CHRONIC LEUKAEMIAS

DISEASE

Note: complete this form only if this diagnosis was the indication for the HCT/CT or if it was specifically requested. Consult the manual for further information.

Date of diagnosis: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

Classification (WHO 2022):

☐ Chronic myeloid leukaemia (CML)

☐ Chronic lymphocytic leukaemia (CLL) / small lymphocytic lymphoma (SLL) / Richter transformation

☐ Prolymphocytic (PLL) and other chronic leukaemias

Chronic Myeloid Leukaemias (CML)

Assessments at diagnosis

Extended dataset

Status of disease:

☐ Chronic phase ☐ Accelerated phase ☐ Blast crisis ☐ Unknown

Haematological values:

Peripheral blood

Haemoglobin (g/dL): _____	☐ Not evaluated	☐ Unknown
Platelets (10^9/L): _____	☐ Not evaluated	☐ Unknown
White Blood cells (10^9/L): _____	☐ Not evaluated	☐ Unknown
Absolute basophils (10^9/L): _____	☐ Not evaluated	☐ Unknown
% basophils: _____	☐ Not evaluated	☐ Unknown
% blasts : _____	☐ Not evaluated	☐ Unknown

Bone marrow

% blasts:_____	**If the precise blast count is not available, please indicate whether it is:** ☐ ≤ 5% ☐ > 5%	☐ Not evaluated ☐ Unknown

Spleen assessment

Palpable splenomegaly: ☐ Absent ☐ Present	☐ Not evaluated	☐ Unknown
If present: physical examination: _____ cm (below costal margin)	☐ Not evaluated	☐ Unknown
Spleen span on ultrasound or CT scan: _____ cm (maximum diameter)	☐ Not evaluated	☐ Unknown

Chronic Myeloid Leukaemias (CML)

CHROMOSOME ANALYSIS

Describe results of all the analysis done before HCT/CT treatment

Chromosome analysis done before HCT/CT treatment:

- ☐ No
- ☐ Yes: **Output of analysis:** ☐ Separate abnormalities ☐ Full karyotype
- ☐ Unknown

Copy and fill-in this section as often as necessary.

If chromosome analysis was done:

What were the results?

- ☐ Normal
- ☐ Abnormal: number of abnormalities present: _____
- ☐ Failed

Date of chromosome analysis: _ _ _ _ **/** _ _ **/** _ _ *(YYYY/MM/DD)* ☐ Unknown

For abnormal results, indicate below whether the abnormalities were absent, present or not evaluated.

t(9;22)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Trisomy 8	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Extra Ph	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
i(17)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
-7/Del	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
3q26	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Other; specify: ___________	☐ Absent	☐ Present		

OR

Transcribe the complete karyotype: ____

MOLECULAR MARKER ANALYSIS

Molecular markers analysis done before HCT/CT treatment:

☐ No
☐ Yes
☐ Unknown

Copy and fill-in this section as often as necessary.

If molecular marker analysis was done:

Date of molecular marker analysis: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Indicate below whether the markers were absent, present or not evaluated.

ASXL1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
BCORL1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
BCR::ABL1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
CBFB-MYH11	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
EZH2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
IDH1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
IKZF1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
KMT2D	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
RUNX1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
SETD1B	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
TET2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
TP53	☐ Absent	☐ Present:	☐ Not evaluated	☐ Unknown
		TP53 mutation type: ☐ Single hit ☐ Multi hit ☐ Unknown		
Other; specify _____	☐ Absent	☐ Present		

PREVIOUS THERAPIES
(between diagnosis and HCT/CT)

Previous therapy lines before the HCT/CT/GT:

☐ No
☐ Yes: **complete the "Treatment — non-HCT/CT/GT/IST" form**
☐ Unknown

Chronic Lymphocytic Leukaemias (CLL)

DISEASE

Sub-Classification (WHO 2022):

☐ Chronic lymphocytic leukaemia (CLL) / small lymphocytic lymphoma (SLL)

☐ Richter transformation:

Transformed from a previous known CLL: ☐ No (primary Richter)
☐ Yes; **Date of original CLL diagnosis:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
☐ Unknown

Type of Richter transformation:
☐ Hodgkin
☐ DLBCL
☐ Other; specify: _______

Richter transformation clonally related to CLL: ☐ No
☐ Yes

CHROMOSOME ANALYSIS

Describe results of all the analysis done before HCT/CT treatment

Chromosome analysis done before HCT/CT treatment:

☐ No
☐ Yes: **Output of analysis:** ☐ Separate abnormalities ☐ Full karyotype
☐ Unknown

Copy and fill-in this section as often as necessary.

If chromosome analysis was done:

What were the results?

☐ Normal
☐ Abnormal: number of abnormalities present: _____
☐ Failed

Date of chromosome analysis: _ _ _ _ **/** _ _ **/** _ _ *(YYYY/MM/DD)* ☐ Unknown

For abnormal results, indicate below whether the abnormalities were absent, present or not evaluated.

Trisomy 12	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
del(13q14)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
del(11q22-23)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
del(17p)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Other; specify: _______________	☐ Absent	☐ Present		

OR

Transcribe the complete karyotype: ____

MOLECULAR MARKER ANALYSIS

Molecular markers analysis done before HCT/CT treatment:

☐ No
☐ Yes
☐ Unknown

Copy and fill-in this section as often as necessary.

If molecular marker analysis was done:

Date of molecular marker analysis: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

IGVH mutational status: ☐ Absent ☐ Present **High risk subset?** ☐ No ☐ Yes

Indicate below whether the markers were absent, present or not evaluated.

TP53	☐ Absent	☐ Present;	☐ Not evaluated	☐ Unknown
		TP53 mutation type: ☐ Single hit ☐ Multi hit ☐ Unknown		
Other; specify: _____		☐ Absent	☐ Present	

PREVIOUS THERAPIES (between diagnosis and HCT/CT)

Previous therapy lines before the HCT/CT:

☐ No

☐ Yes: **complete the "Treatment — non-HCT/CT/GT/IST" form**

☐ Unknown

PREVIOUS THERAPIES
(between diagnosis and HCT/CT)

Extended dataset

Answer the questions below for treated patients only:

Purine analogue-refractory?
(non response or relapse within 6 months after completion of purine analogue-containing chemotherapy)

- ☐ No
- ☐ Yes
- ☐ No purine analogue-containing chemotherapy treatment
- ☐ Unknown

Resistance to a BTK inhibitor?

☐ Absent ☐ Present ☐ No BTK inhibitor treatment ☐ Unknown

If present: has any testing on the resistance mechanism been performed?

☐ No

☐ Yes:

What was tested? *(select all that apply)*	**What was the result ?**
☐ Structural changes in the BTK protein	☐ Absent ☐ Present
☐ Structural changes in downstream proteins	☐ Absent ☐ Present
☐ Other; specify: _____	☐ Absent ☐ Present

☐ Unknown

Resistance to a BCL2 inhibitor?

☐ Absent ☐ Present ☐ No BCL2 inhibitor treatment ☐ Unknown

If present: has any testing on the resistance mechanism been performed?

☐ No

☐ Yes:

What was tested? *(select all that apply)*	**What was the result ?**
☐ Structural changes in the BCL2 protein	☐ Absent ☐ Present
☐ Structural changes in downstream proteins	☐ Absent ☐ Present
☐ Other; specify: _____	☐ Absent ☐ Present

☐ Unknown

Prolymphocytic (PLL) and Other Chronic Leukaemias

DISEASE

Sub-Classification (WHO 2022): Prolymphocytic and other chronic leukaemias

☐ T-prolymphocytic leukaemia (T-PLL)
☐ Hairy cell leukaemia
☐ Splenic B-cell lymphoma/leukaemia with prominent nucleoli (SBLPN)
☐ Other chronic leukaemia; specify: ____________________

CHROMOSOME ANALYSIS - *only applicable for T-PLL*

Describe results of all the analysis done before HCT/CT treatment

Chromosome analysis done before HCT/CT treatment:

☐ No
☐ Yes: output of analysis: ☐ Separate abnormalities ☐ Full karyotype
☐ Unknown

Copy and fill-in this section as often as necessary.

If chromosome analysis was done:

What were the results?

☐ Normal
☐ Abnormal: number of abnormalities present: _____
☐ Failed

Date of chromosome analysis: _ _ _ _ **/** _ _ **/** _ _ *(YYYY/MM/DD)* ☐ Unknown

For abnormal results, indicate below whether the abnormalities were absent, present or not evaluated.

inv(14)/ t(14;14)(q11;q32)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
del(14)(q12)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
t(11;14)(q23;q11)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
t(7;14)(q35;q32.1)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
t(X;14)(q35;q11)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
idic(8)(p11)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
del(17p)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Other; specify: _______________	☐ Absent	☐ Present		

OR

Transcribe the complete karyotype: ____

IMMUNOPHENOTYPING

only applicable for T-PLL

Immunophenotype of T-cells at diagnosis:
Note: Terminal desoxynucleotidyl transferase (TdT) must be negative.

Indicate below whether the phenotypes were absent, present or not evaluated.

CD4+	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
CD8+	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown

Lymphocyte count at diagnosis: _____ 10^9 cells/L ☐ Not evaluated ☐ Unknown

Was mantle cell lymphoma excluded at diagnosis?:

☐ No

☐ Yes; **method**: ☐ FISH on t(11;14)(q23;q11)
☐ Cyclin D1 expression
☐ Both
☐ Other

☐ Unknown

☐ Unknown

Prolymphocytic (PLL) and Other Chronic Leukaemias

Extended dataset

PREVIOUS THERAPIES (between diagnosis and HCT/CT)

Previous therapy lines before the HCT/CT:

☐ No

☐ Yes: **complete the "Treatment — non-HCT/CT/GT/IST" form**

☐ Unknown

Answer the questions below for treated patients only:

Purine analogue-refractory?
(non response or relapse within 6 months after completion of purine analogue-containing chemotherapy)

☐ No
☐ Yes
☐ No purine analogue-containing chemotherapy treatment
☐ Unknown

Resistance to a BTK inhibitor?

☐ Absent ☐ Present ☐ No BTK inhibitor treatment ☐ Unknown

If present: has any testing on the resistance mechanism been performed?

☐ No

☐ Yes:

What was tested? *(select all that apply)*	**What was the result ?**
☐ Structural changes in the BTK protein	☐ Absent ☐ Present
☐ Structural changes in downstream proteins	☐ Absent ☐ Present
☐ Other; specify: _____	☐ Absent ☐ Present

☐ Unknown

Resistance to a BCL2 inhibitor?

☐ Absent ☐ Present ☐ No BCL2 inhibitor treatment ☐ Unknown

If present: has any testing on the resistance mechanism been performed?

☐ No

☐ Yes:

What was tested? *(select all that apply)*	**What was the result ?**
☐ Structural changes in the BCL2 protein	☐ Absent ☐ Present
☐ Structural changes in downstream proteins	☐ Absent ☐ Present
☐ Other; specify: _____	☐ Absent ☐ Present

☐ Unknown