



Siriraj Institute of Clinical Research

2019-2022

**BUSINESS
REPORT**

“Your success is our success.”

 WWW.SICRES.ORG

ABOUT US

The Siriraj Institute of Clinical Research (SICRES) is an academic clinical research institute that operates under the Faculty of Medicine Siriraj Hospital, Mahidol University. Our mission is to conduct and support clinical research to transform patient care, improve human health, and better the community. Our vision is to become the most trusted academic clinical research organization in Southeast Asia.

Our goals are to:

- (1) develop a vibrant and patient-focused research program,
- (2) sustain collaboration with our research partners,
- (3) pursue cost-effective services valuable to our clients, and
- (4) provide effective and timely communications of our findings.

We conduct cost-effective clinical research at international standards and provide full-service clinical trial design and management. We offer a suite of capacities and services, including: experienced principal investigators and highly-trained clinical research staff; phase I-IV clinical trial design and management; bioequivalence studies, feasibility surveys, as well as safety and efficacy evaluations; integrated database development and biostatistical analyses; research staff training and development; high-impact medical publications and presentations; patient safety and adverse event monitoring; access to national and international research networks; and grant application support.

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MISSION & VISION



Our mission is to be the most trusted academic clinical research organization in Southeast Asia.

We seek to conduct and support clinical research trials to transform patient care, improve human health, and better the community.

GOALS

- **A vibrant and patient-focused research program**
- **Sustained collaboration with partners**
- **Cutting edge research that advances clinical practice**
- **Cost-effective services for our clients**
- **Effective and timely communication of our findings**



POLICIES

- **SICRES is committed to the management and conduct of high quality clinical research.**
- **SICRES complies with international standards and regulatory requirement to ensure the safety and well-being of its participants during clinical research trials.**
- **SICRES complies with internal quality assurance systems through effective standard operating procedures (SOPs) and high-quality staff training.**
- **Corporate quality policies have also been established to serve as a framework for continuous improvement within the organization, management of quality objectives, and ensurance that quality expectations are met.**



DEAN'S MESSAGE

Appointed on October 1st, 2022



A handwritten signature in black ink, appearing to read 'Apichat A.', written over a light blue background.

Professor
Apichat Asavamongkolkul, MD.

Dean of
the Faculty of Medicine Siriraj Hospital
Mahidol University

"Over the past three years, the Siriraj Institute of Clinical Research (SICRES) has made significant strides in advancing clinical research. SICRES has become a beacon of excellence, fostering groundbreaking discoveries and innovative approaches in healthcare. Our collaborations, both locally and internationally, have paved the way for transformative advancements in patient care. We would like to thank all of the researchers, healthcare professionals, and support staff who contributed to the success of our institute. Your efforts have facilitated the development of our research institute and helped ensure the highest standards of research and patient-centric care."

FOMER DEAN'S MESSAGE

October 1st, 2014 - September 30th, 2022

"The Siriraj Institute of Clinical Research (SICRES) is an integral part of the Faculty of Medicine Siriraj Hospital and stands as a prominent institution for clinical research. Our primary goal is to advance clinical research for the betterment of humanity, rendering SICRES an essential component to achieving this mission. SICRES plays a key role in establishing domestic and international partners who share our dedication to enhancing patient healthcare. This collective effort, driven by skilled and knowledgeable personnel, can cultivate numerous clinical research projects that hold significant potential for future healthcare advancements."



A handwritten signature in black ink, appearing to read 'Prasit Watanapa', written in a cursive style.

Professor Emeritus
Prasit Watanapa, MD, Ph.D.

Former Dean of
the Faculty of Medicine Siriraj Hospital
Mahidol University

DIRECTOR'S MESSAGE

Appointed on November 1st, 2022



A handwritten signature in black ink, appearing to read "Winai Ratanasuwan".

Associate Professor
Winai Ratanasuwan, MD.

He specializes in infectious diseases and immunodeficiency at the Department of Preventive and Social Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University.

"SICRES supports the Faculty of Medicine Siriraj Hospital, Mahidol University across multiple dimensions per the requirements of principal investigators. Since our establishment three years prior, we have sought research partners both in Thailand and abroad as well as expanded our research facilities and their capabilities. This expansion will continue in the near future, as we construct additional wards to accommodate an ever-increasing volume and quality of research to ensure the betterment of Thai society and humanity as a whole."

FOUNDING DIRECTOR'S MESSAGE

August 20th, 2020 - October 31st, 2022

"SICRES is a rare example of a clinical research institute set up within a large public, tertiary care center in Thailand - namely, Siriraj Hospital. We both facilitate clinical research studies conducted at Siriraj Hospital as well as perform our own clinical research trials. We provide clinical research-related services to numerous entities, from contract research organizations (CROs) to sponsors, funding agencies, business owners, or principal investigators. We collaborate and network with other hospitals and research institutes within Thailand and overseas to form long-lasting partnerships. We seek to transform patient care from bench to bedside, facilitate medical advancements, and ensure the betterment of our global community."



Handwritten signature of Professor Kulkanya Chokephaibulkit, MD.

**Professor
Kulkanya Chokephaibulkit, MD.**

She specializes in pediatric infectious diseases at the Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University. She is the former and founding director of SICRES.



MANAGEMENT TEAM



Assoc. Prof. Winai Ratanasuwan, MD.

Director



Prof. Kulkanya Chokephaibulkit, MD.

Consultant



Assoc. Prof. Pongsakorn
Tantilipikorn, MD. Ph.D.

Vice Director,
Site Management
Organization (SMO)



Assoc. Prof. Somruedee
Chatsiricharoenkul, MD.

Vice Director,
Shared Services
(SS)



Assist. Prof. Suvimol
Niyomnaitham, MD. Ph.D.

Vice Director,
Clinical Research
Support (CRS)

FACILITIES

Our center consists of 740 square meters devoted to conducting high-quality phase I-IV studies under stringent safety measures.

Our facilities consist of:

- 32 standard hospital beds
- Five examination rooms, one treatment room
- A working space for CRAs to access patients' medical records
- 24-hour CCTV monitoring
- Two 2-8 °C, four -25 °C refrigerators, one -20 °C and three -80 °C freezers
- Four refrigerated centrifuges, multiple biosafety cabinets (BSL-2), as well as an emergency trolley equipped with a defibrillator and a 12-lead EKG

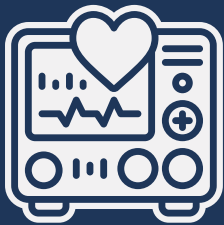




FACILITIES



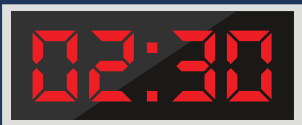
Two separated wards (16 beds each).



SICRES has emergency management equipment (e.g., defibrillators, EKG monitoring) on stand-by to ensure subject safety throughout the clinical trial process. Siriraj Piyamaharajkarun Hospital emergency teams are prepared to arrive within 4 minutes in instances of emergency.



Investigational products (IP) are stored in the pharmacy room, where storage conditions are tightly controlled per sponsors' and/or investigators' preferred national or international standards.



We have ten synchronized clocks that provide accurate timekeeping to ensure synchronized clinical trial procedures as well as effective and efficient communication and coordination between teams.



Specimens are further processed and stored in the specimen room, where calibration equipment are closely managed and fine-tuned for specific analyses.

Services



**Phase I-IV
Studies**



**Bioequivalence
Studies**



**Feasibility
Studies**



**Study Planning &
Budgeting**



**Contract
Management**



**Project
Management**



**IRB/IEC & Regulatory
Submission**



**Financial
Management**



**Investigational Product
Management**



**Sample
Management**



**Clinical Trial
Facilities**



**Data Management &
Statistical Analysis**



**Medical
Writing**



FIRST-IN-HUMAN TRIALS

SICRES is equipped with the facilities and staff to perform bioequivalence, pharmacokinetic, and phase I-IV clinical studies. We recently expanded our services by establishing infrastructure and implementing training regimens required to perform phase I first-in-human (FIH) trials. This guarantees standardized study compliance, that specific sponsor requirements are met, and participants' well-being and safety.



Blood draws are performed at specific time points per the synchronized clock schedule.

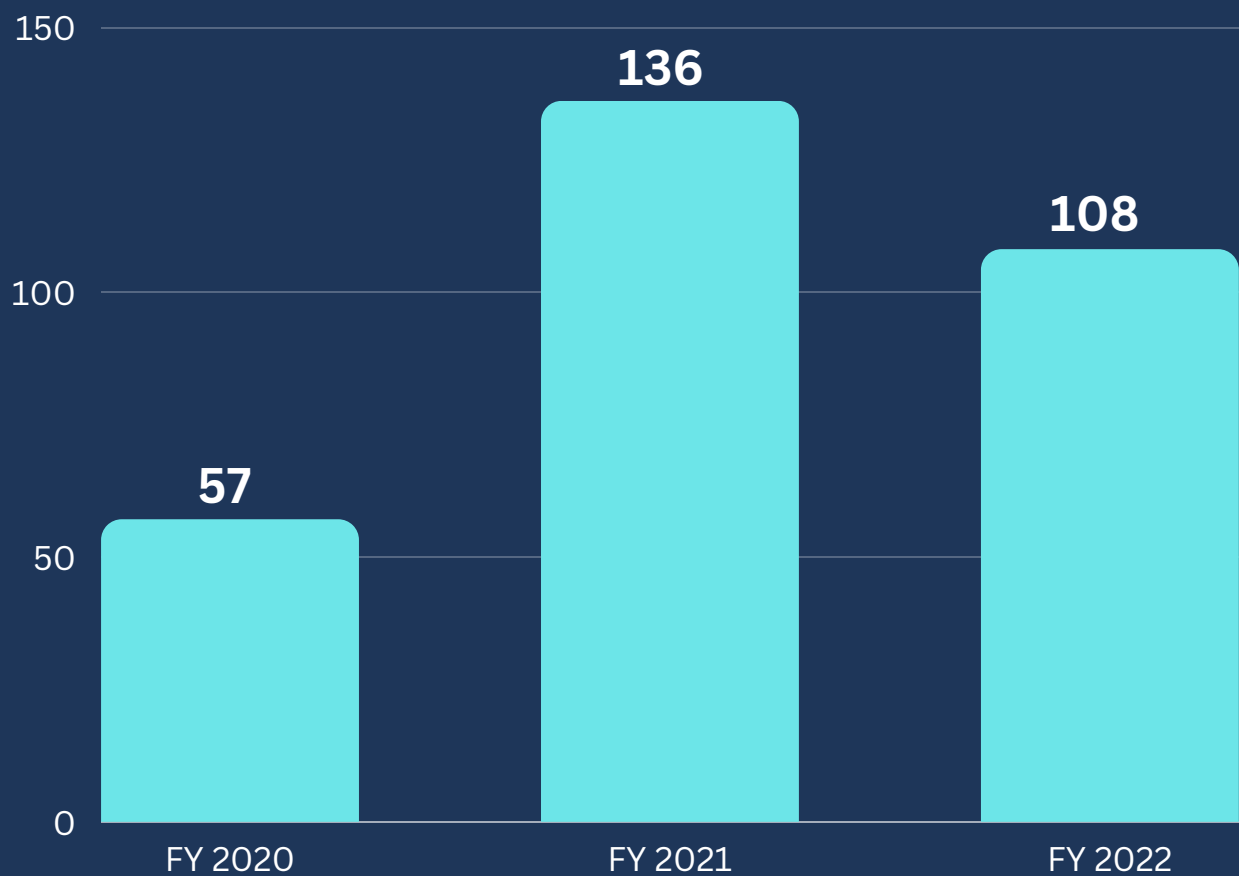
SICRES seeks to become one of the leading research centers capable of FIH trials, both in Thailand and across Southeast Asia.

FIH services adhere to our internal standard operating procedures (SOPs), the ISO 9001: 2015, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) Phase I Accreditation Scheme Guidance. Siriraj Piyamaharajkarun Hospital's agreement to collaborate, as signified through our joint Memorandum of Understanding (MOU), is highly important in instances of emergency. Despite our medical staff's advanced life support training, this agreement ensures that the hospital's Emergency Response (ER) teams will reach SICRES within 4 minutes.

The Siriraj Institutional Review Board (SiRB) Human Research Protection Unit was awarded full accreditation in December 2014 from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and has maintained its accreditation ever since. As an affiliate of the Faculty of Medicine Siriraj Hospital, this accreditation extends to clinical research trials performed and overseen by SICRES, guaranteeing that they adhere to international standards.

FEASIBILITY STUDIES BETWEEN FY 2020-2022

SICRES assists sponsors and clinical research organizations (CROs) evaluate the feasibility of conducting a clinical trial at the Faculty of Medicine Siriraj Hospital or within a particular geographical region. The overall objective is to optimize project completion in terms of timelines, targets, and costs. The feasibility studies between fiscal years (FY) 2020-22 are illustrated below:



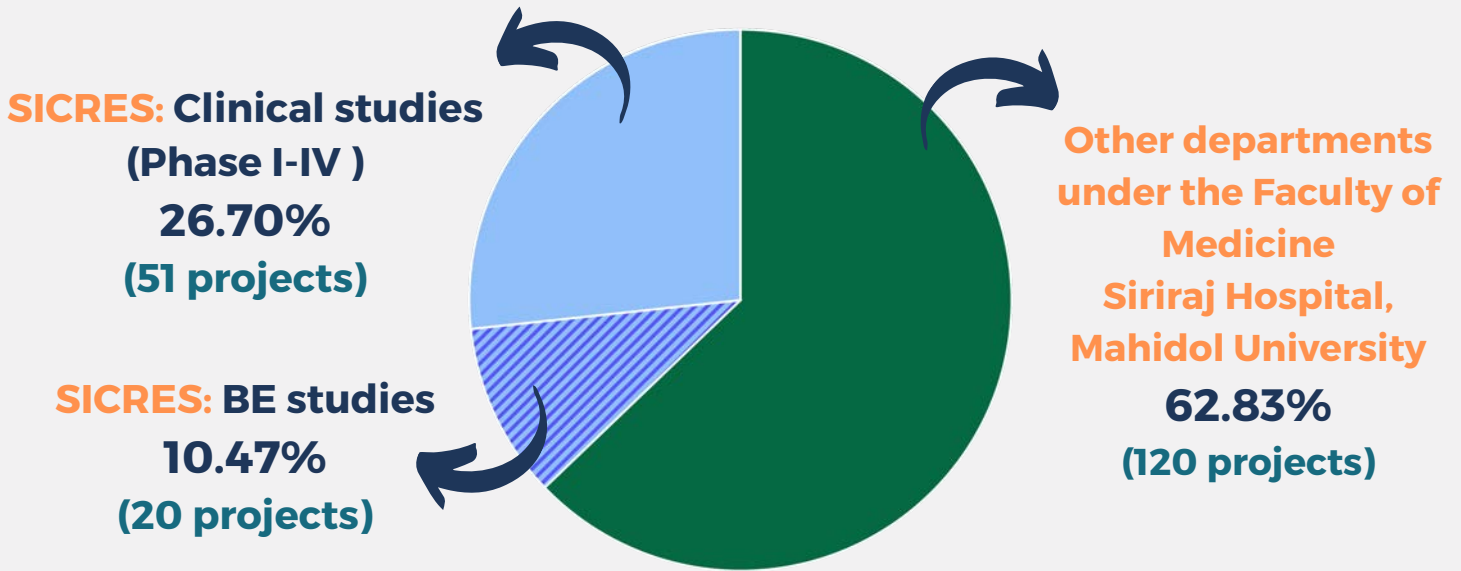


PROJECTS



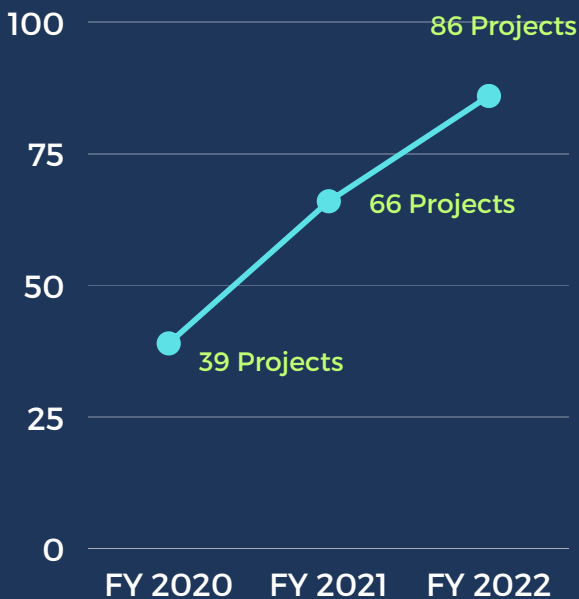
PROJECTS

CLINICAL TRIAL AGREEMENTS (CTAs) BETWEEN FY 2020-2022 BY ORGANIZATION (TOTAL OF 191 PROJECTS)



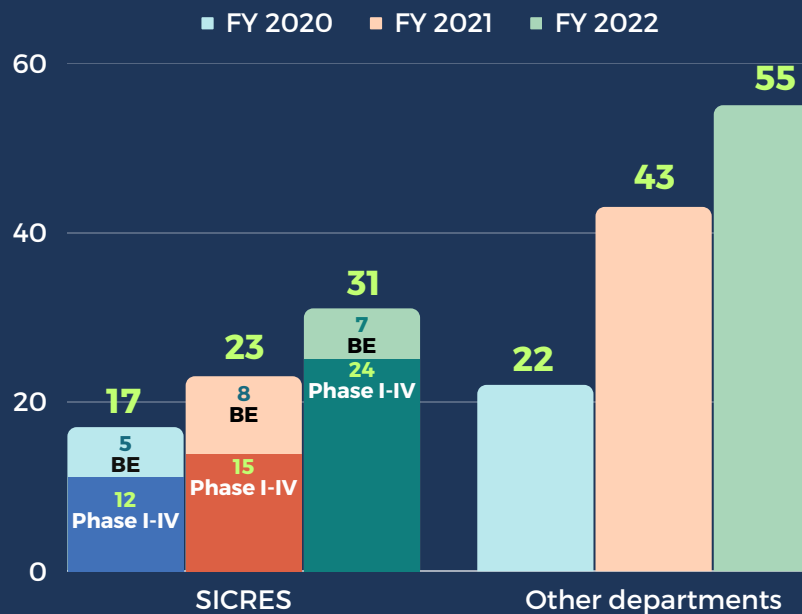
Number of research projects between FY 2020-2022
(Total of 191 projects)

Number of projects



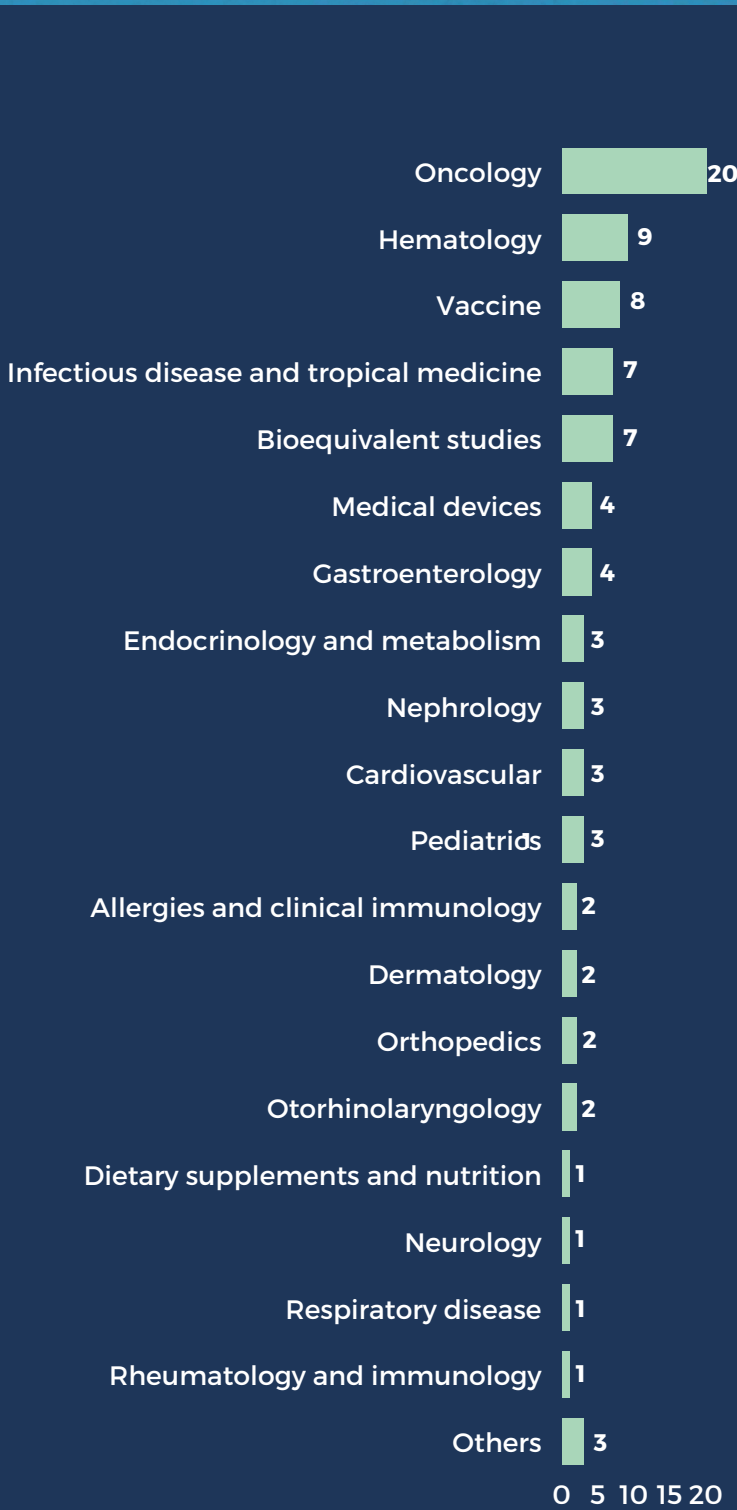
Number of research projects by organization between FY 2020-2022
(Total of 191 projects)

Number of projects

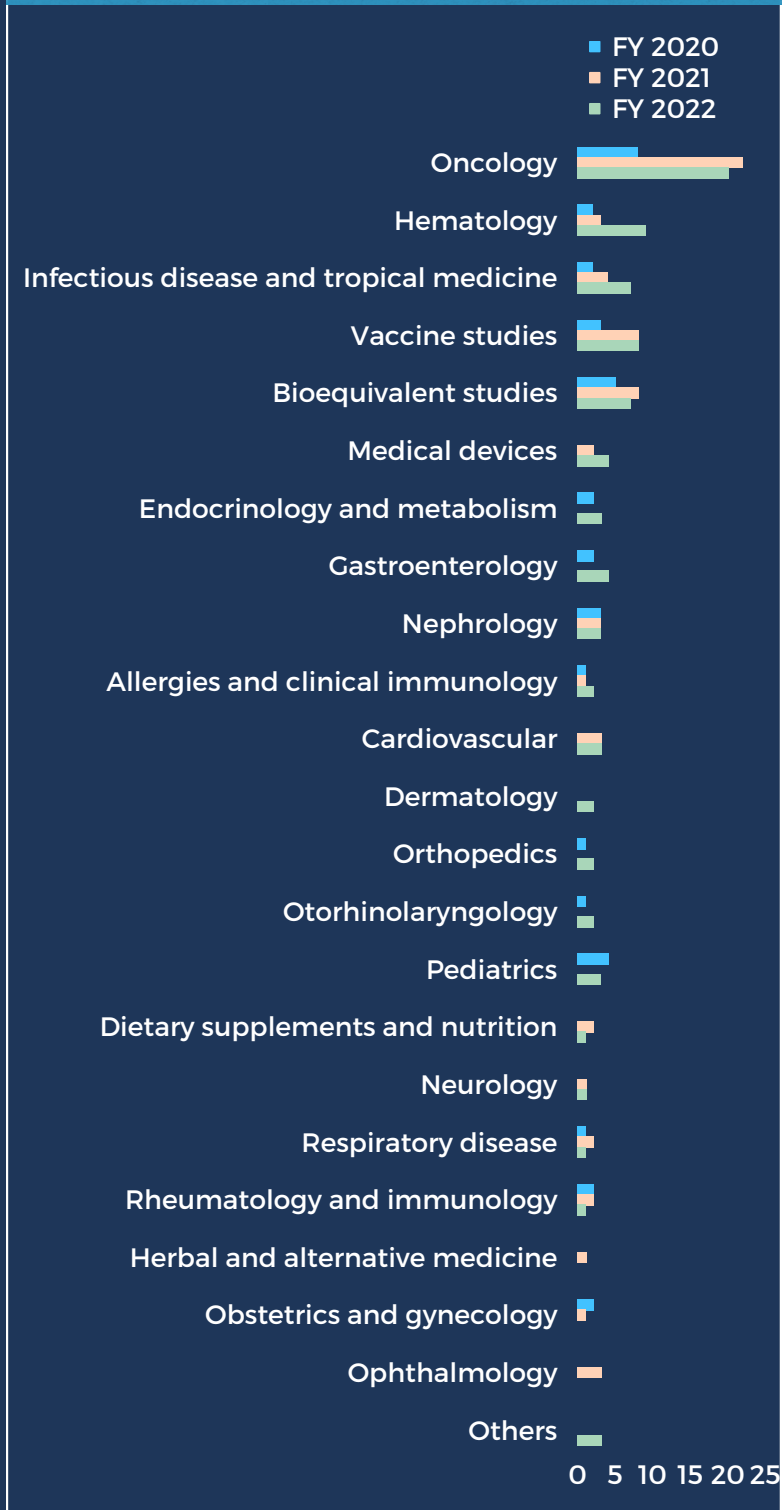


PROJECTS

Number of research projects in FY 2022 by therapeutic area (Total of 86 projects)



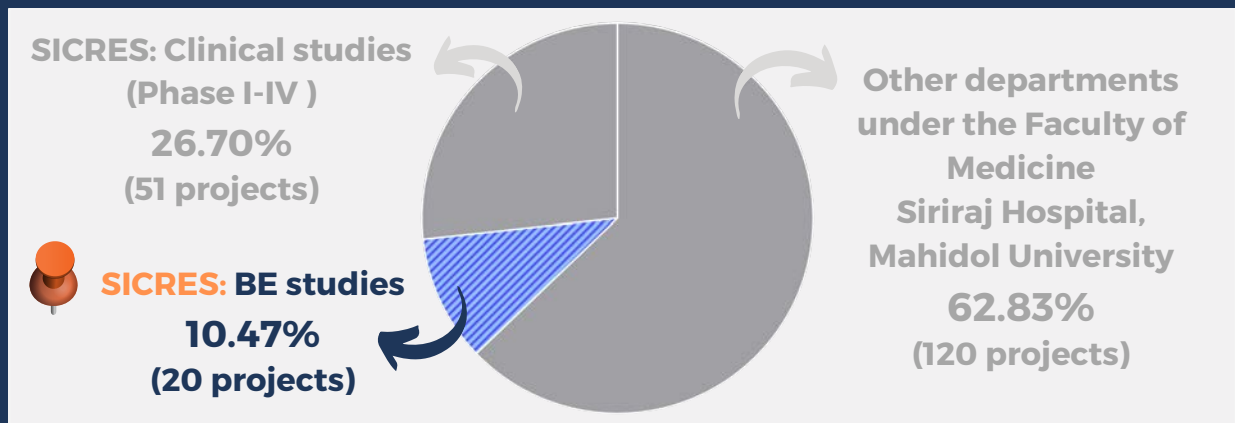
Clinical research projects between FY 2020-2022 by therapeutic area (Total of 191 projects)



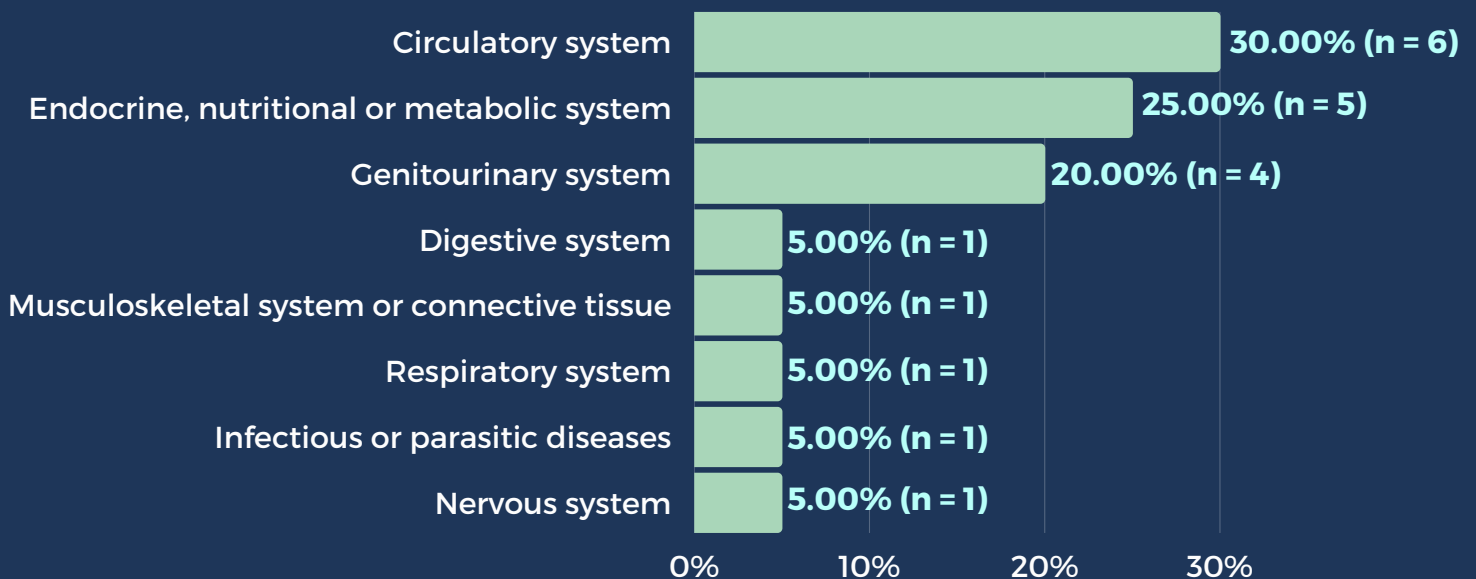
BIOEQUIVALENCE STUDIES



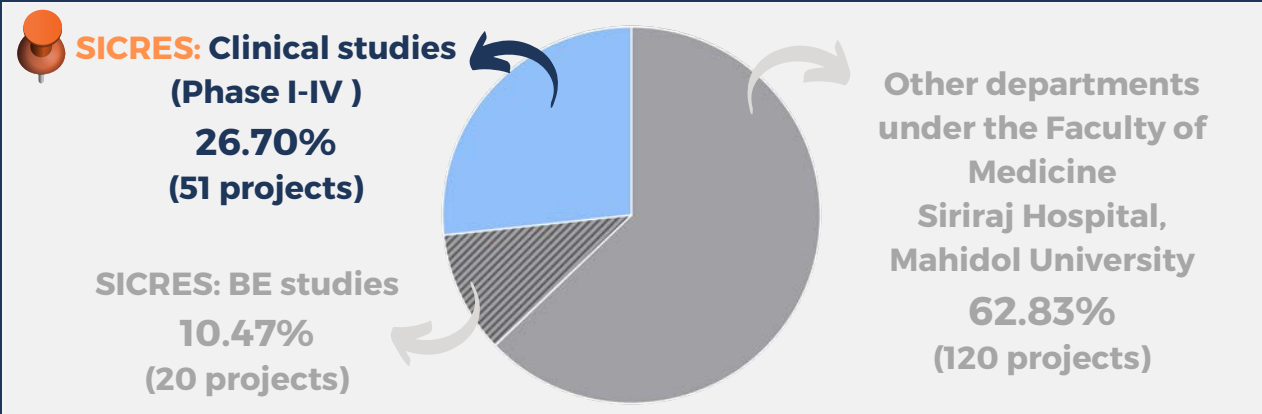
SICRES provides a one-stop shop for bioequivalence (BE) studies, including protocol consultations, ethic committee (EC) submissions, advertisements, volunteer recruitments and conduct clinical trial. We have more than 20 years of experience in conducting BE studies that comply with international standards.



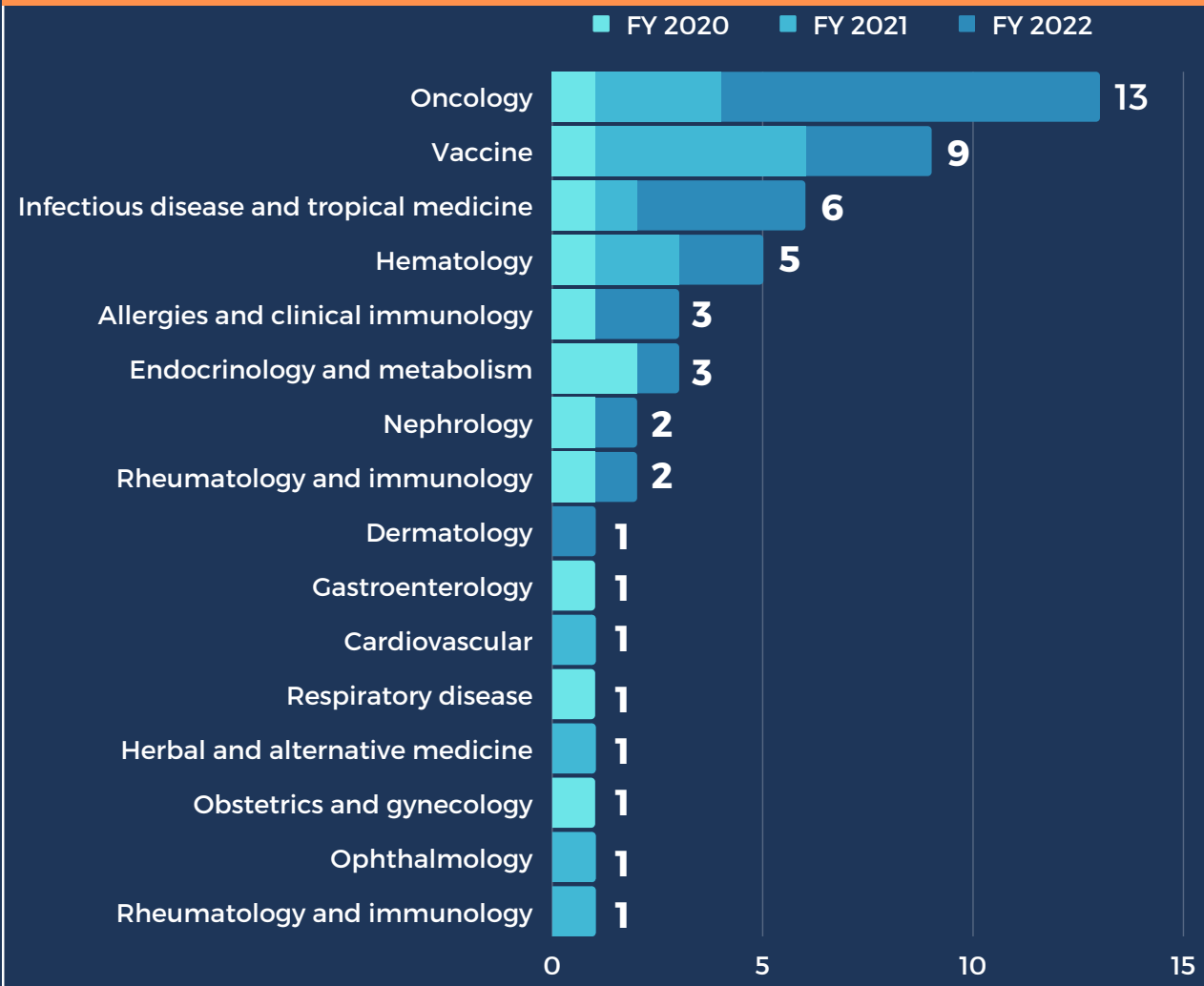
BE studies between FY 2020-2022 by organ system (Total of 20 studies)



CLINICAL STUDIES (PHASE I-IV)

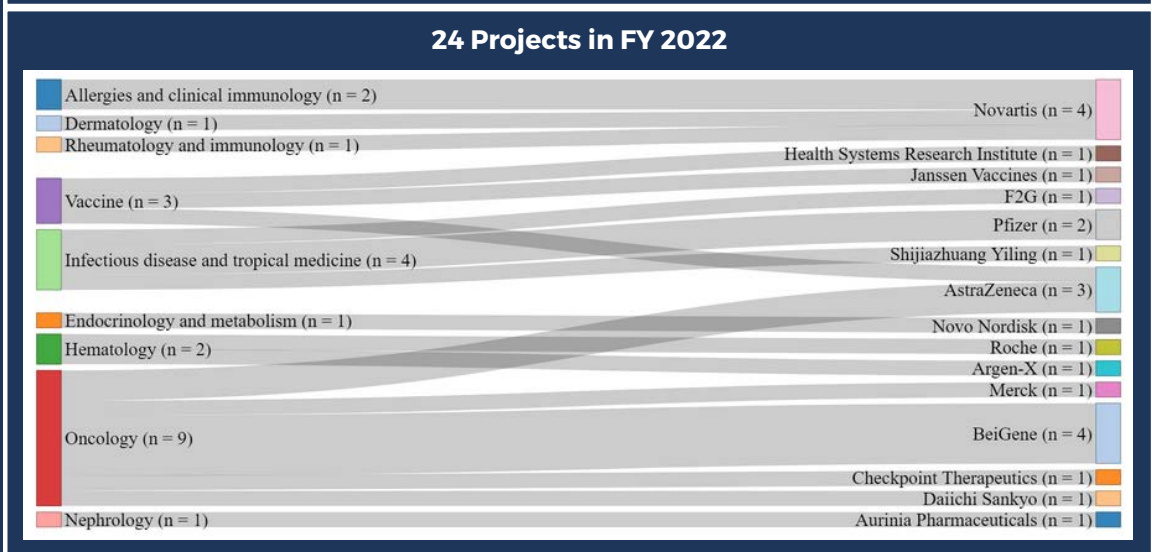
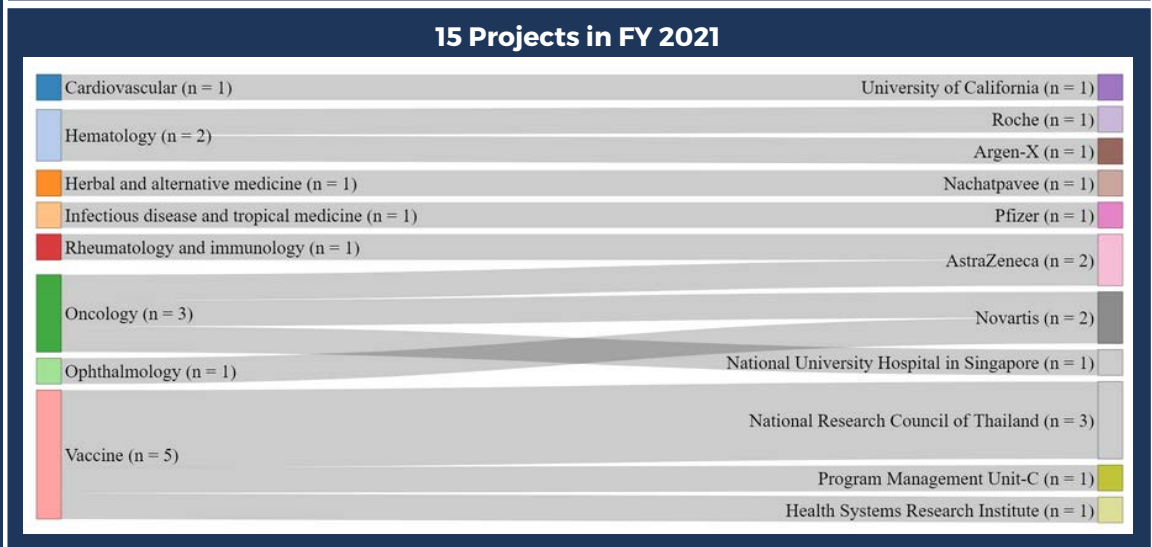
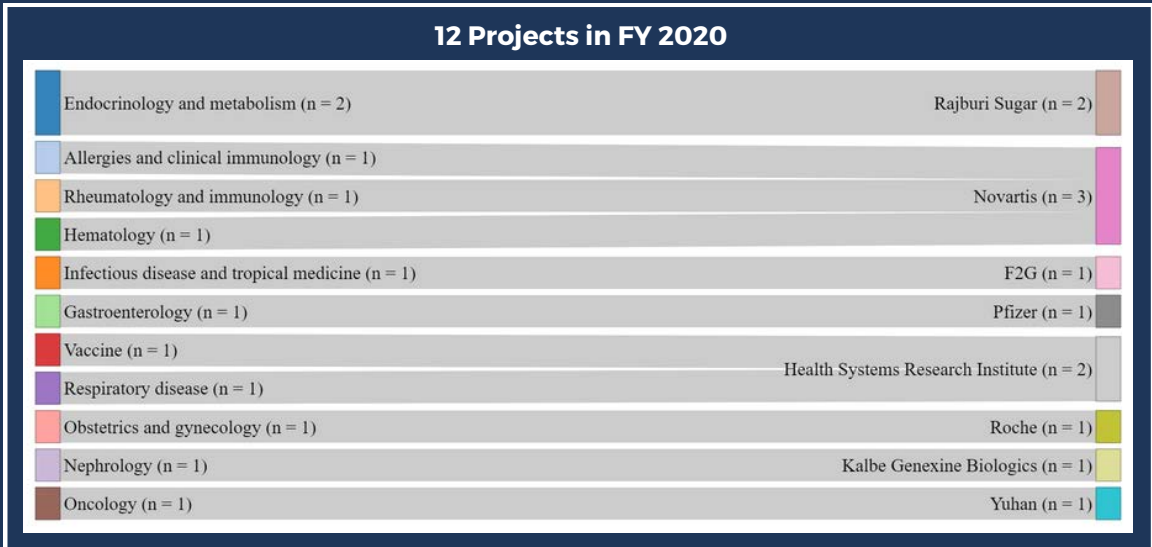


Clinical studies (phase I-IV) managed by SICRES between FY 2020-2022 classified by therapeutic area (Total of 51 projects)



CLINICAL STUDIES (PHASE I-IV)

Sankey diagrams of clinical studies (phase I-IV) managed by SICRES classified by therapeutic area and affiliated sponsor(s)



INVESTIGATOR INITIATED TRIALS (IIT)

Our principal investigators (PIs) work across a plethora of therapeutic areas and play essential roles in healthcare development. Those that join our team of investigators have the opportunity to participate in cutting-edge research, remain up-to-date on the latest medical and technological advancements, and - most importantly - pursue better medical alternatives and procedures for their patients.

Investigator-initiated Trials by Type of Service between FY 2020-2022 (Total of 28 projects)

1. Clinical Trials Initiated and/or Entirely Managed by SICRES (Total of 19 projects)

- | | |
|--|---|
| <ul style="list-style-type: none"> • Study of Self-Assessment of Competencies Among Clinical Research Professionals in Low and Middle-Income Countries in Asia and Africa • Asian Multicenter Prospective Study of Circulating Tumor DNA Sequencing: A-Train, Nasopharyngeal Carcinoma Project Protocol • Asian Multicenter Prospective Study of Circulating Tumor DNA Sequencing: A-Train, Ovarian Clear Cell Cancer Project Protocol • A Prospective Clinical Registry Study of Genetic Profiling And Targeted Therapies in Patients with Rare Cancers In Asia | <ul style="list-style-type: none"> • COVID1901 • COVID1902 • COVID1903 • COVID1904 • COVID1905 • COVID1906 • COVID1907 • COVID1908 • COVID1909 • COVID1910 • COVID1911 • COVID1912 • COVID1913 • COVID1914 • COVID1915 |
|--|---|



INVESTIGATOR INITIATED TRIALS (IIT)

Investigator-initiated Trials by Type of Service between FY 2020-2022 (Total of 28 projects)

2. Clinical Trials Partially Managed by SICRES (Total of 9 projects)

- The Controlled Dengue Human Infection Model in Thailand (DHIT)
- Mixed Methods Study of Factors Associated with Adherence and Engagement in Care Among Adults with Hypertension in Thailand
- Clinical Study of Rice-Based Medical Food for Patients with Diabetes Mellitus or Prediabetes Patients
- Personalized Nutrition for Thai Rice: Reducing Postprandial Hyperglycemia in Healthy Individuals Using Gut Microbiota and Artificial Intelligence
- Safety and Evaluation of Thai Black Garlic Strains: A Randomized Controlled-Placebo Clinical Trial in Healthy Volunteers
- Effect of Black Garlic in Abdominal Fatness
- The Effects of Allulose Towards glp-1 Levels in Obese Patients
- The Effects of Allulose Towards Glucose Homeostasis and Incretin Levels in Patients with Type-2 Diabetes
- Short and Long-term COVID-19 Vaccination Immunity in Previously Infected Patients

DURING THE PANDEMIC

Despite the global COVID-19 pandemic, SICRES initiated numerous clinical studies of its own and disseminated these findings across international journals.

**COVID
1901**

Comparative Effectiveness of Chloroquine and Vitamin C Prophylaxis in Household Contacts of Confirmed COVID-19 Patients

**COVID
1902**

Seroprevalence, Incidence and Immunological Responses to SARS-CoV-2 Infection Among Frontline Healthcare Workers Compared With Non-COVID-19 Healthcare Workers During the COVID-19 Pandemic at Siriraj Hospital, Bangkok

**COVID
1903**

An Investigation of the Efficacy and Safety of Favipiravir in COVID-19 Patients without Pneumonia: An Open-labelled, Randomized Controlled Study

**COVID
1904**

Immunological Responses and Safety after COVID-19 Vaccination in Healthcare Workers at Siriraj Hospital, Bangkok

**COVID
1905**

Safety and Immunological Responses after COVID-19 Vaccination in Thai Pregnant Women

**COVID
1906**

Safety and Immunological Response Following Homologous or Heterologous Booster COVID-19 Vaccination (3rd dose study)

**COVID
1907**

Preliminary Study: Safety and Immunological Response Following COVID-19 Vaccination in COVID-19 Survivors

**COVID
1908**

Safety and Immunological Response Following Heterologous Prime-boost Primary Series and Booster COVID-19 Vaccination

**COVID
1909**

Phase 1/2, Double-blind Study to Evaluate Adverse Events, Humoral- and Cell-Mediated Immune Responses against SARS-CoV-2 Ancestral and Variant Strains after COVID-19 Vaccination in Thai Children and Adolescents.

**COVID
1910**

A Pilot Study: Safety and Immunological Response Following Intradermal COVID-19 vaccination

**COVID
1911**

A Pilot Study: Safety and Immunological Response following Intradermal COVID-19 Vaccination as Boosters (3rd dose)

**COVID
1912**

A Pilot Study: Safety and Immunological Response Following Intradermal COVID-19 Vaccination with Accelerated Regimens

**COVID
1913**

Extension Study of COVID1911: Safety and Immunological Response Following Intradermal COVID-19 Vaccination as Boosters (3rd dose)

**COVID
1914**

Safety and Immunogenicity of Intradermal and Intramuscular Booster COVID-19 Vaccination Following Two-dose Primary Series of AstraZeneca in Aging Populations

**COVID
1915**

Extension Study of COVID1914: Safety and Immunogenicity of Second Intradermal and Intramuscular COVID-19 Booster Doses in Aging Thai Populations.



Much effort was devoted to our COVID-19 research series. This ultimately led to our research findings being incorporated into Thailand's national guidelines for treating COVID-19 and administering vaccines.

Date	Funder	Project
April 2020	Health Systems Research Institute (HSRI)	Seroprevalence, Incidence and Immunological Responses to SARS-CoV-2 Infection Among Frontline Healthcare Workers Compared With Non-COVID-19 Healthcare Workers During the COVID-19 Pandemic at Siriraj Hospital, Bangkok
May 2020	Health Systems Research Institute (HSRI)	An Investigation of the Efficacy and Safety of Favipiravir in COVID-19 Patients without Pneumonia: An Open-labelled, Randomized Controlled Study
March 2021	National Research Council of Thailand (NRCT)	Immunological Responses and Safety after COVID-19 Vaccination in Healthcare Workers at Siriraj Hospital, Bangkok
August 2021	National Research Council of Thailand (NRCT)	Safety and Immunological Responses after COVID-19 Vaccination in Thai Pregnant Women
July 2021	National Research Council of Thailand (NRCT)	Extension study of COVID1904: Safety and Immunological Response Following Homologous or Heterologous Booster COVID-19 Vaccination (3rd dose study)
August 2021	Faculty of Medicine Siriraj Hospital, Mahidol University	Preliminary study: Safety and Immunological Response Following COVID-19 Vaccination in COVID-19 survivors
July 2021	National Research Council of Thailand (NRCT)	Safety and Immunological Response Following Heterologous Prime-boost Primary Series and Booster COVID-19 Vaccination
September 2021	Health Systems Research Institute (HSRI)	A Pilot Study: Safety and Immunological Response Following Intradermal COVID-19 Vaccination and Booster (3rd dose)

TRAINING

To promote distinct skills and experiences, we offer a variety of interesting clinical training courses for our staff and outside research personnel. We have access to unique research expertise from leading pharmaceutical companies, non-profit organizations, and

government agencies at national and international levels through numerous fruitful partnerships. Guest speakers from these institutes and partnerships are invited to share their expertise and knowledge.

Between FY 2020-2022, SICRES organized 8 training courses for personnel within and outside of the Faculty of Medicine Siriraj Hospital, Mahidol University.



Basic Training for Clinical Research Nurses



Basic Training for Study Coordinators



Basic Training for Oncology Trials



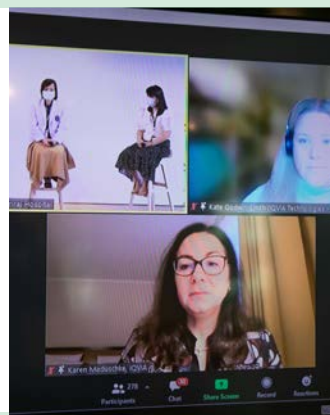
Advanced Study Coordinator Training



Clinical Trial Investigator Training



ICH GCP



Strengthening of Clinical Trials in the Midst of COVID-19: the Rise of Digital Revolution



The IND Journey: First-in-Human (FIH) Trials



TRAINING



Thai FDA speakers

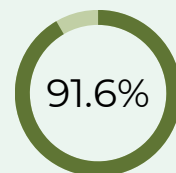


GCP Training workshop

SICRES seeks to develop clinical research knowledge, skills, and expertise in research personnel. Numerous conferences of this nature have been held for investigators, study coordinators, research nurses, research assistants, and medical writers affiliated with the Faculty of Medicine Siriraj Hospital, Mahidol University as well as those interested in clinical research outside this faculty.

2,459

Participants



Satisfaction
at a good-very good level

Since 2020-2022



SICRES STAFF TRAINING

Apart from the training courses mentioned earlier, SICRES officials have participated in various specialized training programs aimed at improving the quality of their work. These include courses such as Clinical Research Overview for non-clinical research professional, Internal training on ISO 9001:2015 requirements, and CPR training to equip the staff with basic life support skills for emergency situations.



PARTNERS & COLLABORATIONS



Mahidol University
Faculty of Medicine Siriraj Hospital



LIST OF MOUs

2016

2020

2021

2022

July 8

**PAREXEL
International
LLC**

Mutually beneficial
collaboration on
clinical research

March 31

**National Center
For Global Health
And Medicine**

Collaboration and
exchange in fields of
shared interest and
expertise

March 10

**Siriraj
Piyamaharajkarun
Hospital**

Support emergency
situations during
clinical trials, including
FIH studies

September 8

**Mahidol University
by Faculty of
Pharmacy**

Promote, support,
and develop
research on herbal
medicines and
supplements

May 27

**GreenLight Clinical
(Thailand) Company
limited**

Conducting clinical
research in humans

March 22

**IQVIA (Thailand)
Co., Ltd**

Increase access to
clinical trials for
patients and
investigators

November 9

**Novotech Clinical
Research (Thailand)
Limited**

Conducting clinical
research in humans

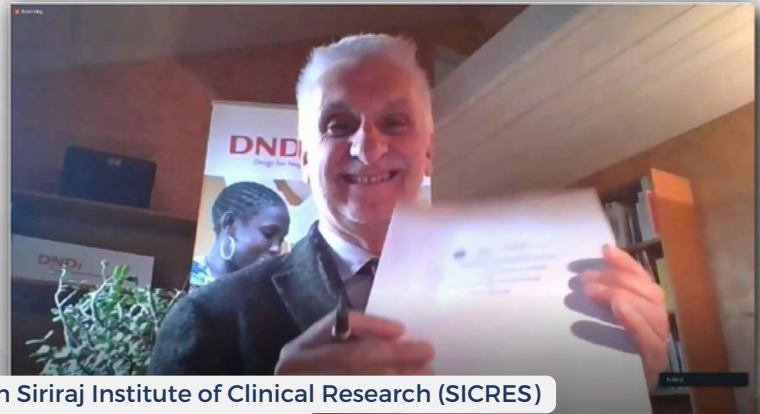
November 10

**The Drugs for
Neglected Diseases
initiative (DNDi)**

Conducting clinical
research in humans



Virtual MOU signing between SICRES and DNDi



The virtual signing ceremony of MOU between Siriraj Institute of Clinical Research (SICRES) and Drugs for Neglected Diseases initiative (DNDi)



The Virtual signing ceremony of MOU between Siriraj Institute of Clinical Research (SICRES) and National Center for Global Health and Medicine (NCGM), Japan



The signing ceremony of MOU between Siriraj Institute of Clinical Research (SICRES) and the Faculty of Pharmacy, Mahidol University

QUALITY STANDARDS

SICRES strictly adheres to the International Conference on Harmonisation's Good Clinical Practice (ICH GCP) guidelines and abides by multiple quality standards for clinical research to ensure the safety of its participants, efficacy of its medical procedures and interventions, and accuracy of its studies' results. SICRES has been awarded several certificates.

One of the most notable quality standards was the ISO 9001:2015 certified by the British Standards Institution (BSI) on March 5th, 2021. This certificate is only given to organizations that demonstrate their commitment to quality management systems and processes. SICRES underwent a rigorous audit process to ensure its processes and procedures met these requirements.

In addition, SICRES has also completed numerous training regimens. One example is the International Air Transport Association (IATA) laboratory sample shipment training regimen. This signifies that our custodians are qualified to handle/offer transport dangerous goods.



RESEARCH FUNDING & DONATIONS



E-Donation Channel



Scan and donate via all mobile banking applications

Our clinical research is mostly funded by government sources that provide support for specific projects; this includes: Health Systems Research Institute (HSRI), the National Research Council (NRC), the Thailand Research Fund (TRF), Program Management Unit for Competitiveness Enhancement ((PMI-C). SICRES also established a research fund for patients under the Siriraj Foundation. Donations from the general public are accepted as well as private companies.

For more information, please contact SICRES Tel. +66 (0) 2414 1914

For donation via Bangkok Bank
Account number: 901-7-06257-2
Swift code: BKKBTHBK
Account name: Siriraj Foundation Fun for patients
D004015

SICRES HIGHLIGHTS



International Network of Partnerships

SICRES is a member of several clinical trial network. Together, we seek to promote multi-regional clinical trials (MRCT) in Asia. SICRES plays an essential role in sharing experiences and participating in clinical research in Thailand and abroad. These communities include, but are not limited to, the ARO Alliance for ASEAN & East Asia (ARISE) Network led by NCGM Japan and the Asian Clinical trials Network for Cancers Project (ATLAS) led by NCC Japan. In addition, we are the trusted country manager for GARDP, facilitating medical monitoring, clinical monitoring for phase-III clinical trials for gonorrhea treatment with Zoliflodacin in Thailand.



NCRN Member

SICRES is a member of the National Clinical Research Network (NCRN) along with clinical research center of the other faculty of medicine or university such as the faculty of medicine Ramathibodi hospital, Mahidol university, Chulalongkorn university, Khon Kaen university, Chiang Mai University, Prince of Songkla University and Thammasat University. Together, our research institutes strive to develop and improve infrastructure of clinical research trials in Thailand.



CRNC Founder

SICRES is one of the founders of a Clinical Research Nurse Consortium (CRNC) to promote clinical research competency and expertise of clinical research nurses as well as create alternative career paths within Siriraj Hospital and other research institutes in Thailand.



Accelerated Start-up Process

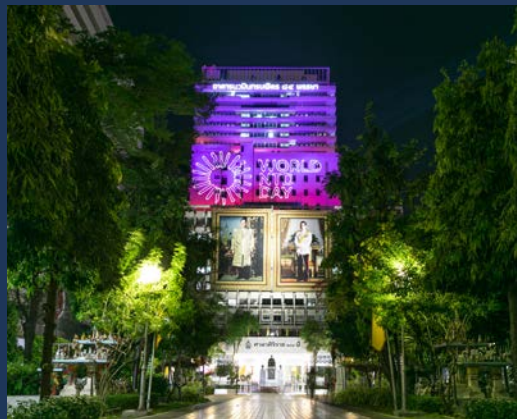
SICRES is renowned for its accelerated 21-working-day clinical trial agreement (CTA) approval process. We continue to increase the efficiency of its study which start from feasibility to first-patient in.




EVENT WORLD NTD DAY 2021-2022



30 January
**WORLD
NTD DAY**
NEGLECTED
TROPICAL
DISEASES



To #BeatNTDs, we must address treatment, manage disability, and do away with social stigma. Join us this #WorldNTDDay and help achieve health equity for all.
www.worldntdday.org



30 January 2022
**WORLD
NTD DAY**
NEGLECTED
TROPICAL
DISEASES

World Neglected Tropical Diseases (NTD) Day is an annual event held on January 30th aimed at raising awareness and mobilizing action against neglected tropical diseases. SICRES joined the World NTD Day 2021 campaign's one in five social media challenge and laser show with the World NTD Day's emblematic color along together with all participating countries around the world in the 84th Anniversary Nawamindra Bopitr Building, Siriraj Hospital. The Faculty of Medicine Siriraj Hospital was one of the key organizers of 2022's World NTD Day, where they launched an awareness campaign week targeting dengue between January 24th and 28th, 2022. The event included: displays; a telemedicine medical consultation; film presentations about the Drug for Neglected Diseases Initiative (DNDi), World NTD Day's dengue fever, as well as interview clips of infectious disease specialists offering insights to dengue prevention. The 84th Anniversary Nawamindra Bopitr Building, Siriraj Hospital again displayed the emblematic color of World NTD Day to indicate our support in eradicating NTDs and improving patient livelihoods.

PUBLICATIONS

2021
-
2022

The 15 COVID-19 research projects conducted by SICRES yielded 7 publications in international medical journals, namely: COVID-1903, -1906, -1907, -1908, -1910, -1911, -1912, and -1913. In addition, 2 preprint are available: COVID-1904 and -1914.

Emerging Microbes & Infections
COVID-1903

Early treatment of Favipiravir in COVID-19 patients without pneumonia: a multicentre, open-label, randomized control study
Rajiv K. Gupta^{1,2*}, Anand Kulkarni^{3,4}, Sunil Kumar^{5,6}, Anand Choudhary⁷, Sakshita Kulkarni^{8,9}, Lakshmi Choudhary¹⁰, Manoj Kumar^{11,12}, Anand Choudhary¹³, Anand Choudhary¹⁴, Anand Choudhary¹⁵, Anand Choudhary¹⁶, Anand Choudhary¹⁷, Anand Choudhary¹⁸, Anand Choudhary¹⁹, Anand Choudhary²⁰

Abstract
Favipiravir (FVP) is an oral nucleoside analogue that is effective against influenza A and B viruses. It is also active against SARS-CoV-2. We conducted a multicentre, open-label, randomized control study to evaluate the efficacy and safety of FVP in COVID-19 patients without pneumonia. The study included 100 patients who were randomly assigned to receive either FVP or standard of care (SOC). The primary endpoint was the time to clinical improvement (TCI). The secondary endpoints were the time to hospital discharge (TOD) and the time to return to normal (TRN). The results showed that FVP was significantly more effective than SOC in terms of TCI, TOD, and TRN. There were no significant differences between the two groups in terms of adverse events. The study was limited by its open-label design and the lack of a placebo group.

Introduction
The COVID-19 pandemic has caused a global health crisis. The World Health Organization (WHO) has declared COVID-19 a global pandemic. The disease is caused by the SARS-CoV-2 virus. The symptoms of COVID-19 range from mild to severe. The most common symptoms are fever, cough, and shortness of breath. The disease can also cause pneumonia, acute respiratory distress syndrome (ARDS), and multi-organ failure. The mortality rate of COVID-19 is approximately 2-3%. The disease is most common in older adults and those with underlying medical conditions. There is currently no specific treatment for COVID-19. The standard of care (SOC) for COVID-19 patients is supportive care. Favipiravir (FVP) is a novel antiviral drug that is effective against influenza A and B viruses. It is also active against SARS-CoV-2. We conducted a multicentre, open-label, randomized control study to evaluate the efficacy and safety of FVP in COVID-19 patients without pneumonia. The study included 100 patients who were randomly assigned to receive either FVP or SOC. The primary endpoint was the time to clinical improvement (TCI). The secondary endpoints were the time to hospital discharge (TOD) and the time to return to normal (TRN). The results showed that FVP was significantly more effective than SOC in terms of TCI, TOD, and TRN. There were no significant differences between the two groups in terms of adverse events. The study was limited by its open-label design and the lack of a placebo group.

Vaccine: X
COVID-1906

Comparison of safety and immunogenicity of Covaxin® and ChAdOx1 against the SARS-CoV-2 circulating variants of concern (Alpha, Delta, Beta) in Thai healthcare workers
Nuttanong Apichanwong^{1,2}, Jiramong Seewawong^{3,4}, Sarinnee Phanthanasri^{5,6}, Nattakorn Sukkavong^{7,8}, Anand Kulkarni^{9,10}, Rajiv K. Gupta^{11,12}, Sunil Kumar^{13,14}, Anand Choudhary^{15,16}, Sakshita Kulkarni^{17,18}, Lakshmi Choudhary^{19,20}, Manoj Kumar^{21,22}, Anand Choudhary^{23,24}, Anand Choudhary^{25,26}, Anand Choudhary^{27,28}, Anand Choudhary^{29,30}

Abstract
The COVID-19 pandemic has caused a global health crisis. The World Health Organization (WHO) has declared COVID-19 a global pandemic. The disease is caused by the SARS-CoV-2 virus. The symptoms of COVID-19 range from mild to severe. The most common symptoms are fever, cough, and shortness of breath. The disease can also cause pneumonia, acute respiratory distress syndrome (ARDS), and multi-organ failure. The mortality rate of COVID-19 is approximately 2-3%. The disease is most common in older adults and those with underlying medical conditions. There is currently no specific treatment for COVID-19. The standard of care (SOC) for COVID-19 patients is supportive care. Covaxin® and ChAdOx1 are two COVID-19 vaccines that are currently being evaluated in clinical trials. We conducted a study to compare the safety and immunogenicity of Covaxin® and ChAdOx1 in Thai healthcare workers. The study included 100 healthcare workers who were randomly assigned to receive either Covaxin® or ChAdOx1. The primary endpoint was the time to clinical improvement (TCI). The secondary endpoints were the time to hospital discharge (TOD) and the time to return to normal (TRN). The results showed that Covaxin® was significantly more effective than ChAdOx1 in terms of TCI, TOD, and TRN. There were no significant differences between the two groups in terms of adverse events. The study was limited by its open-label design and the lack of a placebo group.

JOURNAL OF INFECTION
COVID-1907

Immunogenicity of a high dose of BNT162b2, ChAdOx1 nCoV-19, and mRNA vaccine against SARS-CoV-2 in Thai healthcare workers: An open-label, randomized study
Nuttanong Apichanwong^{1,2}, Jiramong Seewawong^{3,4}, Sarinnee Phanthanasri^{5,6}, Nattakorn Sukkavong^{7,8}, Anand Kulkarni^{9,10}, Rajiv K. Gupta^{11,12}, Sunil Kumar^{13,14}, Anand Choudhary^{15,16}, Sakshita Kulkarni^{17,18}, Lakshmi Choudhary^{19,20}, Manoj Kumar^{21,22}, Anand Choudhary^{23,24}, Anand Choudhary^{25,26}, Anand Choudhary^{27,28}, Anand Choudhary^{29,30}

Abstract
The COVID-19 pandemic has caused a global health crisis. The World Health Organization (WHO) has declared COVID-19 a global pandemic. The disease is caused by the SARS-CoV-2 virus. The symptoms of COVID-19 range from mild to severe. The most common symptoms are fever, cough, and shortness of breath. The disease can also cause pneumonia, acute respiratory distress syndrome (ARDS), and multi-organ failure. The mortality rate of COVID-19 is approximately 2-3%. The disease is most common in older adults and those with underlying medical conditions. There is currently no specific treatment for COVID-19. The standard of care (SOC) for COVID-19 patients is supportive care. BNT162b2, ChAdOx1 nCoV-19, and mRNA vaccine are three COVID-19 vaccines that are currently being evaluated in clinical trials. We conducted a study to compare the immunogenicity of these three vaccines in Thai healthcare workers. The study included 100 healthcare workers who were randomly assigned to receive either BNT162b2, ChAdOx1 nCoV-19, or mRNA vaccine. The primary endpoint was the time to clinical improvement (TCI). The secondary endpoints were the time to hospital discharge (TOD) and the time to return to normal (TRN). The results showed that BNT162b2 was significantly more effective than ChAdOx1 nCoV-19 and mRNA vaccine in terms of TCI, TOD, and TRN. There were no significant differences between the three groups in terms of adverse events. The study was limited by its open-label design and the lack of a placebo group.

Human Vaccines & Immunotherapeutics
COVID-1907

Immunogenicity and reactivity against the SARS-CoV-2 variants following heterologous primary series involving CoronaVac, ChAdOx1 nCoV-19 and BNT162b2 plus BNT162b2 booster vaccination: An open-label randomized study in healthy Thai adults
Nuttanong Apichanwong^{1,2}, Jiramong Seewawong^{3,4}, Sarinnee Phanthanasri^{5,6}, Nattakorn Sukkavong^{7,8}, Anand Kulkarni^{9,10}, Rajiv K. Gupta^{11,12}, Sunil Kumar^{13,14}, Anand Choudhary^{15,16}, Sakshita Kulkarni^{17,18}, Lakshmi Choudhary^{19,20}, Manoj Kumar^{21,22}, Anand Choudhary^{23,24}, Anand Choudhary^{25,26}, Anand Choudhary^{27,28}, Anand Choudhary^{29,30}

Abstract
The COVID-19 pandemic has caused a global health crisis. The World Health Organization (WHO) has declared COVID-19 a global pandemic. The disease is caused by the SARS-CoV-2 virus. The symptoms of COVID-19 range from mild to severe. The most common symptoms are fever, cough, and shortness of breath. The disease can also cause pneumonia, acute respiratory distress syndrome (ARDS), and multi-organ failure. The mortality rate of COVID-19 is approximately 2-3%. The disease is most common in older adults and those with underlying medical conditions. There is currently no specific treatment for COVID-19. The standard of care (SOC) for COVID-19 patients is supportive care. CoronaVac, ChAdOx1 nCoV-19, and BNT162b2 are three COVID-19 vaccines that are currently being evaluated in clinical trials. We conducted a study to compare the immunogenicity and reactivity of these three vaccines in healthy Thai adults. The study included 100 healthy Thai adults who were randomly assigned to receive either CoronaVac, ChAdOx1 nCoV-19, or BNT162b2. The primary endpoint was the time to clinical improvement (TCI). The secondary endpoints were the time to hospital discharge (TOD) and the time to return to normal (TRN). The results showed that CoronaVac was significantly more effective than ChAdOx1 nCoV-19 and BNT162b2 in terms of TCI, TOD, and TRN. There were no significant differences between the three groups in terms of adverse events. The study was limited by its open-label design and the lack of a placebo group.

frontiers in Immunology
COVID-1910

Safety and immunogenicity of intradermal administration of fractional dose CoronaVac®, ChAdOx1 nCoV-19 and BNT162b2 as primary series vaccination
Somwanee Chaitrakarn^{1,2}, Sarinnee Phanthanasri^{3,4}, Nuttanong Apichanwong^{5,6}, Jiramong Seewawong^{7,8}, Nattakorn Sukkavong^{9,10}, Anand Kulkarni^{11,12}, Rajiv K. Gupta^{13,14}, Sunil Kumar^{15,16}, Anand Choudhary^{17,18}, Sakshita Kulkarni^{19,20}, Lakshmi Choudhary^{21,22}, Manoj Kumar^{23,24}, Anand Choudhary^{25,26}, Anand Choudhary^{27,28}, Anand Choudhary^{29,30}

Abstract
The COVID-19 pandemic has caused a global health crisis. The World Health Organization (WHO) has declared COVID-19 a global pandemic. The disease is caused by the SARS-CoV-2 virus. The symptoms of COVID-19 range from mild to severe. The most common symptoms are fever, cough, and shortness of breath. The disease can also cause pneumonia, acute respiratory distress syndrome (ARDS), and multi-organ failure. The mortality rate of COVID-19 is approximately 2-3%. The disease is most common in older adults and those with underlying medical conditions. There is currently no specific treatment for COVID-19. The standard of care (SOC) for COVID-19 patients is supportive care. CoronaVac®, ChAdOx1 nCoV-19, and BNT162b2 are three COVID-19 vaccines that are currently being evaluated in clinical trials. We conducted a study to compare the safety and immunogenicity of intradermal administration of fractional dose CoronaVac®, ChAdOx1 nCoV-19, and BNT162b2 as primary series vaccination. The study included 100 participants who were randomly assigned to receive either fractional dose CoronaVac®, ChAdOx1 nCoV-19, or BNT162b2. The primary endpoint was the time to clinical improvement (TCI). The secondary endpoints were the time to hospital discharge (TOD) and the time to return to normal (TRN). The results showed that fractional dose CoronaVac® was significantly more effective than ChAdOx1 nCoV-19 and BNT162b2 in terms of TCI, TOD, and TRN. There were no significant differences between the three groups in terms of adverse events. The study was limited by its open-label design and the lack of a placebo group.

vaccines
COVID-1911 & -1913

Evaluation of the Safety and Immunogenicity of Fractional Intradermal COVID-19 Vaccines as a Booster: A Pilot Study
Somwanee Chaitrakarn^{1,2}, Sarinnee Phanthanasri^{3,4}, Nuttanong Apichanwong^{5,6}, Jiramong Seewawong^{7,8}, Nattakorn Sukkavong^{9,10}, Anand Kulkarni^{11,12}, Rajiv K. Gupta^{13,14}, Sunil Kumar^{15,16}, Anand Choudhary^{17,18}, Sakshita Kulkarni^{19,20}, Lakshmi Choudhary^{21,22}, Manoj Kumar^{23,24}, Anand Choudhary^{25,26}, Anand Choudhary^{27,28}, Anand Choudhary^{29,30}

Abstract
The COVID-19 pandemic has caused a global health crisis. The World Health Organization (WHO) has declared COVID-19 a global pandemic. The disease is caused by the SARS-CoV-2 virus. The symptoms of COVID-19 range from mild to severe. The most common symptoms are fever, cough, and shortness of breath. The disease can also cause pneumonia, acute respiratory distress syndrome (ARDS), and multi-organ failure. The mortality rate of COVID-19 is approximately 2-3%. The disease is most common in older adults and those with underlying medical conditions. There is currently no specific treatment for COVID-19. The standard of care (SOC) for COVID-19 patients is supportive care. Fractional intradermal COVID-19 vaccines are a novel approach to COVID-19 vaccination. We conducted a pilot study to evaluate the safety and immunogenicity of fractional intradermal COVID-19 vaccines as a booster. The study included 100 participants who were randomly assigned to receive either fractional intradermal COVID-19 vaccine or SOC. The primary endpoint was the time to clinical improvement (TCI). The secondary endpoints were the time to hospital discharge (TOD) and the time to return to normal (TRN). The results showed that fractional intradermal COVID-19 vaccine was significantly more effective than SOC in terms of TCI, TOD, and TRN. There were no significant differences between the two groups in terms of adverse events. The study was limited by its open-label design and the lack of a placebo group.



MEDICAL WRITING SERVICE

2020 - 2022

SICRES assists with medical writing services, from clinical trial protocols to research manuscripts for medical personnel and researchers within the Faculty of Medicine Siriraj Hospital. Our team of editors consist of both Thai and English native speakers with extensive writing experience and publication capabilities in leading international medical journals. Professors from the Faculty of Medicine's Department of Pediatrics have published 10 papers thus far through us. Professors from other departments have published 9.

PLOS ONE

RESEARCH ARTICLE

A retrospective cohort study of major adverse cardiac events in children affected by Kawasaki disease with coronary artery aneurysms in Thailand

Kanokvatee Santimahakulert^{1*}, Chodchanok Vijarnsorn^{1*}, Yuttapong Wongswadiwat¹, Prakul Chenhonthong¹, Sappaya Khongrattath¹, Manat Panamonts¹, Paradorn Chan-on¹, Kritivrom Durengprakitkul¹, Paweena Chungsomprasong¹, Supaluck Kanjanathai¹, Jarupim Soongswang¹

1 Division of Pediatric Cardiology, Department of Pediatrics, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand, **2** Division of Pediatric Cardiology, Department of Pediatrics, Faculty of Medicine, Siriraj Hospital, Khon Kaen University, Khon Kaen, Thailand

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OPEN ACCESS

Citation: Santimahakulert K, Vijarnsorn C, Wongswadiwat Y, Chenhonthong P, Khongrattath S, Panamonts M, et al. (2022) A retrospective cohort study of major adverse cardiac events in children affected by Kawasaki disease with coronary artery aneurysms in Thailand. *PLoS ONE* 17(11): e0263060. <https://doi.org/10.1371/journal.pone.0263060>

Editor: Dong Keon Yoo, Seoul National University College of Medicine, REPUBLIC OF KOREA

Received: May 29, 2021

Accepted: January 12, 2022

Peer Review History: PLOS recognizes the benefits of transparency in the peer review process; therefore, we enable the publication of all of the content of peer review and author responses alongside final, published articles. The editorial history of this article is available here: <https://doi.org/10.1371/journal.pone.0263060>

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Data Availability Statement: The datasets generated and/or analyzed during the current study are available in the PLOS ONE repository.

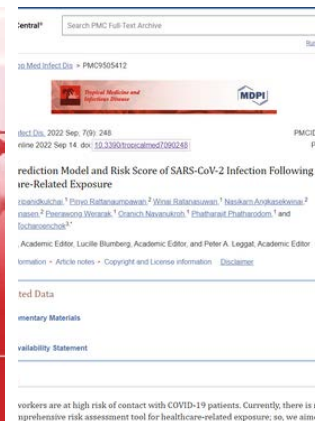
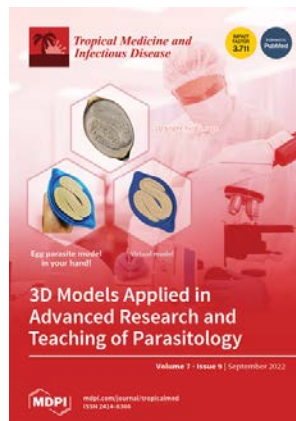
PLoS ONE | <https://doi.org/10.1371/journal.pone.0263060> January 27, 2022

1/11

Abstract

Kawasaki disease (KD) is a common form of vasculitis in children that can be complicated by coronary artery aneurysms (CAAs). Data of long-term outcomes and major adverse cardiac events (MACE) in children with CAAs following KD in developing country are limited. Our aims were to determine the rates of MACE and identify risk factors associated with MACE in children with KD and CAAs in Thailand. We performed a retrospective analysis of data from 170 children diagnosed with KD and CAAs in two tertiary hospitals between 1994 and 2019. During a median (range) follow-up of 5.4 years (22 days to 23 years), 19 patients (11.2%) experienced MACE, that included 12 coronary artery bypass grafting, 2 percutaneous coronary intervention and 5 children with evidence of myocardial ischemia and coronary occlusion. Coronary interventions were performed at a median time of 4 years (0.01 to 9.5 years) after KD diagnosis. Forty-nine patients (28.8%) had giant CAAs. No MACE was reported in children with small CAAs. Independent risks of MACE were from the absence of intravenous immunoglobulin treatment (HR 7.22; 95% CI 2.21 to 23.59; $p = 0.001$), the presence of giant aneurysms (HR 13.59; 95% CI 2.43 to 76.09; $p = 0.003$), and CAAs that involved bilateral branches of coronary arteries (HR 6.19; 95% CI 1.24 to 30.92; $p = 0.026$). Among children with giant CAAs, the intervention-free rate was 93.8%, 78.7% and 52.2%, at 1, 5 and 10 years, respectively. Of note, 81% of the small CAAs regressed to a normal size, and for medium CAAs, 50% regressed to normal size. Overall, ~10% of children with CAAs following KD experienced MACE in this cohort. Timely IVIG treatment in children with KD following symptom onset will reduce the risk of MACE. Cautious surveillance to identify cardiac complications should be recommended for children once medium or giant CAAs develop.

Trial registration: TCTR0190125004.



MEDIA & PUBLIC LECTURES

SICRES and its personnel are actively involved in public lectures and educational initiatives that provide valuable public information. This dissemination of scientific information is performed through multiple mediums, including: media channels, seminars, and conferences. These lectures also cover a wide range of topics, from COVID-19 vaccination to monkeypox, FIH studies, clinical research in Thailand, and much more.

2021

Initial report of decreased SARS-CoV-2 viral load after inoculation with the BNT162b2 vaccine: A real world study

COVID-19 vaccine guidelines (Pfizer) for 1.5 M. dose lot donor vaccine

Updating the media on the latest COVID-19 vaccines supported by the DDC and MoPH

COVID-19 solution and future prospects

เผยแพร่ผลวิจัยการทดลองฉีดวัคซีนโควิด 19 กระตุ้นเป็นเข็มที่ 3 โดยเปรียบเทียบการฉีดวัคซีน 2 แบบ ทั้ง Intradermal และ Intramuscular

SCG special live COVID-19

Siriraj public relations journal

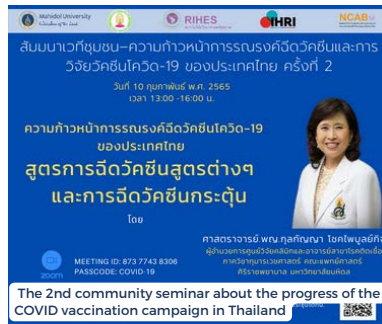
THE STANDARD x Siriraj ตอบคำถามต้องรู้ ทำไมต้องฉีดวัคซีน





MEDIA & PUBLIC LECTURES

2021



Mahidol University Faculty of Medicine Siriraj Hospital
 Department of IMMUNOLOGY presents
 SPECIAL SEMINAR SERIES EP.1
 SIIM 619/620
 IMMUNOLOGY SEMINAR
THE UPDATE OF COVID-19 VACCINE IN CLINICAL USE
 JAN 6, 2022
 TIME: 13:30 - 15:30 HRS.
 Live streaming via **zoom**
Professor Dr. Kulkanya Chokephaibulkit
 Director, Siriraj Institute of Clinical Research
 Immunology Seminar



SICRES VISITORS

2022

Each year, we welcome delegates from various organizations, both within and outside of the Faculty of Medicine Siriraj Hospital, who come to visit, observe, and/or participate in training programs at our center. Our facilities are designed, and our personnel trained, to receive such esteemed guests and ensure their visit at SICRES is fruitful and valuable to their own research endeavors.

List of our research center's visitors across FY 2022

26 Jan 2022

DNDi - Dr. Bernard Pécoul, M.D., MPH.
Founder and Executive Director of Drugs
for Neglected Diseases Initiative (DNDi)

25 Apr 2022

National Cancer Center Japan -
Department of International Clinical
Development

29 Apr 2022

**Sirindhorn School of Prosthetics and
Orthotics** - Director and researchers

10 May 2022

DNDi - Dr. Isabela Ribeiro, Viral Diseases
Cluster Director, and Mr. Peter Sjö, Head
of the Drug Discovery Programme

18 May 2022

Siriraj Medical Student Union - 2-4th
year medical students

27 Jun 2022

**The SIDCER-FERCAP - Global
Fellowship (G1)** - Institutional review
board committee

28 Jun 2022

**Clinical Research Center, Faculty of
Medicine Ramathibodi Hospital**

4 Jul 2022

K Agro-Innovate - Executive director

21 Jul 2022

IQVIA - Director of APAC and Clinical
Operation Head in Thailand

22 Jul 2022

Pediatric Infectious Disease Fellows

25 Jul 2022

**National Center for Global Health and
Medicine** - VR Therapy Study Team

15 Aug 2022

**The SIDCER-FERCAP - Global
Fellowship (G2)** - Institutional review
board committee

19 Aug 2022

**King Prajadhipok's Institute and the
Medical Council of Thailand** - The 9th
group of students of the 'Certificate
Course in Good Governance for
Medical Executives'

26 Aug 2022

Mayo Clinic - Prof. Dr. Stacey Rizza and
Mr. Royston Lek.

6 Sep 2022

**King Prajadhipok's Institute and the
Medical Council of Thailand** - First-
batch of participants for the medical
litigation training program

8 Sep 2022

ERIA - ERIA Healthcare Unit's Director

12 Sep 2022

AstraZeneca - The global team and the
local AstraZeneca team





RAMA CRC



AstraZeneca



King Prajadhipok's Institute and the Medical Council of Thailand

2022

SICRES VISITORS



The SIDCER-FERCAP (G1)



Siriraj Medical Student Union



National Cancer Center Japan



The SIDCER-FERCAP (G2)



DNDi



Mayo Clinic



DNDi



Sirindhorn School of Prosthetics and Orthotics



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2. Assoc. Prof. Sith Sathornsumetee, MD.

3. Prof. Jarupim Soongswang, MD.

4. Prof. Emer. Teerachai Chantarojsiri, MD.

5. Prof. Pakdee Pothisiri, Ph.D.

6. Prof. Emer. Soottiporn Chittmittrapap, MD.

7. Assoc. Prof. Pratap Singhasivanon, MD.Ph.D.

8. Prof. Emer. Prasit Watanapa, MD.Ph.D.

9. Thavirap Tantiwongse, MD.

10. Prof. Kulkanya Chokephaibulkit, MD.

11. Vorakan Burapatana, Ph.D.

12. Assoc. Prof. Winai Ratanasuwan, MD. Committee Secretary (SICRES Director)

2022-PRESENT



1. Prof. Prasit Watanapa, MD. Ph.D

Committee Chairman

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3. Assoc. Prof. Winai Ratanasuwan, MD.

4. Prof. Emer. Soottiporn Chittmittrapap, MD.

5. Prof. Emer. Teerachai Chantarojsiri, MD.

6. Prof. Pakdee Pothisiri, Ph.D.

7. Assoc. Prof. Pratap Singhasivanon, MD. Ph.D.

8. Prof. Emer. Sathit Vannasaeng, MD.

9. Assoc. Prof. Ubolrat Santawat, MD.

10. Amporn Charoensomsak, Pharm.D.

11. Thavirap Tantiwongse, MD.

12. Prof. Kulkanya Chokephaibulkit, MD. Committee Secretary (SICRES Director)

2019-2021

OUR TEAM



SUPPORT OUR RESEARCH BY BEING A



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Volunteer



Team Member



CONTACT CHANNELS



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THANK YOU



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