Serious Adverse Event (SAE) Reporting Form - StiL Study NHL 7-2008

Lfd. SAE Nr_____
(wird von der StiL vergeben)

StiL Protocol:	♦ Prüfzentrums-Nr.:	Eudract-Nr.:	[Internal Study-Nr.]	♦ Randomization:
NHL 7-2008		2008-005859-16	ML 21685	

For Internal Use Only **MCN:** _____ **Received Date:** dd | mmm | yyyy

Complete all Essential Elements (fields marked with ♦ and ♦*). All fields marked with ♦* are valid elements and, if missing, the SAE form will be considered invalid. Complete one form for each SAE.

♦* Investigator Name: _____ **Country:** Germany

Name of Reporter: _____ **Tel. No.:** _____

1. Personal data

♦*Birth Date:	dd	mmm	yyyy

♦*StiL Pat Nr: _____ ♦*Sex: Male ☐ Female ☐

Height: _____ ☐ cm **Weight:** _____ ☐ Kg **Race:** White ☐ Black ☐ Asian ☐ Other ☐

2. Serious Adverse Event (Complete one form for each SAE)

Please note: If the patient has died, the cause of death must be provided as an event.

♦* Event: _____

	dd	mmm	yyyy
Date of onset:			
Date when event became serious:			

♦ Possible causes of the event *(Check off all that apply)*

- Pre-existing/Underlying disease - *specify* ☐ _____
- Study treatment - *specify the drug(s) related to the event* ☐ _____
- Other treatment (concomitant or previous) - *specify* ☐ _____
- Protocol-related procedure ☐
- Other (e.g. accident, new or intercurrent illness) - *specify* ☐ _____

3. ♦ Event Seriousness

Why was the event serious? *(Check all that apply)*:

- Results in death ☐
- Life-threatening ☐
- New in-patient hospitalisation ☐
- Prolonged in-patient hospitalisation ☐
- Persistent or significant disability/incapacity ☐
- Congenital anomaly / birth defect ☐

or *only when no other criteria applies*

- Medically Significant ☐

4. SAE Outcome

SAE outcome at the time of the report:

		dd	mmm	yyyy
Fatal / Date of Death	☐			
Resolved	☐			
Resolved with sequelae	☐			
Improved	☐			
Persisting	☐			
Worsened	☐			
Unknown	☐			

3a. *Use only in exceptional circumstances to indicate when a non-serious event of special interest (as defined by the protocol) is being reported.*

Non-serious event of special interest ☐

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5. ♦* Study Medication (1):

Study Medication Name:	Dose (mg absolute):		Frequency:	Route:	Dosage Form:
Rituximab				i.v.	

Batch Lot Number: _____

Dates for Study Medication:	dd	mmm	yyyy
Start date			
Date of last dose prior to SAE			

Study Regimen altered in response to the Adverse Event? ☐ Yes – *specify below* ☐ No

How was Drug Regimen altered in response to the event?

Reduced – *specify (date and new dose)* ☐

Temporarily Interrupted ☐

Permanently Discontinued ☐

Dates when Drug Regimen altered:

	dd	mmm	yyyy
Reduced			
Stopped			
Restarted			
Discontinued			

Details of new dose:

New Dose	Units	Frequency

5. ♦* Study Medication (2):

Study Medication Name:	Dose (mg absolute):		Frequency:	Route:	Dosage Form:
Bendamustine				i.v.	

Batch Lot Number: _____

Dates for Study Medication:	dd	mmm	yyyy
Start date			
Date of last dose prior to SAE			

Study Regimen altered in response to the Adverse Event? ☐ Yes – *specify below* ☐ No

How was Drug Regimen altered in response to the event?

Reduced – *specify (date and new dose)* ☐

Temporarily Interrupted ☐

Permanently Discontinued ☐

Dates when Drug Regimen altered:

	dd	mmm	yyyy
Reduced			
Stopped			
Restarted			
Discontinued			

Details of new dose:

New Dose	Units	Frequency

StiL Protocol:	♦ Prüfzentrums-Nr.:	Eudract-Nr.:	[Internal Study-Nr.]	♦ Randomization:
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6. Any treatment(s) / procedure(s) for SAE? ☐ Yes – *specify below* ☐ No – *go to Section 7*

Name of treatment / procedure	Total daily dose / unit	Start date			End date			Ongoing
		dd	mmm	yyyy	dd	mmm	yyyy	
1.								☐
2.								☐
3.								☐
4.								☐

7. Any relevant laboratory / diagnostic test(s)? ☐ Yes – *specify below* ☐ No – *go to Section 8*
(Including laboratory values preceding the event)

Details of additional laboratory / diagnostic tests can be completed on the Additional Laboratory / Diagnostic Tests form.

Additional form provided? ☐ Yes → No. of extra pages _____ ☐ No

Name of test	Result (Units)	Normal Values / Reference Ranges	Sample collection date			Result pending
			dd	mmm	yyyy	
1.						☐
2.						☐
3.						☐
4.						☐

8. Relevant previous disease / medical history ☐ Yes – *specify below* ☐ No – *go to Section 9*

Is there any relevant previous disease / medical history to this event (including previous drug reactions)?

Disease / Medical History	Start date			End date			Ongoing
	dd	mmm	yyyy	dd	mmm	yyyy	
1.							☐
2.							☐
3.							☐
4.							☐

9. Relevant previous treatment history / medical procedures ☐ Yes – *specify below* ☐ No – *go to Section 10*

Is there any relevant previous treatment history to this event (including operations or medical procedures)?

Treatment History	Start date			End date			Ongoing
	dd	mmm	yyyy	dd	mmm	yyyy	
1.							☐
2.							☐
3.							☐
4.							☐

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10. Any concomitant medication(s)? ☐ Yes – *specify below* ☐ No – *go to Section 11*

Record drugs being taken at the time of the event

Details of additional Concomitant Medication can be completed on the Additional Concomitant Medication form.

Additional form provided? ☐ Yes → No. of extra pages _____ ☐ No

Name (Do not list drugs used to treat the SAE)	Total daily dose / unit	Start Date			End Date			Ongoing
		dd	mmm	yyyy	dd	mmm	yyyy	
1.								☐
2.								☐
3.								☐
4.								☐
5.								☐

11. Serious Adverse Event Description

Include a history of the event chronologically including: signs and characteristics, severity, dates and outcome of hospitalization and any other relevant information not captured elsewhere on the form. If non-serious events are included in this text, please add (NS) after the event term. ☞ Bitte Arztbrief und alle zusätzlichen Informationen nachliefern ☜

12. ♦* Investigator name and address:

Plunger (Stempel)

Investigator Name: _____

Investigator Address: _____

_____

_____

Investigator/Designee Signature: _____ _____

Date of signature (dd/mmm/yyyy)

If designee, print name: _____