SPIRIT 2
STI571 Prospective International Randomised Trial

Site Delegation Log

SPIRIT 2 CML Trial			EudraCT number: 2007-006185-15	
Site name:		**Site Number:**		
	Name	**Signature**	**Start date:**	**Stop date:**
Principal Investigator *(as documented in Schedule 1 of the Clinical Trial Agreement)*			Do not complete	
Principal Investigator*				
Principal Investigator*				
Principal Investigator*				

The Principal Investigator (PI) may change during the course of the study (eg. maternity leave, leaving post) – changes to the PI should be documented above

	Name	**Role** *See appendix*	**Responsibilities** *Choose code(s) from the table below, or specify*	**Signature**	**Initials**	**Involvement with SPIRIT 2**		**PI Signature**
						Start date	**Stop date**	
1.								
2.								
3.								

RESPONSIBILITIES		
A – Determine eligibility	**C** – Enter data and make corrections in Electronic CRF	**E** – Perform key trial measurements
B – Obtain Informed Consent	**D** – Lock electronic CRF data (sign-off)	**F** – Dispense trial medications
G – Prescribe trial Drug	**H** – Other – specify in table	**I** – Investigator Site File maintenance

SPIRIT 2
STI571 Prospective International Randomised Trial

Site Delegation Log

Principal Investigator (PI):			
Site name:		**Site Number:**	

	Name	**Role** *See appendix*	**Responsibilities** *Choose code(s) from the table below, or specify*	**Signature**	**Initials**	**Involvement with SPIRIT 2**		**PI Signature**
						Start date	**Stop date**	
4.								
5.								
6.								
7.								
8.								
9.								

RESPONSIBILITIES		
A Determine eligibility	**B** Obtain informed consent	**C** Enter data and make corrections in electronic CRF
D Lock electronic CRF data (sign off)	**E** Perform key trial measurements	**F** Dispense trial medications
G Prescribe study drug	**H** Other – specify in table above	**I** Investigator Site File maintenance

SPIRIT 2
STI571 Prospective International Randomised Trial

Site Delegation Log

Principal Investigator (PI):			
Site name:		**Site Number:**	

	Name	**Role** *See appendix*	**Responsibilities** *Choose code(s) from the table below, or specify*	**Signature**	**Initials**	**Involvement with SPIRIT 2**		**PI Signature**
						Start date	**Stop date**	
10.								
11.								
12.								
13.								
14.								
15.								

RESPONSIBILITIES		
A Determine eligibility	**B** Obtain informed consent	**C** Enter data and make corrections in electronic CRF
D Lock electronic CRF data (sign off)	**E** Perform key trial measurements	**F** Dispense trial medications
G Prescribe study drug	**H** Other – specify in table above	**I** Investigator Site File maintenance

SPIRIT 2
STI571 Prospective International Randomised Trial

Site Delegation Log

Principal Investigator (PI):			
Site name:		**Site Number:**	

	Name	**Role** *See appendix*	**Responsibilities** *Choose code(s) from the table below, or specify*	**Signature**	**Initials**	**Involvement with SPIRIT 2**		**PI Signature**
						Start date	**Stop date**	
16.								
17.								
18.								
19.								
20.								
21.								

RESPONSIBILITIES		
A Determine eligibility	**B** Obtain informed consent	**C** Enter data and make corrections in electronic CRF
D Lock electronic CRF data (sign off)	**E** Perform key trial measurements	**F** Dispense trial medications
G Prescribe study drug	**H** Other – specify in table above	**I** Investigator Site File maintenance

Appendix – Roles

Qualified staff involved in study conduct may include:

Co-investigator

Research nurse

Research assistant

Trial co-ordinator

Trial administrator

Data manager

Pharmacist

Pharmacy technician

Additional roles associated with, but not directly involved in the study may include:

Clinicians

specialist nurses

laboratory staff

other support staff e.g. imaging/radiology.