FOOD AND DRUGS AUTHORITY

GUIDELINES FOR CONDUCT OF CLINICAL TRIALS DURING EMERGENCIES

Document No. : FDA/SMC/CTD/GL-EME/2015/01
Date of First Adoption : 18th December, 2015
Effective Date : 6th January, 2020
Version No. : 02

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1.0 INTRODUCTION

Public health emergencies can complicate the already many concerns relating to the conduct of clinical trials. The fear and desperation associated with emergencies, coupled with a heightened sense of urgency, raise challenges for the way in which regulatory requirements for the conduct of clinical trials are interpreted and practically applied.

Although public health and clinical measures are crucial in addressing emergencies and its effects, new interventions to prevent and treat conditions of or relating to emergencies are also desperately needed. To establish the safety, efficacy, and effectiveness of such interventions in the emergency context, interventions need to be tested during the emergency.

Such studies, considering issues arising from the 2014/2015 Ebola Virus Disease outbreak in West Africa, raise difficult ethical, scientific, and practical questions particularly in a context characterized by poverty, vulnerability, and limited infrastructure.

Questions including the following were asked during the outbreak:

1. Do the usual regulatory requirements apply or abridged requirements should be implemented? Which clinical trials should be prioritized?
2. Is it ethical to conduct a trial when the population is already facing a disaster?
3. Can the investigational product be made available to the general population in the absence of adequate clinical data?
4. How will data collected under such circumstances impact on —regularll trials?

If these questions are not properly addressed, conducting a trial in an emergency may continue to be challenging and may even be impossible as experienced in Ghana during the Ebola Virus Disease outbreak.

This Guideline will thus provide an opportunity to carry out ethical, safe and scientifically sound clinical trials of promising new treatments and vaccines in the midst of an emergency. The Guideline also seeks to provide better transparency on regulatory

procedures to gather sound evidence for product safety and effectiveness in a timely manner.

2.0 SCOPE

This Guideline seeks to contextualize the conduct of clinical trials during public health emergencies.

3.0 GLOSSARY

Emergency: An outbreak of a disease with high mortality and which involves significant numbers of individuals and which may have a danger of international transmission.

Epidemic: the occurrence in a community or a region of cases of an illness, specific health-related behavior or other health-related events clearly in excess of normal expectancy.

Fast-track: Fast track is a process designed to facilitate the development, and expedite the review of clinical trial applications for the conduct of clinical trials during emergencies.

Joint review: This process involves a joint assessment of the application by the Authority with the relevant IRBs and other receiving national drug regulatory agencies.

Pandemic: an emergency occurring worldwide or over a wide area crossing international boundaries and affecting a large number of people.

4.0 GENERAL CONSIDERATIONS

4.1 Considerations of clinical trial applications under these circumstances shall be in relation to the underlisted existing Guidelines for the conduct of clinical trials in Ghana:

1. Guidelines for Authorization of Clinical Trials of Medicines, Food Supplements, Vaccines and Medical Devices in Ghana.
2. Guidelines on Good Clinical Practice
3. Guidelines for Conduct of Clinical Trials in Paediatric Populations

4.2 The Role of the Food and Drugs Authority (subsequently referred to as the Authority)

4.2.1 The Authority shall facilitate the processing and approval of clinical trials during public health emergencies.

4.2.2 The Authority may also request for the conduct of clinical trials during public health emergencies.

4.3 The Authority shall require that the Sponsor ensures the underlisted:

4.3.1 An appropriate memorandum of understanding regarding consultations and further actions shall be agreed upon and signed by all parties involved.

4.3.2 The memorandum of understanding shall be binding on all parties involved.

4.3.3 Acceptable amendments to the memorandum of understanding shall be discussed during development of the memorandum of understanding.

4.4 An application to provide of an investigational product being used in a clinical trial under emergency conditions to non-trial participants shall receive prior approval from the Authority.

4.5 Such application shall be in the format as prescribed in the Authority's Form for Irregular Imports.

5.0 ETHICAL CONSIDERATIONS

All the necessary ethical approvals shall be obtained for the study.

6.0 FILING AN APPLICATION

6.1 Requirements for filing a clinical trial application during an emergency shall be same as required under Section 3.0. of the Authority's Guidelines for Authorization of Clinical Trials of Medicines, Food Supplements, Vaccines and Medical Devices in Ghana.

6.2 The timelines for processing such applications shall however be shortened (refer to Appendix I).

6.3 The Sponsor as part of the application may request a joint review of the application.

6.4 Such applications shall be considered by the Authority on a case-by-case basis.

6.5 Applications for the joint review process shall be submitted at least 14 working days before the proposed date of the joint review.

7.0 APPLICATION FORMAT

7.1 The format and content of an acceptable application (minimum critical information required to begin processing of the application) for the conduct of a clinical trial in emergencies shall be as follows:

7.1.1 Covering Letter addressed to the Chief Executive Officer

7.1.2 A non-refundable Application Fee as per the prescribed Fee Schedule.

7.1.3 Completed Food and Drugs Authority Application Forms for Conducting Clinical Trials signed by authorized persons (PI and Sponsor's authorized representative)

7.1.4 A Clinical Trial Protocol

7.1.5 A proof of registration with Pan African Clinical Trials Registry (PACTR)

7.1.6 Investigator's Brochure (IB)/Investigational Product (IP) Dossier

7.1.7 Insurance Cover for all study participants

7.1.8 DSMB Membership and signed Charter

7.1.9 Ethics Committee (EC)/Institutional Review Board (IRB) Approval (at least evidence of submission of application to EC/IRB if final approval is not yet available)

Note however that the following documents shall be required prior to the completion of the study:

7.1.10 Financial Declaration

7.1.11 Sponsor/PI Contractual Agreement

7.1.12 Informed Consent and Assent Forms (if applicable)

7.1.13 Statistical Analysis Plan (SAP)

7.1.14 Materials Transfer Agreement (if applicable)

Note:

a) All clinical trial application documents shall be submitted in hard and soft copies (1 each; format of soft copy of documents submitted should be in searchable PDF).
b) Applicants are to refer to Section 3.1 of the Guidelines for Authorization of Clinical Trials of Medicines, Food Supplements, Vaccines and Medical Devices in Ghana for more details on the content of the above listed documents.

7.2 The Authority shall however, prescribe other relevant information to be provided considering the phase and nature of the intended trial.

8.0 PROCESSING OF APPLICATIONS

8.1 The Authority shall upon receipt of an application liaise with relevant stakeholders (including relevant ethics and other oversight bodies) to draw an appropriate plan to facilitate a holistic review of an application in a fast-track manner.

8.2 Without prejudice to the above, the procedure and timeline outlined in Appendix I shall apply.

8.3 The underlisted prioritization criteria shall be applied in the selection of applications for review;

8.3.1 Epidemiology of the emergency.

8.3.2 Morbidity / mortality associated with the emergency and/or condition under study.

8.3.3 Supporting scientific data/information available of the investigational product at the time of submission.

8.3.4 Feasibility of the implementation of the trial design within the context of the emergency.

8.3.5 Risk: Benefit impact of the intervention and/or trial design.

8.4 Upon conclusion of a review the Authority shall within applicable timelines communicate its decision on the Application to the Applicant.

8.5 The decision of the Authority may be any of the underlisted:

8.5.1 Approved (with consequent issue of a Clinical Trial Certificate as per section 155, subsection 1 of the Public Health Act, 2012, Act 851).

8.5.2 Deferred pending submission of further details that shall be specified.

8.5.3 Rejected; implying non-approval.

9.0 REPORTING

9.1 Reporting on the conduct of the trial shall conform to provisions under Sections 3.5 and 3.6 of the Authority's Guidelines for Authorization of Clinical Trials of Medicines, Food Supplements, Vaccines and Medical Devices in Ghana.

9.2 Monthly reports shall however be submitted to the Authority in the prescribed format.

10.0 COMMUNICATION

10.1 The Sponsor shall develop a communication plan in line with provisions of subsection 159 of the Public Health Act, 2012, Act 851.

10.2 Any communication plan developed shall receive prior opinion from the Authority before implementation.

10.3 The communication plan and related information, educative and communication material shall be developed based on the principle of trust, transparency, rapid communication and adequate dialogue.

10.4 A communication plan shall consist of at least;

10.4.1 Background and environmental analysis
10.4.2 Goals and objectives
10.4.3 The communications team
10.4.4 Identification of key stakeholders
10.4.5 Strategy for ongoing communication with stakeholders
10.4.6 Strategy for managing controversy—crisis communications
10.4.7 Dissemination plan for trial results
10.4.8 Materials to support the trial
10.4.9 Monitoring and evaluation

10.5 Any communication plan proposed shall be implemented through broad-based programs to engage all relevant key stakeholders.

10.6 Information to be provided shall also be in local languages and shall be targeted not only to trial participants but also to key stakeholders, including local officials, medical professionals, the media, traditional leaders, Ministry of Health and others.

10.6.1 Information provided shall include at least;

10.6.1.1 Awareness about the emergency.

10.6.1.2 Awareness about existing supporting system.

10.6.1.3 Awareness about the general objective and intended impact of the proposed study.

10.6.1.4 Shall seek to secure public / civil society support for the trial.

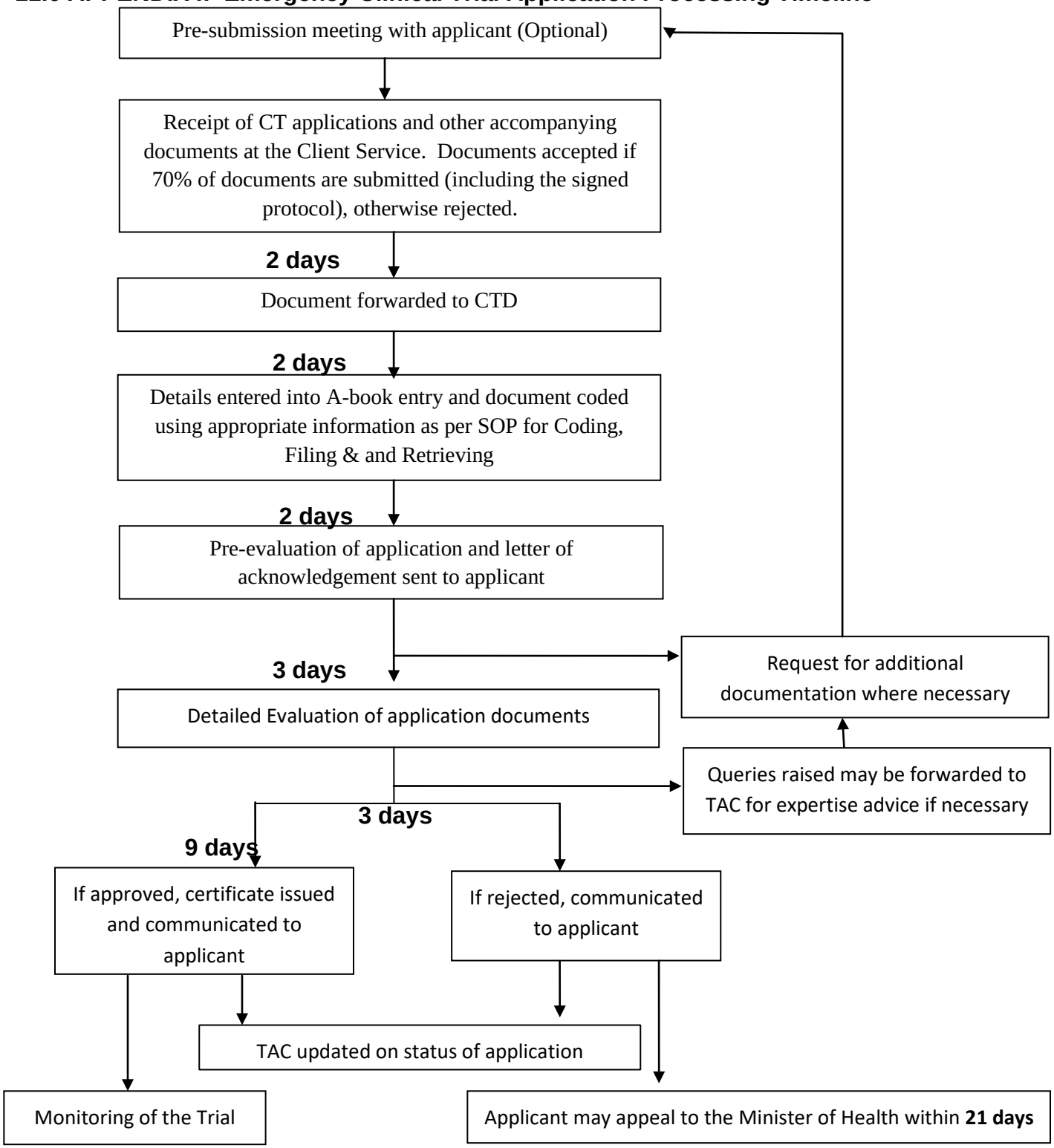
10.6.1.5 Mechanisms and channels available to the public to provide feedback on the trial.

10.6.1.6 Mechanisms and channels to be used to provide further information on the trial to stakeholders including international bodies.

10.6.2 Information, education and communication materials to be used shall receive the appropriate IRB/IEC approval.

10.6.3 The Sponsor shall ensure that information flow mechanisms are developed between investigators and participating communities; and that community are adequately educated on all relevant aspects of trial before recruitment begins.

11.0 APPENDIX I: Emergency Clinical Trial Application Processing Timeline



Note: Processing of submissions shall take a maximum of 21 working days excluding stop clock time.

12.0 REFERENCES

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