

Overview on the variables requested after certain periods of treatment

| Description | Coding/Unit | Month | | | | | | | | | | |
|---|--|-------|---|---|---|----|----|----|----|----|----|---|
| | | 0 | 3 | 6 | 9 | 12 | 15 | 18 | 21 | 24 | 36 | ? |
| Centre | number | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Patient ID | number | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Date of birth | date: ddmmyyyy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Gender | 0=male, 1=female | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| DEMOGRAPHIC DATA | | | | | | | | | | | | |
| Date of evaluation | date: ddmmyyyy | 1 | | | | 1 | | | | 1 | 1 | 1 |
| Smoking status | 0=non-smoker, 1=current smoker, 2=ex-smoker | 1 | | | | 1 | | | | 1 | 1 | 1 |
| Number of daily smoked cigarettes x years /20 | | 1 | | | | | | | | | | |
| Living together with a partner | 0=no, 1=yes | 1 | | | | 1 | | | | 1 | 1 | 1 |
| Marital status | 0=never been married, 1=married, 2=divorced, 3=widowed | 1 | | | | 1 | | | | 1 | 1 | 1 |
| Highest graduation | 0=basic: secondary school / intermediate, 1=high: high school / A-levels / university | 1 | | | | | | | | | | |
| Employment status | 0=unemployed, 1=full time employed, 2=part time employed | 1 | | | | 1 | | | | 1 | 1 | 1 |
| Race | 0=caucasian, 1=black, 2=asian | 1 | | | | | | | | | | |
| Weight | kg | 1 | | | | 1 | | | | 1 | 1 | 1 |
| Height | cm | 1 | | | | | | | | | | |
| DISEASE | | | | | | | | | | | | |
| Date of diagnosis | date: ddmmyyyy | 1 | | | | | | | | | | |
| Date of evaluation | date: ddmmyyyy | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| WHO performance scale | | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Clinical symptoms and signs of disease | 0=no, 1=yes | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Extramedullary manifestations apart from liver and spleen | 0=no, 1=yes | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Description of extramedullary manifestations | text | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Spleen size below costal margin, palpated | cm | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Spleen size, longest diameter, ultrasound | cm | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Palpable spleen | 0=no, 1=yes | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Liver size in MCL | cm | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| PERIPHERAL BLOOD | | | | | | | | | | | | |
| Date of laboratory analysis | date: ddmmyyyy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Hemoglobin | g/dL | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Hematokrit | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| WBC | x10 ⁹ /l | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Blasts | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Promyelocytes | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Myelocytes | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

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| | | | | | | | | | | | | |
|---|--|---|---|---|---|---|---|---|---|---|---|---|
| Metamyelocytes | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Bands | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Polymorphic nucleated cells | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Basophils | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Eosinophils | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Monocytes | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Lymphocytes | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Normoblasts | % | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Platelets | x10 ⁹ /l | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| BONE MARROW | | | | | | | | | | | | |
| Date of BM analysis | date: ddmmyyyy | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| BM cellularity | 0=low, 1=normal, 2=high | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Blasts in BM | %, -2=no aspiration | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Promyelocytes in BM | %, -2=no aspiration | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Basophils in BM | %, -2=no aspiration | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Eosinophils in BM | %, -2=no aspiration | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Fibrosis in BM | 0=no, 1=yes | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| CYTOGENETICS | | | | | | | | | | | | |
| Date of cytogenetic analysis | date: ddmmyyyy | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Philadelphia chromosome | 0=negative, 1=positive | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Number of evaluated metaphases | number | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Number of Ph-positive metaphases | number | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| % of Ph-positive metaphases | % | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Other clonal chromosomal anomalies in Ph-pos. Cells | 0=no, 1=yes | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| If yes, please specify number and type | text | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| Other clonal chromosomal anomalies in Ph-neg. cells | 0=no, 1=yes | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| If yes, please specify number and type | text | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| MOL. BIOLOGY | | | | | | | | | | | | |
| Date of molecular analysis | date: ddmmyyyy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Qualitative RT-PCR | 0=negative, 1=positive | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Level of BCR-ABL transcript | i.e. quant. | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Transcript type | 1=b2a2, 2=b3a2, 3=b2a3, 4=b3a3, 5=e1a2, 6=b2a2 and b3a2, 7=e6a2, 8=e19a2, 9=others | 1 | | | | | | | | | | |
| If other type, please specify | text | 1 | | | | | | | | | | |
| 9q+ deletion | By FISH, 0=no,1=yes | 1 | | | | | | | | | | |
| HLA-status | A, B, C, DR, and DQ | 1 | | | | | | | | | | |
| Real-Time- RT-PCR | 0=negative, 1=positive | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

Overview on the variables requested after certain periods of treatment

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ratio BCR-ABL/ABL according to real-time RT-PCR | % | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Alternative reference gene | please specify | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Alternative ratio | % | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Nested RT-PCR | 0=negative, 1=positive | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| TREATMENT | | repeat for each treatment actually given | | | | | | | | | | |
| Pretreatment | 0=no, 1=yes | 1 | | | | | | | | | | |
| If yes, please specify type of pretreatment | 1=Imatinib, 2=IFN-alpha, 3=Ara-C, 4=HU, 5=AMN107, 6=Dasatinib / BMS 354825, 7=other | 1 | | | | | | | | | | |
| If other pretreatment, please specify | text | 1 | | | | | | | | | | |
| First treatment according to randomisation / study protocol | 1=Imatinib, 5=AMN107, 6=Dasatinib / BMS 354825, 7=other | 1 | | | | | | | | | | |
| If other treatment, please specify | text | 1 | | | | | | | | | | |
| Scheduled dosage of first treatment according to randomisation / study protocol | text: dosage and unit | 1 | | | | | | | | | | |
| Second treatment according to randomisation / study protocol | 2=IFN-alpha, 3=Ara-C, 5=AMN107, 6=Dasatinib / BMS 354825, 7=other | 1 | | | | | | | | | | |
| If other treatment, please specify | text | 1 | | | | | | | | | | |
| Scheduled dosage of second treatment according to randomisation / study | text: dosage and unit | 1 | | | | | | | | | | |
| Treated according to randomisation / study protocol | 0=no, 1=yes | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Treatment actually given to the patient | 0=no treatment, 1=Imatinib, 2=IFN-alpha, 3=Ara-C, 4=HU, 5=AMN107, 6=Dasatinib / BMS 354825, 7=other | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| If other treatment, please specify | text | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Begin of treatment | date: ddmmyyyy | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| End of treatment | date: ddmmyyyy | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Total dosage | number | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Unit | mg, ml, etc. | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Date of definite discontinuation of treatment | date: ddmmyyyy | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Primary cause of treatment discontinuation | 0=treatment failure, 1=adverse events, 2=refusal to continue (for other reasons than failure or adverse events), 3=others | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

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| | | | | | | | | | | | | | | |
|---|---|--|--|---|---|---|---|---|---|---|---|---|---|---|
| If other cause, please specify | text | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| TRANSPLANTATION | | repeat for each transplantation | | | | | | | | | | | | |
| Type of transplantation | 1=autologous, 2=allogenic | | | | | | | | | | | | | 1 |
| Date of transplantation | date: ddmmyyyy | | | | | | | | | | | | | 1 |
| Stage of disease at transplant | 0=chronic phase, 1=accelerated phase, 2=blast phase, 3=second or higher chronic phase | | | | | | | | | | | | | 1 |
| Donor | 0=related, 1=unrelated | | | | | | | | | | | | | 1 |
| Gender of donor | 0=male, 1=female | | | | | | | | | | | | | 1 |
| SURVIVAL STATUS | | one instance per patient (update during follow-up) | | | | | | | | | | | | |
| Date of 1st blast crisis | date: ddmmyyyy | | | | | | | | | | | | | 1 |
| Date of 2nd blast crisis | date: ddmmyyyy | | | | | | | | | | | | | 1 |
| Date of 3rd blast crisis | date: ddmmyyyy | | | | | | | | | | | | | 1 |
| Date of death | date: ddmmyyyy | | | | | | | | | | | | | 1 |
| CML related cause of death | 0=no, 1=yes | | | | | | | | | | | | | 1 |
| Not CML-related cause of death, please specify | text | | | | | | | | | | | | | 1 |
| Transplantation related cause of death | 0=no, 1=yes | | | | | | | | | | | | | 1 |
| Treatment associated toxicity as cause of death | 0=no, 1=yes | | | | | | | | | | | | | 1 |
| Date of last contact alive, if censoring | date: ddmmyyyy | | | | | | | | | | | | | 1 |
| Cause of censoring | 1=end of study, 2=lost to follow-up, 3=others | | | | | | | | | | | | | 1 |
| If others, please specify | text | | | | | | | | | | | | | 1 |