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

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Director General
DCVMN
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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
  o ↓ poverty
  o ↑ cognitive and physical development
  o ↑ education
• ↑ Economic growth

New global health vaccines

Developing Country Vaccine Manufacturer

WHO/SAGE
Gavi/UNICEF
ADVOCACY
NITAGs

Manufacturing
Clinical Development
NRA approval
WHO PQ

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

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

Technology Transfer & Mfr Support

New vaccines

New vaccines

Development
Agencies

NATIONAL VACCINATION PROGRAMS

DELIVERY

Vaccine
Supply

Demand

Labs

Public Health, Access & Vaccine Epi

Development & Delivery

Laboratory

Development Agencies
• KOICA, SIDA, DFID, USAID Foundations / Trusts Donors
IVI imagines, discovers, and executes a vision of vaccines for all

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

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

Field Surveillance & Generating Evidence
Lab Research & Discovery
Vaccine Development & Clinical Trials
Vaccine Registration
Last mile delivery

Epidemiology
Post-introduction studies
Advocacy
Preclinical, Animal, Toxicology Proof of Concept, Process Development
Tech Transfer, Trial Sites, Project Management, Trial Execution, Data Management
Host Country NRA Strengthening & Coordination, WHO Prequalification
Uptake, Access
Health Economics, Vaccination Campaigns

IVI Clinical Sites
Vaccine Products
Manufacturing

IVI Clinical Sites

International Vaccine Institute

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

Unitaid
Funds the purchase of vaccines for routine immunization in LMICs

The Global Fund
Funds intervention, infrastructure, policy for HIV, TB, & malaria

CEPI
Funds select emerging infectious disease (EID) epidemic pathogens
Research & Development Projects

Observational research, burden, effectiveness

Clinical assay development & standardization

Funded R&D activities

Preclinical

Phase I

Phase II

Phase III

Funding anticipated

AVANTI product

IVI products

Vaccine #3

MERS 2

NTS

HAV

Shig

SFTS

Ad55

GAS

Schist

COVID 19

CHIK

COVID 19

MERS 1

ViDT

OCV

ViTT

HPV

TB

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Global typhoid control projects

Dimensions of the global typhoid control strategy

- Supporting at least 2 effective TCVs to achieve WHO PQ by 2020
- Demonstrating proof-of-concept for combination Salmonella vaccine(s)
- Developing and validating new, low-cost surveillance methods to inform TCV use
- Introducing typhoid conjugate vaccines in at least 10 Gavi-eligible countries
- Generating vaccine performance and operational research data to inform optimal typhoid conjugate vaccine use in outbreak and endemic settings
- Building the case for adoption of a global typhoid control goal
- Assessing the feasibility of typhoid elimination

IVI projects

- Vi-DT
- Vaccine #3
- Wellcome Trust iNTS
- SETA/THECA
- SETA/THECA/TyMA
- SETA/THECA/TyMA/MOTiF/Ty-FIVE
- SETA/THECA/MOTIF
- Ty-FIVE
Typhoid eradication proof of concept Ty-Five

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

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

*Vigil D Pitzer et al., Clinical Infection Diseases, Volume 99, Issue Supplement_3, 1 November 2019, Pages S989–S991
Antimicrobial resistance: Fleming Fund Projects

A £205 million UK aid investment managed by the Department of Health and Social Care (DHSC) in partnership with Mott MacDonald, the Fleming Fund Management Agent.

- 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

Example 1: IVI Typhoid Programs 2000 - 2019

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

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
- KMPC
- Ministry of Food and Drug Safety
- 정북바이오산업연구원
  - Gyeongbuk Institute for Bio industry
- SNUH
- Seoul National University Hospital
- NIBSC
IVI collaboration with Korean government pilot plants
• **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**
Thank You!