Challenges in Implementing Clinical R&D Roadmap

To achieve Thailand 4.0 national plan
Investigator perspective

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JITMM ,Dec 7, 2017;Bangkok

- Thailand 4.0 and related background
- Clinical R&D road map
- Challenges

Thailand 4.0, towards a value-based economy

Thailand 4.0 focuses on a “value-based economy,” as the country needs to deal effectively with disparities and the imbalance between the environment and society.

Become a high-income nation

The first element aims to enhance the country’s standing to become a high-income nation through developing it as a knowledge-based economy. With an emphasis on research and development, science and technology, creative thinking, and innovation.

Move toward an inclusive society

In the second element, Thailand will move toward an “inclusive society” with equitable access to the fruits of prosperity and development.

Focus on a sustainable growth and development

The third element focuses on “sustainable growth and development,” in order to achieve economic growth and sustainable development without destroying the environment.

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Thailand Science Technology and Innovation (STI) Landscape

- To revive Thailand's economic prosperity, the Thai Government has placed Science, Technology and Innovation (STI) on its national agenda as they are viewed as keys to move the country up the global value chain by establishing the National Research and Innovation Policy Council (NRIC).

Source: http://www.sti.or.th/

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The National Research and Innovation Policy Council (NRIC)

- Is a single body to set the direction, policy and roadmap of research and innovation to facilitate national development.
- NRIC chaired by Prime Minister and Secretary-General of the National Research Council of Thailand (NRCT), and Secretary-General of the National Science Technology and Innovation Policy Office (STI Office) are the co-secretariat.

Source: http://www.sti.or.th/

Focus on Clinical Research Supporting Five Groups of Technology and Targeted Industries

Source: adopted from Thailand 4.0

	Clinical Research Development and Targeted Industries
Food & Agriculture - Biotech Become the center of premium agricultural products and food, and an exporter of technology in agriculture.	Genomics, Genotype-Phenotype-Microclimate Nutrition
Health & Wellness - Biomedical Build medical infrastructure and move Thailand forward to be "Medical Hub" of ASEAN within 2025.	Clinical research management service, Diagnosis and medical devices, well service and treatment innovation, innovative medicine, Thai herb.
Smart Devices & Robotics - Mechatronics Advance as a leader in automatic system, industrial robotics, and service robotics in ASEAN.	Healthcare & medical and service robotics, e.g., robots for elder care.
Digital, IOT and Embedded Technology: Enhance productivity, quality and innovation in various economic activities including agriculture, healthcare, and tourism.	Usage of digital technology to support healthcare industry, e.g., data analytics for research.
Creativity, Culture and High-Value Services Synergize basic cultural assets, innovation and technology to become one of ASEAN's "Creative hubs" within the next ten years.	Clinical research to enhance innovation capability and support innovative ecosystem.

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Emphasis :
Building up Infrastructure and Capabilities

Roadmap: Health & Wellness – Biomedical

Ref: http://www.samongthailand.com/thailand4-0/thailandevelopmentstrategy/

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1-5 Years	Within 5-10 years	Within 10-15 years
• Generic drug • Biopharmaceutical Products - Biosimilar • Products from probiotics • Herbal Med and Cosmetics • Smart Medical Devices, Robotics for handicapped • Elderly Rehabilitation Centers • Neutraceutical for health and beauty • Medical Tourism	• New Biological Product for Cancer and Allergy • New technology Vaccine • Diagnostic tests with economic potential • Medical Robotics: comply with International Standard • Quality reagents for automated diagnostic services • Smart Village for Aging • Digital Health • Precision Medicine	• Small molecules drug • Drug forTargeted Therapy • New Advanced Vaccine/ new biomaterial product • Medical Robotics and Instruments for surgery • Implanted-devices • Automated diagnostic devices

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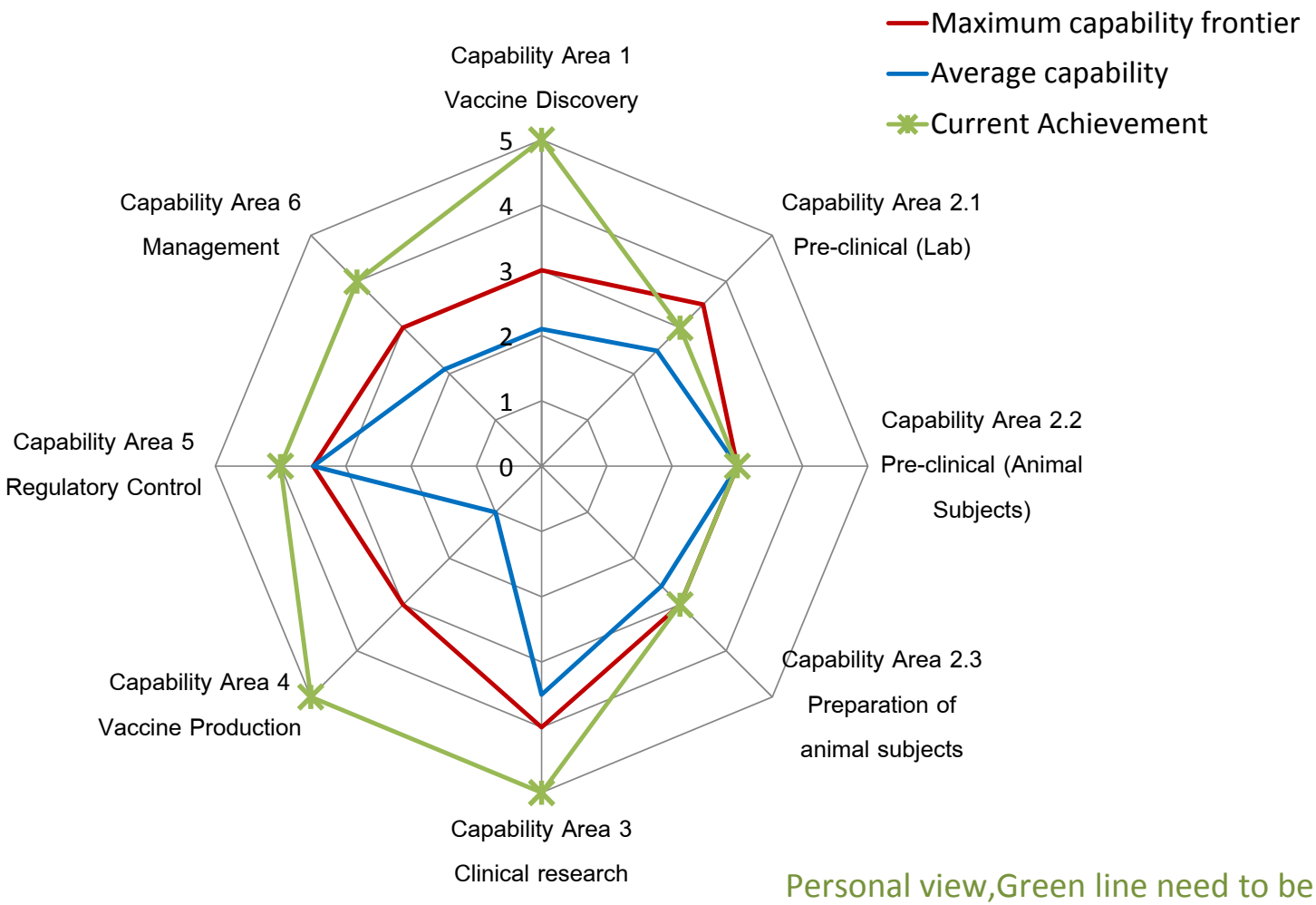
Important Stakeholders :

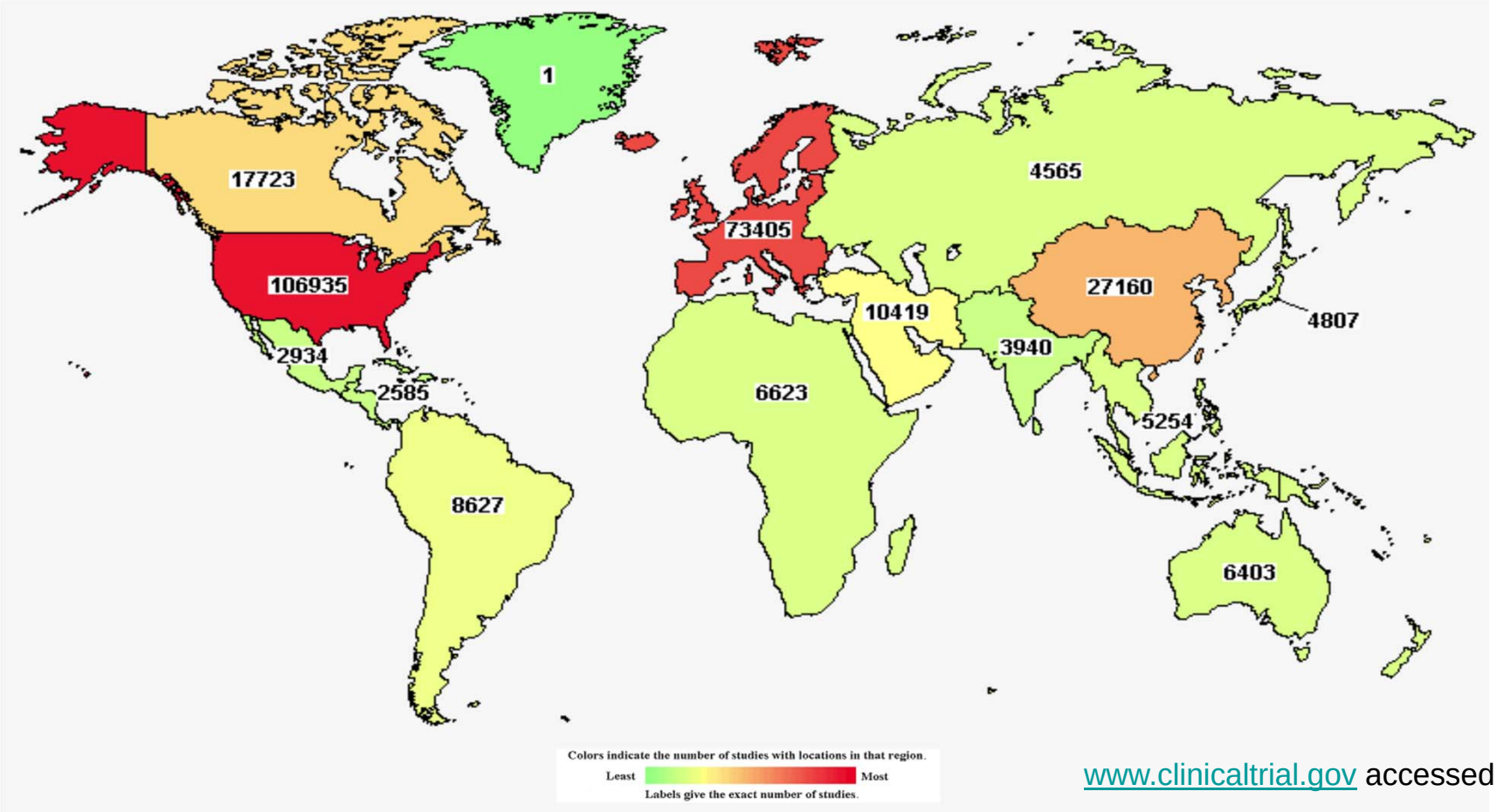
Policy makers & Funders
Industry partners ,
Scientists/Researchers/Investigators
People/Society

Past and Present Capability in Vaccine R&D



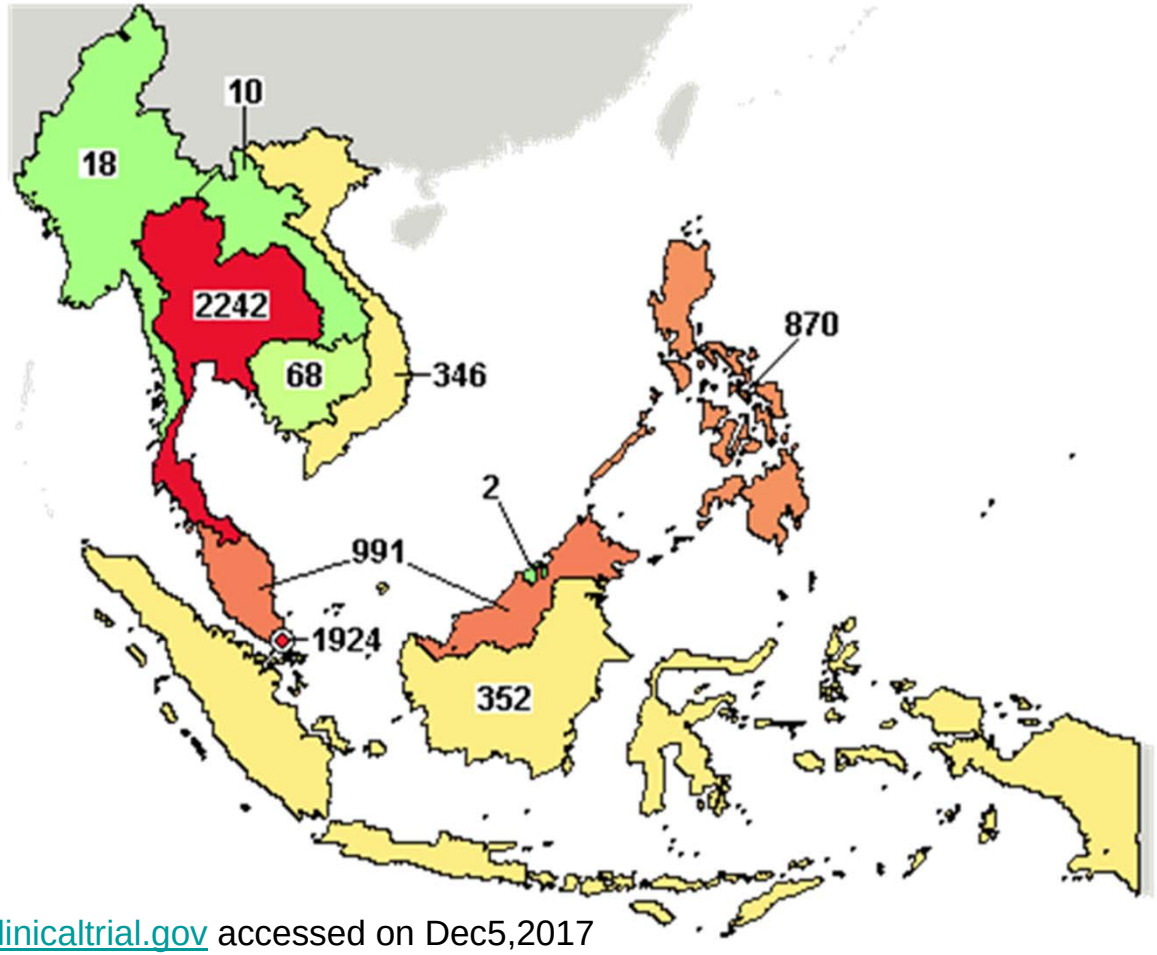
Personal view,Green line need to be

Current situation:
Number of clinical trials registered in www.clinicaltrial.gov



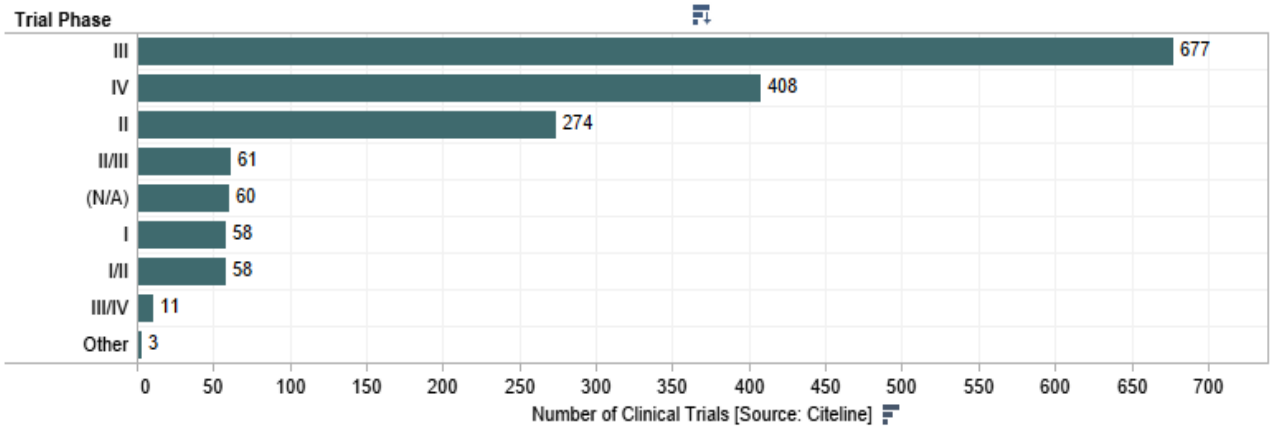
www.clinicaltrial.gov accessed on Dec5,2017

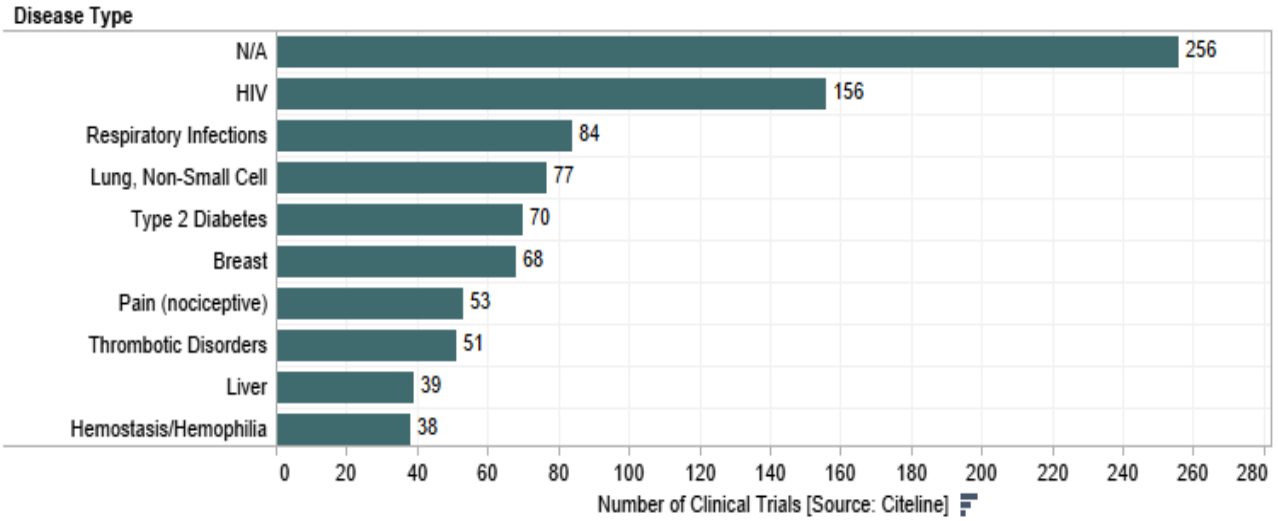
Clinical Research/ trials: Where are we?



www.clinicaltrial.gov accessed on Dec5,2017

TOP INDICATIONS & TRIAL PHASES





Source; Citeline;
01/01/2007 to 01/01/2017

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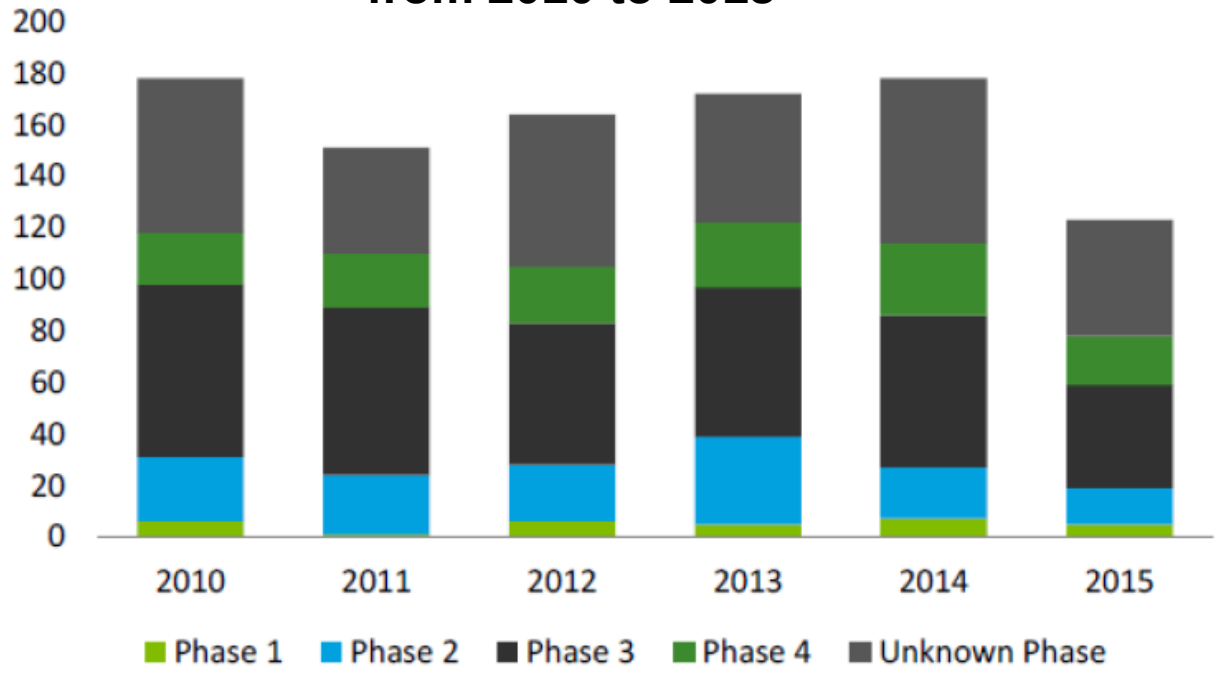
The number of Clinical Trials in Thailand by Phase from 2010 to 2015



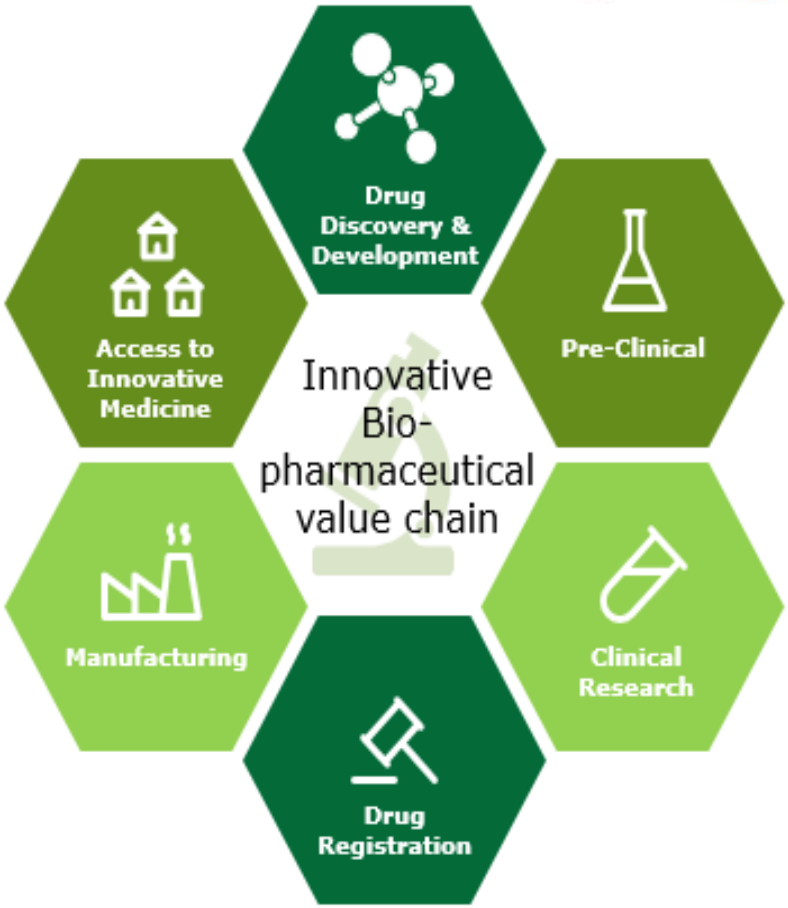
Less phase I and phase II studies

Source: Clinical research impact study in Thailand report 2016, Deloitte Access Economics calculations

Number and Location of Independent Ethics Reviewers Accredited by TDFA across Thailand, 2016

There is limited collaboration between academia, government agencies and industries. More collaborative networks mainly happen vertically within each stakeholder groups.

Source: Deloitte Access Economics



Creates Innovation-driven Economy

Bio-Economy

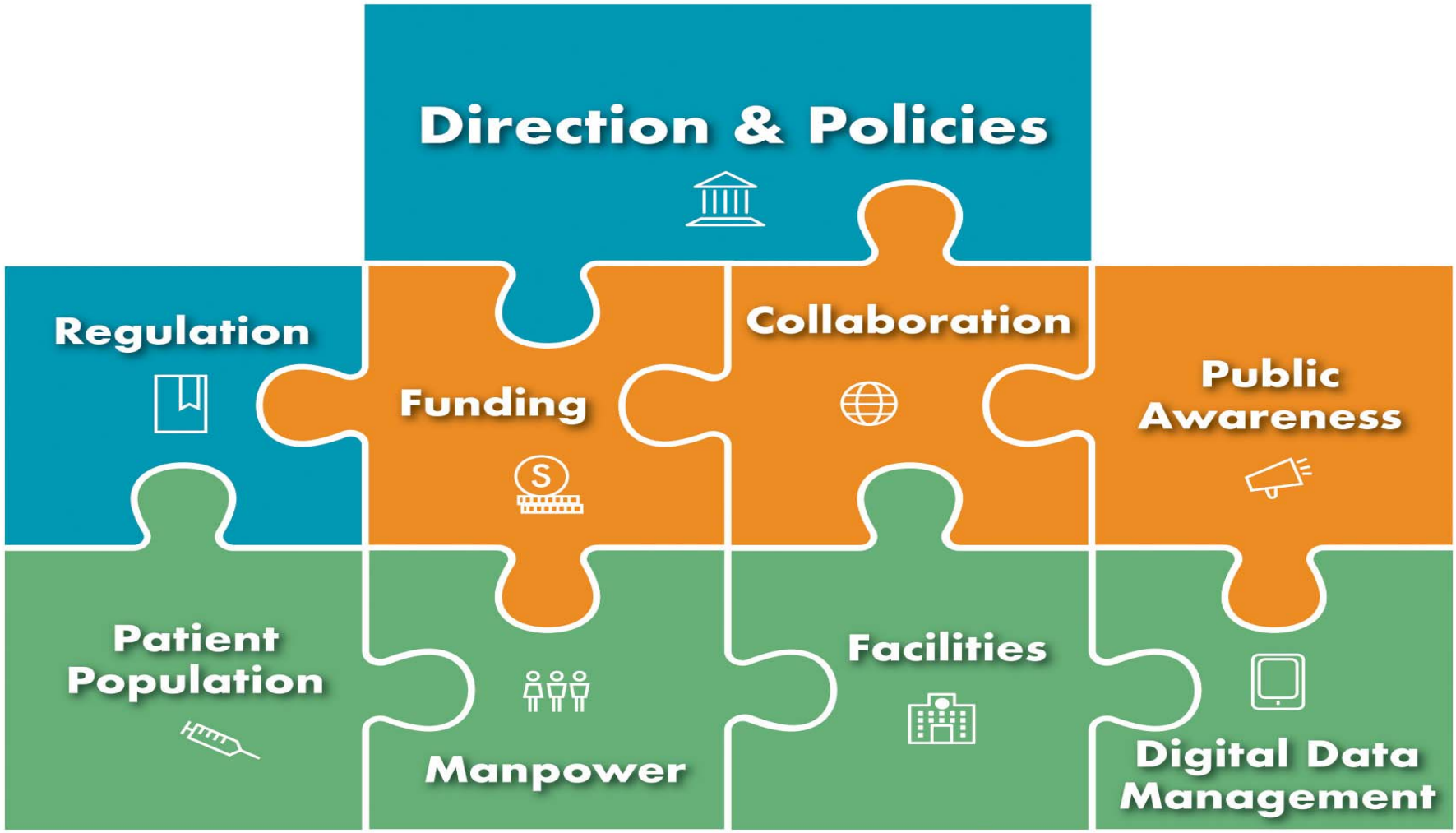
Medical Hub

National Drug System

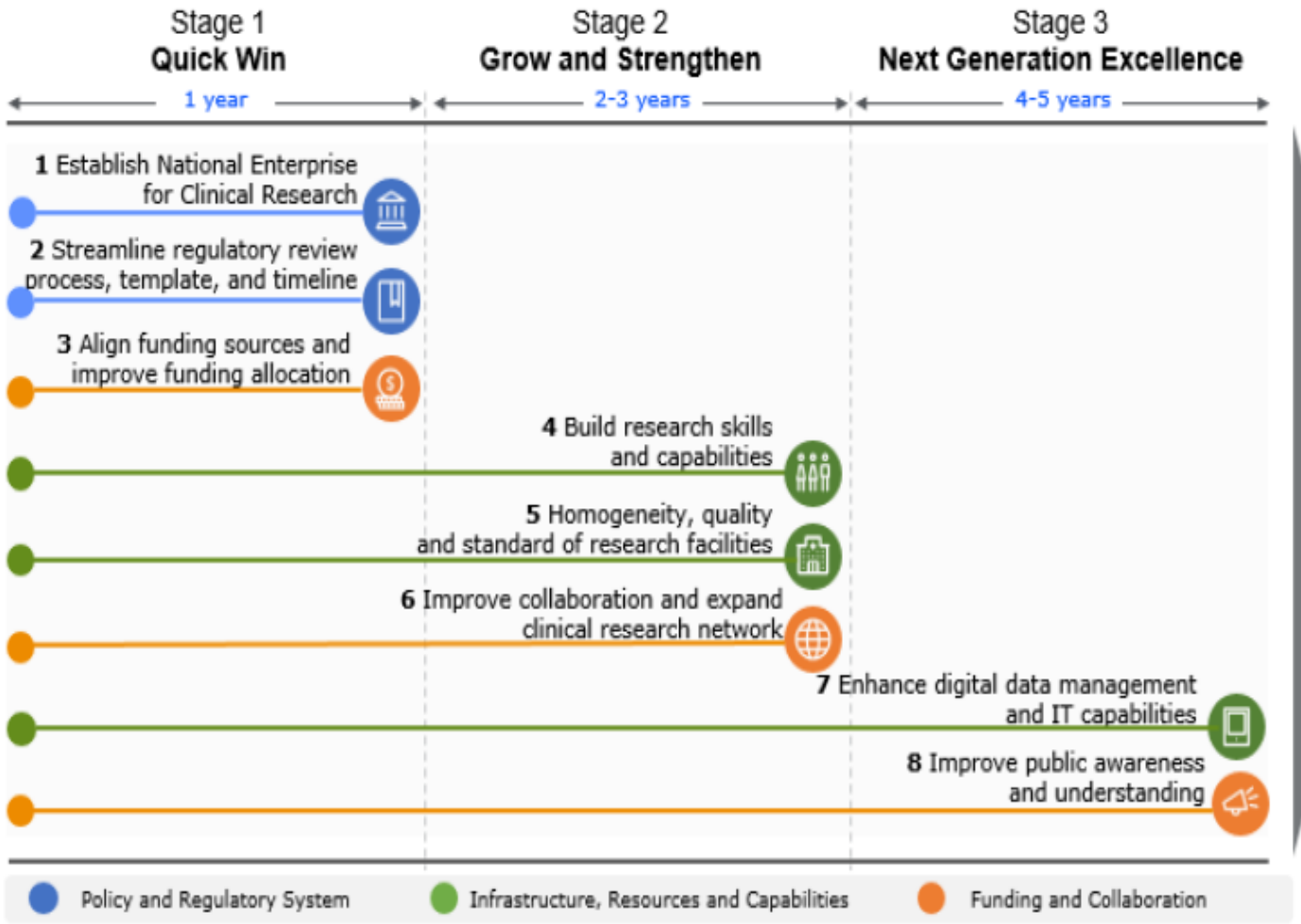
Bio-pharmaceutical value chain supports innovation driven economy in Thailand 4.0

Source: Deloitte research and analysis

Clinical Research Ecosystem



Proposed Five-year Strategic Clinical Research Roadmap



Outcomes

- ✓ Regional hub for CR and R&D innovation
- ✓ Superior patient outcome to quality care and treatment
- ✓ Sustainable and integrated ecosystem for biomedical research
- ✓ Excellence in regulatory frameworks and infrastructure

Source: Deloitte research and analysis

Strategic roadmap for clinical research in Thailand

Stage 1
Quick Win
(1 year)

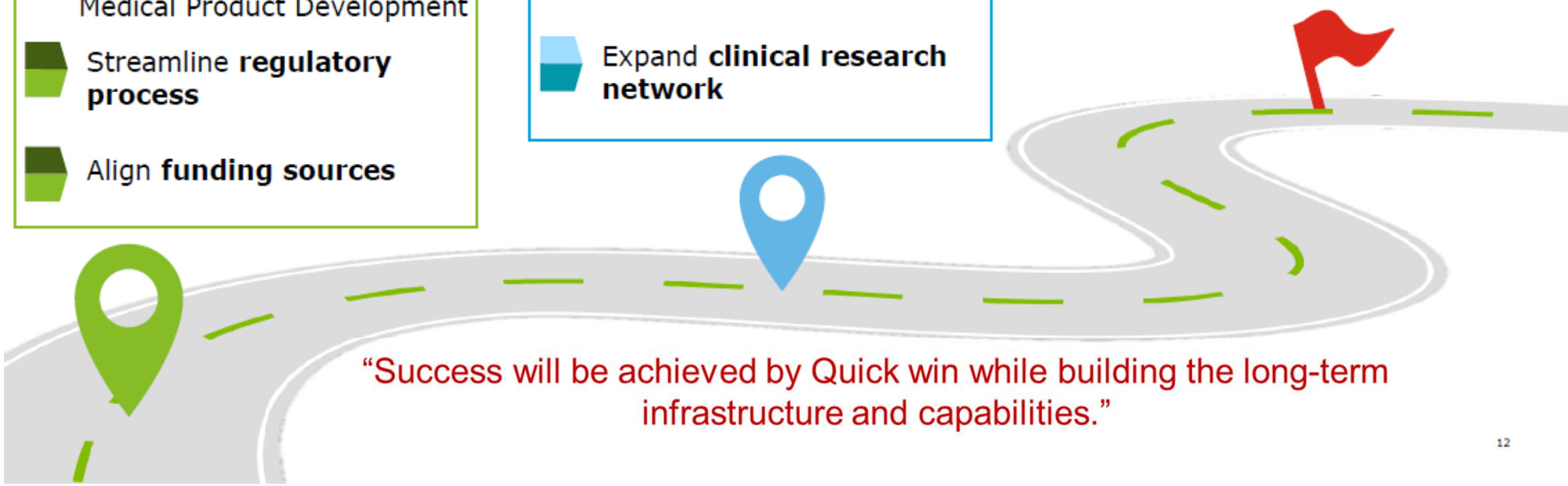
- Establish **National Coordinating Center** for Medical Product Development
- Streamline **regulatory process**
- Align **funding sources**

Stage 2
Grow and Strengthen
(2-3 years)

- Build **research skills and capabilities**
- Homogeneity of **research facilities**
- Expand **clinical research network**

Stage 3
Regional Excellence
(4-5 years)

- Enhance **digital data management**
- Improve **public awareness**



"Success will be achieved by Quick win while building the long-term infrastructure and capabilities."

The Blue print : Health & Wellness – Biomedical (1)

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คลัสเตอร์เทคโนโลยี (Cluster of Technology)	จุดตั้งต้นที่จะต้องริเริ่ม (Killer Applications)	ปัจจัยที่จะต้องเติมให้เต็ม (Missing Links)	กฎหมาย กฎระเบียบ ที่ต้องผ่อนปรน (Constrain Relaxation)
• Clinical Research Management Service • Bio-engineering และ Bioprocess Engineering • หุ่นยนต์ทางการแพทย์และ Biomedical Engineering • Diagnosis และ Medical Devices • Precision Medicine และ Big Data • Wellness Service และ Treatment Innovation • Regenerative Medicine • สมุนไพรและการแพทย์แผนไทย	• Clinical Medicine, Clinical Research Center & Treatment และ Service Innovation - Business - Professional Contracted Research Organization (CRO) • Drug, Biopharm, Neutraceuticals, Drug Delivery, Toxicity Study, Bioequivalence และ Pharmacokinetics - ยาชีววัตถุ โดยเฉพาะอย่างยิ่ง Monoclonal Antibodies - Neutraceuticals สำหรับสุขภาพและความงาม	• ประสิทธิภาพหน่วยงานในการกำกับดูแลและรับรองเช่น องค์การเภสัชกรรม กรมวิทยาศาสตร์การแพทย์ อย. กรมทรัพย์สินทางปัญญา • คณะกรรมการจริยธรรมการวิจัยในมนุษย์กลาง (Central IRB) - ขาดความชัดเจนของนโยบายในการรับรองจริยธรรมที่เป็นแนวทางเดียวกัน • การเพิ่มจำนวน Clinical Research Centers • การเพิ่มจำนวนบุคลากร • การสนับสนุน Translational Research	• เพิ่มประสิทธิภาพ ลดระยะเวลาการขอการรับรองหรือรับบริการจากหน่วยงานในการกำกับดูแลและรับรอง เช่น กรมวิทยาศาสตร์การแพทย์ อย. องค์การเภสัช กรมทรัพย์สินทางปัญญา, GLP PK lab • เพิ่มการจัดซื้อจัดจ้างภาครัฐจากผลงานวิจัยในประเทศ • ISO Certified Testing (ควรใช้สถาบันต่างประเทศมา Certify) • 4. ลดภาระงานสอนและบริการของอาจารย์ในมหาวิทยาลัยวิจัย

Blue Print : Health & Wellness – Biomedical (2)

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คลัสเตอร์เทคโนโลยี (Cluster of Technology)	จุดตั้งต้นที่จะต้องริเริ่ม (Killer Applications)	ปัจจัยที่จะต้องเติมให้เต็ม (Missing Links)	กฎหมาย กฎระเบียบ ที่ต้องผ่อนปรน (Constrain Relaxation)
• Transborder Healthcare • Nano Delivery Systems • Chemical Synthesis / Extraction/ Modification • Nutraceuticals เครื่องสำอางค์และสปา	- ยาสำหรับรักษาโรคใหม่ๆอาทิ Dengue, Zika, Malaria - อาหารสำหรับเด็กอ่อน ผู้สูงวัย และ Non-Communicable Diseases (NCDs) • หุ่นยนต์ทางการแพทย์ - Global Rehab Aging Robotics - การฝึกอบรมทางการแพทย์ • การวินิจฉัยและเครื่องมือทางการแพทย์ - Sleep – Monitor + Imaging	• การเพิ่มจำนวน Knowledgeable Policy Maker • การเพิ่มจำนวน Knowledgeable Regulatory Body • การเพิ่มจำนวน CMO/CRO/Animal Testing • การบริหารจัดการทรัพย์สินทางปัญญา IP • ความเชี่ยวชาญใน Glycotechnology	

Challenges:
1.Harmonizing Clinical Research Centers and Ethical Review Board

1. Establish National Enterprise for Clinical Research • One stop-service and National CR drivers
CTMS, TCELS

CTMS Consortium of Thai Medical Schools
TCELS Thailand Centre of Excellence of Life Sciences

Now-Mahidol University is a system integrater

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Strategic Clinical Research Roadmap Strategy

2. Streamline regulatory review process & timeline	3. Align funding sources & improve allocation on	4. Build research skills and capabilities
• Faster regulatory review timeline	• More matching funds • More oversea funding	• More qualified researchers
CREC, FERCIT, NECAST, Thai FDA, MOPH	MRC, TRF, OHEC, HSRI, TCELS	National Enterprise, MOPH

CREC Central Research Ethics Committee
FERCIT Forum of Ethical Review Committees in Thailand
NECAST National Ethics Committee Accreditation System in Thailand
MOPH Ministry of Public Health

MRC Medical Research Council
TRF The Thailand Research Fund
OHEC Office of Higher Education Commission
HSRI Health Systems Research Institute
TCELS Thailand Centre of Excellence of Life Sciences

MOPH Ministry of Public Health

Strategic Clinical Research Roadmap Strategy

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5. Homogeneity, quality and standard of research facilities

- More qualified research facilities

DMSC, Thai FDA, MOPH

DMSC Department of Medical Science
MOPH Ministry of Public Health

6. Improve collaboration and expand CR network

- Strong CR network
- Outreach programs to oversea networks

TCELS, HSRI, CTMS, ThaiTECT

TCELS Thailand Centre of Excellence of Life Sciences
HSRI Health Systems Research Institute
CTMS Consortium of Thai Medical Schools
ThaiTECT Thailand towards Excellence in Clinical Trials

7. Enhance digital data management and IT capabilities

- CR statistical database
- Protocol e-submission system

NRCT, MOPH, National Enterprise, CTMS

NRCT National Research Council of Thailand
MOPH Ministry of Public Health
CTMS Consortium of Thai Medical Schools

8. Improve public awareness & understanding

- Bigger patient population
- Collaboration in CR development

MOPH, TCELS

MOPH Ministry of Public Health
TCELS Thailand Centre of Excellence of Life Sciences

In Action :
ESTABLISHING NCRC

What's NEXT? (Perspective)

- Listing of potential CLINICAL SITES and GCP compliance sites
- Listing of potential bio pharmaceutical products including herbal products , prioritizing to get near success products with advancement criteria
- Issue of long term funding and commitments
- What's about LONG TERM PLAN?

Long term plan from Bench to Bedside

2. Infrastructure and Capacity Building

One of the important pieces is

Academia

Universities must spearhead the shift to 'Thailand 4.0'

national March 01, 2017 01:00

By Nophakhun Limsamarnphun

The Nation

To successfully implement the national modernization programme dubbed Thailand 4.0, the government needs to work closely with the private sector as well as educational institutes, since human resources are crucial to success.

Need for new curriculum/curricula

- More students go to Science, new methods of teaching
- More on research especially on clinical research
- More researchers works on translational work, and implementation
- More social scientists/researcher
- Career path and incentives
- More of phase I studies

Changing mindset/attitude towards PPPP

Public, Private, People Partnership

3.Collaborations & Clinical Research Network Capabilities

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Location-based

Clinical research networks are formed based on location of resources and infrastructure.

Disease-based

Clinical research networks are formed to tackle specific therapeutic areas such as oncology, respiratory diseases, etc.

Capabilities of each CRC

Research Development
- Budget development and preparation
- Funding & grants
- Protocol development
- Contract negotiation

Regulatory Affair
- Joint IRB/EC submission and review
- Clinical research quality improvement

Data Management & Biostatistics
- Biorepository support – Database of investigator and patient
- study database design and development
- Data collection and management
- Data analysis

Project Management
- Feasibility study
- Site monitoring
- Communications with sponsor
- Budget management
- Sample management
- Study documentation development.

Public Relations & Marketing
PR and marketing with a national and global network.

Education and Training
- Clinical research training and education programs for clinicians, patients and caregivers
- Seminar and workshop

Tox/preclinical ./nonclinical studies

Biomedical product manufacturing under GMP

The medicinal product Information Monitoring

COMPETENT AUTHORITIES- FDA,DMC,IP Departments

Sponsor/Funder //National CRC/CRO

INVESTIGATOR

PATIENTS

Community

ETHICS COMMITTEE

- Independence- Composition -Written opinion -Content of this opinion

CLINICAL LABORATORY ANALYSES

-Equipment
-Staff
-Quality

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More dots/sites to be added here

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4. Knowledge Gaps on Basic Science: Novel Drug/vaccine/ risk markers and…….other aspects like

1. Identifying risk or prognostic factor which should be reproducible
2. If the measure is to be used as a diagnostic test, it should be sensitive and specific and have a high predictive value.

ETC

Need full time highly experienced scientists and researchers with qualified assistants
especially in medical related fields& Multidisciplinary field

Through Effective Collaboration for an Impact of Global Health

- Collaboration among academia,
- government , private within the country.
- International collaboration is one of the
- important keysto fasten the development
- International source of funding as

the country may not have sufficient resources especially on drugs/vaccine/diagnostics/monoclonal antibodies for neglected diseases

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So we are running now :
To achieve the goals within 1-5 Years

- Generic drug
- Biological Products - Biosimilar
- Products from probiotics
- Herbs and Cosmetics
- Smart Medical and Devices Robotics for handicapped
- Elderly Rehab Centers
- Health and cosmetic products
- Medical Tourism

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Health & Wellness – Biomedical

LOOKING FORWARD

Medical Hub of ASEAN
in 2025

Thank you very much

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Deloitte.

Acknowledgement

Academic Institutes
Researchers , Scientists & Educators
Ministry of Public Health
Ministry of Science and Technology
Ministry of Education
Thai Government
The people of Thailand