



Digital Europe Programme (DIGITAL)

Call for proposals

Cloud, data and artificial intelligence DIGITAL-2024-CLOUD-DATA-06

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EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

HADEA. B - Digital, Industry and Space **HaDEA.B.2.01 - Digital Europe**

CALL FOR PROPOSALS

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0. Introduction

This is a call for proposals for EU **action grants** in the field of Cloud, data and artificial intelligence under the **Digital Europe Programme (DIGITAL)**.

The regulatory framework for this EU Funding Programme is set out in:

- Regulation 2018/1046 (<u>EU Financial Regulation</u>)
- the basic act (Digital Europe Regulation 2021/6941).

The call is launched in accordance with the 2023/2024 Work Programme² and will be managed by the **European Health and Digital Executive Agency (HaDEA)** ('Agency').

The call covers the following **topics**:

- DIGITAL-2024-CLOUD-DATA-06-SKILLS Data Space for Skills (deployment)
- DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment)
- DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare

Each project application under the call must address only one of these topics. Applicants wishing to apply for more than one topic, must submit a separate proposal under each topic.

We invite you to read the **call documentation** carefully, and in particular this Call Document, the Model Grant Agreement, the <u>EU Funding & Tenders Portal Online Manual</u> and the <u>EU Grants AGA — Annotated Grant Agreement</u>.

These documents provide clarifications and answers to questions you may have when preparing your application:

- the <u>Call Document</u> outlines the:
 - background, objectives, scope, outcomes and deliverables, KPIs to measure outcomes and deliverables, targeted stakeholders, type of action and funding rate and specific topic conditions (sections 1 and 2)
 - timetable and available budget (sections 3 and 4)
 - admissibility and eligibility conditions (including mandatory documents; sections 5 and 6)
 - criteria for financial and operational capacity and exclusion (section 7)
 - evaluation and award procedure (section 8)
 - award criteria (section 9)
 - legal and financial set-up of the Grant Agreements (section 10)

Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme (OJ L 166, 11.5.2021, p. 1).

Commission Implementing Decision C/2023/8620 of 14.12.2023 amending the Commission Implementing Decision C (2023) 1862 final on the financing of the Digital Europe Programme and the adoption of the work programme for 2023 – 2024.

- how to submit an application (section 11).
- the Online Manual outlines the:
 - procedures to register and submit proposals online via the EU Funding & Tenders Portal ('Portal')
 - recommendations for the preparation of the application.
- the AGA Annotated Grant Agreement contains:
 - detailed annotations on all the provisions in the Grant Agreement you will have to sign in order to obtain the grant (including cost eligibility, payment schedule, accessory obligations, etc).

1. Background

Specific Objective 2 of the Digital Europe Programme aims to reinforce the EU's core Artificial Intelligence (AI) capacities as a crucial driver for the digital transformation of the public and private sectors. The EU Data Strategy³ outlined the importance of building a thriving ecosystem of private actors to generate economic and societal value from data, while preserving high privacy, security, safety and ethical standards. It announced that the Commission will invest in a High Impact Project that will fund infrastructures, data-sharing tools, architectures, and governance mechanisms for thriving data-sharing, Artificial Intelligence ecosystems and the next generation of cloud and edge services. Specific Objective 2 has three main work strands, and this call covers two of these, namely:

- The deployment of a Data for EU strand with a focus on deploying sectorial common data spaces, based on the above federated cloud-to-edge infrastructure and services that are accessible to businesses and the public sector across the EU that were initiated in the first WP.
- AI deployment and support, with the support to AI act and new actions for deployment of innovative AI solutions in health and care and in local communities.

In this context, this call covers:

- 1. DIGITAL-2024-CLOUD-DATA-06-SKILLS Data Space for Skills (deployment)
- 2. DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment)
- 3. DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare

Communication from the Commission, A European strategy for data COM/2020/66 final

2. Objectives — Scope — Outcomes and deliverables — KPIs to measure outcomes and deliverables — Targeted stakeholders — Type of action and funding rate — Specific topic conditions

DIGITAL-2024-CLOUD-DATA-06-SKILLS — Data Space for Skills (deployment)

Objectives

Data is at the core of skills, education, training and employment, offering enormous potential for innovative applications. All data spaces benefit from the Data Space Support Centre (DSSC), which makes sure common tools such as the Simpl software and common concepts are used. The Commission has already laid out work on the European data space for skills via the preparatory action funded under the 2021-22 work programme of DIGITAL and the call DIGITAL-2022-CLOUD-AI-03-PILOTS-CLOUD-SERVICES⁴.

The objective of this call topic is to develop and deploy a secure and trusted data space for skills. Databases of job offers, qualifications, learning opportunities, lists of curricula and certifications, inventory of topics studied at all levels of education and training, as well as skills classifications, can help better define human resource, business, employment as well as education and training policy strategies and add value for learners.

The data space for skills is expected to be a European Common Data Space for sharing and accessing skills data for various purposes, from analytical and statistical purposes to policy development or re-use in innovative applications in line with European values, with a particular emphasis on ethics, diversity, security and privacy.

Companies and organisations in Europe face major shortages of digital experts especially in advanced disciplines such as artificial intelligence, cybersecurity, cloud, internet of things, extended reality or blockchain. Universities are not delivering enough qualified specialists to the labour market and companies lack the ability to provide appropriate reskilling and upskilling opportunities to their employees. By providing the means for enhanced data-based collaboration, the data space for skills should open new opportunities to address, innovate and transform existing and new challenges of the labour market and stimulate the digital transformation.

Scope

This action seeks to deploy a secure and trusted common European data space for skills.

The awarded proposal will integrate, test, and deploy the data space, allowing participants to make data available and accessible, as well as sharing it, in a controlled, simple and secure way. In addition, it will put in place a governance mechanism. The awarded proposal should not only facilitate access to a vast volume of accurate and reliable data, but also ensure there are a strategy and adequate means to allow for data to be updated after the project concludes. The awarded proposal will also provide continuous maintenance operations of the data space, monitor the usage of the data space, and offer a helpdesk. Furthermore, it will take appropriate measures to foster engagement of relevant stakeholders across the EU. The project will have to demonstrate a clear European dimension.

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/digital-2021-cloud-ai-03-pilots-cloud-services

The awarded proposal must build upon the Data Space for Skills Blueprint⁵ and take into consideration the Interactive inventory of skills data initiatives⁶, both of which are outcomes of the EU-funded preparatory action DS4Skills⁷. Furthermore, it is expected to integrate building blocks and infrastructure funded under the Call DIGITAL-2022-CLOUD-AI-03-PILOTS-CLOUD-SERVICES⁸.

In addition, the awarded proposal must work in close partnership with the Data Spaces Support Centre to ensure alignment with the rest of the ecosystem of data spaces implemented with the support of the Digital Europe Programme, in particular in view of a data spaces reference architecture; common building blocks, toolboxes and standards, semantic interoperability; and data governance models. The data space will use, insofar as possible and when available, the smart cloud-to-edge middleware platform Simpl.

Complementarity should be sought with existing initiatives in the domain of skills and qualifications, such as Europass, ESCO, European Digital Credentials for Learning, European Learning Model, EURES, the EU Digital Identity Wallet, Skills-OVATE, and the Digital Skills and Jobs Platform by establishing links to actions of these initiatives as appropriate. Furthermore, the action will ensure close connections with other related common European data spaces and should take into account, to the extent possible, similar public or private data spaces developed at national or regional level across the EU.

The winning proposal is expected to ensure that major stakeholders adopt the data space and its value is proven at an EU wide level. In order to achieve this, particular attention should be paid to:

- The implementation of a minimum of three use cases with a clear impact
 as outlined under Objective. Examples could include, but would not be limited
 to, data-based innovative solutions involving job offers, qualifications, learning
 opportunities, lists of curricula and certifications, etc. The use cases should
 have long-term sustainability prospects and encompass all the European Union
 regions.
- Connecting data and service providers to the data space infrastructure to ensure that the foreseen use cases can be implemented. This entails support for these providers to ease the technical and operational effort. Possible measures include organizing events for presenting advice about onboarding and for providing networking opportunities.

Right from the outset, the awarded proposal is expected to work towards achieving financial sustainability by the end of the project. Therefore, the proposal should consider relevant actions in this respect and establish a clear plan.

The active participation of data providers and users from the project's inception is highly recommended since it will ensure that the data space is designed and structured to meet their needs, making the data space more relevant and leading to increased adoption rates and a stronger sense of ownership of data providers and users by the end of the project.

^{5 &}lt;u>https://skillsdataspace-blueprint.eu</u>

^{6 &}lt;u>https://inventory.skillsdataspace.eu/</u>

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/org details/9999999/project/101083483/program/43152860/details

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/digital-2021-cloud-ai-03-pilots-cloud-services

Outcomes and deliverables

- Technical infrastructure for the deployment of the data space for skills;
- Implementation of three operational use cases;
- Data governance framework, comprising a set of rules of legislative, administrative and contractual nature covering access rights, processing, using and sharing data in a trustful and transparent manner, including code of conduct and contract template;
- Setup of the Data Space Governance Authority;
- Guidance support and training documentation to reduce the entry barrier for stakeholders wishing to participate in the data space. This should also include guidance support and materials on how to adopt a human-centric approach to skills data spaces;
- Update of the Blueprint inherited from the preparatory action DS4Skills to keep it aligned with the most recent version released by the DSSC and considering the lessons learned by the projects funded under the Call DIGITAL-2022-CLOUD-AI-03-PILOTS-CLOUD-SERVICES⁹;
- A long-term economic sustainability business plan for the skills data space, which considers scaling with cross-sectoral operation in mind;
- Once the data space is deployed, reports should be generated covering usage, detected problems, and the solutions provided. The frequency of these reports should be quarterly and on an ad hoc basis;
- A report about the connection of the data space with other relevant local, national and European initiatives on skills and qualifications data, such as for example the Alliances for Sectoral Cooperation on Skills.

KPIs to measure outcomes and deliverables

- 1. Uptake and engagement KPIs:
- Number of individual end users (e.g. students, workers, jobseekers), organisational end users, service providers, data providers, and data intermediaries connected to the data space.
- Number of datasets from existing EC initiatives (Europass, ESCO, European Learning Model, EURES or Skills-OVATE) used during the project to develop solutions.
- Total number of data records (across all datasets) available via the data space.
- Number of data records broken down into categories such as job offers, training offers, CVs, curricula, certifications.

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/digital-2021-cloud-ai-03-pilots-cloud-services

- Number of final users impacted by the developments produced within the project (e.g. through job or training matchings). If applicable, reported separately for Artificial Intelligence, Cybersecurity and Cloud Computing.
- 2. Interorganizational synergies KPIs:
- Total number of private and public organisations that exchanged data. This measurement tracks the extent to which private and public organisations work together, reflecting the level of collaboration and synergy achieved. Reported separately for SMEs.
- 3. Innovation and policy KPIs:
- Number of innovative use cases that have been developed by participants of the data space beyond the initially foreseen use cases. This KPI assesses the degree to which initiatives incorporate and innovate with skills-related data spaces, showcasing the platform's adaptability and potential for various innovative applications.
- Number of new services (as origin of new business models) created during the project by SMEs.
- Number of contributions to educational, labour market, and innovation policies (for example through network effects or policy or research papers for which the data space was used).

Targeted stakeholders

Schools, higher education institutions, vocational education and training institutions, other education and training providers, businesses, Human Resources (HR) organisations and employment agencies, public employment services, guidance providers, IT developers, other private and public actors (particularly in job search and recruitment services as well as data sharing), trade and industry associations, alliances and social partners

Type of action and funding rate

Simple Grants — 50% funding rate



Specific topic conditions

- For this topic, multi-beneficiary applications are mandatory and specific conditions for the consortium composition apply (see section 6)
- For this topic, the following reimbursement option for equipment costs applies: depreciation cost only (see section 10).
- The following parts of the award criteria in section 9 are exceptionally NOT applicable for this topic:
 - extent to which the project would reinforce and secure the digital technology supply chain in the Union*

- extent to which the proposal can overcome financial obstacles such as the lack of market finance*
- extent to which the proposal addresses environmental sustainability and the European Green Deal goals, in terms of direct effects and/or in awareness of environmental effects*

DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE - Data Space for Manufacturing (deployment)

<u>Objectives</u>

The goal of this action is to significantly scale up the deployment and use of the data space(s) for manufacturing by reaching a critical mass of manufacturing industries sharing industrial data and improving company operations and value chains among providers. In addition, the action aims to support data-driven transition to a greener and circular economy, also by enabling new business models, for example, those based on a Manufacturing-As-A-Service (MaaS) approach and Extended Reality for industrial virtual worlds. The action will also contribute to the implementation of measures that accelerate the twin green and digital transition of manufacturing industries, such as the proposed Net Zero Industry Act¹⁰ as part of the Green Deal Industrial Plan¹¹.

Scope

As the manufacturing sector is diverse and complex, the action specifically focuses on data spaces addressing management of supply chains. Proposal(s) for this action need to target one of the following two use cases:

- Data-driven models for supply chain management and the role of data sharing
 in risk mitigation response, such as early-warning predictive material shortage.
 Awarded proposal(s) will perform agile supply chain management and
 execution by continuously monitoring and exchanging status data on e.g.
 purchase orders, sales orders, inventory levels, order progress, demand and
 other forecasts, raw materials, chemicals and energy use and supply, etc.
 across segments of the value chain.
- Manufacturing data spaces using data to drive the transition to a greener and circular economy with enhanced business opportunities for industrial data value added services. End users are machine users, machine vendors, maintenance service providers, and remanufacturers.

The data spaces will specifically enable the compliance with standards and norms, including environmental requirements, product passports, and tax regimes.

The awarded proposal(s) should implement a secure, fair and trustworthy way of making data available and usable between actors throughout the value chain of the product lifecycle on the basis of voluntary agreements, in view of completing, deepening and expanding data sharing with other organisations. The implementation will need to be Data Act-compliant.

In addition, the proposal(s) for this action need to address the following mandatory activities:

• Bringing together relevant stakeholders to conclude data agreement(s) with reference to design, reuse, recycling, and environmental impact and indicators

[.]o COM(2023) 161 final

¹¹ COM(2023) 62 final

for continuous monitoring and exchange of data on product performance and reuse, material content and origin, feedback to design, product recycling, product remanufacturing, etc. Carrying out further activities to effectively track and report resource use (e.g. CO2) from a manufacturer's perspective. Actions should preferably target data sharing for circularity in line with the Circular Economy Action plan (COM(2020) 98 final).

The action shall build on the results and recommendations of the preparatory actions under the previous WP. To ensure a balanced portfolio covering all envisaged data spaces for manufacturing, grants will be awarded to proposals not only in order of ranking but also to at least one proposal per expected use case, provided that the applications attain all thresholds. Furthermore, there should be cooperation with the European Digital Innovation Hubs (EDIHs) for broad uptake by industry as well as the Testing and Experimentation Facility (TEF) for Manufacturing to define European test and training data sets and to provide support in their establishment.

The awarded proposal(s) will use, where possible and when available, the smart cloud-to-edge middleware platform Simpl¹². They will also work in close partnership with the Data Spaces Support Centre to ensure alignment and interoperability with the rest of the ecosystem of data spaces implemented with the support of Digital Europe Programme, in particular in view of a data spaces reference architecture; common building blocks, toolboxes and standards; and data governance models. Right from the outset, the awarded proposal(s) is/are expected to work towards achieving economic and/or financial sustainability by the conclusion of the action.

The active participation of industry in both roles as data providers and data users is recommended, with a focus to ease the deployment of such data spaces linked to business usage. Tools to automate the deployment and configuration of data spaces are expected in order to accelerate adoption rates and a stronger sense of ownership of data providers and users by the end of the projects' runtime.

Outcomes and deliverables

The awarded proposal(s) will set up and deploy data space(s) for manufacturing at scale, which will stay available after the runtime of the project, delivering industrial data sharing among manufacturing companies and service providers. The solutions must be characterized by a high degree of user-orientation in terms of trustworthiness, data sovereignty of the companies and manageability.

More specifically, awarded proposal(s) will need to deliver:

- Technical infrastructure for the deployment of the Common European Manufacturing Data Space(s).
- Data governance documentation, comprising a set of rules of legislative, administrative, and contractual nature covering access rights, processing, using and sharing data in a trustful and transparent manner.
- Code of conduct and contract template.
- Guidance/training documents for the stakeholders willing to join the data space(s).
- Once the data space(s) is/are deployed: quarterly and on an ad hoc basis reporting on usage, problems detected, and solutions provided.

See Simpl: cloud-to-edge federations and data spaces made simple (updated August 2023) | Shaping Europe's digital future (europa.eu)

KPIs to measure outcomes and deliverables

To measure outcomes, the proposals in this action will identify specific KPIs in the following areas:

- Business: increase of organisations participating in the Data Space, their geographical distribution and return on investment.
- · Technical: volume, quality and value of data exchanged; analysis of data actually used by several stakeholders in the value chain.
- Deployment: share of supplier/customer interaction having undergone automation, share of SMEs among data providers and data users.

The consortium should also propose relevant indicators (including industry and service relevant KPIs) for measuring the expansion of usage of the data space.

Indicators should be accompanied by target values.

Targeted stakeholders

All entities, with a focus on manufacturing SMEs and mid-caps, machine-tool industry, IT companies and integrators and related industry associations. The consortium will include at least suppliers and users as well as service providers, any other organisation (such as data brokers, data stewards, data integrators) participating in data interoperability activities and organisations.

Type of action and funding rate

Simple Grants — 50% funding rate



For more information on Digital Europe types of action, see Annex 1.

Specific topic conditions

- For this topic, security restrictions under Article 12(6) of the Digital Europe Regulation apply (see sections 6 and 10 and Annex 2)
- For this topic, multi-beneficiary applications are mandatory and specific conditions for the consortium composition apply (see section 6)
- For this topic, following reimbursement option for equipment costs applies: depreciation and full cost for listed equipment (see section 10)
- For this topic, first exploitation obligations apply (see section 10)
- The following parts of the award criteria in section 9 are exceptionally NOT applicable for this topic:
 - extent to which the proposal can overcome financial obstacles such as the lack of market finance

DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI - Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare

Objectives

Healthcare demands continue to increase due to factors like population growth, aging populations, and the prevalence of chronic diseases. Healthcare technologies can help meet these demands by, among others, increasing effectiveness of treatment and

diagnostic solutions and efficiency of health systems. The deployment of new medical digital technologies and artificial intelligence (AI) powered solutions for healthcare purposes requires access to real world health data. The amount of data available to drive the development of AI should be as large as possible to limit the introduction of biases that could undermine the effectiveness and safety of healthcare AI solutions or increase inequalities in access to care.

The European Health Data Space (EHDS) establishes a common framework for the reuse of health data. It aims to facilitate and streamline access to EU-wide real-world health data for specific purposes such as the development, testing, deployment and uptake of products or services contributing to public health or the training, testing and evaluation of algorithms, including in medical devices, AI systems and digital health applications. The proposal for a Regulation on the EHDS102¹³ provides for Health Data Access Bodies (HDABs) in each country as trusted anchors to support and supervise the reuse of health data.

As part of the wider AI ecosystem in health, such as Testing and Experimentation Facilities (TEFs) for AI and European Digital Innovation Hubs (EDIHs), this action aims to strengthen the role and capabilities of HDABs in streamlining the testing and deployment pathways for healthcare AI solutions.

The aim of this action is also to reduce time-to-market and foster the development of new AI-based healthcare products and services that significantly improve patient safety and wellbeing, while preserving privacy and security. This action is not only relevant to the implementation of the EHDS, but also to the implementation of the Artificial Intelligence Act (AIA)¹⁴, which establishes an overarching framework for trustworthy AI, including in healthcare (e.g. medical devices).

Scope

The action comprises the following:

- Identifying current pathways, i.e. regulatory, organisational and technical processes and means, for the development, testing and deployment of AI in health, as well as limitations, bottlenecks and gaps reducing the overall effectiveness of these pathways;
- Designing more effective pathways by leveraging EHDS and Health Data Access Bodies, and possibly Testing and Experimentation Facilities (TEFs) and European Digital Innovation Hubs (EDIHs);
- Creating and implementing the necessary capabilities at the level of the Health Data Access Bodies to support these pathways for the development, testing and deployment of AI in health, and building around them an appropriate community including where appropriate, data users, data holders, TEFs and EDIHs;
- Testing and showcasing these pathways with Health Data Access Bodies and the relevant actors in the community, based on specific examples in relevant disease areas, e.g. cancer, mental health or cardiovascular diseases;
- Providing guidelines and recommendations for improving the development, testing and deployment pathways for AI in health, taking advantage of the opportunities offered by the EHDS.

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

Outcomes and deliverables

- Report on the identified pathways for testing and deployment of AI in health and their limitations and gaps in the current landscape;
- Description of pathways based on health data access bodies' services and other key actors such as TEFs and EDIHs, where relevant, in light of the EHDS and the AIA;
- Guidelines for creating and deploying the necessary capabilities for HDABs to support the development, testing and deployment pathways for AI in healthcare;
- Reports on the tests and showcases conducted;
- Recommendations for the implementing of development, testing and deployment pathways of AI in health based on the opportunities offered by the EHDS and the requirements of the AIA.

KPIs to measure outcomes and deliverables

- Number of Health Data Access Bodies (HDABs) offering operationalised pathways for testing and deployment of AI in health [target: at least 3 HDABs in 3 different MS by the end of the project]
- Number of tests and showcases conducted of pathways for testing and deployment of AI in health [target: at least 1 test/showcase for HDAB by the end of the project]
- Number of data access applications related to AI processed by HDABs [target: at least 2 applications per pathway by the end of the project]
- Number of HDABs engaged in implementing the pathways for testing and deployment of AI in health [target: at least 10 HDABs by the end of the project]

Targeted stakeholders

Health data access bodies, public sector bodies and Member States' authorities; academia; healthcare providers; private entities such as health technology SMEs and start-ups.

In addition to the eligibility criteria on consortium composition (Section 6), the consortium is highly encouraged to include at least 3 Health Data Access Bodies from 3 different eligible countries, and 3 companies/institutes/developers/innovators developing AI solutions from 3 different eligible countries.

Type of action and funding rate

Coordination and Support Actions — 100% funding rate

For more information on Digital Europe types of action, see Annex 1.

Specific topic conditions

 For this topic, security restrictions under Article 12(6) of the Digital Europe Regulation apply (see sections 6 and 10 and Annex 2)

- For this topic, multi-beneficiary applications are mandatory and specific conditions for the consortium composition apply (see section 6)
- For this topic, following reimbursement option for equipment costs applies: depreciation only (see section 10)
- The following parts of the award criteria in section 9 are exceptionally NOT applicable for this topic:
 - extent to which the project would reinforce and secure the digital technology supply chain in the Union*
 - extent to which the proposal can overcome financial obstacles such as the lack of market finance*
 - extent to which the proposal addresses environmental sustainability and the European Green Deal goals, in terms of direct effects and/or in awareness of environmental effects*

3. Available budget

The estimated available call budget is **EUR 20 000 000**.

Specific budget information per topic can be found in the table below:

Topic		Topic budget	
1.	DIGITAL-2024-CLOUD-DATA-06-SKILLS – Data Space for Skills (deployment)	EUR 3 000 000	
2.	DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE - Data Space for Manufacturing (deployment)	EUR 13 000 000	
3.	DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI - Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare	EUR 4 000 000	

We reserve the right not to award all available funds or to redistribute them between the call priorities, depending on the proposals received and the results of the evaluation.

4. Timetable and deadlines

Timetable and deadlines (indicative)			
Call opening:	29 February 2024		
Deadline for submission:	29 May 2024 - 17:00:00 CEST (Brussels)		
Evaluation:	June-July 2024		
Information on evaluation results:	July 2024		
GA signature:	February 2025		

5. Admissibility and documents

Proposals must be submitted before the **call deadline** (see timetable section 4).

Proposals must be submitted **electronically** via the Funding & Tenders Portal Electronic Submission System (accessible via the Topic page in the <u>Search Funding & Tenders</u> section. Paper submissions are NOT possible.

Proposals (including annexes and supporting documents) must be submitted using the forms provided *inside* the Submission System (NOT the documents available on the Topic page — they are only for information).

Proposals must be **complete** and contain all the requested information and all required annexes and supporting documents:

- Application Form Part A contains administrative information about the participants (future coordinator, beneficiaries and affiliated entities) and the summarised budget for the project (to be filled in directly online)
- Application Form Part B contains the technical description of the project (to be downloaded from the Portal Submission System, completed and then assembled and re-uploaded)
- mandatory annexes and supporting documents (templates available to be downloaded from the Portal Submission System, completed, assembled and re-uploaded):
 - detailed budget table/calculator: not applicable
 - CVs of core project team: not applicable
 - activity reports of last year: not applicable
 - list of previous projects: applicable for the topics:
 - DIGITAL-2024-CLOUD-DATA-06-SKILLS Data Space for Skills (deployment)
 - DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare
 - ownership control declarations (including for associated partners and subcontractors) for the topics:
 - DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment)
 - DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare
 - other annexes.

At proposal submission, you will have to confirm that you have the **mandate to act** for all applicants. Moreover, you will have to confirm that the information in the application is correct and complete and that the participants comply with the conditions for receiving EU funding (especially eligibility, financial and operational capacity, exclusion, etc). Before signing the grant, each beneficiary and affiliated entity will have to confirm this again by signing a declaration of honour (DoH). Proposals without full support will be rejected.

Your application must be **readable**, **accessible and printable**.

Proposals are limited to maximum **70 pages** (Part B) for the topics:

- DIGITAL-2024-CLOUD-DATA-06-SKILLS Data Space for Skills (deployment)
- DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment) and 50 pages (Part B) for the topic:

Proposals are limited to maximum **50 pages** (Part B) for the topic:

• DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI - Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare.

Evaluators will not consider any additional pages.

You may be asked at a later stage for further documents (for legal entity validation, financial capacity check, bank account validation, etc).

For more information about the submission process (including IT aspects), consult the Online Manual.

6. Eligibility

Applications will only be considered eligible if their content corresponds wholly (or at least in part) to the topic description for which they are submitted.

Eligible participants (eligible countries)

In order to be eligible, the applicants (beneficiaries and affiliated entities) must:

- be legal entities (public or private bodies)
- be established in one of the eligible countries, i.e.:
 - EU Member States (including overseas countries and territories (OCTs))
 - non-EU countries (except for topics with restrictions; see below):
 - listed EEA countries and countries associated to the Digital Europe Programme (<u>list of participating countries</u>)

Beneficiaries and affiliated entities must register in the <u>Participant Register</u> — before submitting the proposal — and will have to be validated by the Central Validation Service (REA Validation). For the validation, they will be requested to upload documents showing legal status and origin.

Other entities may participate in other consortium roles, such as associated partners, subcontractors, third parties giving in-kind contributions, etc (see section 13).

Please note however that some topics are subject to restrictions due to security reasons:

- for topics:
 - DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment)¹⁵

This topic will be subject to article 12(6) of Regulation (EU) 2021/694 for security reasons. Refer to Appendix 3 of the 2023-2024 Digital Europe Work Programme and the conditions of this call document.

- DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare¹⁶
- Only the following countries are eligible: EU Member States, EEA countries and countries associated to the Digital Europe Programme (<u>list of participating countries</u>). Entities must not be directly or indirectly controlled from a country that is not an eligible country unless the granting authority agrees to allow for exceptional participation on the basis of a guarantee.

For more information, see Annex 2.

Specific cases

Natural persons — Natural persons are NOT eligible (with the exception of self-employed persons, i.e. sole traders, where the company does not have legal personality separate from that of the natural person).

International organisations — International organisations are not eligible, unless they are International organisations of European Interest within the meaning of Article 2 of the Digital Europe Regulation (i.e. international organisations the majority of whose members are Member States or whose headquarters are in a Member State).

Entities without legal personality — Entities which do not have legal personality under their national law may exceptionally participate, provided that their representatives have the capacity to undertake legal obligations on their behalf and offer guarantees for the protection of the EU financial interests equivalent to that offered by legal persons¹⁷.

EU bodies — EU bodies (with the exception of the European Commission Joint Research Centre) can NOT be part of the consortium.

Associations and interest groupings — Entities composed of members may participate as 'sole beneficiaries' or 'beneficiaries without legal personality'¹⁸. Please note that if the action will be implemented by the members, they should also participate (either as beneficiaries or as affiliated entities, otherwise their costs will NOT be eligible).

Countries currently negotiating association agreements — Beneficiaries from countries with ongoing negotiations for participating in the programme (see list of participating countries above) may participate in the call and can sign grants if the negotiations are concluded before grant signature and if the association covers the call (i.e. is retroactive and covers both the part of the programme and the year when the call was launched).

Following the <u>Council Implementing Decision (EU) 2022/2506</u>, as of 16th December 2022, no legal commitments (including the grant agreement itself as well as subcontracts, purchase contracts, financial support to third parties etc.) can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain. Affected entities may continue to apply to calls for proposals. However, in case the Council measures are not lifted, such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties). In this case, co-

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This topic will be subject to article 12(6) of Regulation (EU) 2021/694 for security reasons. Refer to Appendix 3 of the 2023-2024 Digital Europe Work Programme and the conditions of this call document.

⁷ See Article 197(2)(c) EU Financial Regulation 2018/1046.

For the definitions, see Articles 187(2) and 197(2)(c) EU Financial Regulation 2018/1046.

applicants will be invited to remove or replace that entity and/or to change its status into associated partner. Tasks and budget may be redistributed accordingly.

EU restrictive measures — Special rules apply for certain entities (e.g. entities subject to <u>EU restrictive measures</u> under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)¹⁹). Such entities are not eligible to participate in any capacity, including as beneficiaries, affiliated entities, associated partners, subcontractors or recipients of financial support to third parties (if any).

For more information, see <u>Rules for Legal Entity Validation, LEAR Appointment and</u> <u>Financial Capacity Assessment</u>.

Consortium composition

Proposals must be submitted by:

For the topic: **DIGITAL-2024-CLOUD-DATA-06-SKILLS – Data Space for Skills** (deployment)

minimum of 4 applicants (beneficiaries; not affiliated entities) from 4 different eligible countries

For the topic: **DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE - Data Space for Manufacturing (deployment)**

minimum 3 independent applicants (beneficiaries; not affiliated entities)
 from 3 different eligible countries

For the topic: **DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI - Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare**

- minimum 6 independent applicants (beneficiaries; not affiliated entities)
 from 3 different eligible countries*
- * For further details on consortium composition refer to section 2 Targeted stakeholders.

Eligible activities

Eligible activities are the ones set out in section 2 above.

Projects should take into account the results of projects supported by other EU funding programmes. The complementarities must be described in the project proposals (Part B of the Application Form).

Projects must comply with EU policy interests and priorities (such as environment, social, security, industrial and trade policy, etc).

Financial support to third parties is not allowed.

Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the <u>EU Sanctions Map</u>.

Geographic location (target countries)

Due to restrictions due to security:

- for topic: DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment) the proposals must relate to activities taking place in the eligible countries (see above)
- for topic: DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare the proposals must relate to activities taking place in the eligible countries (see above)

Ethics

Projects must comply with:

- highest ethical standards and
- applicable EU, international and national law (including the <u>General Data</u> Protection Regulation 2016/679).

Proposals under this call will have to undergo an ethics review to authorise funding and may be made subject to specific ethics rules (which become part of the Grant Agreement in the form of ethics deliverables, e.g. ethics committee opinions/notifications/authorisations required under national or EU law).

For proposals involving development, testing, deployment, use or distribution of AI systems, the ethics review will in particular check compliance with the principles of human agency and oversight, diversity/fairness, transparency and responsible social impact, while the experts performing the technical evaluation will assess the robustness of the AI systems (i.e. their reliability not to cause unintentional harm).

Security

Projects involving EU classified information must undergo security scrutiny to authorise funding and may be made subject to specific security rules (detailed in a security aspects letter (SAL) which is annexed to the Grant Agreement).

These rules (governed by Decision $2015/444^{20}$ and its implementing rules and/or national rules) provide for instance that:

- projects involving information classified TRES SECRET UE/EU TOP SECRET (or equivalent) can NOT be funded
- classified information must be marked in accordance with the applicable security instructions in the SAL
- information with classification levels CONFIDENTIEL UE/EU CONFIDENTIAL or above (and RESTREINT UE/ EU RESTRICTED, if required by national rules) may be:
 - created or accessed only on premises with facility security clearance (FSC) from the competent national security authority (NSA), in accordance with the national rules
 - handled only in a secured area accredited by the competent NSA

See Commission Decision 2015/444/EU, Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

- accessed and handled only by persons with valid personnel security clearance (PSC) and a need-to-know
- at the end of the grant, the classified information must either be returned or continue to be protected in accordance with the applicable rules
- action tasks involving EU classified information (EUCI) may be subcontracted only with prior written approval from the granting authority and only to entities established in an EU Member State or in a non-EU country with a security of information agreement with the EU (or an administrative arrangement with the Commission)
- disclosure of EUCI to third parties is subject to prior written approval from the granting authority.

Please note that, depending on the type of activity, facility security clearance may have to be provided before grant signature. The granting authority will assess the need for clearance in each case and will establish their delivery date during grant preparation. Please note that in no circumstances can we sign any grant agreement until at least one of the beneficiaries in a consortium has facility security clearance.

Further security recommendations may be added to the Grant Agreement in the form of security deliverables (e.g. create security advisory group, limit level of detail, use fake scenario, exclude use of classified information, etc).

Beneficiaries must ensure that their projects are not subject to national/third-country security requirements that could affect implementation or put into question the award of the grant (e.g. technology restrictions, national security classification, etc). The granting authority must be notified immediately of any potential security issues.

7. Financial and operational capacity and exclusion

Financial capacity

Applicants must have **stable and sufficient resources** to successfully implement the projects and contribute their share. Organisations participating in several projects must have sufficient capacity to implement all these projects.

The financial capacity check will be carried out on the basis of the documents you will be requested to upload in the <u>Participant Register</u> during grant preparation (e.g. profit and loss account and balance sheet, business plan, audit report produced by an approved external auditor, certifying the accounts for the last closed financial year, etc). The analysis will be based on neutral financial indicators, but will also take into account other aspects, such as dependency on EU funding and deficit and revenue in previous years.

The check will normally be done for all beneficiaries, except:

- public bodies (entities established as public body under national law, including local, regional or national authorities) or international organisations
- if the individual requested grant amount is not more than EUR 60 000.

If needed, it may also be done for affiliated entities.

If we consider that your financial capacity is not satisfactory, we may require:

further information

- an enhanced financial responsibility regime, i.e. joint and several responsibility for all beneficiaries or joint and several liability of affiliated entities (see below, section 10)
- prefinancing paid in instalments
- (one or more) prefinancing quarantees (see below, section 10)

or

- propose no prefinancing
- request that you are replaced or, if needed, reject the entire proposal.

For more information, see <u>Rules for Legal Entity Validation, LEAR Appointment</u> and <u>Financial Capacity Assessment</u>.

Operational capacity

Applicants must have the **know-how, qualifications** and **resources** to successfully implement the projects and contribute their share (including sufficient experience in projects of comparable size and nature).

This capacity will be assessed together with the 'Implementation' award criterion, on the basis of the competence and experience of the applicants and their project teams, including operational resources (human, technical and other) or, exceptionally, the measures proposed to obtain it by the time the task implementation starts.

If the evaluation of the award criterion is positive, the applicants are considered to have sufficient operational capacity.

Applicants will have to show their capacity via the following information:

- general profiles (qualifications and experiences) of the staff responsible for managing and implementing the project
- description of the consortium participants
- list of previous projects (key projects for the last 4 years; template available in Part B) if applicable – see section 5.

Additional supporting documents may be requested, if needed to confirm the operational capacity of any applicant.

Exclusion

Applicants which are subject to an **EU exclusion decision** or in one of the following **exclusion situations** that bar them from receiving EU funding can NOT participate²¹:

- bankruptcy, winding up, affairs administered by the courts, arrangement with creditors, suspended business activities or other similar procedures (including procedures for persons with unlimited liability for the applicant's debts)
- in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts)
- guilty of grave professional misconduct²² (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant

²¹ See Articles 136 and 141 of EU Financial Regulation 2018/1046.

- committed fraud, corruption, links to a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant
- shown significant deficiencies in complying with main obligations under an EU procurement contract, grant agreement, prize, expert contract, or similar (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant
- guilty of irregularities within the meaning of Article 1(2) of EU Regulation 2988/95 (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant
- created under a different jurisdiction with the intent to circumvent fiscal, social
 or other legal obligations in the country of origin or created another entity with
 this purpose (including if done by persons having powers of representation,
 decision-making or control, beneficial owners or persons who are essential for
 the award/implementation of the grant.

Applicants will also be rejected if it turns out that²³:

- during the award procedure they misrepresented information required as a condition for participating or failed to supply that information
- they were previously involved in the preparation of the call and this entails a distortion of competition that cannot be remedied otherwise (conflict of interest).

8. Evaluation and award procedure

The proposals will have to follow the **standard submission and evaluation procedure** (one-stage submission + one-step evaluation).

An **evaluation committee** (assisted by independent outside experts) will assess all applications. Proposals will first be checked for formal requirements (admissibility, and eligibility, see sections 5 and 6). Proposals found admissible and eligible will be evaluated (for each topic) against the operational capacity and award criteria (see sections 7 and 9) and then ranked according to their scores.

For proposals with the same score (within a topic or budget envelope) a **priority order** will be determined according to the following approach:

Successively for every group of *ex aequo* proposals, starting with the highest scored group, and continuing in descending order:

1) Proposals focusing on a theme that is not otherwise covered by higher ranked proposals will be considered to have the highest priority.

Professional misconduct includes: violation of ethical standards of the profession, wrongful conduct with impact on professional credibility, false declarations/misrepresentation of information, participation in a cartel or other agreement distorting competition, violation of IPR, attempting to influence decision-making processes or obtain confidential information from public authorities to gain advantage.

²³ See Article 141 EU Financial Regulation 2018/1046.

- 2) The ex aequo proposals within the same topic will be prioritised according to the scores they have been awarded for the award criterion 'Relevance'. When these scores are equal, priority will be based on their scores for the criterion 'Impact'. When these scores are equal, priority will be based on their scores for the criterion 'Implementation'.
- 3) If this does not allow to determine the priority, a further prioritisation can be done by considering the overall proposal portfolio and the creation of positive synergies between proposals, or other factors related to the objectives of the call. These factors will be documented in the panel report.
- 4) After that, the remainder of the available call budget will be used to fund projects across the different topics in order to ensure a balanced spread of the geographical and thematic coverage and while respecting to the maximum possible extent the order of merit based on the evaluation of the award criteria.

All proposals will be informed about the evaluation result (**evaluation result letter**). Successful proposals will be invited for grant preparation; the other ones will be put on the reserve list or rejected.

No commitment for funding — Invitation to grant preparation does NOT constitute a formal commitment for funding. We will still need to make various legal checks before grant award: legal entity validation, financial capacity, exclusion check, etc.

Grant preparation will involve a dialogue in order to fine-tune technical or financial aspects of the project and may require extra information from your side. It may also include adjustments to the proposal to address recommendations of the evaluation committee or other concerns. Compliance will be a pre-condition for signing the grant.

If you believe that the evaluation procedure was flawed, you can submit a **complaint** (following the deadlines and procedures set out in the evaluation result letter). Please note that notifications which have not been opened within 10 days after sending will be considered to have been accessed and that deadlines will be counted from opening/access (see also <u>Funding & Tenders Portal Terms and Conditions</u>). Please also be aware that for complaints submitted electronically, there may be character limitations.

9. Award criteria

The **award criteria** for this call are as follows:

1. Relevance

- Alignment with the objectives and activities as described in section 2
- Contribution to long-term policy objectives, relevant policies and strategies, and synergies with activities at European and national level
- Extent to which the project would reinforce and secure the digital technology supply chain in the EU*
- Extent to which the project can overcome financial obstacles such as the lack of market finance*

2. Implementation

Maturity of the project

- Soundness of the implementation plan and efficient use of resources
- Capacity of the applicants, and when applicable the consortium as a whole, to carry out the proposed work

3. Impact

- Extent to which the project will achieve the expected outcomes and deliverables referred to in the call for proposals and, where relevant, the plans to disseminate and communicate project achievements
- Extent to which the project will strengthen competitiveness and bring important benefits for society
- Extent to which the project addresses environmental sustainability and the European Green Deal goals, in terms of direct effects and/or in awareness of environmental effects *.

^{*}May not be applicable to all topics (see specific topic conditions in section 2).

Award criteria	Minimum pass score	Maximum score
Relevance	3	5
Implementation	3	5
Impact	3	5
Overall (pass) scores	10	15

Maximum points: 15 points.

Individual thresholds per criterion: 3/5, 3/5 and 3/5 points.

Overall threshold: 10 points.

Proposals that pass the individual thresholds AND the overall threshold will be considered for funding — within the limits of the available budget (i.e. up to the budget ceiling). Other proposals will be rejected.

10. Legal and financial set-up of the Grant Agreements

If you pass evaluation, your project will be invited for grant preparation, where you will be asked to prepare the Grant Agreement together with the EU Project Officer.

This Grant Agreement will set the framework for your grant and its terms and conditions, in particular concerning deliverables, reporting and payments.

The Model Grant Agreement that will be used (and all other relevant templates and guidance documents) can be found on Portal Reference Documents.

Starting date and project duration

The project starting date and duration will be fixed in the Grant Agreement (Data Sheet, point 1). Normally the starting date will be after grant signature. A retroactive starting date can be granted exceptionally for duly justified reasons but never earlier than the proposal submission date.

Project duration:

- for topic the DIGITAL-2024-CLOUD-DATA-06-SKILLS Data Space for Skills (deployment): 36 months
- for the topic DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space
 for Manufacturing (deployment): between 24- 36 months
- for topic DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare: 36 months.

Extensions are possible, if duly justified and through an amendment.

Milestones and deliverables

The milestones and deliverables for each project will be managed through the Portal Grant Management System and will be reflected in Annex 1 of the Grant Agreement.

The following deliverables will be mandatory for all projects:

 additional deliverable on dissemination and exploitation, to be submitted in the first six months of the project

Form of grant, funding rate and maximum grant amount

The grant parameters (maximum grant amount, funding rate, total eligible costs, etc) will be fixed in the Grant Agreement (Data Sheet, point 3 and art 5).

Project budget (maximum grant amount):

- for the topic DIGITAL-2024-CLOUD-DATA-06-SKILLS Data Space for Skills (deployment): EUR 3 000 000 per project
- for the topic DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment): between EUR 3 000 000 and EUR 4 000 000 per project
- for the topic DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare: EUR 4 000 000 per project.

The grant awarded may be lower than the amount requested.

The grant will be a budget-based mixed actual cost grant (actual costs, with unit cost and flat-rate elements). This means that it will reimburse ONLY certain types of costs (eligible costs) and costs that were *actually* incurred for your project (NOT the *budgeted* costs). For unit costs and flat-rates, you can charge the amounts calculated as explained in the Grant Agreement (see art 6 and Annex 2 and 2a).

The costs will be reimbursed at the funding rate fixed in the Grant Agreement. This rate depends on the type of action which applies to the topic (see section 2).

Grants may NOT produce a profit (i.e. surplus of revenues + EU grant over costs). For-profit organisations must declare their revenues and, if there is a profit, we will deduct it from the final grant amount (see art 22.3).

Moreover, please be aware that the final grant amount may be reduced in case of non-compliance with the Grant Agreement (e.g. improper implementation, breach of obligations, etc).

Budget categories and cost eligibility rules

The budget categories and cost eligibility rules are fixed in the Grant Agreement (Data Sheet, point 3 and art 6).

Budget categories for this call:

- A. Personnel costs
 - A.1 Employees, A.2 Natural persons under direct contract, A.3 Seconded persons
 - A.4 SME owners and natural person beneficiaries
- B. Subcontracting costs
- C. Purchase costs
 - C.1 Travel and subsistence
 - C.2 Equipment
 - C.3 Other goods, works and services
- D. Other cost categories
 - D.2 Internally invoiced goods and services
- E. Indirect costs

Specific cost eligibility conditions for this call:

- personnel costs:
 - average personnel costs (unit cost according to usual cost accounting practices)²⁴: Yes
 - SME owner/natural person unit cost²⁵: Yes
- travel and subsistence unit costs²⁶: No (only actual costs)
- equipment costs:
 - depreciation for topic: DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare
 - depreciation + full cost for listed equipment for topics: DIGITAL-2024-CLOUD-DATA-06-SKILLS Data Space for Skills (deployment) and DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment)
- other cost categories:
 - costs for financial support to third parties: not allowed.
 - internally invoiced goods and services (unit cost according to usual cost accounting practices)²⁷: Yes

Decision of 29 June 2021 authorising the use of unit costs based on usual cost accounting practices for actions under the Digital Europe Programme.

Commission <u>Decision</u> of 20 October 2020 authorising the use of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary for the work carried out by themselves under an action or work programme (C(2020)7115).

Commission <u>Decision</u> of 12 January 2021 authorising the use of unit costs for travel, accommodation and subsistence costs under an action or work programme under the 2021-2027 multi-annual financial framework (C(2021)35).

- indirect cost flat-rate: 7% of the eligible direct costs (categories A-D, except volunteers costs and exempted specific cost categories, if any).
- VAT: non-deductible VAT is eligible (but please note that since 2013 VAT paid by beneficiaries that are public bodies acting as public authority is NOT eligible)

– other:

- in-kind contributions for free are allowed, but cost-neutral, i.e. they cannot be declared as cost
- kick-off meeting: costs for kick-off meeting organised by the granting authority are eligible (travel costs for maximum 2 persons, return ticket to Brussels and accommodation for one night) only if the meeting takes place after the project starting date set out in the Grant Agreement; the starting date can be changed through an amendment, if needed
- project websites: communication costs for presenting the project on the participants' websites or social media accounts are eligible; costs for separate project websites are not eligible
- restrictions due to security:
 - country restrictions for subcontracting costs: Yes, subcontracted work must be performed in the eligible countries for topics: DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment) and DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare
 - eligible cost country restrictions: Yes, only costs for activities carried out in eligible countries are eligible for topics DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment) and DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare
- other ineligible costs: No.

Reporting and payment arrangements

The reporting and payment arrangements are fixed in the Grant Agreement (Data Sheet, point 4 and art 21 and 22).

After grant signature, you will normally receive a **prefinancing** to start working on the project (float of normally **80%** of the maximum grant amount; exceptionally less or no prefinancing). The prefinancing will be paid 30 days from entry into force/10 days before starting date/financial guarantee (if required) – whichever is the latest.

There will be one or more **interim payments** (with cost reporting through the use of resources report).

Payment of the balance: At the end of the project, we will calculate your final grant amount. If the total of earlier payments is higher than the final grant amount, we will ask you (your coordinator) to pay back the difference (recovery).

All payments will be made to the coordinator.

Decision of 29 June 2021 authorising the use of unit costs based on usual cost accounting practices for actions under the Digital Europe Programme.

Please be aware that payments will be automatically lowered if one of your consortium members has outstanding debts towards the EU (granting authority or other EU bodies). Such debts will be offset by us — in line with the conditions set out in the Grant Agreement (see art 22).

Please also note that you are responsible for keeping records on all the work done and the costs declared.

Prefinancing quarantees

If a prefinancing guarantee is required, it will be fixed in the Grant Agreement (*Data Sheet, point 4*). The amount will be set during grant preparation and it will normally be equal or lower than the prefinancing for your grant.

The guarantee should be in euro and issued by an approved bank/financial institution established in an EU Member State. If you are established in a non-EU country and would like to provide a guarantee from a bank/financial institution in your country, please contact us (this may be exceptionally accepted, if it offers equivalent security).

Amounts blocked in bank accounts will NOT be accepted as financial guarantees.

Prefinancing guarantees are normally requested from the coordinator, for the consortium. They must be provided during grant preparation, in time to make the prefinancing (scanned copy via Portal AND original by post).

If agreed with us, the bank guarantee may be replaced by a guarantee from a third party.

The guarantee will be released at the end of the grant, in accordance with the conditions laid down in the Grant Agreement (art 23).

Certificates

Depending on the type of action, size of grant amount and type of beneficiaries, you may be requested to submit different certificates. The types, schedules and thresholds for each certificate are fixed in the Grant Agreement (Data Sheet, point 4 and art 24).

Liability regime for recoveries

The liability regime for recoveries will be fixed in the Grant Agreement (Data Sheet point 4.4 and art 22).

For beneficiaries, it is one of the following:

- limited joint and several liability with individual ceilings each beneficiary up to their maximum grant amount
- unconditional joint and several liability each beneficiary up to the maximum grant amount for the action

or

individual financial responsibility — each beneficiary only for their own debts.

In addition, the granting authority may require joint and several liability of affiliated entities (with their beneficiary).

Provisions concerning the project implementation

Security rules: see Model Grant Agreement (art 13 and Annex 5)

Ethics rules: see Model Grant Agreement (art 14 and Annex 5)

IPR rules: see Model Grant Agreement (art 16 and Annex 5):

- background and list of background: Yes
- protection of results: Yes
- exploitation of results: Yes
- rights of use on results: Yes
- access to results for policy purposes: Yes
- access to results in case of a public emergency: Yes
 - access rights to ensure continuity and interoperability obligations:
 - Yes for the topic:
 - -DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment)
- special IPR obligations linked to restrictions due to security:
 - exploitation in eligible countries:
 - Yes for topics:
 - -DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment)
 - -DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI -Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare
 - first exploitation obligation in eligible countries:
 - Yes for topic:
 - -DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE
 Data Space for Manufacturing (deployment)
 - limitations to transfers and licensing:
 - Yes for topics:
 - -DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE Data Space for Manufacturing (deployment)
 - -DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI -Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare

Communication, dissemination and visibility of funding: see Model Grant Agreement (art 17 and Annex 5):

- communication and dissemination plan: Yes
- dissemination of results: Yes
- additional dissemination obligations: No
- additional communication activities: Yes
- special logo: No

Specific rules for carrying out the action: see Model Grant Agreement (art 18 and Annex 5):

- specific rules for PAC Grants for Procurement: No
- specific rules for Grants for Financial Support: No
- specific rules for blending operations: No
- special obligations linked to restrictions due to security:
 - implementation in case of restrictions due to security
 - Yes for the topics:
 - -DIGITAL-2024-CLOUD-DATA-06-MANUFSPACE -Data Space for Manufacturing (deployment)
 - -DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI -Support for Health Data Access Bodies to foster efficient pathways for AI in healthcare

Other specificities

n/a

Non-compliance and breach of contract

The Grant Agreement (chapter 5) provides for the measures we may take in case of breach of contract (and other non-compliance issues).



For more information, see <u>AGA — Annotated Grant Agreement</u>.

11. How to submit an application

All proposals must be submitted directly online via the Funding & Tenders Portal Electronic Submission System. Paper applications are NOT accepted.

Submission is a **2-step process**:

a) create a user account and register your organisation

To use the Submission System (the only way to apply), all participants need to create an EU Login user account.

Once you have an EULogin account, you can register your organisation in the Participant Register. When your registration is finalised, you will receive a 9-digit participant identification code (PIC).

b) submit the proposal

Access the Electronic Submission System via the Topic page in the Search Funding & Tenders section (or, for calls sent by invitation to submit a proposal, through the link provided in the invitation letter).

Submit your proposal in 3 parts, as follows:

Part A includes administrative information about the applicant organisations (future coordinator, beneficiaries, affiliated entities and associated partners) and the summarised budget for the proposal. Fill it in directly online

- Part B (description of the action) covers the technical content of the proposal.
 Download the mandatory word template from the Submission System, fill it in and upload it as a PDF file
- Annexes (see section 5). Upload them as PDF file (single or multiple depending on the slots). Excel upload is sometimes possible, depending on the file type.

The proposal must keep to the **page limits** (see section 5); excess pages will be disregarded.

Documents must be uploaded to the **right category** in the Submission System otherwise the proposal might be considered incomplete and thus inadmissible.

The proposal must be submitted **before the call deadline** (see section 4). After this deadline, the system is closed and proposals can no longer be submitted.

Once the proposal is submitted, you will receive a **confirmation e-mail** (with date and time of your application). If you do not receive this confirmation e-mail, it means your proposal has NOT been submitted. If you believe this is due to a fault in the Submission System, you should immediately file a complaint via the <u>IT Helpdesk webform</u>, explaining the circumstances and attaching a copy of the proposal (and, if possible, screenshots to show what happened).

Details on processes and procedures are described in the <u>Online Manual</u>. The Online Manual also contains the links to FAQs and detailed instructions regarding the Portal Electronic Exchange System.

12. Help

As far as possible, **please try to find the answers you need yourself**, in this and the other documentation (we have limited resources for handling direct enquiries):

- Online Manual
- FAQs on the Topic page (for call-specific questions in open calls; not applicable for actions by invitation)
- Portal FAQ (for general questions).

Please also consult the Topic page regularly, since we will use it to publish call updates. (For invitations, we will contact you directly in case of a call update).

Contact

For individual questions on the Portal Submission System, please contact the $\underline{\Pi}$ Helpdesk.

Non-IT related questions contact Here

Please indicate clearly the reference of the call and topic to which your question relates (see cover page).

13. Important



IMPORTANT

- Don't wait until the end Complete your application sufficiently in advance of the deadline to avoid any last minute technical problems. Problems due to last minute submissions (e.g. congestion, etc) will be entirely at your risk. Call deadlines can NOT be extended.
- **Consult** the Portal Topic page regularly. We will use it to publish updates and additional information on the call (call and topic updates).
- **Funding & Tenders Portal Electronic Exchange System** By submitting the application, all participants **accept** to use the electronic exchange system in accordance with the <u>Portal Terms & Conditions</u>.
- **Registration** Before submitting the application, all beneficiaries, affiliated entities and associated partners must be registered in the <u>Participant Register</u>. The participant identification code (PIC) (one per participant) is mandatory for the Application Form.
- **Consortium roles** When setting up your consortium, you should think of organisations that help you reach objectives and solve problems.
 - The roles should be attributed according to the level of participation in the project. Main participants should participate as **beneficiaries** or **affiliated entities**; other entities can participate as associated partners, subcontractors, third parties giving in-kind contributions. **Associated partners** and third parties giving in-kind contributions should bear their own costs (they will not become formal recipients of EU funding). **Subcontracting** should normally constitute a limited part and must be performed by third parties (not by one of the beneficiaries/affiliated entities). Subcontracting going beyond 30% of the total eligible costs must be justified in the application.
- **Coordinator** In multi-beneficiary grants, the beneficiaries participate as consortium (group of beneficiaries). They will have to choose a coordinator, who will take care of the project management and coordination and will represent the consortium towards the granting authority. In mono-beneficiary grants, the single beneficiary will automatically be coordinator.
- **Affiliated entities** Applicants may participate with affiliated entities (i.e. entities linked to a beneficiary which participate in the action with similar rights and obligations as the beneficiaries, but do not sign the grant and therefore do not become beneficiaries themselves). They will get a part of the grant money and must therefore comply with all the call conditions and be validated (just like beneficiaries); but they do not count towards the minimum eligibility criteria for consortium composition (if any).
- Associated partners Applicants may participate with associated partners (i.e. partner organisations which participate in the action but without the right to get grant money). They participate without funding and therefore do not need to be validated.
- **Consortium agreement** For practical and legal reasons it is recommended to set up internal arrangements that allow you to deal with exceptional or unforeseen circumstances (in all cases, even if not mandatory under the Grant Agreement). The consortium agreement also gives you the possibility to redistribute the grant money according to your own consortium-internal principles and parameters (for instance, one beneficiary can reattribute its grant money to another beneficiary). The consortium agreement thus allows you to customise the EU grant to the needs inside your consortium and can also help to protect you in case of disputes.

- **Balanced project budget** Grant applications must ensure a balanced project budget and sufficient other resources to implement the project successfully (e.g. own contributions, income generated by the action, financial contributions from third parties, etc). You may be requested to lower your estimated costs, if they are ineligible (including excessive).
- **Completed/ongoing projects** Proposals for projects that have already been completed will be rejected; proposals for projects that have already started will be assessed on a case-by-case basis (in this case, no costs can be reimbursed for activities that took place before the project starting date/proposal submission).
- **No-profit rule** Grants may NOT give a profit (i.e. surplus of revenues + EU grant over costs). This will be checked by us at the end of the project.
- **No cumulation of funding/no double funding** It is strictly prohibited to cumulate funding from the EU budget (except under 'EU Synergies actions'). Outside such Synergies actions, any given action may receive only ONE grant from the EU budget and cost items may under NO circumstances be declared under two EU grants. If you would like to nonetheless benefit from different EU funding opportunities, projects must be designed as different actions, clearly delineated and separated for each grant (without overlaps).
- **Combination with EU operating grants** Combination with EU operating grants is possible, if the project remains outside the operating grant work programme and you make sure that cost items are clearly separated in your accounting and NOT declared twice (see AGA Annotated Grant Agreement, art 6.2.E).
- **Multiple proposals** Applicants may submit more than one proposal for *different* projects under the same call (and be awarded funding for them).

Organisations may participate in several proposals.

BUT: if there are several proposals for *very similar* projects, only one application will be accepted and evaluated; the applicants will be asked to withdraw the others (or they will be rejected).

- Resubmission Proposals may be changed and re-submitted until the deadline for submission.
- **Rejection** By submitting the application, all applicants accept the call conditions set out in this this Call Document (and the documents it refers to). Proposals that do not comply with all the call conditions will be **rejected**. This applies also to applicants: All applicants need to fulfil the criteria; if any one of them doesn't, they must be replaced or the entire proposal will be rejected.
- **Cancellation** There may be circumstances which may require the cancellation of the call. In this case, you will be informed via a call or topic update. Please note that cancellations are without entitlement to compensation.
- **Language** You can submit your proposal in any official EU language (project abstract/summary should however always be in English). For reasons of efficiency, we strongly advise you to use English for the entire application. If you need the call documentation in another official EU language, please submit a request within 10 days after call publication (for the contact information, see section 12).

• **Transparency** — In accordance with Article 38 of the <u>EU Financial Regulation</u>, information about EU grants awarded is published each year on the <u>Europa website</u>.

This includes:

- beneficiary names
- beneficiary addresses
- the purpose for which the grant was awarded
- the maximum amount awarded.

The publication can exceptionally be waived (on reasoned and duly substantiated request), if there is a risk that the disclosure could jeopardise your rights and freedoms under the EU Charter of Fundamental Rights or harm your commercial interests.

• **Data protection** — The submission of a proposal under this call involves the collection, use and processing of personal data. This data will be processed in accordance with the applicable legal framework. It will be processed solely for the purpose of evaluating your proposal, subsequent management of your grant and, if needed, programme monitoring, evaluation and communication. Details are explained in the Funding & Tenders Portal Privacy Statement.

Annex 1

Digital Europe types of action

The Digital Europe Programme uses the following actions to implement grants:

Simple Grants

Description: Simple Grants (SIMPLE) are a flexible type of action used by a large variety of topics and can cover most activities. The consortium will mostly use personnel costs to implement action tasks, activities with third parties (subcontracting, financial support, purchase) are possible but should be limited.

Funding rate: 50%

Payment model: Prefinancing – (x) interim payment(s) – final payment

SME Support Actions

Description: SME Support Actions (SME) are a type of action primarily consisting of activities directly aiming to support SMEs involved in building up and the deployment of the digital capacities. This type of action can also be used if SMEs need to be in the consortium and make investments to access the digital capacities.

Funding rate: 50% except for SMEs where a rate of 75% applies

Payment model: Prefinancing – (x) interim payment(s) – final payment

Coordination and Support Actions (CSAs)

Description: Coordination and Support Actions (CSAs) are a small type of action (a typical amount of 1-2 Mio) with the primary goal to support EU policies. Activities can include coordination between different actors for accompanying measures such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure and may also include complementary activities of strategic planning, networking and coordination between programmes in different countries.

Funding rate: 100%

Payment model: Prefinancing – (x) interim payment(s) – final payment

Grants for Procurement

Description: Grants for Procurement (GP) are a special type of action where the main goal of the action (and thus the majority of the costs) consist of buying goods or services and/or subcontracting tasks. Contrary to the PAC Grants for Procurement (see below) there are no specific procurement rules (i.e. usual rules for purchase apply), nor is there a limit to 'contracting authorities/entities'. Personnel costs should be limited in this type of action; they are in general used to manage the grant, coordination between the beneficiaries, preparation of the procurements.

Funding rate: 50%

Payment model: Prefinancing - second prefinancing (to provide the necessary cashflow to finance the procurements) – payment of the balance

PAC Grants for Procurement

Description: PAC Grants for Procurement (PACGP) are a specific type of action for procurement in grant agreements by 'contracting authorities/entities' as defined in the EU Public Procurement Directives (Directives 2014/24/EU, 2014/25/EU and 2009/81/EC) aiming at innovative digital goods and services (i.e. novel technologies on the way to commercialisation but not yet broadly available).

Funding rate: 50%

Payment model: Prefinancing - second prefinancing (to provide the necessary cashflow to finance the procurements) – payment of the balance

Grants for Financial Support

Description: Grants for Financial Support (GfS) have a particular focus on cascading grants. The majority of the grant will be distributed via financial support to third parties with special provisions in the grant agreement, maximum amounts to third parties, multiple pre-financing and reporting obligations.

Annex 5 of the model grant agreements foresees specific rules for this type of action regarding conflict of interest, the principles of transparency, non-discrimination and sound financial management as well as the selection procedure and criteria.

In order to assure the co-financing obligation in the programme, the support to third parties should only cover 50% of third party costs.

Funding rate: 100% for the consortium, co-financing of 50% by the supported third party

Payment model: Prefinancing - second prefinancing (to provide the necessary cashflow to finance sub-grants) – payment of the balance

Lump Sum Grants

Description: Lump Sum Grants (LS) reimburse a general lump sum for the entire project and the consortium as a whole. The lump sum is fixed ex-ante (at the latest at grant signature). on the basis of a methodology defined by the granting authority (either on the basis of a detailed project budget or other pre-defined parameters). The lump sum will cover all the beneficiaries' direct and indirect costs for the project. The beneficiaries do not need to report actual costs, they just need to claim the lump sum once the work is done. If the action is not properly implemented only part of the lump sum will be paid.

Funding rate: 100%/50%/50% and 75% (for SMEs)

Payment model: Prefinancing – (x) interim payment(s)– final payment

Framework Partnerships (FPAs) and Specific Grants (SGAs)

FPAs

Description: FPAs establish a long-term cooperation mechanism between the granting authority and the beneficiaries of grants. The FPA specifies the common objectives (action plan) and the procedure for awarding specific grants. The specific grants are awarded via identified beneficiary actions (with or without competition).

Funding rate: no funding for FPA

SGAs

Description: The SGAs are linked to an FPA and implement the action plan (or part of it). They are awarded via an invitation to submit a proposal (identified beneficiary action). The consortium composition should in principle match (meaning that only entities that are part of the FPA can participate in an SGA), but otherwise the implementation is rather flexible. FPAs and SGAs can have different coordinators; other partners of the FPA are free to participate in an SGA or not. There is no limit to the amount of SGAs signed under one FPA.

Funding rate: 50%

Payment model: Prefinancing – (x) interim payment(s) – final payment

Annex 2

Eligibility restrictions under Articles 12(5) and (6) and 18(4) of the Digital Europe Regulation

Security restrictions Article 12(5) and (6)

If indicated in the Digital Europe Work Programme, and if justified for security reasons, topics can exclude the participation of legal entities *established* in a third country or DEP associated country, or established in the EU territory but *controlled* by a third country or third country legal entities (including DEP associated countries)²⁸.

This restriction is applicable for SO1 (High Performance Computing), SO2 (Artificial Intelligence) and SO3 (Cybersecurity), but at different levels.

- In the case of SO3, the provision is implemented in the strictest way. When activated, only entities established in the EU AND controlled from the EU will be able to participate; entities from associated countries (which are normally eligible) can NOT participate unless otherwise provided in the Work Programme.
- In SO1 and SO2, entities established in associated countries and entities controlled from non-EU countries may participate, if they comply with the conditions set out in the Work Programme (usually:
 - for the associated countries: be formally associated to Digital Europe Programme and receive a positive assessment by the Commission on the replies to their associated country security questionnaire. Currently none of the associated countries have passed the assessment yet.
 - for the participants: submission of a guarantee demonstrating that they have taken measures to ensure that their participation does not contravene security or EU strategic autonomy interests).

EEA countries (and participants from EEA countries) are exempted from these restrictions (and additional requirements) because EEA countries benefit from a status equivalent to the Member States.

In order to determine the ownership and control status, participants²⁹ will be required to fill in and submit an <u>ownership control declaration</u>*as part of the proposal (and later on be requested to submit supporting documents) (see <u>Guidance on participation in DEP</u>, HE, EDF and CEF-DIG restricted calls).

In addition, where a guarantee is required, the participants will also have to fill in the <u>guarantee template</u>*, approved by the competent authorities of their country of establishment, and submit it to the granting authority which will assess its validity.

The activation of these restrictions will also make a number of specific provisions in the Grant Agreement applicable, such as country restrictions for eligible costs, country restrictions for subcontracting, and special rules for implementation, exploitation of results and transfers and exclusive licensing of results.

Thus:

See Article 12(5) and (6) of the Digital Europe Regulation 2021/694.

Beneficiaries and affiliated entities, associated partners and subcontractors — except for entities that are validated as public bodies by the Central Validation Service.

- participation in any capacity (as beneficiary, affiliated entity, associated partner, subcontractor or recipient of financial support to third parties) is also limited to entities established in and controlled from eligible countries
- project activities (included subcontracted work) must take place in eligible countries
- the Grant Agreement provides for specific IPR restrictions.

Strategic autonomy restrictions Article 18(4)

If indicated in the Digital Europe Work Programme, calls can limit the participation to entities *established* in the EU, and/or entities established in third countries associated to the programme for EU strategic autonomy reasons³⁰.

The activation of these restrictions will make a number of specific provisions in the Grant Agreement applicable, such as country restrictions for eligible costs, country restrictions for subcontracting, and special rules for implementation, exploitation of results and transfers and exclusive licensing of results.

For more information, see <u>Guidance on participation in DEP, HE, EDF and CEF-DIG</u> restricted calls.

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³⁰ See Article 18(4) of the Digital Europe Regulation 2021/694.