International Vaccine Institute: IVI's collaborations to develop new vaccines

Dr. Jerome Kim
Director General
DCVMN
5 November 2020

International Vaccine Institute

IVI is an International Organization dedicated to Global Health

Global Vaccine Research Institute

- **HQ and labs at Seoul National University**
- **Field programs in 22 countries: Asia, Africa, Latin America**
- **14 nationalities in workforce of 155**

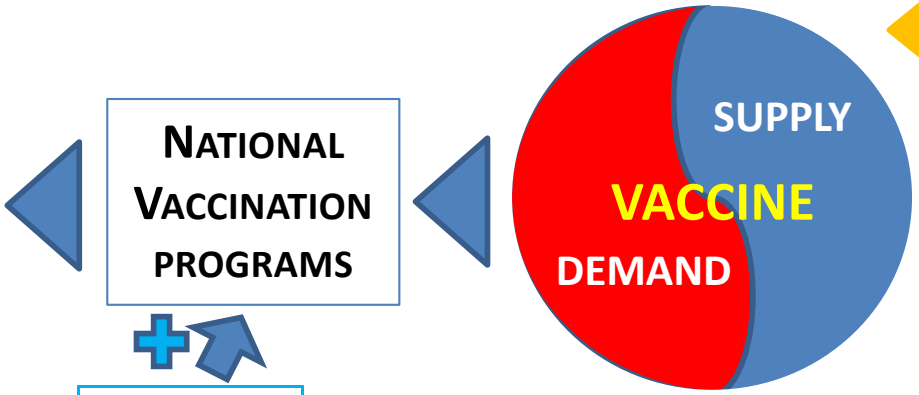
OECD-recognized International Organization (not for profit)

- **UNDP initiative**
- **First international organization in Korea (1997)**
- **36 countries and WHO as state parties (now 37 – Madagascar pending final submission to UN)**

Pending submission of paperwork to UN SG office

IVI works for : *Saving Lives, Building a Stronger, Healthier World*

Impact
- Lives saved
- ↓ DALYs
- Healthier families
  - ↓ poverty
  - ↑ cognitive and physical development
  - ↑ education
- ↑ Economic growth



New global health vaccines

Developing Country Vaccine Manufacturer

NATIONAL VACCINATION PROGRAMS

DELIVERY

WHO/SAGE
Gavi/UNICEF
ADVOCACY
NITAGs

Manufacturing
Clinical Development
NRA approval
WHO PQ

DEVELOPMENT AGENCIES
- KOICA, SIDA, DFID, USAID

FOUNDATIONS / TRUSTS
DONORS

- Burden data
- Cost Effectiveness
- Investment Cases
- Full Public Value of Vaccines Analyses
- Support for NRA / NITAGs

- Clinical Development and Regulatory
- Biostatistics
- Data Management
- Support for PQ

Technology Transfer & Mfr Support

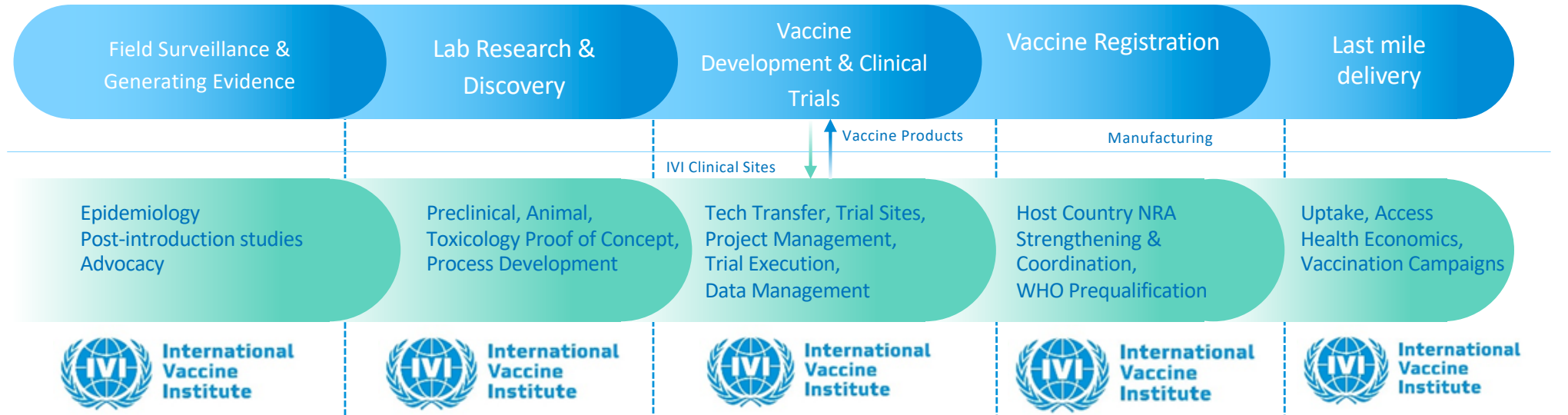
DEVELOPMENT & DELIVERY

PUB HEALTH, ACCESS & VACCINE EPI

LABORATORY

New vaccines

IVI imagines, discovers, and executes a vision of vaccines for all



IVI discovers, develops, and delivers unincentivized vaccines for high burden infectious diseases in LMICs

Global Health Funders

IVI differs from Global Health funders by executing all aspects of vaccine discovery, development, and delivery – inclusive of surveillance to promote understanding of disease burden, and health economics

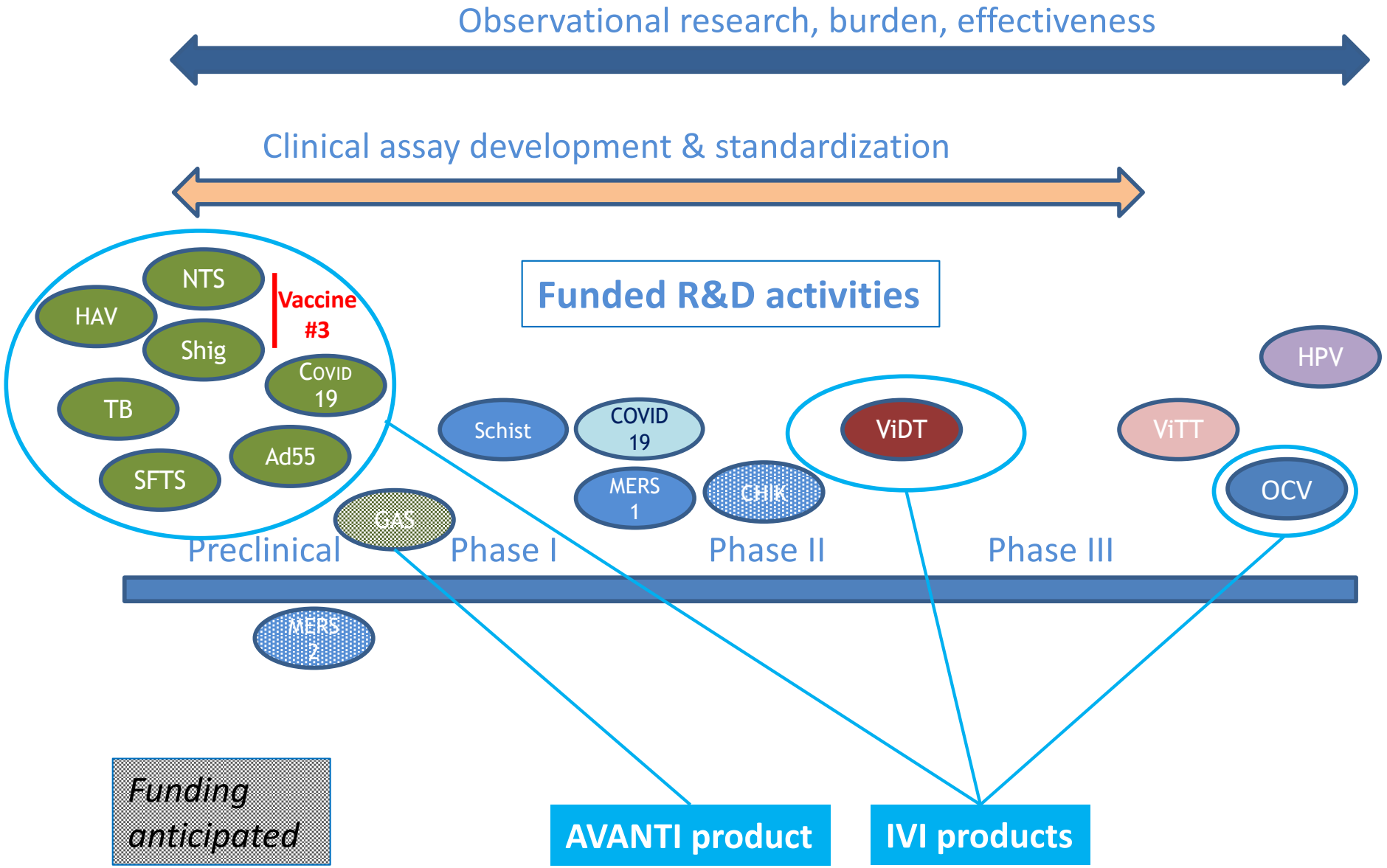
Gavi, The Vaccine Alliance
Funds the purchase of vaccines for routine immunization in LMICs

Unitaid
Funds scale up access to licensed treatment for HIV, TB, malaria only

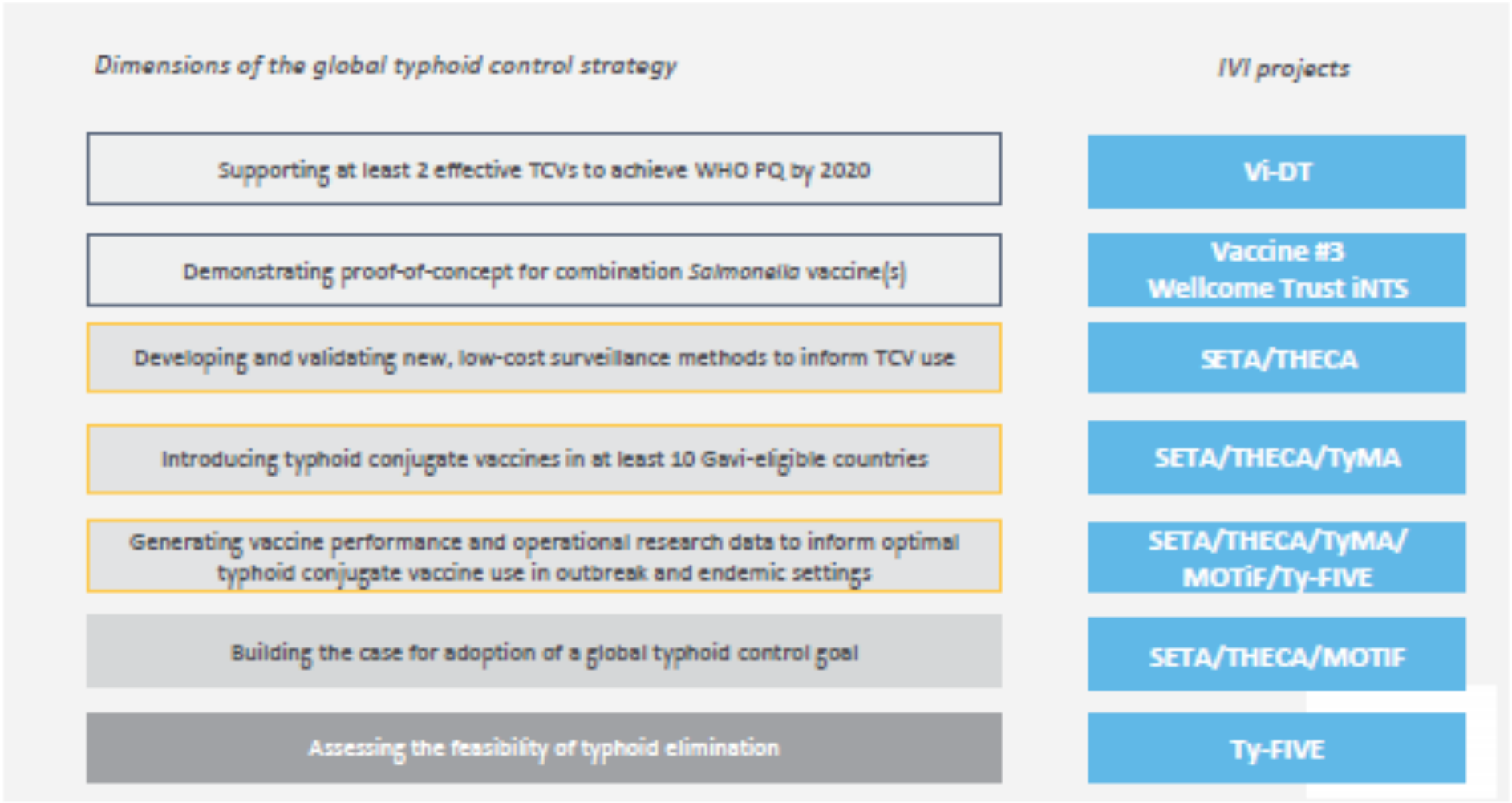
The Global Fund To Fight AIDS, Tuberculosis and Malaria
Funds intervention, infrastructure, policy for HIV, TB, & malaria

CEPI
Funds select emerging infectious disease (EID) epidemic pathogens

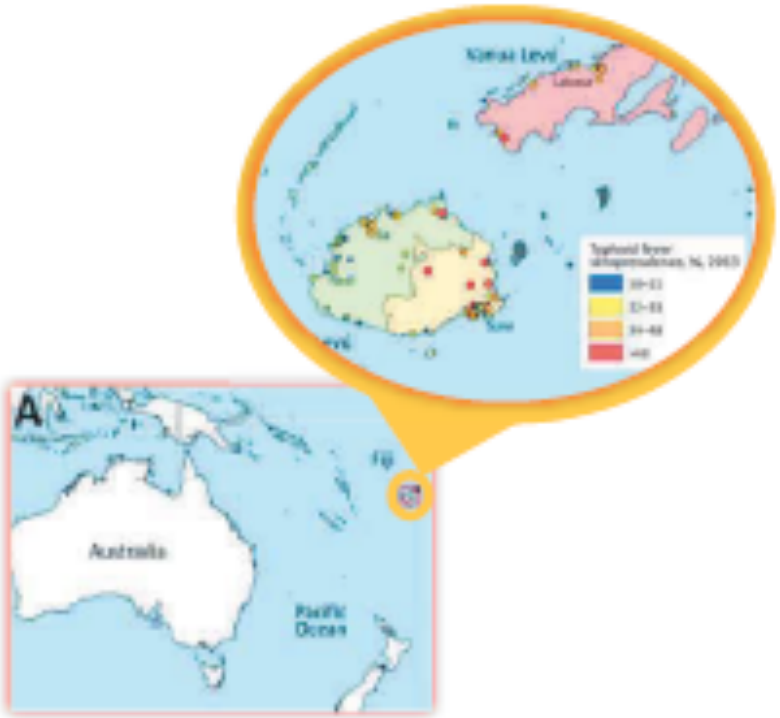
Research & Development Projects



Global typhoid control projects



Typhoid eradication proof of concept Ty-Five



- Population of Fiji in 2019: 890,000*
- Incidence of TF: 21-100/100,000 PYO*

*Vigdis E Pilser et al., Clinical Infectious Diseases, Volume 69, Issue Supplement_5, 1 November 2019, Pages S395–S401

Fiji Intervention and Elimination Program

Goal

- Assess the feasibility of eliminating typhoid fever after a one-dose regimen of the Vi-TT Typhoid Vaccine Conjugate (TCV) given to all individuals >9 months on the island of Vanua Levu

Activities

- Strengthening of typhoid fever surveillance system
- Catch-up campaign followed by routine immunization delivered through the Fijian Government EPI systems

Impact

- Typhoid disease burden reduction/elimination
- Enhanced surveillance for sustainable disease control and prevention
- Improved understanding of potential barriers to typhoid fever eradication

Assess the feasibility of typhoid elimination

Antimicrobial resistance: Fleming Fund Projects

A £265 million UK aid investment managed by the Department of Health and Social Care (DHSC) in partnership with Mott MacDonald, the Fleming Fund Management Agent.

REGIONAL GRANTS

ROUND 1

1) Collection of Historical Data
East & Southern Africa

2) Collection of Historical Data
West Africa

3) Collection of Historical Data
South East Asia

4) Collection of Historical Data
South Asia

ROUND 2

1) External Quality Assurance
Africa

2) External Quality Assurance
Asia

3) Common Surveillance Protocols Global

4) Microbiology & Epidemiology Training
Global

5) Planning, Policy & Advocacy
Global

6) Whole Genome Sequencing Training Africa

- Antimicrobial resistance is considered one of the biggest threats to global public health
- It is estimated that if current trends continue unabated, by 2050 AMR will be the cause of 10 million annual deaths and a yearly cost of $100 trillion dollars.
- Making *better use of existing vaccines* and *developing new vaccines* are important ways to tackle AMR

CAPTURA

RADAAR

Data collection

Data analysis & use

Policy and advocacy

Stakeholder engagement

Capacity building

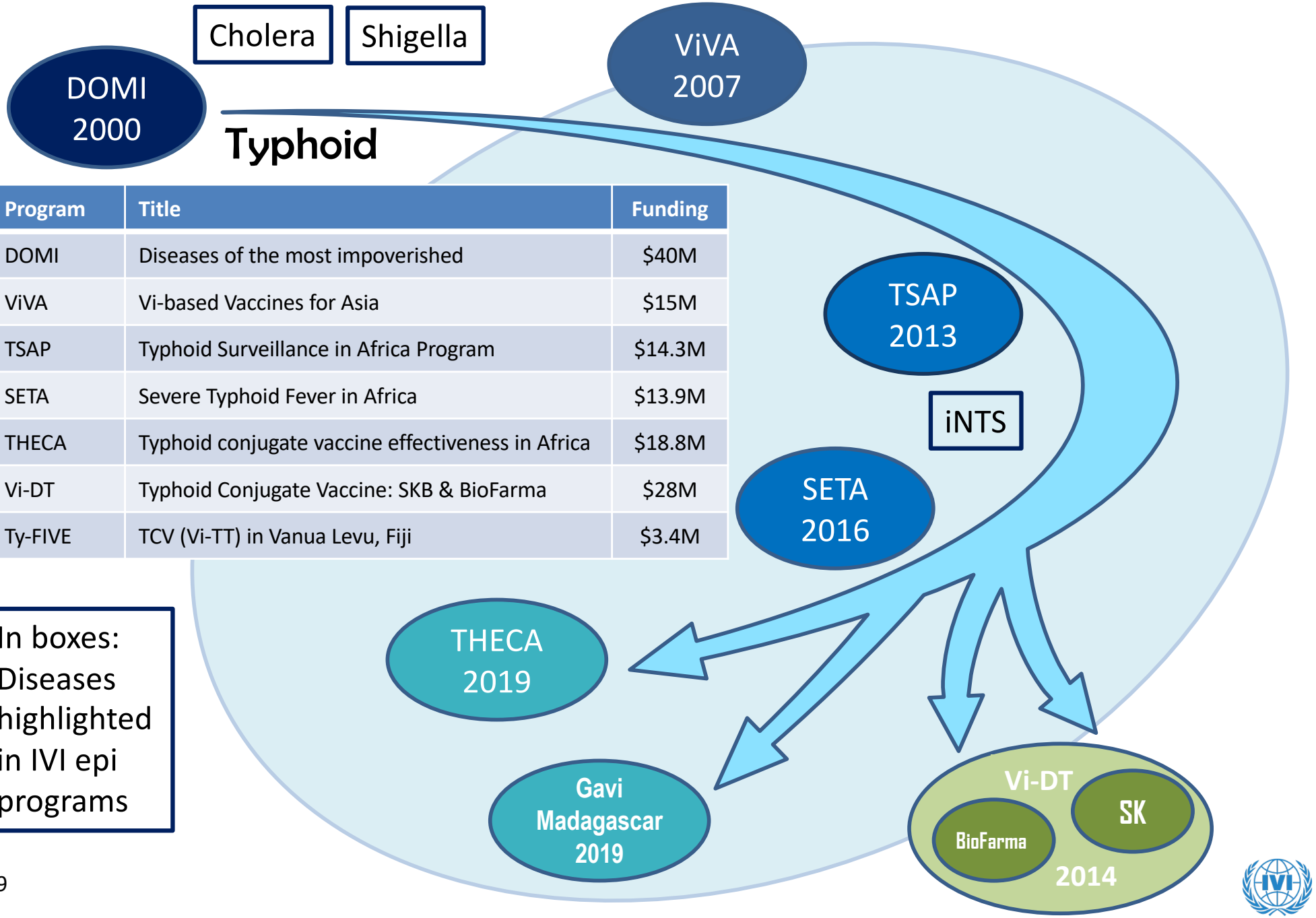
Quality

EQASIA

UKaid

WHO Global action plan on AMR & O'Neill, J., *The review on antimicrobial resistance. Tackling drug-resistant infections globally: final report and recommendations*. 2016

Example 1: IVI Typhoid Programs 2000 - 2019

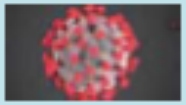


Program	Title	Funding
DOMI	Diseases of the most impoverished	$40M
ViVA	Vi-based Vaccines for Asia	$15M
TSAP	Typhoid Surveillance in Africa Program	$14.3M
SETA	Severe Typhoid Fever in Africa	$13.9M
THECA	Typhoid conjugate vaccine effectiveness in Africa	$18.8M
Vi-DT	Typhoid Conjugate Vaccine: SKB & BioFarma	$28M
Ty-FIVE	TCV (Vi-TT) in Vanua Levu, Fiji	$3.4M

In boxes: Diseases highlighted in IVI epi programs

Novel / Innovative Vaccines

- **COVID-19 (Inovio DNA Vaccine):**
  Pre-Licensure ($4M - CEPI)



- Study Title: A Phase **I/IIa** Dose-Ranging Study to Evaluate Safety, Tolerability and Immunogenicity of INO-4800, a Prophylactic Vaccine against SARS-CoV-2, Administered Intradermally Followed by Electroporation in Healthy Adults in **South Korea**
- Leveraging existing collaborations with Inovio on DNA vaccine platform with MERS-CoV, KNIH, and well-established relationship with MFDS
- First Part A of the Study Completed – Low (1 mg) and High Dose (2 mg) in 40 subjects. No Safety concern.
- 2nd Part B to start in Dec 2020

- **Chikungunya (BBIL Inactivated Vaccine + Alum):**
  Pre-Licensure ($14M - CEPI)

- Study Title: A phase **II/III**, Adaptive Seamless Design, Randomized, Controlled Study to Evaluate the Safety and Immunogenicity of 2 Dose-Regimen of BBV87 Chikungunya Vaccine in Health Subjects Aged 12-65 Years in **Panama, Colombia, and Thailand**
- Opportunity to expand IVI clinical footprint in Latin America
- Study Protocol and related study documents developed and submitted to IRBs/NRAs
- First Subjects from Panama will be enrolled in Jan 2021

- **Schistosomiasis (Sm-p80+GLA-SE):**
  Pre- Licensure ($7.3 - EU Horizon2020)

- Study Title: A Phase **Ib**, Multicenter, Randomized, Placebo-controlled, Observer-blinded, Dose escalation Study to Evaluate the Safety, Tolerability, and Immunogenicity of the Sm-p80 + GLA-SE (SchistoShield®) candidate vaccine in healthy adults in **Madagascar and Burkina Faso**
- Opportunity to be involved in parasitic vaccine development
- Phase Ib Study Protocol being developed
- Phase Ia in US will start in Q1,2021 and Phase Ib in Madagascar and Burkina Faso in Q3-Q4,2021

Lifecycle Management: pre- / post-licensure studies

- OCV Simplified (Euvichol-S):

Pre-Licensure ($4.5M - BMGF)

- Study Title: A phase **III**, multicenter, randomized, observer-blinded controlled trial to evaluate Immune Non-Inferiority and Safety of Oral Cholera Vaccine-Simplified (OCV-S) compared to Oral Cholera prequalified vaccine in healthy children and adults (Shanchol™)
- All technical consultations (i.e., Cholera experts, MFDS, and WHO PQ) completed, including BMGF Stage Gate meeting
- Study protocol and study related documents are being developed
- Sites Budget Assessment (i.e., **Nepal, Mozambique, or Philippines**) being conducted
- Study start in Q2, 2021

- TCV (BBIL Vi-TT):

Post-Licensure ($4.2M - EDCTP)

- Study Title: A cluster-randomized trial assessing the impact of a Vi-Polysaccharide conjugate vaccine in preventing typhoid infection in Asante Akim, **Ghana** (TyVEGHA)
- Study Protocol and study related documents developed and submitted to IRB/NRA
- Study Start in Q1, 2021

- HPV (Cervarix®):

Post Licensure ($7.8M - BMGF)

- Study Title: A community effectiveness study of single dose or two-dose of bivalent HPV vaccine (CERVARIX®) in female school students in **Thailand**
- Year-2 (observational phase) Study Preparation Ongoing
- Year-2 Activities start in Dec 2020

Laboratory Science

- **Vaccine #3**
  - iNTS
  - Shigella
- **COVID-19**
  - Vaccine evaluation system
  - Clinical analysis
  - Pre-clinical studies
  - International Standard
- **Others**
  - Immunological assay development for typhoid vaccine
  - Bivalent vaccine for rVSV-based SFTS and HFRS
  - Ad55 vaccine development
  - MERS-CoV: clinical analysis & international standard material/assay

PARTNERS

SK bioscience

INOVIO

Genexine

CELLTRION

sumagen

NIBSC

KCDC

KMPC

Ministry of Food and Drug Safety

경북바이오산업연구원
Gyeongbuk Institute for Bio Industry

SNUH
SEOUL NATIONAL UNIVERSITY HOSPITAL

sumagen

NIBSC

IVI collaboration with Korean government pilot plants

National Institute of Health

National Infectious Disease Research Institute

- R&D for emerging infectious diseases
- Collaboration w/ academy, research institute and industry

- High level research plan
- Networking with global institutes
- Collaboration for public vaccine R&D
- Communication with industries

Korean Vaccine R&D Center for Public Vaccines

- To be established at Oct. 2020 ($35M)
- Public vaccine R&D
- Supporting commercial vaccine R&D
- Facilities
  - A/BSL-2/3

International Vaccine Institute

Vaccine 3.0 Project

Other Vaccine projects

- IVI branch lab.
- Staff training
- Networking with industries

- Global/domestic networking
- IVI's Vaccine production for clinical trial

GMP facility for animal cell culture-based vaccine

- To be established at 2021 ($86M)
- Supporting vaccine production for clinical trial
- Facilities
  - 200L (2 lines) & 1,000L (1 line) culture facilities
  - BSL-3: 200L culture facility
  - Vial/pre-syringed line

GMP facility for microbia-based vaccine

- To be established at 2021 ($70M)
- Supporting vaccine production for clinical trial
- Facilities
  - Pilot Plant: 50L culture facility
  - 200L (2 lines) & 1,000L (1 line) culture facilities
  - BSL-3: 200L culture facility

Technology supporting center vaccine commercialization

- To be established at 2022 ($23M)
- Supporting pre-clinical studies & business
- Facilities
  - GLP lab.
  - ABSL-2/3: mouse-480 cages, rat-40 cages
  - Bioreactor: 1~20L

IVI COVID-19 vaccine R&D

- **Support for epi & Phase III site development**
  - Sida (Sweden) – two sites in Africa
  - BMBF – sites in S/SE Asia
  - Gates – Phase III site preparation

- **Supporting Clinical trials for COVID-19 vaccine**
  - Two vaccines: INIVIO and Genexine
  - ELISA, wild type neutralization assay

- **International Standard Serum and Assay development**

- **Pre-clinical support for COVID-19 vaccine & therapeutics**

PARTNERS

KMPC 국가마우스표현형분석사업단 KOREA MOUSE PHENOTYPING CENTER

MFDS KOREA

National Institute of Health

SNUH SEOUL NATIONAL UNIVERSITY HOSPITAL

INOVIO POWERING DNA MEDICINES

Genexine

KCDC

NIBSC Confidence in Biological Medicines

SK bioscience

sumagen

Designers' Enzyme GENOFOCUS

GI innovation Great Integration and Innovation to develop breakthrough biologics

CELLTRION

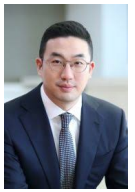
CEPI New vaccines for a safer world

BILL & MELINDA GATES foundation

Sida

Bundesministerium für Bildung und Forschung

MINISTRY OF SOCIAL AFFAIRS AND HEALTH



IVI


International Vaccine Institute
20 Years Advancing Global Health
Thank You!
IVI website
www.ivi.int
Like us
https://www.facebook.com/InternationalVaccineInstitute
Follow us
https://twitter.com/IVIHeadquarters