


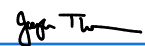
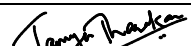


## ECTU Central Office SOP DM\_13: Data Management and Programming (DM&P) Study Guidance and Handover

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Authorship and Approval			
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Tanya Tharakan, QA Manager	QA Authorisation	21-Mar-2025	 <a href="#">Tanya Tharakan (Mar 21, 2025 15:30 GMT)</a>

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1.0	14 Apr 2025	Initial creation/New document

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## **1.0 PURPOSE**

This Standard Operating Procedure (SOP) describes the procedures to follow when preparing guidance documents in the event of a change of Data Management or Programming (DM&P) team personnel or in studies managed by ECTU. This document provides guidance in preparing for periods of long-term absence (for example family leave) and when ECTU responsibilities are transferred to staff external to ECTU.

## **2.0 SCOPE**

This SOP applies to all members of the ECTU Data Management and Programming team and all studies with data management and/or database development managed by the team.

## **3.0 RESPONSIBILITIES**

It is the responsibility of the delegated Data Management and Programming team personnel to ensure that study guidance is created and maintained for the studies they manage.

## **4.0 PROCEDURE**

### **4.1 HANDOVER MANAGEMENT – CHANGE OF DM&P PERSONNEL**

- 4.1.1 A new DM&P staff member may be appointed to a study if the incumbent personnel leaves ECTU employment; is redeployed to work on another study or is absent long-term. Where possible, study-specific training will be provided by the incumbent DM&P personnel. For new UoE/ECTU employees, this will form part of the induction process.
- 4.1.2 In the event of a planned handover the incumbent DM&P personnel will ensure that the guidance documents are fully updated before formally handing over the study. They should arrange a handover programme with the new member of staff which should include arranging appropriate database access as required and any handover meetings throughout the training period. For members of the DM team, this will be documented using template DM018 ECTU Data Management Handover Log (see section 4.2).
- 4.1.3 The DM&P Line Manager will inform the Trial Manager (via study-specific email address) and/or Business Co-ordinator (via [ectu-bus.coord@ed.ac.uk](mailto:ectu-bus.coord@ed.ac.uk)) of the change in personnel. This should include the date the new member of staff is expected to start study-specific activities, including any training/handover period with the incumbent DM&P personnel if applicable.
- 4.1.4 The Trial Manager and/or Business Coordinator will forward this information to relevant parties which may include:
  - Other ECTU Trial Office Teams
  - Chief Investigator
  - Sponsor

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- Site Research Teams

4.1.5 Once the study-specific training/handover period has been completed the incumbent DM&P personnel or DM&P Line Manager will inform the Trial Manager and/or Business Co-ordinator via email that all study activities and responsibilities are now formally transferred to the new member of staff. For the DM Team, the Handover Log will be signed off at this point.

## **4.2 Guidance Documents**

The incumbent DM&P personnel will be responsible for preparing and maintaining all study management and handover guidance for all studies that they manage as and when applicable.

There are two types of study management guidance documents that are applicable when considering study guidance. ECTU templates are available on the shared drive for this purpose. These are:

- DM018 ECTU Data Management Handover Log for the DM team
- OP-T01 External Handover Form

Other guidance documents may be prepared at the discretion of the incumbent DM&P personnel if appropriate to the study and the location of these should be documented Section 9 of the TMF.

### **4.2.1 ECTU Data Management Handover Log**

4.2.1.1 DM018 ECTU Data Management Handover Log is used by the Data Manager, Assistant Data Manager or Data Management Support Officer to document the transfer of any activities to new personnel. This applies only to defined Data Management activities as specified in the document.

4.2.1.2 The incumbent DM personnel is responsible for creating the Data Management Handover Log. Further instructions on the process for transferring responsibilities are provided in the document.

4.2.1.3 The signed document should be saved in Section 9 of the TMF.

### **4.2.2 External Handover Form**

4.2.2.1 OP-T01 External Handover Form (see section 5.0) is a checklist that is to be used where studies or certain responsibilities within a study have commenced within ECTU but are transferred outwith ECTU prior to completion of the study. This form documents the status of the study at the point of handover and details discussions and transfer of responsibilities at this point. Where ECTU responsibilities are being

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transferred to those outside of ECTU the relevant sections of the OP-T01 External Handover document should be completed.

4.2.2.2 The Trial Manager or designee is responsible for creating the OP-T01 External Handover Form and ensuring this is completed with information from the DM&P team where required. Further instructions on the process for transferring responsibilities to external parties are given on the form. For partial service studies, the Business Coordinator will be responsible for circulating the form to ensure relevant sections are completed.

4.2.2.3 Full guidance on the completion and retention of OP-T01 External Handover Form is detailed in ECTU\_SOP\_TM\_19 Study Guidance and Handover

## 5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Shared Drive:

- DM018 ECTU Data Management Handover Log
- [OP-T01 ECTU External Handover](#)
- [ECTU\\_SOP\\_TM\\_19 Study Guidance and Handover](#)

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# ECTU\_SOP\_DM\_13 Data Management and Programming Study Guidance and Handover v1.0

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