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| Form number | **Form 51.016A** | Version | **7.0** |
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# Section 1: Contact Information

## Sponsor and Coordinating Centre

## Chief Investigator details

## *CV*

## *GCP*

## *Mentor confirmation (if applicable)*

# Section 2: Funding

## Peer review documentation (non-eligible funder)

## Funding application

## Funding award letter or equivalent

## Reports to Funding award body

## Relevant correspondence

## File notes (if applicable)

# Section 3: Study Documents

*Note: Each section contains all superseded versions with the most recent version at the top (crossed through with ‘superseded’ written on the front page, signed and dated)*

## Protocol (signed and dated)

## Participant information sheet(s)

## Informed consent form(s)

## GP Letter(s)

## Study-specific Manuals and SOPs

## Other study documentation

## Relevant correspondence

## File notes (if applicable)

# Section 4: Combined Review Submission: REC/HRA/GTAC/MHRA

## Initial combined review submission:

## *Study documents (for MHRA and REC review)*

## *SoECAT/SoE (file note if saved electronically)*

## *Outline OID*

## *Template study mNCA*

## *Cover letters (MHRA/REC)*

## Response to initial combined review (if applicable)

## Combined review letters (REC, MHRA and HRA as applicable)

## *Provisional approval/request for further information (REC)/Grounds for non-acceptance/request for further information (MHRA) (if applicable)*

## *Favourable Opinion/ Clinical Trial Authorisation/ Letter of no objection*

## Non-NHS SSA (if applicable)

## Relevant correspondence

## File notes (if applicable)

# Section 5: CIMD documentation:

*Note: Including documentation provided by the manufacturer. If applicable any File notes and relevant email correspondence should be saved in each of the corresponding sections below.*

### Clinical Investigator’s Brochure

### Device details

### Essential Requirements/General Safety and Performance Requirements Checklist

### Instructions for use of medical device

### Device Labels (indicate if in Pharmacy File)

### Summary of all bench testing and pre-clinical testing conducted

### Summary of clinical experience with the device to date

### List of standards met

### MHRA notification letters (serious breaches, non-compliances and protocol deviations)

*Note: the audit trails/correspondence are held by the R&I Lead Pharmacist and Senior Governance Manager for serious breaches and by Monitor team for non-compliances and protocol deviations.*

### Any other correspondence

### File notes (if applicable)

## Additional CIMD documentation required in specific circumstances (provided by the manufacturer)

*Note: If applicable any file notes and relevant email correspondence should be saved in each of the corresponding sections below.*

### Sterilisation validation report

### Software information

### Biological safety assessment of patient contacting materials

### 5.3.3.1 Biocompatibility report (if applicable)

### Information on animal tissues (if applicable)

### Information on any medicine or human blood derivative incorporated into the device (if applicable)

### Active devices

### Specialist technologies including: infra-red, laser, microwave, MRI, RF ultrasound, ultraviolet, X-ray etc.

### Active Implants

# Section 6: Amendments

## Amendment log

## Amendments

*Note: Amendments filed with the most recent at the top, each containing the documents listed below*

### Amended/new documentation (if applicable)-

### Sponsor amendment checklist

### Notification of amendment forms (Amendment tool)

### Amendment Cover Letters (REC/MHRA)

### Sponsor decision of amendment type letter

### Approvals

### Correspondence

### File notes (if applicable)

# Section 7: Legal

## Coversheet (contracts and parties)

## Contracts

## Vendor assessment approval (if applicable)

## Sponsor/Co-Sponsor insurance

## Correspondence

## File notes (if applicable)

# Section 8: Sponsor Systems

## Sponsor oversight checklist

## Relevant submissions/approvals (e.g. ARSAC, PIBB etc.)

*Note: This does not include combined review submission, each approval contains the documents listed below*

### Application

### Supporting documents (if applicable)

### Approval

### Relevant correspondence

## Risk Assessment (and amendments)

## Signed CI delegation of responsibilities

## TSC

### Lists of members/ funder acceptance (if applicable)

### Letters of invitation/response

### Signed charter (including amendments)

### TSC Reports

## IDMC

### Lists of members/ Funder acceptance (if applicable)

### Letters of invitation template/ response

### Signed charter (including amendments)

### DMC Reports

## Evidence of public database registration

## eCRF user acceptance confirmation

## Sponsor RGL letter

## Trial adoption (if applicable)

## Co-enrolment

*Note: filed with the most recent at the top, each containing the documents listed below*

### Protocol of co-enrolment study

### Sponsor authorisation email

### Signed co-enrolment agreement

### Relevant correspondence

## Correspondence

## File notes (if applicable)

## Complaints

# Section 9: End of Trial

## End of trial declaration and acknowledgement REC/MHRA

## Final Report

## Publications

## Archiving

## Other relevant correspondence

## File notes (if applicable)

# Section 10: IMP Management

## Contact information

* Key IMP management related contacts

## General correspondence

## IMP management for host sites (SFD)

### Sub-section 10.3.1: Pharmacy Site File Documents

* IMP Management and Accountability Manual for Sites
* Other IMP pharmacy site file documents incl. prescriptions, accountability logs, IXRS User Manuals, PIV slides etc.

### Sub-section 10.3.2: Investigator Site File & Other Documents\*

* IMP administration logs
* Other Investigator Site File documents
* Other documents e.g. Training Modules

## Sponsor IMP management (SpD)

### Sub-section 10.4.1: Internal Sponsor Pharmacy Documents

* Sponsor Pharmacy Investigational Medicinal Product Document Control Log (Form 21.014A)
* IMP Management and Accountability Manual for Sponsor/ UK Lead Centre
* R&I Pharmacy Task Planner (Form 21.012B)
* Master Pharmacy Initiation Report/Assessment Form (Form 21.016A)
* Master QP Batch Release Check Form/New Batch Release Notice (Guideline 21.003A)

### Sub-section 10.4.2: Sponsor IMP Checklists

* Site IMP Management & Accountability Manuals (Form 21.003A)
* Sponsor IMP Management & Accountability Manuals (Form 21.003B)
* Site Pharmacy Initiation Training (Form 21.016A)
* Technical Agreement Contract & Work Order Checklist for Delegation of IMP Responsibilities (Form 21.012A)
* Checklist for Periodic Review/End of Trial Management File Check (Form 21.020A)

### Sub-section 10.4.3: IVRS/IWRS Development & Testing

**IMP eCRF Review**

**Emergency Unblinding**

* IVRS/IWRS Outline Specification (Form 21.023A)
* IVRS/IWRS User Acceptance Testing & Approval (Form 21.023B)
* Other IXRS Specification/User Acceptance Testing documentation
* Record of IVRS/IWRS Systems Review for Emergency Unblinding (Form 21.013B)
* IMP Emergency Unblinding Testing Plan (Form 21.013A)

### Sub-section 10.4.4: IMP Related Risk Assessments\*

* Sponsor IMP Management Risk Assessment Process: Permanent Storage of IMP External to Pharmacy (Form 21.004A)
* IMP Storage Assessment: Permanent Storage of IMP External to Pharmacy (Form 21.004B)
* IMP Site-to-Site Risk Assessment Form (Form 21.007A)
* Sponsor Risk Assessment for IMP Delivery from Study Site to Participant’s Home (Form 21.012C)
* Other study- specific IMP related risk assessments

### Sub-section 10.4.5: Ethics & Regulatory Related Submissions

* NHS GG&C Label Specification and Approval (Form 21.008A)

## IMP Manufacture & Quality Documentation

* Specification for IMP Manufacturing Activity (Form 21.001B)\*
* QP batch release and associated batch check documentation\*
* Certificates of Analysis/Certificates of Conformity\*
* Other associated IMP quality related documentation
* IMP Destruction by Manufacturer

## Opened sites: IMP management

*Organised by site to include:*

* Completed Pharmacy Site Initiation Report/Pharmacy Site Assessment Form
* Pharmacy site staff CV & GCP certificates at Set-Up\*
* Sponsor approved site documentation e.g. Prescription accountability logs etc. (as appropriate)
* Site Green for Go/Site Activation Notification *(Retained for information only)*
* IMP release confirmation\*
* IMP disposal records
* Relevant correspondence to and from site

## IMP tracking

* IMP tracking by batch\*
* Orders processed\*
* Shipment notices\*
* Receipt confirmation\*
* Manufacturer IMP reconciliation and destruction documentation\*

## IMP complaints, defects, temperature deviations & sponsor file notes

*Organised by site:*

* Reports/correspondence relating to IMP defects and complaints
* Reports/correspondence relating to temperature deviations
* Sponsor file notes relevant to IMP management

## Site IMP management set-up/Site closure

*Organised by site*

* Site Set – up documentation
* (Instructions: Move all set-up documentation to section 11.6 on receipt of ‘Green For Go’/Site Activation e-mail.)
* Site Close Out – Documentation
* (Instructions: Move all site related documentation from section 11.6 to section 11.9 on site closure.)
* Pharmacy Study Product Reconciliation Check (Form 21.019A),

## IB/SmPC Review for Clinical Management (SOP 55.005)

* Revised IB/SmPC and associated correspondence
* IB/SmPC change tracking forms (Forms 55.006A\* & 55.006B\*)
* (Instructions: File at end of study)

\* filed as appropriate

# Section 11: Pharmacovigilance CTIMPs/CIMD vigilance

## Pharmacovigilance/medical device vigilance plan

## RSI and approvals

## SAE forms/Queries and related correspondence (CTIMPs, held electronically at RCB)/Line listings of SAEs and device deficiencies (devices only, held electronically at RCB)

## Pregnancy reports and associated documentation/correspondence

## SUSAR reports and submission documents

## DSURs and submission documents/Quarterly safety reports (devices only)

## Other correspondence

## File note

# Section 12: Monitoring

## Monitoring plan

### Monitoring Plan – Current Version

### Monitoring Plan - Superseded Version(s), if applicable

## Monitoring Risk Assessment

### Monitoring Risk Assessment – Current Version

### Monitoring Risk Assessment - Superseded Version(s), if applicable

## Monitoring Documentation

Note: For different types of visits, please file with the most recent visit on top e.g. COV, MV, SCV

### Site Number eg.‘01’ and Name (e.g. QEUH) *[ensure to increment for each new site i.e. 12.3.2 etc.]*

#### Fully Signed Site Source Data Plan

#### Monitoring Visit/Site Documentation

##### Visit Agenda

##### Follow-Up Letter

##### Completed Action Resolutions Document\*

##### Site Protocol Deviations Forms \*

##### Site Protocol Deviation Logs\*

##### File note – site specific\*

##### Site Correspondence – relevant\*

##### Site Visit Log(s)^

## Protocol Deviations and Non-Compliances - trial

## Miscellaneous: (Handover documentation, Sponsor study-specific training, etc.)

## File Notes – general

## Correspondence – relevant\*

\* All correspondence between site and Monitor should be filed within the Monitoring Group, RandD mailbox and stored in appropriately titled folders to ensure they are easily accessible and archived. If a piece of correspondence is particularly relevant to a specific document (E.g. CI opinion for a protocol deviation classification), it may be attached to the document and stored in the monitoring study file.

^ If completed remotely the CTM may wish to file a visit log from the site or order to provide evidence of visit. Onsite visit logs will remain at site.

Note: Reference notes, supporting documents, SDV checklists will be saved in the common drive and Monitoring group, RandD mailbox.

# Section 13: Governance

## Serious Breaches

### Reports

### Correspondence

## Vendor Assessments

### Approvals/Rejections

### Assessments

### Correspondence

# Section 13: Project Management

## Contact Information:

### Key contacts

### List of active trial sites / Principal Investigators

*(Note: current list to be stored only, include storage location of electronic copy)*

### 24 hour / emergency contact number / unblinding details

## Participating sites

Note: For multi-centre studies split this section into site specific subsections by site number.

Site contacts – study staff per site / location of current electronic contact list here

### Site Set-up documents

#### Site Capability Assessment Form

#### Participating Site Agreement / mNCA

#### Localised OID

#### Completed OID appendix (for GG&C sites only)

#### Head of department approval (for GG&C sites only)

#### Local Pharmacy approval (for GG&C sites only)

#### Local Support department approvals (E.g. CRF, respiratory lab/ophthalmology/radiology if needed) (for GG&C sites only)

#### Local Management Approval

#### Green for Go checklist

#### Green for Go Email

#### IMP release Email

### Maintenance Documents

#### Completed Responsibilities / Delegation Log (Current and Superseded)

#### Personnel documents

* Staff CV / GCP
* Training records

#### Local Amendment approvals

#### Protocol signature page(s)

#### Record of retained body fluids / tissue samples (if applicable)

### Site close out documents

#### Close out confirmation (confirmation by email correspondence from monitors and pharmacy)

#### Site close out email

### Site specific correspondence: filed in date order with most recent at the top

## Site Training Information

### Study Initiation Visit

* SIV slides
* Other site training materials

### CRF completion guidelines (user manual, training log)

### Investigator Meeting

* IM slides
* Attendance log

## Correspondence

### Correspondence to all sites (study updates, newsletters etc.): filed in date order with most recent at the top

### File notes

## Meetings

### Trial Management Group

* Agenda / minutes: filed in date order with most recent at the top

### Data Monitoring Committee

* Agenda / minutes: filed in date order with most recent at the top

### Trial Steering Committee

* Agenda / minutes: filed in date order with most recent at the top

## Study-Specific SOPs/Forms/Guidelines

# Section 15: Data Management

## Data management plan

*Definition/Purpose: To identify the overall strategy for data management process for the trial; a compilation of documents that may include amendments/appendices but are not limited to: Completion Guidelines, Data Quality Plan, CRF Design Document, Database (build) Specification, Entry Guidelines, and Database Testing.*

## CRF completion requirements

*Definition/Purpose: To provide detailed instructions on how data points on each CRF are to be completed; how to enter on paper and if EDC, how to enter data into the system.*

## Annotated CRF

*Definition/Purpose: To assign variable names and attributes to the fields on the CRF and to link the variables to the tables within the database; may also be used as an aid for database programming on how to structure the database; use for data extraction; may be generated at the time of regulatory submission.*

## Documentation of corrections to entered data

*Definition/Purpose: Any documentation used to query database discrepancies and to record approved corrections to the clinical trial database; may include self-evident corrections, global queries, SAE queries, laboratory queries and any other database queries generated. Additionally, include any agreements per trial and site that trial personnel are permitted to perform without the need to issue a query to the investigator along with acknowledge acceptance/signing of these changes by Investigator. NOTE: This may be fully contained within the trial database or eCRF.*

## Final subject data

*Definition/Purpose: Final Subject data (EDC/ePRO/Paper) for the protocol and a copy of each site's data by-subject. Associated documents may include but are not limited to documentation of subject data corrections, subject diaries, questionnaires, laboratory reports and other third-party specialty data. Does not include the final study datasets. NOTE: This may be filed electronically or paper copies may be stored separate to the TMF or may form part of the eCRF/trial database.*

## Database specifications

*Definition/Purpose: To provide a detailed design framework for the system(s) used to manage and store subject/patient data captured via a paper CRF or eCRF for the specified trial.*

## Validation of data checks

*Definition/Purpose: Specifications that will detect data that is illogical, unexpected, missing, redundant, or is outside of defined study parameters; usually implemented via programming logic.*

## Validation programming

*Definition/Purpose*: *The computer code which satisfies the edit check plan/specification details; may include a reference to where the code resides.*

## Testing of the eCRF/trial database and data check validations

*Definition/Purpose: To provide evidence that the eCRF/database/validations have been implemented correctly; can include the data used to test the programming logic*

## Approval for the database activation

*Definition/Purpose: Documentation that all database specification requirements have been satisfied and system can go live; will also include confirmation that UAT (user acceptance testing) has been successfully completed. May include a modified version to activate implementation of change control.*

## External data transfer specifications

*Definition/Purpose: To document import and export data specifications; includes but is not limited to diary, lab, IVRS, imaging; integration from external systems to database and may include transfer from one group to another.*

## Paper only: Data entry guidelines

*Definition/Purpose: To provide detailed instructions on how CRF data is to be entered into a database; specific to a paper CRF trial (therefore, would not be required with an EDC trial).*

## SAE reconciliation (only relevant where SAEs within clinical database and where both sources capture similar data)

*Definition/Purpose: To document reconciliation and resolution of discrepancies between the SAEs in the safety and the clinical databases has been successfully completed.*

## Dictionary coding

*Definition/Purpose: To document the tools used in medical coding and the final coded terms; includes medical sign off of coding; may include resolution discrepancies.*

## Data quality review documentation

*Definition/Purpose: To describe the procedures for creating and implementing a data quality review process to ensure that quality data is captured into a clinical database on an ongoing basis.*

## Database lock and unlock approval

*Definition/Purpose:* *Confirmation that all of the requirements for database release have been meet; may include all unlock and re-lock documentation as well as a report on data quality issues and summary of essential activities prior to database lock.*

## Database change control

*Definition/Purpose: Summary of requested change, reason for change, relevant approvals, impact / risk analysis, associated requirements, specifications and other documentation describing the validation and implementation of this change.*

## User account management

*Definition/purpose: To capture account management details for all users who received access to the system (e.g.: ePRO, eCRF); intended to include users' security role, date account granted, date account disabled.*

## Technical design documentation

*Definition/purpose: A technical planning and tracking document containing all the elements required to build and test the EDC application including the variables to be collected, their logical arrangement, navigation between the different forms, and the checks for logical consistency. May take the form of a spreadsheet created manually by a programmer and uploaded to the EDC application (e.g. to generate the eCRF or ePRO system), or exported from the application after building as a record of its technical design. May include some code for 10.03.03, Edit Check Programming.*

## Relevant communications

*Definition/purpose: Data management specific agreements, significant discussions or relevant information, but not specifically listed in this Reference Model. Types of correspondence may include, but not limited to: letters, memo, electronic communications and faxes.*

## Meeting material

*Definition/purpose: Agenda, presentation materials and other documentation generated during an internal or external data management related meeting which documents any agreements or significant discussions. Includes meeting minutes or Q&A, attendance sheets and any pre-meeting material.*

## File notes

*Definition/purpose:* *To document any decision or to clarify any information relating to data management*

# Section 16: Vendors

## Laboratory Organogram *(Organisation details of the laboratory)*

## Treatment of Routine Samples *(UKCRC Document and File Note)*

## Staff Records and Training *(Staff Training Log (Form 53.005I) and Certificates)*

## Contract (s) and Service Level Agreement(s) *(Contract and/or SLA between Lab and NHSGGC R&I)*

## Meeting Minutes

## Quality Assurance and Quality Control Checks *(QC checks of processes i.e. Accreditations (external laboratories), Reference ranges for all tests included in the protocol, Temperature logs for sample storage, etc)*

## Deviations and violations *(Record of any shipping, storage or other deviation should be filed here)*

## Correspondence *(All key correspondence should be printed and filed)*

## Approvals *(R&D Permission for each trial)*

## Laboratory Manuals for non- routine trial samples and processing *(Each research trial may have a laboratory manual. The manual will include shipping information, sample storage, method and analytical plan, stock and solution prep and analytical records)*

## Equipment Maintenance *(Calibration Certificates for equipment used in trials)*

## Shipping Documentation *(File all receipts from couriers. Multiple tear-offs slips can be fixed on an A4 sheet and filed)*

## Archiving *(Archiving process)*

## File Note(s) *(File Note template (Form 53.005J). Completed File Notes must be filed in relevant section. General File Notes can be filed here)*

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