

12) General performance (Lansky performance status): DATE (DD/MM/YYYY): __ . __ . ____

- | | |
|--|--|
| <input type="checkbox"/> 100%: fully active, normal | <input type="checkbox"/> 50%: gets dressed, but lies around much of the day, no active play, able to participate in all quiet play and activities |
| <input type="checkbox"/> 90%: minor restrictions in physically strenuous activity | <input type="checkbox"/> 40%: mostly in bed, participates in quiet activities |
| <input type="checkbox"/> 80%: active, but tires more quickly | <input type="checkbox"/> 30%: in bed, needs assistance even for quiet play |
| <input type="checkbox"/> 70%: both greater restriction of, and less time, spent in active play | <input type="checkbox"/> 20%: often sleeping, play entirely limited to very passive activities |
| <input type="checkbox"/> 60%: up and around, but minimal active play keeps busy with quieter activities | <input type="checkbox"/> 10%: no play, does not get out of bed |
| | <input type="checkbox"/> 0%: unresponsive |

13) Examinations at diagnosis:
a) Clinical examination: DATE (DD/MM/YYYY): __ . __ . ____ height: __ cm body weight: __ , __ kg

- splenomegaly: no yes, ____ cm below costal margin
- hepatomegaly: no yes, ____ cm below costal margin
- ultrasound (DD/MM/YYYY) __ . __ . ____ → regular yes no, give details _____
- extramedullary manifestation: no yes, location: lymph nodes skin
- additional clinical pathological findings: _____

b) Blood count: DATE (DD/MM/YYYY): __ . __ . ____

| | | | | | |
|----------------------------------|--|---------------------|--|----------------------------|--|
| Leukocytes / μ l | | Blasts (%) | | Eosinophils (%) | |
| Thrombocytes / μ l | | Promyelocytes (%) | | Basophils (%) | |
| Erythrocytes (Mio/ μ l) | | Myelocytes+Meta (%) | | Monocytes (%) | |
| Hb (encircle [g/dl] or [mmol/l]) | | Bands (%) | | Lymphocytes (%) | |
| MCV (fl) | | Neutrophils (%) | | Reticulocytes ([%] or [%]) | |
| | | | | Normoblasts (%) | |

c) Blood chemistry: DATE (DD/MM/YYYY): __ . __ . ____

| | value | unit | | value | unit | | value | unit |
|-------------------|-------|------|-----------|-------|------|----------------------|-------|------|
| Bilirubin (total) | | | Gamma-GT | | | Creatinine | | |
| ALAT | | | LDH | | | Alkaline Phosphatase | | |
| ASAT | | | Uric acid | | | | | |

d) Bone marrow differentiation: DATE (DD/MM/YYYY): __ . __ . ____

(please add photocopy of laboratory result)

| | | | | | |
|------------|--|-------------------|--|------------------------|--|
| Blasts (%) | | Promyelocytes (%) | | Myelocytes + Meta~ (%) | |
|------------|--|-------------------|--|------------------------|--|

e) Bone marrow biopsy: DATE (DD/MM/YYYY): __ . __ . ____

(please add photocopy of laboratory result)

cellularity: __ % grad of fibrosis: __

f) 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 _____ <input type="checkbox"/> Ph ⁺ negative <input type="checkbox"/> Ph ⁺ positive: → _____% Ph ⁺ cells | karyotype: _____ _____ additional abnormalities: _____ <input type="checkbox"/> none |
|--|--|

g) Molecular analysis: DATE (DD/MM/YYYY): ____ . ____ . ____ (please add photocopy of laboratory results)

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: _____

14) HLA-typing has been performed for the patient? yes no

15) Concomitant medication
 Please complete page "Concomitant medication"

Remarks:

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

☞ Reply:

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 Kinder- und Jugendklinik
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Visit 2-4

| | | |
|--|--|--|
| <input type="checkbox"/> Visit 2 (d14) | <input type="checkbox"/> Visit 3 (d28/ 1 month) | <input type="checkbox"/> Visit 4 (2 months after diagnosis) |
| [only for patients in blastic and accelerated phase] | | |
| (please, complete disease status on date as indicated) | | |

| | | |
|-----------------------------|--|--|
| Patient No.: _____ | Date of birth: __. __. ____ (DD/MM/YYYY) | Date of diagnosis: __. __. ____ (DD/MM/YYYY) |
| Hospital: _____ | | |
| Contact person: | | |
| a) treating physician _____ | ☎ _____/ _____ | e-mail: _____ |
| b) study nurse: _____ | ☎ _____/ _____ | e-mail: _____ |

| |
|---|
| 1) Visit date (DD/MM/YYYY): __. __. ____ |
| 2) Patient alive at this visit: <input type="checkbox"/> yes <input type="checkbox"/> no → day of death (DD/MM/YYYY): __. __. ____ |
| Cause of death: _____ |
| Patients last visit date (DD/MM/YYYY) :: __. __. ____ |
| 3) Therapy continued in another clinic: <input type="checkbox"/> none <input type="checkbox"/> yes, in: _____ |

| | |
|---|---|
| 4) Course of disease: | |
| <input type="checkbox"/> still in 1st Chronic Phase | <input type="checkbox"/> Accelerated Phase on (DD/MM/YYYY) __. __. ____ |
| <input type="checkbox"/> Blastic Phase on (DD/MM/YYYY) __. __. ____ | <input type="checkbox"/> in 2nd Chronic Phase since (DD/MM/YYYY) __. __. ____ |

| | |
|---|---|
| 5) General performance (Lansky performance status): DATE (DD/MM/YYYY): __. __. ____ | |
| <input type="checkbox"/> 100%: fully active, normal | <input type="checkbox"/> 50%: gets dressed, but lies around much of the day, no active play, able to participate in all quiet play and activities |
| <input type="checkbox"/> 90%: minor restrictions in physically strenuous activity | <input type="checkbox"/> 40%: mostly in bed, participates in quiet activities |
| <input type="checkbox"/> 80%: active, but tires more quickly | <input type="checkbox"/> 30%: in bed, needs assistance even for quiet play |
| <input type="checkbox"/> 70%: both greater restriction of, and less time, spent in active play | <input type="checkbox"/> 20%: often sleeping, play entirely limited to very passive activities |
| <input type="checkbox"/> 60%: up and around, but minimal active play keeps busy with quieter activities | <input type="checkbox"/> 10%: no play, does not get out of bed |
| | <input type="checkbox"/> 0%: unresponsive |

| | | | | |
|--------------------|--|--------------------------|--------------------------|----------------|
| 6) Therapy: | | <u>DATE (DD/MM/YYYY)</u> | <u>DATE (DD/MM/YYYY)</u> | |
| Imatinib: | <input type="checkbox"/> no | yes, from __. __. ____ | until __. __. ____ | dose: _____ mg |
| | | yes, from __. __. ____ | until __. __. ____ | dose: _____ mg |
| | | yes, from __. __. ____ | until __. __. ____ | dose: _____ mg |
| Hydroxyurea: | <input type="checkbox"/> no | yes, from __. __. ____ | until __. __. ____ | dose: _____ mg |
| Interferon: | <input type="checkbox"/> no | yes, from __. __. ____ | until __. __. ____ | dose: _____ mg |
| Transplantation: | <input type="checkbox"/> yes, scheduled date (DD/MM/YYYY): __. __. ____ | | | |
| | <input type="checkbox"/> 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:
 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: ____

8) The following examinations should be done:
a) Clinical examination: DATE (DD/MM/YYYY): ____ . ____ . ____ height: ____ cm body weight: ____ , ____ kg

- splenomegaly: no yes, ____ cm below costal margin
- hepatomegaly: no yes; ____ cm below costal margin
- ultrasound (DD/MM/YYYY) ____ . ____ . ____ → regular yes no, give details _____
- extramedullary manifestation: no yes, location: lymph nodes skin
- additional clinical pathological findings: _____

b) 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 (%) | |

c) Blood chemistry: DATE (DD/MM/YYYY): ____ . ____ . ____

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

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

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

d) Molecular analysis: DATE (DD/MM/YYYY): ____ . ____ . ____

(please add photocopy of laboratory results)

→ schedule: only at visit 3 (d28/1 month) and visit 4 (2 month)

 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]

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:

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: ____

8) The following examinations should be done at regular intervals:

a) Clinical examination: DATE (DD/MM/YYYY): __ . __ . ____ height: ____ cm body weight: ____, __ kg

- splenomegaly: no yes, ____ cm below costal margin
- hepatomegaly: no yes, ____ cm below costal margin
- ultrasound (DD/MM/YYYY) __ . __ . ____ → regular yes no, give details _____
- extramedullary manifestation: no yes, location: lymph nodes skin
- additional clinical pathological findings: _____

b) Blood count: DATE (DD/MM/YYYY): __ . __ . ____

| | | | | | |
|----------------------------------|--|---------------------|--|----------------------------|--|
| Leukocytes / μ l | | Blasts (%) | | Eosinophils (%) | |
| Thrombocytes / μ l | | Promyelocytes (%) | | Basophils (%) | |
| Erythrocytes (Mio/ μ l) | | Myelocytes+Meta (%) | | Monocytes (%) | |
| Hb (encircle [g/dl] or [mmol/l]) | | Bands (%) | | Lymphocytes (%) | |
| MCV (fl) | | Neutrophils (%) | | Reticulocytes ([%] or [%]) | |
| | | | | Normoblasts (%) | |

c) Blood chemistry: DATE (DD/MM/YYYY): __ . __ . ____

| | value | unit | | value | unit | | value | unit |
|-------------------|-------|------|-----------|-------|------|----------------------|-------|------|
| Bilirubin (total) | | | Gamma-GT | | | Creatinine | | |
| ALAT | | | LDH | | | Alkaline Phosphatase | | |
| ASAT | | | Uric acid | | | | | |

d) Bone marrow differentiation: DATE (DD/MM/YYYY): __ . __ . ____

(please add photocopy of laboratory result)

| | | | | | |
|------------|--|-------------------|--|------------------------|--|
| Blasts (%) | | Promyelocytes (%) | | Myelocytes + Meta~ (%) | |
|------------|--|-------------------|--|------------------------|--|

e) Bone marrow biopsy: DATE (DD/MM/YYYY): ____ . ____ . ____ (please add photocopy of laboratory result)

→ schedule: only for visit 6, 8, 10 and 12

cellularity: ____ % grad of fibrosis: __

f) 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

karyotype: _____

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: <input type="checkbox"/> bone marrow <input type="checkbox"/> blood | material: <input type="checkbox"/> bone marrow <input type="checkbox"/> blood | material: <input type="checkbox"/> bone marrow <input type="checkbox"/> blood |
| → rearrangement present: | → rearrangement present: | → rearrangement present: |
| <input type="checkbox"/> b2a2, <input type="checkbox"/> b3a2, <input type="checkbox"/> atypical: _____ | <input type="checkbox"/> b2a2, <input type="checkbox"/> b3a2, <input type="checkbox"/> atypical: _____ | <input type="checkbox"/> b2a2, <input type="checkbox"/> b3a2, <input type="checkbox"/> atypical: _____ |
| – qual.: BCR-ABL: <input type="checkbox"/> pos. / <input type="checkbox"/> neg. | – qual.: BCR-ABL: <input type="checkbox"/> pos. / <input type="checkbox"/> neg. | – qual.: BCR-ABL: <input type="checkbox"/> pos. / <input type="checkbox"/> neg. |
| – quantitative result: _____ | – quantitative result: _____ | – quantitative result: _____ |
| _____ | _____ | _____: |

9) Present response on imatinib therapy (see criteria in protocol chapter 18.4)

→ DATE (DD/MM/YYYY): ____ . ____ . ____

a) clinical / hematological response (organomegaly / blood cell count): partial complete

b) cytogenetic response (Ph⁺): 0%, 1-34%, 35-65%, 66-95%, > 95%, 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 medication”

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

- - . - - . - - - - -

☒ Reply:

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Study completion

(Two years after start of imatinib)

| | | |
|-----------------------------|--|--|
| Patient No.: _____ | Date of birth: ____ . ____ . ____ (DD/MM/YYYY) | Date of diagnosis: ____ . ____ . ____ (DD/MM/YYYY) |
| Hospital: _____ | | |
| Contact person: | | |
| a) treating physician _____ | ☎ _____ / _____ | e-mail: _____ |
| b) study nurse: _____ | ☎ _____ / _____ | e-mail: _____ |

| |
|--|
| 1) Date of last imatinib given (DD/MM/YYYY): ____ . ____ . ____ |
|--|

| |
|---|
| 2) Date of last visit (DD/MM/YYYY): ____ . ____ . ____ |
|---|

| | |
|---|---|
| 3) Did the patient complete the study? | <input type="checkbox"/> yes <input type="checkbox"/> no |
| If no, please state the primary reason for discontinuation: | <input type="checkbox"/> Withdrawal of written consent <input type="checkbox"/> Refractoriness to imatinib → <input type="checkbox"/> suboptimal response <input type="checkbox"/> Occurrence of (S)AE → Please complete the “Adverse Event” Form <input type="checkbox"/> Patients behaviour is not compliant <input type="checkbox"/> Bone marrow transplantation <input type="checkbox"/> Death, DATE (DD/MM/YYYY): ____ . ____ . ____ <input type="checkbox"/> Lost to follow up <input type="checkbox"/> Other, specify: _____ |

| |
|---|
| I have reviewed and found all data pertaining to this patient to be complete and accurate. |
|---|

| | | | |
|--------------------------|-------------------------|------------------|-------------------------|
| DATE (DD/MM/YYYY) | NAME (READABLE!) | SIGNATURE | HOSPITAL (STAMP) |
| ____ . ____ . ____ | _____ | _____ | |

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 Pädiatrische Hämatologie und Onkologie
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| |
|--|
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|--|

