Frequently Asked Questions

The "Medicines for Neonates" Applied Research Programme and the National Neonatal Collaborative-Necrotising Enterocolitis Study (NNC-NEC)

1) What is the Medicines for Neonates Applied Research Programme?

"Medicines for Neonates" is a National Institute of Health Research funded Research Programme (RP-PG-0707-10010). The investigators are Jane Abbott, Head of Innovation, Bliss, Deborah Ashby, Professor of Medical Statistics, Imperial College London, Peter Brocklehurst, Professor of Women's Health, University College London, Kate Costeloe, Professor of Paediatrics, Queen Mary University of London, Elizabeth Draper, Professor of Perinatal Epidemiology, University of Leicester, Jacquie Kemp, London Perinatal Director, Azeem Majeed, Professor of Primary Care, Imperial College London, Neena Modi, Professor of Neonatal Medicine, Imperial College London (Lead Investigator), Stavros Petrou, Professor of Health Economics, University of Warwick and Alys Young, Professor of Social Work, Education & Research, University of Manchester. The Programme involves the development of the use for multiple purposes, of operational clinical electronic data captured at the point of care. The Medicines for Neonates Programme includes several interrelated projects, one of which is the National Neonatal Collaborative-Necrotising Enterocolitis Study (NNC-NEC; REC ref 11/LO/1430).

2) What is the National Neonatal Research Database?

Neonatal data entered onto the Badger.net system are released with NHS Trust approval to the Neonatal Data Analysis Unit. These data are merged to create a database, termed the "National Neonatal Research Database", that are held securely as a national resource in a central repository, the NHS server of Chelsea & Westminster NHS Foundation Trust, for use for research purposes and non-research NHS service support. The National Neonatal Research Database is managed by the Neonatal Data Analysis Unit. It has been approved by the National Research Ethics Service (ref 10/H0803/151) and the Ethics & Confidentiality Committee of the National Information Governance Board (ref ECC-05(f)/2010). The National Neonatal Research Database is open to use by other investigators. For details please contact the Neonatal Data Analysis Unit (ndauqueries@imperial.ac.uk).

3) What is the National Neonatal Collaborative?

NHS Trusts contributing data to the National Neonatal Research Database are known as the UK National Neonatal Collaborative.

4) Do research studies involving the National Neonatal Research Database require Research Ethics Committee approval?

Research studies involving the National Neonatal Research Database require specific Research Ethics approval (ie approval that is separate from the approval for the establishment of the National Neonatal Research Database).

5) What approvals are required from contributing NHS Trusts?

Contributing NHS Trusts are asked to confirm that they wish their data to be included in specific research studies. The NIHR Coordinated System for gaining NHS Permission (NIHR CSP) is a centralised method for gaining NHS Trust permission for research studies ("R&D approval"). Participation in the NNC-NEC study (NIHR CSP Ref 83411) does not require NHS permission from each Trust contributing data (see letter from North-West London CLRN dated April 2012); NHS Permission is only required from the lead centre, Chelsea & Westminster NHS Foundation Trust.

6) Does NNC-NEC study activity have to be recorded on the UK Clinical Research Network Portal?

Patient recruitment is entered onto the UK Clinical Research Network Portal. As the NNC-NEC study does not involve patient recruitment, entry of recruitment data does not apply.

7) Will participation in the NNC-NEC study be supported by the Medicines for Children Research Network (MCRN)/Comprehensive Local Research Network (CLRN)?

The remit of the MCRN and CLRN is to support as much clinical research that conforms to eligibility criteria (receive NIHR funding and fulfil NIHR criteria for research). This excludes audit, quality improvement and service evaluations. It also excludes routine banking of data except where this activity is integral to a self-contained research project designed to test a clear hypothesis. NHS Research Ethics Committee approval and NHS permission are prerequisites for research to be supported via the NIHR CRN. For full details go to:
http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_eligibility/p_auto_elig/).

Where no patient recruitment is required, quantification of research support required may be difficult. However most research networks (MCRN/CLRN) will try to be supportive if they have the necessary resources. It is recommended that you discuss any research support you require with your Research Network (MCRN/CLRN) based on local need.

8) How can I get support for data entry in my neonatal unit?

It is in the interests of all NHS Trusts to support the capture of high quality data. Many neonatal units lack support for data entry and would value this. If you intend to seek support for data entry from your Trust you may find it helpful to explain that contribution towards the National Neonatal Database will enable participation in the NNC-NEC study and associated NIHR portfolio research studies, as well as the National Neonatal Audit Programme, and other service support evaluations.