Uniklinikum Erlangen

Visit month 12 (DD/MM/YYYY)	_ _ / _ _ / _ _ _ _
	to be filled by study management
CMLpaed II patient ID#:	☐☐☐☐
Date of first diagnosis (DD/MM/YYYY)**:**	_ _ / _ _ / _ _ _ _
Stage of disease:	□ 1st chronic phase □ blast phase on (DD/MM/YYYY): _ _ / _ _ / _ _ _ _
Institution/Address:	
Responsible physician:	
Contact	☏_____ @_____
date of birth (DD/MM/YYYY)**:**	_ _ / _ _ / _ _ _ _
sex:	☐ male ☐ female

Patient alive at this visit: ☐ yes ☐ no day of death (DD/MM/YYYY): _ _ / _ _ / _ _ _ _

Cause of death:_____

Patients last visit date (DD/MM/YYYY): _ _ / _ _ / _ _ _

General performance (ECOG-score) – Date (DD/MM/YYYY): _ _ / _ _ / _ _ _ _

☐ 100%: fully active, normal

☐ 90%: minor restrictions in physically strenuous activity

☐ 80%: active, but tires more quickly

☐ 70%: both greater restriction of, and less time, spent in active play

☐ 60%: up and around, but minimal active play keeps busy with quieter activities

☐ 50%: gets dressed, but lies around much of the day, no active play, able to participate in all quiet play and activities

☐ 40%: mostly in bed, participates in quiet activities

☐ 30%: in bed, needs assistance even for quiet play

☐ 20%: often sleeping, play entirely limited to very passive activities

☐ 10%: no play, does not get out of bed

☐ 0%: unresponsive

Kenn-Nr.: 134438

Clinical examination:

date (DD/MM/YYYY): _ _ / _ _ / _ _ _ _ height: _ _ _ cm body weigth: _ _ _ , _ kg

- splenomegaly: □ no □ yes, _____cm below costal margin
- hepatomegaly: □ no □ yes, _____cm below costal margin
- extramedullary manifestation: □ no □ yes, location: □ lymph nodes □ skin
- additional clinical pathological findings: _____

Tanner Score: (DD/MM/YYYY) _ _ / _ _ / _ _ _ _

Pubic hair development:
☐ PH° 1 ☐ PH° 2 ☐ PH° 3 ☐ PH° 4 ☐ PH° 5

♀ Breast development:
☐ B° 1 ☐ B° 2 ☐ B° 3 ☐ B° 4 ☐ B° 5 Menarche: □ yes, (MM/YYYY) _ _ / _ _ _ _ □ no

♂ Genital development:
☐ G° 1 ☐ G° 2 ☐ G° 3 ☐ G° 4 ☐ G° 5

Patients < 15 years of age at diagnosis:

Left hand bone age radiograph: (DD/MM/YYYY) _ _ / _ _ / _ _ _ _ Bone age: _ _ , _ _ years

CML specific treatment:

Imatinib: ☐ no yes, from _ _ / _ _ / _ _ _ _

Ongoing? ☐ yes, dose: _____mg ☐ no, until _ _ / _ _ / _ _ _ _

Dasatinib: ☐ no yes, from _ _ / _ _ / _ _ _ _

Ongoing? ☐ yes, dose: _____mg ☐ no, until _ _ / _ _ / _ _ _ _

Nilotinib: ☐ no yes, from _ _ / _ _ / _ _ _ _

Ongoing? ☐ yes, dose: _____mg ☐ no, until _ _ / _ _ / _ _ _ _

Bosutinib: ☐ no yes, from _ _ / _ _ / _ _ _ _

Ongoing? ☐ yes, dose: _____mg ☐ no, until _ _ / _ _ / _ _ _ _

Kenn-Nr.: 134438

Other TKI: ☐ no yes, specify: _____ from _ _ / _ _ / _ _ _ _

Ongoing? ☐ yes, dose: _____mg ☐ no, until _ _ / _ _ / _ _ _ _

additional therapy: □ none □ yes, give details: _____

Concomitant medication

□ none □ yes, give details: _____

_____

Toxicity (maximal grade according to Common Terminology Criteria for Adverse Events CTCAE)

Hematological:

□ anemia → grade: ____ □ neutropenia → grade: ____ □ thrombocytopenia → grade: ____

Non hematological:

□ skin rash → grade: ____ □ nausea → grade: ____ □ vomiting → grade: ____

□ diarrhoe → grade: ____ □ edema → grade: ____ □ muscle cramps → grade: ____

□ headache → grade: ____ □ liver transaminase elevation → grade: ____

□ infection, specify: _____ → grade: ____

□ other, specify (e.g. bone metabolism, hearth function):

_____ → grade: ____

Kenn-Nr.: 134438

Laboratory analysis
(Provide here or add lab report)

Blood count: date (DD/MM/YYYY): _ _ / _ _ / _ _ _ _

Leukocytes (µl)	
Thrombocytes (µl)	
Erythrocytes (Mio/µl)	
Hb (encircle [g/dl] or [mmol/l])	
MCV (fl)	

Blasts (%)	
Promyelocytes (%)	
Myelocytes+Meta (%)	
Bands (%)	
Neutrophils (%)	

Eosinophils (%)	
Basophils (%)	
Monocytes (%)	
Lymphocytes (%)	
Reticulocytes ([‰] or [%])	
Normoblasts (%)	

Blood chemistry: date (DD/MM/YYYY): _ _ / _ _ / _ _ _ _

	value	unit
Bilirubin (total)		
ALAT		
ASAT		

	value	unit
Gamma-GT		
LDH		
Uric acid		

	value	unit
Creatinine		
Alkaline Phosphatase		

Bone marrow differentiation: date (DD/MM/YYYY): _ _ / _ _ / _ _ _ _ (please add photocopy of laboratory result)

Blasts (%)	

Promyelocytes (%)	

Myelocytes+Meta~ (%)	

Cytogenetic analysis of bone marrow: date (DD/MM/YYYY): _ _ / _ _ / _ _ _ _ (please add photocopy of laboratory result)

Location of laboratory:_____

method: □ G-banding [□ interphase; □ metaphase] □ FISH

Number of analyzed mitoses_____

□ Ph^+ negative
□ Ph^+ positive: → _____% Ph^+ cells

normal karyotype: □ yes □ no

karyotype:_____

_____

additional abnormalities:_____ □ none

Kenn-Nr.: 134438

Uniklinikum Erlangen

Molecular analysis
(Provide here or add lab report)

Molecular analysis: date (DD/MM/YYYY): _ _ / _ _ / _ _ _ _

Location of laboratory: _____

material: □ bone marrow □ blood

→ transcript: □ b2a2 □ b3a2 □ b2a2+b3a2 variant:_____

- qualitative PCR: □ BCR-ABL negative
  □ BCR-ABL positive [□ M-BCR-ABL; □ m/M-BCR-ABL; □ m-BCR/ABL]
- quantitative PCR: Ratio control/BCR-ABL: _____

Mutation: _____

Common mutations: V299L, F311L, T315A, F317V, M351T, K387M, H396P, M244V, G250E, G250E, Q252H, F317L, E355G, F355G, F359V, V379I, H396R, T315I, Y253F, Y253H, E255K, E255V

Remarks:

_____	_____	_____	_____
Date (DD/MM/YYYY)	Name (Readable)	Signature	Hospital (Stamp)

Kenn-Nr.: 134438