Paediatric Clinical Research Infrastructure Network
PedCRIN

CSA_ H2020-INFRADEV-2016-2017/H2020-INFRADEV-2016-1 (Individual support to ESFRI and other world-class research infrastructures)
Grant Agreement # 731046

Deliverable D4.2
Criteria for projects selection

Date of preparation: 15th February 2017

Working Package: WP 4

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PedCRIN call for multinational clinical trials in children and neonates

Supporting multinational extension of paediatric clinical trials funded in the coordinating country

Deadline for application: 2nd May 2017 at 17.00 CET

PROPOSAL TEMPLATE

Instructions:

This template is the **required** proposal format, to be completed in full. Please ensure that you follow the instructions bellow:

- Type your responses within the boxes of this template
- The maximum length for brief summary should not exceed more than half a page
- Please return this with a copy of study protocol including a monitoring plan
- Also send documents providing evidence for funding in the coordinator's country and if available the evaluation summary report of the funding application

1. General Information

Study Title	
Sponsor	
Principal investigator (PI)	
Telephone	
Email	

2. Brief Summary

Provide a brief summary of the project *(Max half page)*

3. Timelines

Start date	
End date	

4. Eligibility

1. Is the study : multi-center paediatric or neonatal therapeutic interventional clinical study on medicinal products	Yes ☐	No ☐
2. Is the study Investigator-initiated	Yes ☐	No ☐
3. Is the study conducted in at least three European countries, among the eighteen (18) members of the PedCRIN consortium (Austria, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, United Kingdom)	Yes ☐	No ☐
If YES, please provide names of countries		

5. Subject Population (Neonate/Paediatric)

Briefly describe the subject population to be recruited for this study (disease diagnosis, etc.)		
1. Subjects	Acute ☐ Chronic ☐ Healthy ☐	
	Neonate	

2. Age Range	**Paediatric** *(Under 18years of age)*	
	Both	
3. Gender	Male ☐ Female ☐ both ☐	
4. Expected number of patients that will be enrolled in the study		
5. Follow-up period		
6. Provide information on patient recruitment rate in the study		
7. Total no. of the patients already included in the study		

6. Funding evidence

Provide evidence for secured funding in the coordinating country	
Please provide evaluation report if any?	

7. Study autorisation obstacles

Are there any obstacle to authorization by	
Ethics Committees	Yes ☐ No ☐
Competent authorities	Yes ☐ No ☐
If yes please specify	

8. Risk & risk mitigation

Is there any risk assessment and risk mitigation strategy to overcome potential roadblocks

9. Requested services

Please provide details about study management services		
1. Interaction with ethics committees and competent authorities (submission and follow-up)	Yes ☐ No ☐	*If yes please specify*
2. Support for insurance contracting	Yes ☐ No ☐	*If yes please specify*

3. Translation, back-translation of relevant documents and adaptation of informed consent	Yes ☐ No ☐	*If yes please specify*
4. Site monitoring	Yes ☐ No ☐	*If yes please specify*
5. Local support to adverse event reporting	Yes ☐ No ☐	*If yes please specify*
6. Investigational Medicinal Product (IMP) management	Yes ☐ No ☐	*If yes please specify is it*
7. Is the cost of study management secured in the coordinating country	Yes ☐ No ☐	*If yes please specify the name of country*
8. Is the cost related to patient investigation secured in the coordinating country	Yes ☐ No ☐	*If yes please specify*

10. Please provide estimated budget for study management services

Estimated budget for study management services

Evaluation Criteria

A scoring system from 0 to 5 will be used to evaluate the applications with respect to the different evaluation criteria.

Each item (1.to 4.) will be rated by using rating system of 0-5 scores per category. Proposals with a combined (total) score below 15/20 will be excluded, as well as a proposals whose one or more criteria are scored below 3/5 per item.

Evaluation items

1. Scientific excellence
2. Quality of the methodology
3. Medical relevance, impact on public health and ethical dimension
4. Feasibility of the study within the timelines and in line with the budget (including evidence of secured funding in the coordinating country)
    - Without obstacle to authorization by ethics committees and competent authorities
    - Evidence for rapid patient recruitment
    - Short follow-up period

- Budget for services in the range of €300k to €500k
- Appropriate risk assessment and risk mitigation strategy to overcome potential roadblocks

Scoring system

Score	Rating	Definition
0	**Failure**	The proposal fails to address the criterion in question, or cannot be assessed because of missing or incomplete information
1	**Poor**	The proposal shows serious weaknesses with regards to the criterion in question
2	**Fair**	The proposal generally addresses the criterion, but there are significant weaknesses that need corrections
3	**Good**	The proposal addresses the criterion in question well but certain improvements are necessary
4	**Very good**	The proposal addresses the criterion very well, but small improvements are possible
5	**Excellent**	The proposal successfully addresses all aspects of the criterion in question