CLINICAL TRIALS TIMELINES

1.0 PROCESSING OF APPLICATIONS AND SUBMISSIONS

ACTIVITY	TIMELINE****
Processing of Clinical Trial applications	60 days
Processing of import permits for Investigational Products	10 days
Processing of quarterly progress and safety reports	15 days
Notification of receipt of electronic submissions including SAE reports	5 days
Communicating GCP Inspection findings	21 days
Processing of applications for protocol amendment	30 days
Processing of final Clinical Trial reports	30 days

****Timelines specified are working days and excludes clock stop time

2.0 SERIOUS ADVERSE EVENTS (SAE) REPORTING TIMELINES

Type of ADR Report	Time Frame For Reporting	Format
REPORTS FROM SITES IN GHANA		
Serious Adverse Events	Immediately where possible and in any event, within 48 hours after becoming aware of the information	A Serious Adverse Events form conforming to the CIOMS format or previously approved by the Food and Drugs Authority must be completed and submitted after the site becomes aware of an event. Electronic submissions must be E2B compliant.
• Follow-up reports	Immediately when any of the underlisted occurs: i. Change in the severity of SAE initially reported. ii. Whenever there is any new development on an initially reported SAE. iii. When the SAE resolves.	Follow-up reports should include an assessment of the importance and implication of any findings. All fatal cases must be followed up with formal autopsy report[1].
• Frequent adverse events (greater than or equal to	Immediately where possible and in any event, within 7	Line listing

1% but less than or equal to 10%)	days after becoming aware of the information	
Non Serious Adverse Events	On request and where applicable, submitted as part of an application for registration	Individual reporting in accordance with the data elements specified in the ICH guidance Document E2A
REPORTS FROM FOREIGN SITES (For multicentre studies with Ghana as a participating country)		
Serious Events	Immediately where possible and in any event, within 7 days after becoming aware of the information.	Line listing Reports should include an assessment of the importance and implication of any findings.
Foreign regulatory decisions that affect the safety or use of the product	7 days	Detailed report Records with respect to all adverse events in respect of the drug that have occurred inside or outside the country, including information that specifies the indication for use and the dosage form of the drug at the time of the adverse event may be added.
OTHER REQUIREMENTS		
Literature reports that affect the safety of the product	7 days	Detailed report and / or copy of the publication Records with respect to the enrolment of clinical trial subjects including information sufficient to enable all clinical trial subjects to be identified and contacted in the event that the sale of the drug may endanger the health of the clinical trial subjects or other persons may be added.

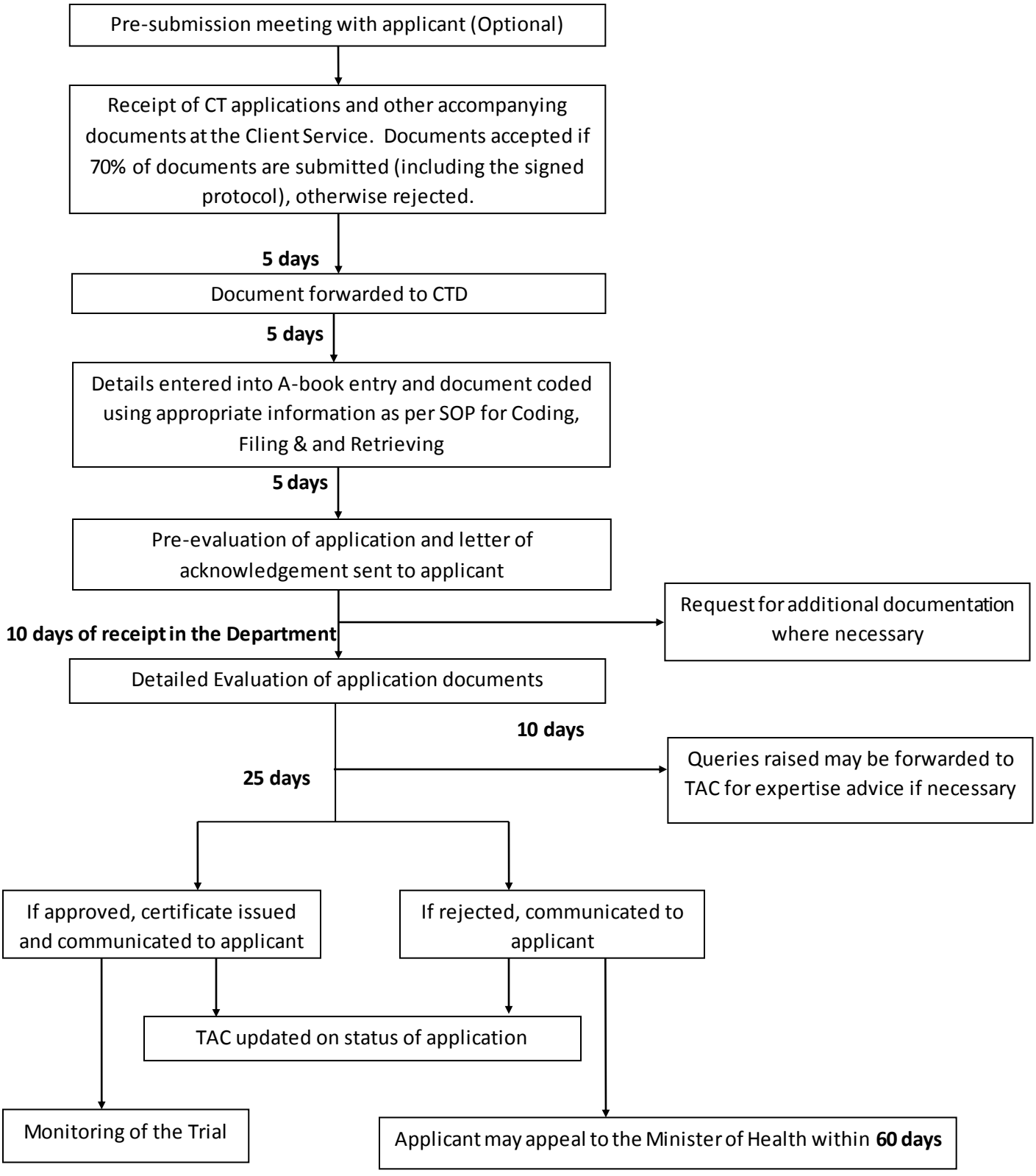
Notification of change in nature, severity or frequency of risk factors	28 days	Complete and accurate records with respect to each change made to the Investigator's Brochure, including the rationale for each change and documentation that supports each change
New information impacting on risk benefit profile of product or conduct of trial	7 days	Communicate with appropriate scientific and medical judgments being applied to each situation. Additional information may include copies of diagnostic test results, laboratory reports or medical record progress notes
Periodic Safety Update Reports (PSUR)	• On request by The Authority • Within 30 days when it is a condition of registration for a new medicinal product	As a Follow Up Report including copies of diagnostic test results, laboratory reports or medical record progress notes

3.0 OTHER TIMELINES

ACTION	REFERENCE	TIMELINE
Notification for the implementation of an urgent amendment necessary to protect the life of subjects	3.1.5.2	Immediate phone call, followed by a written report within forty-eight (48) hours
Quarterly progress reports	3.5.1.3	Within 21 days after the end of the previous quarter. A quarter in this instance is considered as three months beginning from the date of initiation of a specific clinical trial.
Notification of Trial initiation	3.5.1.4	Immediately trial commences or within ninety (90) days of issuance of the Clinical Trial Certificate if the trial does not begin or is delayed as per the date of

		commencement on the Clinical Trial Certificate issued. Failure of notification within the stipulated time would invalidate the Clinical Trial Certificate issued. A new certificate would attract administrative fees.
Notification of interruption of an approved trial before achievement of its purpose.	3.5.1.5	Within ten (10) working days
Submission of preliminary report on the ethical evaluation of the trial after completion.	3.5.1.6	Not later than 30 days after the completion of a clinical trial
Final Report of Clinical Trial as per ICH E3 Guideline (unless otherwise specified on clinical trial certificate)	3.5.3	Not later than 90 days after the completion of the trial

CLINICAL TRIAL APPLICATION PROCESS



Note: Application process takes a maximum of 60 working days excluding stop clock time.