SPIRIT 2
STI571 Prospective International Randomised Trial

Serious Adverse Event Form

Protocol SPIRIT 2 **EudraCT number: 2007-006185-15**	**SITE name**		**CASE NUMBER (trial office use only)**
	SITE number		
	Subject Number		**Trial Drugs** Imatinib (Gleevec) or Dasatinib (Sprycel)
	Subject's Initials		

Contact for Queries	Name (please print)	Email	Phone

SERIOUS ADVERSE EVENT REPORT

Page 1 of 3

1. REPORT TYPE: ☐ Initial ☐ Follow-up | 2. LOCAL CASE ID *(if applicable)*: | 3. COUNTRY: **UK**

DEMOGRAPHIC INFORMATION

4. DATE OF BIRTH	5. AGE	6.RACE	7.SEX	8. HEIGHT	9. WEIGHT
day month year	yrs./mo.	☐ Caucasian ☐ Oriental ☐ Black ☐ Other	☐ Male ☐ Female	cm	kg

ADVERSE EVENT INFORMATION

10. ONSET OF FIRST SIGN/SYMPTOM OF SAE
day month year

11. DATE OF DEATH *(if applicable)*
day month year

12. SERIOUS ADVERSE EVENT IN MEDICAL TERMS (diagnosis, if possible)

Case description of the above SAE (include related signs/symptoms, treatment, course/outcome and suspected cause of the SAE) (continue on P.3 if more space is required):

Is the event due to lack of efficacy? ☐ No ☐ Yes

Is the event due to progression of underlying illness? ☐ No ☐ Yes

EXPEDITED REPORTING CRITERIA

13. CHECK ALL APPROPRIATE TO EVENT

- ☐ Patient died
- ☐ Involved or prolonged inpatient hospitalization
- ☐ Results in persistent or significant disability / incapacity
- ☐ Life-threatening
- ☐ Congenital anomaly/birth defect
- ☐ Other significant medical events

14. ASSESSMENT OF CAUSALITY

Relationship to study drug ☐ Not suspected ☐ Suspected

TRIAL DRUG INFORMATION

15. TRIAL DRUG *(tick one)*	16. DOSE AT OR BEFORE ONSET OF SAE (mg/day)	ROUTE OF ADMINISTRATION
DASATINIB (Sprycel) ☐ IMATINIB (Gleevec) ☐		**ORAL**

17. TRIAL INDICATION	18. THERAPY DATES (from / to)	
Chronic Myeloid Leukaemia	day month year	day month year

19. ACTION TAKEN (mark all as appropriate)

- ☐ No Action Taken
- ☐ Study Drug permanently discontinued due to this adverse event
- ☐ Study Drug dosage adjusted/temporarily interrupted *
- ☐ Hospitalization/prolonged hospitalization
- ☐ Concomitant medication taken **
- ☐ Non-drug therapy given **

* If ticked, enter new dosage information on page 3
** If ticked, provide information on page 3

PLEASE FAX FORM TO 0191 376 0748

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CONCOMITANT DRUGS & MEDICAL HISTORY

20. CONCOMITANT DRUGS *(**NOTE**: **exclude** any therapy to **treat SAE**)*

DRUG NAME(S)	DOSE	UNIT	FREQ.	ROUTE	DATE STARTED day month year	CONT. Yes/No	DATE DISCONTINUED Day month year	REASON FOR USE

21. PATIENT'S PAST MEDICAL HISTORY (e.g. co-existing medical conditions such as disease, allergies, similar experiences)

TEST RESULTS AND EVENT OUTCOME

22. TEST / LABORATORY FINDINGS *(enter only those findings necessary for SAE diagnosis or course description)*

TEST/ LAB NAME	UNIT	DATE day month year	VALUE	DATE day month year	VALUE	DATE day month year	VALUE

23. COMMENTS ON TEST/LABORATORY FINDINGS (Provide normal ranges on page. 3 if not already provided.) (If the SAE is a laboratory abnormality, enter comments on clinical findings and/or treatment on page 3.)

24. OUTCOME OF THE PATIENT/SAE

☐ Completely Recovered — Date of recovery: Day Month Year

☐ Recovered with sequelae

☐ Condition improving

☐ Condition still present and unchanged

☐ Condition deteriorated

☐ Death — Autopsy: ☐ No ☐ Yes

INFORMATION SOURCE

25. NAME, ADDRESS AND TELEPHONE NUMBER OF INVESTIGATOR

Signature:

26. REPORTING DATE BY INVESTIGATOR/PERSON REPORTING EVENT

day month year

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ADDITIONAL INFORMATION:

STUDY DRUG MANUFACTURER INFORMATION *(trial office use only)*

27. NAME AND ADDRESS OF MANUFACTURER	28. MANUFACTURER CONTROL NUMBER

INFORMATION SOURCE

25. NAME, ADDRESS AND TELEPHONE NUMBER OF INVESTIGATOR Signature:	26. REPORTING DATE BY INVESTIGATOR/PERSON REPORTING EVENT day month year

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