Phase II Convalescent Plasma Study: Update

Date: 19/04/2020

ICMR launched the call for intent for the study titled "A Phase II, Open Label, Randomized Controlled Study to Assess the Safety and Efficacy of Convalescent Plasma to Limit COVID-19 Associated Complications" on April 12th, 2020. The response has been overwhelming and we have received 99 applications expressing their interest in participating in the study.

The generic protocol has been approved by the DCGI. We are attaching the DCGI approval. Each Institute that wishes to participate in the study will need to mandatorily obtain ethics clearance locally through their Institutional Ethics Committee.

ICMR will collaborate with eligible institutes from the pool of applicants based on the criteria:

1. Prior experience in conducting clinical studies.
2. Presence of necessary expertise, equipment and infrastructure for the study.
3. Ability to support the cost of care of study participants.
4. Institutional Ethics Committee registered with the CDSCO.
5. Each participating institute will have to buy trial insurance and ICMR will reimburse the premium costs as per rules.

Eligible institutes will be funded by ICMR for study related activities after completion of requisite documentation.

File No. X.11026/78/2020-BD

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi, 110002
Dated: 14/4/2020

To

Indian Council of Medical Research,
Department of Health Research, Ministry of Health and family Welfare
V. Ramalingaswami Bhawan, New Delhi

Subject: Permission for approval of protocol for a multi-center two arm prospective, phase-II open labeled randomized controlled trial of convalescent plasma in COVID-19 patients-Regarding

Sir,

Please refer to your letter dated 07.04.2020 on the above subject. Your proposal was deliberated in the 68th SEC meeting (Anti microbial and Antiviral) held on 13.04.2020 at CDSCO (HQ), New Delhi, wherein your representative made presentation before the committee. After detailed deliberation, the committee recommended that the protocol can be approved in priniciple subject to certain conditions, out of which you have submitted revised protocol. However, Inclusion criteria mentioned at point no. 5 is not deleted, Details of the study sites is annexed, undertaking of the investigators etc., should be submitted

Based on the recommendations of the SEC and your revised protocol, this Directorate has no objection for the conduct of proposed Clinical trial protocol as per protocol version 1.1 dated 12.04.2020 submitted to this office in the light of COVID-19 outbreak subject to the following conditions:

(i) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licensing Authority under Rule 8;

(ii) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of Rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

iii) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

iv) The Central Licensing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;

v) Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;

vi) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

vii) Status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

viii) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority;

ix) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

x) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI of the New Drugs and Clinical Trials Rules, 2019;

xi) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with the Chapter VI of the said Rules and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

xii) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with the Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

xiii) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

xiv) Where the New Drug or Investigational New Drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;

xv) The Laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be

deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

xvi) The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial.

xvii) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

xix) Undertaking by the investigator involved in the conduct of the study should be submitted to CDSCO as per table 4 of third schedule New Drug and Clinical trial Rules 2019 before initiation of the study.

xx) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before initiation of the study.

xxii) For grant of formal permission in Form CT-06 of the New Drug and Clinical trial Rules, 2019 for the conduct of clinical trial, application in Form CT-04 should be submitted to this office before initiation of the study.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002