Southampton Clinical Trials Unit

REMoDL-A

INVESTIGATOR SITE FILE INDEX

SECTION	CONTENTS
	Study Contacts and Information Page
1	**General Correspondence (including letters, emails, faxes, records of significant telephone conversations) between site and following:**
1.1	Southampton Clinical Trials Unit (SCTU)
1.2	R&D
1.3	Pharmacy
1.4	CRN
1.5	Randomisation Service
1.6	GEP Unblinding
1.7	Other *(specify below)*
2	**Screening & Recruitment Records**
2.1	Master Patient List
2.2	Patient Screening Log
2.3	Original signed & dated Informed Consent Forms or Note to File indicating where held
2.4	Completed Eligibility Checklists
2.5	Randomisation confirmations
2.6	Any additional patient-related logs *(specify below)*
3	**Research Personnel**
3.1	Site Delegation Log
3.2	Site Study Personnel signed/dated CVs /GCP certificates (if not evidenced on CV)
3.3	Training Records
4	**Study-Specific Documentation – Current Versions**
4.1	Protocol
4.2	REMoDL-A Patient Information Cards
4.3	Patient Information Sheet (on local headed paper)
4.4	Informed Consent Form (on local headed paper)
4.5	GP letter (on local headed paper)
4.6	Advert for recruitment *(if applicable)*
4.7	Eligibility Checklist
4.8	Acalabrutinib Patient Diary
4.9	PET Acquisition Form
4.10	Any other approved documentation *(specify below)*

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5	**Safety**
5.1	Reporting procedures and guidance for SAEs/SUSARs
5.2	Blank SAE/SUSAR report form
5.3	Acknowledgements of SAE/SUSAR reports from SCTU
5.4	Copies of completed SAE/SUSAR report forms
5.5	Notification of safety information from Sponsor to investigators
5.6	Unblinding procedures *(if applicable)*
5.7	Blank Pregnancy Report Form
5.8	Copies of completed Pregnancy Report Forms *(if applicable)*
6	**Investigational Medicinal Product (IMP) Information**
6.1	Investigators Brochure (IB) and/or Summary of Product Characteristics (SmPC)
6.2	Confirmation from SCTU of Green Light Status
6.3	Template Acalabrutinib Accountability Log
6.4	Template Acalabrutinib Subject Dispensing Log
6.5	Template R-CHOP Dispensing Log
6.6	Other *(specify below)*
7	**Laboratory Information**
7.1	Laboratory accreditation documentation (if not an NHS lab)
7.2	Local laboratory normal values/ranges for tests included in protocol
8	**Sample Collection and Storage**
8.1	Sample collection, processing and storage guidance *(if applicable)*
8.2	Sample Storage Log(s)
8.3	Tissue Samples Dispatch Log(s)
8.4	Central lab information *(if applicable)*
8.5	Lab Manual
8.6	HMDS Sample Shipment Form(s)
8.7	Other *(specify below)*
9	**Research Ethics Committee (REC) Approvals**
9.1	Initial REC Application (Cover Letter & IRAS Form) and Favourable Opinion
9.2	REC Amendment Application(s) (Cover Letter & IRAS Form) and Favourable Opinion(s)
9.3	End of Trial Notification to REC and response/approval
9.4	ARSAC Licence Information (Nuclear Medicines) *(If Applicable)*

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10	**HRA Approvals (for sites in England only)**
10.1	HRA Approval
10.2	HRA Amendment Categorisation(s) and Approval(s)
10.3	Organisation Information Document and Schedule of Events
10.4	Formal Invitation/Confirmation of Site Selection
10.5	Confirmation of Capacity and Capability (initial and amendments)
10.6	HRA Pharmacy Assurance
10.7	HRA Radiation Assurance
10.8	Other *(specify below)*
11	**NHS/HSC R&D Approvals (for sites in Wales, Scotland and Northern Ireland only)**
11.1	R&D Approval (initial and amendments)
12	**Regulatory Approvals (MHRA)**
12.1	Initial MHRA Application and Approval
12.2	MHRA Amendment Application(s) and Approval(s)
12.3	End of Trial Notification to MHRA and response/approval
13	**Data Management**
13.1	Current Data Completion Guidance
13.2	Generic iMedidata Contact Sheet
13.3	Copy of Dataset
14	**Monitoring and Site Visits (Including site initiation)**
14.1	SIV Documentation – (i) agenda, (ii) report, (iii) presentation printout, (iv) other
14.2	Site Visit Log
14.3	Monitoring (i) Confirmation of Monitoring Visit, (ii) Monitoring Follow-Up Letter, (iii) Completed Queries/Issues Lists, (iv) ISF Reviews
14.4	Site Close-out Report/Correspondence
15	**Agreements and Finance**
15.1	Confirmation of Study Sponsorship
15.2	Indemnity Statement
15.3	Signed Clinical Trial Agreement between Sponsor and Site
15.4	Principal Investigator Protocol Acknowledgement (initial and amendments)
15.5	Other *(specify below)*

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16	**Reports**
16.1	R&D Requested Interim Reports
16.2	Final Study Report
17	**Imaging**
17.1	Imaging Manual
17.2	Completed PET Acquisition Form
17.3	Central PET-CT Reports
18	**Superseded Documents (since site opening)**
18.1	Protocols
18.2	Patient Information Sheets
18.3	Informed Consent Forms
18.4	GP Letters
18.5	Investigator Brochure (IB) and/or Summary of Product Characteristics (SmPC)
18.6	Data Entry Guidelines
18.7	Any other superseded documents

NOTES:

- Correspondence relating to section titles should be filed in date order with the most recent correspondence on top
- Please use FORM/5012 (Note to File – Not Applicable Section (ISF)) for non-applicable sections
- Where items/sections are filed elsewhere, a Note to File is completed and placed in the relevant section. All documents filed elsewhere must be printed and filed in the ISF prior to archiving
- Superseded documents should have a diagonal line through the front page, and be signed and dated.