Call for experts in paediatric clinical trials

Conect4children (c4c, www.conect4children.org) invites you to apply for **membership of a Clinical Expert Group** in your area of paediatric drug research.

c4c is an EU funded pan-European consortium with a general aim of facilitating the development and availability of new medicines for babies, children and young people through the creation of a large collaborative paediatric network. One task of the consortium is to deliver the advice needed to improve child health and paediatric medicine development.

Groups of experts (methodological, clinical, and parents/patients) will be set up to provide Strategic Feasibility advice to individual requests from pharmaceutical industry and academic consortia in conducting feasible, innovative and scientifically sound paediatric clinical trials.

Therefore, we are now seeking experts interested to be part of **Clinical Expert Groups** and provide advice.
This call is for clinical experts. For methodology experts, a separate call is being launched.

Who should apply?
Physicians who have been or are practising in their respective paediatric field for more than 5 years and have interest in paediatric clinical trials . Experience as investigator in academic or industry led clinical trials or advisorships for pharmaceutical industry and/or regulatory agencies would be an advantage. Please also look at the suggested criteria for expert group members at the bottom of this letter. We actively encourage physicians with a strong clinical expertise in a specialized field, mid-career physicians, including from across Europe to apply.

Criteria for experts (not all criteria have to be met):

- Has relevant expertise in a specific drug development research field of > 5 years and is currently active in the field of expertise.
- Has knowledge in pediatric clinical trials and the regulatory process (e.g. been lead or co-lead investigator, member of protocol writing committee in academic or industry driven clinical trial).
- Has capacity to provide a minimum of 2 expert advices yearly.
- Is actively taking care of patients in the appropriate therapeutic area.

We aim for diversity, including representatives from different career levels, genders, European regions and from a wide range of clinical subspecialties. If you are a clinician specialized in a very specific patient population, but with less experience in research, we still invite you to apply.

We are looking for approximately of 8-20 experts per group with a diverse background; we may have to do a selection out of the applications. This does not mean we will not need you in the future, as requests maybe very specific. Hence by applying you agree that we keep your contact details in our database so we will able to approach you at later stage.

What I am expected to do?

1. Be available to provide advice on clinical aspects of paediatric clinical trials for at least two projects per year in the *ad hoc* ''strategic feasibility advice groups". When requests for expertise come to c4c, the WP4 leadership together with the relevant Clinical Expert Group leads will form these ad hoc ''strategic feasibility advice groups". These groups may also contain methodology experts and patient/parents.
2. Contribute to the development of a standing expert group in your area. We have already nominated expert group leads for most groups whose task is to organise and develop each expert group.
3. Your expertise may be requested but not limited to on following issues: is the study design the most appropriate, up to date, innovative, meaningful and feasible or is this study design ethically sound. You may also be involved in Paediatric Investigational Plans (PIPs) by advising pharmaceutical industry on relevant indications together with the best approach to paediatric development. We would like to emphasize that the trial operational feasibility issues are not the task of clinical expert groups.
4. Be available for 3 years as expert member, with the possibility to prolong for another term of 3 years if both parties agree

How will I benefit?

1. Involvement in the design of pediatric trials resulting in financial (industry requests) and/or academic recognition.
2. Opportunity to work with your expert group on White papers on innovative methodology.
3. Expand your network and visibility.

Which groups can I apply for:

Gastroenterology & hepatology	lead Nick Croft
Endocrinology & Diabetes	lead Thomas Danne
Reumatology & Autoimmune diseases	lead Nicola Ruperto
Infectious diseases & Vaccinology	lead Theoklis Zaoutis
Cardiology	lead Wim Helbing
Neuroscience & epilepsy	lead Helen Cross
Neuromuscular diseases	lead Volker Straub
Metabolic diseases	lead Maurizio Scarpa
Oncology	lead Gilles Vassal
Nephrology	lead Franz Schaefer
RSV	lead Louis Bont
Respiratory	lead Jonathan Grigg
Intensive care	lead to be nominated
Psychiatry	lead Alessandero Zuddas

Cross-cutting themes/expert groups

Neonatology	lead Karel Allegaert
Adolescent Medicine	lead Alessandero Zuddas

How to apply?
You should fill in the online application form, including motivation and add a short CV.

How is this work reimbursed?
The time that you spend on giving expert advice to pharmaceutical companies will be reimbursed. In addition, expert group leads have been allocated funds to develop the expert groups, e.g. for organizing meetings, travel costs, some secretarial support.

What are the timelines?

Deadline for applications is	26.03.2019
Notification of acceptance	26.04.2019

Additional information
WP4 secretariat – conect4childrenwp4@radboudumc.nl
Prof. Irja Lutsar - Lead Clinical Expert Groups- irja.lutsar@ut.ee
Prof. Saskia de Wildt – Lead Methodology Groups Lead - Saskia.deWildt@radboudumc.nl

We are looking forward to your application.

C4c WP4 Leadership team