

•----- ILTE STUDY NEWSLETTER - April 2007 -----\*

Dear Investigator,

This letter contains RELEVANT INFORMATION for the compilation of the BASELINE FOLLOW-UP CRF and SAE / NON SAE CRFs of the ILTE\_part1.mdb database.

Attached here you find two .pdf files: please have a look at them.

We would like to remind you for clarity that:

- 1) the date of latest follow-up considered in the BASELINE FOLLOW-UP CRF must refer to an assessment performed within 31/12/2006
- 2) all the remaining dates required in the BASELINE FOLLOW-UP CRF must be prior to or coincident to the date of latest follow-up (see the orange circles in baseline\_FUP.pdf)
- 3) the number of SAE and NON SAE reported in the BASELINE FOLLOW-UP CRF must refer to events occurred prior the date of latest follow-up (see the green and blue circles in baseline\_FUP.pdf)
- 4) the compiled SAE and NON SAE CRFs must refer to SAE and NON SAE reported in the BASELINE FOLLOW-UP CRF and the onset date must be prior to or coincident to the date of latest follow-up last follow-up (see the green and blue circles in SAE\_NSAE.pdf)

Available information concerning more recent follow-up visits (i.e. from 01/01/2007) must not be reported in the BASELINE FOLLOW-UP CRF.

You will be asked to report the information concerning the period 01/01/2007 - 31/12/2007 in the ILTE\_part2.mdb that we will send to you in October 2007.

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

We would also like to take this occasion to let you know that we are also organizing two ILTE dinners for investigators attending the next ASCO and EHA meetings; details will follow soon.

With best regards,

Carlo Gambacorti-Passerini MD, Lucia Tornaghi RN, LTE Coordination Office

Maria Grazia Valsecchi PhD, Laura Antolini PhD, ILTE Statistical Unit

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# 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

Fill a new CRF

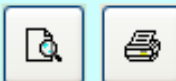
Patient ID

Check/Modify an  
existent CRF

Patient ID

**St. Gerardo  
Hospital - MONZA**

Registered patients with open CRF



Date of latest FUP  Dose at latest FUP  *If OTHER, specify (mg/die)*

*If different from that after 2 years  
from treatment start, specify*

Date of change

Cause of change

## END POINTS

Loss of CCR

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

Date of eval.  n. of metaphases Total  Ph pos

*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

Death

*If YES, specify below*

Date of death

Cause

*If OTHER, specify*

Malignant neoplasm

*If YES, specify below*

Date of diagnosis

Type

*If OTHER, specify*

Serious Adverse Event

*If YES, specify*

No. of SAE

Fill in one SAE CRF for each SAE

Non Serious Adverse Event

*If YES, specify*

No. of NSAE

Fill in one NSAE CRF for each NSAE

## ILTE Study : Serious Adverse Event (SAE)



Report here only SAE indicated in the Baseline FUP

Specify each SAE reported by 'first', 'second', 'third', 'fourth' in the SAE reference field

To be completed by December 31-2006

Fill a new form Patient ID  SAE reference  Pts SAE reference Onset date

Check/Modify an existent form Patient ID and SAE ref.

Patients with one or more open forms  

**St. Gerardo  
Hospital - MONZA**

Onset date

*MAIN MOTIVATION(S) FOR SAE CLASSIFICATION*



## ILTE Study : Non Serious Adverse Event (NSAE)

Report only events judged by the investigator as substantially interfering with the quality of life of the patient

Report here ONLY NSAE indicated in the Baseline FUP.

Specify each NSAE reported by 'first', 'second', 'third', 'fourth' in the NSAE reference field

To be completed by December 31-2006

Fill a new form Patient ID  NSAE reference  Pts SAE reference Onset date

Check/Modify an existent form Patient ID and NSAE ref.

Patients with one or more open forms  

**St. Gerardo  
Hospital - MONZA**

Onset date

*NSAE DESCRIPTION*

