

# Human Clinical Trial to Support the Development of New Vaccines : Perspective from Thailand

**Akanid W.**

Bureau of Drug Control  
Food and Drug Administration, Thailand

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■ Thai FDA

■ Thailand 4.0

■ Implementation Example

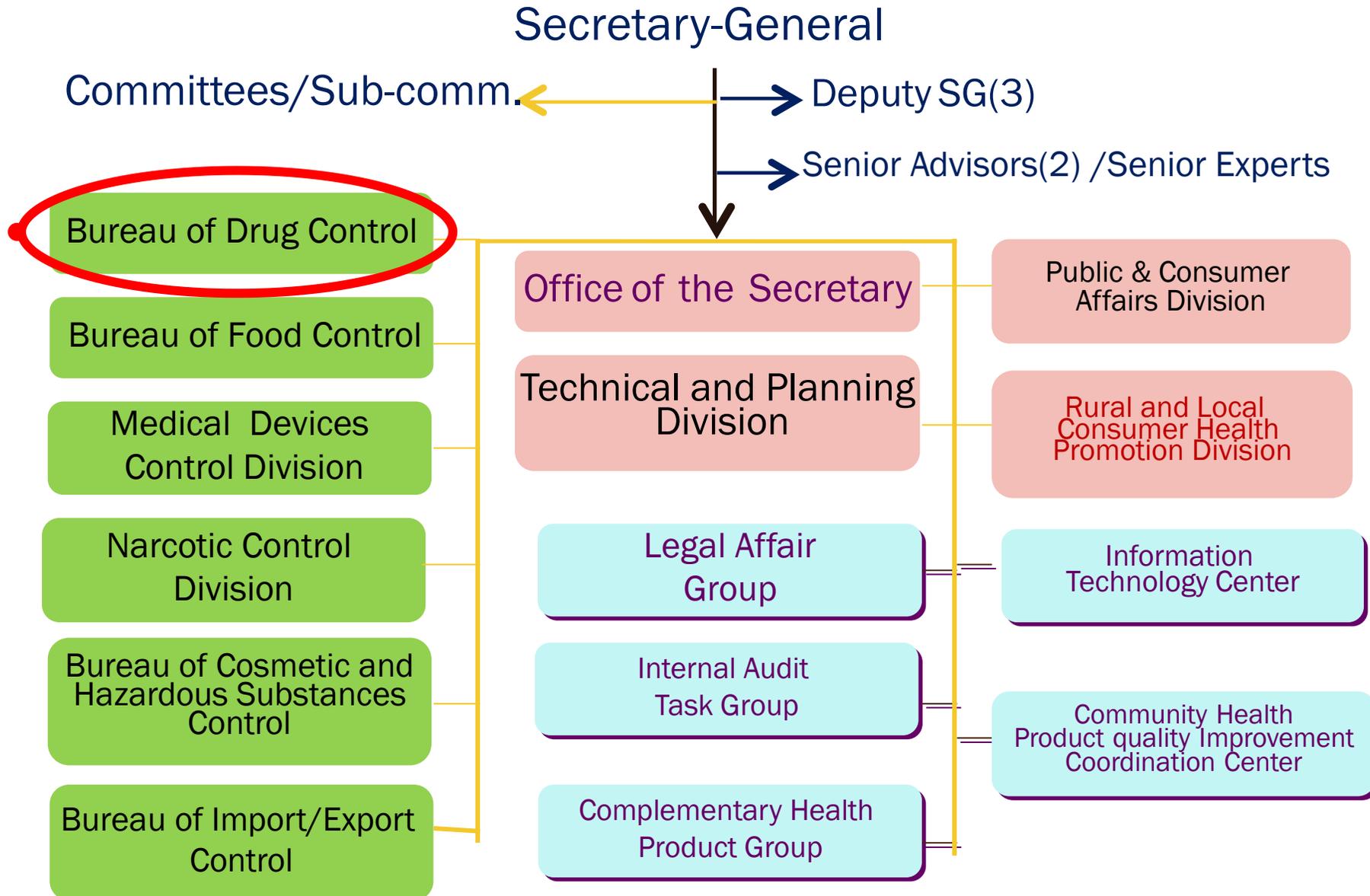
■ Challenges

# Thai FDA

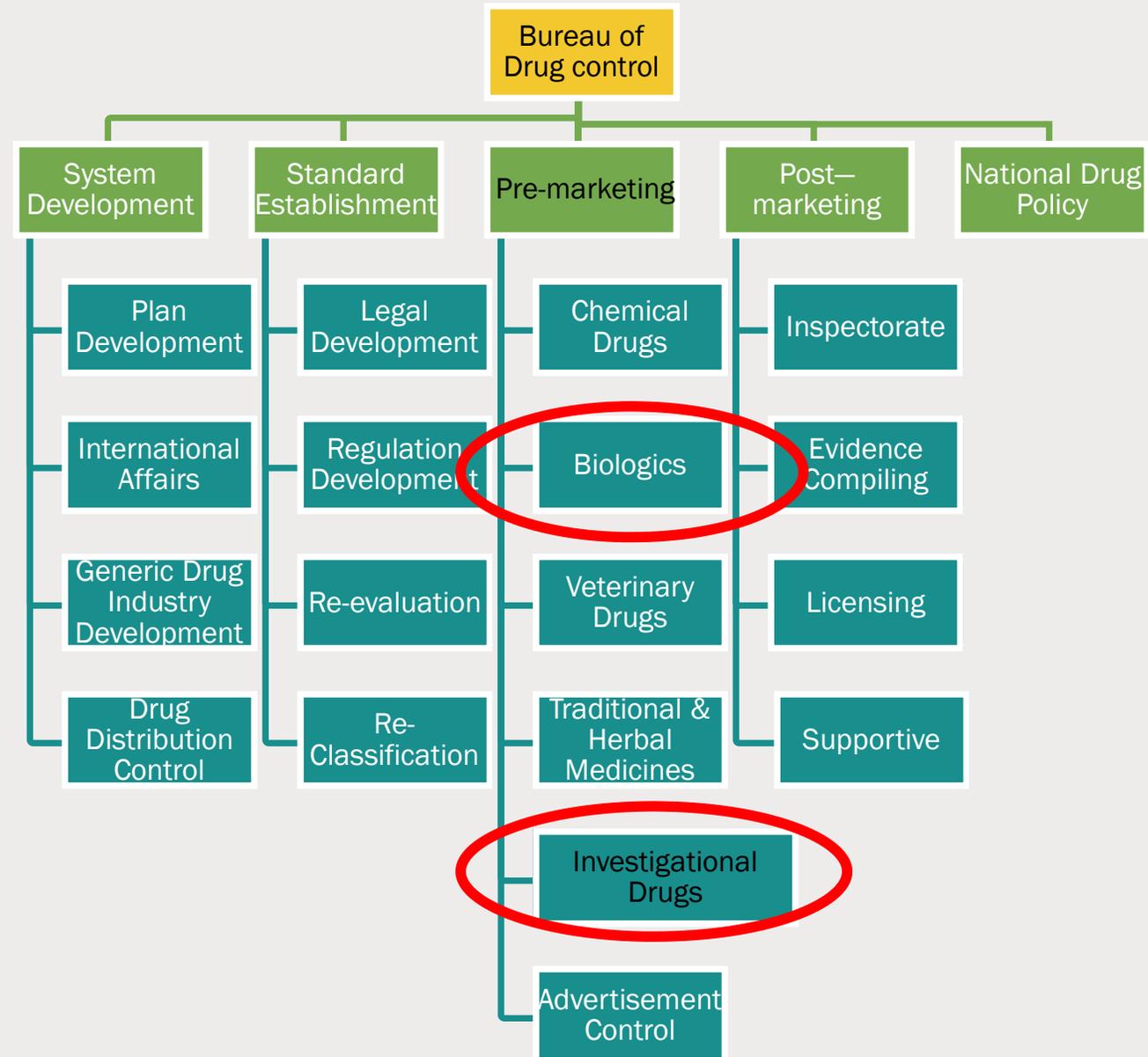


- Food and Drug Administration (Thai FDA)
  - *Under Ministry of Public Health*
  - *National Regulatory Agency*
  - *Medicines, food, medical devices, psychotropic substances, narcotics, volatile substances, cosmetics and hazardous substances*

# Organization Overview : Thai FDA



# Organization Overview : Bureau of Drug Control

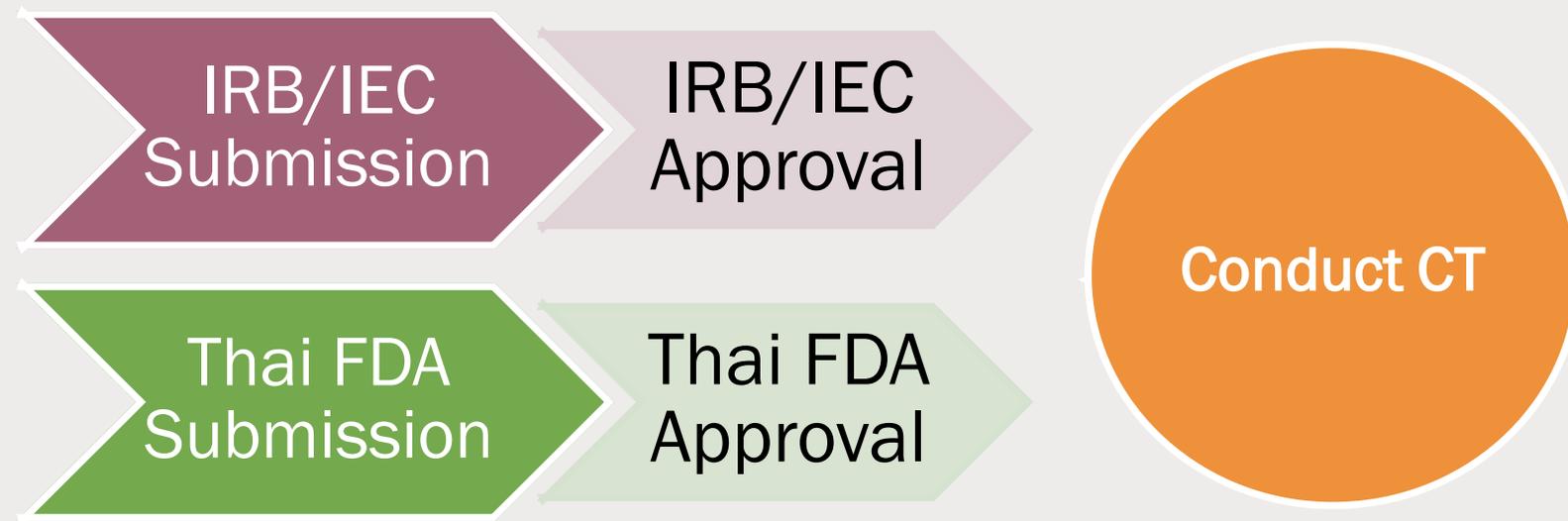


# Clinical Trial Authorization – Before Oct 2016



*Sequential Submission*

# Clinical Trial Authorization – **After Oct 2016** (Current system)



*Parallel Submission*

# Thai FDA's Timeframes

- Clinical Trial Authorization:
  - *Manufacturing Permit for CT : 7-60 working days*
  - *Import Permit for CT : 20-60 working days*
- Registration :
  - *Vaccine : 280 working days*

■ Thai FDA

■ **Thailand 4.0**

■ Implementation Example

■ Challenges

# Thailand 4.0

(Smart Industry + Smart City + Smart People)



Thailand 1.0

Thailand 2.0

Thailand 3.0

Thailand 4.0

Agriculture

Light Industry  
Low wages

Heavy Industry  
Advanced Machine

Creativity + Innovation  
Smart Thailand

# Clusters for Innovation & Start Ups

## Food, Agriculture & Bio-Tech

- Become the center of premium agricultural products and food, and an exporter of technology in agriculture

## Health, Wellness & Biomedical

- Build medical infrastructure and move Thailand forward to be 'Medical Hub' of ASEAN within 2025

## Smart Devices, Robotics & Mechatronics

- Advance as a leader in automatic system, industrial robotics, and service robotics in ASEAN

## Digital, IOT and Embedded Technology

- Enhance productivity, quality and innovation in various economic activities including agriculture, healthcare, and tourism

## 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

# Roadmap : Health Innovation Development

## 1-5 Years

- Generic drugs subject to import substitution
- Biosimilars
- Biopharmaceuticals and products from probiotics
- Herbs and cosmetics
- Smart Medical Devices and Robotics for handicapped
- Elderly rehab centers
- Health supplements
- Medical tourisms

## 5-10 Years

- New biologics for cancer and allergy treatments
- **Advanced vaccines**
- Diagnostics test kits with commercial potential
- Medical robotics that meet international standards
- Quality reagents for automated diagnostic services
- Smart villages for elderly
- Digital health
- Precision Medicine

## 10-15 Years

- New small molecule drugs
- Drugs for targeted therapy
- **New advanced vaccines**
- New biologics
- Surgical robots and medical instruments
- Implanted devices
- Automated Diagnostic Devices
- Specialized Target – Therapeutic Institute

# Our role in Thailand 4.0

- Thai FDA is one of the stakeholders to support Thailand 4.0 model
- As NRA:
  - *Provide consultation in development of new vaccines in Thailand*
  - *Review CT application*
  - *CT inspection for compliance to GCP and our regulations*

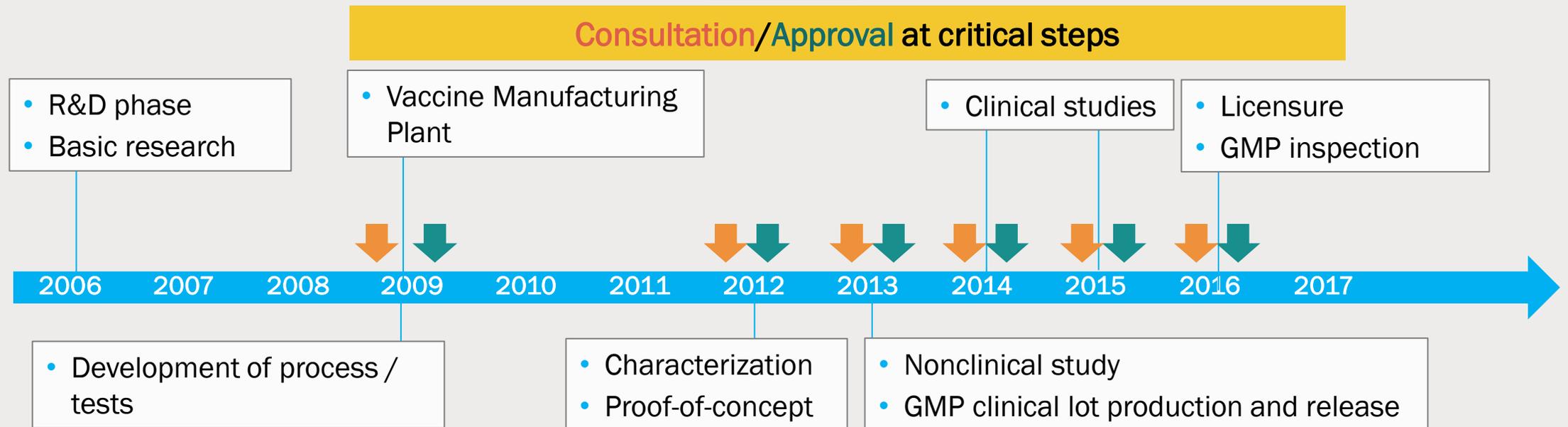
- Thai FDA
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- **Implementation Example**
- Challenges

# Innovative Vaccine Development in Thailand

- Current status
  - *Only few vaccine manufacturers in Thailand.*
  - *Many vaccine R&D but no/less translation from research to manufacturing.*
  - *Limit grants for innovative vaccine development to manufacturing.*
  - *Implementation of all value chains is required.*
- Thai FDA supports local vaccine manufacturers from upstream especially technology/research developed in Thailand.
- For example, new innovative recombinant acellular pertussis vaccine developed by Mahidol University and BioNet-Asia.
  - *First NRA to approve this new recombinant pertussis vaccine for booster use in adolescents and adults.*
  - *No reference for recombinant pertussis vaccine in other countries.*

# Example: New Recombinant Pertussis Vaccine Development in Thailand

- One of key success factors is timely consultation for approval of facility/nonclinical/clinical development/registration with NRA as earliest as possible.



- Thai FDA
- Thailand 4.0
- Implementation Example
- **Challenges**

# Challenges in Vaccine Development

## Human subjects

- vulnerable groups e.g. children, pregnant women, etc

## Innovators

- few innovators
- long R&D process

## Manufacturers

- Few manufacturers
- how to sustain productions & avoid shortages

## EC & Thai FDA

- reviewing timeframe
- advanced in Sciences & Technology

CONCLUSION



*Thank You*  
*For your attention*