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List of Not Applicable Sections

Section	Content	Reason for section not applicable
2.2-2.5	Patient Screening Log, Original Signed and Dated Informed Consent Forms, Completed Registration/Randomisation Forms and Other.	Not applicable. This is a retrospective study in which the patients have been treated.
4.2-4.6	Patient Card, Patient Information Sheet, Informed Consent Form, GP Letter, Study Questionnaire.	Not applicable. Patients will not be screened and recruited for the reason above.
5	Safety	Not applicable. There is no safety reporting and the SCTU will not be submitting safety reports, as this study is retrospective.
6	Investigational Medicinal Product (IMP) Information	Not applicable. There is no Investigator's Brochure for this study as there is no IMP.
7	Medical Device Information	Not applicable. There are no medical devices in use on this study.
8	Sample Collection and Storage	Not applicable. There are no samples involved in this study.

Name (print):	Ben Lindfield	**Position:**	Clinical Trial Coordinator
Signature:	Benjamin Lindfield	**Date:**	20-Oct-2025

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SECTION	CONTENTS
	Study Contacts and Information Page
1.	**General Correspondence**
1.1.	Southampton Clinical Trials Unit (SCTU)
1.2.	R&D
1.3.	Pharmacy
1.4.	Other *(i.e., Randomisation Service)*
2.	**Screening & Recruitment Records**
2.1.	Master Patient List
2.2.	Patient Screening Log
2.3.	Original signed & dated Informed Consent Forms
2.4.	Completed Registration/Randomisation Forms including confirmations
2.5.	Other *(specify below)*
3.	**Research Personnel**
3.1.	Site Delegation Log
3.2.	Site Study Personnel signed/dated CV/GCP certificates
3.3.	Other Training Records
4.	**Study Specific Documentation (current and superseded versions)**
4.1.	Protocol
4.2.	Patient Card
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.	Study questionnaires *(if applicable)*
4.7.	Other documentation *(specify below e.g., Advert for recruitment)*
5.	**Safety**
5.1.	Reporting procedures and guidance for SAEs/SUSARs
5.2.	Blank SAE/SUSAR report form
5.3.	Copies of completed SAE/SUSAR report forms
5.4.	Acknowledgements of SAE/SUSAR reports from SCTU
5.5.	Notification of safety information from Sponsor to Investigators
5.6.	Unblinding procedures

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6.	**Investigational Medicinal Product (IMP) Information**
6.1.	Investigators Brochure (IB) and/or Summary of Product Characteristics (SmPC)
7.	**Medical Device Information**
7.1.	Device Accountability Log(s)
7.2.	Device Request/Order Forms
7.3.	Device Shipment Records
7.4.	Device Destruction Documentation
7.5.	Device Sample Labelling
8.	**Sample Collection and Storage**
8.1.	Laboratory Manual
8.2.	Sample Storage Log(s)
8.3.	Sample Shipment Log(s)
8.4.	Other *(specify below)*
9.	**Regulatory and Ethics**
9.1.	Confirmation of Site Selection
9.2.	Initial approval documentation pack (e.g., key documents and cover letter)
9.3.	Approved Schedule of Events Cost Attribution Template (SoECAT)
9.4.	Confirmation of Capacity and Capability (initial and amendments)
9.5.	Amendment(s) packs (subdivide by amendment number)
9.6.	End of Trial Notification
10.	**NHS/HSC R&D Approvals (for sites in Wales, Scotland and Northern Ireland only)**
10.1.	R&D Approval (initial and amendments)
11.	**Data Management**
11.1.	eCRF Completion Guidelines
11.2.	iMedidata Contact Sheet
11.3.	Copy of Dataset
12.	**Monitoring and Site Visits**
12.1.	SIV Documentation (presentation printout, report)
12.2.	Site Visit Log
12.3.	Monitoring (Confirmation of Monitoring Visit, Monitoring Follow-Up Letter)
12.4.	Site Close-out Documentation
13.	**Agreements and Finance**
13.1.	Confirmation of Study Sponsorship
13.2.	Indemnity Statement

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13.3.	Signed Clinical Trial Agreement between Sponsor and Site
13.4.	Principal Investigator Protocol Acknowledgement (initial and amendments)
13.5.	Other *(specify below)*
14.	**Reports**
14.1.	R&D Requested Interim Reports
14.2.	Final Study Report