

Visit 1

Patient No.:		Date of birth	n:		Sex:	□ m	□ f	
Hospital:								
Contact person:								
a) treating physician			/	e-	mail:			
b) study nurse:			/	e-	mail:			
1) Visit date (DD/MM/YYYY):: _								
2) written informed consent		•	•	•	•			
3) Pre-treatment in another hospital: no yes, in								
4) Reason for diagnosis:								
scheduled health supervision	on visit							
☐ CML detected incidentally								
☐ tumor-related symptoms ca		with physician	→ which symp	otoms				
	5) Malignancies or immunodeficiency among family members: none yes:							
6) DATE (DD/MM/YYYY) when di	agnosis of CN	IL was confirm	ed :					
→ confirmation of diagnosis by cytogenetics □ yes □ no								
	by quantitative PCR							
	by qualita	tive. PCR	yes \square no					
7) Stage of disease (acc. to cr	riteria listed in	the protocol):	☐ Chronic Pl	hase \square Acc	celerated Ph	nase \square	☐ Blastic Phase	
8) First symptoms:								
drop in performance:	\Box no	□ yes						
fever:	\Box no	□ yes						
organomegaly-related	\Box no	□ yes						
loss of body weight:	\Box no	□ yes						
9) Additional complaints / underlying diseases:								
10.70								
10) Therapy with imatinib			4			/ ?		
start date (DD/MM/YYYY):			dose:		mş	g/m²		
11) Additional therapy: n	nono 🗆 was -	A giva dataila:						
11) Additional therapy:	ione — yes	give details:						



12) General perforn	nance (La	nsky perfo	rmar	ice status	s): DATE (DD	/MM/YYYY)	:·				
□ 100%: fully active, normal				50%	□ 50%: gets dressed, but lies around much of the day,						
□ 90%: minor restrict	ions in phys	sically strent	uous a	ctivity	no ao	no active play, able to participate in all quiet play and activities					
□ 80%: active, but tire	es more qui	ckly			40%	: mostly in	bed, p	participates in quiet ac	tivities		
□ 70%: both greater restriction of, and less time,			□ 30%	: in bed, n	eeds as	sistance even for quie	t play				
spent in active play			20%	: often slee	eping, j	olay entirely limited to	very passiv	e activities			
□ 60%: up and around, but minimal active play □ 10%: no play, do				does no	ot get out of bed						
keeps busy with quie	eter activitie	es			□ 0%:	unrespons	ive				
13) Examinations at diagnosis:											
a) Clinical examinat	tion: DATI	E (DD/MM/YY	YY): _	_·_·		he	ight: _	cm b	ody weight	:,_kg	
• splenomegaly: \square no \square yes, cm below costal margin											
hepatomegaly: □ no □ yes, cm below costal margin											
ultrasound (DD/MM/YYYY) → regular □ yes □ no, give details											
extramedullary n			 □ no			tion:	_				
· ·					•	tion	тушр	ii iiodes 🗀 sk	111		
additional clinication	al patholog	ical findin	gs:								
b) Blood count : DA	TE (DD/MM/	YYYY):		_							
	(55)1111	I	· ·						1		
Leukocytes / µl				Blasts (%				Eosinophils (%)			
Thrombocytes / µl				Promyelo	cytes (%)			Basophils (%)			
Erythrocytes (Mio/µl)	1			Myelocyt	es+Meta (%)			Monocytes (%)			
Hb (encircle [g/dl] or	[mmol/l])			Bands (%)			Lymphocytes (%)			
MCV (fl)	CV (fl) Neutrophils (%)					Reticulocytes ([‰] or [%])					
						Normoblasts (%)					
c) Blood chemistry:	DATE (DD	/MM/YYYY):		•							
	value	unit			value	unit	7		value	unit	
Bilirubin (total)	74140		Gan	nma-GT	74146			reatinine	, arac		
ALAT			LDF					lkaline Phosphatase			
ASAT				acid				ikanne i nospiiatase			
ASA1			Onc	acid			_				
d) <u>Bone marrow dif</u>	<u>ferentiatio</u>	on: DATE (DD/MM	/YYYY): _			(p	lease add photocop	y of labora	tory result)	
Blasts (%) Promyelocytes (%			es (%)		I I	Myelocytes + Meta~ (%)				
	injectories (iv)										
e) <u>Bon</u> e marrow bio	e) Bone marrow biopsy: DATE (DD/MM/YYYY):			(r	lease add photocop	y of laborat	ory result)				
cellularity: %		grad of fibro					4	1	•	,	
/		6	_								
f) Cytogenetic analy	f) Cytogenetic analysis of bone marrow: DATE (DD/MM/YYYY): (please add photocopy of laboratory result)					cory result)					
Location of laborator	y:										
method: G-band	ding [□ i	interphase;		metapha	se]	FISH					
memor. — C canoning [— merphane, — memphane] — 11911											



→ number of analyzed mitoses	karyotype:							
☐ Ph ⁺ negative								
\square Ph ⁺ positive: \rightarrow % Ph ⁺ cells	additional abnormalities:							
g) Molecular analysis: DATE (DD/MM/YYYY):	(please	add photocopy of laboratory results)						
Location of laboratory:	materia	l: □ bone marrow □ blood						
\rightarrow transcript: \Box b2a2 \Box b	3a2 □ b2a2+b3a2 □ variant:							
• qualitative PCR: BCR-ABL negation	ive							
☐ BCR-ABL positi	ve [□ M-BCR-ABL; □ m/M-BCR-ABL	;						
quantitative PCR: Ratio Control/BCR-ABL:								
14) HLA-typing has been performed for	the patient? ☐ yes ☐ no							
15) Concomitant medication	-4:"							
Please complete page "Concomitant medic	auon							
Remarks:								
DATE (DD/MM/YYYY) NAME (READABI	E!) SIGNATURE	HOSPITAL (STAMP)						
·								
■ Reply:	In case of questions	please contact:						
Prof. Dr. med. Markus Metzler	Study Chair: Prof. D							
Universitätsklinikum Erlangen Kinder- und Jugendklinik		1/85-33731 (Secretary)						
Pädiatrische Hämatologie und Onkologie Loschgestr. 15 D-91054 Erlangen		1/85-35742 (Fax) tzler@uk-erlangen.de						



Visit 2-4

Visit 2 (d14) [only for patients in blastic and		3 (d28/1 month)	□ Visit 4 (2 months a	fter diagnosis)					
[only for parents in change and		sease status on date a	s indicated)						
Patient No.:	Date of birth	h:	Date of diagnosis:	· ·					
Hospital:									
Contact person:									
a) treating physician		/	e-mail:						
b) study nurse:		/	e-mail:						
1) Visit date (DD/MM/YYYY									
2) Patient alive at this v	isit: \square yes \square no \rightarrow	day of death (DD/MM/YY	YYY): · ·						
		Cause of death:							
		Patients last visit date	(DD/MM/YYYY):: · ·	- —					
3) Therapy continued in another clinic: none yes, in:									
4) Course of disease:		_							
still in 1st Chronic Ph	ase	☐ Accelerated Pha	se on (DD/MM/YYYY) · _ · _						
☐ Blastic Phase on (DD/M	M/YYYY) · ·	☐ in 2nd Chronic I	Phase since (DD/MM/YYYY) · _						
5) Comorol monformono	(I and montaneous as at a tree)	DATE (
_	e (Lansky performance status)								
□ 100%: fully active, norm	in physically strenuous activity	_	ed, but lies around much of the day, ble to participate in all quiet play and						
■ 80%: active, but tires m			ped, participates in quiet activities	activities					
□ 70%: both greater restriction	•		eds assistance even for quiet play						
spent in active play	,		oing, play entirely limited to very pa	assive activities					
□ 60%: up and around, bu	t minimal active play	□ 10%: no play, do	pes not get out of bed						
keeps busy with quieter a	activities	□ 0%: unresponsiv	re						
6) Therapy:	DATE (DD/MM/YYYY)	DATE (DD/MM/YY							
Imatinib: no	yes, from	until	_ dose:	mg					
	yes, from	until	_ dose:	mg					
	yes, from	until	_ dose:	mg					
Hydroxyurea: □ no	yes, from	until	_ dose:	mg					
Interferon: no	yes, from	until	_ dose:	mg					
Transplantation:	es, scheduled date (DD/MM/YYYY):								
	ot scheduled (give additional co	mments by 'Remarks' s	see end of file)						



7) Toxicity (maxi	imal grade ac	cording to	o Common Term	inology Cri	teria for A	dvers	e Events v3.0, CTCA	AE)	
<u>Hematological:</u>									
□ anemia → gra	de:		□ neutropenia	a → grade:			☐ thrombocytoper	nia → grade	e:
Non hematologic	<u>cal:</u>								
□ skin rash → gr	rade:		□ nausea → §	grade:			□ vomiting → gra	de:	
□ diarrhoe → gr	ade:		□ edema → g	grade:			☐ muscle cramps	→ grade: _	
\Box headache \rightarrow g	rade:		☐ liver transa	minase ele	vation → g	rade:			
☐ infection, spec	cifiy:					→ gra	ade:		
\Box other, specify	(e.g. bone me	etabolism,	, hearth function)	:					
						→ gra	ade:		
o = 0 = 1									
8) The following	examination	ns should	be done:						
a) Clinical exam	ination: DAT	ΓE (DD/MM/	YYYY): · ·		he	ight:	cm b	ody weight	t: , _ kg
• splenomegal	y: no	□ yes	s, cm	below costa	l margin				
• hepatomegal	y: 🗆 no	□ yes	s; cm	below costa	l margin				
ultrasound (DD/MM/YYYY) → regular □ yes □ no, give details									
• extramedulla	ry manifestat	tion:	no ye	es, locati	on: 🗆 ly	ymph	nodes	in	
additional cli	nical patholo	gical find	ings:						
b) Blood count:	DATE (DD/MM	I/YYYY):	_ · ·						
Leukocytes / µl			Blasts (%)			Eosinophils (%)		
Thrombocytes / µ	1		Promyelo	ocytes (%)			Basophils (%)		
Erythrocytes (Mic	o/μl)		Myelocyt	tes+Meta (%)		Monocytes (%)		
Hb (encircle [g/dl] or [mmol/l])		Bands (%	5)			Lymphocytes (%)		
MCV (fl)			Neutroph	ils (%)			Reticulocytes ([‰]	or [%])	
							Normoblasts (%)		
c) <u>Blood chemist</u>	<u>ry</u> : DATE (D	D/MM/YYYY	´): · ·			_			
	value	unit		value	unit			value	unit
Bilirubin (total)			Gamma-GT				Creatinine		
ALAT			LDH			A	Alkaline Phosphatase		
ASAT			Uric acid						
1) 3.6 1 1	1					,	1 11 1 .	C1 1	1,)
d) Molecular ana						()	please add photocopy	y of laborat	ory results)
→ schedule: only	at visit 3 (d2	28/1 month	h) and visit 4 (2 r	nonth)					
Location of labor	atory:					n	naterial: bone m	narrow	□ blood
→ transcript:	□ b2a2	2 =	□ b3a2 □	b2a2+b3a2		varia	ant:		
• qualitative Po	CR: BCR	R-ABL neg	gative						
	\square BCR	R-ABL pos	sitive [M-B	CR-ABL;	□ m/M	-BCF	R-ABL; \square m-B	BCR/ABL]	



quantitative PCR: Ratio Control/BCR-ABL:	
9) Present response on imatinib therapy (see criteria in protocol	chapter 18.4)
→ DATE (DD/MM/YYYY):	
a) clinical / hematological response (organomegaly / blood cell c	
b) cytogenetic response (Ph ⁺): \square 0%, \square 1-34%, \square 35-65%, \square	
c) molecular response (BCR-ABL): BCR-ABL-pos	BCR-ABL-reduction BCR-ABL-neg.
10) Results of HLA-typing for patient (schedule: only at visit 3 (d28/1 month)):
HLA – A:/ HLA – DRB:	/
HLA – B: / HLA – DQB:	/
HLA – C:/	
11) AE/SAE	
Please complete pages "Adverse Event" / "SAE-Report"	
12) Concomitant medication	
Please complete page "Concomitant medication"	
Remarks:	
DATE (DD/MM/YYYY) NAME (READABLE!) SIG	GNATURE HOSPITAL (STAMP)
E Reply:	In case of questions please contact:
Prof. Dr. med. Markus Metzler	Study Chair: Prof. Dr. med. M. Metzler
Universitätsklinikum Erlangen Kinder- und Jugendklinik	*** +49/(0) 9131/ 85-33731 (Secretary)
Pädiatrische Hämatologie und Onkologie Loschgestr. 15 D-91054 Erlangen	 → +49/(0) 9131/85-35742 (Fax) ✓ Markus.Metzler@uk-erlangen.de
GERMANY	



Visit 5-12

Visit 5 (3 months) Visit 8 (12 months) Visit 11 (21 months) Visit 6 (6 months) Visit 9 (15 months) Visit 12 (24 months) Visit 7 (9 months) Visit 10 (18 months) Patient No.: Date of birth:
Visit 7 (9 months)
Patient No.: Date of birth: Date of diagnosis:
Patient No.: Date of birth: Date of diagnosis: (DD/MM/YYYY) (DD/MM/YYYY) Hospital:
Hospital:
Hospital:
Contact person: a) treating physician
a) treating physician
b) study nurse:
1) Visit date (DD/MM/YYYY): 2) Patient alive at this visit: □ yes □ no → day of death (DD/MM/YYYY): Cause of death: Patients last visit date (DD/MM/YYYY): 3) Therapy continued in another clinic: □ none □ yes, in:
1) Visit date (DD/MM/YYYY): 2) Patient alive at this visit: □ yes □ no → day of death (DD/MM/YYYY): Cause of death: Patients last visit date (DD/MM/YYYY): 3) Therapy continued in another clinic: □ none □ yes, in:
2) Patient alive at this visit: □ yes □ no → day of death (DD/MM/YYYY): Cause of death: Patients last visit date (DD/MM/YYYY): 3) Therapy continued in another clinic: □ none □ yes, in:
Cause of death: Patients last visit date (DD/MM/YYYY): 3) Therapy continued in another clinic: □ none □ yes, in:
Patients last visit date (DD/MM/YYYY): 3) Therapy continued in another clinic: none yes, in:
3) Therapy continued in another clinic: none yes, in:
4) Course of disease:
still in 1st Chronic Phase Accelerated Phase on (DD/MM/YYYY)
□ Blastic Phase on (DD/MM/YYYY) □ in 2nd Chronic Phase since (DD/MM/YYYY)
5) General performance (Lansky performance status): DATE (DD/MM/YYYY):
□ 100%: fully active, normal □ 50%: gets dressed, but lies around much of the day,
□ 90%: minor restrictions in physically strenuous activity no active play, able to participate in all quiet play and activities
□ 80%: active, but tires more quickly □ 40%: mostly in bed, participates in quiet activities
□ 70%: both greater restriction of, and less time, □ 30%: in bed, needs assistance even for quiet play
spent in active play 20%: often sleeping, play entirely limited to very passive activities
\square 60%: up and around, but minimal active play \square 10%: no play, does not get out of bed
keeps busy with quieter activities \square 0%: unresponsive
6) Therapy: DATE (DD/MM/YYYY) DATE (DD/MM/YYYY)
Imatinib: no yes, from until dose: mg
yes, from until dose: mg
yes, from until dose: mg
yes, from until dose mg Hydroxyurea: □ no yes, from until dose: mg
Interferon: no yes, from until dose: mg



Transplantation: yes, scheduled date (DD/MM/YYYY): not scheduled (give additional comments by 'Remarks' see end of file)									
7) Toxicity (maximal grade according to Common Terminology Criteria for Adverse Events v3.0, CTCAE)									
Hematological:	Hematological:								
□ anemia → grade:		☐ neutropenia	a → grade:			☐ thrombocytopen	nia → gra	ide:	
Non hematological:									
☐ skin rash → grade:		□ nausea → g	grade:			□ vomiting → gra	de:		
☐ diarrhoe → grade:		⊃ edema → g	-			muscle cramps ·		·	_
□ headache → grade: □ liver transaminase elevation → grade:									
□ infection, specifiy: → grade:									
other, specify (e.g. bone metabolism, hearth function):									
→ grade:									
8) The following examinations should be done at regular intervals:									
 splenomegaly: □ no □ yes, cm below costal margin hepatomegaly: □ no □ yes, cm below costal margin ultrasound (DD/MM/YYYY)									
Leukocytes / µl		Blasts (%)			Eosinophils (%)			
Thrombocytes / µl			ocytes (%)			Basophils (%)			
Erythrocytes (Mio/µl)		l	es+Meta (%))		Monocytes (%)			
Hb (encircle [g/dl] or [mmol/l])		Bands (%)			Lymphocytes (%)			
MCV (fl)		Neutroph	ils (%)			Reticulocytes ([%] or [%])			
		J [Normoblasts (%)			
c) Blood chemistry: DATE (DD/M	M/YYYY): _		 value	unit			value		unit
Bilirubin (total)		Gamma-GT			(Creatinine			
ALAT		LDH			-	Alkaline Phosphatase			
ASAT		Uric acid					<u> </u>		
d) Bone marrow differentiation: DATE (DD/MM/YYYY): (please add photocopy of laboratory result)									
Blasts (%)		Promyelocyte	es (%)			Myelocytes + Meta~ (9	%)		



e) Bone marrow biopsy: DATE (DD/MM/YYY) → schedule: only for visit 6, 8, 10 and 12		ease add photocopy of laboratory result)					
cellularity: % grad of fibro	sis:						
f) Cytogenetic analysis of bone marrow:	DATE (DD/MM/YYYY): (pl	ease add photocopy of laboratory result)					
Location of laboratory:	Location of laboratory:						
method: □ G-banding [□ interphase;	☐ metaphase] ☐ FISH						
→ number of analyzed mitoses	karyotype:						
□ Ph ⁺ negative							
\square Ph ⁺ positive: \rightarrow % Ph ⁺ cells	additional abnormalities:	none					
g) Molecular analysis: Location of laboratory: (please add photocopy of laboratory results) → schedule: while Imatinib is given: every 4 – 6 weeks: PCR from peripheral blood for BCR-ABL-analysis							
DATE (DD/MM/YYYY):	DATE (DD/MM/YYYY):	DATE (DD/MM/YYYY):					
material: bone marrow blood	material: bone marrow blood	material: bone marrow blood					
→ rearrangement present: □ b2a2, □ b3a2, □ atypical:	→ rearrangement present:□ b2a2, □ b3a2, □ atypical:	→ rearrangement present: □ b2a2, □ b3a2, □ atypical:					
− qual.: BCR-ABL: □ pos. / □ neg. − quantitative result:	– qual.: BCR-ABL: □ pos. / □ neg.– quantitative result:	− qual.: BCR-ABL: □ pos. / □ neg. − quantitative result::					
9) Present response on imatinib therapy (s	ee criteria in protocol chapter 18 4)						
	•						
→ DATE (DD/MM/YYYY): a) clinical / hematological response (organomegaly / blood cell count): □ partial □ complete							
b) cytogenetic response (Ph ⁺): \square 0%, \square 1-34%, \square 35-65%, \square 66-95%, \square > 95%, \square additional chromosomal aberrations							
c) molecular response (BCR-ABL): BCR-ABL-pos BCR-ABL-reduction BCR-ABL-neg.							
10) AE/SAE							
Please complete pages "Adverse Event" / "	SAE-Report"						
11) Concomitant medication							
Please complete page "Concomitant medical	ation"						



Remarks:

DATE (DD/MM/YYYY) NAME (READABLE!) SIGNATURE HOSPITAL (STAMP)

__._.

Reply:

Prof. Dr. med. Markus Metzler Universitätsklinikum Erlangen Kinder- und Jugendklinik Pädiatrische Hämatologie und Onkologie Loschgestr. 15 D-91054 Erlangen

Germany

In case of questions please contact:

Study Chair: Prof. Dr. med. M. Metzler

= +49/(0) 9131/ 85-35742 (Fax)

Markus.Metzler@uk-erlangen.de



Study completion

(Two years after start of imatinib)

Patient No.:	Date of birth:	Date of diagnosis:					
Hospital:	·						
Contact person:							
a) treating physician		e-mail:					
b) study nurse:	/	e-mail:					
1) Date of last imatinib given (DD/MM/Y	YYY) :						
2) Date of last visit (DD/MM/YYYY):							
3) Did the patient complete the study	? □ yes □ no						
If no, please state the primary reason discontinuation:	for	en consent					
☐ Refractoriness to imatinib							
\rightarrow \square suboptimal response							
	\square Occurrence of (S)AE \rightarrow Please complete the "Adverse Event" Form						
☐ Patients behaviour is not compliant							
	☐ Bone marrow transp	plantation					
	☐ Death, DATE (DD/MI	M/YYYY):					
	☐ Lost to follow up	☐ Lost to follow up					
	Other, specify:	Other, specify:					
I have reviewed and found all dat	a pertaining to this patient t	to be complete and accurate.					
DATE (DD/MM/YYYY) NAME (READ	SIGNATU SIGNATU	URE HOSPITAL (STAMP)					
e Reply:	Ir	n case of questions please contact:					
Prof. Dr. med. Markus Metzler Universitätsklinikum Erlangen Kinder- und Jugendklinik Pädiatrische Hämatologie und Onkolog Loschgestr. 15 D-91054 Erlangen Germany	<u>s</u>	tudy Chair: Prof. Dr. med. M. Metzler +49/(0) 9131/85-33731 (Secretary) +49/(0) 9131/85-35742 (Fax) Markus.Metzler@uk-erlangen.de					

