

This special supplement is intended to clarify whether an event is classed as an Adverse Event or a Serious Adverse event. It will also cover how to report an Adverse Event and the essential information the BADBIR Pharmacovigilance team require.

Is it an Adverse Event?

If the patient has suffered **ANY** untoward medical occurrence, then **YES** we would consider this to be an adverse event.

This could be as simple as a cold, cough, headache, itch or as serious as a malignancy or myocardial infarction. **IF IN DOUBT FILL IT OUT**

We will require full details of all events including start and stop dates. This applies for non-serious events as well as the serious ones. Only events that occur after the patient has been registered will need to be collected. The second decision to be made is whether the event classifies as serious

Need help with an
Adverse Event?
Please feel free to
contact the
Pharmacovigilance team
on 0161 306 1911

Is it a Serious Adverse Event?

An event will be serious if it meets any of the 6 criteria below:

1. Hospital admission

All events that require the patient to be admitted to hospital overnight are classed as serious. If the patient is already in hospital when the event occurs, it is classed as serious if it extends the patient's hospital stay.

2. Life-threatening events

If the event was judged to be immediately life threatening by clinical staff, then it is classed as serious

3. Disability or significant loss of function

Any event that causes a significant loss of function or disability needs to be reported as a Serious Adverse Event. This is often subject to context, for example, an elderly, frail patient might be more affected by having a limb in a plaster cast than a young active patient, therefore clinical judgement is required

4. Serious infection necessitating the use of IV antibiotics/antifungal/antivirals Any infection requiring intravenous antibiotics, antifungal or antivirals is considered a Serious Adverse Event by BADBIR

5. Congenital malformation

Any babies born to patients registered with BADBIR who are born with abnormalities must be reported to us

6 Death

Events of **Special Interest (ESI)**

We collect extra information on certain events that are of special interest (ESIs) to BADBIR.

These events are as follows:

Aplastic Anaemia / Central Demyelination / Congestive Heart Failure / Cerebrovascular

Accident / Pulmonary Embolism / Hepatic Dysfunction / Psoriasis Flare / Lymphoproliferative

Tumour / Serious Infections (Excl. TB) / Tuberculosis / Pregnancy / Coronary Artery

Syndrome / MI / Hypersensitivity / Malignancy / Skin Cancer / Progressive Multifocal

Leukoencephalopathy

Most of the forms for these ESIs can be found on the BADBIR website. An ESI form should be

Reporting **Adverse Events**

At each patient's 6 monthly/yearly follow up all information in relation to changes in therapy, disease severity and **Adverse Events** is collected.

Any adverse events that have occurred since the last follow up need to be documented and added onto the BADBIR database.

What **BADBIR** need to know

When you report an adverse event to us, it is important to include the following information:

Causality

Please include whether you think the event is related to the medication the patient is receiving, and indicate which drug.

Dates

Please provide start dates of the adverse event and if relevant the stop date. If the patient has been hospitalised, please provide the dates of hospitalisation.

Action taken with Drug

Please confirm if the drug was continued, suspended, or withdrawn as a result of the event.

Outcome

Please confirm if the event was resolved or if it is ongoing.

Please ensure this information is fully completed

Something **missing?**

We are grateful for the time you take in reporting SAE and AE to us at BADBIR and we understand that you may not have all the information to hand when reporting events to us. We would be grateful if you let the Pharmacovigilance team know if there is any missing information using the feedback form at the end of each follow up on the database.

Please provide as much information as you can when reporting ANY event to BADBIR

We would rather have too much than too little

Conventional **Patients**

It is just as important to report events for conventional patients as it is for patients on biologic treatment. We require as much information about these patients as possible, so that we can effectively compare the two cohorts.

Test Your **BADBIR** Adverse Events Knowledge

Consider the 4 statements below:

Adverse Event 1

When completing a follow-up questionnaire you find the statement that 'patient underwent routine test for TB' written in the notes. This is the latest entry with no subsequent details provided.

Adverse Event 2

During the patients clinic visit they inform you that they were recently admitted to A&E with a dislocated shoulder. This was resolved with non-surgical intervention and they were discharged the same day.

Adverse Event 3

Patient admitted with chest pains overnight for observation. ECG normal - thought to be gastro-related

Adverse Event 4

The patient's notes state that: "Histology shows skin bearing an area of invasive squamous cell carcinoma, which is well differentiated. No lymphovascular invasion. No perineural invasion. Referred to oncology and SCC excised and skin grafted"

Select which of the following categories best describes each of the 4 statements listed above.

- a) Not an adverse event
- b) A non-serious adverse event
- c) A non-serious adverse event AND an event of special interest
- d) A serious adverse event
- e) A serious adverse event AND an event of special interest

Answer the quiz online in the Adverse Events section of the BADBIR website:

www.badbir.org/adverseevents.aspx