SAE GO-28667/MURANO

Local Investigator: Marcel Nijland
Onderzoeksverpleegkundige: Henriette Klooster tel. 49265
Datamanager: Machteld van der Weg/ Alice Nanninga tel. 15410/10206

- Iedere SAE dient **binnen 24 uur** na kennisgeving van de SAE **gemeld** te worden aan de sponsor/opdrachtgever.
- Vul ieder SAE formulier direct en zo zorgvuldig mogelijk in (probeer bij de eerste melding kort, bondig en stellig te formuleren en aannames te vermijden).
- Breng betrokkenen (Local Investigator, onderzoeksverpleegkundige of datamanager) op de hoogte van de SAE melding.
- Het originele SAE formulier dient in de patiëntstatus te worden gearchiveerd.

Op werkdagen kan voor het invullen altijd ondersteuning worden gevraagd aan de (vervanger van de) research-verpleegkundige of datamanager.

GO-28667/Murano

FAX: (0)0800-0221293
MAIL: genentecheds@quintiles.com

- Fax of mail de SAE pagina's en alle aanvullende informatie binnen 24 uur

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Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) Reporting Form

♦ Protocol:	•Site Number:	♦ Eudract:	♦* Subject ID:	♦ Randomization number:

For Internal Use Only

AER Number:

Company Received Date: dd MMM yyyy

Please provide all available relevant information. Complete all Essential Elements (fields marked with ♦ and ♦*). All fields marked with ♦* are minimal data elements and, if missing, the SAE/AESI form will be considered void. Complete one form in full for each SAE/AESI, using additional forms for the same SAE/AESI if more space is required (e.g. in sections 7, 9 and 12). Complete only the necessary sections on any additional forms.

Additional form provided? ☐ Yes → No. of extra pages ☐ No

♦* Investigator Name: Country:

Name of Reporter: Tel. No.:

1. ♦*Personal Data Note: At least one patient identifier must be provided. Consider local laws regarding data privacy when completing Personal Data section.

Birth Date: dd MMM yyyy

Subject Initials:

Sex: Male ☐ Female ☐

Height: ☐ cm ☐ in

Weight: ☐ Kg ☐ lb

Race: White ☐ Black ☐ Asian ☐ Other ☐

If 'Other' – specify

2. Serious Adverse Event/Adverse Event of Special Interest (Complete one form for each SAE/AESI)

Please note: If the patient has died, the cause of death must be provided as an event.

♦* Event:		dd	MMM	yyyy
	Date of onset:			
	Date event became serious			

3. ♦Study Drug Causality

SAE/AESI suspected to be caused by study drug? ☐ Yes ☐ No

(specify study drug)

Other suspect causes *(select all that apply)*:

None *(only applicable if study drug is related)*	☐	
Disease under study *(specify)*	☐	
Medical history or concurrent illness *(specify)*	☐	
Concomitant medication *(specify)*	☐	
Protocol-related procedure *(specify)*	☐	
Other *(specify)*	☐	

Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) Reporting Form

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4. ♦ Event Seriousness

Why was the event serious? *(Check all that apply)*:

- Results in death ☐
- Life-threatening ☐
- New in-patient hospitalisation ☐
- Prolonged in-patient hospitalisation ☐
- Persistent or significant disability / incapacity ☐
- Congenital anomaly / birth defect ☐

OR *only when no other criteria applies*

- Medically Significant ☐

5. SAE/AESI Outcome

SAE/AESI outcome at the time of the report:

		dd	MMM	yyyy
Fatal	☐			
Not Recovered/Not Resolved	☐			
Recovered/Resolved	☐			
Recovered/Resolved with sequelae	☐			
Recovering/Resolving	☐			
Unknown	☐			

4a. *Use to indicate when a non-serious adverse event, defined as a non-serious adverse event of special interest in the study protocol, is being reported.*

Non-serious adverse event of special interest ☐

6. SAE/AESI Severity Grade

Assess the SAE/AESI severity against the protocol defined grading scale only

Indicate protocol defined grading scale: ☐ NCI-CTCAE ☐ AE Intensity

If NCI-CTCAE, indicate version: ☐ Version 3.0 ☐ Version 4.0 ☐ Other: ____

AE Intensity scale:

AE Initial Intensity: ☐ Mild ☐ Moderate ☐ Severe

AE most extreme intensity: ☐ Mild ☐ Moderate ☐ Severe

NCI-CTCAE scale:

AE initial NCI-CTCAE grade *(1-5)*: Grade: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

AE most extreme NCI-CTCAE grade *(1-5)*: Grade: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Note: Grade 5 must reconcile with Fatal outcome in 'SAE/AESI Outcome' (section 5)

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Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) Reporting Form

♦ Protocol:	•Site Number:	♦ Eudract:	♦* Subject ID:	♦ Randomization number:

7. ♦* Study Medication (1):

Study Medication Name:	Dose:	Units:	Frequency:	Route:	Dosage Form:

Batch Lot Number:

Dates for Study Medication:

	dd	MMM	yyyy
Start date			
Date of last dose prior to SAE/AESI			

Emergency Code broken?

Yes	No	N/A
☐	☐	☐

Study Regimen altered in response to the Adverse Event? ☐ Yes – *specify below* ☐ No

How was Drug Regimen altered in response to the event?

Dates when Drug Regimen altered:

		dd	MMM	yyyy
Reduced – *specify (date and new dose)* ☐	Reduced			
Temporarily Interrupted ☐	Stopped			
	Restarted			
Permanently Discontinued ☐	Discontinued			

Details of new dose:

New Dose	Units	Frequency

7. ♦ Study Medication (2):

Study Medication Name:	Dose:	Units:	Frequency:	Route:	Dosage Form:

Batch Lot Number:

Dates for Study Medication:

	dd	MMM	yyyy
Start date			
Date of last dose prior to SAE/AESI			

Emergency Code broken?

Yes	No	N/A
☐	☐	☐

Study Regimen altered in response to the Adverse Event? ☐ Yes – *specify below* ☐ No

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Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) Reporting Form

♦ Protocol:	•Site Number:	♦ Eudract:	♦* Subject ID:	♦ Randomization number:

How was Drug Regimen altered in response to the event?

Reduced – *specify (date and new dose)* ☐

Temporarily Interrupted ☐

Permanently Discontinued ☐

Dates when Drug Regimen altered:

	dd	MMM	yyyy
Reduced			
Stopped			
Restarted			
Discontinued			

Details of new dose:

New Dose	Units	Frequency

7. ♦ Study Medication (3):

Study Medication Name:	Dose:	Units:	Frequency:	Route:	Dosage Form:

Batch Lot Number:

Dates for Study Medication:

	dd	MMM	yyyy
Start date			
Date of last dose prior to SAE/AESI			

Emergency Code broken?

Yes	No	N/A
☐	☐	☐

Study Regimen altered in response to the Adverse Event? ☐ Yes – *specify below* ☐ No

How was Drug Regimen altered in response to the event?

Reduced – *specify (date and new dose)* ☐

Temporarily Interrupted ☐

Permanently Discontinued ☐

Dates when Drug Regimen altered:

	dd	MMM	yyyy
Reduced			
Stopped			
Restarted			
Discontinued			

Details of new dose:

New Dose	Units	Frequency

8. Any treatment(s) / procedure(s) for SAE/AESI? ☐ Yes – *specify below* ☐ No – *go to Section 9*

Name of treatment / procedure	Total daily dose / unit	Start date			End date			Ongoing
		dd	MMM	yyyy	dd	MMM	yyyy	
1.								☐
2.								☐
3.								☐
4.								☐
5.								☐

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Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) Reporting Form

♦ Protocol:	•Site Number:	♦ Eudract:	♦* Subject ID:	♦ Randomization number:

9. Any relevant laboratory / diagnostic test(s)? (Including laboratory values preceding the event) ☐ Yes – *specify below* ☐ No – *go to Section 10*

Name of test	Result (Units)	Normal Values / Reference Ranges	Sample collection date			Result pending
			dd	MMM	yyyy	
1.						☐
2.						☐
3.						☐
4.						☐
5.						☐

10. Relevant previous disease / medical history ☐ Yes – *specify below* ☐ No – *go to Section 11*

Is there any relevant previous disease / medical history to this event (including previous drug reactions)?

Disease / Medical History	Start date			End date			Ongoing
	dd	MMM	yyyy	dd	MMM	yyyy	
1.							☐
2.							☐
3.							☐
4.							☐
5.							☐

11. Relevant previous treatment history / medical procedures ☐ Yes – *specify below* ☐ No – *go to Section 12*

Is there any relevant previous treatment history to this event (including operations or medical procedures)?

Treatment History	Start date			End date			Ongoing
	dd	MMM	yyyy	dd	MMM	yyyy	
1.							☐
2.							☐
3.							☐
4.							☐
5.							☐

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Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) Reporting Form

♦ Protocol:	•Site Number:	♦ Eudract:	♦* Subject ID:	♦ Randomization number:

12. Any concomitant medication(s)? ☐ Yes – *specify below* ☐ No – *go to Section 13*

Record drugs being taken at the time of the event

Name (Do not list drugs used to treat the SAE/AESI)	Total daily dose / unit	Start Date			End Date			Ongoing
		dd	MMM	yyyy	dd	MMM	yyyy	
1.								☐
2.								☐
3.								☐
4.								☐
5.								☐
6.								☐
7.								☐
8.								☐
9.								☐
10.								☐

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Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) Reporting Form

♦ Protocol:	•Site Number:	♦ Eudract:	♦* Subject ID:	♦ Randomization number:

13. Serious Adverse Event/Adverse Event of Special Interest Description

Include a history of the event chronologically including: signs and characteristics, severity, dates and outcome of hospitalization and any other relevant information not captured elsewhere on the form. If non-serious events are included in this text, please add (NS) after the event term.

Please ensure information in this section is consistent with other sections in the form. In case of inconsistency (e.g. study drug causality) the most conservative information will be taken.

14. ♦* Investigator name and address:

Investigator Name:

Investigator Address:

Investigator Speciality:

Investigator/Designee Signature:

If designee, print name:

Date of signature (dd/MMM/yyyy)

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