

Clinical Trial Regulations in India

Online Clinical Trial Application & Monitoring System



Module 5 Topic 3_3

Online Submission of Applications of Clinical Trial

Clinical Trials

(Online Clinical Trials Application & Monitoring System)
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

In order to improve transparency, accountability and efficiency in processing of clinical trial applications and it's monitoring, CDSCO with the approval of Ministry of Health and Family Welfare, Government of India has taken initiative to create an IT enabled system for online submission and processing of application as well as monitoring of clinical trials in the country.



Sugam: An e-Governance Solution for CDSCO



Online Submission of Applications of Clinical Trial

Project Description

Central Drugs Standard Control Organization (CDSCO), under Ministry of Health & Family Welfare proposed to create an IT enabled system for online submission of various information on clinical trials to streamline the process of approval, maintaining comprehensive database and monitoring of clinical trials for ensuring the protection of rights, safety and well beings of trial subjects and authenticity of the data generated



Online Submission of Applications of Clinical Trial

Project Objectives

- Common Platform for online registration of Clinical Trials irrespective of any scheme
- Facility to submit online application form for Central Drugs Standard Control Organization (CDSCO), under Ministry of Health & Family Welfare
- Online submission of various information on clinical trials to streamline the process of approval
- Maintaining comprehensive database and monitoring of clinical trials for ensuring the protection of rights, safety and well beings of trial subjects and authenticity of the data generated



Online Submission of Applications of Clinical Trial

Project Objectives (contd)

- Uploading the documents as prescribed in the respective scheme
- On-line report generation of respective applicant
- Work flow based application design as approved by Ministry
- Online processing of the application by the role defined in the application
- Complete transparent back office process to keep track of the application forms the stake holders
- Proposals, Checklist and Inspection application



Online Submission of Applications of Clinical Trial

Application Functionalities

- Following functional requirement for project
 - Registration by following Applicant
 - Sponsor
 - LR (Legal Representative)
 - Medical or Research Institute
 - Individual Researcher



Online Submission of Applications of Clinical Trial

Application Functionalities

- Access of the application by authorized Applicant Users
- Proposal Entry on line, saving as Draft and Saving as Final
- Uploading Documents as enclosure as per the CDSCO Division Requirement
- Taking Report of the final submission to CDSCO for checking/verification



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Application Stakeholders

- Central Drugs Standard Control Organization (CDSCO)
- Director General of Health Services
- Ministry of Health & Family Welfare
- Government of India



Online Submission of Applications of Clinical Trial

Application Covers

- Applicant Registration
- Authorization Letter Generation
- Application Submission
- Necessary Document Upload
- Application Status Check
- Report Generation



Online Submission of Applications of Clinical Trial: Advantages

- Quick and hurdle free application process
- Well defined fields to understand the process of application
- Easy for compliance check as strict to follow the mandatory document submission, if not available application can not progress
- Absolutely transparent process
- Quickly available guidance for submission of application
- Paperless application makes the process faster, helpful for investigators to comply with regulations



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For further details please click here



Or Visit following URL

<http://www.cdsco.nic.in/writereaddata/User-Manual-Online-Clinical-Trial-Application-Monitoring-System.pdf>

