sustain healthcare systems?* *Expert Review of Clinical Pharmacology, 01 Jan 2015, 8(1):77-94* *DOI: 10.1586/17512433.2015.990380* *New models based on critical drug evaluation, multi-criteria valuing medicines for orphan diseases and potentially capping pharmaceutical expenditure as well involving key stakeholder groups to assure sustainability of healthcare systems or universal access are proposed.*
Publication	*Tumiene B., Unmet psychosocial needs of parents of children with rare, complex, and severe genetic diseases. Developmental Medicine & Child Neurology 64(1). August 2021. DOI:10.1111/dmcn.15002. The paper focuses on how adequately response to psychosocial needs of parents with children suffering from rare diseases.*
Publication	*Godman B, et al. Dabigatran - a continuing case history for comprehensive models to optimize the utilization of new drugs. Front. Pharmacol., 10.06.2014 https://doi.org/10.3389/fphar.2014.00109* *Development a new model and future guidance proposed to better manage the entry of new drugs, centering on three pillars of pre-, peri-, and post-launch activities while the latter include increasing use of patient registries to monitor the safety and effectiveness of new drugs in clinical practice.*
Publication	*Heirs J., M., et al. Availability, accessibility and delivery to patients of the 28 orphan medicines approved by the European Medicine Agency for hereditary metabolic diseases in the MetabERN network. Orphanet Journal of Rare Diseases (2020) 15:3, https://doi.org/10.1186/S13023-019-1280-5.* *Due to identified persistent unmet needs scrupulous appreciation of treatment value involving all stakeholders at early stage of development, before marketing authorization, and during follow up is required.*
Publication	*Murauskiene L. Pacientų mokėjimų, sutikimo ir galimybių mokėti už sveikatos priežiūros paslaugas lygybės aspektai* *January 2013 Health Policy and Management 1(5):70-81 https://doi:10.13165/SPV-13-1-5-05* *Equality aspects of the patients' OOPs in Lithuania as regards willingness and capacity to pay.*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
Monitoring financial protection in health systems:	*Monitoring financial protection in health systems: developing new evidence in Europe* *https://www.euro.who.int/en/health-topics/Health-systems/health-systems-financing/publications/2017/coverage,-access-and-financial-protection-in-europe-a-regional-overview-2017* *Analysis of financial affordability of medical products and healthcare services in Lithuania under comparative analysis of European countries.*
Assessment of patient payment policies and project	*Assessment of patient payment policies and projection of their efficiency, equity and quality effects. The case of Central and Eastern Europe.* *The international collaborative project financed by the European Commission under FP7 Theme 8 Socio-economic Sciences and Humanities, Project ASSPRO CEE 2007 (GA no. 217431). Mixed methods research to explore Lithuanian case under comparative research of the patients' OOPs.*

Integrating Big Data for predictive computational	*Integrating Big Data for predictive computational models in personalised medicine* *The EU-funded EU-STANDS4PM project (GA no. 825843) is to establish a pan-European expert forum for evaluating existing standards and developing universal guidelines for the harmonised integration of heterogeneous health data for in silico methodologies. https://cordis.europa.eu/project/id/825843*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	**Short description (Max 300 characters)**

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
998619463	*FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD*

Short name: FPS

Address

Street	AVENIDA AMERICO VESPUCIO 15 EDIF S2
Town	SEVILLA
Postcode	41092
Country	Spain
Webpage	juntadeandalucia.es/fundacionprogresoysalud/index.php

Specific Legal Statuses

Legal person	yes
Public body	no
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	no
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	31/03/1997 - no
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name	Área de Evaluación de Tecnologías Sanitarias (AETSA)	☐ not applicable
	☐ Same as proposing organisation's address	
Street	Avda. Américo Vespucio, 15. Edificio S-2	
Town	Sevilla	
Postcode	41092	
Country	Spain	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title Prof.

Gender ○ Woman ◉ Man ○ Non Binary

First name* **Juan Carlos**

Last name* **Rejon**

E-Mail* **juancarlos.rejon@juntadeandalucia.es**

Position in org. Senior Researcher

Department Área de Evaluación de Tecnologías Sanitarias (AETSA)

☐ Same as organisation name

☒ Same as proposing organisation's address

Street AVENIDA AMERICO VESPUCIO 15 EDIF S2

Town SEVILLA

Post code 41092

Country Spain

Website https://www.aetsa.org/

Phone +34 954 712 409

Phone 2 *+xxx xxxxxxxxx*

Other contact persons

First Name	Last Name	E-mail	Phone
Cristina	Medina Prado	cristina.medina.prado@juntadeandalucia.es	+xxx xxxxxxxxx

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
	Juan Carlos	Rejon Parrilla	Man	Spain	juancarlos.rejon@juntadeandalucia.es	Category B Senior resea	Leading	0000-0002-0680-7353	Orcid ID
	Juan Antonio	Blasco	Man	Spain	jantonio.blasco@juntadeandalucia.es	Category A Top grade re	Team member	0000-0002-5500-8187	Orcid ID
	Agnieszka	Dobrzynska	Woman	Poland	agnieszka.dobrzynska@juntadeandalucia.es	Category B Senior resea	Team member	0000-0003-0385-3650	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☐
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☒
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Rejon-Parrilla, J. C., Espin, J., & Epstein, D. (2022). How innovation can be defined, evaluated and rewarded in health technology assessment. Health economics review, 12(1), 1-11.*
Publication	*Rejon-Parrilla, J. C., Jonsson, P., & Bouvy, J. C. (2019). Key enablers and barriers to implementing adaptive pathways in the European setting. British Journal of Clinical Pharmacology, 85(7), 1427-1433.*
Publication	*Love-Koh, J., Peel, A., Rejon-Parrilla, J.C. et al. The Future of Precision Medicine: Potential Impacts for Health Technology Assessment. PharmacoEconomics 36, 1439–1451 (2018). https://doi.org/10.1007/s40273-018-0686-6*
Publication	*Kent, S., Salcher-Konrad, M., Boccia, S., Bouvy, J. C., Waure, C., Espin, J., Facey, K., Nguyen, M., Rejon-Parrilla, J. C., & Jonsson, P. (2021). The use of nonrandomized evidence to estimate treatment effects in health technology assessment. Journal of comparative effectiveness research, 10(14), 1035–1043. https://doi.org/10.2217/cer-2021-0108*
Publication	*Varela-Lema, L., Ruano-Ravina, A., Mota, T., Ibargoyen-Roteta, N., Imaz, I., Gutiérrez-Ibarluzea, I., Blasco-Amaro, J.A., Soto-Pedre, E., & Sampietro-Colom, L. (2012). POST-INTRODUCTION OBSERVATION OF HEALTHCARE TECHNOLOGIES AFTER COVERAGE: THE SPANISH PROPOSAL. International Journal of Technology Assessment in Health Care, 28(3), 285-293. doi:10.1017/S0266462312000232*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
ALLER-SCREENING	*Point-of-care device based on KETs for diagnosis of food allergies (http://www.aller-screening.upm.es/index.php/en/): AllerScreening is a project aimed at translating a diagnostic technology already proven to the clinical routine, addressing a priority healthcare unmet need from the laboratory to the clinic. AETSA-FPS plays a key role advising on the evidence needed to show the value of this device, and on the assessment of the device that will be done as part of the project.*
RedETS	*Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS, https://redets.mscbs.gob.es/en/): AETSA-FPS is a member of the Spanish Health Technology Assessment Network (RedETS). The network is made up of HTA agencies or units of regions and health services within the Spanish State. We work in a coordinated manner, using a common set of methods and under a principle of mutual recognition, focusing particularly on the evaluation of medical devices.*
CORE–MD	*(https://www.core-md.eu/) is a project that review methods for evaluating high-risk medical devices, in order to translate expert evidence into advice for EU regulators and to recommend an appropriate balance between innovation, safety, and clinical effectiveness. As part of this project, AETSA-FPS will perform an analysis of notified bodies' practices in applying conditions to certificates of conformity and a review of how leading agencies internationally approach this issue.*
INAHTA	*International Network of Agencies for Health Technology Assessment (INAHTA, http://www.inahta.org/): AETSA-FPS is a member of INAHTA. INAHTA is a network of 51 HTA agencies that support health system decision making in 32 countries around the globe. There are clear benefits to connecting these agencies together to cooperate and share information about producing and disseminating HTA reports for evidence-based decision making. INAHTA serves this purpose.*

ERN CPGs and CDSTs	*European Reference Network: Clinical Practice Guidelines and Clinical Decision Support Tools' project (ERN CPGs and CDSTs, https://etendering.ted.europa.eu/cft/cft-display.html?cftId=3788): AETSA-FPS is the leader in a consortium of a total of 7 partners developing the 'ERN CPGs and CDSTs project. The overall purpose of this project is to help the commission support the ERNs and their healthcare providers in the process of development, appraisal and implementation of CPGs and other CDSTs.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	**Short description (Max 300 characters)**

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
949829530	*AGENZIA ITALIANA DEL FARMACO*

Short name: AIFA

Address

Street	VIA DEL TRITONE 181
Town	ROMA
Postcode	00187
Country	Italy
Webpage	www.aifa.gov.it

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	no
Research organisation	no

SME Data

Based on the below details from the Participant Registry the organisation is no (small- and medium-sized enterprise) for the call.

SME self-declared status	unknown
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name: Office for Economic Evaluations ☐ not applicable

☒ Same as proposing organisation's address

Street: VIA DEL TRITONE 181

Town: ROMA

Postcode: 00187

Country: Italy

Department 2

Department name: Office for Monitoring Registers ☐ not applicable

☒ Same as proposing organisation's address

Street: VIA DEL TRITONE 181

Town: ROMA

Postcode: 00187

Country: Italy

Links with other participants

Type of link	Participant

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Dr	Pierluigi	Russo	Man	Italy	p.russo@aifa.gov.it	Category A Top grade re	Leading	0000-0003-4881-5703	Orcid ID
Dr	Pier Paolo	Olimpieri	Man	Italy	p.olimpieri@aifa.gov.it	Category B Senior resea	Team member	0000-0001-7934-9034	Orcid ID
Dr	Annalisa	Sammarco	Woman	Italy	a.sammarco@aifa.gov.it	Category D First stage r	Team member	0000-0002-4361-8076	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☒
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☒
Research performer	☐
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*To evaluate the relation between oncology treatment costs and other information available at the time of P&R decision making in Italy. This study provided further support to the literature on the usefulness of negotiation of confidential discounts or other MEAs to ensure that treatment costs of innovative oncology drugs better reflect the magnitude of clinical benefits and the drug value for patients. Guarantee the affordability of innovative oncology drugs and to contain public expenditures.*
Publication	*The simulation showed that price confidentiality may affect the estimated value of the ICER of a new medicine and, consequently, its interpretation. From a different point of view, the published ICER values may also give a completely false economic evidence if non-disclosure agreements are not taken into account. A proposal for editors of pharmacoeconomic journals to improve reliability of CEA is also discussed.*
Publication	*Our study identified legal constraints for the sharing of information on actual prices and confidential agreements among European countries and consequently restrictions in transparency. In conclusion, the EURIPID survey findings suggest that the current possibility to improve the medicines' price transparency across countries is limited and the issue probably requires international institutional engagement, at least to coordinate initiatives toward a greater collaboration among member states.*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
Euripid	*The European Integrated Price Information Database (Euripid) has been established as voluntary non-profit collaboration of national pricing and reimbursement authorities in European countries. National pricing and reimbursement authorities have committed themselves to provide national data and foster information and data exchange between the EU countries.(https://euripid.eu/)*
Medev	*MEDEV provides an informal platform for exchanges between national bodies responsible for the assessment, pricing and reimbursement of medicines to support them in their role at national level. MEDEV collaborates closely with the following organisations and networks: EUnetHTA; EMA; European Commission; European Parliament; WHO.*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)
Monitoring Registers Platform	*activities aimed at ensuring the appropriate use of the medicines being monitored; detection of the outcomes resulting from the use in clinical practice of the medicines subject to monitoring; sharing of the system of registers with the regional representatives and the heads of the health structures*

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
983406274	*INFARMED - AUTORIDADE NACIONAL DO MEDICAMENTO E PRODUTOS DA SAUDE IP*

Short name: INFARMED

Address

Street	AVENIDA DO BRASIL 53
Town	LISBOA
Postcode	1749 004
Country	Portugal
Webpage	

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	no
Research organisation	no

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	01/01/1900 - no
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name: Health Technology Assessment Department ☐ not applicable

☐ Same as proposing organisation's address

Street: Av. do Brasil 53 Pavilhão 21A

Town: Lisbon

Postcode: 1749-004

Country: Portugal

Department 2

Department name: Executive Board ☐ not applicable

☐ Same as proposing organisation's address

Street: Av. do Brasil 53 Pavilhão 21A, 1749-004

Town: Lisbon

Postcode: 1749-004

Country: Portugal

Links with other participants

Type of link	Participant

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
	Rui	Santos Ivo	Man	Portugal	rui.ivo@infarmed.pt			0000-0001-8400-0013	Orcid ID
	Caludia	Furtado	Woman	Portugal	claudia.furtado@infarmed.pt			0000-0002-6754-9319	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☐
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☒
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☒
Research performer	☐
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Cardoso Borges F, Alves da Costa F, Ramos A, Ramos C, Bernardo C, Brito C, Mayer-da-Silva A, Furtado C, Ferreira AR, Martins-Branco D, Miranda A, Lourenço A. Breast. 2022 Feb 8;62:135-143. doi: 10.1016/j.breast.2022.02.005. Online ahead of print. PMID: 35182993 Article on the use of real world evidence on reassessment of medicines reimbursement - https://pubmed.ncbi.nlm.nih.gov/35182993/*
Publication	*Borges FC, Ramos C, Ramos A, Mendes GP, Murteira R, Soares P, Furtado C, Miranda AC, Costa FA; RON network. Pharmacoepidemiol Drug Saf. 2021 Mar;30(3):342-349. doi: 10.1002/pds.5163. Epub 2020 Nov 9. PMID: 33103788 Article on the use of real world evidence on reassessment of medicines reimbursement - https://pubmed.ncbi.nlm.nih.gov/33103788/*
Publication	*Eichler HG, Bloechl-Daum B, Broich K, Kyrle PA, Oderkirk J, Rasi G, Santos Ivo R, Schuurman A, Senderovitz T, Slawomirski L, Wenzl M, Paris V. Clin Pharmacol Ther. 2019 Apr;105(4):912-922. doi: 10.1002/cpt.1226. Epub 2018 Oct 14. PMID: 30178490 Free PMC article. Article on the use of data to support decision making on healthcare - https://pubmed.ncbi.nlm.nih.gov/30178490/*
Other achievement	*Guidelines that support the elaboration and assessmment of economic studies to determine cost effectiveness ratio and Budget impact https://www.infarmed.pt/documents/15786/4001413/Orienta%C3%A7%C3%B5es+metodol%C3%B3gicas+para+estudos+de+avalia%C3%A7%C3%A3o+econ%C3%B3mica+de+tecnologias+de+sa%C3%BAde+%28EN%29/ebcfd930-94e2-c7e1-100a-ee1df3d76882*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
HTA & Payer entity	*Infarmed is the National agency with the responsibility of HTA, Pricing and Reimbursement. The combination of these areas provides knowledge about the needs regarding the actual constraints in financing models and the needs of payers*
Member of EUnetHTA and EUnetHTA21	*Infarmed is member of EUnetHTA https://www.eunethta.eu/about-eunethta/*
Member of NCAPR	*Member of National Competent Authorities for Pricing and Reimbursement https://ppeu2021.infarmed.pt/en/events/network-of-competent-authorities-on-pricing-and-reimbursement-ncapr-online-meeting*
Member of La Valletta Technical Committee meeting	*Voluntary cross-country collaborations that aim to improve sustainable access to medicines through joint activities, including information sharing and joint procedures.*
Member of the International Horizon Scanning In.	*IHSI provides data that empowers political decision-makers and payer organisation negotiators to drive for better pricing in medicinal products. IHSI data enables healthcare systems to prepare for disruptive technologies through data insights that deliver the leverage required to confidently assess new products coming to Market. Link https://ihsi-health.org/*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? ○ Yes ◉ No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
999861063	*LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE*

Short name: LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE

Address

Street	Houghton Street 1
Town	LONDON
Postcode	WC2A 2AE
Country	United Kingdom
Webpage	www.lse.ac.uk

Specific Legal Statuses

Legal person	yes
Public body	no
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	yes
Research organisation	yes

SME Data

Based on the below details from the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

SME self-declared status	21/05/2008 - no
SME self-assessment	unknown
SME validation	21/05/2008 - no

Departments carrying out the proposed work

Department 1

Department name	Health Policy	☐ not applicable
	☐ Same as proposing organisation's address	
Street	Houghton Street 1	
Town	London	
Postcode	WC2A 2AE	
Country	United Kingdom	

Links with other participants

Type of link	Participant

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in the step "Participants" of the submission wizard.

Title: Dr

Gender: ○ Woman ◉ Man ○ Non Binary

First name*: **Panos**

Last name*: **Kanavos**

E-Mail*: **p.g.kanavos@lse.ac.uk**

Position in org.: Associate Professor

Department: Health Policy

☐ Same as organisation name

☒ Same as proposing organisation's address

Street: Houghton Street 1

Town: LONDON

Post code: WC2A 2AE

Country: United Kingdom

Website: www.lse.ac.uk; https://www.lse.ac.uk/health-policy

Phone: +442079556802

Phone 2: *+xxx xxxxxxxxx*

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Dr	Panos	Kanavos	Man	United Kingdom	p.g.kanavos@lse.ac.uk	Category B Senior resea	Leading	0000-0001-9518-3089	Orcid ID
Ms	Erica	Visintin	Woman	Italy	E.Visintin@lse.ac.uk	Category C Recognised	Team member		
Mr	Mackenzie	Mills	Man	Canada	m.j.mills@lse.ac.uk	Category C Recognised	Team member		
Ms	Olina	Efthymiadou	Woman	Greece	a.efthymiadou@lse.ac.uk	Category D First stage r	Team member	0000-0001-9018-7144	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☒
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☐
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☒
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☐
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☒
Other If yes, please specify: (Maximum number of characters allowed: 50)	☐

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Mills M, Kanavos P. Do pharmaceutical budgets deliver financial sustainability in healthcare? Evidence from Europe. Health Policy. 2020 Mar;124(3):239-251. doi: 10.1016/ j.healthpol.2019.12.002. Epub 2019 Dec 12. PMID: 31926651.*
Publication	*Kanavos P, Kamphuis BW, Fontrier AM, Colville Parkin G, Saleh S, Akhras KS. Pricing of in-patent pharmaceuticals in the Middle East and North Africa: Is external reference pricing implemented optimally? Health Policy. 2020 Dec;124(12):1297-1309. doi: 10.1016/ j.healthpol.2020.07.017. Epub 2020 Aug 14. PMID: 32962876.*
Publication	*Miracolo A, Sophiea M, Mills M, Kanavos P. Sin taxes and their effect on consumption, revenue generation and health improvement: a systematic literature review in Latin America. Health Policy Plan. 2021 Jun 3;36(5):790-810. doi: 10.1093/heapol/czaa168. PMID: 33885782; PMCID: PMC8173601.*
Publication	*Kanavos P, Fontrier AM, Gill J, Efthymiadou O. Does external reference pricing deliver what it promises? Evidence on its impact at national level. Eur J Health Econ. 2020 Feb;21(1):129-151. doi: 10.1007/s10198-019-01116-4. Epub 2019 Oct 3. PMID: 31583483; PMCID: PMC7058621.*
Publication	*Angelis A, Linch M, Montibeller G, Molina-Lopez T, Zawada A, Orzel K, Arickx F, Espin J, Kanavos P. Multiple Criteria Decision Analysis for HTA across four EU Member States: Piloting the Advance Value Framework. Soc Sci Med. 2020 Feb;246:112595. doi: 10.1016/ j.socscimed.2019.112595. Epub 2019 Oct 15. PMID: 31874372.*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
IMPACT HTA	*IMPACT HTA - Improved methods and actionable tools for enhancing HTA (Horizon 2020 - GA No779312):* *IMPACT HTA is a research project looking at new and improved methods across ten thematic areas aiming at 1) understanding variations in costs and health outcomes within and across countries, and 2) integrating clinical and economic data from different sources to improve methods in economic evaluation in the context of HTA and health system performance measurement.* *https://www.impact-hta.eu/*
Advance HTA	*Advance HTA - Advancing and strengthening the methodological tools and practices relating to the application and implementation of Health Technology Assessment (FP7 – GA No305983)* *ADVANCE HTA aims to advance and strengthen the methodological tools and practices relating to the application and implementation of Health Technology Assessment (HTA). Its 5 streams focus on value assessment and value for money, rare diseases, quality of life, medical devices and capacity building.* *https://cordis.eur*
Multi criteria value framework for cancer products	*ESMO Magnitude of Clinical Benefit Scale for HTA coverage and reimbursement recommendations of cancer medicines* *Project In collaboration with ESMO identifying the relationship between ESMO-MCBS and HTA coverage recommendations for cancer. It combines descriptive and econometric analyses to identify correlations between ESMO-MCBS and other factors considered by HTA agencies such as cost-effectiveness, evidence uncertainties, and other dimensions of benefit, such as unmet need and innovativeness.*

Financing High-Cost Curative Therapies	*Research project in collaboration with Novartis Pharmaceuticals identifying the additional value and challenges posed by curative high-cost therapies for payers and healthcare systems in terms of clinical efficacy and effectiveness, financing, manufacturing, and real-world evidence. Challenges are explored from both a high-income country perspective and a low and middle-income country perspective. https://www.lse.ac.uk/business/consulting/reports/financing-high-cost-curative-therapies*
Virtual Health Care, Pharma and Population Health	*Research in collaboration with Sanofi Pharmaceuticals to understand how virtual health care can assist population health and the role of the pharmaceutical industry in achieving population health goals. Six virtual case studies were reviewed to analyse key policies and practices for virtual health care, and shape subsequent learning and recommendations. https://www.lse.ac.uk/business/consulting/reports/the-role-of-virtual-health-care-and-the-pharmaceutical-sector-in-improving-population-health*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	**Short description (Max 300 characters)**

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

PIC	Legal name
937795710	*SERVEI CATALA DE LA SALUT*

Short name: CATALAN HEALTH SERVICE

Address

Street	CL TRAVESSERA DE LES CORTS 129 151 EDIFICI O
Town	BARCELONA
Postcode	08028
Country	Spain
Webpage	http://catsalut.gencat.cat

Specific Legal Statuses

Legal person	yes
Public body	yes
Non-profit	yes
International organisation	no
Secondary or Higher education establishment	no
Research organisation	no

SME Data

Based on the below details from the Participant Registry the organisation is no (small- and medium-sized enterprise) for the call.

SME self-declared status	unknown
SME self-assessment	unknown
SME validation	unknown

Departments carrying out the proposed work

Department 1

Department name	Digitalization for the Sustainability of the Healthcare System	☐ not applicable
	☐ Same as proposing organisation's address	
Street	Gran Via de les Corts Catalanes, 591	
Town	Barcelona	
Postcode	08007	
Country	Spain	

Links with other participants

Type of link	Participant

Researchers involved in the proposal

Title	First Name	Last Name	Gender	Nationality	E-mail	Career Stage	Role of researcher (in the project)	Reference Identifier	Type of identifier
Dr	Caridad	Pontes	Woman	Spain	cpontes@catsalut.cat	Category B Senior resea	Leading	0000-0002-3274-6048	Orcid ID
Dr	Marta	Roig-Izquierdo	Woman	Spain	maroig@catsalut.cat	Category C Recognised	Team member	0000-0002-7846-1216	Orcid ID
Dr	Gerard	Carot-Sans	Man	Spain	gerard.carot@catsalut.cat	Category B Senior resea	Team member	0000-0001-5982-7975	Orcid ID
Ms	Montserrat	Gasol	Woman	Spain	mgasol@catsalut.cat	Category D First stage r	Team member		Orcid ID
Mr	Xavier	Garcia	Man	Spain	xgarcia@catsalut.cat	Category D First stage r	Team member	0000-0001-7199-6931	Orcid ID
Ms	Laura	Guarga	Woman	Spain	laura.guarga@catsalut.cat	Category D First stage r	Team member	0000-0001-5960-2442	Orcid ID
Dr	Mercè	Obach	Woman	Spain	mobach@catsalut.cat	Category B Senior resea	Team member	0000-0002-2756-6181	Orcid ID

Role of participating organisation in the project

Project management	☐
Communication, dissemination and engagement	☐
Provision of research and technology infrastructure	☐
Co-definition of research and market needs	☒
Civil society representative	☐
Policy maker or regulator, incl. standardisation body	☐
Research performer	☒
Technology developer	☐
Testing/validation of approaches and ideas	☐
Prototyping and demonstration	☐
IPR management incl. technology transfer	☐
Public procurer of results	☒
Private buyer of results	☐
Finance provider (public or private)	☐
Education and training	☐
Contributions from the social sciences or/and the humanities	☐
Other If yes, please specify: (Maximum number of characters allowed: 50)	☒

Stakeholder

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	Short description (Max 500 characters)
Publication	*Early Access to Medicines: Use of Multicriteria Decision Analysis (MCDA) as a Decision Tool in Catalonia (Spain). J Clin Med. 2022 Mar 1;11(5):1353. doi: 10.3390/jcm11051353.*
Publication	*Description of the use of multicriteria to support pricing and reimbursement decisions by European health technology assessment bodies. BMC Health Serv Res. 2021 Aug 14;21(1):814. doi: 10.1186/s12913-021-06784-8.*
Publication	*Potential approaches for the pricing of cancer medicines across Europe to enhance the sustainability of healthcare systems and the implications. Expert Rev Pharmacoecon Outcomes Res. 2021 Aug;21(4):527-540. doi: 10.1080/14737167.2021.1884546. Epub 2021 Mar 11.*
Publication	*Registry of patients and treatments of hospital medicines in Spain: 10 years of clinical data. Med Clin (Barc). 2020 Mar 13;154(5):185-191. doi: 10.1016/j.medcli.2019.09.009. Epub 2019 Nov 20.*
Publication	*Financial consequences of a payment-by-results scheme in Catalonia: gefitinib in advanced EGFR-mutation positive non-small-cell lung cancer. Journal of Medical Economics, 20:1, 1-7, DOI: 10.1080/13696998.2016.1215991*

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal.

Name of Project or Activity	Short description (Max 500 characters)
ASTERIX	*ASTERIX was a novel EU-funded research project focusing on the development of more efficient and effective research designs to study new drugs and treatments for rare diseases, with focus on statistical and regulatory aspects, as well as patient involvement on project design. (Dr Pontes, Dr Obach)*
BEAMER	*The main objective of the Project is to create BEAMER, a disease-agnostic behavioral and adherence model for improving quality, health outcomes and cost-effectiveness of healthcare, through improving the quality of life of individuals, enhance healthcare accessibility and sustainability. (Dr Pontes, Dr Carot)*
EUnetHTA	*Programme: 3HP. Call: ADHOC-2014-2020-JA-2015. Website . Catalan health Service involvement in collaboration with AQuAS (Catalan Agency for Health Quality and Assessment) (Team members involved: Xavier García-Cuscó, Dr Mercè Obach)*
REVALMED	*The Action Plan for the Consolidation of Therapeutic Positioning Reports is the Spanish expert network for appraisals supporting pricing & reimbursement of drugs. SCS coordinates two nodes and contributes to 8 clinical areas. (Team members involved: Dr Roig-Izquierdo, Ms Gasol, Ms Guarga, Dr Obach)*
CIPM Interministerial commission	*Catalan regional representative at the Spanish Committee on pricing and reimbursement of medicines, dependent from the Spanish Ministry of Health. As such, member involved in pricing and reimbursement decision making. (Team members involved: Dr Caridad Pontes).*

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work.

Name of infrastructure of equipment	Short description (Max 300 characters)

Gender Equality Plan

Does the organization have a Gender Equality Plan (GEP) covering the elements listed below? (•) Yes ( ) No

Minimum process-related requirements (building blocks) for a GEP

- **Publication:** formal document published on the institution's website and signed by the top management
- **Dedicated resources:** commitment of human resources and gender expertise to implement it.
- **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators.
- **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers.
- **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are:
    - work-life balance and organisational culture;
    - gender balance in leadership and decision-making;
    - gender equality in recruitment and career progression;
    - integration of the gender dimension into research and teaching content;
    - measures against gender-based violence including sexual harassment.

3 - Budget

No.	Name of beneficiary	Country	Role	Personnel costs/€	Subcontracting costs/€	Purchase costs - Travel and substistence /€	Purchase costs - Equipment/€	Purchase costs - Other goods, works and services/€	Internally invoiced goods and services/€ (Unit costs-usual accounting practices)	Indirect costs/€	Total eligible costs	Funding rate	Maximum EU contribution to eligible costs	Requested EU contribution to eligible costs/€	Max grant amount	Income generated by the action	Financial contributions	Own resources	Total estimated income
1	Universita Commerciale Luigi Bocconi	IT	Coordinator	792,046	0	70,000	0	131,000	0	248261.50	1241307.50	100	1241308.00	1,241,308	1241308.00	0	0	0	1241308.00
2	Universitaet Hamburg	DE	Partner	340,800	0	12,000	0	10,250	0	90762.50	453812.50	100	453813.00	453,813	453813.00	0	0	0	453813.00
3	Hta Austria - Austrian Institute For Health Technology Assessment Gmbh	AT	Partner	240,114	4,320	8,400	0	2,500	0	62753.50	318087.50	100	318088.00	318,088	318088.00	0	0	0	318088.00
4	Escuela Andaluza De Salud Publica Sa	ES	Partner	219,381	0	12,000	3,000	0	0	58595.25	292976.25	100	292976.00	292,976	292976.00	0	0	0	292976.00
5	Universite Libre De Bruxelles	BE	Partner	150,238	0	6,000	0	14,000	0	42559.50	212797.50	100	212798.00	212,798	212798.00	0	0	0	212798.00
6	Office Of Health Economics	UK	Partner	309,650	0	7,200	0	12,000	0	82212.50	411062.50	100	411063.00	411,063	411063.00	0	0	0	411063.00
7	Fundacio Clinic Per A La Recerca Biomedica	ES	Partner	117,910	0	12,000	0	0	0	32477.50	162387.50	100	162388.00	162,388	162388.00	0	0	0	162388.00
8	Hospital Clinic De Barcelona	ES	Affiliated	55,130	0	0	0	0	0	13782.50	68912.50	100	68913.00	68,913	68913.00	0	0	0	68913.00

9	Imperial College Of Science Technology And Medicine	UK	Partner	377,428	0	8,478	0	13,345	0	99812.75	499063.75	100	499064.00	499,064	499064.00	0	0	0	499064.00
10	Erasmus Universiteit Rotterdam	NL	Partner	319,300	0	12,000	0	5,000	0	84075.00	420375.00	100	420375.00	420,375	420375.00	0	0	0	420375.00
11	Universidade Nova De Lisboa	PT	Partner	215,441	0	12,000	0	6,000	0	58360.25	291801.25	100	291801.00	291,801	291801.00	0	0	0	291801.00
12	Ecole D'economie De Paris	FR	Partner	201,600	0	12,000	5,000	0	0	54650.00	273250.00	100	273250.00	273,250	273250.00	0	0	0	273250.00
13	Vilniaus Universitetas	LT	Partner	67,302	0	4,200	0	0	0	17875.50	89377.50	100	89378.00	89,378	89378.00	0	0	0	89378.00
14	Fundacion Publica Andaluza Progreso Y Salud	ES	Partner	97,898	0	12,000	0	0	0	27474.50	137372.50	100	137373.00	137,373	137373.00	0	0	0	137373.00
15	Agenzia Italiana Del Farmaco	IT	Associated	0	0	0	0	0	0	0.00	0.00	100	0.00	0	0.00	0	0	0	0.00
16	Infarmed - Autoridade Nacional Do Medicamento E Produtos Da Saude Ip	PT	Associated	0	0	0	0	0	0	0.00	0.00	100	0.00	0	0.00	0	0	0	0.00
17	London School Of Economics And Political Science	UK	Partner	285,367	0	12,000	0	7,880	0	76311.75	381558.75	100	381559.00	381,559	381559.00	0	0	0	381559.00
18	Servei Catala De La Salut	ES	Associated	0	0	0	0	0	0	0.00	0.00	100	0.00	0	0.00	0	0	0	0.00
			TOTAL	3,789,605	4,320	200,278	8,000	201,975	0	1049964.50	5254142.50		5254147.00	5,254,147	5254147.00	0	0	0	5254147.00

Proposal ID **101095593**

Acronym **HI-PRIX**

4 - Ethics & security

Ethics Issues Table

1. Human Embryonic Stem Cells and Human Embryos			Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?	○ Yes	◉ No	
Does this activity involve the use of human embryos?	○ Yes	◉ No	
2. Humans			**Page**
Does this activity involve human participants?	◉ Yes	○ No	5-10
Are they volunteers for non medical studies (e.g. social or human sciences research)?	◉ Yes	○ No	5-10
Are they healthy volunteers for medical studies?	○ Yes	◉ No	
Are they patients for medical studies?	○ Yes	◉ No	
Are they potentially vulnerable individuals or groups?	○ Yes	◉ No	
Are they children/minors?	○ Yes	◉ No	
Are they other persons unable to give informed consent?	○ Yes	◉ No	
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	○ Yes	◉ No	
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	○ Yes	◉ No	
3. Human Cells / Tissues (not covered by section 1)			**Page**
Does this activity involve the use of human cells or tissues?	○ Yes	◉ No	
4. Personal Data			**Page**
Does this activity involve processing of personal data?	◉ Yes	○ No	5-10
Does it involve the processing of special categories of personal data (e.g.: genetic, biometric and health data, sexual lifestyle, ethnicity, political opinion, religious or philosophical beliefs)?	○ Yes	◉ No	
Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	○ Yes	◉ No	
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	◉ Yes	○ No	5-10
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved	○ Yes	◉ No	
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? Specify the type of personal data and countries involved	○ Yes	◉ No	
Does this activity involve the processing of personal data related to criminal convictions or offences?	○ Yes	◉ No	
5. Animals			**Page**
Does this activity involve animals?	○ Yes	◉ No	
6. Non-EU Countries			**Page**

Will some of the activities be carried out in non-EU countries?	◉ Yes	○ No	1

UK

In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?	○ Yes	◉ No	
It is planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	○ Yes	◉ No	
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.	○ Yes	◉ No	
Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4.	○ Yes	◉ No	
Does this activity involve low and/or lower middle income countries, (if yes, detail the benefit-sharing actions planned in the self-assessment)	○ Yes	◉ No	
Could the situation in the country put the individuals taking part in the activity at risk?	○ Yes	◉ No	

7. Environment, Health and Safety			Page
Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants.(during the implementation of the activity or further to the use of the results, as a possible impact) ?	○ Yes	◉ No	
Does this activity deal with endangered fauna and/or flora / protected areas?	○ Yes	◉ No	
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity.(during the implementation of the activity or further to the use of the results, as a possible impact) ?	○ Yes	◉ No	

8. Artificial Intelligence			Page
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	○ Yes	◉ No	

9. Other Ethics Issues			Page
Are there any other ethics issues that should be taken into consideration?	○ Yes	◉ No	

I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment as described in the guidelines How to Complete your Ethics Self-Assessment ☒

Administrative forms

Proposal ID **101095593**

Acronym **HI-PRIX**

Ethics Self-Assessment

Ethical dimension of the objectives, methodology and likely impact

The overarching objectives of the HI-PRIX project are:
i) to map extensively and formulate new pricing and payment schemes that can be used across technology classes, therapeutic areas, setting and healthcare systems/geographies together with a related set of principles that may guide successful adjustment and flexible implementation to the particular context of use;
ii) to investigate the impact on competitiveness, innovation, equity and affordability of a pipeline of contracting modalities for health innovations to move from regulatory approval through value assessment to adoption;
iii) to address the challenges and concerns of payers, manufacturers, healthcare professionals, and patients' perspectives about different models of pricing by sustaining an effective dialogue across stakeholders' groups about the trade-offs between affordability, innovation and patient access.
In order to achieve these objectives, we will employ qualitative and quantitative methodologies.
Different stakeholders' groups will be engaged through focus groups, individual interviews, or Delphi round tables.
Econometric analyses will be performed on list prices of different pharmaceutical products, rates of new patents registered, timing of access, simulated profits for the industry. The research activities do not involve patients, nor any vulnerable research population.
The ethical concerns raised by this project are therefore limited to the appropriate data management practices, especially for the primary research data generated through focus groups and interviews, and to avoiding misuse and fallacious implementation of new pricing and payment schemes developed during the project.

Remaining characters 3306

Compliance with ethical principles and relevant legislations

The project coordinator (UB) will ensure an ethical management of the activities being conducted and of the data being collected, and will oversee any ethical issues related to the project activities, both within the Consortium and with third-parties. Given the purpose of activities conducted, any external stakeholders involved will need to confirm existing conflicts of interests. In addition, all partners will make sure that the research activities are conducted in compliance with the health and safety standards of each institutions, and that a respectful and inclusive workplace will be guaranteed. Partners will also guarantee that the researchers involved in the project maintain a balance between work and family commitments. Compliance with ethical and data protection will be monitored throughout the entire project lifecycle (36 months).

Relevant legislation: General Data Protection Regulation (GDPR) is the relevant regulation for data protection.

Data protection and confidentiality measures: Any data collected will be stored on password-protected computers, and will be disseminated only in a strictly anonymous form and at an aggregated level (e.g., through scientific publications, statistics and scientific reports). For the research activities that engage external stakeholders, some personal data will be processed, including name and surname, email, role in the organisation, country of professional practice. The usage of these personal data is for research purposes only and will be anonymized before being stored in the internal repositories. At all time, the coordinator (UB) will apply administrative measures to control the risks of inappropriate disclosure (i.e., pseudonymization) and procedures for secure transfer between locations by using file encryption and encrypted channels. Data will be kept for the purpose of the project until the end of the project (36 months). In the event of publications or presentations, the evidence from these activities will be used in an anonymised formats only, ensuring full confidentiality. To reduce the linkability of the information processed with the original identity of the data subjects, the implementation of pseudonymisation techniques will be considered, with the goal of enhancing the overall security of personal data. Each WP research team will be able to access the identifying information collected in this project; the evidence that will emerge from the qualitative research methodologies (e.g., focus groups or Delphi) will be shared with the other members of the Consortium at an aggregated level only.

Remaining characters 2401

Administrative forms

Proposal ID **101095593**

Acronym **HI-PRIX**

Security issues table

1. EU Classified Information (EUCI)[2]		Page
Does this activity involve information and/or materials requiring protection against unauthorised disclosure (EUCI)?	○ Yes ◉ No	
Does this activity involve non-EU countries?	○ Yes ◉ No	
2. Misuse		**Page**
Does this activity have the potential for misuse of results?	○ Yes ◉ No	
3. Other Security Issues		**Page**
Does this activity involve information and/or materials subject to national security restrictions? If yes, please specify: (Maximum number of characters allowed: 1000)	○ Yes ◉ No	
Are there any other security issues that should be taken into consideration? If yes, please specify: (Maximum number of characters allowed: 1000)	○ Yes ◉ No	

[2]According to the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information, "European Union classified information (EUCI) means any information or material designated by an EU security classification, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union or of one or more of the Member States".

[3]Classified background information is information that is already classified by a country and/or international organisation and/or the EU and is going to be used by the project. In this case, the project must have in advance the authorisation from the originator of the classified information, which is the entity (EU institution, EU Member State, third state or international organisation) under whose authority the classified information has been generated.

[4]EU classified foreground information is information (documents/deliverables/materials) planned to be generated by the project and that needs to be protected from unauthorised disclosure. The originator of the EUCI generated by the project is the European Commission.

5 - Other questions

Essential information to be provided for proposals including clinical Trials / studies / investigations

Clinical study means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

Are clinical studies / trials / investigations included in the work plan of this project?	○ Yes	◉ No

HEALTH INNOVATION NEXT GENERATION PAYMENT & PRICING MODELS **(HI-PRIX):**

Balancing Sustainability of Innovation with Sustainability of Health Care

List of participants

No.	Participant organisation name	Short name	Country
1	Università Commerciale Luigi Bocconi	UB	IT
2	Universitaet Hamburg	UHAM	DE
3	HTA Austria - Austrian Institute for Health Technology Assessment GmbH	AIHTA	AT
4	Escuela Andaluza de Salud Publica SA	EASP	ES
5	Universite Libre de Bruxelles	ULB	BE
6	Office of Health Economics	OHE	UK
7	Fundació Clínic per a la Recerca Biomèdica	FCRB	ES
8	Hospital Clinic de Barcelona	HCB	ES
9	Imperial College of Science Technology and Medicine	ICL	UK
10	Erasmus Universiteit Rotterdam	EUR	NL
11	Universidade Nova de Lisboa	UNL	PT
12	Ecole d'Economie de Paris	PSE	FR
13	Vilniaus Universitetas	VU	LT
14	Fundacion Publica Andaluza Progreso y Salud	AETSA	ES
15	Agenzia Italiana del Farmaco	AIFA	IT
16	Infarmed – Autoridade Nacional do Medicamento e Produtos da Salude IP	INF	PT
17	London School of Economics and Political Science	LSE	UK
18	Servei Catala de la Salut	CATSALUT	ES

1. Excellence

1.1 Background and rationale

The emergence of high-price innovative therapies is exerting strong **financial pressure on healthcare payers** worldwide. Drug prices have been rising rapidly in the past decades, with prices in the USA substantially higher than those in European countries, even after accounting for negotiated discounts and rebates[1]. The main reason why European countries have reaped a return in the form of prices that are lower than the US, is the presence of publicly accountable institutions for **health technology assessment (HTA)** and drug price determination. These bodies, either inside or closely aligned with government, have defined **"value-based" price benchmarks**, which are generally based on the clinical and/or cost-effectiveness of new therapies relative to existing treatments and the prevailing standard of care[2,3], and incorporated these benchmarks into their processes of drug price regulation and negotiation.

Considering cancer drugs, a major component of pharmaceutical spending, launch prices for new oncology products in Europe have increased over a decade from median monthly treatment of around €3,960 to €5,430. By contrast, in the US the increase was from $5,790 to $14,580[4]. This **double digit increase in launch prices** is not commensurate to increases in efficacy, implying that the price per life-year gained increased from $139,000 to $207,000[5]. During the same period, the number of approved cancer drugs has also increased, raising issues of **affordability for public and private third-party payers** on both sides of the Atlantic[6,7].

Most of the recently approved advanced therapy medicinal products (**ATMPs**) are for oncology indications, often in **rare and ultra-rare populations**. Given the high per-patient prices, which can exceed one million Euros, payers' ability to absorb multiple gene therapies while delivering affordable access to healthcare is questionable. The benefits of ATMPs usually accrue over a **patient's lifetime** after a **single administration**, which runs counter to the traditional model where both treatment costs and benefits are spread out over time with yearly assessment of coverage. Financing and reimbursement mechanisms used with these products are i) individual **annuities** that convert a one-time upfront high cost to multi-annual instalments; ii) **performance-based annuities**, that are contingent upon performance

evaluation; iii) in an insurance-based setting, **risk-pooling** for constant payments at plan or employer level using reinsurance or state-level bonding[8,9]. The most common approach in the EU so far has been the use of **outcomes-based reimbursement schemes**[7], where refunds can be made to payers in the case of patient response but where payers only pay for responsive patients[10]. However, these schemes can be difficult to develop and implement[11].

There is a growing awareness that innovative pricing models are required to balance payers' needs for value for money with manufacturers' needs for **incentives to stimulate innovation**. The coronavirus disease 2019 (COVID-19) pandemic has highlighted advantages and limitations of different current mechanisms for funding research, development, manufacturing, and distribution of biomedical innovation[12]. Government agencies and philanthropic organizations have offered large sums not only to support basic research for vaccines, therapeutics and diagnostics, but also to fund late-stage product development, the expansion of manufacturing capacity, and efficient systems for distribution[13]. Traditionally **transparency** about research and development (R&D) costs is lacking, as manufacturers rarely make public the costs incurred in product development, as part of the pricing and reimbursement negotiation. During the COVID pandemic, **advanced market commitments** have been used to fund vaccine research and development with the understanding that recipients will supply vaccines later at prices that only cover the cost of production. With advanced market commitments, the purchaser contracts for a defined number of vaccine doses at a negotiated price, in effect committing the manufacturer to prioritize the contracted purchaser over others. A revised collaborative, market-based financing mechanism for the world to **provide equitable access** to second and third generations of COVID-19 vaccines has been proposed by experts, governmental and philanthropic organizations[14], however the impact of such new mechanism on availability and accessibility of new products must be established[15].

Similarly, after a productive period for **antibiotic discovery** between the 1940s and 1990s, a diminishing pipeline over the last thirty years has emphasised the need to incentivise new research and development. The fundamental issue is that pharmaceutical companies are reluctant to invest because sales volumes are limited by the short treatment duration and by stewardship efforts inherent in antibiotic therapy. To address some of these challenges, the National Institute for Health and Care Excellence (NICE), NHS England, and NHS Improvement launched in 2019 a **world-first subscription payment model** to incentivise pharmaceutical companies to develop new drugs for resistant infections[16]. In April 2022, cefiderecol and ceftazidime with avibactam approved in draft guidelines from NICE, have been announced as available options for patients with risky urinary tract infections, pneumonia and sepsis[17]. The idea behind this scheme involves **decoupling payment from the volume sold** and, instead, rewarding pharmaceutical companies for the development of novel antibiotics with regular payments based on their overall value to society. Like in the case of advanced market commitments for COVID-19 vaccines, this approach is a variation of a pre-existing **"pull" incentive**. Other "subscription" agreements, sometimes termed **"Netflix models"**, are now in place in the US states of Washington and Louisiana for drugs treating hepatitis C. A fixed payment to the manufacturers is established, regardless of the number of patients treated[18]. The arrangement ensures a predictable revenue stream for the drug manufacturer while preventing drug costs from growing uncontrollably, although questions remain about where to set a cap with either free or "extremely low" pricing for any additional patients.

In addition, system access and affordability issues exist for **future Alzheimer's disease treatments**. The launch of aducanumab for patients suffering from Alzheimer's disease in the US has proven to be one of the most controversial in recent memory[19]. The list price of $56,000, ten times higher than the evidence-based benchmark recommended by the independent Institute for Clinical and Economic Review, has been recently described as "a rational manufacturer response to an irrational insurance system"[20]. In the EU there are not yet any licensed treatments, but other disease-modifying therapies for Alzheimer's disease are under scrutiny, with health-care systems facing imminent reimbursement and access challenges. Those therapies will likely be ongoing and not eliminate expensive long-term care and comorbidity management. The **"societal" benefit** for these upcoming treatments, such as family caregiver outcomes, are going to be significant. Like performance-based risk sharing agreements for other indications, payments could be tied to outcomes, thus helping apportion risks associated with initial therapy value estimates between drug manufacturers and payers. Because the target population is potentially very large, even cost-effective treatments may be unaffordable given **skyrocketing budget impact**[21]. Innovation in payment models is warranted to make sure the healthcare systems will be in a position to seize the opportunity of clinical benefit for this large patient population.

A potential avenue in the development of new payment models pertains to shifting the focus **from "buying pills to buying services"**, enabling manufacturers to become partners in the provision of services rather than simply sellers[22]. This situation is closer to the commissioning of health care services, where **non-linear payment systems**, including **price-volume agreements**, **bundled-payments**, **population-based** or **integrated-care approaches**[23], may be recommended[24]. With the exponential growth of digital tools to innovate the delivery of healthcare, the change from

buying pills to buying services looks like an inevitable shift. **Digital health solutions** are typically not sold directly to patients, and individuals are not accustomed to paying for chronic disease treatments beyond standard co-pays for physician visits and prescription drugs. Digital health solutions, together with the process of care they are embedded in, need to be paid for by insurers, providers or health care organizations. A suitable payment model would need to be concerned about the role of patient compliance and the level of productivity-enhancement for providers and clinicians[25]. However, many providers continue to face a **fee-for-service reimbursement** system that pays substantially more for seeing a patient in person than for managing care electronically and remotely, whilst they could pay **monthly fees per member to make an app available to the populations** they cover. In late 2019, Germany's parliament passed the Digital Health Care Act (Digitale-Versorgung-Gesetz, or DVG) — an ambitious law designed to catalyse the digital transformation of the German health care system. DVG promises to provide a standard care environment for manufacturers of new digital health tools to evaluate pricing strategies and understand **how digital health applications fit into health care practice and patients' everyday routines**[26]. The importance of such a major country mandating that all insurers pay for digital health apps is hard to overstate.

This array of contemporary issues facing third-party payers worldwide illustrates how a single payment model is not going to provide an effective answer in every situation, but rather innovative pricing and payment models need to be considered and developed to ensure financial sustainability of both public and private health care systems, adequate incentives for innovation, and fast access for high-cost innovative medicines.

1.2 Objectives and ambition

1.2.1 Objectives

The variety of innovative healthcare products and services with the potential to revolutionize the delivery of health care means that the policy toolbox will likely need **several pricing and payment models**, designed according to the most relevant issue to be addressed. Therefore, more than defining a single payment model, it is important to define a set of principles that payment models should follow, and to allow **flexibility** in their design and **implementation** according to the specific situation. For example, for neglected therapeutic areas, payment models based on **new ways of procuring innovation** can be used. Under asymmetric information between manufacturers and health care payers about the **true value of new products**, the use of health technology assessment provides a means for health systems to learn about such value. When uncertainty exists about the effectiveness of new products in the overall population, **managed entry agreements** (MEAs), with an outcome-based performance component embedded in the payment model may be a useful instrument. Whenever high margins over costs are likely to be present, strengthening the bargaining power of health systems and using payment models that **reduce exercise of market power** may be desirable. Although there are examples of novel pricing and payment models being used today, the lack of appropriate data infrastructure, legal **barriers** and an unwillingness to adapt current systems often prevent their use[27].

Therefore, the overall objectives of the Health Innovation Next Generation Pricing Models (HI – PRIX) project are:

1. to extensively map and formulate **new pricing and payment schemes** that can be used across technology classes, therapeutic areas, setting and healthcare systems/geographies together with a related set of principles that may guide **successful adjustment** and **flexible implementation** to the particular context of use;

2. to investigate the impact on **competitiveness, innovation, equity** and **affordability** of a pipeline of contracting modalities for health innovations to move from regulatory approval through value assessment to adoption;

3. to address the challenges and concerns of payer, manufacturer, healthcare professional, and patient perspectives regarding different models of pricing by **sustaining an effective dialogue across stakeholders'** groups about the trade-offs between affordability, innovation and patient access.

More specifically, the HI-PRIX project will:

⇒ propose a set of pricing and reimbursement contractual agreement-models that formally take into consideration **public investment in R&D** of innovative health technologies;

⇒ provide policy guidance as to how broadening the scope of economic evaluations and budget impact analyses to include **indirect medical and environmental costs** could play a role in pricing and reimbursement decisions;

⇒ develop a dynamic pricing model that accounts for **new evidence generated post-launch** or **newly-approved indications** for the same product;

⇒ propose and test payment schemes for innovative **technologies embedded in primary and integrated care settings**;

⇒ understand the implications of innovative payment schemes on **long-term competition** in health technology markets;

⇒ identify strategies, policy and market-based instruments to **foster innovation** in key areas of need and **reduce inequalities of access** to pharmaceutical innovation;

⇒ investigate the **efficiency-equity trade-offs** associated with various innovative pricing and payment models and offer guidance on potential **equity-issues mitigation** strategies.

The three overall objectives outlined above are completely aligned to the work programme topic "HORIZON-HLTH-2022-IND-13-03: *New pricing and payment models for cost-effective and affordable health innovations*", which seeks proposals tailored towards i) enhancing adoption of new payment models for health technologies and pharmaceuticals, ii) accelerating access to innovation, iii) allowing for affordability of innovative health technologies both on short and longer terms. The HI-PRIX project contributes to all these expected outcomes. Moreover, it aligns with the requested **scope** in terms of consortium composition, which includes **regulators and public entities** that are in charge of attributing value tags to health technologies, negotiating with health technology manufacturers and/or reimbursing medical costs across the EU, and **activities** proposed, which tackle all the nine different areas highlighted in the work programme (*Figure 1*).

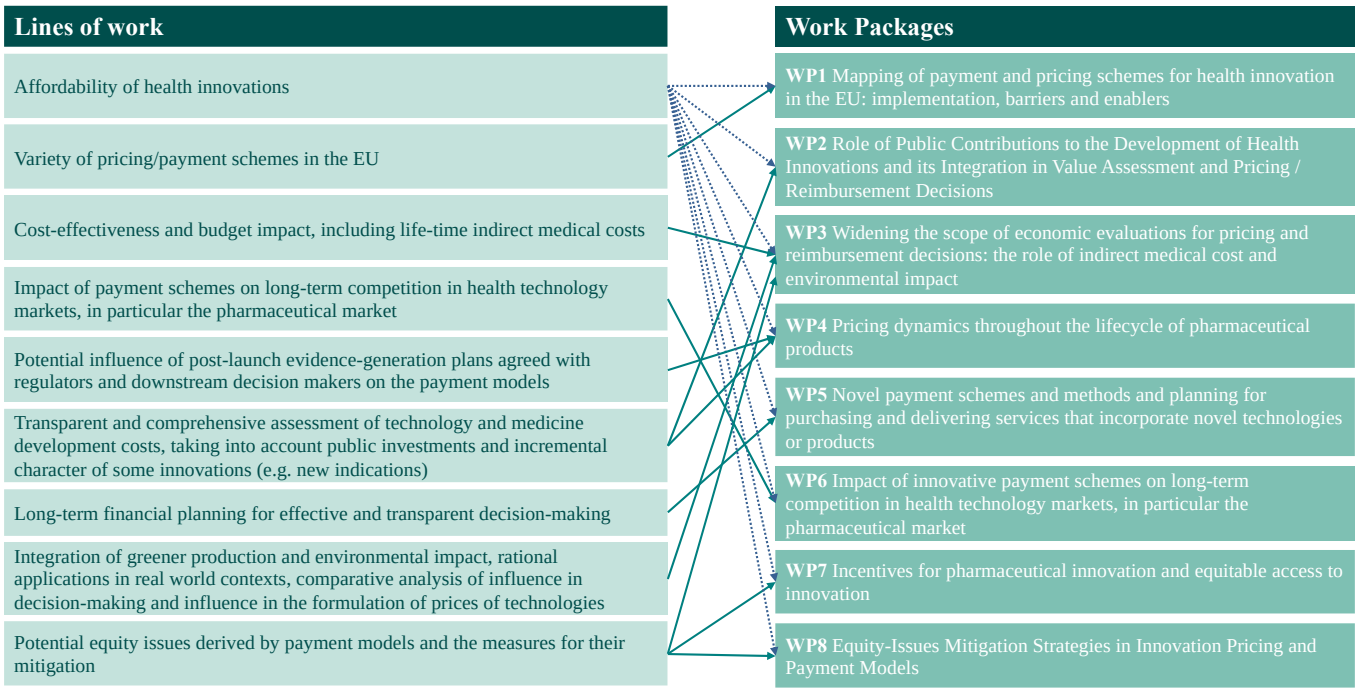


Figure 1 HI-PRIX project alignment with lines of activities in the work programme

1.2.2 Ambition

HI-PRIX is a highly ambitious project, the ultimate goal of which is to **accelerate access to high-quality affordable health innovation** by facilitating the adoption, by European health authorities and insurers, of new pricing and payment models, fit to address the challenges posed by high-priced health technologies. To this end, two important aspects of the proposal should be emphasised. First, an effort to advance scientific knowledge by **developing new schemes** intended to address some of the most pressing issues in the policy agenda: from ensuring sustainability-minded pricing and reimbursement determinations, to acknowledging the role of public investments in R&D in such decisions; from optimizing price dynamics for multi-indication products or when robust clinical evidence is missing, to planning for purchasing and delivering of novel technologies embedded into services. Secondly, a thorough evaluation of costs and benefits, **barriers and enablers of existing schemes**, in close collaboration with the stakeholders involved, underlining the project's aim to ensure a successful implementation of effective pricing and payment models in real-world settings. Thus, striving for **methodological excellence and direct applicability of the research output** is a challenge that HI-

PRIX will fully embrace by engaging in a three-year intensive research endeavour that will develop novel tools for healthcare policy making.

Given the complexity of the health innovation environment, characterised by a variety of key players from development to supply, demand and regulatory processes, a need arises for research and innovation integrating various stakeholders to facilitate market access of health technologies that benefit patients and the population as a whole. In this respect, HI-PRIX strives to initiate a **platform for fruitful and long-lasting dialogue across stakeholders' groups** across Europe, namely payers, manufacturers, healthcare professionals, and patient representatives, around the trade-off between affordability and patient access.

At the same time, HI PRIX has the ambition to contribute to maintain an innovative, **sustainable and globally competitive health industry** within the EU, as stated in Destination 6 of the Horizon Europe Work Programme 2021-2022 for Health. To this end, we aim to build understanding of the impact of a variety of pricing and payment schemes on **long-term competition in the pharmaceutical market** and to assess the **comparative effectiveness of several incentive mechanisms** in ensuring innovation in key areas of need and timely global access to those innovations in countries with different levels of income and affordability. By doing so, we aim to develop science-based policy advice that addresses health industry needs to better anticipate market conditions for innovative health technologies and **mitigate potential equity issues** linked to pricing and payment models.

1.2.3 HI-PRIX's R&I maturity

The research outputs generated by the HI-PRIX project will include, among others, new pricing and payment schemes, contractual agreement models and innovative assessment and reimbursement tools that can help ensure equitable access to effective, efficient, affordable, and sustainable health technologies. To this end, the positioning in the spectrum from 'idea to application' is between technology readiness levels (TRL) 5 (**technology validated in a relevant environment**) and 6 (**technology demonstrated in a relevant environment**) depending on the WP and thanks to the involvement of stakeholders in the project consortium and in the activities proposed. Other pricing and payment models already in use that will be mapped and characterized are already **well established** (TRL 9).

1.3 Methodology

1.3.1 Overall Methodology

HI-PRIX is a three-year research project structured in **8 scientific Work Packages (WPs)**, which culminate in a cross-cutting WP1 aimed at mapping pricing and payment models, together with the features that might sustain their effective implementation in real life, and **2 managerial WPs** dedicated to dissemination and communication practices, management and coordination of the entire project. The methodology adopted in the scientific WPs is a mix of **quantitative and qualitative methods**, from theoretical inquiries, model-based simulations, econometric analyses, to focus groups, individual interviews and consensus generation methods, as it is typical of economics, sociology, political science, and social sciences in general. The **case-studies** selected will draw on the array of contemporary challenging examples illustrated in the introduction: ATMPs, oncology treatments, antibiotics, vaccines, orphan drugs, digital health technologies and beyond. Here we briefly explain the overall methodology, concepts, models and assumptions that underpin our work, as well as challenges and potential solutions we have factored in. More details for each WP will be provided in the section on quality and efficiency of the implementation.

WP1: Mapping of payment and pricing schemes for health innovation in the EU: implementation, barriers and enablers

In the EU and beyond, Member States are struggling to balance sustainability of health innovation with sustainability of health care systems. Central to this challenge is the role of pricing and payment models, as they influence affordability, affect access to products, and provide incentives for directing efforts towards areas of the highest societal value. In this project, **pricing approaches** are those establishing what the manufacturer will seek, typically in light of the value of the product to patients and society overall. **Payment models** refer to conditions, negotiations, contracts, ways to set a balance in power between the payer and the manufacturer, whilst rewarding the manufacturer for the products or services delivered. It is likely that a one-size-fits-all solution cannot be found since no single model of pricing and payment provides a solution for the different objectives to be achieved; therefore, in **WP1** we will extensively **map pricing and payment models** through review of different sources, consultation with actual payers, manufacturers and public authorities, and gather a catalogue freely available online to policy-makers to allow countries to learn from others' experience. Whilst collating the different schemes, we will characterize them across technology classes, therapeutic areas, setting and healthcare systems/geographies. The development and adoption of new payment models raises **implementation challenges** that cannot be overlooked. These could derive from lack of appropriate data infrastructure,

legal barriers, unawareness or unwillingness to change the status quo. For these reasons, the same WP will also investigate in detail costs, benefits, barriers and enablers of implementation of innovative pricing and payment models by relying on one of the available frameworks developed under the implementation science framework. The process of implementing evidence-based practices is often complex and fraught with challenges, hence **implementation science** has been defined as the scientific study of methods to promote the systematic uptake of innovation into routine practice, to identify uptake barriers and facilitators across multiple levels of context, and to develop and apply implementation strategies that overcome these barriers and enhance facilitators to increase the uptake of evidence-based clinical innovations[28]. Several frameworks have been proposed in the literature to guide the different steps concerning how implementation should ideally be planned and executed. For example, the RE-AIM framework focuses on i) reach, ii) effectiveness, iii) adoption by target users, settings, systems and communities, iv) implementation consistency, costs and adaptions made during delivery, v) maintenance/sustainment of intervention over time, to improve the sustainable adoption and implementation of effective, generalizable, evidence-based innovations. Based on the RE-AIM framework, the WP will critically **synthesise conditions and contextual factors for the success of each pricing and payment model**, together with a set of policy recommendations that will guide a **flexible application of different models in real life**.

WP2: Role of Public Contributions to the Development of Health Innovations and its Integration in Value Assessment and Pricing /Reimbursement Decisions

The development of health innovations in the past has been broadly split between basic (preclinical) research, which was mainly funded from public sources, i.e., paid by taxpayers, and applied (clinical) research, which was mainly carried out by the private sector. The logic for this split has traditionally been that basic science is, or should be, a purely **public good**, in the sense that general welfare is best served if the knowledge generated by this science is freely available to all, without payment or other restriction. On the other hand, it has been argued that because **clinical research** has the objective of developing and manufacturing a specific health innovation, this is best placed in the private sector, which assumes the financial risks associated with such R&D and hence, if successful, is allowed to appropriate the corresponding financial rewards in the form of monopoly prices and profits. **Intellectual Property Rights (IPRs)** and high/profitable prices were justified in order to ensure a continuous flow of private investment in R&D in the development of health innovation. Since the second half of the twentieth century, private industry has gradually fought for extension, reinforcement and globalization of their IPRs, while public health systems have attempted to control the corresponding escalating healthcare expenditure by various rationing/rationalizing policy interventions. But the fact is that none of them seems to work well enough. There are different approaches taken by National authorities on the appropriate role of the public sector in the development of health innovations[29]. What seems to be common across them is a **lack of transparency**, partly because of arguments regarding commercial confidentiality[30,31]. Neither the EU nor the Member States seem to have the information/capacity required to gain a global picture of the whole set of direct and indirect public financing obtained by companies either globally (at company level) and much less at the individual health innovation level. A number of alternative pricing or contractual arrangements might be considered. Public financing of R&D – and of health innovation consumption – could justify the **pairing of funds to certain purposes and priorities**, limiting the asymmetry of IPRs, e.g., by sharing those rights between private and public parties in a fair way, or employing IPR modalities where the private innovator retains a right to a royalty, but not a right to withhold others from using the new knowledge. Any assessment of alternative arrangements for R&D needs to consider the incentives generated for innovators as well as the impact on public sector budgets. Therefore, in **WP2** we will aim to (1) design a conceptual framework for analysing the **role of the public sector in the development of new valuable health innovations** and propose forms of interventions to enhance this role, (2) develop a **transparent methodology to identify costs** accrued along the value chain of the development of health innovation, and (3) **propose a set of pricing/reimbursement contractual agreement models** taking into consideration public investment in the development of new health innovations. Through theoretical as well as qualitative investigation, a conceptual model of the financial flows along the value chain of the development process for health innovation will be designed. After "unbundling" the steps and stages along this value chain, data on public and private R&D contributions, with special attention given to the interface when ownership changes (**patents, licencing, royalties**), will be sought, following a methodology proposed by the WP2 leader[32,33,34]. Case-study technologies to analyse development costs in detail will include **orphan drugs, antibiotics**, Advanced Therapy Medicinal Products (**ATMPs**) or other health innovations, the subject of a recent European Commission evaluation[35]. Thereafter, different contractual agreement models that consider public investments will be piloted, with stakeholder consultation used to maximize the pragmatism and applicability of the recommendations issued.

WP3 Widening the scope of economic evaluations for pricing and reimbursement decisions: the role of indirect medical and environmental costs

The urgency to take action regarding environmental protection and the sustainable restructuring of the way our modern industries function has reached the highest ranks of policymaking. In 2019, the European Commission presented its Green Deal, a set of policy initiatives aiming at carbon neutrality by 2050. If the global healthcare sector were a country, it would be the 5th largest contributor in the world[36]. While different players within the sector have made considerable effort to reach carbon neutrality, a systematic approach has yet to be developed that can combine the demands for meeting two important ends of policymaking: improving human health and saving the environment. Two recent national efforts are relevant to this end: the UK NHS effort to estimate its own carbon footprint by area of activity and the Swedish HTA Agency study to develop an environmental premium in the pharmaceutical benefit system[37,38]. In **WP3** we aim to understand **how the dimension of environmental impact can be integrated into existing HTA frameworks** and what implications would arise from this integration for policy-makers, the healthcare industry, and patients. Emissions arising from the production, distribution, use, and disposal of products can be considered externalities. The traditional response to externalities, drawing back on the Coase Theorem, has been internalizing the damage done to a group excluded from the benefits, usually by including it in the price. However, the case of healthcare is complex and comes with ethical and social dimensions many industries lack. Including the prices for **carbon emissions arising from medical products** could severely harm patient access by increasing the financial burden of healthcare. The objectives of environmental protection and human health must therefore be carefully balanced. Marsh et al. have outlined initial principles for introducing this consideration in Cost-Utility and Cost-Benefit-Analysis, later conducting an empirical study to estimate the environmental impact of the treatment of Diabetes Mellitus Type 2[39]. The authors compared clinical pathways based on their carbon footprint, in line with a **Life Cycle Assessment approach** that assesses emissions for every step, from the extraction of raw materials to production, distribution, use, and disposal of products[40,41,42]. Through document review, interviews with stakeholders and empirical case-study development, we will examine the equity implications of including environmental impact in economic evaluations informing pricing and reimbursement decisions and will provide policy guidance as to how **broadening the scope of economic evaluation and budget impact analysis** to include indirect costs could play a role in pricing and reimbursement decisions. Both objectives will also apply to consideration of **indirect medical costs**. In light of the ongoing rapid innovation observed in areas such as **gene-editing technology, stem cell treatments, exosomes, and chimeric antigen receptor T-cell** therapies, which have curative potential in a number of indications that were previously linked to poor prognosis, a question arises on whether and **how to account for costs and benefits of future treatments**[43], age-related extra-morbidity patients and other healthcare costs **unrelated to the initial diagnosis** in pricing and reimbursement decisions. Using two real-life examples of life-prolonging treatments, for **Spinal Muscular Atrophy (SMA) and oncology**, an empirical tool designed to include indirect medical costs in economic evaluation and budget impact analysis will be validated and related insights adopted to inform policy guidance on the subject.

WP4: Pricing dynamics throughout the lifecycle of pharmaceutical products

The core principle of pharmaceutical pricing is that products that offer **large benefits** in terms of safety and efficacy should receive **greater reward** than those that offer only modest value. In order to demonstrate value, evidence is needed, however evidence is often weak during the early years of a product's life cycle though it may strengthen over time[44]. Logically, therefore, **price initially should be set low and then increase as confirmatory evidence becomes available**, assuming it will. In practice, manufacturers establish the price for their product when it is originally launched, according to the competitiveness of the market, expected revenues and other strategic considerations. When uncertainty is high at launch, mandatory requirements for **post-marketing evidence generation** may be enforced by the regulatory authorities or HTA bodies[45]. Outcome-based agreements have been applied quite extensively in Europe for both new drugs and medical devices[46,47,48,49,50]. However, if post-launch evidence is negative, **withdrawing coverage comes with practical challenges** and does not rectify the generous revenues earned from the high prices paid before the publication of the new evidence. Based on empirical data in Italy, Spain, Germany and the US, **WP4** aims to simulate different **dynamic pricing models** that account for the accrual of post-marketing clinical evidence for products approved through expedited regulatory pathways, and to test the acceptability, foreseen challenges and advantages with payers and manufacturers. As pharmaceutical products mature on the market, **new indications** may be proposed for the same compound[51,52,53]. **Price discrimination** reflecting finer stratification of patients, their problems and their needs, together with demand-side and supply-side implications has yet to be incorporated by payers' approaches to price determination for multi-indication products[54]. Through review of the state of the art in other industries and theoretical work, this WP will lead to proposals of new pricing principles rooted in economic theory, distinguishing (1) indirect versus direct price discrimination across patients; (2) use of list prices versus confidential prices; (3) hospital versus ambulatory setting; (4) pricing rules and their updates versus direct negotiation; (5) optimal pricing under strategic entry and exit of products aimed at different indications; (6) optimal pricing under sequential discovery efforts versus multiple indications found simultaneously; (7) licensing in the commercialization of an indication as commitment to multi-indication pricing. The models developed will be tested with stakeholders separately, following Chatham house rules for interaction.

WP5: Novel payment schemes and methods and planning for purchasing and delivering services that incorporate novel technologies or products

One popular argument in the debate on funding of healthcare services and access to new pharmaceutical products is the need to dismiss the outdated but still very prevalent **silo budgeting**. Overcoming this mentality may improve efficiency, by freeing up resources to be used elsewhere in the health system or allow for substitution of spending across areas, both at the same or different temporal moments. New **bundled payment models**, with or without a value-based component accounting for positive and negative patient outcomes defined in a contract, mark a change to simply paying for a product[55]. More in general, **a shift from acquisition of medicines or medical devices to acquisition of health care services** is a promising innovative avenue to explore, leveraging on the combination of diagnostic/therapeutic/preventive products and integration of different levels of care under the same overall goals valid for the health system. As part of the HI-PRIX project, **WP5** will identify and propose payment schemes for innovative technologies embedded in a process of care by a SWOT (strengths, weaknesses, opportunities, and threats) analysis informed by literature reviews and consensus definition across stakeholder groups. The WP will then select two case-studies, in a **primary-care setting and in an integrated-care setting**, respectively, and through use of **real-world data** test the effectiveness of different payment schemes intended to sustain incorporation of innovation in the healthcare delivery process, along with recommendations for their transferability across a range of technologies and contexts.

WP6: Impact of innovative payment schemes on long-term competition in health technology markets, in particular the pharmaceutical market

A recent survey conducted in 32 European countries provides an overview of pharmaceutical policy measures that have been implemented in the latest decade. Most countries implemented a mix of different measures in the areas of both pricing and reimbursement and strove for increased enforcement and efficiency. A major area of focus for policy-makers was medicine prices (price cuts and freezes, discounts, rebates, claw-backs, paybacks, etc.)[56]. While European countries have been implementing a set of policy options, there has been a **lack of thorough impact assessments** of several pricing and reimbursement policies[57]. These policies are frequently assessed against their financial consequences and their ability to contain costs but less so in terms of affordable and equitable access to medicines, competitiveness and innovativeness in the pharmaceutical market. Ensuring that the EU health industry is innovative, sustainable and globally competitive thanks to improved uptake of breakthrough technologies and innovations, which in turn permit EU Member States to be less dependent on imports in terms of access to and supply of critical health technologies, is an expected impact of this research programme. Therefore, in **WP6**, we will propose a scientific model to **simulate the impact of innovative payment schemes** (e.g., pay-for-performance, multi-annual instalments) **on the pharmaceutical market** and apply it empirically to study the consequences of various payment schemes for both manufacturers and society in a relevant case-study, possibly related to **ATMPs**. The WP will allow for examining implications of the different innovative payment schemes on long-term competition in health technology markets.

WP7: Incentives for pharmaceutical innovation and equitable access to innovation

A **fairness** concern of healthcare systems is to direct R&D efforts to areas of higher social value, yielding clear superior benefit for groups of patients that show significant unmet needs. It has been estimated that only a minority of medicines brought to the market are considered truly innovative with important therapeutic gain defined by clinical benefit metrics[58,59]. New payment models that reward any new medicine irrespective of the therapeutic value they bring can, in fact, be detrimental to the social value of R&D efforts compared with alternative discoveries[22]. For example, cost-plus models may not provide the right incentives to produce innovation in the areas where it is most needed, and may even lead companies to inflate costs as a way to secure higher payments. In order to **create the right incentives for and rewarding innovation**, the next generation of pricing and payment models should compensate for the costs of developing a new product, whilst encouraging discovery of products that are more highly valued than others because they address a more important therapeutic gap[60]. In **WP7**, we will identify, map and characterize the **push, pull and hybrid monetary and non-monetary mechanisms to incentivize R&D** and, through quantitative econometric techniques, evaluate their comparative effectiveness on fostering innovation in the selected areas from basic discovery all the way to market launch, **promoting global access to these innovations**, and mitigating global access inequalities. Key areas of interest will be prevention (i.e., vaccines development), **pandemic infectious diseases** and **antibiotics/antimicrobials, rare diseases**.

WP8: Equity-issues mitigation strategies in innovation pricing and payment models

Health systems pursue several objectives, among which equity is of utmost importance. Equitable health care can only occur in an integrated system of value-based care that supports transformations in prevention, treatment, data and analytics, as well as payment models, to improve population outcomes[61]. Payment transformation that occurs through

alternative models that incentivize prevention and optimal health lends itself to improved health system outcomes, especially if the health system works to focus not on disease interventions but on the upstream, localized, and systemic causes of disease[62]. However, there is little evidence regarding **population equity in alternative pricing and payment models**[63]. **WP8** will study the funding of innovation through supplementary allowances at the hospital level. Through theoretical and econometric analysis, the impact of hospital add-on lists adopted in some countries, e.g., France, Germany, to ensure patients equal access to high-priced innovations will be quantified. These add-on lists can be treated as **equity-mitigation strategies**[64], whose conditions for adoption and use must be developed. At the system level, this WP will also investigate the equity-efficiency trade-offs of different policies for early adoption of drugs and medical devices across Europe, and in combination with WP7, the analysis here will identify the equity dimension of the spillover effects of earmarked public funding from rare diseases to more common diseases.

1.3.2 Links with national and international research and innovation activities

The idea behind the HI-PRIX proposal has been preceded by a number of national and international research initiatives that the partners, individually or collaboratively, have been involved in or coordinated.
Bocconi University, has recently completed the COMED project (Pushing the boundaries of Cost and Outcome analysis of Medical Technologies), a 3-year H2020 project coordinated by the Research Center on Health and Social Care Management (CERGAS) at UB. The project has successfully reached its main objectives of improving economic **evaluation methods for medical technologies**, strengthening their **use in policy-making**, and assessing health system performance through the analysis and variation of costs and outcomes of medical devices across different European geographical areas. This latest research initiative was closely linked to a previous FP7 MedTecHTA project (Methods for Health Technology Assessment of medical devices: an European perspective), which CERGAS coordinated in 2015. Both projects signal the experience of UB in **managing large international research activities**. Over the last three years, CERGAS has been WP leader in IMPACT- HTA (Improved Methods and Actionable Tools for Enhancing Health Technology Assessment), another H2020 EU project led by LSE, with a focus on **improving the decision-making processes for rare disease treatments**. More recently, CERGAS has been awarded funding for the CINDERELLA project, under the HORIZON-HLTH-2021-DISEASE-04-04 Clinical validation of artificial intelligence (AI) solutions for treatment and care call, to design and conduct a multidimensional evaluation, including **environmental impact**, of an AI-based tool designed to improve the aesthetical outcome of locoregional treatments for breast cancer.

Among the many national and international research and innovation activities the HI-PRIX consortium has been involved in, the most remarkable for the development and success of this proposal are Monitoring financial protection in health systems: developing new evidence in Europe, with the WHO Regional Office for Europe, where one of the partners analysed **financial affordability of medical products and healthcare services** in Lithuania under comparative analysis of European countries. On a similar note, FP7 Project ASSPRO CEE 2007, *Assessment of patient payment policies and projection of their efficiency, equity and quality effects: The case of Central and Eastern Europe*, explored with mixed methods the Lithuanian case under comparative research of patients' out-of-pocket expenses. Related to the affordability challenge, *When is it too expensive?*[65] was a project funded by the Netherlands Organisation for Health and Research Development (ZonMW), to investigate the appropriate thresholds by which to judge incremental cost-effectiveness ratios, like the value of a quality adjusted life years (QALY) and the marginal cost-effectiveness of current spending. Moreover, four partners in the HI-PRIX consortium (Pedro Barros, Werner Brouwer, Liubove Murauskiene, Claudia Wild) have been members of the **Expert Panel on effective ways of investing in Health (EXPH),** convened by the European Commission to provide sound and independent advice on matters related to health care modernisation, responsiveness, and sustainability. The advice was included in a report on innovative payment models for high-cost innovative medicines, which was key for the development of the HI-PRIX proposal[22].

The role of EU FP7-HEALTH funding, in terms of total EC funding amounts, in relation to late-stage clinical development has been explored in *EU FP7 research funding: a success and a failure*[34]. Other initiatives include FP7 ADVANCE HTA - Advancing and strengthening the methodological tools and practices relating to the application and implementation of Health Technology Assessment, with five streams of work focusing on value assessment and **value for money, rare diseases, quality of life, medical devices and capacity building**, and RARE2030, where ICL leads the programme on **pharmaceutical innovation for rare diseases**. Another large scale program, the Erasmus Initiative Smarter Choices for Better Health, funded by the Erasmus University Rotterdam, is tackling challenges many countries still face when it comes to funding and delivering high quality health care.

As regards value-based procurement, past experience was accrued through FP7 Adopting **Hospital Based Health Technology Assessment in EU** (AdHopHTA) and European **wide innovation procurement in Health Care** (EURIPHI), aimed at developing different tools and contractual arrangements for future in-country and cross-country

innovation procurement, including proposals of procurement for integrated care.
The consortium also has experience with a **joint research and training programme** for researchers at the doctoral level, such as H2020 European Training Network, aimed at improving the quality and performance of European health care systems, and Educating the next generation of Advanced Therapy (ATMP) professionals and advancing ATMP development, supported by Erasmus Plus with the objective to develop a 3-stage blended learning programme to support early-career biomedical scientists in developing currently missing scientific knowledge, transversal skills and competencies to meet the key challenge areas in the ATMP development cycle.

1.3.3 Interdisciplinarity

HI-PRIX is an example of interdisciplinary and transdisciplinary work across health economics, healthcare management, public health and social and political science. In order to develop new and effective value-based pricing and reimbursement models that can help ensure equitable access to affordable health technologies, we sought a **multiple disciplinary approach** which is known to be superior in resolving real-world complex problems, for characterizing different perspectives, and developing consensus and guidelines[66]. All three aspirations and tasks are common in the HI-PRIX work plan.

Bocconi University (UB), project coordinator, is an internationally recognized institution with a wide range of study tracks in economic, managerial and legal disciplines at all levels of higher education. In particular, the Centre for Research in Healthcare and Social Management **(CERGAS)**, founded in 1978, has developed strong expertise in the area of economic evaluation, pharmaceutical policy and HTA. Proven theoretical and applied expertise in health economics and management is also present at **Universitaet Hamburg** (**UHAM**, with the Hamburg Center for Health Economics), **Imperial College (ICL)**, **Universite Libre de Bruxelles (ULB)**, **Office of Health Economics (OHE)**, and **Universidade Nova de Lisboa (UNL)**. Additional research skills and an academic reputation in health policy, social and political science is brought by **Erasmus Universiteit Rotterdam (EUR)** and **London School of Economics and Political Science (LSE)**. Both **Vilniaus Universitetas (VU)** and **Escuela Andaluza de Salud Publica SA (EASP)** are recognized for playing an influential role in public health research. The HI-PRIX consortium benefits from the participation of "**Hospinnomics** - hospital, innovation, economics", a partnership between the **Assistance Publique-Hôpitaux de Paris (AP-HP)** and the Paris School of Economics (PSE) intended for developing evaluation and experimental methods to support decision-making and maximize available resources in the service of patients. **Fundació Clínic per a la Recerca Biomèdica (FCRB)**, and its affiliated entity, **Hospital Clinic de Barcelona (HCB)** complement the consortium with the expertise and competence of direct healthcare providers. By definition, the Health Technology Assessment paradigm is both multidisciplinary and interdisciplinary. Several partner organizations, in particular the **Austrian Institute for Health Technology Assessment (AIHTA)** and **Fundacion Publica Andaluza Progreso y Salud (Andalusian HTA unit)**, will bring this approach to the HI-PRIX project, and will benefit from it in return, leveraging on existing collaborations or collaborations established for the first time with stakeholders' organizations involved in the project. Moreover, the project will provide an extraordinary opportunity, through UB researchers in WP3, to extend the standard health technology assessment framework to cover aspects related to environmental sustainability in health care. Finally, three associated partners have been involved in the HI-PRIX consortium. **Agenzia Italiana del Farmaco (AIFA)** and **Infarmed (INF)** – Autoridade Nacional do Medicamento e Produtos da Salude IP are the national authorities responsible for pricing and reimbursement policies in Italy and Portugal, respectively. **Servei Catala de la Salut (CatSalut)** which acts as both payer and provider of healthcare services in Catalunya, also brings in mature price negotiation experience on many different health technologies.
The structure of the project methodology as well as the partners' allocation to specific WPs was based on the objective to reach a balanced distribution of work based on each partner's capabilities and experience, resulting in what we believe to be a strong consortium. Overall, the research groups will operate synergistically to achieve the final objectives of the work program. Seven of the beneficiaries have a track record of previous successful collaborative work in European FP7 (MedTecHTA, Mapping_NCD) or Horizon 2020 (COMED, IMPACT-HTA) projects. The capacities of each partner, and the mix between academic institutions, healthcare providers, regulatory and public authorities, highlight that complementarities and synergies are amply present on this partnership.

1.3.4 Sex and Gender dimension

HI-PRIX partners are committed to making the necessary effort to foster gender equality in research and are well-aware of the "Gendered Innovation 2: How Inclusive Analysis Contributes to Research and Innovation" guidance.
Gender-neutral pricing and payment schemes for health innovation is an imperative we strive to achieve within the EU. In private insurance markets, sex risk differences may be used to establish risk-based pricing for certain products or services[67]. Whilst gender-based price discrimination is well-documented in the consumer product market[68], there is scarce evidence in the healthcare market, particularly in the pharmaceutical market. Yet, the gender dimension may play

a role in pricing strategies when **adherence to a certain drug-based or device-based treatment**, as in the case of digital therapeutics, is a key component of the pricing formula. Compared to men, women are at higher risk for cardiovascular medication non-adherence and have different reasons for being non-adherent[69]. For HIV-positive people, female gender often predicts lower adherence to antiretroviral therapy[70].
We will explore the relevance of a gender-equity dimension, as well as related intersectional factors, in pricing and payment model schemes as part of the WP8 dedicated to equity-issue mitigation strategies, and as part of WP5, where we will explore, propose and test payment schemes for innovative technologies embedded in primary or integrated care.
UB (project coordinator) is committed to building a diverse and truly inclusive research environment for the HI-PRIX project, making diversity and inclusion key elements of the overall management and coordination strategies (WP10) for the project, as they are for Bocconi University's overall strategic priorities. Partners will ensure that project tasks and responsibilities will be divided between both genders in a balanced way and with no discrimination. Daily project activities will be organized in such way that compatibility between professional, private and family activities is guaranteed. A gender–balanced perspective will be taken in carrying out dissemination and communication activities (WP9), to enhance the suitability to the needs of all people and societal impact of the output of our research and innovation activities.

1.3.5 Open Science practices

HI-PRIX aims at sharing any scientific knowledge generated within the project through the most appropriate channels for dissemination, both in terms of reach of the target audience, and specialty field. All the partners encourage open science practices and embrace the principles of cooperative work and systematic sharing of knowledge and tools as early and widely as possible in the process. For instance, an **online catalogue of pricing and payment schemes for health innovation** (named "Pay for innovation Observatory") will go live at the end of M12 with this purpose in mind and will be updated regularly thereafter. In line with the HI-PRIX ambition to translate research into action, all the tasks and activities will be conducted to ensure the generalizability of the findings, as well as the reproducibility of the methodologies and research outputs.
An appropriate budget to cover Open Access (OA) fees has been allocated, corresponding to an estimate of 2-3 publications in leading peer-reviewed journals per WP. In addition, we plan to leverage on the existing affiliations with leading journals already in place for some Consortium partners, as a basis for the HI-PRIX work to be published and disseminated in OA. The partners will make sure that any publication will be readily accessible either in online and/or print formats once submitted for publication. These aspects will be detailed in a Dissemination and Communication (DC) Plan developed as part of WP9.
A Data Management Plan (DMP) will be developed within the first 6 months of the project in line with the FAIR principles (findable, accessible, interoperable and reusable data/research outputs), and updated regularly throughout the entire project duration. The DMP will be developed in keeping with the HI-PRIX open science strategy, outlining the project's procedures for data management. Data not subject to any IPR, GDPR or security rules restrictions will be uploaded in a publicly available format such as the open-access repository Zenodo (https://zenodo.org) – an Open Data Commons licensing will be adopted using proper unique DOI indexing. All data subject to any restrictions will be logged in OpenAire and securely stored in a private cloud-based account. Access to restricted data might be provided upon signing an appropriate Data Sharing Agreement between the Consortium and third parties. Finally, project outputs and technical reports not subject to any IPR or patenting issues will become publicly available repositories (e.g., GitHub https://github.com).

2. Impact

2.1 Project pathway towards impact

2.1.1 HI-PRIX unique contribution towards the HORIZON-HLTH-2022-IND-13-03

The objectives of the HI-PRIX project are completely aligned with the outcomes described in the HORIZON-HLTH-2022-IND-13-03: *New pricing and payment models for cost-effective and affordable health innovations*.
The table below illustrates the unique contribution of HI-PRIX to each of the three expected outcomes.

Expected outcomes in HORIZON-HLTH-2022-IND-13-03	HI-PRIX contribution
I) Health authorities and insurers adopt new	HI-PRIX aims to extensively **map and develop new pricing and payment schemes** across technology classes, therapeutic areas, settings and healthcare systems/geographies

payment models for health technologies, including pharmaceuticals.	(WP1). More specifically, the project will i) propose a set of pricing/reimbursement contractual agreement-models taking into consideration **public investment in the development of new health innovations** (WP2), ii) provide policy guidance as to how to include **indirect medical and environmental costs** in pricing and reimbursement decisions in different decision contexts (WP3), iii) develop a **dynamic pricing model** whereby prices change in response to new evidence generated post-launch, and recommendations on **pricing principles for multi-indication products** (WP4), iv) explore, test and propose payment schemes for innovative **technologies embedded in a primary/integrated care setting** (WP5).
II) Health industries better anticipate the marketing conditions for innovative health technologies. Patients and health care providers have faster access to innovative health technologies.	HI-PRIX aims to investigate the impact on competitiveness and innovation, of a pipeline of contracting modalities for health innovations to move from regulatory approval through value assessment to adoption. More specifically, the project will i) develop a transparent methodology to identify **costs and benefits for different stakeholders accrued along the value chain** of the development of health innovations (WP2), ii) develop a European Tool for **estimating indirect medical costs**, facilitating their inclusion in economic evaluations (WP3), iii) investigate the **transferability/generalizability of payment schemes** for innovations in a service provision setting and for different types of health technologies (WP5), iv) propose a scientific model to **simulate the impact of innovative payment schemes on the pharmaceutical market** and derive implications in terms of long-term competition for both manufacturers and society (WP6), v) assess the **comparative effectiveness of incentive mechanisms** for pharmaceutical innovation and identify policies and market-based instruments to foster innovation in key areas of need (WP7).
III) Health authorities, insurers and health care providers have affordable innovative health technologies both on short and longer terms.	HI-PRIX aims to address the **challenges and concerns from payer, manufacturer, healthcare professional, and patient perspectives** regarding different models of pricing by sustaining an effective dialogue across stakeholders' groups on the trade-offs between affordability, innovation and patient access. More specifically, the project will i) produce policy recommendations about **successful and flexible implementation of the different schemes** to promote access to high-quality affordable innovative health technologies (WP1); ii) examine the **equity implications** of excluding or including indirect medical costs and environmental impact in economic evaluations informing pricing and reimbursement decisions (WP3), iii) examine the **feasibility of new pricing principles**, based on interaction with regulatory officials and provider representatives (WP4), iv) identify the conditions under which **equity-issues mitigation strategies** are needed and effective and provide policy guidance on how to use them.

The HI-PRIX objectives illustrated above, will in turn link to the long-term impacts specified under Destination 6 of the Horizon Europe Work Programme dedicated to maintaining an innovative, sustainable and globally competitive health industry. This link is specifically based on:

• *Scientific outcomes*: as HI-PRIX aims to develop **scientifically based methodologies and interdisciplinary approaches to assess, determine value and pay for new health technologies** (new dynamic pricing models for drugs with uncertain evidence at launch or approved for multiple-indication), and **create new tools and instruments** (a pay-for-innovation observatory, a handbook to guide transparent assessment of development costs, sources of information and range of estimates; a European Tool for estimating indirect medical costs, a scientific model to simulate the impact of innovative payment schemes) that will be made available to the health industry, regulators and public authorities, and the relevant scientific community;

• *Economic outcomes*: as HI-PRIX has a strong component looking at the **successful implementation and maintenance** of innovative pricing and payment schemes, based on the assessment of their costs, benefits, barriers and enablers. In addition, HI-PRIX will **evaluate the impact of various payment schemes** on the long-term competitiveness of the pharmaceutical market and the effectiveness of incentives to industry to foster innovation that offers significant improvements in health outcomes in disease areas where this is most needed.

• *Societal outcomes:* as HI-PRIX aims to ultimately improve policy- and decision-making processes in Europe as regards pricing and payment models for health innovation, by **promoting the scale-up and uptake of solutions at national,**

regional or local levels, and **sustaining an effective dialogue across stakeholder groups** regarding the trade-offs between affordability, innovation and patient access. Given the urgency to institute effective policies to prevent or reduce the harmful effects of human activities on ecosystems, WP3 in HI-PRIX will provide guidance on equity implications and the role of including **environmental impact in pricing and reimbursement decisions** across Europe.

The outcomes and impacts achieved through HI-PRIX, will benefit different target groups, starting from the **health industry**. Some WPs have a specific focus on pharmaceutical products (WP4, WP6, WP7) and the case-study technologies selected from others will be orphan or non-orphan drugs, vaccines or ATMPs. Other WPs will consider health innovation in general, medical devices or technologies embedded in healthcare services (WP5, WP8). As part of the proposal development stage, we have interacted with a number of different stakeholder organizations to introduce the ideas behind HI-PRIX. We have successfully engaged the **European Federation of Pharmaceutical Industries Associations (EFPIA)**, the **Italian Association of Pharmaceutical Companies Farmindustria**, and **Biocat** (a public-private foundation at the behest of the Government of Catalonia and the Barcelona City Council established to maximize the economic and social impact of the life sciences and healthcare innovation ecosystem in Catalonia), as illustrated by the letters of support received by the HI-PRIX project.

ID	Institution	Country	Link to the letter
1	Agenas	Italy	Link
2	EFPIA	EU (Bruxelles)	Link
3	BioCat	Spain	Link
4	GesFonds Steiermark	Austria	Link
5	Austrian Federation of Social Insurances	Austria	Link
6	Austrian Ministry of Health	Austria	Link
7	National Health Insurance Fund under the Ministry of Health	Lithuania	Link
8	Cancer Research UK	UK	Link
9	Zorginstituut Nederland	The Netherlands	Link
10	AOK Rheinland	Germany	Link
11	Farmindustria	Italy	Link
12	International Foundation for Integrated Care	UK	Link
13	Caisse nationale de l'assurance maladie (CNAM)	France	Link

A second group that will benefit includes **regulators and public entities** that are charged with attributing value tags to health technologies, negotiating with health technology manufacturers and/or reimbursing medical costs. We are glad to include in our HI-PRIX Consortium, **Infarmed**, the Portuguese National agency responsible for HTA, pricing and reimbursement; the Italian Medicines Agency (**AIFA**); and **CatSalut**, a commissioner and direct provider of health care services in Catalonia, which also participates in the Spanish Committee on pricing and reimbursement of medicines, part of the Spanish Ministry of Health, and in REVALMED, the Spanish expert network for appraisals supporting pricing and reimbursement of drugs. In addition to our three Associated Partners in the Consortium, we have interacted with the **Zorginstituut Nederland**; the **Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection**; and the **Italian Agency for Regional Health Care Services (AGENAS)**, who have expressed their support of the HI-PRIX initiative. Insurers are also included in this target group. We have illustrated the HI-PRIX proposal to the **Austrian Social Insurance Institutions** and **Federation of Social Insurances**, the **Steiermark health fund**, the German **AOK Rheinland/Hamburg,** the French **Caisse nationale de l'assurance maladie**, and the **National Health Insurance Fund in Lithuania**, and have received expressions of interest from all in the progress and results of the project.
Finally, results from HI-PRIX will serve as useful information for the broader **public** and particularly for **patients** to enable them to act as informed self-determined partners (patient empowerment) in health care systems. Variations across member states may always exist, but they can be reduced if methods to ensure appropriate access to cost-effective, affordable health technologies are shared and harmonized across the EU. HI-PRIX will provide a number of different platforms for **information and dialogue to discuss and prepare future payment models**, to which organizations such as **Cancer Research UK** and other **EU citizen representative associations** have already expressed interest in.

2.1.2 Expected requirements and potential barriers

Consortium partners have all the required expertise for HI-PRIX to reach completion. However, there are possible barriers to the expected success of the project. The most serious are listed here, as well as the mitigation plan the consortium wishes to follow.

Low interest and engagement in the stakeholder activities consultations –

The HI-PRIX methodology requires consultations with different target groups, and those platforms for information and dialogue are instrumental to discuss and prepare future payment models. Lack of intererst and poor engagement may compromise the success of the discussion, however, this will be mitigated by dissemination activities carried out throughout the project, reliance on the extensive networks that encompass the consortium members, and on the 13 expressions of interest already received from a variety of different organizations across Europe.

Lack of willingness to take up new pricing and payment models –

There might be different obstacles to the adoption and diffusion of new pricing and payment models. These could be political, organizational, logistical (e.g., infrastructure availability), educational (e.g., need for training), legal. A major component of the HI-PRIX project is dedicated to understanding barriers and enablers to the successful implementation of innovative schemes and to provide guidance as to what strategies may sustain their long-term use in real-life.

Extent to which the project results can be transferred across different jurisdictions and countries –

Moving forward in the development of new payment models will require multilateral country cooperation in varying stages of evolution. In this respect, the geographic coverage of the HI-PRIX consortium is an advantage in activating and promoting dialogue on new payment models. The HI-PRIX focus on equity-mitigation strategies will also prevent widening of the gap between Western and Eastern/Southern Europe.

Convergence with other policy objectives –

Decisions on pricing and reimbursement, typically taken by public authorities in Europe, need to be part of a broader policy making process. Lack of convergence and reconciliation with other policy objectives (safety, quality of manufacturing, data security, etc.) limits the applicability of the HI-PRIX results[71]. The feasibility and implementation evaluation will need to account for these factors, too. Furthermore, in the dissemination and communication plan to be developed, we will ensure cooperation between EU-funded projects and other research initiatives to enable cross-fertilisation and other synergies.

2.1.3 Scale and significance of expected outcomes and impacts

In 2020, **health spending** measured as the final consumption of personal and collective health care goods and services ranged between 5.4% and 12.5% of GDP in the European Union, with a different mix of financing arrangements, including government spending and compulsory health insurance, voluntary health insurance and private funds[72]. **Pharmaceutical spending** adjusted for possible rebates payable by manufacturers, wholesalers or pharmacies, accounted for 0.57% to 2.45% of GDP[73]. To guide and regulate the pharmaceutical sector, policy-makers may rely on different options including policies addressing pricing, coverage and reimbursement, which are the specific focus of the HI-PRIX project.

The first expected outcome of the HI-PRIX project is to have health authorities and insurers adopt new payment models for health technologies. **Value based pricing (VBP)** is an approach that aims to set prices for pharmaceutical products based on the value or worth that patients and health systems attribute to the pharmaceutical products[74,75]. Health Technology Assessment (HTA) supports value assessment through a multidisciplinary process evaluating the social, economic, organizational and ethical issues of a health intervention or health technology. Whilst the **HTA process is currently fragmented**, performed by about 50 European HTA agencies across the EU, the **Regulation on Health Technology Assessment** (HTA)[76] adopted by the European Parliament at the end of 2021, and applicable from January 2025, will strengthen cooperation on this subject and **endorse the adoption of value-based approaches for price setting across the EU**. There are several **surveys on the status of pharmaceutical pricing and reimbursement** policies in European countries[77,78,79,80], the most recent and comprehensive was published in 2016 and reported information on 37 European countries[56]. Overall, 557 measures that were implemented between January 2010 and December 2015 were tracked, including measures related to pharmaceutical pricing, reimbursement, distribution and rational use of medicines. Countries that reported the most measures were Portugal, Greece, Belgium, France, the Czech Republic, with more than 30 measures implemented in each. An average of **17 measures per country** (range 4-47) was observed, about 3 per year, but **not all of them may be counted as "innovative pricing and payment schemes**". The HI-PRIX project aims to map and design effective innovative models to address the variety of challenges (affordability, access, innovativeness, competitiveness), associated with high-priced health technologies

and to explore their implementation barriers. HI-PRIX's impact in terms of health authorities and insurers adopting new payment models for health technologies will likely manifest **after the three-year lifespan** of the project, but through our **payers and providers partners in the Consortium**, **organizations which have already endorsed the HI-PRIX proposal, and the networks that they belong to** (e.g., National Competent Authorities for Pricing and Reimbursement, EUnetHTA, La Valletta Technical Committee), we plan to increase awareness, knowledge and competency among **more than 60 different payers and health authorities across Europe**.

The second expected outcome of the HI-PRIX project concerns patients and health care providers faster access to innovative health technologies. In 2022, EFPIA published a report on the Patients **W.A.I.T. (Waiting to Access Innovative Therapies) indicator**, intended as a benchmark of the rate of availability for new medicines and waiting times (measured by the number of days elapsing from the date of EU marketing authorisation to the date of completion of post-marketing authorisation administrative processes) in European countries[81]. The survey showed a highly variable accessibility rate, usually greater in Northern and Western European countries, and mean waiting times that can vary by a factor >7, from as little as 4 months to 29 months, **for patients in Northern /Western Europe** vs patients **in Southern/ Eastern Europe**. Depending on the product (e.g., oncology vs non-oncology, orphan, combination), large variations exist even within countries. It is not an easy task to quantify the impact of HI-PRIX in terms of shortening the time to patient access across Europe. By initiating and sustaining a dialogue across stakeholder groups concerning the trade-offs between affordability, innovation and patient access, we **aim to reduce, in the long-term, the 766 days gap in the mean time for new medicines availability (133 days in Germany and 899 days in Romania)**.

The third HI-PRIX expected outcome, relates to health authorities, insurers and health care providers having affordable innovative health technologies both on short and longer terms. There are different methods to evaluate **affordability of healthcare**. One of them is to consider the amount and nature of direct payments and out-of-pocket spending, which is set around 22% of all health spending in Europe[82]. Public population coverage is quasi-universal in most EU countries. Hence, direct payments faced by people, especially with low income, for the most part, reflect the exclusion of some services from public coverage and co-payments for services whose costs are not entirely covered. Across the EU, **coverage by third party-payers is only around 58% of the costs of pharmaceuticals**, lower than the share covered by public schemes for hospital services and outpatient medical services. Quantifying the exact impact of HI-PRIX project on the affordability of health technologies across the EU in the mid-term is difficult, as an element of willingness to uptake the proposed payment schemes is involved. However, investigating the barriers to the implementation of existing approaches and innovating the portfolio of available tools, as the value-based pricing, "subscription" agreements, performance-based agreements and other experiences highlight[57], can **reduce the gap between the 18% in Cyprus to 84% in Germany of publicly covered share of pharmaceutical spending** in the EU, and reduce the single-most important driver of catastrophic out-of-pocket spending at population level in all EU countries.

2.2 Measures to maximise impact - Dissemination, exploitation and communication

HI-PRIX has dedicated **WP9** to 1) support the widest dissemination, communication and exploitation of HI-PRIX results; 2) actively engage with stakeholders, external experts, payers and regulators, enhancing interactions between them and the wide-ranging HI-PRIX consortium network; 3) facilitate collaboration and information exchange between different organisations and players in charge of attributing value tags to health technologies, negotiating with health technology manufacturers and/or reimbursing medical costs. A **Dissemination and Communication Plan (D9.1)** will be developed at the beginning of the project and updated throughout the life of the project. The dissemination efforts will be coordinated by UB, however, the overall strategy as well as the detailed list of activities have been conceived and will be implemented in close cooperation with all beneficiaries. The plan will identify key elements of the dissemination and communication strategy, including the audience targeted (WHO), the key messages (WHAT), tools and channels (HOW) and the timing of the activities (WHEN), geographical level (local, European, global) (WHERE), providing clear guidance for project and partner dissemination activities to maximise impact. A broad **mixture of both traditional/established (i.e., leaflets and workshops) and state-of-the-art communication channels** will be used with the aim of reaching the target audience of payers, providers, healthcare industry, EU citizens and the media to the widest extent possible. The project will moreover address and exploit the channels of all the **associations, networks and platforms in which HI-PRIX partners participate**. Key Performance Indicators (KPIs) to allow monitoring of the dissemination strategy and implement corrective actions, if necessary, will be developed.

The plan foresees an initial phase [M1-12] aimed at creating **general awareness and visibility** for project objectives and expected results in order to engage all target groups, including the general public, as early as possible. This includes the i) launch of the HI-PRIX website, ii) establishment of a social media presence (e.g., LinkedIn, Twitter) to address both professionals and the public through regular posts, iii) development of dissemination materials such as online brochures, posters, short videos and slide templates, iv) engagement with the general public through the media, including press releases, short communications, webinars, podcasts and blogposts through the newsmagazines and broadcast channels at partner organizations (e.g., “Sarfatti 25”, "Bocconi TV", “Bocconi knowledge”).

Subsequently, activities will aim at **sharing project results and initiating dialogue** on the findings of the research with the health industry, health authorities, payers and other relevant stakeholder groups, in a way that is tailored to the needs and expectations of different target audiences.

(1) *Payers and providers* – Policy-makers and healthcare providers will be directly involved in the project’s activities and informed of the updates via policy briefs, the website and invitations to project events. Communication in person will also be important, subject to the evolution of the ongoing COVID-19 pandemic: targeted **face-to-face meetings** will be organised. Whenever possible, the project will be presented at project events and at relevant external events where such actors will be present. HI-PRIX findings will be presented at conferences such as European Health Forum in Gastein, HTAi meetings and European Health Care Management Association Conferences, providing excellent opportunities to disseminate findings to a broad European audience of health policy-makers, payers and health care managers. The HI-PRIX consortium includes payers and healthcare providers, but the reach of our dissemination activities will be amplified by leveraging on networks that HI-PRIX project partners belong to: National Competent Authorities for Pricing and Reimbursement, EUnetHTA, La Valletta Technical Committee (a voluntary cross-country collaboration that aims to improve sustainable access to medicines through joint activities, including information sharing and joint procedures), International Horizon Scanning (IHSI) Initiative. Members of the various networks will be invited to the three HI-PRIX project workshops to establish and maintain dialogue throughout the lifetime of the project and beyond. The final HI-PRIX project conference will be designed as an opportunity to maximise interaction and networking across these key target groups. The audience will consist of members of industry, payer organizations and citizens representatives invited from all over Europe. Practitioners will be invited to comment on the research findings of each WP to reflect on their impact on the health system and manufacturers.

(2) *Health industry* – The industry, in particular the pharmaceutical industry, will be a key audience for the HI-PRIX research initiative. To enhance interactions with this group, other conferences will be targeted (Annual Pharma Pricing, Reimbursement & Market Access, Annual European Pharma Conference). Members of industry associations (e.g., EFPIA, Farmindustria), thanks to engagement from the early stage of proposal development, will be invited to the three HI-PRIX project workshops to establish and continue a dialogue throughout the lifetime of the project and beyond. Industry will also be a key actor during the final HI-PRIX project conference.

(3) *Scientific community* – We expect to publish about 20 scientific papers in prestigious, international high-ranking journals. We aim to publish in open-access journals or purchase open-access rights in order to ensure universal access to findings in journals such as Value in Health, Medical Decision Making, Health Economics, Journal of Health Economics, Pharmacoeconomics, the European Journal of Health Economics, Health Policy and Applied Health Economics. HI-PRIX will participate in international conferences such as the European Conference on Health Economics (EuHEA Conference 2024), the International Health Economics Association (iHEA World Congress 2023-2025), and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

The dissemination and exploitation activities plan will seek opportunities for **cooperation among EU-funded projects** to enable cross-fertilisation. Under the Health stream of Horizon Europe Work Programme 2021-2022, the HI-PRIX consortium could establish synergies with HORIZON-HLTH-2022-CARE-08-04: *Better financing models for health systems*, HORIZON-HLTH-2021-ENVHLTH-02-03: *Health impacts of climate change, costs and benefits of action and inaction* and HORIZON-HLTH-2021-IND-07-01: *Green pharmaceuticals* (specifically in relation to WP3), HORIZON-HLTH-2021-IND-07-02: *Development, procurement and responsible management of new antimicrobials* (specifically in relation to WP7). Among the recently completed initiatives, the SELFIE EU project,

a H2020 project in PHC-23-2014 *Developing and Comparing New Models for Safe and Efficient Prevention-oriented Health and Care Systems*, represents a timely opportunity for establishing synergies for HI-PRIX WP5. In the short term, project **networking activities** will aim at raising awareness of the main activities being carried out in the project and its expected results, at granting scientific and policy validity to the project findings and at gaining knowledge and understanding of other similar on-going projects, in order to activate a productive cross-fertilisation process. In the medium and long term, the fruitful networking could lead to **joint activities** such as participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities.

A number of activities planned in WP9 will be initiated as soon as the project begins and will be implemented throughout the project's lifespan, while some will continue even after the project's end-date. Beyond the contribution the project will make towards the expected outcomes listed in the work programme, project dissemination activities are expected to ensure that project outputs can be fully exploited and taken up at the European level, ensure that the knowledge and information generated and gathered by the HI-PRIX project will be easily accessible to all interested stakeholders, maintain an effective dialogue across the various stakeholders involved to discuss and prepare future payment models. A summary of the HI-PRIX communication activities is illustrated below.

Activity	Purpose	Target Audience	Timeline	KPI
Logo and Visual guidelines	Establish a consistent public perception of HI-PRIX with the already existing logo and images	All	M3	-
Project website	Provide necessary information regarding HI-PRIX, with easy-to-access content, relevant info & news, and partners' description	Scientific community; industry; Relevant Decision-Makers; General public	M3	Website launch; at least quarterly update of contents
Dissemination materials; Press releases; Audio-visual material	Develop dissemination material (factsheet, brochures, leaflets) and information about the project and ad-hoc press releases to outreach major milestones of the project	Journalists @EU and national level; Relevant Decision-Makers; General public	Dissemination material ready on M4; Press releases ad-hoc; 2 Audiovisuals	1 brochure; annual press releases; 2 audiovisuals
Social media; Digital community	Produce digital content to outreach personal social media profiles through a dedicated profile and those already established by partners' channels (Twitter, LinkedIn, Bocconi TV, Bocconi knowledge)	Scientific community; industry; Relevant Decision-Makers; General public	M3	Account creation; regular posting

Scientific dissemination	Scientific peer-reviewed open access publications; Oral presentations and panel sessions at national and international conferences	Academics; Relevant Decision-Makers; industry	M1-M36	~20 publications; at least 6 presentations at academic conferences
Project Workshops; Final conference	Promote the project to scientific and non-scientific audiences	Academics; Relevant Decision-Makers; industry; General public	M2; M16; M30; M36	3 workshops; 1 final conference

Intellectual Property Management (IPR)

The IPR strategy and management will be defined before the project starts at the level of the consortium agreement (CA) that will be signed by all beneficiaries. The main IPR principles that will be included in the CA are: **confidentiality**, **pre-existing know-how**, **ownership and protection of knowledge**, **use and dissemination of knowledge**, **open data**. This will cover issues such as use of results and will establish a platform to ensure fair and open access to results and other required components during the project and for their exploitation. The main purpose of the CA is to complement the legal framework set up by the EC Grant Agreement for the project, in order to minimize potential conflict within the consortium and to provide legal paths to solutions should such conflicts arise. The CA will enable all partners to carry out their project work whenever it is dependent on transfer of knowledge from other partners, whether this concerns project results or background knowledge. When requested, the CA will protect the legitimate IP interests of all partners by explicitly limiting the rights to background knowledge on a need to use basis. Furthermore, a Data Management Plan (DMP) will be developed and published in M6, and updated thereafter, detailing all the necessary actions to protect Intellectual Property Rights (IPRs) and all the necessary elements of an open access strategy and data management.

2.3 Summary - KEY ELEMENT OF THE IMPACT SECTION

SPECIFIC NEEDS
🔎 Affordability issues for public and private third-party payers due to high-price innovative therapies
🔎 Double-digit increase in launch prices not commensurate to increases in efficacy
🔎 Lack of transparency about R&D costs and societal gains in price formulation
🔎 Lack of appropriate data infrastructure, legal and organizational barriers, pose challenges to the implementation of new pricing and payment models
🔎 Digital tools that are changing the delivery of healthcare call for a shift from buying pills to buying services
🔎 The variety of innovative technologies means that several pricing and payment models, designed according to the most relevant issue to be addressed, are needed
🔎 The impact of new such models on competitiveness, innovativeness, accessibility of new products must be established

EXPECTED RESULTS

- A freely accessible **catalogue of pricing and payment schemes** across technology classes, therapeutic areas, setting and healthcare systems/geographies
- New pricing and payment **models** taking into consideration the public investment in the developing of new health innovations, new evidence generated post-launch or multiple indication for the same products, incorporation of technologies in primary/integrated care services
- New **methods** on how to identify costs and benefits for different stakeholders accrued along the value chain, and to include indirect medical costs and environmental impact in pricing and reimbursement decisions
- New **knowledge** about the impact of innovative payment schemes on the long-term competition in the pharmaceutical market, on the comparative effectiveness of incentive mechanisms for pharmaceutical innovation, on the equity-efficiency trade-offs of payment schemes
- **Policy recommendations** about successful and flexible implementation of the different schemes to promote access to high-quality affordable innovative health technologies
- **Training** of two PhD students

DISSEMINATION, EXPLOITATION AND COMMUNICATION MEASURES

Dissemination to public health authorities and healthcare providers

Invitation to take part in the three project workshops
Presentation of HI-PRIX at dedicated conferences
HI-PRIX final conference

Dissemination towards health industry

Invitation to take part in the three project workshops
Presentation of HI-PRIX at dedicated conferences
HI-PRIX final conference

Dissemination towards the scientific community

Scientific peer-reviewed open access publications to illustrate the scientific output of the project
Oral presentations and panel sessions at national and international conferences

Communication towards the general public

Project Website, project-specific social media; leaflets, press-releases, audio material/videos, webinars, podcasts and blogposts

TARGET GROUPS

- **Regulators and public entities** that are in charge of attributing value tags to health technologies, negotiating with health technology manufacturers and/or reimbursing medical costs (e.g, National Competent Authorities for Pricing and Reimbursement, EUnetHTA, La Valletta Technical Committee, International Horizon Scanning (IHSI) Initiative, insurers)
- **Pharmaceutical and medtech industry** (e.g., European Federation of Pharmaceutical Industries Associations (EFPIA), the Italian Association Farmindustria, Biocat)
- **Patients and general public** (e.g., Cancer Research UK, European Patient Forum, Cittadinanzattiva)

OUTCOMES

- **Scientific -** new scientifically based methodologies, interdisciplinary approaches, tools and instruments to assess, value and pay for new health technologies are available to the health industry, regulators and public authorities, and the relevant scientific community
- **Economic –** recommendations on the successful implementation and maintenance of innovative pricing and payment schemes, promote the scale-up and take-up of solutions at national, regional or local level. Evidence about impact of various payment schemes on competitiveness, innovativeness and equitable access contribute to maintaining an innovative, sustainable and globally competitive health industry and foster innovation in disease areas where this is most needed.
- **Societal -** an effective dialogue across stakeholders' groups about the trade-offs between affordability, innovation and patient access brings to improved policy- and decision-making processes in Europe as regards to pricing and payment models for health innovation

IMPACTS

- Reach more than 60 different payers and health authorities across Europe to increase their awareness, uptake and implementation of innovative pricing and payment models for high-priced health technologies
- Reduce the 766 days gap in the mean time of new medicines availability (133 days in Germany and 899 days in Romania)
- Shrink the gap between the 18% in Cyprus to 84% in Germany of publicly covered share of pharmaceutical spending in the EU, and therefor reduce the single-most important driver of catastrophic out-of-pocket spending at population level in all EU countries

3. Quality and efficiency of the implementation

3.1 Capacity of participants and consortium as a whole

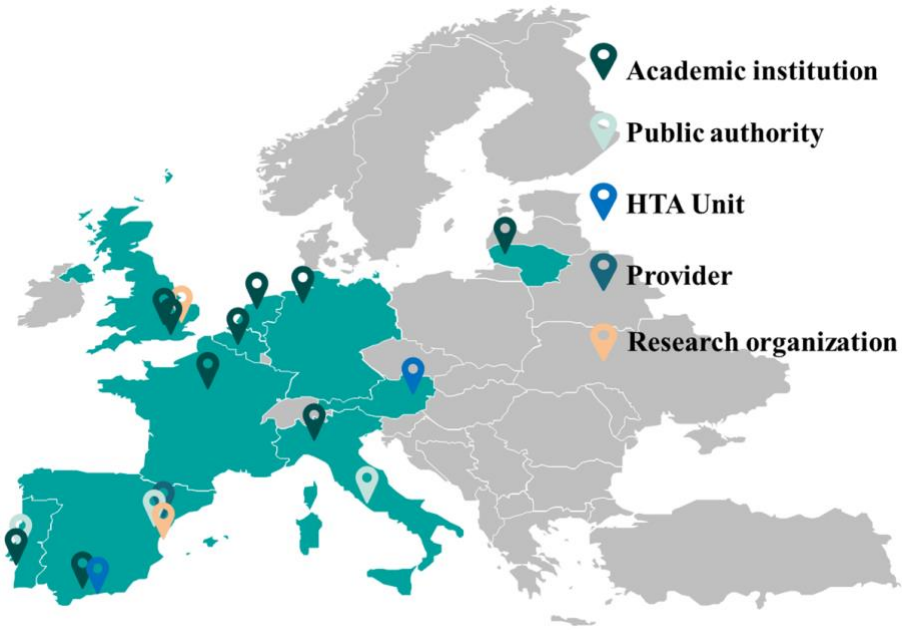


Figure 2 Partner geographic distribution

3.1.1 Consortium as a whole The consortium brings together **18 different partner organizations** from **10 countries** in Europe (Italy, Austria, Belgium, France, Germany, Lithuania, Netherlands, Portugal, Spain, United Kingdom). This geographic spread will ensure European-wide representativeness and good coverage of different context and models of healthcare (e.g., tax-based or insurance-based healthcare systems). As the research should tackle the issue globally, we are pleased to count among the senior experts in the HI-PRIX research team Prof. James Robinson, who is Leonard D. Schaeffer Professor of Health Economics, Director of the Berkeley Center for Health Technology, Health Policy and

Management Division Head at University of California, Berkeley. The essence of the HI-PRIX research methodology is **interdisciplinary** and leverage on partner institutions with a strong track record in **health economics, policy and management, public health, social and political science**. The consortium brings together knowhow in complementary fields, through academic research, previous collaboration in international projects, active role in delivering of healthcare services, and responsibilities in pricing and reimbursement determinations. The WPs and project structure were designed to ensure **cross-collaboration** and exploit the wide academic and practitioner expertise available throughout the consortium. The partner organizations also bring to the project their **extensive networks in healthcare** related research and decision-making processes, which will be fundamental in the reality testing of new pricing and payment schemes proposed and in the identification of their real-world enablers and barriers.

3.1.2 Consortium access to infrastructures

The contribution of pricing experts is the first asset to conduct the HI-PRIX project. While carrying the proposed activities, the Consortium can benefit from a range of infrastructures and technical equipment. Access to data and data processing skills are pivotal for the success of all the initiatives. To this end, ICL has access to a unique dataset (>215k observations between 1960-2019) that merges **R&D data at global level** across all disease areas and ATCs, with health need data. Moreover, ICL can rely on a Data Observatory, namely an infrastructure that allows to visualise data in a way that uncovers new insights, and promotes analyses of complex data sets in an immersive and multi-dimensional environment. ICL's Big Data & Analytical Unit (BDAU) is an ISO27001-compliant, secure computing environment for storing and processing highly sensitive data, including NHS healthcare data providers. BDAU facilitates users in exploring extensive sensitive datasets and supports their research with cutting edge tools. **Historical drug prices data** are available through CatSalut and AIFA. Both partners also manage large **real-world data** sources, for example AIFA, one of the most active public agencies, in implementing managed entry agreements, directly manages **monitoring registries** for new products subjects to outcome-based agreements. HI-PRIX activities will also benefit from NOVA's Social Sciences Data Lab (DataLab), that provides access to **bibliographic and statistical databases** for conducting advanced research in Social Sciences (Economics, Finance & Management), as well as to unique large datasets with microdata. Similarly, UHAM's Hamburg Center for Health Economics provides excellent research **facilities and equipment**, including access to international economic and medical literature, experimental labs, and – more broadly – office space for staff and access to any resource necessary for research. On a more managerial side, the HI-PRIX Consortium, and specifically the coordinator, will benefit from the institutional support and technical assistance necessary when conducting large European research projects, online meeting apps and video conference systems, classrooms, meeting rooms and an auditorium for 300 people to host the final conference event.

3.2 Work plan and resources

3.2.1 Work plan description

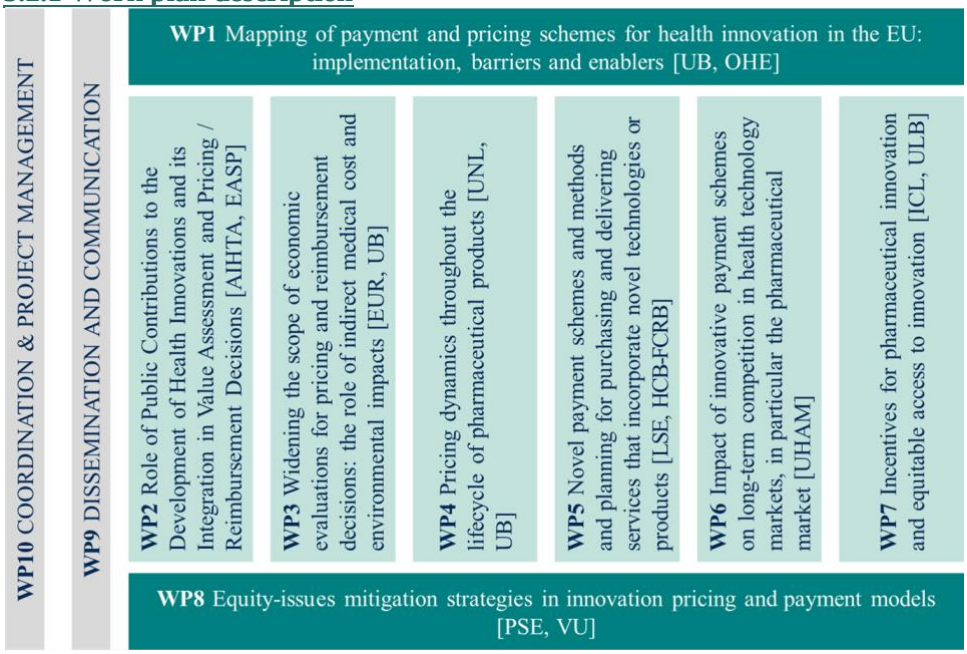


Figure 3 Workplan

HI-PRIX work plan is organized into **10 work packages** (*Figure* 3). WPs from 1 to 8 are scientific WPs. WP1, aimed at mapping payment and pricing schemes and related implementation issues, and WP8, focused on equity-issues mitigation strategies linked with pricing and payment models, are **cross-cutting WPs** that will require a close interaction with, and contribution from the other partners/WPs. WPs from 2 to 7 explore different vertical pricing issues, namely the role of public contributions in financing health innovations (WP2), the incorporation of indirect medical and environmental costs in pricing and reimbursement decisions (WP3), the pricing dynamics related to new evidence development and multi-indication products (WP4), what is required in terms of method, payment schemes, and planning

to deliver services that incorporate novel technologies (WP5), the impact of innovative payment schemes on long-term competition (WP6), and incentives for pharmaceutical innovation (WP7). Lastly, WP9 and WP10 respectively guarantee that project results gain maximum visibility and reach a larger audience with appropriate communication, dissemination and exploitation activities (WP9) and that seamless coordination both within the Consortium and with EU representatives is reached (WP10).

3.2.2 Timing (Gantt Chart)

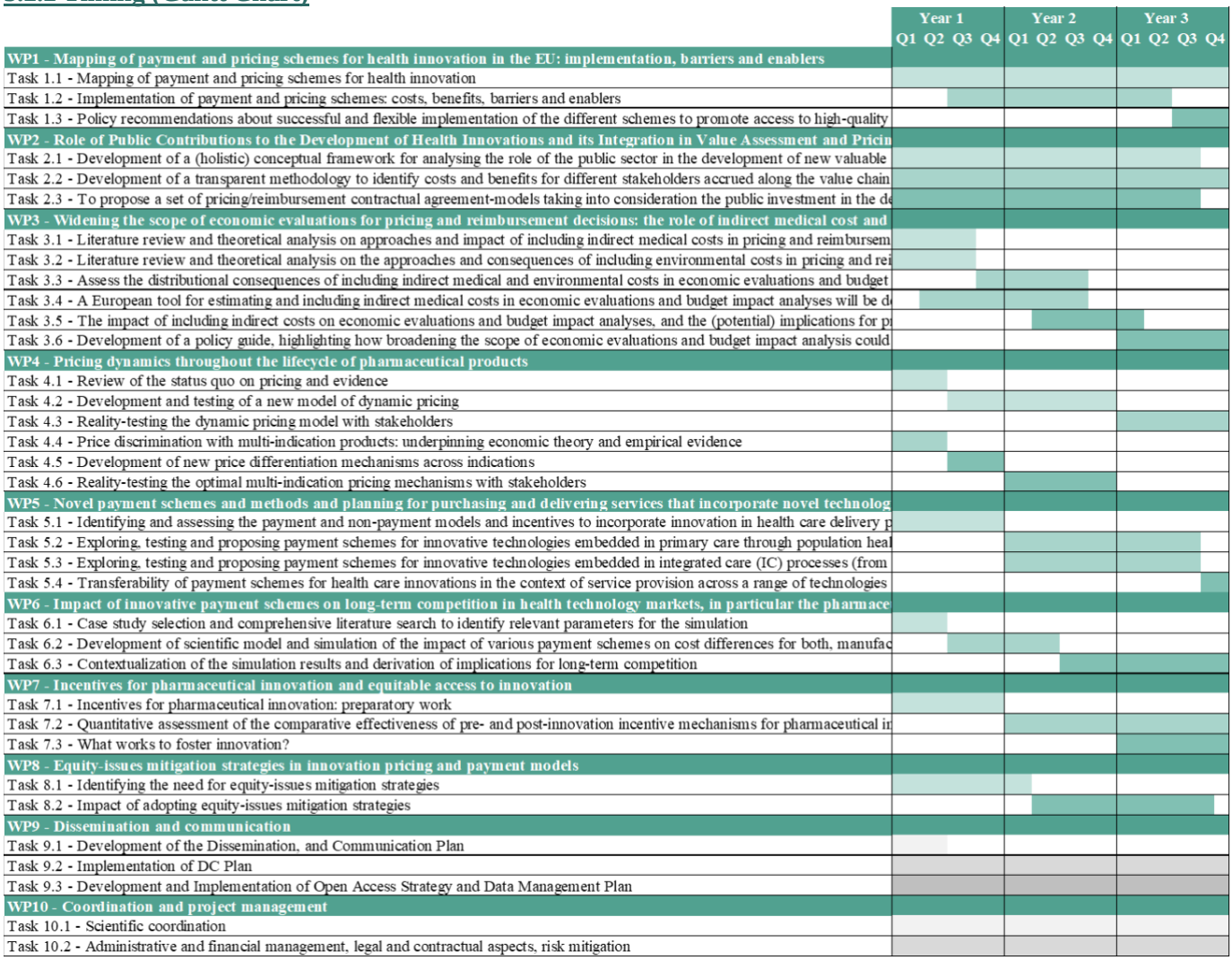


Table 3.2a: List of work packages

WP #	WP Title	LP #	LP Short Name	Person-Months	Start Month	End month
1	Mapping of payment and pricing schemes for health innovation in the EU: implementation, barriers and enablers	1, 6	UB, OHE	93	1	36
2	Role of Public Contributions to the Development of Health Innovations and its Integration in Value Assessment and Pricing / Reimbursement Decisions	3, 4	AIHTA, EASP	95	1	36
3	Widening the scope of economic evaluations for pricing and reimbursement decisions: the role of indirect medical cost and environmental impact	10, 1	EUR, UB	85	1	36
4	Pricing dynamics throughout the lifecycle of pharmaceutical products	11, 1	UNL, UB	83	1	36

5	Novel payment schemes and methods and planning for purchasing and delivering services that incorporate novel technologies or products	17, 7, 8	LSE, FCRB, HCB	95	1	36
6	Impact of innovative payment schemes on long-term competition in health technology markets, in particular the pharmaceutical market	2	UHAM	42	1	36
7	Incentives for pharmaceutical innovation and equitable access to innovation	9, 5	ICL, ULB	77	1	36
8	Equity-Issues Mitigation Strategies in Innovation Pricing and Payment Models	12	PSE	46	1	36
9	Dissemination and communication	1	UB	19	1	36
10	Coordination and project management	1	UB	32	1	36
				Total person-months		

Table 3.2b: Work package description

WP number	1					**Lead beneficiary**									**UB/OHE**
WP title	**Mapping of payment and pricing schemes for health innovation in the EU: implementation, barriers and enablers**														
Participant n°	**1**	2	3	4	5	**6**	7	8	9	10	11	12	13	14	17
Short name	**UB**	UHAM	AIHTA	EASP	ULB	**OHE**	FCRB	HCB	ICL	EUR	UNL	PSE	VU	AETSA	LSE
PM/participant	**36**	2	2	2	2	**30**	2	-	1	2	2	2	4	4	2
Start month	1						**End month**			36					

Objectives:

O1.1: To map pricing and payment schemes across technology classes, therapeutic areas, setting and healthcare systems/geographies;
O1.2: To document and assess the costs, benefits, barriers and enablers of implementation of innovative pricing and payment models;
O1.3: To generate recommendations about the successful and flexible application of the different schemes to promote access to high-quality, innovative health technologies at an affordable cost.

Description of work:

It is important that policy-makers have a thorough understanding of the key features of pricing and payment models currently existing in the EU and beyond, to facilitate learning from each other's experience. Through independent research tasks and intensive collaboration with all other WPs, this cross-cutting WP aims to map pricing and payment models, together with the features that might sustain their effective implementation in real life. The final objective is to formulate a set of policy recommendations to guide the application of different models under different contexts.

Task 1.1: Mapping of payment and pricing schemes for health innovation [M1-M36] Lead: UB; Partners: All. This task will extend through the entire duration of the project to generate a catalogue of pricing and payment schemes, across technology classes (e.g., pharmaceuticals, medical devices, services…), therapeutic areas, settings (e.g., inpatient, outpatient, …), healthcare systems (i.e., tax or insurance-based, extent of the public provision etc.) and geographies. A key preliminary step (*Task 1.1.1*) is to develop a "taxonomy matrix" characterising a variety of pricing and payment schemes applied to (or proposed for) existing or innovative health technologies. The matrix will inform the development of a framework that will guide the data extraction for each entry in the catalogue and its effective visualization. The framework will be developed based on the literature and in consultation with the HI-PRIX consortium and stakeholder groups. After establishing the analytical a framework, we will rely on a comprehensive scoping review of both the scientific literature (including theoretical pricing mechanism proposals) and grey literature (websites, reports and documents from pricing and payment organizations internationally) to map models implemented in real life (*Task 1.1.2*). The catalogue generated will be progressively expanded with the input from all other scientific WPs, including new pricing and payment models developed within the HI-PRIX project or real-world examples of applications of existing schemes (*Task 1.1.3*). The first release of the catalogue will be in the form of a "Pay-for-innovation Observatory" published on a dedicated website which will be available to policy-makers and the general public from month 12. The catalogue will be iteratively updated until the end of the project. We will produce a yearly report synthesising the underlying methodology and main findings (*Task 1.1.4*).

Task 1.2: Implementation of payment and pricing schemes: costs, benefits, barriers and enablers [M6-M30]

Lead: OHE, UV, AETSA, EASP. Building on the previous task, drawing on the implementation and evaluation science literature (e.g., adapting the RE-AIM evaluation framework), the research team will develop a suitable methodology to investigate the barriers and enablers for novel pricing and payment models. This methodology will include a classification of barriers and enablers based on features such as feasibility of implementation, cost of implementation, implementability across Member States / health systems, and potential for value (surplus) creation and distribution between stakeholders (patients, payers, providers). The output of Task 1.2.1 will be a shared HI-PRIX consortium vision on the critical aspects to evaluate the implementation of new pricing and payment models. This output will feed into the quantitative analysis of the within-country performance of novel payment/pricing schemes (*Task 1.2.2*) with special focus on what (from the payment models analysed) worked well or did not work. The objective here is to estimate the implementation costs of the selected payment models and compare them based on the health gains and cost offsets that they generate. Through active dialogue with WPs 2, 4, 6 and 7, we will identify four real-life case studies representing the different European health care systems and payment models. We will then gather data to estimate the impact of the innovative payment models on different dimensions, including costs of implementation, changes in patient access and uptake, and expected health gains. This exercise will provide insights into the beneficial impacts of introducing innovative pricing weighed against their costs. For those payment models that were established with clear and explicit aims, we will evaluate whether they have met them. Finally, we will employ qualitative methods to identify the main barriers and enablers of implementing each selected novel payment model (*Task 1.2.3*). For this task, we will engage with a range of expert stakeholders (including payers, HTA bodies, health care commissioners, policy-makers, regulators, industry representatives, data infrastructure experts, providers, and patient representatives) using a Delphi approach - a well-known qualitative research method that we have used successfully in the past. The advantage of the Delphi method is that is set to achieve maximum convergence of opinions through an iterative process. First, with the help of the framework developed in task 1.2.1, we will run a set of pre-Delphi activities to set out the context for the expert elicitation exercise: (i) identification of countries and experts, (ii) survey and/or interviews to collect individual input and data about the most relevant payment models, barriers and enablers and potential solutions for implementation, and (iii) all-expert meeting to playback the overall results of the survey to the whole group and delimit the framework for the Delphi discussion. Second, we will run a *Delphi roundtable* to facilitate discussion, encouraging reflection on both commonalities and differences of opinion arising from the pre-meeting activities and focussing on creating consensus on the barriers and enablers of payment models, as well as eliciting experience-based (often unwritten) knowledge from the participants, which can thus better inform actionable policy recommendations for their use.

Task 1.3: Policy recommendations about successful and flexible implementation of the different schemes to promote access to high-quality affordable innovative health technologies [M30-M36] Lead: OHE, UB. Partners: All. This task will critically synthesise conditions and contextual factors for the success of each tool, together with a set of policy recommendations that will guide a flexible application of different models in real life, with the ultimate goal of promoting access to high-quality affordable innovative health technologies and competitiveness of the health industry.

Deliverables:

D1.1: Stakeholders judgement on barriers and enablers of novel payment/pricing schemes [M30]
D1.2: Policy recommendations about successful and flexible implementation of the different schemes to promote access to high-quality affordable innovative health technologies [M36]

WP number	2					**Lead beneficiary**						**AIHTA/EASP**			
WP title	**Role of Public Contributions to the Development of Health Innovations and its Integration in Value Assessment and Pricing/Reimbursement Decisions**														
Participant n°	1	2	**3**	**4**	5	6	7	8	9	10	11	12	13	14	17
Short name	UB	UHAM	**AIHTA**	**EASP**	ULB	OHE	FCRB	HCB	ICL	EUR	UNL	PSE	VU	AETSA	LSE
PM/participant	1	-	**36**	**36**	-	1	2	-	-	-	2	-	2	15	-
Start month	1						**End month**			36					

Objectives:

O2.1: To develop a conceptual framework for analyzing the role of the public sector in the development of health innovations;
O2.2: To develop a transparent methodology to identify costs and benefits for different stakeholders accrued along the value chain of the development of health innovations;
O2.3: To propose a set of pricing/reimbursement contractual agreement-models taking into consideration the public investment in the developing of new health innovations.

Description of work:

There is a variety of stances on the appropriate role of the public sector in the development of health innovations. National authorities take different approaches, depending among other factors on the strength and aims of the domestic health technology industry and on their industrial policies. At one end of the continuum there are those claiming that health innovations should be a responsibility of public R&D organizations and that the public sector should at least have a leading role in defining long term priorities and investing public resources accordingly. The EU is taking an intermediate position that combines promoting innovation and a strong (EU) health technology industry, while ensuring a broad and equitable access to health innovations. Hence, while most EU countries provide publicly funded universal health care with price regulation, risk-sharing agreements and other control mechanisms, other arrangements are in place to support and encourage specific health innovation development (e.g., tax exemptions for R&D, early assessment and market exclusivity for orphan drugs under the PRIME scheme). Partly because of arguments about commercial confidentiality, there is a lack of transparency. Neither the EU nor the Member States seem to have the information/capacity required to gain a global picture of the whole set of direct and indirect public financing obtained by companies either globally (at company level) and much less at individual health innovation level. A number of alternative pricing or contractual arrangements might be considered.

Task 2.1: Development of a (holistic) conceptual framework for analysing the role of the public sector in the development of new valuable health innovations [M1-M33] Leader: EASP. Partners: UB, AIHTA, OHE, FCRB, UNL, VU, AETSA. It is increasingly accepted that the spontaneous interaction of private market forces does often not lead to the socially desired/optimal outcomes in terms of the accessibility to health innovations and to the development of innovations for unmet health needs. Although it is perceived by the public that R&D, innovation and production is mainly a responsibility of the private sector, the public sector has a very relevant role in this field too, in activities such as funding basic research, aiming at securing and holding patents, controlling market entry, purchasing final products for the public health system (procurement), regulating prices, etc. Through theoretical as well as qualitative investigation, this initial component of the WP will focus on the development of a conceptual model (or set of models) of the financial flows along the process of health innovation R&D (value chain of the development of health innovation) that helps national and EU decision-makers understand the logic of the development of health innovations, as well as the opportunities for influencing/nudging innovators to address public priorities. The conceptual model(s) will require empirical content, be it from an aggregate (national, EU or world-wide) perspective and/or at the level of single health innovations (selecting a set of appropriate/relevant case studies).

Task 2.2: Development of a transparent methodology to identify costs and benefits for different stakeholders accrued along the value chain of the development of health innovation [M1-M36] Leader: AIHTA. Partners: UB, EASP, OHE, FCRB, UNL, VU, AETSA. Expenditure on research and development (R&D) is mostly used by manufacturers as a justification for their high prices. But actually, the – resource-consuming and high-risk – basic research takes place mainly in the public sector (in universities and publicly funded research institutions). However, little publicized knowledge on public spending, however, exists to date. Objective 2.2 requires us to collect information on public contributions to health innovations´ R&D and thus contribute to the discussion on "Public Return on Public Investment" along the value chain of the development of health innovation. A Scoping Review (*Task 2.2.1*) to explore methods and sources on cost-estimations of health innovation developments and address the challenge of allocating costs as well as the financial flows incurred along the life cycle of a given technology, due to a certain share of investments in failed projects and due to the fact that some R&D activities cannot be assigned to a single health innovation. Special attention will be given to understand R&D contributions at the interfaces when ownership changes (patents, licences, royalties). Information will be synthesized on the general and on the health innovation specific level. Case-study technologies will be selected to analyse in detail development costs (*Task 2.2.2*) from orphan drugs and/or Advanced Therapy Medicinal Products (ATMPs) or other health innovations, analyzed in detail by a recent EC-evaluation. Additional selection criteria might be that these health innovations have also been approved in the USA, where the Bayh–Dole Act (formerly known as the Patent and Trademark Act Amendments) enables universities and non-profit research institutions to own, patent and commercialize inventions developed under federally funded research programs, but also requires disclosure of public funding, and by drug companies. Additionally, since the EU legislation requires pharmaceutical firms seeking an orphan designation for a medical product based on the return-on-investment route to disclose information about their R&D costs, this information will be sought. Finally, a handbook to guide transparent assessment of development costs, sources of information and range of estimates (*Task 2.2.3*) along the value chain of the drug development will be proposed.

Task 2.3: To propose a set of pricing/reimbursement contractual agreement-models taking into consideration the public investment in the development of new health innovation [M1-M33] Leader: EASP. Partners: UB, AIHTA, OHE, FCRB, UNL, VU, AETSA. Health innovation development has become so complex that attaining a

balanced mix of innovation and access objectives cannot be reduced to finding the optimal price for each single product at each point in time. The public sector may be willing to take a leading role in defining innovation and priorities for R&D (orphan drugs, antibiotic resistance, pandemic situations, etc.) bringing large amounts of public funding to these ends. But in order to do so it needs to request clear rules in the partnerships, transparency of information on effectiveness, costs (of development and production) and a fair distribution between suppliers and users of the added value obtained by these partnerships. By using a case-study technology, such as Covid-19, neglected tropical diseases, orphan medicines, we propose to make a pilot example for considering the public investment in the process of setting the price for those technologies, whilst typically this is not considered (far for the "traditional" cost – plus system that some countries indicate that they use – See WHO Pricing Guidelines). More in details, through document review and experts consultation we will: a) explore if any country is using public investment data as a criterion for pricing and reimbursement of such medicines; b) investigate how different mechanisms that consider public investment (as APC – Advance purchase agreement-, social impact bonds, etc.) use development costs in the process of setting prices; c) learn about potential (legal) obstacles to accessing data (e.g., lack of implementation of Freedom of Information Act) (*Task 2.3.1*). Thereafter, different mechanisms that consider public investments (contractual agreement models) will be piloted using 1-5 case-study technologies (*Task 2.3.2*). Finally, recommendations for mechanisms that take into consideration the public investment in pricing and reimbursement will be developed (*Task* 2.3.3). Through stakeholder consultation, we will maximize the pragmatism and applicability of our guidance.

Deliverables:

D2.1: Guidance (Handbook) on estimations (ranges) of cost elements along the value chain for demanding detailed information in price negotiations [M36]
D2.2: Set of recommendations for using the public investment in the negotiation/HTA process and pilot example how price can be different if public investment is considered [M33]

WP number	3						**Lead beneficiary**								**EUR/UB**
WP title	**Widening the scope of economic evaluations for pricing and reimbursement decisions: the role of indirect medical cost and environmental impact**														
Participant n°	1	2	3	4	5	6	7	8	9	10	11	12	13	14	17
Short name	**UB**	UHAM	AIHTA	EASP	ULB	OHE	FCRB	HCB	ICL	**EUR**	UNL	PSE	VU	AETSA	LSE
PM/participant	**36**	-	1	2	4	-	2	2	-	**36**	-	-	2	-	-
Start month	1						**End month**			36					

Objectives:

O3.1: To map approaches and role of indirect medical costs and environmental impact in pricing and reimbursement decisions based on economic evaluations;
O3.2: To examine the equity implications of excluding or including indirect medical costs and environmental impact in economic evaluations informing pricing and reimbursement decisions;
O3.3: To develop a European Tool for estimating indirect medical costs facilitating their inclusion in economic evaluations;
O3.4: To highlight the influence of including indirect medical costs and environmental impact in the context of pricing and reimbursement;
O3.5: To provide policy guidance as to how broadening the scope of economic evaluations and budget impact analysis to include indirect costs could play a role in pricing and reimbursement decisions in different decision contexts.

Description of work:

There are a number of ways in which the evidence base for pricing and reimbursement decision can be widened. However, because of the lack of a clear view on whether various factors should be considered, and if so how, there are differences in practice across the EU. This work package will examine two important factors that might be considered in a broadening of the evidence base (i) indirect medical costs; namely costs not directly related to the health intervention of interest, but that will be impacted by it (e.g., the health care costs for treatment of other health conditions if the patient's life is extended (ii) environmental impacts; namely the costs and benefits for the environment resulting from the development, production, distribution and disposal of health care products. In both cases the objectives will be to explore the role for their inclusion, to examine the impacts of their inclusion and to develop policy guidance on whether they should be used to broaden the scope of pricing and reimbursement decisions in different decision contexts.

Task 3.1: Literature review and theoretical analysis on approaches and impact of including indirect medical costs in pricing and reimbursement based on economic evaluations [M1-M9] Lead: EUR. Partners: UB, AIHTA, EASP, ULB, FCRB, HCB, VU. In this task, an in-depth review and theoretical analysis will highlight how decision rules for pricing and reimbursement based on economic evaluations might be influenced by including indirect medical

costs. On top of mapping whether indirect medical costs are or are not included in economic evaluations, arguments put forward in the different jurisdictions to justify this choice will be tracked. For the latter, the focus will not only be on efficiency arguments, but also equity arguments which are highly influential in healthcare.

Task 3.2: Literature review and theoretical analysis on the approaches and consequences of including environmental impact in pricing and reimbursement based on economic evaluations [M1-M9] Lead: UB. Partners: EUR, AIHTA, EASP, ULB, FCRB, HCB, VU. A scoping review will be performed to explore what metrics, methods and approaches have been proposed to measure environmental impact, within and outside the healthcare sector. Potentially valuable approaches and experiences will be investigated in depth and discussed to generate a framework for estimating the environmental impact of medical products and how it could input to price and reimbursement decisions based on economic evaluations.

Task 3.3: Assess the distributional consequences of including indirect medical and environmental impacts in economic evaluations and budget impact analysis. Theoretical analysis and interviews with key stake holders and experts [M10-M21] Lead: EUR. Partners: ULB, UB, UV, AETSA, UHAM. Including both indirect medical and environmental costs in economic evaluations has clear distributional consequences. The nature of these distributional consequences will be explored through theoretical analysis, highlighting the impact for different situations and interventions (e.g., quality of life enhancing or life prolonging). Based on these insights and results from the previous two tasks, key stakeholders and experts (covering different jurisdictions and viewpoints) are interviewed about these distributional consequences and the desirability of including indirect costs in the context of pricing and reimbursement decisions.

Task 3.4: A European tool for estimating and including indirect medical costs in economic evaluations and budget impact analyses will be developed [M4-M21] Lead: EUR. Partners: UB, AIHTA, EASP, ULB, FCRB, HCB, VU. Inclusion of indirect medical costs in economic evaluations is hampered by a lack of sound and easy to use estimates of indirect medical costs in gained life years. Recently, this issue has been addressed by the development of tools that allow a tailor-made estimation of indirect medical costs (correcting for typically already included *related* future costs) for both The Netherlands and the UK. In this task, a European tool for the estimation of unrelated indirect medical costs will be developed. This will involve the collecting and synthesizing existing datasets and advanced modelling. The final tool, including a manual, will be made freely available to all potential users. It will estimate future unrelated medical costs, and providing information on uncertainty.

Task 3.5: The impact of including indirect costs on economic evaluations and budget impact analyses, and the (potential) implications for pricing and reimbursement decisions will be highlighted using two examples [M16-M27] Lead: EUR, ULB. Partners: UB, AIHTA, EASP, FCRB, HCB, VU. Using two relevant real-life examples, the way in which to include indirect medical costs in economic evaluations and budget impact analysis will be highlighted, as well as the impact this has on outcomes and the implications for pricing and reimbursement decisions. The tool developed in Task 3.3 will be used in this context, which will also serve as validation of the tool. The two examples will relate to life-prolonging pharmaceutical treatments of distinct diseases, like SMA and oncology, and will be selected by ULB and ESHPM.

Task 3.6: Development of a policy guide, highlighting how broadening the scope of economic evaluations and budget impact analysis could play a role in pricing and reimbursement decisions in different decision contexts [M25-M36] Lead: EUR, UB. Partners: AIHTA, EASP, ULB, FCRB, HCB, VU. Drawing on the previous elements of the Work Package, we will draw up a policy guide highlighting how extending economic evaluations to include indirect medical and environmental costs can be used in pricing and reimbursement decisions. The policy guide will address different healthcare and decision-making contexts, importantly distinguishing between a societal and healthcare perspective in performing economic evaluations to inform pricing and reimbursement decisions. The policy guide will be discussed in a focus group session / workshop with relevant stakeholders from European countries for feedback and comments.

Deliverables:

D3.1: Equity implications of including indirect medical costs and environmental impacts in economic evaluations informing pricing and reimbursement [M18]

D3.2: Policy guide on the role of cost-effectiveness and budget impact analyses (including indirect medical costs and environmental impacts) in pricing and reimbursement decisions in different European decision contexts [M36]

WP number	4					**Lead beneficiary**					**UNL/UB**				
WP title	**Pricing dynamics throughout the lifecycle of pharmaceutical products**														
Participant n°	**1**	2	3	4	5	6	7	8	9	10	**11**	12	13	14	17
Short name	**UB**	UHAM	AIHTA	EASP	ULB	OHE	FCRB	HCB	ICL	EUR	**UNL**	PSE	VU	AETSA	LSE

PM/participant	**36**	-	1	2	-	2	2	-	-	2	**36**	-	2	-	-
Start month	1						**End month**			36					

Objectives:

O4.1: To measure if and to what extent, for drugs conditionally approved via accelerated review, prices subsequently evolve in response to new evidence of safety and effectiveness;
O4.2: To develop a dynamic pricing model whereby prices change in response to new evidence generated post-launch;
O4.3: To understand the impact of the new pricing model developed relative to traditional schemes, using historical data and views from the stakeholders;
O4.4: To provide recommendations of pricing principles for multi-indication products, based on analogies with other sectors and own elaboration taking full account of the particular characteristics of the healthcare sector;
O4.5: To examine feasibility of new pricing principles, based on interaction with regulatory officials and with providers representatives.

Description of work:

The evidence available on the safety, efficacy, and real-world effectiveness of drugs is weakest at time of initial market launch but often improves with follow-on studies and real-world clinical experience. This is more often the case in clinical areas where regulators, such as the EMA, grant accelerated approval to promising new products in the interest of making these available to patients as soon as possible. Yet prices tend to be negotiated at time of launch, when the evidence of product performance is most limited. Prices then move due to market opportunities and regulatory pressures with little direct connection with new evidence. This misalignment between the dynamics of evidence and the dynamics of pricing creates a pattern of over-pricing and under-pricing with respect to the clinical evidence, and undermines incentives for innovators to invest in follow-on clinical studies. This work package will develop a pricing method to align the evolution of price with the evolution of clinical evidence for drugs from time of market launch until time of loss of patent exclusivity. As pharmaceutical products mature on the market, new indications may be proposed for the same compound. Price discrimination reflecting finer stratification of patients, their problems and their needs, together with demand-side and supply-side implications is yet to be incorporated by payers' approaches to price determination for multi-indication products.

Task 4.1: Review of the status quo on pricing and evidence [M1-M6] Lead: UB. Partners: AIHTA, EASP, OHE, FCRB, EUR, UNL, VU. This preparatory work will review the dynamics of price for pharmaceuticals approved for market launch via accelerated regulatory review, using the peer-reviewed literature, reports by consulting firms and national payers, and clinical reports from patient registries and post-marketing data collection. We will review how prices are renegotiated in policy practices, policies that seek to align coverage with the evolution of benefit (e.g., conditional coverage; coverage with evidence development) and suggested models of dynamic pricing in the economic and scientific literature.

Task 4.2: Development and testing of a new model of dynamic pricing [M7-M24] Lead: UB. Partners: AIHTA, EASP, OHE, FCRB, EUR, UNL, VU. We will focus this task on oncology drugs authorized by EMA using accelerated review and conditional approval during the period 2010-2019, thereby allowing at least three years to have lapsed after authorization for confirmatory clinical evidence to be developed prior to 2022. For the compounds identified, we will then track the evolution of the clinical evidence, from time of EMA approval to present, using published and grey (e.g., registry, industry reports) literature. We will leverage on the Italian National Medicines Agency (AIFA) mandated creation of patient registries for documentation of real-world evidence. We will also map changes in drug price over time using Italian (Farmadati Gallery® Gold), German (Lauer-taxe®), Spanish (CatSalut) and US (Medicare Part B Drug and Biological Average Sales Price Quarterly Payment files) respectively. Based on the data collected, we will measure if and to what extent prices have evolved. We will then develop a model for dynamic pricing, starting from two principal components: i) a range of initial launch prices will be proposed that incorporate the manufacturer's suggested list price, a net price measured as list price minus the average rebate negotiated for in the same indication, and a value-based price accounting for available cost-effectiveness thresholds. To serve as initial prices in our model, these launch prices will all be discounted to account for the uncertainty of the evidence of benefit at launch; ii) we will develop an algorithm for the adjustment of initial discounted launch prices over time based on the evolution of the available clinical evidence. New evidence of benefit will likely generate prices increases, whilst new evidence of toxicity or lack of efficacy will generate price decreases. We will need to design criteria for assessing the significance of new clinical findings and adjust prices accordingly. The first assessment and price modification will take place three years after market launch, to provide sufficient time for new evidence to accumulate. For older drugs with sufficient time post-launch, we will conduct rounds of reassessment and re-pricing every three years. For the oncology drugs samples, the prices simulated by our model will be compared to the level and evolution of actual pricing for each drug in Italy, Germany, Spain, and the USA, and any discrepancies will be quantified.

Task 4.3: Reality-testing the dynamic pricing model with stakeholders [M25-M36] Lead: UB. Partners: AIHTA, EASP, OHE, FCRB, EUR, UNL, VU. Previous proposals to adjust prices to changes in clinical evidence have faltered due to insufficient consideration of implementation challenges, including criteria for deciding how post-launch changes in evidence changes should influence post-launch adjustments in price. We will submit a draft version of our dynamic pricing model to peer review by scholars and industry observers who are knowledgeable concerning accelerated review, oncology drug pricing, and previous efforts at dynamic pricing. By leveraging on the evaluation framework developed in WP1, we will reality-test our proposed dynamic pricing model with focus groups composed of payers and manufacturers, respectively to highlight potential barriers and enablers for a successful adoption and implementation in real life.

Task 4.4: Price discrimination with multi-indication products: underpinning economic theory and empirical evidence [M1-M6] Lead: UNL. Partners: UB, AIHTA, EASP, OHE, FCRB, EUR, VU. We propose an in-depth literature review covering both the foundations for use, and associated effects, of price discrimination, and the current experience (and lack of experience) with multi-indication pricing. We will also look at areas in which price discrimination under regulated prices exists other than healthcare. The review will have two main components: (*Task 4.4.1*) current pricing mechanisms for multi-indication products and (*Task 4.4.2*) economic principles of price discrimination in price-regulated settings and the specific aspects of the healthcare sector. Overall, the review will provide insights on whether and how price discrimination improves social welfare, in the presence of moral hazard associated with health insurance (public or private), and consequently access to care by patients.

Task 4.5: Development of new price differentiation mechanisms across indications [M6-M12] Lead: UNL. Partners: UB, AIHTA, EASP, OHE, FCRB, EUR, VU. Using analogies with regulated pricing in other industries, and based on the specific features of the healthcare sector, namely, public or private health insurance, common role of explicit bargaining/negotiations, cross-country nature of the innovation produced and its remuneration, this theoretical work will lead to proposals of new pricing principles rooted in economic theory, distinguishing between first-best and second-best situations. In this respect, areas that deserve attention, among others that may emerge from task 4.4, are: (1) indirect versus direct price discrimination across patients; (2) use of list prices versus confidential prices; (3) hospital versus ambulatory setting; (4) pricing rules and its updates versus direct negotiation; (5) optimal pricing under strategic entry and exit of products aimed at different indications, single dose & long lasting effects; (6) optimal pricing under sequential discovery efforts versus multiple indications found simultaneously; (7) licensing in the commercialization of an indication as commitment to multi-indication pricing. In addition to these demand-side implications for the optimal multi-indication pricing, consideration is to be given to the supply-side behavior. Of particular interest here is the role of companies' strategies. These strategies may involve strategic entry decisions, R&D incentives associated with it, and strategic exit of indications to avoid cross-effects among indications of the same product.

Task 4.6: Reality-testing the optimal multi-indication pricing mechanisms with stakeholders [M12-M24] Lead: UNL. Partners: UB, AIHTA, EASP, OHE, FCRB, EUR, VU. Newly developed pricing mechanisms will be discussed with payers and industry players separately (behind closed doors, Chatham house rules), to understand constraints and limitations that may have to be added, including their costs. The planned discussions have the specific objective of testing the potential of new ideas for success under real-life constraints and feasibility of implementation. This procedure creates a filter on the proposals resulting from the conceptual analysis in Task 4.5. As the crucial takeaway from this phase is to identify enablers and facilitators set of pricing principles, a clear synergy with WP1 exists.

Deliverables:

D4.1: A novel dynamic pricing model that links to clinical benefit: impact and acceptability for stakeholders [M36]

D4.2: Recommendations on pricing principles for multi-indication products and conditions for their successful implementation [M24]

WP number	5						**Lead beneficiary**								**LSE/FCRB-HCB**
WP title	**Novel payment schemes and methods and planning for purchasing and delivering services that incorporate novel technologies or products**														
Participant n°	1	2	3	4	5	6	**7**	**8**	9	10	11	12	13	14	**17**
Short name	UB	UHAM	AIHTA	EASP	ULB	OHE	**FCRB**	**HCB**	ICL	EUR	UNL	PSE	VU	AETSA	**LSE**
PM/participant	1	3	3	2	-	-	**36**	**6**	-	4	2	2	2	-	**34**
Start month	1							**End month**		36					

Objectives:

O5.1: To identify and assess payment and non-payment incentive schemes and provision models for incorporating innovation as part of a care provision process;

O5.2: To explore, test and propose payment schemes for innovative technologies embedded in a primary care setting (case study 1);
O5.3: To explore, test and propose payment schemes for innovative technologies embedded in an integrated care setting (i.e., from primary to secondary care) (case study 2);
O5.4: To investigate the transferability/generalizability of payment schemes for innovations in a service provision setting and for different types of health technologies.

Description of work:

The coverage and payment of innovative technologies traditionally have been conducted in a "vacuum-like" approach, where technology is completely dissociated or discontinued from the whole process of care where this technology is indicated. However, health care effectiveness and related real costs of any innovation are influenced by the way they are placed and used in a care pathway to diagnose and treat a specific clinical condition. Conventional payment systems or provision models for specific pathologies may not be able to unlock the full potential of highly valuable innovations. This WP will identify, explore, test and propose payment schemes for innovative technologies embedded in a process of care by means of case-studies using real-world information and data.

Task 5.1: Identifying and assessing the payment and non-payment models and incentives to incorporate innovation in health care delivery processes [M1-M12] Lead: LSE. Partners: UB, UHAM, AIHTA, EASP, FCRB, HCB, EUR, UNL, PSE, VU. This task will explore, identify and study the available evidence on payment and non-payment incentives for innovative therapies, by examining different models of financing as well as provision. Examples in this context will be the introduction of population health approaches to the management of chronic disease, which implies a different model of health care provision; the introduction of social financing through health/social impact bonds; and the concept of re-insurance, among others. The task will explore how selected models might work and what relevant pre-conditions could be relevant in this context. In doing so, a SWOT analysis will be performed by collecting primary evidence (through a series of web-Delphi processes) and secondary data (through a comprehensive literature review). This task will be concluded by making recommendations on the applicability and feasibility of each of the selected mechanisms for health care systems.

Task 5.2: Exploring, testing and proposing payment schemes for innovative technologies embedded in primary care through population health management (case study 1 – Drug as part of service re-organisation) [M13-M30] Lead: LSE. Partners: UB, UHAM, AIHTA, EASP, FCRB, HCB, EUR, UNL, PSE, VU. This case study will focus on the payment approaches underpinning the re-organisation of service delivery in the context of primary health care through the introduction of a population health approach which will address an unmet need in cardiovascular disease. In so doing, it will explore clinical, institutional, and behavioural changes in service delivery and the model of service provision through the introduction of a new therapy which will be delivered to eligible patients twice per annum (once every six months) by injection. The setting in which this will be studied is the English NHS, where a public-private partnership is involved in changing service delivery, whilst also incorporating the new therapy, which has been approved by the relevant health authority, in the healthcare provision. After investigating different potential payment schemes behind this population health management approach (Task 5.2.1), a qualitative structured Delphi process involving key stakeholders (patients, clinicians, NHS staff, HTA experts, national procurement agency, and industry) will be initiated (Task 5.2.2).

Task 5.3: Exploring, testing and proposing payment schemes for innovative technologies embedded in integrated care (IC) processes (from primary to secondary care) (case study 2- Medical Device and digital technology) [M13-M30] Lead: FCRB/HCB. Partners: UB, UHAM, AIHTA, EASP, EUR, UNL, PSE, VU, LSE. The objective of this task will be to develop novel payment systems that promote a shift to an integrated care approach while enabling mHealth, using Aortic Valve Stenosis (AoVS) replacement as a case study. The case study will evolve as follows: First, healthcare management aspects and associated payment systems for AoVS replacement in 4 EU countries (1 tax-based and 1 insurance-based systems) will be studied through (a) face-to-face interviews with selected stakeholders (clinicians, managers and payers/health economists; N=8); (b) peer-reviewed/grey literature examination of current contractual / managerial instruments (Task 5.3.1). Second, an analysis of the impact, in outcomes and costs, of moving from current fragmented care to mHealth-supported integrated. Data from an integrated care approach a single-arm trial (cohort N= 180) and data from real-world electronic health records (N=300) at a University Hospital will be used as case study (Task 5.3.2). Third, develop a set of payment recommendations approaches to promote such a shift. A typology of payments based on SELFIE EU project and on current trends in payment modalities for mHealth will be developed. Then they will be validated through a web-based Delphi panel (composed of clinicians, managers, payers/health economists and HTA professionals). And, fourth, map the gap between current payment approaches and the new ones and develop the required contractual/managerial instruments to facilitate change. This will be done by convening a virtual decision conference (subset of Delphi panel participants) (Task 5.3.3).

Task 5.4: Transferability of payment schemes for health care innovations in the context of service provision across a range of technologies [M31-M36] Lead: LSE. Partners: UB, UHAM, AIHTA, EASP, FCRB, HCB, EUR, UNL, PSE, VU. Based on the results of the two case studies, the objective of this task will be to investigate how the case study results can be transferred and/or generalized across therapy areas and healthcare system archetypes. In close collaboration with WP1 and by using the methodology developed there, this task will assess strengths and challenges, feasibility and transferability of payment schemes proposed for different types of innovations (e.g., diagnostics) or indications (e.g., COPD).

Deliverables:

D5.1: Impact of applying the new payment schemes to (a) a primary care and (b) an integrated care setting [M30]
D5.2: Assessment of transferability and generalizability of results and development of a toolkit for decision-makers [M36]

WP number	6						**Lead beneficiary**								**UHAM**
WP title	**Impact of innovative payment schemes on long-term competition in health technology markets, in particular the pharmaceutical market**														
Participant n°	1	**2**	3	4	5	6	7	8	9	10	11	12	13	14	17
Short name	UB	**UHAM**	AIHTA	EASP	ULB	OHE	FCRB	HCB	ICL	EUR	UNL	PSE	VU	AETSA	LSE
PM/participant	1	**36**	-	-	-	5	-	-	-	-	-	-	-	-	-
Start month	1							**End month**		36					

Objectives:

O6.1: To propose a scientific model to simulate the impact of innovative payment schemes (e.g., pay-for-performance / multi-annual instalments) on the pharmaceutical market;
O6.2: To obtain results of a simulation of the impact of various payment schemes on costs for both manufacturers and society, specifically focusing on different sources of uncertainty for one specific case study;
O6.3: To derive implications of the examined innovative payment schemes on long-term competition in health technology markets.

Description of work:

Most European countries have recently implemented a mix of different measures in the areas of both pricing and reimbursement, and strived for more enforcement and increased efficiency of them. While European countries have been implementing a set of policy options, there is a lack of thorough impact assessments of several pricing and reimbursement policies. These policies are frequently assessed against their ability to contain costs for the healthcare systems but less so in terms of competitiveness and innovativeness of the pharmaceutical market. Ensuring that EU health industry is innovative, sustainable and globally competitive thanks to improved uptake of breakthrough technologies and innovations is an expected impact of this research programme. Therefore, in this WP we address the question of how innovative payment schemes on long-term competition in health technology markets.

Task 6.1: Case study selection and comprehensive literature search to identify relevant parameters for the simulation [M1-M6] Lead: UHAM. Partners: UB, OHE. In this task, an important drug/therapy (e.g., CAR-T, cell & gene therapies) will be selected as a case study for the simulation of the impact of different innovative payment schemes (e.g., pay-for-performance / multi-annual instalments) on the pharmaceutical market. The selection of the case study will be based on evidence from the existing literature and will be led by the following criteria: 1) high annual therapy costs, 2) published efficacy data from clinical studies, 3) remaining uncertainty about the efficacy of the drug/therapy for individual patients, 4) number of competitors in the market. Following the selection of the case study, a comprehensive literature search will be conducted in order to quantify the relevant parameters for the simulation, such as prevalence of the disease to be treated in the population, disease-specific mortality, and probability of progression of the disease. All partners of WP6 will support the literature search and provide additional data available in their jurisdictions.

Task 6.2: Development of scientific model and simulation of the impact of various payment schemes on cost differences for both, manufacturers and society, specifically focusing on different sources of uncertainty [M6-M18] Lead: UHAM. Partners: UB, OHE. In this task we will develop a scientific model, which is capable of evaluating the impact of different innovative payment schemes (e.g., pay-for-performance / multi-annual instalments) on cost differences for both, manufacturers and society, considering the various regulatory frameworks and differences between countries. The model will use state-of-the-art simulation techniques, such as Markov chain Monte Carlo methods to simulate the profit of manufacturers under different payment schemes and in view of the various uncertainties. As a first step, we will simulate disease progression and response to the drug. Second, we will expand the model by simulating the impact of various payment schemes, specifically focusing on different sources of uncertainty,

including different market scenarios.

Task 6.3: Contextualization of the simulation results and derivation of implications for long-term competition [M18-M36] Lead: UHAM, OHE. Partners: UB. The main aim of this task is to contextualise the results of the simulation, ensure transferability of the findings into practice and derive implications of innovative payment schemes on long-term competition in health technology markets, in particular the pharmaceutical market. Furthermore, we will address questions about inter-country confidentiality of net prices and optimal signalling for new entrant optimal decision-making (issues around asymmetric information). As first step a theoretical model will be developed to draw general insights on how innovative payment schemes can impact on short- and long-term market competition (*Task 6.3.1*). This means evaluating the short term (static) effects of innovative pricing models and the long term (dynamic) effects. The latter will allow us to assess the potential impact of the changes in competition on prices, number of competitors/indications approved and consequently in access and affordability. Theoretical findings will be used to inform the design and the execution of semi-structured interviews. Secondly, within this task, semi-structured interviews will be conducted in the participating countries with a purposive sample of leading experts belonging to different classes of stakeholders: Pharmaceutical manufacturers and their representatives, health insurance companies and their associations, patients' and carers' organisations, physicians and their organizations, and policy-makers (*Task 6.3.2*). All partners of WP6 will collaborate in the development of the interview guide, identifying and contacting the relevant stakeholders, and in conducting, transcribing and translating the interviews. The interview guide will be pilot tested with the partnering healthcare authorities of each of the involved project partners. The piloting will give an opportunity to reflect and refine the interview guide and to clarify operational and organizational issues. This part of WP6 will contribute to the WP1 mapping exercise and understanding of facilitators and enablers of payment and pricing schemes. Thematic analysis will be used to analyse the interview data in order to identify important themes and to design a reliable and widely acceptable framework for European (and international) stakeholders. The framework will synthesize the findings with regard to the current use and the regulatory measures, levers and barriers to the widespread practical implementation of the respective payment schemes under investigation, and their impact on long-term competition in health technology markets (*Task 6.3.3*).

Deliverables:

D6.1: Report on contextualization of simulation results and synthesis of findings with regard to the current use and the regulatory measures, levers and barriers to the widespread practical implementation of the respective payment schemes and their impact on long-term competition in health technology markets [M36]

WP number	7						**Lead beneficiary**								**ICL/ULB**
WP title	**Incentives for pharmaceutical innovation and equitable access to innovation**														
Participant n°	1	2	3	4	**5**	6	7	8	**9**	10	11	12	13	14	17
Short name	UB	UHAM	AIHTA	EASP	**ULB**	OHE	FCRB	HCB	**ICL**	EUR	UNL	PSE	VU	AETSA	LSE
PM/participant	1	3	3	-	**36**	-	-	-	**34**	-	-	-	-	-	-
Start month	1							**End month**		36					

Objectives:

O7.1: Assess the comparative effectiveness of pre- and post-innovation incentive mechanisms for pharmaceutical innovation (henceforth broadly defined as policies, regulation, and market-based mechanisms) in: *i)* Ensuring innovation in key areas of need by public and private innovators; *ii)* Ensuring timely global access to those innovations in countries with different levels of income and affordability;

O7.2: Identifying strategies, policy and market-based instruments to foster innovation in key areas of need and to reduce inequalities of access to pharmaceutical innovation.

Description of work:

A common objective of health care payers and pharmaceutical companies is to ensure quick access of patients to more effective new medicines, guided by adequate incentives to R&D efforts towards areas of higher social value. In order to create the right incentives for and rewarding innovation, the next generation of pricing and payment models should compensate for the costs of developing a new product, whilst encouraging discovery of products that are more highly valued than others because they address a more important therapeutic gap. To this end, policies should be accompanied by regular evaluations, facilitated by the use of the appropriate methodology and access to the relevant data, that establish their impact on innovation and equitable global access.

Task 7.1: Incentives for pharmaceutical innovation: preparatory work [M1-M16] Lead: ICL, ULB. Partners: UB, UHAM, AIHTA. In this task, we will define the focus of the analyses by selecting a number of therapeutic and/or disease areas (e.g. vaccines, antibiotics/antimicrobials, rare diseases, pandemic infectious diseases) of relevance for

public health and health systems' financial sustainability. To that endeavour, we will consult the group of stakeholders in the consortium including to help define the scope of the analyses and the selected assessment areas (*Task 7.1.1*). We will then identify, map and characterize the monetary and non-monetary incentive mechanisms and policies to foster: i) the development of medicines in the selected disease/therapeutic areas globally, ii) timely access to these globally. Data will be collected through an in-depth review of the literature and policy documents, triangulated with key opinion leaders (e.g., regulatory agencies). We will focus on push, pull and hybrid mechanisms to incentivize R&D (e.g., advanced market commitments, prizes, IP, etc.) as well as post-market authorization mechanisms (e.g., licensing, IP, agreements, technology transfer) (*Task 7.1.2*). This task will contribute to the mapping activities of WP1. A set of quantifiable indicators will be developed to capture historically each of the policies and incentive mechanisms characteristics in terms of their design and implementation, where they apply and the strength of its incentives. Features will include scope (e.g., disease areas, therapeutic intent), geographical coverage, stakeholders involved, date of implementation and duration, associated incentives (e.g., funding for R&D, reduced time for approval), level of international coordination, risk-sharing between funders and developers, etc. Finally, a unique dataset will be built linking the data from the policy and incentives mapping (*Task 7.1.2*) with R&D activity data, country and firm-level indicators and where feasible market data (e.g., GDP, healthcare expenditure, population characteristics), heath need data. We will explore merging data from different sources including Orbis, IQVIA proprietary data, Dealroom and Crunchbase, World Bank data, Global burden of disease study, orphaned, clinical trials registers, PATStat and data scraping (where possible) from publicly available sources including, among others: Innovation programmes archives (e.g., Horizon Europe, NIH), MedsPal IP status and licensing database, UNICEF COVID-19 Vaccine Market Dashboard, LSHTM COVID-19 vaccine tracker, WIPO Patent Information Initiative for Medicines (PAT-INFORMED), TRIPS Flexibilities database, Patent Opposition Database (*Task 7.1.3*).

Task 7.2 Quantitative assessment of the comparative effectiveness of pre- and post-innovation incentive mechanisms for pharmaceutical innovation [M17-M30] Lead: ICL, ULB. Partners: UB, UHAM, AIHTA. Quantitative analyses rooted in econometrics will be run to evaluate the effectiveness of incentive mechanisms in: i) fostering innovation, including follow-on innovation, in the selected areas from basic discovery all the way to market launch; ii) promoting global access to these innovations; iii) mitigating global access inequalities. Where feasible, a combined analysis of the different policies will be performed to assess the relative strength of the incentives.

Task 7.3: What works to foster innovation? [M31-M36] Lead: ICL, ULB. Partners: UB, UHAM, AIHTA. This closing activity is aimed at identifying the key incentive tools that drive R&D, innovation and access to innovation aligned with public health priorities, the direction and magnitude of their effects. Identify key recommendations to inform the design of innovation policies for public-oriented IP models to increase access to critical health technologies. This task will benefit from active interaction with WP1 and WP2 and will embed in the proposed recommendations the feasibility of designing incentive mechanisms that enable both innovation and equitable access, going beyond the current IP model by which innovation often comes as a trade-off for equitable access and financial sustainability. The insights of this task will feed into WP8 to inform the design of accelerated processes for earlier adoption of potentially high-value healthcare innovations susceptible of mitigating inequities in health and healthcare.

Deliverables:

D7.1: Effectiveness and equity implications of selected pharmaceutical innovation policies and incentive mechanisms [M30]

D7.2: Strength of incentive mechanisms and policy recommendations to incentivize pharmaceutical innovation in key areas of need. [M36]

WP number	8					**Lead beneficiary**						PSE			
WP title	**Equity-issues mitigation strategies in innovation pricing and payment models**														
Participant n°	1	2	3	4	5	6	7	8	9	10	11	**12**	13	14	17
Short name	UB	UHAM	AIHTA	EASP	ULB	OHE	FCRB	HCB	ICL	EUR	UNL	**PSE**	VU	AETSA	LSE
PM/participant	-	2	-	2	-	-	2	1	2	-	1	**18**	18	-	-
Start month	1							**End month**				36			

Objectives:

O8.1: Identify the conditions under which equity-issues mitigation strategies are needed, based on both the nature of innovation and the type of pricing and payment models;

O8.2: Provide evidence on the performance of a number of existing mitigation strategies;

O8.3: Develop policy guidance on the use of equity-issues mitigation strategies.

Description of work:

This WP aims at offering own original inputs and at fostering collaborative work with other WPs, in order to extend the scope to different types of innovations and pricing and payment (PPMs). It fills an important gap as the impact evaluation of PPMs has mainly focused on efficiency issues, with no explicit consideration of the need for equity-issues mitigation strategies, including sex and gender equity dimension. Some innovations may be equity-threatening, for high-priced drugs such as CART-T, while others may be equity-enhancing, such as Point of Care (POC) innovations. This WP will examine equity properties of PPMs and related equity-issues mitigation strategies.

Task 8.1: Identifying the need for equity-issues mitigation strategies [M1-M18] Leader: PSE; Partner: VU, UHAM, EASP, FCRB, HCB, ICL, UNL. Defining a typology of innovations in relation to their expected impact on equity. Published scientific evidence will be synthesized to review the likely equity impacts depending on the type of innovation and given the prevailing PPMs; grey literature evidence will be gathered as well as material drawn from structured exchanges with some of the Hi-PRIX Consortium experts. The sex and gender equity dimensions will be explored (*Task 8.1.1)*. The special case of equity-enhancing innovations. The hurdles encountered in finding market opportunities for equity-enhancing innovations will be explored, in particular when innovations have strong implications on the secondary/primary care division of labour (as illustrated by POCs). Case studies will be drawn from the healthcare digitization program at AP-HP, such as a portable echograph (Echopen) or "low-cost"/inclusive technologies (*Task 8.1.2)*.

Task 8.2: Impact of adopting equity-issues mitigation strategies [M19-M34] Leader: PSE; Partner: VU, UHAM, EASP, FCRB, HCB, ICL, UNL. Funding innovation through supplementary allowances: evidence from France and Germany. A review of the theoretical and empirical literature on the impact of supplementary allowances in European countries will be carried out, and experience will be shared on the expected effects of supplementary payments with HI-PRIX Consortium experts' networks. The theoretical and econometric analysis will focus on add-on lists in hospitals which were adopted in some countries to ensure patients' equal access to high-priced innovations. France has its own list since 2004 and rich data can be used to assess the overall performance of this mitigation strategy (AP-HP's central pharmacy data and data warehouse), beyond existing evidence on delisting. It will be replicated on comparable German data to provide evidence on the potential benefits of implementing such an add-list **(***Task 8.2.1)*. Accelerated process for earlier adoption of potentially high-value healthcare innovations. The time required to access potentially high-value innovations varies across Europe. This task will review a selection of MS policies for early adoption of drugs and medical devices and investigate the likely impact (in terms of efficiency and equity) of adopting such accelerated processes (*Task 8.2.2)*. Earmarked public funding for the development of rare diseases' treatments. Early earmarking of public funding can help targeting populations for whom the low level of demand cannot support the development of innovations. Public healthcare entities have introduced a number of incentives to stimulate R&D and rare disease treatments have become increasingly attractive. The analysis here will identify the equity dimension of the spillover effects of earmarked public funding from rare diseases to more common diseases (*Task 8.2.3*).

Deliverables:

D8.1: Outline of the equity-issues mitigation strategies identified, and related potential obstacles [M18]

D8.2: Report on the overall performance of a selection of equity-issues mitigation strategies and recommendations. [M36]

WP number	9						**Lead beneficiary**								**UB**
WP title	**Dissemination and communication**														
Participant n°	**1**	2	3	4	5	6	7	8	9	10	11	12	13	14	17
Short name	**UB**	UHAM	AIHTA	EASP	ULB	OHE	FCRB	HCB	ICL	EUR	UNL	PSE	VU	AETSA	LSE
PM/participant	**6**	1	1	1	1	1	1		1	1	1	1	1	1	1
Start month	1							**End month**			36				

Objectives: The overall aim of this WP is to: 1) support the widest dissemination, communication and exploitation of HI-PRIX results; 2) actively engage with stakeholders, external experts, payers and regulators, enhancing interactions between them and the wide HI-PRIX consortium network; 3) facilitate collaboration and information exchange between different organisations and players in charge of attributing value tags to health technologies, negotiating with health technology manufacturers and/or reimbursing medical costs.

Description of work:

UB in collaboration with all other partners will be responsible for the optimal dissemination, communication and exploitation of the results of the HI-PRIX project. We will employ a multi-level strategy that relies on a different tools and approaches in order to maximize the project's impact and its outreach and engagement capacities.

Task 9.1: Development of the Dissemination, and Communication (DC) Plan [M1-M6]. Leader UB, Partners:

All At the beginning of the project, UB and consortium members will develop a dissemination and communication strategy, identifying target audiences, internal and external actors and influencers and their connection to and potential interest in the project. Key messages will be defined and for each stakeholder group, the appropriate timing and means of communication (e.g., social media, direct communication, videos, scientific meetings, peer-reviewed publications) will be selected in order to apply the most powerful strategies to convey HI-PRIX goals and findings.

Task 9.2: Implementation of DC Plan [M1-M36]. Lead UB, Partners: All; This task will likely include the following activities: **9.2.1 Set up the HI-PRIX website** by M3 and maintain it for the duration of the project and up to 3 years after its completion as a platform for external communication, update about project progress and deliverables; **9.2.2 Establish social media** accounts (e.g., Twitter) by M3 to address both professionals and public through regular posts; **9.2.3 Develop dissemination materials** by M6. Online brochures, posters, short videos and slides templates will be designed and updated as the project progresses to inform different audiences about the HI-PRIX aims and findings. **9.2.4 Engage the general public through the media** including press releases, short communications, webinars, podcasts and blogposts through the newsmagazines and broadcast channels at the partners organizations (e.g., “Sarfatti 25”, "Bocconi TV", “Bocconi knowledge”) **9.2.5 Disseminate HI-PRIX findings to the scientific community** including open access, peer-reviewed publications in scientific journals (e.g., Health Economics, Pharmacoeconomics, Value in Health, Health Policy, European Journal of Health Economics), oral presentations and panel sessions at major national and international conferences (e.g., ISPOR, HTAi, iHEA, EUHEA); **9.2.6 Present the final results through the HI-PRIX project conference** by M36 where the different stakeholders, regulators, payers and public entities that are in charge of attributing value tags to health technologies, negotiating with health technology manufacturers and/or reimbursing medical costs, will be invited to discuss the findings of this three-year research work.

Task 9.3: Development and Implementation of Open Access Strategy and Data Management Plan [M1-M36] Lead UB, Partners: All HI-PRIX will operate an open publication strategy with each research partner aiming to publish project results in open-access journals and format with a dedicated financial contribution from the project. An open science strategy will be included in the dissemination strategy and will outline project’s procedures and policies on (i) open access to scientific publications and research data and (ii) data management. **Data Management Plan** (DMP) will be developed by M6 and will be updated regularly thereafter. DMP will clearly describe the mode by which the data generated by HI-PRIX will be made as **open and accessible as possible but kept as closed as necessary to protect IPR.** All data that has led to a scientific publication will be uploaded to the appropriate public access repository, such as Zenodo, GitHub and ensure that all data is logged in OpenAire.

Deliverables:

D9.1: Dissemination and Communication Plan [M6]
D9.2: Data Management Plan (DMP, C) [M6]

WP number	10						**Lead beneficiary**								**UB**
WP title	**Coordination and project management**														
Participant n°	**1**	2	3	4	5	6	7	8	9	10	11	12	13	14	17
Short name	**UB**	UHAM	AIHTA	EASP	ULB	OHE	FCRB	HCB	ICL	EUR	UNL	PSE	VU	AETSA	LSE
PM/participant	**18**	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Start month	1							**End month**		36					

Objectives: WP10 aims to ensure the successful management of the project, covering administrative and technical areas, as well as scientific coordination. UB will lead this WP with the involvement of all partners. All the legal, contractual, financial and administrative activities, including keeping the resources and progress under plan, ensuring compliance with the obligations of the Grant Agreement, maintaining the project risks at acceptable levels and taking corrective actions if required will be covered.

Description of work: An efficient management structure will be put in place to ensure the achievement of the project scientific and policy objectives, and the quality of the actions. This governance structure will be reinforced by appropriate feedback mechanisms and contingency plans. The management of the project will deal with all administrative issues on behalf of the consortium such as legal, contractual, ethical, gender equality, and financial matters.

Task 10.1: Scientific coordination [M1-M36] Lead: UB; Partners: All. UB will handle the scientific management of the project to make sure that the project adheres to the work plan, that the deliverables meet quality standards, and that any issues are efficiently resolved. The coordinator will liaise with EC on behalf of the HI-PRIX Consortium. UB will organize project meetings and other administrative events and coordinate internal communication within the Consortium. Three face-to-face wide HI-PRIX Consortium project meetings are expected: First HI-PRIX by M2, Second HI-PRIX workshop by M16, Third HI-PRIX workshop by M30. These will be complemented by regular online

meetings among partners of the Consortium. A project management book illustrating quality management strategies and preferred operational procedures to ensure collaboration among partners will be developed and agreed with the members of the HI-PRIX consortium by M3.

Task 10.2: Administrative and financial management, legal and contractual aspects, risk mitigation [M1-M36] Lead: UB; Partners: All. This task, in close relationship with the previous, will cover budget administration, cost statement coordination, regular financial reporting and project progress monitoring with respect to overall objectives and timeplan. The task leader will coordinate work involving the WP leaders to ensure the preparation of deliverables, internal reviews, and periodic reviews. Risk assessment, follow-up and mitigation will be performed to ensure the execution of the project according to the scientific plan and the financial budget.

Deliverables:

D10.1: Consortium agreement (CA). This will be signed by all beneficiaries [M1]
D10.2: Project management book [M3]
D10.3: Periodic project reports and final report [M12, M24, M36]

Table 3.2c: List of Deliverables

D#	Deliverable name	WP #	Lead participant	Type	Diss. level	Due date (months)
1.1	Stakeholders judgement on barriers and enablers of novel payment/pricing schemes	1	UB, OHE	R	PU	30
1.2	Policy recommendations about successful and flexible implementation of the different schemes to promote access to high-quality affordable innovative health technologies	1	UB, OHE	R	PU	36
2.1	Guidance (Handbook) on estimations (ranges) of cost elements along the value chain for demanding detailed information in price negotiations	2	AITHA, EASP	R	PU	36
2.2	Set of recommendations for using the public investment in the negotiation/HTA process and pilot example how price can be different if public investment is considered	2	AITHA, EASP	R	PU	33
3.1	Equity implications of including indirect medical costs and environmental impacts in economic evaluations informing pricing and reimbursement	3	EUR, UB	R	PU	18
3.2	Policy guide on the role of cost-effectiveness and budget impact analyses (including indirect medical costs and environmental impacts) in pricing and reimbursement decisions in different European decision contexts	3	EUR, UB	R	PU	36
4.1	A novel dynamic pricing model that links to clinical benefit: impact and acceptability for stakeholders	4	UNL, UB	R	PU	36
4.2	Recommendations on pricing principles for multi-indication products and conditions for their successful implementation	4	UNL, UB	R	PU	24
5.1	Impact of applying the new payment schemes to (a) a primary care and (b) an integrated care setting	5	LSE, FCRB, HCB	DEM	PU	30
5.2	Assessment of transferability and generalizability of results and development of a toolkit for decision-makers	5	LSE, FCRB, HCB	DEM, R	PU	36
6.1	Report on contextualization of simulation results and synthesis of findings with regard to the current use and the regulatory measures, levers and barriers to the widespread practical implementation of the respective payment schemes and their impact on long-term competition in health technology markets	6	UHAM	R	PU	36
7.1	Effectiveness and equity implications of selected	7	ICL,	R	PU	30

	pharmaceutical innovation policies and incentive mechanisms		ULB			
7.2	Strength of incentive mechanisms and policy recommendations to incentivize pharmaceutical innovation in key areas of need	7	ICL, ULB	R	PU	36
8.1	Outline of the equity-issues mitigation strategies identified, and related potential obstacles	8	PSE	R	PU	18
8.2	Report on the overall performance of a selection of equity-issues mitigation strategies and recommendations	8	PSE	R	PU	36
9.1	Dissemination and Communication Plan	9	UB	R	C	6
9.2	Data Management Plan	9	UB	DMP	C	6
10.1	Consortium agreement (CA)	10	All	R	C	1
10.2	Project management book	10	UB	R	C	3
10.3	Periodic project reports and final report	10	UB	R	C	12, 24, 36

Table 3.2d: List of milestones

M#	Milestone name	Related WP	Due date (in month)	Means of verification
1	"Pay for innovation Observatory" – an online catalogue of pricing and payment schemes for health innovation	1	12	Publicly available website starting from M12
2	Within-country performance of novel payment/pricing schemes: costs and benefits of implementation	1	24	Public report
3	Conceptual frameworks with recommendations on public interventions aimed at fostering efficient health innovation at a fair cost for society	2	24	Public report
4	Literature review of role of cost-effectiveness and budget impact in pricing and reimbursement decisions and the role of indirect medical costs therein	3	12	Public report
5	Literature review on the approaches and consequences of including environmental impacts in pricing and reimbursement based on economic evaluations	3	6	Public report
6	European tool for estimating and including indirect medical costs and environmental impacts in economic evaluation, freely available, including manual	3	24	Public tool and related manual
7	Impact of including indirect medical costs and environmental impacts in economic evaluations and budget impact analysis and potential implications for pricing and reimbursement using two case studies	3	30	Public report
8	Do prices evolve in response of new clinical evidence generated post-launch? Real-world examples from oncology drugs authorized via accelerated review	4	24	Public report
9	Price discrimination with multi-indication products: underpinning economic theory and empirical evidence	4	6	Public report
10	Key components in payment schemes for health care innovations included in health system provision	5	12	Public report

11	Results of simulation on the impact of various payment schemes on cost differences for both, manufacturers and society, specifically focusing on different sources of uncertainty	6	18	Public report
12	Database with detailed mapping of policies and incentive mechanisms to foster pharmaceutical innovation and access to innovation	7	16	Data set uploaded in open access repository (e.g., Zenodo)
13	HI-PRIX website	9	3	Publicly available
14	HI-PRIX final conference	9	36	Conference proceedings and recordings
15	HI-PRIX yearly Consortium meetings	10	2, 16, 30	Meeting minutes and presentations
16	Finalization of the project	All	36	All project docs delivered

Table 3.2e: Critical risks for implementation

Description of risk (indicate level of (i) likelihood, and (ii) severity: Low/Medium/High)	WP(s) involved	Proposed risk-mitigation measures
Tasks cannot be completed as scheduled in the Gantt chart. Deliverables and/or milestones are not achieved on time (Low/Medium)	All	Careful planning, update, and follow-up of the schedule. Periodic meetings will be held with project coordinator to receive a status updated and pre-check the results.
Partner(s) leaving the Consortium (Low/High)	All	Another partner should take over the tasks and responsibilities. If not possible, eventually, third-parties will be considered.
Low level of stakeholders' engagement in the Consortium (Low/Medium)	All	Every task is evenly distributed. In case one of the partners is experiencing difficulties the rest of the consortium can take over.
Poor Recruitment in interviews, Delphi and focus groups (Low/Medium)	1, 3, 4, 5, 6	A higher number of professionals than needed will be identified as potential participants, ensuring they have worked closely on the topic and they have interest, to reach the expected target participants.
Lack of access to development costs (Medium/Medium)	2	Work on ranges rather than concrete numbers. Introduction of selection criterion (for the case-studies): accessibility of data
Lack of relevant public information about case samples (Low/Medium)	2	Work on cases that cannot be related to medicines but can be data (for example, covid-19 vaccines)
Difficulties and/or delays in access to data (Low/High)	4	No ethical approval is needed to access data. Pricing data are public or accessible to the Consortium via established relationships with providers (e.g., AIFA).
Lack of contribution from the stakeholders in mapping the incentives (Low/Medium)	7	Activities will be planned ahead of schedule to ensure they fit with other commitments
Renewed outbreak of COVID-19 pandemic or other emergencies that may require social distancing measures (Low/Low)	All	The COVID-19 pandemic has forced to embrace virtual platforms and to learn hybrid modes of work. If a similar situation occurs, face-to-face activities will be adapated to virtual events.

Table 3.2f: Summary of staff effort

Participant short name	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10	Total PMs per Participant
UB	36	1	36	36	1	1	1	-	6	18	**136**
UHAM	2	-	-	-	3	36	3	2	1	1	**48**
AITHA	2	36	1	1	3	-	3	-	1	1	**48**
EASP	2	36	2	2	2	-	-	2	1	1	**48**
ULB	2	-	4	-	-	-	36	-	1	1	**44**
OHE	30	1	-	2	-	5	-	-	1	1	**40**
FCRB	2	2	2	2	36	-	-	2	1	1	**48**
HCB	-	-	2	-	6	-	-	1	-	1	**10**
ICL	1	-	-	-	-	-	34	2	1	1	**39**
EUR	2	-	36	2	4	-	-	-	1	1	**46**
UNL	2	2	-	36	2	-	-	1	1	1	**45**
PSE	2	-	-	-	2	-	-	18	1	1	**24**
VU	4	2	2	2	2	-	-	18	1	1	**32**
AETSA	4	15	-	-	-	-	-	-	1	1	**21**
LSE	2	-	-	-	34	-	-	-	1	1	**38**
Total PMs	**93**	**95**	**85**	**83**	**95**	**42**	**77**	**46**	**19**	**32**	**667**

The Hi-Prix project partners are investing relevant resources to achieve the project objectives. The resulting overall project cost and requested funding is **€5,254,143**, distributed as follows:

A. **Direct personnel costs: €3,789,605** (90.1% of Direct Costs) represent the most significant cost item of the project budget. These costs have been calculated considering the appropriate person-months (PM) needed for each task and proposed activities, times the average monthly rate cost of the personnel that will be working in the project.

B. **Direct costs of subcontracting: €4,320** (0.1% of Direct Costs) cover an expert advisor (Louise Schmid) contribution in conducting research (WP2).

C. Purchase costs (9.8% of Direct Costs), that include:

   a. **Travel costs**: €200,278 (4.8% of Direct Costs) cover each participant's travel expenses to participate to annual Consortium Meetings, as well as to participate to the final project event.

   b. **Equipment**: €8,000 (0.2% of Direct Costs) cover the purchase the necessary technology to conduct research (e.g., computer).

   c. **Other goods and services**: €201,975 (4,8% of Direct Costs) cover Open Access fees and expenses associated to website, project's visual identity, conferences' organization, or audit.

D. I**ndirect costs**: **€1,049,965**

Some budget items were centralized in UB's budget (as project coordinator). UB's purchase costs exceed 15% of personnel costs and are detailed hereafter.

Table 3.2h: 'Purchase costs' items (travel and subsistence, equipment and other goods, works and services)

1/UB		
	Cost (€)	**Justification**
Travel and subsistence	€ 70,000	Covers Associated Partners' and external stakeholder advisory board travel expenses (in addition to UB's travel expenses)
Equipment	-	None
Other goods, works and services	€ 131,000	Includes centralized expenses (Open Access), website and visual identity, kick-off and final events
Remaining purchase costs (<15% of pers. Costs)	-	
Total	€ 201,000	

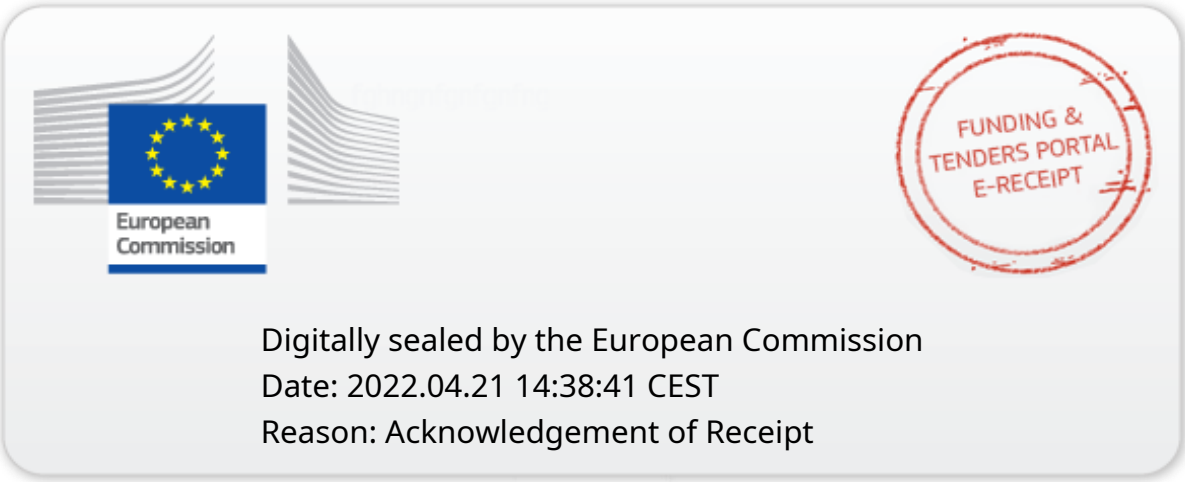
Bibliography

1. Robinson JC, Howell S, Pearson SD. Value-Based Pricing and Patient Access for Specialty Drugs. *JAMA*. 2018;319(21):2169. doi:10.1001/jama.2018.5367
2. Emanuel EJ, Zhang C, Glickman A, Gudbranson E, DiMagno SSP, Urwin JW. Drug Reimbursement Regulation in 6 Peer Countries. *JAMA Intern Med*. 2020;180(11):1510. doi:10.1001/jamainternmed.2020.4793
3. Jommi C, Armeni P, Costa F, Bertolani A, Otto M. Implementation of Value-based Pricing for Medicines. *Clinical Therapeutics*. 2020;42(1):15-24. doi:10.1016/j.clinthera.2019.11.006
4. Vokinger KN, Hwang TJ, Daniore P, et al. Analysis of Launch and Postapproval Cancer Drug Pricing, Clinical Benefit, and Policy Implications in the US and Europe. *JAMA Oncol*. 2021;7(9):e212026. doi:10.1001/jamaoncol.2021.2026
5. Howard DH, Bach PB, Berndt ER, Conti RM. Pricing in the Market for Anticancer Drugs. *Journal of Economic Perspectives*. 2015;29(1):139-162. doi:10.1257/jep.29.1.139
6. Mullard A. 2020 FDA drug approvals. *Nat Rev Drug Discov*. 2021;20(2):85-90. doi:10.1038/d41573-021-00002-0
7. *EMA. Annual Report 2020*. EMA; 2020. https://www.ema.europa.eu/en/documents/annual-report/2020-annual-report-european-medicines-agency_en.pdf
8. Barlow JF, Yang M, Teagarden JR. Are Payers Ready, Willing, and Able to Provide Access to New Durable Gene Therapies? *Value in Health*. 2019;22(6):642-647. doi:10.1016/j.jval.2018.12.004
9. Goodman C, Berntorp E, Wong O, the International Haemophilia Access Strategy Council. Alternative payment models for durable and potentially curative therapies: The case of gene therapy for haemophilia A. *Haemophilia*. 2022;28(S2):27-34. doi:10.1111/hae.14425
10. Ronco V, Dilecce M, Lanati E, Canonico PL, Jommi C. Price and reimbursement of advanced therapeutic medicinal products in Europe: are assessment and appraisal diverging from expert recommendations? *J of Pharm Policy and Pract*. 2021;14(1):30. doi:10.1186/s40545-021-00311-0
11. Michelsen S, Nachi S, Van Dyck W, Simoens S, Huys I. Barriers and Opportunities for Implementation of Outcome-Based Spread Payments for High-Cost, One-Shot Curative Therapies. *Front Pharmacol*. 2020;11:594446. doi:10.3389/fphar.2020.594446
12. Cross S, Rho Y, Reddy H, et al. Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine? *BMJ Glob Health*. 2021;6(12):e007321. doi:10.1136/bmjgh-2021-007321
13. Robinson JC. Funding of Pharmaceutical Innovation During and After the COVID-19 Pandemic. *JAMA*. 2021;325(9):825. doi:10.1001/jama.2020.25384
14. Towse A, Chalkidou K, Firth I, Kettler H, Silverman R. How Should the World Pay for a Coronavirus Disease (COVID-19) Vaccine? *Value in Health*. 2021;24(5):625-631. doi:10.1016/j.jval.2020.12.008
15. *Coalition for Epidemic Perparedness Innovations. COVAX Facility Explainer. Participation Arrangements for Self-Financing Economies*. https://www.who.int/publications/m/item/covax-facility-explainer
16. Anderson M, Mossialos E. Incentivising antibiotic research and development: is the UK's subscription payment model part of the solution? *The Lancet Infectious Diseases*. 2020;20(2):162-163. doi:10.1016/S1473-3099(19)30701-7
17. *NICE Reaches Important Milestone in the UK's Efforts to Tackle Antimicrobial Resistance.* https://www.nice.org.uk/news/article/nice-reaches-important-milestone-in-the-uk-s-efforts-to-tackle-antimicrobial-resistance
18. Hlávka JP, Yu JC, Goldman DP, Lakdawalla DN. The economics of alternative payment models for pharmaceuticals. *Eur J Health Econ*. 2021;22(4):559-569. doi:10.1007/s10198-021-01274-4
19. Alexander GC, Knopman DS, Emerson SS, et al. Revisiting FDA Approval of Aducanumab. *N Engl J Med*. 2021;385(9):769-771. doi:10.1056/NEJMp2110468
20. Robinson JC. Why Is Aducanumab Priced at $56,000 per Patient? Lessons for Drug-Pricing Reform. *N Engl J Med*. 2021;385(22):2017-2019. doi:10.1056/NEJMp2113679
21. Lin P, Cohen JT, Neumann PJ. Preparing the health-care system to pay for new Alzheimer's drugs. *Alzheimer's & Dementia*. 2020;16(11):1568-1570. doi:10.1002/alz.12155
22. European Commission. Directorate General for Health and Food Safety., Expert Panel on effective ways of investing in Health (EXPH). *Opinion on Innovative Payment Models for High-Cost Innovative-Medicines.* Publications Office; 2018. Accessed April 19, 2022. https://data.europa.eu/doi/10.2875/835008
23. Busse R, Stahl J. Integrated Care Experiences And Outcomes In Germany, The Netherlands, And England. *Health Affairs*. 2014;33(9):1549-1558. doi:10.1377/hlthaff.2014.0419
24. *OECD. Better Ways to Pay for Healthcare*. OECD; 2016. Accessed April 14, 2022. https://www.oecd.org/publications/better-ways-to-pay-for-health-care-9789264258211-en.htm

25. Tarricone R, Petracca F, Cucciniello M, Ciani O. Recommendations for developing a lifecycle, multidimensional assessment framework for mobile medical apps. *Health Economics*. Published online April 6, 2022:hec.4505. doi:10.1002/hec.4505
26. Gerke S, Stern AD, Minssen T. Germany's digital health reforms in the COVID-19 era: lessons and opportunities for other countries. *npj Digit Med*. 2020;3(1):94. doi:10.1038/s41746-020-0306-7
27. *Addressing Healthcare Challenges. Novel Pricing and Payment Models: New Solutions to Improve Patient Access*. efpia; 2020. Accessed April 13, 2022. https://efpia.eu/media/554543/novel-pricing-and-payment-models-new-solutions-to-improve-patient-access-300630.pdf
28. Aarons GA, Hurlburt M, Horwitz SM. Advancing a Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors. *Adm Policy Ment Health*. 2011;38(1):4-23. doi:10.1007/s10488-010-0327-7
29. Mazzucato M. *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*. Revised edition. Anthem Press; 2014.
30. Perehudoff K, Mara K, Hoen EFM 't, World Health Organization, Regional Office for Europe, Health Evidence Network. *What Is the Evidence on Legal Measures to Improve the Transparency of Markets for Medicines, Vaccines and Other Health Products (World Health Assembly Resolution WHA72.8)?*; 2021. Accessed April 19, 2022. http://www.ncbi.nlm.nih.gov/books/NBK572572/
31. Galkina Cleary E, Beierlein JM, Khanuja NS, McNamee LM, Ledley FD. Contribution of NIH funding to new drug approvals 2010–2016. *Proc Natl Acad Sci USA*. 2018;115(10):2329-2334. doi:10.1073/pnas.1715368115
32. Schmidt L, Wild C. *Public & Philanthropic Financial Contribution to the Development of New Drugs. Methodology & 3 Case Studies*. Ludwig Boltzmann Institute for Health Technology Assessment; 2019. https://eprints.hta.lbg.ac.at/1214/1/HTA-Projektbericht_Nr.120.pdf
33. Schmidt L, Wild C. Assessing the Public and Philanthropic Financial Contribution to the Development of New Drugs: A Bibliographic Analysis. *STPP*. 2020;4(1):8. doi:10.11648/j.stpp.20200401.12
34. Schmidt L, Sehic O, Wild C. EU FP7 research funding for an orphan drug (Orfadin®) and vaccine (Hep C) development: a success and a failure? *J of Pharm Policy and Pract*. 2021;14(1):37. doi:10.1186/s40545-021-00317-8
35. deJong T, vanBelle J, deRuiter A. *Study to Support the Evaluation of the EU Orphan Regulation*. Technopolis & Ecorys. European Commission; 2019. https://ec.europa.eu/health/system/files/2020-08/orphan-regulation_study_final-report_en_0.pdf
36. *Health Care's Climate Footprint. How the Health Sector Contributes to the Global Climate Crisis and Opportunities for Action*. ARUP; 2019. Accessed April 15, 2022. https://noharm-global.org/sites/default/files/documents-files/5961/HealthCaresClimateFootprint_092319.pdf
37. *Delivering a 'Net Zero' National Health Service*. NHS; 2020. Accessed March 14, 2022. https://www.england.nhs.uk/greenernhs/publication/delivering-a-net-zero-national-health-service/
38. *Regeringskansliet. Assignment Regarding Trial Activities for an Environmental Premium in the Pharmaceutical Benefit System*. https://regeringen.se/regeringsuppdrag/2021/05/uppdrag-angaende-forsoksverksamhet-for-en-miljopremie-i-lakemedelsformanssystemet/
39. Marsh K, Ganz ML, Hsu J, Strandberg-Larsen M, Gonzalez RP, Lund N. Expanding Health Technology Assessments to Include Effects on the Environment. *Value in Health*. 2016;19(2):249-254. doi:10.1016/j.jval.2015.11.008
40. Marsh K, Ganz M, Nørtoft E, Lund N, Graff-Zivin J. INCORPORATING ENVIRONMENTAL OUTCOMES INTO A HEALTH ECONOMIC MODEL. *Int J Technol Assess Health Care*. 2016;32(6):400-406. doi:10.1017/S0266462316000581
41. Sherman JD, Raibley LA, Eckelman MJ. Life Cycle Assessment and Costing Methods for Device Procurement: Comparing Reusable and Single-Use Disposable Laryngoscopes. *Anesthesia & Analgesia*. 2018;127(2):434-443. doi:10.1213/ANE.0000000000002683
42. Schulte A, Maga D, Thonemann N. Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters. *Sustainability*. 2021;13(2):898. doi:10.3390/su13020898
43. van Baal P, Morton A, Brouwer W, Meltzer D, Davis S. Should cost effectiveness analyses for NICE always consider future unrelated medical costs? *BMJ*. Published online November 10, 2017:j5096. doi:10.1136/bmj.j5096
44. Robinson JC. Drug Pricing With Evidence Development. *JAMA*. Published online April 11, 2022. doi:10.1001/jama.2022.5403
45. Boucaud-Maitre D, Altman JJ. Do the EMA accelerated assessment procedure and the FDA priority review ensure a therapeutic added value? 2006–2015: a cohort study. *Eur J Clin Pharmacol*. 2016;72(10):1275-1281. doi:10.1007/s00228-016-2104-3

46. Drummond M, Federici C, Reckers-Droog V, et al. Coverage with evidence development for medical devices in Europe: Can practice meet theory? *Health Economics*. Published online February 26, 2022:hec.4478. doi:10.1002/hec.4478
47. Federici C, Reckers-Droog V, Ciani O, et al. Coverage with evidence development schemes for medical devices in Europe: characteristics and challenges. *Eur J Health Econ*. 2021;22(8):1253-1273. doi:10.1007/s10198-021-01334-9
48. Pouwels XGLV, Grutters JPC, Bindels J, Ramaekers BLT, Joore MA. Uncertainty and Coverage With Evidence Development: Does Practice Meet Theory? *Value in Health*. 2019;22(7):799-807. doi:10.1016/j.jval.2018.11.010
49. Jommi C. Managed Entry Agreements and High Cost Medicines (European Perspective). In: *Equitable Access to High-Cost Pharmaceuticals*. Elsevier; 2018:35-49. doi:10.1016/B978-0-12-811945-7.00004-X
50. *Performance-Based Managed Entry Agreements for New Medicines in OECD Countries and EU Member States: How They Work and Possible Improvements Going Forward*. Vol 115.; 2019. doi:10.1787/6e5e4c0f-en
51. Campillo-Artero C, Puig-Junoy J, Segú-Tolsa JL, Trapero-Bertran M. Price Models for Multi-indication Drugs: A Systematic Review. *Appl Health Econ Health Policy*. 2020;18(1):47-56. doi:10.1007/s40258-019-00517-z
52. Cole A, Neri M, Cookson G. *Payment Models for Multi-Indication Therapies*. OHE https://www.ohe.org/publications/payment-models-multi-indication-therapies
53. Pani L, Cicchetti A, De Luca A, et al. PRICING FOR MULTI INDICATION MEDICINES: A DISCUSSION WITH ITALIAN EXPERTS. *Pharm Adv*. 2022;(online first). doi:10.36118/pharmadvances.2022.28
54. Cole A, Towse A, Lorgelly P, Sullivan R. *Economics of Innovative Payment Models Compared with Single Pricing of Pharmaceuticals*. OHE; 2018. Accessed April 14, 2022. https://www.ohe.org/publications/economics-innovative-payment-models-compared-single-pricing-pharmaceuticals-0
55. Steenhuis S, Struijs J, Koolman X, Ket J, Van Der Hijden E. Unraveling the Complexity in the Design and Implementation of Bundled Payments: A Scoping Review of Key Elements From a Payer's Perspective. *The Milbank Quarterly*. 2020;98(1):197-222. doi:10.1111/1468-0009.12438
56. Vogler S, Zimmermann N, de Joncheere K. Policy interventions related to medicines: Survey of measures taken in European countries during 2010–2015. *Health Policy*. 2016;120(12):1363-1377. doi:10.1016/j.healthpol.2016.09.006
57. Vogler S, Paris V, Ferrario A, et al. How Can Pricing and Reimbursement Policies Improve Affordable Access to Medicines? Lessons Learned from European Countries. *Appl Health Econ Health Policy*. 2017;15(3):307-321. doi:10.1007/s40258-016-0300-z
58. Grössmann N, Wolf S, Rothschedl E, Wild C. Twelve years of European cancer drug approval—a systematic investigation of the 'magnitude of clinical benefit.' *ESMO Open*. 2021;6(3):100166. doi:10.1016/j.esmoop.2021.100166
59. Thomson S, Witzke N, Gyawali B, et al. Assessing the benefit of cancer drugs approved by the European Medicines Agency using the European Society for Medical Oncology Magnitude of Clinical Benefit Scale over time. *European Journal of Cancer*. 2021;150:203-210. doi:10.1016/j.ejca.2021.03.044
60. *EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH (EXPH) Access to Health Services in the European Union*. European Commission; 2016. Accessed April 14, 2022. https://ec.europa.eu/health/system/files/2019-11/015_access_healthservices_en_0.pdf
61. How Do We Reward the Kind of Care We Want? *AMA Journal of Ethics*. 2013;15(7):565-569. doi:10.1001/virtualmentor.2013.15.7.ecas1-1307
62. Anderson AC, O'Rourke E, Chin MH, Ponce NA, Bernheim SM, Burstin H. Promoting Health Equity And Eliminating Disparities Through Performance Measurement And Payment. *Health Affairs*. 2018;37(3):371-377. doi:10.1377/hlthaff.2017.1301
63. Masters SH, Rutledge RI, Morrison M, Beil HA, Haber SG. Effects of Global Budget Payments on Vulnerable Medicare Subpopulations in Maryland. *Med Care Res Rev*. Published online October 26, 2021:107755872110527. doi:10.1177/10775587211052748
64. Rachet-Jacquet L, Toulemon L, Rochaix L. Hospital payment schemes and high-priced drugs: Evidence from the French Add-on List. *Health Policy*. 2021;125(7):923-929. doi:10.1016/j.healthpol.2021.04.012
65. Brouwer W, van Baal P, van Exel J, Versteegh M. When is it too expensive? Cost-effectiveness thresholds and health care decision-making. *Eur J Health Econ*. 2019;20(2):175-180. doi:10.1007/s10198-018-1000-4
66. Choi BCK, Pak AWP. Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. Definitions, objectives, and evidence of effectiveness. *Clin Invest Med*. 2006;29(6):351-364.
67. *THE USE OF GENDER IN INSURANCE PRICING. Analysing the Impact of a Potential Ban on the Use of*

Gender as Rating Factor. Oxera; 2010. Accessed April 14, 2022. https://www.oxera.com/wp-content/uploads/media/oxera_library/the-use-of-gender-in-insurance-pricing.pdf
68. Ferrell OC, Kapelianis D, Ferrell L, Rowland L. Expectations and Attitudes Toward Gender-Based Price Discrimination. *J Bus Ethics*. 2018;152(4):1015-1032. doi:10.1007/s10551-016-3300-x
69. Vervloet M, Korevaar JC, Leemrijse CJ, Paget J, Zullig LL, van Dijk L. Interventions to Improve Adherence to Cardiovascular Medication: What About Gender Differences? A Systematic Literature Review. *PPA*. 2020;Volume 14:2055-2070. doi:10.2147/PPA.S260562
70. Puskas CM, Forrest JI, Parashar S, et al. Women and Vulnerability to HAART Non-Adherence: A Literature Review of Treatment Adherence by Gender from 2000 to 2011. *Curr HIV/AIDS Rep*. 2011;8(4):277-287. doi:10.1007/s11904-011-0098-0
71. Morgan S, McMahon M, Greyson D. Balancing health and industrial policy objectives in the pharmaceutical sector: Lessons from Australia. *Health Policy*. 2008;87(2):133-145. doi:10.1016/j.healthpol.2008.01.003
72. OECD (2022). Health spending. doi:10.1787/8643de7e-en
73. OECD (2022). Pharmaceutical spending. doi:10.1787/998febf6-en
74. Neumann PJ, Cohen JT, Ollendorf DA. *The Right Price: A Value-Based Prescription for Drug Costs*. 1st ed. Oxford University Press; 2021. doi:10.1093/oso/9780197512883.001.0001
75. Jommi C, Armeni P, Costa F, Bertolani A, Otto M. Implementation of Value-based Pricing for Medicines. *Clinical Therapeutics*. 2020;42(1):15-24. doi:10.1016/j.clinthera.2019.11.006
76. *European Commission. Regulation on Health Technology Assessment*. Accessed April 14, 2022. https://ec.europa.eu/health/health-technology-assessment/regulation-health-technology-assessment_en
77. Espin J, Rovira J. *Analysis of Differences and Commonalities in Pricingand Reimbursement Systems in Europe*. European Commission; 2007.
78. Garattini L, Cornago D, De Compadri P. Pricing and reimbursement of in-patent drugs in seven European countries: A comparative analysis. *Health Policy*. 2007;82(3):330-339. doi:10.1016/j.healthpol.2006.11.004
79. Simoens S. A review of generic medicine pricing in Europe. *GaBI J*. 2012;1(1):8-12. doi:10.5639/gabij.2012.0101.004
80. *World Health Organization. Regional Office for Europe. (2015). Access to New Medicines in Europe: Technical Review of Policy Initiatives and Opportunities for Collaboration and Research. World Health Organization. Regional Office for Europe.* WHO; 2015:180. https://apps.who.int/iris/handle/10665/159405
81. *IQVIA. EFPIA Patients W.A.I.T. Indicator 2021 Survey*. IQVIA; 2022. https://www.efpia.eu/media/636821/efpia-patients-wait-indicator-final.pdf
82. *OECD. Affordability and Financial Protection: Insights from Europe*. https://www.oecd-ilibrary.org/sites/53f66e20-en/index.html?itemId=/content/component/53f66e20-en



This electronic receipt is a digitally signed version of the document submitted by your organisation. Both the content of the document and a set of metadata have been digitally sealed.

This digital signature mechanism, using a public-private key pair mechanism, uniquely binds this eReceipt to the modules of the Funding & Tenders Portal of the European Commission, to the transaction for which it was generated and ensures its full integrity. Therefore a complete digitally signed trail of the transaction is available both for your organisation and for the issuer of the eReceipt.

Any attempt to modify the content will lead to a break of the integrity of the electronic signature, which can be verified at any time by clicking on the eReceipt validation symbol.

More info about eReceipts can be found in the FAQ page of the Funding & Tenders Portal.

(https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/faq)