PART 1: SAE Serious Adverse Event Report (from Investigator to Sponsor)

PART 2: SUSAR Suspected Unexpected Serious Adverse Event Report (Sponsors assessment)

EudraCT number: 2018-00484-86			DAN-W	DAN-WAR-D – The Danish Warfarin-Dialysis Study					
	PAR	TT 1 (To be f	illed in by	Investigato	or)				
Awareness date: YYYY MMM DD		Report date: YYYY MMM DD							
Report type									
	Initial			Follov	w up				
Subject Information									
Patient initials Country			Date of		Date of birth	Sex M□ F□			
Patient no.	Site name/no.			YYYY MMM DD					
Serious Adverse Eve	ent:								
SAE: (diagnose)									
SAE Onset date:			SAE End date:						
	YY MMM DD		YYYY MMM DD						
Patient discontinued for	rom study due No □	to SAE	 	Ye	es □ → Date:	 /YYY MM			
SAE Criteria		E	valuation				IM DD		
Serious Criteria			Outcome			Action Taken			
Patient died			Ongoing			No change			
Life-threatening			Resolved	l		Drug chang			
Involved persistence of significant disability or incapacity Involved or prolonged inpatient hospitalization Important Medical Event			Resolved	l w/sequelae					
			Fatal				temporarily ntinue		
			Unknow	n			Drug permanently		
					disco		ntinued		
Other									
Date of death:			Cause of death:						
YYYY MMM DD									
Death certificate:				Autopsy report:					
Yes (attach copy) No			Yes (attach	Yes (attach copy) \square No \square					

Unrelated to study drug \Box	Related to the study drug \square			
(None, unlikely)	(Possible, probable, definite)			
Suspect Drug(s) information				
Suspect Drug(s) name:	Did reaction abate after stopping drug? Yes □ No □ NA □			
Batch no:				
Daily dose(s) (specify units)	Route(s) of administration			
Indications(s) for use	Did reaction reappear after reintroduction? Yes □ No □ NA □			
Therapy starting date	Therapy stopping date			
YYYY MMM DD	YYYY MMM DD			
Event Description				
Event Description				

Concomitant drug(s) and dates (YYYY-MMM-	nn of administration	
Goneomitant araggy and dates (TTT-MANA	of damming action.	
Reporter information	Investigator information	
Name:	Name:	
Address:	Address:	
Phone:	Phone:	
Profession:	Profession:	
Signature	Signature	
& Date	& Date	
Fill in this form and mail or fax it with	in xx hours to sponsor:	
Secure mail:		
Nicholas.carlson.01@regionh.dk		
Fax.no:		
+45 3545 2240 / +45 3545 2672		
Sponsors date and signature for receive	ving this report:	
Date	Signature	

Concomitant Medication(s) relevant to the event (exclude those used to treat event)

PART 2: (To be filled in by sponsor)

Causality Assessment by Sponsor:
Result of causality evaluation:
\square Not related to study drug (Unlikely/doubtful) \rightarrow (If judged related by investigator go to box below)
\square Related to study drug (Possible/Probable/Definite) \rightarrow (Go to box below)
Expectedness Assessment by Sponsor (only relevant if SAE is related to study drug):
Result of expectedness evaluation:
☐ Expected (due to relevant reference document)
\Box Unexpected→ (Go to box below)
Summary:
Category of event:
□ SUSAR (SAE is both related and unexpected)
☐ SAR (SAE is related but not unexpected)
□ SAE (SAE is not related)
Notify relevant authorities according to protocol
Spangare commants (including information regarding unblinding).
Sponsors comments (including information regarding unblinding):
Sponsors date and signature:
Date Signature