

<Eastern Portfolio of Academic Diabetes Studies>

The Eastern Network covers the counties of Cambridgeshire, Norfolk, Suffolk, Hertfordshire, Essex, and Bedfordshire

Report is divided into 2 main sections	
IN SET-UP	These are studies or proposed eastern sites going through approvals and other preparation before recruitment is able to take place.
OPEN	<p>DRN Led Studies Studies where the main disease topic is Diabetes. The network takes a lead in providing monitoring and support.</p> <p>co-adopted by DRN These studies are those where the main disease topic is not Diabetes. Another topic network takes the lead in monitoring and support. They do however have an element of diabetes within them and that's when the DRN can co-adopt the study; offering support in collaboration with the lead network if required. An example is the trial of insulin medication in children, the Medicines for Children Research Network (MCRN) would lead and the DRN would support (co-adopt study)</p>

Key of Field Descriptions in report	
Study Title	The study name and description as stated on the National Portfolio
Chief Investigator (CI)	Chief Investigator of the study
Network area where CI is based	Where the Chief Investigator is located. This is either EASTERN REGION area or OUTSIDE EASTERN REGION area
DRN ID	This is the identifier of the study which has been issued by DRN Co-ordination Centre
UKCRN ID	This is the unique identifier of the study on the National Portfolio
Eastern Sites	This indicates sites for planned recruitment or actively recruiting into the study in the Eastern Region.
Number of participants recruited in the Eastern Region	This indicates the cumulative recruitment into the study from eastern mapped sites (up to the end of previous month). The portfolio contains only records of participants recruited since 01/04/2006. If a study started before 01/04/2006 the actual running total of the study may be different to the figure indicated. The actual running total for these studies will be given where available.
UK Target Sample size	This gives an indication of the size of the study in terms of the recruitment target
Planned Start of Recruitment Date	The planned start of recruitment as indicated on application to the network
Actual Start of Recruitment Date	This is the date when the first participant registered into the study
Planned close of recruitment date	This is the expected date when the last participant is recruited into the study. The study would continue in follow-up.
Comment on status	This gives an indication of why a study is still in set-up, site approvals and whether recruitment is up-to-date on the national portfolio.

Notes:

- 1) This report shows cumulative recruitment data for studies uploading data to the national portfolio database for the current recruitment period. (April – March)
- 2) This report is created around the 15th of every month to show activity up to the end of the previous month.
- 3) Recruitment in this report is defined as one instance of activity per participant. Examples include when a participant is consented into a study or the return of a questionnaire.
- 4) Recruitment is counted only from activated sites that have been mapped to the Eastern DRN.
- 5) The planned closure date and target sample size need to be regularly checked by the Study Team for amendments (e.g. extension to study duration, increase in recruitment target). Study Team should update their study record on the NIHR National Portfolio (Link to UKCRN Portal <https://portal.ukcrn.org.uk/login/>). This information is important as it is linked to funding.

IN SET-UP - Studies undergoing site approvals

Study Title	Chief Investigator (CI)	Network area where CI is based	UKCRN ID DRN ID	Co-adopting Networks	Eastern Sites	Number of participants recorded as recruited in the Eastern Region	UK Target Sample size	Planned Start of Recruitment Date	Planned Close of Recruitment Date	Comment on Status
SCIPI - A randomised controlled trial of continuous subcutaneous insulin infusion (CSII) compared to multiple daily injection (MDI) regimens on insulin in children and young people at diagnosis of type 1 diabetes mellitus (T1DM).	Dr Jo Blair	OUTSIDE EASTERN REGION	10036 MCRN	DRN	Addenbrooke's	0	316	01/04/2011	30/09/2013	Awaiting local approval
Fibreglass casts for heel ulcers - Evaluation of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes	Prof William Jeffcoate	OUTSIDE EASTERN REGION	9299 DRN528	NONE	Addenbrooke's	0	529	Awaiting first participant	30/06/2015	Site approved 21/07/2011 Study in set-up on portfolio
Fibreglass casts for heel ulcers - Evaluation of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes	Prof William Jeffcoate	OUTSIDE EASTERN REGION	9299 DRN528	NONE	Norfolk & Norwich	0	529	Awaiting first participant	30/06/2015	Site approved 21/04/2011 Study in set-up on portfolio
Fibreglass casts for heel ulcers - Evaluation of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes	Prof William Jeffcoate	OUTSIDE EASTERN REGION	9299 DRN528	NONE	Ipswich	0	529	Awaiting first participant	30/06/2015	Site approved 25/05/2011 Study in set-up on portfolio
JUMP - Joining together to Understand diabetes mellitus Type 2 Progression in children. Type 2 Diabetes in Childhood: Building a platform for interventions to prevent the progression to cardiovascular disease	Prof Tim Barrett	OUTSIDE EASTERN REGION	7574 MCRN	DRN	Norfolk & Norwich	0	200	11/11/2009	30/04/2012	Awaiting local approval.
TrialNet Oral Insulin Study	Prof Polly Bingley	OUTSIDE EASTERN REGION	8006 DRN438	NONE	Addenbrooke's	0	25	06/11/2010	01/04/2017	Awaiting local approval
Pre-POINT - A dose-finding safety and immune efficacy study for primary mucosal insulin therapy in islet autoantibody negative children at high genetic risk for Type 1 Diabetes	Prof Polly Bingley	OUTSIDE EASTERN REGION	9129 DRN506	NONE	Addenbrooke's	0	5	24/09/2010	01/05/2012	Awaiting local approval.
Detemir Glargine - A 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	Prof David Dunger	EASTERN REGION	4903	MCRN	Colchester General Hospital	0	112	01/04/2008	30/06/2013	Awaiting local approval.

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August Report - all accrual data up to end of July 2011

OPEN DRN Led Studies - Sites recently approved and awaiting first participant

Study Title	Chief Investigator (CI)	Network area where CI is based	UKCRN ID DRN ID	Co-adopting Networks	Eastern Sites	Number of participants recruited and recorded on the NIHR portfolio mapped to the Eastern Region	UK Target Sample size	Actual Start of Recruitment Date	Planned Close of Recruitment Date	Comment on recruitment (accrual) upload status on the NIHR portfolio
Pre-POINT - A dose-finding safety and immune efficacy study for primary mucosal insulin therapy in islet autoantibody negative children at high genetic risk for Type 1 Diabetes	Prof Polly Bingley	OUTSIDE EASTERN REGION	9129 DRN506	NONE	Norfolk & Norwich	0	5	Awaiting first participant	01/05/2012	Site approved 12/05/2011
TrialNet Oral Insulin Study	Prof Polly Bingley	OUTSIDE EASTERN REGION	8006 DRN438	NONE	Norfolk & Norwich	0	25	Awaiting first participant	01/04/2017	Local site approved Awaiting first participant
JUMP - Joining together to Understand diabetes mellitus Type 2 Progression in children. Type 2 Diabetes in Childhood: Building a platform for interventions to prevent the progression to cardiovascular disease	Prof Tim Barrett	OUTSIDE EASTERN REGION	7574 MCRN	DRN	Addenbrooke's	0	200	Awaiting first participant	30/04/2012	Site approved 06/01/2011 Awaiting first participant
Norfolk DPS - Delivering a Realistic Diabetes Prevention Programme in a UK Community	Prof Mike Sampson	EASTERN REGION	DRN544 DRN545	NONE	GP Practices	0	10000	Awaiting first participant	29/02/2016	Awaiting first participant. FPFV expected mid-July 2011

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ACTIVELY RECRUITING - OPEN DRN Led Studies

Study Title	Chief Investigator (CI)	Network area where CI is based	UKCRN ID DRN ID	Co-adopting Networks	Eastern Sites	Number of participants recruited and recorded on the NIHR portfolio mapped to the Eastern Region	UK Target Sample size	Actual Start of Recruitment Date	Planned Close of Recruitment Date	Comment on recruitment (accrual) upload status on the NIHR portfolio
Comparison of two algorithms for closed-loop control in T1 - An open-label, randomised, three period crossover study to evaluate the efficacy and safety of automated closed-loop insulin delivery in comparison with conventional insulin pump treatment in adults with type 1 diabetes: A comparison of two different algorithms.	Dr Roman Hovorka	EASTERN REGION	9406 DRN508	NONE	Addenbrooke's	7	8	06/05/2011	01/09/2011	Monthly recruitment up-to-date
East Cambs and Fenland Diabetes Integrated Care Initiative	Dr David Simmons	EASTERN REGION	10245 DRN587	NONE	GP Practices	9	35	14/06/2011	01/02/2013	Monthly recruitment up-to-date
RAPSID - Can peer support, delivered as a group or individual intervention, enable people with diabetes and improve their health? (A Randomised controlled trial of Peer Support In Type 2 Diabetes)	Dr David Simmons	EASTERN REGION	6521 DRN261	PCRN	GP Practices Addenbrooke's	145	1200	01/06/2011	30/11/2013	Monthly recruitment up-to-date
Diabetes Risk Communication Trial	Dr Simon Griffin	EASTERN REGION	10231 DRN585	NONE	Addenbrooke's	545	545	07/03/2011	01/10/2011	Monthly recruitment up-to-date
DALI: Group Interviews - Developing a programme for optimal adherence to lifestyle and dietary interventions for the prevention of gestational diabetes mellitus: a group interview study.	Dr David Simmons	EASTERN REGION	8959 DRN503	NONE	Addenbrooke's	1	24	11/04/2011	31/12/2011	No recruitment recorded since April 2011.

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DAN02 (Closing the loop for 36h in adolescents)	Dr Roman Hovorka	EASTERN REGION	8616 DRN 473	NONE	Addenbrooke's Norfolk and Norwich	15	20	29/03/2010	31/09/2011	Monthly recruitment up-to-date
Cardiovascular risk factors in parents of children with type 1 diabetes - Familial aggregation of cardiovascular disease risk factors in parents of adolescents with type 1 diabetes and incipient nephropathy.	Prof David Dunger	EASTERN REGION	9411 DRN539	NONE	Addenbrooke's	50	150	10/06/2010	31/12/2011	Monthly recruitment up-to-date
D-GAP - Type 1 Diabetes and Autoimmune disease: Genes, Biomarkers and Immune phenotypes	Prof David Dunger	EASTERN REGION	5798 DRN231	CRN	Ipswich West Suffolk Addenbrooke's Hinchinbrooke Peterborough District Colchester Watford James Paget Basildon Southend Chelmsford	1636	2200	01/03/2009	01/03/2013	Monthly recruitment up-to-date
D-GAP - Unaffected Siblings: Phase II	Prof David Dunger	EASTERN REGION	8076 DRN450	NONE	Ipswich West Suffolk Addenbrooke's Hinchinbrooke Peterborough District Colchester Watford James Paget Basildon Southend Chelmsford	263	600	22/10/2010	01/03/2013	Monthly recruitment up-to-date

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ACTIVELY RECRUITING - OPEN DRN Led Studies

Study Title	Chief Investigator (CI)	Network area where CI is based	UKCRN ID DRN ID	Co-adopting Networks	Eastern Sites	Number of participants recruited and recorded on the NIHR portfolio mapped to the Eastern Region	UK Target Sample size	Actual Start of Recruitment Date	Planned Close of Recruitment Date	Comment on recruitment (accrual) upload status on the NIHR portfolio
Genetics of Obesity - The genetic basis of severe childhood obesity	Dr Ismaa Sadaf Farooqi	EASTERN REGION	8586 DRN490	NONE	Addenbrooke's Colchester Luton & Dunstable Norfolk and Norwich West Suffolk	31	5000	01/01/1998	31/12/2014	No recruitment recorded since Mar 2011
Phenotypes and Obesity - Phenotypic characterisation of subjects with genetic defects associated with severe childhood obesity	Dr Ismaa Sadaf Farooqi	EASTERN REGION	8612 DRN491	NONE	Addenbrooke's	99	500	01/01/1998	31/12/2014	Monthly recruitment up-to-date
Diabetes and complications associated with obesity - Metabolic and endocrine characterisation of subjects with severe obesity.	Dr Ismaa Sadaf Farooqi	EASTERN REGION	8613 DRN492	NONE	Addenbrooke's	221	500	01/01/1998	31/12/2014	Monthly recruitment up-to-date
Eating behaviour and obesity - Relationships between energy intake, energy expenditure, autonomic nervous system activation and body fat distribution in severe obesity.	Dr Ismaa Sadaf Farooqi	EASTERN REGION	8614 DRN493	NONE	Addenbrooke's	89	500	01/01/1998	31/12/2014	Monthly recruitment up-to-date
FENLAND - A population based cohort study of the interaction between environment and genetic factors in determining obesity, insulin sensitivity and hyperglycaemia	Prof Nick Wareham	EASTERN REGION	2202 DRN055	PCRN	Addenbrooke's (MRC Unit Centres - IMS, Ely and Wisbech)	7714	10000	01/04/2006	01/12/2014	Monthly recruitment up-to-date
Nephropathy Family Study (NFS) - Genetic analysis of risk factors for the development of diabetic complications	Prof David Dunger	EASTERN REGION	2845 DRN085	MCRN	Ipswich Norfolk and Norwich Addenbrooke's Hinchinbrooke West Suffolk	483	6000	01/05/2001	28/02/2011	Monthly recruitment up-to-date
AddIT - Adolescent Type 1 Diabetes Intervention Trial - Adolescent Type 1 Diabetes Cardio-Renal Protection Study. Coordinator Stella Silvester.	Prof David Dunger	EASTERN REGION	3834 DRN068	MCRN	Addenbrooke's Ipswich Norfolk and Norwich	53	650	11/05/2009	30/06/2011	Monthly recruitment up-to-date

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ACTIVELY RECRUITING - OPEN DRN Led Studies

Study Title	Chief Investigator (CI)	Network area where CI is based	UKCRN ID DRN ID	Co-adopting Networks	Eastern Sites	Number of participants recruited and recorded on the NIHR portfolio mapped to the Eastern Region	UK Target Sample size	Actual Start of Recruitment Date	Planned Close of Recruitment Date	Comment on recruitment (accrual) upload status on the NIHR portfolio
SIRS - Study of the genetics of Severe Insulin Resistance	Dr Robert Semple	EASTERN REGION	3792 DRN079	NONE	Addenbrooke's Norfolk and Norwich West Suffolk	73	1000	01/01/1993	01/01/2015	No recruitment recorded since Mar 2011
ASCEND - A randomised 2x2 factorial study of aspirin versus placebo, and omega-3 fatty acid supplementation versus placebo, for primary prevention of cardiovascular events in people with diabetes	Dr Jane Armitage	OUTSIDE EASTERN REGION	2257 DRN023	PCRN	Eastern GP Practices Addenbrooke's Hospital Colchester General Hospital Hemel Hempstead Hospital Ipswich Hospital Peterborough District Hospital Watford General Hospital	1182	15000	15/03/2005	31/03/2011	No Eastern recruitment recorded since May 2011. Monthly recruitment up-to-date. Recruitment of GP practices closed on 31/03/2011. Recruitment of participants continues; study will be open until UK recruitment reaches 15,000
DARE - Diabetes Alliance for Research in England	Prof Andrew Hattersley	OUTSIDE EASTERN REGION	3815 DRN082	PCRN	Eastern GP Practices	2	17000	20/09/2010	31/07/2012	No Eastern recruitment recorded since Sept 2010
Antithyroid drug treatment in paediatric graves' disease	Dr Tim Cheetham	OUTSIDE EASTERN REGION	7551 DRN494	CRN	Addenbrooke's (Prof Dunger)	4	160	06/01/2010	01/01/2014	No recruitment recorded since May 2011
Vitamin D Supplementation in People at Risk of Type 2 Diabetes	Prof Graham Hitman	OUTSIDE EASTERN REGION	7732 DRN415	NONE	Addenbrooke's	149	342	27/07/2010	04/01/2013	Monthly recruitment up-to-date
Emotional Stress and Wound Healing in Diabetes Version 1	Prof Andrew Boulton	OUTSIDE EASTERN REGION	6993 DRN294	NONE	Ipswich	9	75	22/01/2008	31/12/2012	No recruitment recorded since Feb 2011. 3 accruals upload pending for June 2011
ADDRESS Study	Prof Des Johnston	OUTSIDE EASTERN REGION	8009 DRN094	MCRN	Ipswich Norfolk & Norwich QE2 Kings Lynn	36	4000	31/01/2008	31/01/2012	No recruitment recorded since Jan 2011
TrialNet Natural History Study of the Development of Type 1 Diabetes. Phase 1, 2 and 3.	Prof Polly Bingley	OUTSIDE EASTERN REGION	4016 DRN100	NONE	Norfolk & Norwich	60	2000	01/04/2005	01/09/2019	No recruitment recorded since June 2011
DRN 240 DAFNE Research Database. Improving management of Type Diabetes in the UK - the DAFNE programme as a Research Test Bed - DAFNE Research Database.	Dr Peter Mansell	OUTSIDE EASTERN REGION	5853 DRN240	NONE	Addenbrooke's	200	300	01/11/2008	01/10/2011	No recruitment since June 2011. Possible delay in uploading some accruals.

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ACTIVELY RECRUITING - OPEN Studies CO-ADOPTED by DRN

Study Title	Chief Investigator (CI)	Network area where CI is based	UKCRN ID	Lead Network	Eastern Sites	Number of participants recruited and recorded on the NIHR portfolio mapped to the Eastern Region	UK Target Sample size	Actual Start of Recruitment Date	Planned Close of Recruitment Date	Comment on recruitment (accrual) upload status on the NIHR portfolio
JUMP - Joining together to Understand diabetes mellitus Type 2 Progression in children. Type 2 Diabetes in Childhood: Building a platform for interventions to prevent the progression to cardiovascular disease	Prof Tim Barrett	OUTSIDE EASTERN REGION	7574 MCRN	DRN	Princess Alexandra Hospital, Harlow	2	200	30/07/2010	30/04/2012	No recruitment recorded since August 2010
EPIC Project - Evidence into practice: evaluating a child-centred intervention for diabetes medicine management	Prof Jane Noyes	OUTSIDE EASTERN REGION	6092	MCRN	Norfolk & Norwich	38	252	01/03/2011	01/06/2011	Monthly recruitment up-to-date
IRIS - Insulin Resistance Intervention after Stroke	Prof Gary Ford	OUTSIDE EASTERN REGION	7257	Stroke	Luton & Dunstable	6	3136	08/02/2011	31/07/2011	No recruitment recorded since May 2011
Detemir Glargine - A 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	Prof David Dunger	EASTERN REGION	4903	MCRN	Addenbrooke's Ipswich Norfolk and Norwich James Paget West Suffolk	21	112	01/04/2008	30/06/2013	Monthly recruitment up-to-date
EPIC - Norfolk Third Health Check - Diet, lifestyle and biological determinants of health and chronic disease: The Third Health Check of EPIC-Norfolk. A Prospective Population Study.	Prof Kay-Tee Khaw	EASTERN REGION	2219	PCRN	GP Practices	6301	10000	01/06/2004	31/12/2011	Monthly recruitment up-to-date
PATHWAY1 - Comparison of single and monotherapy diuretics in therapy in low-renin hypertension	Prof Morris J Brown	EASTERN REGION	4499	CRN	Addenbrooke's	71	572	02/02/2010	30/09/2011	No Eastern recruitment recorded since Mar 2011
PATHWAY2 - Optimal treatment of drug resistant hypertension	Prof Morris J Brown	EASTERN REGION	4500	CRN	Addenbrooke's	43	346	01/04/2009	01/09/2011	Monthly recruitment up-to-date
PATHWAY3 - Comparison of single and combination diuretics in therapy in low-renin hypertension	Prof Morris J Brown	EASTERN REGION	4501	CRN	Addenbrooke's	43	486	28/09/2009	30/09/2011	Monthly recruitment up-to-date
DECIDE - Delivering Early Care in Diabetes Evaluation - An RCT to assess hospital versus home management at diagnosis in childhood diabetes	Prof John Gregory	OUTSIDE EASTERN REGION	4171	MCRN	Addenbrooke's	6	200	09/07/2008	31/10/2011	No recruitment recorded since Mar 2010