



Predicting Serious Drug Side Effects in Gastroenterology  
- PRED4  
UKIBDGC and International IBDGC project.



Welcome to the autumn edition of the PRED 4 newsletter. Thank you all for all your support with this study. Since the last newsletter we have recruited 125 NEW patients, and new recruiting sites include Coventry, Royal Bolton, Norfolk & Norwich paediatrics, Nevill Hall and Cardiff.

We have extended the study until the end of 2016 , it won't be extended beyond this.

**Thiopurine induced liver injury\*** we have reduced the ALT for inclusion for this arm. Inclusion criteria is below

- History of inflammatory bowel disease
- Normal ALT and bilirubin at baseline
- **Elevation of ALT and/or bilirubin to  $\geq 4$  times ULN**
- History of thiopurine exposure in the previous 30 days of the event occurring.
- Medical opinion indicates thiopurine
- No history of chronic liver disease



CCUK – we recently put an advert on the Crohn's and Colitis UK Facebook and Twitter page and we had lots of patients volunteering to take part in PRED4 including a few in Wales , Northampton and Romford that we haven't got sites open, so if you know of anyone in these areas who would like to take part can you let me know. Thank you.

**NIHR CRN 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. Don't forget, if you recruit one patient to 2 arms this will mean a double NIHR CRN accrual.

TOP TIP recruitment.  
Have a look at patients who are on Anti-TNF (ask IBD nurse) or on methotrexate as these patients are sometimes on these drugs because they are intolerant to thiopurines.

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

**PRED4 Hospital sites - number recruited is based on the samples logged in laboratory by:  
8 October 2015**

**Please note figures exclude any screening log failures or patients withdrawn**

Royal Devon & Exeter Hospital	101	Chesterfield Royal Hospital	6
Guy's Hospital, London	63	Great Ormond Street Hospital - Paediatric	6
Royal Berkshire Hospital	59	Nottingham Children's Hospital - Paediatric	6
Southampton General Hospital	59	<b>Royal Adelaide Hospital, Australia</b>	<b>6</b>
Ninewells Hospital, Dundee	43	Royal Bournemouth General Hospital	6
St James's University Hospital, Leeds	42	<b>Royal Brisbane &amp; Women's Hospital, Australia</b>	<b>6</b>
Gloucester Royal Hospital	39	<b>Canberra Hospital, Australia</b>	<b>5</b>
Hull Royal Infirmary	33	Darlington Memorial & Bishop Auckland Hospital	5
Royal Derby Hospital	30	Freeman Hospital, Newcastle (RENAL)	5
Watford General Hospital	29	Glasgow Royal Infirmary	5
Addenbrooke's, Cambridge	25	Kettering Hospital	5
<b>Florence, Italy</b>	<b>24</b>	Lincoln County Hospital	<b>5</b>
Royal London Barts Hospital	24	Northern Devon Healthcare NHS Trust	5
University Hospitals Bristol	24	Royal Liverpool & Broadgreen Hospital	5
Western General Hospital, Edinburgh	23	<b>St Vincent's Hospital, Melbourne, Australia</b>	<b>5</b>
<b>University of Alberta, Canada</b>	<b>21</b>	Worthing Hospital	<b>5</b>
Nottingham University Hospitals	20	Alder Hey Children's Hospital - Paediatric	4
Poole Hospital	19	Basingstoke & North Hampshire Hospital	4
Barnet & Chase Farm Hospitals	18	Birmingham Children's Hospital	4
Kent & Canterbury Hospital	18	<b>Flinders Medical Centre, South Australia</b>	<b>4</b>
<b>Orebro University Hospital, Sweden</b>	<b>18</b>	Raigmore Hospital, Inverness	<b>4</b>
Royal Hallamshire Hospital, Sheffield	18	<b>Regional Hospital Viborg, Denmark</b>	<b>4</b>
Stoke Mandeville Hospital, Bucks	18	Royal Blackburn Hospital	4
York Teaching Hospital	18	Scunthorpe General Hospital	4
Bradford Royal Infirmary	17	<b>St Vincent's Hospital, Sydney, Australia</b>	<b>4</b>
Derriford Hospital, Plymouth	17	Aberdeen Royal Infirmary	3
<b>University Hospital Padua, Italy</b>	<b>17</b>	Basildon Hospital	3
Warrington Hospital	17	County Hospital Hereford	3
<b>Fremantle Hospital, Australia</b>	<b>16</b>	Leicester General Hospital - Paediatric	3
Musgrove Park Hospital, Taunton	16	<b>Liverpool Hospital, Australia</b>	<b>3</b>
Royal Stoke University Hospital	16	Queen Elizabeth Hospital King's Lynn	3
Shrewsbury & Telford Hospital	16	Royal United Hospital, Bath	3
New Cross Hospital, Wolverhampton	15	Sandwell Hospital, Birmingham	3
Royal Cornwall Hospital	15	<b>South Africa, Groote Schuur</b>	3
Forth Valley Royal Hospital	14	Southmead Hospital, Bristol	3
Salford Royal Hospital	14	<b>Stepping Hill Hospital, Stockport NHS Foundation T</b>	<b>3</b>
Tameside Hospital	14	University Hospital North Tees	3
King's College Hospital, London	13	West Middlesex University Hospital	3
Queen Alexandra Hospital, Portsmouth	13	Countess of Chester	2
Aintree University Hospital	12	Crosshouse Hospital, Ayrshire & Arran	2
Airedale General Hospital	12	Dorset County Hospital	2
<b>Mater Clinic, Brisbane, Australia</b>	<b>12</b>	Eastbourne District General Hospital	2
Royal Sussex County Hospital, Brighton	12	Epsom & St Helier University Hospitals	2
Torbay Hospital	11	Grantham & District Hospital	2
University College London Hospital	11	Harrogate District Hospital	2
Weston General Hospital	11	Ipswich Hospital	2
<b>Chinese University of Hong Kong</b>	<b>10</b>	<b>Kiel, Germany</b>	<b>2</b>
Dudley Group of Hospitals	10	Leeds General Infirmary - Paediatric	2
Frimley Park Hospital	10	Luton and Dunstable Hospital - Paediatric	2
Norfolk & Norwich Hospital	10	Maidstone and Tunbridge Wells NHS Trust	2
St George's Hospital, London	10	<b>Mater Dei Hospital, Malta</b>	<b>2</b>
Wythenshawe Hospital	10	Milton Keynes Hospital	2
Yorkhill Children's Hospital, Glasgow - Paediatric	10	<b>Nevill Hall Hospital, Cardiff</b>	<b>2</b>
Calderdale Royal Hospital	9	Pennine Trust, Manchester	2
Colchester General Hospital	9	Sheffield Children's Hospital - Paediatric	2
John Radcliffe Hospital, Oxford	9	University Hospital Lewisham	2
Mid Yorkshire Hospitals	9	<b>University Hospital of Ioannina, Greece</b>	<b>2</b>
Princess Alexandra Hospital, Essex	9	Wrightington, Wigan & Leigh	2
Royal Free Hospital, London	9	Addenbrooke's, Cambridge - Paediatric	1
St Mark's Hospital, Harrow	9	Norfolk & Norwich Hospital - Paediatric	1
Chelsea and Westminster Hospital	8	North Cumbria University Hospitals	1
<b>Dunedin Hospital, New Zealand</b>	<b>8</b>	Queen Elizabeth Hospital, London	1
Llandough Hospital, Cardiff	8	<b>Royal Bolton Hospital</b>	<b>1</b>
Manchester Royal Infirmary	8	Royal Hampshire County Hospital	1
Queen Elizabeth Hospital, Birmingham	8	Royal Manchester Children's Hospital - Paediatric	1
Royal Victoria Infirmary, Newcastle	8	<b>Shaare Zedek Medical Centre, Israel</b>	<b>1</b>
South Tyneside District Hospital	8	University Hospital Coventry	1
James Cook University Hospital, South Tees	8	University Hospital of Wales	1
Birmingham Heartlands Hospital	7	Worcester Royal Infirmary	1
<b>Haifa, Israel</b>	<b>7</b>		
James Paget University Hospitals	7		
King's Mill Hospital, Nottinghamshire	7		
<b>Mount Sinai, Canada</b>	<b>7</b>		
Yeovil District Hospital	7		
		<b>Total UK Recruited:</b>	<b>1361</b>
		<b>Total International Recruited:</b>	<b>187</b>
		<b>Grand Total:</b>	<b>1548</b>

**SITE HAS RECRUITED SINCE LAST NEWSLETTER**

## Hints and Tips from Research Nurses

This edition of the newsletter includes a new feature where we are sharing some tips from Research Nurses who have been very successful in recruiting to PRED4. Below we have some tips from Ola Olaosebikan from Barnet and Chase Farm Hospitals in London. If you have any hints and tips that you would like to share with other research nurses, please send them in and we will include them in our next newsletter. We'd like to say thank you to Ola for taking the time to compile this list, and also thanks to everyone for your continued support with PRED4.

**Ola believes that using the following as a guideline has been helpful to him but also adds that sometimes different sites/teams might have to adopt different techniques:**

- Team work between clinicians and research practitioners/ nurses is very important and it is facilitated by a healthy and good professional relationship among team members.
- Don't leave the identification of patients mostly to the PI/Consultants as they usually have a lot of commitments. As they are usually running more than one study, they might forget or mix up study criteria.
- Going through weekly clinic lists in advance helps a lot in identifying patients as well as gives enough time in preparing to meet them, rather than running into them at the last minute on clinic days.
- In addition to the above, if you have time and a good patient data base, it might be worthwhile screening the list quickly for eligible patients, even if they are not due to come to clinic soon. This way you can be sure of recruiting at least 2 people every month. For example, at our site, we have identified a number of eligible patients up until April 2016 – then it is just a matter of setting up a reminder to catch up with them when they come around or you could always send the invitation letter out.
- Know or study your PIS inside out, don't just read from the PIS leaflet to the patients, as often times you won't sound confident. You have to let patients know the direct benefit for them and if not a direct benefit, let them know this might help the upcoming generation.