# HOVON 152 NHL



## SERIOUS ADVERSE EVENT REPORT

Use this form to report all Serious Adverse Events as described in the trial protocol. An **initial report** must be sent to the HOVON Data Center within **24 hours**. Complete information in a first **follow up report** must be reported within **2 days**. The final report is to be sent as soon as outcome of SAE is known. For follow up and final reports you may update the existing initial report.

**Send all 4 pages of the report to:**

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

### Patient information

Patient study number |__|__|__|__|

Sex |__| 1=male 2=female

*Safety Desk staff only*

### Report information

Site name .....

Investigator .....

Type of report ☐ Initial report ☐ Follow up report ☐ Final report

Date of initial report [dd/mm/yyyy] |____||____||_____|

Date of follow up report [dd/mm/yyyy] |____||____||_____| |____||____||_____| |____||____||_____|

Date of final report [dd/mm/yyyy] |____||____||_____|

### Serious Adverse Event information

Adverse Event Term .....

Diagnosis of Adverse Event in a single term if no diagnosis is available yet, please provide the most relevant sign or symptom

Date onset AE [dd/mm/yyyy] |____||____||_____|

Date AE became Serious [dd/mm/yyyy] |____||____||_____|

Reason AE is Serious |__| 1=death 2=life-threatening 3=(prolongation of) hospitalization 4=significant / persistent disability 5=congenital anomaly / birth defect 6=other medically important condition

Severity of AE [CTCAE grade] |__|
(highest grade observed)

### SAE description and comments

Describe the course of events, include dates and results of tests / procedures / actions taken (for final report: outcome of adverse event, test result etc.)

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

# HOVON 152 NHL



## 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 Arm and Phase

Treatment arm |__| 9= not applicable

Protocol phase during / after which the SAE occurred |__| 0=before start protocol treatment 1= Induction cycle 1 R-CHOP 2= Induction cycle 2 DA-EPOCH-R 3= Induction cycle 3 DA-EPOCH-R 4= Induction cycle 4 DA-EPOCH-R 5= Induction cycle 5 DA-EPOCH-R 6= Induction cycle 6 DA-EPOCH-R 7= Nivolumab consolidation 8=Follow up

## Investigational Medicinal Products (IMP(s))

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

| **Trial medication** | **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]** |
|---|---|---|---|---|---|
| Cyclophosphamide (i.v) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Vincristine (i.v.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Doxorubicin (i.v.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Rituximab (i.v.)* | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Rituximab (s.c.)* | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Etoposide (i.v.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Prednisolone (p.o.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Nivolumab (i.v) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |

*Brand name Rituximab |___| MabThera |___| Blitzima |___| Rixathon |___| Rituzena |___| Truxima |___| Ritemvia |___| Riximyo

## Other trial medication

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

| **Trial medication** | **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]** |
|---|---|---|---|---|---|
| Prednisone (p.o) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Methotrexate (i.t.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Cytarabine (i.t.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Dexamethasone (i.t.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| Prednisolone (i.t.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |
| G-CSF (s.c.) | ..... | \|____\|\|____\|\|_____\| | \|____\|\|____\|\|_____\| | \|___\| | \|___\| |

# HOVON 152 NHL



## 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

| | [2] Relationship to SAE | [3] Action taken |
|---|---|---|
| | 0=unrelated<br>1=unlikely<br>2=possible<br>3=probable<br>4=definite | 0=none<br>1=next dose reduced<br>7=drug withdrawn (temporarily or permanently)<br>6=not applicable |

### [34] Possible Causes of SAE other than IMP(s) 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) (*e.g. placing IV line or bone marrow biopsy)* |__| 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** | \|____\|\|____\|\|_____\| | ..... |

# HOVON 152 NHL



## SERIOUS ADVERSE EVENT REPORT

**Send the report to:**

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

---

**Safety Desk staff only** **SAE sequence number** *2* |__|__|

Initial report reviewed by (initials) ..... Date review |____||____||_____|

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

Final report reviewed by (initials) ..... Date review |____||____||_____|