

Pharma & Healthcare Update

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REGULATORY WRAP 2024: MEDICAL RESEARCH IN INDIA

The most significant developments in the medical research sector in 2024 are:

- Six countries notified for considering local clinical trial waiver under Rule 101 of the New Drugs and Clinical Trial Rules, 2019
- Requirement for registration of Clinical Research Organizations introduced
- CDSCO published draft Good Clinical Practices guidelines
- Guidelines for Ethical Use of Leftover De-identified/Anonymous Samples for Commercial Purpose released
- CDSCO revised the Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy for Biologicals

INTRODUCTION

The landscape of the medical research sector in India is slowly but steadily evolving and the sector is witnessing increased investments flowing in from foreign manufacturers. The Central Licensing Authority ("CLA") i.e. the Drugs Controller General of India continues to take steps to streamline and encourage the growth of this sector in India.

The major developments in this sector in the past year include the notification by the CLA of numerous countries for the purpose of considering local clinical trial waivers for new drugs and clarification provided by the licensing authority on what would constitute a clinical research organization wherein it has introduced the registration requirement and additional responsibilities applicable to such organizations as stakeholders in the clinical trial sector in the country. The CDSCO is also in the process of revising the Good Clinical Practices guidelines to cater to the growing emphasis on quality assurance. The CDSCO also revised the guidance for industry for submission of clinical trial application for biologicals and released guidelines for ethical use of leftover human biological samples for commercial purposes jointly with the Indian Council of Medical Research ("ICMR").

In this update, we have discussed the key developments in the past year in this sector in India.

DRUG REGULATOR NOTIFIED SIX COUNTRIES UNDER RULE 101 TO CONSIDER LOCAL CLINICAL TRIAL WAIVER

The CLA issued an order dated August 7, 2024 naming the United States of America, United Kingdom, Japan, Australia, Canada and the European Union under Rule 101 of the New Drugs and Clinical Trial Rules, 2019 ("NDCTR").¹

The NDCTR, issued under the Drugs and Cosmetics Act, 1940 lays down the framework for bringing new drugs to the Indian market and includes a provision under Rule 101 which permits the CLA to consider waiving off local clinical trials when the drug has been approved and marketed in certain jurisdictions. Essentially, the CLA provides approval for the new drug on the strength of the review undertaken by the national regulatory agency in these countries in order to expedite the process of making the treatment available in India. Rule 101 states as follows:

"Name of countries for purpose of new drug approval - The Central Licencing Authority, with the approval of the Central Government, may specify, by an order, the name of the countries, from time to time, for considering waiver of local clinical trial for approval of new drugs under Chapter X and for grant of permission for conduct of clinical trial under Chapter V."

The order specifies the categories of new drugs for which this waiver may be granted, these include:

- Orphan drugs for rare diseases;
- Gene and cellular therapy products;
- New drugs used in pandemic situation;
- New drugs used for special defense purpose;
- New drugs having significant therapeutic advance over the current standard of care.

The powers granted to the CLA are discretionary in nature i.e. Rule 101 neither provides for an automatic waiver for these categories of drugs, nor does it prescribe the extent to which the waiver may be granted. Therefore, it permits

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the CLA to assess the appropriateness of both granting a waiver and the extent of the waiver on a case-to-case basis.

At present, no guidance or format for making an application for a waiver under Rule 101 has been issued. There is also no visibility on the conditions that the CLA may impose while granting such waiver, though it is likely that the CLA would require Phase IV trials to be undertaken.

REGISTRATION REQUIREMENT FOR CLINICAL RESEARCH ORGANIZATIONS IN INDIA

The Ministry of Health and Family Welfare ("MoHFW") in a recent notification dated September 19, 2024, notified the New Drugs and Clinical Trials (Amendment) Rules, 2024 ("Amendment Rules"). The Amendment Rules seek to provide clarity on what would constitute a Clinical Research Organization ("CRO") and has introduced a requirement for the registration of CROs with the CLA.²

Pursuant to the amendment, CROs are required to obtain a registration prior to conducting any clinical trial or bioavailability or bioequivalence study for a new drug or investigational new drug in human subjects. In addition to the responsibilities of the CRO arising from the contractual arrangements with the sponsor of a clinical trial, the CRO would also be required to comply with the statutory requirements introduced under the amendment rules. This is a contrast from the existing practice wherein the responsibility of ensuring compliance with applicable laws was shared between the sponsor and the CRO through contractual arrangements in a clinical trial setting. Companies undertaking clinical trials or bioavailability or bioequivalence studies through CROs would be required to ensure that they engage with registered CROs or require the CROs to obtain and maintain the registration in compliance with the Amendment Rules prior to undertaking such trials.

The additional responsibilities of the CROs include the requirement to ensure compliance with applicable laws and guidelines, maintaining facilities and qualified trained personnel for performing the functions of the CRO, maintaining documented processes and procedures in respect of any clinical trial undertaken by it and to submit an undertaking to this regard at the time of making the application for registration with the licensing authority. The CROs also become susceptible to inspection of its premises, records or documents pertaining to the clinical trial or studies.

Pertinently, non-compliance by the CRO with the additional requirements may lead to the rejection of the results of the clinical trial or study by the licensing authority; suspension or cancellation of its registration and may also lead to the debarment of the CRO from conducting any clinical trial or study for a period determined by the licensing authority.

The Amendment Rules will become effective from April 1, 2025, providing CROs with ample opportunity to streamline its operations in compliance with applicable laws.

CDSCO PUBLISHED DRAFT GUIDELINES TO REVISE GOOD CLINICAL PRACTICES

The Central Drugs Standards Control Organization ("CDSCO") vide a circular dated September 12, 2024, published the draft guidelines on Good Clinical Practices to revise the existing Good Clinical Practices ("GCP") guidelines in line with the NDCTR.³

GCP guidelines is a comprehensive set of standards that govern the design, analysis, conduct and documentation of clinical trials involving human participants in India. The CDSCO adopted the GCP to ensure that the research conducted on human subjects is ethical and sound and the rights and safety of the participants is ensured. It sets out the responsibilities of the various stakeholders involved in the clinical trial process, quality control and assurance requirements, standards for documentation and retention of information during the clinical trial process for drugs in the country.

The CDSCO has proposed additions to the GCP guidelines to recognize the growing role played by technology in the clinical trial processes. It seeks to support innovative and efficient approaches to study/research conduct clinical trials in the country while adapting to the technological advances and recognizing them as data acquisition tools. CDSCO has proposed recognition of e-consent and adding guidelines on validation of electronic data processing systems to assess risk associated with the intended use of such systems and the likely impact it would have on the participant's protection and reliability of data generated from such systems. CDSCO has also proposed changes to sections on compensation for research-related harm, confidentiality, quality assurance, quality audits and ethics requiring companies to put in place risk-management mechanisms to incorporate quality standards into the clinical trial process.

The final draft of the GCP is expected to be notified this year and the implementation is likely to enhance the quality assurance mechanisms adopted by companies to generate reliable data while maintaining ethical standards in the clinical trial process.

GUIDELINES FOR ETHICAL USE OF LEFTOVER SAMPLES FOR COMMERCIAL PURPOSES RELEASED

The MoHFW along with the ICMR jointly released Guidelines for Ethical Use of Leftover De-identified/Anonymous Samples for Commercial Purpose ("Ethical Use Guidelines") in October 2024.⁴

The Ethical Use Guidelines provide guidance on the use of leftover human biological samples for development of future product/ technology and or commercial purposes. The source for these specimens may be patients, autopsy specimens, abandoned wastes, tissue banks, IVF clinics, organ donation centres etc.

The Ethical Use Guidelines permit the use of such samples for commercial use⁵ subject to the samples being irreversibly de-identified or pooled samples that are non-identifiable and collected for clinical care/diagnostics not pertaining to research purposes. Leftover research samples are expressly kept outside the scope of the Ethical Use Guidelines given that re-use for commercial purposes would constitute secondary use and such use is required to be aligned with the original informed consent given by the research participant.

The Ethical Use Guidelines provide guidance to various stakeholders for the use and handling of such leftover samples and outlines the role of the hospitals and ethics committee for commercial use of such samples. The guidelines also require companies acquiring such samples to adhere to local, national, and international regulations

governing the collection, storage, and secondary use of biological samples including obtaining necessary approvals and entering into formal agreements such as MoUs and MTAs. The formal agreements entered into by the company are required to capture the intended use of the samples, the roles and responsibilities of parties, dispute resolution mechanism, commercial terms, etc. The Ethical Use Guidelines will assist companies in accessing leftover samples that remain available with hospitals as a viable source for research and development activities undertaken by the companies for development of products, diagnostic kits, innovations, etc.

GUIDANCE FOR INDUSTRY (BIOLOGICALS) REVISED TO ALIGN WITH NDCTR

The CDSCO revised the Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy (Biologicals) ("Guidance") earlier published in 2008 to align with the NDCTR and the SUGAM application processes adopted by the industry.⁶

The Guidance provides general considerations for the industry for conducting clinical trials as per the NDCTR and GCP guidelines for biologicals. The Guidance provides detailed information on the necessary data and documentation required to be submitted by the manufacturer/sponsor of a clinical trial for the purpose of making an application for the clinical trial through the SUGAM/National Single Window System Portal. The Guidance is broken down into parts basis the information required to be submitted for each phase of the clinical trial as per the NDCTR.

The Guidance is a much-needed document that assists companies in preparing and ensuring completeness of the clinical trial application under the relevant forms under the NDCTR. This prevents delay and assists in expediting the process for obtaining the required approvals for the conduct of clinical trials for biologicals from the regulatory authority.

CONCLUSION

The medical research sector is growing steadily with increased investments flowing into the sector. The CLA continues to take measures to focus on streamlining domestic manufacturing activities and clinical research activities by introducing standards to be adopted by the industry at various levels. The implementation of the regulatory developments introduced by the CLA remain to be witnessed in the new year.

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¹ Accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE1ODI=

² Accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIwMTM=

³ Accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE4OTU=

⁴ Accessible here: https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1732704229_guidelinesforethicaluse.pdf

⁵ Commercial Use for the purposes of the Ethical Use Guidelines means for the development of commercial kits/products or technologies that have the potential to improve patient outcomes, provide diagnostic accuracy or offer therapeutic advancements to benefit the society.

⁶ Guidance document accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEyMzU=

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