Academic Haematology
The Medical School
Framlington Place
Newcastle NE2 4HH

Email: c.a.hedgley@ncl.ac.uk

20 April 2009

Dear Sir/Madam,

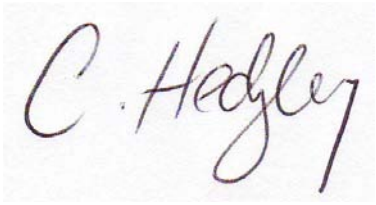
SPIRIT 2 - A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400mg daily versus dasatinib (Sprycel) 100mg daily in patients with newly-diagnosed chronic phase chronic myeloid leukaemia.

MREC reference number: 07/H0718/90

Please find attached 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 (Dr S G O'Brien) or myself.

Yours sincerely,



Corinne Hedgley
Senior Trial Project Manager.

cc Amanda Tortice
R&D Manager, Newcastle-upon-Tyne Hospitals 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:	SPIRIT2 - STI571 Prospective International RandomIsed Trial 2 – A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400mg daily versus dasatinib 100mg in patients with newly-diagnosed chronic phase chronic myeloid leukaemia.
EudraCT number:	2007-006185-15
Research sponsor:	Newcastle-upon-Tyne Hospitals Foundation NHS Trust
Name of Chief Investigator:	Dr S. G. O'Brien
Name of main REC:	London MREC
Main REC reference number:	07/H0718/90

Contact details for person making this notification

Name:	Corinne Hedgley
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National Patient Safety Agency

National Research Ethics Service

	The Medical School Newcastle University NE2 4HH
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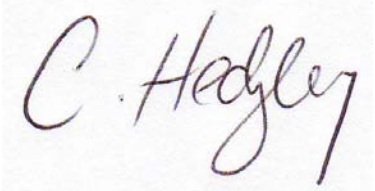
Date of this notification:	20 April 2009
Signature:	

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 Saftey Report	*20 April 2009*

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

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

Signed:	

National Patient Safety Agency

National Research Ethics Service

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.