



STAKEHOLDER POLITICAL ALLIANCE FOR
RADIOLIGAND CANCER THERAPIES



Investment Pathway

**GUIDE FOR THE DELIVERY OF
RADIOLIGAND CANCER THERAPIES**

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ABOUT SPARC-EUROPE

SPARC-Europe (Stakeholder Political Alliance for Radioligand Cancer Therapies) is a European political initiative aiming to build a comprehensive policy framework for radioligand therapies. The group's mission is to provide expert knowledge and the necessary guidance for policymakers in the creation of a clear pathway to institutionalise radioligand therapies and other forms of radiotheranostics and increase their accessibility for patients. The Alliance aims to engage with European policymakers to overcome existing barriers when accessing radioligand therapies.

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ABOUT THE INVESTMENT PATHWAY GUIDE

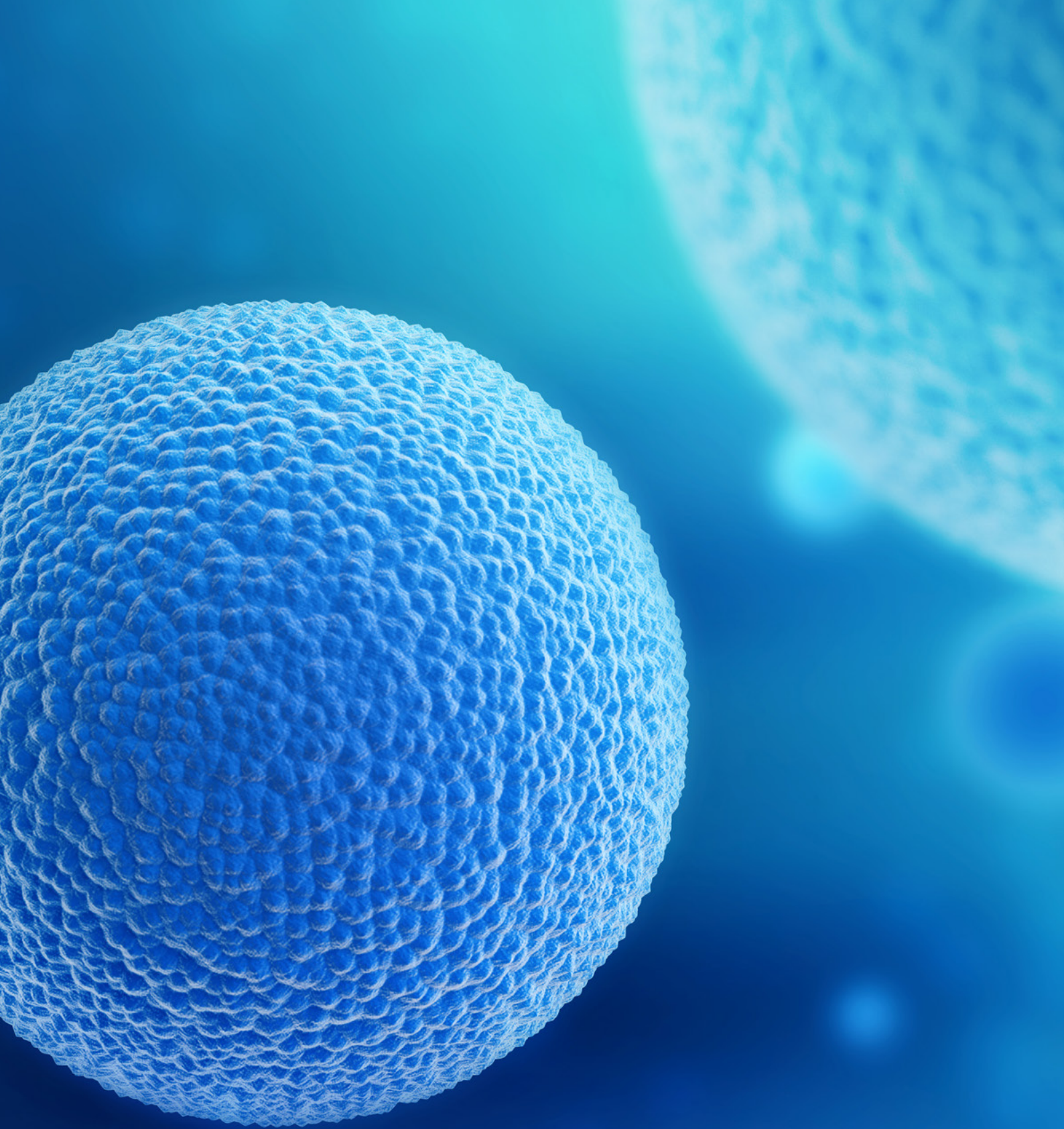
This guide was drafted by Yordan Aleksandrov, Kinga Wójtowicz, and Emily Phillips, RPP, acting as Policy Secretariat to SPARC-Europe. The Steering Committee had full editorial control over the content of the guide.

The Committee members act voluntarily as experts in their respective fields of nuclear medicine, oncology and molecular imaging. This guide aims to lay down the needs for adequate delivery of radioligand cancer therapies and match those needs with available funding mechanisms at the EU level. We aim to draw policymakers' attention to the 1) identified areas of opportunity to improve the delivery of RLTs and 2) EU funding instruments that can be potentially deployed/utilised in these areas.

The **delivery of radioligand therapies is linked to wider challenges of the capacity of healthcare systems**, including the education of healthcare professionals and patients and the need for enhanced cross-border collaboration on cancer treatment.¹

This guide focuses specifically on **healthcare infrastructure effectively accommodating and delivering radioligand therapies**.

¹ High-Level Position Paper on Improving Access to Radioligand Cancer Therapies; SPARC-Europe, 2021.



WHAT ARE RADIOLIGAND CANCER THERAPIES?

Radioligand therapy (RLT) has gained recognition for being an innovative approach in the field of nuclear medicine, delivering radiation directly to specific cells and significantly improving patients' quality of life (QoL). Currently established for neuroendocrine neoplasms (NENs) and metastatic-resistant prostate cancer (mCRPC), this treatment looks promising in other cancer and non-cancer conditions as well.

Centres that include a nuclear medicine department can perform RLT. Patients could receive the treatment in any centre, on the condition that they offer a nuclear medicine department with appropriate infrastructure.

THE ROLE OF HEALTHCARE INFRASTRUCTURE IN DELIVERING RLTs

Due to the nature of RLTs, specific healthcare settings are fundamental for their adequate delivery. Hospital centres that have the intentions to provide these therapies need proper infrastructure.

1. The nuclear medicine departments should include:
 - a. A radiopharmacy capable to prepare, handle and dispense the individual doses of radioligands for therapy.
 - b. Shielded rooms, as a means to protect healthcare personnel, but also civilians from the radiation emitted; shielding should be appropriate to the type of energy of the emitted radiation.
 - c. Adequate storage and nuclear waste systems outside of the work area, while waiting for radioactivity to decayⁱ. The time of storage depends on the half-life of the radioisotopes, which represents the time when the radionuclide content decays to half, measured in hours or days, as well as on the amount of waste generated, which is estimated to be between 0.5 and 2 kg per bed per dayⁱⁱ. The storage facilities should follow the WHO recommendations to ensure storage time to be ten times the half-life.²
 - d. Waiting areas divided in before/after treatment.
 - e. Rooms designed for patients with separate bathrooms, washing facilities and separate excretion collection, as well as waiting areas divided in before/after treatment.
2. Available imaging equipment
 - a. PET/CT and SPECT/-CT scanners necessary for appropriate patient selection, therapy planning and follow-up: despite being well-prepared for the delivery of RLTs, some departments do not hold PET-CT and/or SPECT-CT scanners. In addition, the lifespan of such machines is typically limited to eight years, leading to regular check-ups and potentially making healthcare personnel deal with outdated equipment. Whereas the infrastructure to deliver the treatment does not require substantial funding, the imaging system might create budget-related problems, with hospitals incapable to renew the equipment.ⁱⁱⁱ
3. Available protective equipment for healthcare personnel, which is paramount to ensure safe delivery of the treatment:^{iv} for example, a protective apron, protective eyewear and gloves.

EU DISCREPANCIES

Because of healthcare systems being managed at national and/or regional levels, there are significant discrepancies in terms of centres equipped to deliver RLTs. In the EU, only a few countries have a high volume of experience in RLTs – the Netherlands, Austria, Germany.^v

For the proper delivery of RLTs, healthcare infrastructure needs to be built/renewed and maintained.

In the EU, centres are also facing issues with ageing equipment and the lack of physical space to accommodate patients. According to the 2021 edition of the COCIR Medical Imaging Equipment Age Profile and Density, the percentage of medical imaging equipment in Europe that is more than ten years old is considerably high, creating broad disparities in equipment density between European countries. These range from 21-22% for CT, MRI and PET scanners to 34% for interventional x-ray equipment.^{vi} For instance, Spain ranks second in the EU for general obsolescence of installed PET equipment.^{vii}

The increase of hospital readiness for the delivery of these therapies is therefore fundamental for scaling-up their full treatment potential.



2 An example can be Lutetium-177 that has a half-life of 6.65 days and must be stored for 66.5 days



THE ROLE OF EU HEALTH LEGISLATION

EU health legislation has an immediate impact on citizens and, as such, needs to keep up with innovation and research developments. **Europe's Beating Cancer Plan offers significant opportunities for EU institutions to support Member States in assessing the readiness of hospital centres to deliver RLTs.**

1. SUPPORTING THE DEVELOPMENT OF COMPREHENSIVE CANCER CENTRES



In the context of the European Commission's Beating Cancer Plan, Member States should develop an **EU network of Comprehensive Cancer Centres (CCCs)** by 2025, facilitating the **uptake of quality-assured diagnosis and treatment**, as well as reinforce training, research and clinical trials in the EU.^{viii}

This action will be crucial to delivering higher-quality care and reducing inequalities across the EU, while enabling patients to benefit from diagnosis and treatment close to home.

The Cancer Plan aims to ensure that 90% of eligible patients obtain access to such centres by 2030.

There is a timely call for the European Commission and Member States to ensure that nuclear medicine departments are able to deliver RLTs within CCCs.

When setting up CCCs, **the Commission and national authorities should then take into consideration the need to include a functioning nuclear medicine department**, which would be equipped with sufficient protective equipment, as well as ensure the existence of state-of-the-art imaging technology available.

The support for the development of CCCs is crucial, as capable to perform the treatment in the most optimal environment and conditions, while also offering the imaging technology for the follow-up.^{ix}

CCCs should adopt favourable conditions when developing a follow-up care plan for RLTs. **Cancer care patients/survivors should be able to decide who would be responsible for their follow-up:** a clinician who was responsible for the treatment in a CCC, another healthcare provider who specialises in follow-up care or their primary care doctor. The process would need to ensure there is room for flexibility for both the patient and physician, should the latter wish to continue the follow-up phase.

While the momentum gained around the Commission's intention to create CCCs, it is worth reminding the need to maintain and strengthen existing infrastructures, in particular nuclear medicine departments in order for European healthcare systems to be ready for the uptake of radioligand therapies in the future. .

In the build-up phase of CCCs, **national entities should keep in mind the wide array of EU funding instruments** at their disposal to foster the development of existing nuclear medicine departments in regional hospitals, with some of them listed in the following chapter.

2. TACKLING INEQUALITIES IN HOSPITAL INFRASTRUCTURES



While increasing awareness on the distribution of nuclear departments across Europe is vital for policymakers, clinicians and experts, extensive consideration should be made on the potential offered by EU funding instruments in tackling inequalities in hospital infrastructures.

a. EU4Health programme

As the COVID-19 pandemic recalled the weaknesses of European health systems as well as the need for better preparedness, EU institutions and national governments proved to be prone to investing more in the healthcare sector in the next decade. With the adoption of the EU's Multiannual Financial Framework 2021-2027, the EU is making a broad range of funding instruments available for structural reforms in the 27 Member States.

The EU4Health programme³ **stands out as the main tool at disposal for countries in need of restructuring their healthcare systems.** Entered into force in March 2021, EU4Health programme seeks to improve coordination between EU Member States, by providing more capacity, investments and added value at EU level.

Eligible actions under the EU4Health programme could entail, amongst others, strengthening critical health infrastructures by investing in modern, specialised imaging equipment or adapting waste storage and nuclear waste systems. The programme is implemented through annual work programmes, prepared by the Commission.⁴



EU and national policymakers have tremendous opportunities to set up funding proposals on reinforcing hospital preparedness for the delivery of RLTs.

Funding opportunities under the EU4Health programme are published by the **Health and Digital Executive Agency (HaDEA)**, which manages European programmes and initiatives on behalf of the European Commission. The Agency was specifically established to, for example, reduce the administrative burden of European funding programmes and to take care of the corresponding annual work programmes' management and roll-out.

As the European Commission prepares work programmes on annual basis, **stakeholders have the opportunity to actively call on to tackle specific challenges that are deemed to be addressed. This can be achieved through participation in public consultations of the Commission**, or through joint stakeholder actions, such as the publication of call to action papers or official letters addressed directly to the European Commission.

With the annual work programme being released at the beginning of the year, stakeholders are encouraged to frequently visit HaDEA's pages on [calls for proposals](#) and [calls for tenders](#).



The National Contact Points, composed of national experts for the EU4Health programme in EU countries, can also play a role in supporting stakeholders interested in applying for a call, while also assisting in the implementation at the national level and collecting information on the impact generated by the programme in the respective countries.

A full list of National Contact Points can be [found here](#).

EU policymakers (representatives of the European Parliament, the European Economic and Social Committee, the Committee of the Regions) as well as national policymakers also have continuous opportunity to actively advocate for the need to take into account specific healthcare gaps that can be taken into consideration by the European Commission.

With health challenges being of cross-cutting nature, the EU4Health programme works in tandem with other policies, instruments and actions, such as the EU Cohesion Policy and the Recovery and Resilience Facility.

³ With an allocation of over €5 billion, the EU4Health 2021-2027 budget is more than 12 times higher compared to the previous EU health programme, ranging from 2014 to 2020.

⁴ Under the 2021 work programme, the European Commission earmarked €3.5 mln for an action grant on the quality and safety of radiation technology in diagnosis and treatment of cancer.

b. EU Cohesion policy funds



With cohesion policy being the EU's most fundamental investment policy to date, a **wide plethora of infrastructural needs can be addressed under this financial tool.**

In fact, the EU Cohesion Policy aims at investing in health, a crucial asset for regional development and competitiveness, to pare down economic and social disparities. Investments may address several different areas, such as healthcare infrastructure and fostering modern equipment across European regions. In the financial year 2021-2027, **Cohesion Policy amounts to €392 billion and is delivered through specific funds, such as:**



European Regional Development Fund (ERDF), supporting regions whose development is lagging behind, and regions with structural problems. It aims at fostering economic, social and territorial cohesion in the EU, by correcting inequalities between its regions.^{xi}



European Social Fund (ESF+), the EU's main instrument for supporting jobs, investing in people and tackling inequality for the next seven years. The ESF+ foresees at least a quarter of the funds tailored to measures backing vulnerable groups in accessing healthcare services and addressing health inequalities.

The ERDF can be identified as an effective tool to **improve regional health infrastructure and promote balanced development in different regions of the EU.** According to the latest data on the Cohesion Policy Fund 2021-2027, €200 billion are allocated under the ERDF, offering a milestone opportunity to Member States and allowing the latter to make remarkable investments in hospital infrastructure and modern equipment.

The ERDF is also known to finance programmes in shared responsibility between the European Commission, national and regional authorities in Member States, facilitating the communication and management of fundings among the involved actors. This means that the Member States' administrations choose which projects to finance and take responsibility for the daily management.^{xii} By collaborating with Member States, the European Commission ensures that the projects are successfully conducted and closely monitors the monetary management.

The ERDF and ESF+ can play a role in fostering access to services, as well as developing specialised health infrastructure and capacity to gradually eliminate health inequalities at the regional level.



The ESF+ focuses instead on enhancing "equal and timely access to quality, sustainable and affordable healthcare services", and "the effectiveness and resilience of healthcare systems and long-term care ", according to Article 4 of the ESF+ Regulation.^{xiii}

Most of the funding under the ESF+ (€98.5 billion) is allocated under shared management with the Member States. This means that the ESF+ Managing Authorities in each country will channel the funds to projects that are run by a range of public and private organisations, thereby responding to the country- and region-specific needs.

A full list of National/Regional Managing Authorities or organisations responsible for ERDF and ESF+ fundings can be [found here](#).



Organisations and individuals interested in applying for ERDF or ESF+ fundings - or who wish to submit a project proposal - are advised to consult their national and regional ERDF/ESF+ websites. Alternatively, they may contact the ERDF or ESF+ Managing Authority in their country or region.

The table below provides an overview of the available instruments earmarked for European and national policymakers, with a list of recommendations on how to better benefit from these funds.

European funding instruments	Institution responsible	Description of the EU fund	Recommendations
European Regional Development Fund (ERDF)	Shared responsibility between the European Commission and national/regional authorities in Member States	The Fund promotes balanced development in the different regions of the EU, with health infrastructure and access to healthcare being the main priorities.	When developing the framework for specific grants and/or calls under the presented funds, authorities, both at EU and/or national/regional level should take into consideration the specific infrastructural needs of RLT delivery.
European Social Fund (ESF+)		Main EU instrument investing in people, tackling the socio-economic consequences of the COVID-19 pandemic, promoting high employment levels, and addressing health inequalities.	National authorities should further support national entities eligible to apply for specific programmes.

c. Additional EU regional tools



Regional support is not only limited to the ERDF tool. Other EU funding mechanisms that could lead to the successful delivery of RLTs and fulfil health-related needs in hospital settings are the Interreg Programme and European Social Fund (ESF).

As part of EU cohesion policy for 30 years, the European Territorial Cooperation (ETC), better known as Interreg, has played a significant role in facilitating cooperation between European regions through project funding. It offers a comprehensive framework for the implementation of joint actions and policy exchanges between national, regional and local actors from different Member States. More concretely, the Interreg programme is meant to enhance regions' capacity in identifying shared solutions to common challenges in a wide range of fields, including health.

With Interreg being a successful funding instrument that stimulates cross-border cooperation, **Member States should closely consider investing and work towards the implementation of cross-border healthcare projects.**

In addition, Interreg projects have been shown to contribute significantly to cross-border regions' fight against the COVID-19 pandemic, through the mobility of healthcare professionals and the development of medical equipment.

d. COVID-19 EU funding instruments



In the context of the COVID-19 crisis, other funding opportunities have been set up to respond to the continuous challenges related to revamping modern equipment and treatment rooms in hospitals.

This applies to the Recovery and Resilience Facility, which is the centrepiece of NextGenerationEU and a temporary instrument to help repair the immediate economic and social damage brought by the Covid-19 pandemic. Through the European Recovery & Resilience Facility (RRF), the bloc is tasked with investing €672.5 billion to support investments and reforms across Member States. As a result, this instrument appears to be the right tool to mobilise funding towards the modernisation and reforms of national healthcare systems and infrastructures. When receiving financial disbursements, Member States should carefully consider fostering investments in health infrastructure, as well as the provision of medical equipment, shielded rooms and appropriate disposal systems.

OVERVIEW OF POSSIBLE ACTIONS



Institution responsible for the implementation



A full list of National Contact Points for EU4Health Programme can be found here.

European Policymakers

- Ensure timely set-up of the call for proposal
- Create **synergies** between EU funding mechanisms
- Advocate for specific challenges to be tackled, in **collaboration with CSOs**

Stakeholders

- Frequently **visit** the HaDEA website to consult and **apply for** relevant calls for proposals/tenders.
- Actively **call on** the Commission to include specific challenges in the work programmes through:
- engagement in public consultations,
 - joint collaboration with national/regional entities and/or other stakeholders
 - bilateral discussions with Commission representatives

National Policymakers

- **Engage** with National Focal Points (NFP) of funding programmes at national/regional level Support national entities eligible for funding applications
- **Build** strong relationships with European networks
- **Consult** national medical experts on suggested measures

A list of National/Regional Managing Authorities or organisations responsible for ERDF and ESF+ fundings can be found here.



Authorities responsible for the implementation of the Funds



Suggested actions for national and EU policymakers

- To take into consideration the specific infrastructural needs of RLT delivery
- To further support national entities eligible to apply for specific programmes

Suggested actions for other stakeholders (CSO, academia, etc.)

- Contact the ERDF or ESF+ Managing Authority in the country or region.
- Consult national and regional ERDF/ESF+ websites.

Stakeholders who are interested in learning more about ongoing and future opportunities of various EU funding programmes available to address various RLT-related challenges are invited to contact

SPARC-Europe Secretariat at: secretariat@sparc-europe.com

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