



Predicting Serious Drug Side Effects in Gastroenterology - PRED4

International IBD Genetics Consortium Projects

www.ibdresearch.co.uk/pred4

Welcome to the 2nd edition newsletter of 2014. 20 sites that have recruited patients to PRED4 since the last newsletter. We also have 2 new recruiters Addenbrooke's Paediatrics and Chinese University Hong Kong. Thank you and well done.

•**Targets:** We are happy for you to recruit over your targets set in the SSI form so if you have reached your target please don't let that hold you back.

•**Twitter:** You can follow up to date news on the PRED4 study at **@PRED4research**.

Breaking news...*thiopurine induced pancreatitis (TIP)* REOPENED.

We have some exciting genetic results in this arm of the study. We have submitted a manuscript for review and hope to hear soon. We will keep you updated with this. In light of these promising data we have decided to **REOPEN TIP**. We have ethics approval to extend all the side arms so no further actions needs to be taken in terms of ethics/R&D approval. Therefore all 6 of the studies in PRED4 are open until at least the end of 2014.



Reminder of the inclusion criteria for the 2 new arms: Sulfasalazine Induced Neutropaenia (SAN)

- History of inflammatory bowel disease or Rheumatoid Arthritis
- History of Sulfasalazine exposure in the previous 30 days
- Normal total white cell count and neutrophil count at baseline
- Fall in neutrophil count to $\leq 0.5 \times 10^9/L$
- Medical opinion implicating Sulfasalazine leads to dose reduction or drug withdrawal (even if temporary)

Thiopurine Induced Liver Injury (TIH)

- History of inflammatory bowel disease
- Normal ALT and bilirubin at baseline
- No pre-existing liver disease
- Elevation of ALT and/or bilirubin to ≥ 5 times upper limit of normal (guidance >175 for female and >200 for males.)
- History of thiopurine exposure in the previous 30 days prior to this abnormal blood test
- Medical opinion implicating thiopurine in development of hepatotoxicity



SAN - Please use the rheumatology codes to identify patients for this study.

★ Combine for Ulcerative Colitis (K51) + D70 (**D70.2**) (Agranulocytosis, which includes drug-induced neutropaenia)
Or Combine for Crohn's Disease (K50) + D70 (**D70.2**) (Agranulocytosis, which includes drug-induced neutropaenia)

The new CRFs are available on the database www.ibdresearch.net please contact us for your username and password.

As always if you have any feedback or suggestions on how to improve the study please let us know . If you have found a good way to find patients why not post it on Twitter.

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**PRED4 Hospital sites - number recruited is based on the samples logged in laboratory by:
24th April 2014**

Please note figures exclude any screening log failures or patients withdrawn

Royal Devon & Exeter Hospital	61	Darlington Memorial & Bishop Auckland Hospital	5
Guy's Hospital, London	56	Freeman Hospital, Newcastle (RENAL)	5
Southampton General Hospital	39	Kettering Hospital	5
Royal Berkshire Hospital	29	Princess Alexandra Hospital, Essex	5
St James's University Hospital, Leeds	28	St Vincent's Hospital, Melbourne, Australia	5
Royal Derby Hospital	26	James Cook University Hospital, South Tees	5
Hull Royal Infirmary	25	Weston General Hospital	5
Addenbrooke's, Cambridge	24	Basingstoke & North Hampshire Hospital	4
Florence, Italy	24	Bradford Royal Infirmary	4
Ninewells Hospital, Dundee	24	Flinders Medical Centre, South Australia	4
Gloucester Royal Hospital	21	King's Mill Hospital, Nottinghamshire	4
University of Alberta, Canada	21	Raigmore Hospital, Inverness	4
Western General Hospital, Edinburgh	20	Royal Blackburn Hospital	4
Orebro University Hospital, Sweden	18	Scunthorpe General Hospital	4
University Hospitals Bristol	18	St Vincent's Hospital, Sydney, Australia	4
Fremantle Hospital, Australia	16	Stoke Mandeville Hospital, Bucks	4
Royal London Barts Hospital	15	Aberdeen Royal Infirmary	3
Kent & Canterbury Hospital	14	Alder Hey Children's Hospital - Paediatric	3
Nottingham University Hospitals	14	Basildon Hospital	3
Poole Hospital	14	County Hospital Hereford	3
Royal Cornwall Hospital	14	Glasgow Royal Infirmary	3
Salford Royal Hospital	14	James Paget University Hospitals	3
University Hospital Padua, Italy	14	Liverpool Hospital, Australia	3
Watford General Hospital	14	Nottingham Children's Hospital - Paediatric	3
Aintree University Hospital	12	Royal Free Hospital, London	3
Derriford Hospital, Plymouth	12	Royal Hallamshire Hospital, Sheffield	3
Mater Clinic, Brisbane, Australia	12	Royal Liverpool & Broadgreen Hospital	3
York Teaching Hospital	12	Sandwell Hospital, Birmingham	3
Chinese University of Hong Kong	10	South Africa, Groote Schuur	3
New Cross Hospital, Wolverhampton	10	University Hospital North Tees	3
Torbay Hospital	10	Warrington Hospital	3
John Radcliffe Hospital, Oxford	9	West Middlesex University Hospital	3
King's College Hospital, London	9	Worthing Hospital	3
Musgrove Park Hospital, Taunton	9	Crosshouse Hospital, Ayrshire & Arran	2
Norfolk & Norwich Hospital	9	Dorset County Hospital	2
St George's Hospital, London	9	Epsom & St Helier University Hospitals	2
Wythenshawe Hospital	9	Harrogate District Hospital	2
Yorkhill Children's Hospital, Glasgow - Paediatric	9	Kiel, Germany	2
Airedale General Hospital	8	Leeds General Infirmary - Paediatric	2
Chelsea and Westminster Hospital	8	Leicester General Hospital - Paediatric	2
Dunedin Hospital, New Zealand	8	Luton and Dunstable Hospital	2
Llandough Hospital, Cardiff	8	Mater Dei Hospital, Malta	2
Mid Yorkshire Hospitals	8	Milton Keynes Hospital	2
Queen Elizabeth Hospital, Birmingham	8	Pennine Trust, Manchester	2
Royal Victoria Infirmary, Newcastle	8	Regional Hospital Viborg, Denmark	2
St Mark's Hospital, Harrow	8	Sheffield Children's Hospital - Paediatric	2
University Hospital North Staffordshire	8	University Hospital of Ioannina, Greece	2
Frimley Park Hospital	7	Yeovil District Hospital	2
Haifa, Israel	7	Addenbrooke's, Cambridge - Paediatric	1
Mount Sinai, Canada	7	Ipswich Hospital	1
Queen Alexandra Hospital, Portsmouth	7	North Cumbria University Hospitals	1
Royal Sussex County Hospital, Brighton	7	Queen Elizabeth Hospital, London	1
University College London Hospital	7	Royal Hampshire County Hospital	1
Birmingham Heartlands Hospital	6	Royal Manchester Children's Hospital - Paediatric	1
Calderdale Royal Hospital	6	Royal United Hospital, Bath	1
Chesterfield Royal Hospital	6	Shaare Zedek Medical Centre, Israel	1
Dudley Group of Hospitals	6	Southmead Hospital, Bristol	1
Great Ormond Street Hospital - Paediatric	6	University Hospital Lewisham	1
Forth Valley Royal Hospital	6	University Hospital of Wales	1
Royal Adelaide Hospital, Australia	6	Worcester Royal Infirmary	1
Royal Bournemouth General Hospital	6	Wrightington, Wigan & Leigh	1
Royal Brisbane & Women's Hospital, Australia	6		
Shrewsbury & Telford Hospital	6	Total UK Recruited:	877
South Tyneside District Hospital	6	Total International Recruited:	177
Colchester General Hospital	5	Grand Total:	1054

SITE HAS RECRUITED SINCE LAST NEWSLETTER