DIGIT-PRE

GUIDE FOR APPLICANTS

Open Call for SMEs
aiming to support the development of digital health solutions for prevention, prediction and remote care

This guide for applicants contains information on how to prepare a proposal for the DIGIT-PRE Open Call and become a granted project partner.

Open date for proposals: **27/09/2023** (Brussels Time)
Deadline: **30/11/2023 at 23H00** (Brussels Time)

**DIGIT-PRE is a part of the ERDF-funded
Interregional Innovation Investments (I3) Instrument.**
DIGITal tools delivering PREvention, prediction and remote care
through a resilient EU value network
to reduce health system stressors in a post-COVID world.

Grant Agreement number	101081934
Project Title	DIGIT-PRE
Deliverable	3.1
Dissemination level	Public
WP	3
Task	3.1 Open Call preparation and launch
Contractual delivery date	30/09/2023
Actual delivery date	30/09/2023
Lead beneficiary	Gérontopôle Nouvelle-Aquitaine
Contributors	All DIGIT-PRE partners

1 Introduction to the DIGIT-PRE Open Call

1.1 WHAT IS THE OPEN CALL?

The purpose of the Open Call is to support the creation of interregional **European project consortia of Small and Medium-sized Enterprises (SMEs)[1]** aiming to develop **digital health solutions for prevention, prediction and remote care, which with support from DIGIT-PRE will take the solutions from a Technology Readiness Level 6 to 9**.

> ***Technology Readiness Level:*** *the maturity level in the development of a technological solution*
> *TRL6 is for a technology demonstrated in a relevant environment.*
> *TRL9 is for a system proven in operational environment just before it goes to market.*

The solutions presented by the applying SMEs must both meet the challenges identified (see **3.1.2**) and be located in one of the 10 partners regions:

European regions:

FINLAND	FRANCE	SWEDEN	THE NETHERLANDS
Southwest	**Hauts-de-France** **(Nord Pas de Calais/Picardie NUT2)**	**Skåne (South NUT2)**	**South Netherlands** **(Nord Brabant/Limburg NUT2)**
HUNGARY		**Västerbotten (Upper Norrland NUT2)**	
Central Hungary	**Nouvelle-Aquitaine** **(Aquitaine/Limousin/ Poitou Charentes NUT2)**		**West Netherlands** **(Utrecht/Nord Holland NUT2)**
PORTUGAL			
Norte			
ROMANIA			
Nord-Vest			

By participating in the DIGIT-PRE project, these regions wish to support the development, marketing and internationalisation of next-generation solutions for prevention, prediction and remote care. The DIGIT-PRE Innovation Support Program will include a broad combination of different types of business growth support in order to attain this.

The Open Call is launched on 27/09/2023 and is closing on 30/11/2023 at 23h CET.

The Innovation Support Program will start in March 2024 and end in June 2025.

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[1] **SMEs** are defined in the [EU recommendation 2003/361](#): "The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ **fewer than 250 persons** and which have an **annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million**."

1.2 WHO CAN APPLY?

The above mentioned regions are identified as a part of the I3 instrument from the European Commission, which is a regional enterprise support scheme that seeks to promote innovation through Smart Specialisation strategies and interregional collaboration.

Consortia of 2 or 3 SMEs located in a minimum of 2 different regions of the DIGIT-PRE project (see complete list in section **1.1**; registered company address) **that want to accelerate the development of their proposed solution from TRL6 to TRL9.** The solution can be a product and/or service. The 2 or 3 partnering SMEs from these distinct regions will form a "**sub-project**".

DIGIT-PRE aims to bring together project teams that are complementary and/or cross-sectoral as well as cross-border and interregional in nature. SME partners can hail from either the same country, where there are at least two eligible participating regions, or from different countries combined. However, the project's goal is to promote international cooperation and knowledge-sharing across borders. Therefore, **project proposals that transcend regions and borders are strongly encouraged** and will have a competitive advantage during the evaluation process.

DIGIT-PRE provides a dedicated **online platform to facilitate SME matchmaking between potential applicants that have an interest in taking part in the project.** This is available on the DIGIT-PRE website: www.DIGIT-PRE.eu

Non-SME partners such as larger cooperations, NGOs and public actors, can be involved as "Silent Partners" (see section **8** Glossary) in the creation of a DIGIT-PRE sub-project. They can contribute to the project in whatever manner they see fit (including financially), but they will not be directly eligible for receiving funding under this call.

> *Example: a sub-project with 2 SMEs (partners) and a nursing home (public actor as a Silent Partner) where user tests will be organised means that the nursing home could be declared in the proposal as a partner but could not be a beneficiary of DIGIT-PRE funding.*

In summary, all DIGIT-PRE consortia must be composed of:
- **1 Lead Partner** (SME): intended to become a part of the DIGIT-PRE consortium
- **1-2 Supporting Partners** (SMEs)
- Optional: **Silent Partners** (non-SME partners)

An SME can only send <u>one</u> application in this Open Call.

The support scheme offered, will differ for the Lead Partners and Supporting Partners:
- **Lead Partners** will receive financial support up to €50 000 in direct funding via the DIGIT-PRE grant.
- **Supporting Partners** will receive financial support up to €20 000 in direct funding (Financial Support to Third Parties).
- **Each DIGIT-PRE sub-project (Lead Partners and Supporting Partners combined)** will jointly receive tailored support up to €140 000*

*Tailored and customised business support and guidance will be offered to the chosen projects and will be provided by the DIGIT-PRE project consortium partners. This will take the form of personalised support (mentoring) of an assigned Key Account Manager to each of the Sub-projects and additional choices of innovation services. For more information, please see section **3.4.2** Services.*

1.3 WHAT IS THE SUPPORT AWARDED? THE INNOVATION SUPPORT PROGRAM

Support for SMEs within selected sub-projects

The customised business growth support provided from the DIGIT-PRE project consortium partners is particularly focused on helping SMEs bring their product and/or service to international markets, to scale up internationally.

DIGIT PRE Consortium and Sub-project partnership Composition
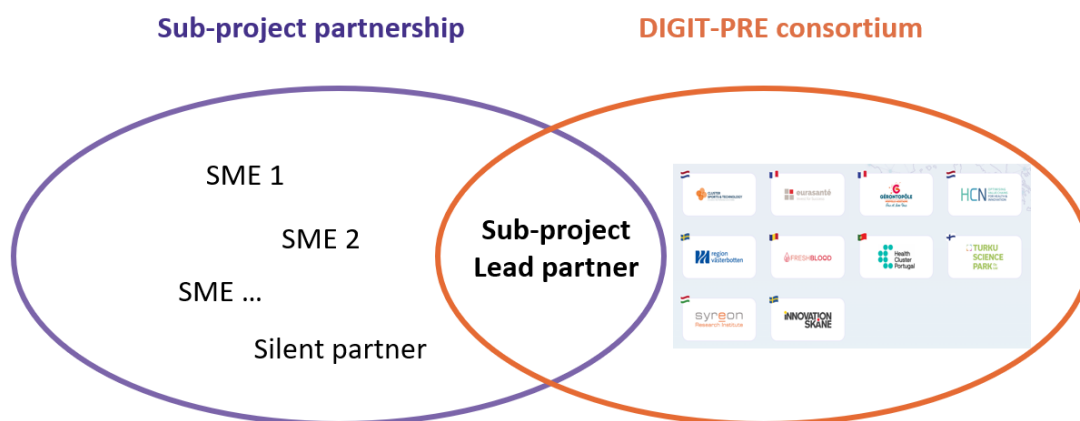
The support may be given by different means from the DIGIT-PRE project consortium partners based on the needs for each sub-project. A personalised Innovation Support Program will be set up following a self-assessment during the early phases after acceptance. A main contact person, a Key Account Manager (KAM) from DIGIT-PRE, will act as a dedicated support and guide the SMEs during all the activities of the support program.

2 About DIGIT-PRE

2.1 OBJECTIVES

DIGIT-PRE is a project designed to generate digital health innovations through cross-border and cross-sector collaborations among Small and Medium-sized Enterprises (SMEs).

In the context of the digital transformation of health and care, **DIGIT-PRE seeks to launch a sustainable EU value network that generates value via support activities to companies that increase their competitiveness and sustainability** as well as market readiness.

A specific focus is made on **consumer-facing** (see section **8** Glossary) **digital solutions for prevention, prediction and remote care** in a post-COVID world. This is because the project seeks to address emerging consumer and patient demand and trends, but also considers the specific needs of SMEs and early-stage growth companies, that prefer to achieve commercial traction in consumer markets first, before considering steps to access institutional markets including private equity.

In collaboration with a broad range of different stakeholders, DIGIT-PRE has identified **five areas** where digital solutions can play a significant role in achieving both project goals and improving health:

1. Mental health	2. Rehabilitation	3. Neurological Conditions	4. Healthy Lifestyle	5. Health & ageing

Within DIGIT-PRE, this set of specific **areas and more detailed challenges have been defined and aggregated during a process of collaborative regional assessment**. They were selected through regional events and linked to each specific region's health needs including **S3 Smart Specialisation Strategy** prioritisation (see section **8** Glossary).

The five areas constitute a framework, in which it is possible for SMEs to either focus on the main area or one of the more dedicated challenges directly. The more detailed challenges are presented on the DIGIT-PRE website and will be further presented in section **3.1.2**.

In summary, DIGIT-PRE aims to generate new health solutions through crossover collaboration between SMEs, while also supporting their entry into international markets. The solutions should focus on health prevention, prediction, or remote care. Furthermore, DIGIT-PRE generated solutions and tools should prioritize putting the user in control and empowering self-care whenever possible.

> The **Interregional innovation investments instrument** as part of the European Regional and Development Fund (ERDF) aims at supporting interregional innovation projects in their commercialisation and scale-up phases giving them the tools to overcome regulatory and other barriers and bring their project to investment level. Interregional is for creating links between European regions around Smart Specialisation (S3), Innovation for testing, validating, market replication, Investment for financial and advisory support, smart economic transformation or direct investment to companies (SMEs).

2.2   DIGIT-PRE CONSORTIUM PARTNERS

The DIGIT-PRE consortium gathers core competencies to accelerate market uptake and scale-up innovation solutions among 10 partners representing as many ecosystems across 7 European countries: Sweden, Finland, the Netherlands, France, Romania, Hungary and Portugal under the coordination of Innovation Skåne (Sweden).

DIGIT-PRE combines 10 regional ecosystems with diverse economic profiles and areas of expertise, such as:
- 5 complementary innovation clusters; competitive value chains for digital health solutions,
- 1 regional public living lab specialised in active and healthy ageing,
- 1 regional authority,
- 1 EIT RIS Hub/EIT Jumpstarter plus 2 specialist intermediaries.

This setup of support providers is unique and designed to provide the best foundation possible for helping SMEs to grow and reach market faster.

3 The DIGIT- PRE Open Call

3.1 OBJECTIVES

3.1.1 Expected results

The Open Call will provide support to the DIGIT-PRE sub-projects – each formed by 2 or 3 SMEs– seeking to develop and move their digital health solutions in prevention, prediction, and remote care from TRL6 to TRL9.

The selected SMEs under this Call must address the scope identified by the DIGIT-PRE project. DIGIT-PRE will support the selected sub-projects to further develop their innovative and commercial solutions to become market ready. This as a direct response to a selected challenge and/or area, which are connected to the 10 different DIGIT-PRE regions and linked to their respective S3 strategies.

3.1.2 Scope

The aim of DIGIT-PRE is to positively impact people's health while reducing stress on the national and European healthcare systems. By providing personalised information and early risk assessment of individual health situations, the goal is to prevent and predict the progression of conditions and diseases, minimize and/or delay hospitalization, and improve peoples' overall health and well-being. DIGIT-PRE generated solutions should be participatory and user-friendly for individuals and take into account usability, equality, and diversity considerations.

In collaboration with a broad range of different stakeholders, DIGIT-PRE has identified **5 AREAS and 14 CHALLENGES** where digital solutions have the potential to play a significant role in achieving project goals:

AREA	CHALLENGE
1. Mental Health	1.1 Early detection of signs and risk factors for mental illness among kids and adolescents
	1.2 Treatment support for eating disorders
	1.3 Palliative remote care
2. Rehabilitation	2.1 Adherence to self-care rehabilitation of Musculoskeletal Disorders
	2.2 Addressing relapse in addiction
3. Neurological Conditions	3.1 Improving care on post-stroke patients
	3.2 Detection of mild cognitive impairment to prevent dementia
	3.3 Early detections of Developmental Language Disorder
4. Healthy Lifestyle	4.1 Improving teenagers' sleep quality with incentive approaches
	4.2 Solutions for improved occupational wellbeing for office workers
	4.3 Exergaming for people aged 60+
5. Health and Ageing	5.1 Predicting emergency care to avoid hospitalizations
	5.2 Preventing falls of older adults
	5.3 Early detection of joint replacement infections
=> Read the full description of AREAS and CHALLENGES here.	

There are three different ways for SMEs to adress the challenges within the DIGIT-PRE Open Call:

- **By responding directly to one of the CHALLENGES** and solutions defined by DIGIT-PRE,

- **By reframing on of the CHALLENGES** and solutions by, for example, by targeting one of them with a different approach, or

- **By proposing an idea that specifically targets a health CHALLENGE that is different to the ones defined above, provided that this challenge** falls within one of the chosen broader AREAS e.g mental health, rehabilitation, neurological conditions, health lifestyle and healthy ageing and meets the general DIGIT-PRE requirements.

3.2 TIMETABLE

	Stage	Date and time or indicative period
1	Publication of the DIGIT-PRE Open Call	27/09/2023
2	Information webinar for applicants	28/09/2023
3	Deadline to submit proposals	30/11/2023 at 23h CET
4	Evaluation period	01/12/2023 – 15/01/2024
5	Approval by the European Commission for Lead Partners of sub-projects to become a part of the DIGIT-PRE consortium	15/01/2024 – 23/02/2023
6	Publication of results and information to all applicants	23/02/2024
7	Implementation of projects – Innovation Support Program activities initiation	March 2024
8	End of supported sub-projects	June 2025

The timeline above is indicative and may be subject to change.

3.3 ELIGIBILITY CRITERIA

In the selection of accepted sub-projects, an initial eligibility check will be performed by the DIGIT-PRE consortium project partners.

Below is a presentation of the evaluation grid which will be used:

Administrative	
English language	The application documents are written in English language and are comprehensible.
SMEs status	All the SMEs partners in the sub-project have an eligible legal status and meet the EC definition of an SME. Silent Partners do not need to have such a SME status.
Number and location of partners	There is a minimum of 2 SMEs from 2 different regions specified by the DIGIT-PRE project.
Sub-project Lead Partner process to be part of DIGIT-PRE (more info HERE)	The Lead Partner has initiated the process to follow the European Commission criteria to join the DIGIT-PRE partnership: Lear appointment, PIC number, Legal Entity Validation and SME assessment.
Documents	
	The Proposal template is provided, with appropriate sections completed.
	The signed declaration of honour of each partner of the sub-project is provided.
	The signed GDPR (General Data Protection Regulation) form is provided for each sub-project partner.
	Copy of certificate of professional liability insurance is provided .
Project	
Minimum TRL level	The digital solution proposed is at a minimum TRL6 (technology demonstrated in relevant environment).
Challenge addressed	The project addresses at least one of the challenges listed by DIGIT-PRE or presents and describes another challenge that is aligned with the 5 broader areas.
Cross-sectoral project	The partners in the sub-project are complementary or have cross-sectoral activities.
Consumer-facing solution	The sub-project considers the consumer-facing requirement which means that the beneficiary of the product/service is also the user.

According to the eligibility criteria listed above, the Lead Partner of the selected DIGIT-PRE sub-project, will in addition need to meet the European Commission (EC) requirements of becoming beneficiary within the I3 program call.

The requirements for this involve four steps and include receiving a Participant Identification Code (PIC number), Legal entity validation, Legal executive appointed representative (LEAR) Appointment and a SME assessment. More specific information on the steps of becoming a direct beneficiary of EC funding can be found here: Registration and validation of your organisation - Online Manual - Funding Tenders Opportunities (europa.eu).

3.4 TECHNICAL AND FINANCIAL SUPPORT

3.4.1 Innovation Support

After the closure of the DIGIT-PRE Open Call, including the evaluation procedure, and signature of sub-grant agreements, the selected sub-projects will benefit from personalised innovation support and business growth support to help the chosen DIGIT-PRE sub-projects on the route to success.

Each supported sub-project will be guided through the Innovation Support Program with the help of a designated Key Account Manager (KAM), who will be a staff member of one of the DIGIT-PRE consortium partners. The KAM will be committed to providing personalised guidance and support for all the sub-project-related activities and will act as the main point of contact. The KAM will start with an individual assessment of services suitable and/or needed for each sub-project. The initial assessments to establish a plan for the support will be in the form of:

- **A self-assessment exercise** with the help of an Innovation Health Check tool , determining the "innovation orientation" of each participating SME;
- **A pitch and critical project assessment event** organised in one of the participating regions. Physical attendance will be mandatory.

Based on the outcome of these assessments, the KAM will provide suggestions to be jointly agreed upon, the KAM will present what types of **services** to be provided during the support phase of the DIGIT-PRE program and will reach out to service providers to initiate the provision of such support. The KAM will frequently evaluate progress and guide towards the most successful development of each sub-project through mentoring, advice and sign-posting to other providers of specialist services. **Services will be provided by experts within the DIGIT-PRE consortium project partners.** The main types of services offered through DIGIT-PRE project are described in more detail in section **3.4.3**.

One of the important services that the DIGIT-PRE project offers is the possibility of validating the proposed prototype product/service in a demonstrator. Access to listed demonstrators and testbeds will be provided by the project.

When suitable, each sub-project/product/service can be supported for investment by for example getting:

- Advice on how to undertake an investment pitch;
- Advice on the possible investment options available;
- Access to a dedicated investors day.

The sub-project and KAM will navigate through all these possible steps and help with the necessary financial and technical report that may be required.

3.4.2 Services within DIGIT-PRE and the Innovation Support Program

A range of services will be made available for the selected sub-projects **according to their needs highlighted** during the Initial intake and assessment with their assigned KAM (see section **3.4.1**).

All sub-projects will have the opportunity to receive expert advice and other services provided by the DIGIT-PRE consortium, please see the non-exhaustive list below.

Note that each sub-projects/SME will also have the possibility to use the cash funding they are given to buy external services.

INTERNAL SERVICES

TESTING

Access to testing facilities

Clinical training centre

Clinical Research Centre

Living-Lab (Public Space, Sport, Work, Technology for older adults)

Test-bed Advice

User tests in controlled environment

User tests in situ, in vivo (real environment)

REGULATORY AND LEGAL ASPECTS

Ethical applications

Initial Regulatory Guidance

IPR (Intellectual Property Rights) Navigation Advice

Soft-Landing in France

Understanding of the Regulatory Constraints and the Legal Environment of your business

FUNDING AND INVESTMENT

Capital Structure

Investment Advice

Investor Onboarding

Investor Networking and Matchmaking

Product Market Fit Advice

Investment or Funding Advice

Public Fund Research

Public Funding

MARKET ACCESS

Environment and Market Analysis

Development of Value Framework

Cost-Effectiveness Model Development

Budget Impact Model Development and Adaptation

Go To Market Strategy Advice

Healthcare Marketing

Health Domain Navigation

Market Access

Market Access Training

Minimum Viable Product Advice

Procurement

Public Funding/New Market Launch

Public Health and Health Promotion

Selection of Target Indications and Populations

Value Proposition

NETWORKING

Dissemination and Networking

Get Access to New Business Opportunities (International Events)

Internationalizing

National Innovation Events

Networking Support

Patient Engagement

Stakeholders Access

Stakeholders Engagement

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BUSINESS DEVELOPMENT AND STRATEGY	CONSULTING
Access to Skilled Workforce	Business Case
Business Development Coaching	Business Mentoring
Business Model Development	Clinical Evaluation
Commercial Business Model Advice	Communication Package
CST Vitaly Accelerator (part of validation in the innovation cycle)	Data/AI/Bigdata/Blockchain Initial Advice
CST Vitaly Ideator (Tool for co-creation with end-user)	Expert Evaluation Panel
	Health Technology Productization
CST Vitaly Monitor (Tool for end user needs assessment)	Investment Readiness Process
	Pilot Production Advice
CST Vitality Pitch Stop (Tool for intake of innovative companies and concepts)	Patient Public Engagement and Involvement
	Showcase and Demonstration
Development of new opportunities with an international business developer	Technical Prototype Development
	Consulting Hour (for business, issues)
Finance/Funding (Dilutive and non-dilutive)	Scoping Review
Growth Team Development Advice	
Innovation management	
Market Study	
Net present Value/Estimation for GO/NO GO Decision	
Patient and Public Involvement and Engagement	
Team Co-Development Advice	
User Needs Assessment	

3.4.3 Help supported SMEs get investment for growth

The DIGIT-PRE network helps supported SMEs to **pitch** to business angels and explore their suitability regarding other investment options. But knowing ones product and having a great pitch is not enough. It is about **understanding the targeted market segment** for growth and to **achieve market traction faster**, meaning how investors are behaving with any corresponding trends analysis, what financial backing is available for each specific value proposition, as well as understanding how to "pitch to" investors and which information is needed in order to make a compelling case to inform negotiations for any further investment and support.

Therefore, the KAMs will work with each SME/sub-project chosen to **produce evidence supporting your value proposition.** This may include a values dossier/providing a form of independent verification with the results of three key assessments: due diligence investment readiness, market readiness and early health technology assessment.

3.4.4 Funding scheme and rules

To be able to receive support and funding from DIGIT-PRE, a set of contractual agreements needs to be in place. These are contained on three different levels, as described below.

1/ Between DIGIT-PRE and the Lead Partner the following contractual agreements need to be signed:

DIGIT-PRE Grant Agreement (see definition in section **8** Glossary)

All **Lead Partners** are intended to sign the **DIGIT-PRE Grant Agreement in order** to join the DIGIT-PRE partnership. The Grant Agreement defines what activities will be undertaken, the duration of the project, overall budget, rates and costs, the EU budget's contribution, all rights and obligations and more.

DIGIT-PRE Consortium Agreement (see definition in section **8** Glossary)

All Lead Partners will have to sign the DIGIT-PRE Consortium Agreement stipulating the rights and obligations between the beneficiaries within DIGIT-PRE with regards to the execution of DIGIT-PRE.

2/ Between DIGIT-PRE and the sub-project the following contractual agreements need to be signed:

Sub-project Grant Agreement (see definition in section **8** Glossary)

Lead Partners and Supporting Partners will have to sign a joint Sub-grant Agreement with DIGIT-PRE which will detail the conditions of the support. The sub-project Grant Agreement will be signed by ALL partners within the sub-project and Innovation Skåne as DIGIT-PRE coordinator.

3/ Between the partners within each sub-project (Lead Partners and Supporting Partners), the following contractual agreements need to be produced and signed:

Sub-project Consortium Agreement (see definition in section **8** Glossary)

Sub-project teams will need to confirm the existence of an Internal Consortium Agreement regulating their financial share/operation of the budget, responsibility between partners and Intellectual Property Rights (IPR).

NB! It is important to note that the agreement contracts shall follow the ERDF Interregional Innovation Investments Instrument (I3) General Model Grant Agreement, article 9, and must include the following two articles:

the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23

EU services can go to the premises of the Granted project's lead by a SME for carrying out checks about the compliance of the conditions for the financial support.

3.4.5 <u>Payments</u>

The financial support provided by DIGIT-PRE will consist of two payments:

- **Pre-financing payment** to be received at the initiation of the Innovation Support Program
- **Final payment** linked to the provision and approval from the European Commission of the final report.

Pre-financing amounting to 50% of the total amount for both the Lead Partner and Supporting Partner, will be paid on commencing the Innovation Support Program (€25 000 for the Lead Partner and €10 000 for each Supporting Partner). The remainder of the financial support will be paid upon delivery of an approved final report of participation in the program (up to €25 000 for the Lead Partner and another €10 000 for the Supporting Partner).

To receive payments, a requisition form will need to be sent to the project coordinator Innovation Skåne. A template will be provided for this.

NB! For Lead Partners to receive the full amount of €50 000, incurred costs of € 80 000 related to the development and exploitation of the DIGIT-PRE product and project involvement must be reported as part of final reporting.

For Lead Partners, costs to be reimbursed must fall within the following three cost categories as specified by the European Commission for the I3 program: personal costs, other costs (travel and subsistence) and/or sub-contracting costs.

3.5 ETHICS AND DATA PROTECTION

3.5.1 <u>Ethics</u>

DIGIT-PRE has a **responsibility to promote the integrity of research and innovation conducted by all supported sub-projects**. Accordingly, all granted sub-projects will be required to sign a discharge of responsibility in favour of DIGIT-PRE and European Commission. This does not preclude the responsibility of funded sub-projects themselves to ensure compliance with ethical principles and relevant national, EU and international legislation. DIGIT-PRE does not support sub-projects that do not comply with ethical principles and regulations including being risk to harm humans and or environment.

A **guideline for ethics and data protection** will be shared together with an initial self-assessment mechanism. Sub-projects with potential risks connected to ethics and ethical standards will be identified and shared with the Ethics Advisory Panel (EAP) for review and recommendations. The EAP is an external and independent organ assigned by DIGIT-PRE with overall objective to ensure the compliance of sub-projects to European Ethical aspects and related regulations. The EAP have the mandate to reject or stop a sub-project if violation of ethics is detected.
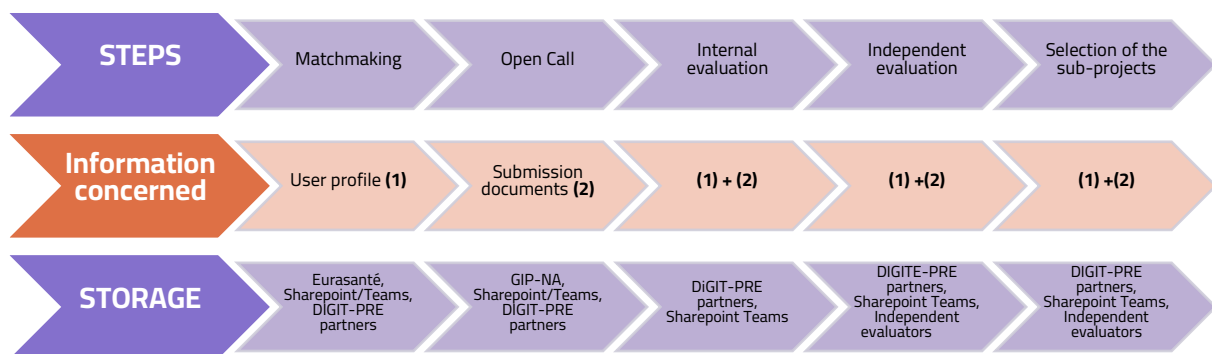
3.5.2 Data flow of the Open Call

DIGIT-PRE partners are committed to protect and respect applicants' privacy. The personal data collected will be processed in accordance with the General Data Protection Regulation EU 2016/679 and the information contained on Google Drive will be accessible only by the administrator (Eurasanté) and the creator of the user profile with a personal and confidential code.

A document about applicants' personal data and their treatment (**DIGIT-PRE GDPR Form**) will be made available during the Open Call and must be signed by all partners from each submitted project.

A **Data Management Plan** (DMP) is implemented by all DIGIT-PRE consortium partners and a platform will be prepared for secure management and monitoring of contracts. The DMP specifies the handling of project results, more specifically which results will be publicly available and which results will be privately used with the proper justification.

It clarifies how data will be handled during and after the project.

STEPS	Matchmaking	Open Call	Internal evaluation	Independent evaluation	Selection of the sub-projects
Information concerned	User profile **(1)**	Submission documents **(2)**	**(1) + (2)**	**(1) +(2)**	**(1) +(2)**
STORAGE	Eurasanté, Sharepoint/Teams, DIGIT-PRE partners	GIP-NA, Sharepoint/Teams, DIGIT-PRE partners	DiGIT-PRE partners, Sharepoint Teams	DIGITE-PRE partners, Sharepoint Teams, Independent evaluators	DIGIT-PRE partners, Sharepoint Teams, Independent evaluators

All selected sub-projects through this Open Call are responsible for their own data management as part of DIGIT-PRE Innovation Support Program.

3.6   INTELLECTUAL PROPERTY RIGHTS

The ownership of all intellectual property created during the Innovation Support Program via the DIGIT-PRE Open Call, will remain with the party having developed it. The Sub-grant Agreement will define provisions regarding joint ownership of the results of the granted projects.

Moreover, the applicants will also define this point in their sub-project Consortium agreement that will be signed between the partners of the project. The responsibility of DIGIT-PRE cannot be engaged in this topic.

4 Prepare and Submit Your Application

4.1 KEY DOCUMENTS

This **Guide for Applicants** is the overarching reference document of the DIGIT-PRE Open Call.

Prior to preparing a proposal, please verify:
- whether your organisation, product or service complies with the eligibility criteria (see **3.3**).
- whether your services/product target one or more of DIGIT-PRE challenges or areas.

4.2 APPLICATION CONTENT

Proposals must be submitted directly on the DIGIT-PRE website in the dedicated Online submission tool.

A full application is composed of:	
1	**A 10 pages (maximum) project proposal** (see *template* – to convert in PDF before submission)
2	**A 10 slides (maximum) PowerPoint pitch** (see *template* – to convert in PDF before submission)
3	**GDPR Form signed by each partner** (document about personal data management during the support of the sub-project) signed by each partner (see *template* – to convert in PDF before submission)
4	**Declaration of honour signed by each partner** (see *template* – to sign and scan: PDF to be submitted)
5	**Proof of TRL6 achievement** for the product/service in focus of the sub-project (video, leaflet, etc.)
6	**Company Registration Certificate** for each SME partner (Ie Chamber of Commerce or other national company registration office)
7	**Professional liability Insurance certificate** (for each partner)
8	**Passport or ID Copy** of Lead Partner executive
9	**Verification of Companies' financial status** for each SME partner (NOT bank statement, but proof of connection between stated accounts and SME)

We remind you that **an SME can only send one application in this Open Call.**

4.3 SUBMISSION COMPLETION

Proposals are submitted in a single stage via the online submission tool available on the DIGIT-PRE website. Proposals submitted by any other means or received past the dedicated deadline will not be evaluated. After the deadline for submission of proposals, changes or additions are no longer possible. The date and time of the submission of the application will be automatically recorded and an acknowledgement of receipt of your proposal will be sent to the applicant by email.

If you have questions before submission of your proposal, you can send an email to:
contact@digit-pre.eu

4.4 ADDITIONAL INFORMATION

10 to 12 sub-projects are expected to be selected in this call. The total grant and/or investment to be made in SMEs through the DIGIT-PRE project **totals €900 000.** Depending on the sub-project consortium setups, the exact number of sub-projects that can be awarded can vary between 10 and 12. **Sub-projects will be financed until the remaining budget is insufficient to fund the next best application**.

An informative webinar will be planned for the potential Lead Partners during the Open Call. The event will be posted on the DIGIT-PRE website and invitations will be extended through the DIGIT-PRE newsletter. On the website, a continuously updated Questions & Answers-section will be made available. In order to guarantee full access to information, make sure to sign up for the DIGIT-PRE newsletter (www.digit-pre.eu).

Applicants are solely responsible for the content of their submission to the DIGIT-PRE Open Call. They are obliged to ensure that no legal obligations are violated and that they act according to the laws of their country. In the event of a dispute during your project's support program, Swedish law will apply, as DIGIT-PRE coordinator, Innovation Skåne, is financially responsible.

Moreover, DIGIT-PRE partners are not responsible for the content of the consortium agreement signed between the individual partners of the proposed sub-project submitted.

The DIGIT-PRE consortium shall not be liable in the event of loss of a submitted proposal namely due to any internet network interruptions.
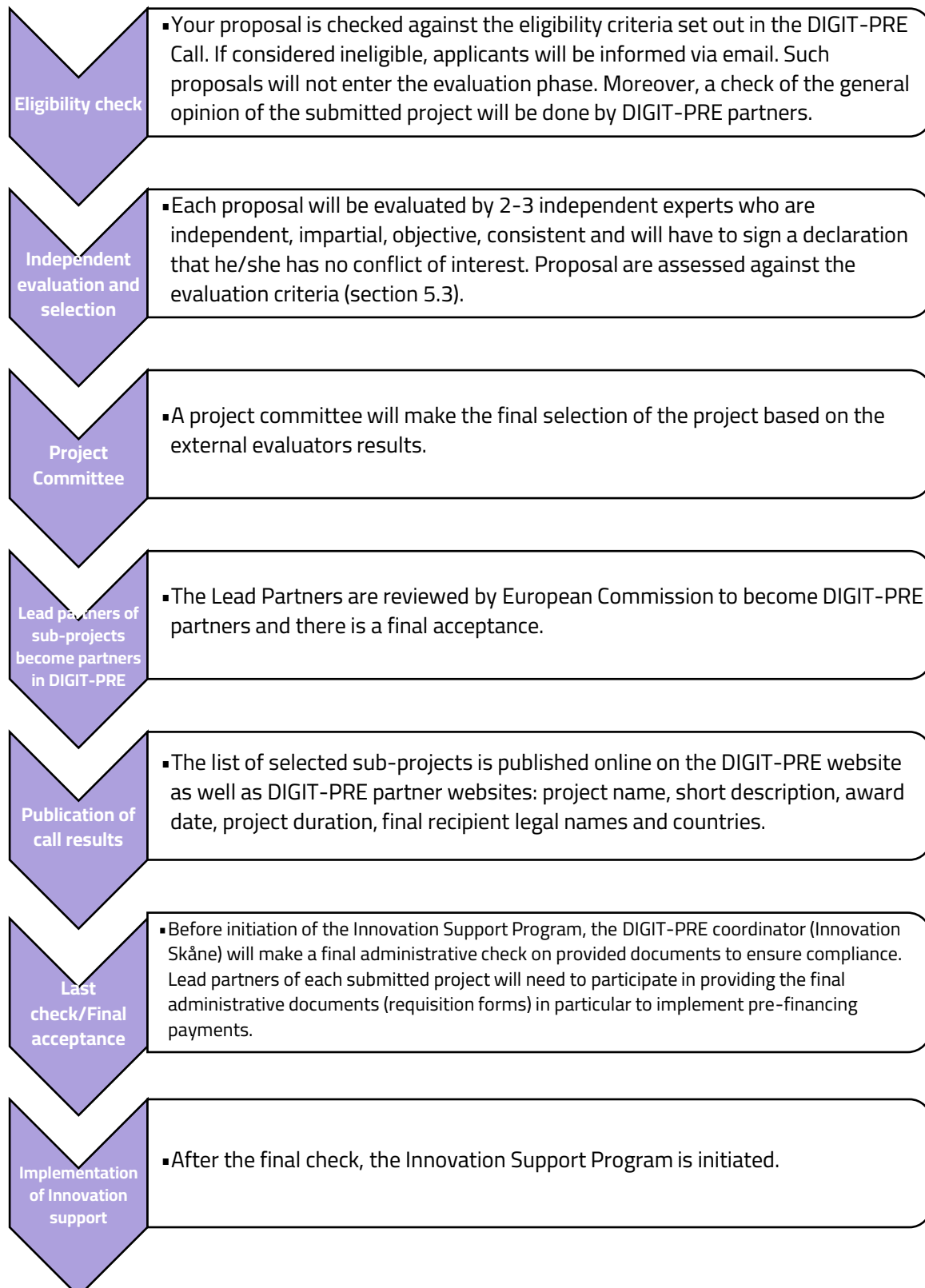
This funding scheme is part of a project that is co-funded by the European Union's i3 Program, under Grant Agreement N° 101081934.

The EU is not participating as a contracting authority in the implementation of the call for proposals.

> **In case of any problems with the submission system,**
>
> **applicants will have to send a timely notification to i-lesterpt@gerontopole-na.fr**

5 Evaluation

5.1 SUMMARY OF THE EVALUATION PROCESS

Eligibility check
- Your proposal is checked against the eligibility criteria set out in the DIGIT-PRE Call. If considered ineligible, applicants will be informed via email. Such proposals will not enter the evaluation phase. Moreover, a check of the general opinion of the submitted project will be done by DIGIT-PRE partners.

Independent evaluation and selection
- Each proposal will be evaluated by 2-3 independent experts who are independent, impartial, objective, consistent and will have to sign a declaration that he/she has no conflict of interest. Proposal are assessed against the evaluation criteria (section 5.3).

Project Committee
- A project committee will make the final selection of the project based on the external evaluators results.

Lead partners of sub-projects become partners in DIGIT-PRE
- The Lead Partners are reviewed by European Commission to become DIGIT-PRE partners and there is a final acceptance.

Publication of call results
- The list of selected sub-projects is published online on the DIGIT-PRE website as well as DIGIT-PRE partner websites: project name, short description, award date, project duration, final recipient legal names and countries.

Last check/Final acceptance
- Before initiation of the Innovation Support Program, the DIGIT-PRE coordinator (Innovation Skåne) will make a final administrative check on provided documents to ensure compliance. Lead partners of each submitted project will need to participate in providing the final administrative documents (requisition forms) in particular to implement pre-financing payments.

Implementation of Innovation support
- After the final check, the Innovation Support Program is initiated.

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5.2 EVALUATION PRINCIPLES

All evaluations are carried out in the light of the same basic principles:

- **Excellence**: the proposals selected for funding must demonstrate high quality in the context of topics such as consumer facing solutions and all other criteria set out in the DIGIT-PRE Open Call.
- **Transparency**: funding decisions are based on clearly described rules and procedures, and all applicants will receive adequate feedback on the outcome of the evaluation of their proposals.
- **Independence**: evaluators assess proposals on an individual basis. Evaluators represent neither their employer nor their region or country.
- **Impartiality**: all proposals submitted to the Open Call are treated equally. They are evaluated impartially on their merits, irrespective of their origin or the identity of the applicants.
- **Objectivity**: evaluators assess each proposal as submitted and not on its potential if certain changes were to be made.
- **Accuracy**: evaluators make their judgment against the official evaluation criteria of the Open Call, and nothing else.
- **Consistency**: evaluators apply the same standard of judgment to all proposals.
- **Confidentiality**: all proposals and related data, knowledge and documents are treated in confidence.

5.3 EVALUATION CRITERIA

All eligible proposals are ranked according to the total number of points attributed in the evaluation grid of the award criteria as you can see in the table below. DIGIT-PRE project will fund between 10 and 12 projects. If all eligible proposals fall below the thresholds, no selection will be made, and another Open Call might be opened later. As indicated previously, cross-regional projects can be submitted but it is recommended to us a trans-national approach when establishing sub-project partnerships.

The independent evaluation experts will be advised to perform the proposal evaluations, including their rating and ranking, in accordance with requirements and objectives specified in the Open Call, according to the following criteria:
- Innovation concept and content
- Impact of the solution and market analysis
- Quality and efficiency of the implementation

Evaluation scale

The proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.	**Very poor**	0
The criterion is inadequately addressed, or there are serious inherent weaknesses.	**Poor**	1
The proposal broadly addresses the criterion, but there are significant weaknesses.	**Fair**	2
The proposal addresses the criterion well, but with at least one moderate weakness.	**Good**	3
The proposal addresses the criterion very well, although with minor weaknesses.	**Very good**	4
The proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.	**Excellent**	5

	Evaluation Criteria	Score
	INNOVATION CONCEPT AND CONTENT	
1	Clarity and pertinence of the project objectives, compliance with Open Call challenges	
2	Soundness and feasibility of the concept and methodology	
3	Innovation potential and demonstration that it is beyond the state of the art	
4	Clear presentation of the digital solution, target audience, components (existing and to be developed) and of the customer journey	
5	A clear explanation of user-centred development of the solution	
6	Proof of TRL 6	
	TOTAL	
	IMPACT AND MARKET	
7	Positive impact of the digital solution, in line with the Open Call objectives	
8	Clear explanation of the need or relevance of the solution and / or the extent of the health issue targeted	
9	Market opportunity (analysis of the existing market for their solution)	
10	Credibility of the strategy and business model	
11	Clear explanation of the European and regional impacts of the solution	
12	Consideration of data ethics and privacy issues	
	TOTAL	
	QUALITY AND EFFICIENCY OF THE IMPLEMENTATION	
13	Realistic and tangible expected results	
14	Clear and realistic project activities (detailed timeline)	
15	Clear added value of DIGIT-PRE to the project	
16	Relevance and efficiency of the environmental and sustainable plan to limit and monitor the project impact	
17	Development barriers well identified, and mitigation measures proposed	
18	Sufficient operational and cross-sectoral capacity to successfully carry out the project activities	
	TOTAL	
FINAL SCORE		

The highest scores will be selected, and the final selection committee will focus on having at least, one project per region partner in DIGIT-PRE.

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6 Manage Your Grant

6.1 DOCUMENTS AND CONTRACTS TO BE PROVIDED

6.1.1 For the eligibility check
- Signed sub-project Consortium Agreement
- PIC Number active for Lead Partners
- Ethics Assessment
- NDA (non-disclosure agreement)
- Bank account information (proof that the account for transactions belongs to the company awarded acceptance – not financial statement)
- Passport or ID Copy of the leader of the project

6.1.2 Upon acceptance:
- LEAR appointment, Legal Entity Validation and SME assessment (only for Lead Partners, managed via the EU Funding and Tenders Portal)
- Detailed budget (specifying Lead Partner costs)
- DIGIT-PRE Grant Agreement and DIGIT-PRE Consortium Agreement signed (for Lead Partner)
- Sub-project Grant Agreement (Lead Partner and Supporting Partner jointly)

6.1.3 Reporting and Documentation:
- Applicants must clearly indicate **in their proposal** the expected achievements from participation in the DIGIT-PRE Innovation Support Program and propose milestones to follow-up progress. This information will be discussed and validated with the KAM, and used during the reviews, in order to receive the distributed payments.
- At the end of the Innovation Support Program, the Lead Partner is to submit a cost claim with a compilation of costs to be reimbursed accompanied by invoices and proofs of payment. A template will be made available for this purpose.

6.2 ADMINISTRATIVE MANAGEMENT

A **set of 5 milestones are planned** for the selected sub-projects during their participation in the DIGIT-PRE Innovation Support Program. To provide timely, accurate and sufficient activity and financial reports is to be considered a legal obligation for all the sub-projects partners involved. The milestone reports are to be delivered on months 3, 6, 9, 12 and 15 (final report), templates will be provided for this purpose:

- 1st Report: May 2024
- 2nd Report: August 2024
- 3rd Report: November 2024
- 4th Report: February 2025
- 5th Report: May 2025

The deadlines can be subject to change and are therefore to be considered indicative. The reports will be reviewed and approved by the Key Account Manager in cooperation with project management.

Sub-projects are requested to keep and maintain all necessary supporting documents and records during the grant period.

All documentation and contracts will be retained in DIGIT-PRE archives until the end of the DIGIT-PRE activities and for another 5 years as compliant with EU Regulations. It is possible to exercise your access, rectify, cancel or opposition rights by contacting DIGIT-PRE **Data Protection Officer** Cecilia Gravin by sending an email to cecilia.gravin@innovationskane.com.

6.3 RESPONSIBILITIES OF AWARDED SUB-PROJECTS

If the action includes providing financial support to third parties (e.g., grants, prizes or similar forms of support), the beneficiaries must ensure that their contractual obligations under the following articles of the DIGIT-PRE Grant Agreement (information available upon request): articles 12 (conflict of interest), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping) also apply to the third parties receiving the support (recipients).

The beneficiaries must also ensure that the bodies mentioned in Article 25 of the DIGIT-PRE Grant Agreement (e.g., granting authority, OLAF (European Anti-fraud Office), Court of Auditors (ECA), etc.) can exercise their rights also towards the recipients.

7 Communication Rules

All external communication from awarded sub-projects related to **activities within DIGIT-PRE have to mention that support has been received from the European Commission I3 fund for the development of the product/service**. The communication must show the DIGIT-PRE and the European Commission logos (these will be provided). Moreover, in case of digital network communication, DIGIT-PRE should be tagged. More detailed instructions will be provided.

All Lead Partners of the sub-projects are intended to become DIGIT-PRE partners and are upon acceptance obliged to follow the same communication requirements as the other DIGIT-PRE partners.

8 Glossary

Consumer-facing: A consumer-facing product or service is one that directly targets and is accessible to individual consumers and/or patients for their personal use or consumption. Consumer-facing solutions are designed with the intention of meeting the needs, preferences, and demands of end-users to maintain or improve their state of health.

DIGIT-PRE Consortium Agreement: The consortium agreement is a cooperation agreement for collaborative projects, involving public and private partners, with no financial flow between parties, each partner being subsidised for the completion of the project. It is a private agreement signed between the partners to define mutual rights and obligations. This type of document will have to be signed pplbetween Leaders of sub-projects and DIGIT-PRE. The DIGIT-PRE Consortium Agreement is based upon the DESCA - Model Consortium Agreement for Horizon Europe, version 1, December 2021.

DIGIT-PRE Grant Agreement: The Grant Agreement is the document which is signed by all DIGIT-PRE partners. It defines what activities will be undertaken, the project duration, overall budget, rates and costs, the EU budget's contribution, all rights and obligations and more. All Leaders of sub-projects will have to sign it to join DIGIT-PRE.

Lead Partner: When SMEs will have found their partner(s) before to candidate to DIGIT-PRE Open Call, they will set up a consortium and one of them will become the Lead Partner for the sub-project. This Lead Partner will be the main contact during the Innovation Support Program and will also become a DIGIT-PRE partner.

S3: Smart Specialisation Strategies are a policy tool which details the prioritisation of specific strategic domains. Each country and region have their own S3 priorities.

Silent Partner: The organisations which are not SMEs (according to [European definition](#) or are SMEs which are not located in DIGIT-PRE Regions are considered as Silent Partners. The Silent Partners cannot be beneficiaries of DIGIT-PRE Open Call support during the Innovation Support Program

Sub-project Consortium Agreement: Sub-projects Lead Partners and Supporting Partners will have to confirm that they have signed a sub-project agreement relating their mutual rights and obligations during their collaboration within their sub-project.

Sub-project Grant Agreement: This document details the condition of the support program provided by DIGIT-PRE. It will be signed by Lead Partners and Supporting Partners of the sub-project with DIGIT-PRE as well as Innovation Skåne as DIGIT-PRE coordinator.

Supporting Partner: Within the consortia, SMEs that are not Lead Partners will be Supporting Partners.

TRL: Technology Readiness Level is a method used to measure and assess the maturity of a particular technology. They allow engineers, managers and project personnel a consistent point of reference for figuring out how a technology is changing. There are 9 levels which are describing the step of development of the technology. [More information here](#). In DIGIT-PRE project, TRL 6 to 9 are targeted. TRL6 is for a technology demonstrated in a relevant environment TRL9 is for a system proven in operational environment.