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Government of India

Ministry of Health & Family Welfare

Directorate GeneralofHealthServices

Central Drugs Standard Control Organisation

FDA Bhawan, Kotla Road, New Delhi-110002

Public Notice

04 MAR 2025

Sub: Launching of registration of Clinical Research Organisation (CRO) applications through SUGAM portal- Reg.

The Ministry of Health and Family Welfare has published G.S.R. 581(E) dated 19th September 2024, wherein registration of Clinical Research Organisation (CRO) has been made mandatory with effective from 1st day of April, 2025.

In this regard, the online registration of Clinical Research Organisation (CRO) is now functional on SUGAM portal (www.cdscoonline.gov.in). Applications for registration shall be submitted through SUGAM portal only along with the prescribed checklist of documents for the registration.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Enclosure: User Manual

Copy to

1.All the Stakeholders Through CDSCO Website
2.CDAC Team

User Manual

for

SUGAM-Ane- Governance solution

Online Forms Submission
CRO(ClinicalResearchOrganisation)

by

Central Drugs Standard Control Organisation (CDSCO)

Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India

Centre for Development of Advanced Computing
(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)

Anusandhan Bhawan,C-56/1,InstitutionalAreaBlock-B,Sector-62,Noida-201309
Phone:91-120-2210800Website:www.cdac.in

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Application for Registration of Clinical Research Organisation

Application for the Form CT07B is now available on SUGAM Portal. Applicants may follow below steps to register themselves as CRO.

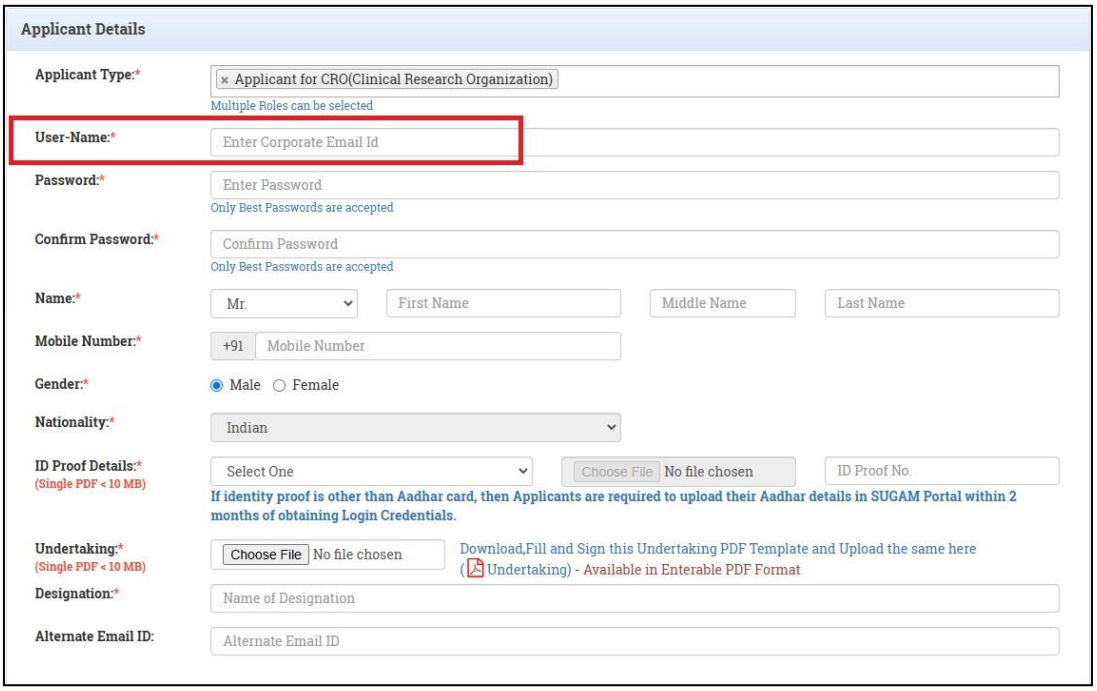
Registration process for new users

New users can visit the SUGAM Portal and click on Login/Sign-Up. Navigate to sign-up here and select the registration purpose as “Clinical Research Organisation”.
Applicants may the fill the registration form as per below screenshot. Please note that the email address mentioned in the username will be used in future for further communication and for the verification of email address upon successful form submission.

Once the email address is verified, competent authority at CDSCO will further review the account request and grant approval accordingly. Once the account is approved by CDSCO, applicants may login into the SUGAM portal.

It is important to complete user profile to enable form submission. Below listed details are required to complete the user profile.

- Add Member Details
- Add Contact Person Details



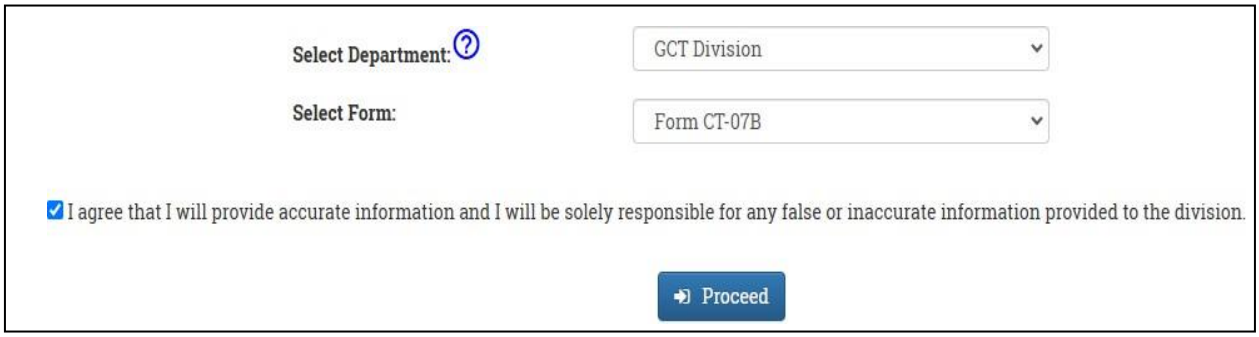
Registration process for existing users

Existing users on SUGAM Portal may submit are quest for additional role from user profile. Applicants may select role as “Clinical Research Organisation”.

It is important to complete user profile to enable form submission.

FORMCT-07B

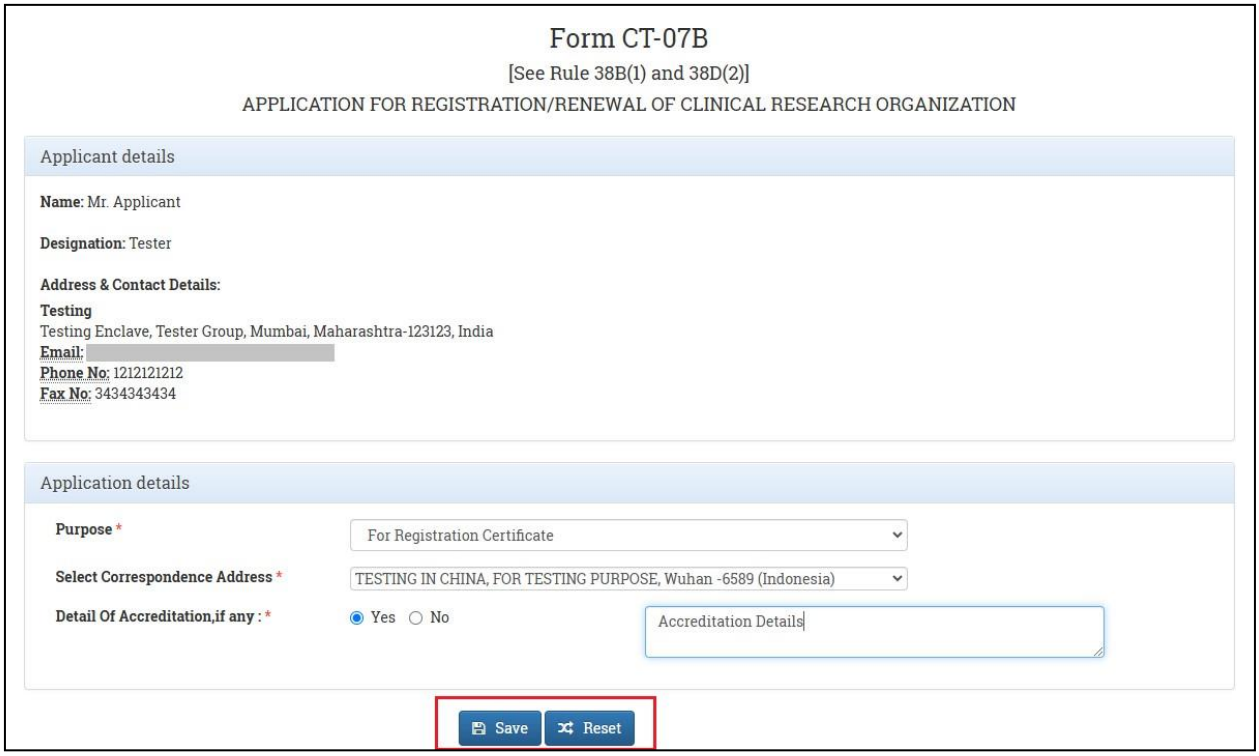
Applicants may login into the SUGAM Portal and click on submit application page. Select “GCT Division” as department and “Form CT07B” as the form. Click on the checkbox for the undertaking and click on “Proceed” button to proceed further.



After clicking on “Proceed” button form for CRO registration or renewal will open. Below mentioned details are to be submitted:

- **Purpose of Application**
  Application in Form CT-07B can be filled either with the registration purpose or renewal purpose.
- **Correspondence Address**
  Kindly select correspondence address from the drop down menu. In case the address details are not available then the same can be added from “Add Address Details” page from “User Profile” available in top left menu.

- **Details of Accreditation**
  Select option as “Yes” incase details of accreditation are available. Upon selecting “Yes” additional field will be visible where details of accreditation can be added.
  In case details of accreditation are not available, kindly select “No”.



Click on the “Save” button to view the preview of the application form. Kindly ensure that the details mentioned in the preview page are in line with the details entered on the application page.

Click on “Proceed to Checklist” button in order to view the checklist. Submit necessary documents on all checklist items and proceed further with the payment for the application.

Upload Essential Documents Form CT-07B

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/altered under the Saved Application link available on the Dashboard
4. Click here to view **Guidelines for PDF documents**

- ☐ **1.** Details of the authorised person and authorisation letter of the person in-charge as per Ninth Schedule of New Drugs and Clinical Trials Rules, 2019.
- ☐ **2.** Details of the constitution of the CRO (Ltd/Pvt Ltd/proprietorship etc.) along with Name & Address of the Director, Memorandum of association, Article of Association, List of Directors to be provided.
- ☐ **5.** Details of facilities, resources, personnel, training etc
- ☐ **5.1** Details of CRO facilities, resources and staff for handling any oversight of clinical trials and bioavailability or bioequivalence studies
- ☐ **5.2** Educational qualification, training records of CRO staff
- ☐ **6.** CRO Site Master File
- ☐ **6.1** Organogram of the organisation including brief Curriculum Vitae of key personnel
- ☐ **6.2** SOP for implementing of quality assurance and quality control as per standard operating procedures designed for the purpose and such standard operating procedures shall be well documented
- ☐ **6.3** SOP for maintaining complete data, documentations and other related records accurately including checking and ensuring that the essential documents required for the conduct of the trial are maintained properly by the investigators
- ☐ **6.4** SOP for ensuring the investigators receive all documents and trial or study related supplies needed to conduct the clinical trial or bioavailability or bioequivalence study properly
- ☐ **6.5** SOP for transferring and assuming study related duties by CRO
- ☐ **6.6** SOP for maintenance of records (written documents, electronic, magnetic or optical records, scans, etc), such as protocols, approvals from the Central Licencing Authority and Ethics committee, investigators particulars, blank consent forms, monitor reports, audit certificates, relevant correspondence, reference pages, completed and the final reports
- ☐ **6.8** Details of accreditation or approval of other regulatory agencies, if any, (self-attested copy of certificate)
- ☐ **6.9** A brief profile of the specific activities or services undertaken by the organisation including facilities, resources and infrastructure
- ☐ **7.** Copy of agreement with third party service providers for site management, translation, biostatistics, data management, and laboratory services etc
- ☐ **8.** Undertakings to be submitted for the following
- ☐ **8.1** Undertaking for all documentation and communication shall be dated, filed and preserved safely for a period of five years after completion of such study or for at least two years after the expiration date of the batch of the new drug or investigational new drug studied, whichever is later
- ☐ **8.2** Undertaking for strict confidentiality shall be maintained during access and retrieval procedures
- ☐ **8.3** Undertaking for constitution or ownership of the Clinical Research Organisation, the organisation shall intimate about the change in writing to the Central Licencing Authority within thirty days of such change
- ☐ **8.4** Undertaking to comply with the conditions imposed on the registration certificate along with the adherence to other guidelines like Good Clinical Practices guidelines and provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940), and the New Drugs and Clinical Trials Rules, 2019
- ☐ **8.5** Undertaking to comply with such further requirements, if any, as may be specified by the Government of India, under the Act and the rules made thereunder
- ☐ **8.6** Undertaking to allow the Central Licencing Authority or any person authorised by him in that behalf to enter and inspect the premises and to examine the process or procedure and documents in respect of any clinical trial conducted by us
- ☐ **9.** Detail Of Accreditation, if any

On the payment page select “Online” as the mode of payment and the purpose.

- Fees for registration application is Rs.500000

Kindly ensure that the payment purpose is selected either as “CRO Registration” or “CRO Renewal” on payment page before generating deposit slip for *bharat kosh*.

Select desired challan from the drop down menu “Payment Reference Number” and click on “Submit”

buttontoproceed further.

Final preview of the application will be displayed, kindly ensure that all details are correct, and payment related details are also captured correctly on preview page. Download system generated legal form by clicking on “Download PDF” button. System generated form needs to be duly signed by the applicant.

Click on “Next” button to proceed further with form submission.

Kindly upload duly signed copy of legal form on the final submission page and click on “Submit To CDSCO” button. Please note application number for future reference. Acknowledgement email for file submission will be sent on registered email address.

Application will be visible under “Submitted Applications” on applicant dashboard. Applicant may utilize *e-vartalap* functionality to communicate with concerned division during the course of file processing.

In case of any query applicant may raise ticket for IT-Helpdesk using “Raise Ticket for Help-Desk” option intopleft menu.