Academic Haematology
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Dr John Keen
London – Central REC
Level 7, Maternity
Northwick Park Hospital
Watford Road
Harrow
HA1 3UJ

27 May 11

Dear Sir/Madam,

SPIRIT 2 - A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400mg daily versus dasatinib (Sprycel) 100mg daily in patients with newly-diagnosed chronic phase chronic myeloid leukaemia.

EUDRACT number: **2007-006185-15**
REC Reference: **07/H0718/90**

Please find enclosed the Annual Safety Report for the above study.

If you have any queries regarding the report please don't hesitate to contact the Chief Investigator (Prof. S G O'Brien) or myself.

Yours sincerely,

C. Hedgley

Corinne Hedgley
Senior Trial Project Manager.

cc Amanda Tortice
R&D Manager, Newcastle-upon-Tyne Hospitals NHS Foundation Trust

National Patient Safety Agency

National Research Ethics Service

CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

SAFETY REPORT TO MAIN RESEARCH ETHICS COMMITTEE

Please indicate which type(s) of safety report you wish to notify with this cover sheet (tick all that apply). Use a separate sheet for notifications relating to different trials. Please only send this to the main REC. For further guidance see: *http://www.nres.npsa.nhs.uk/applicants/after-ethical-review/safetyreports/safety-reports-for-ctimps/*

1. **Expedited report(s) of SUSAR in the UK** ☐
   Notify only Suspected Unexpected Serious Adverse Reactions occurring in the concerned trial at a UK site.

2. **6-monthly safety report** ☐
   Include a global list of all SUSARs related to the investigational medicinal product (IMP) and occurring in the reporting period.

3. **Annual safety report** ☑
   Include a global list of all SSARs (Suspected Serious Adverse Reactions) related to the IMP and occurring in the reporting period.

4. **Other** ☐
   For example, report of Data Monitoring Committee or other safety review.

Full title of study:	SPIRIT 2 - A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400mg daily versus dasatinib (Sprycel) 100mg daily in patients with newly-diagnosed chronic phase chronic myeloid leukaemia.
EudraCT number:	2007-006185-15
Research sponsor:	Newcastle upon Tyne Hospitals NHS Foundation Trust
Name of Chief Investigator:	Prof. S. G. O'Brien
Name of main REC:	London - Central
Main REC reference number:	07/H0718/90

Contact details for person making this notification

Name:	Corinne Hedgley
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Date of this notification:	27 May 2011
Signature:	

List of enclosed documents
Please list each report submitted with this notification (insert extra rows in table as required).

1. Expedited SUSARs (UK only)

Sponsor's report no./reference	Trial site	Date SUSAR first reported to sponsor	Is this a 7 or 15 day report?

2. Other reports

Type of report	Date of report
Annual Safety Report	*26 May 2011*

Acknowledgement of receipt by main REC (please insert name):

The [ ] Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	

Position on REC:	
Date:	

Signed original to be sent back only to the sponsor (or other person submitting the report)
Copy to be kept for information by main REC.