

Penelitian dan Pengabdian Masyarakat Obat Modern dan Tradisional : Peran Institusi Pendidikan



dr. Ahmad Hamim Sadewa, PhD

Sekretaris Program Studi Doktor Kedokteran dan Kesehatan
Fakultas Kedokteran, Kesehatan Masyarakat dan Keperawatan
Universitas Gadjah mada

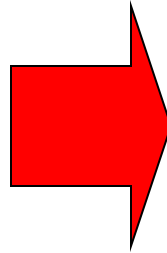
??BIODIVERSITY??



**INDONESIA MERUPAKAN MEGA SENTER
KEANEKARAGAMAN HAYATI TERBESAR DI DUNIA
BERUPA TUMBUHAN TROPIS DAN BIOTA LAUT**



- 30,000 TUMBUHAN TROPIS, 7 000 BERKHASIAT OBAT, 90% TUMBUHAN OBAT ASIA ADA DI INDONESIA



**PERLU DITELITI, DIKEMBANGKAN
DAN DIMANFAATKAN UTK
PENINGKATAN KESEHATAN
MAUPUN TUJUAN EKONOMI DG
TETAP MENJAGA
KELESTARIANNYA**

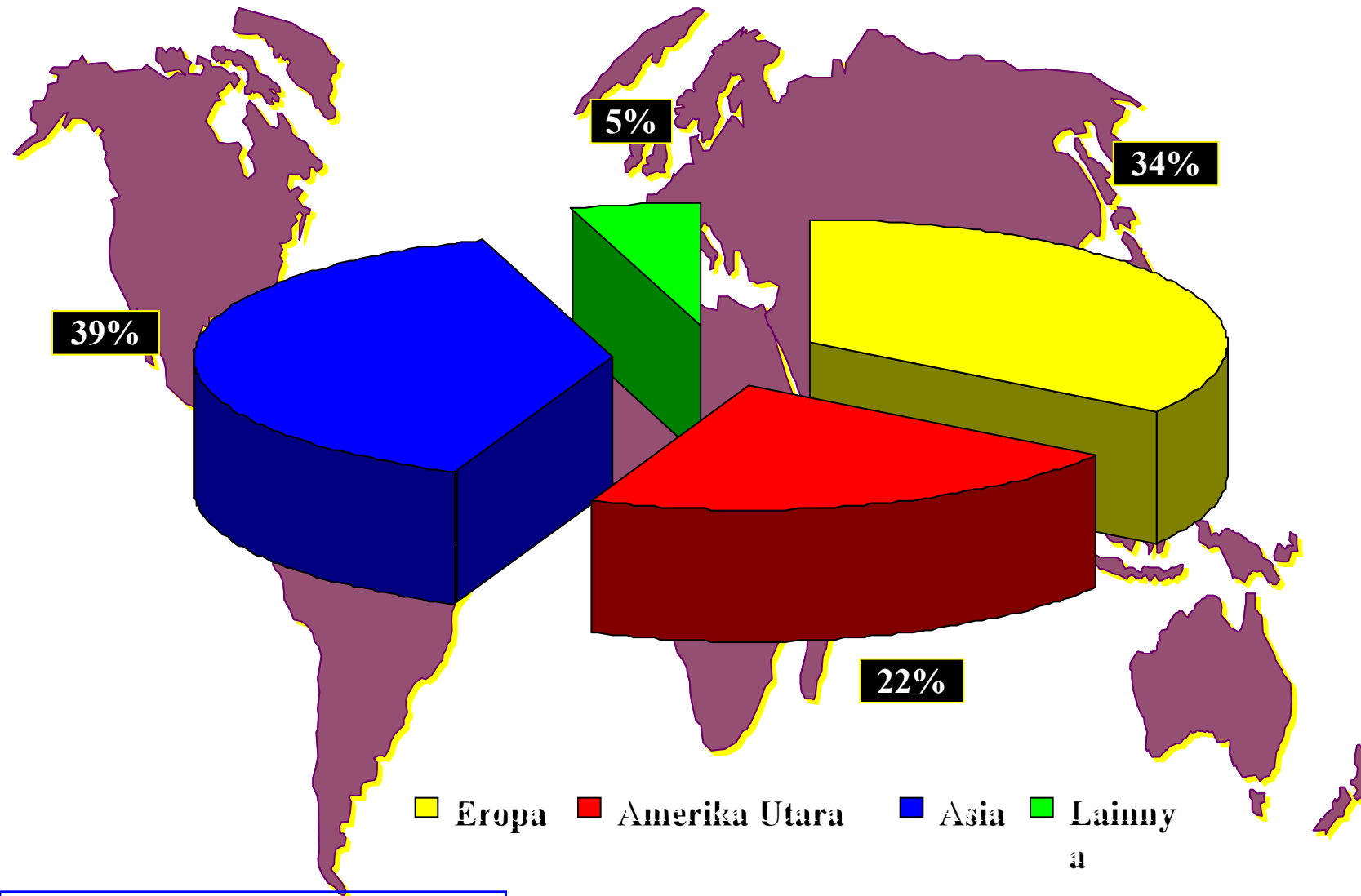
Menteri Perindustrian (Menperin)
Agus Gumiwang Kartasasmita

“sejauh ini hampir 90 persen bahan baku industri untuk farmasi, baik obat-obatan dan vitamin itu masih impor”

PELUANG PENGEMBANGAN OBAT BARU

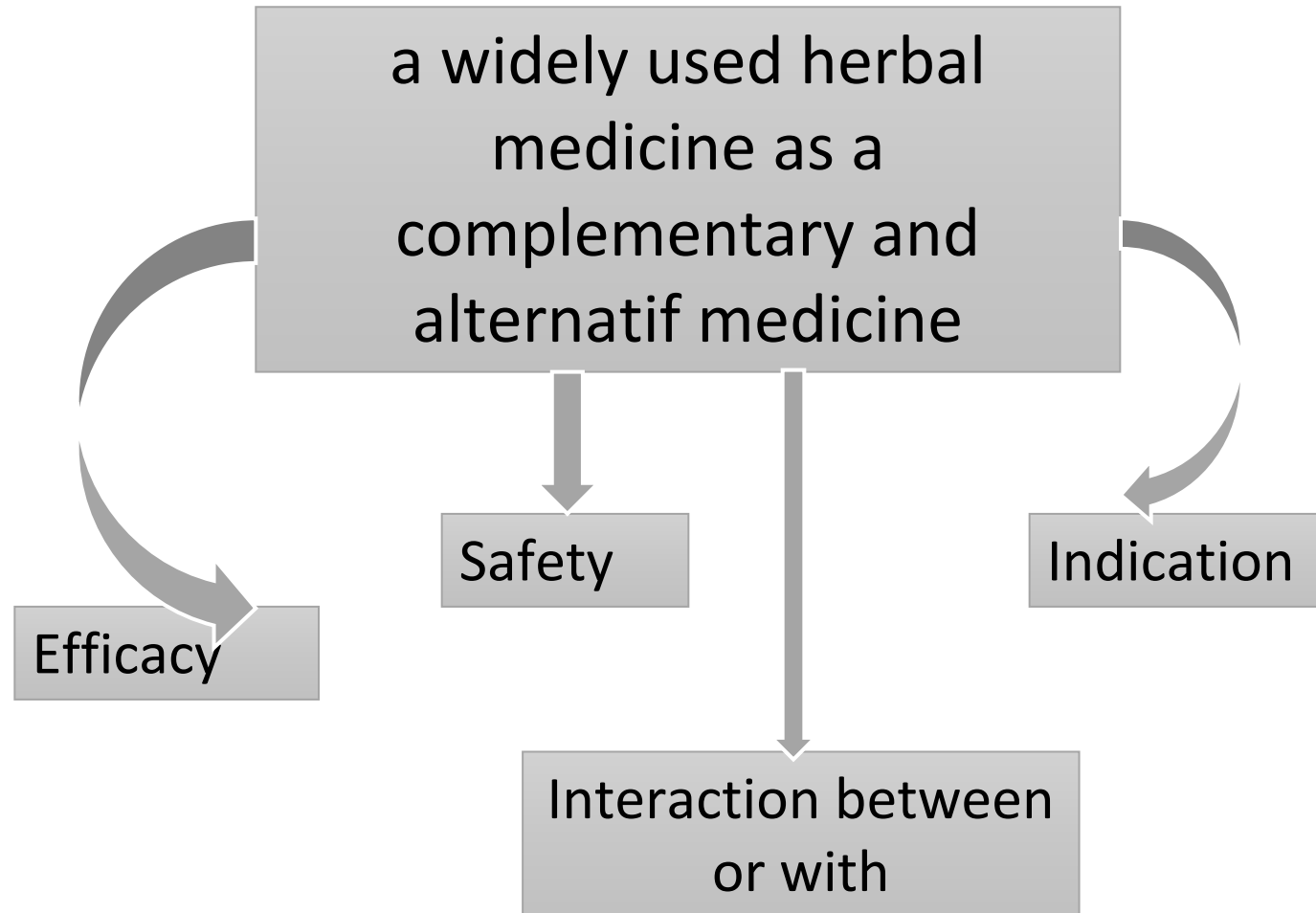


PASAR HERBAL DUNIA 2000

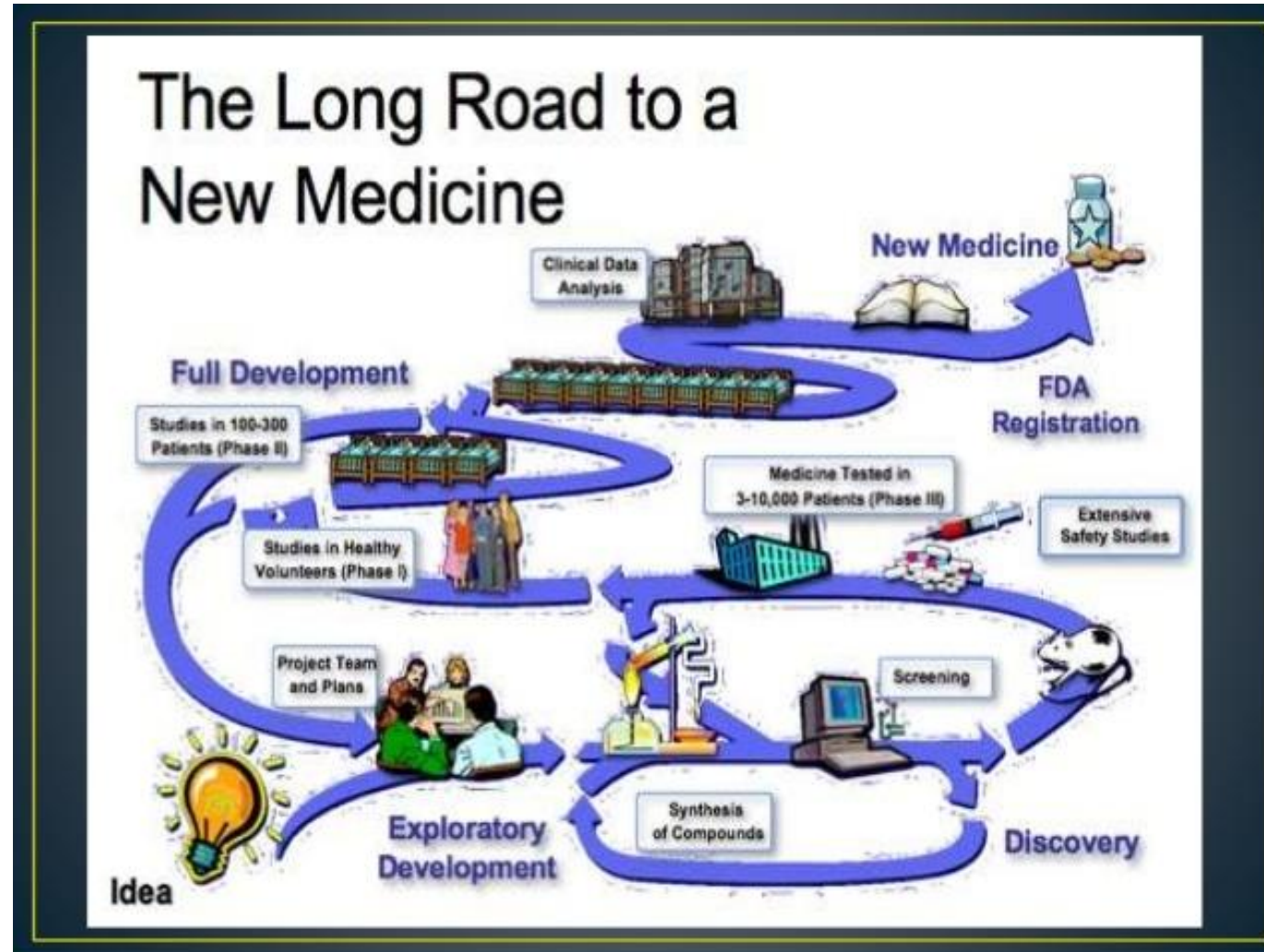


Source : Randy J. Dannin, 2001

ISU PENGEMBANGAN OBAT BARU



PENGEMBANGAN OBAT BARU



Syarat : Evidence-based Medicine

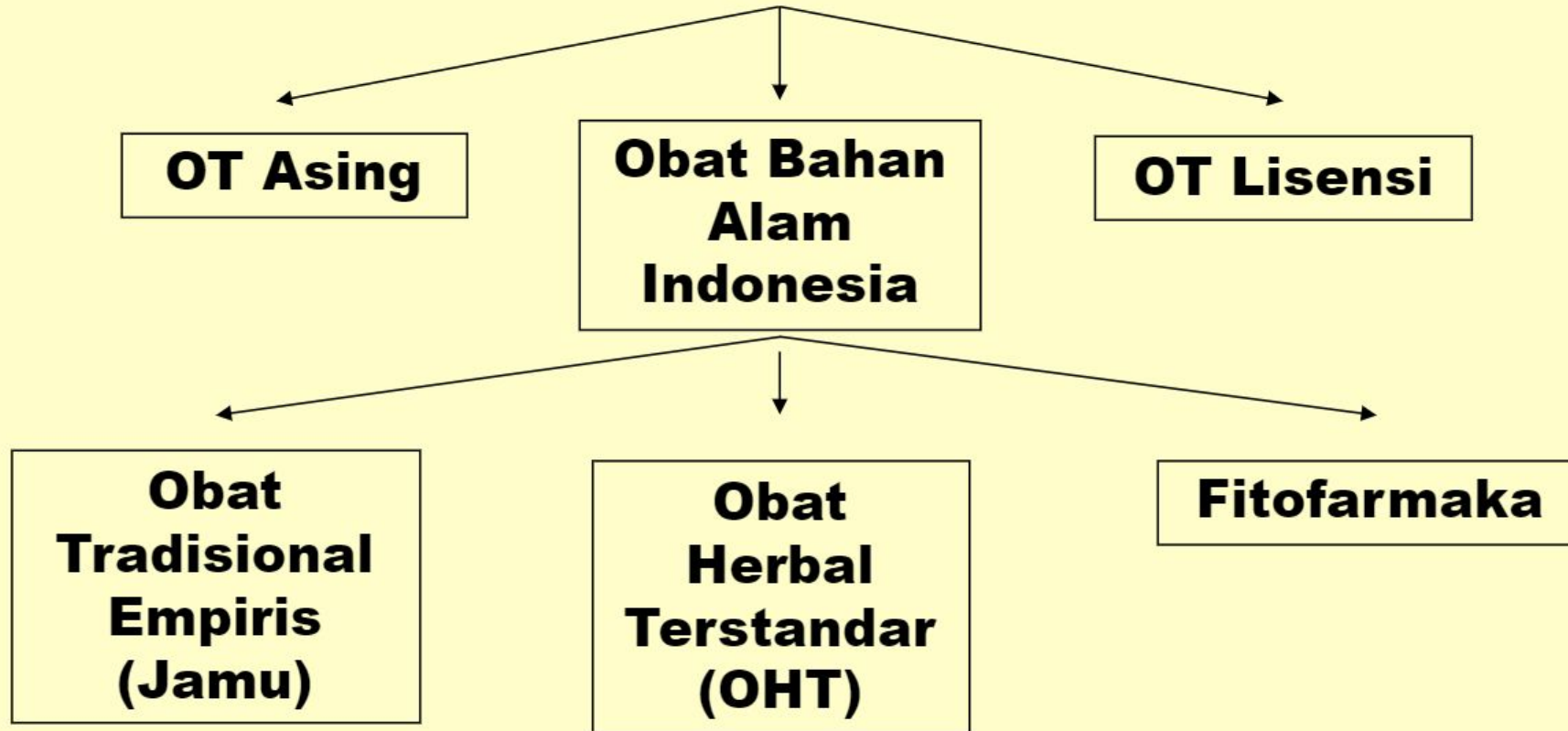
Level	Type of evidence
Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomization
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Posisi Obat
Tradisional?

Grade	Recommendation
A (Evidence levels quality Ia, Ib)	Requires at least one randomized controlled trial as part of the body of literature of overall good and consistency addressing the specific recommendation.
B (Evidence levels IIa, IIb, III)	Requires availability of well-conducted clinical studies but no randomized clinical trials on the topic of recommendation.
C (Evidence level IV)	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality.

Level of claim	Type of claim	Evidence required to support claim
HIGH ¹	<ul style="list-style-type: none"> • Treats/cures/manages any disease/disorder. • Prevention of any disease or disorder. • Treatment of vitamin or mineral deficiency diseases. 	<p>High level. Registration only - evaluated by the CMEC, MEC (Medicines Evaluation Committee) or the ADEC (Australian Drug Evaluation Committee).</p>
MEDIUM	<ul style="list-style-type: none"> • Health enhancement². • Reduction of risk of a disease/disorder. • Reduction in frequency of a discrete event. • Aids/assists in the management of a named symptom/disease/disorder. • Relief of symptoms of a named disease or disorder³. 	<p>Medium level. Sponsor must hold the evidence for Listable goods.</p>
GENERAL	<ul style="list-style-type: none"> • Health maintenance, including nutritional support. • Vitamin or mineral supplementation⁴. • Relief of symptoms (not related to a disease or disorder)³. 	<p>General level. Sponsor must hold the evidence for Listable goods.</p>

OBAT TRADISIONAL



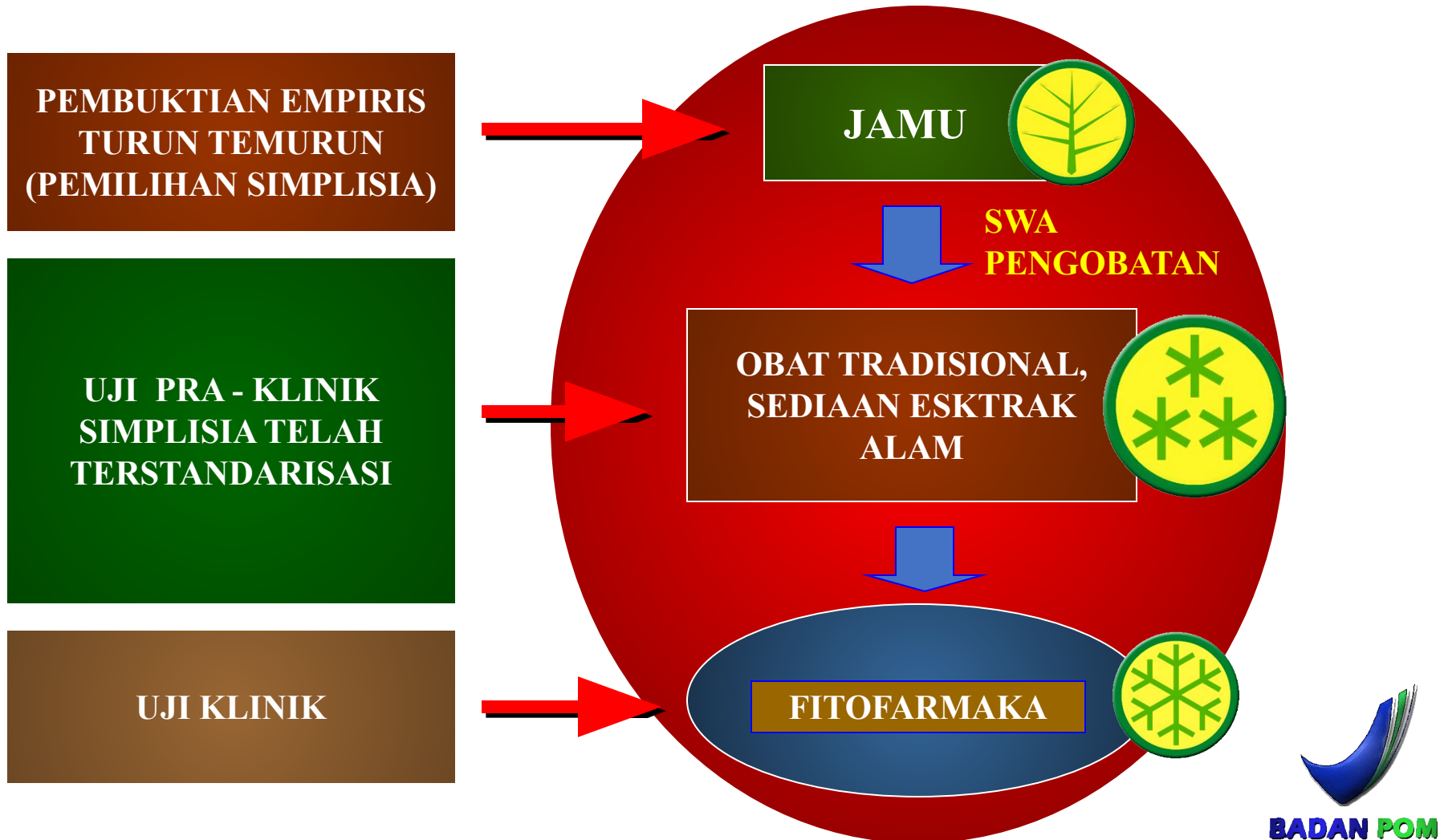
OT EMPIRIK

- **UNTUK PERAWATAN SENDIRI**
- **PROMOTIF DAN PREVENTIF**
- **INDIKASI DAN PARAMETER PENGUJIAN TIDAK JELAS :**
 - **Habis bersalin**
 - **Sehat Lelaki**
 - **Jamu Surga**
 - **Jamu Macan Kera**
 - **Pil Ampuh**
- **BAHAN BAKU BELUM TERSTANDARISASI**

OHT/FITOFARMAKA

- **UNTUK PELAYANAN KESEHATAN FORMAL**
- **KURATIF**
- **INDIKASI DAN PARAMETER PENGUJIAN JELAS**
 - **Anti Diabetes**
 - **Anti Hipertensi**
 - **Anti Hiperlipidemia**
 - **Penurun Asam Urat**
 - **Obat Cacing**
- **SUDAH TERSTANDARISASI**

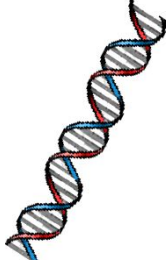
PENGEMBANGAN OBAT TRADISIONAL




Target selection & validation



Studies of Disease Mechanisms



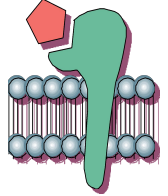
Molecular Studies



Animal Studies

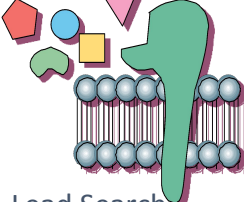
- relevant species
- transgenic KO/KI mice
- conditional KOs
- agonists/antagonists
- antibodies
- antisense
- RNAi

Discovery



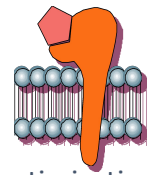
Target

- receptor; -ion channel; -transporter;
- enzyme; - signalling molecule



Lead Search

- Develop assays (use of automation)
- Chemical diversity
- Highly iterative process



Lead optimization

- selectivity
- efficacy in animal models
- tolerability: AEs mechanism-based or structure-based?
- pharmacokinetics
- highly iterative process

Development



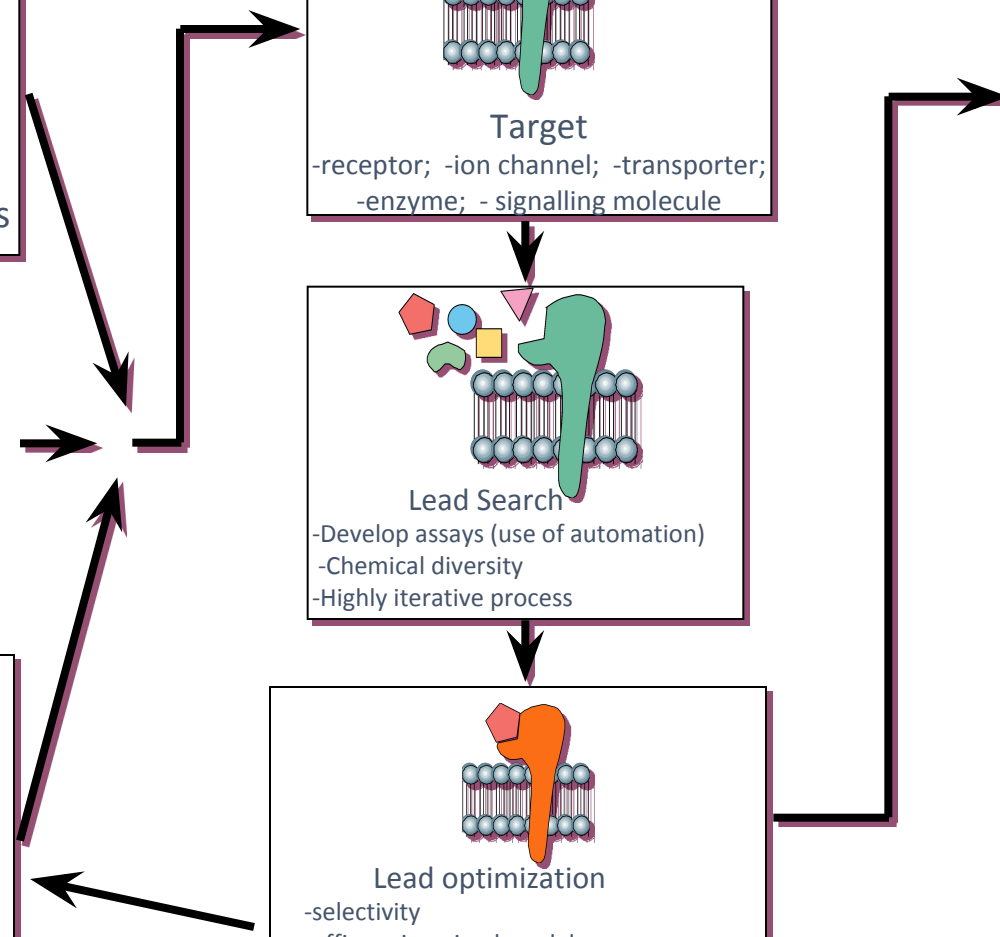
Drug Candidate safety testing



Human Studies
Phases I,II, III



Drug Approval and Registration



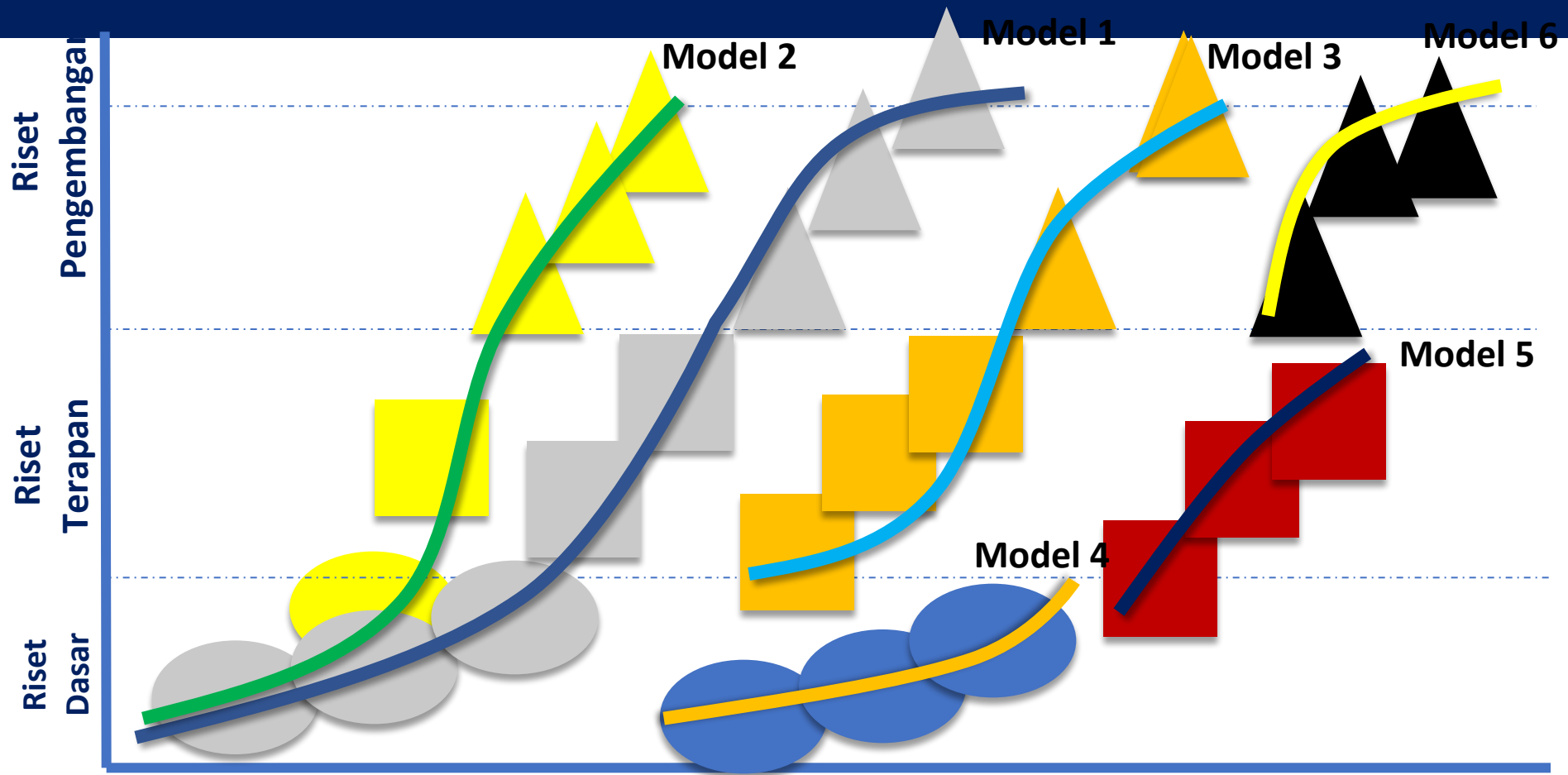
Menyusun Peta Jalan Penelitian

- Mile stones kegiatan penelitian dalam ruang **waktu tertentu (5-20 tahun)** yang dilakukan oleh peneliti (monodisiplin) dan atau kelompok peneliti baik secara multidisipliner atau intra/inter disiplin atau industri R&D .
- peta jalan dapat berupa : peta jalan R&D (Research & pengembangan), peta jalan teknologi dan peta jalan produk.
- Satu peta jalan penelitian **dapat** mencakup 3 bagian sekaligus : riset dasar (R&D), riset terapan (Teknologi) dan riset pengembangan (produk).

Menyusun Peta Jalan Penelitian

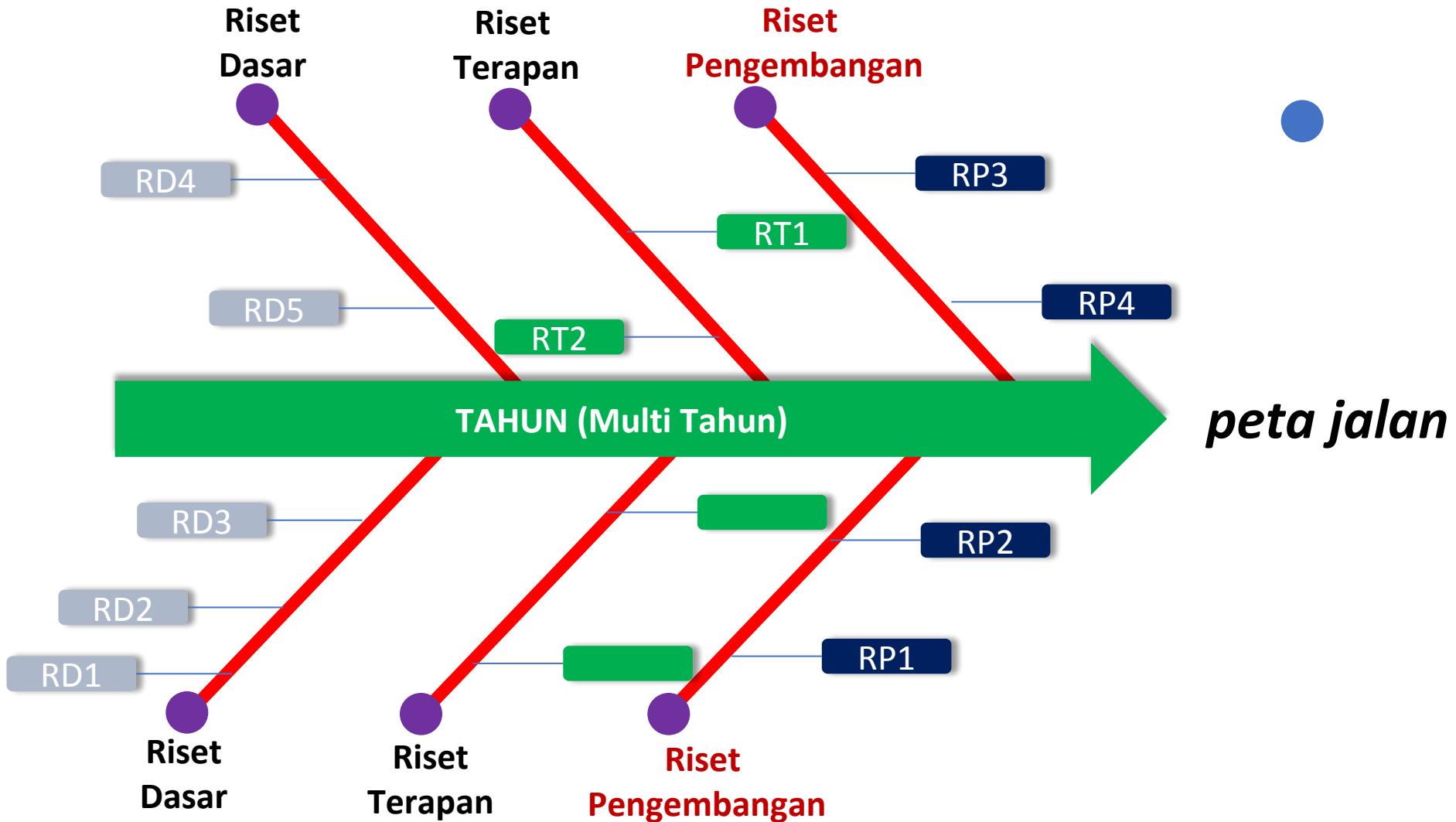
- peta jalan sebaiknya ditampilkan sebagai **bentuk grafik** (sumbu x sebagai waktu, dan sumbu y (sumbu kegiatan penelitian) atau **diagram fishbone**. Atau **bentuk lain diagram**, dengan tujuan untuk memudahkan dalam visualisasi peta jalan
- peta jalan penelitian **bukan** alur penelitian atau metoda
- Luaran (outcome) peta jalan dapat berupa hak Kekayaan intelektual (HKI)

Model peta jalan Penelitian

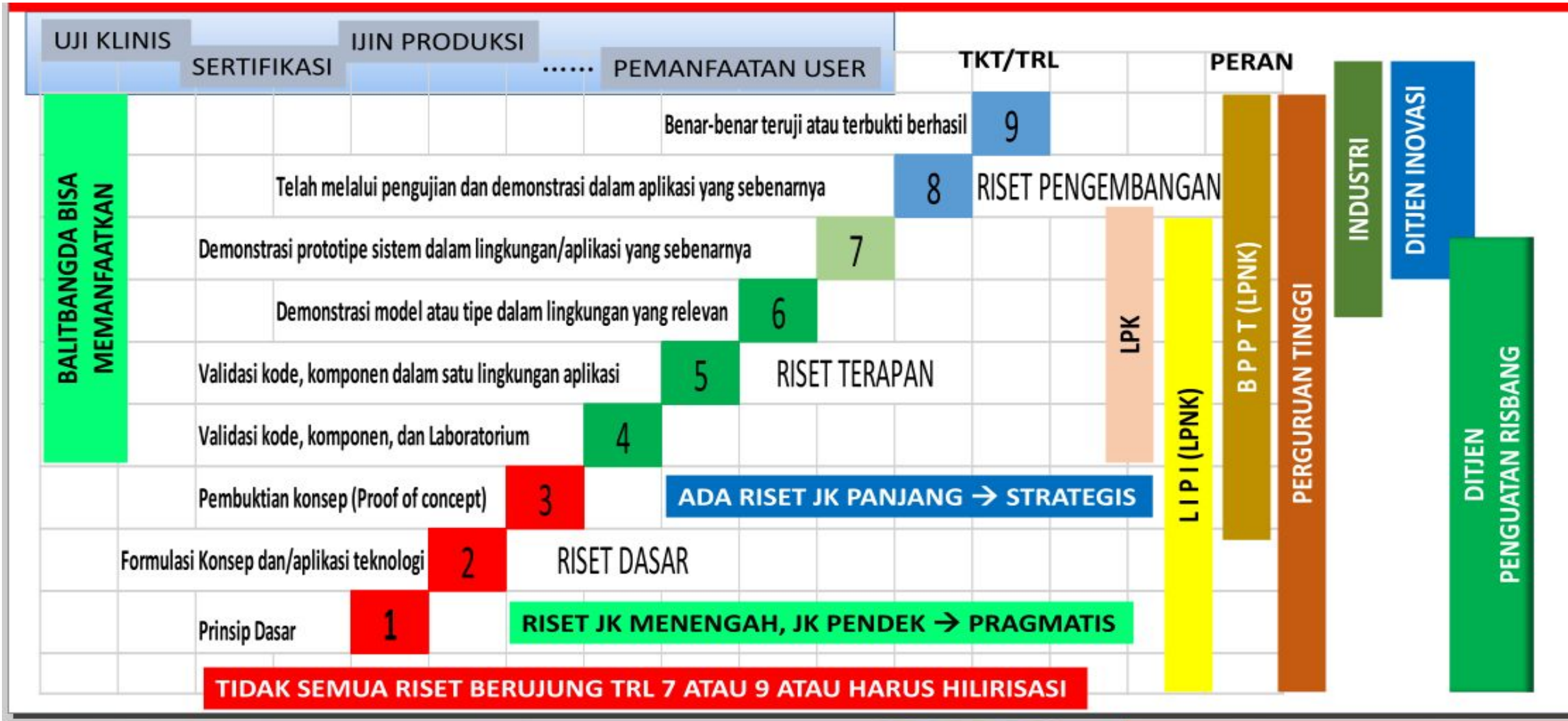


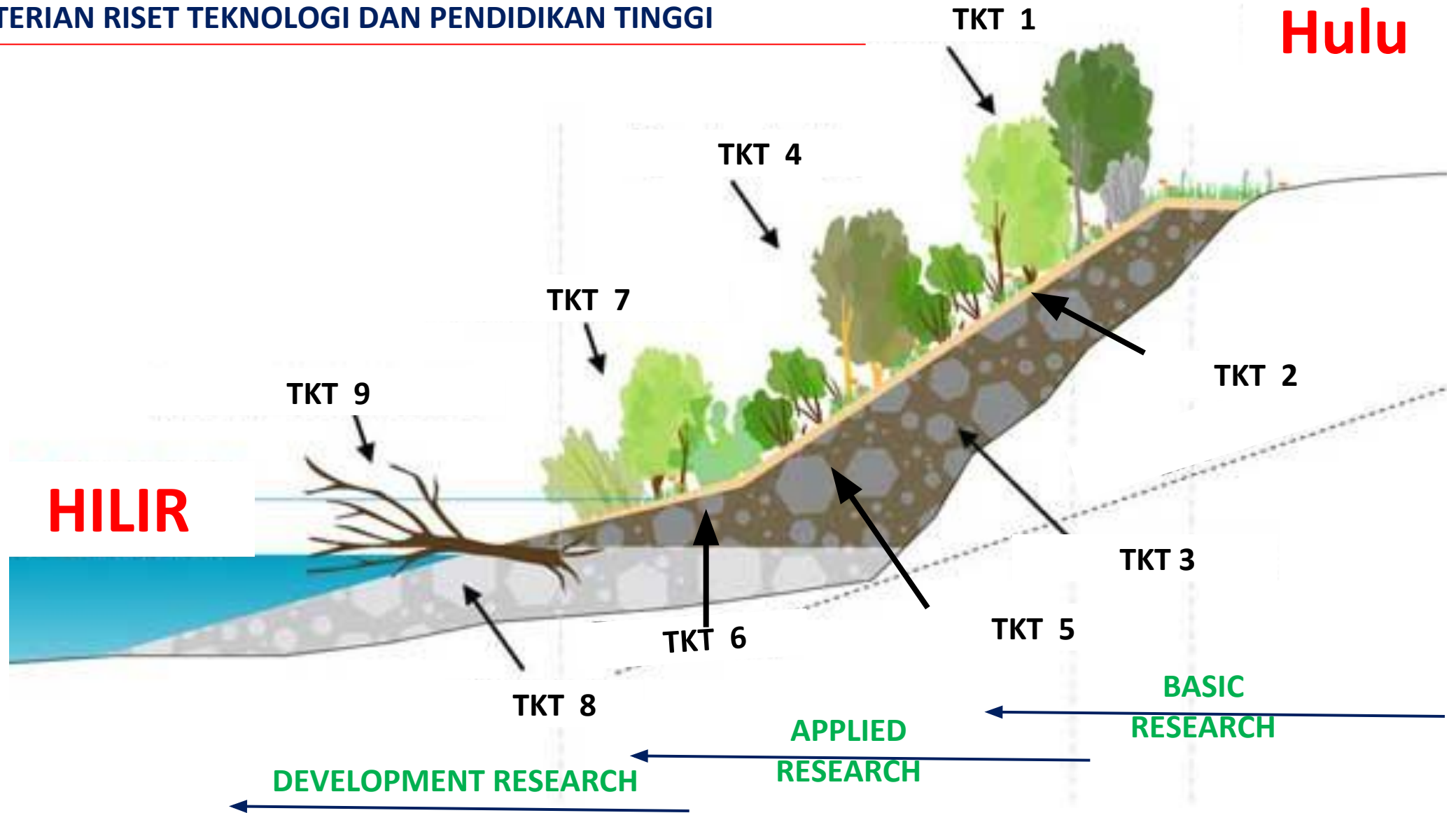
TAHUN (Multi Tahun)

peta jalan : Bentuk Fish Bone



TINGKAT KESIAPTERAPAN TEKNOLOGI - TKT





Ilustrasi Hilirisasi Hasil Riset dan Pengembangan

Translational research



**PUBLIC
HEALTH**

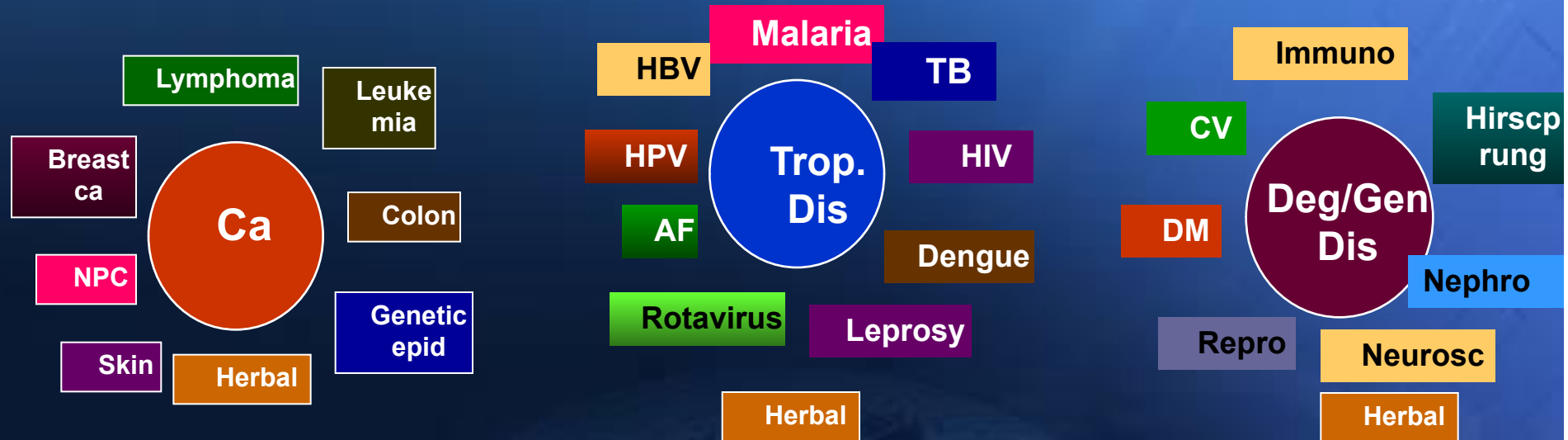
CLINICAL SCIENCES

BIOMEDICAL SCIENCES

RESEARCH ETHICS



Translational research: Multidisciplinary Group



National networking : UGM, UNAIR, UI, UNHAS, UNUD, UNIBRAW, UNDIP, UNS, USU

International : UniMelb, Monash, QIMR, VUmc, AvL, RUG, Unimaas, Utrecht, Leyden, OLVG, KI, Umea, Innsbruck, Leeds, UK, USM, Sabah, Harvard, Canada, USM, UKM

Translational Research on cancer → FP7 – Joint Master

NPC : Asia Link '03-'06
KWF, MoH, MoRT, IARC
VUmc , AvL , Erasmus
IGR ,KI - Nat'l Network
Sustained ??

Colon Ca
APOCP
Multicountries
National Networking

Pathology Courses
AMC - UGM



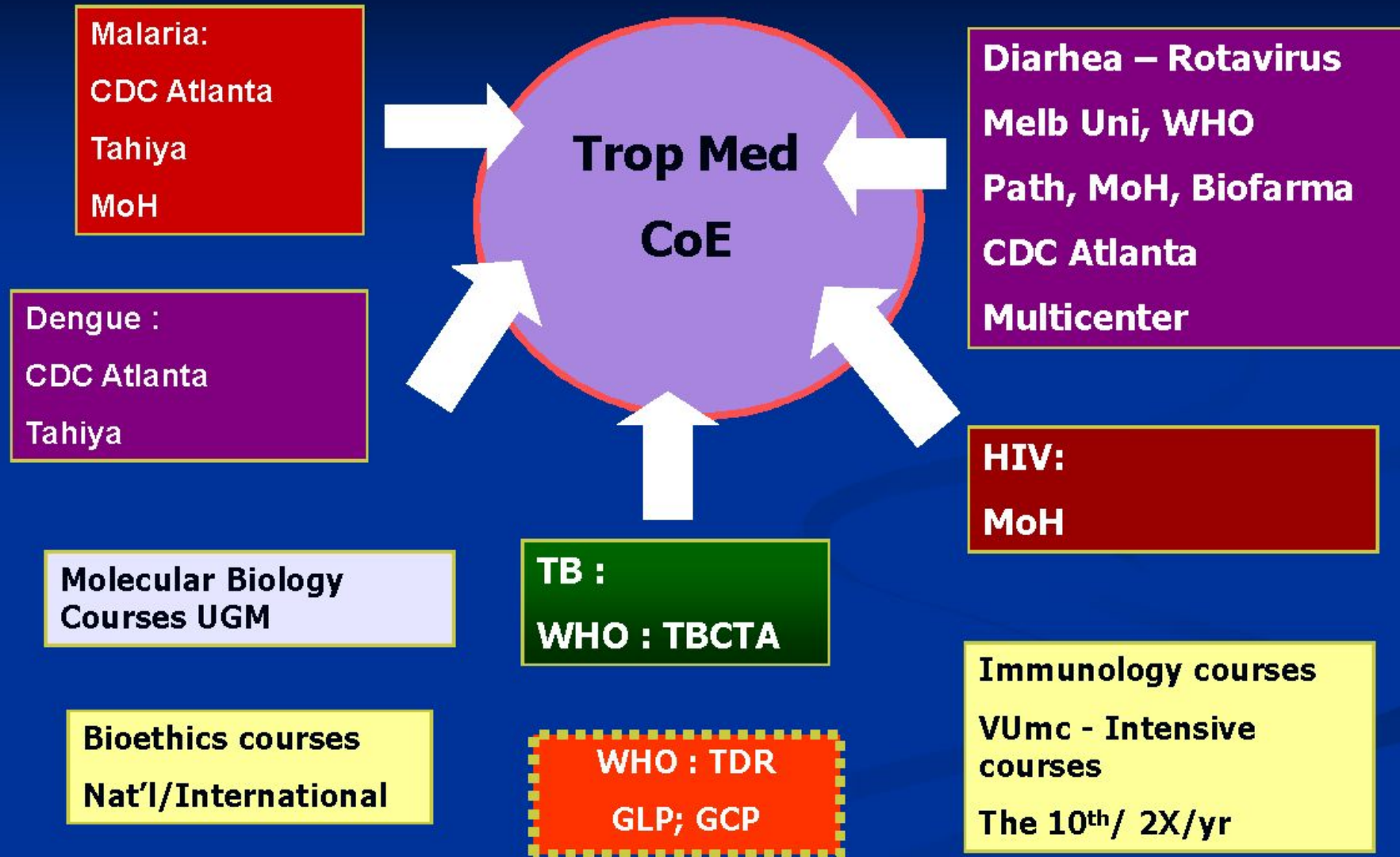
Breast Ca:
VUmc , Utrecht , RUG
National networking -
research

Skin Ca ; lymphoma
Kobe

Leukemia
VUmc, Saskatoon
NUS
National training

Immunology courses
VUmc - Intensive
courses
The 10th/ 2X/yr

Translational Research on Trop Dis → Joint Degree - Asia SPH Okayama, Chulalongkorn, Munipal, UGM



Working Groups



Tropical diseases

- Diarrhea/Rotavirus
- TB/HIV
- Malaria
- Dengue
- Hepatitis – HBV
- TORCH

Nutrition

Degenerative diseases

- Diabetes Mellitus
- Cardiovascular Diseases
- Stroke

Bioinformatics

Biomed Eng

Herbal Med and Drug Development

Cancer

- Breast Ca
- Colon Ca
- Skin Ca
- NPC - EBV

Reproductive health

Bioethics

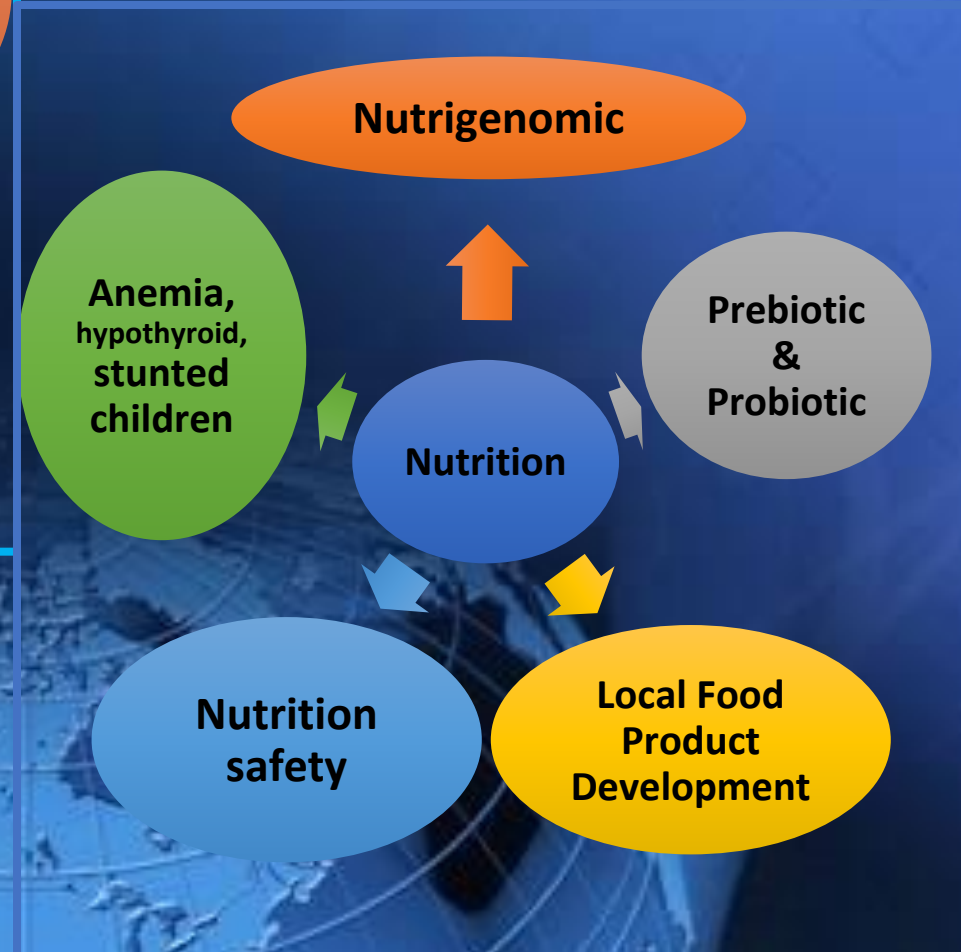
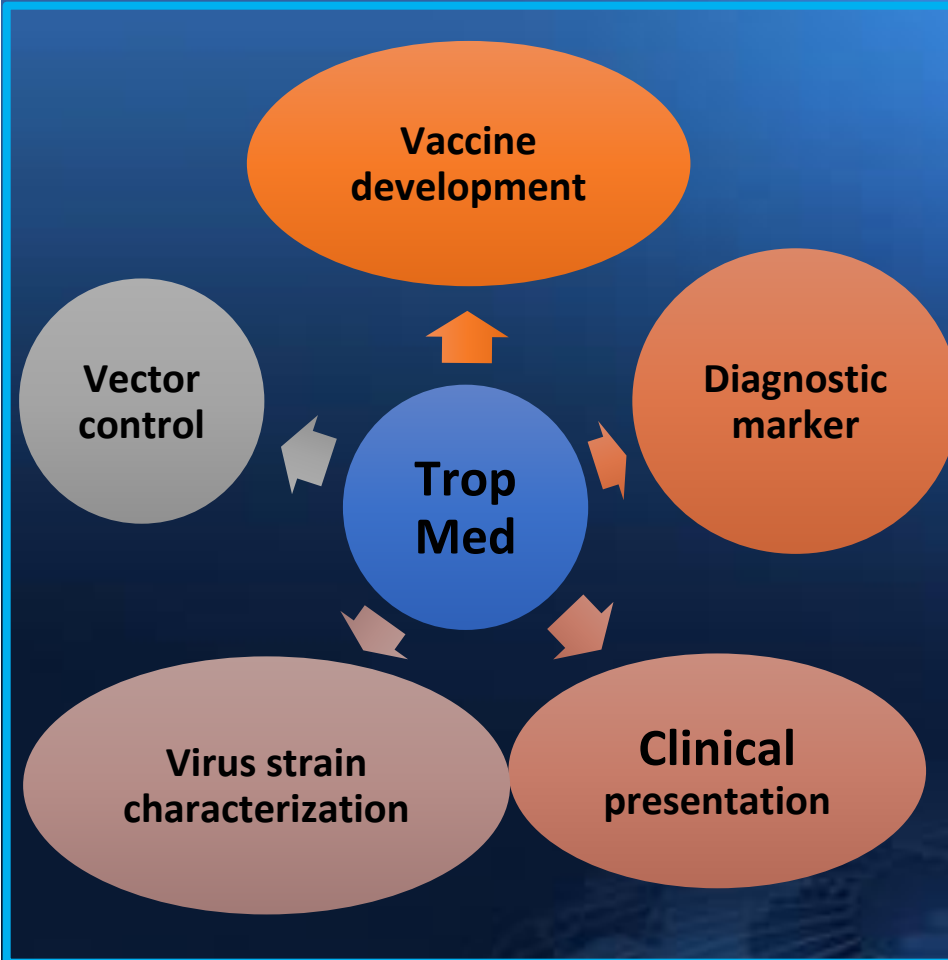
Epidemiology

Health Promotion

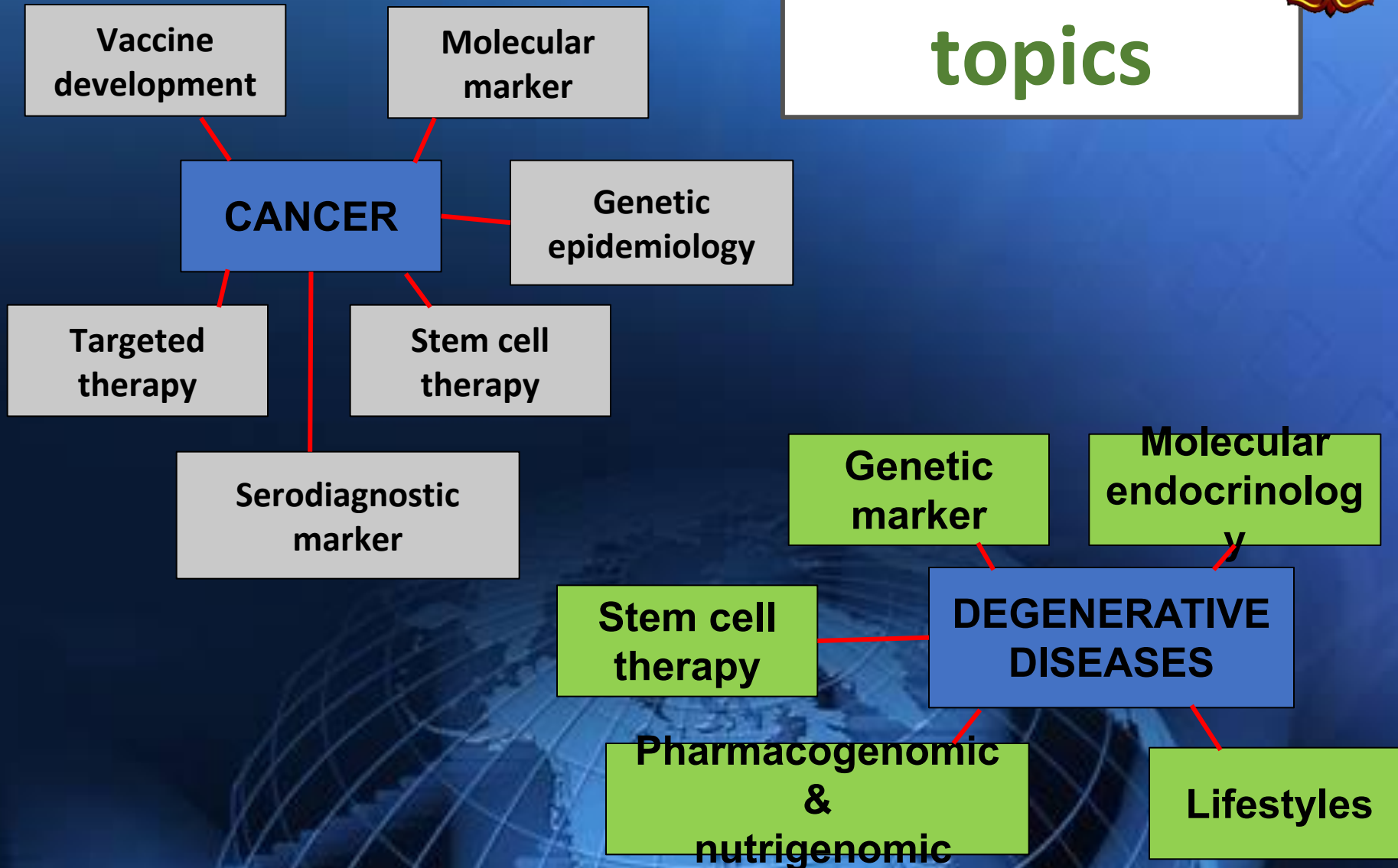
Health Management

Medical equipments

Research topics



Research topics



Research topics



New Diagnostic Test Assay

Innovative medical tools

MEDICAL EQUIPMENTS

Radioimaging

Med Equipment Plastination

Herbal medicine development

Targeted therapy

Pharmacogenomic

DRUG DEVELOPMENT

Pharmacoeconomic

Clinical trials

Laboratorium Riset Terpadu



Laboratorium Riset Terpadu adalah laboratorium riset untuk mendukung peneliti dari berbagai bagian atau prodi dalam melaksanakan penelitian sesuai dengan prinsip praktik laboratorium yang baik (Good Laboratory Practice)

Laboratorium Riset ini dikembangkan sesuai dengan organisasi penelitian, arah dan kebijakan penelitian, kapasitas penelitian dan Sumber Daya yang ada.

Output berupa Hasil Penelitian yang valid dan diakui oleh stake holder dalam rangka memecahkan masalah kesehatan nasional maupun internasional.

Optimasi Hasil-Hasil Penelitian



- 1. Penulisan Manuskrip Publikasi Nasional/Internasional*
- 2. Pengabdian kepada Masyarakat berbasis Pemberdayaan Masyarakat*
- 3. Penulisan Buku Ajar*
- 4. Pendampingan Pengurusan Paten atau Hak Atas Kekayaan Intelektual*
- 5. Advokasi hasil-hasil penelitian*
- 6. Kerjasama dengan Mitra Industri*
- 7. Penulisan Proposal Kolaborasi berdasar hasil-hasil riset sebelumnya*

Thank you very much