

Registry for long-term follow-up of CML patients who discontinued Imatinib after Complete Cytogenetic Response

3rd Form (Restart of Imatinib)

(to be filled out at time of 1st restart of Imatinib and every 3 months thereafter)

Demographics/Patient Characteristics		
Center		□□□□
Patient ID		□□□□
Date of birth	ddmmyy	□□□□□□
Gender	0=male 1=female	□
Disease characteristics		
WHO Performance Scale	%	□□□□
Karnofsky-Index	%	□□□□
Disease related symptoms	0=no 1=yes	□
Extramedullary manifestations (apart from liver and spleen)	0=no 1=yes	□
	If yes, please specify	_____
Spleen size	cm below costal margin, palpated	□□
	The longest diameter in ultrasound, cm	□□
Hematology		
Hemoglobin	g/dl	□□□.□□
Hematokrit	%	□□
WBC	x 10 ⁹ /l	□□□□.□□
Platelets	x 10 ⁹ /l	□□□□□□
Differential (PB) (a minimum of 200 cells should be counted under the microscope)		
Blasts	%	□□
Promyelocytes	%	□□
Myelocytes	%	□□
Metamyelocytes	%	□□
Bands	%	□□
Polymorphic nucleated cells	%	□□
Basophils	%	□□
Eosinophils	%	□□
Monocytes	%	□□
Lymphocytes	%	□□
Normoblasts	(pro 100 leukocytes)	□□
Differential (BM)		
BM cellularity (histopathology or smear)	1=low 2=normal 3=high	□
Blasts in BM	% na=no aspiration nd=not done	□□
Promyelocytes in BM	% na=no aspiration nd=not done	□□
Basophils in BM	% na=no aspiration nd=not done	□□
Eosinophils in BM	% na=no aspiration nd=not done	□□
Cytogenetic features		
Ph-chromosome status	1=positive 2=negative 3=unknown	□

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Number of evaluated metaphases		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Number of Ph-positive metaphases		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Karyotype		_____
Other clonal chromosomal anomalies in Ph-positive cells, if yes, please specify % and type	0=no 1=yes	<input type="checkbox"/>
	%	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	type	_____
Other clonal chromosomal anomalies in Ph-negative cells, if yes, please specify % and type	0=no 1=yes	<input type="checkbox"/>
	%	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	type	_____
Molecular biology		
Date of molecular analysis	ddmmyy	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Source of material	1=PB 2=BM	<input type="checkbox"/>
Volume	ml	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Ratio BCR-ABL/ABL	%	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Other control gene	Please specify	_____
Ratio BCR-ABL/other gene	%	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Nested PCR	1=positive 2=negative 4=not done	<input type="checkbox"/>
Date of molecular analysis	ddmmyy	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Source of material	1=PB 2=BM	<input type="checkbox"/>
Volume	ml	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Ratio BCR-ABL/ABL	%	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Other control gene	Please specify	_____
Ratio BCR-ABL/other gene	%	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Nested PCR	1=positive 2=negative 4=not done	<input type="checkbox"/>
Date of molecular analysis	ddmmyy	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Source of material	1=PB 2=BM	<input type="checkbox"/>
Volume	ml	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Ratio BCR-ABL/ABL	%	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Other control gene	Please specify	_____
Ratio BCR-ABL/other gene	%	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Nested PCR	1=positive 2=negative 4=not done	<input type="checkbox"/>
Level of BCR-ABL transcript, i.e. quantitative	1=positive 2=negative 3=unknown	<input type="checkbox"/>
Treatment		
Start of Imatinib treatment	ddmmyy	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Dosage per day		_____
End of Imatinib treatment	ddmmyy	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	please specify the cause	_____

Institution: _____ Date (ddmmyy): Signature: _____

Center Patient ID
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 Gender (0=male, 1=female)

New CML treatment (after discontinuation of Imatinib treatment)	New CML treatment: 0=no 1=yes <input type="text"/>	
	If yes, please specify below:	
	Drug: _____ Dosis: _____ Period of administration (ddmmyy): from <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> to <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
	Drug: _____ Dosis: _____ Period of administration: from <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> to <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
	Drug: _____ Dosis: _____ Period of administration: from <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> to <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Restart of Imatinib treatment	ddmmyy	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Dosage per day		_____
Please specify the cause for restart of Imatinib		_____
Transplantation		
Transplantation	0=no 1=yes <input type="text"/>	
	If yes, please specify the date (ddmmyy)	
		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Stage of disease at transplantation	1=first chronic phase 2=second or higher chronic phase 3=accelerated phase 4=blast phase <input type="text"/>	
Survival status		
Blast crisis	0=no 1=yes <input type="text"/>	
	If yes, please specify the date (ddmmyy)	
	type of blast crisis	

Date of death	ddmmyy	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Cause of death	1=CML-related 2=BMT-related 3=treatment associated toxicity 4=not CML-related <input type="text"/>	
	If not CML-related, please specify	
