




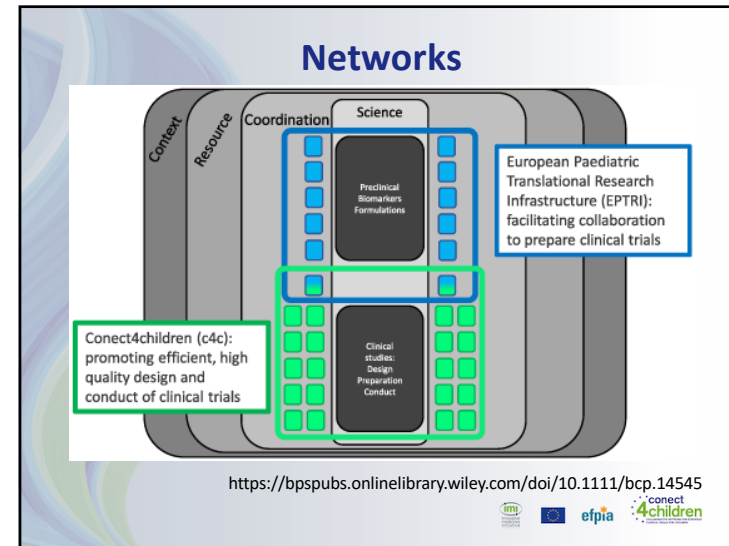
conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

c4c update for EnprEMA

Mark Turner

   EnprEMA Workshop 28th September 2020

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Networks

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REVIEW-THEMED ISSUE

European research networks to facilitate drug research in children

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<https://bpspubs.onlinelibrary.wiley.com/doi/10.1111/bcp.14545>





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Summary for c4c

Progress as expected,
given the COVID pandemic

(within the scope of c4c; other actions will happen with scale-up)


<https://conect4children.org>


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Goals and progress


Goal	Comment	Progress
Setup coordinated work with National Hubs	20 countries working together	
Open non-industry Proof-of-Viability trials	3 trials funded, 2 ready to open in October	
Open industry Proof-of-Viability trials	1 trial identified, others in preparation	
Setup Expert Advisory Groups	9 requests completed	
Setup Educational portal	Several courses available within c4c	
Setup Information Systems	Minimal COVID-related delays	
Develop sustainability	Options appraisal under development	
Patient and Public Involvement and Engagement	Database, training, resources, sustainability	



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- ### Network Infrastructure Office
- Single point of contact
 - Links between industry and hubs
 - Brokered agreements, e.g. CDA
 - Managed network-wide feasibility processes for academic and industry
 - Roles of Hubs aligned
 - Governance
 - Network Committee
 - Trial Commissioning Committee
 - Quality Committee
 - Performance Management
- 

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- ### National Hubs
- Operational:
 - Austria, Belgium, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, United Kingdom
 - Single points of contact
 - Links with sites
 - National Hub Forum
 - National Networks
 - Roles of Hubs aligned
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- ### National Networks
- Are funded by multiple sources
 - Exploring how to work together, e.g. with iACT


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Non-Industry Proof-of-Viability studies

TABLE 1 Academic connect4children proof-of-viability studies

Title of study	Sponsor	Specialty	Nature of trial	Planned sample size	Planned initiation date	Duration
TREOCAPA	INSERM, Paris, France	Neonatology	Phase 3 trial of paracetamol to prevent patent ductus arteriosus	800	October 2020	3.5 y
KD-CAAP	UCL, London, UK	General Paediatrics, cardiology, rheumatology	Phase 3 trial of the effectiveness of adding steroids to standard treatment in children with Kawasaki disease	262	August 2020	3.5 y
cASPerCF	OPBG, Rome, Italy	Pharmacokinetics in cystic fibrosis	Phase 2 trial to assess the dose of posaconazole in children and young people with cystic fibrosis and infection with <i>Aspergillus</i>	130	October 2020	3.5 y

<https://connect4children.org/studies/>




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Non-Industry Proof-of-Viability studies

Feasibility
Contracts
Trial supplies

- National specificities mediated by National Hubs

Ongoing learning



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Industry Proof-of-Viability studies

CDA cascade in place

- One template for CDAs agreed by four companies
- Signed for one trial

Initial site questionnaires completed

Hubs meeting company national affiliates to plan trial specific feasibility questionnaires



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Expert Advice

Advice Requests

- Including PPI Methodology
- White papers under development

Quality Improvement

Multi-Stakeholder Meetings (MSM)

Academic requests...



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IMPROVING THE FUTURE FOR THE TREATMENT OF PAEDIATRIC DISEASES THROUGH A PAN-EUROPEAN CLINICAL TRIALS NETWORK

Mission

- c4c will use a coordinated approach to ensure high quality regulatory processes
- Multiple countries
- Multiple sites
- paediatric age groups

By supporting

- Drug development using resources shared between countries
- The design through a combination of information about national regulatory requirements, appropriate innovation and expert resources
- Optimising trial assessment methods used beyond the network

Vision

Better medicines for babies, children and young people through a pan-European clinical trials network

High quality paediatric trials? We can help!

Clinical Experts

Innovative Methodology Experts

Patients/Parent Involvement

Strategic Feasibility Group

Strategic Feasibility Advice

- PIP development
- Trial methodology
- Patients/Parent Involvement
- Advice on study design
- Practical development
- Study documents
- etc.

More information or apply for advice please contact: SPoC@connect4children.org

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Patient and Public Involvement

Good practice in PPI is followed for all non-industry studies

Family and Young Person voices are present in all Strategic Feasibility Advice

Strong PPI contribution to education and training

- “Train the Trainer” course for PPI successful

PPI-specific aspects of sustainability are under development

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Data

About trials

IS development is well advanced for:

- Network management
- Expert Advice
- PPIE

Within trials

- Core Common Paediatric Data Dictionary v1.0 is under revision in collaboration with CDISC and others

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Education and Training

The c4c Academy learning platform is designed to provide educational tools and training materials specifically tailored to the needs of the c4c beneficiaries involved in the conduct of the proof-of-viability studies (Industry and non-industry) financed by the project. Through the educational platform, c4c beneficiaries will gain greater insight and expertise into all relevant aspects of the organization, implementation and delivery of paediatric clinical trials, including those focused on regulatory approval of new paediatric drugs.

Once logged-in, you are presented with the list of courses associated with your category and are invited to take a user tour that briefly introduces the main features of the platform. You will find educational resources and several activities designed to help you learn. You can access Academy from your computer or mobile device.

The courses are exclusively reserved for the c4c Consortium. Kindly contact your National Hub if you wish to participate.

TRAIN THE TRAINERS COURSE

GOOD CLINICAL PRACTICE COURSES

COURSES FOR FAMILIES AND PATIENTS INVOLVEMENT

SHORT THEMATIC COURSES

POV STUDIES' TRAINING COURSES

OTHER RESOURCES

Click here to access the VLE

Click here to access Educational Resources Library for Patients

<https://connect4children.org/academy-2/>

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Summary

- Good progress
- Extensive discussion is now leading to action
- Adapted to circumstances
- Within scope and timelines
- May need (no-cost) extension

Need to stay within scope to ensure quality of the work

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