2.2	**Data Integrity Control Processes (continued)**
2.2.3	[redacted] staff had write access to eCRFs, this was used to resolve queries, enter some paper CRFs (early in the study when database was not complete), to make self-evident corrections (see finding 2.2.11) and to complete CRF tracking information ("FOR OFFICE USE ONLY" section) at the end of the eCRF. The [redacted] staff were able to make changes to data submitted to the eCRF by investigators without investigator approval of changes and without having been delegated to do so by the investigator. Use of the CRF for such purposes is not recommended, the sponsor (or its delegated party) should only enter data as part of workflow activities, not on the CRF data collection pages. Examples were noted here for the [redacted] Trial, but it is understood this was standard practice for all trials with a [redacted] -built database. Examples noted in [redacted] (not exhaustive).

User	Number of data change instances	Reason noted by sponsor during inspection
[redacted]	215	Updating "FOR OFFICE USE ONLY" section.
	1	Self-evidence corrections by CTU staff
[redacted]	31	Updating "FOR OFFICE USE ONLY" section.
	2	Self-evidence corrections by CTU staff
[redacted]	186	Updating "FOR OFFICE USE ONLY" section.
	1	Self-evidence corrections by CTU staff
[redacted]	6	Self-evidence corrections by CTU staff
	1953	Entry of paper CRFs submitted for participant.

Inspected Organisation's Response - 01	
Evaluation & Root Cause	[redacted]

Inspected Organisation's Response - 01	
	[redacted]
Corrective Action(s)	
Preventative Action(s)	

Inspected Organisation's Response - 01

[redacted]

MHRA Review - 01

[redacted]

Inspected Organisation's Response - 02

[redacted]

MHRA Review - 02

This response is accepted.

[redacted]