**Notice inviting Letter of Expression of Interest**

**to conduct COVID Related Research Projects**

All India Institute of Ayurveda (AIIA), an autonomous organization under Ministry of AYUSH, New Delhi has been established with a vision to be an Outstanding Center of Excellence for Ayurveda Tertiary Health Care and set highest standards of Education, Research and Tertiary Care through Ayurveda for the benefit of humanity. During the COVID-19 pandemic period of current times, the institute is actively engaged various COVID related research activities. Ministry of AYUSH has also committed in researches to develop efficacy of AYUSH practices in COVID manifestations, where the activities are being coordinated by AIIA.

In continuation to the ongoing trials; Ministry of AYUSH is planning to expand the domestic and international clinical studies with AYUSH / Herbal Products in COVID conditions.

To systematically organize these studies, AIIA, Ministry of AYUSH would like to hire a CRO for the time being.

**CROs with minimum five years of experience in conducting / coordinating domestic and international clinical trials may submit their Letter of Expression of Interest along with relevant supporting documents latest by 30th December 2020 at** [**director@aiia.gov.in**](mailto:director@aiia.gov.in)

**Please check website:**

[**https://aiia.gov.in/**](https://aiia.gov.in/)

**for further details**

**Letter of Expression of Interest in the following template are invited till 30th December 2020 from Registered Clinical Research Organizations (CRO) to help AIIA, Ministry of AYUSH in conducting COVID related Research projects.**

The study details in brief, are as follows:

1. **Study design:** Multicentric, Comparative, Interventional, Randomized, Prospective clinical studies
2. **Study arms:** Two - Three arms (One arm will be administered trial drug and the other arms will be controls)
3. **Study locations:** Centres in India, Brazil, South Africa, USA, Germany, UK etc.
4. **Sample size:** Varying from 50 - 2500 in each study divided into two - three arms.

Additional 20% subjects may be recruited.

1. **Primary Outcome Parameters:** Incidence of infection of COVID19 and Non COVID infections in the study population. Recovery rate, Reduction in hospital stay

Site Investigators, research fellows will be provided at each center by respective teams of investigators.

**TERMINATION:**

Either Party may terminate this Agreement by giving not less than 30 days prior written notice to the other Party.

**INDEMNITY:**

Service Provider agrees to indemnify, keep indemnified and hold harmless AIIA, Ministry of AYUSH and its officials against all claims, demands, damages, losses, expenses, suits or proceedings made against, incurred, or suffered in connection with the performance of the Agreement, resulting from or arising out of (whether or not involving a third party claim) of any of your representations and warranties and undertakings under this Agreement.

# RESOLUTION OF DISPUTES

# In the event of any dispute relating to the interpretation or performance of this Agreement arising between the Parties, both Parties will first do their utmost to settle their dispute amicably.

# In the case of failure to resolve the dispute, all such disputes shall be referred to arbitration under the Arbitration & Conciliation Act, 1996 (or any amendments thereof).

1. The place of such arbitration shall be New Delhi. The language of arbitration shall be English only.

**Letter of Expression of Interest**

To,

**The Director**,

All India Institute of Ayurveda, New Delhi

**Subject: Conducting COVID related Clinical Studies on Ayurvedic compounds**

Our company, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, will be glad to be part of this study and would provide the following services:

|  |  |  |
| --- | --- | --- |
| **Activities** | **CRO Role** | **Comments** |
| Development of Protocol and other study documents for IEC approval | Yes | With inputs from AIIA |
| Training on Protocol and GCP of the study staff including investigators and Research Fellows (CRC) | Yes | Site selection, Investigator selection and Research team selection to be done by AIIA |
| E-CRF Preparation | Yes |  |
| Data Management Plan | Yes | - |
| Data Validation Plan | Yes | - |
| Database Specifications | Yes | - |
| Database Designing | Yes | - |
| Edit Check Programming | Yes | - |
| Data Entry Guidelines | Yes | - |
| User Manual | Yes | - |
| User Management | Yes | - |
| Database Live | Yes | - |
| Data Entry | No | Site investigators will perform the real time data entry |
| Query Management | Yes | In discussion with the site and AIIA |
| Source Data Verification | Yes | As required site visit to monitor the study will be done |
| Database Lock / Freeze | Yes | After confirmation from the sites and AIIA |
| Data Extraction | Yes | As per study requirement |
| Reports and Access on Dash Board | Yes | - |
| Final Data Extraction | Yes | After Database is locked |
| Data in CD/Pen drive | Yes | After Database is locked |
| Patient Data Report (in pdf) | Yes | After Database is locked |
| Technical Issues/ Maintenance/ Up gradation | Yes | As and when required |
| Site Monitoring to check with compliance with protocol | Yes | As per the study requirement (Remote monitoring/Risk based monitoring will be done) |
| Statistical Analysis | Yes | - |
| CSR Preparation | Yes | - |
| Publication (Manuscript preparation, submission and resolution of query) | Yes | - |
| Looking into patent related aspects | Yes | - |
| Preparing dossier for FDA approval | Yes | In consultation with AIIA |

All investigators and Study staff will be provided training before initiation of the study and also on regular basis throughout the trial for E-CRF filling

**The cost for the above services will be Rs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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Signature

Authorized Signatory