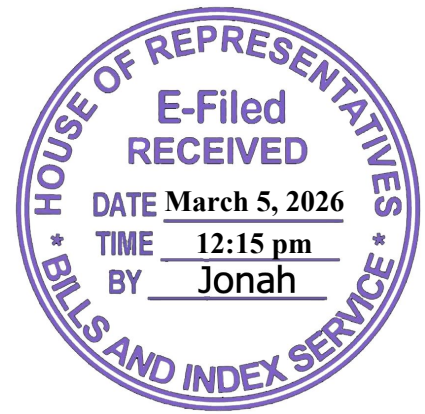


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Constitution Hills, Quezon City

TWENTIETH CONGRESS
First Regular Session

House Bill No. **8300**



Introduced by: **REPRESENTATIVE ERIC L. OLIVAREZ**

EXPLANATORY NOTE

Clinical research plays a vital role in advancing medical science, improving patient outcomes, and expanding access to innovative therapies. As global health innovation accelerates, countries that maintain clear, efficient, and ethically robust regulatory systems for clinical trials are better positioned to attract investments, participate in multi-regional clinical trials (MRCTs), and ensure early access to emerging treatments for their citizens.

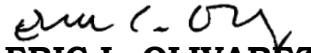
At present, while the Philippines regulates clinical trials through the Food and Drug Administration (FDA) pursuant to Republic Act No. 9711 and coordinates health research under Republic Act No. 10532, there is no comprehensive statutory framework that consolidates clinical trial governance, institutionalizes streamlined review mechanisms, strengthens ethical safeguards, and promotes national competitiveness in this field.

This proposed measure establishes a coherent legal framework for the governance, regulation, and promotion of clinical trials in the Philippines. It creates a specialized Clinical Trials Regulatory Office within the FDA to strengthen oversight of pre-commercial clinical trials while preserving the FDA's authority as the National Regulatory Authority. The bill institutionalizes risk-based review pathways, a national clinical trial registry, enhanced ethics oversight, and clear participant protection mechanisms consistent with international standards of Good Clinical Practice.

The measure likewise promotes equitable access for indigent Filipinos participating in clinical trials, encourages responsible public-private partnerships, and positions the Philippines as a credible and competitive site for global clinical research, including participation in MRCTs.

By strengthening regulatory efficiency while upholding ethical integrity and participant safety, this bill advances the State's constitutional mandate to protect and promote the right to health and to ensure a responsive and effective health regulatory system.

In view of the foregoing, the immediate passage of this measure is earnestly sought.


ERIC L. OLIVAREZ

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Constitution Hills, Quezon City

TWENTIETH CONGRESS
First Regular Session

House Bill No. 8300

Introduced by: **REPRESENTATIVE ERIC L. OLIVAREZ**

“AN ACT
ESTABLISHING A COMPREHENSIVE LEGAL FRAMEWORK FOR THE
GOVERNANCE, REGULATION, AND PROMOTION OF CLINICAL TRIALS
IN THE PHILIPPINES; ESTABLISHING A NATIONAL CLINICAL TRIAL
OVERSIGHT AND REGISTRY; STRENGTHENING ETHICAL
SAFEGUARDS AND PARTICIPANT PROTECTION; PROMOTING
EQUITABLE ACCESS FOR INDIGENT FILIPINOS; ENCOURAGING
PUBLIC PRIVATE PARTNERSHIPS AND PARTICIPATION IN MULTI-
REGIONAL CLINICAL TRIALS; AND FOR OTHER PURPOSES”

CHAPTER 1
GENERAL PROVISIONS

Section 1. Short Title - This Act shall be known as the "Philippine Clinical Trial Act of 2026"

Section 2. Declaration of Policy - The State recognizes that clinical research enhances access to investigational medicinal products and qualified healthcare professionals that address the needs of the Filipino people. Such research is anchored on the principles of beneficence and promoting scientific advancement and medical research. Hence, highlighting the need to establish a centralized, efficient, and transparent regulatory framework for clinical trials in the field of human and veterinary medicine, food safety, medical technology, and cosmetics.

It is the policy of the State to protect and promote the right to health by ensuring that clinical trials involving human participants are conducted ethically, scientifically, transparently, and in accordance with internationally recognized standards of Good Clinical Practice (GCP).

Accordingly, the State shall:

- a. Establish a specialized statutory and institutional framework for clinical trial governance;
- b. Safeguard the rights, safety, dignity, and welfare of participants;
- c. Promote equitable access of indigent Filipinos to innovative therapies;
- d. Position the Philippines as a competitive hub for ethical clinical research and Multi- Regional Clinical Trials (MRCTs)
- e. Encourage responsible public-private collaboration;
- f. Ensure transparency and accountability in clinical research activities.

Section 3. Scope and Coverage This Act applies to all clinical trials conducted within Philippine jurisdiction involving human participants and investigational health products consistent with the regulatory authority of the Food and Drug Administration under Republic Act No. 9711, including:

- a. Drugs, biologics, vaccines and advanced therapies;
- b. Medical devices and In Vitro diagnostics;
- c. Food products requiring human safety, nutritional, or functional substantiation,
- d. Cosmetic products requiring human safety or performance evaluation;
- e. Other health-related products as determined by the Department of Health (DOH).

This Act covers commercial, non-commercial, academic, government-initiated, investigator-initiated, and multi-regional clinical trials (MRCTs).

Nothing in this Act, however, shall be construed to regulate routine laboratory testing, product quality control procedures, or post-marketing surveillance activities already governed by existing FDA regulations.

Section 4. Definition of Terms - For purposes of this Act, the following terms shall have the meanings provided below:

- a. Clinical Trial - A systematic investigation involving human participants to evaluate safety, efficacy, performance, pharmacokinetics, pharmacodynamics, or other effects of an investigational health product.
- b. Contract Research Organization (CRO) - An entity contracted by the sponsor to perform trial-related functions.

- c. Ethics Review Committee (ERC) - An independent body tasked with ethical review and protection of participants.
- d. Indigent Patient - A Filipino citizen classified as financially incapable of affording necessary medical services as defined by DOH guidelines.
- e. Investigational Health Product - A product not yet authorized for commercial distribution, used in a clinical trial.
- f. Investigator - A qualified individual responsible for the conduct of a clinical trial at a site.
- g. Good Clinical Practice (GCP)- International ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials.
- h. Multi-Regional Clinical Trial (MRCT) - A clinical trial conducted simultaneously in multiple countries under a common protocol.
- i. Sponsor - A person, company, institution, or organization that initiates, manages and/or finances a clinical trial.

Section 5 Creation of the Philippine Clinical Trials Regulatory Office (PCTRO)-

There is hereby established a Philippine Clinical Trials Regulatory Office (PCTRO) within the Food and Drug Administration (FDA), which shall serve as the specialized unit responsible for strengthening and institutionalizing the regulation, coordination, and oversight of pre-commercial clinical trials in the Philippines.

The PCTRO shall operate under the supervision and control of the FDA Director General and shall exercise delegated functions consistent with the powers of the FDA under Republic Act No. 9711.

Nothing in this Act shall be construed to diminish, transfer, or modify the statutory authority of the FDA as the National Regulatory Authority over health products, including investigational products used in clinical trials.

The PCTRO shall provide a centralized and streamlined framework for clinical trial authorization, inspection, registry management, ethics coordination, and compliance monitoring, in accordance with applicable laws and internationally recognized standards of Good Clinical Practice (GCP).

The PCTRO shall be headed by a Director appointed by the Secretary of Health upon recommendation of the FDA Director General and shall be supported by technical, legal, pharmacovigilance, inspection, and ethics support divisions, subject to civil service laws, government auditing rules, and existing FDA organizational structures.

Section 6. Powers and Functions of the PCTRO.

The PCTRO shall:

- a. Review and grant Clinical Trial Authorizations (CTA);
- b. Establish risk-based review pathways (standard, expedited, priority);
- c. Conduct routine and for-cause inspections and audits;
- d. Recommend enforcement actions and, where authorized by the FDA Director General, issue administrative orders relating to clinical trial authorization, suspension, or termination;
- e. Accredite and monitor Ethics Review Committees for purposes of FDA-regulated clinical trials, in coordination with the Philippine National Health Research System under Republic Act No. 10532;
- f. Establish and maintain the Philippine Clinical Trial Registry;
- g. Develop national GCP training and certification programs;
- h. Coordinate with international regulators for MRCT participation;
- i. Issue guidance documents, circulars, and technical standards.

Section 7. Delineation of Functions Within the FDA. — The Philippine Clinical Trials Regulatory Office (PCTRO) shall exercise delegated authority, under the supervision and control of the FDA Director General, over the review, authorization, inspection, and monitoring of pre-commercial clinical trials.

The FDA shall retain ultimate regulatory authority under Republic Act No. 9711, including but not limited to:

- a. Evaluation of clinical trial data submitted for product registration;
- b. Issuance of market authorization and certificates of product registration;
- c. Post-marketing surveillance, pharmacovigilance, and enforcement actions involving registered products;
- d. Enforcement of regulatory actions relating to investigational products used in clinical trials.

Nothing in this Act shall be construed as creating a separate regulatory authority apart from the FDA or as transferring jurisdiction granted under Republic Act No. 9711.

Section 8. Scope of Clinical Trials covered by the Regulatory Framework on Clinical Trials Regulated in the Philippines, including but not limited to:

- a. Investigational Drug Products

- i. New chemical entities (NCEs).
- ii. Biologics, including vaccines, gene therapies, and cell-based therapies.
- iii. Biosimilars and reformulated drug products.

b. Bioequivalence Studies Involving Human Participants

- i. Studies designed to compare the rate and extent of absorption of an investigational product with that of a reference drug product.
- ii. Required for the approval of generic drug products and locally manufactured equivalents.
- iii. Subject to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and ethical review, with mandatory informed consent and safety oversight.

c. Food Investigational Products

- i. Functional Foods- Foods fortified with vitamins, minerals, or bioactive compounds (e.g., calcium fortified orange juice, omega-3-enriched eggs), Probiotic and prebiotic foods (e.g., yogurt with live cultures, fiber-enriched products).
- ii. Nutraceuticals and Dietary Supplements - Products containing bioactive compounds.
- iii. Novel Foods - Foods derived from new sources or technologies, such as: Lab-grown or cultured meat, plant-based meat alternatives, foods with genetically modified organisms (GMOs).
- iv. Fortified and Functional Beverages Drinks with added health-promoting ingredients, such as: Energy drinks with herbal extracts, functional waters containing vitamins, minerals, or adaptogens.
- v. Allergen-Free or Hypoallergenic Foods- Foods marketed for individuals with food allergies or intolerances.
- vi. Weight Management Products - Meal replacements, shakes, or bars claiming weight loss or appetite suppression benefits.
- vii. Foods for Special Populations - Infant formula or baby foods, products for the elderly.
- viii. Bioengineered or Fermented Foods - Foods with novel fermentation processes or bioengineered components.
- ix. Claimed Anti-Disease Foods- Products claiming to reduce the risk of illnesses.

d. Medical Devices

- i. Implantable Devices (Pacemakers, Implantable defibrillators, Artificial heart valves, Cochlear implants, Orthopedic implants).
- ii. Diagnostic Devices (MRI and CT scanners, In-vitro diagnostic tests for cancer and infectious diseases), Genetic testing platforms.
- iii. Life-supporting or life-sustaining devices (Ventilators, Dialysis machines, Heart-lung machines).
- iv. Novel or Innovative Devices, Robotic Surgical Systems, Wearable glucose monitors with insulin delivery (closed-loop systems), AI-powered diagnostic tools.
- v. Devices with Drug Combinations (Drug-eluting stents, Contraceptive implants, Infusion pumps with medication reservoirs).
- vi. Devices with a New Mechanism or Material (Devices made from new Biomaterials (e.g., biodegradable implants), Devices using nanotechnology for treatment or diagnosis)

e. Veterinary Investigational Products

- i. New Veterinary Drugs.
- ii. Vaccines.
- iii. Biological Products.
- iv. Medicated Feed Additives.
- v. Veterinary Medical Devices.
- vi. Novel Delivery Systems or Formulations.
- vii. Generic Drugs

Oversight of veterinary investigational products shall be undertaken in coordination with the Department of Agriculture and the Bureau of Animal Industry, consistent with applicable laws.

f. Cosmetics and Personal Care Products.

- i. Products requiring human safety testing, dermal irritation/efficacy trials, and claims validation.

Section 9. Public-Private Partnerships (PPP) in Clinical Trials

The PCTRO shall promote public-private partnerships through the following programs:

- a. Foreign investment will be promoted through streamlined regulatory pathways subject to existing tax and investment incentive laws for foreign-funded clinical trials, while ensuring rigorous regulatory oversight to safeguard ethical and scientific

- standards.
- b. Foreign investors, with assistance from the Philippine Board of Investments (BOI) can primarily facilitate investment promotions and policy guidance, rather than direct financial assistance.
 - c. Strengthening of the Clinical Trial Registry to provide streamlined access to qualified patient populations, thereby minimizing recruitment time for Clinical Trial Sponsors and encourage the conduct of Pre-Clinical and Phase I Studies in the Philippines.

Section 10. National Strategy for MRCT Participation

The PCTRO shall adopt harmonized standards to facilitate Philippine inclusion in global MRCTs. Sponsors with clinical trial sites in the Philippines may receive the following incentives, subject to investment laws:

- a. Streamlined importation of investigational products.
- b. Priority review pathways.
- c. Incentives for sponsors developing innovative health products, subject to existing investment and fiscal laws.

Section 11. Equitable Access and Public Health Benefits

Access of Indigent Filipinos shall be maintained by the Sponsor through the following:

- a. No cost participation;
- b. Coverage of diagnostics and monitoring;
- c. Post-trial access for participants who benefit from the investigational health product through a Post-Trial Access Plan subject to regulatory approval, safety evaluation, feasibility, and applicable intellectual property laws;
- d. Coordination with public hospitals

Section 12. Licensing of Sponsors and CROs

All Sponsors and Contract Research Organizations (CROs) shall obtain a License to Operate (LTO) from the FDA prior to engaging in any trial-related activities. Foreign sponsors shall appoint a duly authorized local representative accountable for compliance with this Act.

Sec. 13. Clinical Trial Authorization.

Sponsors shall secure a Clinical Trial Authorization (CTA) through the PCTRO acting under delegated authority of the FDA prior to the conduct of any clinical trial activities.

An application for CTA shall include evidence of:

- a. Trial protocol and investigator brochure;
- b. Approval from a Level III- accredited Ethics Review Committee;
- c. Scientific and safety justification for the trial;
- d. Risk-benefit assessment;
- e. Investigator qualifications and site capability;
- f. Proof of insurance or compensation mechanism for trial-related injury;
- g. Clinical Performance Study Approval and ISO 13485 Certification for Medical Device Clinical Trials;
- h. Post-Trial Access Plan;
- i. Data management and safety monitoring plan.

Ongoing clinical trials shall be required to submit semi-annual Progress Reports summarizing the status of the clinical trial.

Risk-based review shall be applied proportionate to product type and study phase. The PCTRO shall establish predictable timelines:

- a. Standard review: 60-90 working days;
- b. Expedited review (public health priority): 30-45 working days.

Section 14. Ethics Review Governance and Participant Protection.

All clinical trials shall be reviewed and approved by an Ethics Review Committee (ERC). The PCTRO shall accredit ERCs and conduct periodic audits.

Informed consent shall be obtained from all participants prior to trial enrollment following ICH-GCP E6 (R3). Informed consent must be voluntary, documented, understandable, and culturally appropriate. Where the individual is a member of a vulnerable population, additional safeguards shall be implemented to ensure that consent is truly informed and free from coercion or undue influence.

Confidentiality of participant data shall be strictly observed in accordance with the Data Privacy Act of 2012.

Section 15. Clinical Trial Registry and Data Privacy.

A Philippine Clinical Trial Registry (PCTR) shall be established and maintained under the PCTRO. The PCTR shall be built upon the existing Philippine Health Research Registry (PHRR). Pertinent information regarding ongoing clinical trials shall be encoded and regularly updated in the database.

All approved clinical trials shall be registered prior to participant enrollment, and sponsors shall ensure public disclosure of study results, subject to confidentiality and intellectual property considerations.

Sponsors, investigators, and the PCTRO shall comply with Republic Act No. 10173 and applicable data privacy regulations.

Section 16. Regulatory Inspection by the FDA as the National Regulatory Authority (NRA).

- a. The NRA shall establish and implement an inspection program to ensure compliance of ongoing clinical trials in the Philippines with ICH-GCP, WHO guidelines, ASEAN guidelines, ethical standards, and applicable regulations in the country.
- b. Inspections will be carried out by qualified inspectors possessing valid credentials and relevant knowledge, experience, and training in implementing Good Clinical Practice.
- c. The NRA exercises the right to conduct inspections, enter any area of the premises where activities related to clinical trials and clinical research are carried out, interview relevant personnel, obtain information, access clinical trial data, and carry out other activities as necessary to verify compliance with existing standards governing clinical research in the Philippines;
- d. Inspections may be conducted as announced or unannounced, as necessary.
- e. Inspections may be carried out at Ethics Review Committees (ERCs), Contract Research Organizations (CROs), Sponsors, and Clinical Trial Sites to verify information and compliance with GCP.
- f. All findings and results of inspections shall be documented and made accessible to related parties. Inspections with noted deficiencies and violations may require the submission of a Corrective Action and Preventive Action (CAPA) Plan subject to the evaluation and approval of the involved inspectors;
- g. Inspections where major GCP violations resulting in existing or potential significant harm to the clinical trial participants are noted may result in the imposition of a Violation subject to appropriate legal action:

Section 17. Funding and Appropriations. - An initial budget shall be allocated from the General Appropriations Act (GAA) for the establishment of the

PCTRO. Additionally, the PCTRO may receive additional funding from Public-Private Partnerships (PPPs) with private hospitals, universities, and Pharmaceutical Firms, and international research grants and foreign investment incentives.

No regulated entity shall directly fund regulatory approval or inspection activities of the PCTRO.

Section 18. National Clinical Research and Innovation Fund.

A National Clinical Research and Innovation Fund shall be established to support local investigator-initiated trials, ethics training, and capacity building for regulatory and ethics oversight. The Fund shall support:

- a. Trials addressing priority diseases;
- b. MRCT participation;
- c. Investigator-initiated trials;
- d. Regulatory and ethics capacity building.

Funding sources include appropriations, grants, and lawful contributions under transparency safeguards.

Section 19. Enforcement and Penalties

- a. Administrative Penalties - Any person or entity found in violation of this Act may be subject to administrative fines, suspension, or revocation of authorization or license.
- b. Criminal Penalties - Any person who willfully falsifies trial data, conducts unapproved trials, or endangers participant safety shall be liable to imprisonment of not less than two (2) years but not more than ten (10) years, or a fine of not less than Five Hundred Thousand Pesos (₱500,000) but not more than Five Million Pesos (₱5,000,000), or both.
- c. The imposition of penalties under this Act shall be without prejudice to other administrative, civil or criminal liabilities under existing laws.

Sec. 20. Implementing Rules and Regulations (IRR) - Within ninety (90) days from effectivity of this Act, the DOH, in consultation with the DOST, and relevant stakeholders, shall promulgate the necessary implementing Rules and regulations (IRR).

Section 21. Separability Clause.

If any provision, section, subsection, paragraph, sentence, clause or phrase of this Act is declared unconstitutional, invalid, or unenforceable by a court of competent jurisdiction, such declaration shall not affect the validity or enforceability of the remaining provisions of this Act.

The remaining provisions shall continue to be in full force and effect, provided that the invalidated portion does not render the implementation of the remaining provisions impossible or contrary to legislative intent.

In the event that any specific application of a provision is declared invalid, such invalidity shall not affect other applications of the same provision which can be given effect without the invalid portion. It is the intent of Congress that this Act would have been enacted even if any one or more provisions were declared invalid.

Section 22. Repealing Clause.

All laws, decrees, executive orders, administrative issuances, rules, and regulations, or parts thereof, which are inconsistent with any provision of this Act are hereby repealed amended, or modified accordingly. Nothing in this Act shall be construed to:

- a. Repeal, amend, or diminish the authority of the Food and Drug Administration under Republic Act No. 9711 (FDA Act of 2009) with respect to product registration, market authorization, post-marketing surveillance, and regulation of commercially distributed health products;
- b. Repeal or modify the Data Privacy Act of 2012 (Republic Act No. 10173)
- c. Repeal or modify the Philippine National Health Research System Act (Republic Act No. 10532), except insofar as necessary to harmonize institutional coordination with the Philippine Clinical Trial Regulatory Office;
- d. Repeal or override existing procurement, public-private partnership, or government auditing laws;
- e. Impair vested rights lawfully acquired under existing laws prior to the effectivity of this Act.

Administrative orders, circulars, and guidelines inconsistent with this Act shall be reviewed and harmonized within one (1) year from its effectivity.

Section 23. Effectivity - This Act shall take effect fifteen (15) days after its publication in the official gazette or in a newspaper of general circulation.

Approved,