



“Potensi Kolaborasi Riset dengan Bio Farma”

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Kepala Divisi Surveilans & Riset Klinis
Ketua Tim Advokasi Imunisasi
PT Bio Farma**



DR.dr.Novilia Sjafri Bachtiar,M.Kes

Lahir di Pekanbaru pada tahun 1969, memperoleh gelar Sarjana dan Profesi Kedokteran dari Universitas Padjadjaran Bandung tahun 1994. Memperoleh gelar *Master of Health* dari Universitas Padjadjaran Bandung tahun 2010 dan telah menyelesaikan Program Doktorat dalam bidang Kedokteran juga di Universitas Padjadjaran Bandung. Alumni *Advance Vaccinology Course* di Annecy Perancis tahun 2012. Bergabung dengan PT Bio Farma (Persero) sejak tahun 2001, pernah menjabat berbagai posisi struktural diantaranya sebagai Kepala Bagian Evaluasi Produk, dan Kepala Divisi Surveilans & Uji Klinis menjabat juga sebagai *Ketua Tim Advokasi Imunisasi*. Mengajar di Program Magister Ilmu Kedokteran Tropis, UGM sejak tahun 2016. Pernah menjadi WHO temporary advisor for Measles Laboratory tahun 2008. Aktif di *Council International Organization of Medical Science (CIOMS)* sejak tahun 2008 dan beberapa kali menjadi ekspert dalam *Brighton Collaboration Working Group for Case Definition*. Saat ini mempunyai 23 publikasi internasional, dan 16 publikasi nasional, ikut menulis 2 buku di Indonesia, dan 4 buku internasional seputar vaksin.

Garis Besar (*Outline*)



Bio Farma

Potensi
Kerjasama



BIO FARMA



www.biofarma.co.id

www.infoimunisasi.com

 /  : @infoimunisasi

Company in Brief



Established
in Aug 6, 1890



Moved to Bandung
in 1923

State-owned Enterprise (100 %)
Vaccine & Antiserum manufacturer

Knowledge-based, R&D-based Driven



1300 Employee



Implement Integrated System
GMP, GLP, GCP, ISO9001, ISO14001,
OHSAS18001,
ISO 17025, ISO 27001
ERM, CSR Based ISO 26000



WHO pre-qualified Vac (DTP,
DT, TT, DTP-HB, m/b/tOPV,
Measles and TT, HB in Uniject,
Td, Pentabio)



Philosophy, Vision and Mission

We firmly adopt the working philosophy, vision, mission, and value that make us withstand for more than 100 years.

PHILOSOPHY

Dedicated to Improve Quality of Life.

VISION

To become a World Class Lifescence Company with Global Competitiveness.

MISSION

Provide and Develop Lifescence Products of International Standards to Improve the Quality of Life.



Biotechnology



Indonesia
Self-reliance

Herbal



Chemical



Medical Device



THE STRATEGIC ROLES OF BIO FARMA



**Republic
Of Indonesia**

To secure National Vaccine
availability : Vaccine Self-
Reliance

Vaccine self-reliance
In OIC member countries

OIC
(Organization of
Islamic
Cooperation)

**Bio
Farma**

WHO
(World Health
Organization)

DCVMN

(Developing
Countries Vaccine
Manufacturers
Network)

To Secure Global
Vaccine Supply :
Pre-Qualified WHO/
UNICEF
(GLOBAL PLAYER)

Vaccine Self-Reliance in
developing countries

Bio Farma's Contribution to the World



PRODUCT OF BIO FARMA

VACCINE

BULK



- 1. Polio bulk
- 2. Measles bulk
- 3. Diphtheria bulk
- 4. Tetanus bulk
- 5. Pertussis bulk
- 6. Hib bulk

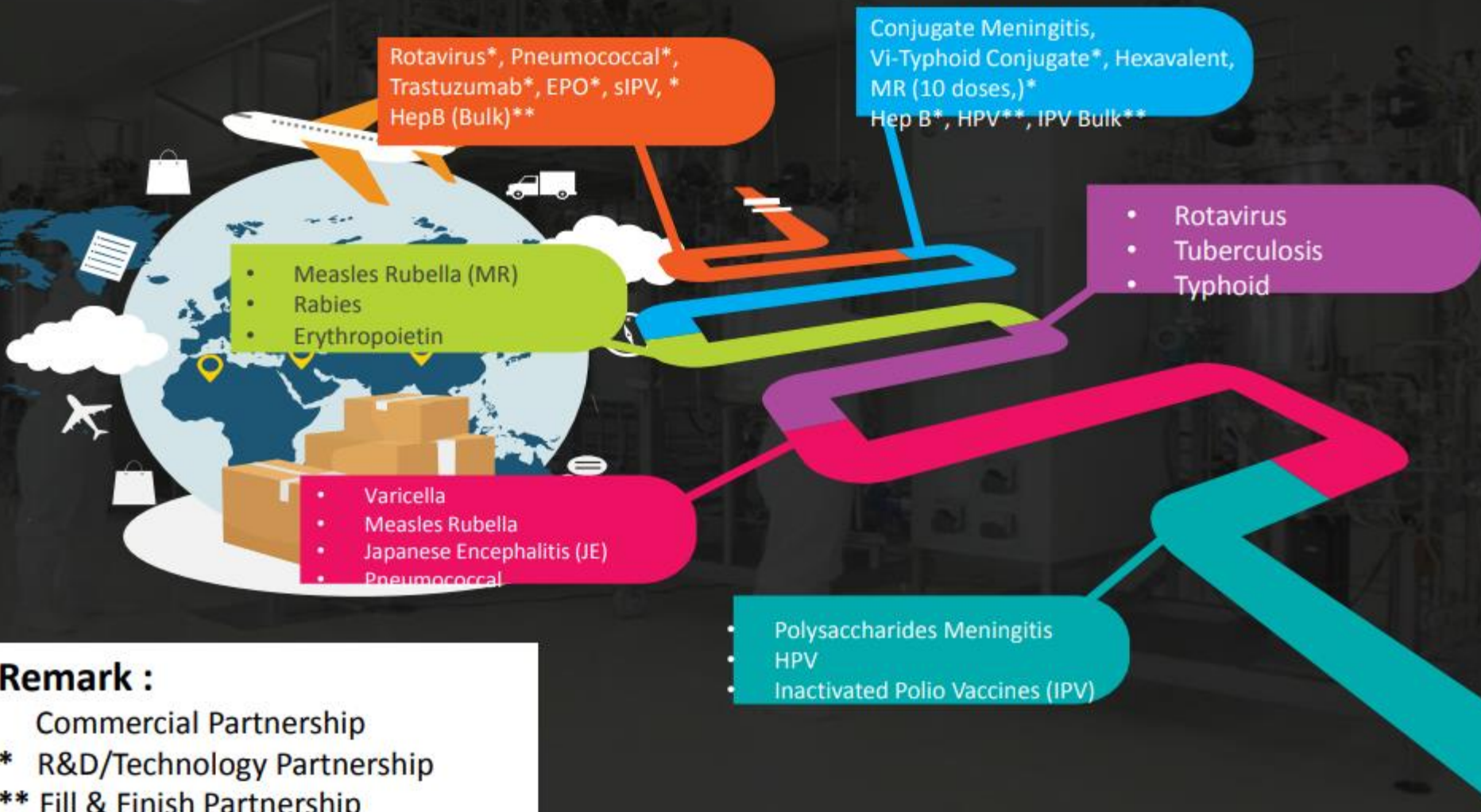
- 1. tOPV (10 ds & 20 ds)
- 2. bOPV (10 & 20 ds)
- 3. mOPV-1 (20 ds)
- 4. Measles (10 ds)
- 5. Hepatitis B 0,5 mL (1 ds)
- 6. Hepatitis B 1 mL (1 ds)
- 7. TT (10 ds)
- 8. Bio TT (1 ds)
- 9. Td (10 ds)
- 10. Bio Td (1 ds)
- 11. DTP (10 ds)
- 12. DTP-HB 10 (10 ds)
- 13. DTP-HB-Hib/Pentabio (1 ds, 5 ds & 10 ds)

mOPV2 & tOPV





Pipeline Product Vaccine & Lifescience



Our International Role



Organisation of Islamic Cooperation (OIC) VACCINE MANUFACTURER GROUP

Islamic Development Bank's Self-Reliance in Vaccine Programs (IDB-SRVP),
Centre of Excellence for Biological



BILL & MELINDA
GATES foundation

Collaborating Partner

Developing Countries Vaccine Manufacturers Network

dcvmmn



International Vaccine Institute (IVI)

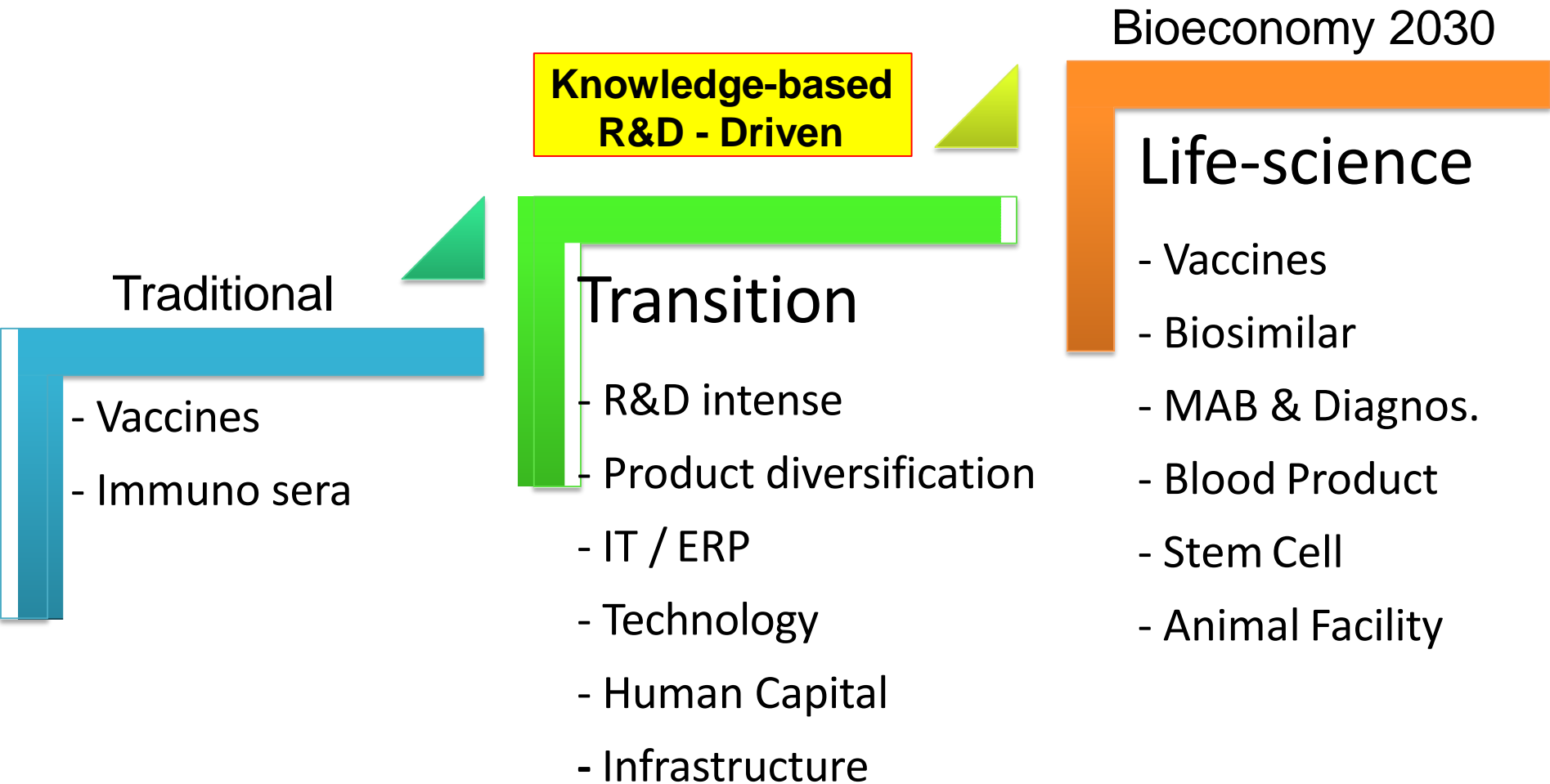


World Health
Organization



unicef

BIO FARMA'S BUSINESS TRANSFORMATION





PERTNERSHIP IN BIO FARMA

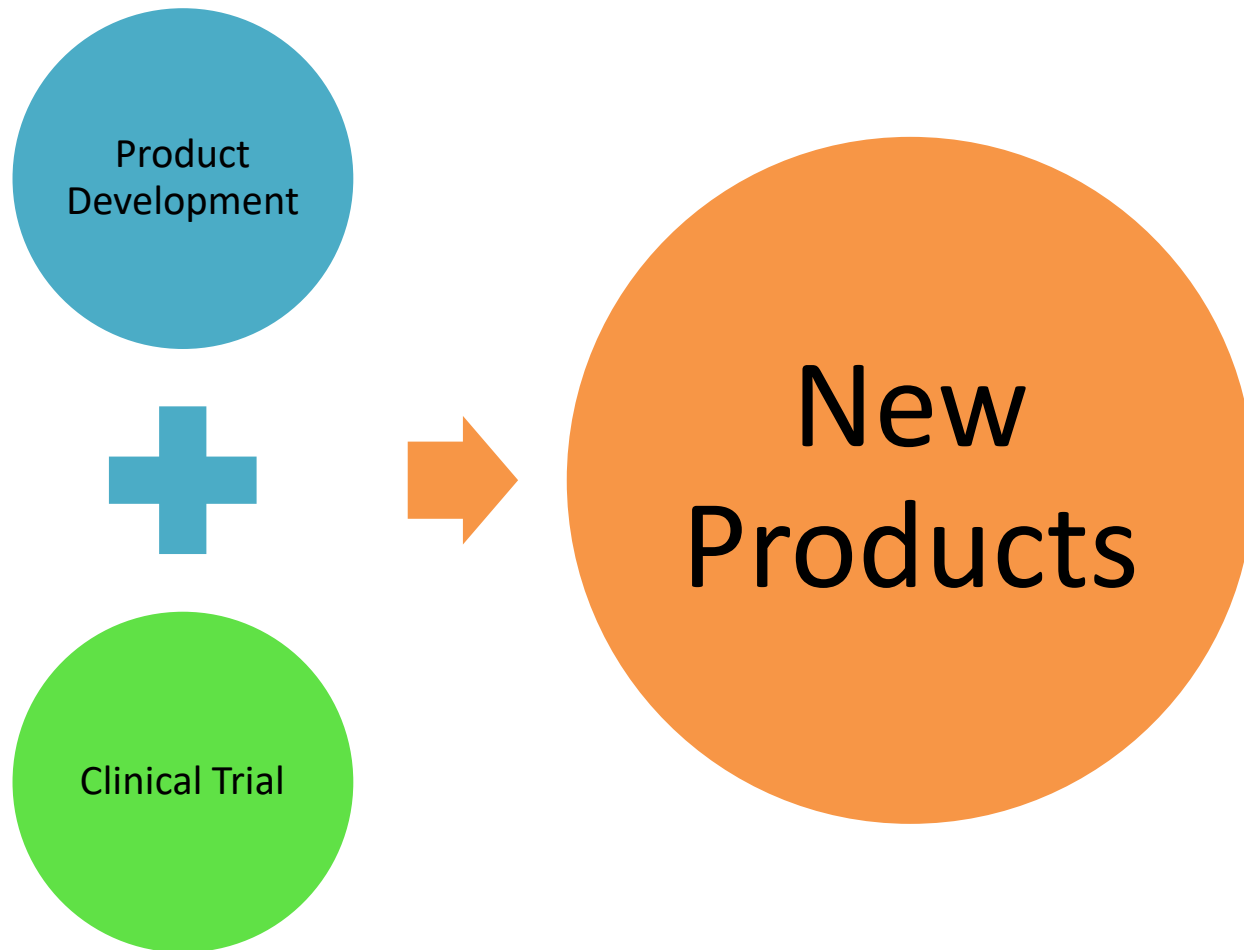


www.biofarma.co.id

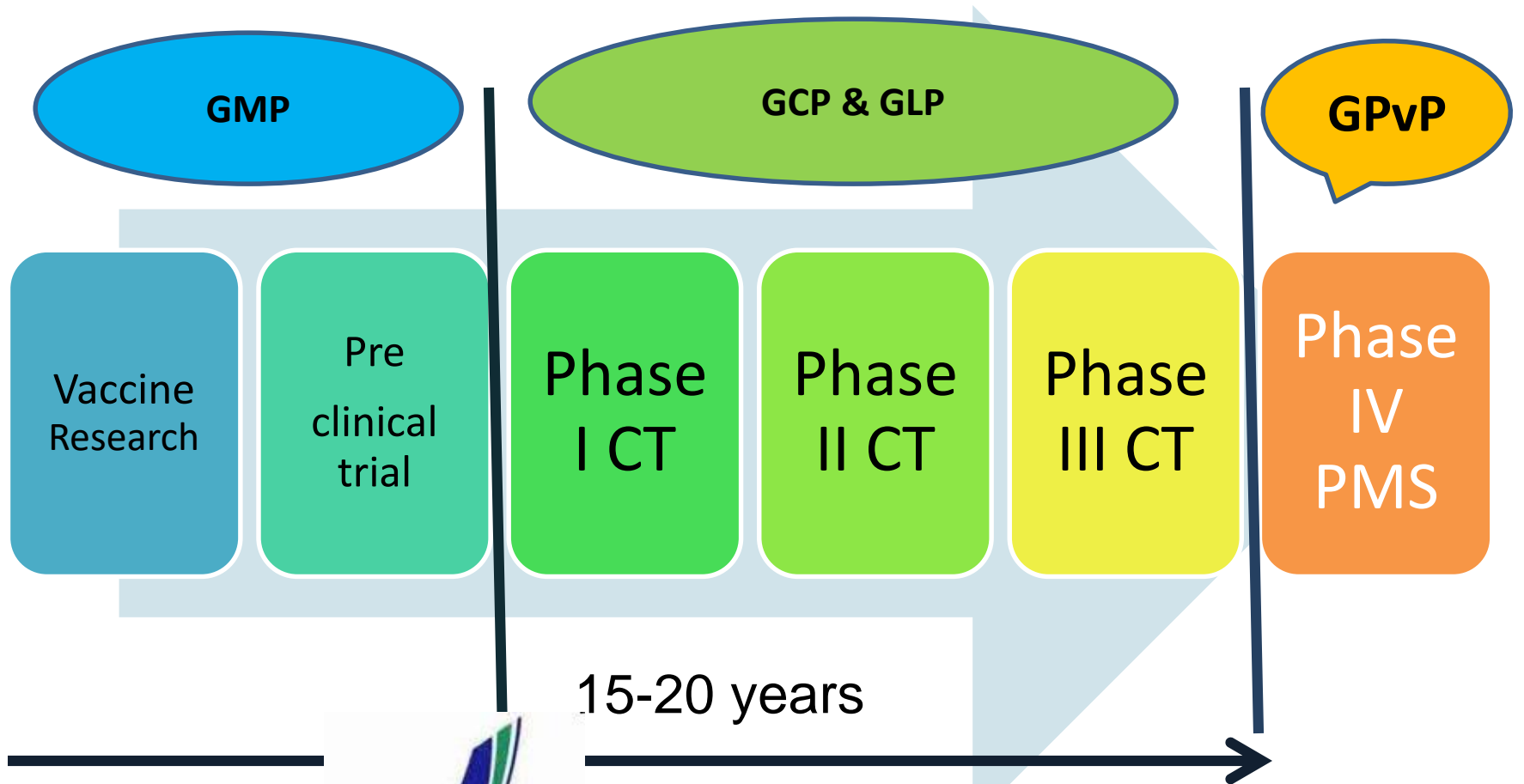
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Types of Partnership

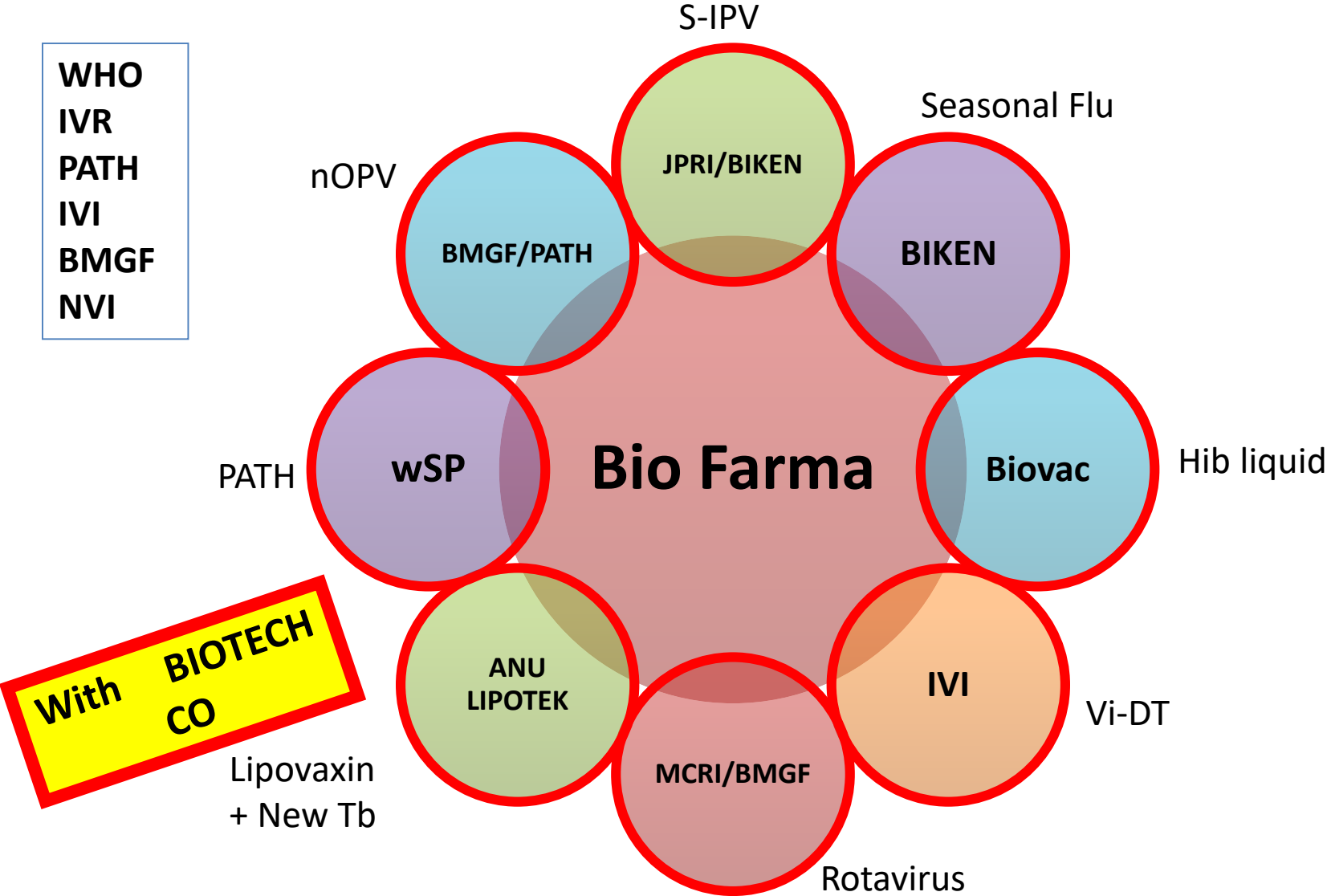


VACCINE DEVELOPMENT FLOW CHART



PARTNERSHIP : Vaccine Dev dan Platform Tech.

WHO
IVR
PATH
IVI
BMGF
NVI



NATIONAL PARTNERSHIP

KONSORSIUM PENGEMBANGAN NEW TB VACCINE



UGM



UI



UNPAD



ITB



UNAIR



UNHAS



LITBANGKES



biofarma

BIO FARMA

KONSORSIUM PENGEMBANGAN DENGUE VACCINE



UGM



UI



UNAIR



EIKKMAN



LIPI

LIPI



BPPT



LITBANGKES



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BIO FARMA



Uji Klinis



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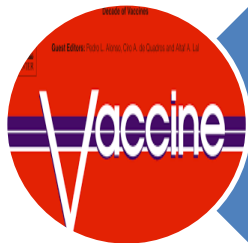
Tujuan



Registrasi Produk



WHO PQ



Publikasi

Kerja Sama Uji Klinis



Universitas Padjadjaran



Universitas Gajah Mada



Universitas Indonesia



Universitas Udayana



Universitas Airlangga



Universitas Diponegoro



Universitas Sebelas Maret

Contoh Kerjasama Uji Klinis Fase I



UNPAD

- Vaksin Hib, Pentavalent
- 2011,2012, Registrasi, WHO PQ, Publikasi



UI

- Vi-DT
- 2017, Publikasi



UGM

- Vaksin Rotavirus 2018, proses publikasi

Contoh Kerjasama Uji Klinis Fase II-III



UNPAD

- 2003-2017, DTP-HB, Hepatitis B, Pentavalent, bOPV, QIV
- Registrasi, WHO PQ, 7 publikasi



UI

- 2018, Vi-DT
- 3 publikasi, fase III masih berjalan



UGM

Phase IIb 3 publications, Phase III on going

RESEARCH ARTICLE

Open Access



The immunogenicity, safety, and consistency of an Indonesia combined DTP-HB-Hib vaccine in expanded program on immunization schedule

Kusnandi Rusmil^{1*}, Hartono Gunardi^{2†}, Eddy Fadlyana¹, Soedjatmiko², Melita Dhamayanti¹, Rini Sekartini², Hindra Irawan Satari², Nelly Amalia Risan¹, Dwi Prasetyo¹, Rodman Tarigan¹, Reni Garheni¹, Mia Milanti¹, Sri Rezeki Hadinegoro², Suganda Tanuwidjaja¹, Novilla Sjafril Bachtiar³ and Rini Mulia Sari³

Abstract

Background: WHO recommended incorporation of *Haemophilus influenzae* type b (Hib) vaccination into immunization program. Indonesia would adopt Hib as a National Immunization Program in 2013. We aimed at analyzing immunogenicity, safety, and consistency of a new combined DTP-HB-Hib (diphtheria-tetanus-pertussis-Hepatitis B-Haemophilus influenza B) vaccine.

Methods: A prospective, randomized, double blind, multicenter, phase III study of Bio Farma DTP-HB-Hib vaccine conducted in Jakarta and Bandung, August 2012 - January 2013.

Subjects were divided into three groups with different batch number. Healthy infants 6–11 weeks of age at enrollment were immunized with 3 doses of DTP-HB-Hib vaccine with interval of 4 weeks, after birth dose of hepatitis B vaccine. Blood samples obtained prior to vaccination and 28 days after the third dose. Safety measures recorded until 28 days after each dose.

Results: Of 600 subjects, 575 (96 %) completed study protocol. After 3 doses, 100.0 and 96.0 % had anti-PRP concentration ≥ 0.15 and ≥ 1.0 $\mu\text{g/ml}$. Anti-diphtheria and anti-tetanus concentration ≥ 0.01 IU/ml detected in 99.7 and 100.0 %; while concentration ≥ 0.1 IU/ml achieved in 84.0 and 97.4 %. Protective anti-HBs found in 99.3 %. The pertussis vaccine response rate was 84.9 %.

None Serious Adverse events (SAEs) considered related to study vaccine or procedure.

Conclusions: The 3-dose of DTP-HB-Hib was immunogenic, well tolerated and suitable for replacement of licensed-equivalent vaccines based on immunologic and safety profiles.

Trial registration: NCT01986335 – October 30th 2013.

Keywords: Combined DTP-HB-Hib vaccine, Infants, Primary vaccination, EPI



Contents lists available at [ScienceDirect](#)

Vaccine

journal homepage: www.elsevier.com/locate/vaccine



Immunogenicity and safety of a Trivalent Influenza HA vaccine in Indonesian infants and children



Soedjatmiko Soedjatmiko^a, Bernie Endyarni Medise^{a,*}, Hartono Gunardi^a, Rini Sekartini^a, Hindra Irawan Satari^a, Sri Rezeki Hadinegoro^a, Novilia Sjafri Bachtiar^b, Rini Mulia Sari^b

^a Department of Child Health, Faculty of Medicine, Universitas Indonesia, Jalan Salemba 6, Jakarta 10340, Indonesia

^b PT. Bio Farma, Jalan Pasteur 28, Bandung 40161, Indonesia

ARTICLE INFO

Article history:

ABSTRACT

Introduction: High rate of influenza infection in children made influenza vaccination strongly recom-

ORIGINAL ARTICLE

Human Neonatal Rotavirus Vaccine (RV3-BB) to Target Rotavirus from Birth

J.E. Bines, J. At Thobari, C.D. Satria, A. Handley, E. Watts, D. Cowley, H. Nirwati, J. Ackland, J. Standish, F. Justice, G. Byars, K.J. Lee, G.L. Barnes, N.S. Bachtiar, A. Viska Icanervilia, K. Boniface, N. Bogdanovic-Sakran, D. Pavlic, R.F. Bishop, C.D. Kirkwood, J.P. Buttery, and Y. Soenarto

ABSTRACT

BACKGROUND

A strategy of administering a neonatal rotavirus vaccine at birth to target early prevention of rotavirus gastroenteritis may address some of the barriers to global implementation of a rotavirus vaccine.

The authors' full names, degrees, and affiliations are listed in the Appendix. Address correspondence to Dr. Bines at the University of Oxford, UK.



USAID
FROM THE AMERICAN PEOPLE

PROPOSAL

Applicant: Faculty of Medicine, Universitas Padjadjaran, Bandung, West Java, Indonesia

DUNS number: 726529733

Research Unit: Clinical Infectious Disease Research Center

Applicant's contact person: Cissy B. Kartasasmita (cbkarta@gmail.com)

U.S. higher education institution partner(s): University of Colorado

Indonesian affiliate higher education institution partners:

Universitas Syiah Kuala, Banda Aceh, Indonesia

Universitas Lambung Mangkurat, Banjarmasin, Indonesia

Universitas Mataram, Mataram, Indonesia

Proposed CCR: Consortium of Respiratory Infectious Disease Study & Prevention

Research Focus Area: Public Health and Infectious Disease

Proposed grant duration: 46 months

Requested funding (in IDR): 38,999,999,999,-

Signature of authorized individual submitting application:



**Universitas Padjadjaran
Bandung, Indonesia**



**Universitas Syiah Kuala
Banda Aceh, Indonesia**



**Universitas
Lambung Mangkurat
Banjarmasin,**



**Universitas Mataram
Mataram, Indonesia**



**PT. Bio Farma (Persero)
Bandung, Indonesia**



**PharmaJet,
Colorado**



**University of
Colorado**

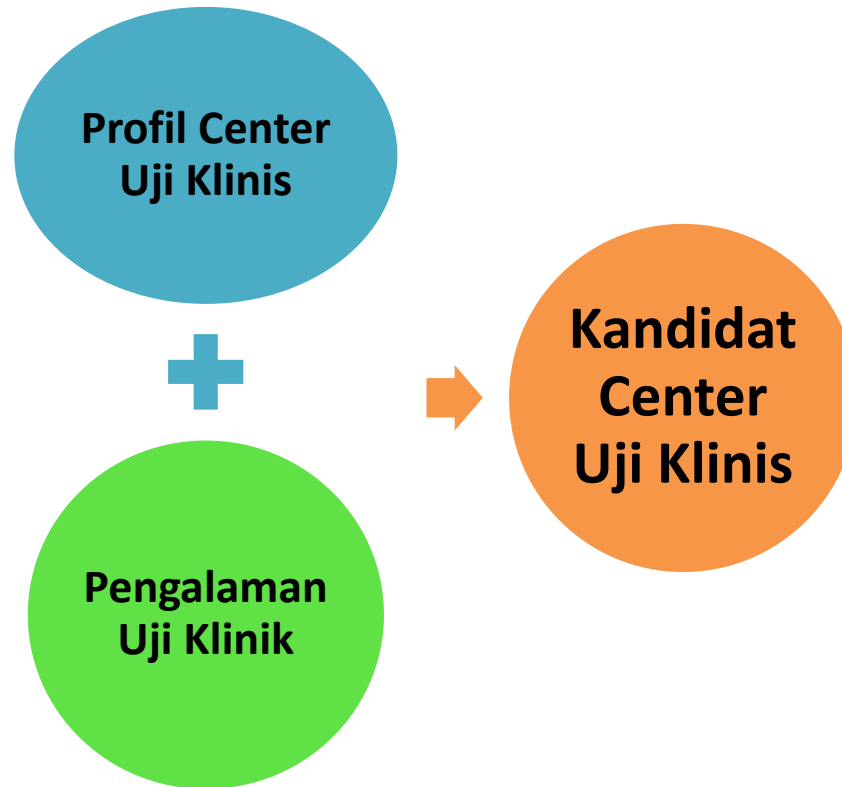
Pemilihan Center Uji Klinis

**Menjamin
perlindungan subjek**

**Menjamin
implementasi GCP**

**Menjamin
implementasi protokol**

Fasilitas Uji Klinis



1. Peneliti



**Pengalaman Uji
Klinis**

Sertifikat GCP

Dedicated

2.Tim Uji Klinis

Tim Uji Klinis
berpengalaman

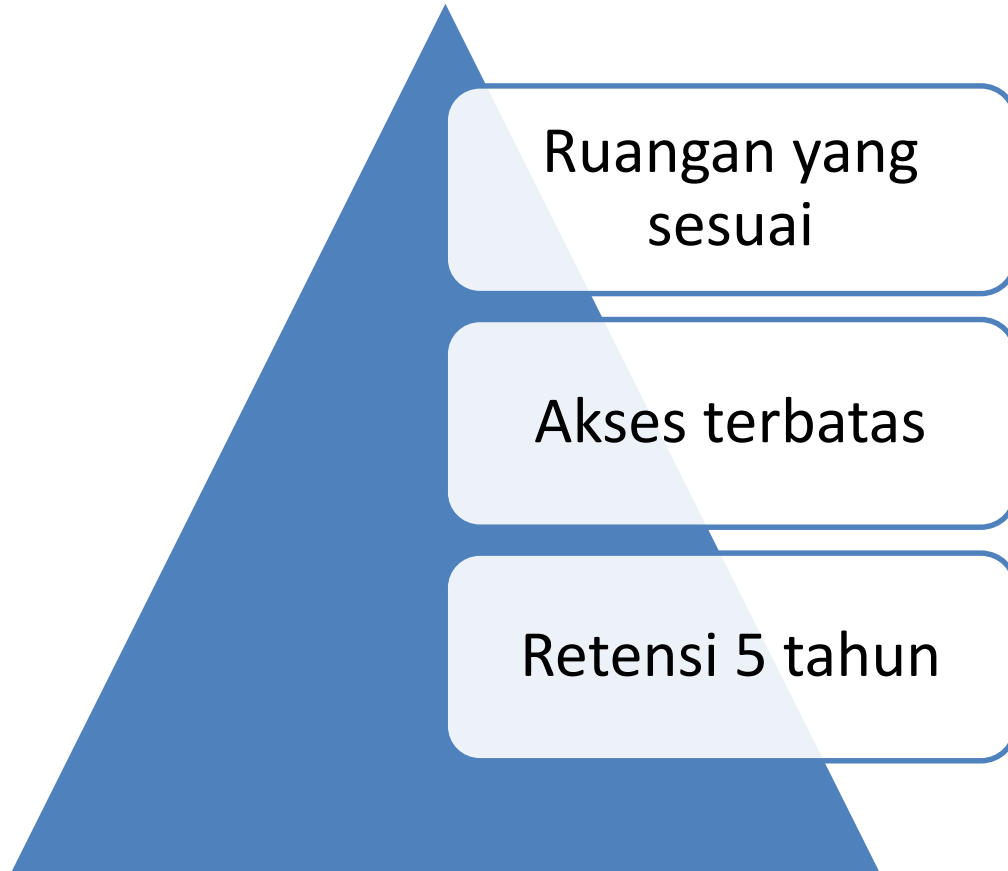
3. Tempat Uji Klinis

Ruangan
khusus

Nyaman

Privasi
terjamin

4. Penyimpanan Dokumen



5. Penyimpanan Vaksin

Ruangan yang
sesuai

Khusus
penyimpanan
vaksin

Suhu terjaga

Dokumen yang Disediakan Center Uji Klinis

Perijinan

Persetujuan
RS

Persetujuan
Dinkes

*Investigator
sheet log*

*Indentification
sheet log*

Kaji Etik

Dokumen yang Disediakan Sponsor

PPUK

Protokol

PKS

*Case Report
Form*

*Investigator
Brochure*

Diary Card

Monitoring, Audits, Inspections

- 
- Monitoring by sponsor
 - Audit quality by QA/ Sponsor
 - Inspection by Badan POM

Rotavirus Vaccine Development Collaboration



MCRI: RV3BB



BF: Further
Development &
CT Sponsor



UGM:
Surveillance &
CT





TERIMA KASIH

