

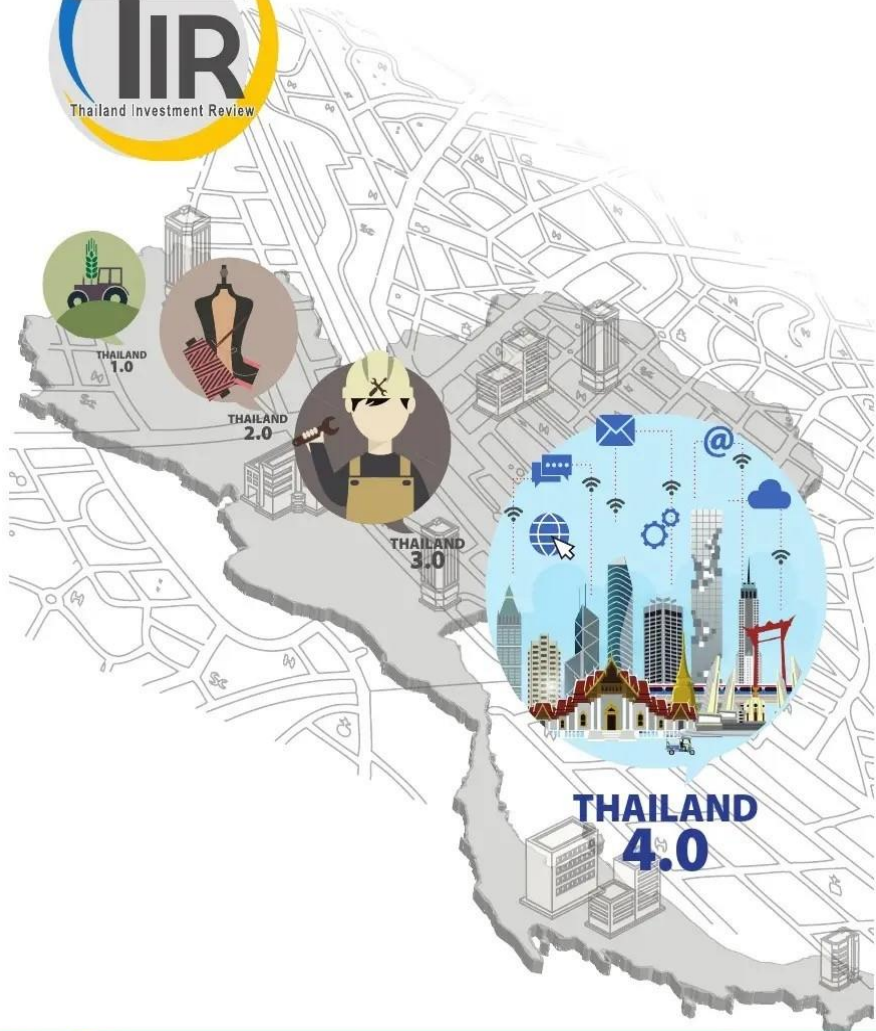
*Prof. Kwanchanok Yimtae, MD*

# Thailand Vaccine Trial Collaboration: the past experience during COVID-19

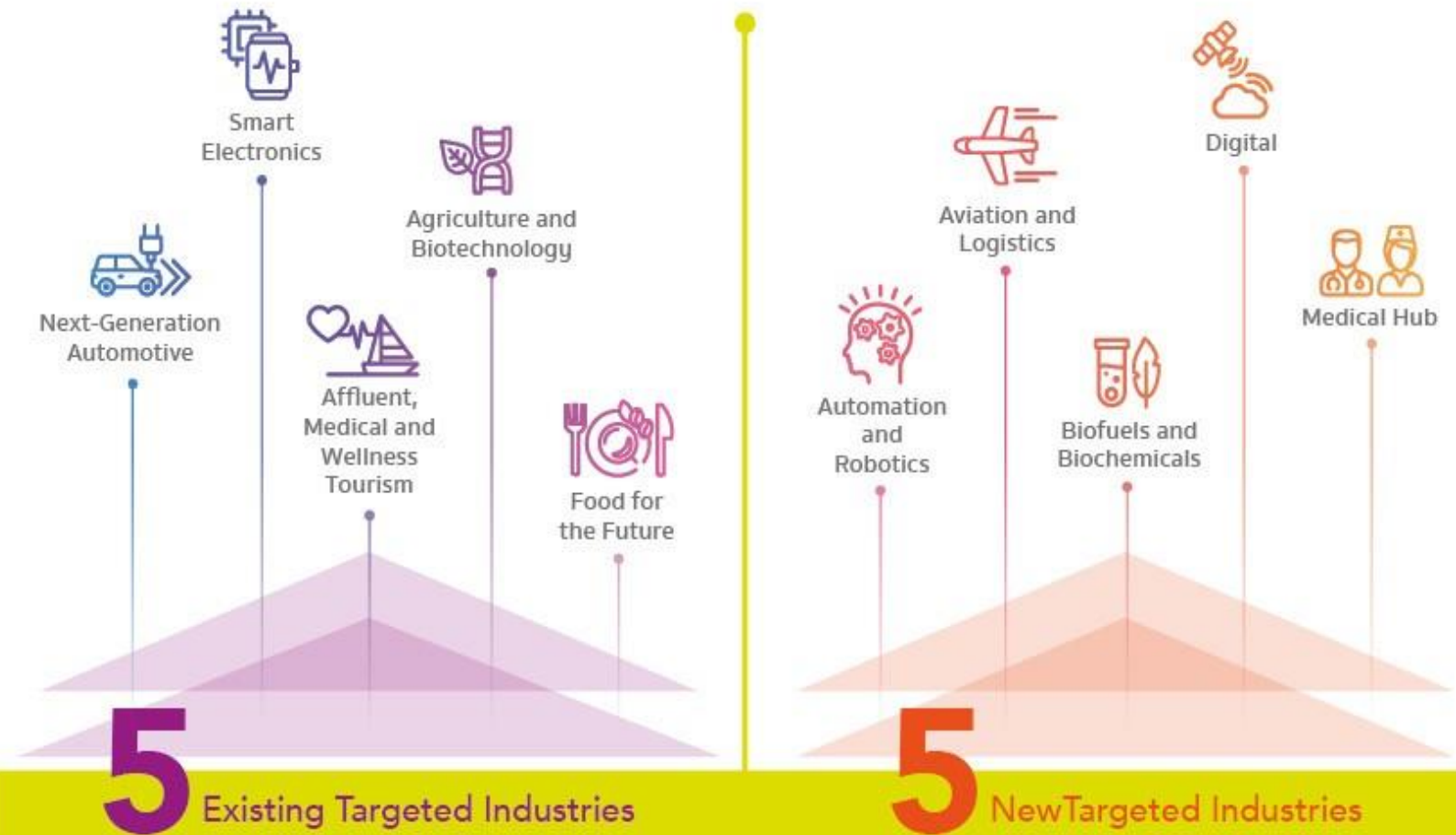


**NCRN**  
NATIONAL CLINICAL  
RESEARCH NETWORK





## Targeted Industries



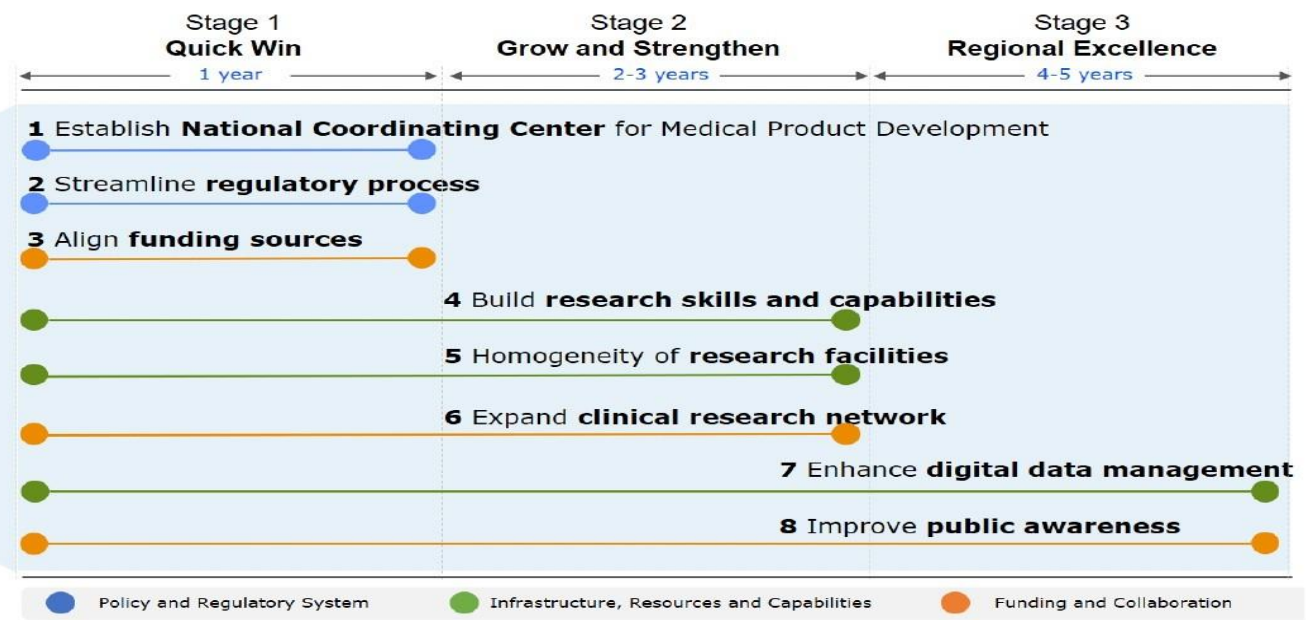
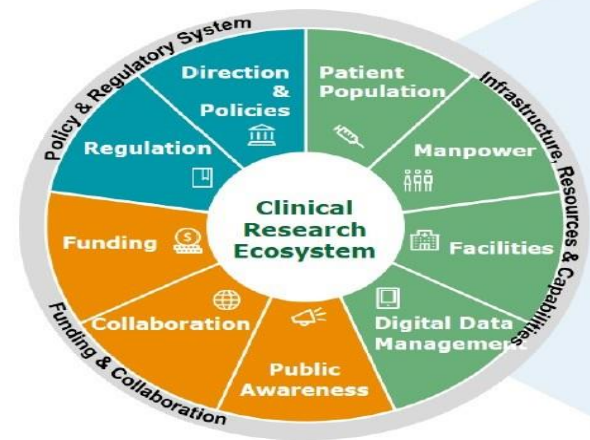


*innovation-driven economy*



■ Emerging      ■ Nascent

Source



Source: Deloitte research and analysis



Faculty of Medicine,  
Chiang Mai University  
(CMU)



Faculty of Medicine,  
Chulalongkorn University  
(CU)



Faculty of Medicine, Khon  
Kaen University (KKU)



Faculty of Medicine  
Ramathibodi  
Hospital, Mahidol  
University (RA)



Faculty of Medicine  
Siriraj Hospital,  
Mahidol University  
(SI)



Faculty of Tropical  
Medicine, Mahidol  
University (Trop Med)



Faculty of Medicine,  
Prince of Songkla  
University (PSU)



Faculty of Medicine,  
Thammasat  
University (TU)

# Ethic Committee Partnership

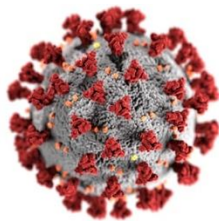


Board of Foundation for Human Research Promotion in Thailand

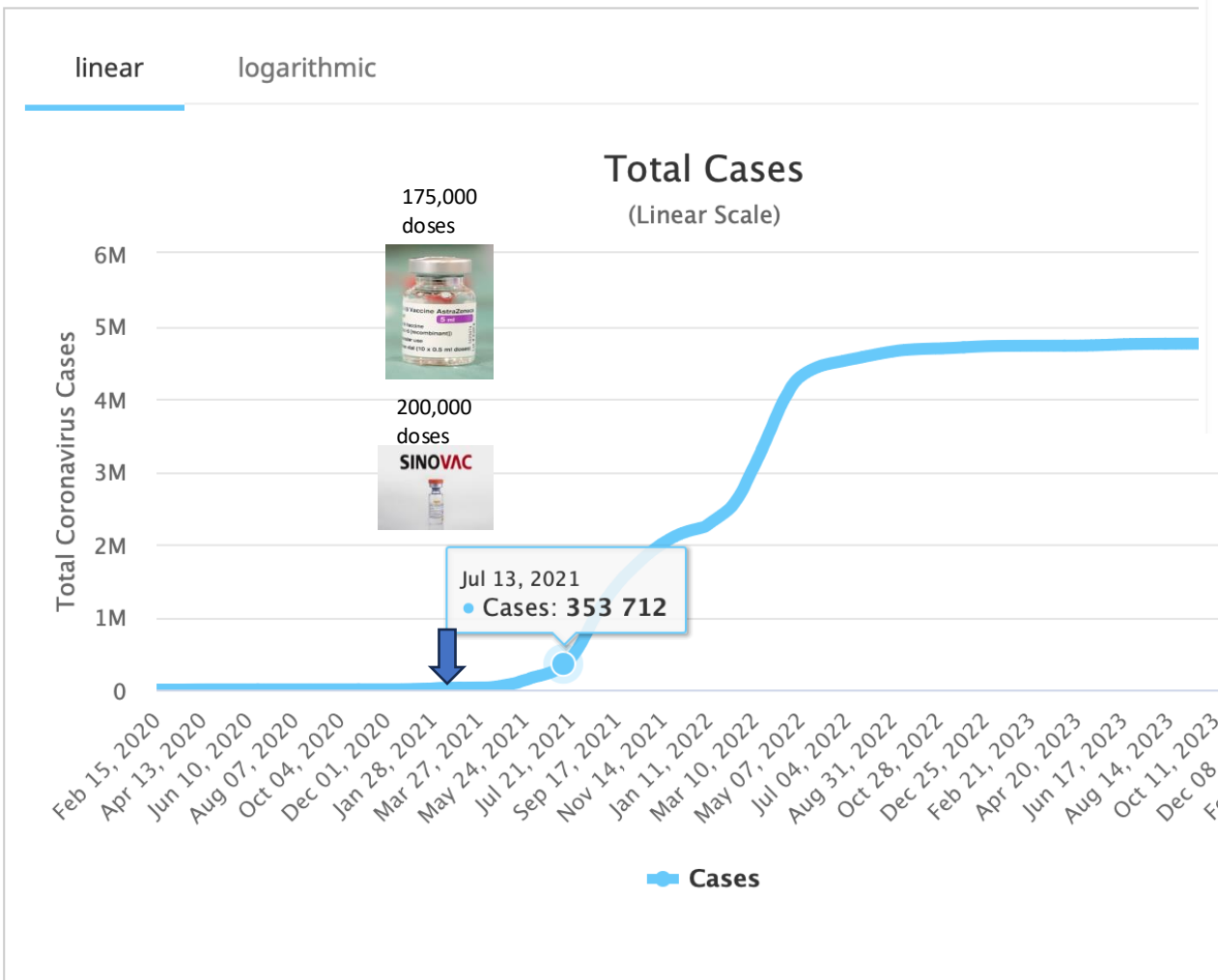




## COVID Vaccine Trial

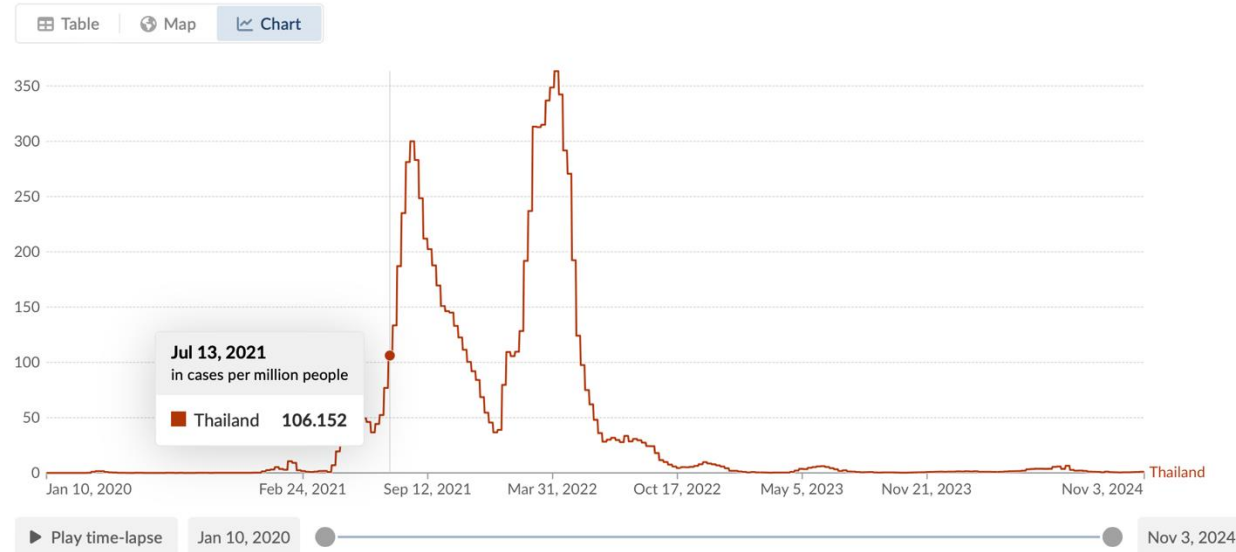


# Total Coronavirus Cases in Thailand



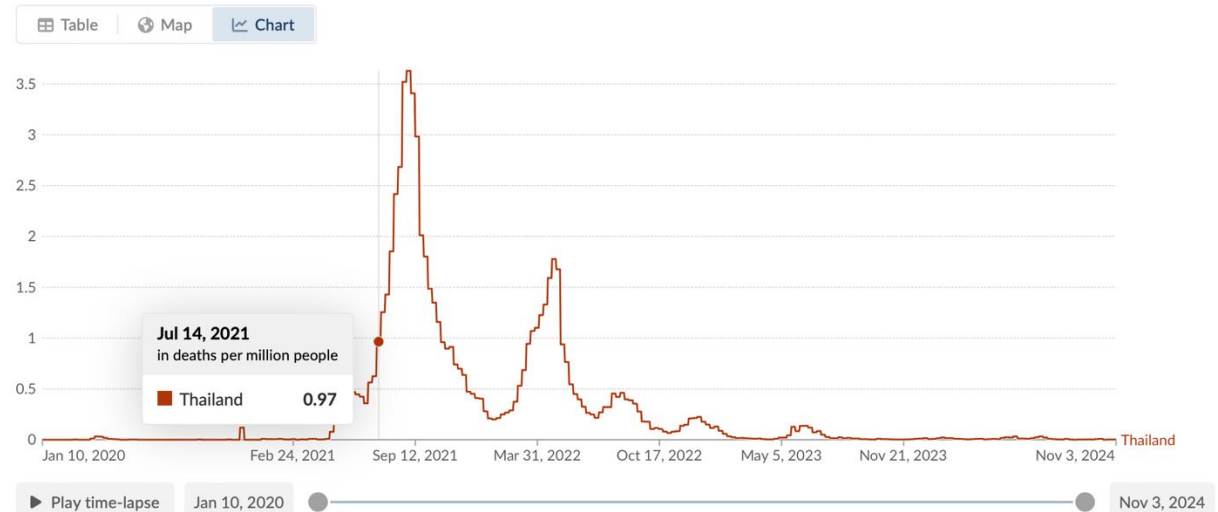
## Daily new confirmed COVID-19 cases per million people

7-day rolling average. Due to limited testing, the number of confirmed cases is lower than the true number of infections.



## Daily new confirmed COVID-19 deaths per million people

7-day rolling average. Due to varying protocols and challenges in the attribution of the cause of death, the number of confirmed deaths may not accurately represent the true number of deaths caused by COVID-19.

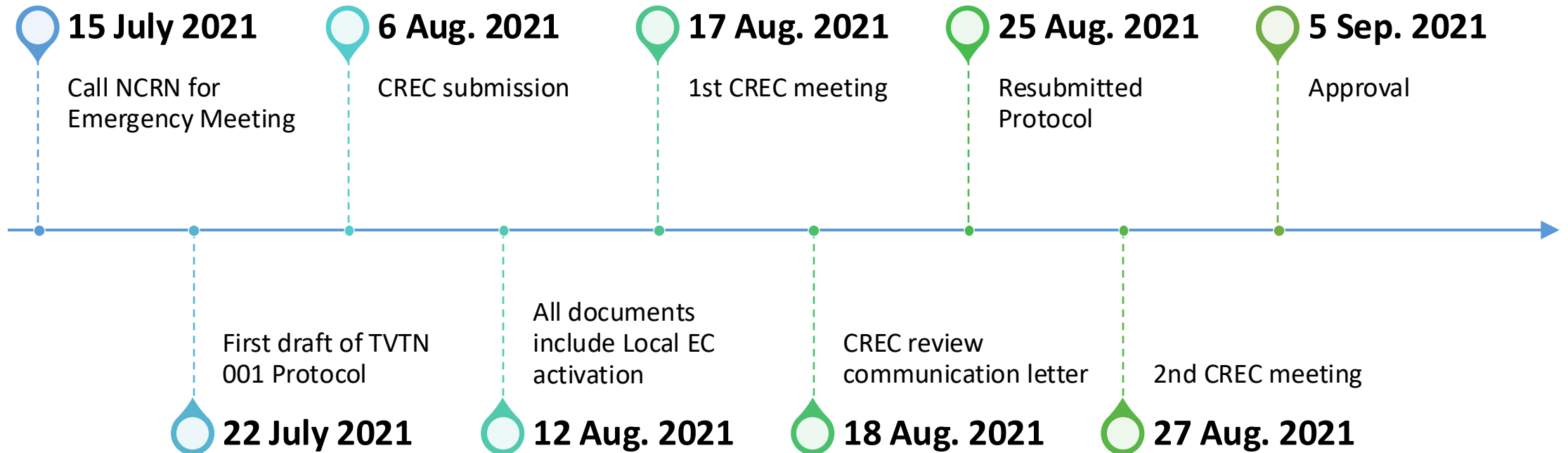


# Vaccine trials

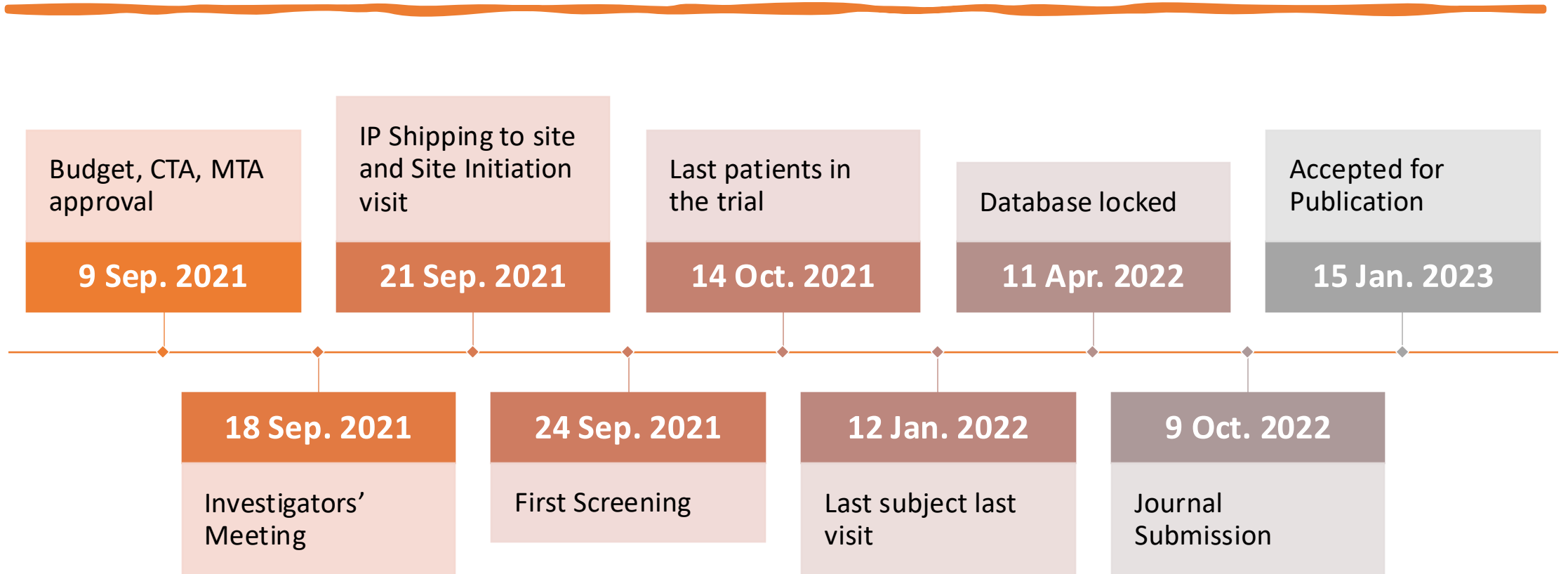
- Establish 3 clinical trials –Core team 1,2,3
  - Core team 1:
    - RCT 1320 participants
    - Previously vaccinated with 2 doses of Sinovac -> booster with 1 Full dose/Half dose of AZ vs 1 Full dose/Half dose of PF in adults -> TVTN 001
  - Core team 2:
    - Prospective 660 participants
    - 1 dose of Sinovac + 1 Full dose of AZ in adult
  - Core team 3:
    - RCT 700 non-vaccinated 5-11 years old children
    - 1 full dose/half dose of Sinovac + 1 Full dose/half dose of PF in children

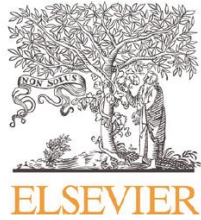


# Timeline of TVTN-001



# Timeline of TVTN-001





Contents lists available at ScienceDirect

## International Journal of Infectious Diseases

journal homepage: [www.elsevier.com/locate/ijid](http://www.elsevier.com/locate/ijid)

### Immunogenicity of a fractional or full third dose of AZD1222 vaccine or BNT162b2 messenger RNA vaccine after two doses of CoronaVac vaccines against the Delta and Omicron variants

Suvimol Niyomnaitham<sup>1,#</sup>, Anan Jongkaewwattana<sup>2,#</sup>, Atibordee Meesing<sup>3</sup>, Nawamin Pinpathomrat<sup>4</sup>, Sira Nanthapisal<sup>5</sup>, Nattiya Hirankarn<sup>6</sup>, Sarawut Siwamogsatham<sup>7</sup>, Suppachok Kirdlarp<sup>8</sup>, Romanee Chaiwarith<sup>9</sup>, Saranath Lawpoolsri<sup>10</sup>, Supranee Phanthanawiboon<sup>11</sup>, Arunee Thitithanyanont<sup>12</sup>, Pokrath Hansasuta<sup>13</sup>, Sansanee Chaiyaroj<sup>14</sup>, Punnee Pitisuttithum<sup>15,\*</sup>

<sup>1</sup> Department of Pharmacology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

<sup>2</sup> National Center for Genetic Engineering and Biotechnology, National Science and Technology Development Agency, Pathumthani, Thailand

<sup>3</sup> Division of Infectious Diseases and Tropical Medicine, Department of Medicine, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

<sup>4</sup> Clinical Research Center, Faculty of Medicine, Prince of Songkla University, Songkhla, Thailand

<sup>5</sup> Clinical Research Center, Faculty of Medicine, Thammasat University, Pathumthani, Thailand

<sup>6</sup> Department of Microbiology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

<sup>7</sup> Maha Chakri Sirindhorn Clinical Research Center, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

<sup>8</sup> Chakri Naruebodindra Medical Institute, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Samut Prakarn, Thailand

<sup>9</sup> Division of Infectious Diseases and Tropical Medicine, Department of Internal Medicine, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand

<sup>10</sup> Faculty of Tropical Medicine, Mahidol University, Bangkok, Thailand

<sup>11</sup> Department of Microbiology, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

<sup>12</sup> Faculty of Science, Mahidol University, Bangkok, Thailand

<sup>13</sup> Division of Virology, Department of Microbiology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

<sup>14</sup> Department of Microbiology, Faculty of Science, Mahidol University, Bangkok, Thailand

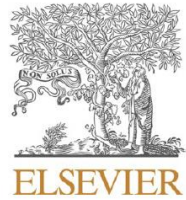
<sup>15</sup> Vaccine Trial Centre, Faculty of Tropical Medicine, Mahidol University, Bangkok, Thailand

### TVTN –001 Finding:

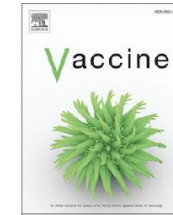
- No safety concerns were detected.
- Noninferior immunogenicity between full doses and half doses.
- Full-dose vaccines and/or longer 120-180-day intervals substantially improved the Key Messages:
  - immunogenicity.
  - Immunogenicity waned more quickly with half doses than full doses but remained high against the Ancestral or Delta strains.
- Against Omicron, the day 28 immunogenicity increased with longer intervals than shorter intervals for full-dose vaccines.

### Key Messages:

- Startup timeline since protocol development until first patient in could be as short as 2 months.
- RCT of 1,243 patients with 3 months follow-up could be finished within 4 months.

Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

# Vaccine

journal homepage: [www.elsevier.com/locate/vaccine](https://www.elsevier.com/locate/vaccine)

## Immunogenicity and reactogenicity of fractional, heterologous primary COVID-19 vaccination schedules with BNT162b2 boosters in 5–11-year-old Thai children: A multicenter, prospective, double-blind, randomized control trial

Orasri Wittawatmongkol<sup>a</sup>, Pornumpa Bunjoungmanee<sup>b,c</sup>, Pope Kosalaraksa<sup>d</sup>, Kamolwish Laoprasopwattana<sup>e</sup>, Sophida Boonsathorn<sup>f</sup>, Napaporn Chantasrisawad<sup>g</sup>, Tavitiya Sudjaritruk<sup>h</sup>, Suvimol Niyomnaitham<sup>i,j</sup>, Sansnee Senawong<sup>k</sup>, Kanjana Srisutthisamphan<sup>l</sup>, Zheng Quan Toh<sup>m,n</sup>, Supattra Rungmaitree<sup>a</sup>, Sira Nanthapisal<sup>b,c,o</sup>, Supraanee Phanthanawiboon<sup>p</sup>, Puttichart Khantee<sup>e</sup>, Chonnamet Techasaensiri<sup>f</sup>, Nattiya Hirankarn<sup>q</sup>, Sipang Pangprasertkul<sup>h</sup>, Kulkanya Chokephaibulkit<sup>a,j,\*</sup>

<sup>a</sup> Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand

<sup>b</sup> Department of Pediatrics, Faculty of Medicine, Thammasat University, Pathum Thani 12120, Thailand

<sup>c</sup> Clinical Research Center, Faculty of Medicine, Thammasat University, Pathum Thani 12120, Thailand

<sup>d</sup> Department of Pediatrics, Faculty of Medicine, Khon Kaen University, Khon Kaen 40002, Thailand

<sup>e</sup> Department of Pediatrics, Faculty of Medicine, Prince of Songkla University, Songkhla 90110, Thailand

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<sup>g</sup> Center of Excellence for Pediatric Infectious Diseases and Vaccines, Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand

<sup>h</sup> Department of Pediatrics, Faculty of Medicine, Chiang Mai University, Chiang Mai 50200, Thailand

<sup>i</sup> Department of Pharmacology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand

<sup>j</sup> Siriraj Institute of Clinical Research (SICRES), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand

<sup>k</sup> Department of Immunology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand

<sup>l</sup> Virology and Cell Technology Research Team, National Center for Genetic Engineering and Biotechnology (BIOTEC), National Science and Technology Development Agency (NSTDA), Pathum Thani 12120, Thailand

<sup>m</sup> Department of Pediatrics, The University of Melbourne, Parkville, Victoria 3010, Australia

<sup>n</sup> Infection and Immunity, Murdoch Children's Research Institute, Parkville, Victoria 3052, Australia

<sup>o</sup> Research Unit in Infectious and Immunology, Faculty of Medicine, Thammasat University, Pathum Thani 12120, Thailand

<sup>p</sup> Department of Microbiology, Faculty of Medicine, Khon Kaen University, Khon Kaen 40002, Thailand

<sup>q</sup> Department of Microbiology, Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand

### Finding:

- Standard and fractional heterologous regimens of CoronaVac-BNT162b2 induced similar or higher humoral immunity than homologous BNT162b2.

9 มกราคม พ.ศ 2566

ณ ห้องบอลรูม 2-3  
โรงแรมพูลแมน ดอนเมือง กรุงเทพฯ

# NORTHEASTERN CLINICAL RESEARCH CENTER NETWORK CONFERENCE 2023

การประชุมสัมมนาทางวิชาการเครือข่ายศูนย์วิจัยทางคลินิก  
ภาคตะวันออกเฉียงเหนือ ครั้งที่ 1

## กำหนดการ

- 08.00-08.30 น. ลงทะเบียน
- 08.30-08.40 น. พิธีเปิด - มอบของที่ระลึก
- 08.45-09.00 น. ถ่ายภาพรวม
- 09.00-09.30 น. บรรยายหัวข้อ "ยุทธศาสตร์และขอบประมาณงานวิจัยและนวัตกรรม  
ด้านการแพทย์และสาธารณสุขของประเทศ
- 09.30-10:45 น. เสวนา เรื่อง "แนวทางการบริหารจัดการงานวิจัยคลินิกแบบ  
Decentralize Clinical Trial"
- 10.45-11.00 น. Break
- 11.00-12.15 น. เสวนา เรื่อง "Digital Health Techno
- 12.15-13.30 น. Luncheon symposium "Drug dev
- 13.30-14.30 น. Show & Share Experience by well



ในวันที่ 21 มิถุนายน 2566 เวลา 8.30 - 16.00 น.  
ณ ห้องประชุม 1201 อาคารภูมิสิริฯ โรงพยาบาลจุฬาลงกรณ์

8.30 - 9.00 น.

**Overview Thailand National Clinical Research Network**

โดย ศ.พญ. ชวัลภิชฌา อิ่มแต่ ประธานโครงการศูนย์วิจัยทางคลินิกแห่งชาติ(NCRC)  
และ ศ.พญ. ธันยวีร์ ภูธมกิจ ผู้อำนวยการศูนย์วิจัยทางคลินิก Chula CRC

9.00 -10.15 น.

**Global Trend of Clinical Trial Therapeutic Areas**

- **Biologic Therapy and Vaccine** โดย กก.วิรัชกร คุณาศิริรัตน์ บ. MSD
- **Innovation in Oncology Research**

โดย รศ.ดร.บพ.วิโรจน์ ศรีอุฬารพงศ์ คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย  
ดำเนินรายการ โดย นพ.สราวุธ ศิวโมกษธรรม Co-Director Chula CRC

10.15 - 10.45 น.

**Pharmacokinetic Study Among Special Population**

โดย ผศ.ดร.พญ.ปาจริย์ อธิวิลาสกุล คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

11.00 - 12.30 น.

**Clinical Research Conduct and Management**

- **Landscape of Clinical Research in Thailand**  
โดย พญ.กนกวรรณ พรประสิทธิ์ บ. Clinixir
- **Digitalizing Clinical Trial**  
โดย ญญ.ธีรธรณ์ เทียรดีโตสกุล บ. PPD part of Thermo Fisher Science
- **Quality Management in Clinical Trial**  
โดย กก.รัฐพล ไทละสุด บ. IQVIA

ดำเนินรายการ โดย พญ. วรณชาม กิจธนานงคผลชัย Chula CRC

13.30 - 15.30 น.

**Workshop: Capacity Building for Clinical Research**

- Room 1 Pharmacy Aspects in Clinical Trial
- Room 2 Clinical Research laboratory





**Health is Wealth: Transforming Biopharmaceutical Innovation to Drive Sustainable Economic Growth**

Commissioned by

A Frost & Sullivan White Paper  
*Powering clients to a future shaped by growth*

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**CliniBiz**  
The Business of Clinical Trials

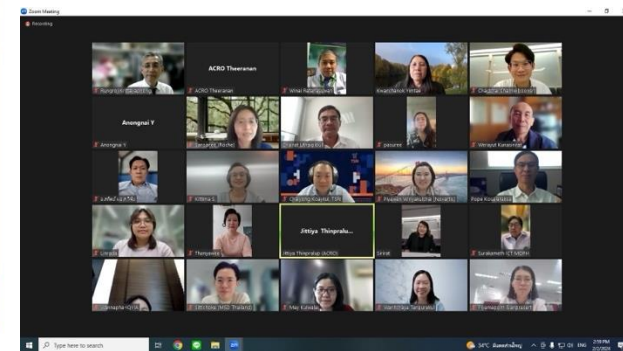
**Clinixir Gap Analysis**

A Gap Analysis for Clinixir on Thailand's Prominent Academic Research Organizations

Moe Alsumdaie July 15, 2021

# Clinical Trial Gap Analysis

Divided team into 5 working groups: Data platform; Ethics; Regulatory; Funders; Training.





**National Clinical Research Network (NCRN) conference 2023**

**"MOVING THAILAND TOWARDS ASIAN CLINICAL RESEARCH HUB"**

15 - 16 November 2023, 8.30 - 16.30 (GMT+7), Bangkok at Phayathai 1-2 Room, 6<sup>th</sup> Floor, Eastin Grand Hotel Phayathai

FREE REGISTRATION LIMITED SEATS DUE ON 5 NOV 2023

We. 15 November 2023		Th. 16 November 2023	
07:30-08:30	Registration	08:00-08:30	Registration
08:30-09:00	Role of Clinical Research Centers in National Research and Innovation	08:30-10:30	Strategic Plans to Drive Innovations & Clinical Researches: Perspectives from Granters and Thai FDA
09:00-09:15	Photo Group	10:30-11:00	Coffee Break
09:15-10:30	Data sharing: Paradigm Shifting from RCT to Pragmatic Trial and Real-World Evidence (Part 1)	11:00-12:00	Sharing the strategies of K-Medi Hub to drive the innovation
10:30-10:45	Coffee Break	12:00-13:00	Lunch Break
11:00-12:00	Data sharing: Paradigm Shifting from RCT to Pragmatic Trial and Real-World Evidence (Part 2)	13:00-14:30	Thailand Clinical Trial Roadmap: Where are we now?
12:00-13:00	Lunch Break	14:30-15:00	Coffee Break
13:00-13:45	Early Phase Trial: Are we ready for it?	15:00-16:15	Thailand Clinical Trial Roadmap: What's next to move ecosystem faster?
13:45-14:30	Sharpening your research skills: Training and Networking opportunities		
14:30-14:45	Coffee Break		
14:45-16.00	Clinical Trial Decentralization: Where are we now?		

**SPEAKERS**

UWU, ANB, TCOLS, CREC, PReMA, MSD, Roche, IQVIA, CLINIXIR

**For more information** Tel: 043-366568 or Miss Jitthaya Thiraphalap 0840282012 / Email : jitthi@kku.ac.th Miss Theeranan Kongyern 0941471336 / Email : theeko@kku.ac.th



**National Clinical Research Conference 2023**

15-16 พฤศจิกายน 2567 รรอีสตินแกรนด์พญาไท กทมจำนวนผู้ร่วมประชุม 179คน





National Clinical Research Network (NCRN)



Thank you