

# Paediatric medicinal clinical trials: How do we organise this in England?

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NIHR Clinical Research Network: Children / Evelina London Children's Hospital

CRN : Networking Locally, Delivering Globally



*Delivering research to make patients,  
and the NHS, better*

# Context

- NIHR
- NIHR CRN
- NIHR CRN: Children
- ELCH



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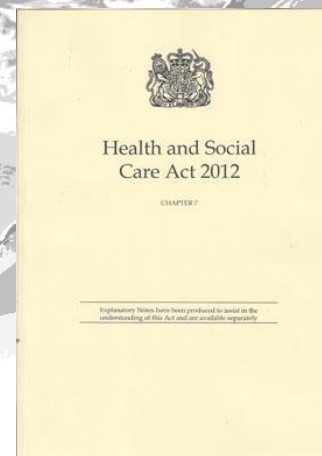
# The UK Health test

- Which countries are in the UK?
- What does the NHS stands for?
- Pediatric or Paediatric?



# Research landscape

- Political commitment to supporting research
- Political commitment to support life-sciences industry
- **Embed clinical research in all aspects of care**





**National Institute for  
Health Research**

Clinical Research Network

# National Institute for Health Research

## An overview



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# History of NIHR

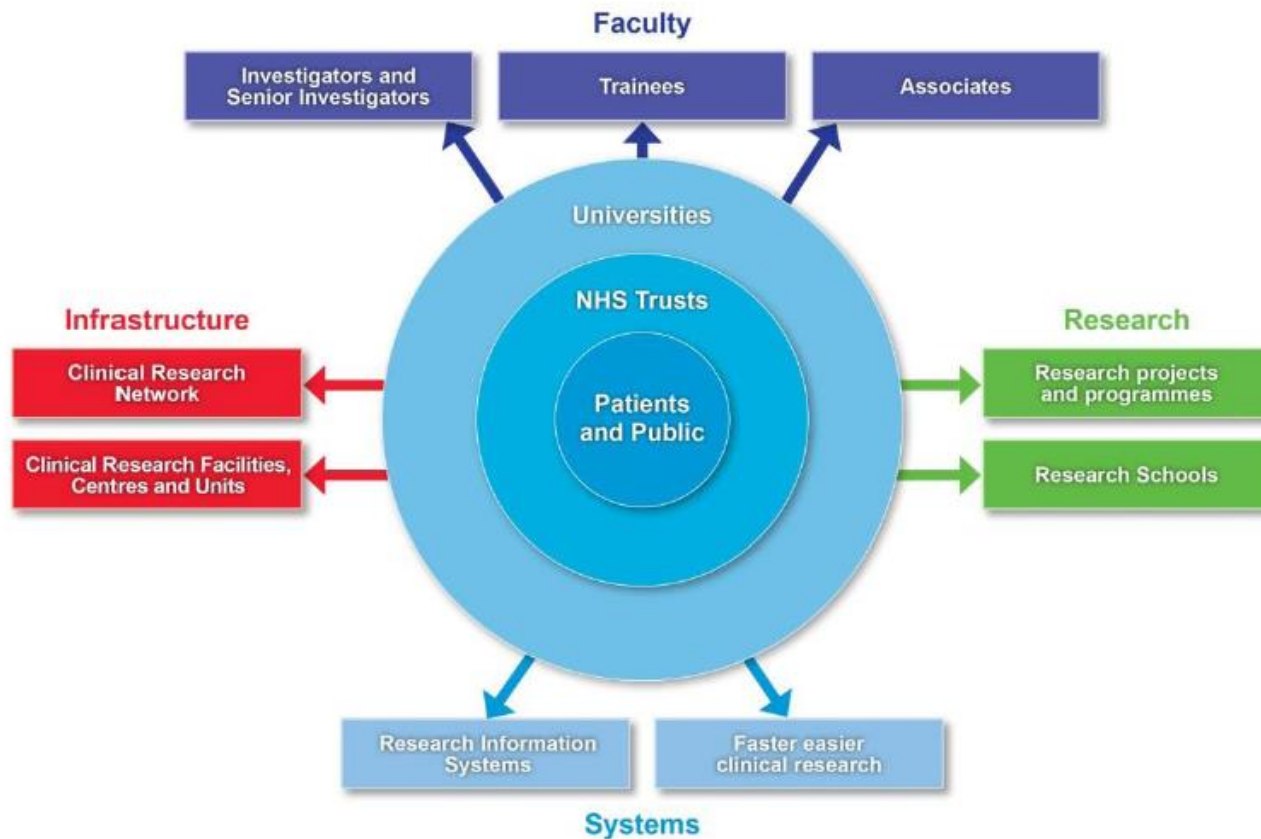
- Before the NIHR was created, applied (patient-based) research in the NHS was conducted and funded through a range of ad-hoc funding programmes and schemes managed by the Department of Health to address questions raised by front-line professionals and policy makers.
- The NIHR was created in April 2006 under the 2005 Government strategy for health research: [Best Research for Best Health](#).
- The NIHR is a large, multi-faceted and nationally virtual organisation.
- The NIHR provides the framework through which the Department of Health can position, maintain and manage the research, research staff and research infrastructure of the NHS in **England** as a national research facility.

# NIHR: Goals

- Establish the NHS as an internationally recognised centre of research excellence
- Attract, develop and retain the best research professionals to conduct people-based research
- Commission research focused on improving health and social care
- Strengthen and streamline systems for research management and governance
- Act as sound custodians of public money for the public good

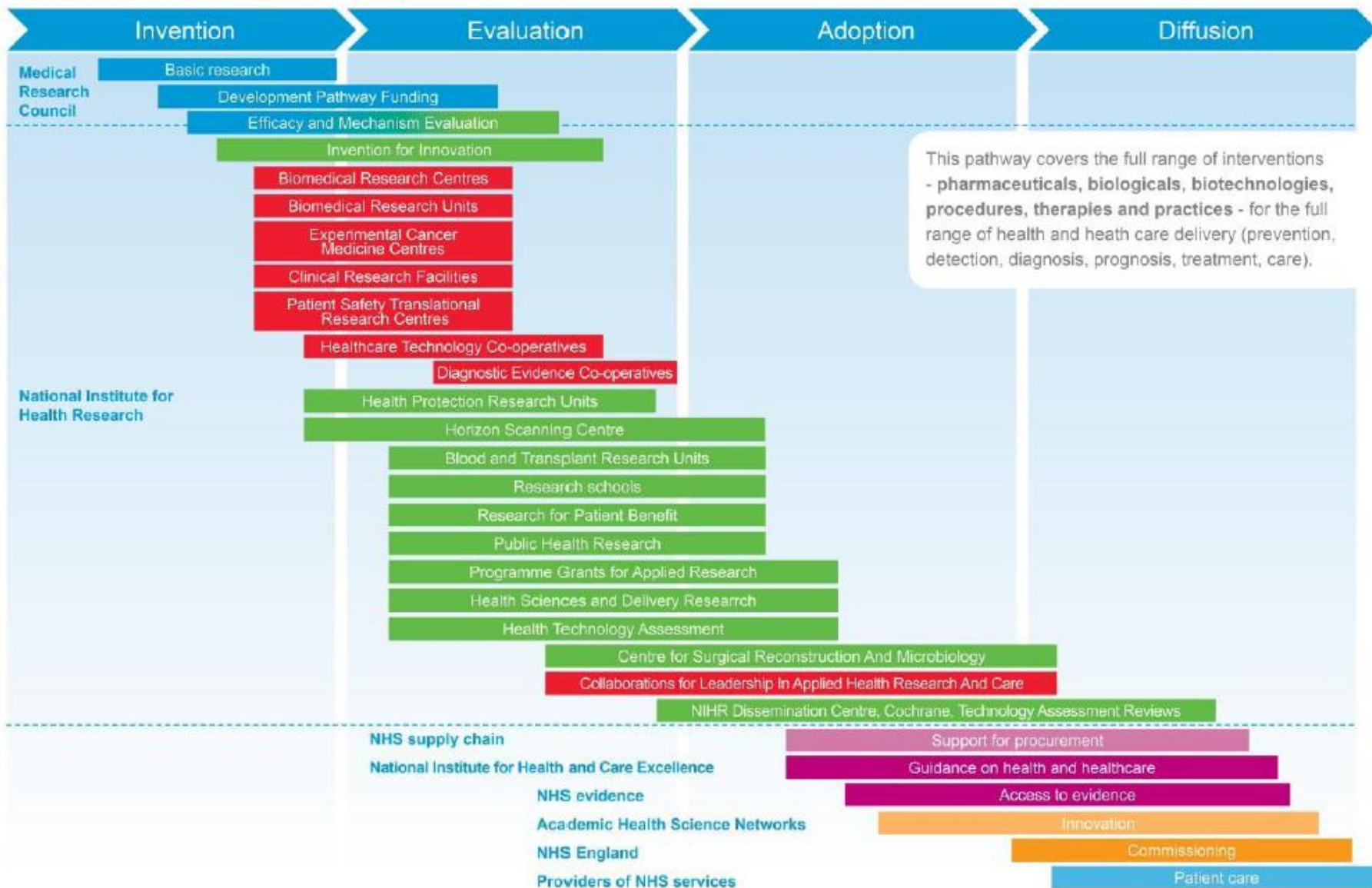
# Integrated health-research system

## The NIHR health research system





# The central role of NIHR research in the innovation pathway



# NIHR Research

- **Commissioned research programmes**
  - Offer a focused source of funding for researchers
  - Operate a peer reviewed funding system
- **Research School**
  - A collaboration between the leading academic centres
  - Commissioning research in primary care, social care and public health
- **Research Design Service**
  - 10 regionally based centres with access to research expertise on research methodologies, statistics, health economics and etc.
  - Advice and support on research design and methodology to researchers making funding applications
- **Health Protection Research Units**

# NIHR Faculty

- **NIHR Faculty**
  - Empowers and develops the NIHR community of research professionals
  - 3 categories of membership: Investigators, associates and trainees
- **Research Training and Career Development**
  - Create new generation of researchers
  - The programmes provide support for the academic training paths of all health care professionals.
  - Enable the development of clinical academics
- **Leadership Support and Development**
  - To develop a strong leadership capability within the NIHR Faculty
  - The programme focuses on leadership development that contributes to research performance and the strategic priorities of the NIHR

# NIHR Systems

- **Faster, Easier Clinical Research**
  - Working to simplify the research approval processes
  - Provide tools to support researchers
  - Performance management
  
- **Information Systems Function**
  - Unify and simplify the administrative procedures for research
  - Enable procedures and input of data to take place once only, recognising the interdependency and interoperability of systems and processes.
  - Make information supporting regulatory approvals and permissions available via secure systems and processes to everyone who needs to act on it.
  - Provide accurate intelligence and analysis on the operation of the NIHR to support planning and resource allocation.

# NIHR Infrastructure

- Clinical Research Network
- Biomedical Research Centres
- Biomedical Research Units
- Clinical Research Facilities for Experimental Medicine
- Collaborations for Leadership in Applied Health Research and Care
- NIHR Office for Clinical Research Infrastructure
- Patient Safety Translational Research Centres
- Experimental Cancer Medicine Centres
- Research Capability Funding
- Translational Research Partnerships
- Health Technology Co-operatives
- Diagnostic Evidence Co-operatives
- MRC-NIHR National Phenome Centre
- NIHR National Biosample Centre

# NIHR Clinical Research Network (NIHR CRN) An overview



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# Integrated health-research system

**NHS**

National Institute for  
Health Research

Clinical Research Network

Invention

Evaluation

Adoption

Early-phase clinical Research

Late-phase clinical Research

NIHR Biomedical Research Centres

NIHR Biomedical Research Units

NIHR Clinical Research Facilities

Experimental Cancer Medicine Centre

Health Technology Cooperatives

Diagnostic Evidence Cooperatives

NIHR Clinical Research Network

Collaboration for Leadership in Applied Health Research and Care

# NIHR CRN Location

- ONE National Network covering all of England
- Operating across 15 geographical areas
- Each covering all study delivery in all therapy areas
- Work closely with Devolved administrations
- Each Local Clinical Network is co-terminous with Academic Health Science Network boundaries
- And hosted by an NHS organisation – CRN is part of the NHS





# NIHR CRN Specialty

The thirty specialities are:

Ageing	Dementia and Neuro Degeneration (DeNDRoN)	Haematology	Metabolic and Endocrine Disorders	Public Health
Anaesthesia, Peri-operative Medicine and Pain Management	Dermatology	Health Services and Delivery Research	Musculoskeletal Disorders	Renal Disorders
Cancer	Diabetes	Hepatology	Neurological Disorders	Reproductive Health and Childbirth
Cardiovascular Disease	Ear, Nose and Throat	Infectious Diseases and Microbiology	Ophthalmology	Respiratory Disorders
Children	Gastroenterology	Injuries and Emergencies	Oral and Dental Health	Stroke
Critical Care	Genetics	Mental Health	Primary Care	Surgery

# NIHR CRN overview

- Provides the infrastructure (e.g. research support staff such as clinical research nurses; and research support services such as pharmacy, pathology and radiology) to support clinical research in the NHS in England.
- Allocates and manages funding to meet NHS Service Support (e.g. additional nursing time; pathology sessions; lab costs; imaging; additional out-patients costs) for eligible studies.
- Embedded within the NHS

# NIHR CRN role

- To provide efficient and effective support for the initiation and delivery of funded research in the NHS.
- We help researchers to identify suitable NHS sites with the facilities and patient populations required by the study (“feasibility”)
- We provide a streamlined system for gaining the necessary permissions to carry out the research study in hospitals and healthcare practices.
- We recruit patients into studies, and managing this process effectively, so that researchers can answer the research question within their required timeframe.
- We give researchers advice on how to make their study “work” in the NHS environment, from a practical point of view.



**National Institute for  
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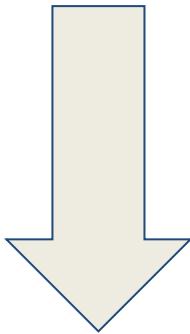
# NIHR CRN: Children



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# History

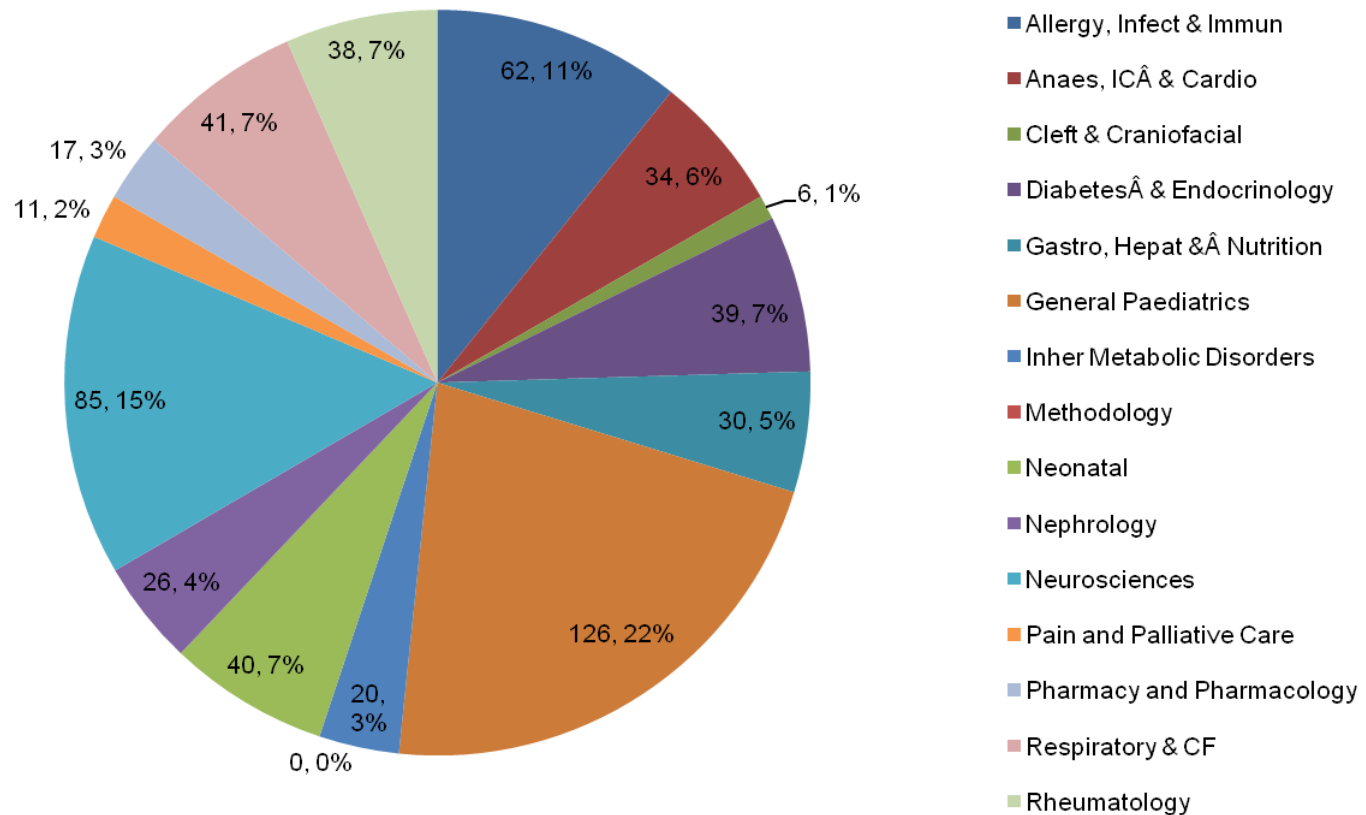
- Medicines for Children Research Network



- **NIHR CRN: Children**



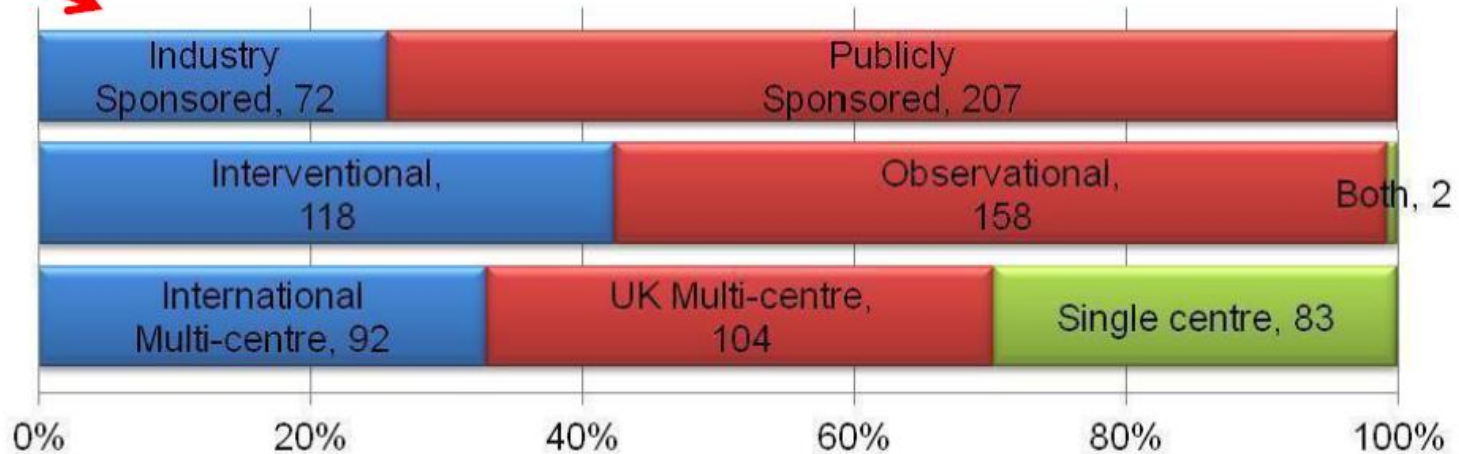
# Children's Portfolio by Specialty



# Children's Portfolio

- All paediatric specialties (except oncology / mental health)
- Total number of studies in portfolio to date - 797
- Number of studies in set up and open - 279
- For 2013/2014 - recruited 27, 814 children

Almost  
all  
pharma



# Clinical Studies Groups

The CSGs help to direct and develop the future research portfolio within their specialty to ensure it is balanced and meaningful by supporting those who are designing study proposals (reactive role) or developing our own research to run across the network (proactive role).

- Focusing ideas and refining the research question
- Facilitating patient and parent input
- Overall study design
- Formulations and pharmacy advice
- Feasibility of study recruitment
- Links up with Clinical Trials Units (expertise in statistics and trial management)
- Sign posting to funding opportunities and NIHR CRN support
- Providing connections with other relevant researchers
- Disseminating and publicising research



# Supporting life sciences industry

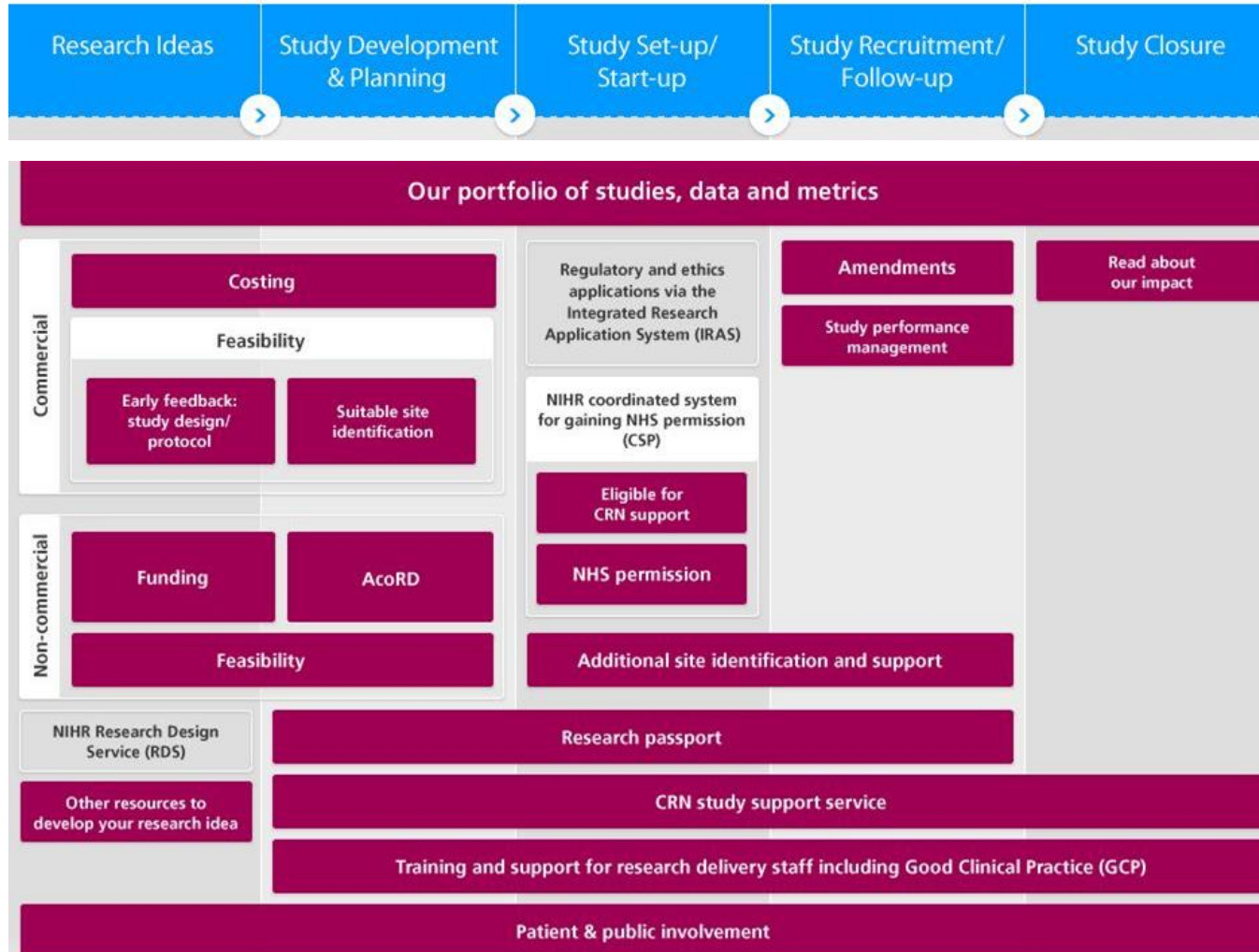
**Feasibility** - The CRN can help identify or confirm potential study sites and targets.

**Setup** - We are constantly working to improve the set-up and delivery of clinical research studies in the NHS. Tools to support study set-up:

- Commercial study costing templates
- Model Clinical Agreements
- Local pharmacy review of research studies

**Performance Management** - Our collaborative approach to the performance management of network supported sites aids consistent delivery of your study to time and target

# Investigator led studies



# Supporting research locally – Evelina (ELCH)



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# Evelina London



- Not a Research and Development (R&D team) – we do not review or approve studies.
- Funded by research activity.
- Investigators can apply on a study-by-study basis for our team's support.
- We help investigators to 'deliver' their studies to 'time and target'.



## Support interventional & observational studies:

- Over 40 studies on a 'full time' basis
- 10-30 studies on an 'ad hoc' basis

# Evelina - our team

**NICU studies RN cover:**  
 Julia Wurie- KCL oversight,  
 Isabel Viac- Xe CTIMP  
 Helen Bromfield- Planet  
 Mary Ann Sharma- imaging

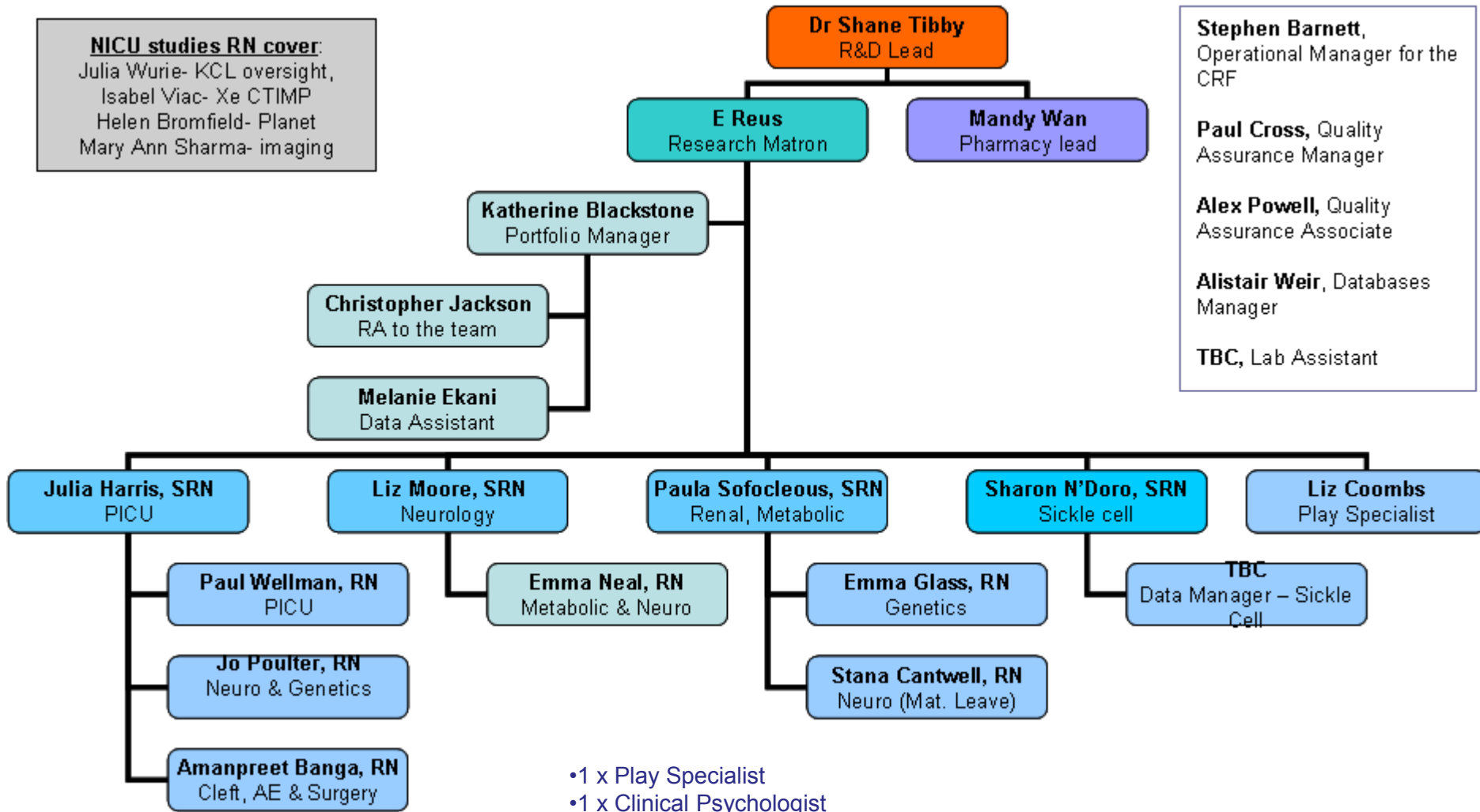
**Stephen Barnett,**  
 Operational Manager for the CRF

**Paul Cross,** Quality Assurance Manager

**Alex Powell,** Quality Assurance Associate

**Alistair Weir,** Databases Manager

TBC, Lab Assistant





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**Thank you!**



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