



FILE NOTE

Re: UKALL14 SAE report v3.0 – not released to sites in error

Date: 01.02.2016

Issues:

Version 3.0 of the SAE report form for UKALL14 (dated 13.12.2013) was approved by the CTC's PV manager on 16.12.2013 (see email correspondence attached). It was not disseminated to sites in error.

On 12.01.2016, the CTC's regulatory team highlighted to the UKALL14 team that a site had submitted an SAE on version 2.0 of the SAE report form, which included the wrong reporting timeframe (1 business day rather than 24 hours). The UKALL14 team was asked to confirm whether the site were using an out dated version of the SAE report.

An investigation was carried out on 14.01.2016 by Pip Patrick, Senior Trial Coordinator. She confirmed that v2.0 was the version of the SAE report currently in use at all sites.

There was no documentation for the reason why SAE report v3.0 was not disseminated to sites, however, a review of the eTMF revealed a further version (v4.0, dated 16.12.2013) in draft form. The most likely scenario is that v3.0 was not released to sites because the trial coordinator had planned to immediately supersede it. There was no evidence that v4.0 had been finalised and approved for release.

Decisions/actions:

On 13.01.2016, a compliant version of the SAE report template was sent to UCL CTC's PV team for review. This was finalised as v4.0, dated 21.01.2016.

On 22.01.2016, SAE report form version 4.0 was disseminated to sites along with a file note stating that v3.0 had not been issued to sites in error.

An incident report was completed, detailing the findings of the investigation and the CAPA carried out as a result (incident database ref ILREG00982). This is filed in the QA section of the TMF.

Signature:

A handwritten signature in black ink, appearing to be 'Pip Patrick', written over a circular scribble.

Date: 1 February 2016

Name: Pip Patrick

Title: Senior Trial Coordinator