

HOVON 151 DLBCL

SERIOUS ADVERSE EVENT REPORT

Send the report to:

HOVON Data Center, e-mail saereports@erasmusmc.nl

Patient Study Number: |__|_|_|_|_|_|

Date of report: |__||__||____|

Initial report

Follow up report

Final report

Treatment Phase

Protocol phase during / after which the SAE occurred |__| 0=before start protocol treatment 1=consolidation 4=follow up

Cycle number |__|

Atezolizumab

Please specify details of the atezolizumab treatment that the patient has received (if not given during this protocol phase, please report last time received)

Trial medication ¹	Total daily dose (please add units)	Date first dose (during this protocol phase)	Date last dose (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
1=atezolizumab	0=unrelated 1=unlikely 2=possible 3=probable 4=definite	0=none 1=next dose reduced 7=drug withdrawn (temporarily or permanently) 6=not applicable

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34 Possible Causes of SAE other than atezolizumab and other trial medication(s)

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

Disease under study could help explain the SAE or may have caused the SAE

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

Any relevant concomitant medication(s) that could help explain the SAE or may have caused the SAE

Trial related procedure(s) |__| 0=No 1=Yes, specify below

Other |__| 0=No 1=Yes, specify below

Specification:.....

Outcome of SAE

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

* Date SAE resolved [dd/mm/yyyy] |__||__||____|

** Date of death [dd/mm/yyyy] |__||__||____|

** Cause of death

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

Report	Name reporter	Function	Date	Signature
Initial	__ __ ____
Follow up	__ __ ____
Follow up	__ __ ____
Final	(sub) investigator	__ __ ____

Safety Desk staff only

SAE sequence number |__|__|

Initial report reviewed by (initials) Date review |__||__||____|

Follow up report reviewed by (initials) Date review |__||__||____|

Final report reviewed by (initials) Date review |__||__||____|