Information about the EATRIS framework

What is an ERIC?

ERIC stands for European Research Infrastructure Consortium and it is a legal entity established with legal personality and full legal capacity recognised in all EU Member States.

In contrast to other legal entities like “Limited”, “GmbH” or an Association, it was created to facilitate cross border research activities. ERIC has been designed to facilitate the establishment and operation of research infrastructures

I am a researcher at a non-EATRIS institute – what do I need to know for my institution to participate in EATRIS infrastructure?

For your institution to be part of the EATRIS infrastructure, you need first to check that your country is in the list of EATRIS member states (https://www.eatris.eu).

If it is the case, certain criteria need to be fulfilled for your institution:

- Availability of state-of-the-art infrastructure and expertise to potentially engage in translational development projects;
- Evidence presented to confirm that quality assurance systems employed are satisfactory, or there are explicit plans to achieve such quality levels;
- Institution contribution to EATRIS infrastructure to increase the scope or capacity of available EATRIS activities and services.

Next to the fulfilling above listed criteria, an **application procedure** needs to be followed:

1. The institution must receive permission to apply for entry to EATRIS infrastructure from its national representative (member of the Board of Governors) in coordination with the National Director for that country. EATRIS Coordination and Support Office (EATRIS C&S) can help you contacting your national representatives. You can contact florencebietrix@eatris.eu for further information.

2. The institution must complete an application to join EATRIS which is to be sent to EATRIS C&S together with the approval for participation obtained from your national representative. This application will describe:

    a. The relevant infrastructure and capacities that would be available for EATRIS activities and/or services.

    b. Relevant expertise in translational research, such as clinical, regulatory and project management capabilities;

c. The Product Platform(s) in which the institution would like to participate, and their envisaged contribution to EATRIS long-term goals. More information on the EATRIS Product Platforms can be found on the EATRIS website (https://www.eatris.eu). You can also contact florencebietrix@eatris.eu

3. Together with EATRIS Product Platform Chairs, The Board of National Directors will assess the application and make a decision. The Board of National Directors will inform EATRIS C&S and the Board of Governors, in writing.

I am a researcher at an EATRIS institute – what do I need to know about EFA and other legal documents?

There are a couple of legal documents that you should be aware of. Let's briefly introduce them and explain how they relate to you.

I. EATRIS Statutes

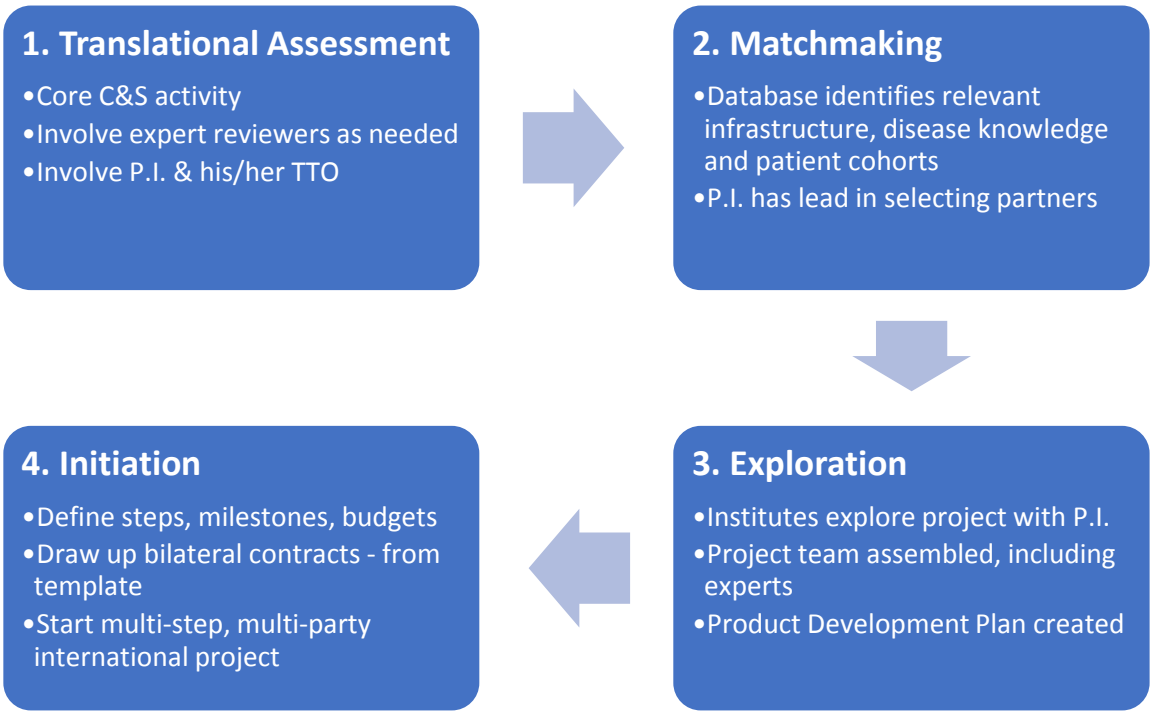
How EATRIS operates as an ERIC is laid out in the Statutes. The statutes can be downloaded from the EATRIS website (https://www.eatris.eu). The statutes are similar to the constitutional laws of countries in that they describe the overall structure of EATRIS but do not describe any operational details. For example, the EATRIS statutes in Article 15 state that the Board of National Directors "*... shall be responsible for all national scientific activities related to EATRIS ERIC and shall maintain coherence and consistency across EATRIS ERIC and collaboration between the Members*". Operational details such as how often this board meets are not described in the Statutes but in a separate document called "Rules of Procedure and Standing Orders".

II. EFA (EATRIS Framework Agreement)

Probably the most relevant legal document for you is the EFA – EATRIS Framework Agreement and its annexes as it describes the relationship between EATRIS and research institutions.

The EFA is THE contract which links the participating institutions to the EATRIS ERIC and thus EATRIS research infrastructure. Only if research institution or university has signed the EFA, it will it be able to execute EATRIS core projects.

With the EFA the institution commits itself to the EATRIS goals such as "to make the translational research infrastructure capacity and expertise from EATRIS Institutions available (...) and to foster innovation and advancement in the field of translational science." The EFA confirms your right to conduct any research or development work in any field and to cooperate with whomever you would like to cooperate. In return by signing the EFA your institution accepts the procedures on Project assignment and performance, distribution and performance in the course of undertaking research Projects as described in the Annexes to the EFA.



The **Annex "EATRIS Client Access and Project Assignment Policy"** to the EFA describes the process of how requests from Clients (from academia, industry or other organizations) are submitted, evaluated and distributed to EATRIS institutions by EATRIS C&S and the rationale behind it. The procedure is pictured above.

Intellectual Property Rights Framework – IPRF is an EFA annex that allows the EATRIS Institutions to have a ready set of principles for negotiation with the Client thus speeding up the negotiation process which is of special importance when negotiating with private companies. The IPRF describes several project scenarios with different IP regulations making sure that you and your TTO/legal advisor can agree on an IP solution that is best fitted the nature of a specific project.

The Annex **"Quality Standards of Pharmaceutical Development in EATRIS"** describes quality standards that must be adhered to in order to participate in EATRIS translational service provision. This ensures that EATRIS fulfils its objective of consistently delivering high quality projects and services.

III. Letter of Engagement

When a client approaches EATRIS with a request for a research service, the Client signs a Letter of Engagement as a basis for EATRIS coordination & support office to perform a matchmaking i.e. identifying which EATRIS partner institutions can offer this service. The matchmaking results are then presented to the Client. When the Client expresses that he wants to proceed with one or more Institutions based upon the Matchmaking results, EATRIS coordination and support office will facilitate the interaction between the client and Institution(s) to discuss a Project Agreement and Project performance until a contract is signed between them.

IV. CDA Confidentiality Agreement

It might be the case that Clients or Institutions exchange proprietary and confidential information before signing of a Letter of Engagement. To protect these confidential information exchanges, we have templates to negotiate a CDA (Confidentiality Agreement).

What does it mean for participation to Horizon 2020 projects?

EATRIS wants to create as much opportunity as possible for your institution to participate to H2020 projects. If EATRIS ERIC participates in a Horizon2020 or IMI project, only the EATRIS-ERIC will need to sign the contracts with the European Commission (EC), thereby reducing the number of contracts your institution will need to deal with. You will be identified in the projects as Linked Third Party and only sign a Linked Third-Party Agreement with EATRIS.