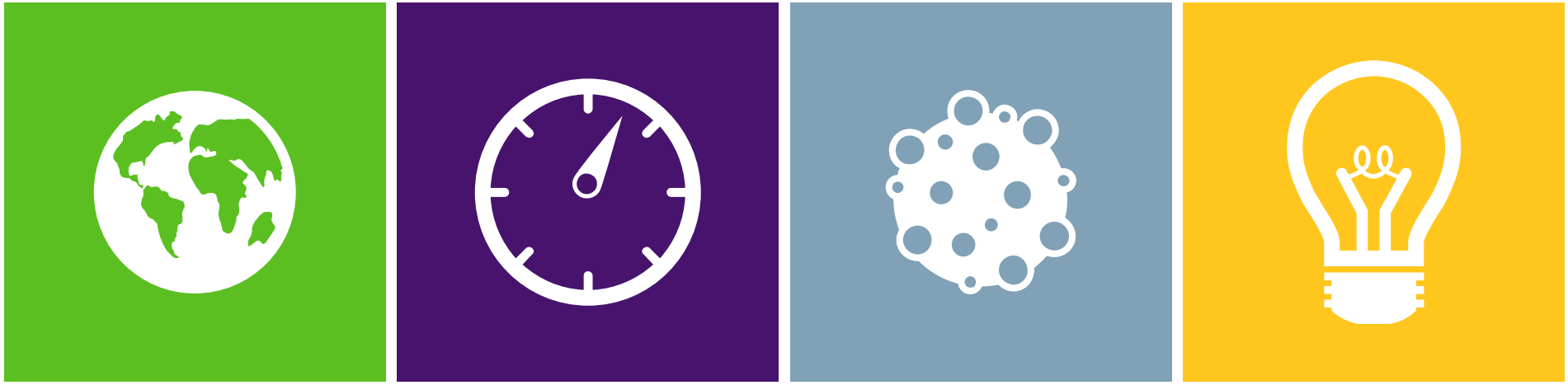


e-Submissions & Public Disclosure: Regulatory Submissions in India

Anitha Gandham
Programming Team Leader, Biostatistics

PPD®

DISCLAIMER

Presentations are intended for educational purpose only and do not replace independent professional judgement. Statements of fact and opinions expressed are those of presenter individually and are not the opinion or position of PPD. PPD does not endorse or approve, and assumes no responsibility for the content, accuracy and completeness of the information presented.


Known to Unknown

CLINICAL TRIAL DATA FLOW

Patient Records at site

CRA

Case Report Form

Data Manager

DM Database

Programming & Tech Ops

TLFs

Medical Writer

Clinical Study Report

Biostatistics & Programming

Analysis Database

Regulatory Affairs

Submission Package

Regulatory Agency

Review & Approval

REGULATORY SUBMISSIONS in INDIA

- Regulatory : is a government agency responsible for exercising autonomous authority over some area of human activity(here pharma/drug) in a supervisory capacity

- Submissions: an act of giving a document, proposal, piece of writing, etc., to someone so that it can be considered or approved

DRUG REGULATORS in INDIA

+ DCGI: Drug Controller General of India

+ CDSCO: Central Drug Standard Control Organization

+ DCA: Drug Control Authority(Each state)

DCGI

+ DCGI lay down the standard and quality of manufacturing, selling, import and distribution of drugs in India.

+ Requires confirmatory\Phase III study that includes a proportion of **local patients**.

+ DCGI suggests that **reviewing and approval timelines** for all types of application be **180 days.** Mandatory registration of **ethics committees** with DCGI

+ Studies approved by DCGI are evaluated and approved by Experts Committee, Technical Committee, Apex committee to **examine applications for Clinical trials in India**

REGULATORY AMENDMENTS in INDIA

- Amendments of **clinical trial regulation** include
  - Improve **patient safety**
  - **Reporting timeliness of SAEs** including deaths during trials
  - Payment of **compensation** to patients.

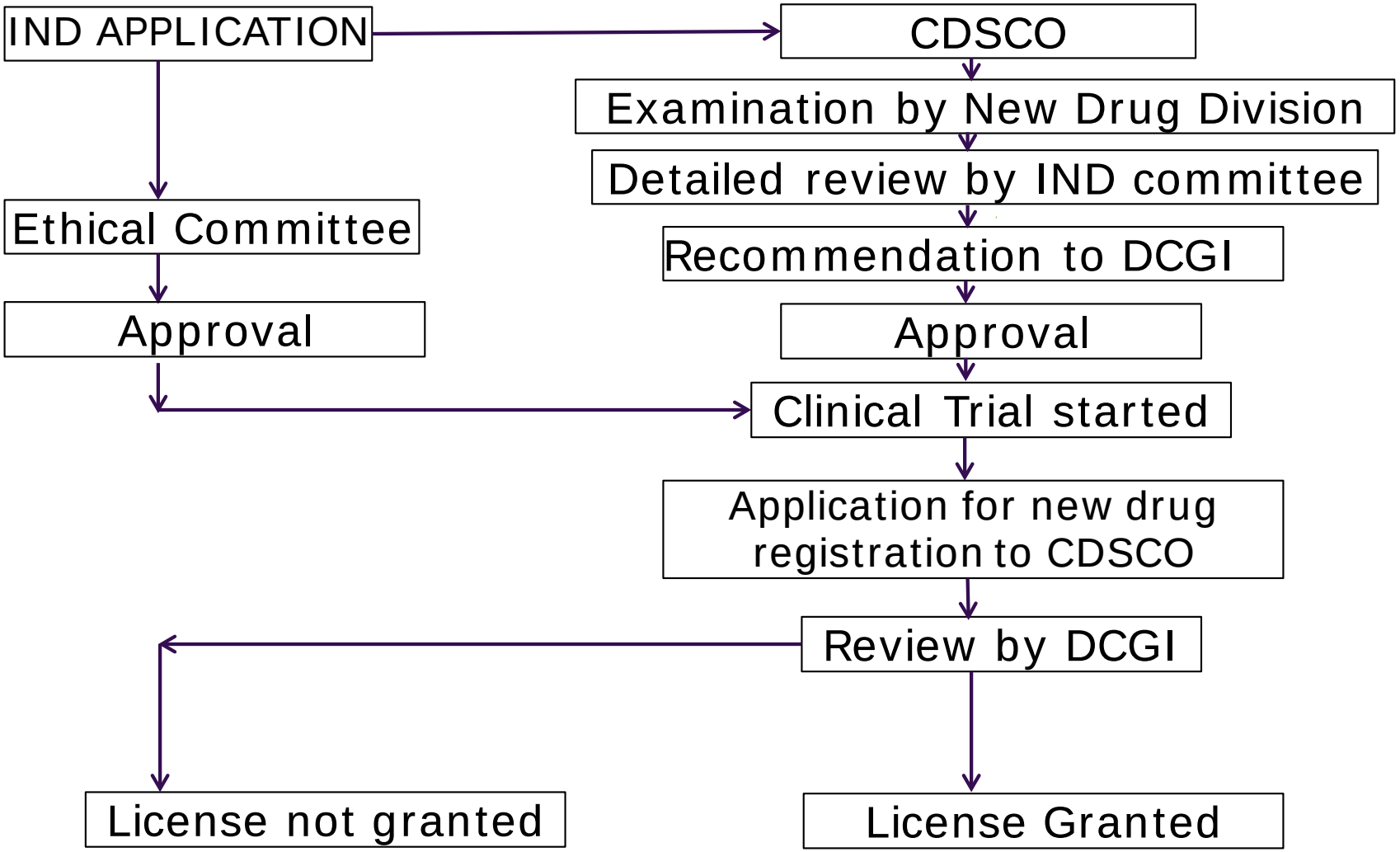
CDSCO

- Major functions of CDSCO:
  - Regulatory control over the import of drugs
  - Approval of new drugs and clinical trials
  - Meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB)
  - Approval of certain licences as Central Licence Approving Authority
  - Handles approval process

DRUG APPROVAL PROCESS

- Stages:
  - Application to conduct clinical trials
  - Conducting Clinical Trials
  - Application to marketing authorization of drug
  - Post-marketing studies

DRUG APPROVAL PROCESS in INDIA



CDSCO/IT/2015 – (48)
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, New Delhi
Dated: 05-10-2016

Notice

You are aware that Central Drugs Standard Control Organization (CDSCO) in pursuance of the implementation of e-Governance has launched various online services through the portal "SUGAM" .The development of software for filing online applications for Global Clinical Trials(GCT) has been completed and its robustness was tested by the industry users in several iterations. The module has already been live and applications can be filed online henceforth. However, those applicants desiring to file applications for obtaining permissions to conduct GCT are requested to register on the portal as per the prescribed procedure, if they have not already registered.

Now, it is decided that the applications for obtaining permissions to conduct GCT have to be mandatorily filed online through SUGAM with effective from 24.10.16. However, the applicants shall continue to submit hardcopies even after 24.10.2016, till such time it is indicated otherwise.

(Dr. G. N. Singh)
Drugs Controller General (India)

To

1. All Pharma Industry Associations/CRO's
2. JDC(I)'s/DDC(I)'s at CDSCO (HQ)

Copy to

1. PPS to DGHS
2. PPS to AS (KBA)
3. PS to JS (KLS)
4. Guard File


Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health &Family Welfare, Government of India
SUGAM - An e-Governance solution for CDSCO
Home
About Us
Downloads
Contact Us
SMS services will not be available at SUGAM portal From 10:00 PM 31st March 2017 till 06:00
LOGIN
Click here to login to the portal
SUGAM
ONLINE LICENSING
Central Drugs Standard Control Organization (CDSCO) is the drug regulatory agency under the Central Government primarily vested to implement the provisions of the Drugs and Cosmetics Act, 1940 which include approval of New Drugs, conduct of their clinical trials, regulation of imported drugs, Pharmacovigilance and coordinating the activities of the States so as to achieve uniformity throughout the country in the administration of the said Act.

SUGAM ONLINE LICENSING

+ The **online submission portal SUGAM** went live in 2015 starting with Product registration and its import license.

+ The DCGI completed pilot, testing for the **online submission of Clinical trial applications in 2016** and made online submission for new clinical trials **mandatory effective 24 Oct 2016.**

+ At present we can submit **only new clinical trial applications** online. Subsequent submissions, amendments post approval submissions still need to be performed as hard copy.

APPLICATION to CONDUCT CLINICAL TRIAL

- Organisation is required to **register** once **on the portal**. The **entity** that submits the application through their login credentials is considered as "**applicant**".

- The DCGI has also brought in the system of **"Sub Login"** whereby sponsor can act as an applicant but the legwork of dossier preparation, submission.. can be performed by **CRO**.

- In simple terms the submission of clinical trial application requires following steps
  - Submit **import license application** if one is importing study drug from outside of India
  - Fill the application form **(Form 44)** and link your import license application to this form.
  - Upload **study documents** as per checklist.

DRUG REGULATION SYSTEM in INDIA

+ When a company in India wish to manufacture/import a new drug, it has to apply to seek permission from DCGI by filing Form-44 along with the data mentioned in **schedule Y of Drugs and Cosmetics Act,1940 and Rules 1945**.

+ In order to prove **safety and efficacy in Indian population**, a clinical trial in accordance with the guidelines specified in Schedule Y is to be conducted and a report is to be submitted in a specified format.

Central Drugs Standard Control Organisation

Director General Of Health Services

Ministry of Health & Family Welfare, Government of India

Step 1 Fill Form | Step 2 Preview | Step 3 Checklist | Step 4 Payment | Step 5 Full Preview | Step 6 Submit Form

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

Form44 (Part 1) | Form44 (Part 2) | Form44 (Part 3)

Purpose of Application

Purpose Of Application *
Select
Field is required.

Category of new drug *
Select
Field is required.

Application applied for *

Type of Drug *
Select
Field is required.

Do you have simultaneously applied for Form 12 ? *
Select
Field is required

Drug Detail

Generic/INN Name(s) of Drug(s) *
Field is required.

User Profile

Permissions Owned

Application Submission

()

Online Payment

Permission Issued By State FDA

Menu ☰ Links....

Central Drugs Standard Control Organisation

Director General Of Health Services
Ministry of Health & Family Welfare, Government of India

Upload Essential Documents For Form 44

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 10 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. Details of animal pharmacology & animal toxicology studies required to be carried out will be as per Appendix IV & Appendix III of schedule Y of drugs and cosmetics Rules respectively. Depending upon the nature of new drugs and disease(s) . Relevant information or justification may be uploaded.
5. In case the particular document or information short in the application is not considers to be applicable or relevant by the applicant. It may be stated so by uploading the justification document for the same.
6. Animal Toxicology Data to be submitted for Phase I, Phase II & Phase III Clinical Trial will be as per guidance given in Appendix III of Schedule Y

REQUIREMENTS and GUIDELINES - SCHEDULE Y

Rule 122A	Permission to import and market New Drug
Rule 122B	Permission to manufacture New Drug
Rule 122 DA	Definition of Clinical Trials/IND
Rule 122E	Definition of New Drugs

+ New substance having therapeutic indication
+ Modified/new claim, new route of administration for already approved drug
+ Fixed dose combination

REGULATED Vs. SEMI-REGULATED

Requirements	US	EU	INDIA
Agency	USFDA	EMEA, CHMP, National health agencies	DCGI
Registration process	One registration process	1. Centralized 2. Decentralized 3. Mutual recognition 4. National	One registration process
Application	NDA/ANDA	MAA	MAA
Approval timelines	~18 months	~12 months	12-18 months
Presentation	eCTD	eCTD	CTD (Paper for legacy studies)

CONCLUSION

+ India has taken a turn towards the **electronic submissions** from 2016 and all the new clinical trails have to be in compliance with the same.

+ **Subsequent submissions**, amendments, post approval submissions (to previous) can be handled as **paper** submissions.

+ Looking forward for the **complete online world**, and stay tuned with the **regulated markets**....

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+ http://nims-icmr.nic.in/NIMS/index.jsp
+ http://ctri.nic.in/Clinicaltrials/login.php?id

QUESTIONS?

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