Safety Management

Frequently Asked Questions – Serious Adverse Events

General information about this document

This Frequently Asked Questions (FAQ) sheet is developed to reduce the number of queries referring to the reported Serious Adverse Events (SAEs). The FAQs are categorized according to the sections on the SAE report where extra information is provided to avoid queries related to the required items.

Please read this sheet carefully so you can use it as extra clarification for filling out your SAE report and report for additional information for SUSAR form. If your question is not in this FAQ sheet or something is still unclear, please don't hesitate to contact the HDC Safety Desk.
When you send us a question by e-mail, please specify in the title: HOVON study number/ patient number/ AE term and specify URGENT if applicable.

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Report information

Q Should I replace the date of final report [box 11] after revising a final SAE?

A No, the first date a final SAE report is received will be used as date of final SAE report. When an updated SAE report is send in, after a final report has been received (e.g. due to query answers), the revised final report must be filed as a Follow Up report.

Serious Adverse Event information

Q What should I fill out as Adverse Event Term [box 12] if the diagnosis is not yet clear?

A The adverse event term should always be a single term which preferably is the main diagnosis that's considered serious. In case it is not possible to determine the diagnosis, please fill out the most important/severe symptom as Adverse Event Term. Once a diagnosis becomes available, the adverse event term on the SAE report should be adjusted accordingly. Please describe this decision at section 'SAE description and comments' [box 16] together with other symptoms and events related to the SAE. Serious events that occur at the same time and which are not related to each other should be reported as separate SAE on separate SAE form(s).

Trial Medication

Q Medication was given on the same day as date onset of SAE, what do I have to fill out as date last dose [box 23]?

A Date last dose should be either **on** or **prior to** the date AE became serious. If medication was given on the same day as the 'AE became serious', date last dose and date onset SAE may be the same. Please note that date last

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dose can't be later than date AE became serious.

Q Reporter filled out SAE form but relationship to SAE [box 24] is not yet determined by the (sub) investigator. Should I already send in the SAE to meet the timeline criteria (<24hours)?

A The relationship to the SAE is a mandatory field (also on the initial report) and should always be filled out. In the absence of the local investigator, a responsible/ replacing physician should fill out this item.

Q The (sub) investigator is not able to determine a relationship [box 24]. How should I report this on the SAE form?

A It is mandatory to provide a relationship to SAE. If the investigator is not available , ask a replacing physician to provide the relationship.

Q Should I report all previously given trial medication on the SAE report?

A No, please only report the trial medication of the last given treatment cycle. If not received during this protocol phase, please provide information of the previous protocol phase. Date first dose and date last dose should always be reported. Provide date first dose and date last dose of only the last cycle.. In case the SAE occurred during follow-up, it is sufficient to only report data of last given IMP treatment.

Additional SAE information

Q The SAE is already finished on the initial report, can I send in a final report?

A Yes, if the SAE is already resolved on the first report or the patient is deceased, this report should be filled out as final report as soon as possible (including signature of (sub) investigator). Please note that the outcome of SAE is only resolved if the AE has disappeared. For an SAE to be a final report, please note that outcome should be either resolved, ongoing closed or death.

Q Patient is again hospitalized for the same event, is this a separate SAE?

A An 2nd hospitalization due to an event should be reported on a new SAE report. An exception is made when 2nd hospitalization for the same event is within one month after the first hospitalization. . In case of doubt, please contact the HDC Safety Desk.

Managing queries from the Safety Desk

Q We receive a lot of e-mails with queries from the Safety Desk. What can I do to reduce the amount of e-mails?

A Queries can be sent upon receipt of a report. Due to regulatory timelines urgent queries, that usually relate to the evaluation whether an SAE qualifies as SUSAR (AE term or causal relationship to SAE) ,should be answered within 2 working days. All other queries should be answered within 2 weeks.

- Please make sure fill out all necessary items on a initial, follow or final report according to the Folder SAE reporting.

- Please answer the e-mails within the time lines set at the bottom of the e-mail. This will reduce the number of reminders. Answers are preferably given by sending a revised report.

- Please make sure to answer all queries in the e-mail at the same time. If some answers can only be provided at a later time point, please indicate when these answers can be expected

- Please check if the query is answered completely. If for example the question is to confirm a protocol deviation and to provide a reason, please make sure to answer both. We sometimes receive answers that do not provide information to the entire question. This will prompt a new query.

- When data has to be changed or when adding follow up information, do not fill out a new SAE report but make the changes on the original report. This will prevent confusion when an updated/revised report needs to be sent in and will take less time for the site to report.

Q I received queries for a patient that is treated by another physician in my (or in another) hospital. What should I do with those queries?

A For each hospital we have registered one responsible local investigator. In principle, all queries will be sent to this person. This addressed person is responsible for answering the queries. The queries might be answered by another physician, e.g. treating physician, however the local investigator will remain responsible for the of answering the queries.

REPORT for additional information for SUSAR form

Q When do we need to fill out the “REPORT for additional information for SUSAR form”?

A Every SAE that qualifies as a SUSAR needs to be reported in EudraVigilance, the European database for reporting of suspected adverse reactions. Not all information requested in Eudravigilance database is already available when receiving a SAE report. Therefore, a “REPORT for additional information for SUSAR form” might be required to gather all the extra information.

Relevant concomitant medication

Q What should be reported as concomitant medication (box 49)?

A This is also described in the ‘SAE report instructions’. Please report any medication given prior to ‘date AE became serious’, that might have contributed to the SAE. Please report “1=yes” in box 49 and enter the medication name at the “specification” field. Please also provide a short explanation on how the concomitant medication may have contributed to the SAE.

Please note:

- Medication that did not contribute and therefore is not related to the SAE, don’t have to be reported over here.

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- Medications given to treat the SAE should not be reported here and can be entered at section ‘SAE description and comments’.

Q Date first dose of concomitant medication [box 32] is not (exactly) known, how should this be reported?

A Please try to provide a ‘best estimate’ of month + year or only the year (e.g. unk/unk/2008). If not possible, please describe clearly that date is unknown.