|  |  |  |
| --- | --- | --- |
|  |  | **Month** |
| **Description** | **Coding/Unit** | **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  | x109/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 |
| 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  | x109/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 |
| 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 protocol  | 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 |
| If other cause, please specify  | text |   | 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 |