Review Policies for Global Drug Development: *Thailand's Perspective*

by

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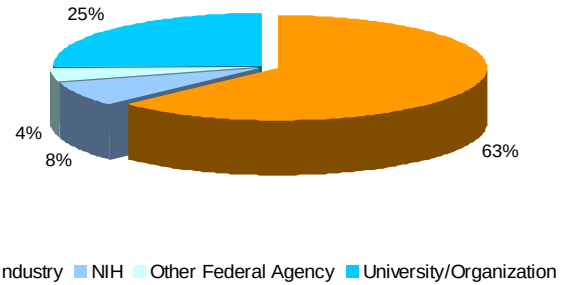
Outline:

- Status of Global Clinical Trial in Thailand
- TFDA's perspective for GDD
- TFDA's policy on review

Status of Global Clinical Trial (GCT) in Thailand

The Clinical Trial – *in Thailand*

Info from http://clinicaltrials.gov
(as of 27-Aug-2007)



Clinical trials in Thailand

Total (IND trial)	291

Major Sponsor

Industry(63 %)	199

Main Areas:

- Cancer
- Cardiovascular
- D.M.
- Digestive system diseases
- Hepatitis,
- HIV/Aids,
- Infectious diseases,
- Mental disorders /behavior study…

Phase: I, II, III, and IV

Awareness on *Global Clinical Trial'* Needs

Quality

- **Investigator**
  - ***knowledgeable***
  - ***experienced***
  - ***compliance to Protocol & GCP***
- **GCP**
  - ***thoroughly understanding***
  - ***fully implement***
- **Sponsor**
  - ***good protocol***
  - ***close internal audit***
- **Regulator (EC, and DRA)**
  - ***competence***
  - ***timely***
  - ***rational and well balance***
    "tech. vs. human protection"

Efficiency

- **world Standards**
- **competitive Time-frame**
- **survival from all Monitoring**
  - ***by various relevant Parties***
  - ***throughout the Trial***
- **acceptable Data/Trial**
- **successful to NDA**

Demographic Overview … (1)

- **Population → *65 million***
- **Medical Hospital Faculty → *12***
- **Health Profession Resources →**
  - ***~ 9,000 Physician,***
  - ***~ 8,000 Dentist,***
  - ***~ 18,000 Pharmacist,***
  - ***~ 153,000 Nurse***

Demographic Overview … (2)

- **Common Non-communicated Disease ;**
  - *Coronary Heart disease*
  - *Hypertension*
  - *Diabetes Mellitus*
  - *Accidental Injury/Trauma*
  - *Cancer*
- **Communicated Disease ;**
  - *Infectious disease*
  - *HIV*
  - *Topical disease*

The Improving / Strengthening

Investigator

- experiencing more in
  - *phase I & II*
  - *pharmacogenomics*
  - *oncology & vaccine*
- Networking approach
  - *HIV-NAT*
  - *CRCN*
  - *ICRCC*
  - *Sirirat-Aclires*
- working to…
  - *increase the Number*
  - *improve Q & Speed*
  - *speed-up Enrollment*
  - *handle High Tech.*
  - *contribute to R&D*

EC

- more specific Training
- more Private ECs
- Joint EC
- Networking
  - *Fercit*
  - *Fercap*
- working to…
  - *SIDCER's Recognition*
  - *competitive timeline*
  - *appropriate Monitoring*

Sponsor&CRO

- more new MNCs
- more CROs
- GCP/CT Training
- closely Consultation
- Internal Auditing
- competitive Start-up

Regulator

- amendment Regulation
- qualifying the System
  - *the review*
  - *the monitoring*
- working to…
  - *handle early Phases CT*
  - *protect the Subject*
  - *meet Regulatory Std.*

Conclusion

- **all Stakeholders, *Aware !***
- **foreseen the Benefit of GCT**
- **interesting and willing to Participate**
- **prepare & get Ready for GCT**
- **working on…**
  - **new Strategic Roadmap**
  - **Pharmacogenetics**
  - **Clinical Research Center**
  - **Strengthening & Networking “Stakeholder”**

TFDA's perspective

for Global Drug Development (GDD)

Notice the Changes

Trend of Global Clinical Trial

- **IND in**
  - ***multi Sites***
  - ***multi Countries***
- **early Phases in the Country**
- **competitive Enrollment**
- **intensive Global monitoring**

Movement of Stakeholders

- **strengthen *Strategic Roadmap***
- **fasten Timeline**
  - ***approvals***
  - ***start-up***
- **enhancing *Quality & Competency***
- **close-follow up the *Global Drug Development situation***

TFDA – *perspective to GDD*

- **world Standard**
- **better coverage on Safety & Efficacy**
  - ***various Ethnics***
  - ***both Intrinsic & Extrinsic factors***
- **fasten CT's Completion**
- **sooner Access to medicine**

TFDA – *perspective to GDD in the Country*

- **better Data on Thai Population**
  - ***Dose***
  - ***ADR***
- **elaborate the National system**
  - ***knowledge***
  - ***experiences***
- **further benefit on R&D**
  - ***contribution to GDD***
  - ***local (i.e. neglected diseases)***
- **facilitate the NDA-registration**

Thai Regulation on IND

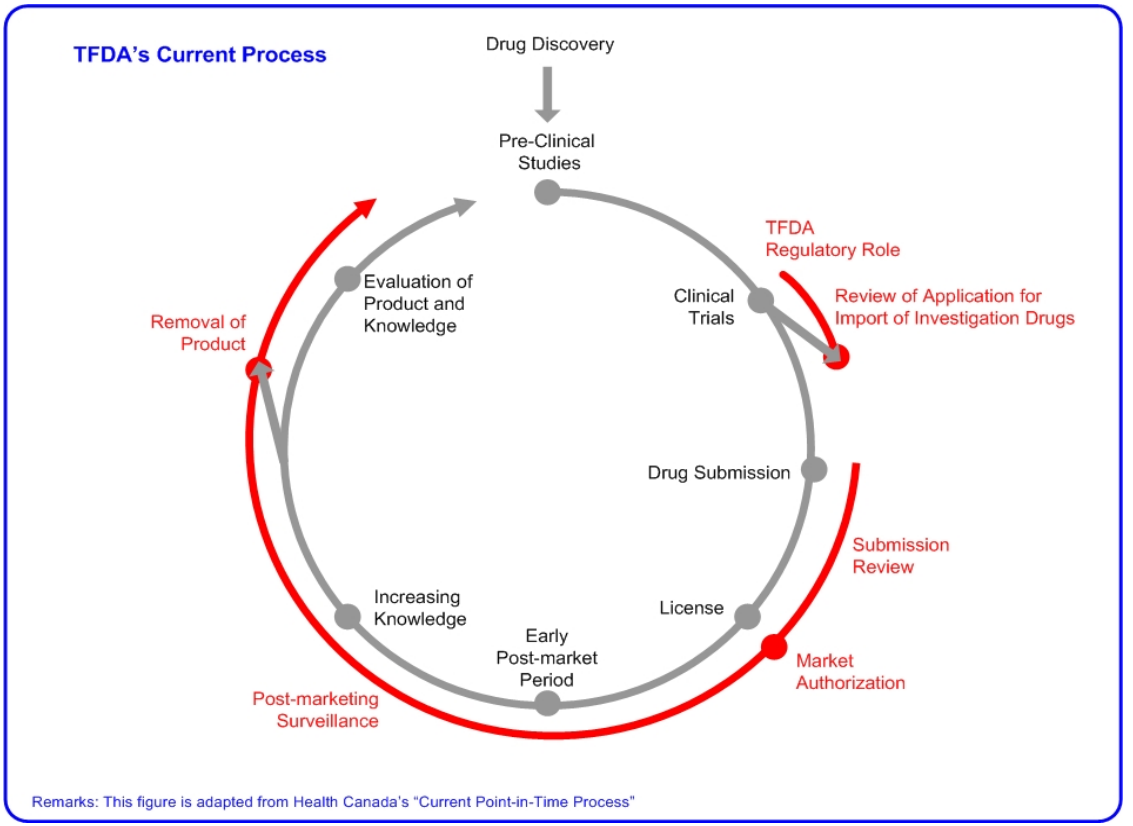
Current

- **sequence Application, after EC Approval**
- **need :-**
  - *Drug label*
  - *Drug leaflet*
  - *CFS (or EC Approval)*
  - *Clinical Trial Report*
  - *Clinical Trial Protocol*
- **Requirement :-*voluntary***
  - *GCP*
  - *Report of "Unexpected-SADR"*
- **Scientific Review/Assessment**
  - *partial & initiative step*
- **Accepted ECs**
  - *design by Sub-National Drug Committee*
  - *total of 9 ECs*
- **GCP Inspection :- N/A**

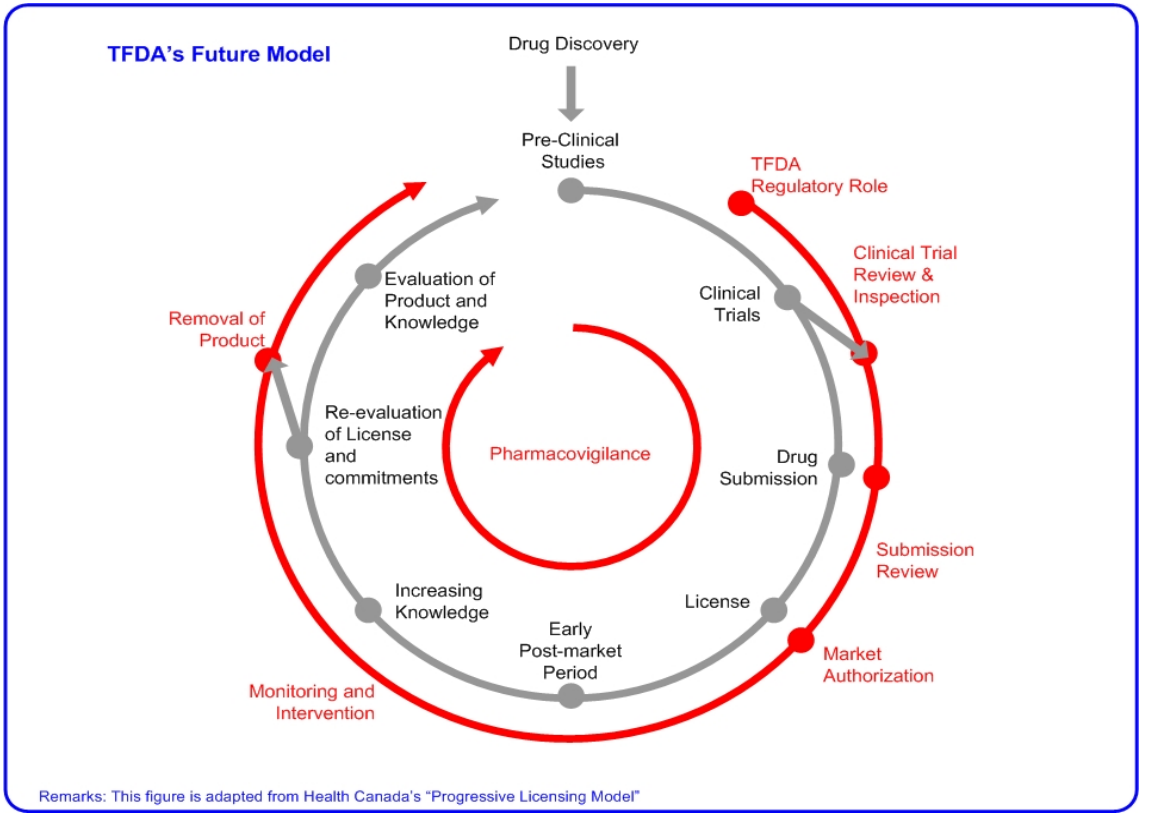
Tentative- New

- **might allow "Parallel Application"**
- **need :-**
  - *Drug label*
  - *Drug leaflet (for registered Drug)*
  - *Investigator Brochure*
  - *Patient Information Sheet (in Thai)*
  - *Clinical Trial Protocol*
  - *Info. on Drug Quality & GMP*
- **Requirement :-*mandatory***
  - *GCP*
  - *GMP*
  - *Report of "Unexpected-SADR"*
- **Scientific Review/Assessment**
  - *Systemic & Fully implement*
- **Accepted ECs**
  - *formal System*
  - *coop. with SIDCER/FERCAP*
- **GCP Inspection :-** *formal System*
- **IND→ NDA**

Current Regulatory Process



Future Regulatory Model



Conclusion

- **welcome and provide Cooperation, *accordingly***
- **preparing for GDD**
  - ***standardize the "Scientific Review"***
  - ***appropriate Timeline***
- **protecting Subject**
  (w/o posing any irrational obstacles)
- **Working on…**
  - ***parallel CTA***
  - ***IND → NDA***

TFDA's policy on Review

TFDA's policy - *Review*

- **Focusing**
  - *quality*
  - *clarity*
  - *transparency*
- **Next**
  - *efficiency*
  - *Good Review Practice*

TFDA's policy – *Review on GCTs*

- **aware on**
  - *- crucial Timeline*
  - *- a need of Competent DRA*
  - *- integrity of Global Protocol*
- **strategy**
  - *- strengthening Reviewer*
  - *- systemic the Procedures*
  - *- providing rational Supports*

Thank you....

กลุ่มสถาบันแพทยศาสตร์แห่งประเทศไทย
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Office of the National Research Council of Thailand

สสส

TCELS
Thailand Center of Excellence for Life Sciences

CRCN

Ref: Dr.Pyatat TATSNAIVAT

CRCN
The Consortium of Thai Medical Schools

- **Members:** *all medical schools (16)*
- **CRCN:** *the only research network of the consortium*
- **over** *12,000 beds*
- **with** *> 18,000 beds* **(Regional Hospital, MOPH)**
- **All** *clinical specialties*
- **Many (over 200) with** *Clinical Epidemiology training*
- **Qualified** *Laboratories*
- **Clinical Trial** *Centers-networking*
- **Virtually** *1 Policy-making body*
- **Shared** *resources-profits*

ICRCC
International Clinical Research Collaboration Center

Ref: Dr.Pyatat TATSNAIVAT

Changing – *Networking (3)*