

# Medicines for Children Research Network: *Support for commercial research in the NHS*



## ***Why does the MCRN help pharmaceutical and biotech companies to conduct research?***

The Medicines for Children Research Network (MCRN) supports the co-ordination, speed and quality of randomised controlled trials and other well designed studies of medicines for children and adolescents. As well as supporting non-commercial research, the MCRN supports commercially sponsored studies to:

- Maximise the development of safe and effective licensed medicines and formulations for children
- Benefit the NHS economically, with full costs and overheads and capacity building being paid by companies
- Develop the UK's paediatric research infrastructure and international reputation

This document outlines how the MCRN and its 6 Local Research Networks (LRNs) work with NHS staff including investigators, R&D Managers and pharmacists to support commercially sponsored studies.

## ***How does the MCRN support commercial research studies?***

The MCRN helps local investigators and sites to work with companies effectively during:

1. Feasibility (Site identification)
2. Implementation (Site setup)
3. Study recruitment & monitoring
4. Study closure

### ***1. Feasibility (Site identification)***

The MCRN alerts investigators to commercial studies that they may be interested in conducting locally. Companies typically provide the MCRN Coordinating Centre with study information, which is then reviewed by relevant clinical experts and, if deemed compatible with UK practice, circulated to potential investigators via the LRNs. If the study is of interest, investigators are asked to give an "expression of interest", with appropriate contact details and an initial estimation of patient numbers.

An expression of interest does not constitute a commitment to future involvement, but should only be given if investigators and other site staff have sufficient time to participate in the study. ***Timelines for the return of expressions of interest (and often other subsequent stages) can be quite short as companies work on strict schedules - typically 7-14 days.***

*(continued overleaf)*

Expressions of interest are reviewed by the company and:

1. Potential investigators are asked to sign company-specific confidentiality agreements (CDA)
2. A full study protocol is circulated for review by the investigator
3. Additional feasibility information is collected using sometimes lengthy questionnaires - timelines can be short for return of this information
4. Sites are then selected using this information and companies will then begin the process of site set up. Competition for sites can be intense and not all may be selected.

## **2. Implementation (Site setup)**

To ensure the appropriateness of studies, protocols are reviewed by the MCRN Industry Study Adoption Committee. Subsequently, MCRN staff can assist investigators and other staff with site setup, in particular:

- *Costing:* LRN staff can work with local colleagues to collate R&D, laboratory, pharmacy and other costs.
- *Local ethics and R&D applications*
- *Contracting:* LRN staff can help local R&D to arrange study contracts (i.e. the model Clinical Trial Agreement; mCTA).
- *Training:* All staff (commercial/non-commercial) associated with adopted studies qualify for free UKCRN/MCRN training, including GCP courses.

## **3. Recruitment/Monitoring**

Following site setup, the MCRN LRN staff work with investigators and other site staff to assist with:

- *Recruitment:* LRN staff can help the recruitment of patients by providing support to site staff.
- *Research nurse support:* Local site nurses typically assist with study procedures, but in some cases, LRN-based nurses may be available to perform roles, subject to existing demands on their schedules.
- *Data collection:* LRN staff can help with form completion/data submissions.

## **4. Closure**

Upon closure of the study, LRN staff work with investigators and other staff to ensure that all regulatory and other requirements are addressed.

## **Where can I get further information?**

For further information on how the MCRN supports paediatric research, please speak to your LRN Manager Sarah Rickard (sarah.rickard@cmmc.nhs.uk)/0161 922 2868

***If you are contacted directly by any companies who want to conduct a paediatric study in the UK, the MCRN would be very grateful if you could please pass details to your Network Manager as we may be able to provide support for the study***