Uniklinikum Erlangen

| | |
|---|---|
| **Visit month 24** (DD/MM/YYYY) | _ _ / _ _ / _ _ _ _ |
| | ***to be filled by study management*** |
| **CMLpaed II patient ID#:** | ☐☐☐☐ |
| **Date of first diagnosis** (DD/MM/YYYYY)**:** | _ _ / _ _ / _ _ _ _ |
| **Stage of disease:** | □ 1st chronic phase □ blast phase on (DD/MM/YYYY): _ _ / _ _ / _ _ _ _ |
| **Institution/Address:** | |
| **Responsible physician:** | |
| **Contact** | ☎_____<br>@_____ |
| **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

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**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 _ _ / _ _ / _ _ _ _

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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: ____

**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 (%) | |

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**Laboratory analysis**
**(Provide here or add lab report)**

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

| | value | unit |
|---|---|---|
| Bilirubin (total) | | |
| ALAT | | |
| ASAT | | |

| | value | unit |
|---|---|---|
| Gamma-GT | | |
| LDH | | |
| Uric acid | | |

| | value | unit |
|---|---|---|
| Creatinine | | |
| Alkaline Phosphatase | | |

**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:**

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