

SAFETY ISSUE



Welcome to the SPIRIT 2 safety newsletter.

We wanted to take this opportunity to focus on key aspects of safety reporting for the trial and also to draw focus on a recent piece of work relating to SAE reporting.

We hope you find this newsletter interesting and informative. If you have any questions relating to safety or safety reporting please do not hesitate to contact the Trial Office.

SAE Audit

Thank you all for completing the recent SPIRIT 2 SAE Audit.

As you are aware, the audit was requested by the MHRA as one of a number of corrective and preventative actions implemented following a serious breach of GCP. We were required to respond to the MHRA with the results of the audit as soon as possible and are very grateful to all the SPIRIT 2 sites for responding so promptly.

As a trial team, we have learnt a lot from this audit and are keen to share the results with you.

- Total number of unreported SAEs identified via audit: **96**
- Number of SPIRIT 2 Sites with at least one unreported SAE identified at audit: **45** (out of 144 – **31%**)
- Number of patients with one or more unreported SAE identified at audit: **64**

From the audit it appears that the most common reasons for missed SAEs were as follows:

- The SPIRIT 2 requirement for elective admissions to be reported and lack of awareness of this.
- Multiple hospital admissions for individual patients for the same condition/symptom. Often the first admission was reported however subsequent admissions were overlooked.

As a trial team we have found this audit to be a useful and informative exercise and are very grateful for all your assistance.

SPIRIT 2 SAE Reporting: 10 top tips

- **Guidance on SPIRIT 2 SAE reporting can be found in the SPIRIT 2 SAE Reporting Guidelines for Sites** (available on the S2 website) **and in section 11.3 of the S2 protocol.**
- **Any event meeting the criteria for SAE reporting in SPIRIT 2** (see protocol section 11.3) **must be reported immediately** (within 24 hours of becoming aware of the event).
- **The paper SPIRIT 2 SAE reporting form** (version 2) **should be used to report SAEs.** You can find a copy in your ISF or on the S2 website.
- **SAE forms should be completed as much as possible before sending.** However it is acceptable to send without the PI or co-investigator signature if it is not possible to obtain the signature within the 24 hour timeline.
- **Completed SAE forms should be faxed to the Trial Office on 0191 376 0748.** If you do not have access to a fax machine you can scan and email forms to the S2 nhs.net account (tnu-tr.spirittrials@nhs.net). SAE emails must be sent from nhs.net accounts for data protection purposes.
- **Causality assessments must be completed and authorised** (via signature) **by the PI or delegated co-investigator.** The signature of a medic who is not on the delegation log cannot be accepted.
- Once reported via the form, **SAEs also need to be recorded on the SPIRIT 2 eCRF as AE pages.** Completed SAE forms should be **filed in section 8 of the SPIRIT 2 ISF.**
- **Any SAE occurring following the start of IMP and up until 4 weeks after the last dose of IMP must be reported** (for patients on continuing supply of dasatinib this means SAE reporting requirements continue beyond visit 15). Any serious adverse reaction (believed to be caused by S2 IMP) must be reported regardless of length of time since last IMP dose.
- **Receipt of all SAE forms will be acknowledged by email.** If you do not receive an email within 2 working days please contact the Trial Office.
- **If in doubt - please ask!** Please contact us on **0191 282 0904** if you have any queries or if you are unsure if an event needs to be reported.