Introduction of PATH and CVIA

Dexiang Chen
PATH is a leader in global health innovation

We harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity...

...to save the lives of women and children.
Our global impact

Work in more than 70 countries. 150 million people reached each year on average.

- **6 billion vaccine vial**
  - monitors ensuring that vaccines are potent when given

- **260 million people**
  - immunized with MenAfriVac® in the African meningitis belt

- **220 million children**
  - vaccinated in six countries with Japanese encephalitis vaccine
CVIA’s primary objective is to accelerate the development and introduction of lifesaving vaccines for optimal public health impact in the world’s lowest resource settings. We focus on vaccines that protect women and children from the leading causes of disease and death.

**DISEASE AREAS**

### Enteric and Diarrheal Diseases
- rotavirus
- enterotoxigenic *Escherichia coli*
- *Shigella* ssp.
- poliovirus
- typhoid

### Malaria
- *Plasmodium falciparum*
- *Plasmodium vivax*

### Respiratory Infections and Maternal Immunization
- pneumococcus
- meningococcus
- group B *Streptococcus*
- *B. pertussis*
- influenza virus
- respiratory syncytial virus

### Zoonotic, Emerging, and Sexually Transmitted Infections
- human papillomavirus
- Japanese encephalitis virus
- dengue virus
- yellow fever virus
- outbreaks
Our work spans the entire vaccine development and delivery spectrum

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3 and Reg/PQ</th>
<th>Pilot/Launch</th>
<th>Scale-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Identify potential vaccine leads and approaches</td>
<td>• Assess proof of concept/efficacy in low-resource settings</td>
<td>• Generate evidence for regulatory review and approval</td>
<td>• Enable evidence-based decision making for public financing and global and national policies</td>
<td>• Capture learnings from early adopters</td>
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<tr>
<td>• Conduct initial candidate evaluations</td>
<td>• Support quality manufacturing and adequate supply</td>
<td>• Facilitate World Health Organization prequalification and regulatory approval at national level</td>
<td>• Ensure sustainable supply</td>
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<tr>
<td>• Address country needs and priorities in product development</td>
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<td>• Support countries on planning, preparation, and introduction</td>
<td>• Facilitate wide-scale use</td>
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<td></td>
<td></td>
<td>• Measure impact</td>
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CVIA’s contribution to PATH’s mission

Serving women and children disenfranchised because they happen to live in broken markets.

Focusing on the middle of the value chain but with a clear line of sight to impact.

Working across a vaccine development to delivery platform in service to public health and country needs.

Putting country needs first by thoroughly understanding the needs of all key stakeholders and the full value proposition.

Driving collaboration by building strong partnerships, the lifeblood of CVIA.
How CVIA fits into PATH’s global footprint

CVIA is part of PATH’s essential medicine portfolio.

PUBLIC HEALTH
- Digital Health Solutions
- Health Systems and Innovation Delivery
- HIV and Tuberculosis
- Maternal, Newborn, and Child Health and Nutrition
- Noncommunicable Diseases
- Malaria and Neglected Tropical Diseases
- Reproductive Health
- Nutrition Innovations Initiative
- Center for Malaria Control and Elimination
- Integrated solutions for childhood illnesses
- BID Initiative
- Enteric and Diarrheal Diseases
- Malaria
- Respiratory Infections and Maternal Immunization
- Zoonotic, Emerging, and Sexually Transmitted Infections

CVIA

INTERNATIONAL DEVELOPMENT
- In-country clinical trials and vaccine manufacturing
- China
- Democratic Republic of the Congo
- Ethiopia
- Ghana
- India
- Kenya
- Malawi
- Mozambique
- Myanmar
- Peru
- Senegal
- South Africa
- Tanzania
- Uganda
- Ukraine
- Vietnam
- Zambia
CVIA operates as a matrix to optimize staffing resources

Through its core functional teams, experience and expertise on every aspect of vaccine development and introduction is applied across CVIA’s broad portfolio.
Multi-disciplinary expertise informs every step

Project and portfolio management expertise provide support along the entire development and delivery spectrum.
The right mix of expertise evolves as projects progress across the spectrum.
CVIA is organized by disease and functional areas

- Executive
- Disease areas
- Functional areas
- Internal partners
- Under development
Enteric and diarrheal diseases area
Malaria disease area
Respiratory infections and maternal immunization area
Regulatory area
Clinical area
Integrated portfolio and financial management area
## Devices & Tools: Vaccine and Pharmaceutical Technologies Group

<table>
<thead>
<tr>
<th>Areas of focus</th>
<th>Examples of current work</th>
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<tbody>
<tr>
<td><strong>Formulation and stabilization technologies</strong></td>
<td>• Formulation and assay assistance to manufacturers</td>
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<tr>
<td></td>
<td>• Heat/freeze stabilization</td>
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<td>• Pediatric formulations</td>
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<td>• Oral/sublingual delivery</td>
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<td></td>
<td>– Thermoresponsive gel</td>
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<td></td>
<td>– Fast-dissolving tablets</td>
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<tr>
<td><strong>Packaging and delivery technologies</strong></td>
<td>• Novel primary containers</td>
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<tr>
<td></td>
<td>– Prefilled, polymers</td>
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<td></td>
<td>• Microarray patches</td>
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<td>• Reconstitution technologies</td>
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<td></td>
<td>• Prefilled and safety syringes</td>
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<td></td>
<td>• Biodegradable implants</td>
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<tr>
<td><strong>Supply systems and equipment</strong></td>
<td>• Barcodes</td>
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<td></td>
<td>• Freeze-free vaccine carriers</td>
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<td>• Solar powered equipment</td>
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<td></td>
<td>• Refrigerator and passive cold box testing</td>
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<td>• Temperature monitoring</td>
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Highlights from PATH’s vaccine work

- Supported development and introduction of MenAfriVac®; over 260 million Africans immunized since 2010.
- Delivered a high-quality, affordable Japanese encephalitis vaccine to over 220 million children in six countries.
- Partnered with GSK to develop RTS,S malaria vaccine, receiving positive scientific opinion from European regulatory authorities and WHO.
- Partnered on the development of the vaccine vial monitor, with more than 6 billion used to date.
- Designed and developed the first autodisable syringe for immunization and drug delivery.
Our portfolio* includes over two dozen vaccines in development and use across 17 disease targets.

* Portfolio snapshot Q1 2017; does not include new/ongoing proposal development work in dengue, Zika, or Ebola, nor ongoing support to the Expanded Programme on Immunization in multiple countries.
Technical assistance and enabling technologies*

<table>
<thead>
<tr>
<th>Manufacturing and Supply</th>
<th>Clinical</th>
<th>Policy, Access, &amp; Introduction</th>
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<tbody>
<tr>
<td>Yellow fever</td>
<td>Sabin IPV</td>
<td>dNLT adjuvant</td>
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<tr>
<td>MR combination</td>
<td>SIPL Q-LAV, cell based</td>
<td>BRV-WBP</td>
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<td></td>
<td>RRV-SIL</td>
<td>bOPV</td>
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<td></td>
<td>HPV</td>
<td>Rotavirus</td>
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*Technical assistance snapshot as of Q1 2017.
Scaling Chinese innovation for health impact in the world

In the next decade, China will play a unique and critical role in promoting health and development in sub-Saharan Africa and other low-resource setting, especially for women and children. PATH looks forward to collaborating with the Chinese government and companies to provide innovative and sustainable health solution to vulnerable population.

Steve Davis
President and CEO
PATH
PATH China had to change its role because environment is changing

- **Politics, Economy, Product and Technology in Public Health**

1. **Economy**
   - China has become the 2nd largest economy entity in the world
   - In 2016, GDP, per capital of China is $8,900 which has been listed into UMIC and international aid is decreasing dramatically
   - China is changing its role from “Recipient country” to “Aid Country”
   - PATH China had to change the traditional role of international NGO from “Receive help” to “Help other people”

2. **Politics**
   - U.S Govt. is pushing Chinese Govt. to take more global responsibility, instead of “taking free ride”

3. **Government:**
   - Chinese government is changing its role from “Recipient country” to “Aid country”.
   - “China-Africa Health Cooperation Platform” is working
     - Build CDC system
     - Malaria treatment
     - Maternal and newborn health
     - Local production of drug / Device and improve access to health and medical product
PATH China had to change its role because environment is changing

*Politic, Economic, Product and Technology in Public Health*

4. **Private / State-owned companies**
   - Great progress of technology, product & service in the area of diagnostic, device & tools in past 10 years
   - Local companies are expanding business globally.

5. **Philanthropy environment**
   - Different local foundations, especially enterprise foundation, are growing up.
   - Different civil organizations are growing up.
Economy & Population comparison – China / India / S. Africa / Vietnam

Population(million) - 2015

- China: 1,371
- India: 1,311
- S. Africa: 55
- Vietnam: 92

GDP per capita-$

- China: 7,925
- India: 1,582
- S. Africa: 5,692
- Vietnam: 2,111

GDP-Billion $

- China: 10,866
- India: 2,074
- S. Africa: 312
- Vietnam: 194

Health Expenditure - % of GDP - 2014

- China: 6
- India: 5
- S. Africa: 9
- Vietnam: 7

Health expenditure per capita -$ 2015

- China: 420
- India: 75
- S. Africa: 570
- Vietnam: 142

Health expenditure - 2015

- China: 32
- India: 62
- S. Africa: 37
- Vietnam: 54

Out-of-pocket health expenditure - % of total health

- China: 56
- India: 30
- S. Africa: 48
- Vietnam: 54

### Health Indicator Comparison – China / India / S. Africa / Vietnam

#### Cause of death, by communicable diseases, maternal, prenatal % nutrition -% of total-2012

<table>
<thead>
<tr>
<th>Country</th>
<th>China</th>
<th>India</th>
<th>S.Africa</th>
<th>Vietnam</th>
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<tr>
<td></td>
<td>28</td>
<td>49</td>
<td>17</td>
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#### Cause of death, by non-communicable diseases-% of total-2012

<table>
<thead>
<tr>
<th>Country</th>
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<tr>
<td></td>
<td>87</td>
<td>60</td>
<td>43</td>
<td>73</td>
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#### Diabetes prevalence(% of population age 20-79) 2015

<table>
<thead>
<tr>
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<td></td>
<td>10</td>
<td>8</td>
<td>9</td>
<td>6</td>
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#### Mortality, neonatal (per 1,000 live birth) - 2015

<table>
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<tr>
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<th>India</th>
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<th>Vietnam</th>
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<td>6</td>
<td>28</td>
<td>11</td>
<td>11</td>
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#### Maternal mortality ratio (per 100,000)-2015

<table>
<thead>
<tr>
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<th>China</th>
<th>India</th>
<th>S.Africa</th>
<th>Vietnam</th>
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<tr>
<td></td>
<td>27</td>
<td>174</td>
<td>138</td>
<td>54</td>
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#### Mortality, infant (per 1,000 live birth) - 2015

<table>
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#### Diabetes prevalence(% of population age 20-79) 2015

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<tr>
<td></td>
<td>68</td>
<td>167</td>
<td>834</td>
<td>140</td>
</tr>
</tbody>
</table>

**Source:** World Bank Data – 2014-2015
China Global Health Cooperation Platform

ONE BELT ONE ROAD

AIIB

CHINA – AFRICA FORUM

CHIA-NAFRICA DEVELOPMENT FUND

BRICKS SUMMITS

NDB

SOUTH TO SOUTH COOPERATION

South to South Aid Foundation
(14 B $ by 20230)

CHINA-AFRICA HEALTH SYMPOSIUM
What China can contribute in global health market?

1. Finance support.
2. Product & Technology
3. Professional public health people
4. Successful experience in public health service and system
## China program management - 2017-beyond

<table>
<thead>
<tr>
<th>VACCINES</th>
<th>DEVELOP/VALIDATE</th>
<th>APPROVE/RECOMMEND</th>
<th>INTRODUCE/OPTIMIZE</th>
<th>SCALE UP/APPLY</th>
</tr>
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<tbody>
<tr>
<td>bOPV, Yellow Fever</td>
<td>HPV – 2 valent</td>
<td>Rotavirus -4 valent</td>
<td>Japanese Encephalitis</td>
<td>TrBD</td>
</tr>
</tbody>
</table>

**DRUGS**

G6PD diagnosis for malaria treatment

**DIAGNOSTICS**

Oxygen concentrator

**DEVICES**

Pulse oxymeter

**SYSTEM & SERVICE INNOVATIONS**

TB comprehensive management program
PATH China Pipeline development - 2018 & beyond

**VACCINE**
- HPV
- Pneumococcal vaccine
- IPV

**DRUG**
- TrBD
- Malaria treatment
  - Artesunate
  - Dihydroartemisinin + Piperaquine
- TB diagnosis

**DIAGNOSTICS**
- HPV

**DEVICE & TOOLS**
- Oxygen concentrator
- Pulse oxymeter
- Others

**Service & System Innovation**
- China – Africa health cooperation
  - build CDC system in 5 countries

- Support Chinese government to play important role in global public health market through our professional expertise and strong global presence.

- Work with local private / state-owned companies across five platforms and support them to become important supplier of public health commodity in global market.
PATH China – Objective and implementation framework

1. PATH China will focus global health market, especially in Sub-Saharan countries, through mobilizing local fund, technology, product and system and service.

2. PATH China role in domestic market will expand from infectious disease to NCD.
PATH China – Objective and implementation framework

CHINA IN GLOBAL HEALTH MARKET

1. Govt. Platform: China-Africa Health Cooperation – Build CDC system
2. Corporate Platform: Diagnostic (Women cancer + TB), Drug (Artemisinin series + TrBD)
   Device & tools - TBD
3. University Platform: NCD Diagnostics / Infectious diseases diagnostics
4. Civil organization: TBD

Where is money?

Funding model

What shall we do?

Business Model

Who will do it?

Cross-Country Model