



## PRESS RELEASE

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# First site open for patient recruitment into ‘Kawasaki Disease Coronary Artery Aneurysm Prevention trial (KD-CAAP)’ study

**The first site is open to recruitment into one of the three inaugural studies which will be utilising the infrastructure and resources of the conect4children network**

The IMI conect4children (c4c) consortium are pleased to announce that the first site is now open for the ‘Kawasaki Disease Coronary Artery Aneurysm Prevention trial (KD-CAAP)’ study as of 28 September 2020 at Great Ormond Street Hospital NHS Foundation Trust. Kawasaki disease is a disease where arteries, particularly the coronary arteries in the heart, become inflamed, sometimes causing irreversible heart damage, heart attacks or even death. To prevent heart damage, Kawasaki disease in children and young people must be recognised by clinicians early, and promptly treated with anti-inflammatory medicines. This study will assess the effectiveness of adding steroids to standard treatment in children with Kawasaki Disease, and aims to recruit 262 children as part of the study. The study will continue to open in approximately 60 sites in 15 countries across Europe.

In April 2019, c4c announced the selection of its first portfolio of pan-European paediatric studies, aimed at advancing the understanding of high priority medicines commonly used in babies, children and young people in Europe. The KD-CAAP study is the first of the proof of viability studies, to begin recruitment. The other academic studies, shown below, plan to begin recruitment later this year, despite initial delays due to the COVID-19 pandemic.

- **TREOCAPA Paracetamol in Premature Babies:** will assess the effectiveness of paracetamol on the closure of the ductus arteriosus and the increase in surviving without severe morbidity of extreme premature infants. The study aims to recruit around 800 babies in 17 European countries. (Lead: Prof. Jean-Christophe Roze of INSERM, a public research organization in Paris, France entirely dedicated to human health)

- **cASPerCF** Prospective validation and clinical evaluation of a new posaconazole dosing regimen for children and adolescents with cystic fibrosis and Aspergillus infection. The study will assess the dose of posaconazole in children and young people with Cystic Fibrosis and Aspergillus infection and aims to recruit 135 children as part of the study (Lead: Prof Adilia Warris of the MRC Centre for Medical Mycology, University of Exeter, Sponsor: Ospedale Pediatrico Bambino Gesù (OPBG), a children’s hospital in Rome, Italy).

These studies will be the first to leverage the scientific quality, rigor and capabilities of the c4c network, a global consortium of more than 30 academics, 10 industry partners and a network of more than 500 affiliated partners. The research collaboration will be used to build and implement a pan-European paediatric clinical trial network whose goal is to improve the European paediatric clinical trial infrastructure in order to facilitate the development of new, innovative and safer medicines for children in Europe.

Paul Brogan, KD-CAAP study sponsor, spoke about the value of the c4c consortium:

“c4c has provided a paediatric network to deliver clinical trials for children in the UK and Europe. This vision will be transformative for more efficient and rapid delivery of clinical trials in paediatrics, [which is] much-needed. In the future it will also facilitate better working with pharma, thus allowing study of novel therapeutics for children.”

More information about each of the studies is available here:

- [KD-CAAP](#)
- [TREOCAPA](#)
- [cASPerCF](#)

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**About c4c <optional background information to include in article, where relevant>**

***“Better medicines for babies, children and young people through a pan-European clinical trial network”***

c4c (conect4children) is a large collaborative paediatric network that aims to facilitate the development of new drugs and other therapies for the entire paediatric population in Europe.

It is a pioneering opportunity to build capacity for the implementation of multinational paediatric clinical trials whilst ensuring the needs of babies, children, young people and their families are met.

c4c endeavours to provide a sustainable, integrated infrastructure for the efficient and swift delivery of high-quality clinical trials in children and young people across all conditions and phases of the drug development process.

By emphasizing inclusiveness and collaboration across geographical, specialty, sectoral, cultural and societal backgrounds, c4c will improve infrastructure to support the development of medicines for children.

For further information, please follow the link below to the c4c website:

<https://conect4children.org/>

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**About the c4c consortium**

The c4c research Consortium brings together pharmaceutical companies, paediatric national networks as well as EU multinational sub-speciality networks, large patient advocacy groups, children's hospitals and other public research organisations from across Europe. The project consortium is a novel collaboration between academic and private sectors that include 33 academic and 10 industry partners from 20 European countries.

**A list of c4c beneficiaries is available to view here:**

<https://conect4children.org/network/>

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#### **About the c4c pan-European academic paediatric studies:**

- **TREOCAPA** Paracetamol in Premature Babies: will assess the effectiveness of paracetamol on the closure of the ductus arteriosus and the increase in surviving without severe morbidity of extreme premature infants. The study aims to recruit around 800 babies in 17 European countries. (Lead: Prof. Jean-Christophe Roze of INSERM, a public research organization in Paris, France entirely dedicated to human health)
  - **KD-CAAP** Kawasaki Disease Coronary Artery Aneurysm Prevention trial: will assess the effectiveness of adding steroids to standard treatment in children with Kawasaki Disease, and aims to recruit 262 children as part of the study (Leads: Dr Despina Eleftheriou and Prof. Paul Brogan of the university College of London (UCL), an academic research institution in the UK.
  - **cASPerCF** Prospective validation and clinical evaluation of a new posaconazole dosing regimen for children and adolescents with cystic fibrosis and Aspergillus infection. The study will assess the dose of posaconazole in children and young people with Cystic Fibrosis and Aspergillus infection and aims to recruit 135 children as part of the study (Lead: Prof Adilia Warris of the MRC Centre for Medical Mycology, University of Exeter, Sponsor: Ospedale Pediatrico Bambino Gesù (OPBG), a children's hospital in Rome, Italy).
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#### **About Innovative Medicines Initiative and c4c**

The c4c project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU), Europe's biggest Public-Private Partnership, under grant agreement No 777389. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA (the European Federation of Pharmaceutical Industries and Association).

Under the name c4c, the new research consortium unites pharmaceutical companies, paediatric national networks as well as EU Multinational sub-specialty Networks, large patient advocacy groups, children's hospitals and other public research organisations from across Europe. The full list of organisations involved in the project can be found at the c4c webpage [www.conect4children.org](http://www.conect4children.org).

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#### **Further information**

For more info on IMI visit [www.imi.europa.eu](http://www.imi.europa.eu) and follow on Twitter at @IMI\_JU.

Project Office/General Enquires: Email us. [communication@conect4children.org](mailto:communication@conect4children.org)

For more information about the research studies, contact: *(To be removed if press release is unrelated to 4 academic studies)*

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**Disclaimer**

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