



Greater Manchester, Lancashire & South Cumbria Medicines for Children's Research Network

End of Year Activity Report

Reporting period: (1 Apr 08 – 31 Mar 09)

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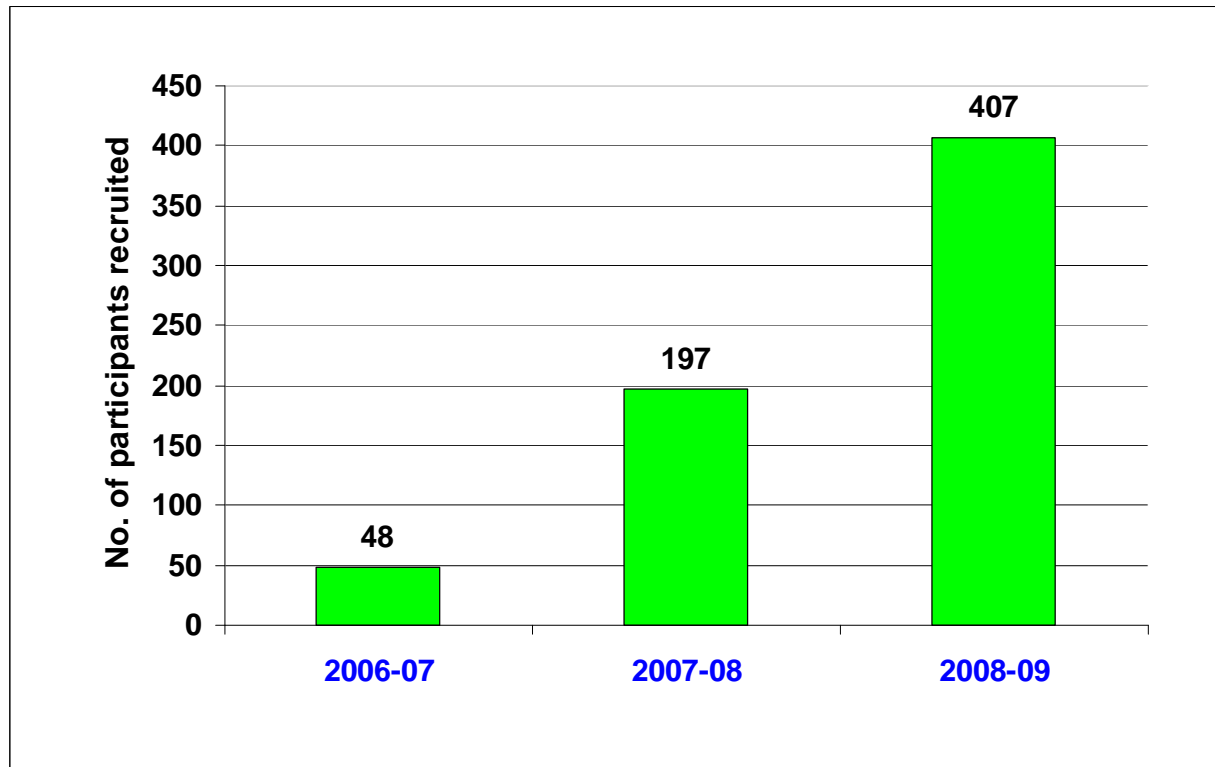
For more information visit: www.gmlc-mcrn.org.uk or email gmlc@mcrn.org.uk

Executive summary:

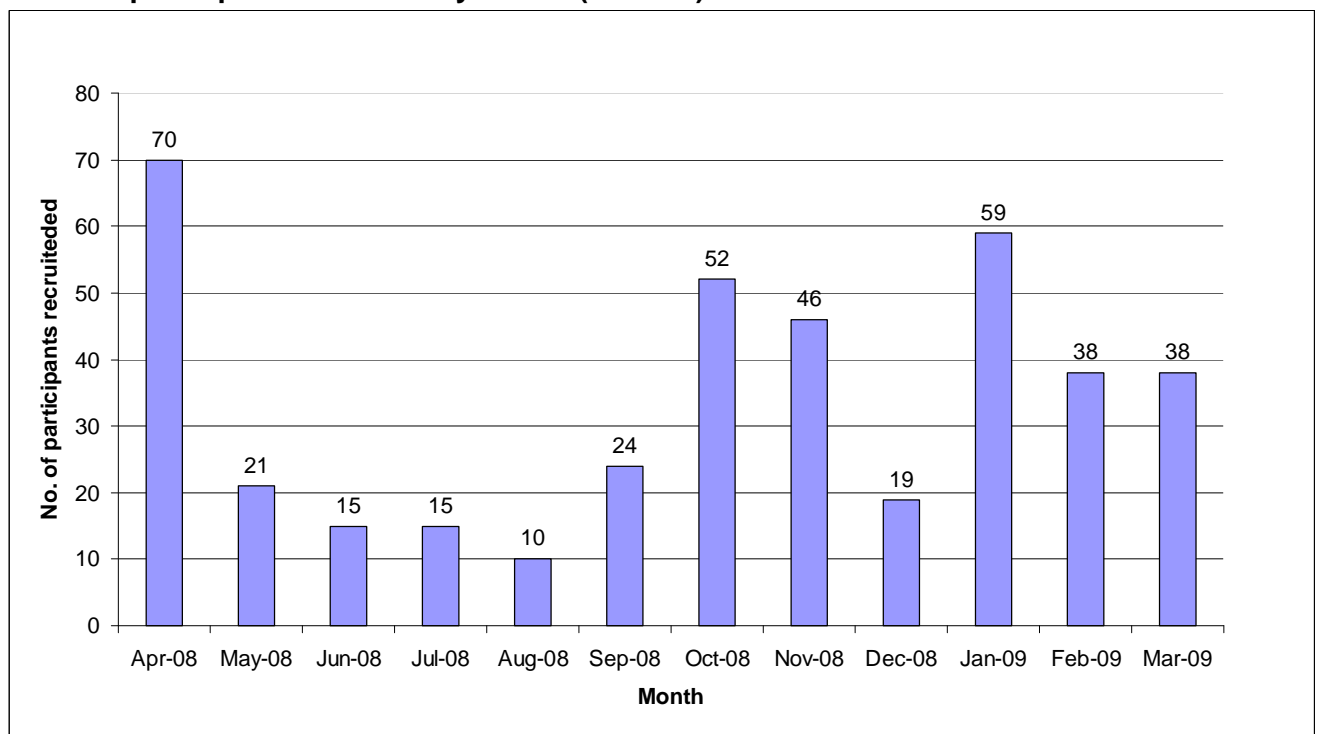
- Recruitment during 2008-09 doubled to 407 participants compared to the previous years total of 197 (2007-08 financial year)
- 43% of 2008-09 recruitment was into randomised controlled clinical trials
- Average monthly recruitment for 2008-09 was 34 participants, up from 16 participants /month in 2007-08
- Our highest recruiting studies in 2008-09 were: Nephropathy Familial Study (NFS) – 84 participants; Lysosomal storage disorder (LSD) – 65 participants; DEPICTED – 51 participants; TIPIT – 35 participants; Information Matters Project – 26 participants
- Our highest recruiting sites in 2008-09 were: Royal Manchester Children's Hospital – 180 participants; Stepping Hill Hospital – 73 participants; St Mary's Hospital – 48 participants; Booth Hall Hospital – 37 participants; Royal Blackburn Hospital – 26 participants. Our second and fifth highest recruiters were district general hospitals.
- In 2008-09, the three sites within Central Manchester University Hospitals NHS Foundation Trust (RMCH, BH & SMH) contributed 65% of total participants recruited, down from 81% in 2007-09. This is due to increased contribution from our districts, a key goal of the network.
- Recruitment at Booth Hall, Royal Manchester and Royal Blackburn Hospitals doubled from the previous year
- Stepping Hill Hospital recruited 73 participants, up from zero in 2007-08
- 9 other district hospitals recruited participants in 2008-09, where in previous years they had recruited none or very few patients
- Studies are running at 22 separate sites within the network
- Our local study portfolio remains diverse in terms of clinical speciality
- 73% of our studies are non-commercially sponsored and 61% are clinical trials
- There are 27 studies open across the network, 12 studies still in set up and 5 studies closed to recruitment

1. Subject recruitment (accrual)

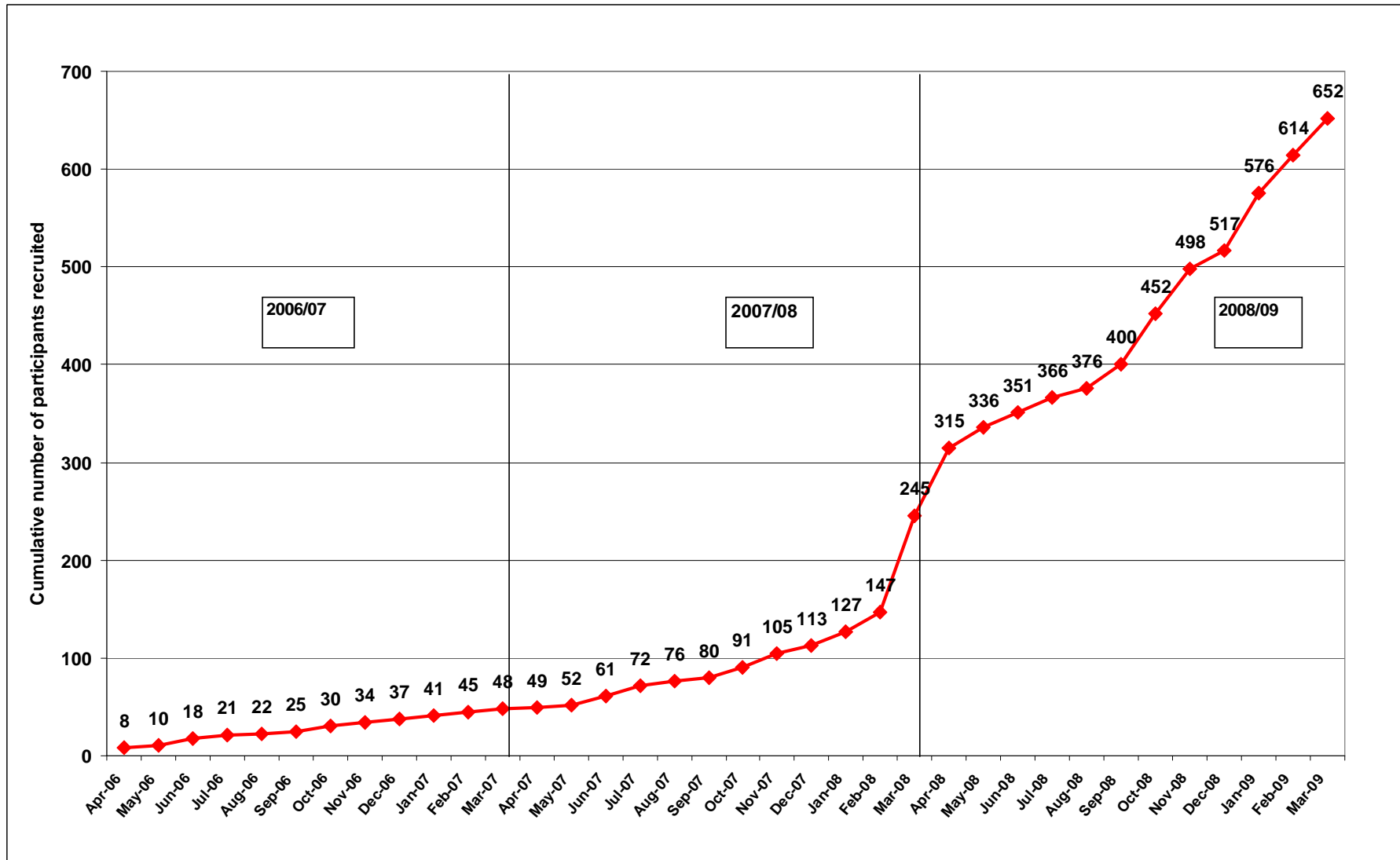
1.1 Total participants recruited by financial year



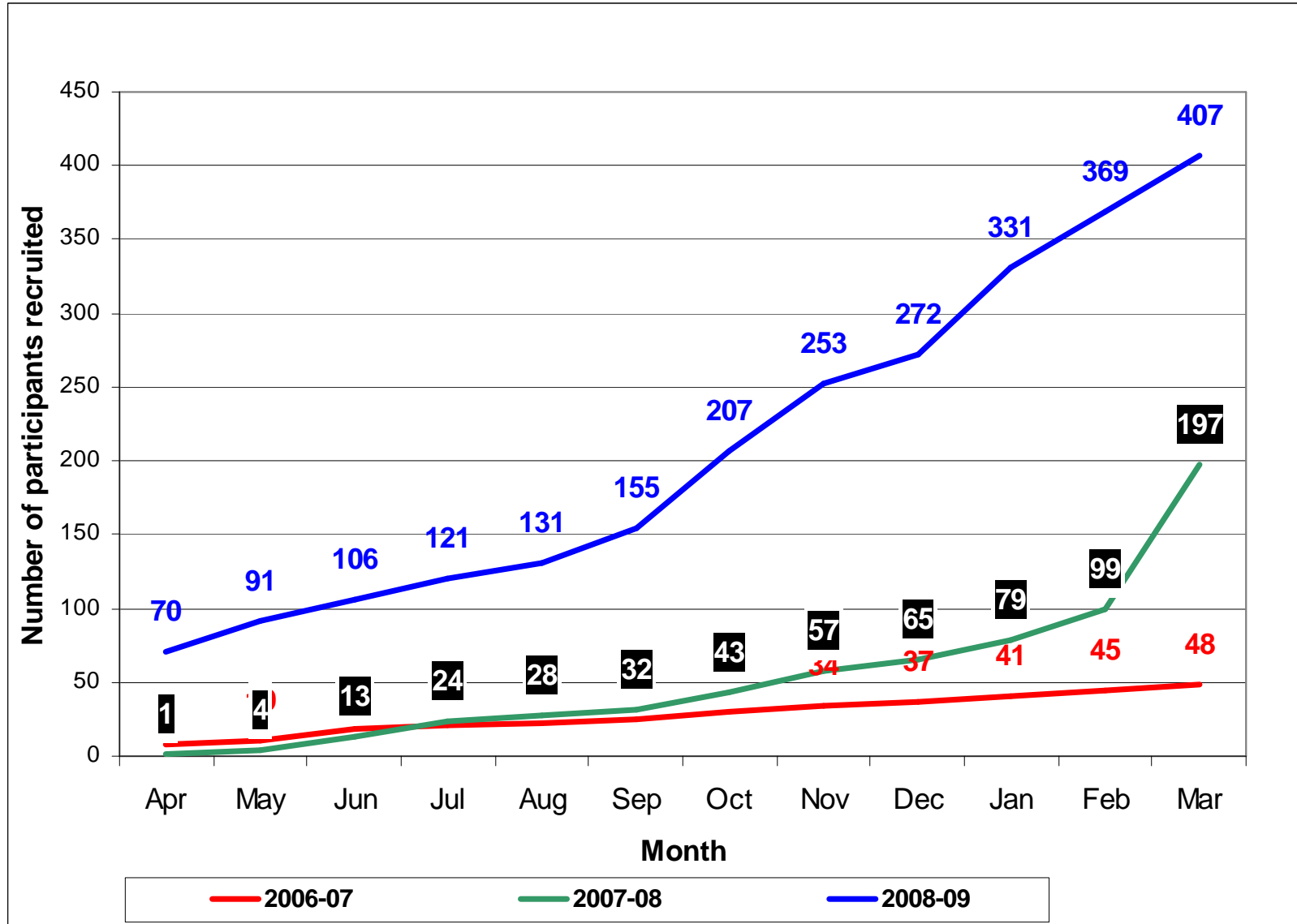
1.2 Total participants recruited by month (2008-09)



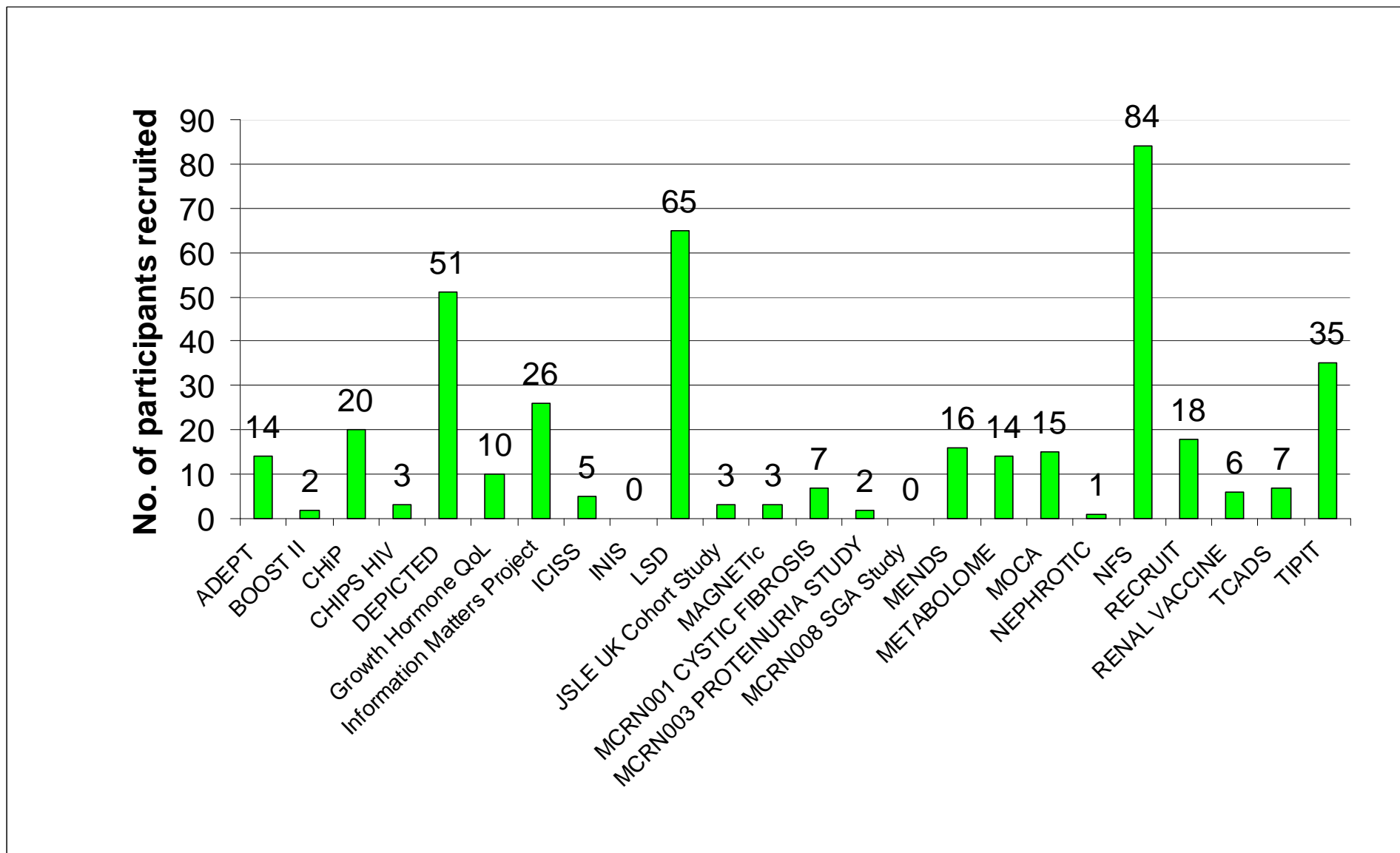
1.3 Total participants recruited by month (cumulative)



1.4 Total participants recruited by month for all years (cumulative)

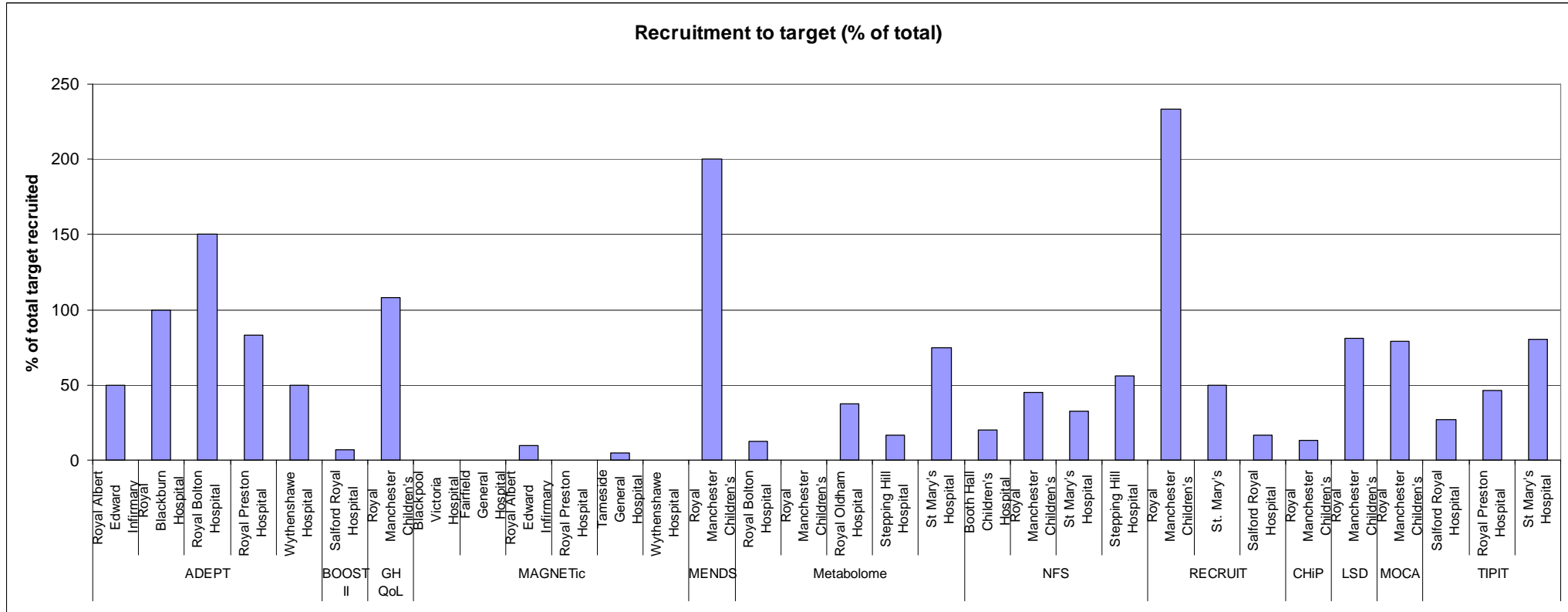


1.5 Total participants recruited by study (2008-09)



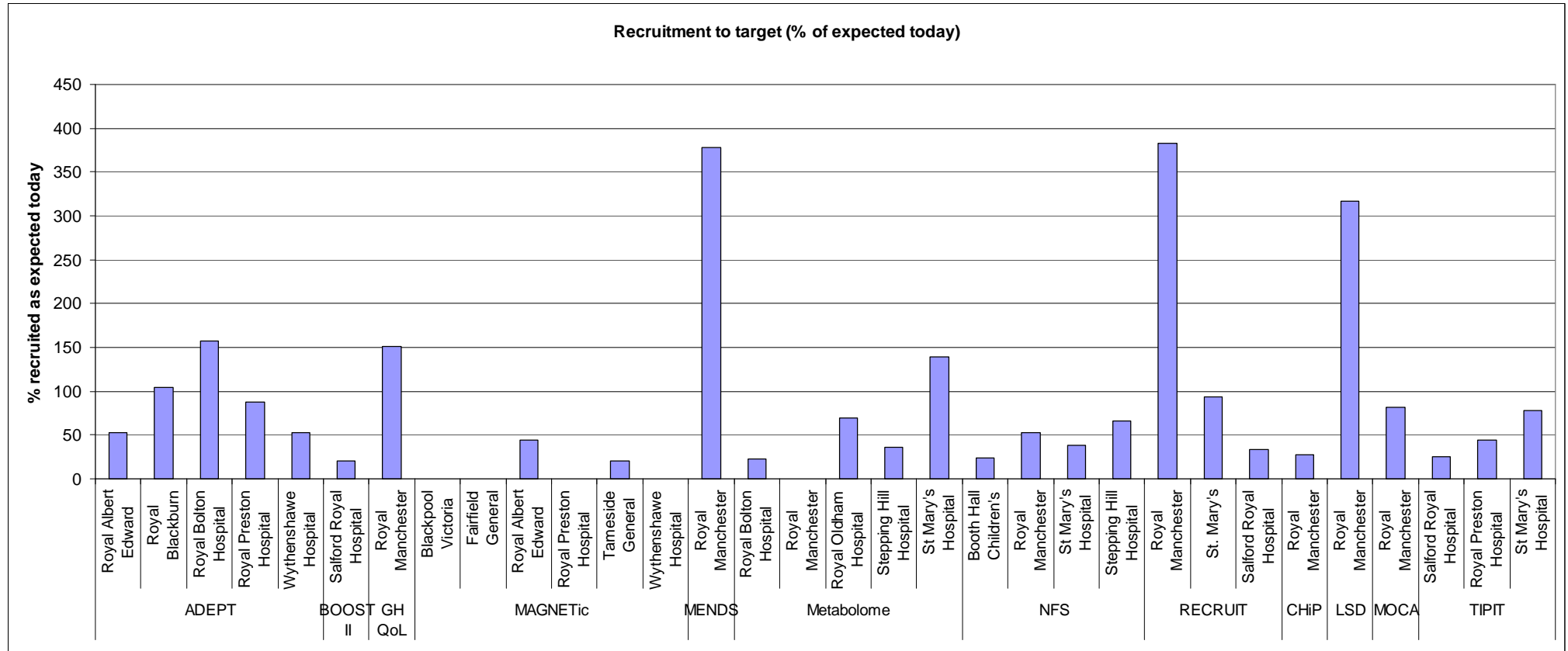
1.6 Recruitment to target by site and study (% total target recruited)

This graph shows the percentage a study has recruited as a proportion of the total target for the site. Studies with no recruitment target (e.g. rare disorders) have been excluded



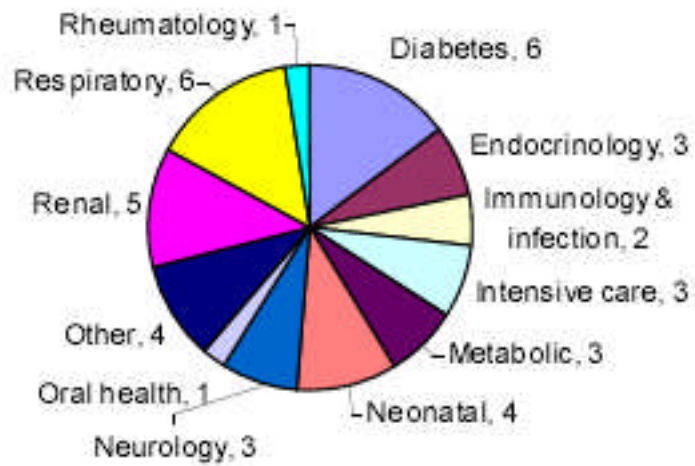
1.7 Recruitment to target by site and study (% of expected participants recruited today)

This graph shows the percentage a study has recruited based on what would be expected today (calculated by dividing the total number of participants by the study duration at site). A study should be at 100% recruitment, or more if ahead of target. Studies with no recruitment target (e.g. rare disorders) have been excluded

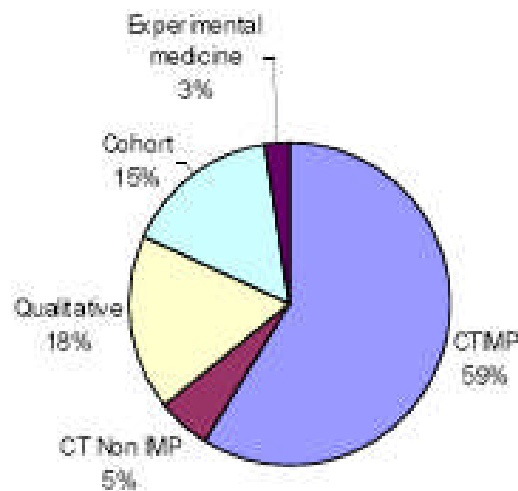
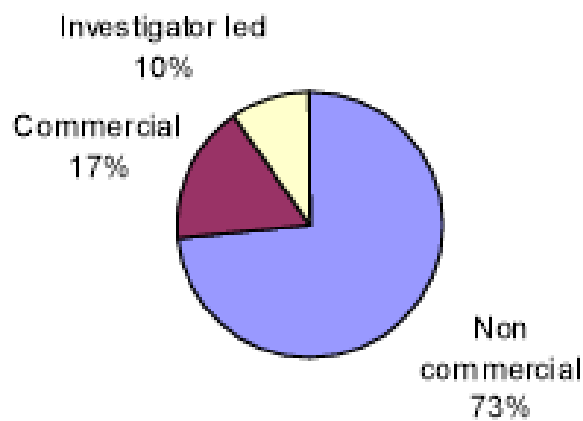


2. GMLC portfolio

2.1 GMLC portfolio by speciality



2.2 GMLC portfolio by type



2.3 List of studies and sites and current status (closed studies not shown)

Short title	Study Full Title	Site	PI	Study status
AdDIT	Adolescent Type 1 Diabetes cardio-Renal Intervention Trial	Stepping Hill Hospital	Cooper, Dr Chris	In Set-up
		St Mary's Hospital	Doughty, Dr Ian	In Set-up
		Royal Manchester Children's Hospital	Amin, Dr Rakesh	In Set-up
		Booth Hall Children's Hospital	Bone, Dr Mark	In Set-up
Address	After Diagnosis Diabetes Research Support System			
		Royal Blackburn Hospital	Smith, Dr Claire	Open
		Rochdale Infirmary	Ariyawansa, Dr Indra	In Set-up
		Booth Hall Children's Hospital	Bone, Dr Mark	Open
		St Mary's Hospital	Doughty, Dr Ian	Open
		Wythenshawe Hospital	Bradbury, Dr Andrew	In Set-up
		Royal Bolton Hospital	Sankar, Dr Vengudi	In Set-up
		Royal Oldham Hospital	Odeka, Dr Egware	In Set-up
		Royal Manchester Children's Hospital	Amin, Dr Rakesh	Open
		Burnley General Hospital	Riddle, Dr Miles	Open
ADEPT	Abnormal Doppler Enteral Prescription Trial			
		Royal Preston Hospital	Gupta, Dr Richa	Open
		Royal Albert Edward Infirmary	Farrier, Dr Martin	Open
		Wythenshawe Hospital	Bowden, Dr Lydia	Open
		Royal Bolton Hospital	Yadav, Dr Mahesh	Open
		Royal Blackburn Hospital	Soni, Dr Narhamal	Open
BOOST II UK	Which oxygen saturation level should we use for very premature infants? A randomised controlled trial			
		Salford Royal Hospital	Settle, Dr Paul	Open
CHIP	Trial Control of Hyperglycaemia in Paediatric Intensive Care: The CHIP Trial			
		Royal Manchester Children's Hospital	Fortune, Dr Peter-Marc	Open
CHIPS (HIV)				
		Halliwel Children's Centre	Ainley-Walker, Dr P	Open
		Blackpool Victoria Hospital	Laycock, Dr Nigel	Open
		North Manchester General Hospital	Tan, Dr Anton	Open
		Royal Preston Hospital	Campbell, Dr Alastair	Open
DEPICTED	Development and Evaluation of a Psychosocial Intervention for Children and Teenagers Experiencing Diabetes			
		Royal Manchester Children's Hospital	Amin, Dr Rakesh	Open
		Booth Hall Children's Hospital	Bone, Dr Mark	Open
		Royal Blackburn Hospital	Smith, Dr Claire	Open
		St Mary's Hospital	Marshall, Ms Marie	Open
DETEMIR	The comparison of the effects of insulin Detemir with insulin Glargine on weight gain in female adolescents and young adults with Type 1 Diabetes on a basal bolus regime			
		Royal Bolton Hospital	Sankar, Dr Vengudi	In Set-up
		Stepping Hill Hospital	Cooper, Dr Chris	In Set-up
EMSC	Validation of early morning salivary cortisol (EMSC) as a non-invasive, patient friendly, reliable, cost effective measure of adrenal reserve in children receiving inhaled corticosteroids			
		Royal Manchester Children's Hospital	Murray, Dr Clare	In Set-up
		Booth Hall Children's Hospital	Murray, Dr Clare	In Set-up
		North Manchester General Hospital	Dasgupta, Dr Suparna	In Set-up
EPIC	Evidence into practice: evaluating a child-centred intervention for diabetes medicine management			
		Royal Bolton Hospital	Sankar, Dr Vengudi	In Set-up
Growth Hormone Quality of Life Study	Growth Hormone, Quality of Life			
		Royal Manchester Children's Hospital	Hall, Dr Catherine	Open
HIVAT	Assessing the impact and safety of home intravenous antibiotic treatment (IVAT) for children with cystic fibrosis			
		Blackpool Victoria Hospital	Johnson, Dr Mary	In Set-up
		Royal Albert Edward Infirmary	Shenoy, Dr Anil	In Set-up

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ICISS	The International Collaborative Infantile Spasms Study: A randomised trial in the medicinal treatment of infantile spasms			
		Royal Preston Hospital	De Goede, Dr Christian	Open
		Rochdale Infirmary	Rifkin, Dr Robin	Open
		Royal Oldham Hospital	Prakash, Dr Nandhini	Open
		Trafford General Hospital	Lewis, Dr Helen	Open
		Wythenshawe Hospital	Yeung, Dr Lap	In Set-up
		Royal Blackburn Hospital	Rakshi, Dr Karl	Open
		Blackpool Victoria Hospital	Thomas, Dr Megan	Open
		Royal Manchester Children's Hospital	Newton, Dr Richard	Open
		Fairfield General Hospital	Levy, Dr Rob	Open
		Royal Bolton Hospital	Hindley, Dr Dan	Open
		Burnley General Hospital		Open
		Furness General Hospital	Olabi, Dr Anas	Open
		Royal Albert Edward Infirmary	Velmuguran, Dr Singara	Open
Information Matters Project	Health, medicines and self-care choices made by children, young people and their families: Information to support decision making			
		Royal Manchester Children's Hospital	Rickard, Ms Sarah	Open
		Royal Bolton Hospital	Power, Dr Simon	Open
		Royal Preston Hospital	Mahmood, Dr Dhia	Open
		Longsight Health Centre	Kaufmann, Dr Lisa	Open
		Royal Albert Edward Infirmary	Shenoy, Dr Anil	Open
		St Mary's Hospital	Rickard, Ms Sarah	Open
		Booth Hall Children's Hospital	Rickard, Ms Sarah	Open
		Stepping Hill Hospital	Cooper, Dr Chris	Open
LYSOSOMAL STORAGE DISORDERS	Proposal to conduct long term cohort study of people with lysosomal storage disorders			
		Royal Manchester Children's Hospital	Wraith, Dr Ed	Open
MAGNETic	A randomised controlled trial of nebulised magnesium in acute severe asthma in children			
		Royal Albert Edward Infirmary	Shenoy, Dr Anil	In Set-up
		Tameside General Hospital	Levy, Dr David	Open
		Blackpool Victoria Hospital	Goldberg, Dr Kate	In Set-up
		Royal Preston Hospital	Mahmood, Dr Dhia	In Set-up
		Fairfield General Hospital	Saab, Dr Michael	In Set-up
		Wythenshawe Hospital	Al-Zidgali, Dr Faisal	In Set-up
MASCOT	Management of Asthma in School Age Children on Therapy			
		Royal Manchester Children's Hospital	Murray, Dr Clare	Open
MCRN008 SGA Study	Commercial SGA Study			
		St Mary's Hospital	Amin, Dr Rakesh	Open
MCRN026 Hypertension Study	Commercial Hypertension Study			
		Royal Manchester Children's Hospital	Webb, Dr Nick	In Set-up
MCRN027 Zoledronic acid Study	Commercial Zoledronic acid study			
		St Mary's Hospital	Mughal, Dr Zulf	Open
		Booth Hall Children's Hospital	Fagbemi, Dr Andrew	Open
MCRN030 MPS Assessment Study	Commercial MPS Study			
		Royal Manchester Children's Hospital	Jones, Dr Simon	In Set-up
MCRN031 MPS Trial	Commercial MPS Study			
		Royal Manchester Children's Hospital	Jones, Dr Simon	In Set-up
MENDS	The use of melatonin in children with neurodevelopmental disorders and impaired sleep: an RCT			
		Royal Manchester Children's Hospital	Martland, Dr Tim	Open

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		Blackpool Victoria Hospital	Thomas, Dr Megan	In Set-up
METABOLOME	A pilot study to assess the use of metabolome profiling in the management of the child born small for gestational age.			
		Stepping Hill Hospital	Cooper, Dr Chris	Open
		Tameside General Hospital	Birch, Dr Jaqueline	In Set-up
		North Manchester General Hospital	Odeka, Dr Egware	In Set-up
		Royal Bolton Hospital	Powell, Dr Peter	Open
		Royal Oldham Hospital	Padmakumar, Dr Beena	Open
		Royal Albert Edward Infirmary	Shenoy, Dr Anil	In Set-up
		Royal Manchester Children's Hospital	Clayton, Professor Peter	Open
		St Mary's Hospital	Victor, Dr Suresh	Open
		Salford Royal Hospital	Settle, Dr Paul	In Set-up
		Fairfield General Hospital	Odeka, Dr Egware	In Set-up
		Rochdale Infirmary	Odeka, Dr Egware	In Set-up
MOCA	Metformin in Obese Children with Abnormal Glucose and Insulin Status: A Randomised Controlled Trial			
		Royal Manchester Children's Hospital	Hall, Dr Catherine	Open
MYCYC	A randomised clinical trial of mycophenolate mofetil versus cyclophosphamide for remission induction in ANCA associated vasculitis			
		Royal Manchester Children's Hospital	Webb, Dr Nick	Open
NFS Diabetic Nephropathy	Genetic analysis of risk factors for the development of diabetic complications			
		Stepping Hill Hospital	Cooper, Dr Chris	Open
		Booth Hall Children's Hospital	Bone, Dr Mark	Open
		Royal Manchester Children's Hospital	Amin, Dr Rakesh	Open
		St Mary's Hospital	Doughty, Dr Ian	Open
P3MC	A double blind parallel group randomised placebo controlled trial of Propranolol and Pizotifen in preventing migraine in children			
		Royal Manchester Children's Hospital	Newton, Dr Richard	In Set-up
PASS	Pharmacogenetics of Adrenal Suppression with Inhaled Steroids			
		Royal Manchester Children's Hospital	Murray, Dr Clare	In Set-up
RECRUIT	Processes in recruitment to randomised controlled trials (RCTs) of medicines for children			
		Royal Manchester Children's Hospital	Martland, Dr Tim	Open
		Royal Manchester Children's Hospital	Murray, Dr Clare	Open
		St Mary's Hospital	Victor, Dr Suresh	Open
		Royal Preston Hospital	Gupta, Dr Richa	Open
SLEEPS	Safety profile, efficacy and equivalence in paediatric intensive care sedation			
		Royal Manchester Children's Hospital	Playfor, Dr Stephen	In Set-up
TIPIT	A Randomised Controlled Trial of Thyroxine in Preterm Infants Under 28 weeks Gestation			
		Salford Royal Hospital	Settle, Dr Paul	Open
		Royal Preston Hospital	Gupta, Dr Richa	Open
		St Mary's Hospital	Victor, Dr Suresh	Open
UK JSLE COHORT STUDY AND REPOSITORY	UK JSLE Cohort Study and Repository UK Juvenile-onset Systemic Lupus Erythematosus Cohort Study & Repository: Clinical Characteristics and Immunopathology of Juvenile-onset SLE			
		Booth Hall Children's Hospital	Riley, Dr Phil	Open