



Predicting Serious Drug Side Effects in Gastroenterology - PRED4

International IBD Genetics Consortium Projects

www.ibdresearch.co.uk/pred4

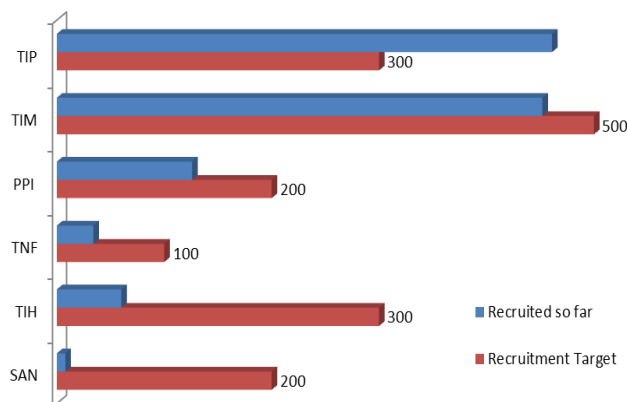
Welcome to the 3rd edition newsletter of 2014. 35 sites have recruited patients to PRED4 since the last newsletter. We also have 2 new recruiters: Canberra Hospital, Australia and Northern Devon Healthcare NHS Trust. Thank you and well done.

• **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**.

Remember all six arms of the PRED4 study are open till the end of this year:

- Demyelination complicating Anti-TNF therapy (TNF)
- Proton Pump Inhibitor (PPI) induced Interstitial Nephritis
- Thiopurine induced Pancreatitis (TIP)
- Thiopurine induced Myelosuppression (TIM)
- Sulfasalazine induced Neutropaenia (SAN)
- Thiopurine induced Liver Injury (TIH)



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 approach your rheumatologist to help with this study. Alternatively, Dr Abhey Singh and Michelle Clarke have devised 'tried and tested methods' to identify these patients and we have attached these strategies to this newsletter. Abhey and Michelle have managed to find 8 patients using these methods.

The electronic CRFs are designed to replace the paper CRFs and can be completed 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:
15th July 2014**

Please note figures exclude any screening log failures or patients withdrawn

Royal Devon & Exeter Hospital	68	Royal Free Hospital, London	6
Guy's Hospital, London	57	Bradford Royal Infirmary	5
Southampton General Hospital	40	Darlington Memorial & Bishop Auckland Hospital	5
Royal Berkshire Hospital	34	Freeman Hospital, Newcastle (RENAL)	5
St James's University Hospital, Leeds	33	Kettering Hospital	5
Ninewells Hospital, Dundee	30	Nottingham Children's Hospital - Paediatric	5
Hull Royal Infirmary	27	Princess Alexandra Hospital, Essex	5
Gloucester Royal Hospital	26	St Vincent's Hospital, Melbourne, Australia	5
Royal Derby Hospital	26	Stoke Mandeville Hospital, Bucks	5
Addenbrooke's, Cambridge	24	James Cook University Hospital, South Tees	5
Florence, Italy	24	Weston General Hospital	5
University of Alberta, Canada	21	Alder Hey Children's Hospital - Paediatric	4
Western General Hospital, Edinburgh	21	Basingstoke & North Hampshire Hospital	4
Orebro University Hospital, Sweden	18	Flinders Medical Centre, South Australia	4
University Hospitals Bristol	18	James Paget University Hospitals	4
University Hospital Padua, Italy	18	King's Mill Hospital, Nottinghamshire	4
Watford General Hospital	17	Raigmore Hospital, Inverness	4
Fremantle Hospital, Australia	16	Royal Blackburn Hospital	4
Royal London Barts Hospital	16	Royal Hallamshire Hospital, Sheffield	4
Nottingham University Hospitals	15	Royal Liverpool & Broadgreen Hospital	4
Kent & Canterbury Hospital	14	Scunthorpe General Hospital	4
Poole Hospital	14	St Vincent's Hospital, Sydney, Australia	4
Royal Cornwall Hospital	14	Aberdeen Royal Infirmary	3
Salford Royal Hospital	14	Basildon Hospital	3
Aintree University Hospital	12	County Hospital Hereford	3
Derriford Hospital, Plymouth	12	Glasgow Royal Infirmary	3
Mater Clinic, Brisbane, Australia	12	Liverpool Hospital, Australia	3
Musgrove Park Hospital, Taunton	12	Sandwell Hospital, Birmingham	3
York Teaching Hospital	12	South Africa, Groote Schuur	3
New Cross Hospital, Wolverhampton	11	University Hospital North Tees	3
Chinese University of Hong Kong	10	Warrington Hospital	3
Torbay Hospital	10	West Middlesex University Hospital	3
Wythenshawe Hospital	10	Worthing Hospital	3
John Radcliffe Hospital, Oxford	9	Yeovil District Hospital	3
King's College Hospital, London	9	Crosshouse Hospital, Ayrshire & Arran	2
Forth Valley Royal Hospital	9	Dorset County Hospital	2
Norfolk & Norwich Hospital	9	Epsom & St Helier University Hospitals	2
St George's Hospital, London	9	Harrogate District Hospital	2
Yorkhill Children's Hospital, Glasgow - Paediatric	9	Ipswich Hospital	2
Airedale General Hospital	8	Kiel, Germany	2
Chelsea and Westminster Hospital	8	Leeds General Infirmary - Paediatric	2
Dunedin Hospital, New Zealand	8	Leicester General Hospital - Paediatric	2
Frimley Park Hospital	8	Luton and Dunstable Hospital - Paediatric	2
Llandough Hospital, Cardiff	8	Mater Dei Hospital, Malta	2
Mid Yorkshire Hospitals	8	Milton Keynes Hospital	2
Queen Elizabeth Hospital, Birmingham	8	Northern Devon Healthcare NHS Trust	2
Royal Victoria Infirmary, Newcastle	8	Pennine Trust, Manchester	2
St Mark's Hospital, Harrow	8	Regional Hospital Viborg, Denmark	2
University Hospital North Staffordshire	8	Sheffield Children's Hospital - Paediatric	2
Dudley Group of Hospitals	7	Southmead Hospital, Bristol	2
Haifa, Israel	7	University Hospital of Ioannina, Greece	2
Mount Sinai, Canada	7	Addenbrooke's, Cambridge - Paediatric	1
Queen Alexandra Hospital, Portsmouth	7	North Cumbria University Hospitals	1
Shrewsbury & Telford Hospital	7	Queen Elizabeth Hospital, London	1
South Tyneside District Hospital	7	Royal Hampshire County Hospital	1
Royal Sussex County Hospital, Brighton	7	Royal Manchester Children's Hospital - Paediatric	1
University College London Hospital	7	Royal United Hospital, Bath	1
Birmingham Heartlands Hospital	6	Shaare Zedek Medical Centre, Israel	1
Calderdale Royal Hospital	6	University Hospital Lewisham	1
Canberra Hospital, Australia	6	University Hospital of Wales	1
Chesterfield Royal Hospital	6	Worcester Royal Infirmary	1
Colchester General Hospital	6	Wrightington, Wigan & Leigh	1
Great Ormond Street Hospital - Paediatric	6		
Royal Adelaide Hospital, Australia	6	Total UK Recruited:	944
Royal Bournemouth General Hospital	6	Total International Recruited:	187
Royal Brisbane & Women's Hospital, Australia	6	Grand Total:	1131

SITE HAS RECRUITED SINCE LAST NEWSLETTER