



NHS
*National Institute for
Health Research*

Medicines for Children Research Network



The Medicines for Children Research Network is part of the
National Institute for Health Research

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WHAT IS THE MEDICINES FOR CHILDREN RESEARCH NETWORK?

The National Institute for Health Research (NIHR) Medicines for Children Research Network (MCRN) has been created to improve the co-ordination, speed and quality of randomised controlled trials and other well designed studies of medicines for children and adolescents, including those for prevention, diagnosis and treatment. The Network has extensive knowledge and experience of paediatric research, and supports non-commercial, pharmaceutical/biotech-sponsored and investigator-led partnership studies in over 100 NHS sites that serve approximately 6 million children. The MCRN supports studies through its infrastructure, which includes the MCRN Coordinating Centre, Local Research Networks (LRNs), Clinical Studies Groups (CSGs), Clinical Trial Units (CTUs) and a Neonatal Network.

The MCRN Coordinating Centre is led by a consortium comprising the University of Liverpool, Royal Liverpool Children's Hospital, Imperial College London, National Perinatal Epidemiology Unit (NPEU; University of Oxford), Liverpool Women's Hospital and the National Children's Bureau.

The NIHR MCRN is funded by the Department of Health and works in partnership with the UK Clinical Research Network (UKCRN) to improve the UK's clinical research environment and maximise the development of safe and effective medicines and formulations for children.

HOW WILL THE MCRN ACCELERATE CLINICAL RESEARCH INVOLVING CHILDREN?

The MCRN provides coordinated, efficient access to a large and diverse population of children across a range of clinical services and demographics through a world-class infrastructure comprising:

MCRN Coordinating Centre

The MCRN Coordinating Centre manages activity during feasibility, setup and all phases of study delivery. The Centre assesses the suitability of studies for adoption into the MCRN portfolio and manages overall study recruitment objectives. It supports the work of the expert Clinical Studies Groups (CSGs; see below), coordinates research training and supports an active and innovative programme of consumer involvement. The Coordinating Centre is based at the University of Liverpool's Institute of Child Health at the Royal Liverpool Children's Hospital and is directed by Professor Rosalind Smyth.

The Coordinating Centre acts as a single point of contact for those conducting or interested in developing clinical studies. If you have questions about non-commercial studies or have general enquires, please email info@mcrn.org.uk, or if you have questions related to industry studies, please email industry@mcrn.org.uk.

Clinical Studies Groups (CSGs)

The MCRN has established CSGs to cover the majority of paediatric specialities (Box 1). CSGs are comprised of a multidisciplinary membership of key opinion leaders and support both non-commercial and commercial investigators that want to conduct studies at MCRN sites. The groups identify research priorities and develop study proposals to address important clinical questions that are of relevance to children. In addition, CSGs work with investigators to ensure that study design is optimal and to assess study feasibility.

If you would like advice from CSGs on any matter, please email csq@mcrn.org.uk.

Box 1: Clinical Studies Groups

- Allergy, Nephrology, Infection, Immunity and Haematology
- Anaesthesia, Intensive Care, Pain Control and Cardiology
- Diabetes, Endocrinology and Metabolic Medicine
- Gastroenterology, Hepatology and Nutrition
- General Paediatrics
- Neonatal
- Neurosciences
- Methodology
- Pharmacy and Pharmacology (including Paediatric Formulations and Pharmacokinetics)
- Respiratory and Cystic Fibrosis
- Rheumatology (arc/MCRN collaboration)
- Children's Cancer and Leukaemia Group (CCLG; please note that this is a Specialist Research Network within the National Cancer Research Network; NCRN)

Local Research Networks (LRNs)

The MCRN LRNs ensure that clinical trials involving children are performed efficiently to the highest standards across NHS sites. In total, there are 6 LRNs that cover over 100 NHS sites that serve approximately 6 million children. (Please see Box 2 and www.mcrn.org.uk for further details of the clinical sites covered). LRNs assist those wanting to conduct studies by improving set-up time and reducing administrative burden. The Networks help with detailed feasibility assessments, assist with site selection and provide support with local financial, ethical and governance arrangements. In addition, LRNs can assist with staff recruitment and training, and facilitate efficient recruitment of participants, monitoring enrolment throughout projects. Clinical staff employed by LRNs have training and experience of working in accordance with Good Clinical Practice (GCP) standards. For further information of the MRN LRNs, please see www.mcrn.org.uk

Box 2: LRNs (in alphabetical order)

- Cheshire, Merseyside & North Wales LRN
cmnw@mcrn.org.uk
- Greater Manchester, Lancashire and South Cumbria LRN
gmlc@mcrn.org.uk
- London - South East, North, Central and East (SENCE) LRN
sence@mcrn.org.uk
- South West LRN
swest@mcrn.org.uk
- Trent LRN
trent@mcrn.org.uk
- West Midlands LRN
wmids@mcrn.org.uk

Where appropriate, Network activities are co-ordinated with other UKCRN-managed Clinical Research Networks and medicines for children networks in Scotland, Northern Ireland and Wales.

MCRN Neonatal Network

The MCRN has developed an extended Neonatal Network to promote and support clinical research in neonatology units across the UK. The Neonatal Network Coordinator, based at the National Perinatal Epidemiology Unit (NPEU; www.npeu.ox.ac.uk) in Oxford, acts as a central resource for those neonatal units that do not fall within the LRN boundaries. Through the Neonatal Network, units can access advice on regulatory approval submissions and are kept informed of regulatory issues and training opportunities.

For further information on the Neonatal Network, please email neonatal@mcrn.org.uk.

MCRN-Affiliated Clinical Trials Units (CTUs)

MCRN CTU: Working in partnership with investigators, the MCRN CTU provides advice and support on all aspects of study design and management, including the preparation of grant applications, protocol and case report form development, regulatory authority and research ethics committee submissions, data management/analysis and the preparation of reports for data monitoring committees. For further information on the MCRN CTU, please email ctu@mcrn.org.uk.

NPEU: The MCRN works closely with the NPEU CTU that is specifically involved in the management of neonatal studies. For further information on the NPEU, please email general@npeu.ox.ac.uk.

Other CTUs: A network of CTUs associated with the design and management of MCRN portfolio studies, including the MCRN and NPEU CTUs, is currently being developed.

Experimental Medicine

As well as supporting large studies, the MCRN assists the development of new medicines through smaller experimental studies of promising drugs. In the early stages of the development of new medicines, study requirements are different; typically there will be only a small number of patients treated, but assessments of the effects of the potential medicine will be much more detailed. The MCRN works with specialised research teams to support experimental studies.

For further information on experimental medicine across the MCRN, please email info@mcrn.org.uk.

Formulations

Many medicines used by children are not available in age-appropriate formulations. To address this, MCRN Formulation Fellows (working closely with CSGs and others in the MCRN) provide advice on pharmaceutical aspects of clinical trial design. This includes the provision of advice on formulation development, extemporaneous formulations and the manipulation of 'adult' dosage forms.

For further information on formulations, please email info@mcrn.org.uk.

WHAT SUPPORT DOES THE MCRN PROVIDE FOR STUDIES?

The MCRN can support investigators at all stages of their study, from the development of an initial idea into a full protocol, to assistance with the wide dissemination of results across the UK and beyond.

Stage 1 – Study Development (Including Feasibility Assessments)

If you have an idea for a study, please contact the MCRN Coordinating Centre for advice in the first instance (for non-commercial studies please email info@mcrn.org.uk, and commercial studies please email industry@mcrn.org.uk). After initial assessments, investigators will be put in contact with the most appropriate CSG for expert advice on study design and methodology, formulations, UK-wide feasibility and regulatory compliance. Where public funding is required, CSGs can assist with the development of study ideas into strong funding applications and provide letters of support to funding bodies. LRNs and the Neonatal Network also have an important role in providing feasibility assessments by conducting detailed site evaluations and can assist with site selection. If required, consumer views can also be gauged during study development. For industry studies, generic UKCRN confidentiality agreements can be used to expedite collaboration with the MCRN.

Stage 2 – Qualifying for MCRN Support (Adoption into the MCRN Portfolio)

After initial discussions with CSGs and after funding is obtained, studies can be adopted into the MCRN portfolio. The MCRN adoption process also allows studies that are currently running without MCRN support to qualify for assistance. The adoption process involves the investigator submitting the study protocol to the MCRN Study Adoption Committee, with the committee subsequently assessing the suitability of the study using the following principles:

- Is the study well designed and of relevance to the NHS and its patients?
- Will the medicine/formulation under investigation provide a therapeutic benefit or meet an unmet therapeutic need?
- Does the MCRN have the current capacity to deliver the study efficiently and within budget?

For further information on adoption to the MCRN portfolio, please email adoption@mcrn.org.uk.

Stage 3 – Study Setup

Following study adoption to the MCRN portfolio, LRNs and the Neonatal Network reduce administrative burden and improve study setup times by providing assistance with:

- Local R&D approval
- Local Research Ethics Committee (LREC) approval
- Staff contracting and recruitment
- Training (with those working on studies having access to free UKCRN and local courses)
- Contracts and financing
- Study publicity

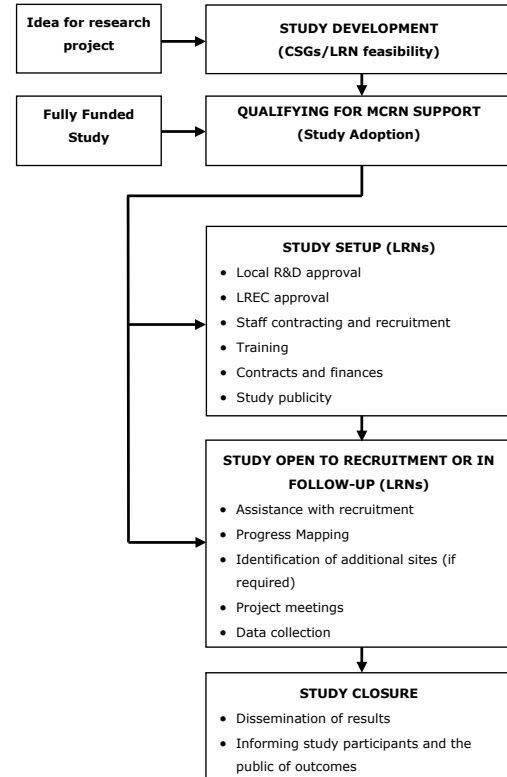
Stage 4 – Studies Open to Recruitment (or in Follow-Up)

There are several ways in which the MCRN can support studies that have been initiated or are in follow-up. LRN staff can help to recruit children eligible for the project and can provide information and support for children and families involved in studies. Furthermore, LRN and Coordinating Centre staff monitor enrolment throughout projects, allowing any problems to be identified early and thereby maximising the chances of an effective solution. If recruitment is below expectations, the MCRN can rapidly enrol additional centres within LRNs. The collection of high quality data is also an important element of the work of LRNs, with expert staff being available to assist studies. In addition, the MCRN is able to support data collection during long-term pharmacovigilance studies.

Stage 5 – Study Closure

Upon the successful completion of a study, the MCRN can assist with the dissemination of results throughout the UK and beyond. Working with consumer involvement partners and patient support groups, the MCRN can inform children, families and the public about study outcomes using a number of strategies. Summaries of study outcomes will also be available on the publicly accessible UKCRN website (www.ukcrn.org.uk). Where appropriate, results will be published in journal articles and presented at conferences, and the MCRN will work to ensure that prescribing practices across the UK are aligned to the findings of studies conducted across the Network.

Flow diagram to show the support that MCRN can provide



SUMMARY

- The MCRN has been created to improve the co-ordination, speed and quality of randomised controlled trials and other well designed studies of medicines for children and adolescents.
- Non-commercial, pharmaceutical/biotech-sponsored and investigator-led (industry funded) studies are supported by the Network.
- The MCRN provides coordinated, efficient access to a large and diverse population of children across a range of clinical services and demographics through a world-class infrastructure.
- Investigators can come to the MCRN for advice on study design.
- MCRN staff can conduct feasibility assessments and accelerate study setup by providing support with financial, ethical and governance arrangements. In addition, the Network can assist with staff recruitment and training.
- During study phases, MCRN staff ensure streamlined recruitment of participants and continually monitor enrolment, taking corrective action where required. MCRN staff also support data collection.
- The MCRN works to ensure that studies are completed on time and within budget.
- As well as supporting large studies, the Network assists the development of new medicines through smaller experimental studies.
- Ultimately, the MCRN will improve the UK's clinical research environment and maximise the development of safe and effective medicines and formulations for children.

FREQUENTLY ASKED QUESTIONS

Will the MCRN fund my study?

The MCRN does not fund studies and full funding must be obtained from public or commercial sources. However, the additional support provided by the MCRN should ensure that recruitment targets will be achieved efficiently, thereby avoiding the need for investigators to gain additional funding to complete the study.

Are MCRN staff available to work on my study full time?

Funding obtained for studies must cover all staffing costs. LRN staff will provide infrastructure support within the NHS to ensure that studies are conducted efficiently and to a high standard.

Will the MCRN cover Service Support Costs?

The MCRN does not manage Service Support Costs and in the future they will be distributed by the Comprehensive Research Network. Only studies adopted into the National Institute for Health Research (NIHR) Portfolio (including studies adopted by the MCRN) will be eligible for Service Support Costs. For further information, please email info@ukcrn.org.uk.

What are the administrative implications of being included in the MCRN portfolio?

To effectively performance manage studies adopted by the MCRN, investigators/study coordinators are required to provide information for the UKCRN Portfolio Database. The Portfolio Database is an excellent way of promoting research studies that is easily accessed via the UKCRN website and can provide searchable access to study information for the research community, service users

and the public (commercially sensitive information is not made publicly available). The activity and performance of the MCRN is measured in part by the rate of accrual to studies included in its portfolio. During recruitment phases, accrual data is required on a monthly basis for all UK sites.

What training can those involved with adopted studies access?

Free courses organised by UKCRN are available to all to staff working on or associated with adopted studies. These range from generic to topic specific courses, including paediatric specific training. Online courses are also available within the training portfolio. If you have any further questions about training, please email training@mcrn.org.uk.

Can studies only be conducted in LRN-supported sites?

Studies adopted by the MCRN are not restricted to being conducted in LRN-supported sites alone. However, MCRN support can only be given to sites in LRN areas. Sites located outside LRNs will receive support from Comprehensive Local Research Networks.

How do studies become adopted within the portfolio?

All relevant non-commercial studies funded by NIHR partners will automatically be included within the MCRN portfolio. Other non-commercial studies may be eligible for inclusion if they investigate medicinal products for children, are prospective, require informed consent and are awarded following open national competition with high-quality peer-review. It is recommended that investigators contact the MCRN Coordinating Centre to gain clarification on whether a study meets these criteria.

As mentioned above, relevant industry-sponsored studies can also be conducted by the MCRN. Once a study has been identified as being eligible for inclusion in the MCRN portfolio, it must go through a process of adoption, which includes an assessment of the feasibility of conducting the study through the Network. For further information on adoption to the MCRN portfolio, please email adoption@mcrn.org.uk.

Does my company need to consider the new EU Regulation on paediatric medicines?

The EU Regulation on paediatric medicines came into force on 26 January 2007. MCRN staff work closely with medicines regulators in the UK and EU, and can assist by providing general information on the Regulation and by directing companies to appropriate experts. For further information, please email industry@mcrn.org.uk.

CONTACTS

Please use the following email addresses for enquires on:

General MCRN matters:

info@mcrn.org.uk

Industry:

industry@mcrn.org.uk

Study Adoption Process:

adoption@mcrn.org.uk

MCRN CTU:

ctu@mcrn.org.uk

CSGs:

csg@mcrn.org.uk

Training and Education:

training@mcrn.org.uk

Consumer Involvement:

consumeractivities@mcrn.org.uk

Neonatal Network:

neonatal@mcrn.org.uk

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