



EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE

# EPTRI Process towards ESFRI

Mariangela Lupo  
EPTRI Open Meeting



This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 777554

# ESFRI - European Strategy Forum on Research Infrastructures

ESFRI is a strategic instrument to develop the scientific integration of Europe and to strengthen its international outreach.

ESFRI LANDMARKS

ESFRI PROJECTS



**The ESFRI Roadmap combines:**



# ESFRI Roadmap 2021

The Roadmap 2021 has been launched on 25 Sept, 2019, with **deadline 9 September, 2020**.

With the Roadmap 2021 ESFRI will update the strategy on European RIs aimed at strengthening the competitiveness, value, excellence and impact of EU research.

6 domains

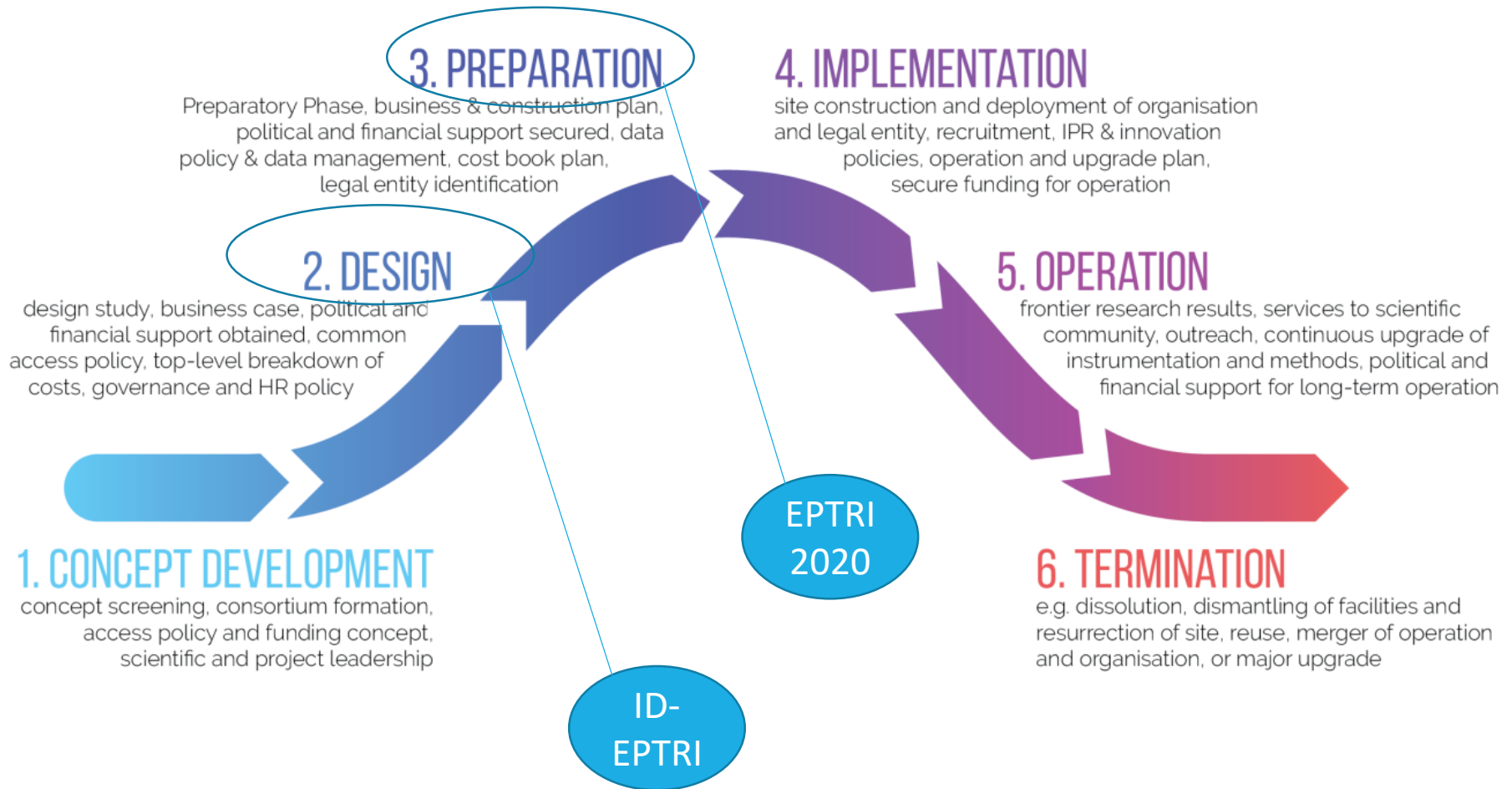


## ESFRI PROJECTS

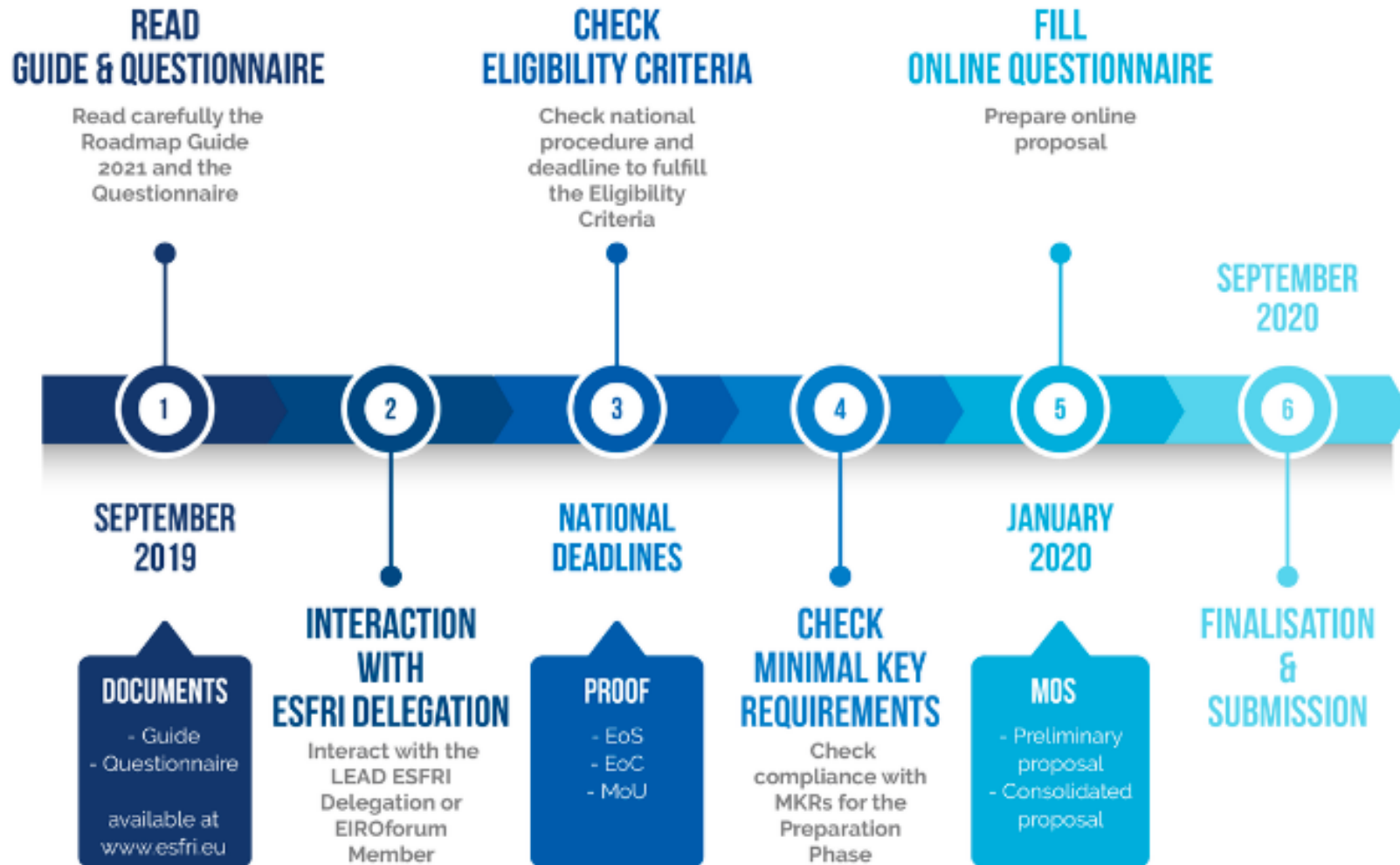
DIGIT ENE ENV H&F PSE SCI

EU-SOLARIS		AnaEE			
MYRRHA		ISBE			
WindSanner		MIRRI			2010
ACTRIS		EMPHASIS	EST	E-RIHS	
DANUBIUS-RI			KM3Net 2.0		2016
IFMIF-DONES	DISSCo	EU-IBISBA		EHRI	
	eLTER	METROFOOD-RI			2018

# RI Lifecycle Approach



# EPTRI process towards ESFRI



SiRESFRI

Funded by EU H2020  
Grant Agreement n° 823711



# EPTRI process towards ESFRI

## READ GUIDE & QUESTIONNAIRE

Read carefully the  
Roadmap Guide  
2021 and the  
Questionnaire

1

SEPTEMBER  
2019

### DOCUMENTS

- Guide
- Questionnaire

available at  
[www.esfri.eu](http://www.esfri.eu)

2

## INTERACTION WITH ESFRI DELEGATION

Interact with the  
LEAD ESFRI  
Delegation or  
EIROforum  
Member

3

## CHECK ELIGIBILITY CRITERIA

Check national  
procedure and  
deadline to fulfill  
the Eligibility  
Criteria

NATIONAL  
DEADLINES

### PROOF

- EoS
- EoC
- MoU

4

## CHECK MINIMAL KEY REQUIREMENTS

Check  
compliance with  
MKRs for the  
Preparation  
Phase

## FILL ONLINE QUESTIONNAIRE

Prepare online  
proposal

5

JANUARY  
2020

### MOS

- Preliminary  
proposal
- Consolidated  
proposal

6

## FINALISATION & SUBMISSION

SEPTEMBER  
2020



SIRESFRI

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Grant Agreement n° 823711

**ePTRI**

EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE



# National Roadmaps

The European Commission and ESFRI encourage EU and associated countries to develop national roadmaps for Research Infrastructures.



The national roadmaps are vital blueprints which enable countries to set national priorities and to earmark funds for both national and pan-European RIs including ESFRI ones.

In addition, the national roadmaps must be linked to the regional smart specialisation strategies: this is a pre-condition to the use of European Structural and Investment Funds.

<https://www.esfri.eu/national-roadmaps>

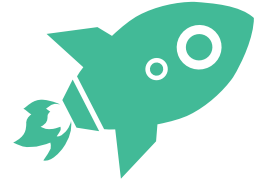
# Actions done!

**Contact national ministries** responsible for the Research Infrastructures and ask for a Expressions of political Support (EoS) and Financial support (EoC)

**Contact national ESFRI delegates** to get information on the requisites and procedures to follow in order to include EPTRI in the national roadmap

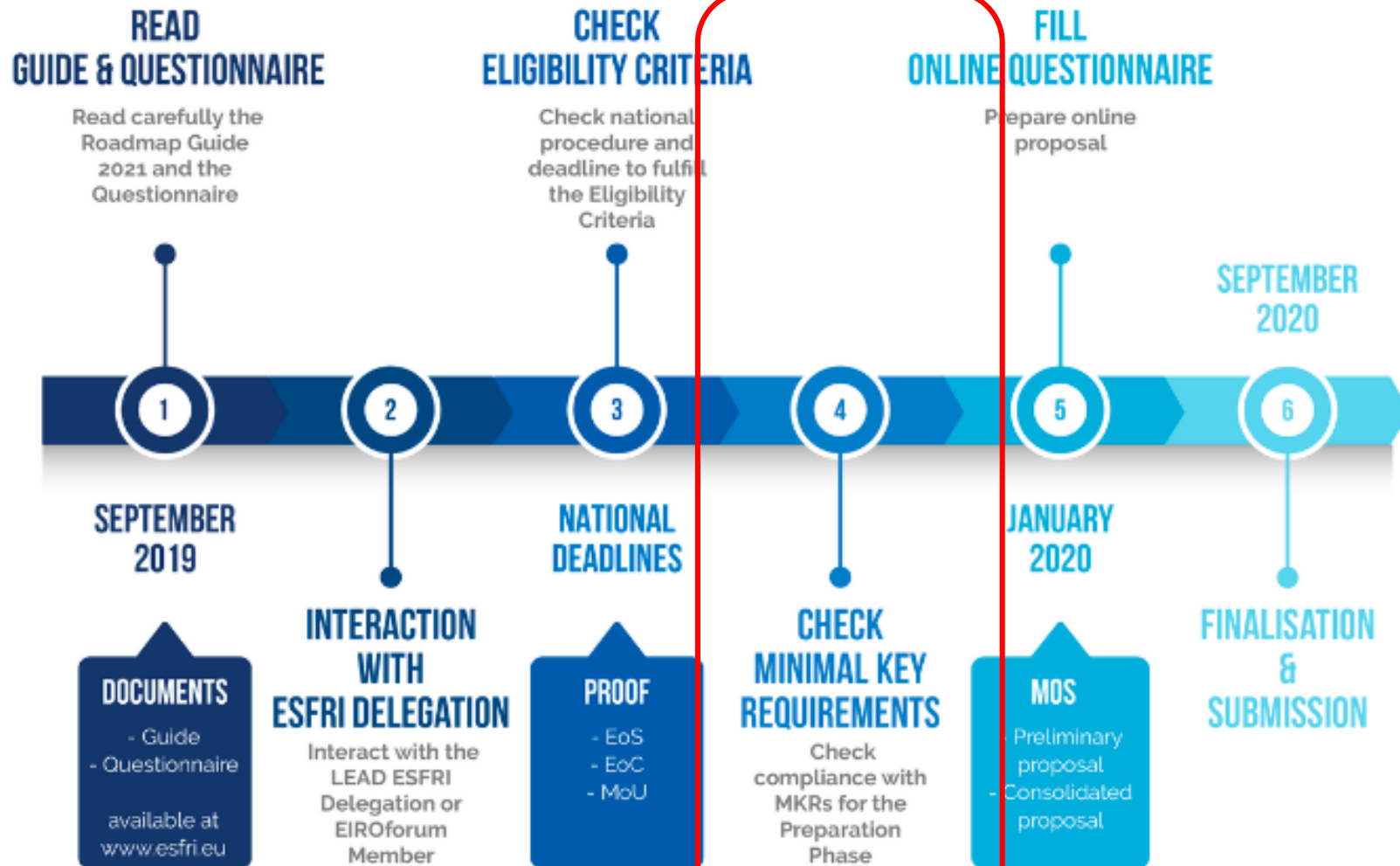


# Procedures submitted



- Austria
- Belgium (ongoing)
- Denmark (ongoing)
- Finland
- Hungary
- Italy
- Ireland
- Poland
- Portugal
- Romania (ongoing)
- Spain
- Switzerland (ongoing)
- The Netherlands
- UK

# EPTRI process towards ESFRI



 **SiRESFRI** Funded by EU H2020 Grant Agreement n° 823711

# Eligibility criteria

NEW PROJECTS MUST DEMONSTRATE ADEQUATE MATURITY LEVEL, PROVIDE:

## **Political support**, i.e.

Expression of political Support (EoS) by the lead country and a satisfactory number of prospective members;



**Clear strategy** how to gather necessary commitment at institutional and governmental level;



PROOF OF:

**Satisfactory inter-institutional and multi-lateral agreement**, e.g. a Memorandum of Understanding (MoU) signed by all core partners -being research institutions -formally involved in the consortium;



**Financial commitment** by lead country and possible other entities satisfactorily covering the preparation and implementation phases



# Political support



Ministry of Health in Albania

DG European Programmes, Coordination and Development of Cyprus

Ministry of Health of Greece

Ministry of Health of Israel

Ministry of University and Research of Italy

Ministry of Industry, Trade and Entrepreneurship of Nizhny Novgorod Region

Ministry of Economic Development of Russia

Ministry of Health of Spain

Ministry of Health of Ukraine

Ministry of Education and Science of Ukraine

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# MoU

Signed by the  
Legal  
representatives of  
more than 90  
organisations

## MEMORANDUM OF UNDERSTANDING

within EPTRI - European Paediatric Translational Research Infrastructure

### GIVEN THAT

Minors represent 20% of the European population and their care is one of the most important priorities and challenge for Europe. Even if paediatricians routinely give adult drugs to children in a 'off-label' prescription (50% up to 90% according to disease areas and age), researchers have demonstrated that children often do not respond to medications in the same way as adults or have different and more serious drug adverse reactions. This is the effect of the large variability of many biological and physiological functions changing during human growth, requiring the paediatric population to be subdivided in at least 5 smaller age groups, defined by the maturation process and having a huge impact on the individual pharmaco-toxicological characteristics. Also, the implementation of leads technologies in the drug development processes (such as -genetic/genomic derived innovation and data science innovation) requires paediatric adjustments and specific paediatric competences and tools.

So far, some progress in the field of paediatric translational research have been realised due to a very large paediatric research community (more than 300 research units mapped within the ID-EPTRI project, H2020 GA n. 777554, <https://eptri.eu/>) but a structured paediatric research infrastructures is still lacking and the existing resources are still dispersed and underfunded.

It is therefore necessary to organise the international scientific community for paediatric research, not only through networks and initiatives, but also by constituting an Infrastructure dedicated to paediatric research, involving the various subjects interested in basic research and innovation in the development of drugs, devices and therapies for the paediatric population.

EPTRI (European Paediatric Translational Research Infrastructure) is a new proposed infrastructure dedicated to paediatric research that will work to accelerate and expand the paediatric drug development processes by enhancing innovative technologies and methods. The EPTRI Infrastructure will collaborate and integrate organisations with international initiatives dedicated to paediatric clinical research that will help to reduce the time developing new drugs and therapies and increase their availability for patients. To this aim support to Paediatric Investigation Plans (PIP) applications, Orphan Drug Designations (ODD) and Advanced Therapy (AT) qualifications will be provided.

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# Expression of Commitment (EoC)



*Il Ministro dell'Università  
e della Ricerca*

m\_pi - Ministero dell'Istruzione, dell'Università e della Ricerca  
AOOUFGAB - Ufficio di Gabinetto del MIUR  
REGISTRO UFFICIALE  
0004515 - 13/02/2020 - USCITA



To ESFRI Chair  
Mr. Jan Hrušák  
[hruusak@kav.cas.cz](mailto:hruusak@kav.cas.cz)

Cc dott.ssa Gelsomina Pappalardo  
[gelsomina.pappalardo@imaa.cnr.it](mailto:gelsomina.pappalardo@imaa.cnr.it)


prof.ssa Caterina Petrillo  
[caterina.petrillo@unipg.it](mailto:caterina.petrillo@unipg.it)

Subject: Expression of Political and Financial Support – Roadmap ESFRI 2021 – EPTRI.

On behalf of Italian Ministry of Universities and Research, I'm pleased to inform you that Italy supports the candidature of the EPTRI project for the ESFRI Roadmap 2021.

Furthermore, based on the coordinator role played by Italy in leading the development of the project, the broad national and international scientific interests that has been raised and the high impact that this project will potentially have on Italian science, education and innovation, Italy also expresses its commitment to support the EPTRI project in its implementation and operation phases.

IL MINISTRO  
Prof. Gaetano Manfredi



# Expression of Commitment (EoC)



We have asked all participating Institutions a letter of financial commitment (EoC) which will serve to demonstrate that EPTRI can be self-sustainable.

The requested contribution is of 15k/year and it can be provided in terms of in-kind (HR) or in cash.

In the meanwhile we are working on different ways of financial sustainability i.e. **INFRAIA-02-2020 call**, ESFRI participation with Governments financial contributions ect..

# Integrated activities

**Deadline postponed to May 14**

## Networking activities

To foster a culture of co-operation between research infrastructures, scientific communities, industries and other stakeholders as appropriate, and to help develop a more efficient and attractive European Research Area

## Joint research activities

To improve, in quality and/or quantity, the integrated services provided at European level by the infrastructures

## Trans-national access or virtual access activities

To support scientific communities in their access to the identified key research infrastructures

**INFRAIA  
02-2020**

All three categories of activities are mandatory as synergistic effects are expected from these different components.

THANK YOU!