

# SICRES: Powering Clinical Trials in in Thailand

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# SICRES

SIRIRAJ INSTITUTE OF CLINICAL RESEARCH  
BANGKOK, THAILAND





# Siriraj Hospital

Faculty of Medicine Siriraj Hospital, Mahidol University

## Expert Faculty and Researchers

>1,000 Specialists in all therapeutic area, world-class Investigator for your clinical trials.

## Advanced Infrastructure

Cutting-edge facilities, including including imaging centers and specialized care units, enable precise precise data collection and adherence to global standards.

## Advanced Infrastructure

>2,000-bed hospital  
85,000 admissions per year  
3.8M OPD visits per year  
large and diverse patient demographic

# SICRES: Your Trusted Partner For Successful Clinical Trials

1

## Dedicated Expertise

A diverse team of specialists and state-of-the-art facilities to ensure the highest standards of clinical research.

2

## Regulatory Expertise

Navigate the Thai regulatory landscape seamlessly  
Strict adherence to international regulations and GCP guidelines, ensuring global regulatory alignment..

3

## Collaborative Ecosystem

Strong partnerships with international institutions and the ability to conduct large-scale, multinational trials.



**Siriraj Institute of Clinical Research**



1

## Consult

Discuss your clinical trial requirements with our experts to explore the possibilities.

- IST: Product owners
- IIT: Investigators/Researchers

2

## Design

SICRES's capabilities to design a high-quality, efficient trial tailored to your needs.

- Grant proposal
- Protocol development
- IRB submission package
- Project management plan
- Data management plan

3

## Execute

Rely on SICRES's proven track record and resources to execute your trial with excellence.

- Project and financial management
- Site Management
- Clinical research operation
- Data management
- Quality management

# Out-Patient unit



Dedicated  
Clinical Trial units



# 2 In-Patient wards







## In-house equipment and facilities

- Sample preparation room
- Centrifuge for sample preparation
- Four adjustable alarmed freezers  
(-80°C and -20°C)
- Synchronized clocks





## STANDARD QUALITY OF EQUIPMENT AND SYSTEM

- **ISO 9001:2015**
- Investigational storage (Pharmacy)
- Fume hood for the investigational products preparation
- Three adjustable temperature controlled, alarmed fridge ( $-70^{\circ}\text{C}$ ,  $-20^{\circ}\text{C}$  and  $2-8^{\circ}\text{C}$ )
- Secure medication storage room

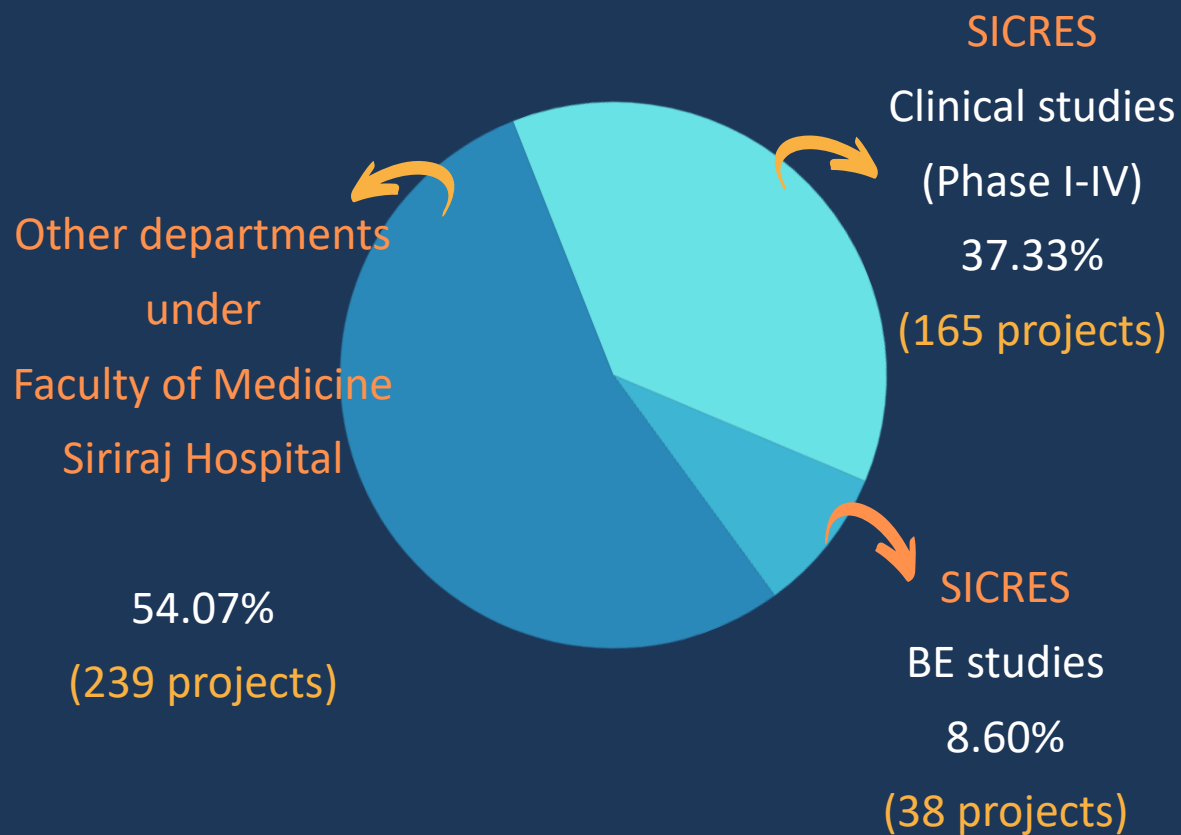


## Clinical Trial Agreement (CTAs)

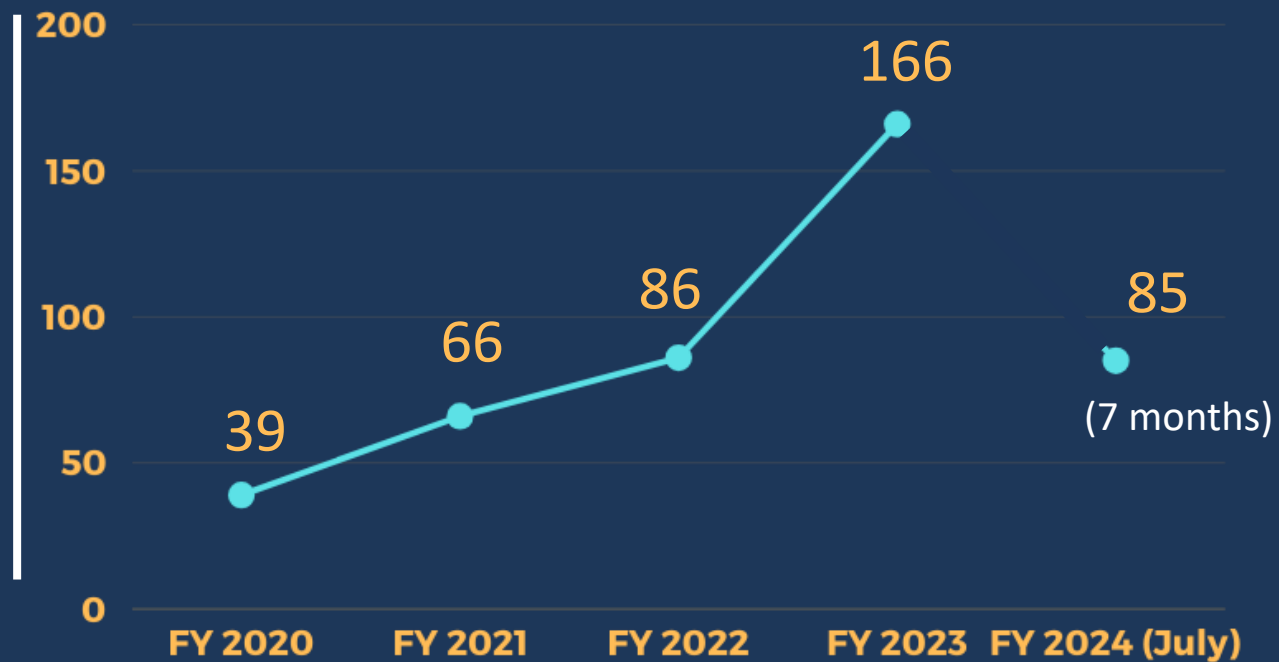
by Operation in Siriraj between FY 2020 - JULY 2024  
(442 Projects)

## Number of New Clinical Trials

between FY 2020 - July 2024  
(442 Projects)



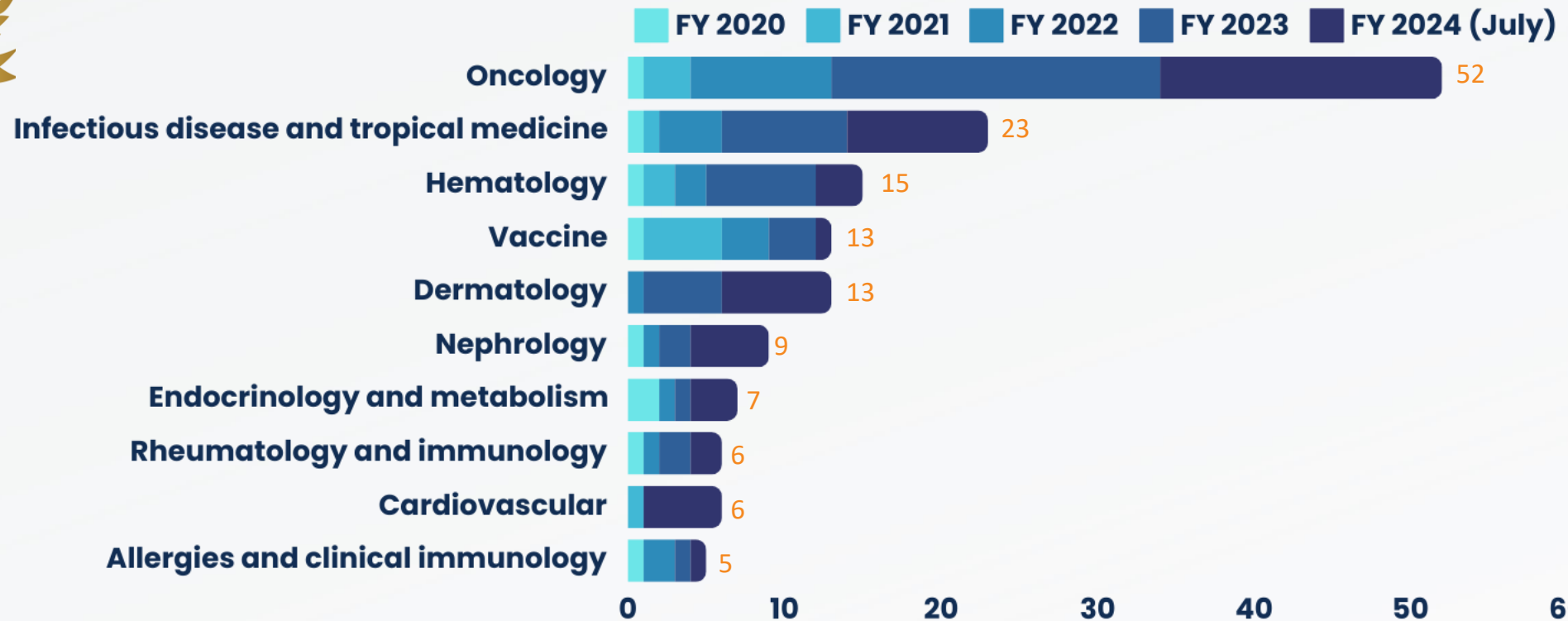
## Number of projects





# Clinical studies (Phase I-IV) conducted by SICRES

(Total of 165 projects)



## Our Investigators

*“Many of the studies that we are conducting provided the very crucial important knowledge to develop and improve the treatment or intervention to the patients.”*



Prof. Kulkanya  
Chokephaibulkit, M.D.  
*Pediatric infectious*

Founding Director of  
SICRES



# Challenges

*faced by*

## Clinical Research Sites In Thailand



### Contract Management:

- Lengthy approval processes
- Complicated legal requirements



### Finance Management:

- Delays in budget approvals
- Insufficient funding at the study start-up



### Human Resources:

- Incentive structures and rewarding system
- Recruitment: difficulties in attracting top

# SICRES Attainments



## Talent Acquisition

Ability to hire talented staff while ensuring organizational sustainability



## Streamlined Clinical Trial Agreement (CTA) Process

More efficient and effective CTA processing



## Financial Management by SICRES

SICRES handles financial aspects for investigators, including:

1. Reimbursement
2. Loan management



## Strategic External Consulting

Develop strategies for utilizing external consultants.



## Facility Setup

Establish facilities to support investigators effectively.



# LOCAL IRB

## : SIRIRAJ INSTITUTIONAL REVIEW BOARD



  
หน่วยจริยธรรมการวิจัยในคน  
คณะแพทยศาสตร์ศิริราชพยาบาล  
ขอเชิญเข้าร่วมรับฟังการอบรมกรรมการจริยธรรมการวิจัยในคน  
คณะแพทยศาสตร์ศิริราชพยาบาล

### First in Human Study for IRB

  
ณ อาคารศรีสวรินทิรา  
ชั้น 2 ห้อง 204  
และผ่านระบบ Zoom Meetings

 Scan QR code  
ลงทะเบียนร่วมอบรม

พญ.อรณี ตั้งเผ่า

- ผู้เชี่ยวชาญสาขาการพัฒนายาทางคลินิก
- อดีตอาจารย์ ภาควิชาเภสัชวิทยา คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
- นักวิจัยด้านวิทยาศาสตร์การแพทย์สาขาเภสัชวิทยาคีตติก มหาวิทยาลัย Stanford
- ทำงานด้านการพัฒนายาจนได้ดำรงตำแหน่งเป็น Chief Medical Officer ในบริษัท start up ที่อเมริกา ปัจจุบันอาจารย์เป็นที่ปรึกษาของหน่วยงานภาครัฐและเอกชนหลายแห่งในไทยและสหรัฐอเมริกา

\*หมายเหตุ : ID และ password จะส่งให้ทาง email ในวันที่ 15 ธ.ค. 2563

# Establishing PHASE 1 in sick patients

- Sometimes, Phase 1 trial need to be conducted in patients, particularly for some disease-specific medications.
- Siriraj is a super tertiary care center with potential volunteer subjects for Phase 1 studies
- The Phase 1 study can be conducted on the patient's ward with research staff support and high standard management







26 July 2024

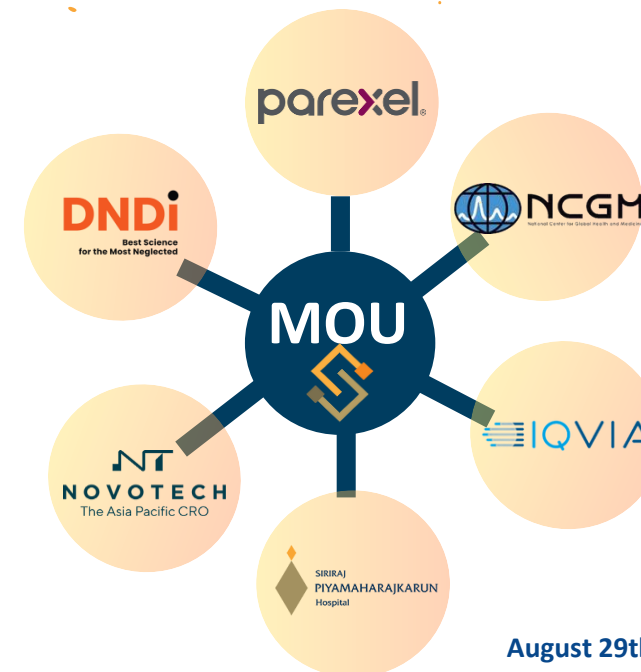


Strategic  
Discussion

Regulatory,  
Industry,  
and Academia

# NETWORKING AND COLLABORATION:

## Sharing and Learning





# Thank you



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