

STAND4kids

SUPPORTING PEDIATRICS TRIALS | PORTUGAL

HIGHLIGHTS

STAND4KIDS AND CONECT4CHILDREN: TOGETHER FOR BETTER PEDIATRIC RESEARCH

May 2018. It's now been almost six years since the formal launch of the European project connected4children (c4c), a public-private partnership funded by what was then the Innovative Medicines Initiative (now IHI). This vast consortium of academic and pharmaceutical industry partners joined forces to tackle the many challenges in developing pediatric medicines, through a multifaceted strategy that included the creation of a pan-European operational trial network, expert advice groups, a training academy, and data-focused activities, partnering professionals, children, and families.

We took on the challenge of joining this consortium because we shared the vision of improving pediatric medicines, whilst recognizing the limitations of our national pediatric research infrastructure, and understanding this was a unique opportunity to progress in this field. Our aims were pragmatic from day one, favoring a solid and measurable stepwise approach, involving key partners and stakeholders, and working towards a sustained and sustainable growth.

Thus, was born STAND4Kids. A National Hub and pediatric trial and research network made up of a team working closely with 10 trial sites that are its starting point and *raison d'être*.



Ricardo Fernandes
Lead STAND4Kids
Chief Medical Officer, conect4children-Stichting

With the support of key partners such as the Portuguese Society of Pediatrics, we seek to showcase and develop our sites' strengths, to empower and invigorate their pediatric community, and thus to contribute to increase research and innovation opportunities for children, young people, and families.

At the core of our activities is our role in supporting and facilitating pediatric clinical trials, using standardized c4c procedures to support sponsors and CROs throughout the entire lifecycle of pediatric studies, to optimize their planning and execution, from feasibility to recruitment. But the network also ensures a range of underpinning activities, providing multiple training content to professionals and the public, dialoguing with stakeholders such as competent authorities, other networks like PtCRIN, and funders, working to involve children, young people, and patient organizations, and contributing with academia to better understand the national pediatric research environment and landscape.



23º National Congress of Pediatrics - 25-27/10/ 2023

CLINICAL STUDIES

Academic Studies



TREOCAPA's recruitment target in Europe has been increased to 769 babies! Our focused site teams have recruited 29 participants so far!

TREOCAPA-LT (Long Term Follow-up)

An observational follow-up of TREOCAPA to assess longer-term outcome among survivors at 2 years corrected aged. S4K has been supporting the planning and implementation.

Industry Studies



Collaboration with Novartis, Bayer and Janssen in 6 *Proof-of-Viability* (PoV) studies and collaboration with MSD in one study.

EDUCATION & TRAINING

Academia c4c: www.academyc4c

Training opportunities with enrolment open:

Until **17 march 2024**:

- *Essential Documents*

Until **30 april 2025**:

- *Paediatric GCP*
- *GCP Refresher course*
- *Involving Children and Young Patients and Families' in Designing Clinical Research*
- *Monitoring*
- *Trial Start up*
- *Development Pharmacology*
- *Concept of Paediatric Investigation Plans (PIPs)*
- *An Introduction to innovative clinical trial design*
- *Practical tips for settings up gene therapy trials*
- *Investigational Medicinal Product Supply*

C4C PARTNERS



BENEFICIARY



THIRD PARTIES



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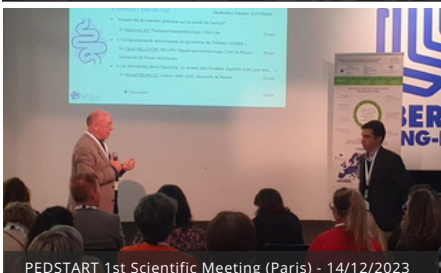
HIGHLIGHTS

The growth and vitality of our network are evident in the recap of our 2023 activities.

- The trial portfolio has grown and now includes **7 industry trials across** with 4 sponsors, in a central and local partnership that grows with experience, collaboration, and mutual knowledge, enabling synergies and providing added value. The academic trial TREOCAPA continued to progress at a good pace with the support of CETERA, the CTU ECRIN.
- We have strengthened our relationships with our sites, through our **Get Together tour with 5 open and operational sessions, and 16 Sharing Sessions online**, on top our routine daily contact.
- We remain in the top 3 in what concerns the use of the educational platform c4c Academy, with **400 users** who have taken advantage of courses such as the pediatric GCP certified and the Advanced course on Paediatric Clinical Trials and Paediatric Drug Development.
- We contributed to various postgraduate training courses and hosted two Master's students from the Clinical Research Master's program at the Faculty of Medicine of the University of Lisbon.
- We met with patient organizations, and the YPAG Lisboa group, the first national Young Persons Advisory Group, pursued its valuable activities.
- We represented the network at **40 events**, national and international, including the National Congress of Pediatrics, and workshops of the ACT-EU initiative of the European Medicines Agency.



World Orphan Drug Congress (Barcelona) - 30/10 a 02/11



PEDSTART 1st Scientific Meeting (Paris) - 14/12/2023

And 2024 promises so much more.

The trial portfolio continues to grow. The Get Together Tour has more dates and destinations, and many more investigators, nurses, study coordinators, leaders, and administrators to meet and engage. The work on Site Standards in which STAND4Kids is involved will progress, in collaboration with the European network Enpr-EMA, and based on the c4c Site Profile database. We will continue to actively collaborate with our 19 sister European networks through our National Hub Forum. We hope the seeds of pediatric communities of research nurses and pharmacists will bear fruit. And we will prioritize expanding contacts with the community of patient organizations.

But the critical challenge is that of sustainability, together with the successor of c4c, the newly created conect4children-Stichting (c4c-S), a nonprofit organization based in the Netherlands. And our team has the privilege of playing a central role in this transition.

Since 2019, we have led one of the Work Packages of c4c, since 2022 we have been contributing to the Network Infrastructure Office, and we are now involved in the leadership of the new c4c-S. In this context, we can broaden our horizons: in a complex pediatric research ecosystem, we will always seek to raise awareness and showcase our clinical and scientific pediatric community, at the European and national levels, and to empower the voices of children and families, from medicines to devices, from common to rare and ultra-rare diseases.

Join us on this journey for better pediatric research.

Ricardo Fernandes

2024

COMING SOON

This year, the STAND4Kids Network will participate and organize several initiatives to promote the network's activities and the dissemination of paediatric clinical trials at national and international level:

Sharing session:
04 april | Online

Get together tour:
15 march | CHLO

National Hub Forum:
20-21 march | Cork, Ireland

STAND4Kids 3^a Progress Meeting:
28 may | Lisbon

c4c General Assembly:
04-06 june | Bergen, Norway

24^o National Congress of Pediatrics:
23-25 october | Vilamoura

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