Supporting paediatric trials: learnings and insights from conect4children

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2023 Annual Meeting of the European network of paediatric research at the EMA (Enpr-EMA)

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777389. The Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

conect 4children

COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

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

imi innovative medicines initiative

efpia

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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 245 clinical sites

The c4c network currently has 20 NHs with 245 sites on the CFS as part of the collective work of the NHs

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

c4c Single Point of Contact Service (SPoC)

Function of the c4c Network Infrastructure Office

Good communication between Sponsors & Sites (NH/SPoC)

Single point of entry for:

- All queries
- All service delivery
- Quality control with metrics focusing on responsiveness and customer satisfaction
- Functioning since May 2019

{ Coordinates all queries with respect to trials and National Hubs }

National Hubs

What are c4c National Hubs?

Members of conect4children (c4c), There are currently 20 National Hubs working in 21 countries

Mostly academic-based institutions with strong links to the national paediatric research and clinical communities.

NHs underpin technical and operational contributions to clinical trials

This holistic approach aims to improve delays and reliability in paediatric clinical research.

What do c4c National Hubs do?

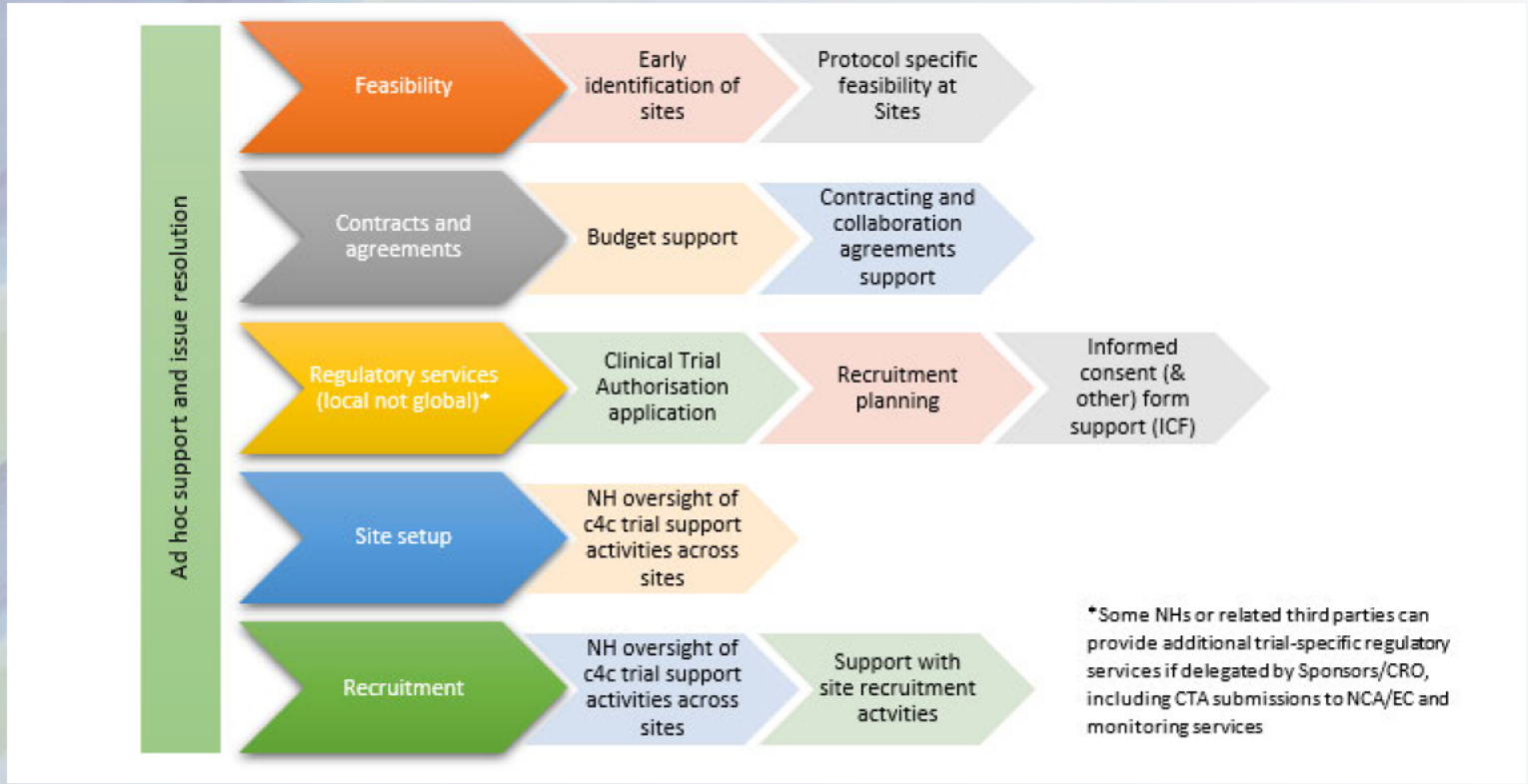
NHs facilitate the conduct of clinical trials across the trial life-cycle, from early site identification to study setup and execution.

Know first-hand the daily constraints of sites in setting up and conducting trials, anticipate potential issues and propose feasible solutions.

- Site and Investigator Identification
- NCA and IEC application support and advice
- Protocol specific feasibility at sites
- ICF & other patient facing documents
- Contract support
- Recruitment planning
- Budget support
- Ad hoc support and troubleshooting

Overview of National Hub Services

These trial-specific services leverage on the network building activities of NHs, including continued relations with sites and national stakeholders, knowledge of the research landscape, training and network support, performance management and quality improvement



C4c Portfolio Overview

PoV = Proof of Viability Study

Non Industry PoV

3 Non Industry PoV studies

2 studies ongoing

1 study in close out

Industry PoV

5 Industry PoV studies

4 studies ongoing

1 study closed out

Additional Industry PoV

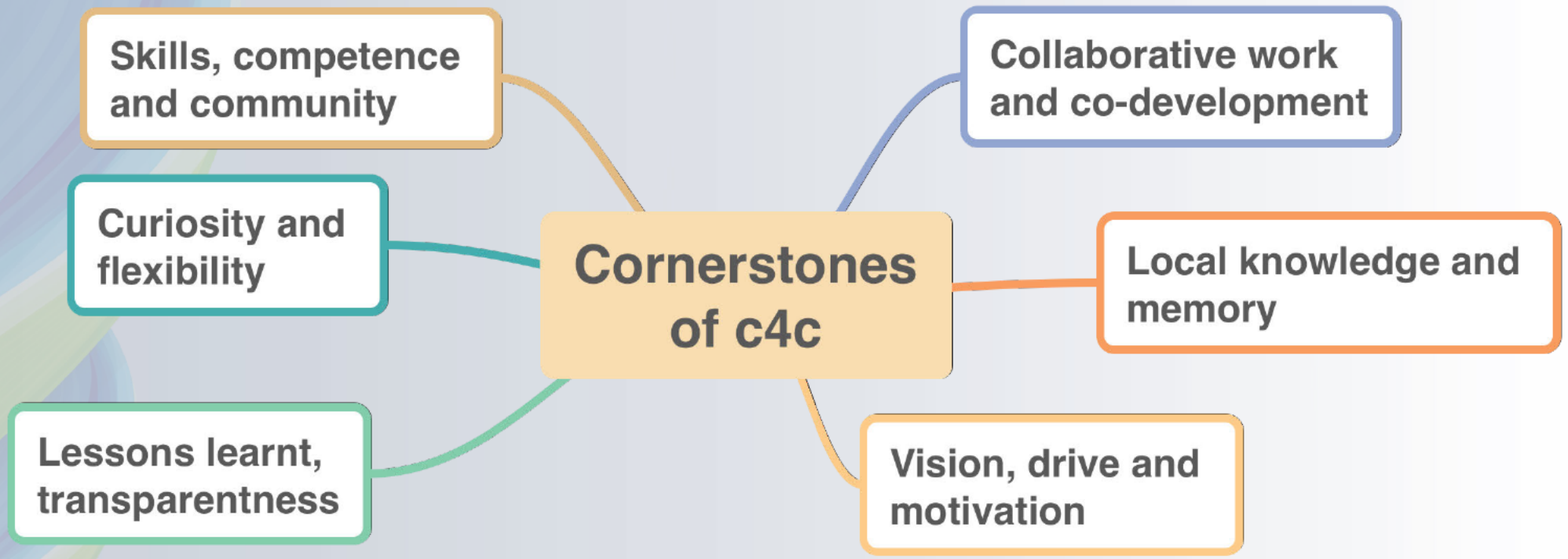
15 Expressions of Interest

6 Sponsors

Pillars of c4c service development

- The services were co-designed by industry and academic partners within the c4c consortium, involving extensive discussion and consultation to develop the underpinning processes within and across the project Work Packages.
- Some expectations
  - Service users and providers would share the same scope of collaboration, would use shared processes and shared information
  - Decisions made by one part of an organization would be enacted by other parts of an organization (e.g. between global and local structures / functions
  - It would be easier to align processes within a country
- Some assumptions
  - Strong set of drivers for collaboration within the paediatric clinical trials enterprise
  - Shared vision in the role of collaboration to achieve the objectives of the project
  - All stakeholders open to implementing new approaches to deal with existing hurdles of paediatric trials
  - Experience with previous infrastructures to be incorporated

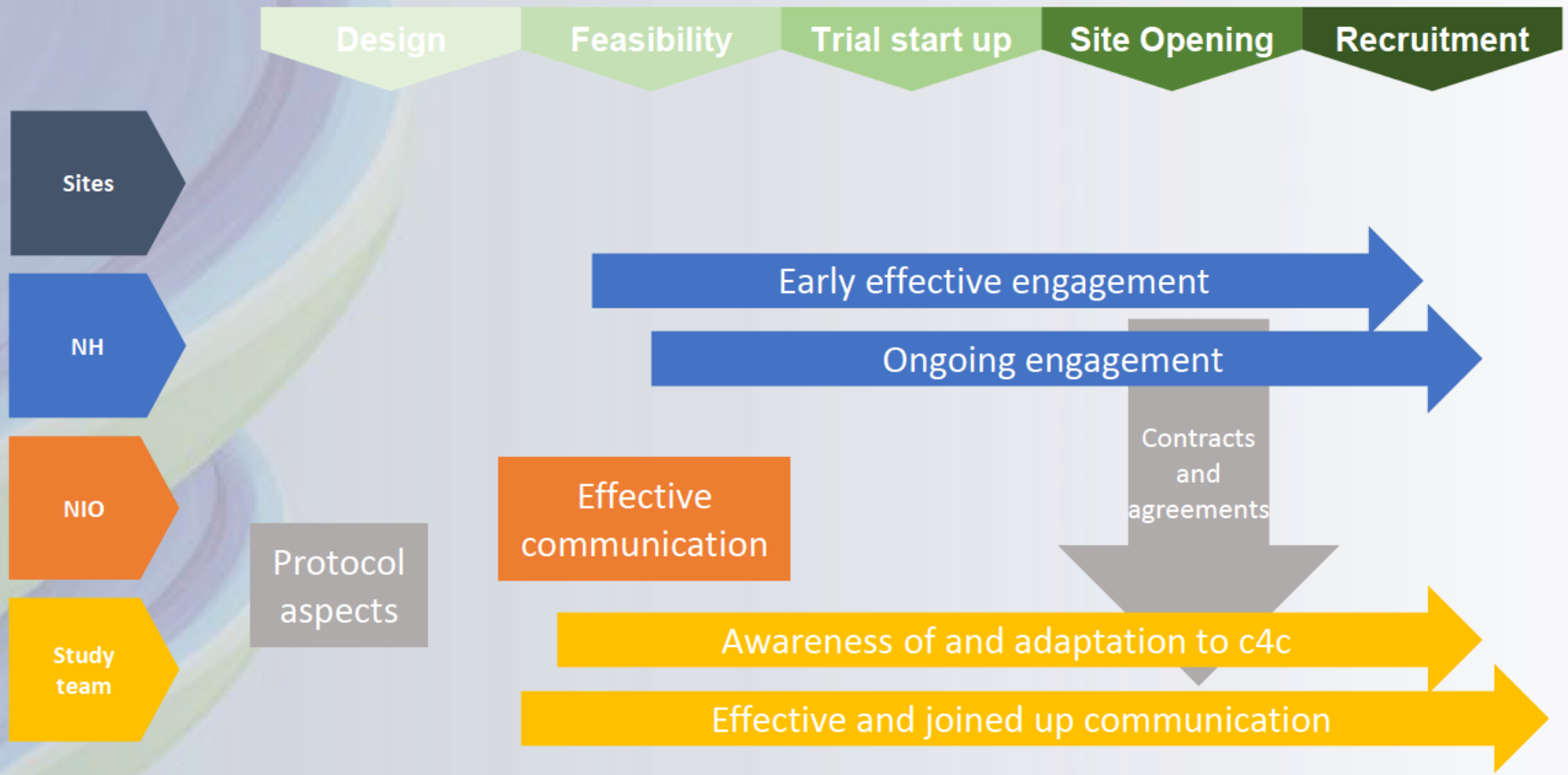
Building a network, generating value



A structured approach to lessons learnt

- Recognition of the importance of identifying lessons learnt during the development and initial deployment of the services through the network, that is shaped by and serves both industry and academic users.
- A comprehensive catalogue was established early in the project and maintained to collect learning points captured
    - Identify themes arising from the lessons learnt;
    - Map lessons learnt and themes to categories of the service;
    - Identify practical implications of the lessons learnt and themes.
- Some learning points discussed by specific trials were generalizable. Some learning points were from success stories or challenges that could be shared across all NHs.
- Ongoing project evaluation activities

Lessons Learnt



Value of collaborative work

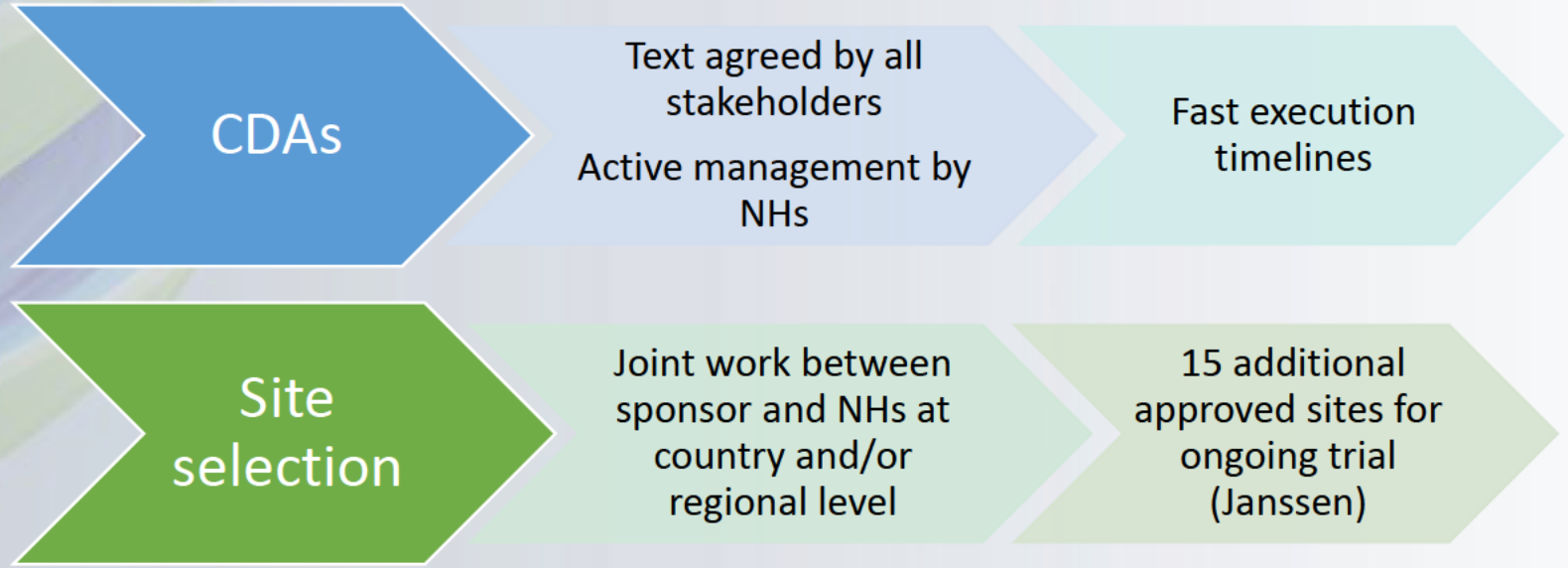
Challenge

Address sponsor needs of efficiency, quality and volume across the trial cycle

Learnings

Co-development of processes, tools and documents/templates

Collaborative implementation by NIO, NHs, Sponsors and sites



Importance of flexibility

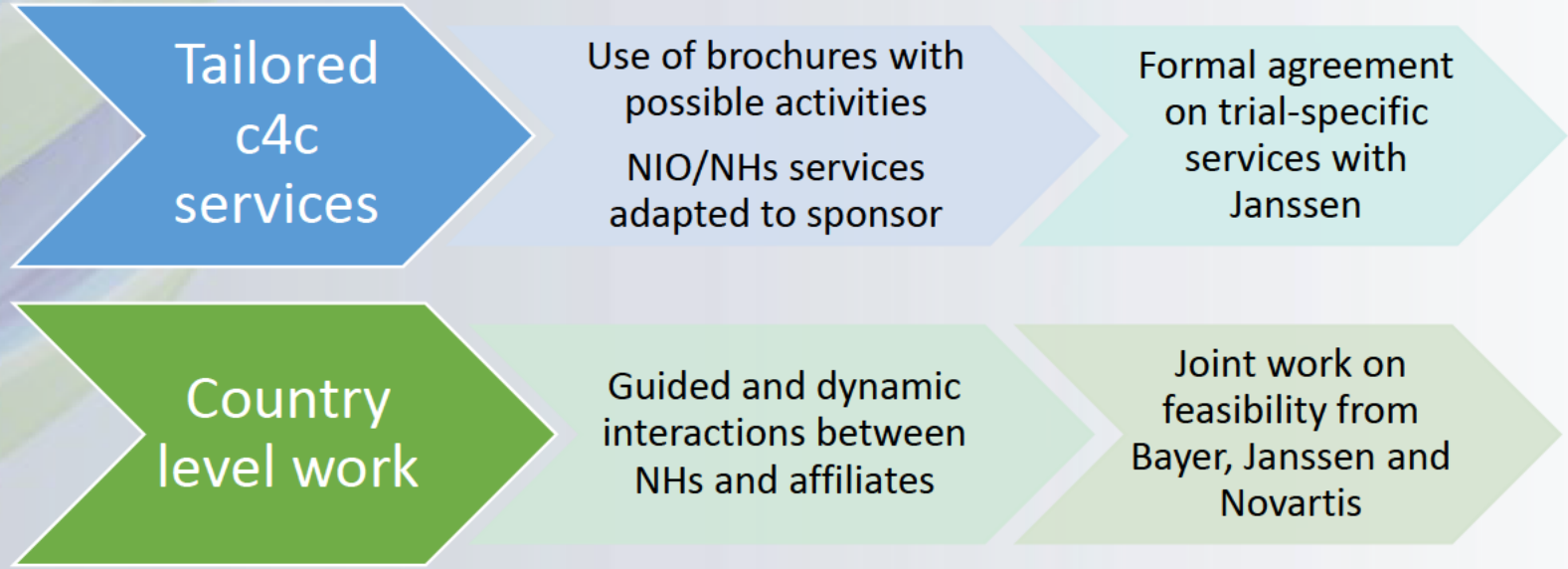
Challenge

Heterogeneity between sponsor expectations, internal organizations and ways of working

Learnings

Liaise with study teams and adapt to needs while using c4c processes

Accommodate both central engagement and country level interactions



Communication as a pillar

Challenge

Need for engagement, information and alignment between all stakeholders

Learnings

Early and clear communication and alignment across the network and with sponsors

Clarity of roles and responsibilities

- Communication cycle for PoV trials (monthly)
- TREOCAPA regular meetings with all trial stakeholders
- RASCI description of activities for c4c and sponsors, with NIO coordination
- Successful joint communication plan with Janssen - template for future trials

Exploring synergies

Challenge

Differences in country requirements, regulations, ethics, contracts in study setup

Learnings

Use network expertise

Early engagement and build relations with NHs for local intelligence and intervention

Sharing experiences between NHs

c4c Success Factors for sustainability

Working towards consistent measurable performance

Portfolio management framework - coordination	Performance management framework - proactivity	Communication	c4c Processes
To oversee and coordinate trials across multiple sites • Database/ list of studies, the stage that each study is at, contacts for each study: Sponsor / CRO, sites	Exerting timely and proactive intervention when necessary • Database/ list of actions indicating which actions are needed, when they are complete	• Rapid responses to communications from sites and Sponsor / CRO	• Consistent adherence to c4c processes including compliance with targets for CDAs, contracts etc. for e.g. for at least 80% of sites

Success Factors:

- Continuity and consistency across c4c and NH activities to build on knowledge and experience ("c4c wide corporate memory")
- "Knowledge of readiness" for NH and sites - critical and key to all activity.

Key Lessons learnt

Early Engagement

Establish and maintain early engagement with key stakeholders as soon as possible to start building relationships

Harmonized approach

Ensure NHs have a clear, harmonised approach, less variability and that NHs continue to learn and support each other, particularly as we expand/scale up and diversify our portfolio

Site engagement

Consistency is required. Sponsors value the close relationship between NHs and sites, which can be leveraged to achieve faster timelines and performance metrics

Adaptable Processes

Recognising when processes should be adaptable to support sponsor requests

Less resource intensive NIO

The function of Network Infrastructure Office (NIO) is resource intensive e.g. accommodating different sponsor requirements, time and human resource for cycles of meetings for each trial. Need to make efficiencies whilst retaining quality of service delivery

Underpinning NH activities

Ensure support to the sustainability plans of NHs, particularly in maintaining national underpinning activities, in continuity of learnings and pathways to keep up with new developments (e.g. regulatory)

Challenges of Rescue Studies

Consider the different implications, opportunities and risks of adopting "rescue" studies

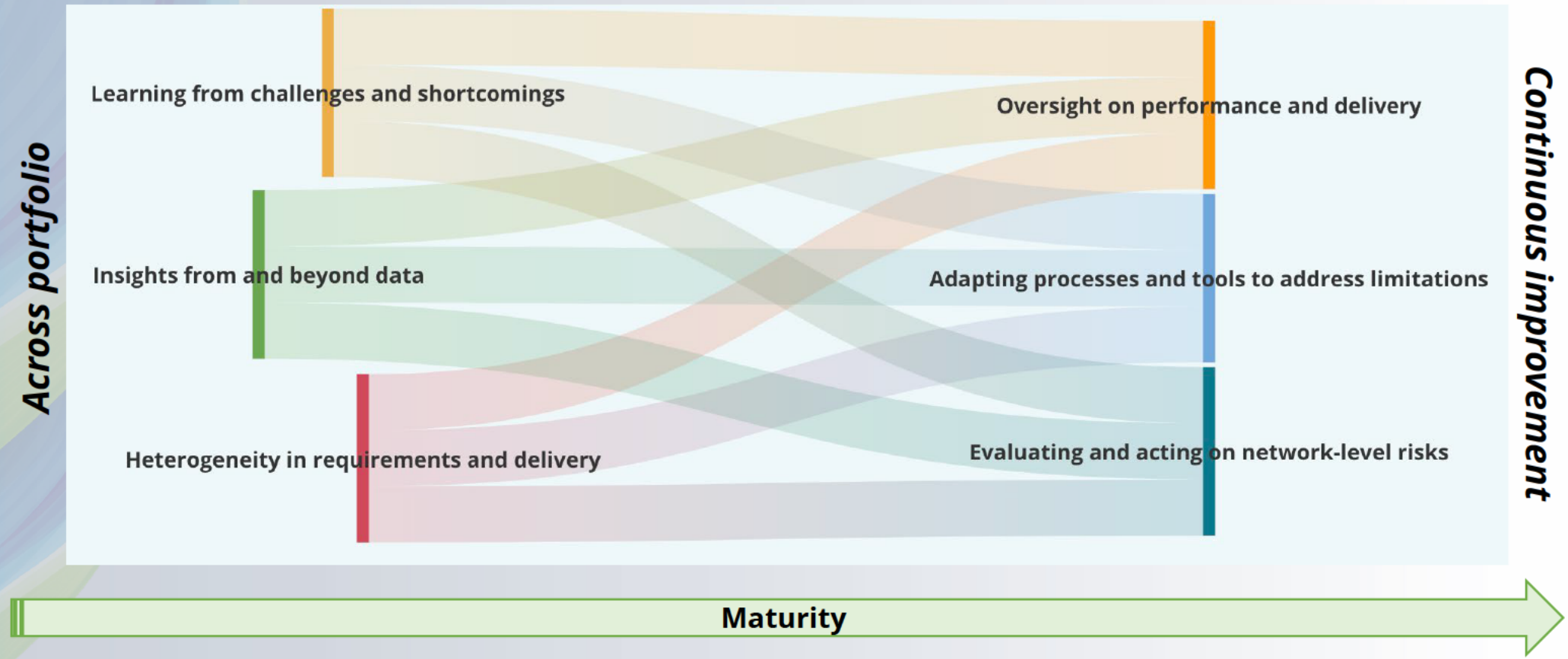
Value after feasibility

Clear, defined support packages need to be created that demonstrate the value of NHs beyond feasibility

Reducing Site Burden

Consider perception from site teams around c4c adopted trials, by agreeing with sponsors/CRO's on a single way of site approach to decrease the burden for the sites and proof that this European network/NLE is actually also advantageous for the sites

Distilling and refining the value of the network



The arithmetics of the c4c network