Template Data Management Plan

For UHBW sponsored CTIMPs a Data Management Plan must be completed. For other interventional trials a risk based decision should be made regarding the need for a DMP. The detail provided in each section should be proportionate to the size and complexity of the study.

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| **Study Details** |
| *Include the study title and relevant reference numbers* |
| **Risk Assessment** |
| *Has a formal risk assessment been carried out around data management or have any risks been identified? Provide details here or as an appendix, referencing the number here. Alternatively if data management issues have been documented under a separate, more comprehensive, risk assessment identify where this is located.* |
| **Personnel** |
| *Key personnel with responsibility for data quality, which may include; Chief investigator, Data Manager, developer, statistician, testers, co-ordinators, QA monitors etc* |
| **Design** |
| **System Formats** |
| *What type of systems will be used for data capture storage and analysis? This should include all systems, not just electronic. Pay particular attention to whether any electronic systems are self built, vendor provided, customisations of standard software or combinations. Include file formats and software used paying attention to data sharing between systems and long term validity of formats* |
| **Hardware and Physical Security** |
| *Please note what hardware will be used during the study to store, collect or analyse data. Where this is not UHBW-owned and operated equipment, evidence of Computer System Validation for the hardware used should be included in the Quality Assurance section. Describe the physical security arrangements related to both electronic and paper records. Standard documentation across multiple trials may be provided, for example by University of Bristol IT departments.* |
| **Data Types and Scale** |
| *Describe the types and formats of data to be collected eg qualitative, quantitative, clinical measurements, interviews etc and the expected volume of data to be collected no. of records etc.* |
| **Backup and Recovery Arrangements** |
| *Please describe what back-up and recovery arrangements are in place for the study data.* |
| **CRF Design Process** |
| *Describe the type of CRF (paper, electronic) that will be in use, and whether standardised blocks will be used to develop the CRF or whether it will be designed from first principles. For paper CRFs describe the mechanism by which a sponsor copy and a site copy will be provided.* |
| **Database Design** |
| *Database design creates a trial specific database and data entry system with fields and tables created to reflect the CRF. An annotated CRF can document the structure of the database and provide a link between the source data and the database.*  *What is the system specification, what processes are in place to inform its design and who has contributed to these? How are changes to the CRF or protocol incorporated?* |
| **Data Collection Processes** |
| *How and where will source data be collected?* |
| **Data Flow** |
| *How will the data flow through the lifecycle of the study and how is it processed and stored? It may be useful to show this in a flowchart or similar. What are the Data Transfer Arrangements, particularly if data are transferred between organisations?* |
| **Database Activation** |
| *What are the criteria and process for formal activation of the database? Include details of user acceptance testing.* |
| **Study Conduct** |
| **Training** |
| *How will training of users be conducted and documented?* |
| **Access Arrangements** |
| *What will be the permission structure for electronic systems, how will access be granted, who will have permission to perform what actions and how will this be documented and controlled? For multi-centre studies using eCRFs, what arrangements will exist to ensure the site maintains a true and accurate copy of the data as entered which can be verified against data held centrally?* |
| **Data Entry** |
| *Who will be responsible for entering data, and what are the arrangements for this? Please comment on the data validation plan?* |
| **Data Query Processes** |
| *What will be the process for managing data queries including a definition of resolution?* |
| **Data Security** |
| *How will data security be managed throughout the trial?* |
| **Amendments/Change Management** |
| *How will changes to CRF, Database Design or other aspect of data management, be requested, agreed, developed, tested, documented and implemented?* |

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| **Post Data Collection** |
| **Data Lock** |
| *How will data be locked and protected from further changes being made, accidental loss or deletion of data or file? Will there be any process for a later unlock of the database and in what circumstances may this be permitted?* |
| **Release and Access** |
| *How will data be provided for analysis and what is the process for extraction?* |
| **Long-term Storage and Curation** |
| *Where and how will the data be archived, who will have custodianship of it? How long must the data be stored, and what arrangements are in place for long term storage and to ensure future compatibility of file formats (up to 25 years beyond the end of the trial).*  *Is it anticipated that all or part of the dataset be made available to other researchers? If so what are the governance arrangements for such future collaborations?* |
| **Quality Assurance** |
| **Computer System Validation** |
| *Evidence of Computer System Validation should be available for all hardware and software involved in the trial and should be included here. This may take the form of certificates for vendor provided databases or reports and certificates for self built databases.*  *Document the process by which the decision to use a system was made and the risk assessment conducted as part of that decision making process, the agreed and approved specification (functional and user requirements), validation plan, code-testing documentation, that any issues with the system identified through testing have been resolved and the specification is met (validation report), instructions for use and how users will be trained, training records, how the final system will be released.*  *Please refer to Validation and Backup of Computer Systems used in Research SOP for further information.* |
| **Data Verification Plan** |
| *A data verification plan should be produced to cover the lifecycle of the study. It should include both automatic and manual checks of the data for logical consistency, protocol deviations, missing/incorrect or implausible data. It should test both central systems and source data. The plan should enable researchers to identify and resolve data queries and reconcile with the pharmacovigilance data. Suitable data verification will enable a good quality dataset to be available for analysis.* |