



PERAN PENELITIAN BIOMEDIK (BAGI KESEHATAN)

Desy Andari

FK UMM

BIOMEDIK ADALAH

- Cabang ilmu kedokteran yang mempelajari sel, organ dan fungsi sistem dalam tubuh manusia, dan mempelajari tentang penyakit serta pengobatannya. (oxford)



BIOMEDIK ADALAH

- Cabang ilmu kedokteran yang menggunakan asas-asas dan pengetahuan dasar ilmu pengetahuan alam (biologi, kimia dan fisika) untuk menjelaskan fenomena hidup pada tingkat molekul, sel, organ dan organisme utuh, hubungannya dengan penyakit dan mencari serta mengembangkan bahan yang tepat untuk mencegah, mengobati dan memulihkan kerusakan akibat penyakit (FKUI, 2008)



PENELITIAN BIOMEDIK

- Biomedical research → experimental medicine : the scientific investigation of medical problems by experimentation on animals or by clinical research. (farlex partner medical dictionary, 2012)
- Penelitian ilmiah tentang masalah kesehatan dengan percobaan menggunakan hewan coba atau penelitian (uji) klinis



PENELITIAN BIOMEDIK

- The broad area of science that involves the investigation of the biological process and the causes of disease through careful experimentation, observation, laboratory work, analysis and testing. (California biomedical research association)



TUJUAN:

- Mencegah penyakit
- Mengembangkan produk bermanfaat
- Mengembangkan Pengobatan
- Mengembangkan prosedur perawatan dan penyembuhan penyakit dan kondisi lain yang menyebabkan kesakitan dan kematian



PEMANFAATAN:

- Manusia
- Hewan
- Tumbuhan
- Lingkungan



PENELITI:

- Dokter
- Dokter hewan
- Ahli komputer
- Sarjana teknik
- Teknisi
- Peneliti (MIPA)
- Lain-lain



METODE PENELITIAN

- Model *in-vitro* (penelitian yang dilakukan di laboratorium dengan menggunakan sel/jaringan yg diisolasi)
- Model *in-vivo* (penelitian dengan menggunakan hewan coba atau relawan manusia) → implikasi etik, hukum dan sosial (*Ethical Legal and Social Implication, ELSI*)



UJI CALON OBAT

- Uji Praklinik (in vitro dan in vivo → hewan coba)
- Uji Klinik → manusia



PENGGUNAAN HEWAN COBA

- Setelah model *in-vitro* ditindaklanjuti dengan menggunakan hewan coba (*animal laboratory*)



PENELITIAN KLINIS

- A clinical study involves research using **human** volunteers (also called participants) that is intended to add to **medical knowledge**.

(clinicaltrials.gov)



PENGGUNAAN HEWAN COBA

- Upaya mutu etik penggunaan hewan coba; konsep 3 R (Reduce, Refinement & Replacement) yang pada hakekatnya menerapkan bahwa apa yang dirasakan sakit pada manusia adalah sama pula pada hewan



PENELITIAN YANG MELIBATKAN MANUSIA (CLINICAL STUDY)

- two main types :
 - **clinical trials** (also called **interventional** studies)
 - **observational** studies.

(clinicaltrials.gov)



PENELITIAN YANG MELIBATKAN MANUSIA

clinical trials (also called **interventional studies**)

- any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

(who.int)



clinical trials (also called **interventional** studies)

- may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. (who.int)



PENELITIAN YANG MELIBATKAN MANUSIA

observational studies

- investigators assess health outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator

(clinicaltrials.gov)

- Normal setting

(nia.nih.gov)



TAHAP UJI KLINIK OBAT

- Uji Klinik Tahap I: pertama kali pada sekelompok kecil partisipan → evaluasi dosis aman dan menemukan efek samping (side effects).

(who.int)

- Subyek sehat, 20-80 partisipan

(nia.nih.gov)



TAHAP UJI KLINIK OBAT

- Uji Klinik Tahap II: lanjutan tahap 1 pada kelompok partisipan yang lebih besar → monitor efek yang berlawanan (adverse effects)

(who.int)

- Sakit/kondisi tertentu, 100-300 partisipan

(nia.nih.gov)



TAHAP UJI KLINIK OBAT

- Uji Klinik Tahap III: populasi besar dan daerah serta negara yg berbeda → sebelum disetujui oleh badan otoritas (BPOM).

(who.int)

- Kombinasi obat lain, s/d 3000 partisipan.

(nia.nih.gov)



TAHAP UJI KLINIK OBAT

- Uji Klinik Tahap IV dilakukan setelah obat mendapat ijin untuk digunakan dan dipasarkan oleh negara. Populasi lebih luas dan waktu yg lebih lama

(who.int)

- Monitor efikasi dan safety.

(nia.nih.gov)



SAFETY

Is the investigational medication/treatment safe?

- Are there side effects?
- How does it affect or move through the body?
- Is it safe to use at the same time as other medications?

Who's in it?

Small group of healthy people—generally less than 100



EFFICACY

Is the investigational medication/treatment effective in treating the targeted condition?

- Does it relieve, reverse or stop the progression of the condition?
- How safe is it?
- What is the most effective dosage?

Who's in it?

Generally 100-300 people with the exact condition being studied



FOLLOW UP

After the investigational medication/treatment is approved, how does it work for other patients with the condition?

- More safety/efficacy information is gathered
- Are there long-term benefits?
- Are there long-term risks?

Who's in it?

Often several thousand people who have been prescribed the investigational medication



CONFIRMATION

How does the investigational medication/treatment compare to the standard treatment for the condition?

- More effective, less effective, or the same?
- Longer-term adverse effects?
- How does it affect quality of life, or survival?
- How might it be used along with existing treatments?

Who's in it?

Often 300-3,000 people with the exact condition being studied



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