



Application and Approval Pathways:

- The SUGAM portal is a user-friendly online platform launched by CDSCO to make regulatory processes easier
- It helps people apply online for licenses, registrations, permissions and approvals related to drugs, cosmetics, medical devices and clinical trials
- Users can submit applications, track their status, respond to queries and download approvals all in one place, saving time and reducing paperwork
- The SUGAM portal operates exclusively in English, which serves as the official language for all regulatory communications, form submissions and documentation

Clinical Trial Application:

This is an application submitted to get an approval for conducting clinical trials in India

- **Application:** Submit an application using Form CT-04 via the SUGAM Portal
- **Deemed approval:** Response (approval/ deficiencies / rejection) from Central Licensing Authority can be expected within 90 working days
- **Validity:** The permission to conduct a trial is valid for two years
- **Required data:** The application must include comprehensive data, such as chemical and pharmaceutical information, animal study data and clinical safety and efficacy data

Application and Approval Pathways:

New Drug Application: This is an application submitted to get an approval for marketing a new drug in India after successful trials

- **Application:** Submit an application using Form CT-21 for manufacturing and Form CT-18 for importing via the SUGAM Portal
- **Deemed approval:** Permission to manufacture or import the new drug is expected within 90 working days
- **Validity:** The validity of approval is 3 years from the date of issue
- **Required data:** The application must include chemical and pharmaceutical information, pre-clinical and clinical data

Inspection:

Clinical trial inspection programme of CDSCO covers all clinical trial sites and sponsor / CRO's facilities involved in clinical trial of drugs including biological and medical devices covered under Drugs & Cosmetics Act.

The aims of the programme are:

- A. To verify GCP compliance to protect the rights, safety and well being of the subjects involved in clinical trial
- B. To verify the credibility and integrity of clinical trial data generated
- C. To verify the compliance with various regulatory provisions as per New Drugs and Clinical Trial Rules, 2019

What do they check?

Protocol compliance, subject records, informed consent, source documents, proper documentation and compliance with the guidelines For more information on guidance on clinical trial inspection click here : [Global Clinical Trial](#)