การแลกเปลี่ยนเรียนรู้ด้านงานวิจัย

Standard Course in Clinical Trial 2013

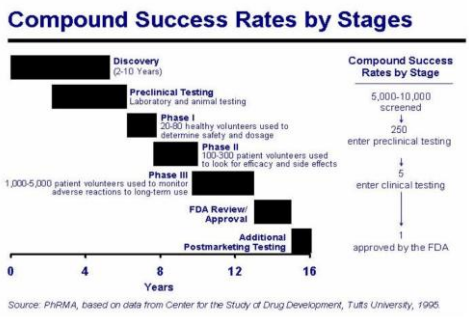
อ.ภก.นพดล นันตี๊ะมูล

อ.ภญ.ปนัดดา เดชวงศ์ญา

3 เมษายน 2556

Clinical Trials

- Epidemiology: the study of the *distribution* and *determinants* of health related states or event in specified populations, and the application of the study to *control* health problems.
- Intervention study: an investigation involving intentional change in some aspect of the status of the subjects, e.g., introduction of a *preventive* or *therapeutic regimen*, or designed to test a *hypothesised relationship*; usually an *experiment* such as a *randomised controlled trial*.

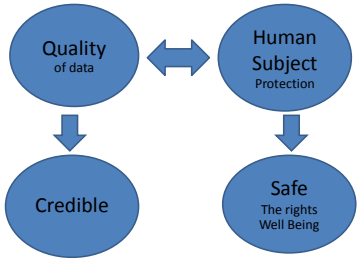


Clinical Equipoise

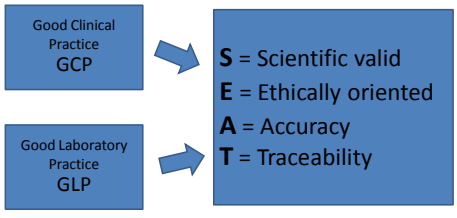
- According to this concept of "***clinical equipoise***", the requirement is satisfied if there is genuine uncertainty within the expert medical community – not necessarily on the part of the individual investigator – about the preferred treatment.

ICH-GCP

- Why GCP?



Good Clinical Trial



To find a New drug or New Rx regimen or Strategy or Vaccine: Better efficacy, less toxic, less expensive, better compliance, prevention of infection or cancer

ICH : USA, EU, Japan

- The **International Conference on Harmonisation** of Technical Requirements for Registration of Pharmaceuticals for Human Use
- GCP: Good Clinical Practice (การปฏิบัติการวิจัยทางคลินิกที่ดี)
  - เป็นมาตรฐานสากลด้านจริยธรรมและด้านวิชาการ สำหรับใช้ในการวางรูปแบบการดำเนินงาน การบันทึกข้อมูล และการเขียนรายงาน การศึกษาวิจัยในมนุษย์การปฏิบัติตามเกณฑ์มาตรฐานนี้เป็นการรับประกันต่อสาธารณชนว่า **สิทธิ ความปลอดภัย และความเป็นอยู่ที่ดีของอาสาสมัคร**ได้รับการคุ้มครอง ตามหลักการแห่งคำประกาศเฮลซิงกิ (Declaration of Helsinki) และ**ผลการวิจัยทางคลินิกเชื่อถือได้**

วัตถุประสงค์ของแนวปฏิบัติ ICH-GCP

- เพื่อให้มีมาตรฐานเพียงหนึ่งเดียว สำหรับการศึกษาวิจัยทางคลินิกของประเทศใน
  - สหภาพยุโรป
  - ญี่ปุ่น
  - สหรัฐอเมริกา
- ซึ่งจะเอื้อให้หน่วยงานควบคุมระเบียบกฎหมาย ยอมรับข้อมูลทางคลินิกของกันและกัน

IRB or REC

- IRB (Institutional review board) / REC (Research ethics committee)
  - also known as an **independent ethics committee** or **ethical review board**, is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.
- Review
  - Protocol
  - consent
  - Investigator (+site)

Informed Consent and Assent

- Informed consent in ethical guidelines
  - Declaration of Helsinki
  - ICH GCP
- Consent VS. Assent
- Waivers

Waiver

- Waiver of the consent requirement – Investigators should never initiate research involving human subjects without obtaining each subject's informed consent, unless they have received explicit approval to do so from an ethical review committee.
- The ethical review committee may waive some or all of the elements of informed consent when
  - The research design involves no more than minimal risk
  - A requirement of individual informed consent would make conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records)

Monitoring and Auditing

- Monitoring
  - Ensure that the study is being conducted and documented properly
- Auditing
  - Systemic and independent examination, snapshot
- Inspection
  - To assess compliance with FDA's regulations governing the conduct of clinical trials

Safety Report and SAE Handling

- Serious Adverse Event (SAE): adverse event which
  - Result in death
  - Is life-threatening
  - Requires in-patient hospitalization or prolongation of existing hospitalization
  - Results in persistent or significant disability/incapacity
  - Is congenital anomaly/birth defect
  - Medically significant
- All SAEs should be reported immediately to the sponsor (within 24 hours).

CIOMS

- Council for International Organizations of Medical Sciences
- When will SAE be on CIOMS form to notify Investigator?
  - Serious, Unexpected (SAE not in Investigator's Brochure), Suspected (SUSAR)
- Investigator sent to EC

Selection of Investigators and Study Sites

- A review of previous experience with the sponsor/CRO
- Recommendation by colleagues and other investigators
- Review of literatures
- Contact during professional meeting
- Reputation (e.g. an opinion leader in the field of interest)
- EC

Items to be considered at pre-study assessment visits

- Study site personnel
- Facilities
- Suitable study subject population
- Monitoring procedures

Important considerations for proposal preparation

- Novel and high impact research questions
- Qualified principal investigator and investigator team
- Appropriate research sites
- Appropriate granting agency
- Good writing skills

Five important components for writing a successful application based on US NIH Guidelines for Peer Review Process

- **Significance:** Does the study address an important problem?
- **Innovation:** Does the project develop or use novel concepts?
- **Approach:** Are the concepts and methods well thought out and appropriate to the aim?
- **Investigators:** Are the investigators appropriately trained and well suited to carry out the work?
- **Environment:** Will the setting for the research (facilities, resources, institutional support) contribute to probability of success?

Research administration

- Storage
- Facilities
- Money management
- Responsibility
- Funding