

ADVISORY BOARD ASSESSMENT

Name, surname and email

Title of feasibility study proposal analyzed

If you are a rapporteur, please indicate your expertise

Paediatric research methodology;

Toxicology/Pre-clinical;

Biomarkers/Biosamples;

Developmental Pharmacology;

Formulation/Devices;

Data-science/Bioinformatics;

HTA/Ethics/Regulatory.

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a) the proposal meets EPTRI mission and abilities:

(Please consider that EPTRI activities are divided according to technical area of interest in four platforms. Which should be involved? More than one Platform could be considered. Are centralized services involved?)

b) the proposal is likely to be completed by the end of ID-EPTRI project:

(Have the project phases been clearly indicated/detailed? Is the project feasible in the planned period? Is a plan included to cover risks and unexpected events?)

c) the scientific contents are valuable:

(Please express your opinion on the excellence of the proposal, the added value for EPTRI and the possible capacity to attract funds and new users)

d) Services and facilities within EPTRI are available to perform the work:

(Have services and facilities needed to perform the study been clearly indicated? Is the applicant aware of which is the Platform/ expert/ partner that is to be addressed to perform the proposed study? Is the proponent aware on how to receive support from EPTRI central HUB?)

e) Is the opinion of the EPTRI Ethical Advisory Board necessary?

(Please explain why an EAB opinion is needed)

f) Which could be the interest for paediatric patients?

(Which role paediatric patients could cover to implement the proposal? This box is to be completed by the AB member representing patients and eventually also by other AB members)


Annex 1

Pilot Model for Feasibility studies

ID- EPTRI foresees the conduction of some feasibility studies. These studies will be aimed to test the process, the scientific interest, the availability of requested services and facilities that could be needed to conduct paediatric research in the areas of competence of EPTRI. To the aim of conduct feasibility studies, a provisional procedure has been created within WP9. It includes the setting up of an advisory board (AB) to assess these feasibility studies. The provisional procedure includes:

- An official opening of the call for applicants to be sent by the Coordinator.
- Coordinator staff will act as Central Hub managing the contact with the service providers (Platforms, Central Services, Common Services).
- Defined Procedures to apply a proposal send to the users including instruction for the secure use of IT tools, for the contents of the proposal and the timing for issuing the AB opinion.
- Defined Format of the application. It should comprise a structured abstract, specific questions regarding the ability of EPTRI to provide a specific service (either technical or expertise based).
- Defined format for the AB consultation process and the points on which the opinion should be articulated including:
 - the proposal meets EPTRI mission and abilities;
 - the proposal is likely to be completed by the end of ID-EPTRI project;
 - the scientific contents are valuable;
 - services and facilities within EPTRI are available to perform the work; etc.

After receiving the opinion on the feasibility of the proposed studies, the Coordinator, (acting as Central Hub) in collaboration with WP9-Other RIs, will contact the concerned thematic Platform that will be in charge to identify the research units and the services needed to conduct the study, to coordinate it and to prepare a study report. After AB will provide its opinion, the Coordinator will disseminate the results to the applicants. Next figure summarises the flow and timing of the feasibility studies procedure :



Document Owner	Document name	Phase of the process	Resources needed
User \ applicant	Request of service	Application	Template 1
Hub coordinator	Request of feasibility assessment		Certification <ul style="list-style-type: none"> The application include the information required
AB	Assessment of feasibility \ gap identification	Assessment	Template 2 <ul style="list-style-type: none"> Criteria List of service \ providers
Hub coordinator	Reply to request	Negotiation	Template 3 Contract Template and annex: <ul style="list-style-type: none"> CDA template SOP for access to and distribution lists of contacts and supporting services
User/applicants	Study report internal	Execution	Template 4 <ul style="list-style-type: none"> Study report internal (positive negative list of contract alteration and service gaps)
AB	Study feasibility results evaluation	Assessment	Template 5 <ul style="list-style-type: none"> Criteria
Hub coordinator	Study ratification and release	Release	Template 6 <ul style="list-style-type: none"> Study report internal Study report external

Description of AB feasibility assessment procedure

Annex 2

Criteria

One or more AB members (depending on the area of expertise) should state if:

- a) the proposal meets EPTRI mission and abilities;**
- b) the proposal is likely to be completed by the end of ID-EPTRI project;**
- c) the scientific contents are valuable;**
- d) services and facilities within EPTRI are available to perform the work.**