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Status of *Clinical Trial Environment* in Thailand

by

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Outline:

- Sponsor & CRO
- Investigator
- Ethical Committee (EC)
- Regulation
- Others

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Sponsor & CRO

- **Current Sponsors (for 291 trials -as of 27 Aug 07)**
  - major are MNCs (63%)
  - also others (University/Organization 25%, NIH 8%, and other Federal Agency 4%)
- **CRO**
  - domestic CRO (Medica Innova,..)
  - normal CRO (Apex, Covance, Quintites)
  - Institute-CRO networking (Aclires, Apec-IATEC)
- **Trend & Plan :-**
  - provide Training
  - internal Auditing
  - enhance Successful in competitive enrollment
  - imported Tax

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Investigator

- **experienced** (in Pharmaceutical, and Biological Trials)
  - various Phases :- *I, II, III, and IV*
  - Vaccines
  - various area :-Cancer, Cardiovascular, D.M., Hepatitis, HIV/AIDs, Infectious & Topical diseases, Accidental Injury/Trauma)
- **Networking**
  - CRCN (Clinical Research Collaboration Network)
  - HIV-NAT (The Thai Red Cross AIDS Research Center)
- **Trend & Plan :-**
  - to increase in a Numbers
  - to improve Quality & Speed of the Trial
  - to work in New highly technology (i.e. Snip,
  - enhancing the contribution to the R&D

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Ethical Committee

- **Current ECs (~ 20 ECs)**
  - Types:- *government, academic, private*
  - Joint Research Ethics Committee (JREC)
- **Standards**
  - International Std. (CIOMS, ICH-GCP, Declaration of Helsinki, WHO)
  - Strengthening Members (Training, and Study Visit-WIRB)
- **Networking :-**
  - FERCIT – *Forum of Ethical Review Committees in Thailand*
  - FERCAP – *Forum of Ethical Review Committee in the Asian & Western Pacific Region*
- **Trend & Plan :-**
  - SIDCER / FERCAP audit-recognition programme
  - OHRP/FWA Registration
  - acceptant by the TFDA
  - competitive Timeline

Regulation by TFDA

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**

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**

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Others

Infrastructure

- pop. ~ 65 mill.
- Med.Hospital Faculty =12
- Health Professional Resources ;
  - ~ 29,000 Physician
  - ~ 8,000 Dentist
  - ~ 18,000 Pharmacist
  - ~ 153,000 Nurse

ICRCC

(International Clinical Research Collaboration Center)

- **Members:**
  - *CRCN*
  - *PReMA*
  - *TCELS*
  - *TDRI*
- **Activites:**
  - *info. exchange*
  - *management team*
  - *research collaboration& services*
  - *Quality system*
  - *network to all Stakeholder*
- **Outcome :**
  - ***Clinical Research Center***

SIDCER

(The Strategic Initiative for Developing Capacity in Ethical Review)

- **Primary Objective:**
  to contribute to human subject protections globally by developing capacity in ethical review and the ethics of health research.
- **Activites:**
  - *survey*
  - *training*
- **Cooperation with TFDA :**
  - *Acceptance EC's List*
  - *Capacity building*

Situation

- GCP adopted in 2000
~ 6,000 trainees on GCP(y.2002-7)
- active and closely cooperation
- regular *Annual Seminar*
- willing & ready for participate - "Global Drug Development"

Thank You

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