



PRECISEU

HANDBOOK ON TRAINING

Deliverable 7.1

31/07/2025

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Project information	
Project title	PeRsonalised medicine Empowerment Connecting Innovation ecoSystems across EUrope
Acronym	PRECISEU
Project URL	https://cordis.europa.eu/project/id/101161301
Grant Agreement n.	101161301
Call	HORIZON-EIE-2023-CONNECT-03
Call Topic	HORIZON-EIE-2023-CONNECT-03-01 - Implementing co-funded action plans for connected regional innovation valleys
Type of Action	HORIZON-COFUND - HORIZON Programme Cofund Actions
Project start/end date	01/07/2024-30/06/2029
Project duration	60 months
EU Project officer	Christina Nanou (EISMEA)
Project coordinator	Montse Daban (Biocat)
Project manager	María Cejas (Biocat)

Deliverable information	
Deliverable n.	7.1
Work package n.	WP7. Training and Cultural Change
Deliverable title	Handbook on training
Lead beneficiary	HLSC
Participants	HLSCB, DIZNE, Biovia, Eatris
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Submission date	31/07/2025
Due date	31/07/2025
Document status	Final
Document version number	1
Document type*	R (REPORT)
Dissemination level	Public

CONSORTIUM PARTNERS

	Name of the Entity	Acronym	Role	Country
1	BIOCAT LA FUNDACIO BIOREGIO DE CATALUNYA	BIOCAT	COO	ES
2	DEPARTAMENT DE SALUT - GENERALITAT DE CATALUNYA	SALUT	BEN	ES
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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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HOW TO CITE THIS DOCUMENT

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ABBREVIATIONS AND ACRONYMS

Acronym	Meaning
AI	Artificial Intelligence
AWP	Annual Work Plan
D#. ##	Deliverable (e.g. D7.1 = deliverable 7.1)
DMP	Data Management Plan
EATRIS	European Infrastructure for Translational Medicine
EHDS	European Health Data Space
EISMEA	European Innovation Council and SMEs Executive Agency
ELSI	Ethical, Legal, and Social Implications
EU	European Union
FAIR	Findable, Accessible, Interoperable, and Reusable (data)
GAM	General Assembly Meeting
GEDI	Gender Equality, Diversity and Inclusion

GDPR	General Data Protection Regulation
HLSCB	Health and Life Sciences Cluster Bulgaria
IC PerMed	International Consortium on Personalised Medicine
IP	Intellectual Property
IR	Internal Report
KPI	Key Performance Indicator
M#	Month Number (e.g. M13 = month 13)
Ms	Milestone
PM	Personalised Medicine
PMS	Personalised Medicine School
PoP	Platform of Platforms (Bulgaria)
RIS	Research and Innovation Smart Specialisation
RIS3	Research and Innovation Smart Specialisation Strategy
RIVs	Regional Innovation Valleys
RRI	Responsible Research and Innovation
RP	Reporting Period
S3	Smart Specialisation Strategy
SC	Steering Committee
SG	Strategic Group
SKG	Stakeholders Group
SME	Small and Medium-sized Enterprise
SRIA	Strategic Research and Innovation Agenda
T#. #	Task (e.g. T7.4 = task 7.4)
WP	Work Package



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1. BACKGROUND INFORMATION

1.1 About PRECISEU PM School Handbook

This Handbook constitutes **Deliverable 7.1** under **Work Package 7 (Training and Cultural Change)** of the PRECISEU project. It captures the design, implementation, and cumulative insights from the **eight editions of the PRECISEU Personalised Medicine (PM) School**, conducted across the project's lifecycle. More than a record of events, this deliverable serves as a strategic and transferable **knowledge resource**—demonstrating how decentralised, regionally embedded training initiatives can advance a **connected, inclusive, and innovation-driven European ecosystem for personalised medicine**.

The PM Schools were conceived under **Task 7.3** as flagship training and engagement platforms. Each edition was co-designed with regional hosts and aligned with the Smart Specialisation Strategies (S3), ecosystem maturity, and stakeholder needs of the host region. Locations included **Romania, Sweden, Bulgaria, and Spain (Barcelona)**, with further editions to be adapted in response to project evolution. Regional partners, including HLSCB, DIZNE, Biocat, ImagoMol, ACCIÓ, PoP, Salut, BioRN, and the Innovation Agency Lithuania, led the in-person delivery. At the same time, strategic contributions from European networks, such as EATRIS and Biovia, as well as Digital Innovation Hubs, enriched the programme through hybrid participation.

The PM Schools served several interrelated objectives. They provided modular, hands-on training to enhance both individual and institutional capacities in applying personalised medicine approaches. They promoted the exchange of experience, methods, and best practices across regional and national boundaries. They also served as dynamic platforms for dialogue among clinicians, researchers, entrepreneurs, students, policy actors, and representatives from civil society. Sessions covered a broad range of evolving topics—from omics and data governance to artificial intelligence, regulatory frameworks, market access, and regional innovation strategies—delivered through lectures, co-creation workshops, policy roundtables, study visits, and interactive networking activities.

A defining strength of the PM Schools was their integration with other components of the PRECISEU project. Close coordination with Task 7.1 enabled the systematic collection and integration of session materials and learning content into a shared digital repository, strengthening long-term impact and accessibility. Under Task 7.2, award-winning regional practices were featured as case studies during School sessions, reinforcing peer learning and cross-regional visibility. The PM Schools also served as a living lab for Task 7.4, where policymakers engaged with design-thinking methodologies and directly contributed to the co-creation and validation of policy tools such as the Biodesign Policy Guidelines.

The PM Schools also played a key role in disseminating and contextualising findings from other work packages. WP3 contributed expertise in data interoperability, cybersecurity, and European data governance; WP4 introduced case studies and regulatory insights related to advanced therapies; WP5 and WP6 provided frameworks for business modelling, innovation transfer, and impact evaluation; and WP8 leveraged the PM Schools as a vital platform for communication, engagement, and ecosystem-building. This cross-WP synergy ensured that the PM Schools were not isolated events, but integral,

operational nodes in the broader PRECISEU architecture—linking technical outputs with real-world applications and stakeholder practices.

By capturing the structure, content, participant feedback, and lessons learned from all eight editions, this Handbook offers a comprehensive account of implementation while also serving as a foundation for replication. It provides practical tools, adaptable formats, and strategic insights that can be reused by regional innovation actors within and beyond the PRECISEU network. It also contributes directly to reducing territorial disparities in the uptake of personalised medicine, strengthening cross-border knowledge flows, and building sustainable training infrastructures aligned with European values of equity, cohesion, and open innovation.

The PRECISEU PM School Handbook is not only a retrospective deliverable, but a forward-looking asset. It offers a model for how regionally embedded training can foster long-term system transformation in healthcare innovation, policy integration, and capacity building—ensuring that the knowledge generated within the project continues to grow and evolve well beyond its formal conclusion.

1.2 Overall Objective

The overall objective of the PRECISEU PM School initiative will be to **strengthen regional capacities and European collaboration in the field of personalised medicine** through targeted, inclusive, and practice-oriented training. By offering eight editions across diverse European regions, the PM Schools aimed to equip a wide range of stakeholders—from healthcare professionals and researchers to policymakers, entrepreneurs, and civil society actors—with the knowledge, tools, and connections necessary to design, implement, and sustain innovation in personalised healthcare.

The PM Schools served as a key instrument within Work Package 7 (WP7) of the PRECISEU project, supporting the broader mission to reduce fragmentation, promote responsible innovation, and advance the integration of Smart Specialisation Strategies in the health sector. The initiative emphasised regional anchoring, cross-sector engagement, and EU-level alignment—thereby creating an agile and replicable model for **ecosystem-driven capacity building** in personalised medicine across Europe and beyond.

1.3 Specific Objectives

Building on the overarching goal of advancing regional capacity and European collaboration in personalised medicine, the PRECISEU PM Schools pursued a set of specific objectives that guided the design, delivery, and evaluation of all eight editions:

1. **Enhance stakeholder knowledge and skills:** To provide targeted training on key topics in personalised medicine—including health data governance, digital tools, AI, advanced therapies, ethics, and regulatory frameworks—tailored to the needs of diverse stakeholder groups.



2. **Support Smart Specialisation implementation:** To align training content with regional Smart Specialisation Strategies (S3) and reinforce the capacity of innovation ecosystems—especially in moderate and emerging regions—to integrate PM into regional development planning.
3. **Foster multi-stakeholder and cross-sector dialogue:** To create an inclusive platform for researchers, clinicians, policymakers, entrepreneurs, patient organisations, and citizens to exchange perspectives, co-create solutions, and build a shared language for innovation in PM.
4. **Bridge regional and EU-level innovation efforts:** To ensure that local and regional initiatives are connected to broader European policy frameworks, funding opportunities, and technical infrastructures, enhancing scalability and coherence across levels.
5. **Promote ethical, inclusive, and gender-responsive innovation:** To embed ethical reflection, gender sensitivity, and social responsibility into the learning environment and content of each School edition, ensuring equitable access and long-term societal impact.
6. **Facilitate uptake of PRECISEU outputs:** To use the PM Schools as a platform for disseminating, testing, and adapting outputs from other project work packages—such as award schemes (WP7.2), policymaker training tools (WP7.4), and evidence from WP3–WP6.
7. **Build lasting partnerships and networks:** To initiate and strengthen regional, national, and cross-border networks for personalised medicine by connecting stakeholders during the training and encouraging follow-up collaboration.

2. METHODOLOGY

The methodology underpinning the design, implementation, and documentation of the PRECISEU PM School series reflects the project’s commitment to flexibility, co-creation, and cross-sectoral integration. Grounded in the objectives of Work Package 7 and aligned with the broader logic of Horizon Europe, the approach combines strategic planning, participatory design, iterative learning, and structured feedback mechanisms.

The initial phase involved a mapping exercise to identify regional capacities, thematic gaps, and stakeholder needs across the PRECISEU network. A partner-wide survey was conducted to gather input on preferred host regions, suggested themes, delivery formats, and expected outcomes. This consultation informed the strategic allocation of School editions, ensuring a balance between innovation-leading and moderate/emerging regions, and enabling alignment with Smart Specialisation Strategies (S3) and regional innovation agendas.

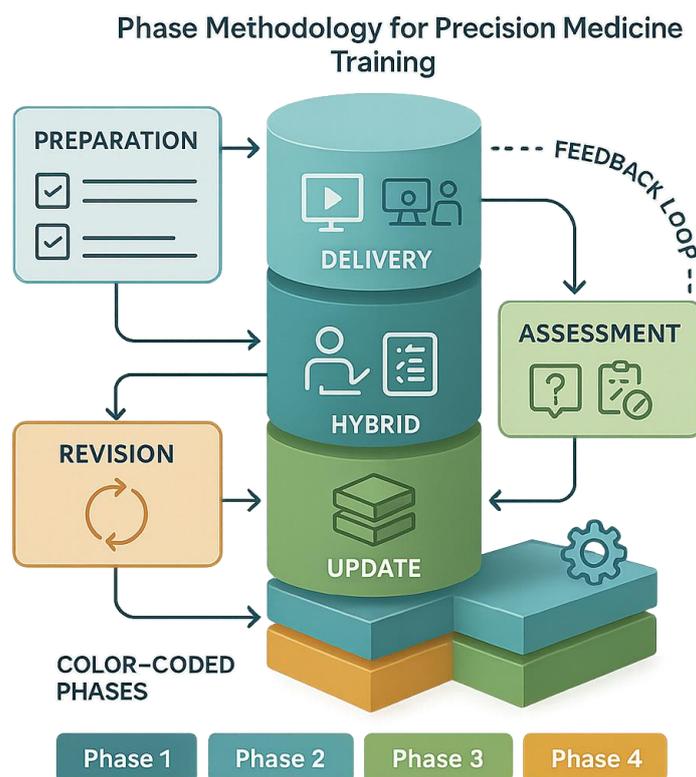
Each PM School was co-developed in partnership with local host institutions and regional stakeholders. Planning committees—consisting of representatives from Work Package 7, the host region, and relevant technical WPs—collaboratively defined the content, format, and target audiences. This co-design approach allowed the programme to reflect both the regional context and project-wide priorities, ensuring local ownership while maintaining coherence with the overarching PRECISEU framework.

The PM Schools followed a modular and adaptive format, combining core themes with regionally relevant focus areas. Programme components included expert lectures, case-based sessions, study

visits, interactive workshops, innovation showcases, and policy roundtables. Wherever possible, content from other Work Packages (e.g. WP3 on health data, WP4 on ATMPs, WP5 on business models, and WP6 on evaluation) was integrated to ensure knowledge circulation and reinforce cross-WP alignment.

Hybrid formats were used to maximise accessibility and inclusion, particularly for stakeholders from associated countries such as Ukraine. Simultaneous translation, digital access, and real-time facilitation tools were employed to ensure meaningful participation. In-person editions were augmented by online sessions, and recorded materials were made available through the shared training repository developed under Task 7.1.

Evaluation was embedded throughout the process. Each edition included pre- and post-event reflection surveys, informal feedback rounds, and debriefing sessions with organisers, speakers, and participants. Insights were systematically collected and analysed to refine subsequent editions, improve content quality, and adjust formats in response to participant needs and contextual developments. These findings are documented in the present Handbook and have contributed to the evolution of PRECISEU’s broader training and engagement model.



Explanation of the Complex Methodology Infographic for PRECISEU PM Schools

The complex methodology infographic visually maps out the multi-phase, iterative process underlying the design, implementation, and continual improvement of the PRECISEU PM School series. Each component is designed to communicate not only the sequence of steps but also their interconnections

and the cyclical, evolving nature of the programme. Below are the main elements represented in the graphic:

Initial Needs Assessment & Mapping: The methodology begins with a comprehensive needs assessment and mapping phase. In this stage, project partners systematically collect and analyse data on regional capacities, strengths, innovation gaps, and the specific needs of stakeholders. Various tools—such as surveys, stakeholder interviews, and data analysis—are employed to gain a nuanced understanding of the landscape across the PRECISEU network. This foundational work ensures that subsequent activities are evidence-based and tailored to the unique characteristics of each region.

Stakeholder Engagement & Co-creation: Building on the insights from mapping, the process moves into deep stakeholder engagement. Here, diverse regional actors are brought together through planning committees, workshops, and collaborative sessions. This co-creation model actively involves representatives from partner institutions, relevant work packages, and local stakeholder groups in shaping the programme content, delivery format, and anticipated outcomes. Through ongoing dialogue and collective decision-making, ownership is fostered, ensuring the programme resonates with both local priorities and the broader project vision.

Strategic Allocation & Modular Programme Design: After initial engagement, strategic allocation and programme design take centre stage. The structure is both flexible and modular, with key curriculum elements adapted to meet regional contexts and thematic needs identified earlier. The allocation of school editions, selection of core and region-specific modules, and customisation of programme pathways are all guided by these strategic choices. This phase ensures the balanced inclusion of both standardised content and innovative, locally relevant components.

Implementation via Hybrid Delivery: Next, the programme is implemented using a hybrid delivery model. This approach combines in-person and virtual formats to maximise accessibility and participation, especially for geographically distant or underrepresented regions. Sessions may include live translations, digital facilitation tools, and the use of a centralised training repository for online resources. This hybrid system bridges physical and digital engagement, widening the reach and impact of the PM School.

Integration of Cross-cutting Themes: A distinguishing feature of the methodology is the seamless integration of cross-cutting themes and knowledge from related work packages. Flows and connections are established between programme modules and thematic areas (such as health data, ATMPs, business models, and evaluation), enabling participants to benefit from holistic and interdisciplinary learning. This ensures the dynamic circulation of knowledge, fostering collaboration and innovation across the project ecosystem.

Embedded Evaluation & Feedback Loops: Evaluation processes are embedded throughout each phase. Continuous feedback is solicited via pre- and post-event surveys, informal check-ins, and debriefing sessions. These mechanisms are depicted as interconnected loops, symbolising the ongoing collection, analysis, and utilisation of feedback. Insights gleaned from evaluation are systematically fed back into programme planning, supporting real-time course correction and responsiveness to participant needs.

Integration of Cross-Cutting Work Package Themes: A distinctive feature of the PRECISEU PM School methodology is the intentional integration of cross-cutting insights and content from key technical Work Packages, ensuring that participants gain a holistic understanding of the digital precision and personalised medicine (DPPM) landscape. From **WP3**, the Schools incorporate essential knowledge on health data interoperability, federated infrastructures, and GDPR-compliant innovation practices—crucial for shaping data-literate professionals and responsible digital health adoption. **WP4** contributes content on advanced therapy medicinal products (ATMPs), covering readiness levels, regulatory considerations, and integration into clinical innovation pathways. **WP5** informs modules on business model design, public-private collaboration, and value-based innovation strategies, equipping participants with tools to translate research into scalable, market-ready solutions. Lastly, **WP6** underpins the training programme’s evaluation logic by embedding performance indicators, participant feedback tools, and impact tracking mechanisms. Together, these cross-WP contributions ensure that the PM School curriculum is not only multidisciplinary but also directly aligned with PRECISEU’s systemic objectives, fostering actionable knowledge and long-term capacity across regions.

Iterative Improvement & Knowledge Sharing: Finally, the methodology emphasises iterative improvement and knowledge sharing. Lessons learned from each PM School edition are documented, analysed, and disseminated through handbooks, digital repositories, and internal briefings. The process forms a continuous learning cycle, with best practices and innovations shared across the PRECISEU network. This cyclical model ensures that the training programme evolves in step with changing contexts, stakeholder expectations, and emerging opportunities.

The PRECISEU PM School methodology ensures tailored, impactful training by combining thorough regional needs assessment with deep stakeholder collaboration. Its modular and hybrid design enables both core consistency and local relevance, making programmes accessible and engaging for diverse audiences. Integrated cross-sectoral themes and continuous feedback loops drive ongoing improvement and innovation, while alignment with strategic priorities maximizes both regional and broader European impact.

3. TRAINING MODEL

The training model of the PRECISEU PM Schools is designed to be **modular, flexible, inclusive, and ecosystem-oriented**, responding to the complex, multi-actor challenges of implementing personalised medicine across European regions. The model combines theoretical grounding with hands-on engagement, facilitating the transfer of knowledge, the exchange of good practices, and the co-creation of locally relevant solutions.

3.1 Modular Content Framework

Each School edition will be built around a core structure that can be adapted to regional needs and thematic priorities. The core modules include:

- Introduction to personalised medicine and its systemic implications

- Health data infrastructure, AI applications, and digital transformation
- Translational pathways and value-based health innovation
- Regulatory and ethical considerations in PM
- Stakeholder engagement, S3 alignment, and policy integration

Elective modules or region-specific deep dives will be added depending on local strengths (e.g., biotechnology in Barcelona, cybersecurity in Bulgaria, or policy labs in Romania).

3.2 Hybrid and Inclusive Delivery

The model enabled **hybrid participation**—combining in-person, online, and recorded formats—to allow broad access across geographic and institutional boundaries. Real-time translation and online facilitation will be included where necessary (e.g., for Ukrainian participants), thereby removing barriers related to language and mobility.

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3.3 Experiential and Role-Based Learning

The PM Schools will be grounded in **experiential learning** approaches, including:

- Study visits to hospitals, innovation hubs, or research labs
- Role-based simulation workshops (e.g., policymaker roundtables, ethical scenario debates)
- Peer-to-peer case sharing and guided group work
- Hands-on tools for S3 mapping, business model innovation, or policy design

These formats ensured that learning will be actionable and tailored to participants' roles in their ecosystems.

3.4 Multi-Stakeholder Co-Creation

Sessions will be deliberately designed to **mix with stakeholder groups** (academia, healthcare providers, SMEs, policymakers, patient organisations, and civil society actors), encouraging dialogue and collaboration between clinicians, data scientists, policymakers, SMEs, students, and patients. Several editions featured co-creation labs or innovation cafés, where participants jointly explored solutions to real regional challenges.

3.5 Scalable and Transferable Format

The training model will be structured to be **replicable** in other contexts. By documenting each edition's methodology, content, and results, PRECISEU developed a reusable training framework that can be adapted by other regions, Digital Innovation Hubs, or educational institutions post-project.

Through this dynamic and participatory training model, the PM Schools supported the emergence of skilled, networked, and policy-aware communities capable of accelerating personalised medicine at both regional and European levels.

3.6 Co-Design Approach

Each PM School edition will be developed in close collaboration with local and regional partners, building on Smart Specialisation Strategies (S3), institutional capabilities, and ecosystem needs. The co-design process included topic selection, partner mapping, speaker identification, and logistics planning. This ensured that each edition will be not only relevant to local challenges but also linked to broader European health innovation goals.

3.7 Integration with PRECISEU Work Packages

The methodology will be tightly aligned with other PRECISEU tasks and WPs. Content from WP3 (AI/data), WP4 (therapies), WP5 (economics), WP6 (impact), and WP7.2/7.4 (awards and policy) will be embedded into the sessions, case studies, and discussion formats. This ensured that the schools will be not isolated events but part of a broader learning and policy ecosystem.

3.8 Continuous Feedback and Iteration

Participant feedback will be gathered through surveys and informal reflection sessions after each edition. This input will be used to adapt the content, improve facilitation methods, and shape future editions. Reporting templates ensured consistent documentation of learning outcomes, stakeholder input, and organisational lessons.

4. PRECISEU PM SCHOOL

4.1 Calendar and locations

Throughout the PRECISEU project, eight editions of the Personalised Medicine (PM) School will be organised between 2025 and early 2028. Each edition is designed to address regional challenges and opportunities while contributing to a shared European vision for capacity-building in personalised medicine. Sessions will be developed collaboratively with local, regional, and European partners, and delivered in hybrid or in-person formats to maximise accessibility and engagement.

The PM Schools are not predefined in content or structure. Instead, the model prioritises flexibility and responsiveness—tailoring agendas to the needs, priorities and maturity of the host ecosystems, while ensuring strong alignment with the overarching goals of PRECISEU. Sessions will include expert lectures, study visits, interactive co-creation labs and policy dialogues, with all materials made openly accessible through the project's digital repository.

Each edition is co-designed with direct input from relevant Work Package leads, ensuring integration with both technical (WP3–WP6) and policy-oriented activities (T7.2, T7.4). To enhance multi-sectoral relevance, editions are also aligned with local innovation agendas and Smart Specialisation priorities. The timing and locations of upcoming editions may be further refined based on ecosystem readiness and partner consultations.

The inaugural edition, held in Iași, Romania (July 7–11, 2025), successfully tested this approach. Organised in a hybrid format, it brought together diverse stakeholders from healthcare, academia, policy and industry, and validated the core components of the integrated training model developed under Task 7.3. Key lessons and best practices include:

- **Co-designed curricula** aligned with regional priorities fostered relevance and stakeholder ownership.
- **Hybrid format with recorded sessions** enhanced accessibility and created a reusable training resource.
- **Cross-sector networking formats** such as innovation breakfasts and roundtables built durable local linkages.
- **Operational insights** (e.g. pacing, logistics, and seasonal scheduling) highlighted key areas for improvement.
- **Thematic framing and facilitators** helped ensure coherence and energy across the full programme.

These findings confirmed the importance of keeping future editions agile and user-informed, using continuous feedback loops rather than fixed agendas. Subsequent PM Schools will retain this collaborative and iterative design approach.

Informed by the pilot edition, future events will be scheduled in spring and autumn, avoiding common periods of reduced attendance in summer and winter due to holidays or institutional closures. This strategy maximises participation from key stakeholder groups including healthcare professionals, researchers, policymakers, patient representatives and entrepreneurs, helping ensure both reach and impact.

To support the strategic roll-out of the series, the coordination team conducted a dedicated survey across partners and host regions. The consultation helped identify thematic priorities, institutional capacities and ideal timelines, resulting in the following preliminary plans:

- **November 2025 – Sweden:** Thematic focus on Nordic excellence in biobanking and gender-sensitive innovation. Co-designed with WP leads to ensure cross-WP integration and learning.
- **June 2026 – Bulgaria:** Organised alongside the PRECISEU General Assembly and the Spinoff Conference to enhance visibility and partner engagement.

These plans reflect the project's commitment to flexibility, relevance and cross-WP collaboration. Anchoring each edition in regional strengths and aligning them with ongoing project activities ensures that the PM School remains a high-impact, strategic pillar of PRECISEU's mission.

4.2 Learning outcomes

Participants in the PRECISEU Personalised Medicine (PM) Schools gain a range of valuable learning outcomes that reflect the program's commitment to interdisciplinary, participatory, and practice-

oriented training. These outcomes ensure that graduates are better equipped to support and drive innovation in personalised healthcare within their professional and institutional environments.

Core Learning Outcomes

- **Systems Understanding of Personalised Medicine:** Graduates develop a holistic grasp of PM, recognizing it as an evolving paradigm integrating health data, genomics, AI, clinical practice, and policy. They can articulate the wider implications of personalised medicine for innovation at both regional and health system levels.
- **Familiarity with European Policies and Frameworks:** Participants build awareness of key European Union strategies, funding mechanisms (such as Horizon Europe, EU4Health, and Digital Europe), and regulatory instruments (GDPR, EHDS, AI Act) that shape the landscape for PM implementation.
- **Cross-Sector Communication and Stakeholder Engagement:** The program emphasizes collaborative skills—enabling participants to communicate effectively across disciplines and sectors. Graduates are adept at engaging with policymakers, researchers, SMEs, and patient organizations to co-design and implement PM initiatives.
- **Practical Tools and Insights:** Through exposure to real-world case studies, ethical frameworks, data governance models, and innovation tools, participants gain actionable skills for decision-making, policy design, and solution development. Interactive components, such as workshops and roundtables, ground learning in practical experience.
- **Commitment to Responsible and Inclusive Innovation:** The training fosters heightened awareness of ethical, legal, gender, and equity issues. Graduates understand the importance of designing and implementing PM strategies that are socially responsible and inclusive, especially for underserved or emerging regions.
- **Integration into a European PM Network:** Graduates become part of an active community of practice, opening pathways for continued collaboration, knowledge exchange, and joint advocacy for personalised healthcare innovation across Europe

4.3 Entry Profile and Exit Profile

The **entry profile** for participants in the PRECISEU PM Schools will be intentionally broad and inclusive, reflecting the multidisciplinary nature of personalised medicine and the project's mission to build capacity across Europe's diverse health and innovation ecosystems. Each edition welcomes individuals from a wide spectrum of professional backgrounds, institutions, and regions, with a strong emphasis on cross-sector dialogue and ecosystem relevance.

Participants typically included:

- **Healthcare professionals** (clinicians, geneticists, public health experts) seek to integrate personalised approaches into care delivery.
- **Researchers and academics** working in biomedical sciences, health economics, bioinformatics, AI, or digital health.

- **Policymakers and regional authorities** engaged in Smart Specialisation Strategies (S3), innovation policy, health system design, or EU programme implementation.
- **Entrepreneurs and SMEs** developing digital health solutions, diagnostics, or biotechnologies relevant to personalised medicine.
- **Patient organisations and civil society representatives** advocating for ethical, inclusive, and accessible innovation.
- **Students and early-career professionals** with an interest in future roles in health innovation, policy, or translational research.

In selecting participants, the PRECISEU team aimed to ensure **geographic balance**, with special attention to **RIS (Research and Innovation Smart Specialisation) regions**, underrepresented areas, and stakeholders from associated countries, including Ukraine. Efforts will be also made to achieve **gender balance**, cross-generational diversity, and institutional variety.

No specific academic degree or level of experience is required. Instead, the main selection criteria are:

- **Relevance of motivation** to the edition's thematic focus
- **Potential to apply or disseminate learning** in a professional or institutional context
- **Willingness to engage** in dialogue, share insights, and participate actively in sessions

Upon completion of a PRECISEU PM School edition, participants emerged with an enhanced **capacity to understand, engage with, and apply personalised medicine (PM) concepts** in their professional and institutional contexts. The **exit profile** reflects the targeted learning outcomes and competencies developed through the PM Schools' interdisciplinary, participatory, and practice-oriented approach.

Graduates of the PM School will be expected to demonstrate the following capabilities:

- **Systems understanding of personalised medicine:** A holistic grasp of PM as an evolving paradigm that intersects health data, genomics, AI, clinical practice, and policy. Participants could articulate the systemic implications of PM for regional innovation and health system reform.
- **Familiarity with European policies and frameworks:** Awareness of relevant EU strategies, funding mechanisms (e.g. Horizon Europe, EU4Health, Digital Europe), and regulatory developments (e.g. EHDS, GDPR, AI Act) related to the implementation of personalised healthcare.
- **Cross-sector communication and stakeholder engagement:** The ability to collaborate across disciplines and sectors—communicating effectively with policymakers, researchers, SMEs, and patient organisations to co-design PM initiatives or projects.
- **Practical insights and tools:** Exposure to real-world case studies, ethical frameworks, health data models, and innovation tools that support decision-making, policy design, or solution development in PM contexts.

- **Commitment to responsible and inclusive innovation:** A heightened awareness of ethical, legal, gender, and equity considerations in the development and implementation of personalised medicine, including challenges in underserved or emerging regions.
- **Integration into a growing European network:** Participation in a dynamic and supportive community of practice committed to shaping the future of PM in Europe, with opportunities for continued exchange, project collaboration, and joint policy advocacy.

Graduates received a **Certificate of Participation**, and in some editions, will be invited to contribute to follow-up activities (e.g. mentoring, policy labs, stakeholder panels, or WP7.2 award initiatives). The PM School experience will be intended to not only strengthen individual skills but also activate participants as **change agents within their ecosystems**, advancing the PRECISEU mission well beyond the duration of the training.

4.4 Certificate of Participation

All individuals who successfully participated in a PRECISEU PM School edition received a **Certificate of Participation** issued by the organising partners and the PRECISEU coordination team. The certificate served as formal recognition of the participant's engagement in structured training aligned with European priorities in personalised medicine.

The certificate included the following elements:

- Full name of the participant
- Title and edition number of the PM School
- Dates and location (or online format) of participation
- Summary of key thematic areas covered
- Logos of the host partners and the European Union
- Signature of the project coordinator, local coordinator or WP7.3 lead

Certificates will be issued digitally, typically within two weeks following the completion of each edition. In some cases, particularly for in-person editions, printed certificates will be also handed out on-site during closing sessions.

Participants who contributed actively as speakers, moderators, or case study presenters received an enhanced version of the certificate, acknowledging their role and contribution to the learning process. For hybrid or online editions, attendance will be confirmed based on login duration, active participation in group work, or engagement in follow-up surveys.

4.5 Application process

Participation in the PRECISEU PM School will be open to a diverse range of stakeholders committed to advancing personalised medicine in Europe. Each edition targeted a multidisciplinary audience, including healthcare professionals, researchers, policymakers, entrepreneurs, patient advocates, and graduate students. The application process will be designed to ensure accessibility and regional balance while maintaining relevance to the school's thematic focus.

Interested participants applied through an online registration form, which was promoted via the PRECISEU website, partner networks, and social media channels. Each edition published an open call approximately six to eight weeks before the PM School dates, outlining the topics, learning objectives, speaker highlights, session formats, and any eligibility criteria. Applicants will be asked to provide basic information, including their institutional affiliation, motivation for participation, and preferred mode of attendance (on-site or online, depending on the format).

In cases where attendance will be limited due to space or thematic fit—particularly for in-person study visits or interactive workshops—priority will be given to candidates from partner regions, awardees of WP7.2 Best Practices, and individuals involved in relevant innovation ecosystems. The selection process will be conducted by the local organising team in consultation with the WP7 Task 7.3 lead.

Accepted participants received confirmation along with preparatory materials, access links for hybrid sessions, and logistical guidance. A certificate of attendance will be issued to all who complete the full program. By applying to the PRECISEU PM School, participants joined a growing community committed to shaping the future of personalised healthcare across Europe.

Step-by-Step Roadmap

Step	Duration	Description
Open Call & Promotion	2 months before School	Announcement via website, partners, and social media
EOI Submission	1 month before School	Online Expression of Interest form: background & motivation
Selection Process	1–2 weeks after EOI closes	Review for thematic fit, balance, diversity
Acceptance Notification	Immediately after selection	Official acceptance & preparatory materials sent
Formal Registration	1 week	Admin/logistics details, consent, accessibility, code of conduct
PM School Participation	3–5 days	Active participation in sessions/workshops
Certificate Issuance	Within 2 weeks post-event	Digital certificates for attendees meeting criteria

4.6 Geographical scope

The geographical scope of the PRECISEU PM School embodies the project’s strategic ambition to foster a truly interconnected, inclusive, and territorially cohesive European innovation ecosystem for personalised medicine. The eight School editions are deliberately distributed across regions with varying levels of innovation maturity and healthcare system development—ranging from advanced innovation hubs to moderate and emerging regions. This intentional diversity aligns with the European Innovation Scoreboard and supports the integration of Smart Specialisation Strategies (S3) into regional health and innovation agendas.

Stakeholders from more than twelve EU Member States, as well as from associated countries such as Ukraine, have participated through a combination of in-person, hybrid, and fully online formats. Regional partners played a key role in ensuring local relevance and stakeholder mobilisation. At the same time, transnational actors—including EATRIS, Biocat, and various Digital Innovation Hubs—contributed to the schools’ pan-European visibility, knowledge exchange, and policy alignment.

The hybrid delivery model enabled broad participation beyond the immediate host locations, making the schools accessible to actors from non-hosting RIS and non-RIS regions alike. This broadened reach not only enhanced equity in access to high-quality training but also promoted peer learning across diverse institutional and geographic contexts.

By deliberately spanning different innovation geographies and engaging both established and emerging ecosystems, the PM Schools have helped reduce territorial disparities, accelerated the diffusion of good practices, and strengthened cross-border collaboration. This geographical breadth is not simply a feature of the initiative—it is a cornerstone of PRECISEU’s contribution to building a cohesive and future-ready European health innovation landscape.

4.7 Submission

Submission to the PRECISEU PM School will be structured as a two-step process, beginning with the Expression of Interest (EOI) and followed by formal registration upon acceptance. Once participants are selected based on thematic fit, geographical balance, and relevance to ecosystem objectives, they will receive a direct invitation to complete the official registration form. This form collected key logistical and administrative details, including consent for participation, dietary or accessibility needs (for in-person attendees), preferred learning tracks, and agreement to the code of conduct.

For participants involved in knowledge-sharing or speaker roles, an additional submission form will be used to collect presentation abstracts, speaker bios, and institutional logos for visibility and dissemination purposes. In some editions, participants will also be encouraged to submit short case studies or policy examples ahead of time, which will later be integrated into session discussions and PM School materials.

All submissions will be processed and managed via secure online platforms, with support from the local organisers and Task 7.3 leads. Data protection standards will be fully observed in line with Horizon Europe guidelines. Participants who completed the submission and participated in the training received a certificate of attendance. In selected editions, their contributions will also be featured in the PM School session summaries and highlighted in the PRECISEU repository.

4.8 Selection of Mentors and Educators

The selection of mentors, educators, and expert contributors for the PRECISEU PM School was guided by principles of excellence, relevance, diversity, and cross-disciplinary representation. Recognising the central role facilitators play in shaping learning experiences and driving ecosystem engagement, the

process was designed to ensure both scientific rigour and contextual alignment with the objectives of each School edition.

Mentor and educator selection began during the co-design phase of each edition, led jointly by the local host institution and the WP7.3 coordination team, in consultation with relevant Work Package leaders and ecosystem partners. Candidate profiles were proposed based on their demonstrated expertise, regional relevance, and alignment with the thematic focus areas of the upcoming School. These included domains such as health data governance, clinical genomics, artificial intelligence in healthcare, translational research, regulatory science, advanced therapies, innovation management, ethics, and policymaking.

To ensure scientific and technical depth, several contributors were nominated by Work Package leaders, particularly from WP3–WP6, where subject-matter expertise was directly linked to ongoing research and innovation outputs. This helped ensure a coherent flow between project-level knowledge production and real-world capacity building within the PM Schools. For policy and governance-focused sessions, experts were also drawn from networks connected to Task 7.4, including regional authorities, EU-level advisors, and representatives from Smart Specialisation platforms.

Each edition also actively sought to feature practitioners and innovation actors who could present hands-on experiences and use cases, including awardees from Task 7.2, startup founders, cluster managers, and hospital-based innovators. Their inclusion aimed to ensure that training sessions were grounded in practical realities and informed by real-life implementation challenges and successes.

Diversity and inclusion were key considerations throughout the selection process. Attention was paid to achieving gender balance, a mix of senior and early-career profiles, geographic representation across EU regions (including RIS and non-RIS), and the inclusion of voices from civil society and patient organisations. This was aligned with PRECISEU's commitment to equity, openness, and stakeholder engagement.

Mentors and educators were thoroughly briefed on the format, objectives, and audience profile of each School. In many cases, they contributed not only as presenters but also as facilitators of group work, co-creation sessions, and policy dialogues. Their role extended beyond content delivery to actively enable peer learning, dialogue, and reflection.

4.9 Course Syllabus

The PRECISEU PM School syllabus is intentionally designed as a **modular and adaptive framework**, allowing each edition to tailor its content to the specific needs, capacities, and strategic priorities of the host region and participating stakeholders. Rather than prescribing a fixed curriculum, the schools follow a **core structure that enables flexibility**, while ensuring coherence with the overall objectives of the PRECISEU project and Horizon Europe policy directions.

Each edition draws from a curated pool of thematic areas—including but not limited to health data governance, artificial intelligence, translational research, regulatory pathways, ethical frameworks, and

policy integration. Modules are selected and adapted based on regional strengths, emerging topics, and input from relevant Work Packages to maximise relevance and cross-WP learning.

Interactive and experiential learning formats such as stakeholder roundtables, policy co-creation labs, study visits, and peer-to-peer exchanges are embedded throughout the training design. The schools also serve as a platform to showcase practical use cases and award-winning initiatives, while offering space for multi-stakeholder dialogue and institutional collaboration.

No two editions are identical by design. This approach ensures that the syllabus remains future-proof, inclusive, and responsive—capable of addressing specialised topics such as Advanced Therapy Medicinal Products (ATMPs), gender-sensitive innovation, or cross-border health resilience as needed.

Through this flexible, participatory training model, the PRECISEU PM Schools empower participants to apply new knowledge within their own ecosystems and contribute to a more connected and innovation-driven personalised medicine landscape across Europe.

4.10 Programme Content

The content of each PRECISEU PM School is not predetermined but **strategically co-developed** through an iterative and inclusive process that reflects the dynamic priorities of the project and its regional partners. Rather than adhering to a fixed syllabus, the programme for each edition is shaped through a combination of inputs from PRECISEU Work Packages, local host institutions, and direct feedback from past participants and ecosystem stakeholders.

Content planning begins with a dialogue between the WP7.3 coordination team and the local organisers to identify the most relevant themes, competencies, and challenges for the host region. This is complemented by consultation with Work Package leaders—particularly from WP3 to WP6—to ensure alignment with ongoing project outputs, technical findings, and policy insights. Topics such as health data governance, AI-enabled diagnostics, regulatory frameworks, advanced therapies, ethical innovation, and policy design may be prioritised depending on the regional context and project stage.

A key element of this process is the **feedback loop** established after each School. Pre- and post-event surveys, debriefs with facilitators and speakers, and reflections from WP contributors help refine the focus of upcoming editions and identify content gaps or emerging areas of interest. This ensures that each edition builds on lessons learned and contributes to a cumulative and responsive learning ecosystem.

The **format of the programme** is equally adaptive. In addition to expert lectures and thematic panels, each School typically includes interactive formats such as policy co-creation labs, study visits, stakeholder roundtables, and showcases of award-winning practices (Task 7.2). These methods enable participants to engage with real-world challenges, translate project outputs into practice, and contribute actively to shaping regional innovation pathways.

By embedding flexibility, cross-WP integration, and local relevance into the content development process, the PRECISEU PM Schools function not only as training events but as dynamic platforms for ecosystem mobilisation, knowledge exchange, and policy experimentation in personalised medicine.

4.11 Assessment

The assessment strategy of the PRECISEU PM Schools is intentionally designed to foster **reflection, engagement, and practical application**, rather than formal testing or grading. As a training programme rooted in capacity-building and cross-sectoral exchange, the assessment approach aligns with the experiential, inclusive, and collaborative pedagogical model that defines the PM School format.

Assessment is primarily **participation-based**, with active involvement in sessions—whether online or in person—serving as the main indicator of successful engagement. Attendance is monitored through registration records, virtual participation analytics, and physical sign-in sheets at each venue. Beyond its presence, the quality of interaction during the programme is a central consideration. Participants are encouraged to engage in interactive elements, including case-based exercises, group discussions, policy co-creation labs, and innovation workshops. While these contributions are not graded, facilitators observe participation informally to help shape follow-up opportunities, including the issuing of Certificates of Participation or invitations to mentoring and showcasing activities in future editions.

To support learning reflection, each edition incorporates **pre- and post-event surveys**. These tools capture participants' initial expectations, baseline knowledge, and interests before the PM School, and then follow up with feedback on satisfaction, content relevance, and perceived learning outcomes. The surveys also explore changes in participants' confidence in applying new concepts and tools, as well as the networking and collaboration potential unlocked through the event.

Several editions of the PM School incorporate informal self-assessment tools, including reflection prompts, mapping exercises, and goal-setting worksheets. These are designed to help participants track their learning journey and identify areas for future development. Peer feedback and facilitated group dialogue further support shared learning and the exchange of diverse perspectives.

In some cases, particularly during editions involving **awardee showcases or stakeholder policy labs**, participants are invited to submit optional deliverables. These may include short case studies, institutional implementation plans, or regional policy insights. While submission is voluntary, these contributions are reviewed by organisers and may be featured in project dissemination materials or highlighted in follow-up activities under relevant PRECISEU tasks.

Feedback from educators, speakers, and organisers plays a critical role in the continuous improvement of the PM School model. Trainers are asked to reflect on the responsiveness of participants, the depth of engagement, and the effectiveness of the learning environment. Their input, alongside participant feedback, informs iterative refinements to session design, facilitation methods, and thematic focus across future editions.

4.12 Suggested Learning Resources

To support continued learning beyond the PM School editions, participants will be provided with access to a range of curated open-access resources, tools, and platforms aligned with the thematic focus areas of personalised medicine, regional innovation, digital health, and EU policy frameworks. These resources will be selected to cater to diverse professional backgrounds and to reinforce key concepts introduced during the training.

Key Open-Access Resources

1. **European Commission – Personalised Medicine Portal:** A comprehensive entry point for EU-level strategies, funding calls, and key documents related to PM. https://ec.europa.eu/health/policies/personalised_medicine
2. **EATRIS – Personalised Medicine Toolbox:** Offers roadmaps, training modules, and infrastructure information for translational research in PM. <https://eatris.eu/services/personalised-medicine/>
3. **European Health Data Space (EHDS) Overview:** Key regulatory and implementation documents regarding EU-wide health data governance. https://health.ec.europa.eu/european-health-data-space_en
4. **Gendered Innovations in Health Research** (by Stanford University & the European Commission) Methodologies and case studies for integrating sex and gender into research and innovation. <https://genderedinnovations.stanford.edu/>
5. **OECD Health at a Glance – Digital Health & PM Indicators:** Provides comparative data and trends on health system digitalisation and PM adoption. <https://www.oecd.org/health/health-at-a-glance.htm>
6. **Horizon Europe – EU Funding & Tenders Portal:** Helpful in identifying follow-up funding, policy pilots, and networking under PM-related calls. <https://ec.europa.eu/info/funding-tenders>
7. **PRECISEU Capacity-Building Repository:** A dedicated platform (under WP7.1) offering access to School recordings, slides, tools, and awardee showcases from across the project, currently under development and expected in the Fall 2025.

Recommended Reading

- *"Personalised Medicine: A New Medical and Social Paradigm"* (European Alliance for Personalised Medicine, White Paper)
- *"Implementing Responsible Research and Innovation in Health"* (EU RRI Tools Project)
- *"AI for Health: A Roadmap for Trustworthy Innovation"* (World Health Organization & European Commission)

Tools and Templates

- Smart Specialisation Strategy (S3) mapping templates
- Policy Lab facilitation guides (from WP7.4)
- Business model canvas for digital health startups

- Data ethics checklist for PM project design

These resources will be introduced during the PM Schools and remain available for participants, partners, and regional stakeholders to support **lifelong learning**, **capacity reinforcement**, and **policy alignment** in personalised medicine.

4.13 Expected Outcomes and Impact

The PRECISEU PM Schools will be conceived as a strategic instrument to empower regional and European health innovation ecosystems with the knowledge, skills, and connections needed to advance personalised medicine (PM). The expected outcomes will be both immediate—linked to each training edition—and systemic, aimed at long-term transformation aligned with the project’s mission to bridge innovation gaps across Europe.

At the individual level, the PM Schools aimed to increase awareness, competencies, and cross-sector understanding among participants. Healthcare professionals, researchers, policymakers, students, and entrepreneurs will be equipped with up-to-date knowledge on health data governance, AI tools, translational pathways, and ethical frameworks in PM. Participants will also be introduced to EU-level funding instruments, regulatory frameworks, and examples of regional best practices, enabling them to apply insights in their local contexts.

At the institutional level, the schools fostered collaboration between academic, clinical, industrial, and policy actors. Each edition created a temporary ecosystem where ideas, solutions, and experiences could be exchanged—contributing to capacity building in regions with varying levels of innovation maturity. These multi-stakeholder interactions seeded new partnerships and reinforced inter-regional cooperation, especially among RIS regions and less connected innovation players.

The PM Schools also served as a platform for amplifying and integrating outputs from other PRECISEU work packages. For example, award-winning initiatives from Task 7.2 will be showcased to inspire replication; policymaker training formats developed in Task 7.4 will be piloted and refined through live interaction; and content from WP3–WP6 will be translated into practical sessions, case studies, and ecosystem dialogues.

In terms of impact, the PM Schools contributed to reducing fragmentation in the European PM landscape by building a shared language, shared competencies, and shared commitments across borders. The inclusion of Ukrainian stakeholders further underscored PRECISEU’s role in promoting resilience and cooperation beyond the EU.

The cumulative impact of the eight editions—supported by the PRECISEU Guidelines and now documented in this Handbook—positions the PM Schools as a replicable, scalable model for advancing personalised medicine through training, dialogue, and policy innovation.

5. CONSIDERATIONS

Preparing each edition of the PRECISEU Personalised Medicine (PM) School requires a coordinated, context-aware approach that supports both the educational objectives of the initiative and its broader role in ecosystem development. To achieve this, several key aspects must be addressed in advance to ensure strategic relevance, operational quality, and cross-regional impact.

Each School will be developed in close alignment with the specific priorities and needs of the host region. Programme content and thematic focus will be shaped by the region's innovation maturity, healthcare infrastructure, and ongoing policy agendas. Early engagement with local stakeholders—including clinicians, academic institutions, regional authorities, and SMEs—will help tailor the design and secure participation from relevant communities.

Preparation will also involve structured collaboration with other PRECISEU work packages. By drawing on knowledge and outputs from across the project—such as WP3 on health data, WP4 on advanced therapies, WP5 on innovation models, and WP6 on impact evaluation—the PM Schools will serve as an interface for knowledge translation. Contributions from WP7.2 and WP7.4 will be integrated to ensure that award-winning practices and policymaking tools are reflected in both content and format.

The quality and relevance of each edition will depend on the timely identification and coordination of speakers and contributors. Experts from within the consortium and external networks will be invited based on thematic expertise, regional relevance, and experience in stakeholder engagement. Care will be taken to ensure balance in gender, geography, and institutional representation. Technical and logistical arrangements will also be made to support online participation, particularly for hybrid editions.

Accessibility and inclusivity will be central considerations in planning. Physical venues will be selected to accommodate diverse participant needs, while digital platforms will be evaluated for their user-friendliness and suitability for multilingual formats. For Schools involving Ukrainian or other international stakeholders, real-time interpretation and moderated online facilitation will help overcome language and access barriers.

The structure of the school programmes will include a mix of expert-led sessions, collaborative workshops, study visits, and networking opportunities. Time will be allocated for co-creation, policy dialogue, and practical case work, aligning with experiential learning principles and allowing for the piloting of tools developed in WP7.4.

Participant recruitment will follow an open and transparent process. Calls for expression of interest will be promoted widely across the PRECISEU network and beyond. Selection criteria will aim to ensure representation across disciplines, professional roles, and EU regions, with a focus on involving actors from RIS areas and institutions linked to Smart Specialisation Strategies.

A communications strategy will support each edition through coordinated pre-event outreach, targeted promotion of sessions and speakers, and post-event dissemination. Multimedia content, session summaries, and recorded material will help extend the visibility and reuse of training outputs.

Logistical planning will include venue management, travel coordination, accommodation, technical infrastructure for hybrid formats, and risk mitigation strategies. Each edition will appoint a local organising team responsible for operational delivery and on-site coordination.

5.1 Integration of Gender Dimension

The integration of the gender dimension will be a cross-cutting priority in the design and delivery of the PRECISEU PM Schools, in line with Horizon Europe requirements and the project's broader commitment to inclusive and responsible innovation. Gender considerations will be embedded in both the **content** and **structure** of the schools, ensuring that issues of equity, access, and representation are actively addressed throughout the training program.

From a content perspective, several sessions explicitly explored sex- and gender-specific aspects of personalised medicine, including differences in disease risk, diagnostic accuracy, treatment response, and health technology assessment. In editions hosted in Sweden and Spain, special emphasis will be placed on showcasing gender-sensitive research, participatory methods in patient engagement, and the design of inclusive clinical trials. These sessions will be supported by contributions from gender experts and case studies illustrating how overlooking sex and gender variables can limit the effectiveness and ethical soundness of PM innovations.

In terms of structure, the organisation of the PM Schools sought to ensure **balanced gender representation** among speakers, moderators, and participants. The speaker selection process aimed for parity, and efforts will be made to highlight the leadership of women in science, clinical practice, policymaking, and entrepreneurship. The open call and EOI forms also invited participants to self-identify gender, enabling the organising teams to monitor and promote inclusive participation across all editions.

Moreover, the PRECISEU PM Schools encouraged a culture of inclusiveness and respect, with session formats that fostered diverse perspectives and equitable participation in dialogue. Particular attention will be given to ensuring that women from underrepresented regions or institutions have equal access to learning opportunities and visibility.

By embedding gender considerations into both the technical and operational dimensions of the PM Schools, PRECISEU contributed to strengthening the role of gender in research excellence, policy relevance, and societal impact. This approach reinforces the school's position as a forward-looking training platform that supports equity not only in medicine, but in the design of innovation ecosystems themselves.

5.2 Ethical Dimension

The ethical dimension will be a foundational element in the conceptualisation and implementation of the PRECISEU PM Schools, reflecting the complex moral, legal, and societal considerations surrounding the advancement of personalised medicine. Across all eight editions, ethical reflection will be integrated both **explicitly**, through dedicated sessions, and **implicitly**, through the values embedded in the program’s inclusive, participatory, and regionally grounded approach.

Key ethical themes addressed during the schools included data privacy and consent in health data sharing, responsible use of artificial intelligence in clinical decision-making, equity of access to personalised treatments, and the governance of genomic information. These discussions will be framed by the European values of dignity, autonomy, and solidarity, and often take the form of moderated panels, case-based discussions, or interactive workshops. Contributions will be drawn from ethics experts, patient representatives, regulatory agencies, and clinicians navigating ethical dilemmas in practice.

The schools also served as a platform for raising awareness of emerging bioethical challenges, such as algorithmic bias, predictive diagnostics, and the tension between innovation speed and safety. Participants engaged in debates about how to ensure that innovation in personalised medicine does not reinforce existing disparities, particularly for vulnerable populations or under-resourced regions.

Beyond content, the ethical dimension will be reflected in how the schools will be organised. Efforts will be made to ensure fair selection procedures, protect participant data in accordance with the GDPR, promote respectful dialogue, and guarantee the free and informed participation of all attendees, including online contributors from diverse geopolitical contexts, such as Ukraine.

By embedding ethics into both the **substance** and **practice** of the Schools, PRECISEU fostered a learning environment that not only promoted technical excellence but also cultivated a culture of **responsibility, reflection, and alignment with societal values**. This ethical foundation enhances the legitimacy and long-term sustainability of the personalised medicine agenda being advanced through the project.

5.3 Data Management and Security

Data security and management are both foundational and cross-cutting pillars of the PRECISEU PM School series, aligning with the project’s broader commitment to responsible digital transformation in precision medicine. As the field increasingly relies on cross-border health data exchange, AI-driven decision-making, and interoperable digital tools, the PRECISEU PM Schools integrate security considerations at multiple levels: **cybersecurity, data integrity, user privacy, and operational platform reliability**. These layers of protection are embedded throughout the design and delivery of the programme, ensuring both compliance and trust across diverse regional and institutional settings.

From a **thematic perspective**, several School editions—most prominently the 4th edition hosted in Bulgaria—featured dedicated modules and expert-led sessions on secure health data infrastructure and digital risk management. Topics covered include GDPR implementation, European Health Data Space (EHDS) compliance, and strategies for safeguarding sensitive medical information during data sharing,

AI model training, and remote diagnostics. In addition, sessions highlighted evolving cyber threats linked to AI misuse, third-party platform integration, and the deployment of digital tools in real-world clinical workflows.

On the **operational side**, strict data protection protocols govern all aspects of participant engagement and hybrid delivery. Digital platforms used for application, registration, and participation (e.g., Zoom, Webex, SharePoint) are selected based on their security credentials. Access to online events, shared resources, and recordings is tightly managed through password protection, multi-factor authentication, and role-based permissions. All personal and institutional data are handled in full alignment with GDPR and institutional data protection policies.

In **sensitive contexts**—such as editions involving participants from Ukraine or those linked to ongoing policy dialogues—additional safeguards were employed. These included secure translation channels, closed-session formats, pre-screened participant lists, and enhanced moderation protocols to protect both the privacy and safety of contributors. Similarly, for **in-person editions**, logistical protocols included badge-controlled venue access, identity verification procedures, and contingency measures to ensure the physical security of participants, especially when operating in politically or socially complex environments.

5.4 Confidentiality and Data Protection

Confidentiality and data protection will be fundamental principles guiding the organisation and implementation of all PRECISEU PM School editions. In accordance with the General Data Protection Regulation (GDPR) and Horizon Europe requirements, the consortium adhered to strict standards to safeguard personal data, ensure informed consent, and maintain the confidentiality of both participants and contributors.

Personal data collected during the application, registration, and participation phases—such as names, institutional affiliations, contact details, and session preferences—will be processed exclusively to organise the schools and monitor project outcomes. Data collection will be managed through secure online systems and stored on protected servers in compliance with each partner's institutional policies and national legal frameworks.

All participants will be provided with **clear information notices** outlining how their data will be used, including consent for inclusion in attendance lists, issuance of certificates, and access to event materials. For hybrid and online editions, additional consent will be sought regarding the recording of sessions, appearance in screenshots or videos, and participation in interactive tools such as surveys or polls.

When speakers or participants shared **confidential content** (e.g., early-stage research, unpublished results, or commercially sensitive material), appropriate precautions will be taken to limit access. These included closed sessions, restricted downloads, non-disclosure agreements where applicable, and clearly marked presentation slides. Any confidential materials will be excluded from public dissemination unless express permission will be granted.

Data processing responsibilities will be distributed across hosting partners, with WP7.3 coordination overseeing compliance and maintaining records of consent forms and privacy declarations. Furthermore, participants had the right to withdraw their consent or request access, correction, or deletion of their data at any time.

5.5 Dissemination and Exploitation

Dissemination and exploitation will be central to the PRECISEU PM Schools' value proposition, ensuring that the knowledge generated, partnerships formed, and tools tested during the training programs would extend far beyond the events themselves. A strategic dissemination plan will be developed in coordination with WP8, aiming to raise awareness, engage target audiences, and increase visibility at both regional and European levels.

Each edition of the PM School will be actively promoted through the PRECISEU website, social media channels, institutional newsletters, and partner networks. Visual materials such as flyers, speaker spotlights, and short video teasers will be created in advance, while live coverage and post-event highlights—including participant testimonials, session recordings, and infographics—will be shared across platforms to expand outreach. Press releases and cross-posting by regional innovation agencies further boosted visibility in local media and stakeholder communities.

In terms of exploitation, session content, speaker contributions, and best practices identified during the schools will be systematically captured and transferred into the PRECISEU **capacity-building repository** (Task 7.1), making them accessible to stakeholders beyond the original participants. Educational formats, presentation templates, and policy workshop methodologies piloted during the schools will be also shared for reuse by other EU regions, Digital Innovation Hubs, and health authorities. The schools functioned as real-world testbeds for outputs from WP3–WP6, thus directly contributing to their exploitation through field validation, stakeholder feedback, and contextual adaptation.

Moreover, connections made during the schools have already led to concrete follow-up actions: collaborations in Horizon Europe proposals, invitations for regional twinning, and pilot activities to integrate PM training into institutional curricula. Dissemination and exploitation will be further reinforced through the engagement of Ukrainian partners, which opened pathways for knowledge transfer in support of healthcare resilience and digital transformation beyond the EU.

5.6 Use of Disclaimer

In compliance with Horizon Europe guidelines and to ensure transparency regarding project funding and responsibility, all dissemination materials related to the PRECISEU PM Schools included in the official disclaimer. This applies to digital and print materials used for promotion, communication, and reporting—such as event agendas, registration pages, training materials, session presentations, certificates, videos, and this Handbook itself.

The following standard disclaimer will be systematically applied:

“Funded by the European Union. Views and opinions expressed are, however, those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HaDEA). Neither the European Union nor HaDEA can be held responsible for them.”

This disclaimer served to clarify that while the project is supported under Horizon Europe, the content presented in the PM Schools and associated outputs reflects the positions and interpretations of the PRECISEU consortium and its contributors. The use of the disclaimer will be coordinated with WP8 (Communication, Dissemination, and Exploitation) and aligned with the visual identity and branding guidelines of the European Commission.

The consistent and correct application of the disclaimer enhanced the professionalism, legal compliance, and institutional credibility of all PM School editions, and ensured that all participants and external audiences clearly understood the project’s funding framework and scope of responsibility.

Translated into local languages where appropriate: “Founded by the European Union and [name of the Funding Agency]. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the Funding Agency]. Neither the European Union nor the Funding Agency can be held responsible for them”.

5.7 Open Science and Open Access

The PRECISEU PM Schools will be fully aligned with the principles of Open Science and Open Access, ensuring that the knowledge produced, shared, and discussed during each edition will be accessible, reusable, and inclusive. This commitment reflects both Horizon Europe requirements and the consortium’s broader vision of fostering transparent, collaborative, and democratised innovation in personalised medicine.

All non-confidential training materials developed or presented during the PM Schools—including slides, recordings, speaker contributions, and summaries—will be made publicly available through the PRECISEU online repository (linked to Task 7.1). These materials will be released under open-access licenses where applicable, allowing participants and external stakeholders to reuse content for educational, institutional, and policy purposes. Recordings of key sessions will be uploaded with subtitles and, when necessary, accompanied by translated or adapted versions to enhance accessibility across linguistic and regional boundaries.

The PM Schools also contributed to the culture of Open Science by encouraging the use of FAIR (Findable, Accessible, Interoperable, Reusable) principles, particularly in sessions related to health data, AI, and digital infrastructures. Presentations showcased open datasets, EU-funded platforms, and collaborative research projects committed to data sharing and ethical reuse. Researchers will be encouraged to cite preprints, publish in open-access journals, and share methodologies that support reproducibility.

In line with PRECISEU’s values, Open Science will not be limited to technical transparency but will be extended to the **inclusiveness of dialogue**. Multi-stakeholder engagement—bringing together patients,

citizens, SMEs, policymakers, and scientists—will be a deliberate design choice that operationalises open knowledge exchange and co-creation of insights.

5.8 Intellectual Property Management

The organisation and delivery of the PRECISEU PM Schools followed a clear and transparent approach to Intellectual Property (IP) management, aligned with the Horizon Europe rules and the PRECISEU Grant Agreement. While the PM Schools focused on training, awareness-raising, and capacity-building rather than the development of patentable technologies, it will be essential to ensure that knowledge sharing respects ownership rights, confidentiality agreements, and ethical standards.

Materials explicitly developed for the schools—such as training presentations, templates, visual content, and participant guides—will be produced collaboratively by PRECISEU partners and are considered foreground results of the project. These materials will be made available through open access where appropriate and will be subject to the PRECISEU internal IP agreement, which defines rights of use, citation, and attribution. Contributors retained the right to be acknowledged as authors or content creators, and all publicly shared materials included appropriate credits and copyright information.

External speakers and contributors invited to the PM Schools will be informed in advance of the open-access and dissemination strategy. Consent will be requested for recording and publishing their contributions, and any proprietary or unpublished research content will be handled with appropriate restrictions. Where relevant, presentations or case studies marked as confidential or under commercial protection will be excluded from public dissemination and shared only with registered participants under non-disclosure conditions.

The PM Schools also served as an opportunity to raise awareness about IP rights within the personalised medicine innovation ecosystem. Several sessions, particularly those aligned with WP5, addressed issues such as intellectual property strategies for health startups, data ownership in multi-stakeholder research, and licensing of digital tools or AI models in healthcare.

6. COLLABORATION AND NETWORKS

Collaboration and network-building are central pillars of the PRECISEU PM School model. Each edition is conceived not only as a standalone training opportunity but as a catalyst for sustained, cross-sector, cross-regional, and cross-border cooperation in personalised medicine. The schools are deliberately designed to bring together a diverse mix of stakeholders—including researchers, clinicians, policy actors, entrepreneurs, patients, students, and civil society representatives—within a shared learning environment that fosters mutual understanding and long-term partnerships.

At the core of this collaboration is **strong internal coordination across the PRECISEU consortium**. Task 7.3 is implemented with active engagement from all Work Packages and consistent support from regional hosts, including HLSCB, Dizne, ImagoMol, Biocat, ACCIÓ, PoP, and the Innovation Agency

Lithuania. This ensures that each School is grounded in regional priorities while remaining connected to the project's broader technical and policy objectives. External contributions from established networks—such as EATRIS, Digital Innovation Hubs, medical clusters, academic consortia, and patient organisations—further enrich the content and expand the schools' reach and impact.

The open and inclusive design of the schools—via public calls and Expressions of Interest—has proven effective in attracting new stakeholders into the PRECISEU ecosystem. Many participants forged direct connections with local innovation actors, policymakers, and fellow trainees. These engagements often continued beyond the school itself, through invitations to join task-specific working groups, policy labs (T7.4), or recognition platforms such as the Best Practices Award (T7.2).

Several editions have already led to **concrete collaborations**, including pilot project development, co-authorship of Horizon Europe and Interreg proposals, student and staff mobility exchanges, and the alignment of Smart Specialisation Strategies (S3) to embed personalised medicine priorities at the regional level.

In addition, the PM Schools are designed to **complement and create synergies with other EU- and nationally funded training programmes** that share objectives in capacity-building, digital health, advanced therapies, and responsible innovation. Where relevant, Schools may integrate content, methodologies, or case studies from initiatives such as EIT Health, EU4Health, Digital Europe, Erasmus+, or national R&I schemes. This alignment not only enhances efficiency and coherence but also contributes to a broader, interconnected training ecosystem for personalised medicine in Europe.

Special emphasis is placed on strengthening collaboration with Ukrainian stakeholders, who are supported through adapted hybrid formats, real-time translation, and structured follow-up with European partners. These efforts reflect PRECISEU's commitment to inclusive innovation and pan-European solidarity.

7. MONITORING AND REPORTING

Monitoring and reporting processes will be built into the design and delivery of each PRECISEU PM School to ensure quality, accountability, and the continuous improvement of training outcomes across all editions. These processes also contributed directly to the documentation required for Deliverable 7.1 and to the evidence base for cross-WP alignment and project impact assessment.

Each edition of the PM School will be monitored through a combination of **quantitative and qualitative indicators**. Quantitative data included the number of participants (disaggregated by stakeholder type, region, gender, and participation mode), session attendance, speaker engagement, and social media reach. Qualitative feedback will be collected through structured post-event surveys, moderated discussion sessions, and informal debriefs with speakers and organisers.

To support transparent and consistent reporting, a standardised **PM School Reporting Template** will be developed and shared with local organising teams. This template included sections on agenda

structure, speaker profiles, session summaries, participant demographics, highlights, challenges encountered, lessons learned, and follow-up actions. These reports will be submitted to the WP7.3 coordination team shortly after each edition and reviewed collectively to identify trends and inform future planning.

Monitoring also extended to **ensuring alignment with project goals and relevance across work packages**. WP leads will be invited to contribute short reflections after participating in or contributing to a School, particularly where content from WP3–WP6 or policy pilot actions under WP7.4 had been showcased or tested. These reflections informed the strategic integration across tasks and contributed to WP6’s evaluation and foresight activities.

Results from the monitoring process will be synthesised in internal WP7 meetings and contributed to PRECISEU’s broader dissemination, exploitation, and sustainability strategies (WP8). In addition, insights from participant feedback and session analytics will be used to refine the design of future editions, ensuring continuous improvement based on user needs and the evolution of the ecosystem.

8. CONCLUSIONS

The PRECISEU Personalised Medicine (PM) Schools have demonstrated the power of collaborative, regionally anchored, and strategically adaptive training to advance personalised medicine capacity across Europe. Over eight editions, the PM Schools have successfully engaged a diverse spectrum of participants—from clinicians and researchers to policymakers, entrepreneurs, and patient representatives—supporting both individual and institutional transformation in line with European health and innovation goals.

Key conclusions emerging from the design, implementation, and impact evaluation of the PM Schools include:

- **Tailored, Evidence-Based Approach:** The modular, needs-driven training model—co-created with local stakeholders and systematically refined through feedback—ensured strong alignment with both regional ecosystem needs and European strategic priorities for health innovation.
- **Inclusivity and Accessibility:** Hybrid and multilingual formats removed barriers related to geography, language, or mobility, while open, transparent application processes promoted broad participation, particularly from underrepresented regions and stakeholder groups.
- **Hands-on, Experiential Learning:** The Schools’ emphasis on interactive workshops, case studies, and co-creation labs fostered actionable learning and practical skill development that participants could directly apply within their professional contexts and ecosystems.
- **Cross-Sectoral and Cross-Border Impact:** By integrating thematic content from other PRECISEU work packages and involving contributors from across the EU and associated countries, the PM

Schools served as dynamic platforms for multi-stakeholder dialogue, knowledge circulation, and the diffusion of best practices.

- **Continuous Improvement:** Embedded evaluation mechanisms and participant feedback enabled real-time adaptation of content and delivery; this iterative ethos ensured that each edition remained relevant, user-informed, and aligned with evolving policy and scientific developments.
- **Sustainability and Replicability:** Comprehensive documentation, open-access resources, and the creation of a shared capacity-building repository ensure that the benefits of the PM Schools extend well beyond individual events—providing a scalable model for similar initiatives across Europe and supporting ongoing capacity building in personalised medicine.
- **Ethical and Social Responsibility:** The explicit integration of gender, ethical, and data protection considerations has set a standard for responsible innovation training in Europe, aligning with Horizon Europe values and ensuring that the schools not only advanced technical knowledge but also fostered a culture of equity and societal engagement.

The PRECISEU PM Schools represent a best-practice model for ecosystem-driven, multi-actor training in personalised medicine. Their strategic design, flexible implementation, and broad impact serve as both a legacy and a blueprint—supporting the diffusion of innovation, the reduction of regional disparities, and the emergence of a resilient, connected European health innovation landscape. The lessons, resources, and networks established through these Schools will continue to empower future initiatives, ensuring the ongoing evolution of personalised medicine in Europe and beyond.

ANNEXES

Annex 1: Certificate of Participation Template

[Visual Sample Description]

(A formatted certificate to be graphically designed and printed digitally. Below is the textual layout for official use.)

PRECISEU – Personalised Medicine Ecosystems

Certificate of Participation

This is to certify that

[Full Name]

has actively participated in the

[Xth Edition of the PRECISEU PM School]

held in **[City, Country]**, from **[Dates]**,

and successfully completed training activities on

Personalised Medicine, Innovation Systems, and Regional Policy Integration.



Signed,

[Signature]

WP7.3 Coordination Team / Local Host Representative

Logos:

- PRECISEU Project Logo
- Host Partner Logos
- European Union emblem with Horizon Europe disclaimer:

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the granting authority. Neither the European Union nor the granting authority can be held responsible for them.

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Issuance Guidelines:

- Minimum attendance requirement: **70% of total training hours** (tracked online or in-person)
- Engagement in **at least one workshop or group activity**
- Submission of feedback or post-training reflection (encouraged, not mandatory)
- Certificates issued **digitally within 2 weeks** post-event via host partner

Annex 2: Consent and Privacy Forms

GDPR-Compliant Registration Consent (Template)

Participant Consent Form – GDPR Compliance

In accordance with the General Data Protection Regulation (EU) 2016/679, I hereby consent to the processing of my personal data for the purposes of participation in the PRECISEU PM School:

- Full name, contact information, institutional affiliation
- Dietary or accessibility requirements (if attending in person)
- Session attendance logs for issuing certificates
- Inclusion in follow-up communications (optional)

I understand that:

- My data will be securely stored and used solely for project reporting and communication.
- I can withdraw consent at any time by contacting [Data Controller Email].

I consent to the use of my data as described above.

I would like to receive updates about future PRECISEU activities.

Signature: _____

Date: _____



Media Release and Recording Consent Form

Media Consent – Photo/Video/Recording

I hereby give my consent for [Hosting Organisation] and the PRECISEU Consortium to:

- Photograph me during the PRECISEU PM School
- Record audio/video of sessions in which I may appear
- Use images/recordings in non-commercial project dissemination, reports, and communication (including online publication)

I understand that:

- My image will not be used for commercial purposes.
- Consent can be revoked by notifying the organisers at any time.

- I give my consent for photo and video usage as described.
- I do NOT give consent and prefer not to be recorded.

Signature: _____

Date: _____

Annex 3: Activities Sheets

Activity Sheet 1: Stakeholder Mapping Exercise

Objective:

Identify key actors in your regional personalised medicine (PM) ecosystem and analyse their roles, influence, and interdependencies.

Stakeholder Group	Example Institution	Role in PM	Influence (Low/Med/High)	Current Collaboration	Priority for Engagement
Academia					
Healthcare					
SMEs/Industry					
Policymakers					
Civil Society					
Patients					

Activity Sheet 2: Ethical Scenario Reflection

Objective:

Reflect on ethical challenges in personalised medicine through a real or hypothetical case.

Case Example:

A regional hospital implements AI-based risk prediction in cancer diagnostics, but patients are unaware that their data are being used for algorithm training.

Questions:

1. What are the ethical risks in this scenario?
2. Who are the affected stakeholders?
3. What actions would you recommend ensuring ethical compliance?
4. How would you communicate these risks to the public?

Activity Sheet 3: Regional Action Planning

Objective:

Draft a simple action plan for integrating personalised medicine into your region's innovation strategy.

Step	Action	Lead Actor	Support Needed	Timeline	Indicators of Success
1					
2					
3					

Activity Sheet 4: Policy Co-Creation Lab

Objective:

Work in a multi-stakeholder group to define a regional policy recommendation.

Topic:

How can your region support the integration of ethical AI in personalised health solutions?

Instructions:

- Define the challenge (10 min)
- Identify relevant actors (10 min)
- Draft 2–3 concrete policy actions (15 min)
- Prepare a short pitch for feedback (5 min)

Activity Sheet 5: Learning Reflection Journal

Objective:

Capture individual insights and learning outcomes from the PM School experience.

Prompt	Your Reflection
One new concept I learned that will change my work is...	
A stakeholder I plan to follow up with is...	
A challenge I want to address in my region is...	
I will apply what I've learned by...	