Serious Adverse Event- Initial Report

Serious Adverse Event n.	

Trialcode	

Patient Information	Age	Weight (Kg)	Height (cm)	Gender

Investigational Medical Product (IMP)/ Study Drug	Study drug administered	
	Intended dose	☐ Half dose ☐ Full dose
	Administered dose	
	Start date	
	Last administration date	

SAE Details	Date of SAE awareness	
	Serious adverse event Term/Diagnosis	

Signature of reporting person	

	Seriousness	☐ mild ☐ moderate ☐ severe ☐ life-threatening ☐ fatal
	Causal relation to IMP/Study Drug	☐ related ☐ probable ☐ possible ☐ not related ☐ unknown
	Action taken with IMP	
	SAE Start Date	
	SAE Stop Date	

Suspected IMP/Study Drug	Did event abate after stopping drug?	☐ yes ☐ no ☐ unknown
	Was suspected drug re-administered?	☐ yes ☐ no
	If yes, please specify the date	
	Did event reappear after drug reintroduction?	☐ yes ☐ no ☐ unknown
	Outcome	☐ solved ☐ not solved ☐ ongoing ☐ fatal
	Death due to the SAE?	☐ yes ☐ no ☐ unknown

Signature of reporting person	

	Date of death	

Disease under study	Was the dismetabolic condition that allowed the eligibility of the patient the primary cause of the SAE?	☐ yes ☐ no ☒ unknown

Concomitant Treatments/ Procedures (also prophylactic medications, procedures to obtain central venous access)	Name			
	Indication			
	Daily Dose			
	Route			
	Start Date			
	Stop Date			
	Ongoing	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown
	Primary cause of the SAE?	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown
	If yes, does it require modification of the conduct of the trial?	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no

Signature of reporting person	

Relevant Medical Conditions (pre-existing relevant medical conditions, family history)	Disease/ Allergies/Risk Factors			
	Start Date			
	Stop Date			
	Ongoing	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown
	Primary cause of the SAE?	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown

Signature of reporting person	

SAE Narrative (Please describe chronologically the clinical sequence of the events, results of any confirmatory procedures, treatment of the event and outcome. Attach separately laboratory results and other relevant documents like hospital or post-mortem reports when available)	

Reported by (name and surname)	
Date of report	

Signature of reporting person	