

Site Name: Andhra Medical College, Visakhapatnam.

Study Title: Strengthening the Capacity for Conduct of Human Clinical Trials for COVID-19 Vaccine at Andhra Medical College, Visakhapatnam Mission COVID Suraksha.

Proposal Reference Number:	BT/CS0031/CS/03/20
Grantee Name:	BIRAC (Biotechnology Industry Research Assistance Council) Department of Biotechnology, India.
Gratn-in-Aid Letter Agreement	Signatories: 1. Mission Director: Dr.Shirshemdu Mukherjee 2. Institution Head: Principal (Dr.G.Buchi Raju) 3. Principal Investigator: Dr.Y. Padmasri.

Background of the site:	<p>The Sanctioned site facility is the Rural field practice area of Andhra Medical College situated at Simhachalam. Rural Health Center, Simhachalam is established in 1958. Apart from delivery of health services to the population it serves as field practice area of Andhra Medcial College for training the students and postgraduates of Community Medicine. The Rural Health Center has 12 sub-centres with 12 MPHWs f & 58 ASHAs. The Hospital has 10 beds and the services provided include outpatient and emergency in patient services, lab. Services, etc through Medical officers and ancillary staff. The patient turnover 100-140 per day, 3800-5000per month.</p> <p>It is under control of Andhra Medical College with attached King George Hospital and is with in 15-16 kms distance from Andhra Medical College. It is now included in ward -98 of Greater Visakhapatnam Muncipal Corporation .</p>
Objectives of the Project:	<p>Objective 1: Capacity Building</p> <p>Objective 2: Volunteer Data Base Development</p> <p>Objective 3: To make the site ready for Clinical Trial conduct</p>
Current Status:	<p>Objective 1: Capacity Building</p> <p>Adequate space: The site is refurbished and is having the amenities to conduct Clinical Trial for COVID Vaccine and Therapeutic Trial with dedicated space for Laboratory, Clinical Examination, AV consenting, Pharmacy/Cold Chain and office with storage facility.</p> <p>Recruited Man power for the Project (17 personnel) and Trained the staff on GCP and GCLP.</p>

Procured and installed all the Equipment as per the protocol to store Vaccines and Clinical Trial Bio samples.

Objective 2: Volunteer Data Base Development

22 Community Meetings were conducted for awareness of vaccine clinical Trials and encourage participation in COVID Vaccine Trial. Collected about 4569 volunteers Data till date.

Objective 3: To make the site ready for Clinical Trial conduct

- The Medical College has a VRDL laboratory, however NABL certification only for HIV parameter.
- Developed clinical trial centre which included Clinical examination room, consenting room, sample collection facility, Trial pharmacy, participant observation room, data management and record-keeping facility. Site Readiness to take up clinical trials.
- Developed SOPs for managing and reporting Adverse Events
- MOU signed with tertiary care hospital for the management of SAEs.

Site assessment by industry / third party for readiness to take up clinical trial through audit visits from vaccine manufacturers and subsequent signing of service agreements.

Submitted Letter of Interest/ Feasibility Questionnaire for contacted Sponsor/CRO/Investigator.

- Trial Update:
- Sponsor Studies:
- Pharm Olam – Site Selection done and Awaiting for EC Submission Dossier – CTA (Clinical Trial Agreement) – negotiation is in process.
- CDSA Sponsor – Site Selection done and awaiting for further procedure.