SERIOUS ADVERSE EVENT FORM

A serious adverse event (SAE) has to be reported within 24 hours after occurrence of the SAE. A written report has to be sent to the Data Center by email: drugsafety@nki.nl (preference)
In case of questions tel nr: +31 (0) 20-512 9047

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Protocol Number / Name	Patient study number	Patient birth year	Age	Report type: *(circle)*
M15CRI (CRITICS II)				1. Initial 2. Follow up 3. Final

Gender *m/f*	Treating physician	Institution *name/city*

MAIN SAE, please indicate ONLY 1 with "X"	Adverse event(s)	Onset date *(dd/mm/yyyy)*	Stop date *(dd/mm/yyyy)*	Severity *(CTC)* 1= grade I/mild 2= grade II/ moderate 3= grade III/severe 4= grade IV/life threatening 5= grade V/death	Relationship with treatment 1= unrelated 2= unlikely 3= possible 4= probable **5= certain**								Action taken regarding study drug 1= none 2= dose reduced 3= delayed 4= interrupted **5= discontinued**								SAE outcome 1= recovered 2= recovered with sequelae 3= improved 4= unchanged 5= worsened **6= fatal**
					A*	B*	C*	D*	E*	F*	G*	H*	A*	B*	C*	D*	E*	F*	G*	H*	

***Please complete the study drug/treatment here**: A*= Docetaxel; B*= Oxaliplatin; C*= Capecitabine; D*= Paclitaxel; E*= Carboplatin; F*= Radiotherapy; G*= Surgery
H*= Deviated Treatment

Date AE became SERIOUS: (*dd/mm/yyyy*)		**End date of seriousness:** (*dd/mm/yyyy*)	

SAE category *(circle)*	**In case of death**	**Description of event** *(including date onset, diagnose, treatment for SAE)*
1. Death 2. Life threatening 3. Permanently disabling 4. Hospitalization/ Prolongation Date:…../……../…… 5. New cancer 6. Congenital anomaly 7. Overdose 8. Other ……..	Date of death *(dd/mm/yyyy)* ……/……/…… Cause of death: ☐ 1. Malignant disease 2. Toxicity 3. Other, specify …… Autopsy performed: 0=No / 1=Yes ☐ *If yes, include report*	

Protocol Number / Name	Patient study number	Age	CCMO number
M15CRI (CRITICS II)	☐☐☐☐		

Randomized treatment ARM:		Treatment week at time of SAE:			
☐	Arm 1: DOC + Surgery	**DOC:** ☐C1 ☐C2 ☐C3 ☐C4		☐ Surgery	☐ Follow Up
☐	Arm 2: DOC + CRT +Surgery	**DOC:** ☐C1 ☐C2	**CRT:** ☐W1 ☐W2 ☐W3 ☐W4 ☐W5	☐ Surgery	☐ Follow Up
☐	Arm 3: CRT + Surgery		**CRT:** ☐W1 ☐W2 ☐W3 ☐W4 ☐W5	☐ Surgery	☐ Follow Up

Trial drug(s) / Trial treatment	**Start date first course** *dd/mm/yyyy*	**Most current treatment /administration** dd/mm/yyyy	**Dose** *+ units*	**Route** *PO, IV, TOP, etc.*	**Frequency**
Docetaxel			mg	IV	
Oxaliplatin			mg	IV	
Capecitabine			mg	PO	
Paclitaxel			mg	IV	
Carboplatin			mg	IV	
Radiotherapy			Gy	Local	
Surgery				Local	
Number of last course given:	**Indication for use:**				

Relevant concomitant medications				**Relevant tests**			
Name	**Start date** *dd/mm/yyyy*	**Stop date** *dd/mm/yyyy*	**Daily dose** **+** *units*	**Test**	**Date** *dd/mm/yyyy*	**Result** *value/units*	**Normal range** *value/units*

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M15CRI (CRITICS II)	⌊_ _ _ _⌋		

Relevant medical history/ additional comments:

In which group does this SAE report belong?

☐ *an unexpected outcome of an expected serious event*

☐ *a SAE related to the study – intervention or study procedure*

☐ *a SAE related to a medical device*

☐ *a SAE related to malfunctioning equipment*

☐ *other, specify,* ☐ *progressive disease*

☐ *other, specify……*

Name investigator:	Signature investigator:	Date *dd/mm/yyyy*: