Adverse Event Newsletter 2017

The collection of adverse is events is essential in achieving BADBIR's goal of monitoring the long term safety of biologic drugs used for the treatment of psoriasis. Adverse event data is analysed and used in BADBIR publications, such as 'Risk of serious infection in patients with psoriasis on biologic therapies'.

This and all other BADBIR publications can be found on the website: www.badbir.org/publications.

Adverse event data will not only help determine the safety of biologic therapies but help clinician and patients make more informed choices on treatment options

Collecting Adverse Events

- **All adverse events** occurring since the patient's baseline or last follow-up need to be collected

- **All** sections of the **patient's hospital case notes** should be reviewed to collect this information and not only dermatology section

- The patient should be asked if they suffered from any **new illnesses**, were prescribed any **new drugs**, attended **A&E**, suffered an **exacerbation** of a current illness or attended any medical appointments

- All adverse events should be **collected** whether or not they **were related to therapy**

What BADBIR does with Adverse Events

- All adverse events entered onto the register are coded using a software called **MedDRA**. This allows each event to be classified into a hierarchy of terms which are then used for **analysis**

- In order to code events for analysis, it is important to have **accurate** information in the description

- Serious adverse events will be **reported** to the relevant pharma company subject to BADBIR reporting risk windows. BADBIR is required to do this within **24 hours** of being aware of a serious event

Adverse Event Descriptions

- Descriptions of adverse events should be **clear** and indicate the **nature, intensity** and **outcome**
- Information should be **relevant** to the event and give a clear reconstruction of the incident
- **Abbreviations** should be **avoided** and **spellings** should be **checked** to minimise queries

The format below should be used to detail adverse events:

Symptoms

Detail the background to the event and the symptoms the patient presented with

Diagnosis

A complete diagnosis will help provide a full understanding of the event but also allow BADBIR to categorise the event better

Treatment

List the treatment that was provided including relevant test results. Document any changes in therapy

Why are adverse events queried?

- Mostly because there is **not enough detail** or **conflicting information** provided in the description

- Some events are of **special interest** and may be queried to obtain a more in-depth understanding of what has occurred

- If an event has been **entered incorrectly,** a query is generated to inform a centre of this (particularly if the SAE category of the event is amended)

Updating Ongoing Events

Where available **stop dates** should be added for events.

An adverse event without a stop date will **rollover** to the next follow-up. If there is an **update** for this event, or a stop date, this can be added there.

If the original event has **progressed** into a **serious adverse event**, than this should be entered as a separate event and not updated.

For example, if a patient had been suffering from dyspnoea and 3 months later was hospitalised for a respiratory infection, these would be two separate events

File An Adverse Event

On the patient summary page, you will find a *"File an adverse event"* link.

Adverse events are entered onto the database retrospectively at each patient follow-up.

However, if you would like to report adverse events as they occur you can use this link to file new adverse events if the next follow-up cannot be opened yet.

The link **should not be used** to enter **deaths** or events that should have been entered in **previous follow-ups**

Entering Deaths

Death should be entered at the patient's **next follow-up.**

If the follow up is **unavailable** for entry, please contact the BADBIR office who will open the follow-up for you.

Any further information since the last follow-up date, including **drug changes** and **adverse events** should be entered.

Where possible, please provide the **date of death** and the **cause**.

Surgery

When entering an event of **surgery** for a patient, it is important to also enter the **indication** for the surgery. The indication can affect the analysis of the event.

For example, a patient may have knee surgery, this could be due many reasons such as a sport's injury or degenerative changes.

Please note for the purpose of BADBIR, **elective surgeries** are collected.

For serious events of surgery (those which result in hospitalisation or IV antibiotics being used), a **surgery ESI** form is required to be completed.

For further information or if you require any assistant with adverse events, please contact the pharmacovigilance team:
✉ **BADBIRPV@manchester.ac.uk** ☎ **0161 306 1911**