# SAE / SUSAR / SADE Report Form

## Terminology in CTIS: SUSAR/ UNEXPECTED EVENTS/URGENT SAFETY MEASURES

**send within 24 hrs of notification to:** plancton@antoniusziekenhuis.nl

| | | | |
|---|---|---|---|
| Date of report | | | |
| PaNaMa no. / Study acronym | PLANCTON | Study Site number | |
| Sponsor & Principal Investigator**:** | **Radboudumc**<br>Name:Martijn Stommel<br>Dept.:Heelkunde<br>Fax / E-mail:<br>martijn.stommel@radboudumc.nl | Site contact details | Investigator name<br><br>Phone<br>E-mail |

1. **Report status:** ☐ **Initial*** ☐ **Follow-up** ☐ **Final**

2. ☐ **SAE** ☐ **SUSAR** ☐ **SADE** ☐ **UNEXPECTED EVENTS** ☐ **URGENT SAFETY MEASURES**

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| 3. **Subject study ID number*:**<br>Gender: ☐ Male<br>☐ Female: pregnancy: ☐ Unk ☐ No ☐ Yes, week:<br>☐ Unk/Other<br><br>Age (at time of event): y | |
| 4. **Event onset date:**<br><br>Date:<br>Time (24h): | 5. **Event stop date:**<br><br>Date:<br><br>Time (24h):<br>Ongoing (see section 15.) |
| 6. **Event Term** (please refer to CTCAE v5.0)**:**<br><br>Enter term: | 7. **CTCAE severity Grade:**<br><br>Grade: 5. Death<br>Choices 'Severity': 1. Mild; 2. Moderate; 3. Severe; 4. Life-threatening; 5. Death) |

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| 8. **Event description:** | |
| 9. **Event Seriousness Criteria:**<br>Other, specify<br><br>(Choices 'Criterium': Death; Life-threatening; Initial or prolonged hospitalisation; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Could have developed in an SAE; Other, specify) | 10. **Causality (relatedness with study treatment, or with investigational medicinal product [IMP]):**<br>Not<br><br>(Choices 'Relation': Definitely; Probably; Possibly; Unlikely; Not) |

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| 11. **SUSAR (for clinical study with an IMP[i] only)**<br><br>☐ Yes (also complete 12. >>>see right section)<br><br>☐ No (go to 13.)<br><br>☐ N/A (not a clinical drug trial; go to 13.) | 12. **Last administration of study drug (IMP)** (i.e. before start of event):<br><br>☐ N/A<br><br>Date:<br>Time (24h clock):<br><br>**Continuation of (IMP) treatment:**<br>Other<br>(Choices 'treatment': Per protocol treatment unchanged; Dose change; treatment temporary postponed; per protocol treatment has stopped; Patient withdrawn from study (drop-out); Unknown; Other)<br>if Other, specify here: |
| 13. **Event Outcome:**<br>Select Outcome* Unknown (choices 'Outcome': Fatal; Not resolved/ongoing; Recovered; Recovered with sequelae; unknown)<br>* in case of Fatal, Recovered, or Recovered with sequelae: enter stop date in section 4. | |
| 14. **Other relevant information:** | |

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| 15. **Investigator** | 16. **Authorised signature** |
|---|---|
| Name:<br><br>Date: | |

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**! Please send a Follow-up / Final Form as soon as the outcome of this Event is known !**

[i] IMP = Investigational Medicinal Product; SUSAR = Suspected Unexpected Serious Adverse Reaction