





# Mirror Regions Call for SMEs Guidelines for applicants

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# **General details**

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Project Coordinator	TICBIOMED (TBM)
	Myriam Martín
	myriam.martin@ticbiomed.net
	Elena López
	Elena.lopez@ticbiomed.net
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#### Disclaimer

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# **History of changes**

Ver.	Date	Changes
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# Glossary

Term	Description
Application	Submission of online form to apply for the Call for SMEs, through the F6S platform.
Cascade Funding Calls / Financial Support for Third Parties (FSTP)	Cascade funding, also known as Financial Support for Third Parties (FSTP), is a Commission mechanism to distribute public funding in order to assist beneficiaries, such as start-ups, scaleups, SME and/or mid-caps, in the uptake or development of digital innovation.
Challenge	A description of a real and specific organisational innovation need, which is currently not met and for which a solution is not yet available or widely available on the market.
Challenger	Healthcare organisation that has a Challenge that requires an innovative solution and aims to co-create a pilot with an innovative company (or companies).
Co-creation agreement and Pilot Action Plan	A plan signed between the Mirror Region Ecosystem Supporter, the Challenger (healthcare organization), and the awarded SME, outlining the implementation scope, each partner responsibilities, engagement procedure with end-users, success KPIs for the pilot, IPR ownership and exploitation rights, among other key issues. It will be annexed to the subgrantagreement.
Ecosystem supporter	A business association, cluster or other type of intermediate organisation that leads the ecosystem, linking its stakeholders, connecting it between cross-border regions and delivering business support to the SMEs solving the Challenge in their ecosystem.
Founding Region	European territory, part of the 5 regions group that initially participated in the design and implementation of the HealthChain model. Each region has a Healthcare Organisation (HO) with the role of Challenge identifier that proposes the needs and
	pilots the proposed solutions in their premises; IT companies (or Solvers) with mature IT/digital technology at least in TRL 6, and a regional ecosystem Supporter (ES) that delivers business support and leads the connection between cross-border regions. The HealthChain founding regions are Murcia (Spain), Centro (Portugal), Primorsko Goranska (Croatia), West (Slovenia) and East (Netherlands).





Mirror Region	European region receiving funding and support to implement the HealthChain model in their territory. It is led by an Ecosystem Supporter, who is working closely with a Challenger with an unmet need. The Mirror Regions are Navarra (Spain), Western (Greece), Castilla y León (Spain), Flanders (Belgium) and North-West (Romania). The Mirror Regions are assisted by the HealthChain Founding Regions for the implementation.
Mirror Regions Call for SMEs	Open call inviting innovative companies to submit pilot proposals to solve Mirror Regions Challengers' needs.
Proposal	A PDF file detailing a solution/pilot, following the template provided in this Mirror Regions Call for SMEs (Annex 2 - Proposal Template).
SME	Small and Medium Enterprise <u>as defined by</u> the European Commission.
Sub-Grant agreement	A contract signed between the HealthChain Coordinator (Ticbiomed), the Mirror Region Ecosystem Supporter, and the awarded SME, defining the framework of rights and obligations of the contracting parties, including but not limited to ground rules for receiving financial support and a description of the work to be carried out.
Sub-grantee	The awarded SME that signs a Sub-Grant agreement with the HealthChain Consortium and works with the Mirror Region to solve their challenge.





# 1. Introduction

#### 1.1. This document

This document explains how the **HealthChain Mirror Regions Call for SMEs** works, defining the terms and conditions to apply for it, including the eligibility and evaluation criteria, financial support available, application and evaluation process. It is complemented by other open call documents listed in section 6, which can be found on the HealthChain website: <a href="https://healthchain-i3.eu/mirror-regions-call-smes/">https://healthchain-i3.eu/mirror-regions-call-smes/</a> and that must be considered by applicants for the submission of a proposal.

#### 1.2. Context

The acquisition of innovation by healthcare organisations enables better and more efficient service delivery to citizens and patients. These organisations can acquire innovation via direct procurement from the market when a mature solution is available. However, frequently these organisations have unmet needs that require innovative solutions that are not yet widely available in the market.

HealthChain has launched different funding opportunities targeted at SMEs willing to solve the healthcare organisations (Challengers) unmet needs via innovative solutions. **Through the Mirror Regions Call for SMEs, HealthChain is looking for 5 SMEs to solve the challenges identified by the Mirror Regions**. The awarded SMEs will co-create and pilot an innovative solution with the Challenger in the Mirror Region, supported by the Ecosystem supporter. In exchange, the SME will receive €50,000 equity-free funding and support for business development and commercialisation.

#### 1.3. The I3 instrument

HealthChain is a European project funded by the <u>I3 Instrument</u> under Strand 2a. I3 provides advisory and financial support to innovation projects in joint smart specialisation areas on the road towards commercialisation and scale-up. Strand 2a focuses on increasing the capacity of regional innovation ecosystems in less developed regions to participate in global value chains, as well as the capacity to participate in partnerships with other regions.

#### 1.4. HealthChain model

#### Boosting value chains in health at regional and EU level

HealthChain, leverages the I3 Instrument to bring together the public and private sectors in the regional ecosystems to develop demand-driven digital health solutions through cocreation between Healthcare Organisations (HOs) and IT companies.

HealthChain proposes an innovation model that is demand-driven, co-creative, geared to adoption and ecosystem enabled to complement current instruments. The project aims to develop health solutions meeting existing needs that will improve the quality of the health services for the citizens.

HealthChain builds up on top of five founding regional ecosystems from different EU countries: Murcia (Spain), Centro (Portugal), Western (Slovenia), Primorsko-Goranska (Croatia) and East Netherlands (The Netherlands). As part of the HealthChain Community of Practice, five additional ecosystems are involved to replicate the model known as **Mirror Regions: Western** 





(Greece), Navarra (Spain), Castilla y León (Spain), Flanders (Belgium) and Northwest (Romania). The interregional component provides a unique opportunity to cross-fertilise actual instruments and facilitate the market uptake of the solutions developed.

HealthChain model will be implemented and validated in the regional ecosystems based on local quadruple-helix connections from different EU countries. Each region brings together the same structure of roles:

- Healthcare organisation (HO) with the role of Challenge identifier that proposes the needs and pilots the co-creation of the proposed solutions in their premises.
- IT Companies (Solvers) with the role of solvers with expertise in IT/digital technology.
- Regional Ecosystem Supporter (ES) as business support experts for the IT companies but also leading the connection between cross-border regions.

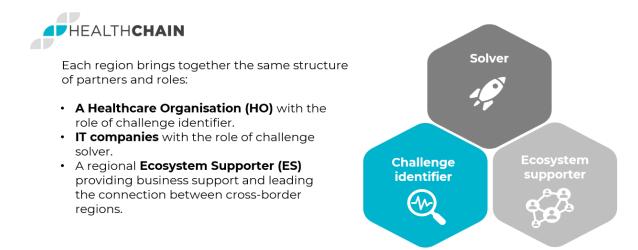


Figure 1. An ecosystem in HealthChain



Figure 2. The HealthChain founding regions.





# 1.5. The Mirror Regions and their challenges

A mirror region is a European region receiving funding and support to implement the HealthChain model in their territory. It is led by an Ecosystem Supporter, who is working closely with a Challenger with an unmet need. The Mirror Regions are Navarra (Spain), Western (Greece), Castilla y León (Spain), Flanders (Belgium) and North-West (Romania). The Mirror Regions are assisted by the HealthChain Founding Regions for the implementation.



Figure 3. The HealthChain Mirror Regions

#### 1.5.1. Navarra (Spain)



Figure 4. Navarra ecosystem





Navarra leads innovation and technology transfer in Spain, investing 1.79% of its GDP. The region allocates millions to promote collaboration between companies, SMEs, and research centres, particularly in health. Navarra actively supports international initiatives like EP Permed, engages in the ERRIN network, and plays a key role in the Euroregion NAE.

	Description
Ecosystem Supporter	<u>Navarrabiomed</u> is a public biomedical research centre with 20 research units that connect the University Hospital of Navarra with SMEs, offering technical advice and managing innovation in the region's public health system.
Challenger	<u>University Hospital of Navarra</u> (HUN) is the reference centre in the Pamplona Area also being a general hospital for those demands that come from all over Navarra and, on occasions, for populations from neighbouring communities; it also has a series of diagnostic support services that are also of reference for the area of the Autonomous Community of Navarra.
	The HUN has just over a thousand beds and a total staff of nearly 6,500 professionals in 2021. It records an annual volume of more than 40,000 admissions, 33,000 surgical interventions and more than 750,000 consultations.
	Its strategic vision is to move towards a hospital that is more accessible to patients and their healthcare needs. Its actions are oriented towards the provision of quality services. The HUN defines itself as a centre committed to research and the promotion of innovation in healthcare. In concrete, Radiotherapy oncology service offers specialized radiation oncology treatments to patients of all ages and types of cancer. The rapid progress in technology and the needs to improve their services and the effectiveness of treatments, make this service ideal for applying to innovative procedures.
Challenge	<b>OPER-ART</b> - Addressing the uncertainty challenges of radiotherapy through personalised 3D molds used in radiotherapy and brachytherapy.

Table 1.Navarra ecosystem and proposed challenge





#### 1.5.2. Western (Greece)

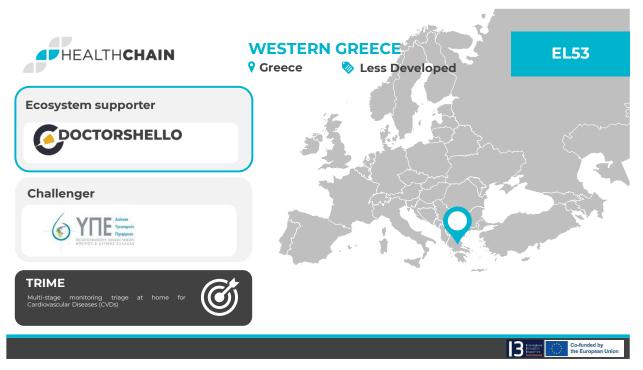


Figure 5. Western Greece ecosystem

Western Greece comprises the western part of continental Greece and the northwestern part of the Peloponnese peninsula. It occupies an area of 11,336 km2 and its population is, according to the 2011 census, at 679,796 inhabitants. The capital of the Western Greece is Patras, the third largest city in the country. The Gross domestic product (GDP) of the region is 4.5% of Greek economic output (2028 data).

	Description
Ecosystem Supporter	<u>Systserv</u> runs <u>Doctorshello</u> , a patient-centric healthcare ecosystem focused on senior well-being. It collaborates with hospitals and stakeholders to tackle real medical challenges, optimizing healthcare processes for societal well-being.
Challenger	The General Hospital of Pyrgos ANDREAS PAPANDREOU is located in the area of Syntriada, two kilometers outside the town of Pyrgos. extends over a plot of 80,000 m2, has a capacity of 280 beds.  The last years although the hospital is the main healthcare unit of the capital city Pyrgos and all surrounding towns, still faces continuous staff shortages, struggling to cope with the needs of the patients. Facing this challenge, a more radical solution is suggested through shifting some care services at home, prior to visiting the hospital or especially supporting the outpatient monitoring at home, decreasing, in that way, the readmissions.
Challenge	<b>TRIME:</b> Multi-stage monitoring triage at home for Cardiovascular Diseases (CVDs)

Table 2.Western Greece ecosystem and proposed challenge





#### 1.5.3. Castilla y León (Spain)



Figure 6. Castilla y León ecosystem

Castilla y León, covering 20% of Spain with 2,248 municipalities over 94,000 km², is a rural region and a tech pioneer since 1997. With RDI expenditure at 1.35% of GDP in 2019, above the national average, CYL is a leader in the Silver Economy. The region's commitment to innovation addresses the specific needs of an aging population and rural dispersion, positioning CYL at the forefront of global health trends.

	Description
Ecosystem Supporter	<u>INTRAS</u> is a non-profit organization with 30 years of expertise, focusing on integrated mental health and aging care, and coordinates initiatives for well-being and independent living promotion.
Challenger	Los Montalvos Hospital (Palliative Care Unit, 1998) has been, for more than 20 years, the reference centre of the health system of Castilla y León in charge of the integral socio-health care of advanced patients, providing training, assistance and research in palliative care. In addition to the Hospitalisation Unit, another important service is the Home Support Teams, specifically, the hospital has two, one for the rural area and the other for the urban area, which provide services 365 days/24 hours a day.
Challenge	<b>iMOTION</b> : Virtual assistant for voice-activated emotional state recognition in palliative care patients.

Table 3.Castilla y León ecosystem and proposed challenge





# 1.5.4. Flanders (Belgium)



Figure 7. Flanders ecosystem

Flanders has +6.5 million inhabitants and with its 5 universities is one of the innovation leaders in Europe. +3.3% GDP is spent on R&D which is significantly above the EU average. Lifesciences and heath are one of the strategic domains of the region. 12% of the regional startups are active in digital health.

	Description
Ecosystem Supporter	MEDVIA is an industry-driven public-private partnership to stimulate innovation in healthcare. Facilitates collaborations between companies, knowledge centres, universities, hospitals and other institutions.
Challenger	AZ Groeninge is a dynamic general hospital located in Kortrijk (Belgium) with more than 1000 recognized beds. AZ Groeninge is known for its advanced medical services and high-quality care. More than 2800 employees and approximately 260 hospital doctors strive every day to provide quality, safe, accessible, expert and integrated care to every patient, with respect for everyone's individuality. In order to respond to the changing needs of the patient, the broadest possible medical offering is provided based on multidisciplinary and trans-mural collaboration with other healthcare institutions and primary care.  AZ Groeninge does not shy away from innovative projects with clear added value for patient care. 'The greenhouse', an institute for clinical growth, was initiated because innovation, development, research, education and expertise are extremely important to AZ Groeninge. A cluster of specialists who aim to build bridges for new trends, innovative treatments and quality.







**MoveBuddy:** Intrinsically motivate obese children with an innovative and child-friendly digital solution that promotes long-term physical activity through gamification.

Table 4.Flanders ecosystem and proposed challenge

#### 1.5.5. North-West (Romania)



Figure 8. Northwest Romania ecosystem

North-West Romania is a dynamic hub known for its top universities and a thriving medical sector, including the highly ranked Medical University and the healthcare focused UBBMed initiative by Babes Bolyai University. The region boasts a robust pool of IT companies, both local and multinational, with numerous startups led by individuals experienced in international IT projects.

	Description
Ecosystem Supporter	Asociatia INIT & FreshBlood Healthtech supports healthcare innovation in Romania, focusing on digital health startups. They represent EIT Health, guide startups, and organize programs like Hubvantage. Their work is recognized in the National Health Digitalisation Strategy, with a focus on digital health due to historical and cost limitations in biotech.
Challenger	Medisprof Cancer Centre is an oncology hospital providing healthcare services mainly in Transylvania and also in the rest of the regions of Romania since 2003 (opening the second centre in Romanian region of Moldova this year). The clinic serves about 4000 patients yearly (70% from Cluj County) and provides diagnostic and treatment services: Imaging (CT, MRI, Mamo, Ultrasound), Bronchoscopy, Colonoscopy, Gastroscopy, Blood sampling laboratory,





	as well as oncology treatments such as radiotherapy (IMRT, SRS) and chemotherapy. It is the only clinic in Romania and one of the few in eastern Europe to have ASCOs QOPI Certification for services quality in oncology. Medisprof has developed an EMR along with a local partner and is a paper-free clinic (prints are made only for the National Insurance Home). The hospital is relying heavily on digitalization solutions for all its departments and has started partnerships with national software developers in MedTech in order to benefit from the creation of tools that can improve the quality of care and productivity.			
	creation of tools that can improve the quality of care and productivity.			
Challenge	<b>AITRIS</b> : Automated Imagery Tool Results for Diagnostic and Stadialisation			

Table 5.Northwest Romania ecosystem and proposed challenge





# 2. The Mirror Regions Call for SMEs

## 2.1. Open Call Objectives

The Mirror Regions Call for SMEs aims to select and support 5 SMEs (Solvers) to co-create a solution addressing the specific innovation needs (Challenges) identified by the Mirror Regions healthcare organisations (Challengers). The solvers will receive financial support, expertise and connections for the co-creation and piloting of solutions to untap further investments in digital health innovation where the public and private sectors from different countries can work together and deliver better and more efficient services to citizens.

The key information about the Open Call is summarised in the table below and further explained in the following sections:

Who can apply?  Open Call deadline	Small and medium-sized enterprises (SMEs).  SME must be based in a HealthChain Region.  Solution in TRL¹ minimum 6.  Other eligibility criteria may apply as described in section 4.  5 <sup>th</sup> August 2024 at 17:00 Central European Time (CET).
Activities to be funded	Solution co-creation and pilot in collaboration with the Challenger and the Ecosystem Supporter.  Participation in the business support activities to develop the solution business model and go to market strategy.
Duration of the activities	12 months
Funding available	Up to 50.000 EUR budget per selected SME
Type of funding	Grants (equity-free). as a lump sum amount where payment is based on milestones achieved. For more details, please refer to the <u>budget section</u> (3.4).
Number of SMEs to be selected	5 SMEs (1 SME per Mirror Region challenge) will be awarded through the FSTP Call.
Payments scheme	<ul> <li>Payments are associated with the results achieved by the selected applicants:         <ul> <li>lst payment after approval of interim report on co-creation, pilot deployment, and go-to-market strategy.</li> <li>2<sup>nd</sup> payment after approval of final report on co-creation, pilot deployment, and go-to-market strategy.</li> </ul> </li> </ul>
How to apply?	Fill in the proposal template. Then, go to the F6S platform to submit the application.

Table 6.The open call in a nutshell

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<sup>&</sup>lt;sup>1</sup> https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016\_2017/annexes/h2020-wp1617-annex-g-trl\_en.pdf





#### 2.2. Benefits for SMEs

Awarded SMEs will:

- Jointly co-create and pilot an innovative solution with the Mirror Region stakeholders for 12 months.
- Access funding up to 50.000 EUR equity-free.
- Get expert support on business modelling and market insights, and access to networks and resources.
- Network with other European SMEs and organisations in the HealthChain consortium and explore opportunities for forthcoming projects.

## 2.3. Who can apply?

According to the I3 instrument rules<sup>2</sup>, to be eligible, the applicants must:

- be a Small and Medium-sized Enterprise (SME).
- be established in a region already part of the HealthChain consortium.

Note: in case an SME collaborates with another organisation (e.g. other SME, research, ...) it is the sole responsibility of the SME to manage the relation. HealthChain only supports one SME per Mirror Region.

All the eligibility requirements to apply to this Open Call are further described in <u>section 4 of</u> this document.

# 2.4. Challenges to address

The applicants must address one of the 5 mirror regions challenges described in <u>section 1.5 of this document</u>. Detailed requirements per challenge are specified in **Annex 1: Mirror Regions Challenges**.

#### 2.5. Timeline

Below are presented the current tentative dates for the different phases. The dates can be subject to change in case of any modifications to the HealthChain project's schedule.

Open Call for SMEs deadline	5 <sup>th</sup> August 2024 17:00 CET
Eligibility checks	6 <sup>th</sup> to 23 <sup>rd</sup> August 2024
Appeal of Eligibility results	29 <sup>th</sup> August 17.00 CET
Eligibility appeal decision	30 <sup>th</sup> August
Evaluation of applications	2 <sup>nd</sup> September to 20 <sup>th</sup> September 2024

 $<sup>\</sup>frac{2}{https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/i3/wp-call/2021/call-fiche\_i3-2021-inv2a\_en.pdf}$ 





Communication of results	September 2024
Sub-grant Agreement <sup>3</sup> signature with selected SMEs	September 2024
Co-creation, Pilot deployment and business support	October 2024 to September 2025 (12 months)

Table 7.Mirror Regions Call for SMEs – timeline.

<sup>&</sup>lt;sup>3</sup> A contract signed between the HealthChain Coordinator (Ticbiomed), the Mirror Region Ecosystem Supporter, and the awarded SME, defining the framework of rights and obligations of the contracting parties, including but not limited to ground rules for receiving financial support and a description of the work to be carried out.





# 3. Activities to be funded

# 3.1. Co-creation and pilot deployment

#### 3.1.1. Objectives

The awarded SMEs are expected to jointly collaborate with the Mirror Region for period of 12 month to cocreate and pilot the solution that addresses the challenge, notably by:

- 1. Implementing a round of co-creation sessions bringing together healthcare organisation and SMEs personnel, for co-developing a joint solution.
- 2. Piloting the co-created solution to test its functionality and assess its effectiveness.

#### 3.1.2. **Mentors**

For each awarded SME, a contact person from the Mirror Region Ecosystem Supporter will be appointed to support the company in the liaison with the different regional stakeholders, especially the Challenger.

#### 3.1.3. Activities

Each Mirror Region and awarded SME can organise the design, prototyping and piloting activities according to their own methodology and schedule as long as they commit to the general HealthChain conditions (start and end dates are respected and total duration of the collaboration with HealthChain does not exceed 12 months).

#### 3.1.4. **Timeline**

From October 2024 to September 2025.

More information will be provided to the selected SMEs at the programme start.

# 3.2. Business development

#### 3.2.1. Objectives

SMEs will get expert support on business modelling and market insights, and access to networks and resources, to address the following objectives:

- 1. To find a sound business model for the solution.
- 2. To develop a go-to-market strategy.
- 3. To untap new investments for the sustainability of the solution.

#### 3.2.2. **Mentors**

This support is led by the Mirror Regions ecosystem supporters (Ess) and complemented by <u>Instituto Pedro Nunes</u>, expert in the promotion of innovation and the transfer of technology, with a special focus in the internationalisation, and other HealthChain partners like <u>Parsek</u>.





#### 3.2.3. Activities

To kick-off the business support activities, the SME will receive a **Rapid Business Readiness Check** to assess business support needs.

Next, the SME will be assigned a **mentor from the local ecosystem** they are developing the solution for. They should jointly develop the value proposition and business model aspects, identify Key Opinion Leaders (KOLs) to validate the business model hypotheses and create a Go2Market strategy, and investments plan for the sustainability of the solution.

In addition, up to 3 joint workshops with other HealthChain SMEs will be organized. The topics will depend on the SMEs needs and could include, among others, EU Medical Device regulation, access to private or public funding, or internationalisation.

Finally, **on demand 1:1 sessions with experts from other regions** will be considered too, if of interest for the SME.

#### 3.2.4. Timeline

The business support will run in parallel to the co-creation: from October 2024 to September 2025.

More information will be provided to the selected SMEs at the programme start.

#### 3.3. Deliverables

The selected follower SMEs are expected to submit deliverables according to the details presented in the table below.

#	Deliverable	Description	Due Date	Payment
D1.1	Co-creation Agreement and Pilot Action Plan	Report outlining the objectives, activities, timeline, and resources for testing the innovative solution before its implementation.	M2 - November 2024	Not linked to payment
D1.2	Interim report on co-creation & pilot deployment	Report describing the implementation of the activities, including co-creation sessions held, the status of the pilot deployment and results achieved at this stage. It must indicate and justify any major deviations from the original plan and lessons learnt to improve the rest of the co-creation period. In addition, the SME provides a draft business model for the commercialization of the developed solution.	M6 - March 2025	Linked to payment (50%)
D1.3	Final report on co-creation and pilot deployment	Report presenting an overview of the implementation of the activities, including co-creation sessions held, pilot deployed, and results achieved. It must include an evaluation by the Challenger team of whether the solution achieved the initial objectives.  In addition, the SME have to provide the business model, validated by KOLs, and goto-market strategy for the	M12 – September 2025	Linked to payment (50%)





commercialization solution.	of	the	developed	

Table 8. Deliverables to be submitted by the awarded SMEs.

## 3.4. Evaluation of successful completion

The Mirror Region challenger and ecosystem supporter will evaluate the SME work and progress based on the deliverables provided - that must be submitted within the deadlines.

After the submission of the interim and final deliverables, an online review meeting will take place via a teleconference platform (e.g. Zoom) in which the SME will make a presentation of the work done, analyse their progress and answer questions from the Mirror Region partners. After each online review, the SME will receive a review report, including comments and potential recommendations. The report will also state if the deliverables are accepted or not.

- On acceptance of the deliverables, the SMEs will be requested to send a financial statement (a template will be provided) to their corresponding Ecosystem Supporter requesting the voucher for the corresponding milestone. Payments will be released no later than thirty (30) natural days after the HealthChain Consortium receives the financial statement.
- On rejection of any of the deliverables, or in case of not satisfactory review, the HealthChain Consortium reserves the right to withdraw a SME from the programme and without paying the corresponding voucher.

#	Meetings	Description	Date
R1	Interim Review	Review meeting to present the results from the first 6-months of the co-creation, specially D1.1 and D1.2 will be reviewed.	April 2025
R2	Final Review	Review meeting to present the final results from the cocreation, specially D1.3 will be reviewed.	October 2025

Table 9. Review Meetings

# 3.5. Support provided and origin of funds.

## 3.5.1. Financial support

HealthChain funding is results-driven, provided as vouchers in a lump sum. As such, there is no need for a traditional administrative justification system (e.g., counting hourly dedication or calculating workload), but getting the funding is associated with the acceptance of the agreed deliverables. Payments will be made in instalments based on concrete results, deliverables and reviews.

The maximum amount of funding a selected SME can get and retain is €50.000. A summary of funding support and a tentative payment schedule is presented in the table below:





#	Deliverable	Payment trigger	Expected payment date	Amount
1	Submission of D1.2 Interim report on co- creation & pilot deployment		May 2025	25.000 €
2	Submission of D1.3 Final report on co-creation and pilot deployment	Acceptance of the submitted deliverable by the Mirror Region.	November 2025	25.000€

Table 10. Mirror Regions Call for SMEs Payment Schedule

Detailed payment schedule and payment conditions will be settled in the Sub-grant Agreement.

#### 3.5.2. Origin of funds

The awarded SMEs will sign a Sub-Grant Agreement with HealthChain, represented by the relevant Mirror Region Ecosystem Supporter, who owns the funds for their Mirror Region, and Ticbiomed as HealthChain coordinator.

The funds attached to the Sub-Grant Agreement come directly from the funds of the European Project HealthChain, funded itself by the SMEs Executive Agency (EISMEA), and remain, therefore, property of the EU until the payment of the balance, whose management rights have been transferred to the project partners in HealthChain via European Commission Grant Agreement Number 101094676. As can be seen in the Model Sub-Grant Agreement (Annex 5), this relationship between the selected applicants and the European Commission through the HealthChain project carries a set of obligations to the Subgrantees with the European Commission. It is the task of the Subgrantees to accomplish them, and of the HealthChain consortium partners to inform about them.





# 4. Eligibility criteria

All applicants must comply with the requirements described in this section, and subsections, to be considered eligible for the Mirror Regions Open Call for SMEs.

#### 4.1. Beneficiaries

#### 4.1.1. **SME** status

The applicants that choose to address one of the 5 challenges proposed by HealthChain Mirror Regions must be Small and Medium-sized Enterprises (SMEs).

#### Smal and Medium-Sized Enterprises (SMEs) definition

An SME will be considered as such if it complies with the European Commission Recommendation 2003/361/EC21 and the SME user guide. As a summary, SMEs are enterprises which:

- a) employ fewer than 250 persons; and
- b) have either an annual turnover not exceeding EUR 50 million or an annual total balance sheet not exceeding EUR 43 million.

Start-ups that do not have an annual turnover or balance sheets yet, are also considered eligible given that they fulfil the criteria (a) and (b) of section 4.1.1 at submission time.

In case an SME is awarded, it will remain eligible even if, at a certain point during the execution of HealthChain activities, it does not fulfil criteria (a) or (b) of section 4.1.1.

## 4.1.2. Geography

According to I3 Instrument rules<sup>4</sup>, the SMEs must be legally established within regions that are already represented in the HealthChain consortium. The list of eligible regions, according to NUTS code<sup>5</sup>, is the following:

- a) ES62 Murcia Region (Spain)
- b) ES51 Catalonia (Spain)
- c) PT16 Centro (Portugal)
- d) PT11 North (Portugal)
- e) Any region in Slovenia
- f) Any region in Croatia
- g) NL2 East Netherlands
- h) NL3 West Netherlands
- i) EL63 Western Greece
- j) ES22 Navarra (Spain)
- k) ES41 Castilla y León (Spain)
- I) BE2 Flanders (Belgium)

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<sup>4</sup> https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/i3/wp-call/2021/call-fiche\_i3-2021-inv2a\_en.pdf

<sup>&</sup>lt;sup>5</sup> https://ec.europa.eu/eurostat/web/nuts





m) RO11 - Northwest Romania.

SMEs based in regions different to the ones mentioned above are not eligible to apply.

#### 4.1.3. Additional conditions

In addition, the following conditions apply:

- The applicants should not:
  - o have convictions for fraudulent behaviour, other financial irregularities, unethical or illegal business practices.
  - o have been declared bankrupt or have initiated bankruptcy procedures.
  - o be under liquidation or an enterprise under difficulty accordingly to the Commission Regulation No 651/2014, art. 2.18.
  - o be excluded from the possibility of obtaining EU funding under the provisions of both national and EU law, or by a decision of both national and EU authority.
  - Proposals from Linked SMEs<sup>6</sup> must demonstrate that there is no risk of double funding. The fundamental principle underpinning the rules for public expenditure in the EU states that no costs for the same activity can be funded twice from the EU budget, as defined in the Article 111 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation. In the case of proposals submitted by linked SMEs, all must clearly state the differences between them including but not limited to, technical aspects, market strategy and team composition, so that it remains no doubt that there is no risk of double funding. In order to properly assess these concerns HealthChain may assign all proposals to the same set of evaluators and, should any doubt remain, exclude all proposals.

## 4.2. Language

English is the official language for the Mirror Regions Call for SMEs. Proposals submitted in any other language will not be evaluated.

English is also the official language to be used to communicate with the HealthChain consortium during the whole execution of the HealthChain programme, for example in meetings, deliverables listed in <u>section 3.3</u>, and other administrative documents.

Other languages can be used between the Mirror Regions and SMEs for the co-creation according to the language requirements defined by the Mirror Region in the challenge.

# 4.3. Multiple submission

Only one proposal will be accepted for funding per applicant. In the case of a multiple submission, only the last one received (timestamp of the system) will enter into the evaluation process, the rest being declared as non-eligible. If the last submitted proposal is declared non-eligible or fails to reach the thresholds of the evaluation, the other proposals submitted earlier will not be considered for evaluation in any case.

<sup>&</sup>lt;sup>6</sup> Please check the definition of Linked SME on the "User guide to the SME definition" available at <a href="https://op.europa.eu/s/n3t]">https://op.europa.eu/s/n3t]</a>





#### 4.4. Documentation format

Any document requested in any of the phases must be submitted electronically in PDF format without restrictions for printing.

## 4.5. Submission system

Only proposals submitted through the Open Call submission tool (F6S platform) and within the Call duration will be accepted. Proposals submitted by any other means will not be evaluated. Only the documentation included in the application will be considered by evaluators. It will be composed of a form with administrative questions to be completed directly on the platform, and the Annex 2: Proposal template. The information provided should be actual, true, and complete and should allow the assessment of the proposal. The regular functioning of the F6S platform limits one application submission per F6S user in each call.

#### 4.6. Deadline

Only proposals submitted before the deadline will be accepted. After the call closure no additions or changes to received proposals will be taken into account. The deadline for this call is 5th August 2024, at 17:00 CET (Brussels time).

#### 4.7. Absence of conflict

Applicants shall not have any actual or/and potential conflict of interest with the HealthChain selection process and during the whole project. All cases of conflict of interest will be assessed case by case. In particular, applicants cannot be HealthChain Consortium partners or affiliated entities nor their employees or co-operators under a contractual agreement.





# 5. Evaluation criteria

The criteria for proposal evaluation will be the following:

CRITERIA	DESCRIPTION	WEIGHTING
Relevance	<ol> <li>Clarity and consistency of the proposal objectives, in compliance with the open call.</li> <li>The extent to which the solution is aligned with the targeted challenge, notably with the tasks to be performed by the follower SME.</li> <li>Relevance and effectiveness of the proposed innovation in terms of novelty and ambition.</li> </ol>	40%
Quality	<ol> <li>Sound methodology for implementing the project.</li> <li>Feasibility of the project within the proposed time frame</li> <li>Experience of team members in the challenger's sector.</li> </ol>	20%
Cost effectiveness	<ol> <li>Sufficient/appropriate budget for proper implementation.</li> <li>The budget is developed following a best value for money approach.</li> </ol>	20%
Impact	<ol> <li>Extent to which the proposal demonstrates that the SME is committed to exploit the solution beyond the project,</li> <li>Ambition and expected long-term impact of interregional cooperation.</li> </ol>	20%

Table 11. Evaluation Criteria

HealthChain will score each award criterion on a scale from 0 to 5 (decimal and centesimal point scores may be given):

- 0 = Proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.
- 1 = Poor: criterion is inadequately addressed or there are serious inherent weaknesses.
- 2 = Fair: proposal broadly addresses the criterion, but there are significant weaknesses.
- 3 = Good: proposal addresses the criterion well, but a number of shortcomings are present.
- 4 = Very good: proposal addresses the criterion very well, but a small number of shortcomings are present.
- 5 = Excellent: proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.





For each criterion, the minimum threshold is 3 out of 5 points. The overall default threshold, considering the sum of the individual scores is 12. That means if a proposal receives less than 3 in one criterion or less than 12 in the overall score it is automatically rejected.





# 6. Application submission

## 6.1. Application preparation and submission

The Mirror Regions Call for SMEs has been launched through the HealthChain project website comprising the 5 regional sub-calls to ease the open call management process.

To submit an application, applicants should follow these steps:

- Go to <a href="https://healthchain-i3.eu/mirror-regions-call-smes/">https://healthchain-i3.eu/mirror-regions-call-smes/</a> and carefully read the open call documents composed by the **Guidelines for Applicants** (this document) and its annexes:
  - a. Annex 1: Mirror Regions Challenges
  - b. Annex 2: Proposal template

If selected, you will also be requested to send the following documents:

- c. Annex 3: Declaration of honour
- d. Annex 4: Bank account information
- e. Annex 5: Sub-Grant agreement template
- f. Annex 6: SME declaration
- 2. Go to <a href="https://www.f6s.com/healthchain-mirror-regions-call-for-smes/apply">https://www.f6s.com/healthchain-mirror-regions-call-for-smes/apply</a> to fill in the application form through the F6S platform (applicants are required to register a profile at F6S to be able to submit an application) and answer all mandatory questions.

Applicants are encouraged to be concrete and concise. Each proposal shall not exceed the page limits indicated in the Proposal Template.

It is strongly recommended not to wait until the last minute to submit the application. Failure of the application to arrive in time for any reason, including network communications delays or working from multiple browsers or multiple browser windows, is not acceptable as an extenuating circumstance. The time of receipt of the application as recorded by the submission system will be definitive.

# **6.2.** Application reception

Submissions will ONLY be done via the F6S platform: <a href="https://www.f6s.com/healthchain-mirror-regions-call-for-smes/apply">https://www.f6s.com/healthchain-mirror-regions-call-for-smes/apply</a>

A full list of applicants will be drafted containing their basic information for statistical purposes and clarity, which will be also shared with the European Commission for transparency.

# 6.3. Data protection

#### 6.3.1. **F6S platform**

The F6S platform's system design and operational procedures ensure that data is managed in compliance with the General Data Protection Regulation (EU) 2016/679 (GDPR). Each applicant will accept the F6S terms to ensure compliance. Please refer to <a href="https://www.f6s.com/privacy-policy">https://www.f6s.com/privacy-policy</a> to review the F6S platform's privacy policy and data security policy.

Please note that the HealthChain consortium must retain generated data until five years after the balance of the HealthChain project is paid or longer if there are ongoing procedures (such as audits, investigations or litigation). In this case, the data must be kept until the end.





#### 6.3.2. HealthChain

In order to process and evaluate applications, the HealthChain consortium will need to collect Personal and Industrial Data. Ticbiomed, as project coordinator, will act as Data Controller for data submitted through the F6S platform for these purposes. Apart from the F6S platform, data will also be stored in the Ticbiomed One Drive.

A Data Protection Officer (DPO) has been appointed by Ticbiomed generally, to ensure compliance with data protection regulations, such as the General Data Protection Regulation (GDPR), and that personal data is collected, processed, and stored in a secure manner. For more information, please refer to HealthChain privacy policy <a href="https://healthchain-i3.eu/privacy-policy/">https://healthchain-i3.eu/privacy-policy/</a>

Please note that HealthChain requests the minimum information needed to deliver the evaluation procedures or the support programme. The annexes Declaration of Honour, Bank Account Information and Sub-Grant Agreement are provided for reference and will only be requested if the applicant is accepted in the HealthChain support programme.





# 7. Evaluation process

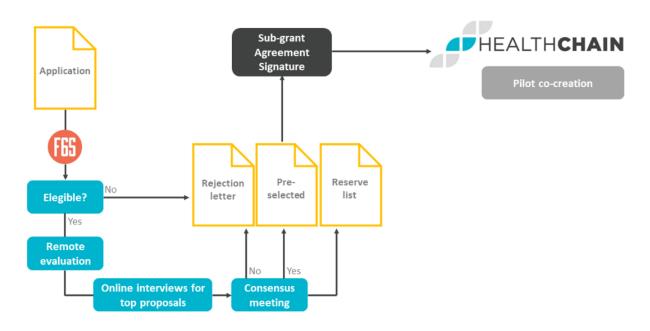


Figure 9. HealthChain evaluation process

# 7.1. Eligibility check

A combination of automated filtering and manual review processes will be utilised to sift through applications, ensuring adherence to the eligibility criteria outlined in Section 4 of this document. Applicants should be mindful that, given the semi-automated evaluation tools in use, all provided information will undergo thorough verification. It is the applicant's responsibility to ensure the accuracy of all fields within the online form. Any inclusion of erroneous information may result in the rejection of the proposal on the grounds of ineligibility. In cases where a proposal is deemed ineligible through manual verification, applicants will be promptly notified of its status and provided with at least a 48-hour window to submit a rebuttal.

#### 7.2. Remote evaluation

After the eligibility filter, the final proposals shortlist for evaluation will be created.

Then, the proposals will be given to the relevant Mirror Region which count on technical expertise for the proposed solutions, bound by a confidentiality agreement and non-conflict of interest declaration. Every proposal will be evaluated according to the evaluation criteria described in section 5, by an Evaluation Committee established between the Challenger and the Ecosystem Supporter. At the end of this phase, the proposals will be ranked.





#### 7.3. Online interviews

The top 2 applications related to each challenge proposed by the Mirror Region will be invited for the online interview stage.

During the online interview the applicants will start by doing a pitch of their pilot project concept, followed by Q&As. This will be an opportunity for evaluators to ask questions that they may have about the written application, as well as about the commitment and engagement of applicants towards participating in HealthChain.

#### 7.4. Consensus and final scores

After the online interviews, the evaluators will have the opportunity to share, compare and revise, if necessary, their scores aiming to have a consensus about the ranking of proposals.

# 7.5. Final ranking and selection

#### 7.5.1. Final ranking

At the end of the evaluation process, the proposals will be ranked taking into account the revised scores from the online interviews and consensus process. The criteria for the ranking of the proposals will be semi-automatic following the rules below:

- Rule 1: The proposals will be ranked based on their overall score.
- Rule 2: In case following Rule 1 there are proposals in the same position, priority will be given to proposals that have a higher score on the Relevance award criterion.
- Rule 3: In case following Rule 2 there are proposals in the same position, priority will be given to proposals that have a higher score on the Impact award criterion.
- Rule 4: In case following Rule 3 there are proposals in the same position, priority will be given to the proposal with a higher gender balance.

#### 7.5.2. Selection

The top-ranked proposal for each Mirror Region challenge proposed will be selected for funding.

#### 7.6. Communication of results

Every applicant will receive via e-mail:

- An Evaluation Summary Report (ESR)
- A letter informing of a rejection decision or invitation to enter the negotiation phase.

# 7.7. Changes in the Open Call

HealthChain may conclude that there are not enough proposals with adequate quality (indicated by their evaluation scores meeting or exceeding specific predefined thresholds), in which case it will make no selection or select fewer proposals than the funding budget allows. This conclusion is obligatory if not enough proposals score above the threshold given on the bespoke evaluation form.





HealthChain reserves the right to cancel the Open Call at any point due to any unforeseen circumstances beyond control.

## 7.8. Appeal procedure

If, the applicant considers that a mistake has been made or that the evaluators have acted unfairly or have failed to comply with the rules of this Call for SMEs, and that their interests have been prejudiced as a result, the following appeal procedure is available.

A complaint should be drawn up in English and submitted by email to <a href="hello@healthchain-i3.eu">hello@healthchain-i3.eu</a>.

Any complaint made should include the following:

- contact details,
- the relevant open call [in this case: Mirror Regions Call for SMEs]
- the subject of the complaint,
- information and evidence regarding the alleged breach.

Anonymous complaints or those not providing the mentioned information will not be considered.

Complaints should also be made within **five calendar days** since the evaluation results are presented to the applicants.

As a general rule, the HealthChain Consortium will investigate the complaints with a view to arriving at a decision to issue a formal notice or to close the case within no more than twenty days from the date of reception of the complaint, provided that all required information has been submitted by the complainant. When this time limit is exceeded, the HealthChain Consortium will inform the complainant by email.

#### Please note:

- This procedure only concerns the evaluation process. The HealthChain Consortium will
  not call into question the scientific or technical judgement of appropriately qualified
  experts.
- A re-evaluation will only be carried out if there is evidence of a shortcoming that affects the final decision on whether to fund an applicant or not. This means, for example, that a problem relating to one evaluation criterion will not lead to a re-evaluation if a proposal has failed anyway on other criteria.
- The evaluation score following any re-evaluation will be regarded as definitive. It may be lower than the original score.





# 8. Negotiation

## 8.1. Contract preparation

After the Open Call evaluation conclusion and application selection, each Mirror Region, led by the Ecosystem Supporter, will start the contract preparation (Sub-Grant Agreement) with their awarded SME, in collaboration with the HealthChain coordinator. Contract preparation will go via administrative and financial checking (and potentially into technical or ethical/security negotiations) based on evaluators' comments. On a case-by-case approach, a phone call or teleconference may be needed for clarification.

The objective of the contract preparation is to fulfil the legal requirements between the HealthChain Consortium and every beneficiary of the open call. The items covered will be:

- Inclusion of the comments (if any) in the Evaluation Summary Report of the proposals and mapping to the Sub-Grant Agreement (contract).
- To validate the status information of the SMEs according to the definition included in section 4 'Eligibility Criteria' of this document. The following documents will be required.
  - Legal existence: Organisation Register, Official Gazette or another official document per country showing the name of the organisation, the legal address and registration number and a copy of a document proving VAT registration (in case the VAT number does not show on the registration extract or its equivalent).
  - Declaration of honour: Document that ensures that the sub-grantee complies with the rules and is not in a situation that would exclude it from receiving EU funding.
  - Bank account information: The account where the funds will be transferred will be indicated via a form signed by the sub-grantee representative and the bank representative. The account should be a business bank account of the SME.
  - o **SME declaration:** A self-assessment document confirming that the IT companies complies with the SME definition.

The request, by the relevant HealthChain Mirror Region, for the above documentation will be done within the deadlines. In general, the negotiation should be concluded **within 15 days**. An additional week may be provided by the Mirror Region, in case of significant reasoning. In case negotiations have not been concluded within the above period, the proposal can be rejected and the next proposal in the ranking list can be invited.

# **8.2.** Contract signature

At the end of the negotiation phase, a Sub-Grant Agreement (Contract) will be signed between the HealthChain Mirror Region, represented by its Ecosystem Supporter<sup>7</sup>, the HealthChain coordinator (Ticbiomed) and each selected SME.

Please note:

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<sup>&</sup>lt;sup>7</sup> As described in section 1.5 the ecosystem supporters are: Navarrabiomed (Navarra), Systserv (Western Greece), INTRAS (Castilla y León), MEDVIA (Flanders) and Asociatia INIT & FreshBlood Healthtech (Northwest Romania).





- The Sub-Grant Agreement/contract will cover the whole pilot co-creation process (12 months).
- The Sub-Grant Agreement will automatically expire at the end of September 2025. Note that some obligations will remain after the contract expiration (e.g. record keeping for 5 years). Check <u>Section 9 Responsibilities of beneficiaries</u> for more information.





# 9. Responsibilities of beneficiaries

The selected applicants are indirect beneficiaries of European Commission funding. As such, they are responsible for the proper use of the funding and ensure that the recipients comply with obligations under the I3 Instrument. The obligations that are applicable to the recipients include the following.

#### 9.1. Conflict of interest

The selected applicants must take all measures to prevent any situation where the impartial and objective implementation of the HealthChain activities is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('conflict of interests').

They must formally notify the HealthChain coordinator and, if possible, the Mirror Region without delay of any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The HealthChain coordinator may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

If the selected applicant breaches any of its obligations, the Sub-Grant Agreement may be automatically terminated. Moreover, payments may be stopped.

## 9.2. Data protection and confidentiality

During the implementation of the HealthChain activities and for five years after the end of the activities, the parties must keep confidential any data, documents, or other material (in any form) that is identified as confidential at Sub-Grant Agreement signing time ('confidential information').

If a selected applicant requests, the Commission and the HealthChain Consortium may agree to keep such information confidential for an additional period beyond the initial five years. This will be explicitly stated in the Sub-Grant agreement.

If the information has been identified as confidential during the HealthChain programme or only orally, it will be considered confidential only if this is accepted by the HealthChain coordinator and confirmed in writing within 15 days of the oral disclosure. Unless otherwise agreed between the parties, they may use confidential information only to implement the Sub-Grant Agreement.

The selected applicants may disclose confidential information to the HealthChain consortium and to the Mirror Region evaluators, who will be bound by a specific Non-Disclosure Agreement.

# 9.3. Promoting the action and giving visibility to the EU funding

The selected SMEs must promote the HealthChain programme and its results, by providing targeted information to multiple audiences in a strategic and effective manner and highlighting the financial support of the European Union.





Unless the European Commission or the HealthChain coordinator requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.), any publicity, including at a conference or seminar or any type of information or promotional material (brochure, leaflet, poster, presentation etc.), and any infrastructure, equipment and major results funded by the grant must:

- (a) display the EU emblem.
- (b) display the HealthChain logo and
- (c) include the following text:

"This project has received funding from the Interregional Innovation Investments (I3) Instrument under the Grant Agreement 101094676".

When displayed in association with a logo, the European emblem should be given appropriate prominence. This obligation to use the European emblem in respect of projects to which the EC contributes implies no right of exclusive use. It is subject to general third-party use restrictions which do not permit the appropriation of the emblem, or of any similar trademark or logo, whether by registration or by any other means. Under these conditions, the subgrantee is exempt from the obligation to obtain prior permission from the EC to use the emblem. Further detailed information on the EU emblem can be found on the European Commission web page<sup>8</sup>

Any publicity made by selected SMEs in respect of the HealthChain programme, in whatever form and on or by whatever medium, must specify that it reflects only the author's views and that the EC or HealthChain project is not liable for any use that may be made of the information contained therein.

The EC and the HealthChain Consortium shall be authorised to publish, in whatever form and on or by whatever medium, the following information:

- the name of the selected SMEs;
- contact address of the selected SMEs;
- the general purpose of the SMEs' participation in the HealthChain programme;
- the amount of the financial contribution foreseen for the SMEs; after the final payment, and the amount of the financial contribution actually received;
- the geographic location of the activities carried out;
- the list of dissemination activities and/or of the patent (applications) relating to the foreground;
- the details/references and the abstracts of scientific publications relating to the foreground and, if funded within the HealthChain project, the published version or the final manuscript accepted for publication;
- the publishable reports submitted to HealthChain;
- any picture or any audio-visual or web material provided to the EC and HealthChain in the framework of the project.

The selected applicants shall ensure that all necessary authorisations for such publication have been obtained and that the publication of the information by the EC and HealthChain does not infringe any rights of third parties.

Upon a duly substantiated request by a selected SME, the HealthChain Consortium, if such permission is provided by the EC, may agree to forego such publicity if disclosure of the

https://ec.europa.eu/info/funding-tenders/managing-your-project/communicating-and-raising-euvisibility\_en





information indicated above would risk compromising the beneficiary's security, academic or commercial interests.

Upon a duly substantiated request by a selected SME, the HealthChain Consortium, if such permission is provided by the EC, may agree to forego such publicity if disclosure of the information indicated above would risk compromising the beneficiary's security, academic or commercial interests.

#### 9.4. Financial audits and controls

The European Commission (EC) will monitor that the HealthChain consortium partners and the selected SMEs comply with the conditions for financial support to third parties such as set out in the HealthChain grant agreement and may take any action foreseen by the grant agreement in case of noncompliance vis à vis the selected SMEs concerned.

Moreover, the EC may at any time during the implementation of the HealthChain project and up to 5 (five) years after the end of the HealthChain project, arrange for financial audits to be carried out, by external auditors, or by the EC services themselves including the European Anti-Fraud office (OLAF). The audit procedure shall be deemed to be initiated on the date of receipt of the relevant letter sent by the EC. Such audits may cover financial, systemic and other aspects (such as accounting and management principles) relating to the proper execution of the grant agreement. They shall be carried out on a confidential basis.

The selected applicants shall make available directly to the EC all detailed information and data that may be requested by the EC or any representative authorised by it, with a view to verifying that the grant agreement is properly managed and performed in accordance with its provisions and that costs have been charged in compliance with it. This information and data must be precise, complete and effective.

The selected applicants shall keep all deliverables and the originals or, in exceptional cases, duly authenticated copies – including electronic copies – of all documents relating to the Sub-Grant Agreement for up to five years from the end of the project. These shall be made available to the EC when requested during any audit under the grant agreement.

In order to carry out these audits, the selected SMEs shall ensure that the EC´s services and any external body(ies) authorised by it have on-the-spot access at all reasonable times, notably to the selected SMEs' offices, to their computer data, to their accounting data and to all the information needed to carry out those audits, including information on individual salaries of persons involved in the project. They shall ensure that the information is readily available on the spot at the moment of the audit and, if so requested, that data be handed over in an appropriate form.

On the basis of the findings made during the financial audit, a provisional report shall be drawn up. It shall be sent by the EC or its authorised representative to the HealthChain Consortium or SME concerned, which may make observations thereon within one month of receiving it. The Commission may decide not to take into account observations conveyed or documents sent after that deadline.

The final report shall be sent to the HealthChain Consortium or SME concerned within two months of expiry of the aforesaid deadline. On the basis of the conclusions of the audit, the EC shall take all appropriate measures that it considers necessary, including the issuing of recovery orders regarding all or part of the payments made by it and the application of any applicable sanction.

The European Court of Auditors shall have the same rights as the EC, notably the right of access, for the purpose of checks and audits, without prejudice to its own rules.





In addition, the EC may carry out on-the-spot checks and inspections in accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities.

# 9.5. Intellectual Property Rights (IPR)

#### 9.5.1. Mirror Regions and Awarded SMEs

The ownership of results is regulated by contract: 1) the sub-grant agreement and 2) the cocreation agreement and pilot action plan. The general rules are that each party retains ownership of the Intellectual Property Rights attached to their background (what they bring to the project), and, regarding the foreground (what is generated during the project), the results are owned by the party that generates them. For joint results, the terms of Intellectual Property Rights must be mutually agreed. In addition to the sub-grant agreement, a Cocreation Agreement and Pilot Action Plan will be signed upon by the SME, and the Mirror Region partners (Ecosystem Supporter and Challenger) during the co-creation process, detailing the scope of work, expected results and ownership of those results, and will be annexed to the subgrant agreement.

As a general rule, the Mirror Regions, especially the Challengers (healthcare organisations), are not interested in the Intellectual Property Rights to commercialise the solution, but to explore potential benefits arising from their involvement in the co-creation process. For instance, in the event of a successful pilot, if the Healthcare Organisation decides to continue utilizing the solution beyond the HealthChain project, to benefit from a preferential pricing. This acknowledgment stems from the clinical insights contributed by the Challenger to enhance the solution. This will be discussed case by case. Check each challenge description for the specific conditions per region.

## 9.5.2. Originality of the proposals

It is required that proposals submitted are based on the original situations of the applicants and that their foreseen developments (pilot co-creation) are free from third-party rights. HealthChain consortium is not obliged to verify the authenticity of the ownership of the foreseen products/ services. Any issues delivered from third-party claims that arise as a result of the sub-granted projects/pilots are the sole responsibility of the sub-grantees.

#### 9.5.3. Evaluators

Each evaluator will sign a non-disclosure agreement (NDA) before receiving access to the database of proposals in order to protect the intellectual property of the applicants. However, HealthChain and the European Commission may ask participants who have received funding to present their work as part of public relations and networking events in order to showcase the benefits of the HealthChain project.

#### 9.5.4. Liability

The HealthChain consortium and the European Commission cannot be held liable for any acts or omissions of the applicant in relation to the selected sub-granted project/pilot implemented by the subgrantees. The HealthChain consortium shall not be liable for any defaults of any products, processes or services created in the sub-granted project/pilot. Including, for instance, anomalies in the functioning or performance thereof. In case any damage is caused to a third





party by the subgrantee, the subgrantee will assume full responsibility for the damage caused. In no way will the HealthChain Consortium be responsible for any damages caused by the subgrantee.

# 10. Self-assessment before submission

- 1) Does your application fit with the open call? Check that your proposal does indeed address the objectives of Mirror Regions Open Call for SMEs, as there may be other HealthChain calls open at the same time.
- 2) Is your application eligible? The eligibility criteria are given in chapter 4 "Eligibility Criteria".
- **3) Budgetary limits.** Check that you comply with any budgetary limits as expressed in chapter 3.4 "Financial support provided and origin of the funds".
- 4) Is your application complete? Have you completed all mandatory questions?
- **5) Does your application fulfil the requested information?** Proposals should be precise, and concise and must answer to requested information, which is designed to correspond to the applied evaluation. Omitting requested information will almost certainly lead to lower scores and possible rejection.
- **6) Have you maximised your chances?** There will be strong competition. Therefore, edit your application tightly, and strengthen or eliminate weak points.
- 7) Have you submitted your application before the deadline? It is strongly recommended not to wait until the last minute to submit your proposal. Failure of the proposal to arrive in time for any reason, including network communications delays, is not acceptable as an extenuating circumstance. The time of receipt of the message as recorded by the submission system will be definitive.
- **8) Have you provided the necessary annexes?** Annex 2: Proposal template.
- **9) Do you need further advice and support?** You are strongly advised to communicate with the HealthChain consortium via online Q&A.

# 11. Other Open Call documents

The HealthChain Call for SMEs will be supported by two types of documents.

#### Documents needed at the application stage (for all applicants)

- Guidelines for Applicants, this document.
- **Annex 1: Mirror Regions Challenges**. Read the challenges to understand the technical requirements to be addressed by the SMEs.
- Annex 2: Proposal template, to apply for one of the 5 challenges proposed by HealthChain Mirror Regions. This document must be completed and uploaded to the F6S platform in PDF format.

#### Documents needed at the contracting stage (only for selected applicants)

- **Annex 3: Declaration of Honour**, which declares that all conditions related to the Mirror Regions Call for SMEs are accepted by the applicants' legal representatives.
- **Annex 4: Bank Account Information**, which collects information on the applicants' bank account to where the HealthChain payments will be sent.





- **Annex 5: Model Sub-Grant Agreement,** which provides a template of the Sub-Grant agreement that the successful applicants will be requested to sign.
- **Annex 6: SME declaration:** A self-assessment document confirming that the companies comply with the SME definition.

# 12. Additional information

All the information is available at <a href="https://healthchain-i3.eu/mirror-regions-call-smes/">https://healthchain-i3.eu/mirror-regions-call-smes/</a>

Informative webinars will be planned for the potential applicants during the Open Call. The events will be posted on the HealthChain website and invitations will be extended through the HealthChain newsletter (subscribe here).

HealthChain will provide information to the applicants via the <u>F6S blog</u>, so that the information (questions and answers) can be visible to all participants. Please, make your questions directly in F6S page. HealthChain partners will get back to you as soon as possible via that same page.

- Online Q&A: <a href="https://www.f6s.com/healthchain-mirror-regions-call-for-smes/discuss">https://www.f6s.com/healthchain-mirror-regions-call-for-smes/discuss</a>
- Apply via: <a href="https://www.f6s.com/healthchain-mirror-regions-call-for-smes/apply">https://www.f6s.com/healthchain-mirror-regions-call-for-smes/apply</a>
- For IT support on the F6S platform, contact F6S support team: <a href="mailto:support@f6s.com">support@f6s.com</a>
- More info at: <a href="https://healthchain-i3.eu/mirror-regions-call-smes/">https://healthchain-i3.eu/mirror-regions-call-smes/</a>
- For extraordinary communication needs, please contact the HealthChain Help Desk: hello@healthchain-i3.eu