PRECISEU

WORK PACKAGE 7

D 7.3 Guidelines
Design Thinking for Policymaking

Biocat

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TABLE OF CONTENTS

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WORK PACKAGES AND LEADERS

Work Packages Name		WP Leader
WP 1	Project Management and Coordination	Biocat
WP 2	Communication and Dissemination	NE RDA
WP 3	Interregional Collaboration and Partnership Bridging	IA Lithuania
WP 4	Use of Health Data	ART-ER
WP 5	Multistakeholder infrastructure to enable access to ATMP on large scale	BIO PRO
WP 6	Market and Patient Access	SSP
WP 7	Training and Cultural Change	HLSCB
WP 8	Adoption of PM innovations in the HealthCare System	SALUT
WP 9	Innovation Support Program	Biocat

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LIST OF ACRONYMS

Acronym	Meaning
AB	Advisory Board
ACT	Activity
AWP	Annual Work Plan
BEN	Beneficiary
CT	Coordination Team
D#.##	Deliverable (as in D1.4 = deliverable 1.4)
DMP	Data Management Plan
DoA	Description of Action
EHDS	European Health Data Space
EISMEA	European Innovation Council and SMEs Executive Agency
FAIR	Findability, Accessibility, Interoperability, and Reusability
GA	Grant Agreement
GAM	General Assembly Meeting
GEDI	Gender Equality Diversity and Inclusion
IC Permed	International Consortium on Personalised Medicine
IR	Internal Report
KPI	Key Performance Indicator
M#	Month (as in M13 = month 13 of the project)
Ms	Milestone
NEIA	New European Innovation Agenda
PM	Personalised Medicine
PMS	Personalised Medicine School
RIS3	Regional Smart Specialisation Strategy
RIVs	Regional Innovation Valleys
RP	Reporting Period
SC	Steering Committee
SG	Strategic Group
SKG	Stakeholders Group
SMEs	Small and Medium Enterprises
SRIA	Strategic Research and Innovation Agenda
ToA	Triplets of Action (referred to IC PerMed's SRIA on Personalised Medicine)
T#.#	Task (as in T9.2 = task 9.2)
WP	Work Package

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TABLE OF CONTENTS

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INTRODUCTION TO THIS DELIVERABLE

Current challenges in health, ageing, digital transformation, resilience, autonomy, that can be solved with more research, innovation and higher level of adoption of solutions in public systems and in markets are urging us to take agile policy action at all levels, engaging with all relevant stakeholders.

Expert voices are increasingly referring to the need in Europe to priorities innovation and industrial strategies, as other regions in the world do, combining policies ranging from fiscal area to domestic production. The Draghi report[1] highlights the importance of aligning policies across different governance levels to achieve strategic objectives. This same report stresses that streamlining regulations can enhance competitiveness across all sectors and that Europe needs to address regulatory challenges to support innovation and entrepreneurship.

In this context, PRECISEU consortium sees an increasing need to facilitate spaces and methodologies for the quintuple helix of stakeholders (knowledge, industry, policymaking, end users and advocates for challenge to be addressed) to co-create solutions and overcome barriers to progress. There are some reflections and proposals available in the literature and the practice.[2,3,4].

As task 7.4 lead, Biocat has devised a program inspired on Stanford Mussallem Center for Biodesign's Policy Program. Biocat has already been implementing for years Stanford-based Design Thinking Methodology with its d·HEALTH Program, following Stanford University's Biodesign methodology program for graduates. The program is aimed for researchers and professionals who want to learn about entrepreneurship and innovation in healthcare. Several partners in the PRECISEU consortium have also expertise in Design Thinking methodologies to boost generation of cocreated ideas, products and services (Biovia, POP, CLustER, HLSCB, SSP...). Those will actively participate in some of the phases of the program, either in this first pilot edition in Barcelona or in the future editions in Flanders, Sofia or Emilia Romagna. Other partners involved in this task are Salut (Health Department, Government of Catalonia), ClustER, and POP (Platform of Patients' Organisations). Those will be actively participating in the program in its different editions.

TRAINING AND CULTURAL CHANGE STRATEGY IN PRECISEU

Work Package 7 "Training and Cultural Change" is a cornerstone work package within the PRECISEU project, dedicated to building the skills, mindsets, and cross-sectoral collaboration

[1] https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en
[2] https://link.springer.com/chapter/10.1007/978-3-030-23898-8_19
[3] https://www.researchgate.net/publication/305622603_Design_Thinking_in_Policymaking_Processes_Opportunities_and_Challenges_Mintrom_and_Luetjens
[4] https://www.researchgate.net/publication/371021070_When_design_meets_power_design_thinking_public_sector_innovation_and_the_politics_of_policy-making

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needed to drive the adoption and success of personalised medicine (PM) across Europe. The objectives of this WP are:

- Mentoring stakeholders to acquire the skills necessary for an improved approach to market on their Health data and ATMP innovations. Training will leverage the existing accelerators and activities organised by the partners.
- Promoting cultural change through a deign thinking program for policymakers.
- Empowering professionals by developing their skills and confidence and effective understanding of health-related data use and ATMPs for PM models.
- Driving positive change within innovators, policymakers, patients, SMEs, and healthcare organizations.
- Fostering the culture of deep tech within healthcare regarding resistance and scepticism while encouraging the adoption of innovative approaches.
- Recognising the commitment of individuals or teams that lead the advancement of PM, to inspire and advocate for the broader adoption of the model.

By achieving these objectives, the work package aims to **accelerate the adoption of the introduction of PM within healthcare systems, improve healthcare outcomes, and create a collaborative ecosystem that values and embraces innovation.**

To foster an innovation mindset among health policymakers across Europe, PRECISEU consortium, led by Biocat in this task 7.4, applies the Design Thinking methodology as it introduces an innovative, co-creative process deeply interconnected with the overall objectives and activities of WP7, which extends beyond classical training to embed cultural change, inclusivity, and continuous improvement in all capacity-building actions.

By adapting the Stanford Design Thinking framework to the realities of policymaking, this task facilitates user-centred problem definition, ideation, prototyping, and testing of health policy interventions. As a consequence, PRECISEU Deliverable D7.3 drafted as a guideline of implementation of the Design Thinking tools to face personalised medicine (PM) ecosystem challenges linked to cultural and mindset change regarding innovation challenges.

The Design Thinking for Policymaking pilot and future editions will stand out as cross-cutting instruments of methodological innovation within WP7. Importantly, these activities are not siloed—they directly support and enhance the other WP7 tasks, such as the Personalised Medicine Schools (T7.3), masterclasses, and workshops. For example, the participatory, co-creation elements piloted in T7.4 have already provided inspiration and modular content (e.g., on stakeholder engagement and policy prototyping) for inclusion in other training formats, ensuring that novel methods reach diverse audiences from clinicians to institutional leaders.

T7.4's strong emphasis on regional adaptation and stakeholder diversity mirrors WP7's core commitments to inclusivity and ecosystem relevance. As DTPM pilots in regions such as Catalonia, Flanders, Emilia Romagna, and Sofia, the program leverages the cross-WP ecosystem mapping efforts—drawing on talent needs (WP7), regulatory barriers (WP6), and health data maturity (WP4)—to construct context-specific training. This ensures that the upskilling of

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policymakers is grounded in actual gaps and opportunities identified collaboratively across work packages.
T7.4's iterative, feedback-driven approach embodies WP7's ethos of continuous improvement and impact evaluation. Insights from DTPM pilots—such as participant experiences, policy outputs, and lessons learned—are disseminated across the consortium, feeding into the refinement of all WP7 activities. This mutual reinforcement strengthens both quality assurance mechanisms and the mainstreaming of best practices, in line with the ethos of dynamic, user-informed capacity building.

The outputs and prototypes developed in T7.4 (e.g., policy briefs, models, or guidelines) serve as practical examples of innovation in policy that can be recognized, awarded, and scaled through WP7's dissemination channels. They also embody a commitment to gender, ethical, and diversity considerations, upholding WP7's ambitions for responsible and inclusive training.
T7.4 acts both as a methodological testbed and an integrative force across WP7. By embedding Design Thinking at the heart of policymaker training—and linking its outputs, lessons, and innovations to the broader spectrum of WP7 activities—T7.4 ensures that PRECISEU's training and cultural change strategy is agile, ecosystem-responsive, and sustainable. This synergy positions the PRECISEU consortium to catalyse deep, cross-sectoral transformation in personalised medicine, tailored to the needs and realities of Europe's diverse regional health innovation ecosystems.

THE PROGRAM

Design Thinking for Policymaking (DTPM)5

As PRECISEU Task 7.4 lead, Biocatwill launch the first pilot edition of the "Design Thinking for Policymaking" (title and branding under construction) program in the framework of PRECISEU, the EU funded regional Innovation Valley on Personalised Medicine coordinated by Biocat. The project, that runs for 5 years (July 2024-June 2029), will organise at least 4 editions of the program, adapted to the different regions serving as main location during the project timeline (Barcelona, Ghent, Bologna and Sofia). The program, to be developed under Task 7.4 in the project, will be first implemented as a 2-week pilot between end of October and mid-November 2025, online and onsite (in Barcelona).

The PRECISEU Grant Agreement indicate as a purpose:
To build capacities in the intersection between health policy and health technology innovation – specifically, how policy can accelerate the use of technology to improve health outcomes.
The Methodology applied will be Design Thinking, with the aim to delivering policy pieces, papers, guidelines, in real policymaking environments.
The target are policymakers in health decision-making organisations (procurers, payers, administration, MPs, legislators, regulators...)

[5] provisional name, brand under construction at the moment of submitting this deliverable

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With the aim of fostering the discussion of new avenues for policy alignment to personalised medicine strategies at the regional level, T7.4 will bring together policymakers active in the field to become familiar with the needs and solutions defined in the project (regarding gaps in personalized medicine implementation, advanced therapies and secondary use of health data).

The task entails the implementation of a design thinking methodology for policymaking inspired on the Stanford Biodesign Innovation Policy Fellowship.

The cohorts will follow an up to 2-weeks of online and onsite sessions analysing best practices and policies and immersing in the process of Deep Tech-based health innovation, led by startups, corporates, large health data infrastructure representatives, patients… experts from within the consortium members and partners.

Experts from Stanford Mussallem Center will be invited to kick-off the sessions and discuss the program.

Participants are expected to help bridge the divide between PM stakeholders and policymakers through the presentation of the main outputs in a real policy-making environment (Government, Parliament Health commission, or an event linked to EU Presidency agenda).

The different editions are foreseen to be delivered in 2025-2028 at Fall.

DESIGN THINKING METHODOLOGY

For consistency this program will use as reference the Design Thinking Methodology by Stanford University. However, there are multiple adaptations and related methodologies for the broadly extended process.
Stanford Design Thinking is a human-centred approach to solving complex, ambiguous problems creatively. It focuses on understanding the people you're designing for, and crafting solutions based on empathy and experimentation rather than assumptions. Originating from Stanford's d·school, it is widely adopted in innovation and product development across industries. As main traits, the methodology:

- Prioritises user needs and experiences
- Promotes collaboration and creativity
- Encourages iteration over perfection
- Is suitable for tackling "wicked problems" with no clear solution

The process in a nutshell

The process unfolds in five key phases that may appear linear, but in practice are iterative, with teams often looping back based on insights.

- Empathise – Observe and listen to users to understand their needs
- Define – Frame a clear, actionable problem statement
- Ideate – Generate a wide range of possible solutions
- Prototype – Build quick, low-fidelity versions of ideas to test

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- Test – Collect feedback to refine and improve the solution

To work effectively, teams must adopt the right mindset. Design Thinking relies on openness, curiosity, and mutual respect. It's not just about methods but how people interact and think together.

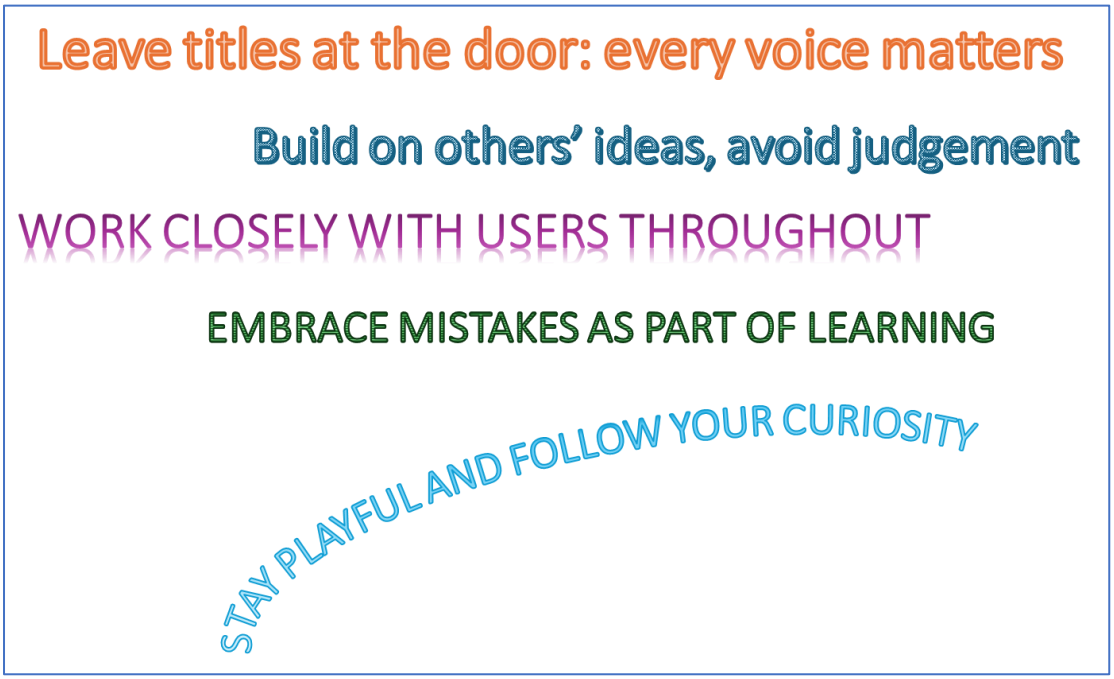

Fig. 1: Some key messages for the Stanford Design Thinking methodology[6] that the DTPM program will spread.

This process shines when addressing ill-defined or user-related problems that can't be solved through analytical reasoning alone. Design Thinking broadens perspectives and integrates user feedback to develop novel ideas. It's great for problems involving human behaviour or systems, ideal for early-stage product development or services, it's not a fit for purely technical or efficiency-based issues, and complements methods like Lean Startup or Design Sprints.

Getting started with the methodology

To begin, teams must clarify the challenge, get stakeholder buy-in, and commit to user involvement at each step. Some examples of Stanford's d·school and IDEO are used here as a reference and illustrated as follows (fig 2.):

[6] https://makeiterate.com/the-stanford-design-thinking-process/

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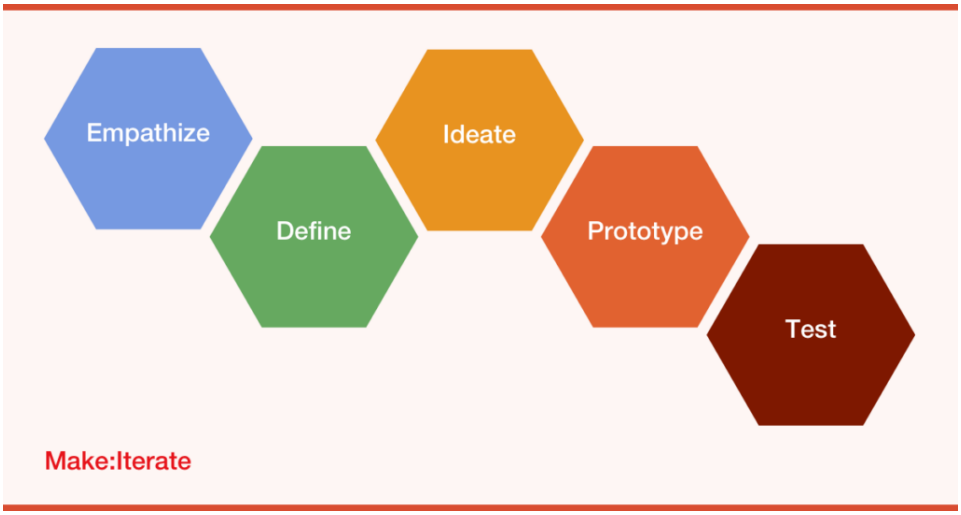

Fig. 2: Stanford's design school (d·school) and IDEO model depicted

In 2022 Stanford Mussallem Center launched the Policy Program to build a bridge between innovators and policymakers and help the latter appreciate how different policy choices can impact the ecosystem and facilitate novel technologies reach the patient and improve health outcomes. Based on this idea of connecting innovators and policymakers, PRECISEU consortium has devised a **co-creation program based on the Design Thinking Methodology to promote the innovation mindset at policymaking level** and **build capacities among the decision-makers regarding the innovation process, in a purposeful and structured way**.

The Design Thinking methodology, as applied in PRECISEU Task 7.4 "Design Thinking for Policymaking" (DTPM), strongly supports the project's mission by embedding a human-centered, co-creative process in policymaker training. This ensures policy innovations are shaped by real needs from a broad spectrum of stakeholders across Europe's personalised medicine ecosystem.

Design Thinking's focus on empathy enables policymakers to deeply understand the perspectives of patients, healthcare professionals, and the wider innovation ecosystem, helping PRECISEU drive solutions that are not only relevant but also impactful within health systems. Its creative, iterative process encourages policymakers to ideate freely, rapidly prototype, and refine solutions in response to ongoing feedback. This flexibility and responsiveness are particularly crucial for the fast-evolving field of personalised medicine, allowing policy and regulatory strategies to keep pace with accelerating scientific and technological advances.
Cross-disciplinary and inclusive collaboration is a fundamental tenet of Design Thinking, closely aligning with PRECISEU's commitment to inclusivity, ethical responsibility, and diversity. By facilitating structured encounters between policymakers and clinicians, innovators, researchers, and patients, PRECISEU ensures that policy is grounded in a thorough, context-specific understanding of barriers and opportunities within varying regional ecosystems, supporting its objective to reduce disparities and build capacity throughout Europe.
The methodology further reinforces continuous improvement and quality assurance. Insights and lessons from Design Thinking pilots are shared consortium-wide, which allows other PRECISEU training actions—like PM Schools and workshops—to continually integrate the latest

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co-creation tools and processes. This enables PRECISEU's capacity-building programs to remain dynamic, user-informed, and fine-tuned to emerging needs.
The tangible outputs generated through Design Thinking—such as policy briefs, practical models, and guidelines—become scalable resources for PRECISEU's dissemination, recognition, and cross-sectoral dialogue. These materials exemplify responsible innovation and demonstrate gender and diversity awareness in practice.

NEEDS IDENTIFICATION

Background research

Europe has the foundations in place to be a highly competitive economy, and yet, its growth is slowing down. According to **Mario Draghi's Competitiveness Report**, which was released on 9 September 2024, closing innovation gaps must be Europe's priority. Europe is strong in innovation creation. For example, the medical technology sector in Europe files a patent every 30 minutes[7]. However, Europe's international competitiveness gap is widening.

Draghi's report also highlights the need to address regulatory obstacles that hinder innovation and commercialization of new technologies within the EU. The report also identifies the need for regulatory reform to remove obstacles to innovation and investment and suggests that regulations should be streamlined and made more consistent across the EU to facilitate the growth of businesses and the adoption of new technologies. In summary, Draghi is explicit in identifying regulation as an obstacle to European Union's innovation potential.[8]

The **EU Competitiveness Compass** "to regain competitiveness and secure sustainable prosperity", suggests 5 key horizontal enablers to advance in the core areas of action. One of these enablers is simplification, and points at reducing drastically the regulatory and administrative burden. Among the efforts required, we highlight here making procedures for accessing EU funds and getting EU administrative decisions simpler, faster, and lighter. For example, the Compass sets a target of cutting by at least 25% the administrative burden for firms and by at least 35% for SMEs. Another transversal enabler identified by the Compass is improved coordination of policies at EU and national level, to ensure implementation at EU and national level of shared EU policy objectives. Again, policies are at the focus of competitiveness.

If we go back some years, but still fully in force, the New European Innovation Agenda[9] (inspiring the EIE program in which PRECISEU is operating), 2 of the flagships draw our attention to policymaking:
Enabling innovation through experimentation spaces and public procurement will facilitate innovation through improved framework conditions including experimental approaches to regulation (e.g. regulatory sandboxes, test beds, living labs and innovation procurement).

[7] https://www.medtecheurope.org/news-and-events/news/medtech-europe-statement-closing-innovation-launch-gaps-in-health-is-key-to-europes-prosperity-and-competitiveness/
[8] https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059
[9] https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/new-european-innovation-agenda_en

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Improving policy making tools will be the key for development and use of robust, comparable data sets and a shared definitions (startups, scale-up) that can inform policies at all levels across the EU and for ensuring better policy coordination at the European level through the European Innovation Council Forum.

Mission-oriented policymaking: Mission-Oriented Innovation Policies (MOIPs) are emerging in governments worldwide. MOIPs provide strong directional innovation policies which are intended to mobilize actors across sectors to tackle grand societal challenges. Since "Mission-oriented innovation policies: challenges and opportunities" paper by Mariana Mazzucato analysing how policies can transform the policy makers' tool kit, a lot has been written in the direction of further connecting players to cocreate solutions. This paper recommends "*to stimulate the innovation process by shaping and creating technologies, sectors, and markets, missions require dynamic relationships to be developed which create trust between actors. It is essential in this process for the lead public organizations to galvanize the interests of relevant actors and organize itself so that it has the "intelligence" to think big and formulate bold policies that create a sense of ownership among diverse public, private, and academic stakeholders. It is also crucial to be able to implement the policies by coordinating the efforts of this network of stakeholders through the state's convening power, brokering of trust relationships, and the use of targeted policy instruments."*[10]

Other literature pieces highlight the barriers to personalized medicine across Europe[11] from qualitative study under Regions4PerMed EU-funded project. Among many other outcomes, it is worth highlighting the need for a greater emphasis on the patient perspective.

Consultation to ecosystem

In general, in health industries, Deep-tech innovation procurement has been highlighted as an excellent sandbox if used as an open laboratory for public policy. In the process of healthcare innovation, public policies in Europe play a crucial role fostering or burdening innovation procurement. This area requires providing a supportive framework for public entities to acquire innovative solutions and drive economic growth. Supporting policies can help modernize public services, address societal challenges, and create opportunities for European companies, particularly SMEs, to develop and commercialize new technologies.

In particular, in the implementation of PRECISEU, a mapping of barriers and enhancers has been conducted through in-depth interviews, guided by a shared interview protocol. These conversations focused on identifying the main access barriers to personalised medicine, examples of successful practices, and challenges around accessing secondary health data. Each region aimed to conduct around ten interviews with representatives from key groups like academia, healthcare organisations, SMEs and larger companies, public agencies, and patient organisations. The interviews took place during January and February 2025 and were mostly held online, lasting 30 to 60 minutes. The outcomes will be submitted in D6.1 as a Cross-

[10] https://www.researchgate.net/publication/329760183_Mission-oriented_innovation_policies_Challenges_and_opportunities
[11] https://pmc.ncbi.nlm.nih.gov/articles/PMC9965772/

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Regional Report. Also, during March 2025, each region[2] hosted a workshop—either in person or online—with participants from the interviews and other relevant actors. The workshops were designed to confirm the key barriers, gather different perspectives, and discuss the region's strengths and weaknesses in personalised medicine. Using group discussions participants helped refine the findings and bring in new viewpoints. Most workshops involved 10 to 40 participants. The mapping has identified barriers that the WP6 leads have organized into six overarching categories that reflect their systemic nature. Two of those are instrumental for the purpose of this Design Thinking for Policy making program (see fig 3.)

Regulatory barriers	7. Regulatory uncertainty of AI in healthcare
	8. Regulatory complexity within the field of ATMPs
	9. Unclear rules for hospital exemption
Competence and awareness	10. Competence gaps across healthcare and innovation ecosystems
	11. Patient awareness
	12. Understanding, knowledge and support from policy makers and decision makers

Fig 3. Extract from the barriers identified in the PRECISEU Mapping of Personalised Medicine access to market.

As particular needs identified, the WP6 consultation to the ecosystems has revealed poor…

- Understanding, knowledge and support from policy makers and decision makers: A recurring theme across regional reports is the limited understanding and strategic engagement of policymakers and decision-makers with the evolving field of precision medicine. In several regions, decision-makers lack sufficient awareness of the clinical, economic, and societal value of personalised medicine, which contributes to delays in regulatory approvals, rigid reimbursement frameworks, and fragmented policy support.

- Budget Adaptation Needed: Policymakers often underestimate the long-term cost-effectiveness of precision approaches, instead prioritizing short-term budget constraints that hinder investment in essential infrastructure and innovation. This limited perspective slows the integration of technologies such as AI-driven diagnostics, genomic testing, and advanced therapy medicinal products (ATMPs) into healthcare systems.

- Lack of Policy Coordination:
Moreover, the absence of cohesive policy frameworks and coordination mechanisms at both national and regional levels results in fragmented implementation. Where regional disparities in access are overlooked, or where local providers are excluded from national strategies, systemic inefficiencies persist.

Other recommendations from the collaboration with other Regional Innovation Valleys

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A joint event celebrated in Brussels on March 11 2025[12], organized by the Regional Innovation Valley Consortium SystemEU and with the participation of the other 4 Regional Innovation Valley Consortia (ECIV, PRECISEU, RIV Circular and UNITE), provided insights and policymaking recommendations that are summarised below:

- Europe has an opportunity to lead globally not just through its technologies, but through its governance models. Co-creation—where citizens, entrepreneurs, researchers, and policymakers collaborate from the outset—should be at the heart of policy design and project implementation.
- Institutionalize co-creation methodologies (such as innovation labs, citizen assemblies, and foresight exercises) into regional innovation strategies and the EU Innovation Agenda.
- Develop policy tools that embed startups within innovation ecosystems—through procurement, challenge-based funding, and structured collaboration with public actors and corporates
- Additionally, narrative change is critical. The language of policy must shift to embrace diversity in innovation models. Excellence should be redefined to include resilience, inclusion, and capacity-building, especially in regions undergoing economic transition. EU-level storytelling—through case studies, awards, and media partnerships—can highlight the contributions of underrepresented regions and inspire broader systemic recognition.
- Institutionalizing startup-centric policy means elevating their role from beneficiaries to system actors—shaping, driving, and co-owning the transformation agenda.
- the EU must act with clarity and coordination. It must create permanent policy homes for ecosystem-building, back innovation with sustained financial instruments, and remove the procedural barriers that discourage risk-taking and experimentation. It must also recognize and reward those who bridge silos, scale social and environmental solutions, and cultivate inclusive growth.

Consultation to PRECISEU consortium

Biocat has also consulted PRECISEU partners in two processes: 1) the first involved WP7 partners with roles in the DTPM program (Task 7.4); and 2) Work Package leads received an online survey. Their feedback has provided insight about the program structure, format and focus.

As main outcomes:

- A 2-week program is suitable but requires high involvement (might be challenging for public servants).
- The time of the year is a relevant aspect, as are hybrid mode or virtual asynchronous with fixed delivery dates.
- Opinions on frequency of sessions was quite balanced: once a month (50%) vs. consecutive (50%)

[12] https://preciseu.eu/from-interconnected-ecosystems-to-a-pact-for-innovation-in-europe/

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- The partners thought that a broad representation of stakeholders is good
- Topics should be sufficiently broad to repeat them in the different regions, with adaptation to local needs.

Inspirational models

Stanford Biodesign Policy Fellowship (discontinued) and Policy Program[13]

Stanford Mussallem Center for Biodesign Policy Program starts with a clear need: After investing years of effort and funding to develop a new technology, innovators must navigate an unpredictable landscape of complex, time consuming, and expensive requirements in order to advance their solutions into patient care. The inefficiencies inherent in the system result in delays that keep promising technologies from the people who so desperately need them. The program produces data-driven research to help current and future policymakers better understand how health policies impact innovation. This program and the Policy Fellowship Program inspired PRECISEU DTPM program in the first place.

NIHR: "How can policy and practice support an innovating healthcare system?[14]

NHS, RAND Europe and the University of Manchester conducted a study on the potential of innovation to help deliver an efficient and effective healthcare service. The research was funded by the National Institute for Health Research (NIHR) Policy Research Programme, in close collaboration with the Department of Health and Social Care, NHS England and the Office for Life Sciences. The study examined questions like how organisations working in and closely with the NHS perceive and understand innovation, who drives and contributes to innovation, what practical changes to policy, culture and behaviour can support system-wide improvements in the healthcare innovation landscape or how can we measure the contributions of innovation to the social and economic performance of the healthcare sector. The outcomes of this research have inspired PRECISEU program too.

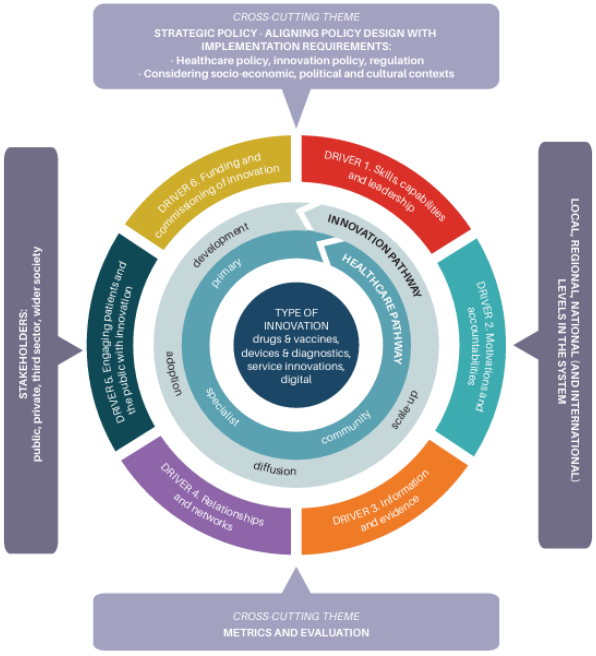

Fig. 4 depicts the systems perspective on the innovating health system with six drivers of innovation and two cross-cutting themes produced in the NIHR report.

[13] https://biodesign.stanford.edu/programs/policy-program/publications-testimony-events.html
[14] https://www.rand.org/content/dam/rand/pubs/research_briefs/RB10100/RB10110/RAND_RB10110.pdf

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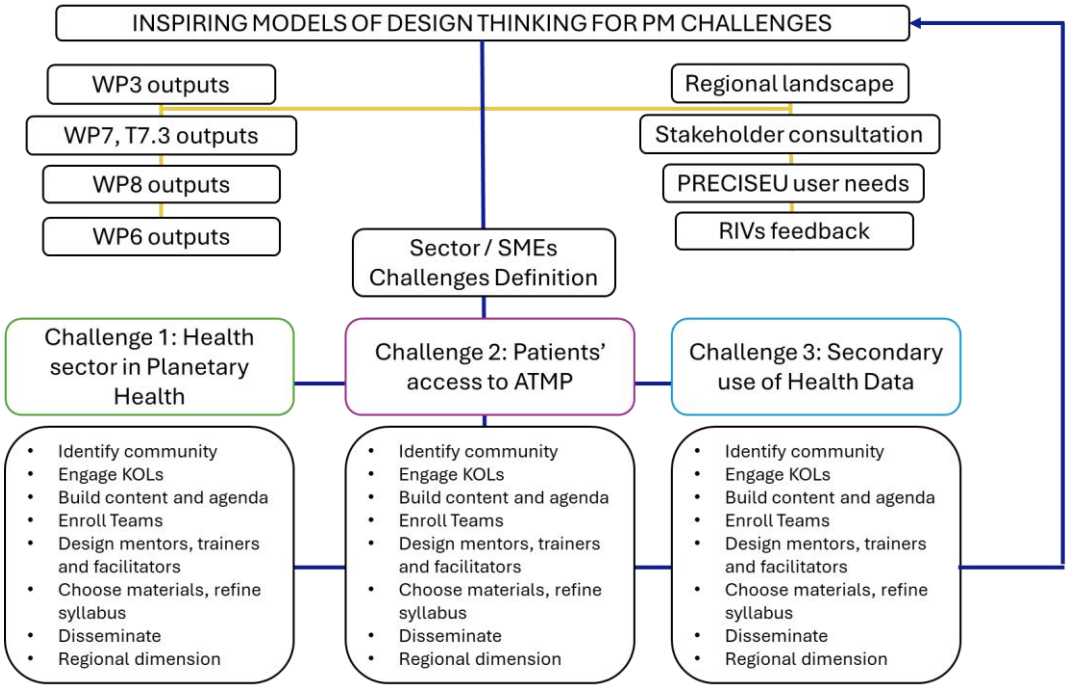

Fig 5. Summary of the design process followed for the DTPM program in PRECISEU

DESIGN

Initial considerations

The design thinking methodology offers a valuable approach for policy makers to better understand how innovative solutions are developed in healthcare. Following the inspiring Stanford's d·school, the program should focus on empathy and understanding user needs and iteratively prototype and test. With such a process, policymakers can create more effective and user-friendly healthcare policies and interventions. The program will apply some of the basic Design Thinking principles such as needs assessment to understand the problem and collaboratively build solutions to it. The main building blocks of the program, adapted to policymaking, are:

- **Empathy:** Understanding the needs and perspectives of patients, healthcare providers, and other stakeholders.
- **Problem Definition:** Clearly defining the specific healthcare challenges that need to be addressed is essential before brainstorming solutions.
- **Ideation:** Generating a wide range of potential solutions through brainstorming and collaborative workshops.
- **Prototyping and Testing solutions:** In the policy world, this means gathering feedback from stakeholders and identifying where there could be policy solutions or where there are policy barriers. In particular, the program will help create "prototypes" of policy solutions (such as service blueprints or policy simulations), test prototypes with stakeholders to gather feedback and iterate and refine policy solutions based on feedback.

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The program will engage diverse stakeholders throughout the process to ensure that sessions are inclusive and meet the needs of all those affected. Design thinking can lead to policies that are more effective, efficient, and aligned with the needs of the population, and by involving users in the design process, policies are more likely to be adopted and implemented successfully. Additionally, the design thinking program will foster a culture of innovation and encourage the development of creative solutions to complex healthcare challenges, and by identifying and addressing problems early, design thinking can help to reduce the costs associated with failed or ineffective policies.

From benchmark conducted on some existing programs and case studies using design thinking to address policymaking barriers, several lessons and best practices to be applied are:

- Collaborate with diverse stakeholders: Design thinking requires collaboration with citizens, stakeholders, and experts from various fields.
- Be open to experimentation and iteration: Design thinking is an iterative process that requires policymakers to be open to trying new approaches and refining them based on feedback.
- Use data and evidence to inform decision-making: Design thinking is not just about intuition; it's also about using data and evidence to inform decision-making.

Ecosystem adaptation

Understanding and effectively navigating regional ecosystems requires a comprehensive mapping of the various actors and their interconnections. This includes identifying businesses, government entities, research institutions, civil society organisations, and individual citizens, all of whom contribute to the region's dynamics. By evaluating the specific social, economic, and environmental challenges that define the territory—alongside its assets and areas for potential growth—stakeholders can begin to develop targeted, relevant strategies. Crucially, any analysis must take into account the cultural identity and values embedded in the region, as these elements profoundly influence decision-making and collaboration patterns.

The PRECISEU consortium is well prepared for this adaptation thanks to the following attributes:

1. Mapping performed at different levels:
    - Regional personalised medicine landscapes (WP3)
    - EHDS Maturity grid and factsheets at regional and national level (WP4)
    - ATMP landscapes (WP5)
    - Market access enablers and barriers (WP6)
    - Talent needs and gaps (WP7)
    - Health adoption and reimbursement (WP8)
2. In depth knowledge of ecosystems: the consortium includes representatives of regional authorities, healthcare and deep tech clusters, research infrastructures, industry players, patients and entrepreneurial networks capable of activating added value collaborations across the entire European landscape. PRECISEU teams are integrated by a set of remarkable experts, with extensive experience in overcoming the additional challenges related to data literacy and exchange, advanced diagnostics and therapies, business cases and market access for cutting-edge technologies, as well as expert

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organizations in the healthcare sphere who can facilitate patient involvement and the swift resolution of ethical, legal, and social issues within the PM domain.

Applying design thinking principles can significantly enhance regional development initiatives by fostering a more human-centred and participatory approach. This begins with empathy—engaging directly with stakeholders to deeply understand their perspectives, concerns, and aspirations through interviews, co-creation workshops, and other interactive methods. An iterative process that values experimentation, feedback, and adaptation allows solutions to evolve responsively. Central to this approach is collaboration: bringing together diverse actors to contribute their insights and expertise ensures that outcomes are not only innovative but also broadly supported. Ultimately, the emphasis on user-centred design ensures that policies and interventions are both relevant and effective for the communities they are intended to serve.

To be truly effective, design thinking must be adapted to the specific context of each regional ecosystem. Existing frameworks should be flexibly adjusted to reflect the region's unique size, complexity, and cultural traits. Local knowledge plays a vital role here, grounding solutions in lived experience and enhancing their legitimacy. Capacity-building efforts—including training and support—are essential to empower stakeholders to confidently apply design thinking methods. Monitoring and evaluation mechanisms should be embedded from the outset to track impact, enable course correction, and foster a culture of continuous improvement. By integrating strategies like transformative adaptation, circular economy principles, and smart specialisation, regions can strengthen their innovation ecosystems and promote sustainable, resilient development tailored to their distinct characteristics.

The first Pilot- Edition (2025) will be held in Catalonia. The following years the program will be adapted to Flanders (2026), Emilia Romagna (2027) and Sofia Region (2028).

Final design

Participants are expected to better understand innovation, help bridge the divide between personalized medicine stakeholders and policymakers and foster transformation within their institutions.

The main outputs would be shared in real policy-making environments.

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Fig. 6: this infographic summarises the Program main traits (teams' composition, themes/challenges, duration of the pilot and location of next editions).

Program structure and Content development

As mentioned, after consultations and discussions with the PRECISEU partners, the program in all its editions will be arranged around three main work topics: 1) Planetary health and health systems as active agents; 2) ATMPS: Innovative therapies for all; and 3) Health data for empowering and healing. Those three topics, aside from being relevant across Europe and in the context of PRECISEU, have different nuances and relevance in the participant regions. Thus, establish an overarching program focus whilst enabling an adapted outcome to the different realities of the regions.

The Barcelona pilot will be testing the implementation of the program content in two parts:

1) First two-week sessions providing attendees content on:

Design thinking	Before anything attendees will get familiar with the design thinking methodology, building blocks and principles
Regulatory and legal frameworks	Both European and local legal frameworks relevant for the topics will be presented by experts, offering also space to identify barriers and limitations. Additional international perspectives will be offered for consideration
Use cases	Specific use cases and success cases will be discussed

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Sessions are envisioned as presential. However, it is foreseen to enable a certain percentage of online participation to respond and adapt to working obligations and schedules of participants and enhance their engagement.

2) After these two weeks of joint training, work groups will be organized mixing profiles so that policymakers are collaborating with other stakeholders in the generation of a final policy paper or brief in relation with one of the main topics. The work group will be supported by mentors and communication enabled through the training section of the PRECISEU platform. It is foreseen to give participants a month or a month and a half to prepare the final training deliverable through group work. A closing event will be organized for the presentation of all work done to the local ecosystem actors.

Analysis and Improvement	Teams will analyse how the regulation the processes, their interpretation and implementation can become barriers or enablers to innovation.
International Perspective	Good practices as ARPA H, FDA or MHRA will be analysed and discussed. Patients will have their voice specially in these matters
Research and design	Teams will engage in a research work to ideate and produce “improved scenarios”, and they will test them and discuss them with stakeholders in the weeks following, as part of their research
Preparation of presentation	A closing event will be organized for the presentation of all work done to the local ecosystem actors in a regional Parliament commission or Administration unit related

Calendar

The Barcelona piloting program will be organized in the autumn of 2025, with the two-week training sessions taking place from late October to mid-November, and the work group lasting from late-November 2025 to January 2026. A final event will close the edition.
Future trainings will be initially planned on annual basis around the same period but adapted to the local setting characteristics.
Based on the work devoted to the pilot organization it is foreseen that local partners of future editions will require some months for preparation, engagement at the local ecosystem, identification and invitation of stakeholders, and implementation.

Program Attendees and Collaborative Teams

Participants are primarily policymakers who are actively involved in health decision-making organizations—such as public health authorities, government agencies, payers, regulatory bodies, and legislative institutions. The program specifically targets those positioned to shape or influence policies impacting the implementation of personalised medicine, to help them become familiar with the needs and solutions defined in the context of PRECISEU.

Enrolment is foreseen to be done by invitation, coordinated by local PRECISEU partners who identify suitable attendees through stakeholder mapping and direct outreach. The selection

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process aims for diversity in professional roles, geographic representation, and backgrounds, ensuring a broad spectrum of experiences and perspectives within each program edition.

Attendees will be experiencing the program methodology with other stakeholder profiles, analysing policies and regulations, as well as best practices, and immersing in the process of deep tech-based health innovation, with startups, entrepreneurs, professionals from the industry, infrastructures and research institutions representatives, patients, etc.

Throughout the program, attendees are expected to work collaboratively in project teams in the analysis of existing policies, the identification of gaps or barriers, and the prototyping of actionable solutions using the design thinking methodology. Teams will be deliberately mixed to bridge policymaking with innovation, clinical practice, and patient perspectives, maximizing relevance and creativity in policy outputs. This multi-actor, multidisciplinary team structure is central to the DTPM approach, fostering not only capacity-building but also the kind of ecosystem connectivity and systemic insight essential for transformative personalised medicine policy in Europe.

Trainers, mentors and facilitators

The program foresees to engage three major roles to accompany trainees in each edition.

Trainers: The program leverages trainers drawn from both the consortium's internal expertise and external leaders, such as Stanford Mussallem Biodesign Center specialists. Trainers provide core content on design thinking, regulatory frameworks, and policy best practices.

Mentors: Each team will be assigned at least one mentor—an expert familiar with both design thinking and health policy—who will offer guidance, supports problem-solving, and ensure application of the methodology to real-world policy challenges, and that will accompany during the work group period.

Facilitators: Dedicated facilitators will manage interactive group sessions, ensuring that workshops proceed smoothly and that all voices are heard in co-creation processes.

Local Experts and Guest Speakers: In each edition, local experts are engaged to provide context-specific insights, regional policy realities, and real-world use cases tailored to the program location.

Program Coordinators: Local partners responsible for logistics, participant support, communication, and collaborating with BIOCAT in the maintenance of the digital learning environment through the PRECISEU platform.

Program Committee: Involvement of Stanford Mussallem Biodesign Center: It is the intention of the consortium to invite experts of the center as members of a Program Committee to be created, including KOLs of the different ecosystems.

Communication: branding and campaigns

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To maximize impact and recognition across regions, the DTPM program will have a distinctive branding and communication strategy, in line with the overarching PRECISEU project identity. The branding will be flexible enough to allow adaptation to local contexts—for example, incorporating regional motifs, language variants, or imagery reflecting each host ecosystem—while maintaining a consistent core identity throughout all editions.

A branding guide will be produced, detailing logo usage, colour schemes, typographies, iconographies, tone of voice, and imagery. Communication toolkits will be developed in collaboration with WP2 and will include ready-to-use assets such as banners, digital signatures, presentation templates, program briefs, and region-specific factsheets, ensuring that all partners and local coordinators can easily implement and localize materials.

Dissemination campaigns

Specific campaigns will be developed for each edition in collaboration with both WP2 and local PRECISEU program coordinators, with the aim to generate awareness, enhance enrolment and engage stakeholders at each of the program settings.

Targeted Messaging: Content will highlight the program's relevance for local stakeholders, emphasizing the concrete benefits (capacity-building, policy innovation, cross-sectoral networking) tailored to each ecosystem's interests and challenges.

Multichannel Outreach: Campaigns will leverage digital channels (website, social media, and targeted mailings) and on-site promotional activities at key ecosystem events or partner institutions.

Localized Adaptations: Where needed, materials will be translated and culturally tailored, ensuring resonance and clarity for regional audiences.

Engagement Touchpoints: Regular updates, visual storytelling, testimonials from alumni and trainers, and interactive content will help maintain momentum and participant engagement throughout the program lifecycle.

Measurement and Iteration: Communication efforts will be monitored for reach and effectiveness (engagement metrics, participant feedback, social media analytics), with insights used to refine both campaign tactics and visual identity for future editions.

IMPLEMENTATION

Enrolment and engagement

The program initial approach prioritizes a targeted, relationship-based approach to enrolment and engagement, including:

1) An initial selection of participants carried out through invitation, with local PRECISEU partners leading one-on-one and targeted communications within their regional ecosystems. This hands-on outreach will both raise awareness of the program and ensure that selected attendees

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possess the relevant background and commitment, while also allowing partners to fine-tune details of program delivery to suit local realities.

2) To further boost engagement and understanding, tailored communication materials—both online and offline—will be created, adapting language and emphasis as needed to resonate with each region's stakeholders and clearly articulate the tangible benefits of participation for individuals and their broader organizations.

3) Continuous engagement of both participants and trainers will sustained throughout the program via dedicated communications, reminders, and streamlined access to resources and updates made available through the PRECISEU platform.

Registration and trainees' management

The pool of trainees identified in collaboration with local policymaking entities, local governments and regulatory organizations will be invited to the training program, providing all relevant information about content, sessions, materials, calendar, and relevance for them through targeted messages and communications.

Once they agree to register, a simple registration form will be filled in and they will be granted access to the PRECISEU platform training section, where they will be able to consult all relevant materials and resources, venue, as well as trainers, mentors, facilitators and co-participants. Details on calendar, expected deliverables and workload required to complete the program will be also facilitated.

PRECISEU Platform: educational materials and Alumni community

The PRECISEU Platform will have a specific training module where trainers and trainees will be able to access all program related content and information before, during and after their edition. Upon completion of the edition, and as the program grows the platform will provide the possibility to network and interact with the alumni community. Alumni will be invited to follow the final event of the different editions via online attendance whenever possible.

Quality, GEDI and ethics assurance

Quality assurance measures will be implemented in all editions, with the use of evaluation surveys to assess trainers, program, supporting materials and PRECISEU platform, as well as to get feedback on attendees' experiences and suggestions for improvement.

Open science principles and ethic surveillance will be implemented by Biocat in close collaboration with the different local program coordinators in each edition.

FINAL EVENT ORGANISATION

Each edition of the program will have a final event, to be organized by the local program coordinators in close collaboration with the stakeholders in their ecosystem. The event will aim at providing a public presentation of the final deliverables developed by each of the participating teams (ranging from policy briefs to actionable guidelines). The event will have an opening section (with the participation of the local PRECISEU partners and local policymaking

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stakeholders), an introduction by one of the program trainers or keynote speakers, a presentation by each of the program teams presenting its results and a closure from the PRECISEU consortium. The European Commission, local and international stakeholders and PRECISEU members will be invited to attend in addition to the program participations, trainers, mentors and facilitators. Communication and disseminations resources and actions will be specifically developed to support each event.

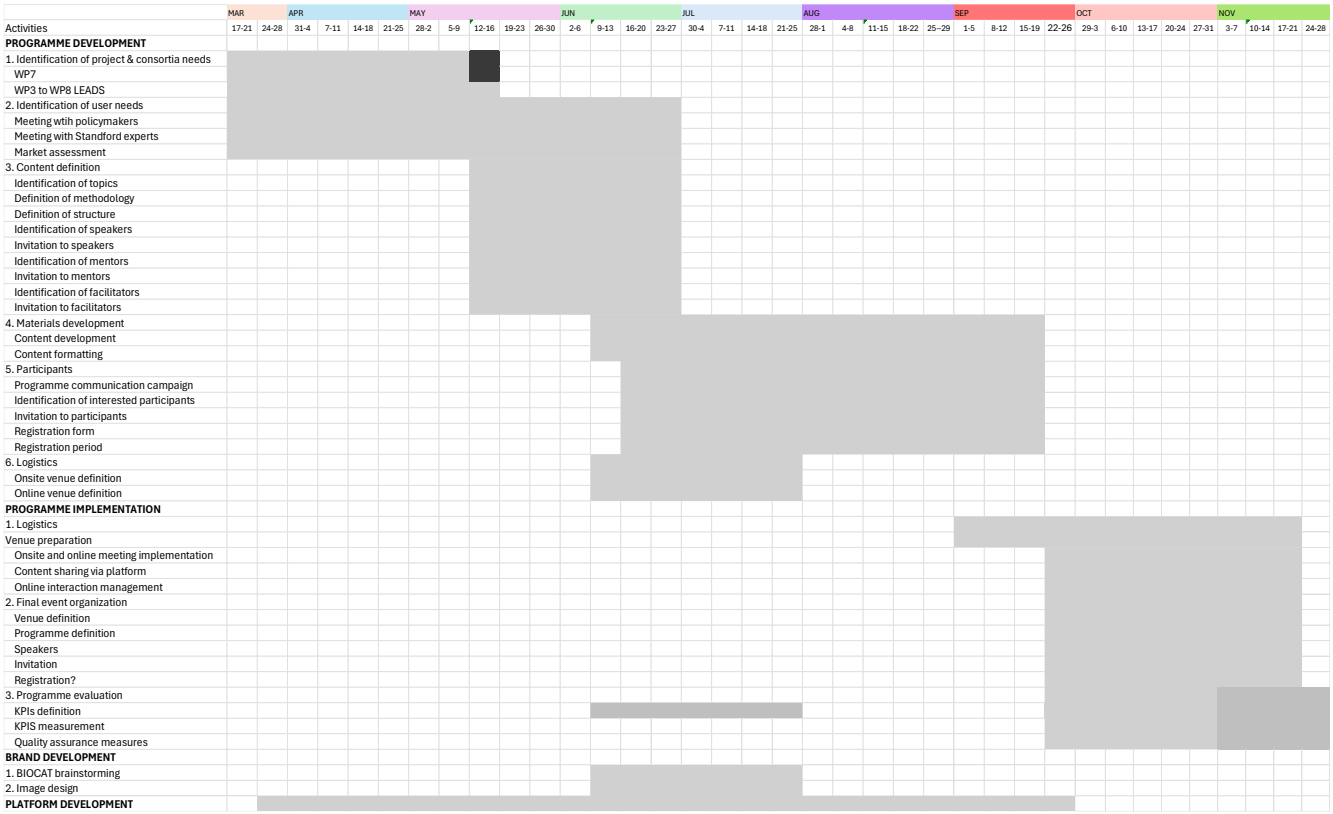

Fig 7: Implementation calendar for the different phases of the pilot program in Catalonia, the first region to test the T7.4 task.

SUSTAINABILITY OF THE MODEL AND PROGRAM EVALUATION

The program has been designed understanding the limitations of enrolling a diverse team of stakeholders in a cocreation activity where the final purpose is to overcome barriers of diverse nature and hampering the advancement of innovation. Additionally, the novelty of the program and the lack of consolidated models will make its difficult sustainability difficult in its first iterations. The risks to the sustainability plans are related to

- Target groups addressed
- Lack of consolidated models
- Regional particularities
- Novelty of the program in the regions where it will be implemented
- Reduced funds availability

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However, the challenges addressed, the interest of the industry to overcome the barriers and the ongoing engagement of key opinion leaders allow for optimism on the opportunities to make the program sustainable on the long run. Nonetheless, the consortium decided to make the program a PRECISEU program for the duration of the process, and the authors of this design will consider the regional implementation according to the outcomes of it.

To evaluate the success, several measures and KPIs will be considered

- Time necessary to compose the teams
- Satisfaction of participants
- Easiness to enrol relevant mentors
- Engagement of Administration and regional authorities
- Success in generating research pieces
- Possibility to present the outcomes in an actual policymaking environment
- Interest raised from other regions
- Success in the selection of the challenges
- Interest to include the program in policymaking trainings
- Possibility to include other subjects
- Possibility to implement the whole process in the same region for a second time
- Possibility to raise additional funds
- Interest from the industry
- Alumni cohorts becoming trainers
- Connection to other large initiatives

NOTE:
At the moment of submitting this deliverable, the preparation of the program is in process, as the calendar needed to be delayed due to accumulation of events within the project. As a consequence, the engagement of the different teams and participants, the elaboration of contents and other specifications and technical details are under construction.

Final words

According to the OECD, "Design thinking, considered as the parallel creation of a thing and its way of working (see Dorst, 2011), pushes policy decision-making towards 'a fundamentally creative form of deliberation, which operates with different decision processes to those of rational choice"[15]

[15] https://www.oecd.org/en/publications/systemic-thinking-for-policy-making_879c4f7a-en.html

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