STANDARD OPERATING PROCEDURE

CONFIDENTIAL

SOP : CTA_002G	Effective date : _____/ _____/ _____	
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Title: **Study File Initiation, Maintenance and Archiving**

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1 AREA OF SOP APPLICATION

This SOP is applied to any study conducted by CNRFP.

The objective of this SOP is to describe how the study specific records (SSR) are filed and archived. It provides guidance by providing details on the management of Sponsor Study Records, including their structure, maintenance and archiving.

SSR are study specific records that are collected across trial conduct and that meets the definition of essential documents, as described in Section 8 of ICH guidelines.

2 ABBREVIATIONS

SOP : Standard Operating Procedure

CTA : Clinical Trial Assistant

CNRFP : Centre National de Recherche et de Formation sur le Paludisme

3 RESPONSIBILITIES

The CTA will be in charge of the implementation of this Procedure. The Principal investigator will oversee all the activities related to this SOP.

4 LEGISLATION AND REGLEMENTATION

In compliance with ICH E6: Good Clinical Practice, Study specific records (SSR) should be field properly.

5 GUIDANCE

5.1 General File Quality Standards

- SSR contain only essential trial documents outlined in the checklists (Annex 1).
- SSR documents need to have an identifier (e.g., Protocol Number) to associate the documents with the correct study.
- If a required document cannot be obtained, a Reference Note to File documenting the reason for the omission is maintained within the appropriate category in the SSR file.

- Documents that are on thermal paper are photocopied. Both the photocopied version and the thermal paper version are maintained with the SSR.

5.2 When to set up the study File

Upon a new study is allocated to the CNRFP, it is the responsibility of the CTA to initiate the SSR file.

5.3 Sections of the study File

Refer to ISF Content List and Guidance (Annex 1)

5.4 How to File Documents within Each Category

Documents are filed in reverse chronological order (document with most current information or date is seen first in the file). If the study team chooses to sub divide the category each sub category is also filed in reverse chronological order

5.5 Reference Note to File

Examples of when a Reference Note to File is used:

- To document the reason(s) for missing document(s). The reference note for this missing document is retained in the most relevant category.
- To document the reason(s) for unused categories

When a memo to file is generated, it is best practice, for it to be signed. If the memo documents a decision, the person making the decision is identified in the document and if possible that person signs the memo. If the memo is for informational purposes only, the person generating the memo includes their name.

5.6 Archiving of Correspondence for the SSR

Only maintain and archive relevant communications which document any agreements or significant discussions regarding trial administration, protocol deviations, trial conduct, or adverse event reporting. The type of documents can be, but are not limited to, letters, e-mails, meeting notes, or documentation of

telephone calls. Using their best judgment, the person who is filing determines if the document is "Relevant" and then files it as part of SSR.
Correspondence that meets the above criteria is filed in the most appropriate category that fits the topic of information.

5.7 Maintenance of the SSR Prior to Archive

The SSR is maintained in a variety of containers (such as, binder, manila folder, accordion folder) during the conduct of the study. During the course of a study, not all documents may fit into a single type of container. If this is the case, the documents may be housed in multiple containers. All containers need to be labeled with the same identifiers and an indication that there are multiple containers (i.e. binder 1 of 2).

5.8 Study File Archiving Process

At the appropriate study milestone, the contents of the Study File plus any clinical study documents and data specified for retention are archived.
Prior to sending the file to archive the individual with primary responsibility for managing the records:

- Performs a final review of records.
- Ensures completeness and integrity of the records.
- Removes the plastic wallets/sleeves, metal clips (staples may stay) and ring binders with metal rings and clips.
- Check the SSR according to the General File Quality Standards.

6 APPENDIX1

INVESTIGATOR SITE FILE
Content List and Guidance

Section	Title	Sub-Headings
1	**Contact Details**	1.1 Sponsor Contact List
		1.2 Investigator Contact List
2	**Site Visit Log**	2.1 Site Visit Log
3	**Study Communications**	3.1 Correspondence with sponsor
		3.2 Internal correspondence
4	**Subject Information**	4.1 Subject Screening / Enrolment log
		4.2 Immediately Reportable Adverse Event (IRAE) Log
		4.3 Pregnancy log (Reports)
		4.4 Protocol Deviation log/Form
		4.5 Blank subject ID or safety card
		4.6 Blank set of informed consent forms and subject information sheets
5	**Protocol and amendments**	5.1 Final Protocol / Amendment
		5.2 Protocol /Amendment Signature Page (s)
		5.3 Superseded versions of Protocol / Amendments
6	**Safety Information**	6.1 Investigator's Brochure (IB)
		6.2 IB Receipt page
		6.3 Safety reports
7	**Regulatory**	7.1 Notifications and approvals
		7.2 Site specific regulatory documentation/correspondence
8	**Independent Ethics Committee (IEC)/Institutional Review Board (IRB)**	8.1 Notifications and approvals (IEC)
		8.2 Notifications and approvals (IRB)
		8.3 Composition IEC/IRB
9	**Investigator Agreement**	9.1Clinical Trial Agreement/Financial contract
		9.2 Indemnification/ Insurance certificate/ documentation
10	**Site Staff Details**	10.1 Study Personnel Signature / Delegation Form
		10.2 CV of Principal Investigator
		10.3 CV of sub-investigator
		10.4 CV of other relevant study staff

		10.5 Other relevant documents as applicable
11	**Investigational Product**	11.1 IP accountability records
		11.2 Study material accountability records
		11.3 Certificate of analysis
		11.4 IP storage records
12	**Case Report Form**	12.1Blank copy of CRF
13	**Laboratory**	13.1 Laboratory certificates
		13.2 Reference ranges/Normal values
		13.3 Laboratory Correspondence
14	**Other Study Specific Documents**	14.1 Confirmation list/ Certificate (s) of investigator meeting attendance
		14.2 Study Instruction Materials/User manuals
		14.3Pre-trial Documentation
		14.4 Initiation visit documentation
		14.5 Monitoring visit reports
		14.6 Additional Site Staff Training
15	**Study Results/Reports**	15.1Clinical study report
16	**Confidential Site documents**	16.1 Subject Identification list
		16.2 Signed copies of informed consents and subject information sheets
		16.3 Source documents available for all subjects
17	**Site Financial documentation**	17.1 Site Financial documentation
18	**QA/Audit**	18.1 Audit certificate
		18.2 QA Documentation
19	**Miscellaneous**	19.1 SOP
		19.2 Note to file
		19.3 Others