Clinical Research in Academia

A viewpoint from Indonesia

Rianto Setiabudy
Department of Pharmacology
Faculty of Medicine, University of Indonesia
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Introduction (1)

- Indonesia is an archipelago with more than 17,000 islands
- Current population: more than 220 million with per capita income of US$ 2271
- There are 69 medical schools, 53 of them have been accredited
- Currently, about 10 medical schools are actively involved in clinical research activity
- Until August 2008, there were 56,750 GPs and 15,499 specialists in Indonesia (Data: KKI, 2008)
Today the implementation of simultaneous global clinical trials are very important to speed up new drug development.

The implementation of clinical research in Indonesia and other Asian countries is associated with some potential benefits such as:

- Lower trial cost
- Less strict regulations
- Wide variety of diseases
- Availability of research subjects
Introduction (3)

- The question is: How can we be convinced that clinical trials in Asian countries meet the global standard?

- The purpose of this presentation is to share information on various aspects of clinical research activity in academia in Indonesia.
Introduction
Outlines

- Ethics Committee
- Local regulations
- Inspection
- GCP in academia
- Major health problems
- Issues to be settled
Ethics Committee

- 1982: the first EC in the country was established
- Today ECs exist in the majority of schools and hospitals which are conducting clinical research
- 2003: the Minister of Health established the National Committee on Ethics of Health Research with the tasks to improve the capability of the ethics committees
- 2009: there are 34 ECs throughout the country
Local regulations related to GCP and clinical trials (1)

Pre-marketing clinical trials (Phases 1, 2, and 3):

- All have to follow the GCP standard
- These trials should get the authority’s approval prior to their implementation
- The sponsor should submit an application (using form UK-1) plus with the following documents:
  - Research Protocol and written information for the research subjects
  - Approvals from the Ethics Committee and Scientific Committee
Local regulations related to GCP and clinical trials (2)

• Investigator’s brochure
• Amount of drug needed for the trial
• If approved by the RA, both the letter of approval and license for drug importation will be sent to the investigator in 10 working days
• This policy is applied also for:
  • Studies on drugs that are already on the market but apply for new indications (pivotal study)
  • BA/BE studies
Local regulations related to GCP and clinical trials (3)

Post marketing trials (Phase 4 studies):

• All have to follow the GCP standard
• The sponsor should send a notification letter to the RA prior to the implementation of the study
• If there is no response from the authority within 10 working days, the trial may be started
• In Indonesia, post-marketing surveillance is not classified as clinical trial
Local regulations related to GCP and clinical trials (4)

Post marketing trials for educational purpose (medical students, residents, etc):

• All have to follow the Declaration of Helsinki, but not the GCP standard
• The investigators should send a notification to the Regulatory Authority prior to the implementation of the study
Local regulations related to GCP and clinical trials (5)

Other regulations:

• The Regulatory Authority requires that research protocols be reviewed not only by the Ethics Committee but also by the Committee

• If an institution does not have a Scientific Committee, then the scientific aspect should be reviewed by the Ethics Committee

• Reason: clinical research with poor methodology is unethical
**Inspection**

- Currently inspection is carried out routinely by the Regulatory Authority
- Types of inspection:
  - Routine
  - ‘For cause’
- Places of inspection:
  - Trial site(s)
  - CRO’s office
- Priority: pre-marketing and BA/BE studies
GCP in academia (1)

• Prior to 2000:
  • Mostly were small scale marketing trials
  • No mechanism to control the quality of these trials
  • Ethics Committees did not exist in most institutions
  • Most investigators had no idea what GCP was
  • Informed Consent were often neglected

• Year 2000: the Clinical Trial Working Group (CTWG) was established with a mission to improve the quality of clinical trials in Indonesia
GCP in academia (2)

• The CTWG consisted of people from academia, industries, clinical lab, and regulatory authority
• In 2001: Indonesia adopted the ICH-GCP and the Regulatory Authority issued some regulations related to the implementation of the GCP
• Since 2001 the CTWG carries out trainings in GCP and research methodology in various medical faculties and research centers
GCP in academia (3)

• Later on other organizations also participate in giving the GCP trainings
• Today, approximately 150 clinical researchers throughout the country hold the GCP certificate
• Typically a GCP certificate could be obtained after a person attended a 2-day course and passed an examination
• GCP courses are often provided by the sponsors prior to the commencement of a clinical trial
## Major causes of death in Indonesia (Year 2007)

<table>
<thead>
<tr>
<th>No</th>
<th>Diseases</th>
<th>%</th>
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<tbody>
<tr>
<td>1</td>
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<tr>
<td>9</td>
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</tr>
<tr>
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<td>lower resp. tract infections</td>
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</table>

(Riskesdas, Ministry of Health of Indonesia, 2007)
Important health problems in Indonesia (1)

Proportion of contagious diseases

<table>
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<tr>
<th>No</th>
<th>Diseases</th>
<th>%</th>
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<td>tuberculosis</td>
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<tr>
<td>2</td>
<td>liver infections</td>
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<tr>
<td>6</td>
<td>malaria</td>
<td>4.6</td>
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<tr>
<td>7</td>
<td>meningitis/encephalitis</td>
<td>3.2</td>
</tr>
<tr>
<td>8</td>
<td>dengue hemorrhagic fever</td>
<td>2.1</td>
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<tr>
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<tr>
<td>10</td>
<td>septicemia</td>
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</table>

(Riskesdas, Ministry of Health of Indonesia, 2007)
Important health problems in Indonesia (2)

Proportion of non-contagious diseases

<table>
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<th>Diseases</th>
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(Riskesdas, Ministry of Health of Indonesia, 2007)
Issues to be settled

• Local insurance
• Sending material to foreign countries
• Sophisticated information for trial subjects
• Trial monitors
• GCP trainings
• Ethical approvals for multi-center clinical trials
• Scarcity of publications
Conclusions

• Currently the conditions required to conduct GCP-compliance trials are much improved in Indonesia

• Indonesia, and many other Asian countries, could carry out clinical trials with good quality and contribute significantly to the global drug development

• Asian studies may offer certain benefits to the sponsors

• Academia play the key role in the implementation of good clinical research
Thank You