

Supporting Paediatric Trials through c4c National Hubs and National Networks

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4th Nordic conference on Paediatric Medicines, Sep 2022

Hubs, networks and sites



belgian pediatric clinical research network



4th Nordic conference on Paediatric Medicines, Sep 2022

The c4c services

Strategic feasibility advice and patient/parent involvement

Access to over 300 Clinical and methodological paediatric experts

Inclusion of YPAGs, patients and parent groups in advice meetings

Single centralized contracting structure, coordination/organization of Expert advice meetings

Single Point of Contact

Access to local networks in 21 European countries
and over 150 clinical sites

Aligned processes across the entire network increase efficiency and quality

c4c Training Academy

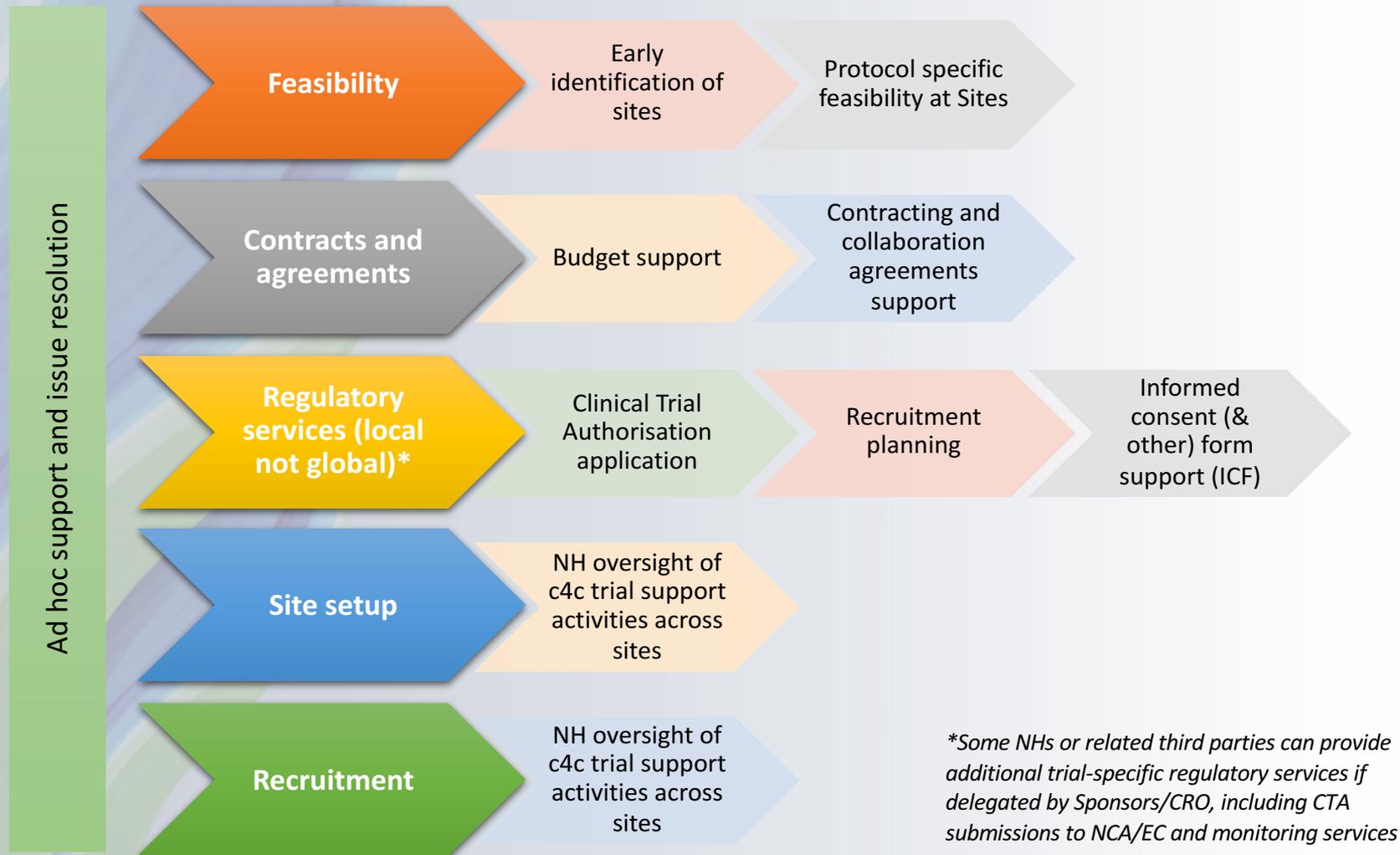
Providing standardized training to all study sites and site personal

Master courses on Pediatric Drug Development open for all beneficiaries

Paediatric Data Dictionary & Therapeutic Area User Guide

1st Paediatric Data Dictionary established to allow standardization of
data collection across Paediatric studies

NH services for PoV trials



Where have NHs been able to influence?

Translations of trial documents or emails

Budget discussions and negotiation

Non responsive sites

Contract negotiation and local law requirements

Cultural differences

Navigating regulatory submissions and queries

Site identification and PI identification

Resolving issues or bottlenecks at sites

Advising on site suitability

NHs achieve this through expert knowledge and experience at a national level

Testing and learning from PoV trials

NHs as active partners

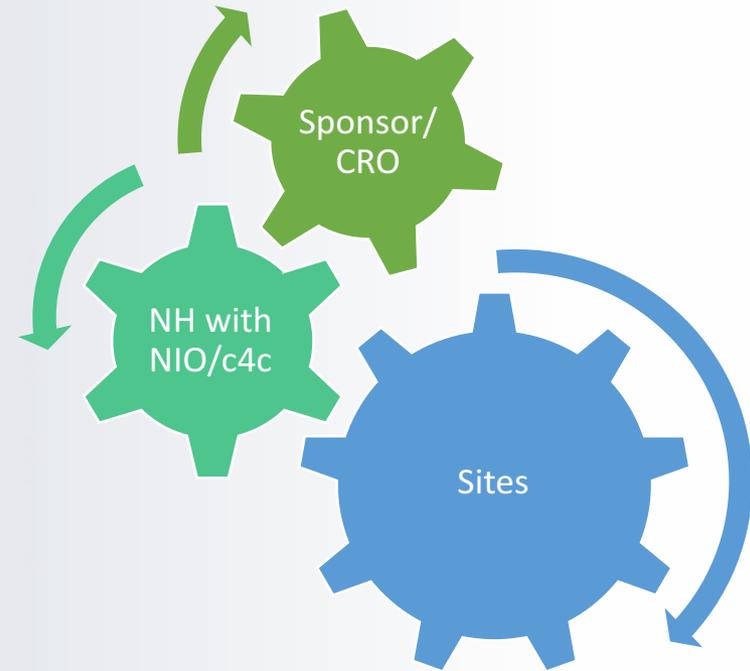
- Site support
- Reviews, informs, advises, anticipates, supports and mediates
- Flexible responders in-country with local knowledge of research landscape and trial environment

Prototyping c4c trial services

- Learning by doing

Principles of the c4c approach

- Collaboration between partners
- Continuous cycle of improvement
- Comprehensive evaluation



A NI trial sponsor perspective:

“NH team greatly involved. Great work and nice collaboration since the very beginning”

A site perspective:

“It has been a pleasure working with the National Hub. The personal approach and broad clinical trial support has substantially helped our site with its pediatric clinical trials”

What makes a successful collaboration?

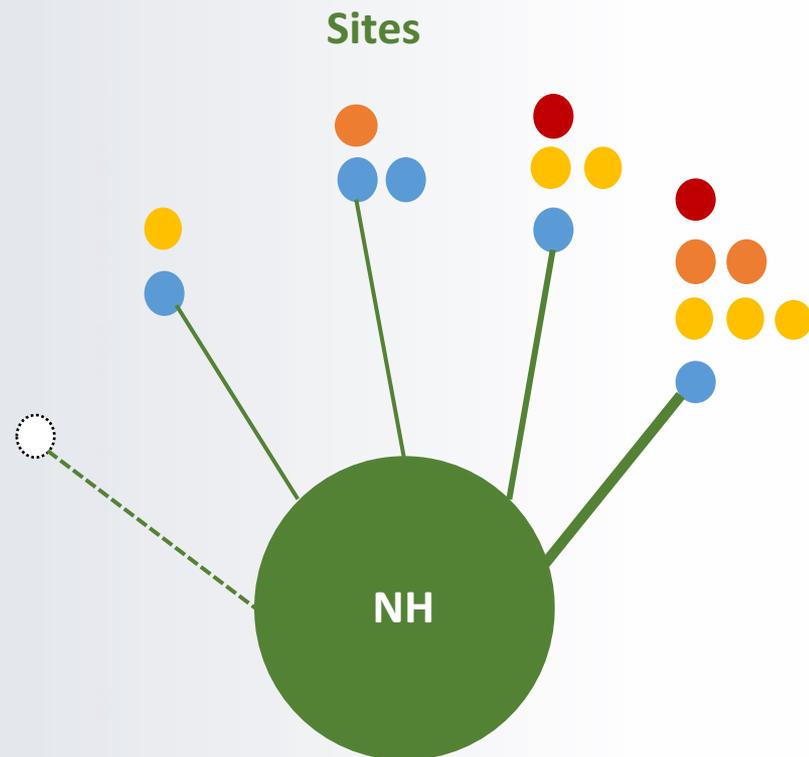
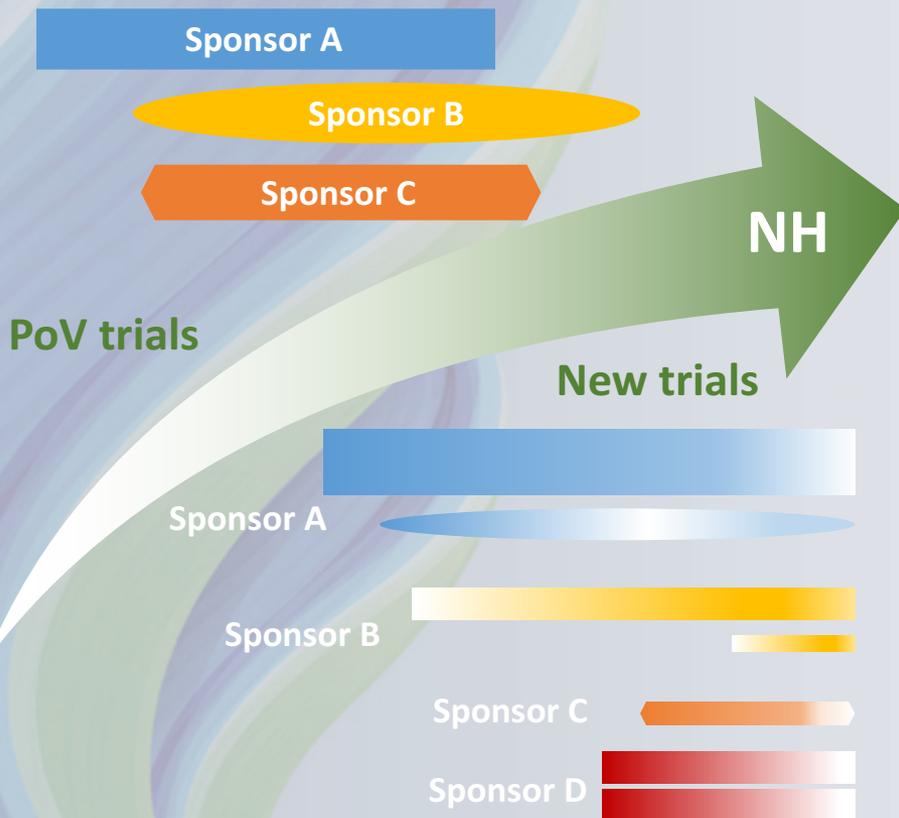
NIO and NHs working together with sponsor/CRO teams (academic/industry, central/local) to deliver the study:

- Establishing contact early on – build good relationships
- Regular, responsive and aligned communication
- Specifying requirements, defining roles and responsibilities
- Sharing information: study progress, timelines
- Informing, reviewing, advising on actionable potential hurdles or bottle necks at local level
- Identify and collaborate with key partners

PoV trials: learning curve of NHs, NIO and sponsors

From PoV trials to a trial portfolio

Growing number of trials across sponsors, conditions, NHs and sites
Continuity and scaling up, experience and lessons

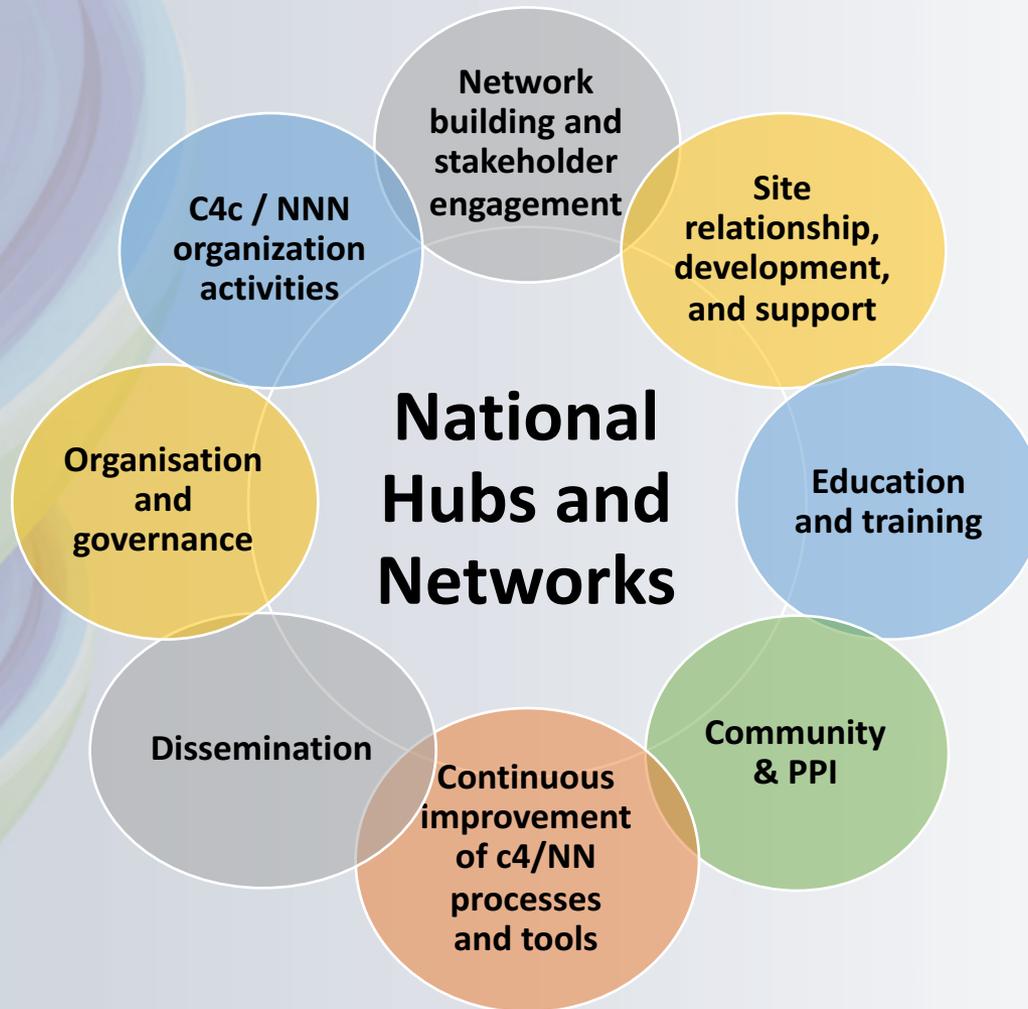


Beyond trials: NHs/NNs in action

NH Forum



Networking of NN



Beyond trials: NHs/NNs in action

National Hubs and Networks

- *STAND4Kids & HELPNet NIO roles*
- *BPCRN & PEDMED-NL work with other networks*

C4c / NNN organization activities

Network building and stakeholder engagement

- *PEDSTART in specialty networks & rare diseases*
- *POLPEDNET involvement in Ukraine*

Site relationship, development, and support

- *NorPedMed Study Nurse Network*
- *DanPedMed & NordicPedMed work on trial preparedness*

Organisation and governance

Education and training

- *CzechPharmNet student involvement*
- *MCRN Hungary cooperation with NHRA*

Dissemination

Continuous improvement of c4/NN processes and tools

Community & PPI

- *NH-supported YPAGs*

- *OKIDS 10-year experience*
- *INCIPIT legal entity*
- *In4Kids new model*

- *PEDMED-NL & GERMANNETPAET budget tools*
- *RECLIP & FINPEDMED work on business plans*

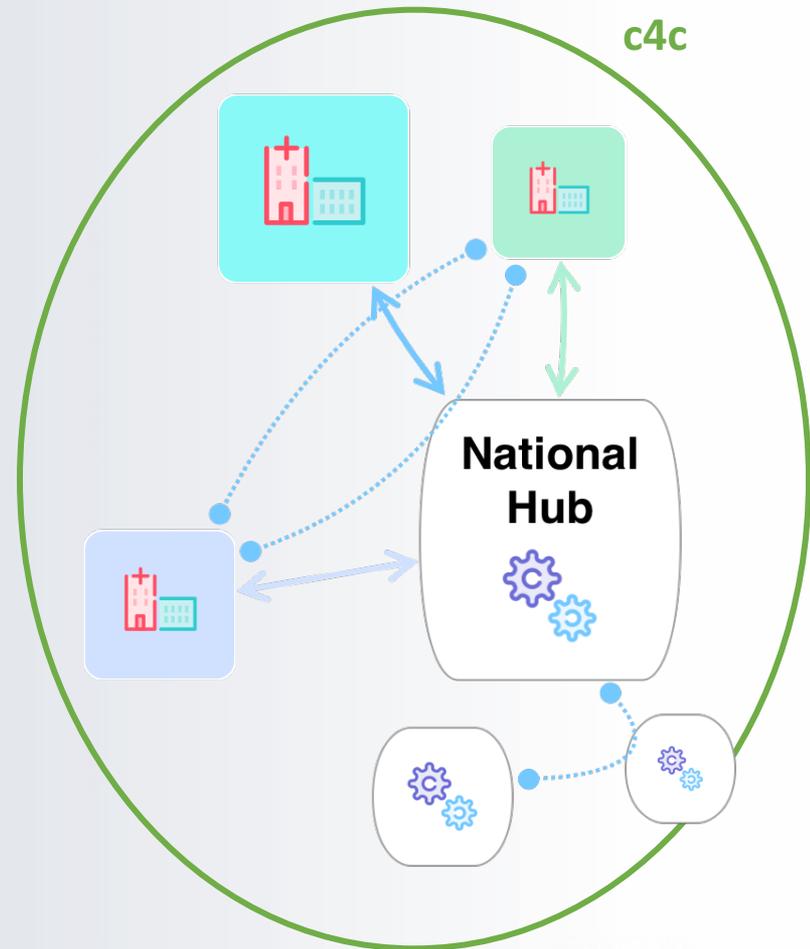


Impact of c4c at national level

Development and/or support to national paediatric research infrastructure

- New national funding for integrated research infrastructure: Ireland, Poland
- New sustainable legal entity for integrated research infrastructure: Italy
- New national networks: Spain, Portugal, Sweden, Czech Republic, Hungary, Greece, Belgium, Germany
- Reinforced existing networks: Finland, Norway, Austria, Estonia, Netherlands

Sites: destinations of c4c



Road to (and beyond) standards

- High quality of NHs is a key element as NHs play a central role in the consortium and the service delivery

	NETWORK ORGANIZATION	RESOURCES AND STAFF	QUALITY MANAGEMENT	RESEARCH EXPERIENCE AND ABILITY	SCIENTIFIC COMPETENCIES AND EXPERT CAPACITY	TRAINING AND EDUCATIONAL CAPACITY TO BUILD	IMPACT	PPI INVOLVEMENT
FIVE								

- High-quality of NHs will foster the excellence of sites and facilitates the site standards implementation

Gold-standards sites



Accredited sites



Opportunities in the road to pediatric innovation

Pediatric devices

Drug repurposing

Accelerated approvals and revised HTA

Use of RWE

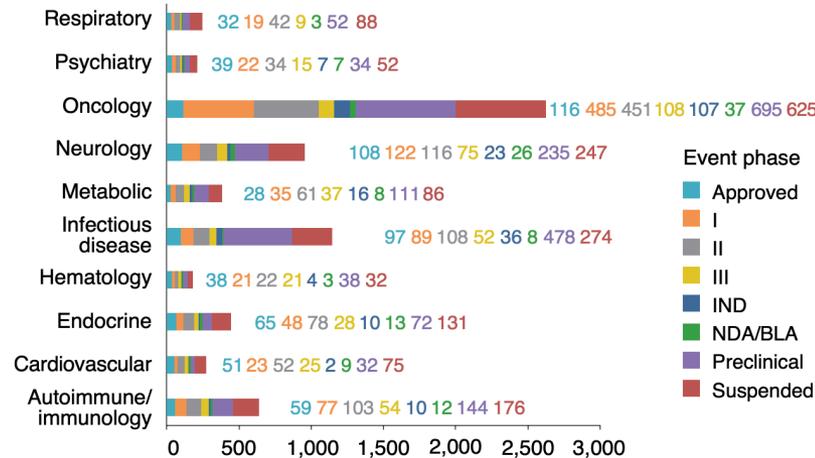
Innovative methods, including platform and adaptive trials

Dedicated clinical networks & sites

Involvement of children and young adults

Bridges between translational & clinical research and personalized approaches

Increasing pipeline of new interventions



Data for all ages; BioMedTracker 2020

EU regulation

Decentralized clinical trials

Big data and AI

Learning for sustainability

- Experiencing how to undertake work in the 'real' world
- Focus on critical success factors
- Ready for scale up when the new legal entity is opened
- Collaboration and trust key to a sustainable future



Kiitos! Tak! Takk!

