Application Format for Clinical Trial Protocol Approval

(Application has to be submitted in organization official Pad)

Dated:

To

The Director General

Directorate General of Drug Administration,

Mohakhali, Dhaka-1212.

Subject: Application for the protocol approval of "Name of the Clinical/Performance Trial".

Dear Sir

Enclosed: (As per the attached requirements)

Name of the Principal Investigator

Designation

Organization.

Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Aushodh Bhaban, Mohakhali,
Dhaka-1212, Bangladesh

Documents submitted to DGDA for Clinical Trial

Documents required for conducting clinical trial:

1. Detailed description of Clinical Research Protocol Checklist (According to Annexure-I)
2. Ethical Clearance for conducting Clinical Trial from IRB/IEC
3. Investigator Brochure (IB)
4. Informed Consent Form (ICF)
5. Signed agreement between Sponsor/ CRO//Trial center/ Principal investigator (PI)
6. CV of PI and associates
7. GMP certificate of Investigational Product
8. Certificate of Analysis of Investigational Product
9. Detailed funding of the trials
10. Case Record Form (CRF)
11. SOPs of different activities
12. GCP training certificate of PI and team members

Documents need to submit to DGDA during clinical trial:

1. Any amendment/ addendum/ site change or any modification of clinical trial study need to be approved from DGDA
2. CV of new investigators (if added after initiation of the study)
3. Certificate of Analysis of Investigational Product, if new batch of product is used
4. Any Serious Adverse Effect (SAE) and DSMB Report of SAE need to be submitted to DGDA
5. Progress Report of clinical trial (6 months interval)

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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure-3		
	Title: Required information for Clinical Trial Protocol Application.	

1. General information

1.1 Name and address of the sponsor and monitor (if other than the sponsor).
1.2 Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.
1.3 Name, title, address and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.
1.4 Name Protocol title, protocol identifying number and date. Any amendment(s) should also bear the amendment number(s) and date(s).
1.5 Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).
1.6 Name, title, address and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).
1.7 Name(s) and address (es) of the clinical laboratory (ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

2. Background Information

2.1 Name and description of the investigational product(s).
2.2 A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that is relevant to the trial.
2.3 Summary of the known and potential risks and benefits, if any, to human participants
2.4 Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).
2.5 A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).
2.6 Description of the population to be studied.
2.7 References to literature and data that are relevant to the trial and that provide background for the trial.

3. Trial Objectives and Purpose

A detailed description of the objectives and the purpose of the trial.

4. Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design should include:

Annexure-3		
	Title: Required information for Clinical Trial Protocol Application.	

4.1 A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.
4.2 A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.
4.3 A description of the measures taken to minimize/avoid bias, including:
(a) Randomization.
(b) Blinding.
4.4 A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labeling of the investigational product(s).
4.5 The expected duration of participant participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.
4.6 A description of the "stopping rules" or "discontinuation criteria" for individual participants, parts of the trial and entire trial.
4.7 Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.
4.8 Maintenance of trial treatment randomization codes and procedures for breaking code.
4.9 The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.

5. Selection and Withdrawal of Participants

5.1 Participant inclusion criteria.
5.2 Participant Exclusion Criteria.
5.3 Participant withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying:
(a) When and how to withdraw participants from the trial/investigational product treatment.
(b) The type and timing of the data to be collected for withdrawn participants.
(c) Whether and how participants are to be replaced.
(d) The follow-up for participants withdrawn from Investigational product treatment/trial treatment.

6. Treatment of Participants

6.1 The treatment(s) to be administered, including the name(s) of all the product(s), and dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for participants for each investigational product treatment/trial treatment group/arm of the trial.
6.2 Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.
6.3 Procedures for monitoring participant compliance.

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7. Assessment of Efficacy

7.1 Specification of the efficacy parameters.
7.2 Methods and timing for assessing, recording, and analyzing of efficacy parameters.

8. Assessment of Safety

8.1 Specification of safety parameters.
8.2 The methods and timing for assessing, recording, analyzing safety parameters.
8.3 Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.
8.4 The type and duration of the follow-up of participants after adverse events.

9. Statistics

9.1 A description of the statistical methods to be employed, including timing of any planned interim analysis (ses).
9.2 The number of participants planned to be enrolled. In multi centre trials, the numbers of enrolled participants projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
9.3 The level of significance to be used.
9.4 Criteria for the termination of the trial.
9.5 Procedure for accounting for missing, unused, and spurious data.
9.6 Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).
9.7 The selection of participants to be included in the analyses (e.g. all randomized participants, all dosed participants, all eligible participants, evaluable participants).

10. Direct Access to Source Data/Documents

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.

11. Quality Control and Quality Assurance

Annexure-3		
	Title: Required information for Clinical Trial Protocol Application.	

12. Ethics

Description of ethical considerations relating to the trial. (Section 1.33)

13. Data Handling and Record Keeping

14. Financing and Insurance

Financing and insurance if not addressed in a separate agreement.

15. Publication Policy

Publication policy, if not addressed in a separate agreement.

16. Supplements

(NOTE: Since the protocol and the clinical trial/study report are closely related, further relevant information can be found in the ICH Guideline for Structure and Content of Clinical Study Reports.)

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Annexure-4		
	Title: Clinical Trial protocol amendment application format	

Detailed Summary of Protocol Amendment

Protocol No:

Protocol Title:

Sl No	Section Number, Section Title, Page Number(s)	Old Text	New Text	Rational of Change

	Version no	Version Date
Current Approved Protocol		
Amend Protocol		

Total Revision History

Version No:
Version Date:
Summary of Revisions made:
Version No:
Version Date:
Summary of Revisions made:

Administrative changes: Minor changes involving grammar, word-smithing, punctuation, and other editorial modifications have been applied throughout the document. All of these changes are highlighted in the track-changes version of the amendment.

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Annexure-1

Title: Checklist of preclinical trial data submission/ preclinical study.

Documents required to be submitted	STATUS	
	YES	NO
Pharmacokinetics		
Analytical Methods and Validation Reports		
Pharmacokinetics: Absorption after a Single Dose		
Pharmacokinetics: Absorption after Repeated Doses		
Pharmacokinetics: Organ Distribution		
Pharmacokinetics: Plasma Protein Binding		
Pharmacokinetics: Study in Pregnant or Nursing Animals		
Pharmacokinetics: Other Distribution Study		
Pharmacokinetics: Metabolism In Vivo		
Pharmacokinetics: Metabolism In Vitro		
Pharmacokinetics: Possible Metabolic Pathways		
Pharmacokinetics: Induction/Inhibition of Drug-Metabolizing Enzymes		
Pharmacokinetics: Excretion		
Pharmacokinetics: Excretion into Bile		
Pharmacokinetics: Drug-Drug Interactions		
Pharmacokinetics: Other		
Toxicology		
Toxicokinetics: Overview of Toxicokinetics Data		
Toxicology: Drug Substance		
Single-Dose Toxicity		
Repeated-Dose Toxicity: Non-Pivotal Studies		
Repeat-Dose Toxicity: Pivotal Studies		
Genotoxicity: In Vitro		
Genotoxicity: In Vivo		
Carcinogenicity		
Reproductive and Developmental Toxicity: Non-Pivotal Studies		
Reproductive and Developmental Toxicity – Fertility and Early Embryonic Development to Implantation (Pivotal)		

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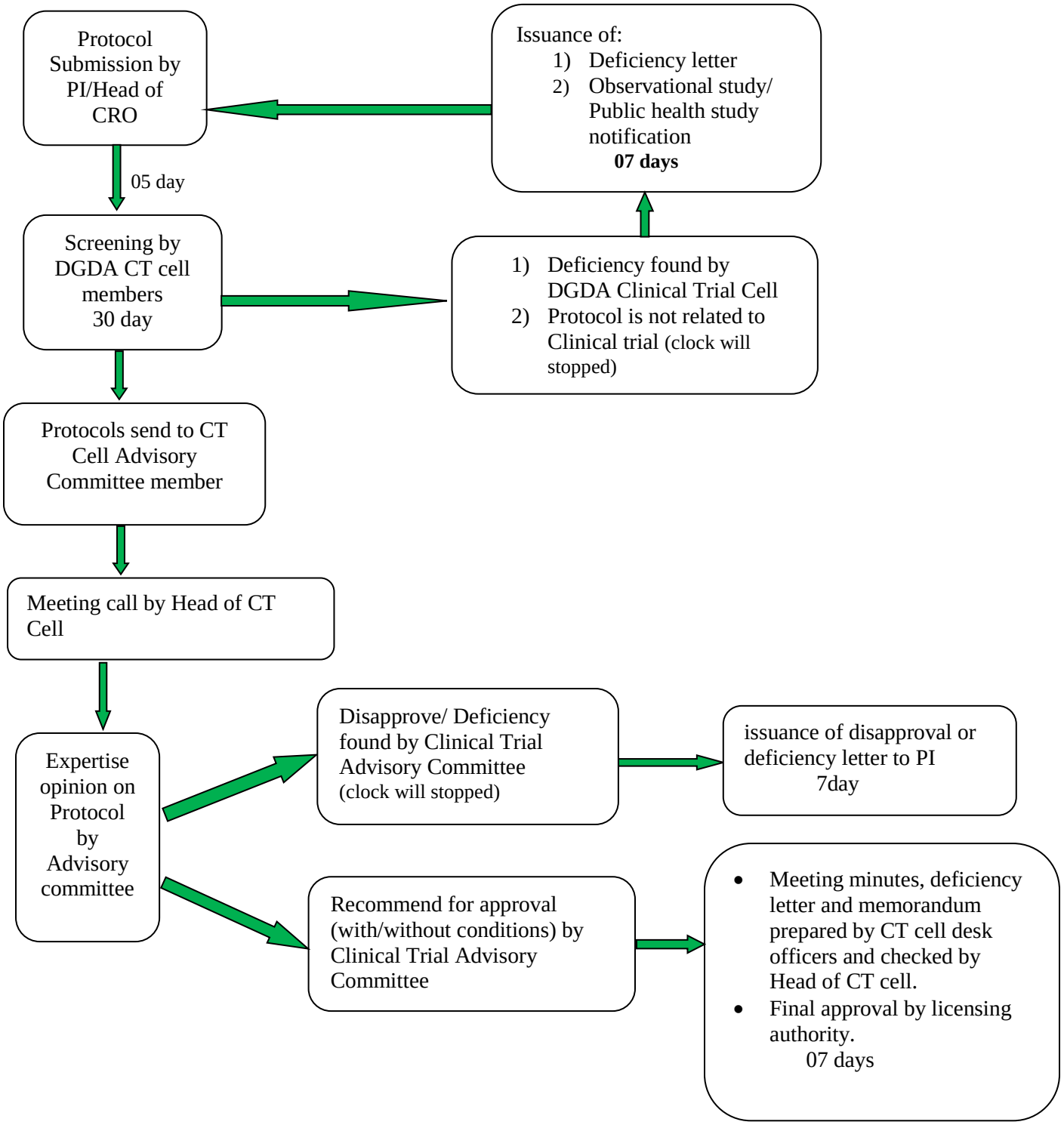
	Title: Checklist of preclinical trial data submission/ preclinical study.	

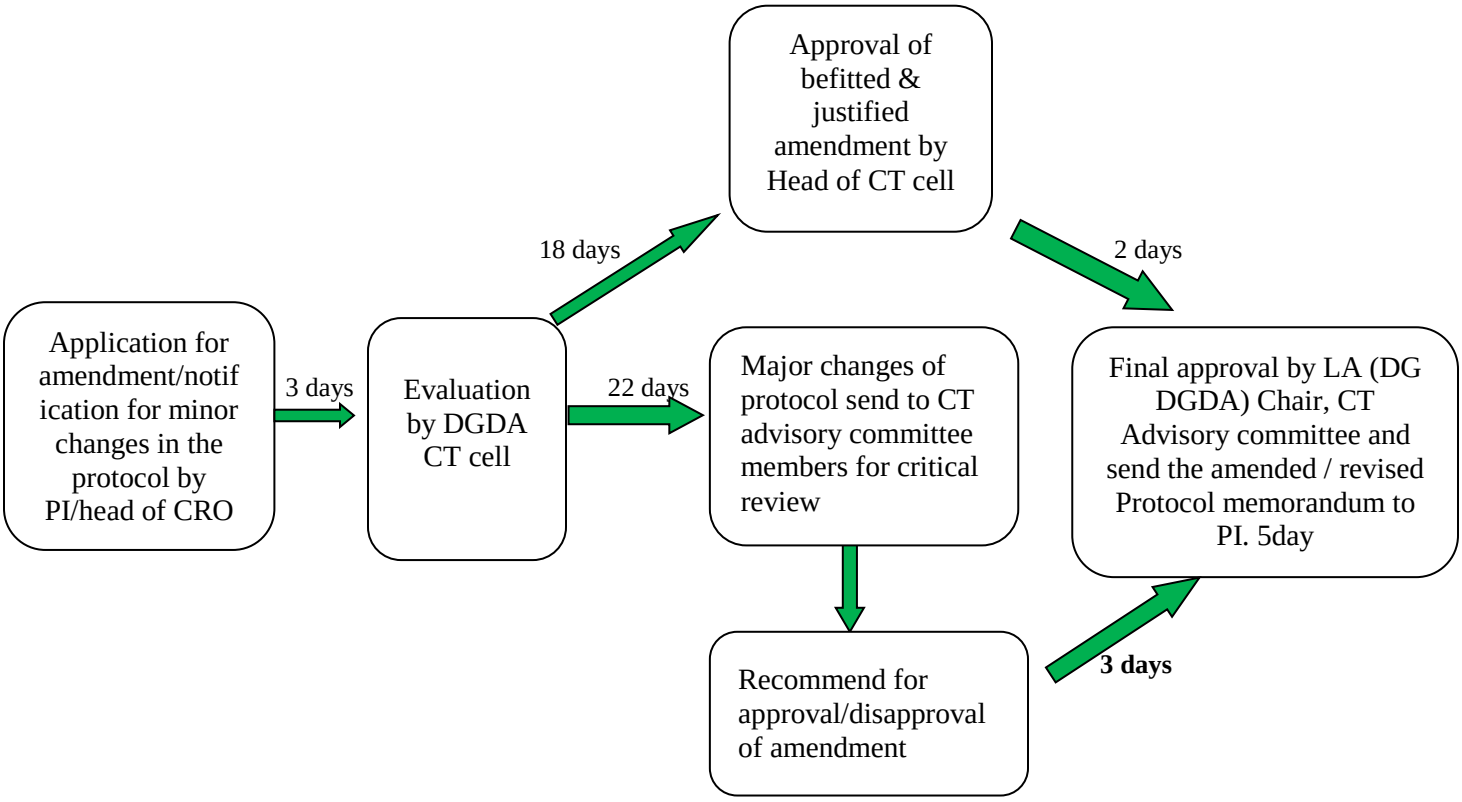
Documents required to be submitted	**STATUS**	
	YES	**NO**
Reproductive and Developmental Toxicity – Effects on Embryo-Fetal Development (Pivotal)		
Reproductive and Developmental Toxicity – Effects on Pre- and Postnatal Development, Including Maternal Function (Pivotal)		
Studies in Juvenile Animals		
Local Tolerance		
Other Toxicity Studies		

Clinical Trial Protocol Approval Flowchart



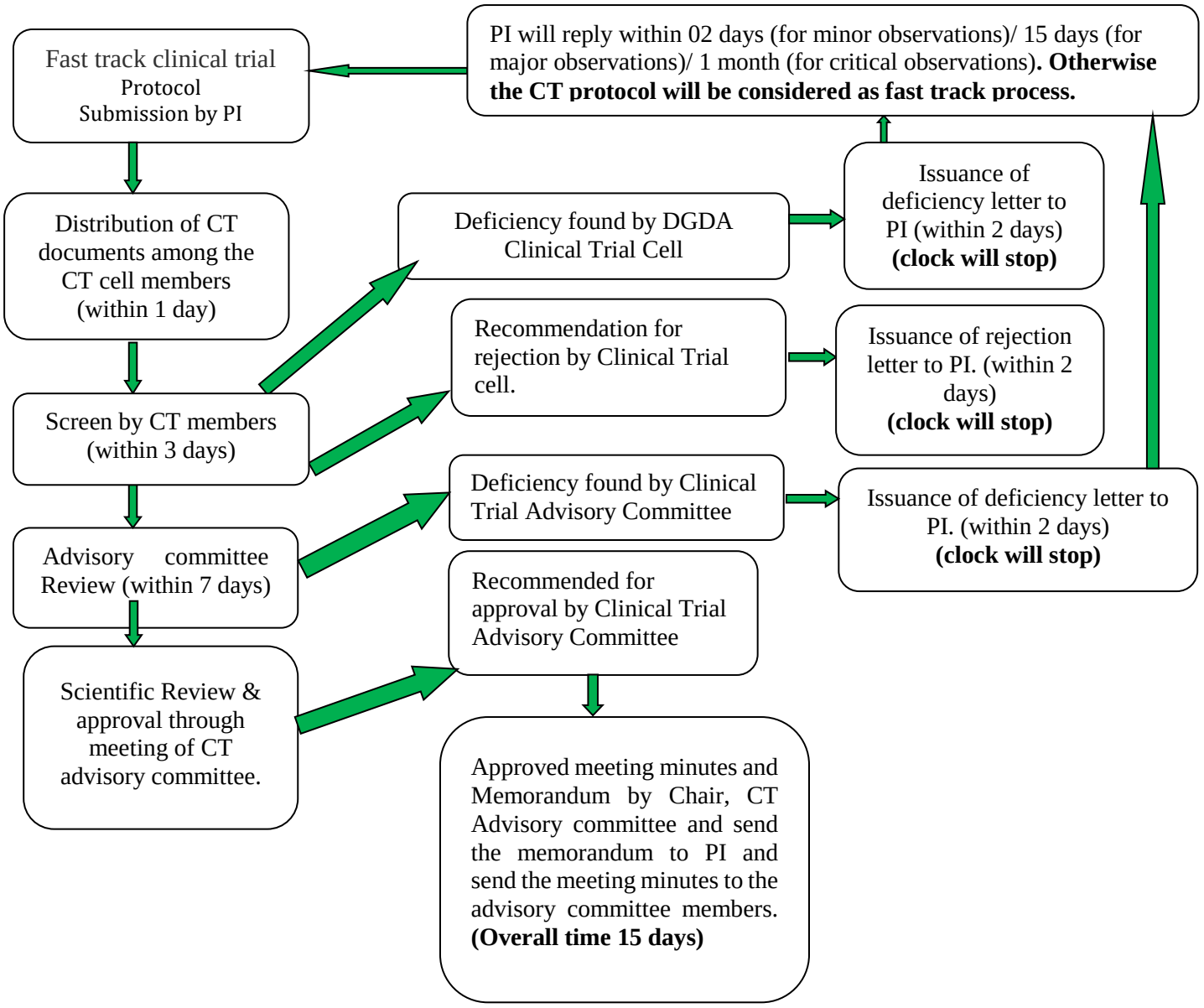
Total Time for Approval of Clinical Trial Protocol: 60 working days

Amended/ Revised Protocol Approval Flowchart



Total Time for Approval of Clinical Trial Protocol Amendment/Addendum: 30 working days

Fast Track Clinical Trial Protocol Approval Flowchart



Total Time for Fast Track Clinical Trial Protocol Approval: 15 working days