



Paediatric Clinical Research Infrastructure Network PedCRIN

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Deliverable D1.4 Advisory Board Report #3

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Working Package: WP1 (ECRIN)

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1. Executive summary

The current document is the third report on the activities of the PedCRIN project's External Expert Advisory Board (EEAB). The document summarises the key points of the meetings, as well as the recommendations suggested by the experts for the period M28 (May 2019) until M36 (29th January 2020).

2. Advisory Board Members

The member list of the EEAB has remained unchanged, as the experts involved from the beginning of the project were capable to cover all the needs emerged.

The PedCRIN EEAB members are shortly presented below along with their updated expertise:

| | |
|---------------------------------------|---|
| Pr Thierry Lacaze | Neonatologist and the section head of neonatology at the Cumming School of Medicine. And the regional program director of Neonatology at Alberta Health Services. |
| Prof. dr. C.B. (Kit C.B.) Roes | Leads the methodology group UMC Utrecht Clinical Trial Center. |
| Pr Régis Hankard | Professor of Pediatrics at the University François Rabelais in Tours and the coordinator of PedStart-CIC. |

A short description of their qualifications and position can also be found on the PedCRIN website: <https://www.ecriin.org/pedcrin-advisory-board>

3. Activities of the PedCRIN Advisory Board

Throughout the whole duration of the PedCRIN project, the consortium has kept a continuous and fluent communication with the members of the EEAB. The 3rd EEAB meeting provided a careful oversight regarding the overall management of the project, sustainability of PedCRIN, tools developed for the neonatal and the paediatric clinical trials, the progress of the PedCRIN funded pilot trials (WE study, OTBB3 & POPART) and the patient involvement and communication plan and outcomes achieved during the third year of the project.

4. Meeting Overview

The Third Advisory Board meeting was held in ECRIN Paris on 29th January 2019. Leaders and co-leaders of each work package (WP1-5) provided an update to the advisory board members about their activities. Following the update by the WPs several interesting and useful recommendations were provided by the PedCRIN Advisory Board members.

5. Advisory Board Recommendations

Recommendations by the Advisory Board

Jan 29, 2020

Pr. Thierry Lacaze, Pr Régis Hankard, Prof dr Kit CB Roes

Comments/Recommendations

PedCRIN project Overview (WP1)

- PedCRIN goals were reminded as well as the background for the development of the other paediatric projects and the inter-related challenges.
- Instead of focusing on the overlaps and duplication, suggestion was made to concentrate on taking the best advantage of all these paediatric projects in order to build something comprehensive. The board proposed also to take advantage of projects/discussions that are broader than paediatric such as challenges related to data; data sharing, data reuse and HER.
- Overall, good progression of the PedCRIN project.

Sustainability, strategy, governance, business plan (WP2)

- Need to update the strategy plan and to organize the sustainability board meeting including government representatives from 18 countries participating in the project; countries already members of ECRIN through ECRIN Assembly of Members and the PedCRIN partners not ECRIN members such as Austria, Finland, Greece, Estonia, The Netherlands, UK and Sweden, through their relevant ministry representatives.
- After the end of the funding of the project, one objective is to establish a long-term collaboration between the paediatric community and ECRIN so that the tools and standards developed during the project could be maintained, updated and made available to the paediatric community and this should be the part of the sustainability plan.
- As the project is close to its end, sustainability should be the priority in the coming months.
- Suggestion to broadly use the tools developed within the PedCRIN project when possible to avoid reinventing the wheel.

Tools for neonatal & paediatric trials (WP3)

CTU certification Criteria

- Valuable document that would require external validation, testing and identification of problems in fulfilling the requirements and then dissemination through appropriate channels.
- Suggest to use the term requirements rather than criteria.
- The document (used as check list) could help units to develop, keeping in mind that not all the tasks have to be in a single place but can be distributed in several units as the CTUs organization and functions vary depending on country.
- It is also suggested to bench mark the CTUs that are doing the c4c investigator initiated trials against this criteria document and track success.

Neonatal and paediatric tools

- Advisory board would like to congratulate the PedCRIN WP3 team for its achievements. The work done for tool development is impressive particularly for neonates. After the end of the PedCRIN project, it is critical to ensure these tools remain available for further projects and adapted to future standards in paediatric clinical research.
- Input from professional organisations would be a plus, however should not delay the finalization of these tools and making them available to the paediatric community.

Pilot Trials (WP4)

- Needs to put efforts to finalize the two trials POPART (already near to reach the target) and WE (experiencing difficulties in the recruitment). For WE, one option already discussed with PI was to open more sites (either by extending to new countries or opening new sites in the 2 countries already involved). This was not considered by the PI as they are working with investigators they used to collaborate with and expert centers. It would be interesting to know if the slow recruitment is due to unavailability of the patients or the lack of resources at site level.
- OTBB3 trial is a very useful case study to show the needs to be considered during the selection process and risks evaluation and what type of funding would be suitable for such type of trials. It is important to think about the allocation of the OTBB3 trial leftover funding to the other two studies.
- Important to report about lessons learnt (success and failure) and publish about challenges encountered in setting multinational paediatric clinical trials for the benefit of future trials. To this end, the questionnaire developed to collect PIs and investigators feedback and followed by structured interviews will be a useful instrument.

Patient and parents' involvement (WP5)

- Comparison of YPAG feedback with those of patients groups would be interesting.
- Prepare the dissemination campaign for the tools including social media and communication towards general public.

Annex1: Agenda of the PedCRIN Advisory Board 2020



Agenda: PedCRIN Advisory Board Meeting 29th January 2020

Venue: ECRIN, Salle de Conseil 5 rue Watt, Paris, 75013

| Time: | Description: | Who: |
|-------------|--|---|
| 10h30-11h00 | Arrival/Coffee | |
| 11h00-11h20 | WP1: PedCRIN Project overview | Prof Jacques Demotes |
| 11h20-11h40 | WP3: Tools for neonatal trials | Donato Bonifazi |
| 11h40-12h00 | WP3: Tools for paediatric trials | Evelyne Jacqz-Aigrain |
| 12h00-12h20 | WP4: Pilot trials | Saskia De Wildt Lepola Pirkko Christine Kubiak |
| 12h20-12h40 | WP2: Sustainability, strategy, governance, business plan | Mark Turner |
| 12h40-13h00 | WP5: Communication, dissemination, empowerment | Joana Claverol Torres Eric Vermeulen |
| 13h00-14h00 | Lunch | |
| 14h00-16h50 | General discussion and recommendations by the Advisory Board | Pr. Thierry Lacaze Prof dr Kit CB Roes Pr Régis Hankard |
| 16h50-17h00 | Any other business | |

PedCRIN WP1: Advisory Board meeting _29th January 2020



PedCRIN has received funding from the European Union's Horizon 2020 programme under grant agreement number 731048

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Annex 2 : List of the PedCRIN Advisory Board participants



Project Title:

Work Package:

Name of the organising Project Partner Organisation:

LIST OF PARTICIPANTS PedCRIN WP1: Advisory Board Face-to-face Meeting 29th January 2020

Salle du Conseil Ecrin-Éric Office Paris BioPark, 5 Rue Watt, Paris, 75013
Salle du Conseil (11h00-17h00)

| | Board Members | Organisation | Available |
|---|---------------------|-----------------------------------|-----------------------------------|
| 1 | Pr Régis Hankard | INSERM | GoToMeeting (Yes) |
| 2 | Pr. Thierry Lacaze | Alberta Health Service (AHS) | Yes |
| 3 | Prof Dr Kit CB Roes | University Medical Center Utrecht | Yes <i>GoToMeeting (Yes)</i> |
| 4 | Mark Tuner | University Liverpool (WP2) | Yes <i>Yes</i> |
| 5 | Donato Bonifazi | CVBF (WP3) | GoToMeeting (No) |
| 6 | Cristina Manfredi | CVBF (WP3) | GoToMeeting <i>Yes available.</i> |
| 7 | Tessa VanderGeest | Radboudumc (WP4) | GoToMeeting (No) |
| 8 | Saskia deWildt | Radboudumc (WP4) | GoToMeeting (No) |

PedCRIN WP1: Advisory Board meeting _29th January 2020



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|----|-------------------------|--------------|--------------------------------------|
| 9 | Janna Kallio | HUSFI (WP4) | GoToMeeting Yes <i>yes available</i> |
| 10 | Pirkko Lepola | HUSFI (WP4) | Yes <i>[Signature]</i> |
| 11 | Evelyne Jacqz-Aigrain | INSERM (WP3) | Yes <i>[Signature]</i> |
| 12 | Beate Aurich | INSERM (WP3) | Yes <i>[Signature]</i> |
| 14 | Joana Claverol Torres | FSJD (WP5) | Yes <i>[Signature]</i> |
| 15 | Begonya Nafria Escalera | FSJD (WP5) | GoToMeeting (No) |
| 16 | Eric Vermeulen | VSOP (WP5) | GoToMeeting Yes <i>yes available</i> |
| 17 | Jacques Demotes | ECRIN (WP1) | Yes <i>[Signature]</i> |
| 18 | Christine Kubiak | ECRIN (WP1) | Yes <i>[Signature]</i> |
| 19 | Salma Malik | ECRIN (WP1) | Yes <i>[Signature]</i> |
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