## Eksempel på skema til indberetning af SAE/SUSAR

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| --- |
| PART 1: SAE Serious Adverse Event Report (From investigator to Sponsor) |
| PART 2: SUSAR Suspected Unexpected Serious Adverse Event Report (Sponsors Assessment) |

|  |
| --- |
| **Protocol title:** |
| **EudraCT no./EU CT no:** | **Protocol code (if relevant):** |

**PART 1 (To be filled in by Investigator)**

**Awareness date:** \_ \_ \_ \_ -\_ \_ \_ - \_ \_ **Report date:** \_ \_ \_ \_ -\_ \_ \_ - \_ \_

 YYYY MMM DD YYYY MMM DD

**Report type:**

|  |  |
| --- | --- |
| Initial | [ ]  |
| Follow-up | [ ]   |

**Subject Information:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Patient initials: | Country: | Date of birth: \_ \_ \_ \_ -\_ \_ \_ - \_ \_ YYYY MMM DD | Male:  | [ ]   | Height: |
| Patient no.: | Site name/no.: | Female:  | [ ]   | Weight: |

**Serious Adverse Event:**

|  |  |
| --- | --- |
| **SAE (diagnose):** |  |
| **SAE Onset date:** | **SAE End date:** |
|  \_ \_ \_ \_ -\_ \_ \_ - \_ \_ YYYY MMM DD |  \_ \_ \_ \_ -\_ \_ \_ - \_ \_ YYYY MMM DD |
| **Patient discontinued from study due to SAE:** |
| Yes [ ] , date: \_ \_ \_ \_ -\_ \_ \_ - \_ \_ YYYY MMM DD | No [ ]  |

|  |  |
| --- | --- |
| **SAE Criteria** | **Evaluation** |
| Patient died | [ ]  | **Outcome** | **Severity** | **Action taken** |
| Life threatening | [ ]  | Ongoing | [ ]  | Grade 1 | [ ]  | No change | [ ]  |
| Involved persistence of significant disability or incapacity | [ ]  | Resolved | [ ]  | Grade 2 | [ ]  | Drug dose changed | [ ]  |
| Involved or prolonged inpatient hospitalization  | [ ]  | Resolved w/sequelae  | [ ]   | Grade 3 | [ ]  | Drug temporarily discontinue | [ ]  |
| Important Medical Event  | [ ]  | Fatal | [ ]  | Grade 4 | [ ]  | Drug permanently discontinued | [ ]  |
| Other | [ ]  | Unknown | [ ]  |  |  |  |  |

|  |  |
| --- | --- |
| Date of death: | Cause of death: |
| \_ \_ \_ \_ - \_ \_ \_ - \_ \_ YYYY MMM DD |
| Death certificate:Yes (attach copy) [ ]  No [ ]   | Autopsy report:Yes (attach copy) [ ]  No [ ]   |

Relationship to study drug:

|  |  |  |  |
| --- | --- | --- | --- |
| Unrelated to study drug (None, unlikely) | [ ]  | Related to the study drug (Possible, probable, definite) | [ ]  |

Suspect Drug(s) information:

|  |  |
| --- | --- |
| Suspect Drug(s) name: | Did reaction abate after stopping drug?  |
| Batch no: | Yes [ ]  | No [ ]  | NA [ ]  |
| Daily dose(s) (specify units): | Route(s) of administration: |
| Indications(s) for use: | Did reaction reappear after reintroduction? |
| Yes [ ]  | No [ ]  | NA [ ]  |
| Therapy starting date: | Therapy stopping date: |
| \_ \_ \_ \_ - \_ \_ \_ -\_ \_ YYYY MMM DD | \_ \_ \_ \_ - \_ \_ \_ -\_ \_ YYYY MMM DD |

Event Description

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| --- |
|  |

Concomitant Medication(s) relevant to the event (exclude those used to treat event)

|  |
| --- |
| Concomitant drug(s) and dates (YYYY-MMM-DD) of administration. |

|  |  |
| --- | --- |
| **Reporter information** | **Investigator information** |
| Name: | Name: |
| Address: | Address: |
| Phone: | Phone: |
| Profession: | Profession: |
| Signature & Date: | Signature & Date: |

Fill in this form and mail or fax it within xx hours to sponsor:

|  |  |
| --- | --- |
| Secure mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | *Forsendelse af helbredsoplysninger relateret til et ID-nummer (= pseudonymiserede data) bør fortages med sikker e-mail.* |
|  |  |

Sponsors date and signature for receiving this report:

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PART 2: (To be filled in by sponsor)**

1. Relationship to study drug assessed by Investigator (from PART 1)

|  |
| --- |
| Result of causality evaluation |
| Not related to study drug (Unlikely/doubtful) | [ ]  |
| Related to study drug (Possible/Probable/Definite) 🡪 if yes, go to box 2. | [ ]  |

1. Causality Assessment by Sponsor:

|  |
| --- |
| Result of causality evaluation |
| Not related to study drug (Unlikely/doubtful) | [ ]  |
| Related to study drug (Possible/Probable/Definite) 🡪 if yes, go to box 2. | [ ]  |

1. **Expectedness** **Assessment by Sponsor (only relevant if SAE is related to study drug):**

|  |
| --- |
| Result of expectedness evaluation |
| Expected (due to relevant reference document) | [ ]  |
| Unexpected 🡪 If yes, go to box 3. | [ ]  |

1. **Summary:**

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| --- |
| Category of event |
| SUSAR (SAE is both related and unexpected) | [ ]  |
| SAR (SAE is related but not unexpected) | [ ]  |
| SAE (SAE is not related) | [ ]  |
| ***Notify relevant authorities according to protocol*** |

Sponsors comments (including information regarding unblinding):

|  |
| --- |
|  |

Sponsors date and signature:

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_