F.No. 3-55/2020-CCRAS/Admin/CRO/VOL-I

केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद्
आयुष मन्त्रालय, भारत सरकार
जवाहर लाल नेहरू भारतीय चिकित्सा एवं होम्योपैथी अनुसंधान भवन
61-65, सांस्थानिक क्षेत्र, सम्मुख 'डी' ब्लाक, जनकपुरी, नई दिल्ली-110058
CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Ministry of AYUSH, Govt. of India
Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan
61-65, Institutional Area, Opp. 'D' Block, Janakpuri, New Delhi-110058

ग्राम : आयुष
Gram : "AYUSH"
Fax : 28520748
EPBX
28525852, 28520501
28522524, 28525831
28525862, 28525883
28525897

Sub: Tender for engagement of Contract Research Organisation (CRO) in respect of various clinical studies to be undertaken by Ministry of AYUSH By CCRAS, Govt.Of India related to COVID-19 by CCRAS.

The DG,CCRAS invites sealed quotations for engagement of Contract Research Organisation (CRO) in respect of various clinical studies to be undertaken by Research Councils and National Institute under Ministry of AYUSH by CCRAS, Govt. of India related to COVID-19 preferably for a period **6 months to One year from** the date of signing of CSA contract:-

2. **General information about the tender:-**

a)	Tender Reference No.	**F.No. 3-55/2020-CCRAS/Admin/CRO/VOL-I**
b)	Last date and time for receipt of Tenders	23.06.2020 upto 02.00 PM
c)	Time and date of opening of Tenders	23.06.2020 at 03.00 PM
d)	Place of opening of Tenders	Conference hall Room No. 223, 2nd Floor, CCRAS HQs Office, No. 61-65, Institutional Area, Opp. 'D' Block, Janakpuri, New Delhi-110058.
e)	Details of background activities to be carried out as well as essential requirements for CRO, technical requirements & activities for clinical trials etc.	**Annexure-I**

3. The Tender shall be submitted in two bid system, technical bid and financial bid:-

i. Technical bid (as per Annexure-II) consisting of all technical details, and

ii. Financial bid (as per Annexure-III) indicating protocol mentioned in the technical bid.

Technical bid and the financial bid should be sealed by the bidder in separate covers duly super scribed and both these sealed covers are to be put in a bigger cover which should also be sealed and duly super subscribed **"Engagement of Contract Research Organisation (CRO) in respect of various clinical studies to be undertaken by Ministry of AYUSH by CCRAS, Govt.Of India related to COVID-19 by CCRAS.** The sealed Tenders may be put in the Tender Box placed on the 2nd floor near in the chamber of Deputy Director (Admn.), Room No. 222, and CCRAS or by post at the aforesaid address latest by due date and time. Tenders received late will be rejected outright.

iii. **A Pre-bid Conference will be held on date 09-06-2020 at 15.00 Hours (IST) in Conference** room of Central Council of Research in Ayurvedic Sciences through digital

mode. All prospective bidders are requested to kindly submit their queries, if any to the address indicated above so as to reach the office **by Date 08-06-2020**

iv. **For terms of reference for engagement of Contract Research Organisation (CRO) for conduct various clinical studies undertaken by Ministry of AYUSH (AYUSH-CSIR studies/Ministry's Research studies) by CCRAS and the background of study, details for CRO & it's essential requirement and technical requirements for CRO and list of activities proposed to be carried out by CRO for clinical trials on AYUSH PRODUCTS) etc must be full filled as per Annex-I.**

4. **The tenders shall be subject to the following Terms and condition:-**

i. Each bidder should submit an **EMD of Rs75000/ (Seventy five thousand)** along with the quotation for comprehensive drug-drug interaction studies. EMD should be in the form of Demand Draft, drawn in favour of Director General, CCRAS, and New Delhi. The EMD of unsuccessful Bidders will be refunded after award of contract and EMD of successful bidder will be returned on receipt of **performance security as per GFR-2017 w.r.t** the bid amount.

ii. The technical Bid must contain information/documents signed by the authorized signatory of the bidding firm/agency should be kept in Technical Bid envelope along with other documents/information prescribed in this tender notice.

iii. The firm should not handover execution of order to any other/sister firm(s) and in such a case it will amount to violation of contract and may entail cancelation of contract and forfeiture of Performance Security.

iv. The tenders will be opened on stipulated date and time in the presence of the tenderers or their authorized representatives who may like to be present.

v. The tenderers should quote their rates (excluding taxes) for all the studies mentioned in the technical bids without any fail.

vi. If any tenderers withdraw his tender before the expiry of the period fixed for keeping the rates firm for acceptance, the earnest money, if any, deposited will be for-fitted and no correspondence in this regard will be entertained thereafter.

vii. Communication of acceptance of the tender constitutes concluded contract.

viii. In case where a successful tenderers, does not provide the service or in time or to provide the services, the Council at its discretion may obtain such services from the next higher tenderer and the loss, if any, caused to the Council due to increased rates shall be borne by the defaulting tenderers.

ix. The performance security shall be returned to the contractor within two months after expiry of the contract period, but in the event of any dispute arising between the Council and the contractor, the Council shall be entitled to deduct such sums which in the opinion of the Council are due from/not payable to the contractor.

x. Any sum of money due and payable to the contractor, including Performance Security under this contract may be appropriated by the Director General, CCRAS and set off against any claim of the Director General, CCRAS against the tenderers.

xi. No enhancement of rates will be considered during period of contract.

xii. The Bidder firm should not have been blacklisted by any Govt. /Semi Govt./Semi Govt. Deptt. Therefore, bidder should furnish an Undertaking to this effect that any Govt../Semi Govt., Deptt. /Office has not blacklisted their firm/agency.

xiii. The bidder must have GST registration number (copy of the Certificate should be enclosed as a proof), if the same is applicable to his firm.

xiv. The bidder must submit the copy of last 03 years Income Tax Return (ITR).

xv. The bidder shall quote/indicate the rates for all items (in Indian Rupees) offered by it in the 'Proforma for Financial Bid' attached with this tender notice at Annexure-III.

xvi. The Director General has every right to reject/accept any bid without assigning any reasons.

xvii. The Technical bids will be opened and evaluated by a committee and only the bids technically acceptable would be considered further.

xviii. The bids received after due date and time will not be accepted while incomplete bids are liable to be ignored.

xix. The tender received without EMD will not be entertained under any circumstances.

xx. The TDS will be deducting u/s 194 of the It Act, 1961.

xxi. Taxes and any other charges should be indicated separately.

xxii. The period of contract shall be for six months to one year from date of award of contract extended for further two years on the same rate, terms & conditions subject to satisfactory performance of the agency/contractor.

xxiii. The service provider should have a minimum **TEN** years experience in the field of **clinical studies and population studies.**

xxiv. The DG, CCRAS reserves the right to accept or reject any bids or accept all tenders either in part or in full or to split the order, or to annul the bidding process without assigning any reason.

xxv. The others point which not covered in above points will be covered as per GFR-2017 or any other latest Govt. guidelines whichever is latest.

Critical Date Sheet		
S.No.	**Stage**	**Date**
1	Publish Date	02-06-2020
2	Download Started	02-06-2020
3	Pre-Bid Conference if any	09-06-2020 at 15.00 Hrs
4	Bid submission Last date	23-06-2020
5	Bid Openning date & time	23-06-2020 at 3.00PM at Conferrence Room of CCRAS

xxvi. **Amendment of Tender Documents if required**

a. At any time prior to the deadline for submission of bids, the Purchaser may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective bidder, modify the tender documents by amendment. The same would also be hosted on the website of the Purchaser and all prospective bidders are expected to surf the website before submitting their bids to take cognizance of the amendments. However, the copies of the amendments would be sent by registered post/speed post/courier/e-mail to all the bidders who have purchased the tender documents.

b. In order to allow prospective bidders' reasonable time in which to take the amendment into account in preparing their bids, the Purchaser, at its discretion, may extend the deadline for the submission of bids and host the changes on the website of the Purchaser.

xxvii. Code of Integrity

a. The bidders/suppliers should sign a declaration about abiding by the Code of Integrity for Public Procurement in bid documents. In case of any transgression of this code, the bidder is not only liable to be removed from the list of registered suppliers, but it would be liable for other punitive actions such as cancellation of contracts, banning and blacklisting or action in Competition Commission of India, and so on.

b. Code of integrity for Public Procurement: The Purchaser as well as bidders, suppliers, contractors and consultants should observe the highest standard of ethics and should not indulge in the following prohibited practices, either directly or indirectly, at any stage during the procurement process or during execution of resultant contracts:

i) "corrupt practice": making offers, solicitation or acceptance of bribe, rewards or gifts or any material benefit, in exchange for an unfair advantage in the procurement process or to otherwise influence the procurement process or contract execution;

ii) "Fraudulent practice": any omission or misrepresentation that may mislead or attempt to mislead so that financial or other benefits may be obtained or an obligation avoided. This includes making false declaration or providing false information for participation in a tender process or to secure a contract or in execution of the contract;

iii) "anti-competitive practice": any collusion, bid rigging or anti-competitive arrangement, or any other practice coming under the purview of the Competition Act, 2002, between two or more bidders, with or without the knowledge of the purchaser, that may impair the transparency, fairness and the progress of the procurement process or to establish bid prices at artificial, non-competitive levels;

iv) "coercive practice": harming or threatening to harm, persons or their property to influence their participation in the procurement process or affect the execution of a contract;

v) "conflict of interest": participation by a bidding firm or any of its affiliates that are either involved in the consultancy contract to which this procurement is linked; or if they are part of more than one bid in the procurement; or if the bidding firm or their personnel have relationships or financial or business transactions with any official of purchaser who are directly or indirectly related to tender or execution process of contract; or improper use of information obtained by the (prospective) bidder from the purchaser with an intent to gain unfair advantage in the procurement process or for personal gain; and

vi) "Obstructive practice": materially impede the purchaser's investigation into allegations of one or more of the above mentioned prohibited practices either by deliberately destroying, falsifying, altering; or by concealing of evidence material to the investigation; or by making false statements to investigators and/or by threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or by impeding the purchaser's Entity's rights of audit or access to information;

c. Obligations for Proactive disclosures

i) The Purchaser as well as bidders, suppliers, contractors and consultants, are obliged under Code of Integrity for Public Procurement to sue-moto proactively declare any conflicts of interest (coming under the definition mentioned above – pre-existing or as and as soon as these arise at any stage) in any procurement process or execution of contract. Failure to do so would amount to violation of this code of integrity; and

ii) The bidder must declare, whether asked or not in a bid document, any previous transgressions of such a code of integrity with any entity in any country during the last three years or of being debarred by any other Procuring Entity. Failure to do so would amount to violation of this code of integrity;

iii) To encourage voluntary disclosures, such declarations would not mean automatic disqualification for the bidder making such declarations. The declared conflict of interest would be evaluated and mitigation steps, if possible, taken by the purchaser.

d. Punitive Provisions

Without prejudice to and in addition to the rights of the Purchaser to other penal provisions as per the bid documents or contract, if the Purchaser comes to a conclusion that a (prospective) bidder/supplier, directly or through an agent, has violated this code of integrity in competing for the contract or in executing a contract, the purchaser may take appropriate measures including one or more of the following:

i) If his bids are under consideration in any procurement:

a) Forfeiture or encashment of bid security;

b) Calling off of any pre-contract negotiations; and

c) Rejection and exclusion of the bidder from the procurement process.

ii) If a contract has already been awarded

a) Cancellation of the relevant contract and recovery of compensation for loss incurred by the purchaser;

b) Forfeiture or encashment of any other security or bond relating to the procurement;

c) Recovery of payments including advance payments, if any, made by the purchaser along with interest thereon at the prevailing rate.

iii) Provisions in addition to above:

a) Removal from the list of registered suppliers and banning/debarment of the bidder from participation in future procurements of the purchaser for a period not less than one year;

b) In case of anti-competitive practices, information for further processing may be filed under a signature of the Joint Secretary level officer, with the Competition Commission of India;

c) Initiation of suitable disciplinary or criminal proceedings against any individual or staff found responsible.

iv. The Bidding Documents

(S.K.Panigrahi)
Administrative Officer

Annexure - I

TECHNICAL BID

M/s. _____

_____

_____

(Name, address Landline and Mobile Nos.
of the bidding firm/agency firm/ agency):-

SI. No.	Documents kept in the Technical Bid envelope	Whether enclosed (The firm would write Yes OR No in the respective columns)
1.	EMD	
2.	Copy of Registration/License and other documents as proof.	
3.	Self certificate in respect of not being blacklisted by any Govt. /Semi. Govt. Office	
4.	Details & copy of GST registration of firm	
5.	Copy of PAN of firm	
6.	Copy of rate contract for providing the similar services in for last ten years	
7.	Documentary proof that the CRO should have ten years working experience in the field.	
8.	Documentary proof that the CRO have an Ayurveda/AYUSH expert as a member of core team for better understanding of the implementation of clinical trials.	
9.	Documentary proof that the perspective bidders have capability to cater service throughout the Country across states and UTs with adequate Human Resources and Infrastructure.	
10.	Acceptance of the condition that Confidentiality of the study data will be maintained with utmost care.	
11.	Acceptance to sign Memorandum of Understanding (MoU) to be executed between CCRAS and CRO.	
12	Along with all the necessary documents/certificates required as per the tender conditions, the bidder should furnish a brief write-up, backed with adequate data, explaining his available capacity (both technical and financial), for manufacture and supply of the required goods/equipment, within the specified time of completion, after meeting all their current commitments	

13	Supporting documents submitted by the bidder must be certified as follows: i) All copy of supply/work order; respective completion certificate and contact details of clients; documents issued by the relevant Industries Department/National Small Industries Corporation (NSIC)/ manufacturing licence; annual report, etc., in support of experience, past performance and capacity/capability should be authenticated by the by the person authorised to sign the tender on behalf of the bidder. Original Documents must be submitted for inspection, if so demanded. ii) All financial standing data should be certified by certified accountants, for example, Chartered Accountants/Cost Accountants or equivalent in relevant countries; and Indian bidder or Indian counterparts of foreign bidders should furnish their Permanent Account Number. f	
14.	Proof for Others terms of reference as in Annex-I (if any)	

It is hereby declared that the Terms & Conditions of the CCRAS F.No. 3-5/2020CCRAS/Admin/CRO/VOL-I/dated..... are fully acceptable to our firm/agency.

(To be signed by the Authorized Signatory)
of the Firm/Agency with Name and Stamp)

Annexure-II

Financial bid:

Sl. No.	Study	Estimated sample size and centres (may very)	Price quoted (Excluding GST)
II.	**Details of Ministry of AYUSH/CCRAS studies**		
1.	A Randomized, Open Label, Parallel Efficacy, Active Control, Multi Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation AYUSH-64 as Adjunct Treatment to Standard	**Sample size: 150 at 3 centres**	
2.	Evaluation of Efficacy and Safety of Ayurveda Intervention (AYUSH-64) add-on therapy of patients with COVID-19 infection (stage-l)-A Randomized Controlled clinical Trial	**Sample size: 180 (30 in each arm) (60 at each centre) at 3 centres in Nagpur**	
3.	A Randomized, Open Label, Parallel Efficacy, Active Control, Exploratory Clinical Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation (AYUSH-64) as Adjunct Treatment to Standard of Care for the management of Mild to moderate COVID-19 Patients	**Sample size: 80 (40 in each arm) at Patiala at 3 centres**	
4.	A Pilot Study ot assess the efficacy of AYUSH-64 in COVID Cases	**Sample size: 40 at CBPACS New Delhi**	
5.	Evaluation of Efficacy and Safety of Ayurveda Intervention (AYUSH-64) in the management of COVID-19 infection (Asymptomatic & Mild to moderate symptoms) – An open label single arm prospective clinical trial.	**Sample size: 40 at A and U Tibbia College and Hospital**	
6.	Evaluation of the efficacy of an Ayurvedic intervention (Chyawanprash) in the prevention of COVID-19 among Health Care Personnel – An open label single are prospective study	**Sample size: 50 at A and U Tibbia College and Hospital**	
7.	Evaluation of the efficacy of an Ayurvedic Rasayan (Chyawanprash) in the preventing of COVID-19 among Health Care Personnel – An open label, prospective Randomized Controlled parallel group study	**Sample size: 200 (100 in each arm) at CBPACS, Khera Dabar, New delhi**	
8.	Data analysis and drafting of Research paper for app based studies 'impact assessment of effectiveness, acceptance and usage of AYUSH advisories & measures in prevention of COVID-19: A digital technology enabled study, by AYUSH Sanjivani app	**Target population: 50 Lakhs**	
9.	Impact of Ayurvedic Interventions in prevention of COVID-19 infection in identified containment area of Mandi	**Sample Size: 1500, study site one at Mandi**	

Signature & Seal of the Bidder/Agency/firm

To,

Director General,
Central Council for Research in Ayurvedic Sciences,
Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan
No. 61-65, Institutional Area,
Opp. 'D' Block, Janakpuri,
NEW DELHI – 110058

Respected Sir,

I/We ..... who are established and certified research institute/organization involved in various clinical studies to be under taken/ R&D work hereby offer our quotation against the tender ref. No. ..... and accept the terms & conditions of the tender and enclose a copy of the tender document duly signed by the authorised signatory.

Yours faithfully,

(Name) for and on behalf of M/s.....
(Name of Manufactures)

Note: This letter of authority should be on the letterhead of the concern and should be signed by an authorized signatory.

Annex-I

Terms of reference for engagement of Contract Research Organization (CRO) for conduct of various clinical studies undertaken by Ministry of AYUSH (AYUSH- CSIR studies/Ministry's Research Studies) by CCRAS.

(3)

Councils and The Central Council for Research in Ayurvedic Sciences
Ministry of AYUSH
Govt of India

Background

The Ministry of AYUSH has taken initiatives to address the COVID 19 pandemic problem in the country through clinical studies (prophylactic and add-on interventions) of AYUSH systems and also studying the impact of AYUSH based prophylactic interventions in high risk population and also studying impact of AYUSH advocacies and AYUSH measures for prevention of COVID 19 among population. Ministry of AYUSH has setup an *Interdisciplinary AYUSH Research and Development Task Force* with a group of experts to formulate and develop strategies for this initiative.

Various initiatives are taken to address the COVID 19 pandemic problem viz. **(i) Clinical research studies on Ayurveda interventions as prophylaxis and as an add-on to standard care to COVID 19:** Collaborative clinical studies as a joint initiative of Ministry of AYUSH and CSIR. The *Interdisciplinary AYUSH Research and Development Task Force* has formulated and designed clinical research protocols for prophylactic studies and add-on interventions in COVID-19 positive cases through thorough review and consultative process of experts of high repute from different organisations across the country for studying four different interventions viz. *Ashwagandha, Yashtimadhu, Guduchi + Pippali* and a poly herbal formulation (AYUSH-64). Also certain studies on AYUSH intervention as standalone and as add on therapy are undertaken by Ministry of AYUSH through Research Councils **(ii) Population based interventional studies on impact of AYUSH based prophylactic interventions:** The ministry of AYUSH is initiating population based studies to study the impact of Ayurvedic Interventions in prevention of COVID-19 infection in high risk population. The core objectives comprise of, assessment of preventive potential of AYUSH interventions for COVID 19 and also to assess the improvement in Quality of Life in high risk population. The study will be carried out through four research Councils under Ministry of AYUSH and National Institutes in 25 states across the country covering approximately 5 lakhs population and Application based survey to assess the 'Impact assessment of effectiveness, acceptance and usage of AYUSH advisories & measures in prevention of COVID 19: A digital technology'.

These Research activities will be implemented and monitored by Ministry of AYUSH through Central Council for Research in Ayurvedic Sciences (CCRAS) as a nodal organization. CCRAS is an autonomous body of the Ministry of AYUSH, Government of India. It is an apex body in India for the formulation, coordination, development and promotion of research on scientific lines in Ayurveda and Sowa-Rigpa system of medicine.

Further for smooth execution of Research activities related to COVID 19 under Ministry of AYUSH, it has decided to engage a Contract Research Organization (CRO) by

CCRAS and which will be monitored by the Council. The essential and technical requirements desired from the CRO and details of the studies and initiative to address COVID 19 to be managed by the CRO has been provided in the document.

Details for CRO are as under:

A. Essential requirements for CRO are:

- The CRO should have ten years working experience
- The CRO should have an Ayurveda/AYUSH expert as a member of core team for better understanding of the implementation of clinical trials.
- They should have capability to cater service throughout the Country across states and UTs with adequate Human Resources and Infrastructure.
- Confidentiality of the study data should be maintained with utmost care
- Memorandum of Understanding (MoU) to be executed between CCRAS and CRO

B. Technical requirements for CRO (List of activities proposed to be carried out by CRO for clinical trials on AYUSH Products)

- Training on Protocol and GCP of the study staff including investigators and Research Fellows (CRC) (Site selection, Investigator selection and Research team selection to be done by department and paid by the department)
- E-CRF Preparation (Paper CRF or Excel CRF to be prepared by the department)
- Data Management Plan
- Data Validation Plan
- Database Specifications
- Database Designing
- Edit Check Programming
- UAT of Screens and Edit Checks
- Data Entry Guidelines
- Training of SEDC tool (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)
- User Manual
- User Management
- Database Live
- Data Entry (Site will perform the real time data entry)
- Query Management (In discussion with the site and the department)
- Source Data Verification (Remote SDV will be done and as required site visit to monitor the study will be done)
- Database Lock / Freeze (After confirmation from the sites and department)
- Data Extraction (As per study requirement)
- Reports and Access on Dash Board

- Final Data Extraction (After Database is locked)
- Data in CD/Pen drive (After Database is locked)
- Patient Data Report (in PDF) (After Database is locked)
- Technical Issues/ Maintenance/ Up gradation (As and when required)
- Site Monitoring to check with compliance with protocol (As per the study requirement (Remote monitoring/Risk based monitoring will be done)
- Statistical Analysis
- CSR Preparation
- Publication (Manuscript preparation, submission and resolution of query)
- Any other as assigned with prior discussion with CRO

C. Tentative Proposed list of activities

I. Details of AYUSH-CSIR studies

S. N.	Study title	Estimated sample size and centres (may vary)
1.	Ashwagandha for the Prophylaxes Against SARS-COV-2 in subjects with increased risk during the COVID 19 Pandemic: A comparison with Hydroxychloroquine in the health care providers	**Sample size:** 400 in 8 centres
2	A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation Guduchi + Pippali as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients	**Sample size**: 150 at 3 centres
3.	A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation Yashtimadhu as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients	**Sample size**: 150 at 3 centres

II. Details of Ministry of AYUSH/CCRAS studies

S. N.	Study title	Estimated sample size and centres (may vary)
1	A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation AYUSH-64 as Adjunct Treatment to Standard	**Sample size**: 150 at 3 centres
2.	Evaluation of Efficacy and Safety of Ayurveda Intervention (Ayush-64) add-on therapy for patients with COVID-19 infection (Stage I)-A Randomized controlled clinical trial	**Sample size**: 180 (30 in each arm) (60 at each centre) at three centres in Nagpur
3.	A Randomized, Open Label, Parallel Efficacy, Active Control, Exploratory Clinical Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation (AYUSH 64) as Adjunct Treatment to Standard	**Sample size**: 80 (40 in each arm) at Patiala

	of Care for the management of Mild to Moderate COVID-19 Patients	
4.	A Pilot Study to assess the efficacy of Ayush - 64 in COVID - 19 Cases	**Sample size**: 40 at CBPACS New Delhi
5.	Evaluation of Efficacy and Safety of Ayurveda Intervention (Ayush - 64) in the management of COVID-19 infection (Asymptomatic &Mild to Moderate symptoms)- An open label single arm prospective clinical trial.	**Sample size**: 40 at A and U Tibbia College and Hospital
6.	Evaluation of the efficacy of an Ayurvedic intervention (Chyawanprash) in the prevention of COVID-19 among Health Care Personnel – An open label single arm prospective study	**Sample size**: 50 at A and U Tibbia College and Hospital
7.	Evaluation of the efficacy of an Ayurvedic Rasayan (Chyawanprash) in the prevention of COVID-19 among Health Care Personnel – An open label, prospective Randomized controlled parallel group study	**Sample size**: 200 (100 in each arm) at CBPACS Khera Dabar New Delhi
8.	Data analysis and drafting of Research paper for app based studies 'Impact assessment of effectiveness, acceptance and usage of AYUSH advisories & measures in prevention of COVID 19: A digital technology enabled study' by AYUSH Sanjivani app.	**Target population: 50 lakhs**
9	Impact of Ayurvedic Interventions in prevention of COVID-19 infection in identified containment area of Mandi	**Sample size**: 1500, study site one at Mandi

III. Population based studies by Research Councils and National Institutes

S. N.	Study title	Details
1	A prospective non-randomized open label controlled interventional study on the effect of AYUSH as a prophylactic measure among high risk population (Health Care Workers/Containment Zone population) exposed to COVID 19	Around 5 lakhs population across 60-70 districts in 35 states