

Lifecycle

EPTRI lifecycle

ESFRI applies a Lifecycle Approach coherent and consistent with RI funding under the EU Framework Programme for Research and Innovation (FP) which represents a reference to understand the needs and targets of RI at a given time and at various levels.

EPTRI aims to become a European Research Infrastructure Consortium (ERIC) upon reaching the fully operation stage through three different phases: design, preparation, implementation.

The description of the different phases of the lifecycle foresees the evolution of the business model which has to adapt to the process of maturation of the RI.

The **Design phase** has been supported by the INFRADEV-01-2017 grant which has covered the proof of the scientific concept and technical feasibility of the RI, the analysis of the potential user community - both science and innovation oriented, the outline of a business case and the rationale for the international consortium.

The **Preparation phase** is planned from 2021 to 2023 and is expected to be funded through the H2020 funds for Integrating activities (INFRAIA-02-2020) which will provide support by accelerating the implementation of EPTRI on European scale, and by supporting the trans-national access provided to European researchers, the cooperation between research infrastructures, scientific communities, industry and other stakeholders as well as the improvement of the services delivery and access.

During the Preparation phase the country organisation (in National Nodes) and the specialistic organisation (in Thematic Research Platforms) will be started both through the support of the governments and the reference stakeholders and the integration within the already existing basic, preclinical and translational paediatric research infrastructures will be strengthened. Networking efforts will be also aimed to connect the national and regional research infrastructures and facilitate cross-fertilizations between academia and non-academic stakeholders. A specific attention will be dedicated to the networking with the policy-makers in EU and not EU countries in order to receive expression of political support and the inclusion in the national funding plan and Roadmaps.

In this phase, EPTRI will start offer trans-national access to its centralised and integrated services to external users free of charge, as their costs will be covered by the European grant.

The **Implementation phase** is planned from 2024 to 2027 and is expected to be funded through the European funds dedicated to Integrating Activities for Advanced Communities (INFRAIA-01), dedicated to research infrastructures showing an advanced degree of coordination and networking at present, attained, in particular, through Integrating Activities awarded under previous projects.

In the **Operation phase**, the business model based on the provision of services will be consolidated and there will also be greater opportunity to access funding assuming that EPTRI has already been included in the ESFRI Roadmap 2021 and has become an ERIC. EPTRI will produce frontier research and deliver advanced services for excellent science satisfying the users' demand, boosting the mobility of early career scientists and trainees, therefore improving the ranking of their academic and research institutions.



Outreach plan

A global outreach and networking approach to paediatric research will: increase the impact of EPTRI services and initiatives and its global partnership; reduce the barriers between basic science and citizens' wellbeing providing evidence of the direct benefits to society; liaise with the many paediatric initiatives conducted at national and international level as well as with the international research programmes and projects. Key to the success of these activities will be the critical involvement of the patient community and the building of liaisons with all the relevant stakeholders, including the Scientific Community, Policy and Regulatory decision makers, Pharma and Biotech Industries and SMEs.

The **principal target groups for outreach and networking activities** are:

- Potential infrastructure users from public and private sector;
- The biomedical paediatric R&D community;
- the relevant ESFRI and other world-class research infrastructures / networks, including European Reference Networks (ERNs);
- paediatric biopharmaceutical and medical device industry, SMEs, CROs, start-ups;
- patient organisations, Young Patients Advisory Groups (YPAGs) representatives, citizens, etc.;
- Governments, EU bodies, Regulators, Policy Makers and Funders.

In order to maximise the outreach and networking strategy, communication activities and a comprehensive set of tools will be designed for the specific target audiences, according to the different channels and implementing informative materials to promote dissemination activities such as: participation in meetings and congresses organised by research groups also in the framework of existing initiatives and projects (e.g. EJPRD, c4c, etc.), interaction with the scientific communities through workshops/publications/papers, specific actions towards policy and funding bodies at EU and national levels as well as the industrial community.

In particular, an **External Stakeholder Forum (ESF) will be developed with the aim to:**

- a) promote the much-needed research in the paediatric population with special attention to the high unmet need areas like rare diseases, neonates and rare cancers;
- b) leverage the existing initiatives, projects and knowledge;
- c) deal with the research fragmentation;
- d) keep the paediatric medicines development high in the EU agenda.

Tailored activities will be organized to involve all **relevant ESFRI and other world-class research infrastructures/Networks** as well as to liaise with **Industry, Patients, Public and Governments**.

Networking with the Governments

During the design phase, EPTRI has already received support letters from the governments that have recognized its value in enhancing paediatric research and providing a wider implementation of Key Enabling Technologies for drug development. As EPTRI aims to become a European Research Infrastructure Consortium upon reaching the fully operational stage, it needs to receive support from the Governments of the participating countries. To this aim, a coherent and strategy-led approach to policy-makers in EU and not EU countries will be developed in order to receive expression of political support and the inclusion in



the national funding plan and Roadmaps. The networking activities with the National Governments will be also supported by EPF and its member national umbrella patient organizations and will be promoted in their national advocacy activities.

To this aim, meetings and other tailored initiatives will be organised at governmental level to negotiate the support to EPTRI future RI. Ad hoc communication materials will be developed to outreach with Governments.

To making the funding bodies aware of the strategic/funding needs of the paediatric scientific community involved in the project and to convince them to establish long-range plans and roadmaps, the following measures will be planned:

1. Identification of the relevant stakeholders to be contacted in each country to spread the word about EPTRI and start a collaborative pathway.
2. Dispatch of materials describing EPTRI aims and operational characteristics as the EPTRI Brochure.
3. Involving the regional and local authorities to enhance the possibility of benefiting of EU structural and investment funds or other financial support facilities at national or European level.
4. Testing the interest of governments on setting up a RI dedicated to paediatric research through interviews, focus groups, short questionnaires.
5. Organisation of face-to-face meetings or teleconferences between the identified research units/paediatric initiatives, the relevant national authorities' representatives, the coordinators of the TRPs and the national nodes, and the EPTRI coordination team to present EPTRI and discuss the possible type of involvement.
6. Identification of the common areas and possible actions, they may include collaborative research projects, participation to scientific meeting and social initiatives, common sponsorship of initiatives, financial and political support.
7. Formalisation of the involvement in EPTRI (endorsement letter, MoU, partnership agreement, etc.).

Outreach with the paediatric research community

Specific actions will be planned to liaise with related EU-funded projects, societies, paediatric networks, ERNs and professional associations to engage with relevant communities beyond the consortium of EPTRI as well as to strengthen cooperation with the European joint programming and research initiatives. To this aim, a Working Group will be created to elaborate a position paper on how to strengthen collaboration with the paediatric research initiatives. Moreover, online consultations on specific topics will be organised, in order to identify expectations, willingness to collaborate, actions that could be conducted in collaboration with the European Paediatric Translational Research Infrastructure.

Common activities will be promoted including:

- Training and staff exchange
- Scouting of projects of common interest in the field of paediatric medicines, products and devices
- Meetings and conferences organisation/participation.

Ad hoc initiatives will also be developed to address the question of the paediatric medicines for rare diseases. To this aim, all the services available at EPTRI level will be proposed to be used by the rare diseases' community, including open access and data exchange available in EPTRI.



Of particular interest will be the setting up of an EPTRI centralised service dedicated to the identification and further exploitation of project proposals considered relevant to underpin paediatric clinical research. This activity could be organised in partnership with paediatric initiatives operating in the paediatric clinical trials and studies' field.

Outreach with European Strategy Forum on Research Infrastructures – ESFRI

Tailored activities will be planned to involve all relevant ESFRI and other world-class research infrastructures to exploit synergies, to reflect on sustainability and to ensure complementarity and coherence with the existing European Infrastructures landscape.

In particular, a Working Group with representatives from relevant Biomedical ESFRI RIS will further investigate the opportunity of common services. A common position paper will be released with the aim to set up a framework of collaboration, investigate the respective fields of actions and exploit the synergies.

Outreach with the paediatric biopharmaceutical and medical devices industry and CROs, including SMEs and start-up

Specific activities will be aimed to tackle actions related to business development in research areas that have a potential to address patients' needs and communicating the project to industrial stakeholders.

To this aim, a series of meetings will be organised to identify possible areas of collaboration and business opportunities between EPTRI and the different industrial stakeholders, including SMEs and start-ups, will be held. It will also include the strategy on how to best market offers of TA services, which are convincing and attractive for industrial clients, related future business models, and handling of IPR.

To attract interest from industry, the following actions will be put in place:

- Communicate the portfolio of TA can be provided regularly;
- Testing the interest of companies in using the TA services through interviews, short questionnaires or dedicated meetings;
- Presenting the project (with poster or oral presentations) in commercial workshops.

Outreach and networking with Patients and Public

Key to the EPTRI development is the engagement with young patients and young people, patient organizations and the public, in order to promote paediatric basic research using a patient centric approach. This will facilitate a feasible translational research development of the programmes of EPTRI and ensure translational research focuses on community and patient-relevant priorities.

The young patients' voice is instrumental in the RI development from the early start. In order to ensure the meaningful and impactful involvement of the young patients, a dedicated board of EPFs Youth Group members (which consists of well trained and highly motivated young patient experts) and YPAGs (which are established groups of young people - patients and healthy volunteers - linked to academic institutions and children's hospitals) will be involved.

Patients representatives, families and patients' organizations will be also involved.

Moreover, dedicated actions such as organisation of roundtables and forum discussions, will be foreseen to involve patient organisations, representatives, families, YPAGs and citizens and several materials for patients/patients' organizations/patients' advocates focused on empowerment, education and information in the field of basic research will be developed.

