

Invitation for Expression of Interest for providing Clinical Trials Liability Insurance for SOLIDARITY

PLUS trial

ICMR through ICMR-National AIDS Research Institute, Pune is coordinating a trial, titled “An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care SOLIDARITY TRIAL PLUS” or “WHO-India (ICMR) SOLIDARITY trial plus”, with atleast 15 participating trial sites.

The PI is Dr. Sheela Godbole, Sc-F, Head, Div. of Epidemiology, ICMR-National AIDS Research Institute, Pune.

In this study, adults (age ≥ 18 years) recently hospitalised, or already in hospital, with definite moderate or severe COVID-19 and, in the view of the responsible doctor, no contra-indication to any of the study drugs and naïve to study drugs will be randomised to ‘Local standard of care’ alone (excluding study drugs) OR ‘Local standard of care’ plus only one of 1. IV Infliximab as a single IV infusion OR 2. Tab. Imatinib given once a day for 14 days. The primary outcome is all-cause mortality, by severity of disease at the time of randomisation.

This being an adaptive protocol new drugs may be added to the trial or discontinued based on findings from interim analysis and recommendations of the DSMB.

The trial plans to recruit upto 750 patients meeting the inclusion and exclusion criteria set for the study, across atleast 15 trial sites across India till completion of recruitment and follow up.

Clinical trial insurance for the following is required:

- **Professional Indemnification** for 250 investigators physicians and nurses
- **Compensation for ‘Trial related injuries’** for study participants as per ‘*New Drugs and Clinical Trials Rules, 2019, [G.S.R. 227(E)] dated 19 March 2019*’ and **medical management for adverse events related to study drugs and not natural disease progression**

Duration- 1.5 years (10-12 months of study and post study wrapup)

Request for proposals are invited from eligible parties who are interested in providing clinical trials liability policy or liability insurance, indicating the conditions and extent of coverage, date of commencement and expiry of coverage, and conditions thereof, including the premium and other costs, as per rules, for the aforementioned studies.

The terms for the policy are –

1. Maximum of 75 Lakh Rupees per occurrence
2. Aggregate insurance of 20 Crore Rupees.

Please submit your expression of interest to Email -solidarity.icmrindia@gmail.com with complete documentation.

Please email on the aforementioned email if you need any further clarifications-
solidarity.icmrindia@gmail.com, with copy to mmamulwar@nariindia.org