

Study Amendment 8 is Now Approved

If you have any queries on any aspect of these changes then please contact the BADBIR office
(badbir@manchester.ac.uk / 0161 306 1896)

Thanks to all centres for their ongoing contribution to BADBIR

1 New Protocol Approved

The ethics committee have now approved study amendment 8 which introduces **Protocol v15 01/07/2015**. This supersedes the previous version 14. We have notified your R&D department, once we receive trust approval we will provide you with the relevant documents and instructions on where to file these in your site file.

2 Extension of study end

The study end date for the BADBIR was to be 31/07/2018. This has now been extended for a further 10 years to **31/07/2028**. The reason for the extension is there are plans to include some of the new biologic and small molecules therapies which have recently become available for the treatment of psoriasis.

3 Removing the minimum age limit

We now have approval to include psoriasis patients who are **under the age of 16** who are being treated with a biologic or conventional therapy.

Despite the small number of children being treated with biologic or conventional therapy, it remains important that the long term safety is evaluated in this group. The combination of exposure to immunosuppressive therapy on an immature immune system and a potentially high lifetime exposure, may place them at a higher risk than adults.

4 Increasing size of Conventional Cohort

The target of 4000 registrations for the conventional comparison group has now increased to an overall maximum of **7000**.

The reason for this increase is the anticipation of the inclusion of the new biologic therapies and the desire to have a contemporaneous comparator cohort of patients, as this is likely to be more representative of current prescribing patterns. In addition, it has been noted that there is attrition from the conventional cohort over time with patients moving to the biologic cohort.

Procedure:

- ◆ The parent/guardian will be provided with adult version of the current BADBIR Patient Information sheet (Version 4, dated 14/05/2009)
- ◆ An age appropriate version of BADBIR information sheet will be provided and discussed with the child participant.
- ◆ We will require both the **Patient Assent Form** (version 4, 14/05/2009) signed by the child participant and the **Consent form for Parent or Guardian** (Version 4 14/05/2009) for patient registration.
- ◆ The following Patient Reported Outcome Measures will be substituted for the adult versions at each assessment:
 - * Children's Dermatology Life Quality Index (CDLQI)
 - * EQ 5D-Y
 - * Child Health Assessment Questionnaire (CHAQ)

5 Minor revision to questionnaires

Minor revisions have been made to guide better data collection. The revisions clarify the type of information required opposed to collecting more information with the exception of the **"batch number"** of the medication which is being added to comply with European Medicines Agency regulations.

6 Biologic Drug Trade Names

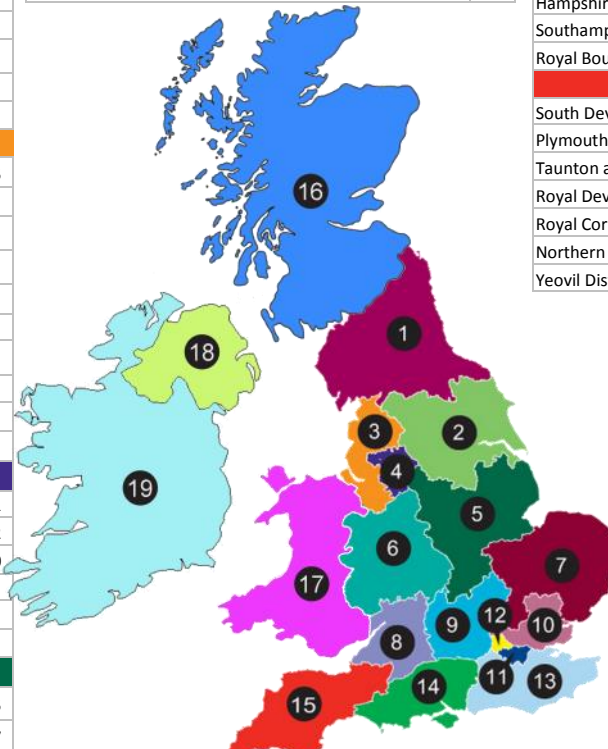
BADBIR will now use the trade name of the biologic drugs instead of their originator names. All existing information will automatically change. List of drugs from this change is as follows:

Originator Name	Trade Name
Adalimumab	Humira
Etanercept	Enbrel
Ustekinumab	Stelara
Infliximab	Remicade



1 - North East & North Cumbria	
County Durham and Darlington NHS Foundation Trust	299
Newcastle upon Tyne Hospitals NHS Foundation Trust	233
South Tees Hospitals NHS Trust	124
North Cumbria University Hospitals NHS Trust	35
North Tees & Hartlepool NHS Foundation Trust	17
2 - Yorkshire & Humber	
Bradford Teaching Hospitals NHS Foundation Trust	328
Leeds Teaching Hospitals NHS Trust	182
Hull and East Yorkshire Hospitals NHS Trust	171
Harrogate and District NHS Foundation Trust	79
York Teaching Hospital NHS Foundation Trust	50
Northern Lincolnshire & Goole Hospitals NHS Trust	48
The Rotherham NHS Foundation Trust	45
Doncaster and Bassetlaw Hospitals NHS Foundation Trust	44
Sheffield Teaching Hospitals NHS Foundation Trust	41
Calderdale & Huddersfield NHS Trust	35
York Teaching Hospital (Scarborough)	31
Mid Yorkshire Hospitals NHS Trust	20
Barnsley Hospitals NHS Trust	20
3 - North West Coast	
Royal Liverpool and Broadgreen University Hospitals	355
University Hospitals of Morecambe Bay	88
Blackpool, Fylde and Wyre Hospitals	74
Countess Of Chester Hospital NHS Foundation Trust	68
Wirral University Teaching Hospital NHS Foundation Trust	58
St Helens & Knowsley NHS Trust	40
Aintree University Hospitals	30
Southport and Ormskirk Hospital NHS Trust	30
The Mid Cheshire Hospitals NHS Trust	20
Lancashire Teaching Hospitals Foundation NHS Trust	17
4 - Greater Manchester	
Salford Royal NHS Foundation Trust	581
East Lancashire Hospitals NHS Trust	172
Wrightington, Wigan and Leigh NHS Foundation Trust	110
Tameside Hospital NHS Foundation Trust	32
East Cheshire NHS Trust	8
Pennine Acute Hospitals NHS Trust	3
5 - East Midlands	
Nottingham University Hospitals NHS Trust	345
University Hospitals Leicester NHS Trust	147
United Lincolnshire Hospitals NHS Trust	85
Derby Hospitals Foundation Trust	59
Sherwood Forest Hospitals NHS Trust	49
Kettering General Hospital NHS Trust	41
Chesterfield Royal NHS Foundation Trust	26
Northampton General Hospital NHS Trust	14
6 - West Midlands	
University Hospitals of North Midlands NHS Trust	215
Sandwell And West Birmingham Hospitals NHS Trust	173
Burton Hospital NHS Trust	128
University Hospitals Birmingham NHS Foundation Trust	105
The Dudley Group of Hospitals NHS Foundation Trust	76
The Royal Wolverhampton NHS Trust (Cannock Chase)	71
Heart of England NHS Foundation Trust	63
Wye Valley NHS Trust	46
Worcestershire Acute Hospitals NHS Trust	37
University Hospitals Coventry & Warwickshire NHS Trust	31
The Royal Wolverhampton Hospitals NHS Trust	29
Shrewsbury and Telford Hospitals NHS Trust	20
South Warwickshire General Hospitals NHS Trust	14

7 - Eastern	
Norfolk & Norwich University Hospitals NHS Trust	83
Peterborough & Stamford Hospitals NHS Trust	74
Ipswich Hospital NHS Trust	55
Queen Elizabeth Hospital Kings Lynn NHS Trust	38
Cambridge University Hospitals NHS Foundation Trust	37
Bedford Hospital NHS Trust	23
James Paget University Hospitals NHS Foundation Trust	22
East and North Hertfordshire NHS Trust	10
8 - West of England	
Royal United Hospital Bath NHS Trust	127
University Hospitals Bristol NHS Foundation Trust	125
Great Western Hospitals NHS Foundation Trust	46
Gloucestershire Hospitals NHS Foundation Trust	12
Weston Area Health NHS Trust	6



9 - Thames Valley & South Midlands	
Oxford University Hospitals NHS Trust	127
Buckinghamshire Healthcare NHS Trust	33
Royal Berkshire NHS Foundation Trust	20
Milton Keynes Hospital NHS Foundation Trust	11

10 - North Thames	
Barts Health NHS Trust (Whipps Cross)	92
Barnet And Chase Farm NHS Trust	82
The Princess Alexandra Hospital NHS Trust	67

Royal Free London NHS Foundation Trust	66
West Hertfordshire Hospitals NHS Trust	50
BHR University Hospitals NHS Trust	56
Basildon and Thurrock University Hospitals	47
Barts Health NHS Trust (Barts)	34
Mid Essex Hospital Services NHS Trust	31
Homerton University Hospital NHS Trust	24
Whittington Health	19
University College Hospital NHS Foundation Trust	5

11 - South London	
Guys & St Thomas NHS Foundation Trust	474
Kings College Hospital NHS Foundation Trust (Orpington)	145
Epsom and St Helier University Hospitals NHS Trust	84
Queen Elizabeth Woolwich Hospital NHS Trust	76
St Georges London NHS Trust	54
Kings College Hospital NHS Foundation Trust	42
Lewisham & Greenwich NHS Trust	14
Croydon Health Services NHS Trust	12

12 - North West London	
West Middlesex University NHS Trust	110
Ealing Hospital NHS Trust	33
Chelsea and Westminster NHS Foundation	16
North West Healthcare NHS Trust (Northwick Park)	8
Imperial College Healthcare NHS Trust	3

13 - Kent, Surrey & Sussex	
Frimley Park Hospital NHS Foundation Trust	83
Surrey And Sussex Healthcare NHS Trust	78
East Kent Hospitals NHS University Foundation Trust	77
Brighton And Sussex University Hospitals NHS Trust	67
Medway NHS Foundation Trust	59
Western Sussex Hospitals NHS Trust	51
East Sussex Hospitals NHS Trust	35
The Royal Surrey County Hospital NHS Trust	17

14 - Wessex	
Portsmouth NHS Trust	103
Hampshire Hospitals NHS Trust (Basingstoke)	33
Poole Hospital NHS Foundation Trust	27
Dorset County Hospital NHS Foundation Trust	25
Salisbury NHS Foundation Trust	14
Hampshire Hospitals NHS Trust (Winchester)	13
Southampton University Hospitals NHS Trust	7
Royal Bournemouth And Christchurch Hospitals	6

15 - South West Peninsula	
South Devon Healthcare NHS Foundation Trust	79
Plymouth Hospitals NHS Trust	59
Taunton and Somerset NHS Foundation Trust	47
Royal Devon And Exeter NHS Foundation Trust	45
Royal Cornwall Hospitals Trust	43
Northern Devon Healthcare NHS Trust	25
Yeovil District Hospital NHS Foundation Trust	23

16 - Scotland	
NHS Greater Glasgow and Clyde	325
NHS Grampian	129
NHS Lothian	110
NHS Fife (Victoria Hospital Kirkcaldy)	48
NHS Fife (Dunfermline Queen Margaret)	46
NHS Tayside	43
NHS Highland	35
Ayrshire & Arran NHS	24
NHS Lanarkshire	20
NHS Dumfries & Galloway	3

17 - Wales	
Aneurin Bevan Health Board	157
Cardiff & Vale University Health Board	106
(West Wales) Hywel Dda Local Health Board	87
(Bridgend) ABM University Health Board	55
Betsi Cadwaladr University (Glan Clwyd)	48
(Withybush) Hywel Dda Local Health Board	39
Betsi Cadwaladr (Ysbyty Gwynedd)	37
(Swansea) ABM University Health Board	32
Betsi Cadwaladr Health Board (Wrexham)	18
(Port Talbot) ABM University Health Board	11

18 - Northern Ireland	
Belfast Health & Social Care Trust	268
Southern Health and Social Care Trust	89
South Eastern Health and Social Care Trust	75
Northern Health and Social Care Trust	13

19 - Eire	
St Vincents Hospital (Dublin)	172
St James's Hospital Dublin	156
University Hospital Galway	86
South Infirmary Victoria University Hospital	40
Limerick Regional Hospital	33
Waterford Regional Hospital	30
Mater Misericordiae University Hospital	19
Sligo General Hospital	11

11,144 patients were registered on BADBIR on 13th October 2015
Thanks for your help.
For more information please contact:

Tel: 0161 306 1896
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Approved and Awaiting 1st Recruit:

**Shropshire Skin Clinic,
 University College London,
 The Adelaide and Meath Hospital**