SPIRIT 2
STI571 Prospective International Randomised Trial

Pregnancy Form

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

CLINICAL TRIAL PREGNANCY FORM

1. Country: UK

2. LOCAL CASE ID:

I. MATERNAL INFORMATION

3. DATE OF BIRTH day month year

4. AGE yrs./mo.

5. RACE
☐ Caucasian ☐ Oriental
☐ Black ☐ Other

6. HEIGHT Cm

7. WEIGHT kg

8. Date of Last Menstrual Period day month year

9. Expected Date of Delivery day month year

10. Method of Contraception

11. Contraception used as instructed
☐ yes ☐ no ☐ uncertain

II. HISTORY

12. PATIENT'S PAST MEDICAL HISTORY (include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy e.g. alcohol, smoking, other substance consumption, infections, hypertension, diabetes including gestational, environmental or occupational exposure that may pose a risk factor).

13. PREVIOUS OBSTETRIC HISTORY – provide details on all previous pregnancies below, including abortion or stillbirth (use page 3 if needed)

	Gestation week	Outcome including any abnormalities
1		
2		
3		
4		

14. DRUG INFORMATION – please list SPIRIT 2 Study Drugs first and all other therapies taken prior to or during pregnancy

Drug Names	Dose / Units / Frequency	Route	Treatment Dates Start	Treatment Dates Stop	Indication	(specify week of pregnancy) Start	(specify week of pregnancy) Stop

PLEASE FAX FORM TO 0191 376 0748

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III. PREGNANCY INFORMATION

18. PRENATAL
Have any specific tests, e.g. amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far?
☐ No ☐ Yes ☐ Not known
If yes, please specify test date and results:

19. PREGNANCY OUTCOME
Delivery
☐ Normal ☐ Forceps/Ventouse ☐ Caesarean section
Maternal complications or problems related to birth: _____
Abortion
☐ Therapeutic ☐ Planned ☐ Spontaneous Please, specify reason and any abnormalities (if known) _____
_____
Date of abortion/delivery day month year
at week _____ |_____|_____|_____|

20. MATERNAL PREGNANCY ASSOCIATED EVENTS:
If the mother experiences a serious adverse event (SAE) during a pregnancy, please complete an SAE form and submit as requested

IV. CHILD INFORMATION

21. Neonate
☐ Normal ☐ Abnormal ☐ Stillbirth please specify any abnormalities with dates: _____

Sex	Height	Weight	Apgar Scores	Head circumference
☐ Male ☐ Female	cm	kg	1 min. 5 mins. 10 mins.	cm

For additional information, please use page 3 (please provide copies of relevant documentation)

V. ASSESSMENT OF PREGNANCY OUTCOME

22. SERIOUSNESS CRITERIA
☐ Non Serious
☐ Mother died day month year |_____|_____|_____|
☐ Stillbirth / Neonate died day month year |_____|_____|_____|
☐ Involved or prolonged inpatient hospitalisation
☐ Life-threatening
☐ Results in persistent or significant disability/incapacity
Other Seriousness Criteria: ☐ Congenital anomaly/birth defect ☐ Other significant medical events

23. ASSESSMENT OF CAUSALITY Please indicate the relationship between pregnancy outcome and investigational drug

Dasatinib (Sprycel)	☐ Not suspected	☐ Suspected
Imatinib (Gleevec)	☐ Not suspected	☐ Suspected

INFORMATION SOURCE

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

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CLINICAL TRIAL PREGNANCY FORM

2. LOCAL CASE ID:

FOR ADDITIONAL INFORMATION:

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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