

1. What is Clinical Research Organisation?

The Clinical Research Organisation means the Sponsor or a body, commercial or academic or of other category, owned by an individual or an organisation having status of legal entity by whatsoever name called, to which the sponsor may, delegate or transfer in writing, some or all of the tasks, duties or obligations regarding clinical trial or bioavailability or bioequivalence study.

2. Are Clinical Research Organisation regulated in India?

As per GSR 581(E) dated 19/09/2024, no Clinical Research Organisation shall conduct any clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug in human subjects without registration granted by the Central Licencing Authority under these rules.

3. Is there any registration required for Clinical Research Organisation?

Yes, application for registration of grant/ renewal of Clinical Research Organisation shall make in Form CT-07B to the Central Licensing Authority for conducting clinical trial or bioavailability or bioequivalence study along with the documents as per ninth schedule and Central Licensing Authority grant permission in Form CT-07C.

4. Where to apply for registration of Clinical Research Organisation?

The Clinical Research Organisation shall make an application in Form CT-07B to the Central Licencing Authority via online mode in **Sugam Portal** of CDSCO website(www.cdscoonline.gov.in) for the purpose of registration for conducting clinical trial or bioavailability or bioequivalence study.

5. When can the renewal of Clinical Research Organisation (CRO) registration be applied to CDSCO?

An application for renewal of registration shall be made in Form CT-07B to the Central Licencing Authority along with documents as specified in the Ninth Schedule prior to date of expiry of its registration.

6. What is the validity of Clinical Research Organisation registration?

The registration granted under Rule 38C of NDCT Rules, 2019 in Form CT-07C, shall remain valid for a period of five years.

7. Shall previous registration be valid till renew the registration in form CT-07C?

As per Rule 38D of NDCT Rules 2019, if the application for renewal of registration is received by the Central Licensing Authority prior to the date of expiry, the registration shall continue to be in force until the orders are passed by the Central Licensing Authority on the application.

8. What is the fee structure for grant of registration/renewal of registration for CRO?

As per Sixth Schedule of the NDCT Rules, 2019, a fee of Rs. 500000 shall be paid for grant/renewal of application for registration of Clinical Research Organisation.

9. What is the fee structure for reconsideration for registration for CRO?

In case of rejection of application, the applicant may request the Central Licencing Authority to reconsider the application within a period of sixty days from the date of rejection of the application on payment of fees of Rs. 1,00,000/-.

10. Will there be inspection of the facilities of CRO prior to issuing a registration certificate?

The inspection of CRO prior to issuance of registration certificate will be decided by CLA on case to case basis. The inspection in CRO covered under Rule 38E of NDCT Rules 2019, and CRO shall allow any officer authorised by the Central Licencing Authority, who may be accompanied by an officer authorised by the State Licencing Authority, to enter the premises of the Clinical Research Organisation with or without prior consent, to inspect, search or seize, any record, document, investigational product and other related material and reply to queries raised by the inspecting authority in relation to functioning of the Organisation.

11. Do we need to apply if we are changing our CRO name in the near future?

As per Ninth Schedule of NDCT Rules 2019, if there is any change in 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 email at cru.division@cdsco.nic.in, dcu@nic.in and cro@cdsco.nic.in .

12. Should the copy of agreement with third party service providers for site management, translation, biostatistics, data management, laboratory services to be submitted?

As per Ninth Schedule of NDCT Rules 2019, the particulars and documents shall be submitted for the registration of CRO such as copy of agreement with third party service providers for site management, translation, biostatistics, data management, laboratory services etc.

13. What is the maximum size of the document to upload for registration of CRO?

There is provision for uploading files in Sugam portal up to 50MB. In addition to that the submission of the documents in e-vartalap, can be made, if required.

14. Who are considered as key personnel as per checklist item no.6.1?

As per Ninth Schedule of NDCT Rules, 2019, the authorised person and the competent persons who are thoroughly familiar with the investigational products, the protocol, written informed consent forms or other information provided to the subjects, the standard operating procedures by the sponsors, good clinical practices guidelines and other rules applicable to the conduct of clinical trial and or bioavailability or bioequivalence study shall be considered as key personnel.

15. What are the salient highlights of specific areas to be scrutinised?

CRO has to submit the list of SOPs highlighting the specific areas with respect to activities required to be performed related to specific clinical trial or Bioavailability and Bioequivalence study and same to be securitized by CLA prior to issuance of registration certificate.

16. In Sec 8 (8.1 to 8.6), of SUGAM checklist several undertakings are required. Could you share template and can these be consolidated as single undertaking?

The undertakings are to be submitted separately on the letter head of the CRO for the specific undertakings asked in section 8.

17. Do individual/company involve with medical writing or statistical programming need CRO registration, as they are not directly conducting clinical trials?

As per GSR 581 (E) dated 19th Sept 2024, definition, individual or an organisation which the sponsor may, delegate or transfer in writing, some

or all of the tasks, duties or obligations regarding clinical trial or bioavailability or bioequivalence study need CRO registration. If such individual or company is legal entity and involved with medical writing or statistical programming, required to be registered as a CRO.

18. Do companies conducting Clinical trials need CRO registration if they are already registered as BA/BE centre?

Yes, as per NDCT Rules, 2019, any bioavailability or bioequivalence study centre already registered under rule 44 of NDCTR 2019 for the purposes of bioavailability or bioequivalence study and in case they are willing to conduct Clinical Trials, the company has to be registered as CRO.

19. Whether the CLA has the authority to audit/inspect the third-party service providers?

Yes, the CLA has the authority to audit/inspect the third-party service providers.

20. Whether the Form CT-07B to be signed digitally?

Yes, the Form CT-07B to be signed digitally by the competent person

21. Whether separate registration is required for a company having multiple offices/sites in India?

If any company having multiple offices/sites in India under the same legal entity, in such case, each site required to be registered as CRO individually.

22. How the post approval changes done in registration of CRO will be intimated to CLA?

The post approval changes done after registration of CRO will be intimated to CLA via email at cru.division@cdsco.nic.in, dcu@nic.in and cro@cdsco.nic.in till the development of submission of PAC applications through Sugam Portal.

23. Whether freelancers/individuals carry out work related clinical trials such as protocol writing should be registered as CRO?

If freelancers/individuals are legal entity and such work is assigned/delegated by Sponsor directly, then they required to be registered as CRO.

24. Whether Service providers who are not involved in regulatory trials, eg. Phase IV non-regulatory trials do need to get registration of CRO done?

Any entity or organisation conducting clinical trial of a new drug or investigational new drugs where sponsor may delegate/transfer some or all the tasks in writing falls under the purview of registration of CRO

25. In case of clinical trial conducted by the organisation outside India and its subsidiary is processing clinical trial data in India, whether the domestic organisation require CRO registration?

If the subsidiary firm is legal entity and registered as company in India under Company Act 2013 and processing clinical trial data of Indian trial participants, in such case, it should be registered as CRO.

ILLUSTRATION 1:

X, a sponsor, delegates or transfers some or all of the tasks, duties or obligations regarding clinical trial or bioavailability or bioequivalence study to Y, an others . In this case, Y has to be registered as CRO.

X (Sponsor) → Y (Others/Individuals/Company, having legal existence) → Y Registers as CRO

ILLUSTRATION 2:

X, a sponsor, delegates or transfers some or all of the tasks, duties or obligations regarding clinical trial or bioavailability or bioequivalence study to Y, a CRO and simultaneously delegates the task to some other body Z (Third party). In this case, Z has also to be registered as CRO.

