Expert Group Meeting on Strengthening Regional Cooperation in Healthcare Biotechnology and Biomedical Sector

Asian and Pacific Centre for Transfer of Technology (APCTT) of the United Nations Economic and Social Commission for Asia and the Pacific (ESCAP) - 22 March 2022

Strengthening healthcare biotechnology R&D facilities, enabling resources and good practices, and regional cooperation

Jean-Louis Excler, MD Program Director, New Initiatives

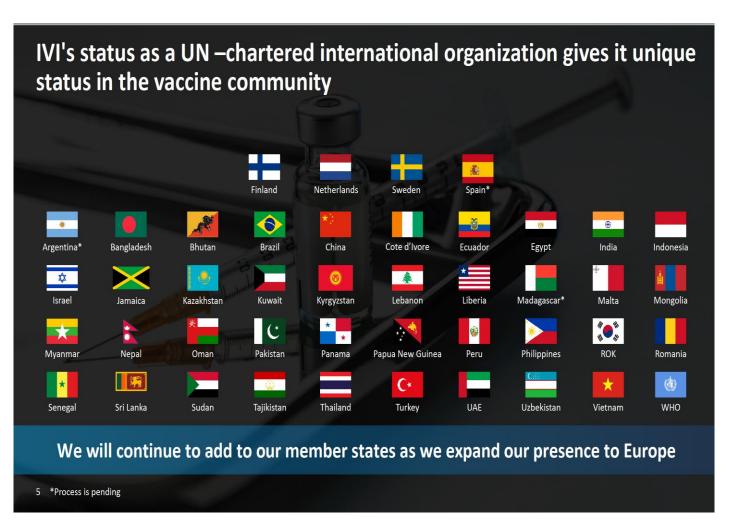




IVI is an UN-chartered international organization dedicated to accelerating vaccine R&D for global health

- ... is to discover, develop and deliver safe, effective and affordable vaccines to enable the world's most vulnerable people to have full, productive lives
- ... is to expand our global presence and expand our collaborative partnerships and innovative capabilities
- ... we can achieve our *VISION* of developing countries free of suffering from infectious disease







IVI provides translational and support services to accelerate vaccine development We can cater to potential partners to select the activities that align to our shared goals

	oiscover		Develop	•	Deliver	© Epi	i. Surveillance
Pre-Clinical Study & Support	Material production, test & release for	Assay Validation	Critical assay development & optimization	Health Economic Study	Field-based data collection incl. costing & willingness to pay	Epidemiology/ Observational Study Support	Protocol dev. incl. definition of endpoint, bio investigation, & database
	toxicology studies	& Clinical Samples	Method validation according to ICH guidelines				Prevalence & incidence est. of
	Protocol dev.	Tech Transfer	Clinical sample evaluation in GCLP lab		Global/country analyses incl. invest., budget impact, cost- effectiveness, demand & disease burden		infection/disease severity
	CMO/CRO identification		Candidates & process transfer to CMOs				Data for decision on vaccine introduction
Process & Analytical Dev.	Carlable O and are	Support Mfg. Support	& stability plan dev.				Site preparedness for Ph.3 tria effectiveness study
	Scalable & optimized processes for candidate Ag		Process scale-up & ensuring of commercial-scale mfg. & vaccine candidate supply			AMR Monitoring	AMR assessment & public database creation
			IPDP & CDP development	Policy & Advocacy Research			Mass vaccination campaign
	Analytical methods for qual. testing	Clinical Dev. & Regulatory	Clinical trial implementation &	Modeling	Vaccine impact & disease risk mapping etc.	Vaccine Impact & Effectiveness Study	Vaccine intro through health authorities
	<i>In vivo</i> animal studies	Support	management in HIC & LMIC Regulatory affairs consultation				Real-life vaccine performance assessment
 Invasive Non- typhoidal typhoidal Tuberculosis Salmonella HAdV-55 (iNTS) Non- typhoidal SFTSV Salmonella (NTS) Shigella (NTS) Hep A COVID-19 		 MERS-CoV Chikungunya Schistosomiasis Typhoid Non-typhoidal salmonella COVID-19 Cholera 		HPV Hepatitis E Cholera		TyphoidCOVID-19	



IVI develops and supports:

Translational Hubs Innovation Vaccine
Research Centers

Globalization Centers



Major Partners

IVI has 160 partners worldwide ranging from government, industry, academia and civil society to intergovernmental organizations

Major Partners

Industry

Tech transfer and vaccine development partnerships with 8 manufacturers from 6 countries

Korea

Engage with all sectors, in addition to government ministries and agencies, in host country









Government

Partnerships to develop vaccines and build capacity in developing countries

























VABIOTECH









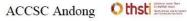








PCMO Hwasun







Universities, academic societies, research institutes, medical associations

























Global Health

Conduct public health research and immunization campaigns in collaboration with WHO, GAVI, UNICEF, CEPI, and health ministries



TIGHT FUND





CEPI



Philanthropy

- Bill & Melinda Gates Foundation, a key supporter since 2000
- Samsung Foundation supports our MERS vaccine development program















helped to build the Korean vaccine manufacturing capacity

2016 2018 2020 2021



"Vaccine 3.0"
Infrastructure building project for vaccine self sufficiency 2016-2020



- Funded by ROK government, BMGF, Korean manufacturers
- R&DE.g. Cholera ConjugateVaccine (CCV)

Focuses on global health



- Partner with Vaccine Innovative Technology Alliance (VITAL) Korea to promote R&D for global health
- Promote vaccine sovereignty of Korea and preparedness against EID

"K-Vaccine Hub"

Center of Excellence, providing essential support required in establishing K-Bio Hub

- Vaccine research: platform technology (mRNA, viral vector), adjuvant
- Innovation center: vaccine evaluation system through standard assays and reagents
- Translational hub: clinical development, regulatory affairs, and quality assurance
- **Globalization**: provide networking to industry to move to the next level

Vaccine product
development
partnerships
with Korean
manufacturers
& agencies



OCV, TCV, HEP B, HEP A, MERS Vaccine



- Vi-DT TCV
- iNTS



Hep A

eubiologics 🛊

 Euvichol® & Euvichol-Plus® OCV



QuadMedicine

 Hep B microneedle patch



MERS













eubiologics ?



Genexine









IVI works throughout the value chain to enable our global partners in COVID-19 vaccine development

Pre-clinical and International Standard **Serum & Assay Development**

Clinical Development

- Laboratory: EIA, PRNT, PsVNa
- Phase I-III / effectiveness

Capacity Building

Support for Epi. and Phase III site development

































































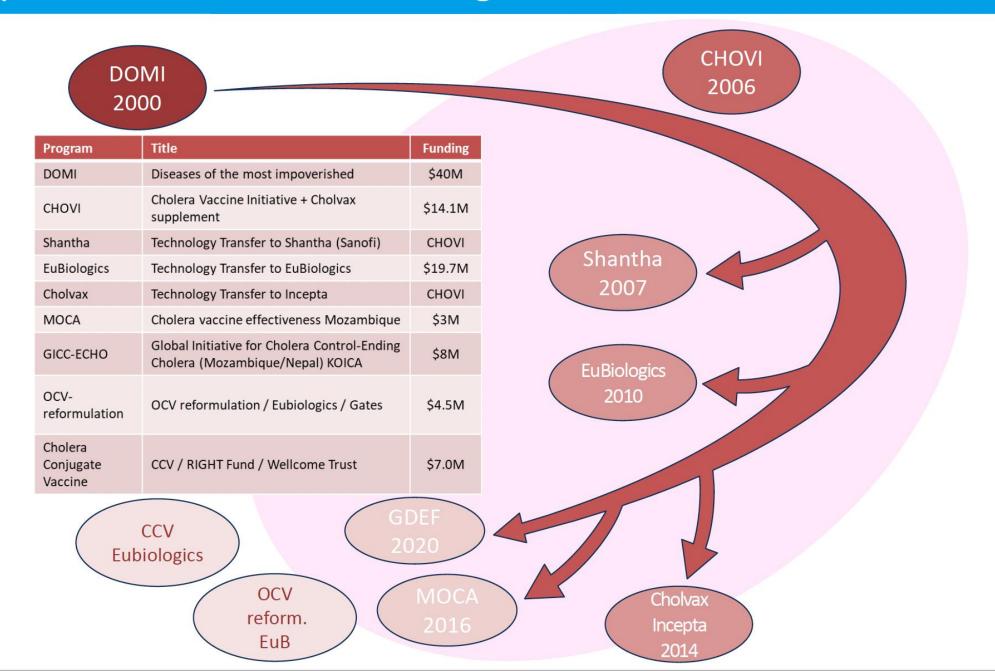








Example: IVI Cholera Vaccine Programs 2000 - 2020





IVI Vaccines Bring Affordable Innovation to Global Health

VACCINE

COST

MANUFACTURER

VACCINE #1 ORAL CHOLERA VACCINE Cost thru PQ: \$28M





SHANCHOL PQ 2011



EUVICHOL, EUVICHOL PLUS PQ 2016, 2018

VACCINE #2 Vi-DT TCV (Typhoid) Estimated
Cost thru
PQ: \$33M
BILL& MELINDA
GATES foundation



Phase III to begin 2020 in Nepal & Philippines



Phase III to begin 2020 in Indonesia

VACCINE #3

- •Non-typhoidal Salmonella
- Shigella

IVI internal investment preclinical POC; Wellcome Trust \$3.2M







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 Hep B microneedle patch



MERS













eubiologics



Genexine









K-Vaccine Training Program – IVI Lead

Program Title	Intensive Training Course Operator for Global bio manufacturing workforce training				
Donor	Ministry of Health and Welfare, Republic of Korea				
Activities	 Activity 1: Introductory course for biologics development and manufacturing 80 hrs. offline course for 150 trainees in Seoul (free of charge, except air fair) Free 30 hrs. online course Activity 2: Introductory course for standard practice (GxP Course) 120 hrs. offline course for 300 trainees in Seoul (free of charge, except air fair) / twice a year (150 each) Free 30 hrs. online course Activity 3: Onsite training and consultation LMIC manufacturers, whose employees participated in the course, can apply The first mock training for needs analysis, and without selection process Activity 4: Coordination between WHO and MoHW /Coordination with sub-hubs Upon nomination of RoK as training hub by WHO (expected to be announced in Feb.) 				

Thank you for your support and contribution!!

