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 D3.1**
**Survey on infrastructure and service needs for paediatric and neonatal trials**

Date of preparation: 21\textsuperscript{st} March 2017

Working Package: WP 3

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PedCRIN - Survey on infrastructure and service needs for paediatric and neonatal trials

Dear Colleague,

The H2020-funded project PedCRIN (Paediatric Clinical Research Infrastructure Network, GA 731046) has recently launched its activities to enrich the ECRIN tools and actions with paediatric specificities.

In order to optimize the forthcoming PedCRIN services and activities, we sought your collaboration in the identification of the needs and expectations of paediatric medical research communities.

For this purpose, we kindly ask you to complete the following brief questionnaire (5 minutes).

Please do not hesitate to contact us at the following e-mail address (helpdesk@teddynetwork.net) for any question about the survey and any further information.

Thank you in advance for your collaboration!

There are 18 questions in this survey

I. GENERAL

[ ] Your name *

Please write your answer here:

[ ] Your organisation *

Please write your answer here:

[ ] Your country *

Choose one of the following answers

Please choose only one of the following:

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
Cocos (Keeling) Islands
Colombia
Comoros
Congo
Congo, Democratic Republic of
Cook Islands
Costa Rica
Côte d'Ivoire
Croatia
Cuba
Curaçao
Cyprus
Czech Republic
Denmark
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Falkland Islands
Faroe Islands
Fiji
Finland
France
French Guiana
French Polynesia
French Southern Territories
Gabon
Gambia
Georgia
Germany
Ghana
Gibraltar
Greece
Greenland
○ Panama
○ Papua New Guinea
○ Paraguay
○ Peru
○ Philippines
○ Pitcairn
○ Poland
○ Portugal
○ Puerto Rico
○ Qatar
○ Réunion
○ Romania
○ Russian Federation
○ Rwanda
○ Saint Barthélemy
○ Saint Helena
○ Saint Kitts and Nevis
○ Saint Lucia
○ Saint Vincent and the Grenadines
○ Saint-Martin (France)
○ Samoa
○ San Marino
○ Sao Tome and Principe
○ Saudi Arabia
○ Senegal
○ Serbia
○ Seychelles
○ Sierra Leone
○ Singapore
○ Sint Maarten (Dutch part)
○ Slovakia
○ Slovenia
○ Solomon Islands
○ Somalia
○ South Africa
○ South Georgia and the South Sandwich Islands
○ South Korea
○ South Sudan
○ Spain
○ Sri Lanka
- Zambia
- Zimbabwe
- Other

[ ] Email address *

Please write your answer here:
I. GENERAL

[ ] Your profile *

Check all that apply

Please choose all that apply:

☐ Paediatrician
☐ Specialty paediatrician
☐ Medical Doctor
☐ Researcher from academy/research centre
☐ Pharmacologist
☐ Pharmacist
☐ Other: ___________________________

[ ] Please specify the specialty

Only answer this question if the following conditions are met:
Answer was at question ‘5 [a5]’ (Your profile)

Please write your answer here:


[ ] Your disease-related area *

Check all that apply

Please choose all that apply:

☐ Neonatology
☐ Neonatal/paediatric Intensive Care
☐ Cardiology/Vascular Diseases
☐ Endocrinology/Gynaecology
☐ Gastroenterology
☐ Haematology
☐ Immunology/ Rheumatology
☐ Infectious Diseases
☐ Nephrology
☐ Neurology/ Psychiatry/Psychology
☐ Nutrition
☐ Oncology
☐ Pulmonary/Respiratory
☐ Surgery
☐ Other: ___________________________
II. PREVIOUS EXPERIENCE IN PAEDIATRIC CLINICAL RESEARCH

[ ] Did you actively take part in any clinical trials involving paediatric subjects (0-18 years)? *

Please choose only one of the following:

- Yes
- No

[ ] Did any of the trials you took part in involve pre-term and term neonates? *

Only answer this question if the following conditions are met:
Answer was 'Yes' at question '8 [a7]' (Did you actively take part in any clinical trials involving paediatric subjects (0-18 years)?)

Please choose only one of the following:

- Yes
- No

[ ] Please specify your role in the clinical trial *

Only answer this question if the following conditions are met:
Answer was 'Yes' at question '8 [a7]' (Did you actively take part in any clinical trials involving paediatric subjects (0-18 years)?)

Check all that apply

Please choose all that apply:

- Principal Investigator
- Co-investigator
- Other: [ ]
III. NEEDS FOR INFRASTRUCTURE SERVICES AND TOOLS FOR PAEDIATRIC CLINICAL TRIALS

Research infrastructures (RIs) provide services to the scientific community to conduct top-level research in their respective field. PedCRIN is supported by the European Commission to develop services and tools for paediatric trials within ECRIN (www.ecrin.org). This questionnaire will be used to establish priorities in the development of paediatric clinical research tools by PedCRIN.

[] Please indicate, for which of the following activities do you think a research infrastructure for paediatric clinical research should provide support to?
<table>
<thead>
<tr>
<th>Item</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design protocols for paediatric interventional clinical trials</td>
<td>0</td>
</tr>
<tr>
<td>Design protocols for paediatric non-interventional clinical studies</td>
<td>0</td>
</tr>
<tr>
<td>Identification of the target population</td>
<td>0</td>
</tr>
<tr>
<td>Statistical methodology for paediatric clinical trials</td>
<td>0</td>
</tr>
<tr>
<td>Application of innovative study design</td>
<td>0</td>
</tr>
</tbody>
</table>

Please choose the appropriate response for each item:
**COLLABORATION AND SUPPORT FOR CLINICAL TRIALS START-UP**

*Please choose the appropriate response for each item:*

<table>
<thead>
<tr>
<th>Item</th>
<th>0 - No need at all</th>
<th>1 - Slightly needed</th>
<th>2 - Moderately needed</th>
<th>3 - Very needed</th>
<th>4 - Extremely needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of relevant network/scientific societies to help the selection of clinical trial sites</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Establishing contacts with Young Patients Advisory Groups/Patients Advisory Boards/Patients Associations</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Identification of relevant calls for funding paediatric trials at Eu/international level and support for project application</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Involvement of parties and subcontractors to define the distribution of all the responsibilities and tasks related to clinical trials (including CROs, insurance companies, etc)</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Preparation of standard models agreements for the implementation of clinical trials</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Definition of a budget model based on standard costs for general activities, investigation (per patient), services, etc</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
### REGULATORY EXPERTISE

* Please choose the appropriate response for each item:

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No need at all</td>
<td>Slightly needed</td>
<td>Moderately needed</td>
<td>Very needed</td>
<td>Extremely needed</td>
</tr>
<tr>
<td>Database of national regulatory and ethical requirements for paediatric trial authorisation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
</tr>
<tr>
<td>Preparing and submitting documents to Ethics Committees/Competent Authorities for the approval/authorisation of paediatric clinical trials</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
</tr>
<tr>
<td>Preparing consent and assent models + Patient information sheet, including clinical trials involving special patients populations (PICU, NICU, neonates, neurological impairment, etc)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
</tr>
<tr>
<td>Preparing the Investigator’s Brochure for submission</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
</tr>
<tr>
<td>Interaction with national/European regulatory agencies</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tr>
</tbody>
</table>
PAEDIATRIC PHARMACOVIGILANCE

Please choose the appropriate response for each item:

<table>
<thead>
<tr>
<th>Method</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods for identifying and communicating ADRs in paediatric patients</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Age-adapted scales for severity and causality assessment in paediatric patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Targeted Serious Adverse Events notification forms, age-adjusted</td>
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</tr>
<tr>
<td>Certification of pharmacovigilance expertise</td>
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</tr>
</tbody>
</table>
PAEDIATRIC CLINICAL TRIALS CONDUCT ACCORDING TO GCP AND PAEDIATRIC GUIDELINES/RECOMMENDATIONS

Please choose the appropriate response for each item:

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No need at all</td>
<td>Slightly needed</td>
<td>Moderately needed</td>
<td>Very needed</td>
<td>Extremely needed</td>
</tr>
</tbody>
</table>

- Design Case Report Forms for paediatric studies
- Managing paediatric clinical trial data (data-management) (collection, integration, validation and analysis of clinical trial data)
- Managing paediatric IMPs (drug management) (packaging, labelling, delivering, storing, administering, accountability, disposal)
- Managing paediatric clinical trial technical aspects & logistics (e.g. shipping agent, operative instructions, laboratory procedures, biobank samples management, etc.)
- Preparation of monitoring plans, also based on risk-based approach
- On-site and remote monitoring visits and reporting
**TRAINING**

* Please choose the appropriate response for each item:

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<tr>
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<td>Very needed</td>
<td>Extremely needed</td>
</tr>
</tbody>
</table>

- Training regarding Good Clinical Practices, including responsibilities of principal investigators, co-investigators and study nurses involved in paediatric clinical trials:
  - [ ]
- Training course(s) designed for specific paediatric/neonatal trials:
  - [ ]
- Training on drug safety and toxicity stratified by age:
  - [ ]
III. NEEDS FOR INFRASTRUCTURE SERVICES AND TOOLS FOR PAEDIATRIC CLINICAL TRIALS

[]
Please list any other activity for which do you think that it is required support from a research infrastructure

Please write your answer here:
Thank you for the collaboration.

PedCRIN Project team

Submit your survey. 
Thank you for completing this survey.