Final peer reviewed protocol with early collaborations with the CRN, R&D, Clinical Trials unit, and pharmacy leads

Complete Clinical Trials Application from MHRA & Ethics Submission from NRES
This application process can now be integrated via the Integrated Research Application System (IRAS)

Obtain R&D approval from main sponsor

Determine type of approval required for step-down sites involved in the transfer of recruited baby.

**Full approval** – allows recruitment, the trial intervention and follow-up to be undertaken on the specified site. This requires (i) the appointment of a Principal Investigator who has to undergo GCP training, (ii) Local Research Ethics Approval (LREC), (iii) SSA recognition, (iv) local R&D approval, and (v) local pharmacy set up.

**SSA exempt approval** – allows only the stated follow-up aspects of a baby’s care to be undertaken on the specified site and requires a ‘Named Clinician’ to be identified as the responsible person at the site. The site does not require LREC SSA approval but requires Trust R&D approval.

Identify a Principal Investigator or Named Clinician at each step down site and establish collaboration with the MCRN LRN team to promote study to nursing, medical and R&D staff at local units

Submit for either LREC SSA approvals or contact MREC to approve Named Clinician and list of SSA exempt follow up assessments

Submit full R&D approvals for all step-down sites
Collaboration with CRNs to assist in submission of individual Trust R&D approvals and honorary contract applications for investigators

Develop transfer packs with appropriate Standard Operating procedures for recruiting and non-recruiting centres

Ensure regular meetings between all study collaborators, the research network team and investigators.