



Unit H3 - eHealth,
Ageing and Wellbeing
DG CNECT
11 March 2024

#DigitalEuropeProgramme



Webinar on DIGITAL Europe Programme – Digital Health topics in the 2024 call

Disclaimer: information not legally binding

The meeting will start at 10:00.

Please keep your microphones muted and your video switched off.

If you have any questions, please type them in the chat.



The main graphic area of the slide. It features a large, stylized graphic on the left with the text "DIGITAL EUROPE PROGRAMME" and several icons representing digital health and technology. To the right of this graphic is the title "Digital Europe Programme" in large white letters. Below the title is a circular graphic with the text "DIGITAL HEALTH CALLS 2024" in yellow. At the bottom right of the graphic area is the hashtag "#DigitalEU". The background is dark purple with a grid of small white dots on the right side and abstract white lines at the bottom.



Agenda: 11 March 2024, 10:00 – 12:00 CET

Disclaimer: information not legally binding

- 10:00 – 10:05 Welcome and agenda
- 10:05 – 10:20 Introduction to the DIGITAL Work Programme for the year 2024
- 10:20 – 10:40 **Supporting patients' access to their health data in the context of healthcare services for citizens across the EU - [DIGITAL-2024-CLOUD-AI-06-HEALTHACCESS](#)**
- 10:40 – 11:00 **Demonstrating the in-service use of the European Electronic Health Record Exchange Format (EEHRxF) in healthcare settings - [DIGITAL-2024-CLOUD-AI-06-HEALTHRECORD](#)**
- 11:00 – 11:20 **1+ Million Genomes: sustainability and uptake - [DIGITAL-2024-CLOUD-DATA-AI-06-GENOME](#)**
- 11:20 – 11:40 Q&A session & Timeline
- 11:40 – 11:50 Participant Identification Code (PIC) - registration & validation (REA)
- 11:50 – 12:00 Closing remarks



Online Webinar 11 March 2024

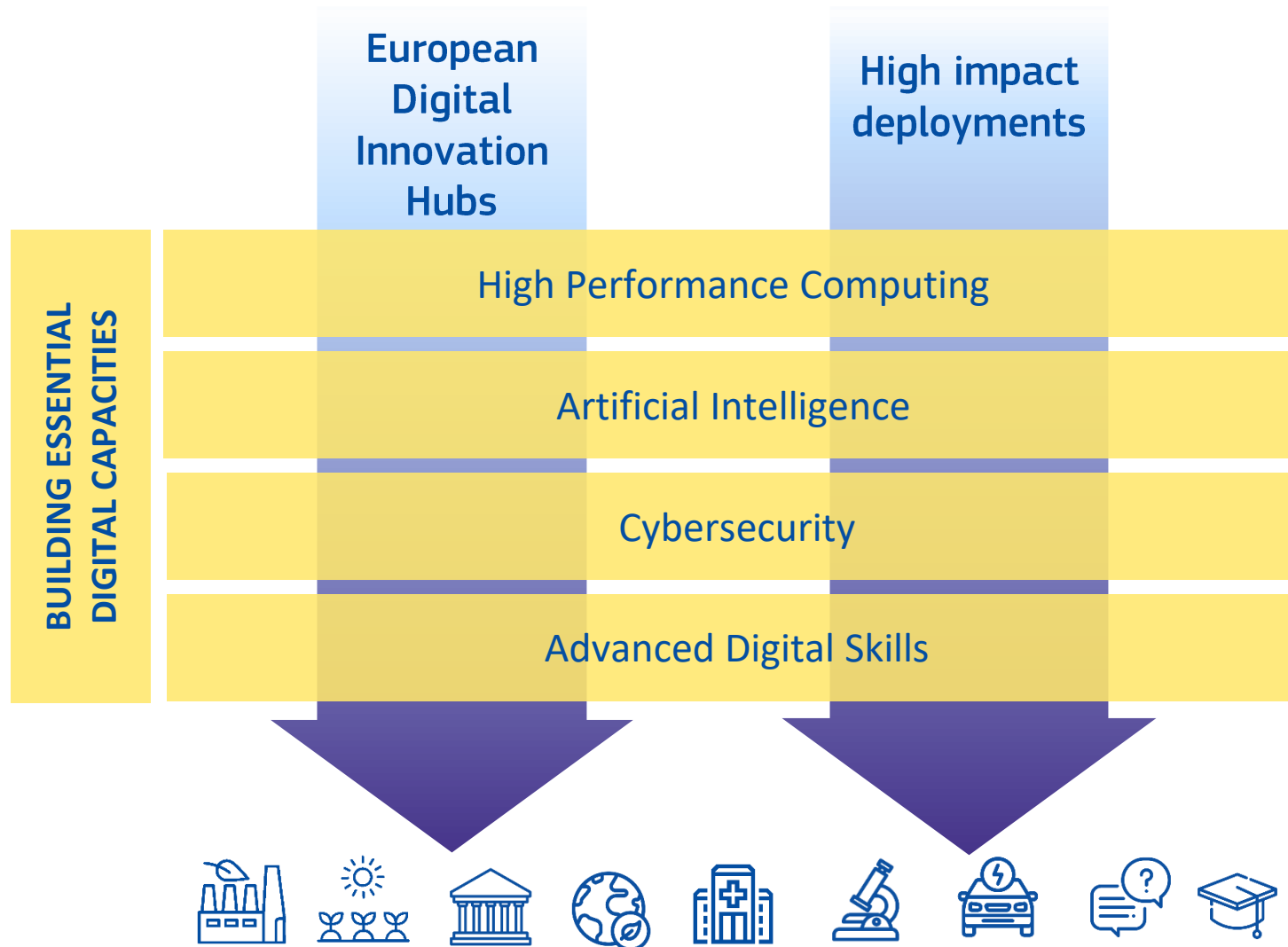
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Introduction to the DIGITAL Europe Work Programme for the year 2024

Digital Europe programme structure

Disclaimer: information not legally binding

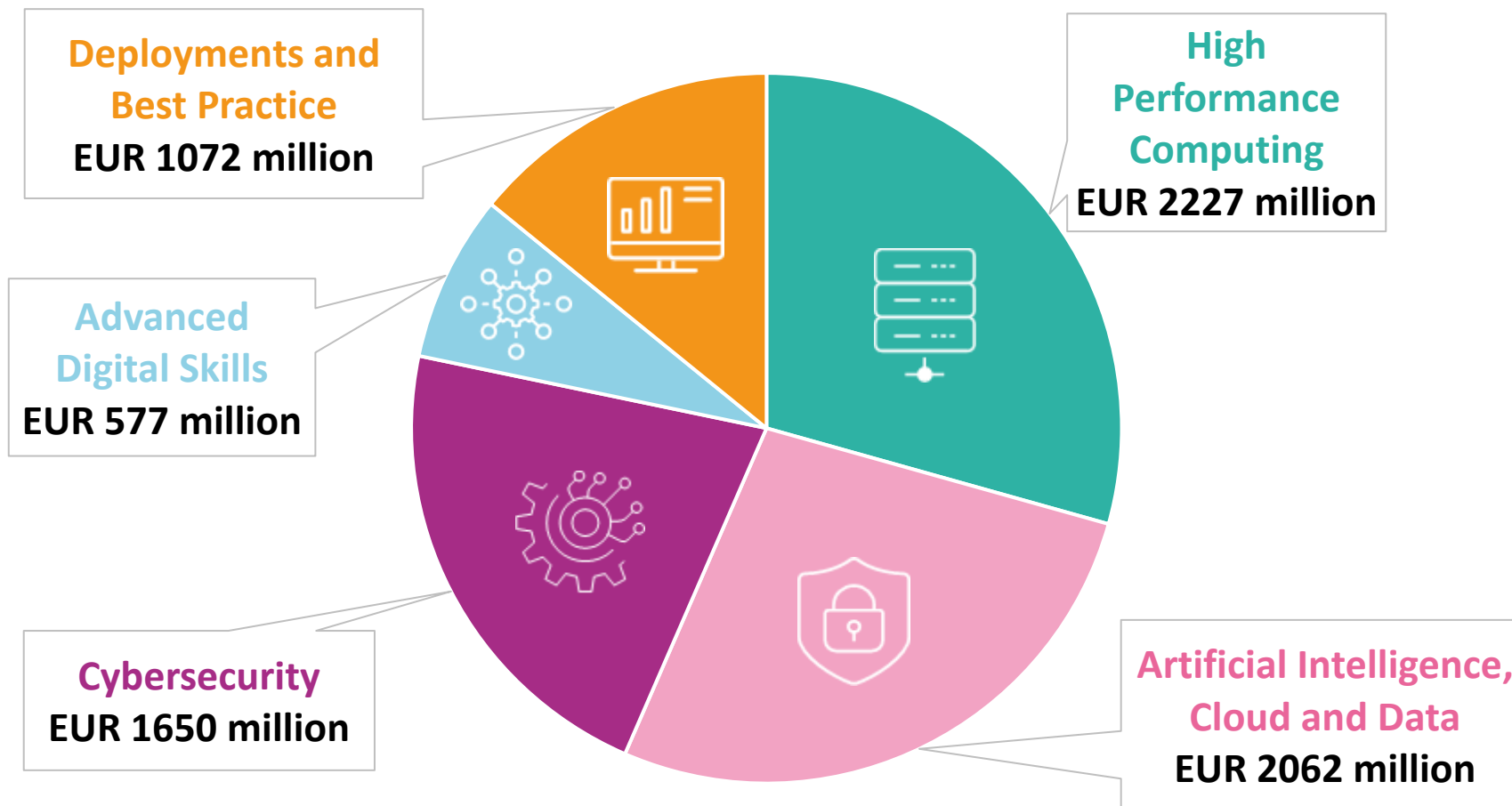
ACCELERATING THE BEST USE OF DIGITAL TECHNOLOGIES





Digital Europe Programme Budget as in Regulation

Disclaimer: information not legally binding



Total: EUR 7588 million for 2021-2027

SO2: Artificial Intelligence, Cloud and Data

3rd set of calls



Cloud-to-Edge infrastructure

Reference deployments of
European cloud-edge
services

Data Spaces

Skills

Energy

Agriculture

Health Data Spaces

Mobility

3D

Green Deal

Manufacturing

AI

Regulatory sandboxes

Pilot Testing Facilities

Quantum systems

Language Technologies

Open-source models

Health



ARTIFICIAL INTELLIGENCE, DATA AND CLOUD

(Health) Data spaces

Demonstrating the in-service use of the European Electronic Health Record Exchange Format (EEHRxF) in healthcare settings

3rd Call Q1/2024

Supporting patients' access to their health data in the context of healthcare services for citizens across the EU

3rd Call Q1/2024

1+ Million Genomes: sustainability and uptake

3rd Call Q1/2024

Artificial Intelligence

***Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare**

3rd Call Q1/2024



Supporting patients' access to their health data in the context of healthcare services for citizens across the EU

[DIGITAL-2024-CLOUD-AI-06-HEALTHACCESS](#)



Supporting patients' access to their health data in the context of healthcare services for citizens across the EU

Disclaimer: information not legally binding

Indicative budget: EUR 10 million (simple grant, 50% funding)

Indicative call identifier: [DIGITAL-2024-CLOUD-AI-06-HEALTHACCESS](#)

Indicative duration of the action: 36 to 48 months

Objective

- *to enable patients to access their health data in the context of healthcare provision for individual citizens **AND** to scale up and leverage the results from existing projects, frameworks and technologies, such as 'MyHealth@EU', the EEHRxF, the EU DCC, or the EU Digital Identity Wallet.*



Supporting patients' access to their health data in the context of healthcare services for citizens across the EU

Disclaimer: information not legally binding

Activities

- **Review and Map Projects:** Evaluate and chart relevant ongoing projects for standards tech methods of electronic identification of patients and digital solutions for MyHealth@EU development.
- **Design Consolidated Patient Solution:** Create a unified patient data access solution, building on past projects, for cross-border use regardless of Member State, aligning with EEHRxF and collaboration with NCPeHs and patients.
- **Deploy NCPeH and MyHealth@EU:** Establish NCPeHs and MyHealth@EU services for cross-border health data exchange, enhancing data consolidation.
- **Scale Solution:** Roll out the solution widely in healthcare settings, linking to MyHealth@EU's NCPeHs, including user-facing features and backend APIs.
- **Test Patient Access Acceptance:** Collaboratively assess patient access via MyHealth@EU, working closely with NCPeHs and stakeholders, reporting on user experience, especially in cancer-related domains.
- **Engage Users and Assess Implications:** Involve users and stakeholders in design, assessing ethical, legal, and societal impacts during technical deployment



Supporting patients' access to their health data in the context of healthcare services for citizens across the EU

Disclaimer: information not legally binding

Targeted stakeholders

The consortium can include public and private entities such as (but not limited to):

- *Public administrations and Member State authorities (e.g. national contact points for eHealth, digital health authorities)*
- *Hospitals, medical centres*
- *End-users (such as patients' and healthcare professionals' organisations)*
- *Not-for-profit organisations*
- *Industry, SMEs*

KPIs to measure outcomes and deliverables

- *Number of data categories supported by the solution*
- *Number of open-source components made publicly available for reuse*
- *Number of Member States where the solution is deployed – at least 10*
- *Number of individuals who used the solution*
- *Number of unique transactions of the solution per month*
- *Number of relevant user communities (including patients, survivors, their carers and families, vulnerable populations etc.) engaged in testing the solution.*



Demonstrating the in-service use of the European Electronic Health Record Exchange Format (EEHRxF) in healthcare settings

[DIGITAL-2024-CLOUD-AI-06-HEALTHRECORD](#)



Demonstrating the in-service use of the European Electronic Health Record Exchange Format (EEHRxF) in healthcare settings

Disclaimer: information not legally binding

Indicative budget: EUR 4 million (simple grant, 50% funding)

Indicative call identifier: [DIGITAL-2024-CLOUD-AI-06-HEALTHRECORD](#)

Indicative duration of the action: 36 to 48 months

Objective

*to showcase in-service, **sustainable implementation** of the European Electronic Health Record Exchange Format (**EEHRxF**) in healthcare settings.*



Demonstrating the in-service use of the European Electronic Health Record Exchange Format (EEHRxF) in healthcare settings

Activities

- **Collect information** on technical and non-technical **challenges in EEHRxF adoption** and data entry tools.
- **Design, implement and deploy user-friendly EEHRxF demonstrators and data entry tools** in operational clinical settings.
- Through real-world implementations, **demonstrate the added value of the use of the EEHRxF** and its **user friendliness** for health professionals and **cost-effectiveness** for health systems, by:
 - increasing the availability of high-quality and structured health data;
 - increasing interoperability of health data for healthcare services at local, regional, national and European level;
 - increasing quality and completeness of health data included in electronic health records for use at national level and across borders through MyHealth@EU;
 - increasing the accessibility for patients to their health data using the EEHRxF;
 - increasing the cost-effectiveness and sustainability for health systems.
- Provide **guidelines for the implementation of the EEHRxF**, following the lessons learnt from the demonstrators.



Demonstrating the in-service use of the European Electronic Health Record Exchange Format (EEHRxF) in healthcare settings

Targeted stakeholders

The consortium can include public and private entities such as (but not limited to):

- **Public administrations and MS authorities** (e.g. digital health authorities, national contact points for eHealth in MyHealth@EU);
- **Hospitals, medical centres;**
- **End-users** (e.g. patients' and healthcare professionals' organisations);
- **Not-for-profit organisations;**
- **Industry** (particularly, electronic health record systems manufacturers) and **SMEs**.

KPIs to measure outcomes and deliverables

- Number of Member States where the complete implementation of the EEHRxF demonstrators was achieved.
- Number and percentage per Member State of health professionals reached who provided feedback on the use of the EEHRxF in clinical settings.
- Satisfaction rate with the use of EEHRxF.
- Number of users from different user groups actively using the EEHRxF.
- Number of patients covered by the EEHRxF demonstrators



1+ Million Genomes: sustainability and uptake

[DIGITAL-2024-CLOUD-DATA-AI-06-GENOME](#)



1+ Million Genomes: sustainability and uptake

Disclaimer: information not legally binding

Indicative budget: EUR 2 million (CSA, 100% funding)

Indicative call identifier: [DIGITAL-2024-CLOUD-DATA-AI-06-GENOME](#)

Indicative duration of the action: 36 months

Objective

to enable sustainable operation and uptake of the European Genomic Data Infrastructure (GDI) that implements the EU Member States' initiative 1+ Million Genomes (1+MG).



1+ Million Genomes: sustainability and uptake

Disclaimer: information not legally binding

Activities

- *support workshops, working groups, meetings with private and public stakeholders, necessary for creating the EDIC for the 1+MG initiative and supporting its implementation roadmap,*
- *make analysis and proposals on the necessary legal and ethical enablers and arrangements specific to this EDIC,*
- *identify and analyse gaps, challenges and unmet needs, and propose the respective actions for the EDIC feeding into the EDIC sustainability roadmap including legal, ethical, organisational and economic aspects, and covering implementation for research, healthcare and public health purposes,*
- *explore the implications of the EHDS Regulation and operationalise the EDIC's participation in the HealthData@EU infrastructure,*
- *establish the evidence base for the health impact and economic implications of genomics (costs/benefits),*
- *explore models for public-private partnerships for genomics in healthcare,*
- *maintain and promote the use of the Maturity Level Model (MLM) developed by the "Beyond 1 Million Genomes" (B1MG) project to ensure coordinated alignment across healthcare systems towards implementation and equity in access to genomics medicine,*
- *design actions to promote the literacy level and education of citizens, health professionals and policy makers on genomic medicine,*
- *establish frameworks for data standards and quality requirements, and for the specific roles of the EDIC, for those data made available via 1+MG.*



1+ Million Genomes: sustainability and uptake

Disclaimer: information not legally binding

Outcomes & Deliverables

- *Documentation on ethical, legal, privacy-related and economic aspects of 1+MG implementation necessary to operate an EDIC on genomics.*
- *Sustainability roadmap for the EDIC.*
- *Reports on gaps, challenges, needs and the necessary actions to implement genomics in healthcare and public health.*
- *Data on clinical utility and economic aspects of genomics (costs/savings) for economic models and policymaking.*
- *Frameworks for 1+MG data/metadata standards' maintenance and data quality assurance.*

Minimum KPIs to measure outcomes and deliverables

- *Number and type of events with private and public stakeholders promoting the implementation of genomics in research, healthcare and public health policy.*
- *Number of countries using the Maturity Level Model to assess the implementation of genomics in healthcare.*
- *Number of countries covered by the project's evidence-base on the economic aspects of genomic implementation in healthcare.*



1+ Million Genomes: sustainability and uptake

Disclaimer: information not legally binding

Targeted stakeholders

The consortium can include public and private entities such as (but not limited to):

- *Public administrations (national, regional and local level)*
- *Hospitals, medical centres*
- *Research institutes, research agencies*
- *Research infrastructures*
- *Biobanks*



***Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare (HaDEA)**

[DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI](#)

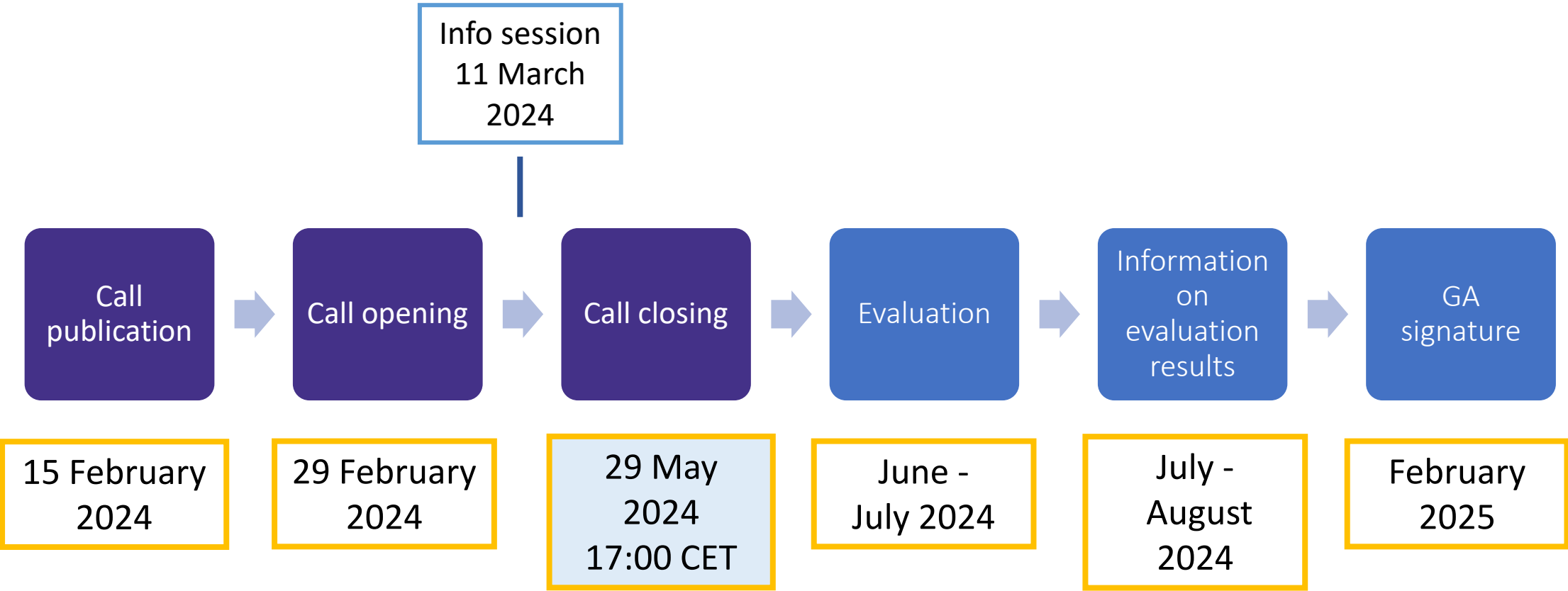
[Online Webinar](#)

Wednesday 13 March 2024, 10:00 - 12:00 (CET)



Timeline

Disclaimer: information not legally binding







Funding & tender portal (F&T portal)

Disclaimer: information not legally binding

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>



Funding & tender opportunities
Single Electronic Data Interchange Area (SEDIA)

English 

[Register](#) [Login](#)

 [SEARCH FUNDING & TENDERS](#) [HOW TO PARTICIPATE](#) [PROJECTS & RESULTS](#) [WORK AS AN EXPERT](#) [SUPPORT](#)

Find calls for proposals and tenders

ERA corona platform

Brexit info

 Report fraud

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EU Programmes

Asylum, Migration and Integration Fund (AMIF)	Border Management and Visa Instrument (BMVI)	Citizens, Equality, Rights and Values Programme (CERV)	Creative Europe (CREA)	Digital Europe Programme (DIGITAL)	Europe Direct (ED)
European Parliament (EP)	European Solidarity Corps (ESC)	Erasmus+ Programme (ERASMUS+)	European Social Fund + (ESF)	Innovation Fund (INNOVFUND)	Internal Security Fund (ISF)
Horizon Europe (HORIZON)	Single Market Programme (SMP)	Social Prerogative and Specific Competencies Lines (SOCPL)	EU External Action (RELEX)	Justice Programme (JUST)	Pilot Projects and Preparatory Actions (PPPA)



Disclaimer: information not legally binding

Q&A



REA Central Validation Service

**Getting started -Registering your
organization, Legal validation and Ownership
control**

**RADU SORA
CHARLOTTE VIANE**

Presentation Outline

REA Central
Validation Service

Registration of
participants

Legal validation
and Legal entity
appointed
representative
(LEAR)

Communication

Ownership control
assessment

Guidance
documents

REA Central Validation Service (REA CVS)

- Verifies **legal existence and legal statuses** of entities
- Validates the appointment of **Legal Entity Appointed Representatives (LEARs)**
- Validates **legal changes** of validated entities
- Assesses **universal takeovers (UTROs)** of validated entities
- Encoding **Bank Account requests**
- Prepares the **Financial Capacity Assessment**
- Performs **ownership control assessments** for specific programmes
- Performs ex-post status verifications (e.g. **SME & MID cap status checks**)

Registration of an organisation (at proposal stage)

Participant Register

 Need help?

If you want to participate in a call for proposals or in a call for tenders with eSubmission, your organisation needs to be registered and have a 9-digit Participant Identification Code (PIC). Please quote your PIC in all correspondence with the Commission.

The register contains all participants of EU programmes.

Is your organisation already registered? PIC search

Please check whether your organisation has already been registered. If so, no need to register it again.

Search a PIC

**Search for a
registered
organisation**

Register your organisation

To register your organisation or as a natural person, you need to login into the Portal or, if you are a new user, create your account.

Check what information you need to register in the Online Manual - and keep it to hand during the registration procedure. To start registration, click on the button below.

Register your organisation

New registration

How to register in the Participant Register

Participant's Register [Need help?](#)

1 2 3 4 5 6

Identification Organisation Data Legal Information Authorised Users Summary Success

Identification

Legal name * 240

Registration country * 50

Registration number 50

VAT number * 20 ☐ not applicable 500

[Review the Form](#) [Next](#)

Identification

(e.g. Legal name, VAT number)



Organisation data



Legal information



Authorised users

(e.g. Name, e-mail address of the self-registrant and the back-up)

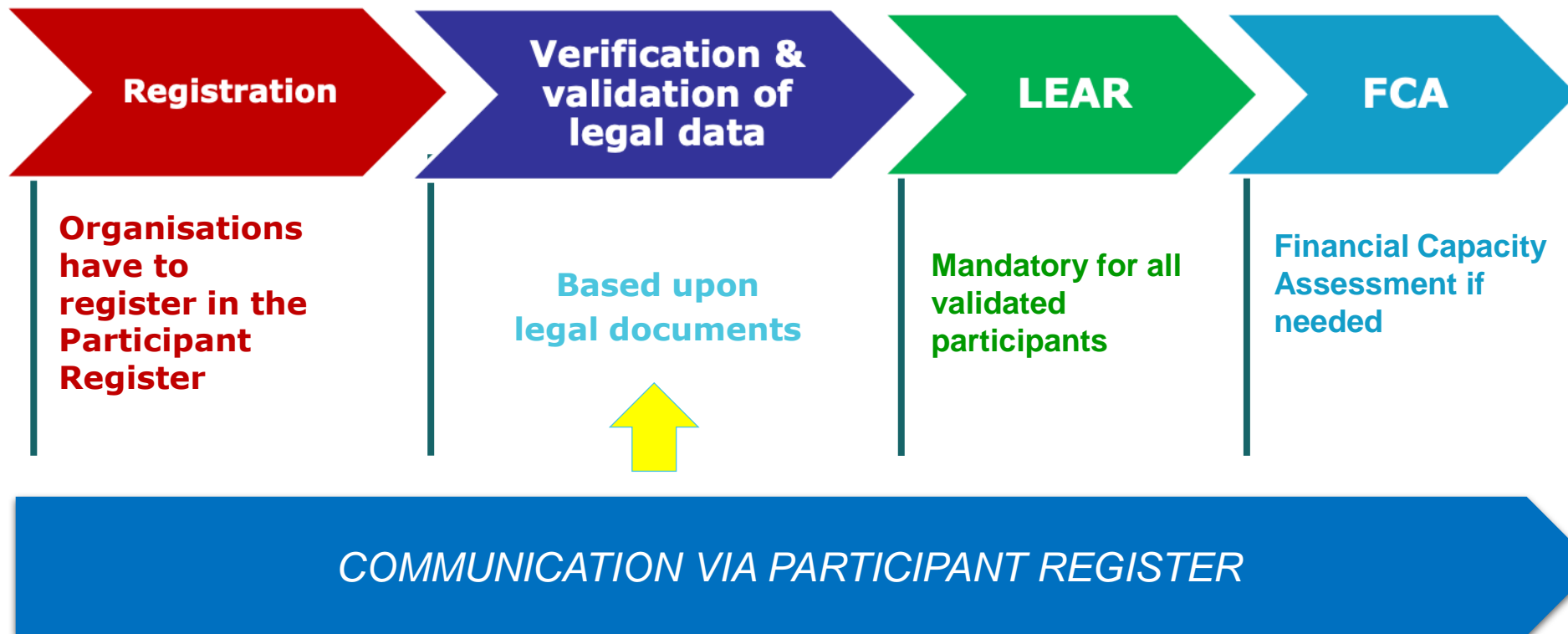


Registration completed



New Participant Identification Code (PIC) in a "declared" status

Validation Process Overview



Legal validation

- Registration data is verified by REA Central Validation Service before the signature of the Grant Agreement or Contract
- The legal validation of a participant is done **once**, when the entity has to sign its first Grant Agreement or Contract and it is reused for future participations in EU grant and procurement actions
- Validation is always performed on the basis of supporting documents, in accordance to EU Financial Regulation and the Rules on Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment for EU Grants and Tenders

Legal validation documents

- ✓ **Legal entity form** (template to be completed, dated, stamped and signed)
- ✓ **VAT extract** (< 1 year)
 - ✓ *If not registered for VAT – proof of VAT exemption*
- ✓ **Registration extract** (< 1 year) – for private law bodies
- ✓ **Law/decreed/decision** – for public law bodies
- ✓ **Treaty** – for international organisations
- ✓ **Statutes** – for non-profit organisations

Communication

(e.g. request to submit legal documents or to appoint a LEAR)

All communication is exclusively managed through the Participant Register

European Commission <EC-NO-REPLY-GRANT-MANAGEMENT@nomail.ec.europa.eu>

to me ▼

Europa / Funding & Tenders Portal notification

Dear User,

You have been granted the role of **Self Registrant** for the organisation arquicios.

In order to access your organisation data on the Funding & Tenders Portal/Supplier portal, you need to log in on the F&T Portal/Supplier Portal. If you did not have an EU Login yet, it was launched automatically for a separate e-mail with a hyperlink to finalise your account.

For more information on the Funding & Tenders Portal roles, please refer to the [Online Manual](#) if you participate in the [programmes managed on the Funding & Tenders Portal](#).

For more information on the roles for e-Procurement, please refer to the [e-Procurement wiki page](#), if you participate in a tender call.

With kind regards,

EU Single Electronic Data Interchange Area - F&T Portal team

This email has been auto-generated. Please do not reply to this account. Your email will not be read. For any inquiries please contact the Grants Procurement Systems Support +32 (2) 29 71063 or EC-FUNDING-TENDER-SERVICE-DESK@ec.europa.eu.

Messages are notified via e-mail to the contact person
(i.e. self-registrant or the appointed LEAR)

Access lost to a declared or valid PIC

Declared PIC

- In case the self-registrant left the organisation and no one has access to a declared PIC – a new PIC needs to be created and REA CVS informed

Valid PIC

- If the LEAR is not available anymore and there are no Account Administrators, a new LEAR needs to be appointed – LEAR recovery procedure

<https://ec.europa.eu/research/participants/urf/lear-recovery/request/>

Ownership control assessment (OCA)



Ownership control assessment (OCA)

- **Legal basis:**

1. Regulation (EU) 2021/694 establishing the Digital Europe Programme (Article 12(5)).
2. Rules on Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment for EU Grants and Tenders.
3. Guidance on Participation in Digital Europe Programme (DEP), Horizon Europe (HE) and European Defence Fund (EDF) restricted calls.

- **Exceptions** - OCA is not performed for:

- Entities which are validated as **public bodies**, which are considered as controlled by their country.
- Entities which self-declare to be controlled by a **non-eligible country**.

Ownership control assessment (OCA)

- **Ownership Control Declaration:**

- Submitted with proposal and presenting the current ownership structure and corporate governance based on official supporting documents.
- **Ownership structure:** complete ownership structure, i.e., including all layers of ownership/control up to the ultimate owners.
- **Corporate governance:** the decision-making bodies, rules regarding election, appointment, nomination or tenure, decision-making procedures within your organisation and its shareholders up to the ultimate owners.
- Commercial and financial links or other sources conferring control: if applicable.

Ownership control assessment (OCA)

- Ownership Control Declaration:

EU Grants: Ownership control declaration: V3.0 – 01.10.2023

OWNERSHIP CONTROL DECLARATION

(To be filled in by the project participants as part of the application. All declarations must be assembled by the coordinator and uploaded in a single file in the Portal Submission System.

Beneficiaries and affiliated entities must always provide the form; associated partners and subcontractors must provide it only if required by the call conditions (for HE, associated partners always). Entities that are validated as public bodies by the Central Validation Service are exempted since they will automatically be considered as controlled by their country.

Supporting documents do not have to be provided at application stage, but will be requested later on. You will receive a task notification asking you to upload the documents to your PIC account in the Portal Participant Register.

⚠ The supporting documents should reflect the situation at the moment you sign this declaration. Please be aware that additional evidence may also be requested later on, in case there are open questions about your ownership/control status.

⚠ Please note that the information in this declaration may be reused in case you apply to other EU calls that have ownership/control restrictions.

⚠ Please also note that you must inform the granting authority in case of changes in your shareholding during the project implementation, if these could impact the ownership/control requirements.)

DECLARATION ON OWNERSHIP AND CONTROL	
Participant	
Legal name:	
PIC:	
Legal registration number:	
Place of establishment: (country of registration; full address)	
Headquarters	
Location of global headquarters/head office: (full address)	
Location of the executive management structure: (if different from the location of global headquarters/head office; full address)	
<small>Executive management structure means a body appointed in accordance with national law, and, where applicable, reporting to the chief executive officer, which is empowered to establish the strategy, objectives and overall direction, and who oversees and monitors management decision-making.</small>	
Listed, subsidiary or controlled	
Supporting documents: report/minutes of the last three shareholders meetings, for each of the listed companies.	
Are you listed on a stock exchange?	Yes/No
Are you a subsidiary of a listed company?	Yes/No
Are you controlled by a listed company?	Yes/No
If the reply is YES to any of these three questions, please provide:	
Which stock exchange?	
Legal name of the listed company:	

EU Grants: Ownership control declaration: V3.0 – 01.10.2023

Share of the float in the total outstanding shares:

“Floating stock” is the result of subtracting closely-held shares from the total number of issued shares. It represents the portion available for unrestricted trade on a regulated stock market.

Ownership structure and specific rights

In the table below, detail any owners that:

- detain, directly or indirectly, at least 5% in the capital or at least 5% of the voting rights, including through any content, understanding, relationship^{IV} or/and intermediary
- have one or more of the following specific rights in relation to their ownership:
 - right to veto a transfer of shares
 - pre-emption rights
 - right to purchase additional shares or investment subject to conditions
 - right to sell shares (only for owners that are not established in eligible countries (i.e. legal entity) or do not have the nationality of one of the eligible countries (i.e. individual) and holding more than 5% of the voting rights).

Supporting documents:

- commercial registry extracts, shareholders book or a declaration signed by the legal representative of the organisation and any other relevant document containing clear mention of the shareholders and their percentage of interest/voting rights.
- shareholders’ agreement, memorandum of understanding among shareholders, statutes, articles of association or other relevant documents regarding the decision-making procedures within the legal entity, investment agreements between the shareholders, etc.
- If there are legal persons as shareholders^{IV}, please provide also a graph describing the different ownership layers/chain of control until the ultimate owners.

⚠ The supporting documents must show the complete ownership structure, for the entity and all its layers of ownership, up to the ultimate owners and should reflect the situation at the moment you sign this declaration.

^{IV} This includes voting agreements between shareholders that would together have more than 5% of the voting rights or 5% of the capital.

^{IV} Detaining at least 5% in the capital or at least 5% of the voting rights.

Owner name	Country of establishment/ or nationality	How is the ownership/control held		Specific rights attached to shares
		by share [%]	by voting right [%]	

Corporate governance

Describe briefly:

- the decision-making bodies, their composition as well as their nationality or place of establishment (where applicable);
- the rules regarding election, appointment, nomination or tenure of members of the decision-making bodies or other management positions;
- the decision-making procedures, including information regarding the required majority and/or quorum needed for decisions.

Supporting documents: Documents establishing/describing the decision-making bodies, rules regarding election, appointment, nomination or tenure, decision-making procedures within the legal entity (e.g. articles of association bylaws, reports on corporate governance, etc).

You can refer to specific sections of your supporting documents.

⚠ The same documents and information should be provided for each intermediate legal entity holding directly or indirectly 5% or more of the capital or voting rights, up to the ultimate owners of all the layers involved.

Ownership control assessment (OCA)

- **Supporting documents:**
 - **Ownership structure:** official documents demonstrating all direct and indirect shareholders, up to the ultimate owners. For instance: trade register extracts, shareholders' book, ...
 - **Corporate governance:** official documents describing the decision-making processes within your organisation and its shareholders up to the ultimate owners. For instance: statutes, articles of association, shareholders' agreement, ...
 - **Confidentiality:** All data and documents provided in the context of validation processes, including ownership control assessment are treated as confidential.

Guidance documents



Rules on Legal validation, LEAR appointment and financial capacity assessment:
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/rules-lev-lear-fca_en.pdf



How to register in the Participant Register:
<https://webgate.ec.europa.eu/funding-tenders-opportunities/display/OM/Online+Manual>



Online Manual, IT How to, IT and RES Helpdesk and specific FAQs on the Funding and Tenders Portal:
<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/support>



Legal notice on the Funding and Tenders Portal (terms and conditions, data protection):
<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/legalnotice>

Thank you for your attention!

Questions?



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Thank you!



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