DAC Study Report R5 – Serious Adverse Event Report

The first page of the report will be generated automatically as soon as a form is entered which triggers the report.

If the SAE is (possibly probably, or definitely) related to the study medication (item 12, code 2, 3 or 4) and unexpected (including life threatening events) or expected, but more severe than described in the consent (item 13, code 1 or 2), then it is an SAE, which needs to be reported immediately to FDA following the procedure described below. Deaths with unknown relationship to the study drug will be reported following the same procedure.

- The first page will be e-mailed to the Clinical Center, the NIH and the DCC.
- If this is one of your Center's first few SAEs, call the DCC
- After receiving this first page of the report, the Clinical Center personnel will have to fill in and key-enter the second page.
- The whole report has to be forwarded to the Project Officer at the NIH, and the local IRB and the DCC.
- The NIH will report the SAE to the FDA.

If the SAE is either expected, or not related to the study medication, then this is an SAE, which needs to be reported to the FDA as a part of an annual summary of SAEs and the procedure is the following:

- The first page will be e-mailed to the Clinical Center and the DCC.
- After receiving this first page of the report, the Clinical Center personnel will have to fill in and key-enter the second page.
- The whole report has to be forwarded the DCC.
- These reports will be summarized annually and will be submitted by the DCC to the NIH and by the Clinical Center to the local IRB.
- The NIH will report these SAEs to the FDA annually.

The fax number for the Project Office at the NIH (John Kusek / Catherine Meyers) is:

(301) 480 3510

The fax number for the DCC is: (216) 445 2781

DAC Study Report R5 – Serious Adverse Event Report

Page 1 of this report is generated automatically every time when a form, which triggers the report, is completed. This page is e-mailed to the Clinical Center, the NIH and the DCC depending on the relation of the event to the study drug medication and on the expectedness of the event.

1. Patient ID *(comes from the form which triggered the report)*
2. Patient Name Code *(comes from the form which triggered the report)*
3. Patient's Study *(comes from the consent form)*
4. Clinical Center *(comes from the form which triggered the report)*
5. Principal Investigator's Name *(comes from the dataset)*
6. Date of Report *(today's date filled in automatically)*
7. Date of Event *(comes from the form which triggered the report)*

Patient Information

8. Gender (1 = Female, 2 = Male) (*comes from Form 301 / 311*)
   Race (*comes from Form 331)*
9. Age (*calculate as of today*)
10. Date of Randomization (*comes from the randomization table*)

11. Type of SAE (0 = No, 1 = Yes)

1 = Death *(comes from Form 371)*
Primary cause of death *(comes from Form 371)*
2 = Major Additional Information for a Death *(comes from Form 372)*
Primary cause of death (comes from Form 372)
3 = Admission for Required Hospitalization *(comes from Form 360)*
Primary reason for hospitalization (comes from Form 360)
4 = Major Additional Information for Required Hospitalization *(comes from Form 361)*
Primary reason for hospitalization (comes from Form 361)
5 = Prolongation of Existing Hospitalization *(comes from Form 361)*
Reason for prolongation of existing hospitalization (comes from Form 361)
6 = Permanent Disability *(comes from Form 364)*
7 = Life threatening event *(comes from Form 363 or 365)*
Was this a life threatening bleed?
8 = Congenital abnormality *(comes from Form 366)*

12. Relationship of the event to the study medication (*comes from the form which triggered the report*)
    0 = Not related
    1 = Unlikely to be related
    2 = Possibly related
    3 = Probably related
    4 = Definitely related
    8 = N/A, patient has not been randomized yet
    9 = At this time we do not know if the death was related to the study drug
13. In case the event is related to the study medication (code 2, 3, or 4 from Item 12), the expectedness of the event is *(comes from the form which triggered the report)*

1 = Unexpected - not mentioned in the informed consent.
2 = Expected, but of greater severity than mentioned in the informed consent.
3 = Expected and accurately described in the informed consent.

14. The severity of the event is *(comes from the form which triggered the report)*
    1 = Mild - awareness of the sign or symptom, but easily tolerated
    2 = Moderate - enough discomfort to interfere with usual activity
    3 = Severe - incapacitating, with inability to do usual work or activity

Page 2 – The Clinical Center personnel need to fill out this form and key-enter it immediately after page 1 of the report is received. The whole report will then need to be forwarded to the DCC, and if the event in both unexpected and related to the study medication (see introduction explanation on p. 1) – to the Project Officer at the NIH and the local IRB.

Patient ID .....__ __ __ __ __ __

Patient Name Code .....__ __ __ __

Date of Event ..... __ __/__ __/__ __ __ __

Type of Event, which triggered the report.....__ __

Nature of Event

15. Full clinical description (including symptoms and diagnosis) to the extent required by your local IRB

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16. Date faxed to the DCC..... __ __/__ __/__ __ __ __

Reporter Information

Physician in Charge:

Name: _____ Signature: _____

Date Signed: _____

Name of the person completing this page:_____

Signature of the person completing this page: _____

Date this page completed:..... __ __/__ __/__ __ __ __