**Source Data Agreement**

|  |  |
| --- | --- |
| **Site:** |  |
| **Study:** |  |
| **PI:** |  |

This document describes the key source data/source documents that can possibly be recorded over the conduct of a clinical trial, whether they are paper or electronic, electronic systems used (where applicable) and the storage location.

**Clinical Trial Monitors and auditors will have supervised access to the electronic systems for source data review and verification even though certified copies will be routinely provided for monitoring purposes.**

*Please review the form with the clinical trial monitors/sponsor representative during the site initiation visit and mark the source data format and primary source relevant for this specific study. If additional study data needs to be added please complete section 5.*

**Abbreviations**

|  |  |  |  |
| --- | --- | --- | --- |
| AE | Adverse Event | IVRS | Interactive Voice Response System |
| Barts Health | Barts Health NHS Trust | LVEF | Left Ventricular Ejection Fraction |
| CRA | Clinical Research Associate | MUGA | Multiple Gated Acquisition Scan |
| CRS | Central Referral Service | PACS | Picture Archiving and Communication System |
| CT | Computerised Tomography | PET | Positron Emission Tomography |
| ECG | Electrocardiogram | PI | Principal Investigator |
| ECHO | Echocardiogram | PN | Participants Notes |
| ECOG | Electrocorticography | PRO | Participant Reported Outcome |
| EMS | Electronic Monitoring System | QA | Quality Assurance |
| EPR | Electronic Patients Records | SAE | Serious Adverse Event |
| ICF | Informed Consent Form | SDW | Source Data Worksheets |
| ISF | Investigator Site File | SOP | Standard Operating Procedure |
| IMP | Investigational Medicinal Product | SUSAR | Suspected Unexpected Serious Adverse Reaction |
| IV | Intravenous | US | Ultrasound |

# Source Data:

**\***Only ONE Primary Source can be selected.

| **Study Data** | **Primary Source\***e.g. PNs, assessment report, Source Data Worksheet (SDW) | **Format**Paper=PElectronic=ECertified Copy=CC | **Electronic source system** *(If applicable)* | **Location** | **Comments**  |
| --- | --- | --- | --- | --- | --- |
| ICF *(including optional consent and future research)*  | Signed ICF | P | N/A | ISF-Research Office / PNs  | Original Informed consent form filed in ISF, copy in PNs and copy given to patient. |
| Informed consent process |  [ ]  PNs [ ]  Electronic notes | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Inclusion / Exclusion Criteria  |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder | If Eligibility checklist is provided by the sponsor it will be completed, signed and dated by the PI (or delegate) and filed in Patient Study Binder. |
| Eligibility decision (documentation must be confirmed by a medic in writing) |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Medical, surgical and radiotherapy History  |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Clinic letters | Data uploaded from investigator’s dictation of clinic visit | E (CC) | EPR/CRS | PNs / Patient Study Binder | Certified copies of clinic letters will be provided. |
| Randomisation / Study Enrolment |  [ ]  email allocation [ ]  Electronic- IVRS notification | E (CC) | Vendor IVRS system | PNs / Patient Study Binder and PSF | IVRS electronic notifications will be printed and filed. |
| Provision of the subject identification card |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Concomitant Medications (drug prescribed) |  [ ]  PNs [ ]  Electronic notes | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Concomitant Medication (indication, start and end date, dose, route and frequency) | [ ]  PNs[ ]  Electronic notes | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Demographics*(Inc. DoB, Age, Gender, Ethnicity)* |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Histopathology Reports |  Electronic report | E (CC) | CRS | Patient Study Binder | Histopathology reports can be received from referral sites either in paper or electronic format. If electronic, certified copies will be provided. |
| Physical Examination  |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder | Please detail how this will be documented for your study/trial (making sure all steps within the protocol has been discussed/completed). |
| Performance Status (i.e. ECOG) |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Vital Signs, weight and height |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| ECG results | ECG report*(If thermal paper is used a copy will be made as this paper fades over time.)* | P | N/A | PNs / Patient Study Binder | Report will be reviewed, signed and dated by the PI (or delegate) |
| Laboratory Sample Collection | SDW | P | N/A | Patient Study Binder |  |
| Samples storage and shipment | Sample Inventory log | P | N/A | Sample inventory log folder (which will be part of the ISF at the end of the study) (freezers room )) |  |
| Local Laboratory Resultse.g. Biochemistry / Haematology / Coagulation | Electronic Lab Report  | E (CC) | CRS  | Patient Study Binder | Paper copies will be reviewed, signed and dated by the PI (or delegate) |
| Pregnancy test  |  [ ]  PNs [ ]  SDW | P | N/A | PNs / Patient Study Binder |  |
| Central Laboratory Results | Electronic Central Lab Report  | E (CC) | Vendor central lab system | Patient Study Binder | Paper copies will be reviewed, signed and dated by the PI (or delegate) |
| LVEF (ECHO /MUGA scan) | Electronic Imaging report | E (CC) | CRS | Patient Study Binder | Paper copies will be reviewed, signed and dated by the PI (or delegate) |
| Patient Diaries | Diary:[ ]  paper diary[ ]  electronic diary | [ ]  P [ ]  E  |  If electronic, Sponsor’s vendor system | Paper- Patient Study BinderElectronic- Sponsor vendor system | Where using eDiaries- source data will not be printed and filed. Instead it will be retained by the sponsor. |
| PRO | PRO:[ ]  paper questionnaires[ ]  electronic questionnaires | [ ]  P [ ]  E  | If electronic, Sponsors vendor system | Paper- PNs / Patient Study BinderElectronic- Sponsor | Where using ePRO- source data will not be printed and filed. Instead it will be retained by the sponsor. Please list all trial specific questionnaires.  |
| Treatment and dosing decisions (i.e. going ahead for next treatment cycle, dose reductions) |  [ ]  PNs [ ]  SDW [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| IMP (Drug) Administration (IV only) |  [ ]  SDW [ ]  Electronic prescribing system | [ ]  P [ ]  E (CC) | ARIA | PNs / Patient Study Binder | Where using ARIA prescribing system for recording administration of IMP certified copies will be printed and filed. |
| Adverse Events (AE/SAE/SUSAR) – event  |  [ ]  PNs [ ]  SDW AE log [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder | If applicable, certified copies of discharge summary kept on the electronic system will be provided. |
| Adverse Events (AE/SAE/SUSAR) -*onset and end date, grade, action take, expectedness, seriousness and causality assessment* | SDW-AE Log | P | N/A | PNs / Patient Study Binder |  |
| Tumor Response Assessments - if applicable(i.e. RECIST v#1.1) | Electronic Report  | E (CC) | CRS | Patient Study Binder | Paper copies will be reviewed, signed and dated by the PI (or delegate) |
| Radiologic Imaging(e.g. CT / MRI / Bone / PET / X-rays / US scans)  | Electronic images | E  | PACS  | Radiology department | Anonymised scans (identified by patient study number) will be transferred to the sponsor if required, following the study specific manual. |
| Withdrawal, Termination or End of Study involvement |  [ ]  PNs  [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Follow-up Phone calls *(if required per protocol)* |  [ ]  PNs [ ]  SDW  [ ]  Electronic notes  | [ ]  P [ ]  E (CC) | CRS | PNs / Patient Study Binder |  |
| Pharmacy |  |  |  |  |  |
| IMP (Drug) Allocation | Fax or email allocation, according to Sponsor’s arrangements. | [ ]  P [ ]  E (IVRS) | Vendor IVRS system | Patient Study Binder and PSF | IVRS electronic notifications will be printed and filed. |
| IMP (Drug) Ordering | If paper: order form If electronic system: IVRS notification  | [ ]  P [ ]  E (IVRS) | Vendor IVRS system | PSF | IVRS notifications will be printed and filed. |
| IMP (Drug) Preparation Records (IV only) | ITHOS worksheets | P | N/A | Pharmacy Site File |  |
| IMP / Drug Prescription Records | ARIA prescribing system | E (CC) | ARIA | Patient Study Binder (IV and oral)Pharmacy Site File (oral only) |  |
| IMP (Drug) Accountability | Barts Accountability log | P | N/A | Pharmacy Site File  |  |
| IMP Storage- temperature monitoring system | IV: Electronic (EMS system)Oral: Manual monitoring (Min/Max) | [ ]  P (oral IMP)[ ]  E (IV IMP) | IV only: Pharmagraph | All temperature records are stored centrally in pharmacy with a NTF in PSF |  |
| IMP Destruction | [ ]  SDW  [ ]  Electronic notes | [ ]  P [ ]  E (CC) | ARIA |  |  |
| IMP Returns | [ ]  SDW  [ ]  Electronic notes | [ ]  P [ ]  E (CC) | ARIA | Pharmacy Site File (PSF) |  |

**Where sections on SDWs are left blank because the required information has been captured in another location (e.g Patient notes or electronic system) the section will refer to the source document and this must be made available, but transcription is not allowed.**

Additional comments:

# List of Electronic Systems:

| **System** | **Data held** | **Maintained by** | **Access** |
| --- | --- | --- | --- |
| CRS | * Lab results
* Scan results
* Histology reports
* In patient documentation
* Patients personal information
* Appointments / dates / times
 | Barts Health NHS Trust | * Smart card required to access
* Training but no certificate
* Data change with audit trail
 |
| EPR | * Clinic letters
* Referral notes
* Consultation notes
* Appointments
 | Barts Health NHS Trust | * Unique ID access with password
 |
| ARIA | * IMP (drug) prescribing
* IMP (drug) administration
 | Barts Health NHS Trust | * Unique ID access with password
* Training but no certificate
* SOP
* Data change with audit trail
 |
| PACS | * Reviewing and checking scans
 | Barts Health NHS Trust | * Smart card required to access
 |
| EMS-Pharmagraph | * Temperature monitoring (pharmacy department)
 | Barts Health NHS Trust | * Unique ID access with password
 |

# Site Archive Facility:

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| --- |
| Barts Health NHS TrustCorporate Records ManagementLower Ground Floor9 Prescot StreetLondonE1 8PREmail address:  |
| **Contact for retrieval:** | Please contact the study PI (name@ nhs.net) and the QA Manager: (name@qmul.ac.uk)  |

# Additional study specific data source:

| **Study Data** | **Format**Paper=PElectronic=ECertified Copy=CC | **Primary Source**e.g. Patient Notes (PNs), report, Source data worksheets (SDW) | **Electronic source system***(if applicable)* | **Location** | **Comments** |
| --- | --- | --- | --- | --- | --- |
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# Study specific signatures:

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| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| Principal Investigator: |  |  |  |  |  |
|  | Print Name |  | Signature |  | Date (DD/MMM/YY) |
|  |  |  |  |  |  |
| CRA / Monitor: |  |  |  |  |  |
|  | Print Name |  | Signature |  | Date (DD/MMM/YY) |

*The JRMO would like to thank the CECM for this template.*