SPIRIT 2
STI571 Prospective International Randomised Trial

Serious Adverse Event Form

Protocol SPIRIT 2 **EudraCT number: 2007-006185-15**	**ID** **Site No.**		**CASE NUMBER**
	Subject No.		**Trial Drugs** STI571 – Imatinib or Dasatinib (Sprycel)
	Subject's initials		

SERIOUS ADVERSE EVENT REPORT

1. REPORT TYPE: ☐ Initial ☐ Follow-up | 2. Country: **UK** | 3. CASE ID:

I. ADVERSE EVENT INFORMATION

4. DATE OF BIRTH	5. AGE	6.RACE	7.SEX	8. HEIGHT	9. WEIGHT	10. ONSET OF FIRST SIGN/SYMPTOM OF SAE
day month year	yrs./mo.	☐ Caucasian ☐ Oriental ☐ Black ☐ Other	☐ Male ☐ Female	cm	kg	day month year

11. SERIOUS ADVERSE EVENT(S) 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

12. CHECK ALL APPROPRIATE TO EVENT

☐ Patient died — day month year

☐ Involved or prolonged inpatient hospitalization

☐ Results in persistent or significant disability / incapacity

☐ Life-threatening

Other Seriousness Criteria:

☐ Congenital anomaly/birth defect

☐ Other significant medical events

II. TRIAL DRUG INFORMATION

13. TRIAL DRUG AT OR BEFORE ONSET OF SAE

Comments (Continue on P.3 if more space is Required):

14. LAST VISIT/WEEK BEFORE ONSET OF SAE
VISIT NO.: MONTH NO.:

15. DOSE AT OR BEFORE ONSET OF SAE		16. ROUTE OF ADMINISTRATION	17. THERAPY DATES (from / to)	
Trial Drug	Dose			
	Per day	**Oral**	day month year	day month year

18. TRIAL INDICATION	19. THERAPY DURATION UNTIL ONSET OF FIRST SIGNS/SYMPTOM OF SAE	20. TIME ELAPSED BETWEEN LAST DRUG ADMINISTRATION AND ONSET OF FIRST SIGNS/SYMPTOM OF SAE
Chronic Myeloid Leukaemia	hrs/days/months	mins/hrs/days/months

III. HISTORY

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

PLEASE FAX FORM TO 0191 376 0748

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25. CONCOMITANT DRUGS RELEVANT TO THE SAE (**NOTE**: exclude any therapy to treat SAE)

DRUG NAME(S)	DOSE ROUTE	UNIT SCHEDULE	DATE STARTED day month year	CONT. 0=No 1=Yes	DATE DISCONTINUED Day month year	REASON FOR USE

26. COMMENTS (If adverse event is considered to be caused by a comedication, please note it here)

27. ACTION TAKEN (mark all as appropriate)

☐ No Action Taken
☐ Imatinib [(a)] dosage adjusted/temporarily interrupted *
☐ Dasatinib [(b)] dosage adjusted/temporarily interrupted *
☐ Imatinib [(a)] permanently discontinued due to this adverse event
☐ Dasatinib [(b)] permanently discontinued due to this adverse event
☐ Non-drug therapy given **
☐ Concomitant medication taken
☐ Hospitalization/prolonged hospitalization

* If ticked, enter new dosage information in field 11
** If ticked, provide therapeutic measures in field 11

(a) leave blank if no action taken with imatinib dose or patient not randomised to receive imatinib

(b) leave blank if no action taken with dasatinib or patient not randomised to receive dasatinib

28. 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

29. COMMENTS ON TEST/LABORATORY FINDINGS (Provide normal ranges on Pg. 3 if not already provided.) (If the SAE is a laboratory abnormality, enter comments on clinical findings and/or treatment in field 11.)

30. 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

31. ASSESSMENT OF CAUSALITY

Relationship to study drug *(tick only for applicable study drug)*		
Imatinib	☐ Not suspected	☐ Suspected
Dasatinib	☐ Not suspected	☐ Suspected

V. INFORMATION SOURCE

32. NAME, ADDRESS AND TELEPHONE NUMBER OF INVESTIGATOR

Signature:

32. REPORTING DATE BY INVESTIGATOR/PERSON REPORTING EVENT

day month year

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FOR ADDITIONAL INFORMATION:

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