SUSAR Form

send within 24 h to: plancton@antoniusziekenhuis.nl

Use ONLY for Radboudumc-sponsored clinical trials. READ INSTRUCTIONS before completion.

To be filled in by the Radboudumc CRU upon receipt	
Date report received by CRU:	**Unique case ID nr:**

The following section should be completed by the Radboudumc Principal Investigator (Acting as the Sponsor)

Sponsor details (complete grey section before study start)			
PaNaMa no. Study acronym ABR/NL-nr EU CT (CTIS) number	113098 PLANCTON NL80570.091.22 2023-505220-57-03	Sponsor & PI	**Radboudumc** Name PI:Martijn Stommel Dept.:Surgery E-mail: martijn.stommel@radboudumc.nl
Date report received by Sponsor (PI Radboudumc): ☐ Not applicable (monocenter study)		**Confirm subject ID nr:**	
Sponsor agrees with *seriousness* (see 9.) ☐ YES ☐ NO: ☐ Not applicable (monocenter study)		**Sponsor agrees with *relatedness* (see 15.)** ☐ YES ☐ NO: ☐ Not applicable (monocenter study)	

the following sections should be completed by the Site Principle Investigator

Date of this report:		**Reporting Study Site name / number**	☐ monocenter study
Site Contact details	Same as Sponsor PI name Contact name Phone Email	☐	

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

2. **Event category:**

☐ **SAR**[a] ☒ **SUSAR**[b] ☐ **Other**[c]

3. **Subject ID number:**

Gender: ☐ Male
☐ Female: pregnancy: ☐ Unk ☐ No ☐ Yes, week:
☐ Unk/Other

Age (at time of event): y months / weeks / days (for pediatric studies only)

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4. **Event onset date:** Date: Clock (24h):	5. **Event end date:** Date: Clock (24h): ☐ Not (yet) recovered
6. **Event Term** (Enter event symptoms or diagnosis. Refer to CTCAE or MedDRA in case required by the study protocol): Enter term:	7. **CTCAE Severity Grade[d]:** ☐ 1. mild ☐ 2. moderate ☐ 3. severe ☐ 4. life-threatening ☐ 5. death
8. **Event description and actions taken:**	
9. **Event Seriousness Criteria:** ☐ death ☐ life threatening ☐ initial or prolonged hospitalization ☐ medical or surgical intervention ☐ persistent/significant disability / incapacity ☐ congenital anomaly / birth defect ☐ other, specify:	10. **In case fatal:** Date patient died: Cause of death: Autopsy done: ☐ Yes ☐ No Cause of death according to autopsy report: 11. **In case congenital anomaly/birth defect:** Age of mother:
12. **Study drug (IMP/AxMP) name** ☐ Name ☐ Name-code (XEVMPD) if known	13. **Study drug administration (IMP/AxMP)** ☐ Last dose administered: Date: Clock (24h): ☐ Continuation of drug treatment**:** Other if Other, specify here:

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14. Event Outcome: ☐ Recovered* ☐ Recovered with sequelae* ☐ Ongoing / Not (yet) resolved ☐ Fatal* ☐ Unknown * in case of Fatal, Recovered, or Recovered with sequelae: enter “Event End date” in section 5.	**15. Causality (relatedness with study treatment):** ☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely/Causal
16. Other relevant information:	
17. Site Investigator Name: Date:	**18. Investigator Sign**
19. Sponsor Investigator Name: Date:	**20. Sponsor Sign**

send this report within 24 hours of notification:

☐ to CRU (SUSAR@radboudumc.nl) (-> in case submitter = PI Radboudumc)

☐ to Radboudumc PI (-> in case submitter = PI participating center)

(plancton@antoniusziekenhuis.nl)

SUSAR Form

Instructions for use

This form should be used by Local Principal Investigators (acting as Study Site) and by Radboudumc Principal Investigators (acting as the Sponsor) to report SUSARs to the health authorities. Data entry of completed SUSAR forms into EudraVigilance has been mandatory delegated to the Clinical Research Unit (CRU) of Radboudumc. Therefore, upon expedited review by the Radboudumc Principal Investigator (either acting as the Sponsor or as the Principal Investigator), completed SUSAR reports should always be forwarded to the CRU (SUSAR@radboudumc.nl). Contact the CRU for support, before the start of your study.

Please note that SUSAR reporting always requires (partial) unblinding. For unblinding follow the procedures as depicted in the study protocol, and according to the Radboudumc SOPs.

Instructions before the start of your study

1. Download the template SUSAR form from the IQS
2. Safe a customized (study-specific) version of the SUSAR template in your study site file (TMF/ISF), including study details and correct email/contact details.
3. In case of **multicenter** studies initiated by Radboudumc: Share the customized template with the participating Study Sites.
4. For **multicenter** studies: Have a written procedure in place (preferably in the study protocol) how the Site Principal Investigator should report SUSARs to the Principal Investigator of Radboudumc (acting as the Sponsor).

Instructions for completion

GENERAL

For multicenter studies: SUSAR forms should be reviewed, dated and signed by the reporting Local Principal Investigator, before submission to the Radboudumc Principal Investigator (acting as the Sponsor). Upon receipt, SUSAR forms should be reviewed, dated, and signed by the Principal Investigator of Radboudumc, before forwarding to the CRU via SUSAR@radboudumc.nl.

For both monocenter and multicenter studies: The Radboudumc Principal Investigator is responsible for timely submission of completed SUSAR reports to the CRU, via SUSAR@radboudumc.nl.

Upon receipt, the CRU will verify the correct completion, and record the SUSAR as an Individual Case Safety Report (ICSR) into EudraVigilance (EVWEB) within one working day.

Follow-up: Upon request, or in case follow-up information becomes available, updates should be submitted to the CRU by the Radboudumc Principal Investigator using additional SUSAR-forms.

CRU SECTION

Date of report received and **unique case ID number** (*f.i.* PaNaMa nr + sequential) should be entered by authorized personel at the CRU of Radboudumc. Please make sure the study delegations log has been completed.

SPONSOR SECTION

Sponsor details (grey section): The grey section should be completed by the Radboudumc Principal Investigator (acting as the Sponsor) before the start of the study, and save the form as a study-specific template in the trial master file. In case of multicenter clinical trials, share the customized SUSAR template with the participating study sites and make sure it is saved in the local investigator site file.

The Radboudumc PI (acting as the Sponsor) should confirm study subject ID nr and evaluate **event seriousness** and **relatedness,** as was indicated by the local investigator in sections 9 and 15, respectively. No downgrading is allowed. Leave blank and chose Not applicable in case of monocenter studies by Radboudumc.

INVESTIGATOR SECTION

Fill in site investigator details and enter date of report creation. Chose Same as Sponsor in case of monocenter study.

Section 1. **Report status**. Enter “Follow-up” only if additional information becomes available or is requested (upon initial report). Check “Final” only if the event has been completely resolved.

Section 2. **Event category**. This SUSAR form only applies for clinical trials with investigational medicinal products (IMP, AxMP, i.e. that fall under the CTR).

Section 3. Enter **subject ID number** according to the enrolment/subject ID log, gender and age. Do not provide other subject identifiers, unless required by the approved study protocol.

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Section 4. Provide **event onset date** in dd/MMM/yyyy format (f.i.:12/DEC/2023). To prevent misread add time in 24h clock unit, if known.

Section 5. Enter **event end date** in dd/MMM/yyyy format (f.i.:12/DEC/2023). To prevent misread add time in 24h clock unit, if known. In case of Ongoing event, select tickbox “Not yet recovered” and check Event outcome (section 14) accordingly.

Section 6. Enter **event term** (symptoms or diagnosis). Only use CTCAE or MedRA terms if required by the study protocol.

Section 7. Please note: Only complete **severity grade** in case CTCAE should be used, according to the study protocol.

Section 8. Summarize **event and all actions taken**.

Section 9. Enter **event seriousness criteria**. More than one may apply.

Section 10 & 11. Only complete if applicable.

Section 12. Enter study **drug name** and EudraVigilance/XEVMPD **code** (if known).

Section 13. Enter **drug administration** details, select last dose, or chose continuation + select from options.

Section 14. Check **event outcome**, and check the event end-date (section 5) whenever applicable.

Section 15. Enter **event relatedness.** The sponsor may agree, or increase relatedness, but never decrease.

Section 16. Enter **other relevant information**, or refer to attached local surgery/discharge/radiology/etc reports. Please make sure to label attached reports with subject ID number only and remove all other personal identifying data.

Section 17 & 18. For multicenter studies: Local Site PI should **Sign and date** before sending to the Radboudumc PI (acting as the Sponsor). Keep original in your local Investigator Site File.

Section 19 & 20. Radboudumc PI should always **Sign and date** before sending to the CTU. Keep original in your Investigator Site File/Trial Master File.

Before sending, tick correct checkbox: Local investigators of participating sites should tick the checkbox and submit to the Radboudumc principal investigator (or study team email), according to provisions detailed in the study protocol. The Radboudumc principal investigator, acting as the Sponsor, should always submit to the CRU (SUSAR@radboudumc.nl).

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[a] A serious adverse reaction (SAR) is defined as an adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect

[b] An **unexpected** serious adverse reaction is defined as serious adverse reaction, the nature, severity or outcome of which is not consistent with the reference safety information of the medicinal product.

[c] In case “Other” describe the event in section 8, according to the instructions of the protocol ad/or PI.

[d] Only apply in case CTCAE coding is used. Grades refer to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline: Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. Grade 2 Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL. Grade 3 Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL. Grade 4 Life-threatening consequences; urgent intervention indicated. Grade 5 Death related to AE.