

\* ----- ILTE STUDY NEWSLETTER - February 2007 ----- \*

Dear Investigator,

We would like to provide you with some further instruction to ease the use of the ILTE\_part1.mdb package.

1) From the feedback we received from some centres, we noticed that sometimes the cytogenetic status was assessed by FISH instead of the standard cytogenetics procedure.

Since the ILTE\_part1.mdb package was designed to record only the standard assessments, we have set the following codes to record the assessments made by FISH :

1.a) the total number of cells examined must be reported in the "n. of metaphases - TOTAL" field

1.b) the number of positive cells must be reported in the "n. of metaphases - Ph pos" field

1.c) a reference to the FISH methodology must be introduced in the "additional notes" field according to the following :

- REGISTRATION CRF (see Registration.pdf attachment for an example)

start=FISH denotes assessment made by FISH at IMATINIB start

2 years=FISH denotes assessment made by FISH at 2 years from IMATINIB start

- BASELINE FOLLOW\_UP (see BaselineFUP.pdf attachment for an example)

loss CCR=FISH denotes assessment made by FISH at the time of CCR loss

last status=FISH denotes assessment made by FISH at the last cytogenetics assessment

Although FISH data can be used, we encourage you to enter results from conventional cytogenetics whenever available.

2) A second point raised by some centres refers to the isolated occurrence of 1-2 Ph+ metaphases during CCyR. Since the confidence interval for 0/20 ranges from 0 to 10%, the isolated occurrence of no more than 10% Ph+ metaphases must not be considered in this study as loss of CCyR.

Please feel free to contact us for any problems you can encounter during the data entry process.

With best regards,

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Cytogenetic Status assessed by **FISH at both**

- \* **IMATINIB start and**
- \* **2 years from IMATINIB start**

## IMATINIB Long Term Effects (ILTE) Study : Registration

Register all consecutive CML patients who : started IMATINIB from 01/09/1999 to 31/12/2004  
were in CCR 2 years after the treatment start  
To be completed by December 31-2006

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<i>CYTOGENETIC STATUS (up to 2 years from IMATINIB start)</i>							
at IMATINIB start	Date of eval.	01/01/1999	<i>n. of metaphases</i>	Total	200	Ph pos	175
	Date of CCR	01/06/2000					
2 years from IMATINIB start	Date of eval.	01/09/2001	<i>n. of metaphases</i>	Total	100	Ph pos	0
<i>Additional Notes</i>	start=FISH 2 years=FISH						

Cytogenetic Status assessed by

- \* **Standard Procedure** at IMATINIB start and
- \* **FISH** at 2 years from IMATINIB start

## IMATINIB Long Term Effects (ILTE) Study : Registration

Register all consecutive CML patients who : started IMATINIB from 01/09/1999 to 31/12/2004  
were in CCR 2 years after the treatment start  
To be completed by December 31-2006

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<i>CYTOGENETIC STATUS (up to 2 years from IMATINIB start)</i>							
at IMATINIB start	Date of eval.	01/01/1999	<i>n. of metaphases</i>	Total	20	Ph pos	20
	Date of CCR	01/06/2000					
2 years from IMATINIB start	Date of eval.	01/09/2001	<i>n. of metaphases</i>	Total	200	Ph pos	0
<i>Additional Notes</i>	2 years=FISH						

# Cytogenetic Status assessed by FISH at the loss of CCR

## ILTE Study : Baseline Follow-up

To be completed by December 31-2006

Report only events occurred after the first two years of treatment with IMATINIB

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### Loss of CCR

YES

*If YES, specify the cytogenetic status at the loss of CCR*

Date of eval. 15/12/2006 n. of metaphases Total 190 Ph pos 150

*If NO, specify the latest cytogenetic status*

Date of eval. n. of metaphases Total Ph pos

*If NO, specify the last PCR analysis*

Date of eval. Assay Result

*If PCR negative*

Date of start of continuous negativity

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Additional Notes

loss CCR=FISH

# Last Cytogenetic Status assessed by FISH

## ILTE Study : Baseline Follow-up

To be completed by December 31-2006

Report only events occurred after the first two years of treatment with IMATINIB

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<b>Loss of CCR</b>	NO <input type="button" value="v"/>
<i>If YES, specify the cytogenetic status at the loss of CCR</i>	Date of eval. <input type="text"/> n. of metaphases <input type="text"/> Total <input type="text"/> Ph pos <input type="text"/>
<i>If NO, specify the latest cytogenetic status</i>	Date of eval. 15/12/2006 n. of metaphases <input type="text"/> Total 190 Ph pos <input type="text"/>
<i>If NO, specify the last PCR analysis</i>	Date of eval. <input type="text"/> Assay <input type="text"/> <input type="button" value="v"/> Result <input type="text"/> <input type="button" value="v"/>
<i>If PCR negative</i>	Date of start of continuous negativity <input type="text"/>

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<i>Additional Notes</i>	last status=FISH
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