| **Work Instruction** | **Data entry for data managers** |
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| Author | Julie Cunningham |
| Authorised by | Julie Pascoe |

CONTENTS:



| **1.0** | **Purpose, Scope & Objectives** |
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| | This instruction describes the various process of managing data entry in the context of a clinical trial |
| **2.0** | **Personnel & Responsibilities** |
| | All Oncology Clinical Trial Staff |
| **3.0** | **Background** |
| | Full and accurate data collection is the cornerstone to a trials success, it is imperative that Sponsor companies have full and complete data sets in order to publish accurate results that in turn inform researchers and clinicians how best to treat our patients and change medical practice. All data must be collected in accordance with ICH GCP guidelines.<br><br>The senior research nurses create source data checklists for every clinical trial. These checklists are used by the research nurses during patient visits in order to check everything that needs to be done for the visit has been completed, this will include vital signs, bloods, scan dates, medications etc.<br><br>Once the nurses have completed the patient visit, the source data checklist is |

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| | completed and passed to the data manager to input the information.<br><br>As well as the source data checklists information will for each visit will be recorded in several other places as follows:<br>**IPM**<br>- Checking appointment dates<br>- Tracing notes for data and monitor visits<br>- Patient record enquiry section (inpatient, outpatient and theatre bookings)<br>- Printing front sheets and labels<br>- Looking up patient details i.e to call GPs<br>- To check survival status<br><br>*Call IT on 37000 for any problems and they can put you through to the iPM team.*<br><br>**ICM (I. Clinical Manager)**<br>- Blood results<br>- Histopathology reports<br><br>*Contact IT for access; they will put you through to clinical systems*<br><br>**INSIGNIA (Scanning management system)**<br>- Scans<br><br>*Contact IT who will put you through to imaging IT for access*<br>*(NB You have to put the '%' sign before the hospital number when searching for a patient in INSIGNIA.)*<br><br>**ARIA (chemotherapy management system)**<br>- Chemotherapy<br>- Other drug administration<br><br>*Contact Amy King for training and access: amy.king18@nhs.net*<br>*(NB Remember to tick 'all but errored' on the right hand side when looking at chemotherapy. This system will give you all the information you need for cycles, stop and start times, doses and drugs.)*<br><br>**Somerset Cancer Registry**<br>- Useful for finding out staging, grading and diagnosis information<br><br>Contact Lisa Glover for access: lisa.glover@nhs.net Tel: 37504<br><br>**Oncology Clinic Letters**<br>- Useful for finding out patient information generally, including AE's, con meds, medical history, and to get general information on how the patient is doing on study. The monitors will also read this information from the patient's hospital notes.<br><br>**Onc Deceased**<br>- Separate folder on the shared drive to get access to clinic letters for deceased patients.<br><br>Contact Jean Dawes for help with the clinic letter access – jeandawes@nhs.net<br><br>It is the responsibility of the data manager to accurately upload the required data from the visit to either the electronic or paper system using the systems described |

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| | above. |
| **4.0** | **Definitions** |
| | ICH GCP – International Conference for Harmonisation Good Clinical Practice<br>EDC – Electronic data capture<br>SIV – Site initiation Visit<br>CRFs – Case Report Forms<br>PI – Principal Investigator<br>AE – Adverse Event<br>IPM – I Patient Management<br>ICM – I Clinical Management |
| **5.0** | **Health & Safety** |
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| **6.0** | **Equipment & Documentation** |
| | Electronic Data Capture systems e.g. Medidata Rave, Inform & MACRO<br>Paper CRFs, where required |
| **7.0** | **Procedure** |
| | **Electronic data capture (EDC)**<br>- Most common EDC systems used in clinical research are Medidata Rave, Inform & MACRO; however some studies use databases designed especially for their study.<br>- Each system will require completion of a training package and attainment of a certificate of competence. Once you have the certificate it can often be used for other studies using the same system.<br>- Additionally, most studies will also have a guide/power point presentation, which will have been delivered at the SIV by the trial monitor on how to navigate the database. These presentations will be sent to the study team by the Sponsor and should be reviewed by everyone on the team who will be using the system. They will be saved in the shared drive and are a really handy way to familiarise yourself with the system as well as a useful to resource to go back to throughout the study.<br>- Once competent to use the EDC to enter the trial data it is important that before you log in and start you check that the nurse has completed the source data checklist fully so that you can enter the data in one sitting.<br>- Failure to enter all the data will often result in a data query, queries are generated through the database automatically in order to clarify any data omissions or errors.<br><br>**Paper Case Report Forms (CRFs)**<br>- Some studies may use paper CRFs, these are booklets that will be saved on the shared drive and can be printed off in anticipation of the patient visit. It is useful to print out the whole booklet and have it in the patient's source data folder so that you can see what forms need to be completed at what time point.<br>- The paper CRFs are usually completed by the research nurses at the patient visit. However, on occasion the data managers or HCA's may complete some CRF's for follow up visits, if delegated to do so.<br>- On completion, the original is posted to the trial centre and copies are taken to keep with the patient notes.<br>- Any data queries arising from a paper CRF will be sent through by email or post. Resolution of queries / changes will need to be made where required and signed and dated. The original will again be sent to the trial centre and |

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| | locally copies will be kept.<br>- Keeping the paper CRFs as neat and tidy as possible will assist your colleagues in maintaining an accurate record of any changes made.<br><br>**General Data Management Information**<br>- Most studies would like all data entered within 5 days of the patient visit, and data queries answered within 5 days.<br>- If data is incomplete a data query will be generated which in turn increases workload, therefore it is important that all the data for the visit is entered in one sitting. If there is any missing data, check with the nurse who conducted the visit as to why the data is missing and record why the data was not collected before proceeding to upload to the EDC or CRF.<br>- At certain time points in a study there will be a data lock, this is where the Sponsor check and 'clean' all the data before locking the pages so no further changes can be made. You are generally given a few weeks' notice and may arrange a call/visit to go through any queries you have prior to the data lock. When the pages are complete they will require investigator sign off, this is when the PI needs to log in to the system and sign the pages.<br>- Accurate collection of source data information (e.g. blood results, histopathology results, treatment prescriptions, scans etc) ensures compliance with ICH GCP guidelines and will be required for monitoring visits. Therefore, keep all source data used for each visit with the hospital notes / CRF<br>- NB – source data such as scans, bloods and ECG's need to be signed and dated by the PI/Sub-I |
| **8.0** | **References** |
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| **9.0** | **List of Appendices** |
| | N/A |
| **10.0** | **Document Control** |
| | All Work Instructions are stored on the shared research drive: G/Research Common/Training & Education/How To work instructions/<br><br>Printed copies are not controlled and therefore may not be the current version of the document. |
| **11.0** | **Training Record & Competency Assessment** |
| | Records of the training and competency assessment for this work instruction shall be retained by the nominated educator for the staff group involved.<br><br>All staff members have a responsibility to retain their own training records for continuing personal & professional development. |
| **12.0** | **Monitoring Compliance and Effectiveness** |
| | All staff are responsible for ensuring that if they are entering data as part of a clinical trial, they are ICH GCP trained and have completed any online or face to face training required by the Sponsor.<br><br>Staff are to sign the delegation log for any trial they are working on to state they are delegated to do this aspect of work and ensure the PI has signed the delegation log where indicated. |

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| **13.0** | **Revision History** |
| | Issue 1 – First issue |
| **14.0** | **Managerial Approval** |

| Name | Signature | Title | Date |
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| **Author** | | | |
| Julie Cunningham | | Service Improvement Facilitator | |
| **Reviewers** | | | |
| Julie Pascoe | | | |
| Ben Hyams | | | |