

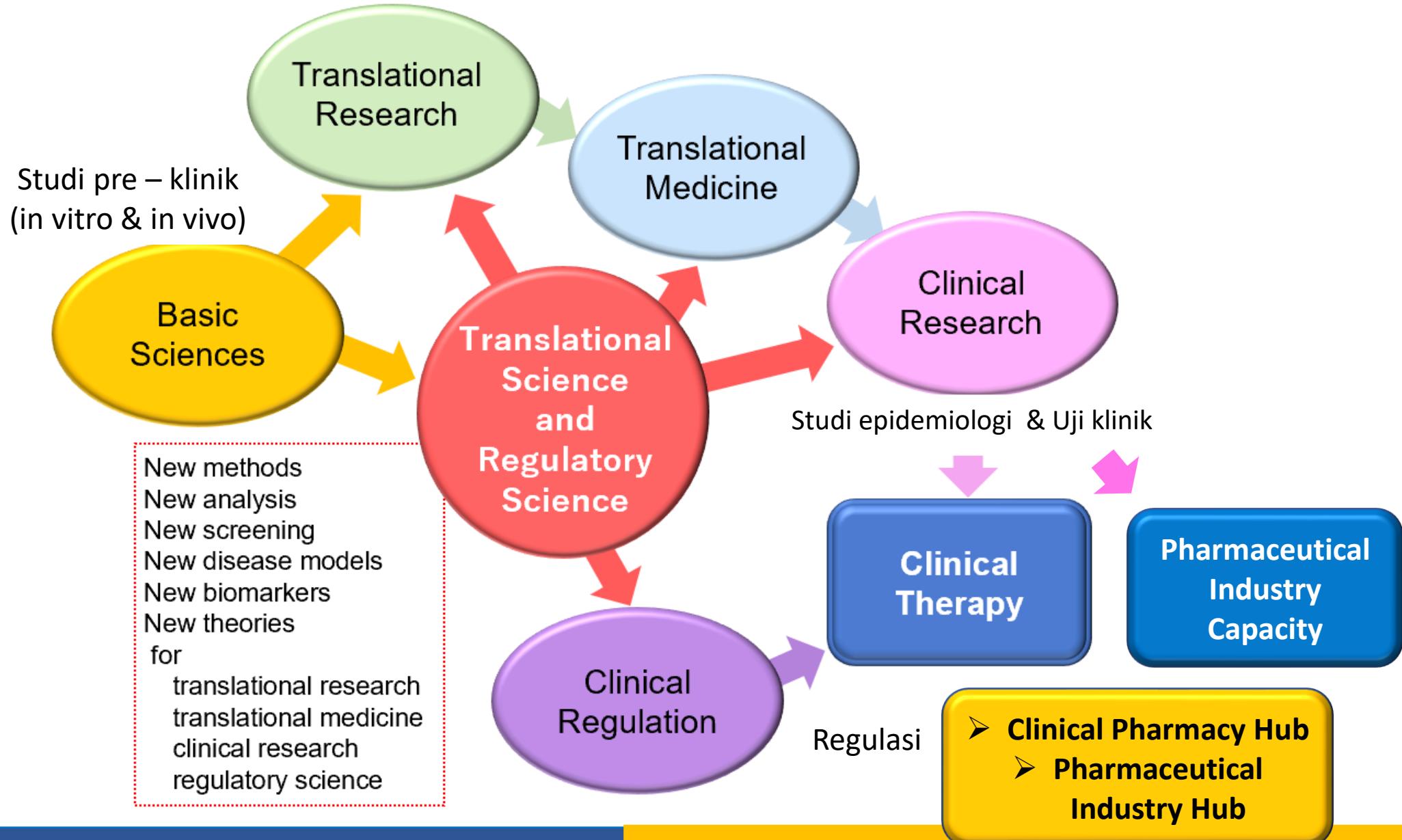
EKOSISTEM RISET BIOMEDIK DAN FARMASI KLINIK MENGHILIRKAN KUALITAS LAYANAN DAN KAPASITAS INDUSTRI



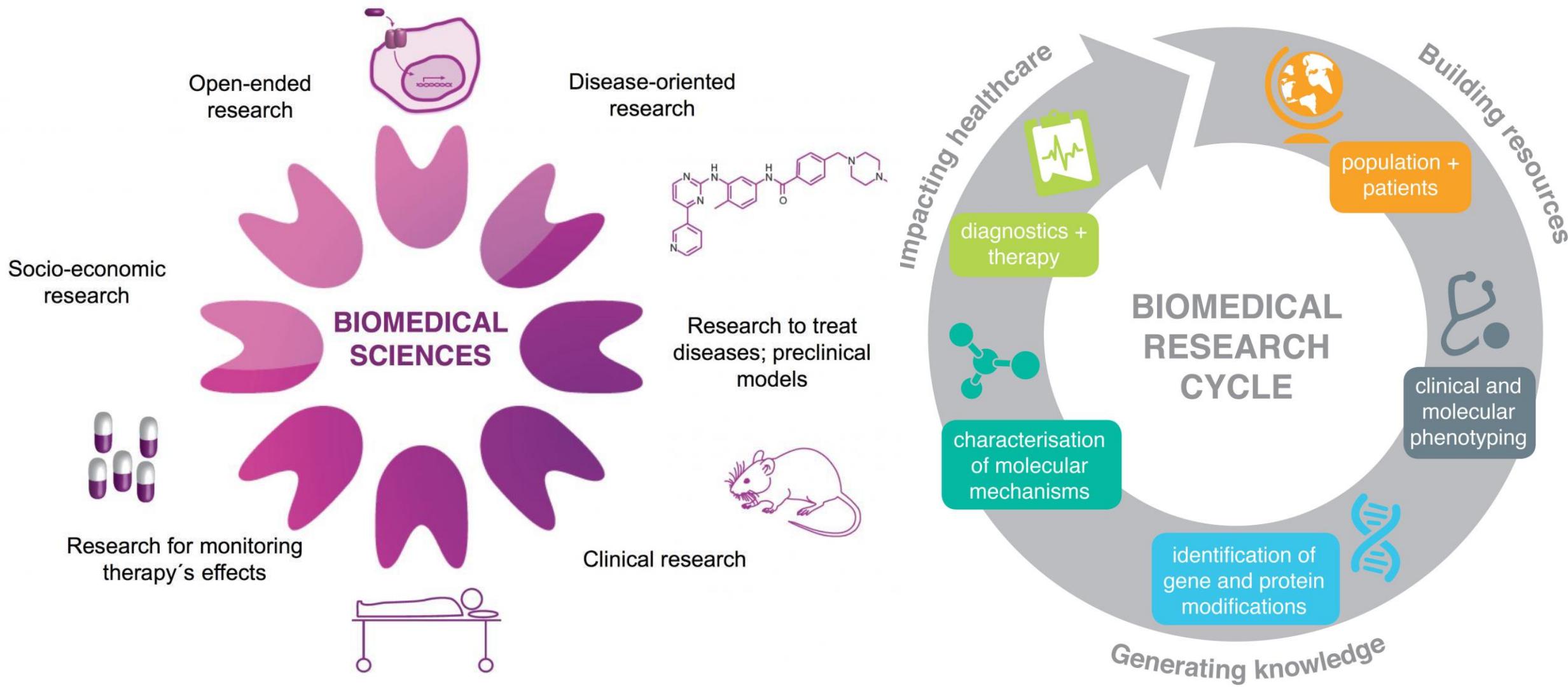
Universitas Airlangga
Excellence with Morality

Junaidi Khotib
Fakultas Farmasi Universitas Airlangga

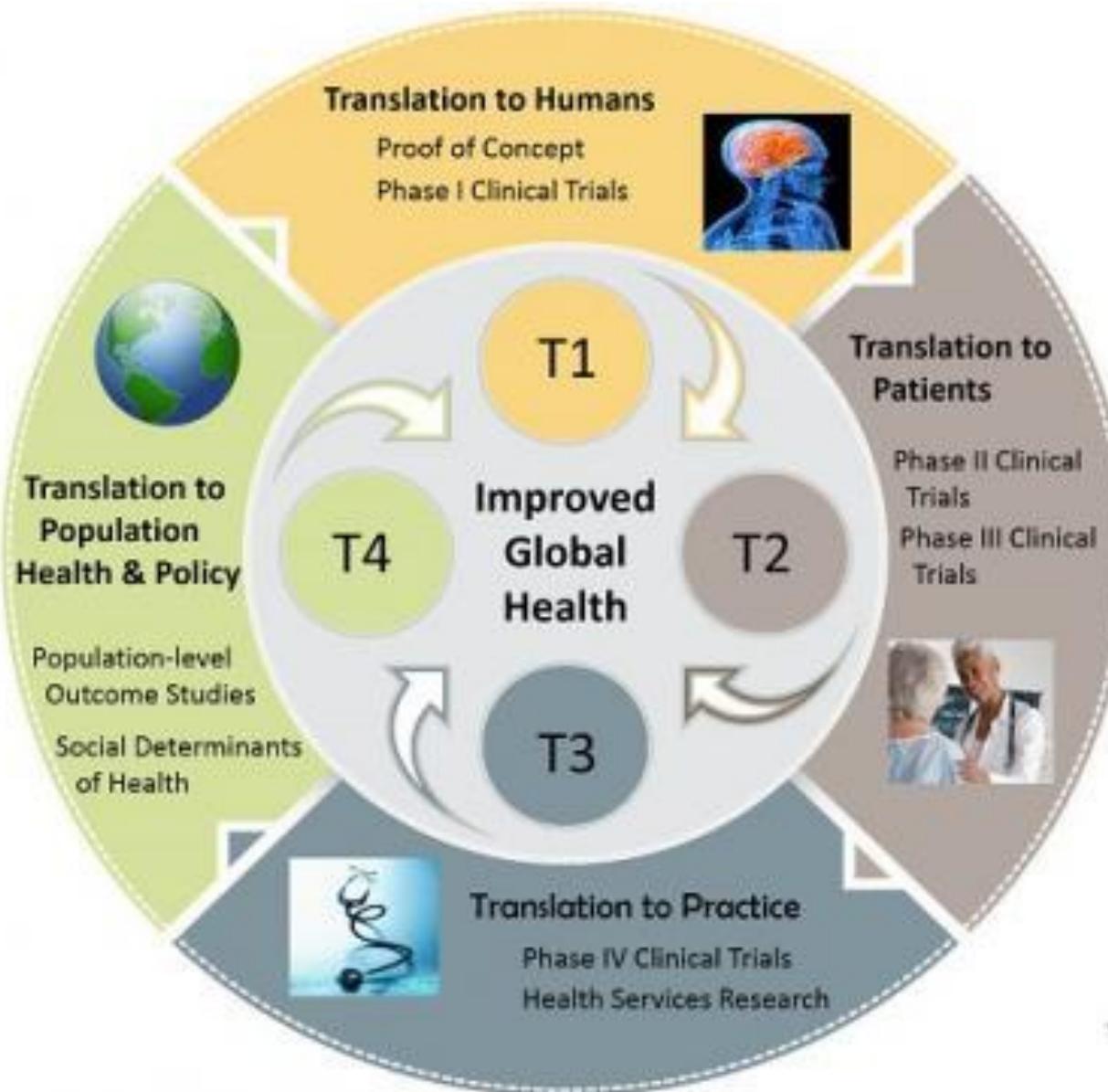
PENELITIAN BIOMEDIK DAN FARMASI KLINIK



PENELITIAN BIOMEDIK FARMASI



PENELITIAN TRANSLASIONAL



- T0: Penetapan senyawa utama, molecular target dan mekanisme kerja (Basic Research)
- T1: Metode baru dalam evaluasi dan validasinya serta uji coba pada manusia (sehat)
- T2: Pengujian efektivitas dan resiko suatu pengobatan atau tindakan
- T3: Pengujian keamanan pada pasien
- T4: Implementasi penggunaan temuan pada masyarakat



PENELITIAN FARMASI KLINIK

Phase I	Phase II	Phase III	Phase IV
20–80 participants	100–300 participants	1,000–3,000 participants	Thousands of participants
Up to several months	Up to two years	One–four years	One year +
Investigates the safety profile of the drug and aims to identify a safe dose that can be used in humans	Investigates the safety of the drug at the dose selected for use in humans and looks for signs of efficacy	Investigates both safety and efficacy of the selected dose, often comparing against standard treatment	Investigates long-term effectiveness, benefits and cost effectiveness of treatment. Phase IV trials are conducted once a medicine has been approved for use and is on the market



PENGEMBANGAN EKOSISTEM RISET KEFARMASIAN

(Inovasi – Teknologi – Network)

Farmasi Klinik

**Industri Farmasi
Regulator**

**Academia
Riset center**

Target, Mekanisme
Kerja, Pre-klinik

Investigasi

Skala Pilot

Fase 1

Uji Pada Manusia

Pengujian
Efektivitas
Keamanan

Skala Industri
Validasi Proses

Fase 2

Efficacy

Penggunaan, DUS-DUR
Surveillance

Perijinan

Skala
Industri

Fase 3

Efikasi & Keamanan

Fase 4

Pemastian Keamanan

Pusat Riset

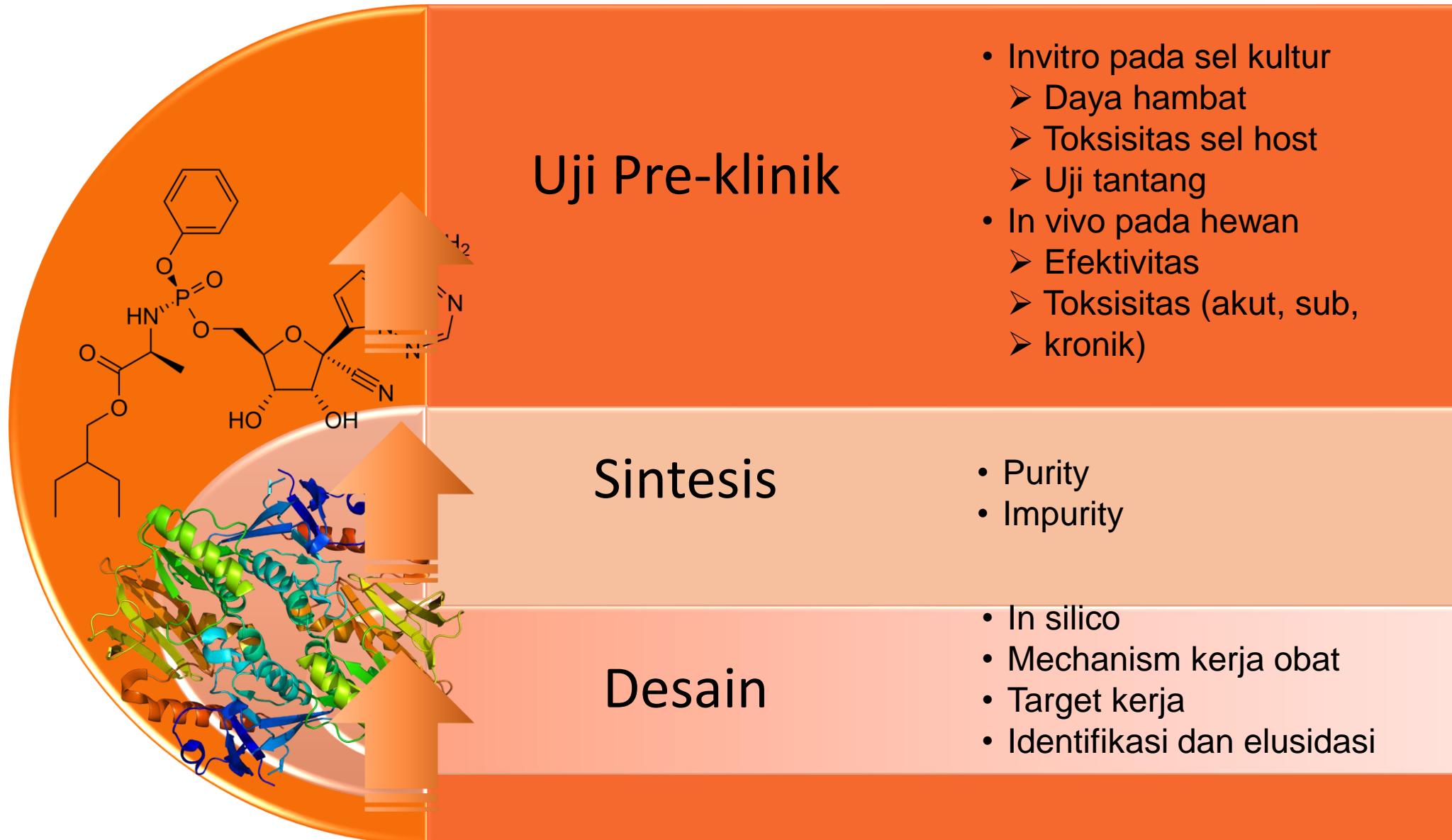
Teaching Industry

Industrial Hub

Science Techno Park



IMPLEMENTASI 1: PENGEMBANGAN OBAT COVID-19



IMPLEMENTASI 1: PENGEMBANGAN OBAT COVID-19

Rumah Sakit

Pengujian
Efektivitas
Keamanan

Penggunaan, DUS-
DUR Surveillance

Industri Farmasi
Regulator

Skala
Pilot

Skala
Industri
Validasi
Proses

Perijin
an

Skala
Industri

Pusat Riset

Target,
Mekanisme
Kerja, Pre-
klinik

Fase
1

Fase
2

Fase
3

Fase 4

Investigasi

Uji Pada Manusia

Efficacy

Effikasi
Keamanan

Modifikasi dari Lurie et al, Developing Covid-19 Vaccines at Pandemic Speed, NEJM 2020



IMPLEMENTASI 2: PENGEMBANGAN BOVINE HYDROXYAPATITE

Farmasi Klinik

Industri Farmasi
Regulator

Pusat Riset

Pengujian
Efektivitas
Keamanan

Penggunaan, DUS-
DUR Surveillance

Survey
pasar

Skala Pilot
Validasi
Proses

Perijin
an

Skala
Industri

Karakteristik fisiko-
kimiawi, Stabilitas,
Survey kebutuhan

Compa
tibilitas
(vitro-
vivo)

Pre-
klinik

Klinik

Survaillance
Study

Investigasi

Uji Pada Manusia

Efficacy

Efikasi dan Keamanan



TEACHING INDUSTRY BHA





| TEACHING INDUSTRY BHA



TEACHING INDUSTRY BHA





Terima Kasih