



EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE

EPTRI Governance and Business Model

Giovanni Migliaccio
Scientific Director, CVBF

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Governance model

EPTRI future Governance model will be described in the D2.9 Final CDR

It is the basis for the Preparation Phase, Member State negotiation and Operation Phase of EPTRI

EPTRI GENERAL DESCRIPTION

ID-EPTRI (European Paediatric Translational Research Infrastructure) is an EU project aimed to design the framework for a new infrastructure dedicated to paediatric research that will work to accelerate the paediatric drug development processes from medicines discovery, preclinical research and developmental pharmacology to age tailored formulations and medical devices.

The project's final goal is to facilitate the translation of the acquired new knowledge and scientific innovation into paediatric clinical studies phases and medical use.

EPTRI GOVERNANCE CONTEXT

- 3.1. EPTRI GENERAL DESCRIPTIONS
- 3.2. GOVERNANCE OF RESEARCH INFRASTRUCTURES (RIs)
- 3.3. GOVERNANCE FRAMEWORK – ERIC MODEL
- 3.4. Distributed Research Infrastructure (DRI) STRATEGIC AND CRITICAL REQUIREMENTS
- 3.5. DRI OPERATIONAL LEGAL REQUIREMENTS

GOVERNANCE OF DISTRIBUTED RI

Distributed RIs are especially tailored Research Infrastructures (RI) proposed in disciplines, such as biological, environmental or social sciences, which until recently did not require large or complex equipment or resources.

In order to carry out its activities a DRI seeks a legal structure that allows achieving the scientific goals with the minimum legal, financial and administrative complications.

An ERIC is an entity with a legal status that is recognised in all European Member states. It meets the needs for recognition of the European identity on a non-economic basis.

What is an ERIC

A European Research Infrastructure Consortium (ERIC) is a legal entity with legal personality and full legal capacity recognised in all EU Member States.

An ERIC requires commitments from at least 3 member states for funding and support.

After entry into the ESFRI Roadmap an operational ERIC is prepared and implemented within the next ten years. Successfully launched ERICs have taken 8-11 years from Roadmap acceptance to establishment of an operational ERIC.

ERIC governance model

Each ERIC is free to choose its own internal organisation respecting the prescription of the Regulation 723/2009. Article 12 of the ERIC Regulation lists the minimum governing bodies required which are:

- a) an **assembly of members** as the body having full decision-making powers, including the adoption of the budget;
- b) an **executive director or a board of directors**, appointed by the assembly of members, as the executive body and legal representative of the ERIC. The Statutes shall specify the manner in which the members of the board of directors legally represent the ERIC.

EPTRI governance model

As detailed, it is best practice in the case of any DRI, and mandated in the case of an ERIC, that there are at least two levels of governance.

The structure of EPTRI is based on a **Central Hub** (C-Hub) that incorporates two decisional boards, the **Governing Board** (GovB) and the **Executive Board** (ExeB), an **Advisory Board** (AB) and an operational **Central Management Office** (CMO).

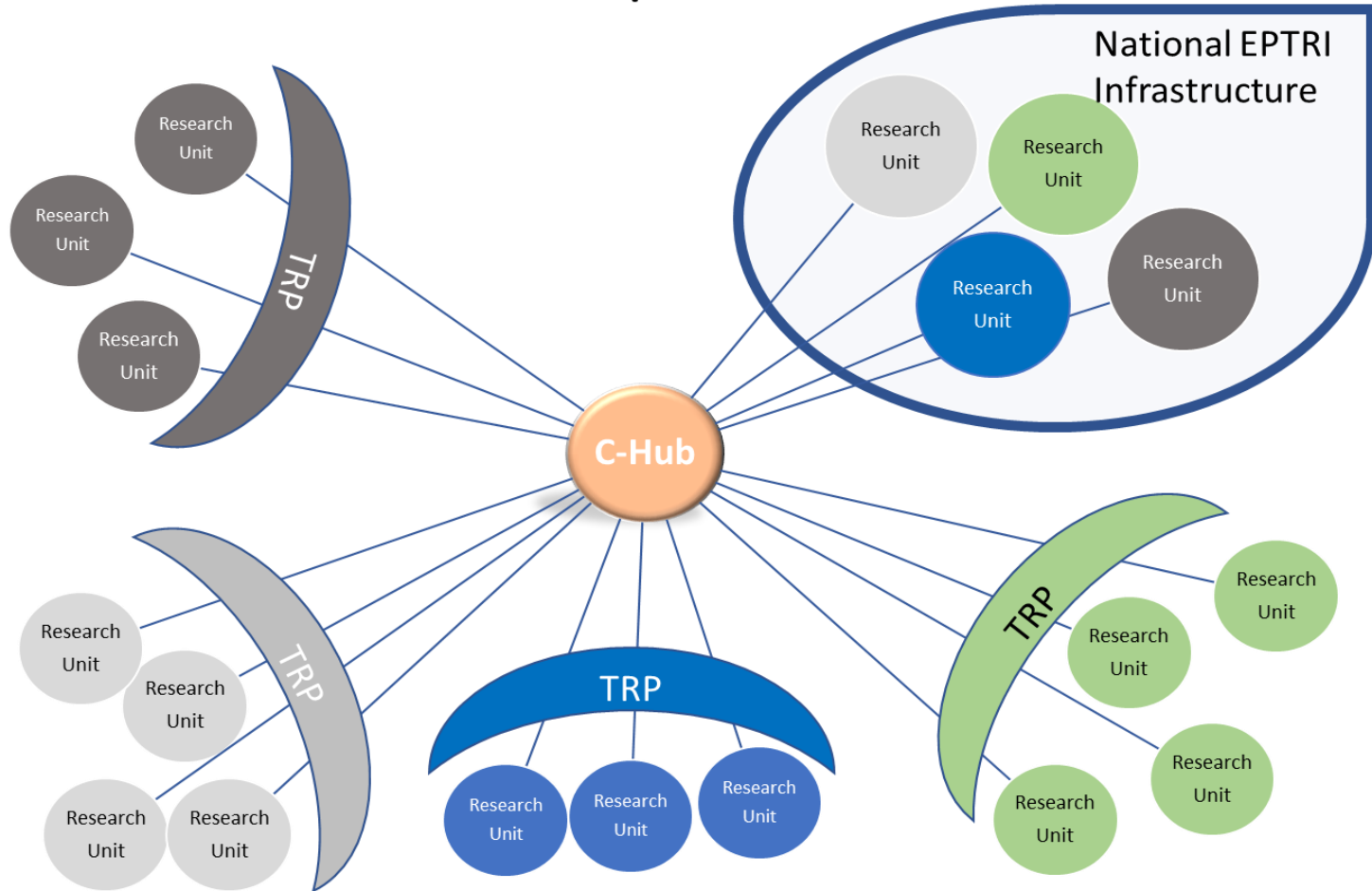
EPTRI partnership

The EPTRI ERIC will have operational interaction with a number of partners located in many countries and subject to different legal requirements.

- Member States, Associated Countries and Observers
 - Research Institutes as Participants
 - National nodes of EPTRI Infrastructures (N-EPTRI)
 - Thematic Research Platforms
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- Users and stakeholders
 - Research Infrastructures

Hub and Spoke operational model

Hub and Spoke model



EPTRI GOVERNANCE MODEL

4.1. CENTRAL HUB

- 4.1.1. Governing Board (GovB)
- 4.1.2. Executive Board (ExeB)
- 4.1.3. Advisory Board (AB)
- 4.1.4. Central Management Office

4.2. EPTRI PARTNERSHIP

- 4.2.1. Member States and Observers
- 4.2.2. Research Institutes as Participants
- 4.2.3. National EPTRI Infrastructures (N-EPTRI)
- 4.2.4. Research Institutes coordinating an EPTRI TRP



EPTRI Governing Board (GovB)

The GovB will make strategic decisions such as:

- Adopt a strategic plan (technological, scientific and administrative), based upon advice from the Advisory Board;
- Adopt the annual budget and plan prepared by the Executive Board (ExeB);
- Approve audited financial statements;
- Approve the annual report prepared by the CMO and proposed by the ExeB;
- Admit new member states;
- Revoke the membership;
- Terminate the Infrastructure if necessary;
- Appoint the EPTRI ExeB members;
- Establish the Advisory Board upon proposal from the ExeB.

EPTRI Executive Board (ExeB)

The ExeB will take on the operational decisions, including:

- Adopt or change the list of services offered by EPTRI;
- Appoint or terminate Central Management Office personnel;
- Arbitrate any conflict between members of EPTRI. If the arbitration is not accepted, the GovB will take the final decision on the issue;
- Propose to the GovB changes to the composition of the Advisory Board (AB);
- Propose to the GovB changes to the AB's Terms of References;
- Adopt and amend the Annual Plan and the annual budget according to the GovB indications.



EPTRI Advisory Board (AB)

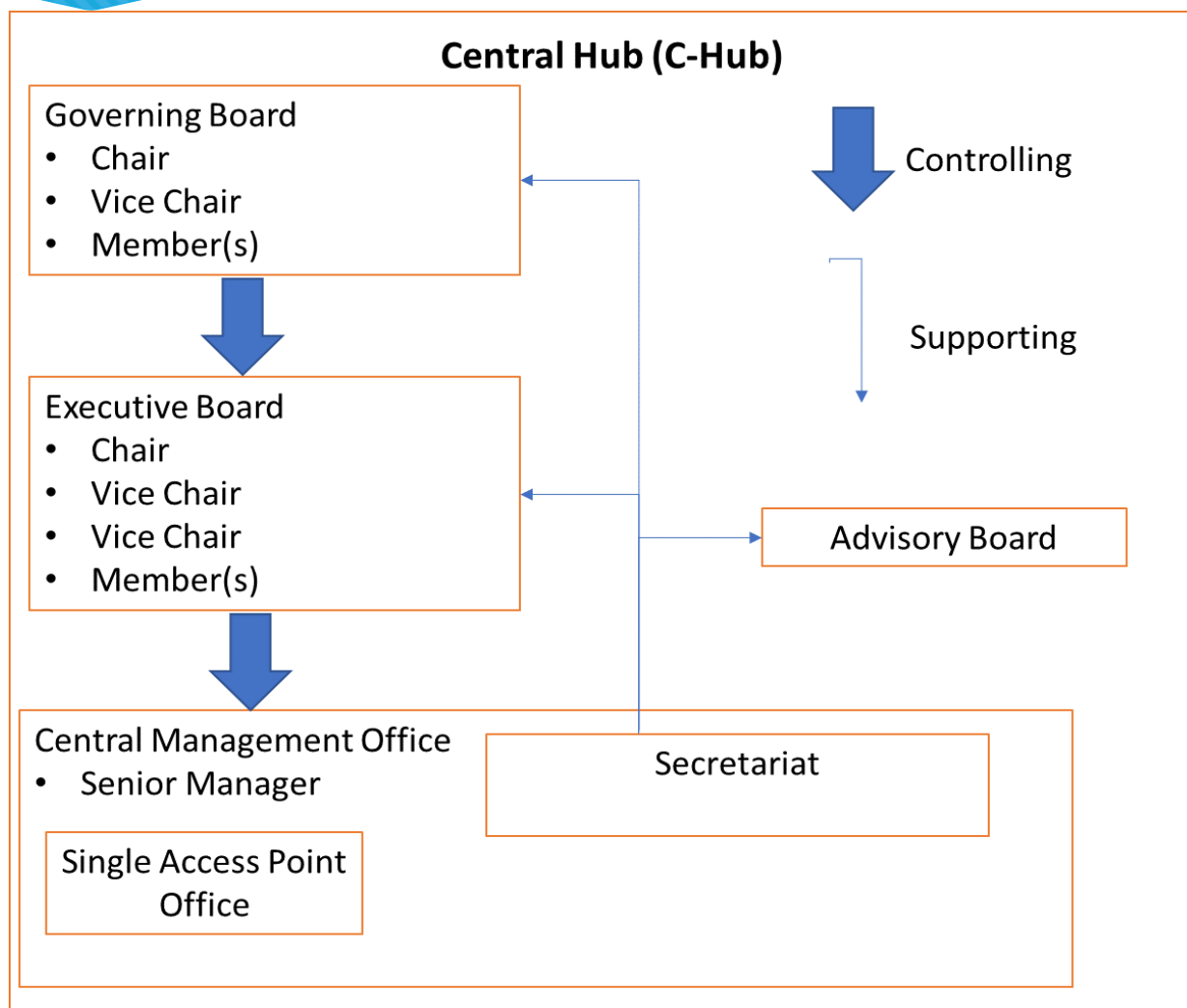
The AB is an independent body composed by individuals with specific and multidisciplinary expertise, having the primary function to advise EPTRI on scientific and ethical issues.

The AB composition will be proposed by the ExeB and established by the GovB

The Advisory Board will include individuals who bring unique knowledge and skills which complement the knowledge and skills of the formal ExeB members in order to more effectively govern the organization.

The Advisory Board will not have formal authority to govern the organization, rather it serves to make recommendations and/or provide key information and materials to the decisional Boards.

Central Hub components



EPTRI Central management Office (CMO)

EPTRI foresees a Central Management Office (CMO) located in one of the Member States.

The Research Infrastructure will be coordinated by this office.

The ExeB will be based in the CMO and it will be the headquarter of EPTRI.

The EPTRI's CMO provides a Single Access Point (SAP) to available resources as well as appropriate facilities and expertise.

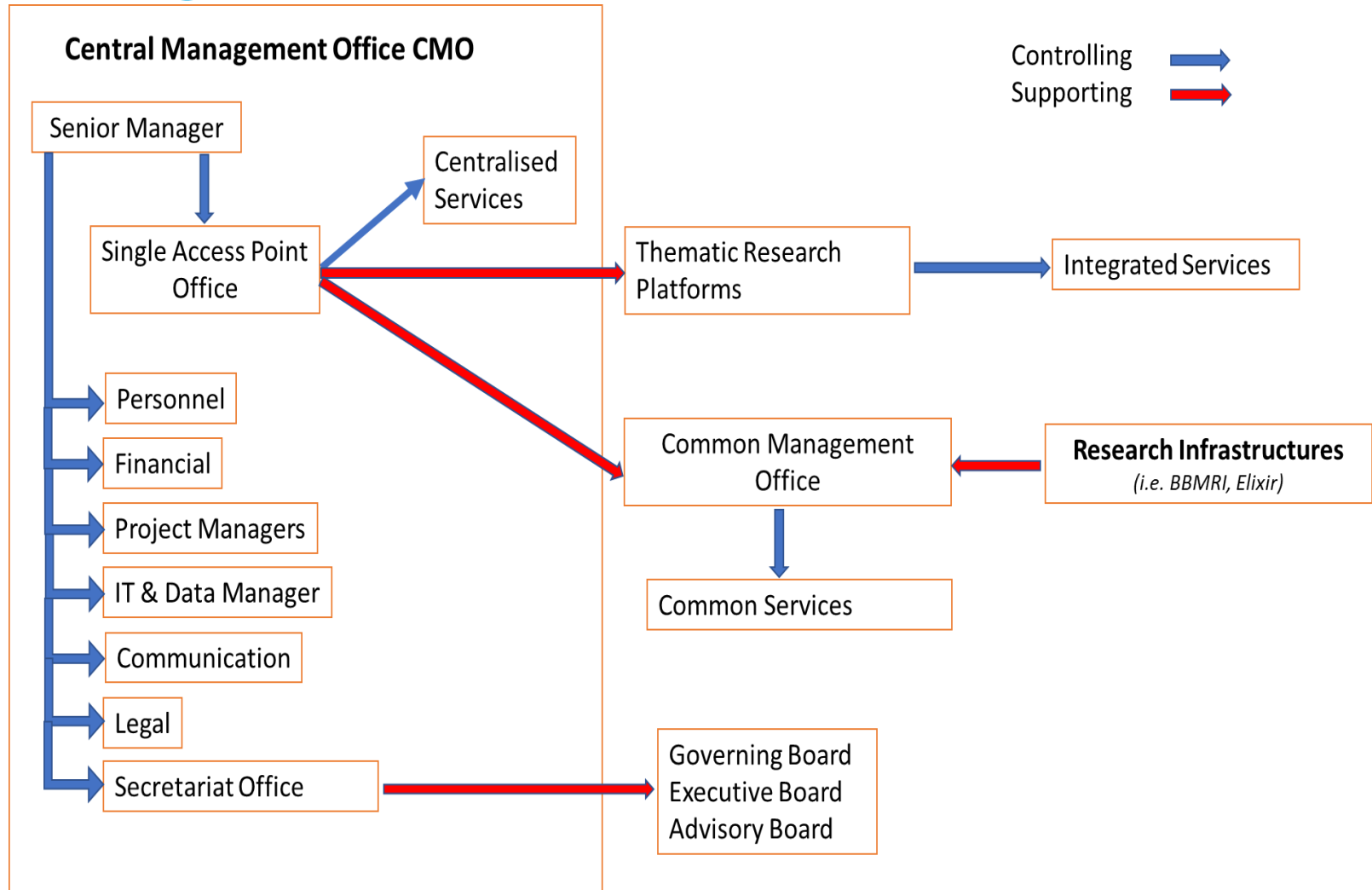
Single Access Point

A **web based system** allowing the Users to ask for services from the DRI

An **Access Management Committee** which will include a:

- **Selection Panel** composed of external expert from the Advisory Board &
- **Internal Panel** composed by the Thematic Research Platform coordinators

Central Management Office



EPTRI Services

The CMO is also in charge to provide access to all the EPTRI different types of services:

- Centralised services which for their own nature are best supplied in a centralised manner.
- Integrated Services provided by the Thematic Research Platforms (TRPs) according to their specific research area of expertise.
- Common Services, integrating EPTRI and other RIs activities and set up according to a contractual agreement with other RIs.

Thematic Research Platform

The four **Thematic Research Platform** as defined now:

1. *PAEDIATRIC MEDICINES DISCOVERY*
2. *PAEDIATRIC BIOMARKERS*
3. *DEVELOPMENTAL PHARMACOLOGY*
4. *PAEDIATRIC MEDICINES FORMULATIONS & MD*

Revenues & Sustainability

- Government contribution will cover the cost of the central office
- Government contribution are also expected to sustain the National Node operations and the upgrade, maintenance of the national Infrastructures
- Services to Users will have to be paid by cost recovery fees. A fee differentiation between Academic (internal to EPTRI or external), non-profit entities and Industry is planned. However, no more than 30% of the total annual budget may come from for profit activities.

EPTRI Framework Agreement

Each Institution will sign a bilateral long-term Framework Agreement (FrAg) with the ExeB, as EPTRI legal representative.

The text of such agreement will describe obligation and rights of the EPTRI participants.

It will be an annex to the statute of EPTRI being a requisite to the participation as a service provider Institution.

The Framework Agreement will at least include:

- Services capacities;
- Rights and responsibilities to access projects and services requests;
- Publishing and acknowledgement stipulations and principles;
- Confidentiality;
- Intellectual Property rights;
- Adherence to standards, guidelines and laws; and
- Mutual use of name, trademarks, etc.



EPTRI operational model

