CORRA SAE Form V02 F

Fax within 24 hours after awareness of SAE to KKS Marburg: 06421 28 66 517

EudraCT-No. : 2012-004074-25	SAE-REPORT		SP	SPONSOR: Ruhr-Universität Bochum					
STUDY IDENTIFICATION: CORRA		SAE-ID: (to be completed by Sponsor)							
1. PATIENT CHARACTERISTIC	S								
Patient No.:	Sex: M F	Age (years	s):	Heig	ht (cm):	Weight (kg):			
2. REPORT INFORMATION									
☐ INITIALREPORT	Date: (dd.mm.yyyy)			Date of no	otice at site: yyy)				
☐ FOLLOW-UP REPORT No	- Date: (dd.mm.yyyy)		7	Γο Initial F	Report dated: (dd.mm.	уууу)			
Name of investigator:			Site No.:						
Address Institution:			Country:						
			Telephone:						
			Fax:						
			E-Mail:						
3. SERIOUSNESS CRITERIA OI	R REPORTABLE R	EASON							
Results in death					ent or significant disal	oility /	incapacity		
☐ Life-threatening☐ Requires in-patient hospitalisation	or prolongation of exis	sting	☐ Congenital anomaly / birth defect ☐ Other medically important condition						
hospitalisation									
4. SERIOUS ADVERSE EVENT Please enter only ONE Reactio If more than one Reaction/Ever Reaction/Event or Diagnosis:	n/Event or Diagnos		me patient,	, comple	ete a separate Fori	n for	each SAE.		
Onset date of SAE:			Date of res	olution:					
(dd.mm.yyyy)			(dd.mm.yyy						
5. DESCRIPTION OF SAE: (Sum In	marize history of the e clude signs and sympt								
6. SEVERITY / INTENSITY									
□ Mild / CTCAE Grade 1 □	Moderate / CTCAE Grade 2	□ Sever CTCA	e / .E Grade 3		Life-threatening / CTCAE Grade 4		Death / CTCAE Grade 5		

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7. DRU	G INFORMATIO	ON – <mark>BLINDED II</mark>							,				
Drua	name:		Dose:		NDING: not a		quency:	∐ no L	」yes Rout			Dosa	age
				Troquentsy			4					Form	
PredniHexal / Placebo													
Start	date (dd.mm.yyyy	')	Date of la	st dose	prior to SAE (dd.	mm.y	ууу):	Batch-No).:		i_		
Related	dness: □ Cert	ain 🔲 Probable	☐ Possible	☐ Unlik	ely	ed	☐ Not as	ssessable	□ N	lot applica	ıble	☐ Ur	nknown
	dministration alter	red in response to th	e Adverse Ev	ent?	□ no □ yes	3	If application	able, details	s of n	ew dose	:		
, ,	when drug admini	stration altered:					New. o	dose:	Uni	Unit: Freque		ency:	
Dates	When drug darriin	dd	mm		уууу								
	Reduced:								I	<u> </u>			
	Increased:						If application	able:					un-
	Stopped:							action abate topping dru		yes □	no		known
	Restarted:							action recur		<u> </u>			un- known
	Withdrawn:							inistration?	-	yes 🗌	no		Chrown
7 0011	O INFORMATIO	DMADD - //	D:	-1: <i>e</i> :	A (!l (!								
7. DRU	GINFORMATIC	DN – <mark>DMARDs (</mark> I			g Antirneumati NG: ☐ not appl			no □ye	s				
Drug	name:		Dose:		Jnit:		quency:		Rout	ie:		Dosa	
												Form	1.
Start date (dd.mm.yyyy) Date of last dose prior to SAE (dd.mm.yyyy): Batch-No.:													
Related	dness: □ Cert	ain Probable	Possible	Unlik	tely Not relat	ed	☐ Not as	ssessable	□ N	lot applica	ible	☐ Ur	nknown
Drug a	dministration alter	ed in response to th	e Adverse Ev	ent?	☐ no ☐ yes	3	If applic	able, details	s of n	ew dose			
(If 'yes	' specify)				•		New. o	dose:	Uni	t:	Freque	encv:	
Dates	when drug admini	stration altered:	1	1		_						,	
		dd	mm		уууу								
	Reduced:						If applic	able:					
	Increased:					\dashv		action abate	е				un- known
	Stopped: Restarted:							topping dru		yes 🗌	no		un-
	Withdrawn:							action recur		,,co [20	_	known
]		1	1	l.			readm	inistration?		yes 🗌	no		Ш

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(to be completed by openion)										
7. DRUG INFORMATION - DMARDs (Disease-Modifying Antirheumatic Drugs) UNBLINDING: not applicable no yes										
Drug name:	Dose:	Unit:		Frequency	•	Route:			Dosage Form:	
								. 0.		
Start date (dd.mm.yyyy)	Date of la	st dose prior	to SAE (dd.	mm.yyyy):	Batch-N	0.:				
Relatedness:	☐ Possible	☐ Unlikely	☐ Not relate	ed 🗌 Not	assessable		lot applica	ible 🔲	Jnknown	
Drug administration altered in response to the (If 'yes' specify)	e Adverse Eve	ent? 🗌 r	no 🗌 yes	s If appl	icable, detai	ls of n	ew dose:	:		
Dates when drug administration altered:				New	dose:	Uni	it:	Frequency	/ :	
dd	mm		уууу							
Reduced:				If appl	cable.					
☐ Increased:					eaction aba	to			un- known	
Stopped: Restarted:					stopping dr		yes 🗌	no 🗌	un-	
☐ Withdrawn:				l I	eaction recu		yes □	l no □	known	
readministration? yes no										
7. DRUG INFORMATION – DMARDs (I			<mark>tirheumati</mark> 3:		no] yes				
Drug name:	Dose:	Unit:		Frequency	:	Rou	te:	Do: For	sage m:	
Start date (dd.mm.yyyy)	Date of la	st dose prior	to SAE (dd.i	mm.yyyy):	Batch-N	0.:				
Start date (dd.mm.yyyy) Date of last dose prior to SAE (dd.mm.yyyy): Batch-No.:										
Relatedness:										
Drug administration altered in response to the (If 'yes' specify)	e Adverse Eve	ent? 🗌 r	no 🗌 yes		cable, detai					
Dates when drug administration altered:	_			New	dose:	Uni	t:	Frequency	/ :	
dd	mm		уууу							
Reduced:				If appl	cable:					
☐ Increased: ☐ Stopped:				Did r	eaction aba				un- known	
Restarted:				after	stopping dr	ug?	yes 🗌	no 🗌	un-	
☐ Withdrawn:				1 1	eaction recuministration?		yes 🗌	no 🗌	known	

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8. RELEVANT MEDICAL	concurrent c				Stop date (dd.mm.yyyy)				
1.						(dd.mm.yyyy)	(dd.mm.yyyy)		
2.									
3.									
4.									
9. RELEVANT CONCOMI	TANT MEDIC	CATION	none						
Drug name:	Dose (e.g.1-0-1)	Unit (e.g.mg, µg, ml)	Form (e.g. tablet, capsule)	Route (oral, iv)	Indication	Start date (dd.mm.yyyy)	End date (dd.mm.yyyy)		
1.									
2.									
3.	+								
4.	+					-			
5.	1								
6.	+								
7.	 								
8.									
9.									
10. RELEVANT LAB FIND	DINGS OR IN	1		GNOSIS O					
		Normal rang	ge (low/high)		Date (dd.mm.y	yyy) Result, Unit	ː 		
1. 2.									
3.									
4.									
5.									
6.									
7.									
8.									
9. 11. SAE OUTCOME:									
		unknown	Τ						
Recovered / Resolved	fatal								
Recovering / Resolving							уууу)		
☐ Not recovered / Not resolv	Cause of death: Autopsy: yes no unknown								
Recovered / Resolved with 12. SAE TREATMENT:	ı sequelae		Autopsy: L	yes r	no 🗌 unknown				
□ None									
☐ Drug treatment → specify:									
☐ Others → specify: 13. ATTACHMENTS: ☐ r		f yes, please	specify:						
14. INVESTIGATOR SIGN	IATURE :								
Name			Signa	ature	Date (dd/mm/yyyy)				