CLINICAL RESEARCH IN INDONESIA: ARE WE READY?

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Introduction (1)

- Indonesia is an archipelago with more than 17.000 islands
- Current population: more than 230 millions With per capita income of US $ 1.810 in 2014
- There are 72 medical schools, 32 of them have been accredited A or B
- Currently, about 12 medical schools and special hospitals are actively involved in clinical research activity
- Until 2014, there were 110.776 GPs and 19.367 specialists in Indonesia (Abidin Z – IDI, 2014)

Introduction (2)

- Today the implementation of simultaneous global clinical trials are very important to speed up new drug development
- Roughly, 1 day delay of marketing approval causes loss of US $ 1.000.000,-
- The implementation of clinical research in Indonesia and other Asian countries is associated with some potential benefits:
  - Lower trial cost
  - "Less strict" regulations
  - Wide variety of diseases
  - More availability of research subjects
  - Many tropical diseases could not be explored in non-tropical countries

Introduction (3)

- The question is: How can we be assured that:
  - the quality of the trial meets the global standards?
  - are there clear regulations that control the conduct of clinical trials in Indonesia?
  - are the local regulations compatible with the internationally accepted principles?

Fig. 1


MAP OF INDONESIA
ANDAMAN SEA
THAILAND
SOUTH CHINA ASIA
Banda Aceh
Medan
MALAYSIA
Kuala Lumpur
SINGAPORE
MALAYSIA BORNEO
PACIFIC OCEAN
Manado
HALMAHERA
Padang
KALIMANTAN
Balikpapan
Palu
Raja Ampat
Sorong
Jayapura
SUMATRA
SULAWESI
IRIAN JAYA
BANDA ISLANDS
N
W
E
S
Krakatoa
Jakarta
Makassar
BANDA SEA
JAVA
Surabaya
KOMODO
Jogyakarta
BALI
FLORES
ALOR
EAST TIMOR
LOMBOK
SUMBAWA
SUMBA
Kupang
INDIAN OCEAN
WEST TIMOR
Darwin
AUSTRALIA
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Outlines

- Ethics Committee
- Local regulations
- Inspection and audit
- GCP
- Our strength and weakness
- Major health problems in Indonesia
- Issues to be settled

Why do we have to do clinical research?

1. It helps us to solve various health problems in the most efficient way
2. It helps us to reduce cost of health care
3. It helps us to use the most efficacious and safe drugs or methods to improve the our health care
4. It improves the scientific image of our scientists and our nation
5. It opens the door for our scientists to contribute to mankind

Ethics Committee

- 1982: the first EC was established in Indonesia
- 2003: the MoH established the National Committee on Ethics of Health Research (KNEPK) with task to improve the capability of ECs in Indonesia
- Today there are 55 ECs throughout Indonesia registered in the KNEPK, 8 of them have been recognized by the FERCAP: Litbangkes KemKes, FK Unhas, FKUI, FK UGM, FK Unpad, FK Univ. Udayana, FK Univ Brawijaya

Local regulations related to the GCP and clinical trials (1)

- All pre-marketing CTs in Indonesia must meet the GCP standard (SK Kabadan POM, 2001)
- All of these trials must obtain ethical and authority approvals prior to their implementation.
- The procedure to obtain regulatory authority's approval are well described (Buku CUKB, 2001)
- In Indonesia, trials involving drugs already approved for marketing are not required to apply for approval if they are not intended for claiming new indications

Local regulations related to the GCP and clinical trials (2)

- In Indonesia, in addition to evaluating the ethical aspect, the ECs must also evaluate the scientific aspect of clinical trial protocols
- Majority of pivotal drug-related CTs will be inspected by the regulatory agency (routine and "for cause")
- All CTs must be registered to MoH
- All biological materials are not allowed to be sent to foreign countries, except if the assays required for the trials could not be performed by local labs

Issues requiring attention

1. Contract Research Organization
2. Material Transfer Agreement
3. Accreditation of ECs
4. GCP trainings
5. Local insurance companies

Our strengths

Availability of :

- Hospitals and health centers (puskesmas)
- Capable and qualified manpower
- Regulations related to clinical research
- CROs
- Accredited clinical labs
- Strong and high quality pharmaceutical industry
- Wide variety of diseases

Our weaknesses

- Less standardized Ethics Committees
- Lack of network in drug development research
- Low quality of some clinical trials
- Some “less friendly” regulations
- Lack of insurance companies
- Small number of research-oriented local pharmaceutical industry
- Most of our pharmaceutical companies lack spirit to innovate

Our opportunities

- The global need to develop new drugs in short period of time
- Large patient populations
- Competitiveness of research cost
- The piling up of health problems in Indonesia

Our threats

- Competing countries (especially China, Thailand, and Vietnam)

What do we have to do?

- Quality improvement of CT implementation: CRO, inspection, audit, GCP, protection of human subjects
- Quality improvement of ECs: accreditation, SOPs, independency, GCP, trainings
- Regulations: removal of regulations that may hamper development of the role Indonesian scientists in global clinical research, esp. for premarketing trials

Table 1

Major communicable diseases in Indonesia

Diseases
Upper resp. tract infection
Pneumonia
Lung tuberculosis
Hepatitis
Diarrhea
Malaria

(Riskesdas, Ministry of Health of Indonesia, 2013)

Major non-communicable diseases in Indonesia

Diseases
Asthma
Chronic obstruct. Pulmonary disease
Cancer
Diabetes mellitus
Hiperthyroidism
Hypertension
Coronary heart disesase
Stroke
Chronic renal failure
Kidney stone
Rheumatic diseases

(Riskesdas, Ministry of Health of Indonesia, 2013)

Conclusions

- Clinical research is the key solution for various health problems throughout the world
- Indonesia potentially has a big opportunity to become a prominent player in clinical research
- Some research institutions in Indonesia are ready to carry out high quality clinical research
- More opportunity has to be given by the sponsors to Indonesia to show its ability in executing high quality clinical research

THANK YOU