

To: Leads methodology expert groups

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-	conect4childrenwp4@radboudumc.nl	

Subject
Membership of Methodology Expert Group(s)

Dear WP4 Methodology Expert lead,

We kindly ask you to distribute the following call for c4c Experts within your wider network (websites of societies, newsletters, LinkedIn).

Please do not hesitate to contact us if you have any questions.

Yours sincerely,

Prof. Saskia de Wildt - Lead Methodology Expert Groups & WP4 Academic Lead - Saskia.deWildt@radboudumc.nl
Prof. Irja Lutsar - Lead Clinical Expert Groups- irja.lutsar@ut.ee

Call for experts in paediatric clinical trials

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

c4c is an EU funded pan-European consortium with the 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 expert advice, known as *Strategic Feasibility Advice*, to improve child health and paediatric medicine development.

Groups of Experts (methodological, clinical, and [parents/patients](#)) were set-up in 2019 to provide advice services to individual requests from c4c industry and academic beneficiaries.

Currently we are now expanding our network of Experts and are seeking Experts interested to be part of **Methodology Expert Groups** to provide advice. Depending on the nature of the incoming advice request, experts from the relevant Expert Group will be selected to form an Ad-Hoc Strategic Feasibility Advice group to provide the advice.

This call is for methodology experts. A separate call is being launched for clinical experts, in paediatric subspecialties.

Who should apply?

People with an expertise in methodology related topics. Experience as an investigator in academic or industry led clinical trials or advised for pharmaceutical industry and/or regulatory agencies would be an advantage but is not a requirement. Please also look at the suggested criteria for Experts down below. We actively encourage Methodologists with a strong expertise in a specialized field, mid-career physicians, including all regions of Europe to apply.

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

- Relevant expertise in a specific (paediatric) drug development research field of > 5 years and is currently active in the field of expertise.
- Knowledge in and experience with methodology advisement and is familiar with regulatory requirements within drug development research.
- Capacity to provide a minimum of 2 expert advices yearly.
- Enthusiastic to contribute to building an international expert group in his/her field.

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

We are looking for core and/or extended Experts with a diverse background.

Core Experts will, as well as providing advice, be involved in group meetings, twice a year, and will support the lead in building the Expert Group network and collaboration on quality improvement activities. Extended Experts will mainly be involved in the advice services but are expected to contribute to other activities.

In your application, please indicate whether you would prefer to be a core or an extended Expert. Depending on the number of applications received, we may carry out a selection process of received applications. This does not mean we will not need you in the future, as requests may be very specific. Hence by applying you

agree that we keep your contact details in our database (for 5 years) so that we can approach you at a later stage. Data will be stored in compliance with the c4c Advisory Group Privacy and data protection policy.

What are you expected to do?

Core & Extended Experts

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 advice are received c4c, the WP4 leadership and the relevant Clinical Expert Group Leads will select appropriate expert group members to form these *ad hoc* "strategic feasibility advice groups" (one for each advice request). These groups may also contain methodology experts and patient/parents.
2. Your expertise may be requested (but not limited to) on following issues: is the study design (incl. Assessments, targeted population, endpoints etc) the most appropriate, up to date, innovative, meaningful and feasible and/or is this study design ethically sound. You may also be involved in Paediatric Investigational Plans (PIPs) by advising c4c industry partners on their paediatric plans or responses to regulatory agency comments. We would like to emphasize that site feasibility issues are not the task of clinical expert groups.
3. Be available for 3 years as expert member, with the possibility to prolong for another term of 3 years if both parties agree.

Core Experts only

1. Contribute to the development of the Expert Group in your area of expertise. By working together with the Expert Group Lead on quality improvement action items, building the network, gain visibility for c4c, build collaborations with already existing networks etc. A meeting with the core Expert of the Clinical Expert Group will be organised at least twice a year to support these activities. As a core Expert you are expected to participate to these meetings.

How can you benefit?

1. Involvement in the design of paediatric trials
2. Opportunity to work with your expert group on (White) Papers on innovative methodology
3. Expand your network and visibility
4. Opportunity to follow the following courses (1) concepts of Paediatric Investigational Plan (2) Paediatric GCP

Which groups can I apply for:

Name Expert Group	Expert Group Lead	Specifics requested (if applicable)
Development Pharmacology	Anne Smits	
Ethics	Dirk Lanzerath	
Formulations	Catherine Tuleu	
Health Technology Assessment	Francesco Moretti	Core as well as extended Experts preferred. Need for expertise in health economics
Pharmacometrics	Jean Marc Treluyer	
Pharmacogenomics and other OMICS technologies	Matthias Schwab	Expertise in specific omics technologies e.g. mass spectrometry, next generation sequencing, AI is a preferred
Pharmacovigilance	Ian Wong	

Study design & Clinical Trial Methodology	Kit Roes	Core as well as Extended Experts are welcome. Need to have either background as statistician or data management, specifically FAIR data, reuse of data, historical control of data etc.
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How to apply?

You should fill in the online [application form](#), including motivation a short CV, highlighting your expertise.

How is this work reimbursed?

The time that you spend on giving Strategic Feasibility Advice to c4c industry partners will be financially reimbursed. In case of providing Strategic Feasibility Advice to an academic requester academic recognition is the intended reimbursement for your time. 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	28.03.2022
Notification of acceptance	30.04.2022

Additional information

WP4 secretariat- conect4childrenwp4@radboudumc.nl

Prof. Saskia de Wildt - Lead Methodology Expert Groups & WP4 Academic Lead - Saskia.deWildt@radboudumc.nl

Prof. Irja Lutsar - Lead Clinical Expert Groups- irja.lutsar@ut.ee

We are looking forward to your application.
C4c Advisory Service Leadership team