Training Log Audits: an Evaluation and Reconciliation of Missed Training within the Experimental Cancer Medicine Team

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Background

The Experimental Cancer Medicine Team (ECMT) run a number of complex and varied early phase trials.

Due to the adaptive nature of early phase studies there may be many amendments made to the protocols throughout the study. Following these amendments, study staff are then trained on the amended documents – this can be face-to-face, remotely or self-paced – they are then required to complete training logs to document that they have read and understood the training and updated documents.

To comply with Good Clinical Practice (GCP), staff are to ensure that they are adequately trained prior to completing their delegated duties. To ensure that this had been documented correctly, a training log audit was conducted.

A prior training log audit revealed that some documentation had been missed, therefore we investigated this further by implementing training audits for all superseded training logs within the active studies portfolio within the ECMT.

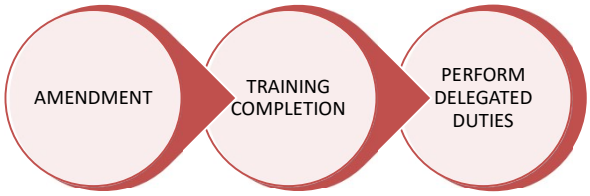

Figure 1: Flow diagram to show when training is required

Aims

- To ensure that training has been fully documented correctly
- To explore and identify common themes into missed training documentation
- To analyse data so that we may create processes to prevent future documentation being missed

Methods

Create a standardised study tracker containing lists of: delegates, roles, delegation dates & training requirements

Create formatting to easily identify training requirements based on implementation & delegation dates (Figure 2)

		Delegation log					Training log		
Page	Order	Forename	Surname	Role	Signed on	Signed off	01. SIV/ Protocol v1	02. SA01 / Protocol v2	03. SA03 / Protocol v3
							01/01/20	02/01/20	03/01/2022
1	1	Katrina	Koordinator	CTC	01/01/2022	03/01/2022	!	!	NA
	2	Sue	Binvestigator	Sub-I	02/01/2022		NA	!	!

Figure 2 – Figure to demonstrate automations on Training Audit, dependant on delegation log dates and amendment implementation dates

Review of Investigator Site Files (ISF's) of all superseded training logs and upload data to study trackers

Findings for individual trials were then shared and feedback was provided to the lead Clinical Trial Coordinator (CTC) on the trial

Results

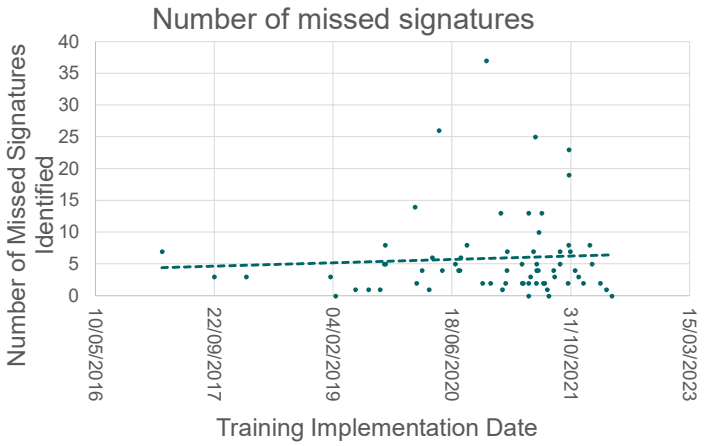

Figure 3: Graph to show number of missing signatures on training logs and when the respective training was implemented

The results in Figure 3 demonstrate that, though some, there is no strong correlation between when the amendment was implemented and the number of missed signatures. However, they do demonstrate that there were some spikes in the number of missing signatures from early 2020 to late 2021.

Upon discussion with the CTC's whose studies the outliers occurred, it appears that there are several factors that may account for why there are missing signatures, such as:

- Multiple training logs within a short time period, causing confusion as to what training is required at any one time
- Human error, accidentally signing the wrong log, missing a delegate when assigning tasks
- COVID-19:
  - working from home causes differing office working hours to the CTC who could assist with training logs
  - shielding means staff may go a long time before being available to sign training documents
  - Suspension of monitoring visits and audits meant that issues were not being monitored effectively

Despite there being some outliers, the data shows that the majority of training logs are completed to a high standard – only missing on average 5 signatures (out of up to 60 delegates)

Conclusion

In conclusion, there is scope for improvement in order to obtain full documentation of training.

As a result of this work, the ECMT will be implementing training audits on a rolling basis. When new training is provided, an audit of the previous training log will be completed prior to filing. This will ensure that missing signatures or note to files can be obtained in a timely manner during the active phase of a study.

Despite initial audits being a time consuming process, we expect that when implemented as a rolling audit completion times will be significantly reduced.

Acknowledgements – The authors would like to acknowledge the NIHR, ECMC, CRUK and the ECMT CTC team.

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