

Supporting Paediatric Trials through c4c National Hubs and National Networks

Ricardo Fernandes

c4c Network Infrastructure Office and NH Forum;
WP7 Co-Lead; STAND4Kids PT NH

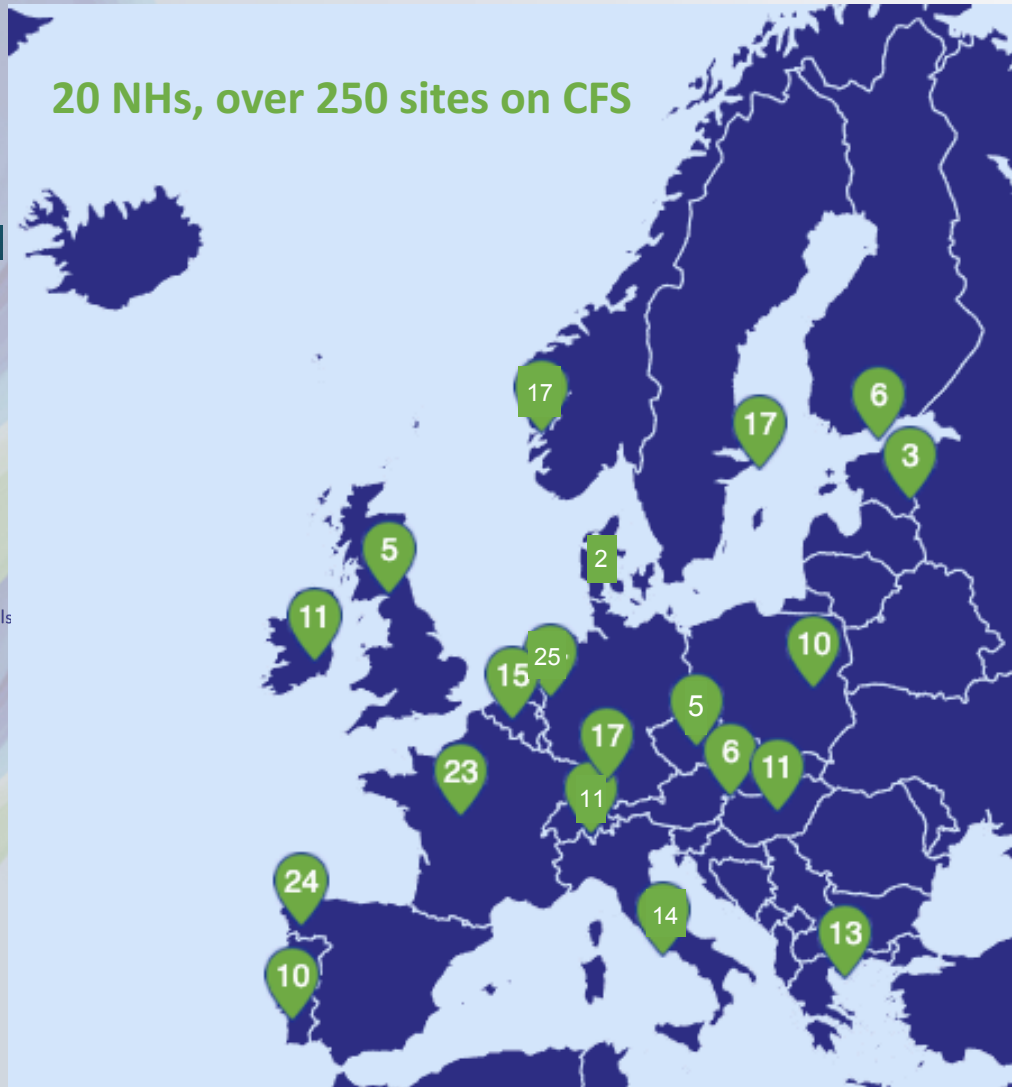
4th Nordic conference on Paediatric Medicines, Sep 2022

Hubs, networks and sites



STAND4kids
SUPPORTING PEDIATRICS TRIALS | PORTUGAL

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

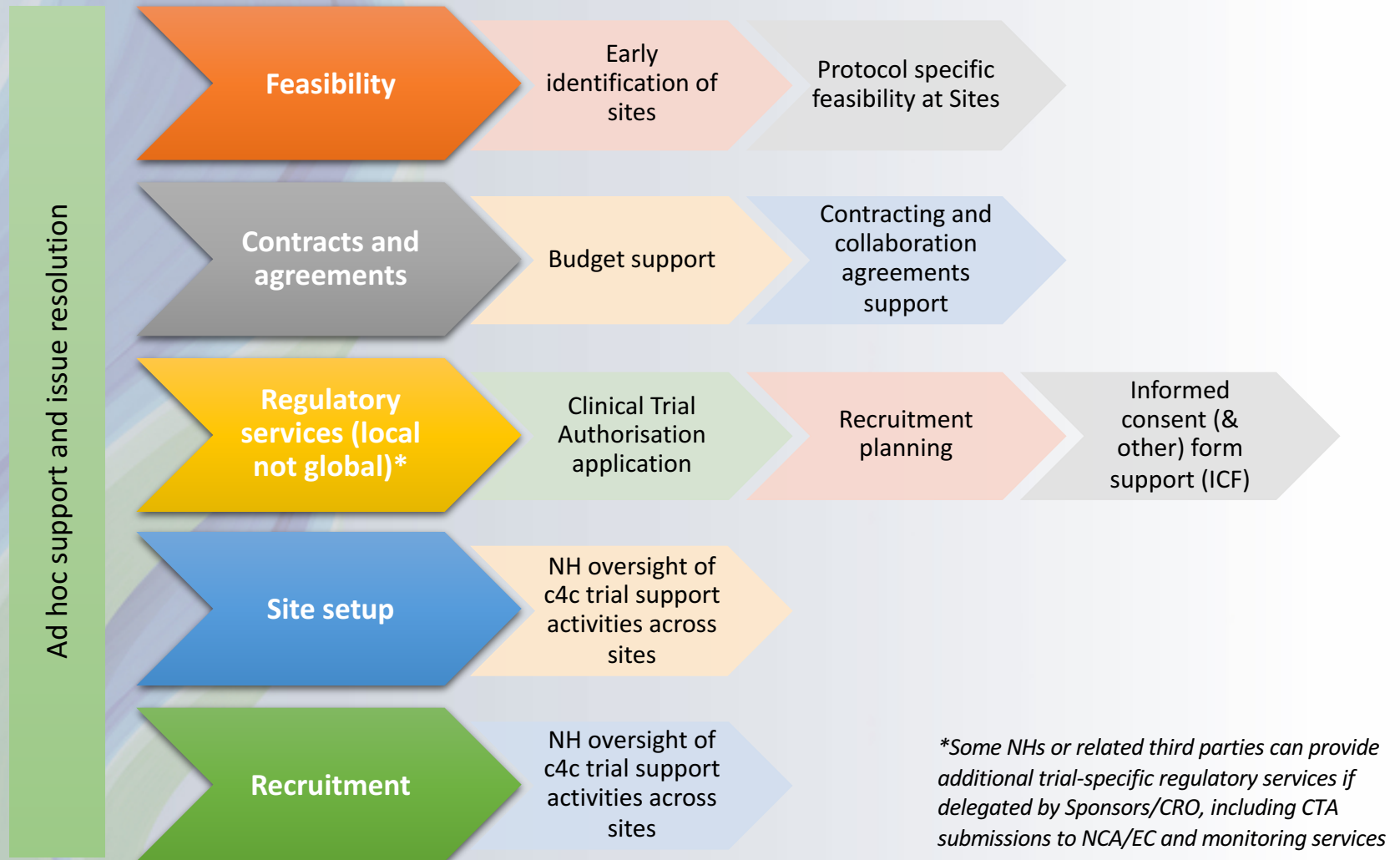
Providing standardized training to all study sites and site personal

Master courses on Pediatric Drug Development open for all beneficiaries

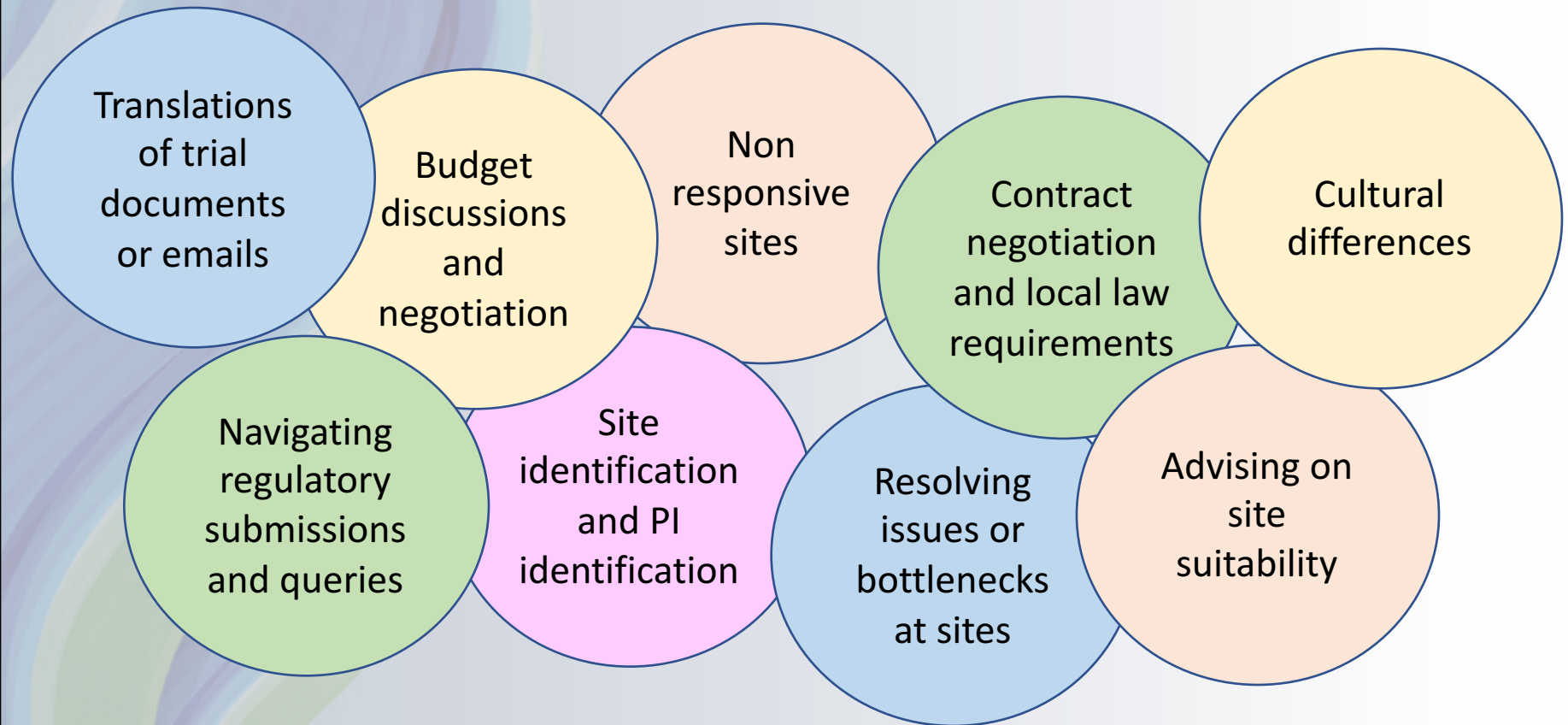
Paediatric Data Dictionary & Therapeutic Area User Guide

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?



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

Testing and learning from PoV trials

NHs as active partners

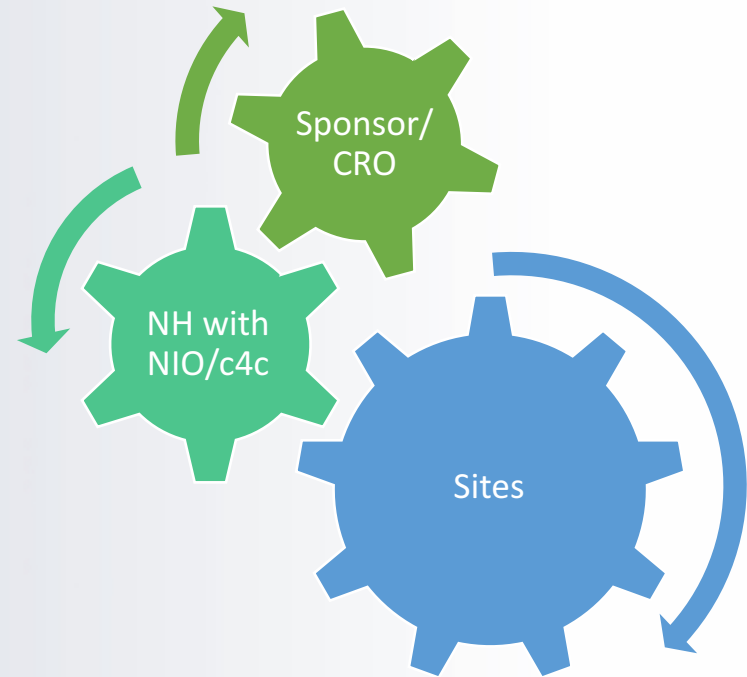
- Site support
- Reviews, informs, advises, anticipates, supports and mediates
- Flexible responders in-country with local knowledge of research landscape and trial environment

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?

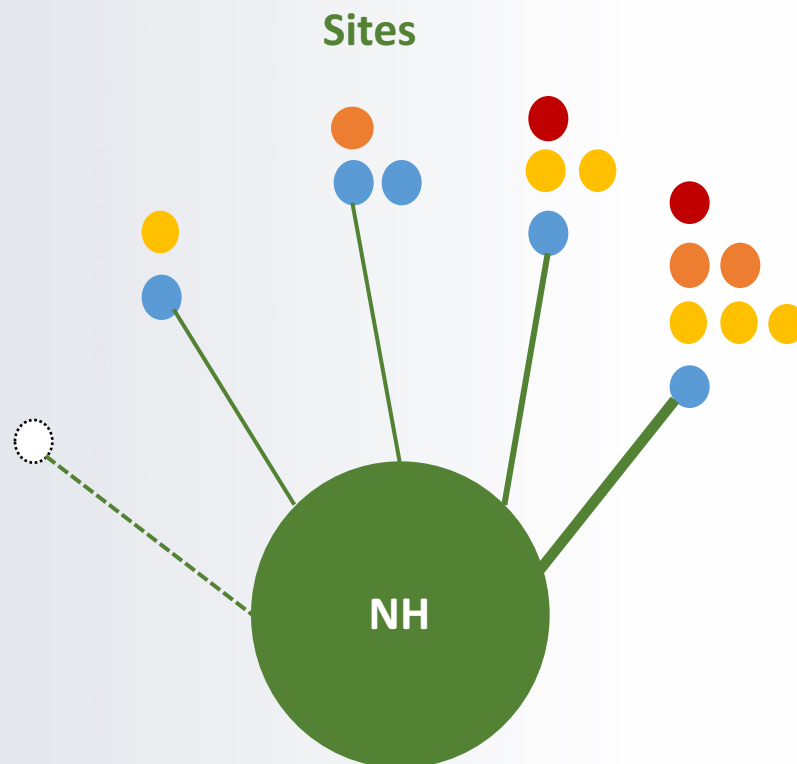
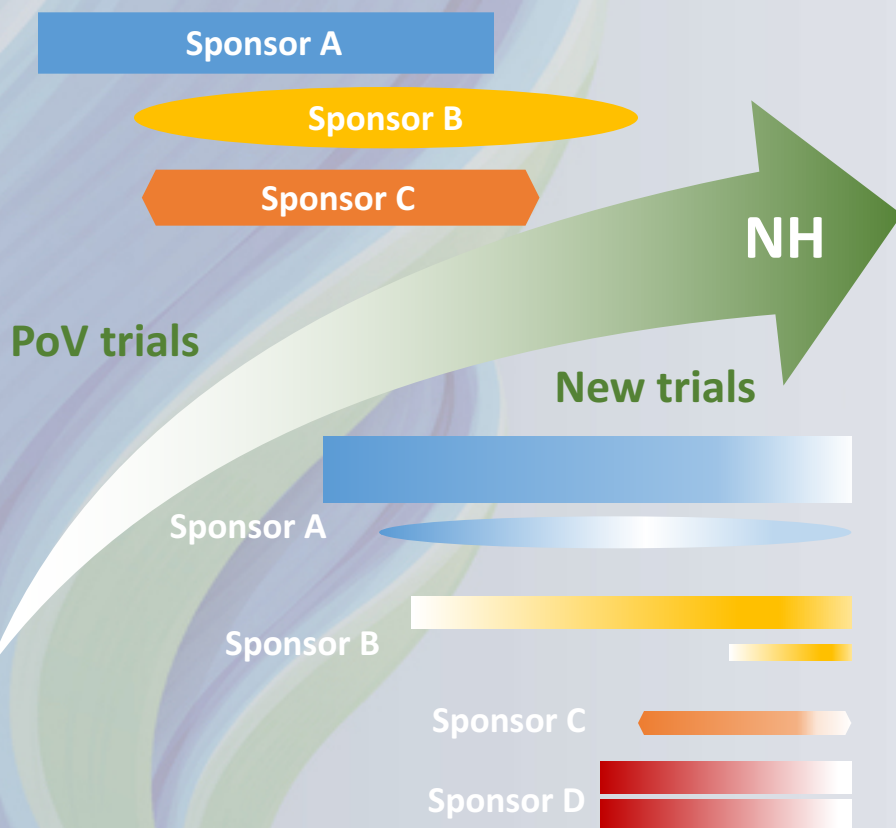
NIO and NHs working together with sponsor/CRO teams (academic/industry, central/local) to deliver the study:

- 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

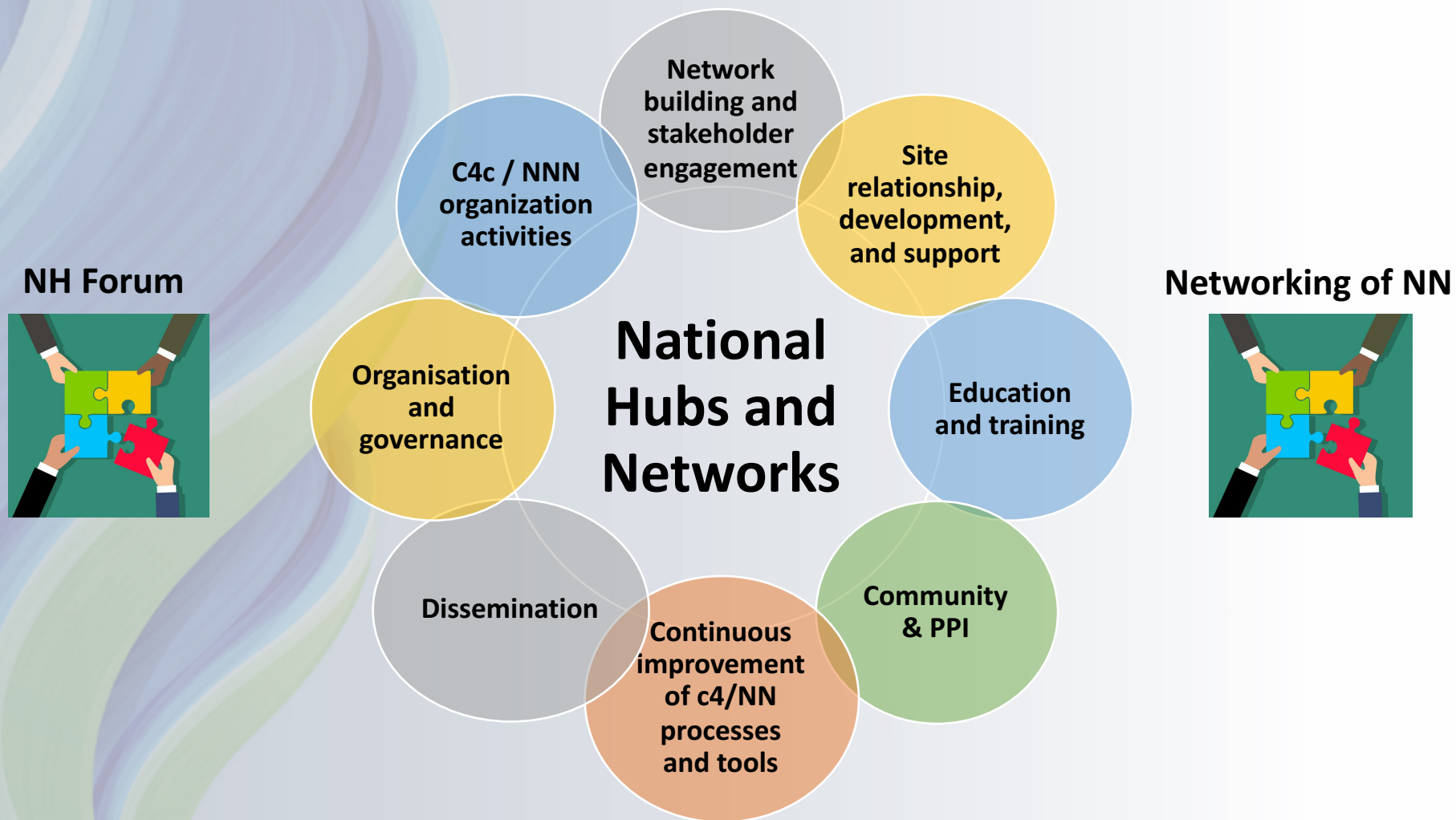
PoV trials: learning curve of NHs, NIO and sponsors

From PoV trials to a trial portfolio

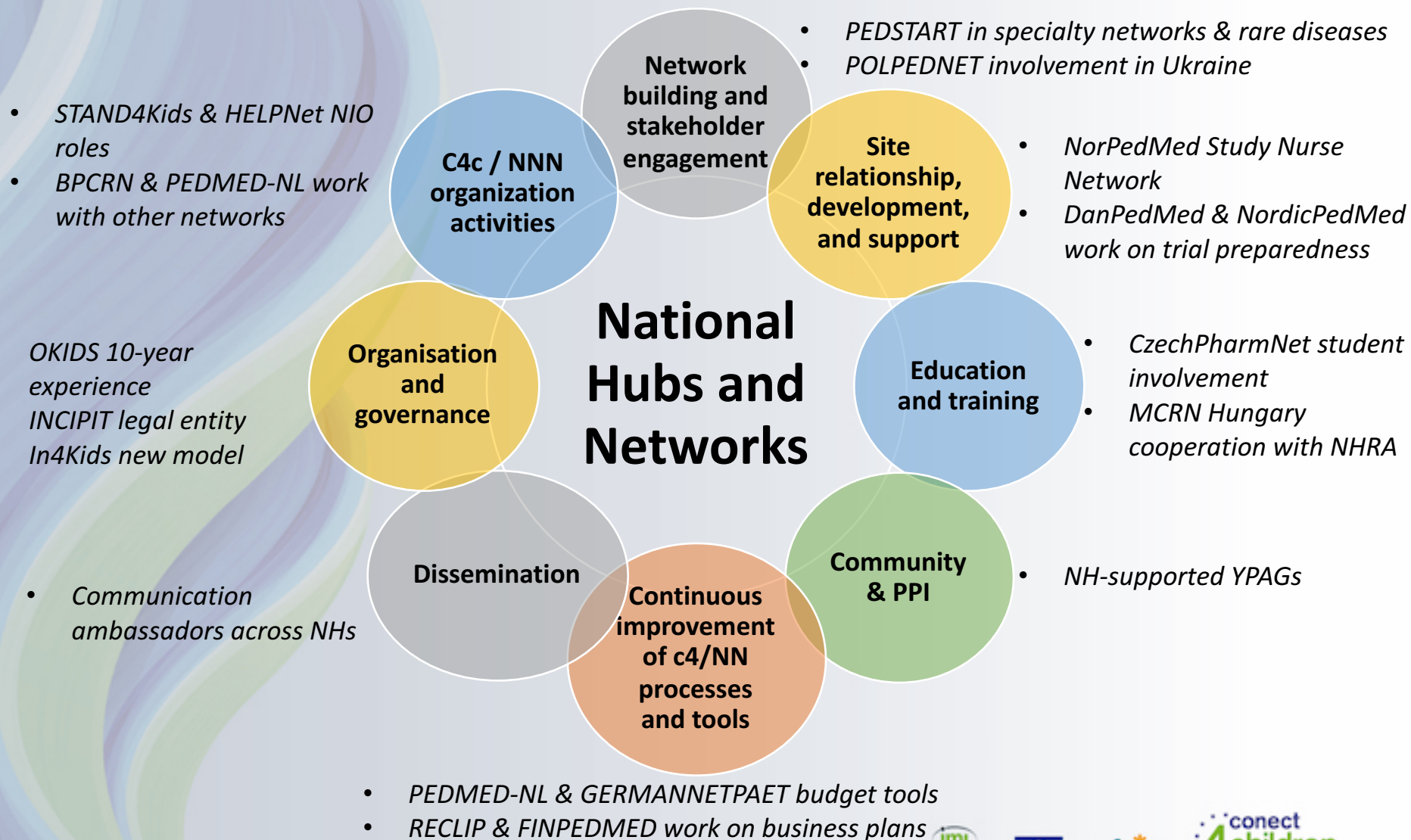
Growing number of trials across sponsors, conditions, NHs and sites
Continuity and scaling up, experience and lessons



Beyond trials: NHs/NNs in action



Beyond trials: NHs/NNs in action

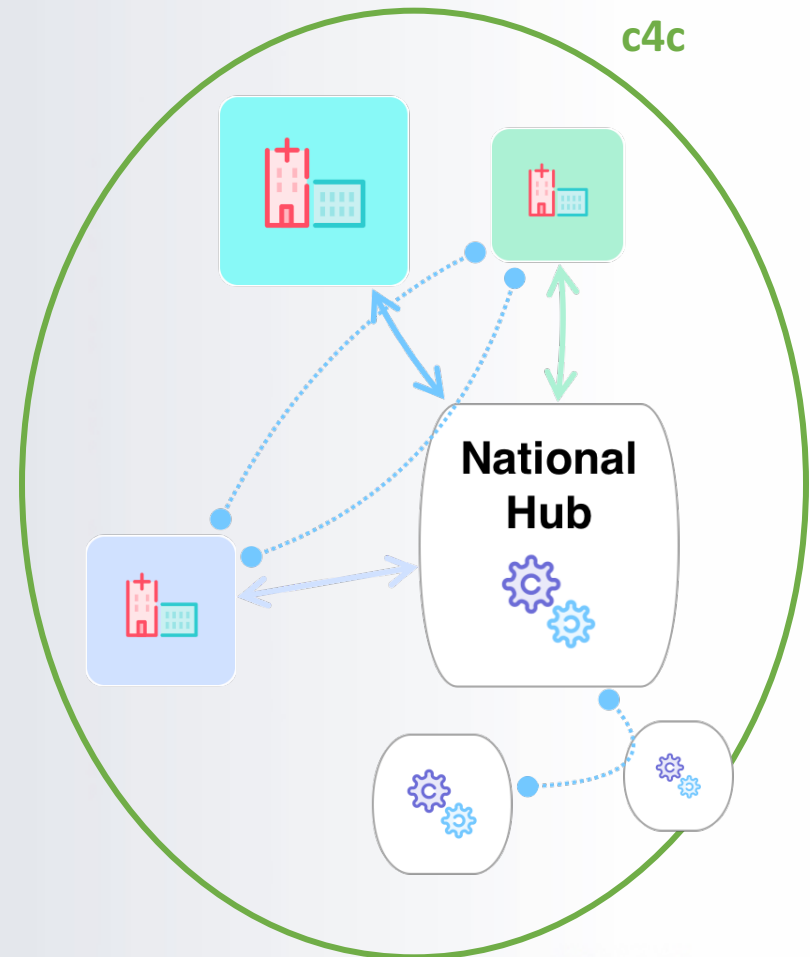
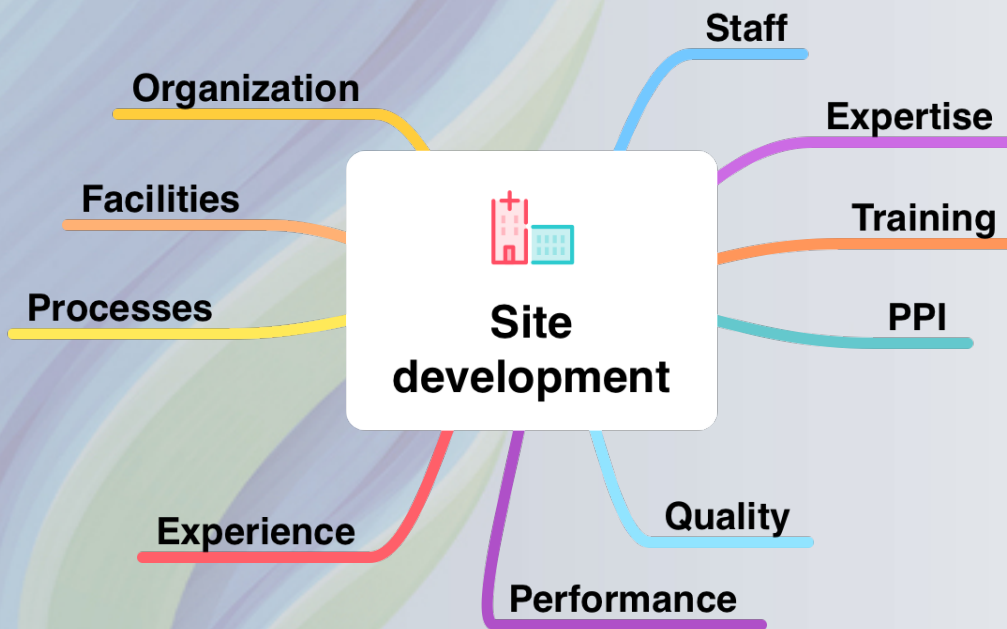


Impact of c4c at national level

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									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

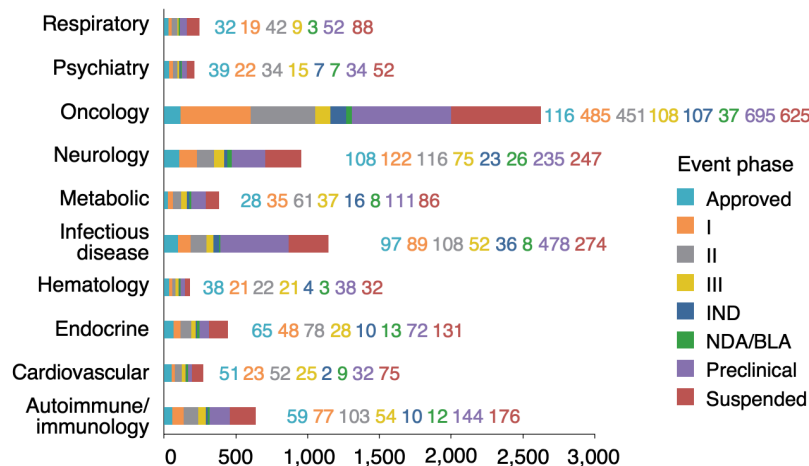
Innovative methods, including
platform and adaptive trials

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!

