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	IMP Distribution Centre – Phoenix Medical
1.4	CRN
1.5	~~Randomisation Service~~
1.6	Unblinding Service
1.7	Other *(specify below)*
2	**Screening & Recruitment Records**
2.1	Master Patient List
2.2	Patient Screening Failure Log
2.3	Original signed & dated Informed Consent Forms or Note to File indicating where held
2.4	Template Eligibility / Randomisation forms
2.5	Completed Eligibility / Randomisation forms and confirmation of randomisation email
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	Study-Specific Prompt Sheet for Clinicians
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
4.7	Qualitative Invitation Letters
4.8	Patient Trial Card
4.9	Contact Details Proforma
4.10	Patient Medication Information Leaflet
4.11	Summary Patient Information Sheet (on local headed paper)
4.12	Pregnancy Patient Information Sheet (on local headed paper)

INVESTIGATOR SITE FILE INDEX

4.13	Pregnancy Informed Consent Form (on local headed paper)
4.14	Any other approved documentation
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~~
5.7	~~Blank Pregnancy Report Form~~
5.8	Copies of completed Pregnancy Report Forms *(if applicable)*
6	**Investigational Medicinal Product (IMP) Information**
6.1	Safety Dossier and GP Safety Summary
6.2	Confirmation from SCTU of Green Light Status
6.3	SOP EXCALIBUR IMP handling
6.4	IMP Storage Assessment form
6.5	Drug Accountability Log
6.6	Other *(specify below)* *Completed dispatch forms and confirmation emails from SCTU that IMP is fit for use*
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	~~Sample Shipment Log(s)~~
8.4	~~Central lab information *(if applicable)*~~
8.5	~~Lab Manual~~
8.6	~~Other *(specify below)*~~
9	**Research Ethics Committee (REC) Approvals**
9.1	Copy of 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	Copy of end of Trial Notification to REC and response/approval

EXCALIBUR

INVESTIGATOR SITE FILE INDEX

9.4	Copy of final study report
9.5	~~ARSAC Licence Information (Nuclear Medicines) *(If Applicable)*~~
10	**HRA Approvals (for sites in England only)**
10.1	HRA Approval
10.2	HRA Amendment Categorisation(s) and Approval(s)
10.3	Statement of Activities and Schedule of Events
10.4	Formal Invitation/Confirmation of Site Selection
10.5	Confirmation of Capacity and Capability (initial and amendments)
10.6	Other *(specify below)*
11	**NHS/HSC R&D Approvals (for sites in Wales, Scotland and Northern Ireland only)**
11.1	~~SSI Form~~
11.2	~~R&D Approval (initial and amendments)~~
12	**Regulatory Approvals (MHRA)**
12.1	~~Copy of initial MHRA Application and Approval~~
12.2	~~Copy of MHRA Amendment Application(s) and Approval(s)~~
12.3	~~Copy of End of Trial Notification to MHRA and response/approval~~
13	**Data Management**
13.1	Template Baseline Worksheet
13.2	Completed Baseline Worksheets
13.3	Current Participant Diary (example)
13.4	Current Data Completion Guidance
13.5	Generic iMedidata Contact Sheet
13.6	Copy of Dataset
14	**Monitoring and Site Visits (Including site initiation)**
14.1	SIV Documentation – (i) agenda, (ii) report, (iii) presentation printout, (iv) correspondence
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

INVESTIGATOR SITE FILE INDEX

15.2	Indemnity Statement/Insurance certificate
15.3	Signed Clinical Trial Agreement between Sponsor and Site
15.4	Principal Investigator Protocol Acknowledgement (initial and amendments)
15.5	Other *(specify below)*
	Invoices for patient recruitment
16	**Reports**
16.1	Copy of R&D Requested Interim Reports
16.2	Copy of Final Study Report
17	**Superseded Documents (since site opening)**
17.1	Protocols (since site opening)
17.2	Patient Information Sheets
17.3	Informed Consent Forms
17.4	GP Letters
17.5	Safety Dossier and GP Safety Summary
17.6	Data Entry Guidelines
17.7	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.