

Investigator Site File

Volume 1 of 2	Main Investigator Site File <ul style="list-style-type: none"> • Table of contents* • Document version control* • Monitoring log • Monitoring reports
Section 1.1	Contact details*
Section 1.2	General Correspondence
Section 1.3	Screening and Recruitment Record <ul style="list-style-type: none"> ▪ Screening log* ▪ Patient log*
Section 1.4	Study Specific Documentation (part 1) <ul style="list-style-type: none"> ▪ Location of Source Documents*. ▪ Copy of Patient Information Sheet / Informed Consent Form* printed on local hospital headed paper (template). ▪ Copy of GP letter* printed on local hospital headed paper (template). ▪ Completed Consent Forms with Patient Information Sheet. ▪ Protocol*.
Section 1.5	Study Specific Documentation (part 2) <ul style="list-style-type: none"> ▪ Local laboratory normal ranges*. ▪ Shipping form*: Biobank - Glasgow and PCR – Hammersmith (template). ▪ FACT BRM and EQ5D Quality of Life questionnaires* (template). ▪ Completed Quality of Life questionnaires.
Section 1.6	Safety <ul style="list-style-type: none"> ▪ SPIRIT 2 SAE form* (template). ▪ Completed SAE forms (NB: these should be faxed to the Trial office within 24 hours of becoming aware of the event, and the original filed here). ▪ Annual Safety Reports* ▪ SUSAR reports*

Section 1.7	Research personnel <ul style="list-style-type: none"> ▪ Delegation log*. ▪ CVs (updated, signed and dated on an annual basis).
Section 1.8	Training documentation <ul style="list-style-type: none"> ▪ GCP training certificate (dated within last 3 years). ▪ eCRF training. ▪ Site initiation. ▪ Other training.
Section 1.9	Local approvals <ul style="list-style-type: none"> ▪ R&D approval ▪ SSI form ▪ Correspondence with R&D/LREC (as applicable) ▪ Fully signed Clinical Trial Agreement
Section 1.10	Central approvals (sponsorship) <ul style="list-style-type: none"> ▪ Sponsor confirmation* ▪ Liability / indemnity cover* ▪ CV of Chief Investigator*
Section 1.11	Central approvals (Ethics)*
Section 1.12	Central approvals (MHRA)*
Section 1.13	Investigational Medicinal Product (IMP) <ul style="list-style-type: none"> ▪ Dasatinib: Investigator Brochure* ▪ Imatinib: Summary of Product Characteristics*
Section 1.14	Location of Section 2 – Pharmacy Site file
* Documents or templates available from SPIRIT 2 website www.spirit-cml.org .	