SURAT TUGAS

Nomor : 1231 /SPs/TU/2024

Pimpinan Sekolah Pascasarjana Universitas Muhammadiyah Prof. DR. HAMKA memberikan tugas kepada:

Nama	: **1. Dr. apt. Numlil Khaira Rusdi, M.Si.** **2. Dr. apt. Fith Khaira Nursal, M.Si.**
Tugas	: Menjadi **Moderator** Kegiatan Visiting Profesor yang diselenggarakan oleh Program Studi Magister Ilmu Farmasi Sekolah Pascasarjana UHAMKA bermitra dengan Lembaga Penjaminan Mutu UHAMKA.
Hari/Tanggal	: Rabu, 31 Juli 2024
Waktu	: 13.00 s.d. 17.30 WIB
Media	: Aplikasi Zoom Meeting
Catatan	: 1. Setelah melaksanakan tugas diharapkan membuat laporan secara tertulis kepada yang memberi tugas 2. Semua biaya dan akomodasi selama kegiatan berlangsung ditanggung oleh LPM UHAMKA

Demikian surat tugas ini diberikan untuk dilaksanakan sebaik-baiknya sebagai amanah dan ibadah kepada Allah Subhanahu Wata'ala.

Jakarta, 25 Muharram 1446 H
30 Juli 2024 M

a.n. Direktur
Sekretaris Bidang II,

Dr. Hj. Ihsana El Khuluqo, M.Pd.

Tembusan Yth.:
Direktur SPs UHAMKA (sebagai laporan)

Visi : Sekolah Pascasarjana Profetik dalam mendidik sumberdaya manusia yang memiliki kecerdasan spiritual, intelektual, emosional, dan sosial

Uhamka
SEKOLAH PASCASARJANA

Integrity
Trust
Compassion

SERTIFIKAT

Nomor: **1237/SPs/KM/2024**

diberikan kepada:

Dr. apt. Numli Khaira Rusdi, M.Si.

MODERATOR

Pada kegiatan **Visiting Profesor Program Studi Magister Ilmu Farmasi** Sekolah Pascasarjana Universitas Muhammadiyah Prof. DR. Hamka.

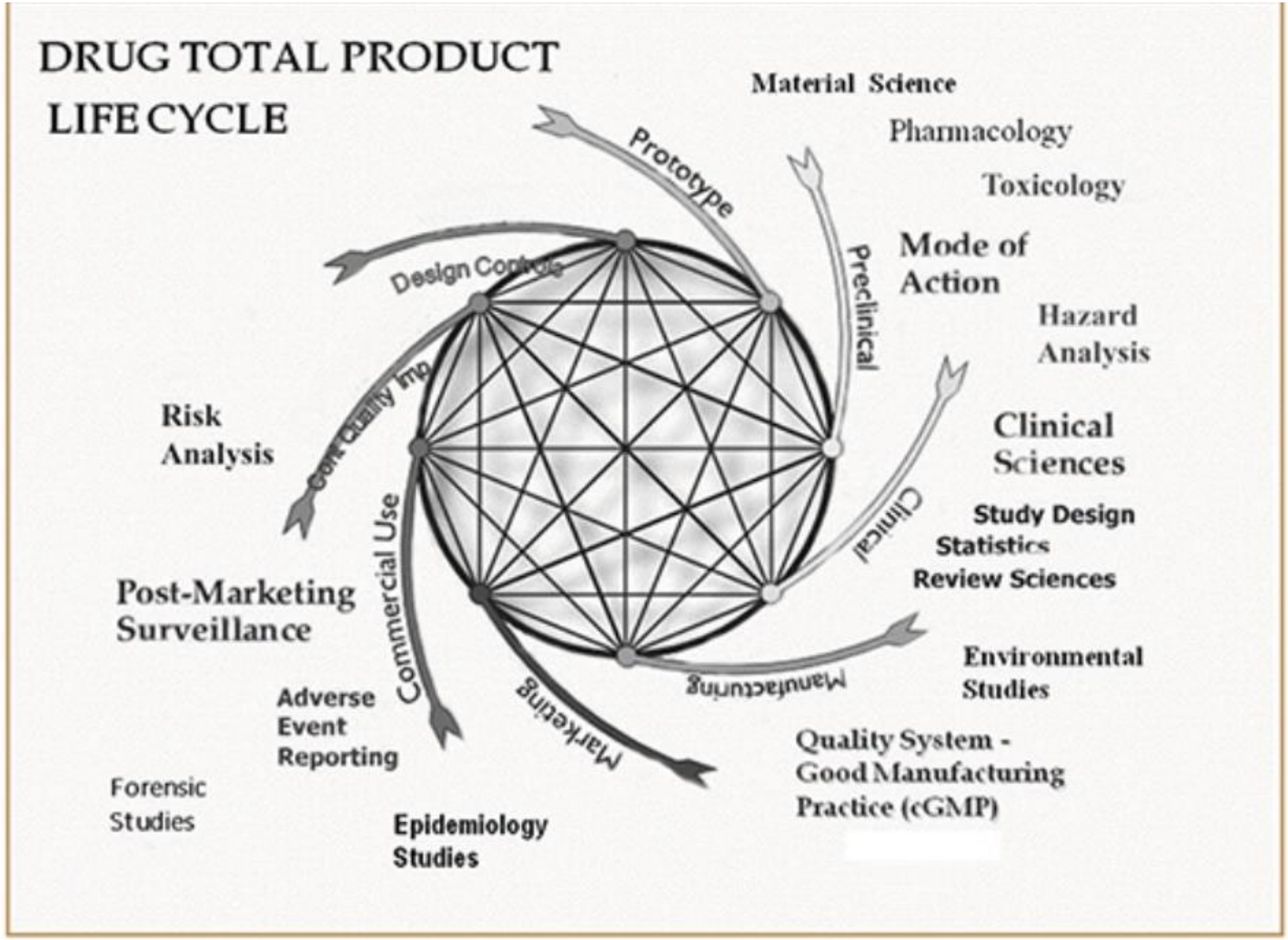
Jakarta, 31 Juli 2024
Direktur Sekolah Pascasarjana UHAMKA

Prof. Dr. H. Ade Hikmat, M.Pd.

Biomedical and Clinical Pharmacy Research: Future, challenge, and Implementation

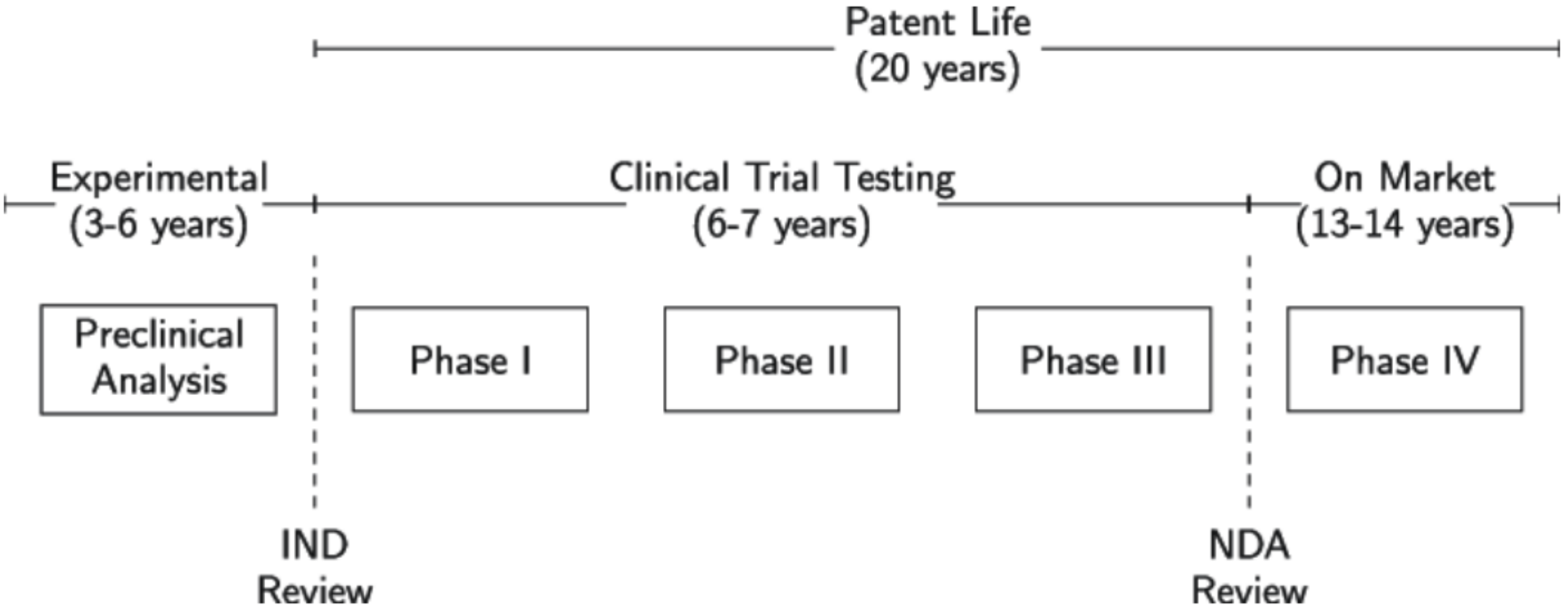
Prof. apt. Rani Sauriasari, M.Med.Sci., Ph.D.

Fakultas Farmasi Universitas Indonesia



Aziz, KJ. (2018). FDA Update: The FDA's New Drug Approval Process: Development & Premarket Applications. Drug Development and Delivery

Drug Approval Process



FDA Drug Development and Approval Process

FDA develop disease-specific approval guidelines based on underlying disease-related severity, prevalence, and characteristics of the drug development process and existing market.

Preclinical Trial

Laboratory and animal studies

→ - To find a promising agent

- Assess safety and biological activities

(e.g. uji farmakodinamik, farmakoinetik, dan toksikologi in vitro maupun in vivo)

Definition for Biomedical Research

Biomedical Research:

The use of fundamental scientific principles in medical and biological research is directed toward developing tools to detect, prevent, or treat human disease. Basic biomedical research is commonly encountered in the discovery and exploratory stages of product/drug development.

WHO, HANDBOOK: QUALITY PRACTICES IN BASIC BIOMEDICAL RESEARCH

The area of science devoted to the study of the processes of life, the prevention and treatment of disease, and the genetic and environmental factors related to disease and health.

STATES UNITED FOR BIOMEDICAL RESEARCH

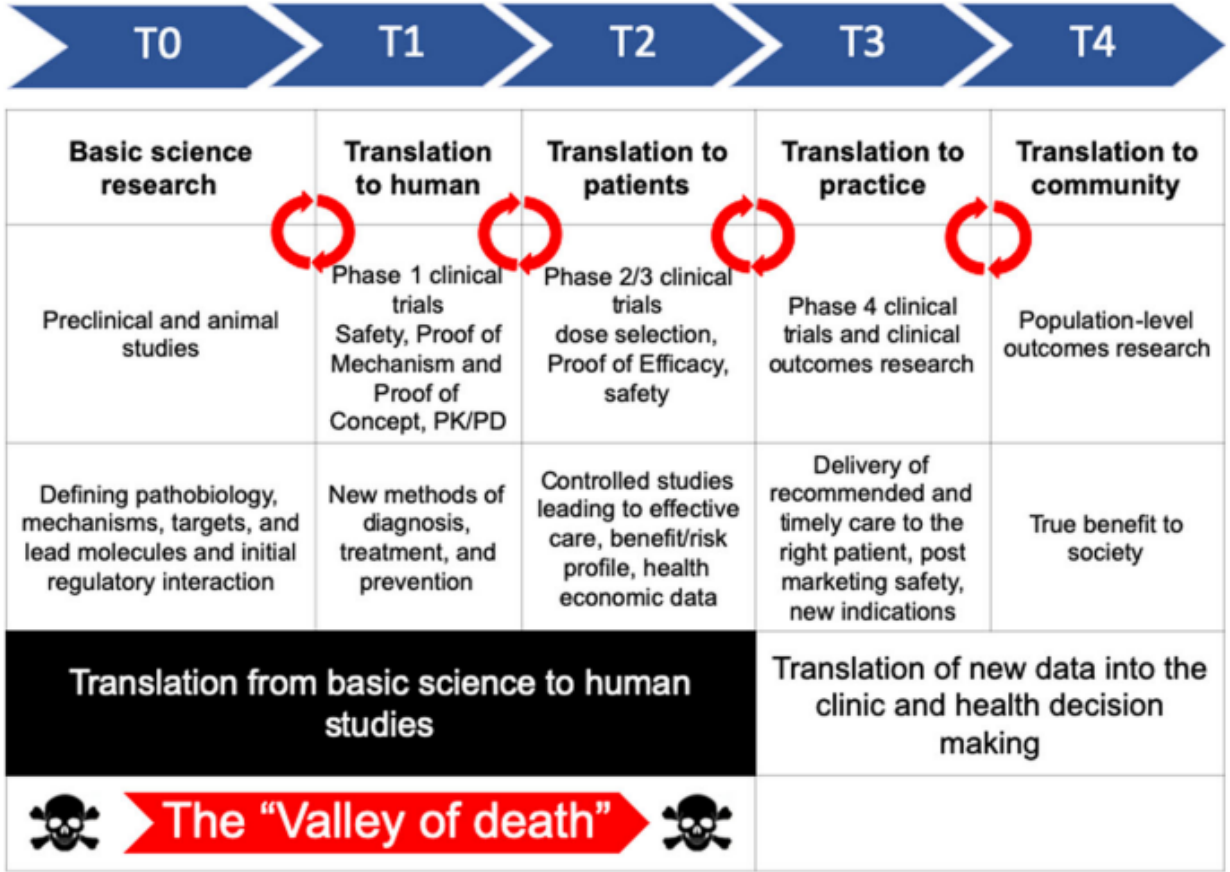


Fig. 1 Operational phases and associated challenges for translational research. Translational research has many layers (T0-T4) and associated operational obstacles that must be overcome. T0, basic science research that define cellular mechanisms, their relationship to disease and, consequently, the identification of therapeutic targets and development of methods of treatment (new molecular entities). T1, is the proof of concept studies conducted in volunteer human subjects as phase 1 clinical trials that aim to define proof of safety, mechanism, and concept. T2, phase 2 and 3 clinical (ideally randomized) trials that are necessary to test the proof of efficacy of the therapeutic agent in cohorts of patients representing the relevant disease that may include control groups. T3, phase 4 clinical trials that are associated with optimizing the therapeutic use of a therapeutic agent in clinical practice. T4, Population-level outcomes research or comparative effectiveness research aims to determine the ultimate utility and cost effectiveness of a therapeutic agent relative to others currently in use. Translation from basic science to human studies form the critical path, as defined by the FDA, or the "valley of death", as defined by the pharmaceutical industry. This "valley of death" encompasses T0-T2 phases of research. However, each of these phases have overlapping sets of challenges as discussed in the text. Adapted from [15, 16]

Seyhan, Attila. (2019). Lost in translation: the valley of death across preclinical and clinical divide – identification of problems and overcoming obstacles. Translational Medicine Communications. 4. 10.1186/s41231-019-0050-7.

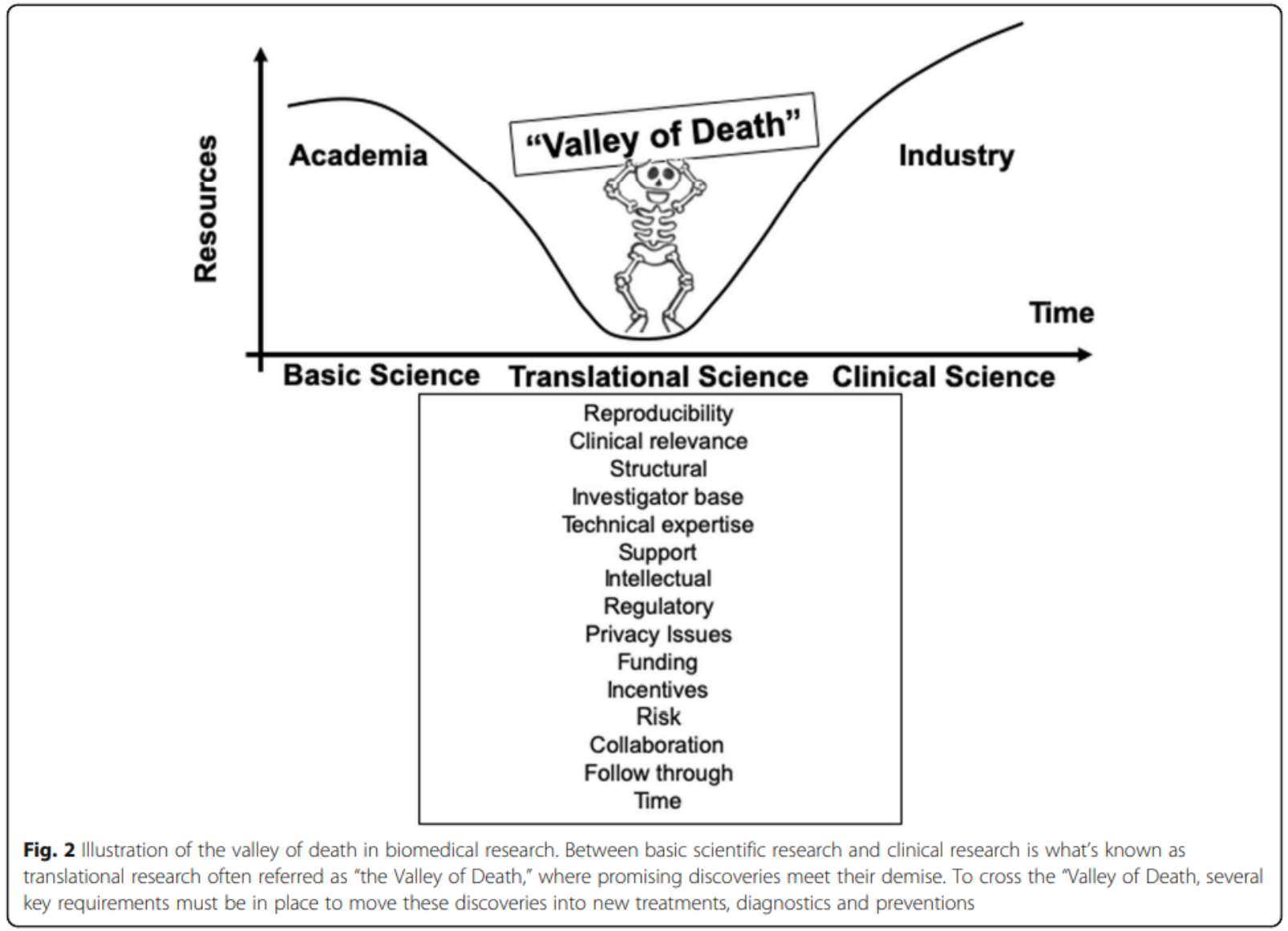
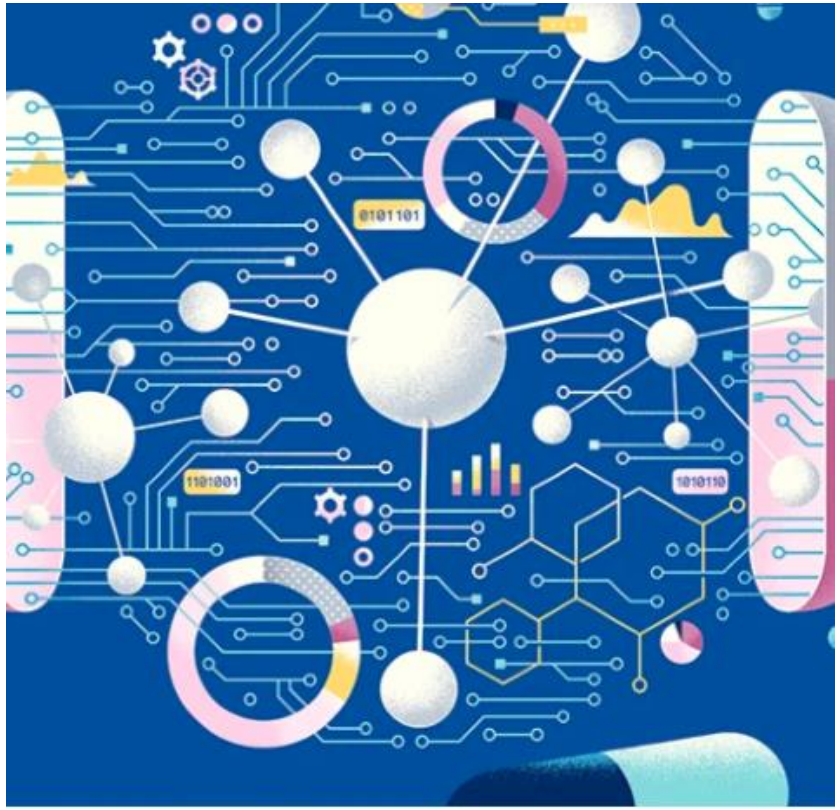


Fig. 2 Illustration of the valley of death in biomedical research. Between basic scientific research and clinical research is what's known as translational research often referred as "the Valley of Death," where promising discoveries meet their demise. To cross the "Valley of Death, several key requirements must be in place to move these discoveries into new treatments, diagnostics and preventions

Seyhan, Attila. (2019). Lost in translation: the valley of death across preclinical and clinical divide – identification of problems and overcoming obstacles. Translational Medicine Communications. 4. 10.1186/s41231-019-0050-7.

AI is changing Drug Discovery

- The traditional method of identifying and validating drug targets is a lengthy and often hit-and-miss process.
- AI, through deep learning algorithms, can analyze vast datasets, including genomic, proteomic and clinical data, to identify potential targets more accurately and swiftly.
- AI-discovered drugs in Phase I clinical trials have an 80-90 per cent success rate, far outpacing drugs discovered by humans, new research has found. Human-discovered drugs have an average success rate of 40-65 per cent in Phase I.



le Marconi

Clinical Trial

1. Phase 1

   → Determine safety and pharmacology of a compound stage

   - low doses of a compound are administered to a small group of healthy volunteers who are closely supervised
   - In cases of severe or life-threatening illnesses (e.g. cancer), volunteers with the disease may be used
   - Generally, 20 to 100 volunteers are enrolled in a phase 1 trial. These studies usually start with very low doses, which are gradually increased. On average, about two thirds of phase 1 compounds will be found safe enough to progress to phase 2.

2. Phase 2

   → Determine the effective dose, the method of delivery (eg, oral or intravenous), and the dosing interval, as well as to reconfirm product safety

   - To avoid unnecessarily exposing a human volunteer to a potentially harmful substance, studies are based on an analysis of the fewest volunteers needed to provide sufficient statistical power to determine efficacy.
   - Typically, phase 2 studies involve 100 to 300 patients who suffer from the condition the new drug is intended to treat.
   - Patients in this stage are monitored carefully and assessed continuously.
   - A substantial number of these drug trials are discontinued during phase 2 studies. Some drugs turn out to be ineffective, while others have safety problems or intolerable side effects

3. Phase 3

→ Verify further safety (monitor adverse long-term use) and efficacy, and to determine the best dosage

- Final step before seeking FDA/NADFC approval
- Larger population (thousands of patients across multiple sites)and longer term (from 2 to 10 years).
- Establish effectiveness of final formulation, indications for clinical use, labeling, marketing claims, drug product stability, packaging, and storage conditions

Note:

Sponsors of product studies are required to control risks to clinical trial participants.

All personnel involved in clinical trials must understand the regulations and guidelines that govern the protection of human subjects while evaluating the efficacy of the products.

PIC should be GCP certified.

- Overall, the entire process, on average, takes between 9 to 13 years.
- Drug development can generally be divided into phases. The first is the preclinical phase, which usually takes 3 to 6 years to complete. If successful, this phase is followed by an application to the FDA as an **Investigational New Drug (IND).**
- The IND application includes:
    1. Chemical and manufacturing data
    2. Animal test results, including pharmacology and safety data, the rationale for testing a new compound in humans, strategies for protection of human volunteers
    3. Plan for clinical testing

- After an IND is approved, the next steps are clinical phases 1, 2, and 3.
- The manufacturer then files a **New Drug Application (NDA)** with the FDA for approval.
- An NDA contains:
  1. All the preclinical and clinical information obtained during the testing phase.
  2. The application contains information on the chemical makeup and manufacturing process, pharmacology and toxicity of the compound, human pharmacokinetics, results of the clinical trials, and proposed labeling.
  3. Can include experience with the medication from outside the United States as well as external studies related to the drug.

- Once the review is complete, the NDA might be approved or rejected.
- Once a drug is approved, it can be marketed.
- Some approvals contain conditions that must be met after initial marketing, such as conducting additional clinical studies.
- FDA might request a postmarketing, or phase 4, study to examine the risks and benefits of the new drug in a different population or to conduct special monitoring in a high-risk population.
- The manufacturer must report adverse drug reactions at quarterly intervals for the first 3 years after approval, including a special report for any serious and unexpected adverse reactions.

Conducting Clinical Trial in INDONESIA

1. High percentage of specialized patient (Diabetes, Cardiovascular, Pediatric, Geriatric, Infection, etc)
2. High Percentage of Drug-Naive patient population
3. Ethnic Diversity
4. High Population
5. Comply with ICH-GCP (International Conference on Harmonization-Good Clinical Practice)
6. High Recruitment Rates
7. Potential Market for Approved Drug Usage
8. Competitive Cost
9. Availability of CRO
10. Support of Central Laboratory
11. Full support from Indonesian FDA (BPOM)

Clinical Trial

- Apoteker dapat berkolaborasi dengan menggunakan keahliannya dalam aspek kefarmasian:
  komposisi obat, pengawasan indikasi, dosis, pemberian, kontraindikasi, efek samping, dan interaksi, serta dapat membantu menjamin keselamatan subjek manusia dan hak-haknya.

- Oleh karena itu, apoteker harus memahami protokol studi, formulir *informed consent*, lembar pengumpul data, dan POB pusat penelitian yang mencakup persyaratan peraturan, etika, dan hukum ***-> Good Clinical Practice***
- ***Apoteker dapat menjadi PI (Principal Investigator) dalam CT***

GUIDANCE FOR PHARMACIST PRINCIPAL INVESTIGATOR

Background and Purpose

During the public consultation on the Therapeutics Products Port-over to the Health Products Act in 2015, HSA received suggestions to consider allowing registered pharmacists to be principal investigators (PIs) in clinical trials. MOH noted the potential benefit of having registered pharmacists as PIs in appropriate trials in the push for meaningful clinical research and pharmacists can add value to research by leading and carrying out translational and implementation science type research, tailored to the local setting. This could also strengthen the types of research done.

The Health Products (Clinical Trials) Regulations were hence amended on 1 October 2021 to allow registered pharmacists to be PIs of clinical trials.

Scope of guidance

The guidance is intended to apply to clinical research involving locally registered products of lower risk profiles, including regulated clinical trials.

General Requirements for Pharmacist PIs

The following conditions should be satisfied:

(i) the pharmacists are appropriately qualified by education, training and experience;

(ii) the pharmacists have adequate resources; and

(iii) the pharmacists are able to fulfil the responsibilities of the PI[1] under the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations ("the CT Regulations")

MOH, Singapore

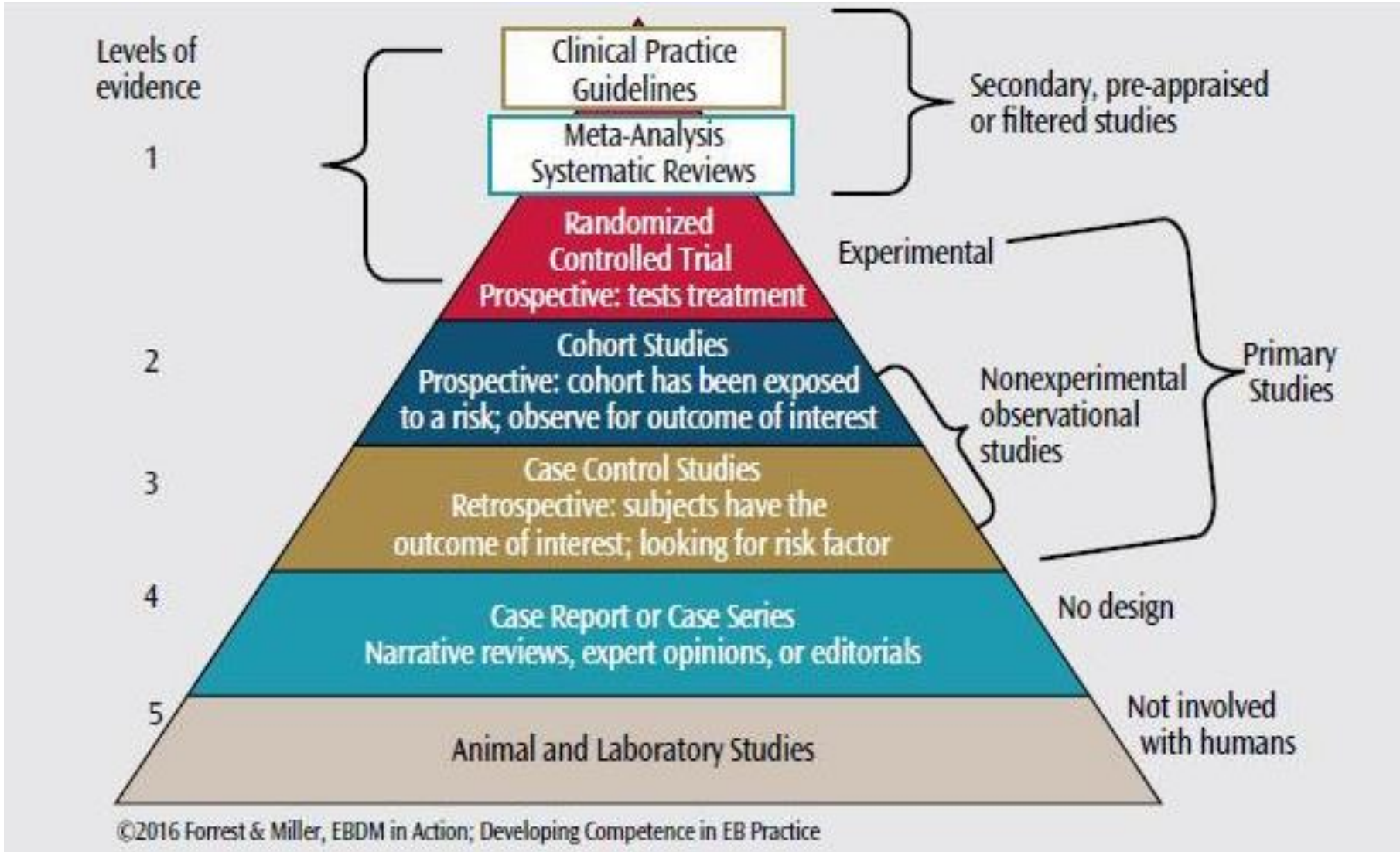
HSA, Health Science Authority (Singapore FDA)

Keterbatasan Uji Klinik Fase 1-3

1. Too few. Terlalu sedikit (umumnya < 1500 pasien)
2. Too simple. Terlalu sederhana (menggunakan pasien tanpa komplikasi, atau ada kondisi medis lainnya)
3. Too median-age. Terlalu median (pasien terlalu tua/muda dikeluarkan, wanita hamil tidak dimasukkan)
4. Too narrow. Terlalu sempit (indikasi terbatas)
5. Too brief. Terlalu singkat (waktu terbatas)

(A.E. Roger. Drug Intelligence and Clinical Pharmacy, Vol. 21, Nov, 1987)

→ **Penting Uji Klinik Fase IV (Post-Marketing Study)**


Levels of evidence
1
2
3
4
5
Clinical Practice Guidelines
Meta-Analysis Systematic Reviews
Randomized Controlled Trial Prospective: tests treatment
Cohort Studies Prospective: cohort has been exposed to a risk; observe for outcome of interest
Case Control Studies Retrospective: subjects have the outcome of interest; looking for risk factor
Case Report or Case Series Narrative reviews, expert opinions, or editorials
Animal and Laboratory Studies
Secondary, pre-appraised or filtered studies
Experimental
Nonexperimental observational studies
Primary Studies
No design
Not involved with humans
©2016 Forrest & Miller, EBDM in Action; Developing Competence in EB Practice

Classification of pharmacoepidemiologic study designs

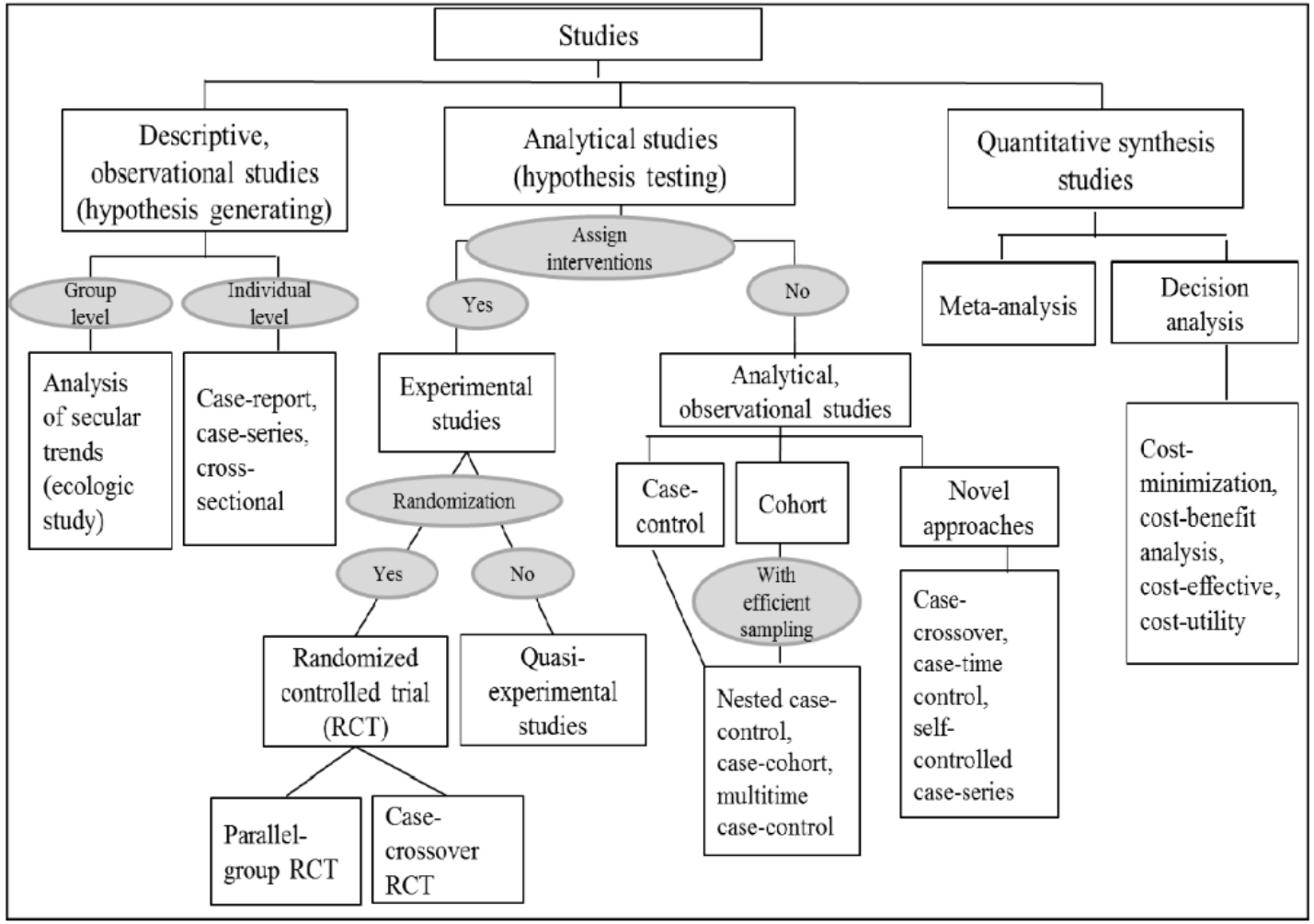


Figure 1. Study Designs Used in Pharmacoepidemiology

What is pharmacoepidemiology?

Kata farmakoepidemiologi berasal dari kata “Pharmacon” (Obat), “Epi” (Pada), “Demos” (Penduduk) dan “logos” (Ilmu).

Menurut Strom[1], farmakoepidemiologi adalah ilmu yang mempelajari tentang penggunaan obat dan efeknya pada sejumlah besar manusia.

Porta dan Hartzema dalam bukunya Pharmacoepidemiology: an introduction[2] menyatakan bahwa farmakoepidemiologi adalah aplikasi latar belakang, metode dan pengetahuan epidemiologik untuk mempelajari penggunaan dan efek obat dalam populasi manusia.

Sumber Data

Sources	Characteristics	Advantages	Limitations / Biases	Examples
Automated Data Systems: Often considered as the gold standard for medication data				
Administrative claims databases (claims databases)	• Arises from a person's use of health care system and the submission of claims to insurance companies for payment (health insurer databases) • Uncommon outcomes can often be studied • Can study drugs and devices as used in real-world clinical practices • Include membership data, physician services, outpatient pharmacy claims, hospital services, laboratory services	• Large sample, quicker, less expensive • Very high-quality data on drug exposure • Minimize recall/interview bias • Usually have standard formats	• Uncertain validity on diagnosis data (especially outpatient) • Unavailable confounders • Limited medication coverage • Lack of information on clinical data, patient history, OTC drugs, outside of the insurance's plan, or uninsured population, patient's adherence • Instability of the population (e.g., job changes)	• US: HMO, Medicare, Medicaid, State blue cross/blue shield plans, commercial insurance (e.g., HealthCore, UnitedHealth group, Ingenix Research database) • Canada: Canadian provincial databases (e.g., BCLHD)
Electronic health records (EHRs), or Electronic medical records (EMRs)	• Used by healthcare professionals in the delivery of care to patients • Uncommon outcomes can often be studied • Can study drugs and devices as used in real-world clinical practices • Include patient data, activity, prescription, clinical/lab observations, orders (diagnosis and procedure codes)	• Large sample, quicker, less expensive • Better quality on diagnoses • Minimize recall/interview bias • Able to extract data from clinical text (e.g., through natural language processing method)	• Require data manipulation • Uncertain completeness of data from other physicians/sites • Unavailable confounders • Lack of information on clinical data, OTC drugs, patient's adherence • Complex and costly of computer hardware and software	• US: HMORN, VA data, PPD, Cerner's Health Facts Database • UK: GPRD, THIN • The Netherlands: PHARMO • Denmark: OPED, AUHD • Other: IMS Disease Analyzer
Ad-Hoc Studies				
De Novo: Field study	• Epidemiologic studies in which data are collected in the field for evaluating specific hypothesis • At least partially enroll the subjects and collect data • Mostly, self-reported data about medication use (recall or brown bag medication inventory)	• More rigorous defined outcomes • Feasible to enroll subjects with very rare conditions • Feasible to obtain information/confounders not collected in the pre-existing databases • Capture actual medication use (prescription, OTC medications and dietary/herbal supplements)	• Time-consuming • Relatively expensive • Logistic challenges • Completeness of ascertainment of drug exposure varies from different study designs: e.g., recall accuracy on drug exposure in case-control study • Potential biases influencing study validity	Studies in the elderly: CHS, EPESE, Health ABC, NSHAP, MrOS, SOF, WHAS, WHI

Table 3. Overview of Sources of Data to Access Safety/Benefit of Drugs

Protokol Studi - PICO Framework to Define the Question

Things to be considered in PICO Framework

- Your **P**atient is a member of a population as well as a person with (or at risk of) a health problem.
  - may also need to consider ethnicity, socioeconomic status or other demographic variables.
- A **C**omparison is not always present in a **PICO** analysis.
- **O**utcomes should be measurable as the best evidence comes from rigorous studies with statistically significant findings.
- An **O**utcome ideally measures clinical wellbeing or quality of life, and not alternates such as laboratory test results.

Step 1: Define the question

Framework item:	Think about:	Example:
Patient Problem (or Population)	What are the patient's demographics such as age, gender and ethnicity? Or what is the or problem type?	Work-related neck muscle pain
Intervention	What type of intervention is being considered? For example is this a medication of some type, or exercise, or rest?	Strength training of the painful muscle
Comparison or Control	Is there a camparison treatment to be considered? The comparison may be with another medication, another form of treatment such as exercise, or no treatment at all.	Rest
Outcome	What would be the desired effect you would like to see? What effects are not wanted? Are there any side effects involved with this form of testing or treatment?	Pain relief

Protokol Studi – Outcome/Endpoint

Choice of Endpoints

- The choice of endpoints used in a study or comparison will be influenced by the purpose for which they are measured
  - Patient reported outcome (e.g., QoL) might not specific and susceptible to changes in patient's circumstances
  - Clinical endpoints (e.g., mortality) most common in clinical trials
  - Surrogate endpoints (e.g., viral load) when final endpoints are not possible or require long follow-up period
  - Composite endpoints combine multiple single events into one endpoint
  - Adverse events concern the safety of a technology
  - Sensitivity and specificity measures of diagnostic and screening test accuracy

Protokol Studi – Pertanyaan Penelitian

Identify the type of question

Question Type	Patient Problem or Population	Intervention or Exposure	Comparison or Control	Example OutcomeMeasures
Therapy (Treatment)	Patient's disease or condition.	A therapeutic measure, eg., medication, surgical intervention, or life style change.	Standard care, another intervention, or a placebo.	Mortality rate, number of days off work, pain, disability.
Prevention	Patient's risk factors and general health condition.	A preventive measure, e.g., A lifestyle change or medication.	Another preventative measure OR maybe not applicable.	Mortality rate, number of days off work, disease incidence.
Diagnosis	Specific disease or condition.	A diagnostic test or procedure.	Current "reference standard" or "gold standard" test for that disease or condition.	Measures of the test utility, i.e. sensitivity, specificity, odds ratio.
Prognosis (Forecast)	Duration and severity of main prognostic factor or clinical problem.	Usually time or "watchful waiting".	Usually not applicable.	Survival rates, mortality rates, rates of disease progression.
Etiology (Causation)	Patient's risk factors, current health disorders, or general health condition.	The intervention or exposure of interest. Includes an indication of the strength/dose of the risk factor and the duration of the exposure.	Usually not applicable.	Survival rates, mortality rates, rates of disease progression.

1. Schardt, C., Adams, M. B., Owens, T., Keitz, S., & Fontelo, P. (2007). Utilization of the PICO framework to improve searching PubMed for clinical questions. *BMC Medical Informatics and Decision Making*, 7, 16. doi: http://dx.doi.org/10.1186/1472-6947-7-1
2. Fineout-Overholt, E., & Johnston, L. (2005). Teaching EBP: asking searchable, answerable clinical questions. *Worldviews On Evidence-Based Nursing*, 2, 157-160.

Area Penelitian Farmasi di Fasyankes

- Clinical trial obat baru, modifikasi, indikasi baru dll
- TDM & Farmakokinetik
- Drug Utilization Review
- Dispensing system untuk control drug abuse dan overconsumption
- Studi biofarmasetik (ADME)
- Inkompatibilitas fisikokimia
- Studi efektivitas dan keamanan (observasional: cohort, case-control, cross-sectional, test-negative case-control, nested-case control. case cross-over, etc))
- Studi farmakoekonomi (Cost utility, cost benefit, cost effectiveness, cost minimization, cost avoidance, cost savings, in-hospital cost, treatment cost, etc)
- Studi manfaat intervensi apoteker

Analysis of the Risk of Injection Incompatibilities in the ICU and Pharmacists' Contribution toward Avoiding Such Incompatibilities

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Accepted January 23, 2019)

Abstract

Objective: Avoiding injection incompatibilities is important. At our hospital, pharmacists are present at the intensive care unit (ICU), where they manage drip lines and use a lookup table for injection incompatibilities. We assessed the risk of injection incompatibilities in the ICU and the contribution of pharmacists toward their avoidance.

Methods: We investigated the number of injections and main drip lines used for outpatients admitted to the general ward and ICU from an emergency setting. We further investigated inappropriate drip line conditions, subsequent interventions by pharmacists, and the actual number of injection incompatibilities. The investigation period lasted 1 year from April 2016 onward.

Results: The number of injections and drip lines used in the ICU was significantly higher than that used in the general ward ($p<0.001$). Patients in the ICU received multiple continuous intravenous injections from one drip line despite the number of main drip lines being high. Even using the lookup table, 78.3% inquiries made by nurses were related to injection incompatibilities. Fourteen inappropriate drip lines selected by nurses were associated with a risk of injection incompatibility; these occurred during the absence of pharmacists and involved a combination of continuous intravenous injections to be administered from a side line. Subsequently, pharmacists intervened and avoided injection incompatibilities. There was no report of injection incompatibilities in the ICU.

Conclusion: At ICU, the risk of injection incompatibilities is high and it is necessary to focus on the combination of injections to be administered from main drip lines and side lines as well as incompatibilities of multiple continuous intravenous injections to be administered from side lines. A lookup table is insufficient to avoid injection incompatibilities. Therefore, pharmacists can contribute to avoiding injection incompatibilities by maintaining constant presence in the ICU, designing drip line layouts, and proposing line selections.

Key words: injection incompatibilities, intensive care unit, pharmacists

J Young Pharm, 2017; 9(3): 386-390
A multifaceted peer reviewed journal in the field of Pharmacy
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Original Article

Role of Pharmacy on Alteration of Drug Cost and Drug-Related Problem Prevention for the National Health Insurance Geriatric Outpatient

Latifah[1], Rani Sauriasari[1]*, Firzawati[2]
[1]Faculty of Pharmacy, Universitas INDONESIA.
[2]Bekasi Area Health Department, Ministry of Health, INDONESIA.

ABSTRACT

Context: Indonesia has just taken a significant step in its efforts to roll out universal healthcare by established National Health Insurance (NHI) since 1 January 2014. Under NHI coverage, pharmacists' have an important role in preventing Drug Related Problems (DRPs) in geriatric patients through prescription review. **Aims:** The purpose of this study was to analyze the role of pharmacy in alteration drug costs through the prescription review to geriatric outpatient under NHI coverage and to determine the cost avoidance through a focus group discussion. **Settings and Design:** This study was held in general state hospital in Depok City and consist of two phase. The first phase was done with observational, retrospective, and pre-post study design. The second phase the discussion group were formed to determine cost avoidance. **Methods and Material:** The samples were taken from geriatric outpatient prescriptions from January to April 2016 and were designed to compare prescription costs before and after review by pharmacy staff. **Statistical analysis used:** Bivariate analysis was carried out to determine whether there is any difference between the cost of a prescription before and after pharmacists' prescription review. **Results:** The evaluation was performed on 599 prescriptions of geriatric outpatients. Prescription review resulted in cost savings of 3.78% from the total cost of pre-review prescriptions (Rp 1,773,642). The prescription cost pre- and post-review was statistically significant by the Wilcoxon test ($p<0.05$). The cost increased to Rp. 97,392 after being given recommendations regarding the drug-related problem through discussion groups, but these increments can result in cost avoidance by Rp. 1,466,711.4. **Conclusion:** Optimization of pharmacists' roles can generate significant economic benefits (cost savings and cost avoidance).

Key words: Alteration of drug cost, Cost avoidance, Cost saving, Drug related problems, Geriatrics, Prescription review.
Key messages: The role of pharmacist in preventing DRPs in geriatric patients through prescription review in NHI era not only can improve medication in elderly but also have an economic impact such as saving and cost avoidance.

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DOI: 10.5530/jyp.2017.9.77

Thank You