Source data agreement

SPIRIT 2 CML TRIAL	EudraCT NUMBER: 2007-006185-15
Site number:	**Site name:**
Principal Investigator name:	**Principal Investigator signature:**

Source data and documents
GCP defines ***source data*** as: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source documents are: Original documents, data, and records relevant to the clinical trial. For SPIRIT 2 these may include hospital notes (including clinic notes, clinical letters, quality of life questionnaires, laboratory results etc).

Source data must adhere to ALCOA standards:
Attributable: is it obvious who wrote it (signed/initialled)?
Legible: can it be read?
Contemporaneous: been recorded in a timely fashion (and dated)?
Original: or if it is a copy has it been verified as an exact (accurate and complete) copy of the original?
Accurate: is this a correct reflection of events?

By signing the consent form the patient is confirming that responsible individuals from the trial team may have access to their records. SPIRIT 2 monitors will require direct access to source data and documents for verification of trial procedures and/or trial data.

Please indicate below where the source data for the SPIRIT 2 data will be recorded:

Item	Location of source data
e.g. Adverse events:	*Medical notes including patient history pages and medical letters (correspondence section).*
e.g. Bone marrow reports: cytogenetics	*A verified copy of the electronic report will filed in the patient's CRF.*
Medical history:	
Physical examinations: liver, spleen, lymphadenopathy.	
Physical examination: ECOG score	
Bone marrow reports: cytogenetics	
Bone marrow reports: morphology	
Adverse events	
Concurrent medications	
Laboratory results:	