



**National Institute for
Health Research**

Clinical Research Network

Lessons learnt by a national, generic network

Mark Turner

Associate Director for European Affairs

NIHR-MCRN



The NIHR Medicines for Children Research Network is part of the National Institute for Health Research Clinical Research Network, and forms part of the UK Clinical Research Network. The Networks support and deliver high quality clinical research studies.

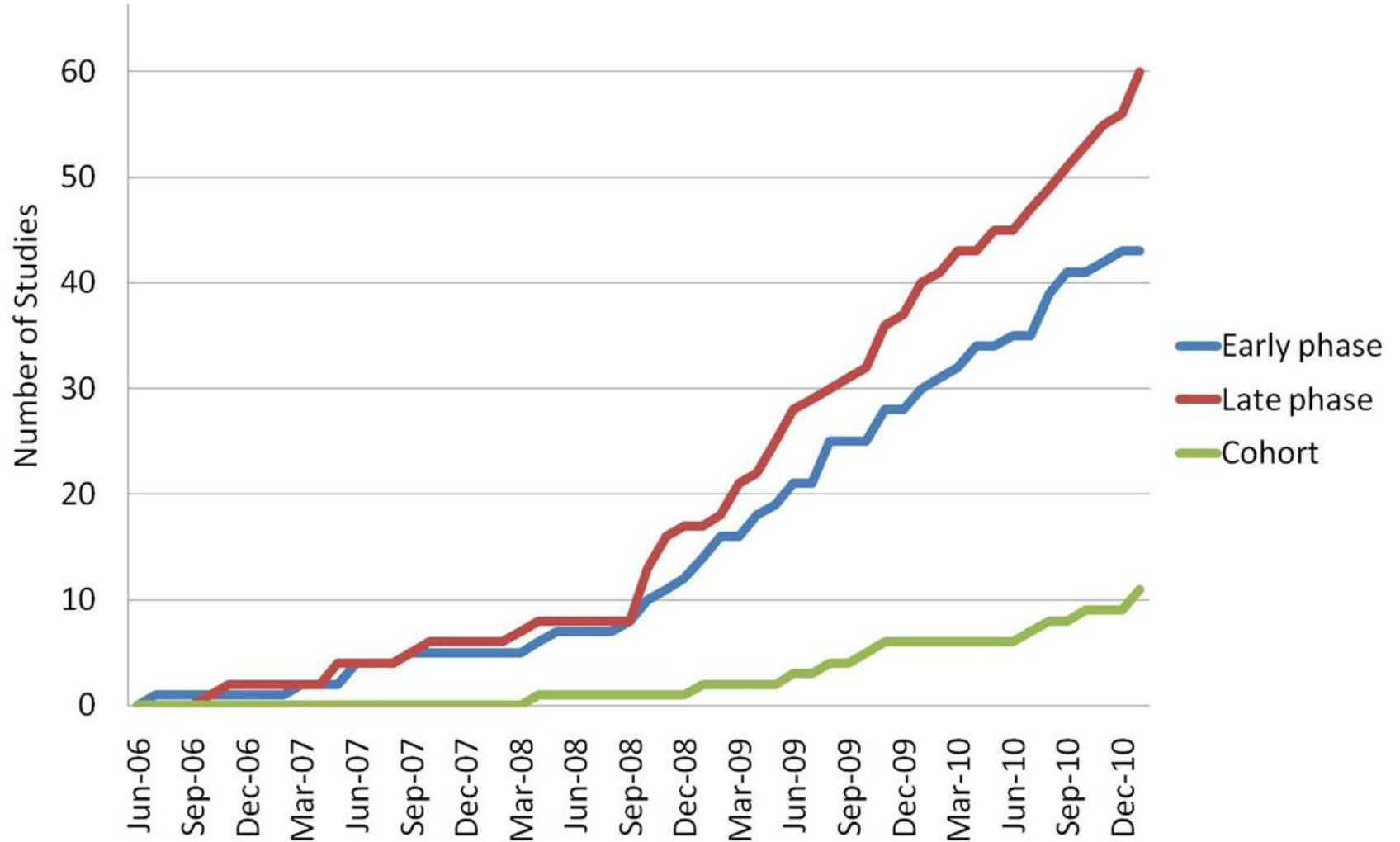


Lessons Learnt

- Trials in general
- Doing trials for children
- Added value of a generic network
- Problems with a generic network

Industry Portfolio

Clinical Research Network



Trials in general

Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study

Campbell et al. Health Technology Assessment 2007; Vol 11: No 4

<http://www.hta.ac.uk/execsumm/summ1148.htm>

- “Emphasis on 'conduct' (the process of actually doing trials). This implies learning lessons from successful trialists and trial managers, with better training for issues relating to trial conduct.”
- “The complexity of large trials means that unanticipated difficulties are highly likely at some time in every trial.... successful trials were those flexible and robust enough to adapt to unexpected issues.”



Trials in general

Need early engagement with relevant stakeholders

- PIP Design
 - Necessary
 - Appropriate
- Study design
 - Necessary
 - Appropriate
- Feasibility
- Set-up
- Delivery



Doing trials for children

- Children get health care in surprising places
- Age-appropriate formulations
- Trial-supply issues
- Continuing care sites

- Parents, children and young people can contribute a great deal to all stages of trial development
 - But need sensitive support (and feedback)
 - Parents are even busier than clinicians
 - Balance between comprehensive and tokenistic involvement – useful is somewhere in between.



Added value of a generic network

- Avoid re-inventing the wheel
- Multiple approaches to the same problem
- Single points of contact
- Can fill gaps
 - Feasibility
 - Set-up
- Re-usable infrastructure
- Support good habits in trials

Generic work is worth investing in



Feasibility

- Detailed feasibility assessments
- Assess if investigators have sufficient time to support studies and co-investigator
- PI/team experience helps

Set-up

- Communication and engagement
- Hospital management
- Resources and planning



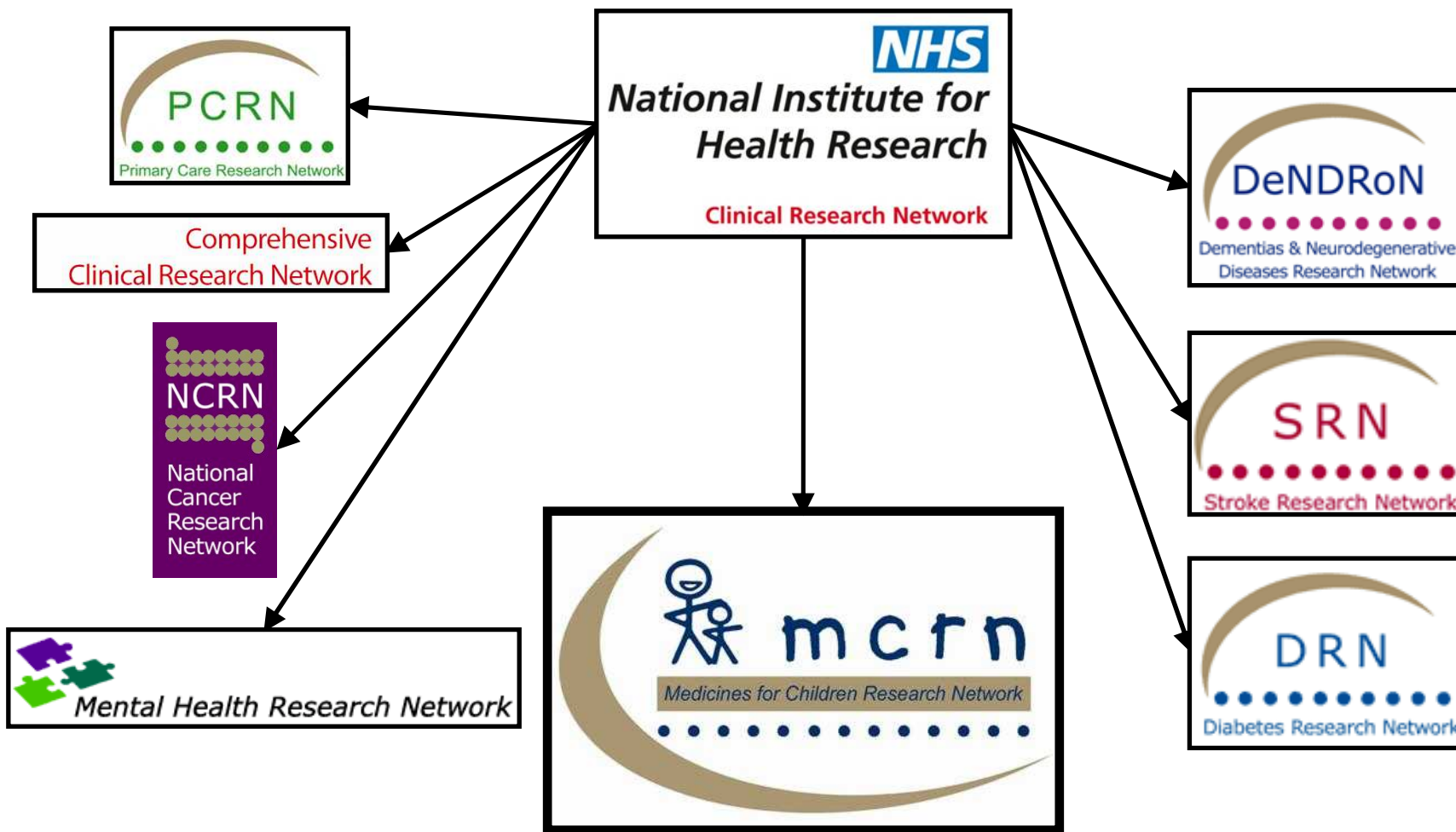
Reusable infrastructure

Once communication links are in place they can be reused

- Parents and children / young people
- Feasibility
- Setup
- Continuing care sites



NIHR Clinical Research Networks



Potential problems with a generic network

- Duplication
- Everyone thinks they are important
 - Network can impede investigators
- Good things can happen by accident, but consistency requires hard work
 - Do not be misled by low-lying fruit
- Managing personalities is important
- Do not be discouraged by learning curves

Best approach

- Clear expectations
 - With feedback
- Performance management
- Flexible implementation
- Continuous negotiation
- Engaged advisory groups
- Multiple perspectives
 - Expert groups, Pharmacists, parents etc.