

PREOPANC-2 (2018-004)

SERIOUS ADVERSE EVENT REPORT

Mail all pages of the reports to: sae.invent.ctc@erasmusmc.nl, fax +31 (0)10 70 41 028

Pat. Study number: |_|_|_|_|_| Date of report |_|_|_|_|_|

Initial report Follow up report Final report

Trial medication

Please specify details of the trial medication/treatment that the patient received in this protocol phase:

Trial medication ¹	Total daily dose (please add units)	Date first administration (during this protocol phase)	Date last administration (Date last dose prior to SAE)	Relationship to SAE ²	Action taken as a result of this SAE ³
_	_ _ _	_ _ _	_	_
_	_ _ _	_ _ _	_	_
_	_ _ _	_ _ _	_	_
_	_ _ _	_ _ _	_	_
_	_ _ _	_ _ _	_	_

¹ Trial medication		² Relationship to SAE	³ Action taken	
0= Not applicable	3= Irinotecan	0= unrelated	0= none	3= interrupted
1= Oxaliplatin	4= Fluorouracil	1= likely	1= next dose reduced	4= discontinued
2= Leucovorin	5= Gemcitabine		2= delayed	5= restarted

Possible Causes of SAE other than Trial medication

Please specify if there are circumstances other than trial medication that may have contributed to the SAE or could help explain the SAE

Disease under study (including progression) 0= No 1= Yes

Medical condition(s) 0= No 1= Yes, specify below
Any relevant past or current medical disorders (not disease under study), allergies, surgeries that could help explain the SAE

Concomitant medication(s) 0= No 1= Yes, specify below

Other 0= No 1= Yes, specify below

Specification:.....

Outcome of SAE

1= resolved* 4= ongoing at death (death due to another cause)**
 2= ongoing 5= ongoing closed (because stable situation reached)
 3= death (caused by SAE)**

* Date SAE resolved [dd/mm/yyyy] |_|_|||_|||_|

** Date of death [dd/mm/yyyy] |_|_|||_|||_|

** Cause of death

Action taken regarding the SAE

Signature for report – the (sub) investigator should always review and sign at least the final report

Date |_|_|||_|||_| Name: Signature

Date |_|_|||_|||_| Name: Signature

Date |_|_|||_|||_| Name: Signature

Date |_|_|||_|||_| Name: Signature

Date |_|_|||_|||_| Name: Signature