Version: March 2012

Therapy Study ALCL-Relapse

Studienleitung: Prof. Dr. A. Reiter, Universitäts-Klinikum Gießen, Kinderklinik, Päd. Hämatologie und Onkologie, Feulgenstr. 12, 35385 Gießen, Tel.: 0641 - 985-43627 (Studienzentrale); -43626 (Studiendokumentation); Fax: 0641 - 985-43629

Registration

All patients who fulfil the registration criteria are registered in the study, regardless whether they are eligible for trial's result evaluation. The registration fax must be sent to the responsible data centre within 14 days.

Surname (or initial): _____ First name (or initial): _____

Date of birth: |__|__|.|__|__|.|__|__| (dd mm yy) sex: ❑ male ❑ female
(age < 22 years)

Please note: before sending this form to the responsible data centre, the informed consent for data exchange, digital data storage and data processing must be signed by patient / guardian(s)

Eligibility to the study

- Progression or relapse of an anaplastic large cell lymphoma diagnosed by histomorphological and/or cytomorphological characterisation? ❑ no ❑ yes
- Slides of relapsed lymphoma available for national/international pathological and/or cytomorphological review? ❑ no ❑ yes
- Signed informed consent for participation in the study ALCL-Relapse? ❑ no ❑ yes
- For female patients: No evidence for pregnancy or lactation period and assured contraception? ❑ no ❑ yes
- Simultaneous participation in another clinical study? ❑ no ❑ yes
  If "yes": which clinical study _____

Evaluable for trial's results?

- 1st relapse of ALCL? ❑ no ❑ yes
  if no, (subsequent relapse of ALCL) Number of relapse |__|
- significant pre-treatment for first relapse? ❑ no ❑ yes
- adequate hepatic, renal and cardiac function? ❑ no ❑ yes
- HIV infection or AIDS? ❑ no ❑ yes
- severe immunodeficiency? ❑ no ❑ yes
  if "yes": specify: _____
- previous organ transplantation? ❑ no ❑ yes
  if "yes": specify: _____
- Previous malignancy prior to the ALCL? ❑ no ❑ yes
  if "yes": specify: _____
- Other pre-existing disease prohibiting therapy as per instruction of the protocol? ❑ no ❑ yes
  if "yes": specify: _____
- pre-condition prohibiting the conditioning regimen as per instruction of the protocol? ❑ no ❑ yes
  if "yes": specify: _____

Study Group: _____ Treating centre: _____

Responsible physician: _____

Phone: _____ Fax: _____

Hospital-Stamp	Date (dd mm yy)	Name (in block letters)	Signature
			responsible physician

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Diagnosis of Relapse (page 1/3).

Surname (or initial): _____ First name (or initial): _____

Date of birth: |__|__|.|__|__|.|__|__| (dd mm yy) Registration number: |__|__|__|__|__|

Please note: before sending this form to the responsible data centre, the informed consent for data exchange, digital data storage and data processing must be signed by patient / guardian(s)

Anamnesis

history / anamnesis lymphomatoid papulomatosis: ❑ no ❑ yes

General condition at diagnosis of relapse:

Score	Karnofsky Description (patients older than 16 years)	Lansky Description (Patients younger than 16 years)
100%	normal, no complaints, no evidence of disease.	Fully active, normal.
90%	Able to carry on normal activity; minor signs or symptoms of disease.	Minor restrictions in physically strenuous activity.
80%	normal activity with effort; some signs or symptoms of disease.	Active, but tires more quickly.
70%	Cares for self, unable to carry on normal activity or do active work.	Both greater restriction of and less time spent in play activity.
60%	Requires occasional assistance, but is able to care for most of his/her needs	Up and around, but minimal active play, keeps busy with quieter activities.
50%	Requires considerable assistance and frequent medical care.	Gets dressed, but lies around much of the day; no active play; able to participate in all quiet play and activities.
40%	Disabled, requires special care and assistance.	Mostly in bed; participates in quiet activities.
30%	Severely disabled, hospitalisation indicated. Death not imminent.	In bed; needs assistance even for quiet play.
20%	Very sick, hospitalisation indicated. Death not imminent.	Often sleeping; play entirely limited to very passive activities.
10%	Moribund, fatal processes progressing rapidly.	no play; does not get out of bed.

Diagnosis of relapse by

❑ puncture of bone marrow or malignant effusion

❑ surgery: ❑ fine-needle biopsy ❑ biopsy ❑ (partial-) resection

Date of diagnostic surgery / puncture: |__|__|.|__|__|.|__|__| (dd mm yy)

Please give the organ(s) / localisation(s) / anatomic area(s) from which the biopsy or puncture was taken:

_____

_____

Diagnostic before start of therapy:

- **Bone marrow:** Lymphoma-cells in bone marrow aspirates (%): |__|__|__| ❑ not done
- **CSF:** nucleated cells /µl CSF: |__|__|__|__|__|

  blasts / lymphoma-cells in CSF ❑ no ❑ yes

<u>Local</u> diagnosis / on-site findings:

- <u>local Histology:</u> *(Please send a copy of the report to the responsible data centre!)*
  ❑ relapse of ALCL CD3: ❑ positive ❑ negative ❑ not tested
  ❑ other diagnosis: _____
  ❑ not done
- <u>local Cytomorphology:</u> *(Please send a copy of the report to the responsible data centre!)*
  ❑ relapse of ALCL
  ❑ other diagnosis: _____
  ❑ not done

<u>Reference</u> diagnosis of relapsed ALCL:

- Reference histology initiated: ❑ no ❑ yes, at: _____
  (Please send a copy of the report to the responsible data centre!)
- Reference cytomorphology initiated: ❑ no ❑ yes, at: _____
  result: ❑ relapse of ALCL ❑ other:_____ _____
  (Please send a copy of the report to the responsible data centre!)

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Therapy Study ALCL-Relapse

Diagnosis of Relapse (page 2/3).

Surname (or initial): _____ First name (or initial): _____

Date of birth: |__|__|.|__|__|.|__|__| (dd mm yy) Registration number: |__|__|__|__|__| (if known)

Manifestations of relapsed ALCL	clinical examination			ultrasound			x-ray			CT / MRI		
	Please tick the appropriate box for each examination and for each localisation, even if examination was not carried out or if there were no pathological findings!											
	not tested	-	+	not tested	-	+	not tested	-	+	not tested	-	+
CNS												
CNS: tumour intra-cerebral	❑	❑	❑							❑	❑	❑
intra- medullary	❑	❑	❑							❑	❑	❑
CNS: cerebral nerve palsy	❑	❑	❑									
PERIPHERAL LYMPH NODES (LN)												
LN cervical, submandibular, nuchal	❑	❑	❑	❑	❑	❑				❑	❑	❑
LN supra- / infraclavicular / axillary	❑	❑	❑	❑	❑	❑				❑	❑	❑
LN inguinal	❑	❑	❑	❑	❑	❑				❑	❑	❑
other peripheral LN	❑	❑	❑	❑	❑	❑				❑	❑	❑
HEAD AND NECK												
area of ear, nose and throat (ENT)	❑	❑	❑	❑	❑	❑				❑	❑	❑
other manifestation(s) of head and neck	❑	❑	❑	❑	❑	❑				❑	❑	❑
THORAX												
mediastinum				❑	❑	❑	❑	❑	❑	❑	❑	❑
pleura / pleural effusion	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
pericard / pericardial effusion				❑	❑	❑	❑	❑	❑	❑	❑	❑
lung				❑	❑	❑	❑	❑	❑	❑	❑	❑
other thoracal manifestation(s)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
ABDOMEN												
ascites				❑	❑	❑				❑	❑	❑
bowel	❑	❑	❑	❑	❑	❑				❑	❑	❑
liver	❑	❑	❑	❑	❑	❑				❑	❑	❑
spleen	❑	❑	❑	❑	❑	❑				❑	❑	❑
kidney(s) ❑ unilateral ❑ bilateral	❑	❑	❑	❑	❑	❑				❑	❑	❑
abdominal LN	❑	❑	❑	❑	❑	❑				❑	❑	❑
other abdominal manifestation(s)	❑	❑	❑	❑	❑	❑				❑	❑	❑
OTHER LOCALISATIONS												
testis/ovary/adnexa ❑ unilateral ❑ bilateral	❑	❑	❑	❑	❑	❑				❑	❑	❑
soft tissue ❑ unilocular ❑ multilocular	❑	❑	❑	❑	❑	❑				❑	❑	❑
skin ❑ unilocular ❑ multilocular	❑	❑	❑									
bone(s) ❑ unilocular ❑ multilocular	❑	❑	❑							❑	❑	❑
↳ bone scan: ❑ not tested ❑ neg. ❑ pos.												
epidural				❑	❑	❑				❑	❑	❑
other localisation(s): _____	❑	❑	❑	❑	❑	❑				❑	❑	❑

Stage (Murphy/St. Jude): ❑ I ❑ II ❑ III ❑ IV

Frontline treatment:

Date of first diagnosis of ALCL: |__|__|.|__|__|.|__|__| (dd mm yy)

CD3 (immunohistochemical / immunological) in first diagnosis of ALCL:

- local pathologist: ❑ not done ❑ negative ❑ positive
- reference pathologist: ❑ not done ❑ negative ❑ positive

Date of the end of intensive treatment of first ALCL: |__|__|.|__|__|.|__|__| (dd mm yy)
❑ not applicable (relapse during the intensive frontline treatment)

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Therapy Study ALCL-Relapse

Diagnosis of Relapse (page 3/3).

Surname (or initial): _____ First name (or initial): _____

Date of birth: |__|__|.|__|__|.|__|__| (dd mm yy) Registration number: |__|__|__|__|__|__| (if known)

Treatment of relapsed ALCL

Date of the beginning of the protocol treatment ("ALCL-Relapse"): |__|__|.|__|__|.|__|__| (dd mm yy)

Treatment according to protocol ALCL-Relapse

- ❑ Arm 1: progression during frontline therapy: Re-induction ICM-ICI and doner search for allogenic SCT
- ❑ Arm 2 : relapse after end of frontline therapy; initially CD3 positive: Re-induction CC-CC(-CVA) and doner search for allogenic SCT (2a) or Vinblastine treatment for 24 months (2b new)
- ❑ Arm 3new: relapse after end of frontline treatment, initially CD3 negative: Vinblastine treatment for 24 months
- ❑ other: _____

Notes:

_____	_____	_____	_____
Hospital-Stamp	Date (dd mm yy)	Name (in block letters)	Signature
		responsible physician	

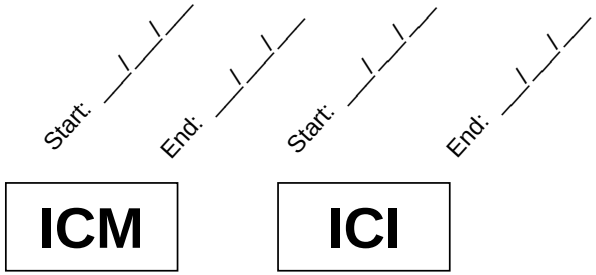
Therapy Study ALCL-Relapse: Chemotherapy after the 1st Relapse
Treatment-Overview (Re-Induction Treatment)

Version: March 2012

Name: _____ **Date of Birth:** |__|__|.|__|__|.|__|__| **Registration Number:** |__|__|__|__|

Progress during First Line Treatment (Arm 1)

Please give the dates and list treatment deviations and significant toxicities.



Treatment deviations: ☐ no
☐ yes: please describe and give the reason(s)

Severe toxicities: ☐ no
☐ yes: please describe and give NCI-grades and dates

Remarks:

Hospital stamp **Date** **Signature**

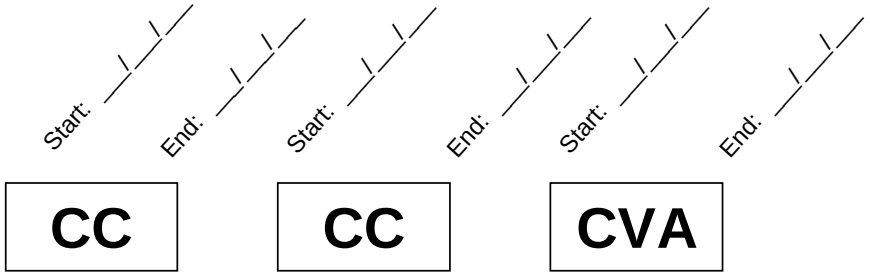
Therapy Study ALCL-Relapse: Chemotherapy after the 1st Relapse
Treatment-Overview (Re-Induction Treatment)

Version: March 2012

Name: _____ **Date of Birth:** |__|__|.|__|__|.|__|__| **Registration Number:** |__|__|__|__|

Progress of CD3 positive ALCL after Intensive Phase of Initial Treatment (Arm 2)

Please give the dates and list treatment deviations and significant toxicities.



Treatment deviations: ☐ no
☐ yes: please describe and give the reason(s)

Severe toxicities: ☐ no
☐ yes: please describe and give NCI-grades and dates

Further treatment:

- Matched sibling donor, 10/10, or 9/10 MUD found? ☐ no ☐ yes
- Further treatment: ☐ allogenic SCT planned on |__|__|.|__|__.|__|__| (dd.mm.yy)
  ☐ Vinblastine maintenance treatment

Remarks:

Hospital stamp **Date** **Signature**

Version: March 2012

Therapy Study ALCL-Relapse

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Treatment documentation
VBL for 24 months
(Please fill in one form every 12 weeks!)

Surname (or initial): _____ First name (or initial): _____

Date of birth: |__|__|.|__|__|.|__|__| (dd mm yy) Registration number: |__|__|__|__|__| (if known) Body weight: |__|__|__|,|__| kg Body height: |__|__|__| cm BSA: |__|,|__|__| m²

full dose VBL iv 6 mg/m²/week |__|__|, |__| mg (maximum single dose 10 mg)

Number of week	|__|__|	|__|__|	|__|__|	|__|__|	|__|__|	|__|__|	|__|__|	|__|__|	|__|__|	|__|__|	|__|__|	|__|__|
Date of VBL injection:												
VBL given [mg]	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|	|__|__|, |__|
In case of modification: reason												
haematological toxicity	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes
neurological toxicity	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes
other toxicity	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes
other reason *(if "yes": specify)*	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes	❑ no ❑ yes
blood count (if carried out)												
Leukocytes/µl:												
Hb g/dl:												
Platelets/µl:												
neurotoxicity (grade)*	|__|	|__|	|__|	|__|	|__|	|__|	|__|	|__|	|__|	|__|	|__|
other toxicity • **specify** • **NCI-grade** (see toxicity form)	|__|	|__|	|__|	|__|	|__|	|__|	|__|	|__|	|__|	|__|	|__|

*) Grade of Neurotoxicity: 0 = none; 1 = parethesias, mild subjective weakness; 2 = severe paresthesias and/or mild weakness;
3 = unbearable paresthesias, deficits in motoric function; 4 = paralysis

_____ _____ _____ _____

Hospital Stamp Date (dd mm yy) responsible physician:Name (in block letters) responsible physician: Signature

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Allograft (page 1/5)

Patient's name	Registration number	date of birth (dd mm yy)	UPN	Sex (m/f)
|_____|	|__|__|__|__|__|	|__|__|.|__|__|.|__|__|	|__|__|__|__|	|__|

This form should be submitted on day 100 and should reflect information until day 100 only.

Day 100 post transplant: |__|__| |__|__| |__|__| (dd/mm/yy)

Patient

HLA Type:

Molecular typing done: Class I ☐ no ☐ yes
Class II ☐ no ☐ yes

|__|__|__|__| A |__|__|__|__| B |__|__|__|__| C |__|__|__|__| DRB1 |__|__|__|__| DQB1
|__|__|__|__| A |__|__|__|__| B |__|__|__|__| C |__|__|__|__| DRB1 |__|__|__|__| DQB1

Disease status before SCT:

status ☐ CR after reinduction
☐ CR never achieved after diagnosis of ALCL relapse
☐ further relapse during / after reinduction

SCT after |__|. relapse. *(Please fill in the number of the relapse.)*

Donor

Relationship to recipient: ☐ unrelated ☐ related:
☐ monocygotic twin
☐ sibling
☐ parent
☐ other: _____

HLA Type:

Molecular typing done: Class I ☐ no ☐ yes
Class II ☐ no ☐ yes

|__|__|__|__| A |__|__|__|__| B |__|__|__|__| C |__|__|__|__| DRB1 |__|__|__|__| DQB1
|__|__|__|__| A |__|__|__|__| B |__|__|__|__| C |__|__|__|__| DRB1 |__|__|__|__| DQB1

Allograft (page 2/5)

Patient's name |_____| Registration number |__|__|__|__|__| date of birth (dd mm yy) |__|__|.|__|__|.|__|__| UPN |__|__|__|__|

Conditioning Regimen

Body height: |__|__|__| cm Body weight: |__|__|__|,|__| kg BSA: |__|,|__|__| m^2

Therapy

drugs, ATG, mono AB (product name)	daily dose given	mg/kg/d	$mg/m^2/d$	days of administration	total dose given (mg)	dosage according to protocol no	yes
Example: *Endoxan*	*40*	☒	☐	*-3*	*1200*	☐	☒
		☐	☐			☐	☐
		☐	☐			☐	☐
		☐	☐			☐	☐
		☐	☐			☐	☐

if dose modification, specify: |_____|

	no	yes	total dose	number of fractions	start day (dd.mm.yy)	end day (dd.mm.yy)
TBI	☐	☐	|__|__| Gy	|__|__|	|__|__|.|__|__|.|__|__|	|__|__|.|__|__|.|__|__|
CNS boost	☐	☐	|__|__| Gy	|__|__|	|__|__|.|__|__|.|__|__|	|__|__|.|__|__|.|__|__|
other boost	☐	☐	|__|__| Gy	|__|__|	|__|__|.|__|__|.|__|__|	|__|__|.|__|__|.|__|__|

if other, specify: |_____|

Transplantation

Date of transplantation (dd/mm/yy) |__|__| |__|__| |__|__|
Number of this transplantation |__|
Source of stem cells:
☐ BM
☐ PBSC
☐ cord blood

Manipulation of graft:
☐ no ☐ yes
If yes, type of manipulation:
T-Cell-Depletion: ☐ no ☐ yes method: |_____|
other: |_____| ☐ no ☐ yes method: |_____|

Cells infused: Number of nucleated cells: _____ $*10^8$/kg
CD34+ cells: _____ $*10^6$/kg
CD3+ cells: - T-cell depleted graft: _____ $*10^4$/kg
- unmanipulated graft: _____ $*10^7$/kg

Allograft (page 3/5)

Patient's name |_____| Registration number |__|__|__|__|__|__| date of birth (dd mm yy) |__|__|.|__|__|.|__|__| UPN |__|__|__|__|

Engraftment

Evidence of haematopoietic reconstitution: (dd/mm/yy)

Leucocytes	>1,000/µl:	|__|__|	|__|__|	|__|__|	☐ not reached
Neutrophils	>500/µl:	|__|__|	|__|__|	|__|__|	☐ not reached
Platelets	>20,000/µl:	|__|__|	|__|__|	|__|__|	☐ not reached
Platelets	>50,000/µl:	|__|__|	|__|__|	|__|__|	☐ not reached
last platelet transfusion:		|__|__|	|__|__|	|__|__|	☐ transfusions ongoing
last red cell transfusion:		|__|__|	|__|__|	|__|__|	☐ transfusions ongoing

Graft failure:

☐ no ☐ yes, date of diagnosis |__|__| |__|__| |__|__| (dd/mm/yy)

Reason of graft failure:
- ☐ non-engraftment / poor graft function
- ☐ rejection (=not reversible with cytokine treatment or reduction of immunosuppression)

GVHD prophylaxis

Cyclosporine A:

☐ no

☐ yes ⇒ target level of CSA: |__|__|__| ng/ml
date of CSA stop |__|__| |__|__| |__|__| (dd/mm/yy) ☐ CSA ongoing

Methotrexate:

☐ no ☐ yes ⇒ dose MTX: |____| |____| |____| |____| mg/m^2/d
days: +|___| +|___| +|___| +|___|

other GVHD prophylaxis:

☐ no ☐ yes ⇒ specify: |_____|

Acute GvHD

☐ no ☐ yes, date of onset: |__|__| |__|__| |__|__| (dd/mm/yy)

diagnosis based on: ☐ clinical evidence ☐ histologic evidence

overall grade ☐ 0 ☐ I ☐ II ☐ III ☐ IV

skin:	stage:	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
liver:	stage:	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
gut:	stage:	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

aGVHD resolved ☐ no ☐ yes, date |__|__| |__|__| |__|__| (dd/mm/yy)

Acute GvHD treatment

☐ no ☐ yes, specify:
- ☐ increase of CSA
- ☐ Methylprednisolone
- ☐ other: _____

_____

Allograft (page 4/5)

Patient's name	Registration number	date of birth (dd mm yy)	UPN
|________________________|	|__|__|__|__|__|	|__|__|.|__|__|.|__|__|	|__|__|__|__|

Chimerism

☐ not done ☐ done, please specify the results

PB/ BM	date of examination	% of donor cells	Method (FISH, VNTR, other)	Treatment Immunosuppression: none	unchanged	increased	reduced	stopped	DLI
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐
				☐	☐	☐	☐	☐	☐

Toxicities / complications < day 100

Please give grade 4 toxicities / complications:

____

____

____

____

Best response to SCT

☐ continued CR
☐ CR achieved: date CR achieved: \|__\|__\| \|__\|__\| \|__\|__\| (dd/mm/yy)
☐ no CR

Remission status – day 100 or at date of death

Relapse after SCT: ☐ not applicable (never in CR)
☐ no
☐ yes → *Please fill in an "Event" form.*

Allograft (page 5/5)

Patient's name |_____| Registration number |__|__|__|__|__| date of birth (dd mm yy) |__|__|.|__|__|.|__|__| UPN |__|__|__|__|

Survival status – day 100

☐ alive date of last follow up: |__|__| |__|__| |__|__| (dd/mm/yy)

Performance status criteria (Please mark the appropriate value)

Score	Karnofsky Description (patients elder than 16 years)	Lansky Description (Patients younger than 16 years)
100 %	normal, no complaints, no evidence of disease.	Fully active, normal.
90%	Able to carry on normal activity; minor signs or symptoms of disease.	Minor restrictions in physically strenuous activity.
80%	normal activity with effort; some signs or symptoms of disease.	Active, but tires more quickly
70%	Cares for self, unable to carry on normal activity or do active work.	Both greater restriction of and less time spent in play activity.
60%	Requires occasional assistance, but is able to care for most of his/her needs	Up and around, but minimal active play, keeps busy with quieter activities.
50%	Requires considerable assistance and frequent medical care.	Gets dressed, but lies around much of the day; no active play; able to participate in all quiet play and activities.
40%	Disabled, requires special care and assistance.	Mostly in bed; participates in quiet activities.
30%	Severely disabled, hospitalization indicated. Death not imminent.	In bed; needs assistance even for quiet play.
20%	Very sick, hospitalization indicated. Death not imminent.	Often sleeping; play entirely limited to very passive activities.
10%	Moribund, fatal processes progressing rapidly.	no play; does not get out of bed.

☐ Died → *Please fill in an "Event" form.*

Notes

Hospital Stamp | Date (dd mm yy) | Name (in block letters) responsible physician | Signature

Version: March 2012

Therapy Study ALCL-Relapse

Studienleitung: Prof. Dr. A. Reiter, Universitäts-Klinikum Gießen, Kinderklinik, Päd. Hämatologie und Onkologie, Feulgenstr. 12, 35385 Gießen, Tel.: 0641 - 985-43627 (Studienzentrale); -43626 (Studiendokumentation); Fax: 0641 - 985-43629

Follow up – SCT (page 1/2)

Patient's name	Registration number	date of birth (dd mm yy)
|_____|	|__|__|__|__|__|__|	|__|__|.|__|__|.|__|__|

☐ **1 year** ☐ **2 years** ☐ **3 years** ☐ **4 years** **|__| years after SCT**

Please report on all events occurring during the following period only:
|__|__| |__|__| |__|__| (dd/mm/yy) to |__|__| |__|__| |__|__| (dd/mm/yy)

Disease status

☐ continued CR
☐ no remission
☐ relapse → *Please fill in an "Event" form.*

Chronic GvHD

☐ no

☐ yes: ☐ limited ☐ extended

cGvHD resolved: ☐ no ☐ yes, date |__|__| |__|__| |__|__| (dd/mm/yy)

Complications / Late Effects

	no	yes		Date of 1st occurrence (dd mm yy)	Specification of late effect(s)	NCI-Grade
• cardiovascular system	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• CNS / peripheral nerves	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• endocrinology	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• lung / respiratory tract	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• psychosocial late effects	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• kidney / urinary tract	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• sensory organs	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• musculoskeletal system	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• liver	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• skin	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• haematology	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• gastrointestinal tract	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• other	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|

Secondary malignancy

☐ no ☐ yes → *Please fill in an "Event" form.*

Follow up – SCT (page 2/2)

Patient's name	Registration number	date of birth (dd mm yy)
|_____|	|__|__|__|__|__|	|__|__|.|__|__|.|__|__|

Survival status

☐ Alive Date of last follow up: |__|__| |__|__| |__|__| (dd/mm/yy)

☐ Died → *Please fill in an "Event" form.*

Notes

Hospital Stamp	Date (dd mm yy)	Name (in block letters) responsible physician	Signature

Version: March 2012

Therapy Study ALCL-Relapse

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Follow up – Vinblastine

Patient's name |_____| Registration number |__|__|__|__|__|__| date of birth (dd mm yy) |__|__|.|__|__|.|__|__|

☐ **1 year** ☐ **2 years** ☐ **3 years** ☐ **4 years** **|__| years after end of VBL**

Please report on all events occurring during the following period only:
|__|__| |__|__| |__|__| (dd/mm/yy) to |__|__| |__|__| |__|__| (dd/mm/yy)

Disease and Survival Status

Alive? ☐ no ☐ yes ⇒ date of last follow up: |__|__| |__|__| |__|__| (dd/mm/yy)

Event (relapse / progression, secondary malignancy, late event, death) occurred?
☐ no ☐ yes ⇒ *Please fill in an event form!*

Late Effects

Late effect(s):	no	yes		Date of 1st occurrence (dd mm yy)	Specification of late effect(s)	NCI-Grade
• cardiovascular system	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• CNS / peripheral nerves	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• endocrinology	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• lung / respiratory tract	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• psychosocial late effects	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• kidney / urinary tract	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• sensory organs	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• musculoskeletal system	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• liver	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• skin	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• haematology	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• gastrointestinal tract	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|
• other	❑	❑	→	|__|__|.|__|__|.|__|__|	_____	|__|

Notes / Specification of late Effects

_____ Hospital Stamp _____ Date (dd mm yy) _____ Name (in block letters) _____ Signature
responsible physician

Version: March 2012

Therapy Study ALCL-Relapse

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Events

should be sent at lastest two weeks after occurrence of any event

Surname (or initial): _____ First name (or initial): _____

Date of birth: |__|__|.|__|__|.|__|__| (dd mm yy) Registration number: |__|__|__|__|__|__| (if known)

Progression / Relapse ❑ no ❑ yes, at |__|__|.|__|__|.|__|__| (dd mm yy)

Localisation(s) of progression / relapse:

- bone marrow ❑ no ❑ yes
- CNS ❑ no ❑ yes
- reappearance or increase of residuals ❑ no ❑ yes:_____
- appearance of new location(s) ❑ no ❑ yes:_____

Therapy of progression or relapse planned / done?

❑ no ❑ yes:_____

Second Malignancy ❑ no ❑ yes, at |__|__|.|__|__|.|__|__| (dd mm yy)

Diagnosis: ❑ AML ❑ MDS other:_____

Therapy after diagnosis of second malignancy

❑ no ❑ yes: _____

Patient died ❑ no ❑ yes, at |__|__|.|__|__|.|__|__| (dd mm yy)

Autopsy: ❑ no ❑ yes

Reason for death:

❑ caused by progression of lymphoma

❑ caused by therapy complications

❑ chemotherapy-related causes

❑ transplantation-related causes

- GvHD ❑ no ❑ yes
- graft failure ❑ no ❑ yes
- pulmonary toxicities ❑ no ❑ yes
- cardiac toxicities ❑ no ❑ yes
- infection ❑ no ❑ yes
- veno occlusive disorder (VOD) ❑ no ❑ yes
- posttransplant lymphoproliferative disorder (LPD) ❑ no ❑ yes
- unknown ❑ no ❑ yes
- other ❑ no ❑ yes, please specify: _____

❑ caused by other reasons:_____

Date of last examination |__|__|.|__|__|.|__|__| (dd mm yy)

Notes:

Hospital Stamp	Date (dd mm yy)	Name (in block letters) responsible physician	Signature

Version: March 2012

Therapy Study ALCL-Relapse

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Serious Adverse Events (SAE)

Please send a Fax to the National Study Centre within 48 hours.

Surname (or initial): _____ First name (or initial): _____

Date of birth: |__|__|.|__|__|.|__|__| (dd mm yy) Registration number: |__|__|__|__|__|(if known)

Reasons for SAE Report

- death of the patient — please fill in the "Event" form and send it to the responsible data centre ❑ no ❑ yes
- life-threatening event ❑ no ❑ yes
- impairment of further therapy as per instruction of the protocol ❑ no ❑ yes
- unscheduled in-patient hospitalisation or prolongation of hospitalisation ❑ no ❑ yes
- persistent significant disability or incapacity ❑ no ❑ yes
- medically significant event or an event which requires intervention to prevent one or other of the outcomes listed above ❑ no ❑ yes
- unexpected, severe side effects, which can not be documented on the toxicity form ❑ no ❑ yes

NCI-CTC toxicity grading of SAE: ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ unknown / not to arrange

Beginning resp. detection of the SAE: at |__|__|.|__|__|.|__|__| (dd mm yy)

During/after therapy element: ❑ 1st CC ❑ 2nd CC ❑ CVA ❑ ICM ❑ ICI ❑ Conditioning regimen ❑ after SCT ❑ other, please specify:_____

Please describe the event and the taken measures:
(Symptoms, localisation, laboratory reports, diagnostics, duration, therapy and course; if necessary please attach additional sheet)

_____

_____

Medication at the occurrence of the SAE

N°	Medicament	Daily dosage	Application	Dates of therapy (from/to)	Relationship between medication and event					
					not related	unlikely	possible	probable	related	insufficient data to assess
1.					❑	❑	❑	❑	❑	❑
2.					❑	❑	❑	❑	❑	❑
3.					❑	❑	❑	❑	❑	❑
4.					❑	❑	❑	❑	❑	❑
5.					❑	❑	❑	❑	❑	❑
6.					❑	❑	❑	❑	❑	❑
7.					❑	❑	❑	❑	❑	❑
8.					❑	❑	❑	❑	❑	❑
9.					❑	❑	❑	❑	❑	❑
10.					❑	❑	❑	❑	❑	❑

- Has (have) one (or several) treatment(s) been stopped? ❑ no ❑ yes, N°: _____
- Did reaction abate after stopping the treatment(s)? ❑ no ❑ yes, N°: _____
- Has (have) one (or several) treatment(s) been reintroduced? ❑ no ❑ yes, N°: _____
- Did reaction reappear after reintroduction? ❑ no ❑ yes, N°: _____
- Was (were) the dosage(s) changed? ❑ no ❑ yes, N°: _____

According to your opinion, SAE is related to:

❑ Disease aggravation, which the patient was in the trial for ❑ Other concomitant disease(s)
❑ Treatment according to Protocol ALCL-Relapse ❑ Other concomitant treatment(s)
❑ Other known or suspected cause(s), please comment: _____

Outcome of the SAE

❑ Ongoing ❑ Recovered without after-effects ❑ Recovered with after-effects
❑ Death due to the SAE ❑ Death unconnected with the SAE

Date of recovering or of death: |__|__|.|__|__|.|__|__| (dd mm yy) or ❑ not applicable (still ongoing)

_____ _____ _____ _____
Hospital Stamp Date (dd mm yy) Name (in block letters) Signature
responsible physician

Version: March 2012

Therapy Study ALCL-Relapse

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Histopathological and Immunohistochemical Review page 1/2

(form to be completed by the reference pathology center)

Surname (or initial): _____ First name (or initial): _____

Date of birth: |__|__|.|__|__|.|__|__| (dd mm yy) Registration number: |__|__|__|__|__|(if known)

Local histology number ..... |_____|

Type of review ..... National (1) International (2) |__|

Date of review ..... |__|__| |__|__| |__|__|__|__|

For the national review, name of the reviewer ..... |__|__|__|__|__|__|__|__|__|__|

Review histology number ..... |_____|

Site of biopsy :

- Lymph node ..... no (0) yes (1) |__|
- Skin ..... no (0) yes (1) |__|
- Soft tissue mass ..... no (0) yes (1) |__|
- Other ..... no (0) yes (1) |__|

Bone marrow biopsy ..... negative (0) positive (1) ND (X) |__|

- If positive ..... no HE (0) after IHC (1) |__|

Diagnosis :

- ALCL 1
- Hodgkin's disease 2
- B-NHL 3
- T-NHL 4
- NHL NOS (not otherwise specified) ..... 5 |__|
- Other 6
  - Specify : ..... |__|__|__|__|__|__|__|__|__|__|

Subtype of ALCL according to WHO classification[43]:

- Classical ..... 1 |__|
- Giant cell 2
- Small cell 3
- Lymphohistiocytic 4
- Hodgkin's like 5
- Mixed 6
  - Component (example : for Classical + small cell + Lymphohistiocytic = 1-3-4) .....
- Other ..... 7 |__| |__| |__|
  - Specify ..... |__|__|__|__|__|__|__|__|__|__|
- Unclassifiable 8

Other Morphologic parameters :

- Perivascular pattern ..... no (0) yes (1) |__|
- Other ..... no (0) yes (1) |__|
  - Specify ..... |__|__|__|__|__|__|__|__|__|__|

Histopathological and Immunohistochemical Review page 2/2

(to be completed by the reference pathology center)

Patient's name |_____| Registration number |__|__|__|__|__| date of birth (dd mm yy) |__|__|.|__|__|.|__|__|

Immunophenotype on paraffin embedded tissue

Mandatory antibodies :					
Alk 0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
For Alk,	Nuclear and cytoplasmic 1				
	Cytoplasmic restricted 2				
	Cytoplasmic with membrane reinforcement 3				
	Restricted to the membrane 4				|__|
CD30 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 3 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
Optional antibodies :					
CD 2 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 5 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 20 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 43 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 56 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
Perforin 0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
Granzyme B 0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
EMA 0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
bcl-2 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 15 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CLA (CD45) 0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
Cytotoxic markers :					
Tia 1 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
T cell markers :					
CD 4 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 7 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 8 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
B cell markers :					
CD 79a 0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD 22 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
Other antibodies :					
UCHL1 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
ß-F1 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
LMP 1 .....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
CD68/KP1 or PGM1 .0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|
.....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|__|__|__|__|__| |__|
.....0 (0)	+ (1)	++ (2)	+++ (3)	ND (4)	|__|__|__|__|__|__| |__|

Cell lineage :

..... null (0) T/NK (1) B (2) Undeterminate (3) |__|