

Developing Clinical Research Unit in National Respiratory Center Hospital

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Abstract

Background: Persahabatan Hospital, Indonesia's National Respiratory Center, has strategically aligned its clinical and research missions to advance evidence-based respiratory care. In accordance with the 2020–2024 strategic plan, the hospital established a Clinical Research Unit (CRU) as part of its transformation into a center of innovation and ethical scientific excellence. This article provides a narrative review of the establishment and strategic development of the CRU at Persahabatan Hospital.

Methods: Data were obtained from official regulatory and institutional documents, including Law No. 17 of 2023 on Health, Minister of Health Decree No. HK.01.07/Menkes/1458/2023, Director General Decree No. HK.02.02/D/1782/2025, and the Organizational Structure and Work Procedures (SOTK) of the CRU Persahabatan Hospital. Additional data were drawn from the hospital's official website and recent academic literature, including Wang et al. (2025) in *Systematic Reviews*, which examines the impact of Clinical Research Units on institutional research quality and productivity. All sources were reviewed descriptively.

Conclusion: The establishment of the CRU at Persahabatan Hospital represents a milestone in institutionalizing research governance and fostering innovation in respiratory medicine. The CRU's structure integrates administrative, ethical, and scientific oversight through three core subunits, Collaboration with national networks such as the Indonesia Clinical Research Center (INA-CRC) and adherence to Good Clinical Practice (GCP) principles have strengthened research coordination and enabled participation in multicenter studies. The CRU's presence has enhanced research efficiency, data quality, and investigator engagement, positioning Persahabatan Hospital as a credible contributor to both national and international research efforts.

Keywords: Research, Clinical Research Unit, Respiratory Hospital

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Persahabatan Hospital has emerged as one of Indonesia's leading hospitals with a particular strength in respiratory health. Within the framework of the 2020–2024 strategic plan, the institution introduced flagship initiatives aimed at both clinical innovation and public health impact. The development of a lung transplantation program marks a milestone, as it represents the first and only service of its kind in the country. This initiative is projected to not only address the growing burden of end-stage lung disease domestically but also to elevate the hospital's position within the global landscape of advanced respiratory care. Complementing this program is the establishment of the Women and Children's Respiratory Center, which was designed to improve healthcare standards by focusing on maternal and child health indicators such as life expectancy, infant mortality, and childhood nutrition. The center is further distinguished by its adoption of the green hospital concept, aligning clinical goals with sustainable healthcare practices.¹

The institutional vision positions Persahabatan Hospital as a world-class hospital in respiratory services with a commitment to sustainable growth. Its mission encompasses multifaceted strategies, including the enhancement of patient satisfaction through improved facilities and reduced waiting times, the advancement of human resource capacity through equitable remuneration and career development, and the integration of standardized clinical guidelines and medical research. Furthermore, modernization efforts emphasize digital transformation in hospital management, while national health equity is supported through capacity building of regional hospitals. Finally, the hospital underscores the importance of education and research in fostering evidence-based practices, thereby reinforcing its role as a center for both clinical excellence and academic contribution in the field of respiratory health.¹

In line with its vision to integrate patient care with scientific advancement, Persahabatan Hospital identified the establishment of a Clinical Research Unit (CRU) as a critical step toward fostering research innovation, ensuring ethical and

standardized clinical trials, and translating evidence into improved clinical practices. The Clinical Research Unit (CRU) was established based on the Policy of the President Director of Persahabatan Hospital No. TK.03.02/D.IV/413/2024 concerning the appointment of the Head Candidate for CRU, thereby mandating the formation of the unit. The development of the Clinical Research Unit is also grounded in Law No. 17 of 2023 on Health, the Policy of the Minister of Health No. HK.01.07/Menkes/1458/2023, the Policy of the Director General of Advanced Health Services No. HK.02.02/D/1782/2025, and the Policy of the President Director of Persahabatan General Hospital No. HK.02.03/D.XX/7851-4/2024. In which collectively provide the legal and administrative foundation for the unit's establishment. The unit primarily focuses on integrating cutting-edge technology with clinical care, supporting rigorous clinical studies that adhere to international standards such as ICH-GCP. By providing facilities including specialized testing rooms, laboratories, and drug storage, the CRU ensures an infrastructure that supports comprehensive research activities. It manages clinical trials, fosters data integrity, and promotes ethical research practices, thereby driving innovations in healthcare treatments and protocols.

METHODS

This narrative review was developed using official documents and credible institutional sources related to the establishment and governance of the Clinical Research Unit (CRU) at Persahabatan Hospital. Information was gathered from key regulatory documents, such as Law No. 17 of 2023 on Health, Minister of Health Decree No. HK.01.07/Menkes/1458/2023, Director General Decree No. HK.02.02/D/1782/2025, and the Organizational Structure and Work Procedures of the CRU. Complementary institutional references included the 2025 Semester I CRU Performance Report and the official Persahabatan Hospital website. Supporting literature such as the systematic review by Wang et al. (2025) on the impact of CRUs on research performance was also incorporated. All

materials were reviewed and synthesized to identify core themes concerning the CRU's structure, functions, coordination, and collaborative roles within the hospital system. The information was analyzed descriptively to provide an integrated overview of how the CRU at Persahabatan Hospital develops, operates, and contributes to advancing clinical research and innovation at Persahabatan Hospital. This descriptive study was approved by the Ethical Committee of Persahabatan Hospital (No. 0223/KEPK-RSUPP/11/2025).

DISCUSSION

Establishment and Strategic Development of the Clinical Research Unit at Persahabatan Hospital

The establishment of the Clinical Research Unit (CRU) at Persahabatan Hospital represents a key milestone in developing Indonesia's capacity for evidence-based clinical research. As one of Indonesia's leading respiratory centers, RSUP Persahabatan recognized the need for formal research capable of development, coordination, and governance of clinical studies in line with global and national standards.¹

Before the CRU was established, research activities were coordinated under the Health Technology Development and Research Unit (Instalasi Pengembangan dan Penapisan Teknologi Kesehatan dan Penelitian, IPPTKP) as outlined in the 2023 Organizational Structure (SOTK) of Persahabatan Hospital. The IPPTKP primarily managed internal research, health technology assessment, and innovation screening within the hospital. However, as Indonesia's research governance evolved, with new policies mandating Good Clinical Practice (GCP) compliance, national research registration, and integration into the Indonesia Clinical Research Center (INA-CRC) network, the hospital recognized the need for a more comprehensive, regulated research structure.²

Consequently, the IPPTKP was formally restructured into the CRU through the Decree of the President Director of RSUP Persahabatan No. TK.03.02/D.IV/413/2024, aligning with the Director

General of Health Services Decree No. HK.02.02/D/1782/2025. This transition marked the hospital's shift from an internally focused innovation office to a comprehensive research governance center overseeing clinical trials, multicenter studies, and international collaborations. The change also ensured that all institutional research activities complied with updated national regulations and Good Clinical Practice (GCP) standards.^{3,4}

The creation of the CRU also aligns with the Minister of Health Decree No. HK.01.07/Menkes/1458/2023 on the establishment and governance of Clinical Research Units, which serves as the operational blueprint for hospitals across Indonesia seeking to formalize their research infrastructure. This regulation requires that each CRU be institutionally authorized by the hospital director and equipped with clear functions covering research coordination, ethics management, quality control, and innovation dissemination.⁵ At Persahabatan Hospital, these principles were implemented through the Director General of Advanced Health Services Decree No. HK.02.02/D/1782/2025, which further provides technical guidance on clinical trial management, coordination with the Indonesia Clinical Research Center (INA-CRC), and compliance with Good Clinical Practice (GCP).⁶ Complementing these national directives, the hospital enacted its own internal policy — Decree No. HK.02.03/D.XX/7851-4/2024 — outlining the organizational structure and standard operating procedures of the CRU. This framework defines the CRU's subunits, functional responsibilities, and accountability mechanisms, ensuring operational transparency and regulatory consistency.⁴

Strategically, the formation of the CRU reflects Persahabatan Hospital's institutional vision of becoming a world-class respiratory center hospital that integrates clinical care, education, and research. Within this vision, the CRU serves as a structural platform to translate scientific discovery into clinical application, facilitating innovation in respiratory medicine, infectious disease management, and health technology development. The unit also

supports major hospital initiatives such as the Lung Transplantation Program and the Women and Children's Respiratory Center by providing the ethical, scientific, and regulatory infrastructure required for multidisciplinary and translational research.¹

Furthermore, the CRU's strategic development is closely tied to national goals for academic health system strengthening. By aligning its programs with the INA-CRC network, the CRU at Persahabatan contributes to the national agenda of decentralizing clinical research and enhancing Indonesia's global competitiveness in biomedical science. This alignment allows the hospital to participate in multicenter trials, share research data, and adopt standardized methodologies that meet both local and international expectations for quality and transparency.

In essence, the establishment of the CRU at Persahabatan Hospital represents more than an administrative expansion, it marks a transformative shift toward institutionalized research governance, collaborative innovation, and sustainable scientific growth. Through its strategic design and alignment with national health research policies, the CRU has become a cornerstone for advancing ethical, high-impact, and globally recognized clinical research within Indonesia's respiratory health system.

Core Functions and Operational Scope of the Clinical Research Unit

The Clinical Research Unit (CRU) at Persahabatan Hospital serves as a fundamental for promoting innovation and improving healthcare through research. Its main purpose is to drive the advancement of health technology by supporting well-designed clinical studies and developing clear guidelines to ensure that new treatments are applied safely and effectively in clinical practice. The unit takes an active role in conducting research aimed at finding better and more efficient ways to treat patients, while also ensuring that every participant receives the best possible care throughout the study process. At the same time, the CRU is committed to producing accurate and reliable data that can be

shared with sponsors and research collaborators to support scientific progress. Beyond research activities, the unit is also responsible for managing and coordinating the entire clinical research process within the hospital, ensuring that each step follows ethical standards and national regulations.¹

The Clinical Research Unit (CRU) at RSUP Persahabatan functions as a central hub supporting clinical innovation, ethical compliance, and the advancement of medical science. It facilitates both investigator-initiated and sponsor-driven clinical trials, fostering collaboration across hospital departments to generate high-quality evidence relevant to improved patient care and therapeutic progress. The research scope of the Clinical Research Unit (CRU) at RSUP Persahabatan encompasses a broad and comprehensive range of study types and thematic areas. These include observational studies such as cross-sectional (potong lintang), cohort, case studies, retrospective analyses, diagnostic studies, prognostic research, longitudinal assessments, and investigations into the pathophysiology of diseases. Additionally, CRU conducts experimental and clinical trials aimed at evaluating the efficacy and safety of new drugs, adding new indications to existing medications, assessing biomedical and diagnostic devices, and testing vaccines. The unit also engages in post-marketing studies to monitor long-term safety and efficacy and explores innovative treatment modalities. Beyond these, the CRU is involved in emerging research fields including biotechnology, DNA analysis, and gene therapy, addressing cutting-edge challenges in molecular medicine. This wide-ranging research agenda supports RSUP Persahabatan's mission to advance healthcare through rigorous, ethical, and impactful clinical research.^{1,4}

To support these activities, CRU Persahabatan maintains advanced facilities. These include dedicated clinical trial rooms ensuring safe and structured interventions; epidemiology rooms for population health analysis; secure document storage for safeguarding protocols and research data; basic laboratories for sample processing; controlled drug

storage areas; specialized spaces for biospecimen collection; confidential informed consent rooms; and advanced laboratories for biomedical, genome, and stem cell research. This infrastructure ensures research integrity, participant safety, and regulatory compliance.¹

Functionally, the unit streamlines clinical trial implementation by managing recruitment, data collection, and regulatory documentation. It collaborates closely with the hospital's Ethics Committee to maintain rigorous research governance and protect participant welfare. Moreover, CRU Persahabatan invests in continuous education by conducting training and seminars for investigators, research nurses, and study managers, thereby promoting regulatory adherence and research excellence. The integration of advanced IT systems such as electronic health records and electronic data capture platforms further enhances data accuracy and accessibility.⁴

Governance Structure and Collaborative Relations of the Clinical Research Unit at Persahabatan Hospital

The Clinical Research Unit (CRU) at Persahabatan Hospital plays a central role in ensuring that all research activities are carried out effectively, ethically, and in accordance with institutional and national standards. It works in close coordination with research coordinators, investigators, and the Health Research Ethics Committee (KEPK) to supervise study planning, implementation, and monitoring. The CRU also collaborates across hospital divisions to strengthen research capacity, promote innovation, and integrate research activities into the hospital's continuous quality improvement initiatives.⁴

The CRU at Persahabatan Hospital operates under the Directorate of Human Resources, Education, and Research, reflecting the hospital's commitment to integrating scientific advancement with quality healthcare and education. Within this framework, the CRU acts as a dedicated unit that manages, coordinates, and oversees clinical research activities across the institution. Its structure

consists of three interconnected subunits: Administration; Development, Implementation, and Management; and Monitoring and Evaluation.⁴

The Administration Subunit manages documentation and coordination, while the Development and Implementation Subunit manage research initiation, innovation, and compliance. The Monitoring and Evaluation Subunit ensures adherence to study protocols and research quality through regular reviews, fostering integrity and continuous improvement.⁴ Through this integrated structure, the CRU functions efficiently and transparently while fostering collaboration and innovation in clinical research. This organization reinforces Persahabatan Hospital's role as a leading institution for ethical, high-quality, and impactful research that advances patient care and respiratory medicine.

Collaboration with external partners also plays a crucial role in advancing the hospital's research agenda. The CRU collaborates with national agencies such as the Indonesia Clinical Research Center (INA-CRC), the Ministry of Health (MoH), and the National Agency of Drug and Food Control (BPOM) to ensure regulatory alignment, ethical clearance, and feasibility assessment for multicenter and international clinical trials. The hospital also partners with the Faculty of Medicine, Universitas Indonesia (FKUI) through the Academic Health System (AHS) framework integrating education, research, and clinical care within a unified framework. This collaboration strengthens scientific mentorship and ensures that research outcomes directly support evidence-based policy and medical education.

On the international front, Persahabatan Hospital has formalized collaborations with leading institutions across multiple countries to enhance its global research presence. In Japan, the hospital works with Toranomon Hospital and the National Cancer Center Japan on joint studies in sleep medicine, oncology, and advanced respiratory care. Through partnerships with Hiroshima University Hospital and JICA (Japan International Cooperation Agency), Persahabatan has also expanded

academic exchanges and institutional capacity development. In South Korea, cooperation with Gangnam Severance Hospital focuses on thoracic surgery and clinical education, while in Singapore, collaboration with the National University Hospital (NUH) supports investigator meetings and training for multicenter trials. Meanwhile, engagement with Taiwan University Hospital has fostered collaboration in pulmonary and infectious disease research.

Persahabatan Hospital partners with Suzhou Abogen Biosciences (China) and PT Etana Biotechnologies Indonesia for the development of respiratory vaccines, and with ORCA Biotek and PT Arfiko Duta in creating the M-Gene TB PCR Open System Kit—an innovative diagnostic platform designed to detect tuberculosis and drug resistance mutations. This product development leverages the national PCR infrastructure established during the COVID-19 pandemic, representing a concrete outcome of translational collaboration between the hospital and the biotechnology industry.

All joint research activities are governed by formal Clinical Trial Agreements (CTAs) to ensure clarity, ethical integrity, and data protection. Collaborations involving hospitals, Contract Research Organizations (CROs), or internal units such as the Health Technology Assessment (HTA) team undergo ethical review by accredited committees. This structured governance reinforces the CRU's commitment to transparency, regulatory compliance, and research excellence at Persahabatan Hospital.

Ethical Governance, Regulation, and Quality Assurance

The Clinical Research Unit (CRU) at Persahabatan Hospital operates under a comprehensive framework that integrates ethics, regulation, and quality standards defined by Indonesia's national health research system. Its foundation is built on Law No. 17 of 2023 on Health, which emphasizes that all forms of medical and health research must be conducted responsibly—guided by science, ethical integrity, and respect for human dignity. This law establishes the

government's responsibility to ensure that clinical research not only protects participants but also promotes innovation and contributes to better public health outcomes.³

Further guidance is provided through the Minister of Health Decree No. HK.01.07/Menkes/1458/2023, which sets out the requirements for the establishment and governance of Clinical Research Units in hospitals. It mandates that each CRU must have a defined organizational structure, authorized by the hospital director, with responsibilities that include research coordination, ethical supervision, quality management, and the translation of findings into clinical practice. This decree also requires adherence to Good Clinical Practice (GCP) principles and alignment with the ethical standards reviewed by the Health Research Ethics Committee (Komite Etik Penelitian Kesehatan, KEPK). Together, these standards ensure that patient safety, informed consent, and data confidentiality remain central to every study.⁵

Operational details are further refined in the Director General of Advanced Health Services Decree No. HK.02.02/D/1782/2025, which provides practical guidance for managing clinical trials. It outlines steps for research submission, ethics review, feasibility assessment, and study monitoring, and highlights the need for coordination among CRUs, the Indonesia Clinical Research Center (INA-CRC), BPOM, and the Ministry of Health. This coordination ensures that all research activities comply with both national regulations and international best practices.⁶

Within Indonesia's evolving clinical research ecosystem, the Indonesia Clinical Research Center (INA-CRC) functions as a central coordinating platform linking the Ministry of Health with Clinical Research Units (CRUs) established in major hospitals. Formed under the Director General Decree No. HK.02.02/D/1782/2025, INA-CRC plays a pivotal role in standardizing the conduct of clinical research nationwide. It provides technical guidance, facilitates sponsor engagement, and ensures that studies conducted at institutional CRUs adhere to both national regulations and internationally accepted

ethical and scientific standards.⁶

At Persahabatan Hospital, collaboration with INA-CRC strengthens the operational capacity of the CRU in multiple domains, including clinical trial management, feasibility assessment, and data harmonization. This partnership also enables the hospital to participate in multicenter studies, optimize research resources, and contribute to Indonesia's broader strategy for advancing evidence-based medicine. Through this interconnected system, the CRU at Persahabatan operates not only as a hospital-based research entity but also as a strategic node within the national infrastructure for high-quality and ethically responsible clinical research.

Beyond its national integration, the CRU Persahabatan is also aligned with the international framework of clinical research governance. Collaborative projects involving global institutions or industry sponsors are carried out in accordance with the International Council for Harmonisation – Good Clinical Practice (ICH-GCP) guidelines, alongside other universally recognized ethical standards. These frameworks uphold the integrity of research design, data collection, and participant protection while promoting transparency and accountability. For studies involving international partners, all protocols are reviewed and approved by an accredited Health Research Ethics Committee (KEPK) and the relevant national regulatory authorities, as stipulated by the Director General Decree No. HK.02.02/D/1782/2025.⁶

By adhering to these interconnected national and international standards, the CRU Persahabatan reinforces its role as a credible and compliant institution within Indonesia's clinical research landscape. Its integration into both the INA-CRC network and global research systems exemplifies a commitment to scientific excellence, ethical rigor, and collaborative innovation aimed at improving health outcomes locally and beyond.

At the institutional level, the Organizational Structure and Work Procedures (SOTK CRU), Policy of the President Director of Persahabatan General Hospital No. HK.02.03/D.XX/7851-4/2024, translates these national standards into operational practice at

Persahabatan Hospital. It defines specific roles for administration, research management, and monitoring units, each governed by clear Standard Operating Procedures (SOPs). These internal mechanisms strengthen quality assurance by ensuring consistent documentation, adherence to research protocols, and evaluation of study performance. The Monitoring and Evaluation Subunit plays a vital role in maintaining research integrity through regular oversight, audits, and continuous improvement initiatives.⁴

By following these legal and institutional standards, the CRU at Persahabatan Hospital upholds the highest ethical and scientific benchmarks in clinical research. Its integrated system of governance, regulation, and quality control not only safeguards participants and data integrity but also reinforces the hospital's position as a trusted center for responsible and innovative health research in Indonesia.

Performance and Research Outcomes

Since its establishment, the Clinical Research Unit (CRU) at Persahabatan Hospital has significantly strengthened the hospital's research capacity, scientific quality, and collaboration network. The 2025 mid-year report recorded steady growth in research activity and interdepartmental coordination, reflecting its role as the central hub for clinical research. Throughout the first half of 2025, the CRU facilitated feasibility assessments for multiple clinical trials, coordinated protocol submissions for investigator-initiated studies, and provided regulatory support to ensure compliance with Good Clinical Practice (GCP) and Ministry of Health (MoH) standards. These activities not only strengthened institutional readiness for multicenter and international research participation but also fostered a culture of regulatory awareness among clinicians and research staff.⁷

In addition to administrative and operational achievements, the CRU has contributed directly to scientific productivity. Several research initiatives have advanced through the CRU's structured oversight. The unit's facilitation of standardized

documentation, data management, and quality control procedures has improved data reliability and accelerated research timelines. According to the 2024 and 2025 institutional performance data, Persahabatan Hospital consistently achieved and even surpassed its research targets, with the number of completed and ongoing studies exceeding projections. Performance data show that total research exceeded annual targets, highlighting the CRU's tangible impact on productivity. This progress mirrors global findings, such as those reported by Wang et al. (2025), which emphasize that hospitals equipped with structured CRUs exhibit higher research throughput, improved methodological rigor, and enhanced multidisciplinary engagement. These outcomes underscore how organizational investment in research infrastructure yields tangible improvements in both scientific and institutional performance.⁸

Figure 1 shows that research projects rose from 50 in 2024 to 67 by mid-2025, exceeding institutional targets more than threefold.⁷ This pattern reflects the conclusions of the systematic review by Wang et al. (2025), who reported that hospitals with dedicated CRU infrastructure experience substantial growth in the number of clinical studies conducted. Wang et al emphasized that the establishment of dedicated CRUs leads to a measurable increase in research productivity, data quality, and investigator participation across healthcare institutions.⁸

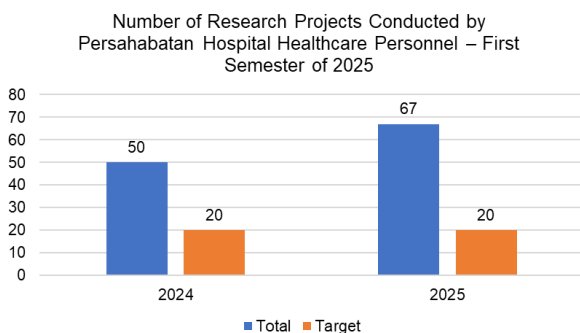


Figure 1. Total number of research projects conducted versus institutional research targets at Persahabatan Hospital in 2024 and 2025

In parallel with this increase in research activity, Persahabatan Hospital also demonstrated consistent progress in scientific dissemination at both national and international levels. As illustrated in

Figure 2, the total number of national publications rose from 25 in 2022 to 34 in 2023, followed by 30 in 2024 and 6 in mid-2025. Although 2025 figures represent only a mid-year snapshot, the overall trend highlights stable productivity and sustained institutional commitment to national research engagement. Most publications were featured in Sinta-accredited journals and covered topics such as pulmonology, oncology, infectious diseases, and health management — aligning with the hospital's clinical priorities. The CRU's establishment improved manuscript preparation and submission workflows, shortened review times, and ensured ethical and methodological compliance for national-level publications.⁹

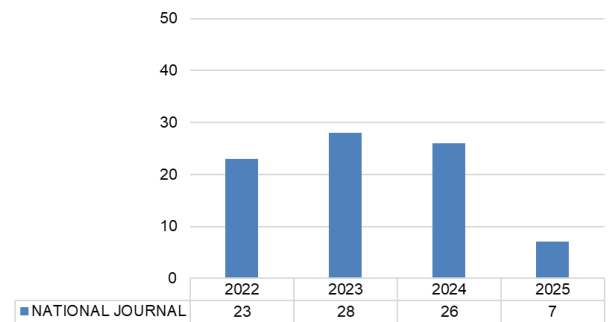


Figure 2. Total number of national publications from Persahabatan Hospital, 2022-2025.

Figure 3 presents the trend of international journal publications from 2022 to 2025, categorized by Scimago Journal Rank (Q1–Q4). The total number of international publications peaked at 42 in 2023, followed by 28 in 2024 and 7 in mid-2025, reflecting a strategic transition from quantity-driven output toward more selective, high-impact dissemination. The proportion of publications in Q1 and Q2 journals remained consistent, indicating sustained improvement in research visibility and quality. This pattern corresponds with the hospital's reorganization of research governance under the CRU, which emphasizes quality assurance, ethical integrity, and adherence to international publication standards.⁹

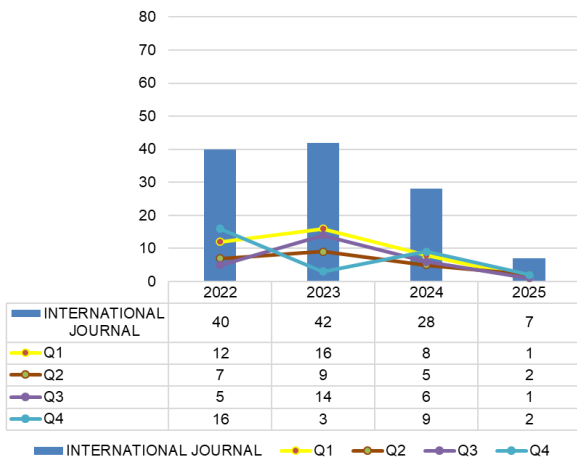


Figure 3. Trend of international publications from Persahabatan Hospital by Scimago Journal Quartile (Q1-Q4), 2022-2025.

The CRU also serves as an academic and training hub, supporting capacity building for investigators, coordinators, and research nurses through workshops and technical assistance. In parallel, data from Persahabatan Hospital's research reports and journal publication archives (2022–2025) show a consistent increase in national and international publications, particularly in respiratory and infectious disease research, reflecting strengthened academic performance following the CRU's establishment. This approach aligns with Persahabatan Hospital's strategic vision of fostering a sustainable research ecosystem that integrates education with innovation. By combining administrative support with technical expertise, the CRU ensures that clinical studies conducted within the hospital not only meet ethical and regulatory standards but also produce meaningful scientific contributions that inform clinical practice.⁷

The achievements documented in the 2025 performance review highlight the CRU's transition from a developing unit to a mature institutional research hub. Its operational efficiency, data governance systems, and cross-sector collaboration with the Indonesia Clinical Research Center (INACRC) collectively strengthen its position as a key driver of evidence-based medicine in Indonesia. The steady rise in total research numbers and publication outputs not only validates the CRU's effectiveness but also reflects Persahabatan Hospital's growing role as a model for integrated clinical research governance and translational science in Indonesia.

As the unit continues to refine its processes and expand research partnerships, the CRU Persahabatan is poised to play a leading role in advancing translational and respiratory research at both national and international levels.⁷

Translational Research and Innovation at Persahabatan Hospital

The Clinical Research Unit (CRU) at Persahabatan Hospital serves as a cornerstone for translational research that bridges laboratory innovation with clinical application, particularly in respiratory and infectious diseases. Translational research within the hospital aims to accelerate the movement of discoveries from bench to bedside, ensuring that breakthroughs in genomics, diagnostics, and therapeutics can be applied effectively in clinical care. By embedding ethical governance, scientific rigor, and multidisciplinary collaboration into every project, the CRU provides a systematic framework that enables research outcomes to generate measurable clinical and public health benefits.⁹

A key milestone in Persahabatan Hospital's translational research journey is its involvement in the Biomedical and Genome Science Initiative (BGSi), where it serves as one of Indonesia's sequencing hubs for tuberculosis and respiratory pathogens. The program aims to strengthen national genomic surveillance and enable precision medicine by identifying genetic variations that influence disease transmission, resistance, and treatment response. Through the CRU's oversight, the hospital ensures data quality, bioethical compliance, and harmonization with national health databases. This initiative contributes not only to local patient care but also to Indonesia's broader goal of integrating genomics into public health decision-making. In parallel, the hospital participates in the M72/AS01E tuberculosis vaccine trial, a global effort to evaluate the safety and efficacy of a next-generation TB vaccine. The CRU facilitates this trial by coordinating ethical review, participant monitoring, and data reporting, ensuring Indonesia's meaningful contribution to international TB control and vaccine

development.⁹

Persahabatan Hospital has also established a one-stop service for early lung cancer detection, combining imaging, cytopathology, and biomolecular tumor-marker analysis in a single integrated workflow. This translational model directly links laboratory findings with clinical diagnostics, improving early detection rates and allowing for more timely therapeutic intervention. Complementing these diagnostic advances, the hospital leads Indonesia's first lung transplantation program, a multidisciplinary initiative translating global best practices in thoracic surgery, immunology, and post-transplant management into local clinical standards. The CRU supports this program by ensuring ethical governance, data documentation, and outcome monitoring, positioning Persahabatan as a reference center for complex respiratory interventions. Additionally, innovations such as cryobiopsy for lung cancer diagnosis, introduced through interventional pulmonology training and clinical studies, demonstrate the hospital's role in translating procedural research into safer, less invasive diagnostic methods.

Collectively, these initiatives illustrate how Persahabatan Hospital, through its Clinical Research Unit, embodies the principles of translational medicine—transforming scientific discovery into tangible healthcare improvements. By aligning research activities with national and global health priorities, the CRU contributes to strengthening Indonesia's capacity in genomic innovation, vaccine development, precision diagnostics, and advanced respiratory therapeutics. Ultimately, this integrated approach reinforces Persahabatan's position as a leader in evidence-based, patient-centered translational research within Indonesia's evolving health ecosystem.

Impact of Clinical Research Units on Research Quality and Productivity

The establishment of Clinical Research Units (CRUs) has a profound impact on improving the quality, productivity, and sustainability of clinical research within hospital systems. The systematic

review by Wang et al. (2025) analyzed the role and effectiveness of CRUs across multiple healthcare and academic institutions and found that the introduction of structured research units consistently led to measurable improvements in research output, data quality, investigator engagement, and institutional performance. These impacts were not only quantitative, such as an increase in the number of trials and publications, but also qualitative, influencing the overall research culture, ethical compliance, and interdisciplinary collaboration within hospitals.⁸

One of the key findings from the review was that CRUs substantially enhance research efficiency and productivity. Institutions with dedicated CRUs experienced an increase of approximately 5 to 23 new clinical studies per year, reflecting the capacity of these units to streamline administrative procedures, accelerate ethics approvals, and facilitate participant recruitment. Centralizing functions such as protocol submission, budgeting, regulatory documentation, and data monitoring allows clinical investigators to focus more on scientific aspects rather than administrative burdens. The presence of trained coordinators, data managers, and ethics officers within CRUs also ensures greater adherence to study timelines and regulatory standards, minimizing protocol deviations and delays.⁸

CRUs were also shown to have a strong influence on research quality and methodological rigor. According to the review, hospitals with active CRUs demonstrated higher rates of Good Clinical Practice (GCP) compliance and fewer audit findings compared to institutions without them. This improvement stems from standardized operating procedures, regular internal audits, and capacity-building programs for research staff. The review highlighted that CRUs serve as learning environments, offering structured mentoring, research methodology training, and data management support, which empower clinicians and junior investigators to engage confidently in research activities. As a result, CRUs help foster a sustainable research ecosystem where quality assurance and

ethical integrity are institutionalized practices rather than administrative formalities.⁸

Beyond individual studies, CRUs contribute to institutional innovation and collaboration. The review noted that CRUs often act as central nodes for research networking, enabling hospitals to participate in multicenter or international clinical trials. This expanded collaboration increases an institution's visibility and strengthens its role in translational and precision medicine research. CRUs also promote cross-disciplinary integration, linking clinical departments, laboratories, and administrative divisions into a cohesive research system. The result is an institutional environment that values data-driven decision-making, innovation, and continuous quality improvement.⁸

Ultimately, the integration of CRUs into national hospitals such as Persahabatan represents a transformative model for health research governance. It illustrates how institutional structures, when guided by clear regulatory frameworks and supported by technical networks like INA-CRC, can generate measurable outcomes that extend beyond publication metrics. These include improved patient safety, accelerated access to innovative therapies, stronger ethical compliance, and the development of evidence that informs national health policy. In this way, the CRU Persahabatan not only aligns with the findings of Wang et al. but also embodies the broader vision of sustainable, globally connected, and high-quality clinical research that drives better health outcomes for Indonesia's population.⁸

CONCLUSION

The establishment of the Clinical Research Unit (CRU) at Persahabatan Hospital marks a strategic milestone in advancing Indonesia's clinical research capacity, particularly in respiratory medicine. The unit has institutionalized ethical governance, quality assurance, and scientific innovation within the hospital, creating a structured system that integrates clinical care, research, and technology. Through its specialized subunits, the CRU ensures adherence to Good Clinical Practice

(GCP) standards while fostering continuous improvement and professional development.

In alignment with the Indonesia Clinical Research Center (INA-CRC) and the Ministry of Health, the CRU strengthens national clinical trial capacity, harmonizes research processes, and promotes participation in multicenter and international studies. As a result, Persahabatan Hospital has emerged as a leading hub for high-quality, ethically sound, and policy-relevant clinical research in Indonesia.

Evidence from the systematic review by Wang et al. (2025) underscores the broader significance of CRU implementation, indicating that hospitals with dedicated research units experience measurable improvements in research output, ethical compliance, and institutional performance. The CRU Persahabatan exemplifies these findings in practice. By consolidating administrative, technical, and ethical functions within a unified framework, it has enhanced efficiency, reduced procedural delays, and promoted high-quality, ethically sound research outcomes. Furthermore, it fosters an institutional culture that values innovation, accountability, and collaboration-principles essential for the sustainability of research excellence in Indonesia's health system.

Overall, the CRU at Persahabatan Hospital stands as a model for integrating research governance with clinical service delivery in a way that advances both institutional and national health priorities. Its development marks not only an institutional milestone but also a critical contribution to Indonesia's broader vision of achieving global competitiveness in biomedical research. As the CRU continues to expand its capacity and partnerships, it will play an increasingly vital role in shaping the future of clinical research, driving innovation, ensuring patient safety, and strengthening the foundation for evidence-based respiratory healthcare.

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CONFLICT OF INTEREST

The authors declare no conflict of interest in this research

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