Review Article

# New Drugs and Clinical Trials Rules, 2019: Towards Fast-track Accessibility of New Drugs to the Indian Population

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## ABSTRACT

**Background:** To fulfil the objective of fast-tracking the accessibility of new drugs and promoting clinical research in India, the Union Ministry of Health and Family Welfare, India has notified the "New Drugs and Clinical trials Rules, 2019" on 25th March 2019. The prime objective of the new rule is to initiate unambiguous, foreseeable and effective regulations for the clinical trials in India. Drugs Controller General of India (DCGI) affirmed that the new rules would apply to all new drugs, investigational new drugs, bioequivalence and bioavailability study (BA/BE) and ethics committees. The new rules would replace part XA and schedule Y of drugs; however, the existing rules (Drugs and Cosmetics Act, 1940; Drug and Cosmetics Rules, 1945) and licenses, orders or directions will remain valid. **Purpose:** This brief review aims at presenting the key highlights of the "New Drugs and Clinical Trials Rules, 2019" of India. **Methods:** Literature review in existing and new clinical trials rules in India was conducted by referring the articles published in the indexed journals and official websites and compared. **Conclusion:** The clinical trials approval timeline has moved down to 30 days for the domestic trials and 90 days for the approval of global clinical trials. This faster approval timelines in the newly amended rules have enabled approval of more number of clinical trials and as a result, India may again turn out to be the preferred centre for conducting the trials.

**Key words:** Clinical trials, New Drugs and Clinical trials Rules 2019, DCGI, India.

**Key Message:** India has notified the "New Drugs and Clinical Trials Rules, 2019". The clinical trials approval timeline has come down to 30 days for the domestic trials and 90 days for the global clinical trials. This step by CDSCO will help in the fast-track accessibility of new drugs to the Indian population.

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## INTRODUCTION

A clinical trial is a systematic study of a new drug or investigational new drug in human subjects to generate data to determine the safety, efficacy or toxicity of a new drug or investigational new drug in a view to discover the new molecule. Changes in lifestyle and environmental ambience have led to the emergence of various health disorders that may have a significant impact on public health. Due to such conditions, the discovery of a new molecule is vital to protect public health. For a new molecule to be commercialized, it has to undergo various rigorous phases of preclinical and clinical studies. In general, it takes about 10-12 years of intense study on the new molecule before the release of the drug into the market.[1] Clinical studies involve the research to estimate the safety and efficacy of the drugs in humans. It is necessary to take their consent before subjecting the group of people (participants) in clinical studies. However, the safety of the participants being a major concern, the sponsors and the investigators must follow ethical principles and must implement Good Clinical Practice.[2] The

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advantage of launching a new drug must not have a detrimental influence on the participants.

## Clinical Trials in India

Indian population is estimated to be 133.92 crores in 2017. Due to the vast population and less cost of clinical trials, the country turns out to be the hub to conduct clinical studies. A clinical trial in India is headed by the drug regulatory authority Central Drug Standard Control Organization (CDSCO). The current regulations in India are the Drugs and Cosmetic Act 1940 and Rules 1945. Schedule Y gives the detailed regulatory requirement to import, manufacture the new drug for sale, or conduct clinical trials. In 2005, amendment in schedule Y was ratified and consequently, India saw a gradual increase in the number of clinical trials. In 2012, the practice of conducting trials without informed consent and not educating patients on the possible risk associated with the trials came into light. Massive crackdown happened and the year 2012 turned out to be apprehensive to all unethical practice that was hidden behind the shot up of clinical trials. As per the data furnished by the Indian Health Ministry, 668 clinical trial participants died all over India in 2010. However, the families of the deceased and injured participants were not be paid a reasonable compensation and that was considered being the worst scenario by the Health Ministry of India.[3] Then the government tightened the clinical trial regulations in the form of Amendment vide Gazette notification G.S.R.53(E) dated 30-01-2013.[4]

Consequently, many pharmaceutical companies began conducting clinical trials outside India. The US National Institutes of Health (NIH) confirmed about postpone of 30 clinical trials and likewise stopped enrolling participants in some more trials in India after the announcement of the new clinical trials rule in 2013.[5] List of CDSCO approved clinical trials from 2013 to 2019 is shown in Figure 1. By observing the drop in clinical research, the Indian government fragmented some of these rules in 2015. The decline in the sum of clinical trials persisted the Indian regulators to amend the new rules and regulations pertaining to clinical trials and as a result 'New Drugs and Clinical trials Rules, 2018' G.S.R.104 (E) was framed on 1st February 2018. They released the draft guideline in February and notified to supplant XA and Schedule Y of Drugs and Cosmetic Act. The full-fledged guideline 'New Drugs and Clinical trials Rules, 2019' G.S.R.227(E) was published on 19th March 2019 applicable to 'new drugs' and 'investigational new drugs' for human use, 'clinical trial', 'bioequivalence study', 'bioavailability study' and 'ethics Committee'. Except for chapter IV all rules came in force from the date of their publication in the Official Gazette and Chapter IV will come in force after 180 days from there. A brief view of the general procedure of clinical trial approvals in India is depicted in Figure 2 and the compensation procedure in case of injury, death or permanent disability is depicted in Figure 3.

## Features of the New Drugs and Clinical Trials Rules 2019

New Drugs and Clinical trials Rules 2019 comprise thirteen chapters and eight schedules as given in Table 1. The new rules provided new definitions such as biomedical and health research, clinical trial site, efficacy, good clinical practice guidelines, orphan drugs, post-trial access, a registered pharmacist, similar biologic, trial subject. Moreover, the functioning of the Central Licensing Authority (CLA) lacked clarity before. The amended rule states the importance, role and responsibilities of CLA and he/she will be the Drug Controller General of India (DCGI) nominated by the Central Government denotes to the CDSCO. This rule emphasizes on the constitution, requirement, registration and functions of the ethics committee. It subdivides the role of the ethics committee in clinical trials, bioequivalence studies and also its role in biomedical research. The new rule is highly focused on the compensations for the clinical trial participants on serious adverse events and death. It has popped up with levels of penalties such as cancellation of the license, restriction on conducting furthermore clinical trials in India, blacklisting of the study centre, investigator, debarring the Contract Research Organization (CRO), penalty, imprisonment, penalty and imprisonment both. It has also introduced the concept of orphan drugs, provisions for academic clinical trials and shortening of the approval timeline.[6]

## Highlights of the Special Features of New Drugs and Clinical Trials Rules 2019[7-9]

### *Clinical trials on drugs already approved outside India*

Phase III of clinical studies can be overlooked in India, if the drugs are already approved in countries like the US, EU, Australia, Canada and Japan. Clinical studies can only be exempted if there is no serious adverse effect reported for the approved molecule and there should not be any significant differences in the metabolism pathway in the Indian population. This decision has led to easier access of pharmaceuticals to the Indian population and hence improving the health status of Indians. It saves money and the time invested in conducting clinical studies on the new molecule. This amendment emphasises on post-marketing surveillance of the drugs ensuring patients' safety.

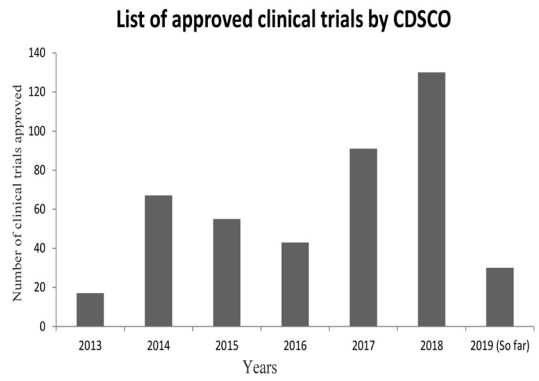


**Figure 1: List of CDSCO approved clinical trials from 2013 to 2019. Source: Seyom business solutions, URL:https://seyom.in/blog_clinical.html**

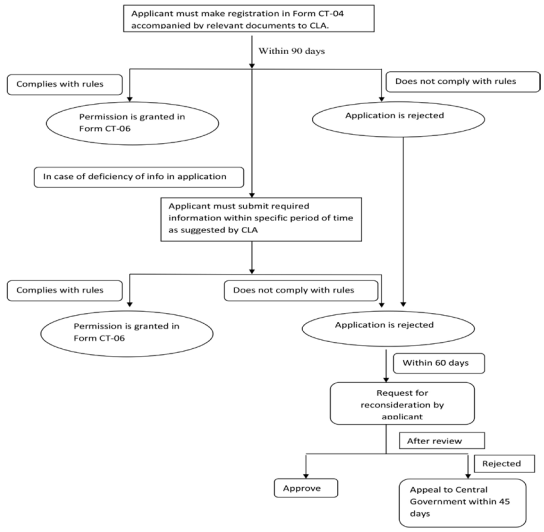


**Figure 2: Flow chart on general procedure of grant of approval to conduct clinical trials in India.**

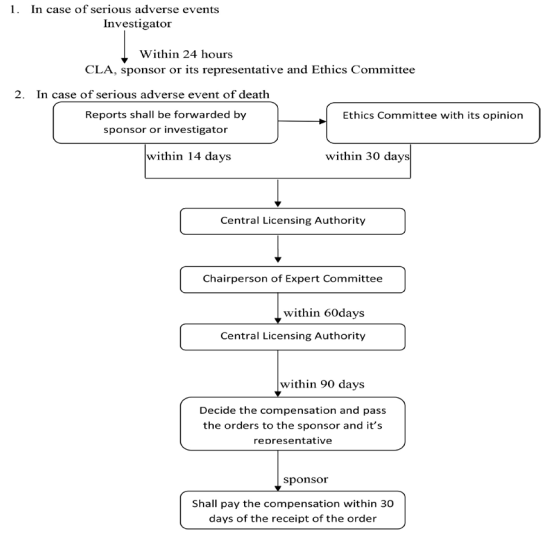


**Figure 3: Flow chart on the compensation procedures in case of serious adverse events and death during the clinical trials.**

## Approval timeline

In 2010, the approval timeline for the clinical trials was outstretched to 18 months. The unethical practices followed and the scandals involved in the trial studies showed up in the year 2012, which led down the number of clinical trials in India. The consequences led to the introduction of a three-tiered regulatory review process by DCGI in 2013. The amendment done in 2017 had decreased the timeline of the review process to 8 months. The contemporary rule has further reduced the approval review timeline. The approval timeline has come down to 30 days for the domestic trials and 90 days for the approval of global clinical trials. This huge step taken by CDSCO will certainly have a significant impact on the Indian population for the betterment of the health. The three-tiered regulatory process to review clinical trial applications is given in Figure 4.

## Ethics Committee

In the current rules, they defined the role of the ethics committee to oversee drug developments during clinical trials. Earlier the ethics committee had a restricted work of inspecting only bioequivalence studies where its role was to check whether a patented drug and its generic version act in a similar direction. The new rule states that the ethics committee registered with the Department of Health Research (DHR) should play an active role in reviewing the institutional clinical trials. This will certainly put a break on the earlier unethical practices of researchers and the university ethics committees which were present only to rubberstamp the proposed projects.

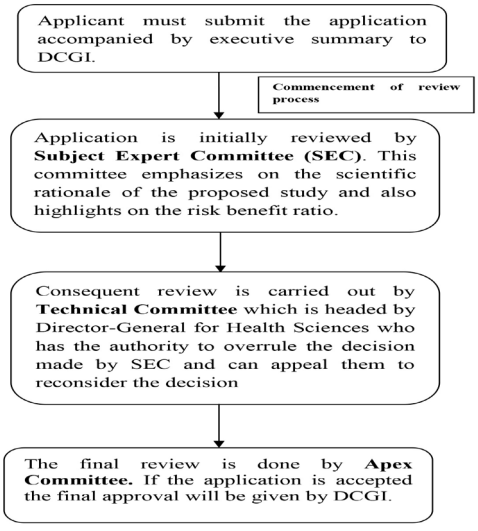


**Figure 4: The three-tiered regulatory process to review clinical trial applications.**

| Table 1: Chapters and Schedules of New Drugs and Clinical Trials Rules, 2019. | |
|---|---|
| **Chapters** | **Schedules** |
| Preliminary | General principles and practices for clinical trial |
| Authorities and officers | Requirements and guidelines for permission to import or manufacture of new drug for sale or to undertake clinical trial |
| Ethics committee for clinical trial, bioavailability and bioequivalence study | Conduct of clinical trial |
| Ethics committee for biomedical and health research | Requirements and guidelines for conduct of bioavailability and bioequivalence study of new drugs or investigational new drugs |
| Clinical trial, bioavailability and bioequivalence study of new drugs and investigational new drugs | Post market assessment |
| Compensation | Fee payable for licence, permission and registration certificate |
| Bioavailability and bioequivalence study centre | Formulae to determine the quantum of compensation in the cases of clinical trial related injury or death |
| Manufacture of new drugs or investigational new drugs for clinical trial, bioavailability or bioequivalence study or for examination, test and analysis | Application for registration/renewal of ethics committee relating to clinical trial or bioavailability and bioequivalence study or biomedical health research |
| Import of new drugs and investigational new drugs for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis | |
| Import or manufacture of new drug for sale or for distribution | |
| Import or manufacture of unapproved new drug for treatment of patients in government hospital and government medical institution | |
| Amendments of drugs and cosmetics rules, 1945 | |
| Miscellaneous | |

| Table 2: New and Old License Application Fees Structure. | | | |
|---|---|---|---|
| **Types of Applications** | | **2019 Fees structure (INR)** | **Old Fees Structure (INR)** |
| Clinical Trials | Phase-I | 3,00,000 | 50,000 |
| | Phase-II&III | 2,00,000 | 25,000 |
| | Phase-IV | 50,000 | No fees |
| Bioavailability-Bioequivalence study | | 2,00,000 | 25,000 (drugs approved within 1 year)<br>15,000 (drugs b/w 1 to 4 years) |
| Registration of Bioavailability-Bioequivalence study center | | 5,00,000 | No fees |
| Reconsideration of | Clinical Trial application | 50,000 | No fees |
| | BA / BE study application | 50,000 | No fees |
| | BA / BE centre study application | 1,00,000 | No fees |

## Concept of Orphan Drugs

According to the new rule, orphan drugs are defined as "drug intended to treat a condition which affects not more than 5 lakh persons in India." The rule states the exemption of phase III and phase IV studies for orphan drugs. Expeditious review process is adopted for such drugs and the application fee is excluded helping Indians to develop more drugs to treat rare disease conditions in Indian population.

## Provisions for academic clinical trials

Academic clinical trials means a "clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or a new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the CLA or regulatory authority of any country for marketing or

**Table 3: Overall comparison of new rules with former rules.**

| Sl. No. | Key features | New Drugs and Clinical trials Rules, 2019 | Former rules |
|---|---|---|---|
| 1 | Clarity of terms and definition | Terms like biomedical and health research, clinical trial site, efficacy, Good clinical practice guidelines, orphan drugs, post-trail access, A registered pharmacist, similar biologic and trial subjects are clearly defined. | Not clearly defined |
| 2 | Reorganisation of term New drug | The definition has been extended to for sustained or modified released formulation or a novel drug which has been approved earlier and shall be considered new for 4 years from the date of approval. | Sustained or modified released formulation or a novel drug was not regarded as a new drug for 4 years after approval |
| 3 | Significance of Central Licensing Authority (CLA) | CLA will be the drug controller nominated by the Central Government and who is not below the rank of Assistant Drug Controller (India). He can delegate his powers after obtaining the consent from central government to the officers of CDSCO who is not below the rank of assistant drug controller. | Delegation of powers was limited to signing the license and registration certificate and the powers can be given to any person who the licensing authority wishes for after obtaining approval from the central government. |
| 4 | Amendments in the constitution of ethics committee | Minimum of 50% members nominated must be outside the organization in which the ethics committee is constituted. It also mandates the requirement of at least one woman in the committee. | Not highlighted on this requirement |
| 5 | Responsibility of ethics committee | Rules highlights on the training that every member must undergo in order to be eligible for an ethics committee. | Rule compelled that the members of an ethics committee must be familiar with the schedules of clinical trials, he must follow good clinical practices and must follow the principles to protect human subjects. |
| 6 | Validity of approved licence | 5 years, the renewal must be done 90 days prior to the expiry of license. | 3 years |
| 7 | Timelines for reporting changes in the constitution of ethics committee | Reported within 30 working days to the central licensing authority | Timeline was not lucid |
| 8 | Maintenance of records and the documents required | 5 years from the date of completion of trials. Documents submitted are Recommendation given by Ethics Committee for determination of compensation. Records relating to the serious adverse event, medical management of trial subjects and compensation paid | 5 years from the date of completion of trials. No compulsion on the requirement of specific documents. |
| 9 | Responsibility of ethics committee in the aspect of conducting trials for biomedical and health research | Compelled to follow National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. The ethics committee must register with authority as stated by central government in the Ministry of Health and Family Welfare, Department of Health Research. | Ethics committee must be registered with DCGI office under rule 122DD. |
| 10 | Application filed for conducting clinical trials | CT-04 | Form 44 |
| 11 | Consent granted in the form of application | CT-06 | No specific application, permission is granted through an application letter |

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| 12 | Timeline for the grant of approval | 90 days | 120 days |
| 13 | Regulations of clinical trials for the purpose of discovery, research and manufacture | These regulations were introduced with the new rules, encouraging discovery, research and manufacture. Approval timeline is 30 days. This rule also motivates the manufacturers by introducing the law of pursuing the trial studies even if no information is received by CLA. | No regulation on the aspect of discovery, research and manufacture existed. |
| 14 | Regulations that must be followed in case of protocol rejection by ethics committee | The applicant must inform to the central licensing authority (CLA) in case if the protocol is rejected by the ethics committee. This must be asked prior to seeking consent from other ethics committee. The approval granted must be informed to central licensing authority within 15 working days of the approval | No information on this regard was provided. |
| 15 | Guidelines pertaining to BABE studies<br>Application number for the grant of permission to conduct BABE studies<br>Timeline for the grant of permission<br>Approval application | <br>CT-05<br><br>15 days<br><br>CT-07 | No clear information on this aspect was provided<br>-<br><br>-<br><br>- |
| 16 | Compensation to the trial subjects | Emphasizes on the equal responsibility of the sponsor and the investigator to report the incidences within 14 working days to CLA and the head of the institution. | Reported within 14 working days of the occurrence of such an incident |
| 17 | Procedures followed for compensation in case of injury to the trial subjects | Ethics committee shall forward the report to CLA along with its opinion on the financial compensation within the period of 30 days of receiving such reports from the sponsor or the investigator. The expert committee shall provide its opinion to the CLA within the period of 60 days. CLA shall pass the command within the period of 90 days to the sponsor and the sponsor must provide compensation to the event within the period of 30 days of receiving the order from CLA. | The expert committee will take up to 105 days to present their opinion to licensing authority and the licensing authority will give their opinion to sponsor within the period of 150 days. The sponsor must do the necessities within the period of 30 days of receiving the order from the sponsor. |
| 18 | Regulations on the trial centres for the conduct of BABE studies<br>Grant of permission for the trial centres for the conduct of BABE studies<br>Application of consent<br>Maintenance of record | <br>CT-08<br><br>CT-09<br>5 years after the completion of the study | <br>No guidelines in this regards were established |
| 19 | New drugs or investigational new drugs for the purpose of examination, test or analysis:<br>Manufacturing purpose<br>Application to seek permission<br>Consent application<br>Timeline for the approval<br>Validity of the license | <br><br><br>CT-10<br><br>CT-11<br>90 days<br>3 years | <br><br>No specific format of application, the validity period and the manufacturing practice was not clearly defined |

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| 20 | 2. For the purpose of import<br>Application to seek permission<br>Consent application<br>Timeline for the approval<br>Validity of the license | <br>CT-16<br><br>CT-17<br>90 days<br>3 years | <br>Form 12<br><br>Form 11<br>45 days<br>3 years |
| 21 | Rules with regard to the import of a new drug<br>1. Active Pharmaceutical Ingredients<br>Application to seek permission<br>Consent application<br>Timeline for the approval<br>2. Finished formulation<br>Application to seek permission<br>Consent application<br>Timeline for the approval | <br><br><br><br>CT-18<br>CT-19<br>90 days<br><br>CT-18<br>CT-20<br>90 days | <br><br><br><br>Form 44<br>Form 45<br>180 days<br><br>Form 44<br>Form 45A<br>180 days |
| 22 | Rules with regard to manufacture of a new drug<br>Application to seek permission<br>Consent application<br>Timeline for the approval | <br><br>CT-21<br>CT-22<br>90 days | <br><br>Form 44<br>Form 46<br>180 days |
| 23 | Guidelines with regards to import of unapproved drugs for treatment in government hospitals and institutions<br>Application to seek permission<br>Consent application<br>Validity of the application | <br><br><br>CT-24<br>CT-25<br>3 years | <br><br><br>12-AA<br>11-AA<br>No regulations on this regard |
| 24 | Provisions regarding the manufacture of unapproved drugs | Medical institution must prescribe a special condition where such drug is required to treat patients suffering from a life-threatening disease and such drug is not approved by CLA but the drug is undergoing clinical trials and he must also state that no other treatments are available.<br>CT-26 | No provisions were provided. |
| 25 | Rules pertaining to pre-submission meeting | Applicant can do a pre- submission meeting with the CLA or any designated officer in case of any queries or to seek information and guidance about the newly amended rule. The pre-submission meeting shall be accompanied by documents as per the second schedule and the fees as per sixth schedule of the rule. The CLA shall ask the applicant to furnish the information if required within the period of 30 days. The CLA or any other designated person shall clarify the queries and provide information to the applicant in the pre-submission meeting. With regard to the queries related to the pending application, the applicant has the provisions to apply for post submission meeting within the period of 15 days of receiving the query on a pending application. | No concept on pre-submission meeting ever existed. |

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| 26 | Accelerated approval process and expedited review process | The second schedule of the rule highlights on the provisions for the accelerated approval process. This schedule also provides provisions for the applicant to apply for the expeditious review process for approval of new drugs under the following conditions: Where the drugs clinical safety and efficacy are established without the completion of the clinical studies. Such drugs are used for defense use or for the mishaps like a disaster, radiation exposure. In such cases the drugs have been formulated but did not undergo real-life clinical trials. Expedited review is also possible for orphan drugs. | No such provisions existed |
| 27 | Requirements on the stability data | Stability data for the storage of new drug and formulations in general conditions, the new rule insists long term conditions – 30 °C ± 2 °C/ 75% RH ± 5% RH – 6 or 12 months | Stability data for the storage of new drug and formulations in general conditions, is 30 °C ± 2 °C/ 65% RH ± 5% RH - 12 months. |
| 28 | Requirements on the additional information | The third rule of the schedule gives provisions related to the conduct of clinical trials where the format of investigational brochure format is as per Indian GCP and regarding the prescribing information, the new rules ask for additional information like 'Patient counselling information', 'Details of manufacturer', 'Details of permission or license number with the date' | No such additional data required |
| 29. | Post-marketing surveillance requirements | The fifth schedule of the rule gives requirements that must be followed for the post marketing surveillance. The fee for the study is INR 200000. These studies require the approval of DCGI. The periodic safety update report (PSUR) must be elaborate as per the new rules and the risk management plan is also incorporated under PSUR document and the copy of the marketing authorization application must be incorporated with PSUR | Risk Management Plan was not the part of PSUR and no copy of marketing authorization was required as per former rules. |

commercial purpose". The current guidelines provide far-sightedness on the convenience of academic clinical trials. If the study is designed for academic purposes, then the study does not require the permission of CLA. However, the study must be initiated after the approval of the ethics committee. In case if there is an uncertainty among academic clinical trial and commercial clinical trials, then it is an utmost duty of ethics committee to notify CLA within 30 days of the issue of application. The CLA will review the documents and resolve the issue and provide notification to the committee. If there is no communication obtained from CLA, then they can initiate trial studies. The applicant must conduct the trial bearing in mind the basic norms that must be followed during the studies.

## Revised application fees for procurement of licenses

According to the new rule, application fees were revised for the procurement of licenses. Table 2 shows a comparison of the new fee structure with the previous one and Table 3 shows overall comparison of new rules with former rules.

## CONCLUSION

The amended rule will undoubtedly develop a new horizon for conducting clinical trials in India. The faster approval timelines have enabled approval of more number of clinical trials and as a result, India may again turn out to be the preferred centre for conducting the trials. The primary question arises here; will the faster available medicines be safe? How far may physicians recommend it to assure the patient's safety? DCGI stated that amended rules have also implemented stringent regulations which ensure the patient's safety and drugs quality; however, safety can be assured only after the careful examination of post-marketing surveillance of such drugs.

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## CONFLICT OF INTEREST

There is no conflict of interest.

## ABBREVIATIONS

**DCGI:** Drugs Controller General of India; **BA/BE:** Bioequivalence and Bioavailability study; **CDSCO:** Central Drug Standard Control Organization; **NIH:** US National Institutes of Health; **CLA:** Central Licensing Authority; **CRO:** Contract Research Organization; **DHR:** Department of Health Research; **PSUR:** Periodic Safety Update Report.

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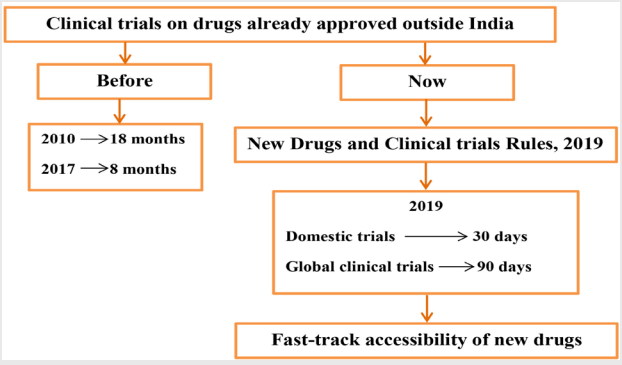
## PICTORIAL ABSTRACT

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