Adverse Event Newsletter 2018

BIR Biologics and Immunomodulators Register

IN THIS ISSUE

Why we collect Adverse Event (AE) data

1 The primary aim of the BADBIR study is to assess the long-term safety of drugs used to treat psoriasis. For as long as the patient is enrolled on BADBIR, ANY* adverse event data **should** be reported to BADBIR even if the patient has stopped their psoriasis treatment.

*Events include colds, accidents, known drug side-effects etc.

2 Adverse event data is analysed by researchers and the results are published in medical journals such as JAMA Dermatology. These publications can help shape healthcare delivery of psoriasis treatments and improve psoriasis management for e.g. it was found that patients receiving biologic treatment are at **NO** increased risk of serious infection. Hence it was concluded that the risk of serious infection should **NOT** be a concern when deciding treatment options.

A full list of our publications can be found at:
http://www.badbir.org/Publications/

Tips on how to collect adverse event information

Usually dermatology clinic letters and other hospital department clinic letter/patient notes should mention adverse events experienced by the patient, if any. Please note, ALL adverse events must be reported to BADBIR even if the event was unrelated to the psoriasis treatment e.g. stress/accidents etc.
If some details of an AE/SAE cannot be found in the notes, please ask the patient on their next clinic visit if this is possible.

Tips on how to enter AE information

- Rather than copying and pasting the results of scans, a clinical interpretation of the results would be more useful
- Please don't forget to update and enter event stop dates in subsequent FUPs otherwise events such as the common cold seem to be ongoing for years and years! (This is not very accurate data as you can imagine, and makes analysis of results more difficult).

Tips on how to avoid AE/SAE queries

Proof-read event descriptions to ensure :

- There is enough information provided to make a clinical decision on the event
- The description is clear and does not contain conflicting information
- There are no spelling mistakes or abbreviations.

The same rules apply for comorbidity entries as we also query unclear comorbidity entries.

The GOLD STANDARD for adverse event entry:

Symptoms – Diagnosis – Treatment