BADBIR Adverse Events Supplement November 2013

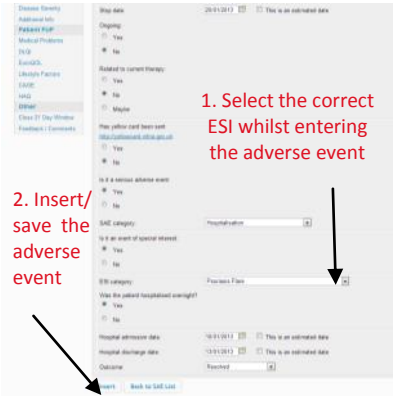
BIR Biologic Interventions Register

Over the past year more than 15,000 adverse events have been entered onto the BADBIR database. Each event is reviewed by the BADBIR Pharmacovigilance team. The event is coded and categorised accordingly, some of these events are then reported to the appropriate pharmaceutical company. Therefore it is important that accurate and relevant information is provided when entering adverse events onto the BADBIR database

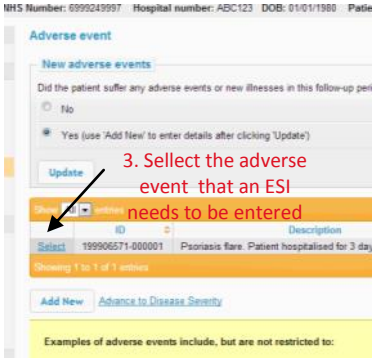
ESI Procedures

Events of Special Interest (ESI) forms are to be entered directly onto the database in the adverse events section. This can be done using the following steps:

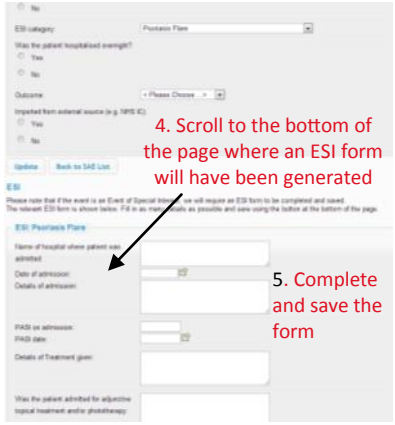
1



2



3



Please do not fax paper copies of the ESI form to the BADBIR office as these are no longer required . All ESI information will be directly retrieved from the database.
ESI forms for Psoriasis flare and surgery only need to be completed if patients are hospitalised overnight.

Medically Important Events

Pregnancy

Please note all pregnancies are to be entered as serious under the category 'medically important event'. Even if the pregnancy ended in a miscarriage or abortion the event is still marked as serious on the database. Regardless of the end endpoint, a pregnancy ESI form will also need to be completed.

Malignancy

All malignancies are classed as serious. Even if at the time of reporting the event has resolved.

For e.g. *Histology shows skin bearing an area of invasive squamous cell carcinoma which is well differentiated SCC on leg, excised completely and patient is fine*

Although the event has resolved the initial incident still needs to be reported and classed as serious.

Adverse events are a crucial part of the BADBIR register, so please provide accurate detailed information

Planned Operations

All operations that require an overnight stay whether they are planned or not are classed as **serious.** Day cases for surgery are not classed as serious but still need to be entered as adverse events.

Adverse Event Stop Dates

Any event which is entered as on going automatically appears on to the patient's next follow up. It is extremely important stop dates are entered for both serious and non serious adverse events. Some events will be on going and will not have stop dates at the time of entry. These on going events should be reviewed at each follow-up and a stop date entered if they have been resolved.. For any events which have resolved the stop date should be entered .

What information do I need to enter for adverse events?

- Event details
- Cause of event
- Diagnosis
- Results of any tests
- Dates
- Treatment
- Outcome
- Discharge Summary if hospitalised

At each follow up please review the patient's notes against adverse events entered onto the register to ensure nothing has been previously missed out