Impact of Law 14,784/24 on Clinical Research in Oncology

https://doi.org/10.32635/2176-9745.RBC.2024v70n4.4958

Impacto da Nova Lei 14.784/2024 na Pesquisa Clínica em Oncologia

Impacto de la Ley 14784/24 sobre la Investigación Clínica en Oncología

Cecilia Ferreira da Silva[1]; Andréia Cristina de Melo[2]

Since the consolidation of the regulatory framework for clinical trials with human beings in Brazil in 1996, the country has been standing out in the international scenario. Populational diversity, epidemiological profile, strategic geographic location, potential of enrollment and patient retention make Brazil an attractive environment for clinical trials, especially in oncology. The positive background in Good Clinical Practice reinforces its position as a reliable partner for research and development.

Brazil's 20th position in the world ranking of clinical trials and nearly 2% of the global studies, makes it an outstanding player. Oncology emerges as the main therapeutic area in Brazilian clinical trials, concentrating 30%, 25% and 40% of the dossiers registered at the Brazilian Health Surveillance Agency (Anvisa) in 2020, 2021 and 2022, respectively[1].

This mirrors the improvement, growth and strategic importance of oncology. Globally, 28% of the medications launched between 2011 and 2015 originated from clinical trials were targeted to cancer[2]. The relevance of oncology in Brazilian clinical trials reveals the potential for the development of new therapies and improvement of oncologic treatment.

The Brazilian regulatory process, although relevant to protect research participants is quite challenging with clear impacts on how clinical trials are conducted. The predominance of phase III studies – 57% in 2021 and 59% in 2022[1] – reflects these challenges. The morosity of regulatory processing through multiple analyzes and extended timeline, discourages initial phase studies, which reduces the participation of the country in the development of new therapies and may delay the access of the population to innovative treatments.

Agile processing concomitantly with human beings protection appears to be the key to redesign the regulatory process for improved conduction of clinical trials. Although the robust normative backbone ruling clinical trials in Brazil based on the National Health Council (CNS) and Anvisa's directives, the scientific community discussed thoroughly the necessity of a specific legislation for the area. Its non-statutory nature limits the evolution of the science and demands generated from clinical trials, although the norms usually determine how the conduction of clinical trials with human beings should function. In this context, the novel law 14,874[3] ruling clinical trials with human beings was sanctioned by the President with vetoes on May 18, 2024.

This law is a significant progress for clinical trials in Brazil as it met a historical demand of the scientific community for a more agile and focused regulatory framework. However, despite promising, there are gaps and uncertainties requiring attention as the complexity of the law and further regulation raises doubts about its practical applicability and potential delays for its full implementation. The scientific community waits the publication of regulating decrees with details on conduction of researches and effective structuring of the Brazilian System of Research Ethics.

The major change the law brought was the full reformulation of the regulatory flow with the creation of a new ethical evaluation system and redesigning of assignments and timelines for all the entities involved. Article 14, § 7th of the Law 14,874/2024[3] determined that a single Institutional Review Board (IRB) will be assigned the ethical review of multicenter studies, contrary to Directive 346/2005 of the National Health Council[4] which can fragilize the ethical governance of the studies as the autonomy of the IRBs of the participating sites will disappear.

As most of the IRB's are currently found in the State of São Paulo, the centralization may discourage the participation of other Brazilian sites located in other regions and deepen regional inequalities. Decentralization of IRBs is pivotal to ensure the diversity and representativeness of ethical review.

[1,2]Instituto Nacional de Câncer (INCA), Divisão de Pesquisa Clínica e Desenvolvimento Tecnológico. Rio de Janeiro (RJ), Brasil.
[1]E-mail: cecilia.silva@inca.gov.br. Orcid iD: https://orcid.org/0000-0003-4691-4505
[2]E-mail: andreia.melo@inca.gov.br. Orcid iD: https://orcid.org/0000-0002-1201-4333
Corresponding author: Cecília Ferreira da Silva. Rua André Cavalcanti, 37, 4º andar (sala 18), prédio anexo – Centro. Rio de Janeiro (RJ), Brasil. CEP 20231-050. E-mail: cecilia.silva@inca.gov.br

Este é um artigo publicado em acesso aberto (Open Access) sob a licença Creative Commons Attribution, que permite uso, distribuição e reprodução em qualquer meio, sem restrições, desde que o trabalho original seja corretamente citado.

Shorter review times by Anvisa and IRBs are among the positive aspects of the regulatory changes, a significant achievement with potential reduction of time analysis, speeding up the participants access to new therapies and making Brazil an attractive hub for international clinical trials.

The new rule of post-study access is another critical topic which may directly impact the context of oncology. Guarantee of free access to post-clinical trials medications already determined by Directive 466/2012[5] of the National Health Council (CNS), and regulated by the Resolution of the Collegiate Board (RDC) 38/2013[6], is a potential benefit for clinical trials participants, particularly within the context of the National Health System (SUS). However, the flexibilization of the criteria to offer post-study medications and assigning the sponsor the decision to offer these drugs can jeopardize the guarantee and access to the medications.

Of the 701 active study participants of clinical trials in 2023 of the Clinical Trial and Technological Development Division of the National Cancer Institute (INCA), 1.8% alone were enrolled at an assistance program (expanded access, compassionate or post-study use) and was initiated between 2014 and 2023. Similar scenarios are expected to occur in other research sites. Given the magnitude of the investments in research and development and survival profile of participants of cancer clinical trials, the budget impact for the sponsors to secure access to these oncology programs would be negligible, making this measure viable, fair and ethical.

The new guidelines of Law 14,874/2024[3], in addition to the themes emphasized before directly impact the entire research ecosystem. Currently, the parties involved live in expectation and restlessness awaiting the publication of complementary regulatory documents for the effective regulation of the law. Optimistically, the potential benefits of the law are expected to offset the bottlenecks and promote an efficient and prosperous ethical-scientific environment for the technological development of the country.

REFERENCES

1. Agência Nacional de Vigilância Sanitária, Coordenação de Pesquisa Clínica em Medicamentos e Produtos Biológicos. Relatório anual de atividades 2020/2021. Brasília, DF: Agência Nacional de Vigilância Sanitária; 2022.
2. Peig D, Fujioka W, Miguel A, et al. A importância da pesquisa clínica para o Brasil. Rev Bras Pesqui Clín. 2022;12(3):123-30.
3. Presidência da República (BR). Lei n.º 14.874, de 28 de maio de 2024. Dispõe sobre a regulamentação de produtos biológicos no Brasil. Diário Oficial da União, Brasília. 2024 maio 28; Seção 1:3-5.
4. Conselho Nacional de Saúde (BR). Resolução CNS n.º 346, de 13 de janeiro de 2005. Aprova as diretrizes e normas para a pesquisa em saúde. Diário Oficial da União, Brasília,DF. 2005 jan 13; Seção 1:23.
5. Conselho Nacional de Saúde (BR). Resolução nº 466, de 12 de dezembro de 2012. Aprova as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial da União, Brasília, DF. 2013 jun 13; Seção I:59.
6. Agência Nacional de Vigilância Sanitária (BR). Resolução da Diretoria Colegiada (RDC) n.º 38, de 24 de setembro de 2013. Aprova o Regulamento Técnico sobre a produção, o controle e a comercialização de produtos biológicos. Diário Oficial da União, Brasília, DF. 2013 set 25; Seção 1:31

Recebido em 13/9/2024
Aprovado em 13/9/2024

Scientific-editor: Anke Bergmann. Orcid iD: https://orcid.org/0000-0002-1972-8777

Este é um artigo publicado em acesso aberto (Open Access) sob a licença Creative Commons Attribution, que permite uso, distribuição e reprodução em qualquer meio, sem restrições, desde que o trabalho original seja corretamente citado.