Data Manager Handover Schedule

*The following is a suggested schedule of handover of duties, with a proposed order and breakdown of what could be covered at each stage of the handover. It could be used to devise agendas for the handover meetings and working sessions if required.*

*Update or remove elements as appropriate based on the type and stage of the study. For example, part of the study data management sessions for an eDC study would need to include ‘data checking procedures explained and demonstrated.’*

*The template schedule below inlcudes data management related practice sessions, but no others, so these will need to be added as required for the study.These practice session could be incorporated into the discussion/demonstration sessions rather than being separate as the example below suggests.*

*In the description of the handover duties, reference any documents that may be used during the session, some examples have been provided e.g. Handling of completed/received CRFs explained and demonstrated (DMP section x.x). Similarly any documents to be completed/created as part of the activity being described could also be included herefor reference if it would be helpful.*

*Some things to consider when creating a handover schedule are:*

* *Explanation of the protocol could be broken down into sections, prioritising the most important elements*
* *Similarly introducing the DMP might be best done in separate sessions*
* *Ensure the most relevant tasks to the study are listed for explanation and demonstration – this will depend on the stage and nature of the study*
* *Explain all MRC CTU at UCL specific terminology and jargon if the NDM is new to the unit.*

*Key:*

*Departing Data Manager – DDM*

*New Data Manager - NDM*

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| --- | --- | --- | --- |
| Pre Handover work | | Who | Date Completed |
| To Do: | DMP reviewed/updated to ensure it is reflective of current data management practice  (If the DDM is one of a team of DMs, ensure any sections of the DMP they have responsibility for are reviewed/updated) | DDM |  |
| To Do: | Handover notes written | DDM |  |
| To Do: | All other associated data management documents are reviewed and updated to ensure they are reflective of current data management practice. These may include:   * CRF Completion Guidelines * Data Provision Guidelines * Working Practices * Manual of operating Procedures | DDM |  |
| To Do: | Access to database systems for the study arranged. These may inlcude:   * Study database * TMS * Randomisation Server * TRACKER | DDM or specified alternative |  |
| Introductions | | Who | Date Completed |
| To Do: | Introduce NDM to all study team members, including CPM, statisician, database programmer, data scientist, clinician etc | DDM or specified alternative |  |
| To Do: | Share the Handover Schedule with the NDM | DDM or specified alternative |  |
| To Do: | Sites and collaborators notified of new NDM and timelines for handover | DDM or specified alternative |  |
| To Do: | Ensure the NDM has completed any relevant training prior to further handover sessions, including R&U of unit SOPs and training on TAPP | Line Manager of NDM |  |
| Study Background | | Attendees | Meeting Date/s |
| To Cover: | Training provided on the latest protocol, the study design, CRFs, any guidelines and the Investigator’s Brochure etc, as applicable | NDM, DDM, TM |  |
| To Cover: | Clinical overview of the study | NDM, Trial Physician (if possible) |  |
| To Do: | -Invite NDM to future study meetings  -Invite NDM to site training sessions, eg eDC site training | DDM or specified alternative |  |
| Study Data Management Training Sessions | | Who | Session Date/s |
| To Cover: | -Introduce the Data Management Plan and any other associated data management documentation for the study  -Handover notes shared with NDM | NDM, DDM or specified alternative |  |
| To Cover: | -CRFs and metadata | NDM, DDM or specified alternative |  |
| To Cover: | -Training on study database/s and reports | NDM, DDM or specified alternative |  |
| To Cover: | -Handling of completed/received CRFs explained and demonstrated (*DMP section* *x.x*)  -Data entry processes explained and demonstrated (*DMP section* *x.x*) | NDM, DDM or specified alternative |  |
| To Cover: | -Query processes explained and demonstrated (*DMP section* *x.x*)  -Monitoring related processes explained and demonstrated e.g central monitoring checks (*DMP section* *x.x*) | NDM, DDM or specified alternative |  |
| Practice session -  To Do: | -Conduct CRF receipt tasks  -Practice data entry in the test database | NDM, DDM or specified alternative |  |
| Practice session -  To Do: | -Conduct query management tasks  -Conduct any monitoring related activties e.g central monitoring, reporting etc | NDM, DDM or specified alternative |  |
| Practice session -  To Do: | - Data entry training and checking of % of NDM entered forms in the live database, as per unit data entry checking process | DDM or specified alternative |  |
| Study Training Sessions | | Who | Session Date/s |
| To Cover: | -Training on study working practices relevant to the NDM’s role  -Current study timelines, targets, reports and deadlines discussed relevant to the NDM’s role  - TMF location and training (both hard copy and electronic)  -Location of important reference documents  -Location of sites and collaborators contact details shared and explained to NDM | NDM, DDM or specified alternative |  |
| To Cover: | -Any study related meetings (regular slots or incidental); ensure handover of all information regarding meeting organisation including responsibilities of DM eg taking minutes  - Explanation of study communication. This might include:   * Regular incoming/outgoing communications, eg newsletters * Management of phone/email queries * Management of study inbox | NDM, DDM or specified alternative |  |
| To Cover: | - Location of Investigator Site files  - Discuss any issues with sites, (e.g. previous low data return rates etc) | NDM, DDM or specified alternative |  |