

Adverse Events Newsletter September 2016



Definition of an Adverse Event

Any untoward medical occurrence in a patient or clinical investigation subject being administered a pharmaceutical product, which does not necessarily have to have a causal relationship with the product.

Event of Special Interest (ESI) forms

For certain serious adverse events we require additional data to be recorded. These are collected via ESI forms.

An ESI can be added once a serious adverse event from the adverse event section of each follow up. Once the event has been entered it will appear on the page as show below. Next to each event there will be a button labelled “Add new ESI Category”. This will take you to a page which allows you to add the ESI form you require. Once you have selected ‘insert’ select ‘add form’ next to the event and the ESI questions will appear for entry.

You can repeat this action as many times as required as some events may need more than one ESI form.

Adverse event

New adverse events

Did the patient suffer any adverse events or new illnesses in this follow-up period?

No

Yes (use 'Add New' to enter details after clicking 'Update')

[Update](#)

Show **All** entries Search:

	ID	Short Description	Start	Stop	Ongoing	Carried Forward	SAE	ESI
Open	<input type="text"/>	<input type="text"/>	02/12/2015	14/04/2016	Yes	No	Yes	Remember to add all applicable ESI categories to this event + Add New ESI Category
Open	<input type="text"/>	<input type="text"/>	14/04/2016	14/04/2016	No	No	Yes	Death + Add New ESI Category

Showing 1 to 2 of 2 entries ⏪ ⏩

[Add New](#) [Advance to Disease Severity](#)

Queries

BADBIR may query events for further information or clarification. This is due to there not being information or clarity within the description. To minimise these queries, please ensure that the information entered is consistent and accurate, and that there is as much information as possible.

Side Effects / Drug reactions

Any side effects of drugs should be entered on to the database as adverse events whether the patient is on biologic or conventional treatment. The description should be clear in stating the symptoms are due to the drug. If the patient has stopped their drug due to the event this should also be included in the description as well as being added to the drug section of the follow up. Please also specify whether the patient is being treated with an originator drug or the biosimilar.



Common errors

Squamous cell carcinomas and **basal cell carcinomas** are always serious, even if the neoplasm has been excised.

Pregnancies are always serious, even if the pregnancy results in a miscarriage or abortion. These events also still require a pregnancy ESI form.

New diagnoses of conditions such as diabetes, hypertension, etc. without an overnight hospitalisation are **non serious** adverse events.

Historic **Myocardial Infarctions** and **Transient Ischaemic Attacks** may be picked up on test results—please be clear in letting us know if these are new instances or events which occurred prior to registration on the study,

Descriptions of adverse events should be **clear** and **concise**. It should be clear which symptoms/diagnoses are comorbidities and which are exacerbations, new occurrences or new diagnoses.

Events from National Registries

BADBIR patients are flagged to national registries by the following organisations: **NHS Digital , NHS Central Register, Northern Ireland Cancer Registry, National Cancer Registry Ireland, Business Services Organisation, and NHS Wales Informatics Service.**

These organisations collect data on cancers and deaths. This data is then sent to BADBIR on a quarterly basis, and any new events which we were not previously aware of will be added to the patient's record. The information we receive consists of a start date and the diagnoses which relate to the event.

Example: Patient Death. Causes of death: Myocardial Infarction, hypertension.

Surgery

BADBIR class all surgeries where the patient was hospitalised overnight as serious. This includes both emergency and elective surgeries.

A day case surgery where the patient is given IV antibiotics is classed as serious. When entering information on surgeries please state whether:

- the patient was hospitalised overnight
- the patient's psoriatic therapy was stopped for the procedure
- the patient was given IV or standard antibiotics
- the patient had any complications such as infections



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