

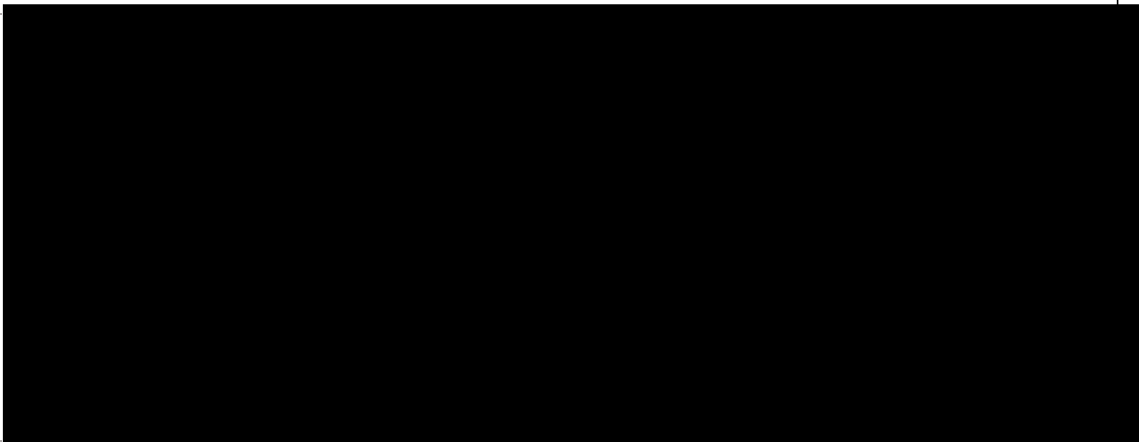


3.9	Project Management
3.9.1	The [REDACTED] trial risk assessment was not updated in a timely manner to address new risks arising in the study and the strategies put in place to mitigate these. The trial was put on temporary halt in [REDACTED] following a SAE experienced by one of the participants in the trial. The trial team conducted various investigations relating this which ultimately led the update of the protocol which was submitted as Substantial amendment [REDACTED] in [REDACTED]. However, the risk assessment was not updated until [REDACTED].

Inspected Organisation's Response - 01	
Evaluation & Root Cause	
Corrective Action(s)	
Preventative	

Inspected Organisation's Response - 01

Action(s)

**MHRA Review - 01**

This response is accepted.