SERIOUS ADVERSE EVENT FORM TEMPLATE
SAVE FGR TRIAL

Subject information

Subject Study Number |__|__|__|__|__|__| Age: |__|__|__|

All Serious Adverse Events must be reported within 24 hours after onset. Please email the SAE to:
savefgr@amsterdamumc.nl

A follow up report must be sent within 7 days and final report when outcome of SAE is known

Investigator Information

Local Investigator : _____ Site: _____

Email: _____ Phone: _____

Date of Report (Follow up reports can be completed in this initial report)

Initial ____/_____/_____ (DD MMM YYYY) Follow up (FU) ____/_____/_____ FU ____/_____/_____ FU ____/_____/_____

Final ____/_____/_____ (DD MMM YYYY)

Date of awareness SAE ____/_____/_____ (DD MMM YYYY)

Serious Adverse Event Information

What is the Adverse Event _____

Date Onset AE: ___/____/_____ (DD MMM YYYY) Date AE became serious: ___/____/_____ Date AE resolved: ___/____/_____

Category of SAE:	Status of SAE at time of this report
☐ Death	☐ Fatal
☐ Life threatening	☐ Completely resolved on ___/____/_____ (date)
☐ Hospitalization/prolongation	☐ Resolved with sequelae, ___/____/_____ (date)
☐ Congenital anomaly/birth defect	☐ Not completely resolved:
☐ Persistent/significant disability	☐ ongoing unchanged
☐ Important medical event	☐ ongoing with increased intensity
	☐ ongoing with decreased intensity

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In case of death ☐ *Not applicable*

PATIENT	**CHILD**
Date of death (if applicable): ____/_____/_____ DD MMM YYYY	Date of death (if applicable): ____/_____/_____ DD MMM YYYY
Was the patient's death related to study drugs: ☐ Yes ☐ No. If yes, please specify:	Was the patient's death related to study drugs: ☐ Yes ☐ No. If yes, please specify:
Causes of death (listed primary cause of death first):	Causes of death (listed primary cause of death first):

Serious Adverse Event Information: Provide a brief narrative description of the SAE (presenting symptoms (diagnosis), including:

Diagnosis and symptoms

Tests and treatment

Relevant Medical History

Information of the child

Brief summary

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Relevant concomitant medication: report medication limited to relevant prophylaxis and supportive care and medication that the investigator considers to be possibly contributing to the occurrence of the SAE. **Do not report medication given to treat the SAE.**

Drug (generic name)	**Dose** (units)	**Route** (iv, po,...)	**Date first dose** (DD/MMM/YYYY)	**Date last dose** (prior to SAE)
_____	_____	_____	____/___/_____	____/___/_____
_____	_____	_____	____/___/_____	____/___/_____
_____	_____	_____	____/___/_____	____/___/_____
_____	_____	_____	____/___/_____	____/___/_____
_____	_____	_____	____/___/_____	____/___/_____
_____	_____	_____	____/___/_____	____/___/_____
_____	_____	_____	____/___/_____	____/___/_____

Signatures:

_____ Investigator printed name

_____ Investigator signature

_____ Date (DD/MMM/YYYY)

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To be completed by Staff study team:

Receipt date of SAE report |___||___||_____| SAE sequence number: SAE I__I__I__I

SAE evaluation has been performed by Staff Member of project team:

Name: …….. Signature: Date:|___||___||_____|

Medical review has been performed by Principle Investigator of study

Name: …….. Signature: Date:|___||___||_____|

Comments by medical reviewer:

1. Has SAE consequence for safety of subject ☐ NO ☐ YES which and any action taken? Specify:

2. SAE category: ☐ related to study treatment of study procedure ☐ related to medical device ☐ related to failure of device ☐ other, specify,