



SAE Fax Cover Sheet

Urgent!

To: UMCG Fax: (0031) 50 3615960
AND x.kahle@umcg.nl, m.nijland@umcg.nl

From:

Representative: (Name)
(Phone)

Date:

No. of pages (including SAE Fax cover sheet)

SAE FORM status Only Initial

Concerning patient

Year of birth:

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Patient study ID:

PDL1 - DLBCL - UMCG - __ __

HN151 - - __ __ __ (Please fill in HN151 center if available)

Comments:



HOVON 151 PDL1 imaging in DLBCL Serious Adverse Event form

Patient Data

Patient study ID: PDL1 - DLBCL - UMCG - __ __
HN151 - - __ __ __ (Please fill in HN151 center if available)

Year of birth

Sex: Female

Male

SAE FORM

Event: _____

Grade: _____

Event Start date Start time

Date when event became serious Start time



HOVON 151 PDL1 imaging in DLBCL Serious Adverse Event form

Patient number: PDL1 - DLBCL - UMCG - __ __
HN151- - __ __ __ (please fill in HN151 center if ID available)

Serious Criteria

- Death
- Life-threatening
- New in patient hospitalization
- Prolonged in-patient hospitalization
- Significant disability / incapacity
- Congenital anomaly
- Medically important, specify: _____

Possible causes of the event

- Pre-existing/underlying disease, specify: _____
- Concomitant/previous treatment, specify: _____
- Protocol-related procedure, specify: _____
- Other (e.g. accident, new illness), specify: _____



HOVON 151 PDL1 imaging in DLBCL Serious Adverse Event form

Patient number: PDL1 - DLBCL - UMCG - __ __
HN151- - __ __ __ (please fill in HN151 center if ID available)

Additional study medication

Any treatment(s) procedure(s) for SAE?

No

Yes*

*if yes, please complete the table below

| Name of treatment/Procedure | Dose | Units | Start date DD/MMM/YYYY | End date DD/MMM/YYYY | Ongoing at study termination |
|-----------------------------|------|-------|------------------------|----------------------|------------------------------|
| | | | | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> |



HOVON 151 PDL1 imaging in DLBCL Serious Adverse Event form

Patient number: PDL1 - DLBCL - UMCG - __ __
HN151- - __ __ __ (please fill in HN151 center if ID available)

Outcome

- Resolved: End date Stop time
- Resolved with sequel: End date Stop time
- Resolving at study termination
- Unresolved at study termination
- Death
- Unknown

Serious Adverse Event description

Please include a history of the event with signs and characteristics, severity and any relevant information not captured elsewhere on the form (e.g. relevant lab/diagnosis, relevant previous disease/medical history, relevant previous treatment history)



HOVON 151 PDL1 imaging in DLBCL Serious Adverse Event form

Patient number: PDL1 - DLBCL - UMCG - __ __
HN151- - __ __ __ (please fill in HN151 center if ID available)

Investigator data

Investigator name: _____

Investigator address & Phone: _____

Date

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

Investigator signature _____

- Please send this SAE form within 24 hours of discovery of the event

to m.nijland@umcg.nl, x.kahle@umc.nl

AND

FAX (0031) 50 3615960

- After sending the SAE form by mail or fax, the eCRF should be filled in
- Only the initial SAE need to be send by mail or fax, the follow up SAE should only to be filled in by eCRF