ECTU Central Office SOP_TM_21: Evidencing Competency, Training and Delegation of Tasks in the Trial Management Team

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	16 Jun 2022	Initial creation
2.0	24 May 2024	Minor clarification to Section 4.2. Second Reviewer added. Title of the SOP has been amended. Minor formatting changes.

1.0 PURPOSE

The Medicine for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031) require clinical trials of investigational medicinal products (CTIMPS) to be conducted according to the principles of Good Clinical Practice (GCP). One of these principles, as laid down in the medicine for Human Use (Clinical Trials) Amended Regulations 2006 (SI2006/1928), is that:

'Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.'

Delivery of clinical trials requires a team of experienced and skilled staff to follow complex and regulated procedures. This SOP outlines the use of the competency and knowledge framework and delegation of activities within the ECTU Trial Management Team (TMT) to ensure that the appropriate skills and experience are achieved.

2.0 SCOPE

This SOP applies to all TMT staff comprising Senior Trial Managers (STM), Trial Managers (TM), Assistant Trial Managers (ATM) and Trial Management Support Officers (TMSO).

3.0 RESPONSIBILITIES

All TMT staff are responsible for ensuring the procedures outlined with this SOP are followed.

4.0 PROCEDURE

4.1 Competency and knowledge

4.1.1 ECTU will use the UK Trial Managers Network (UKTMN) Competencies framework which is a self-assessment tool nationally recognised by the UKTMN.

4.1.2 All TMT staff will complete this tool on an annual basis in preparation for their Annual Review. Following completion of the tool a summary report will be generated automatically, this should be used as a basis for discussion with their line manager either before or during the Annual Review. Any gaps in knowledge/training which may impact competency to complete a task should be identified and opportunities for training identified where appropriate. This should be documented on the Annual Review form.

4.1.3 For new staff the self-assessment tool should be completed by the end of the probationary period. The report should be reviewed and discussed with their line manager prior to the end of the probationary period, to identify gaps in training/knowledge to allow for further training to be identified and provided prior to performing required tasks as required. This should be documented on the final probationary review form.

4.1.4 The self-assessment tool report should be signed and dated by the staff member and placed in their training folder (Section 4)

4.1.5 In addition to yearly Annual Reviews, regular informal individual meetings will be held with each staff member and their Line Manager/ STMs to review work and identify any additional training needs.

4.2 Delegation of Tasks

4.2.2 There may be circumstances where it may be appropriate to delegate tasks, usually the responsibility of a TM, to a more junior member of staff. (e.g. within a sponsor SOP which specifies TM responsibility (without a designee).

4.2.3 In the first instance, delegation of such tasks should be discussed with a Senior TM or Team Lead to assess if appropriate to delegate the task.

4.2.4 Following agreement appropriate training should be provided and evidenced on the TM-F01 Delegation of TM Activity document. This should be completed and signed by the trainer and the Senior Trial Manager. The completed form should be held in the TMF (Section 6) and within the individuals training folder (Section 4)

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU SOP AD 01 Creating and maintaining staff training records

ECTU Shared Drive

- TM-F01 Delegation of TM Activity
- TM005 Alignment of Tasks to Staff Grade within ECTU TM Team

Others

- https://www.ed.ac.uk/files/atoms/files/grading_and_regrading_processes_and_principles.docx.pdf
- Competency Framework for Trial Management | UK Trial Managers' Network (tmn.ac.uk)