WHY ARE ADVERSE EVENTS IMPORTANT TO BADBIR?

Identification of the benefits and risks of the long-term exposure to these therapies is clinically important. It is unlikely a pattern of events will be identified during exposure to therapy without accurate adverse event reporting, which could affect patient safety.

Improving the understanding of the safety profiles for these therapies will help patients in their decision on the best treatment for them with their dermatology team.

IDENTIFIABLE INFORMATION

When entering adverse events at follow-up, please ensure that any identifiable information within the description is removed. This includes:

- Patient names
- Names of family members
- Patient occupation
- Patient address
- Doctor / nurse / staff names
- Hospital names

HOW BADBIR REVIEW EVENTS

Each adverse event is reviewed by the BADBIR Pharmacovigilance (PV) team to ensure:

- the event has enough relevant information, including symptoms, diagnosis and treatment received;
- the description is clear, accurate and easy to understand;
- the event was correctly categorised as serious or non-serious;
- no conflicting information within the description were reported;
- an Event of Special Interest (ESI) form was completed for relevant events;
- the hospitalisation dates have been entered, if the patient was hospitalised;
- the event does not have identifiable information within the description

DISCHARGE SUMMARIES

For all overnight admissions, BADBIR would be grateful if a copy of the discharge summary is provided.

This will help BADBIR obtain as much information as possible about the treatment and diagnosis.

These can be faxed to 0161 306 1912 or emailed to badbir@manchester.ac.uk
SKIN CANCERS

All skin cancers, including SCC / BCC and Bowen’s disease, are to be entered onto the BADBIR database as SERIOUS adverse events under the category ‘Medically Important Event’.

An ESI form for Melanoma Or Skin Cancer, including Bowen’s Disease needs to be completed for each individual event.

Where possible please provide full histology details within the ESI.

SKIN LESIONS

If the patient has a skin lesion which is being investigated please provide the outcome once it is available.

It is important BADBIR know which lesions are malignant and which are benign.

EVENT DESCRIPTIONS

- Provide the diagnosis rather than the symptoms
- If no diagnosis is available provide the symptoms and treatment given
- Be specific

Rather than entering Collapse: Did the patient Faint? Did they lose consciousness? Did they fall? Was it a circulatory collapse?

Rather than entering Sore throat: Was the patient prescribed antibiotics? Was the sore throat pharyngitis, tonsillitis or a throat infection?

DEATHS

Deaths are to be entered onto the database as SERIOUS adverse events.

Details from the death certificate should be provided, when available.

When an adverse event of death is entered, details of the patients psoriatic therapy, PASI details, and any other adverse events up until the patient’s death should be entered at the next follow up.

Please DO NOT enter events of death using the ‘File an adverse event’ function. This is for all events except death.

MEET THE PHARMACOVIGILANCE TEAM

Hello my name is Victoria. I have worked at BADBIR as a Drug Safety Assistant since 2011. My role is to report serious adverse events to the relevant drug companies, code all adverse events using the MedDRA system, and to raise and respond to queries.

I am the first point of contact for any queries you may have regarding entering adverse events on the database.

I am currently working to complete a postgraduate certificate in pharmacovigilance.
1. North East & North Cumbria

- County Durham and Darlington NHS Foundation Trust 309
- Newcastle upon Tyne Hospitals NHS Foundation Trust 238
- South Tees Hospitals NHS Trust 126
- North Cumbria University Hospitals NHS Trust 35
- North Tees & Hartlepool NHS Foundation Trust 17

2. Yorkshire & Humberside

- Bradford Teaching Hospitals NHS Foundation Trust 179
- Leeds Teaching Hospitals NHS Trust 181
- Hull and East Yorkshire Hospitals NHS Trust 171
- Harrogate and District NHS Foundation Trust 80
- York Teaching Hospital NHS Foundation Trust 50
- Northern Lincolnshire & Goole Hospitals NHS Trust 48
- The Rotherham NHS Foundation Trust 47
- Doncaster and Rotherham Hospital NHS Foundation Trust 45
- Sheffield Teaching Hospitals Foundation Trust 41
- Calderdale & Huddersfield NHS Trust 35
- York Teaching Hospital (Scarborough) 33
- Barnsley Hospitals NHS Trust 20
- Mid Yorkshire Hospitals NHS Trust 18

3. North West Coast

- Royal Liverpool and Broadgreen University Hospitals 304
- University Hospitals of Morecambe Bay 91
- Blackpool, Fylde and Wyre Hospitals 77
- Countess Of Chester Hospital NHS Foundation Trust 70
- Wirral University Teaching Hospital NHS Foundation Trust 69
- St Helens & Knowsley NHS Trust 40
- Southport and Ormskirk Hospital NHS Trust 31
- Aintree University Hospital 30
- The Mid Cheshire Hospitals NHS Trust 20
- Lancashire Teaching Hospitals Foundation NHS Trust 18

4. Greater Manchester

- Salford Royal NHS Foundation Trust 591
- East Lancashire Hospitals NHS Trust 175
- Wigan and Leigh NHS Foundation Trust 111
- 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 346
- University Hospitals of Leicester NHS Trust 153
- United Lincolnshire Hospitals NHS Trust 87
- Derby Hospitals Foundation Trust 59
- Sherwood Forest Hospitals NHS Trust 49
- Kettering General Hospital NHS Trust 41
- Chesterfield Royal NHS Foundation Trust 27
- Nottingham University Hospitals NHS Trust 23

6. West Midlands

- University Hospitals of North Midlands NHS Trust 219
- Sandwell and West Birmingham Hospitals NHS Trust 173
- Burton Hospital NHS Trust 128
- University Hospitals Birmingham NHS Foundation Trust 104
- The Dudley Group of Hospitals NHS Foundation Trust 76
- The Royal Wolverhampton NHS Trust (Cannock Chase) 72
- Heart of England NHS Foundation Trust 64
- Wye Valley NHS Trust 48
- Worcestershire Acute Hospitals NHS Trust 37
- University Hospitals Coventry & Warwickshire NHS Trust 34
- The Royal Wolverhampton Hospitals NHS Trust 32
- The Shrewsbury and Telford Hospital NHS Trust 23
- South Warwickshire General Hospitals NHS Trust 14

7. Eastern

- Norfolk & Norwich University Hospitals NHS Trust 83
- Peterborough and Stamford Hospitals NHS Trust 74
- Ipswich Hospital NHS Trust 59
- Queen Elizabeth Hospital Kings Lynn NHS Trust 39
- Cambridge University Hospitals NHS Foundation Trust 29
- Bedford Hospital NHS Trust 26
- James Paget University Hospitals NHS Foundation Trust 23
- East and North Hertfordshire NHS Trust 10

8. West of England

- Royal United Hospital Bath NHS Trust 129
- University Hospitals Bristol NHS Foundation Trust 127
- Great Western Hospitals NHS Foundation Trust 47
- Gloucestershire Hospitals NHS Foundation Trust 12
- Weston Area Health NHS Trust 6

9. Thames Valley & South Midlands

- Oxford University Hospitals NHS Trust 128
- 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 (Whips Cross) 93
- Royal Free London NHS Trust (Barlaston & Chase Farm) 88
- The Princess Alexandra Hospital NHS Trust 67
- Royal Free London NHS Foundation Trust 66
- West Hertfordshire Hospitals NHS Trust 61
- BHR University Hospitals NHS Trust 56
- Basildon & Thurrock University Hospitals NHS Trust 47
- Barts Health NHS Trust (Barts) 34
- Mid Essex Hospital Services NHS Trust 32
- Homerton University Hospital NHS Trust 26
- Whittington Health 19
- University College Hospital NHS Foundation Trust 5

11. South London

- Guys & St Thomas NHS Foundation Trust 476
- Kings College Hospital NHS Foundation Trust (Ophthalmic) 145
- Epsom and St Helier University Hospitals NHS Trust 84
- Lewisham & Greenwich NHS Trust (Queen Elizabeth) 77
- St Georges London NHS Trust 55
- Kings College Hospital NHS Foundation Trust 42
- Lewisham & Greenwich NHS Trust 14
- Croydon Health Services NHS Trust 13

12. North West London

- West Middlesex University NHS Trust 114
- London North West Healthcare NHS Trust (Faling) 36
- Chelsea and Westminster NHS Foundation 16
- London North West Healthcare NHS Trust (Northwick Park) 8
- Imperial College Healthcare NHS Trust 3

13. Kent, Surrey & Sussex

- Frimley Health NHS Foundation Trust 84
- Surrey and Sussex Healthcare NHS Trust 81
- East Kent Hospitals NHS University Foundation Trust 80
- Brighton and Sussex University Hospitals NHS Trust 71
- Medway NHS Foundation Trust 59
- Western Sussex Hospitals NHS Trust 55
- East Sussex Hospitals NHS Trust 34
- The Royal Surrey County Hospital NHS Trust 17

14. Wessex

- Portsmouth NHS Trust 114
- Hampshire Hospitals NHS Trust (Basingstoke) 33
- Dorset County Hospital NHS Foundation Trust 26
- Poole Hospital NHS Foundation Trust 25
- Salisbury NHS Foundation Trust 14
- Hampshire Hospitals NHS Trust (Winchester) 14
- Southampton University Hospitals NHS Trust 7
- Royal Bournemouth And Christchurch Hospitals 6

15. South Peninsula

- South Devon Healthcare NHS Foundation Trust 87
- Plymouth Hospitals NHS Trust 60
- Taunton and Somerset NHS Foundation Trust 47
- Royal Devon And Exeter NHS Foundation Trust 46
- Royal Cornwall Hospitals Trust 43
- Northern Devon Healthcare Trust 27

16. Scotland

- NHS Greater Glasgow and Clyde 328
- NHS Grampian 132
- NHS Lothian 112
- NHS Tayside 49
- NHS Fife (Victoria Hospital Kirkcaldy) 46
- NHS Fife (Dundee) Queen Margaret 43
- NHS Highland 35
- NHS Ayrshire & Arran 25
- NHS Lanarkshire 21
- NHS Dumfries and Galloway 3

17. Wales

- Aneurin Bevan Health Board 107
- Cardiff & Vale University Health Board 105
- (W (Wales) Hywel Dda Local Health Board 67
- AMB University Health Board (Bridgend) 55
- Betsi Cadwaladr Health Board (Glan Clwyd) 50
- (W (Wales) Hywel Dda Local Health Board 39
- Betsi Cadwaladr Board (Ysbyty Gwynedd) 37
- AMB University Health Board (Swansea) 32
- Betsi Cadwaladr Board (Wrexham Maelor) 18
- AMB University Health Board (Neath) 11

18. Northern Ireland

- Belfast Health & Social Care Trust 277
- Southern Health and Social Care Trust 102
- South Eastern Health and Social Care Trust 79
- Northern Health and Social Care Trust 15

19. Eire

- St Vincents Hospital (Dublin) 176
- St James’s Hospital Dublin 160
- University Hospital Galway 87
- South Infirmary Victoria University Hospital 40
- University Hospital Limerick 33
- University Hospital Waterford 30
- Mater Misericordiae University Hospital 19
- Sligo General Hospital 14

Approved and Awaiting 1st Recruit:
Shropshire Skin Clinic, The Adelaide and Meath Hospital

11,355 patients were registered on BADDIR on 2nd December 2015

Thanks for your help.
For more information please contact:
Tel: 0161 306 1896
badbir@manchester.ac.uk
www.badbir.org