

**European Treatment and Outcome Study
for Chronic Myeloid Leukemia
(EUTOS for CML)**

European CML Registry – ‘population-based’ section

Case Report Form (CRF) (10 June 2010)

When filling out this CRF, please remember:

1. The patient must have provided written informed consent, as or if required by national ethic and regulatory procedures.
2. The patient must live in the country, region, department or land that has been selected for this registry.
3. The date of diagnosis of CML must be subsequent to the date of activation of this registry in the country.
4. It is of a paramount importance to report the clinical/laboratory data at diagnosis, **before any treatment.**
5. This CRF is composed by two parts.
 - Part I for baseline data
 - Part II for follow-up data
6. Follow-up data are due every 12 months – you can download a follow-up CRF each year!
7. This Paper CRF is only for your local handling, the data must be entered in the eCRF System.

For any questions/concerns, please contact ELN-EUTOS Registry – Info:

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This box is to be filled out by the study centre, not by the treating clinician!

UNIQUE PATIENT NUMBER (UPN) PATIENT COUNTRY _ _ _

Part I		Date (dd.mm.yyyy) ____-____-____	
BASELINE DATA			
INFORMED CONSENT			
Was the informed consent signed by the patient*?		<input type="checkbox"/> Yes <input type="checkbox"/> No <small>*If required by national ethic and regulatory procedures</small>	
If yes, please specify date of signature (dd.mm.yyyy)		____-____-____	
DEMOGRAPHIC DATA			
Date of birth (dd.mm.yyyy)	Country of birth	Gender <input type="checkbox"/> Female <input type="checkbox"/> Male	Weight _____ kg Height _____ cm
Date of diagnosis (dd.mm.yyyy)	Region		
ECOG/WHO score: <input type="checkbox"/> 0 Asymptomatic <input type="checkbox"/> 1 Symptomatic but completely ambulatory <input type="checkbox"/> 2 Symptomatic, <50% in bed during the day <input type="checkbox"/> 3 Symptomatic, >50% in bed, but not bedbound <input type="checkbox"/> 4 Bedbound <input type="checkbox"/> 5 Dead <input type="checkbox"/> 6 Unknown		Comorbidities: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes please specify <input type="checkbox"/> Neurological disorders <input type="checkbox"/> Cardiovascular disorders <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes <input type="checkbox"/> Chronic liver disease <input type="checkbox"/> Chronic renal disease <input type="checkbox"/> Behavior disorders <input type="checkbox"/> Other <input type="checkbox"/> Unknown <input type="checkbox"/> None	
Marital status: <input type="checkbox"/> Never been married <input type="checkbox"/> Married <input type="checkbox"/> Divorced <input type="checkbox"/> Widowed <input type="checkbox"/> Unknown		Smoking status: <input type="checkbox"/> Non smoker <input type="checkbox"/> Current smoker <input type="checkbox"/> Former smoker <input type="checkbox"/> Unknown Number of daily smoked cigarettes: _____	
Highest graduation: <input type="checkbox"/> Elementary school <input type="checkbox"/> Secondary (high) school <input type="checkbox"/> University <input type="checkbox"/> Unknown		Employment status: <input type="checkbox"/> Unemployed <input type="checkbox"/> Full time employed <input type="checkbox"/> Part time employed <input type="checkbox"/> Unknown	
Living together with a partner <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
CLINICAL DATA BEFORE ANY TREATMENT			
Spleen size (cm below the costal margin) _____ cm	Disease-related symptoms <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, please specify: <input type="checkbox"/> Weight loss, <input type="checkbox"/> Other <input type="checkbox"/> Fever <input type="checkbox"/> Fatigue <input type="checkbox"/> Bone Pain <input type="checkbox"/> Infection <input type="checkbox"/> Abdominal pain, <input type="checkbox"/> Hemorrhagic syndrome	Extramedullary involvement (with the exception of liver and spleen) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, please specify: <input type="checkbox"/> Skin <input type="checkbox"/> Lymphnodes <input type="checkbox"/> Bone <input type="checkbox"/> CNS <input type="checkbox"/> Other	
PHASE OF THE DISEASE AT DIAGNOSIS			
<input type="checkbox"/> Chronic <input type="checkbox"/> Accelerated <input type="checkbox"/> Blastic			

HEMATOLOGICAL DATA	
Date of laboratory analysis (dd.mm.yyyy) _____ Hemoglobin (g/dl) _____ Hematocrit (%) _____ WBC ($\times 10^9/L$) _____ Was the above analysis carried out before any treatment?	Platelets ($\times 10^9/L$) _____ Blasts in peripheral blood (%) _____ Basophils (%) _____ Eosinophils (%) _____ <input type="checkbox"/> Yes <input type="checkbox"/> No
RISK SCORE	
The risk score will be calculated automatically if the above data refer to diagnosis prior to any treatment.	
Sokal score _____, _____ EURO score _____	
CYTOGENETICS	
Chromosome banding analysis <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown date _____ If yes, please specify: Ph+ t(9;22)(q34;q11) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Variant translocations <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Number of evaluated metaphases _____ <input type="checkbox"/> Unknown Number of Ph+ metaphases _____ % of Ph+ metaphases (%) _____ Clonal chromosome abnormalities in Ph+ cells <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Interphase FISH analysis <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown date _____ If yes, please specify: Number of scored nuclei _____ <input type="checkbox"/> Unknown Number of positive nuclei _____ <input type="checkbox"/> Unknown % of positive nuclei (%) _____ <input type="checkbox"/> Unknown
MOLECULAR BIOLOGY	
BCR-ABL transcript type Date _____ Type of transcript <input type="checkbox"/> b2a2 <input type="checkbox"/> b3a2 <input type="checkbox"/> Other, please specify _____ _____ _____ <input type="checkbox"/> Unknown	BCR-ABL transcript level Date _____ Control gene <input type="checkbox"/> ABL <input type="checkbox"/> GUS <input type="checkbox"/> $\beta 2M$ <input type="checkbox"/> BCR <input type="checkbox"/> Other; please specify _____ _____ _____ <input type="checkbox"/> Unknown BCR-ABL/control gene % _____, _____ On International Scale? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

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UNIQUE PATIENT NUMBER (UPN) PATIENT _____ COUNTRY _____

Part II

End date of reporting period (dd.mm.yyyy) _____

Follow-up data

CRF No: _____ date of initial diagnosis _____ date of birth: _____

TREATMENT

Was the patient enrolled in a clinical study?

Yes No Unknown

Investigator sponsored trial Yes No

If yes, please specify EudraCT number _____

Company sponsored trial Yes No

If yes, please specify Company sponsored Trial number _____

Treatment received during the first year

Hydroxyurea Yes No Unknown

Interferon (IFN- α) Yes No Unknown

Start date of first TKI-treatment (dd.mm.yyyy) _____

Imatinib Yes No Unknown

Initial daily dose _____ | Discontinued for side effects Yes No

Maximum daily dose _____

Last daily dose _____ | Discontinued for failure (ELN criteria) Yes No

Dasatinib Yes No Unknown

Initial daily dose _____ | Discontinued for side effects Yes No

Maximum daily dose _____

Last daily dose _____ | Discontinued for failure (ELN criteria) Yes No

Nilotinib Yes No Unknown

Initial daily dose _____ | Discontinued for side effects Yes No

Maximum daily dose _____

Last daily dose _____ | Discontinued for failure (ELN criteria) Yes No

Bosutinib Yes No Unknown

Initial daily dose _____ | Discontinued for side effects Yes No

Maximum daily dose _____

Last daily dose _____ | Discontinued for failure (ELN criteria) Yes No

Other Yes No Unknown

TRANSPLANTATION

Allogeneic SCT Yes No

Date of transplantation Transplant center (*text*)

(dd.mm.yyyy) _____

CYTOGENETICS	
Were cytogenetic tests performed during the year? <input type="checkbox"/> Yes <input type="checkbox"/> No	
CHROMOSOME BANDING ANALYSIS OF MARROW METAPHASES <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, please specify: How many test were performed during the year? _____ Date of cytogenetic test (dd.mm.yyyy) _____ Number of evaluated metaphases _____ <div style="text-align: right;"><input type="checkbox"/> Unknown</div> Number of Ph+ metaphases _____ % of Ph+ metaphases (%) _____ Clonal chromosome abnormalities in Ph+ cells <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	FISH ANALYSIS <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, please specify: Date of FISH analysis (dd.mm.yyyy) _____ Number of scored nuclei (total) _____ <div style="text-align: right;"><input type="checkbox"/> Unknown</div> Number of positive nuclei _____ <div style="text-align: right;"><input type="checkbox"/> Unknown</div> % of positive nuclei (%) _____
MOLECULAR BIOLOGY	MUTATIONAL ANALYSIS
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown How many molecular tests were performed during the year? _____ Date of molecular test (dd.mm.yyyy) _____ BCR-ABL/control gene (%) _____ On International Scale? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown How many mutational analyses were performed during the year? _____ Date of mutational analysis (dd.mm.yyyy) _____ Type of mutation _____
Space for additional cytogenetic and molecular biological tests:	
CYTOGENETICS	
CHROMOSOME BANDING ANALYSIS OF MARROW METAPHASES Date of cytogenetic test (dd.mm.yyyy) _____ Number of evaluated metaphases _____ <div style="text-align: right;"><input type="checkbox"/> Unknown</div> Number of Ph+ metaphases _____ % of Ph+ metaphases (%) _____ Clonal chromosome abnormalities in Ph+ cells <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	FISH ANALYSIS Date of FISH analysis (dd.mm.yyyy) _____ Number of scored nuclei (total) _____ <div style="text-align: right;"><input type="checkbox"/> Unknown</div> Number of positive nuclei _____ <div style="text-align: right;"><input type="checkbox"/> Unknown</div> % of positive nuclei (%) _____
MOLECULAR BIOLOGY	MUTATIONAL ANALYSIS
Date of molecular test (dd.mm.yyyy) _____ BCR-ABL/control gene % _____ On International Scale? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Date of mutational analysis (dd.mm.yyyy) _____ Type of mutation _____

CYTOGENETICS		
CHROMOSOME BANDING ANALYSIS OF MARROW METAPHASES Date of cytogenetic test (dd.mm.yyyy) _____ Number of evaluated metaphases _____ <input type="checkbox"/> Unknown Number of Ph+ metaphases _____ % of Ph+ metaphases (%) _____ Clonal chromosome abnormalities in Ph+ cells <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	FISH ANALYSIS Date of FISH analysis (dd.mm.yyyy) _____ Number of scored nuclei (total) _____ <input type="checkbox"/> Unknown Number of positive nuclei _____ <input type="checkbox"/> Unknown % of positive nuclei (%) _____	
MOLECULAR BIOLOGY	MUTATIONAL ANALYSIS	
Date of molecular test (dd.mm.yyyy) _____ BCR-ABL/control gene % _____ On International Scale? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Date of mutational analysis (dd.mm.yyyy) _____ Type of mutation _____	
SERIOUS ADVERSE EVENTS (SAEs) AND GRADE 3/4 ADVERSE EVENTS (AEs)		
SAEs	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
Grade 3/4 AEs	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
SURVIVAL STATUS		
Date of last contact/seen (dd.mm.yyyy) _____	Progression to AP/BC <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please specify date (dd.mm.yyyy) _____	Death <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify date (dd.mm.yyyy) _____