conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

c4c aims to enhance the development of Better Medicines for babies, children and young people through a pan-European clinical trial network

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CONECT4CHILDREN

COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

Why IMI

The **paediatric clinical trial infrastructure in the EU is fragmented and not sufficiently developed**.
A broad **multidisciplinary public-private collaboration is required to meet the challenges** and to be transformative and to **collectively address children's needs for better medicines**.

Impact

Improved pediatric development plans and study designs
More efficient implementation and conduct of Paediatric clinical trials
Improved data quality, better trial feasibility and faster enrollment

Status & Value

Expert 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 contracting structure, coordination/organization of Expert advice meetings

Single Point of Contact

Access to local networks in 21 European countries and over 250 clinical sites
Aligned processes across the entire network increase efficiency and quality

c4c Training Academy

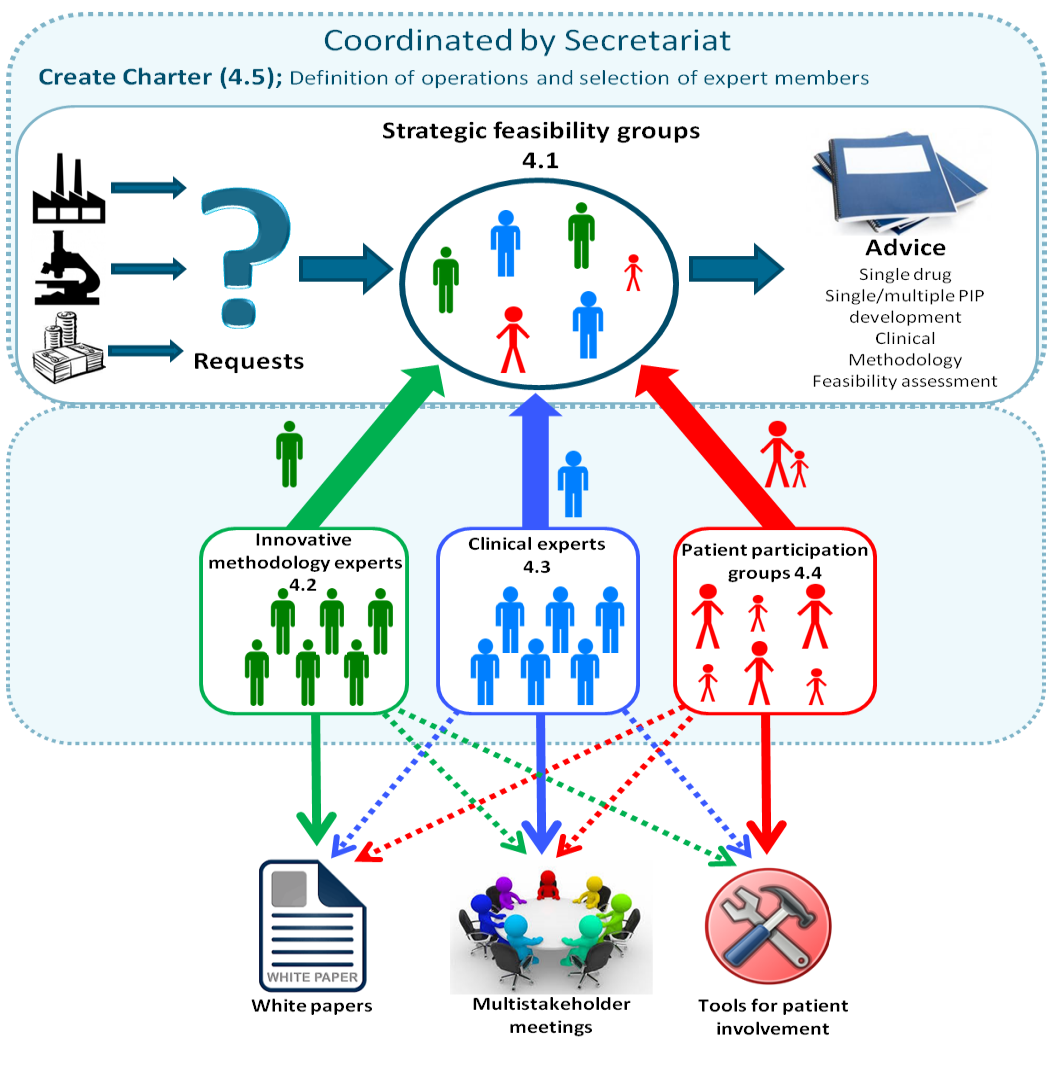
Providing standardized training to all study sites and site personal
Master courses on Pediatric Drug Development open for all beneficiaries

Paediatric Data Dictionary & TAUG

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

Strategic Feasibility Advice

Improving the way paeditric studies are planned and designed



25 Expert Groups – over 300 registered experts	
Adolescent Medicine	Neuromuscular diseases
Cardiology	Neuroscience & Epilepsy
Endocrinology & Diabetes	Oncology (incl. heamatology)
Developmental pharmacology	Pharmacogenomics and other Omics technologies
Ethics	Pharmacometrics
Formulations	Pharmacovigilance
Gasteroenterology & Hepatology	PPI (carers, parents, patients, patient organisations, YPAGS)
Health Technology Assesment	Psychiatry
Infectious diseases & Vaccinology	Respiratory
Intensive care	Rheumatology & Autoimmune diseases
Metabolic diseases	RSV
Neonatology	Study design & Clinical trial methodology
Nephrology	

Implementation of the advice

Impacting the design of Pediatric Investigational Plans (PIPs)

29 requests for advice
(7 industry partners & 2 academic sponsors)

5 did not proceed

17 completed

6 ongoing

7 include PPI

19 include one or more Clinical Expert Groups

11 include one or more Innovative Methodology Groups

 # advice requests per group:

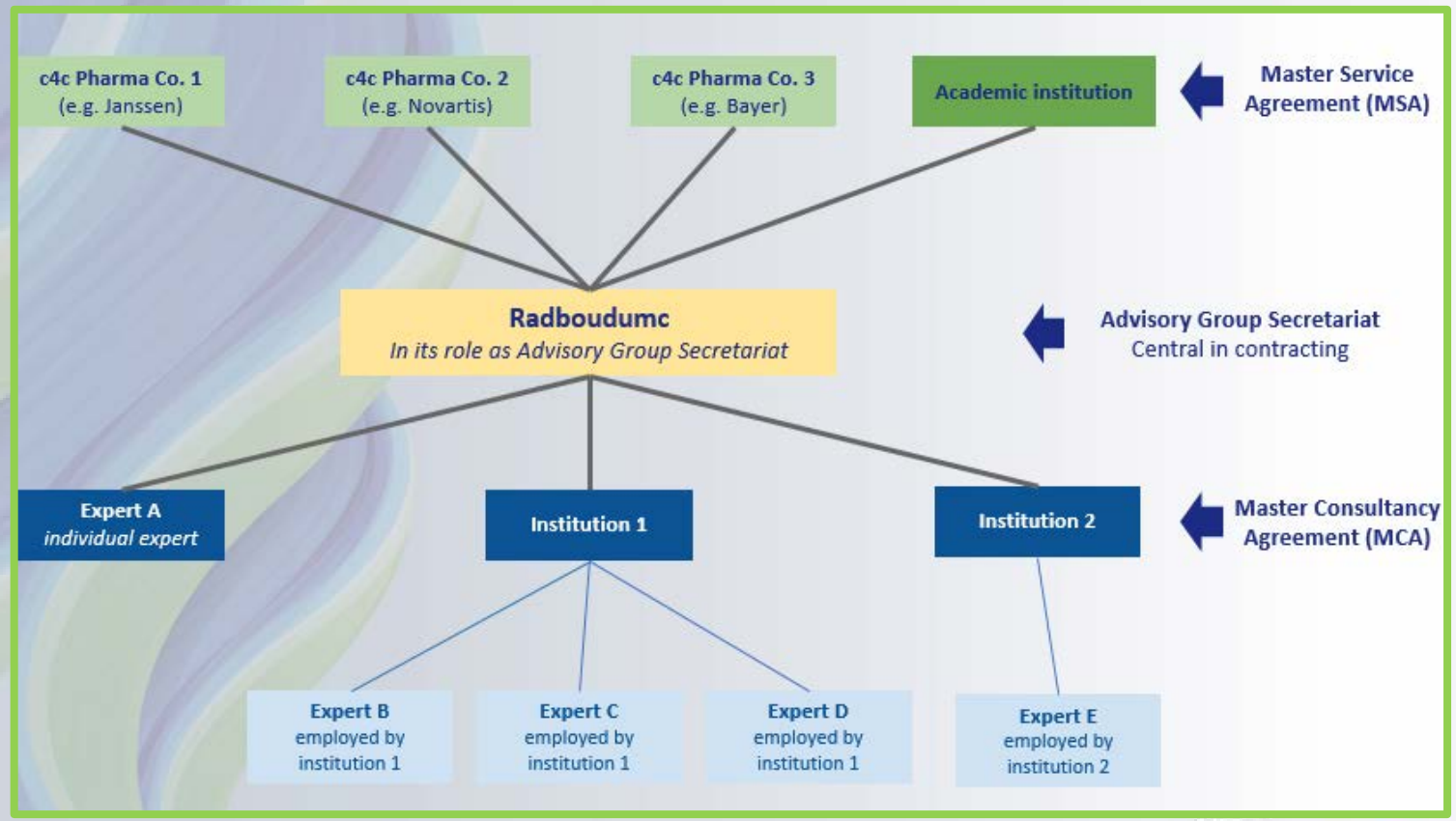
- Adolescent medicine (2)
- Cardiology (2)
- Developmental Pharmacology (2)
- Ethics (3)
- Formulations (1)
- HTA (1)
- Infectious diseases & Vaccinology (3)
- Intensive Care (3)
- Neonatology (2)
- Nephrology (3)
- Neuroscience & Epilepsy (3)
- Oncology/Heamatology (2)
- Omics (1)
- Psychiatry (2)
- Respiratory (4)
- RSV (1)
- Study design and Clinical trial methodology (4)
- Other; dermatology (1)

12 advice requests provided on Pediatric development strategy
5 reports included in submissions to regulatory bodies

Centralized contracting structure (CCS)

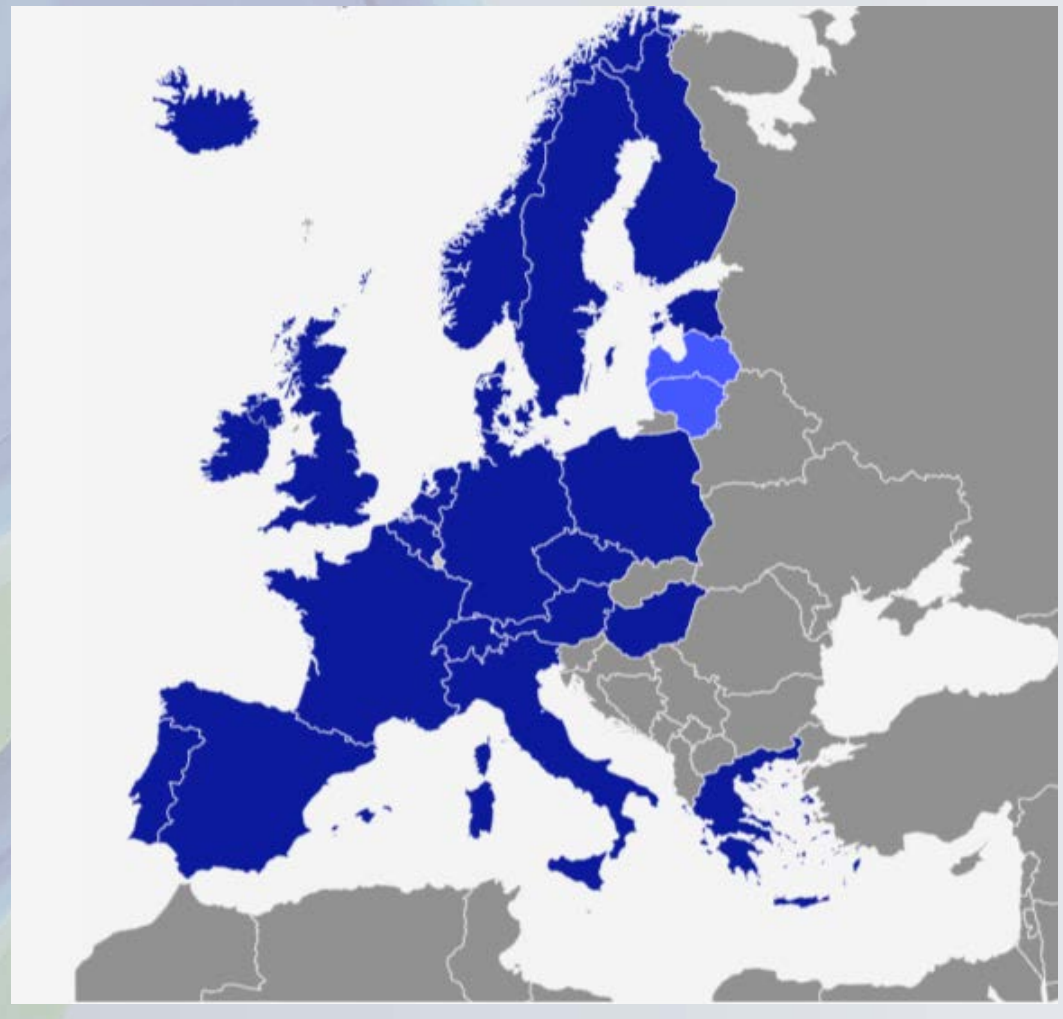
Improving efficiency by accelerating contracting timelines

- 128 master consultancy agreements with Experts signed to date
- 8 master service agreements in place with companies
- Facilitating the advice process by reducing number of contracts



19 National Hubs serving 21 countries across Europe

Providing access to over 250 clinical sites



* Finland & Iceland and Norway & Denmark are joined networks

c4c established

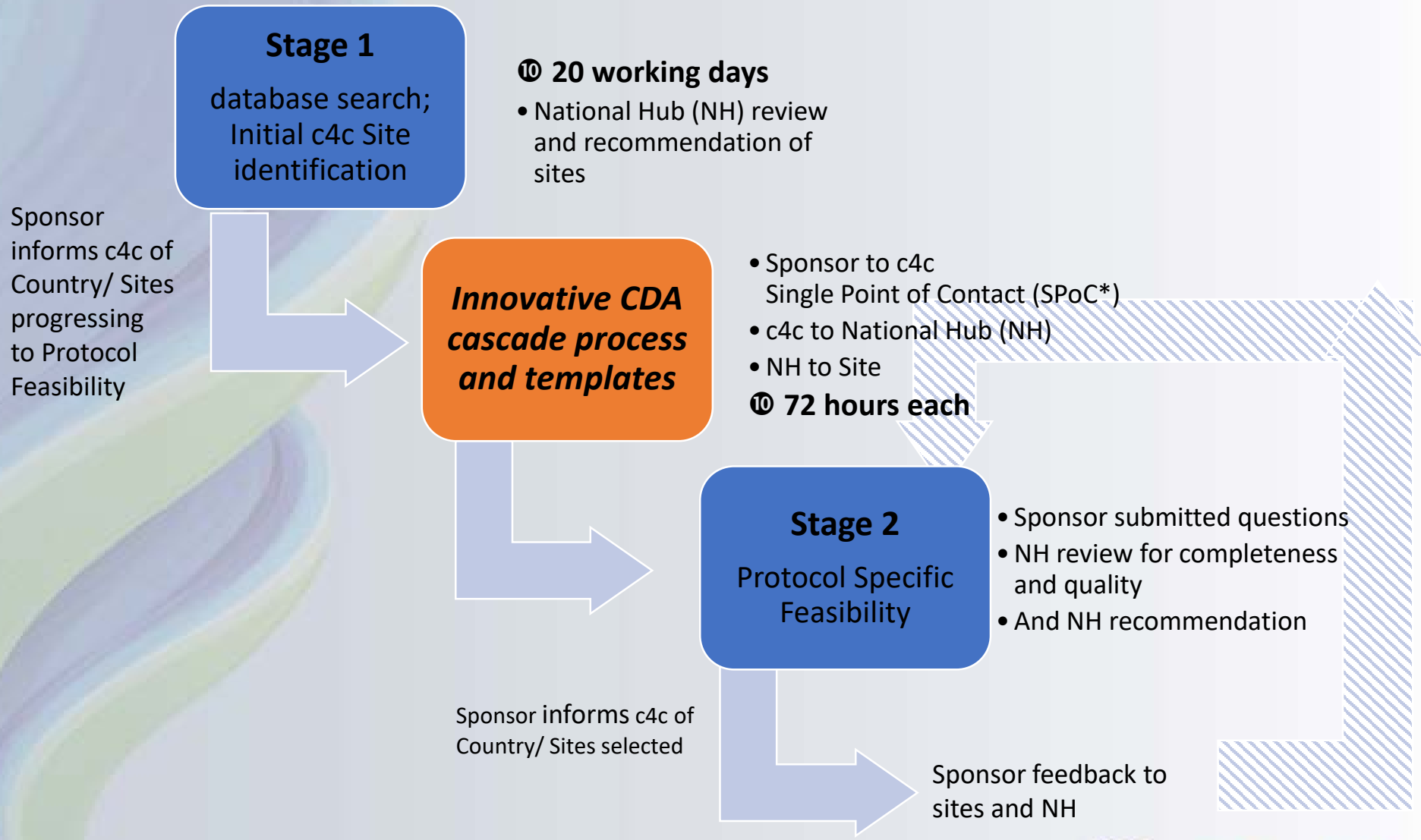
- 19 paediatric national networks in 21 countries*
- 2 new paediatric national networks under negotiation

Closely cooperating with

- 8 European multinational specialty networks
- 3 global research networks

c4c Site Feasibility Services

Increased efficiency through unique CDA process



c4c Site Identification and Feasibility Service

Fast identification of high number of high quality sites

Stage 1- Initial sites identified by c4c

Within 20 working days

Trial	Number of c4c sites identified
Sponsor A	101
Sponsor B	142
Sponsor C_a	161
Sponsor C_b	160
Sponsor D	171

Stage 2- Protocol specific feasibility

	Number of sites	Mean Time to complete*
Sponsor A	8	15 days
Sponsor B	74	9 days
Sponsor C_a	65	16 days
Sponsor C_b	ongoing	
Sponsor D	ongoing	

- *Minimum time 2 days;
- *Maximum time 38 days

c4c Service for Trial Feasibility

Major reduction in time needed to finalize CDAs

"The c4c team was amazing during the CDA process for site identification. Having the c4c team's help during this process was invaluable and allowed for a more efficient process" ***Sponsor trial team***

Trial		Number of CDAs	Time to complete (working days)	Mean time to complete (working days)*
Sponsor A	Sponsor to c4c	1	< 1	< 1
	SPoC to NH	15	80% within 3	3
	NH to site*	38	97% within 5	8
Sponsor C_a	Sponsor to SPoC		< 1	< 1
	SPoC to NH	18	78% within 3	3
	NH to site*	91	68% within 5	7
Sponsor B	Sponsor to SPoC	1	< 1	< 1
	SPoC to NH	19	79% within 3	2
	NH to site*	111	82 % within 5	9

*Minimum time 1 working day; *Maximum time 29 working days

C4c work supporting Data Harmonisation and standardisation

Paving the way for better data quality and re-usability

Cross Cutting Paediatric Data Dictionary

IMPACT: *More harmonised paediatric data = More efficient and effective trials*

Data Recommendations

IMPACT: *Higher quality more interoperable data = increased scientific knowledge*

Therapeutic Area User Guide (TAUG)

IMPACT*: c4c is influencing standards development on a global level = potential to de-risk paediatric trials*

c4c makes a difference

Areas of highest impact

Design and planning of studies

Advice requests

- Outcomes directly impacting studies designed and conduct
- Reports supporting discussion with Regulatory authorities

Opening sites

Significant decrease in time to sign CDAs
Increase in number of high quality sites available for site selection and feasibility

Data standards

Cross-Cutting Paediatric Data Dictionary as basis for CDISC TAUG

- Supporting sharing and interoperability of data

Education

Multiple short courses
Advanced Course in Paediatric Clinical Trials and Drug Development is in progress

Patient and Public Involvement (PPI)

Improving PPI plan`s of sponsors
Impact design and planning of studies

Thank you!