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European Vaccine Initiative

## **Supporting the development of urgently needed vaccines for global health**

**Sophie Houard, Director of Vaccine Development**

GHIT-PDP Webinar Session 5 EVI/MVI Developing Effective and Affordable Vaccines through  
Partnerships March 24 2022

*Today's catalyst for tomorrow's vaccines*

## Situation

### Important Infectious Diseases are Neglected by funders

Only USD \$4.05 billion (<2%) of the estimated \$240 billion annual spend on health R&D is for poverty-related diseases

Every year diseases of poverty affect 1.7 billion people, and kill >10 million

## Problem

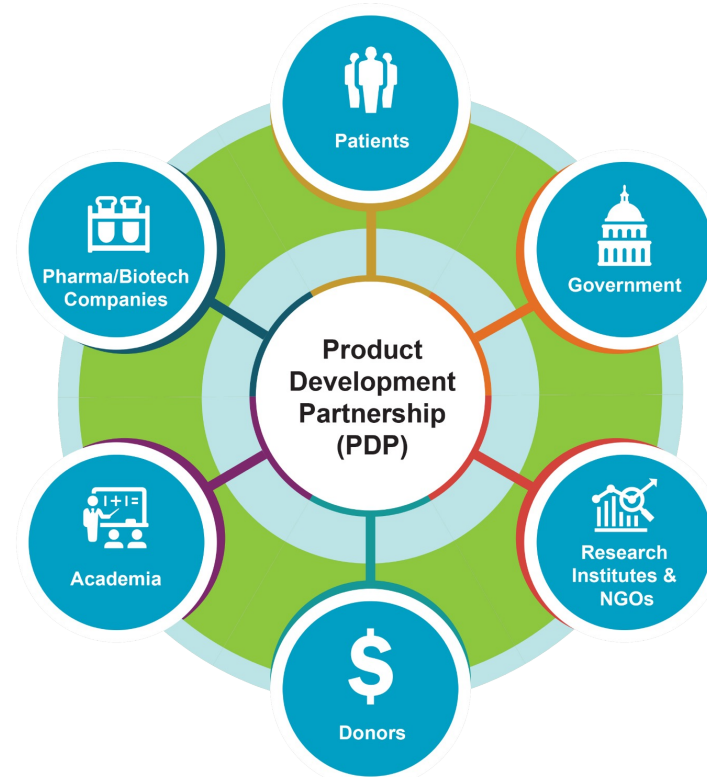
- Absence, or limited market potential of products for low-income populations, even with major public health value but low commercial return, results in low private sector engagement and restricted innovation in global health R&D technologies



This triggered in the 1990's the creation of **Product Development Partnerships (PDPs)** focusing on technologies that:

1. target diseases that are disproportionately affecting low- and middle-income countries
2. are affordable, accessible and available to low-income populations

- Non-profit organisations** that work to address the absence of commercial incentive to develop innovative tools for populations affected by poverty-related, neglected diseases
- Public health-driven and focused on patients' needs** in low- and middle-income populations (LMIC) with a high disease burden
- Cover specific research gaps or the full innovation cycle**, from early discovery stages to the implementation of a product
- R&D portfolio approach**: an R&D process that simultaneously develops multiple candidates to minimize risks associated with product failures during the lengthy development process and helps facilitate a greater number of appropriate products and combinations of products passing through the pipeline
- Partnership-based**: work with academic, public research institutions, private sector, governments, and civil society - including partners from LMIC
- Bring together financial, technical & in-kind contributions from public & private**



## PDP

**Technologies:** vaccines, treatments, diagnostics, devices and vector controls

**Diseases:** poverty-related diseases and TB, HIV/AIDS, and malaria, as well as improved tools for women's and children's health

### 2010-2020 achievements

**66 products** reached the market

**>375 products** in development

Research capacity strengthened at **>550 sites**  
in **> 80 countries**

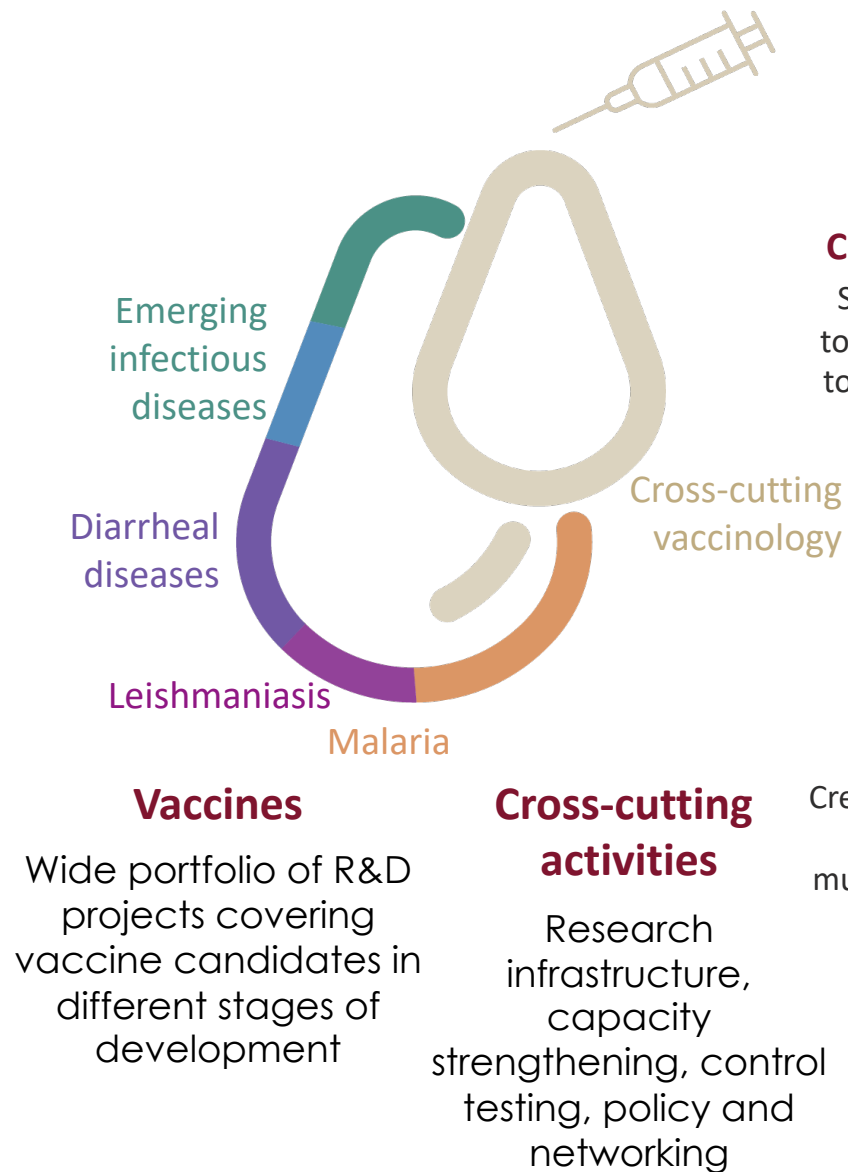


## Keeping the Promise: PDP COALITION MEMBERS



- **European Vaccine Initiative (EVI)** is a non-profit, science-driven organisation
- Supports the development of safe, effective and affordable **vaccines** for global health
- Lean, cost-efficient virtual biotech business model
- 1998: European Malaria Vaccine initiative (EMVI), hosted by SSI in Copenhagen (**first European PDP**)
- 2010: Independent legal structure; new name (EVI), broader scope, HQ in Heidelberg.

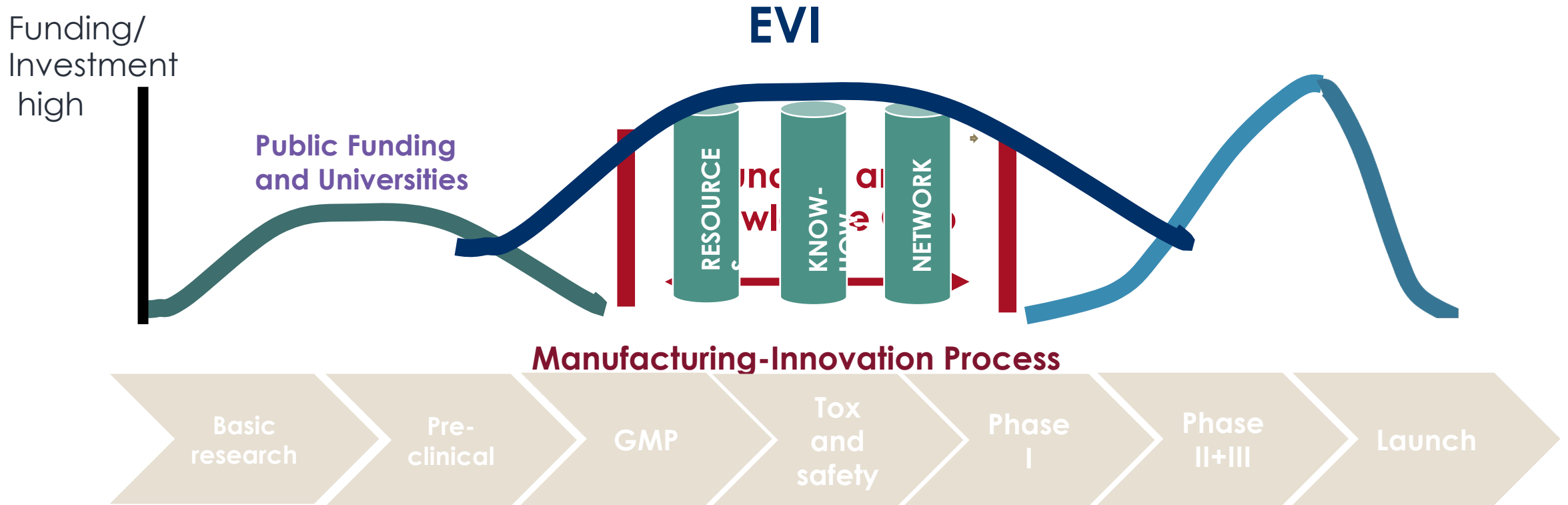
## About EVI



## Our strengths



# Valley of Death for diseases of poverty



## EVI main expertise



late preclinical and early clinical development

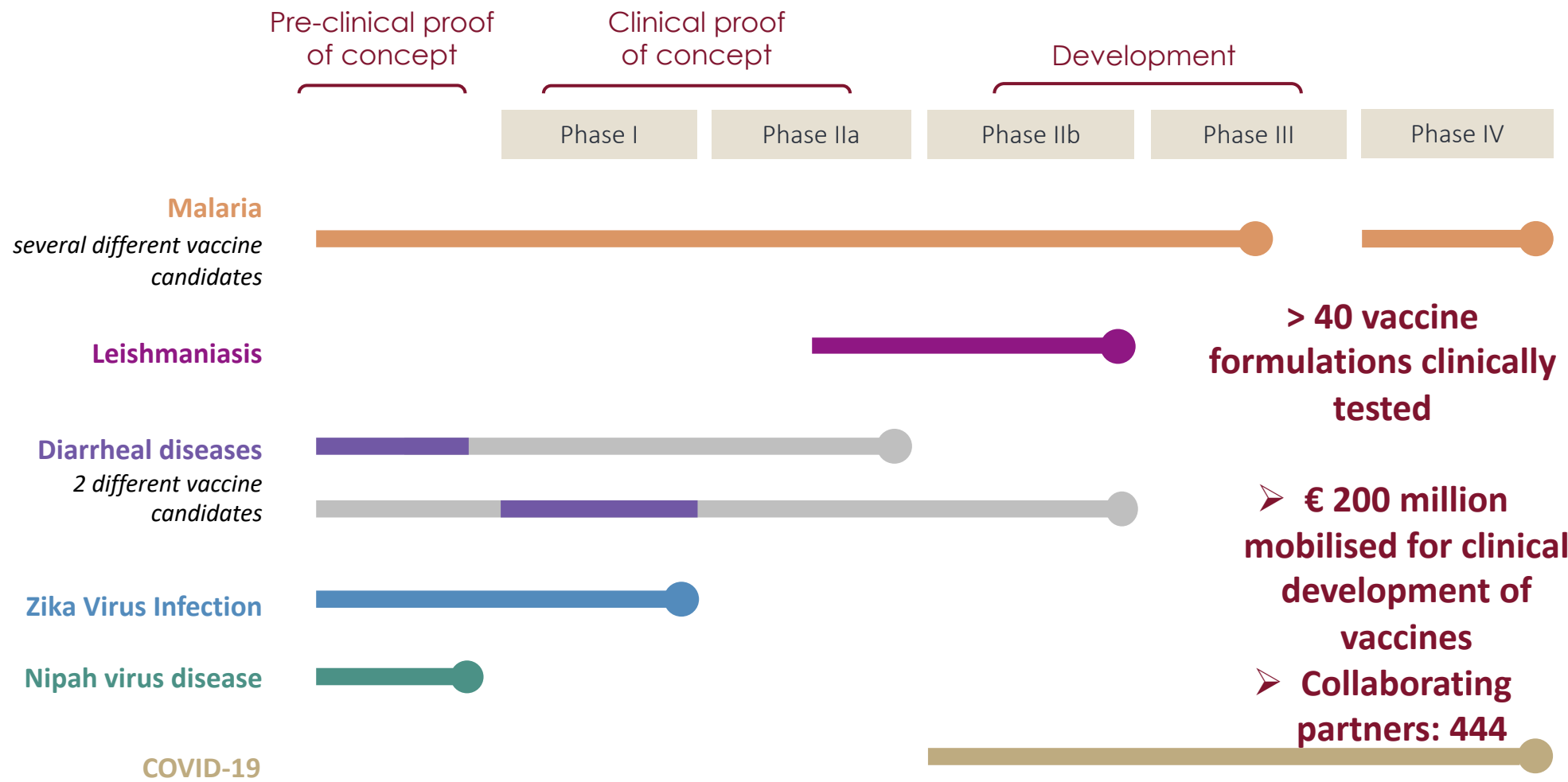


Vaccine manufacturing



Target product profile, roadmaps, Regulatory affairs, science communication

# EVI Projects Portfolio

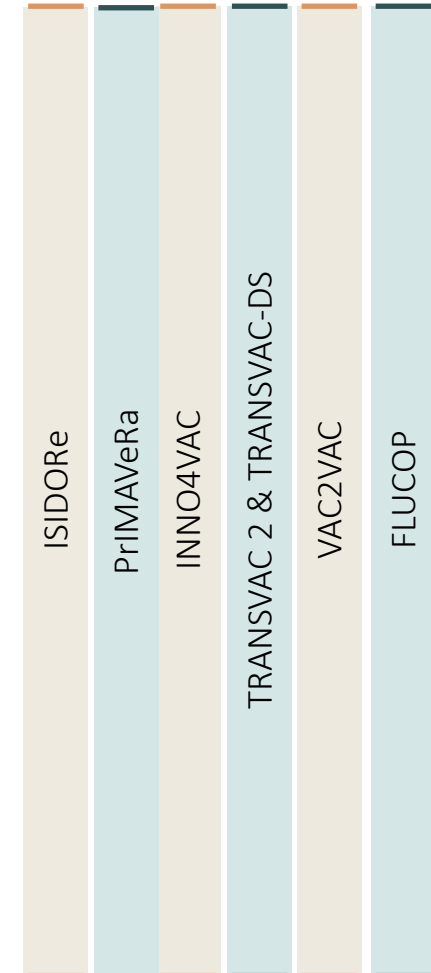


> 40 vaccine formulations clinically tested

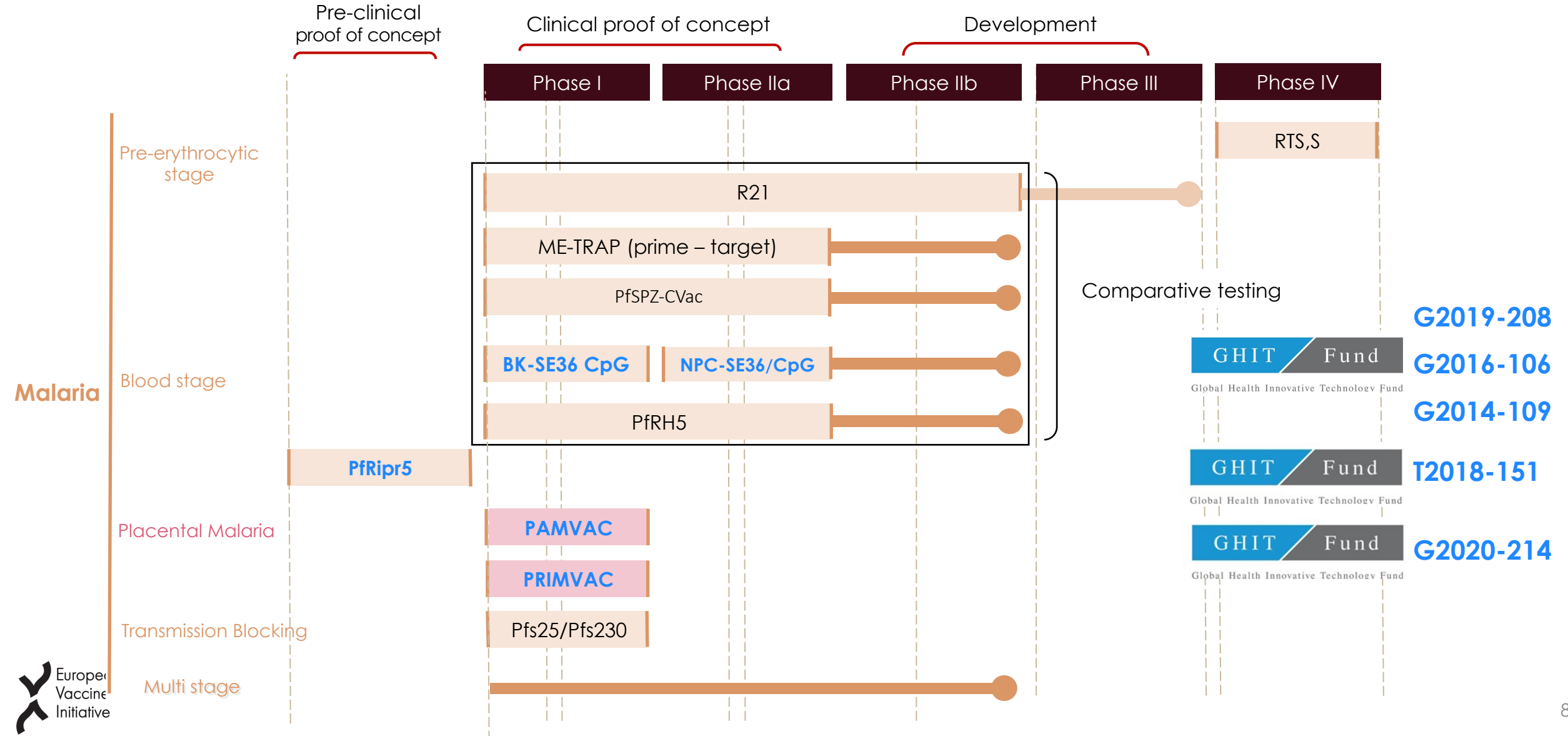
➤ € 200 million mobilised for clinical development of vaccines

➤ Collaborating partners: 444

## Cross-cutting activities



# Malaria Vaccine candidates





## Partnerships with GHIT Fund and Japanese partners

**PAMVAC and PRIMVAC** Placental malaria vaccine candidates developed by University of Copenhagen and Inserm to reduce the incidence and severity of malaria in pregnancy, protecting the **mother and unborn child** already early in pregnancy

G2020-214

Clinical development



UNIVERSITY OF COPENHAGEN



UNIVERSITY OF GHANA

Noguchi Memorial Institute for Medical Research



Inserm

La science pour la santé  
From science to health



愛媛大学  
EHIME UNIVERSITY



GROUPE DE RECHERCHE  
GRAS  
ACTION EN SANTÉ



Institut de Recherche  
pour le Développement  
FRANCE

**SE36** Malaria blood stage vaccine candidate developed at RIMD, Osaka University aiming at protecting against clinical disease

G2014-109

Phase Ib SE36+ AIOH

G2016-106

Phase Ib Improving the immunogenicity SE36+ AIOH with CpG adjuvant (Ken Ishi)

G2019-208

Preparing Phase II NPC-SE36/CpG



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GRAS  
ACTION EN SANTÉ



RIMD  
Research Institute for Microbial Diseases  
大阪大学微生物研究所



**PfRipr5** Protein malaria blood stage vaccine candidate developed by Ehime University in collaboration with Sumitomo Dainippon Pharma Co., Ltd., Japan.

T2018-151

Preclinical development



iBET  
Instituto de Biologia Experimental e Tecnológica



愛媛大学  
EHIME UNIVERSITY



Sumitomo Dainippon  
Pharma

## Partnerships with GHIT Fund and Japanese partners

### 1. *Why the business model of PDPs is important to vaccine R&D of infectious diseases (Malaria, TB, NTDs)?*

Industry has limited economic incentive, such as intellectual property rights, to develop drugs or technologies for conditions like poverty-related and neglected diseases.

PDP are non-profit (focused on their **mission not profitability**), this allows development of health products/ technologies for people who are neglected by traditional markets.

PDPs facilitate global collaborations between public, private, academic and philanthropic sectors. They generally use private sector approaches in their R&D activities, while leveraging mainly public and philanthropic funds and working with external partners. **This allows for sharing of risks and benefits in pursuit of a common goal that would not otherwise be attainable.**

### 2. *How GHIT's establishment in 2013 impacted the R&D work of EVI?*

- providing access to Japanese innovations, capacity and investment
- allowing to establish new scientific collaborations with Japanese R&D entities
- catalyzing synergies between organizations
- supporting R&D research from early stage to full clinical development, insuring for the most promising products a start and continued development.

**GHIT Fund has been crucial in supporting R&D work to develop a more robust pipeline to fight against infectious diseases.**

## Partnership with GHIT fund and Japanese partners

### Experience working with Japanese partners

- Achievements

From basis science to clinical development: successful preclinical developments and phase I clinical trials and future clinical development underway for neglected population, and for **even more neglected population: mother and babies**

- Lessons learned

Complementary multidisciplinary expertise is important, however trustful relationship between partners is critical.

**The support, openness and flexibility of GHIT Fund team has been instrumental to overcome project hurdles**

- Challenge

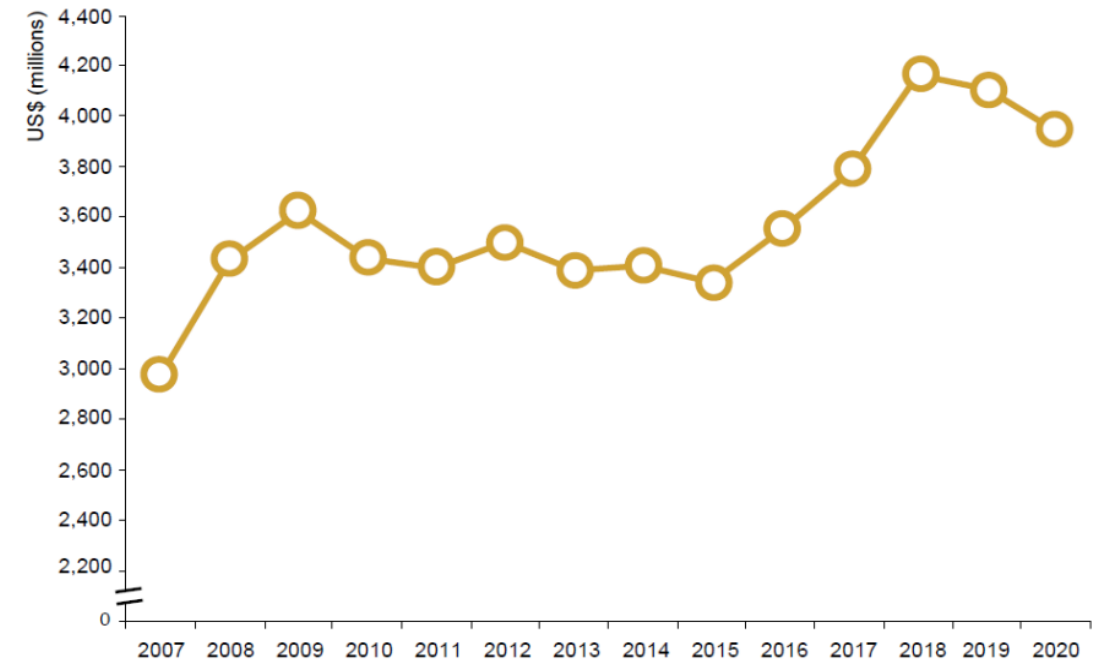
Distance between Japan and Europe and Africa: lowering the frequency of face-to face meetings that are important for nurturing relationship and affecting the shipment of clinical trial samples between partners. This is even more exacerbated by travel restriction, supply chain disruption related to COVID-19 pandemics or geopolitical situation

- Expectations from Japanese partners

Continuation of the current partnerships, more innovation from Japanese researchers to continue filling the pipeline for poverty-related, neglected diseases, looking for new collaborations

1. In 2020, the first year of the COVID-19 pandemic, global funding for basic research and product development for neglected diseases was \$3,937m, a drop of \$172m (-4.2%) from 2019 (single year story won't tell the whole story)
2. The immediate impact of COVID-19 seems to have fallen mostly on clinical trials
3. COVID-19 interrupted clinical trials in low- and middle-income countries
4. It is assumed that this drop was due to the difficulties of conducting trials in the face of lockdowns and travel restrictions

Figure 2. Total R&D funding for neglected diseases 2007-2020



G-Finder 2021

The COVID-19 pandemic

- severe economic reduction around the world
- fight against the virus has cost governments billions of dollars
- the policy focus is shifting towards pandemic preparedness.

As a consequence, PDPs are already facing the risk of a funding shortfall.

Other infectious diseases continue to devastate vulnerable populations, year after year, in much the same way as COVID-19 has over the last 2 years.

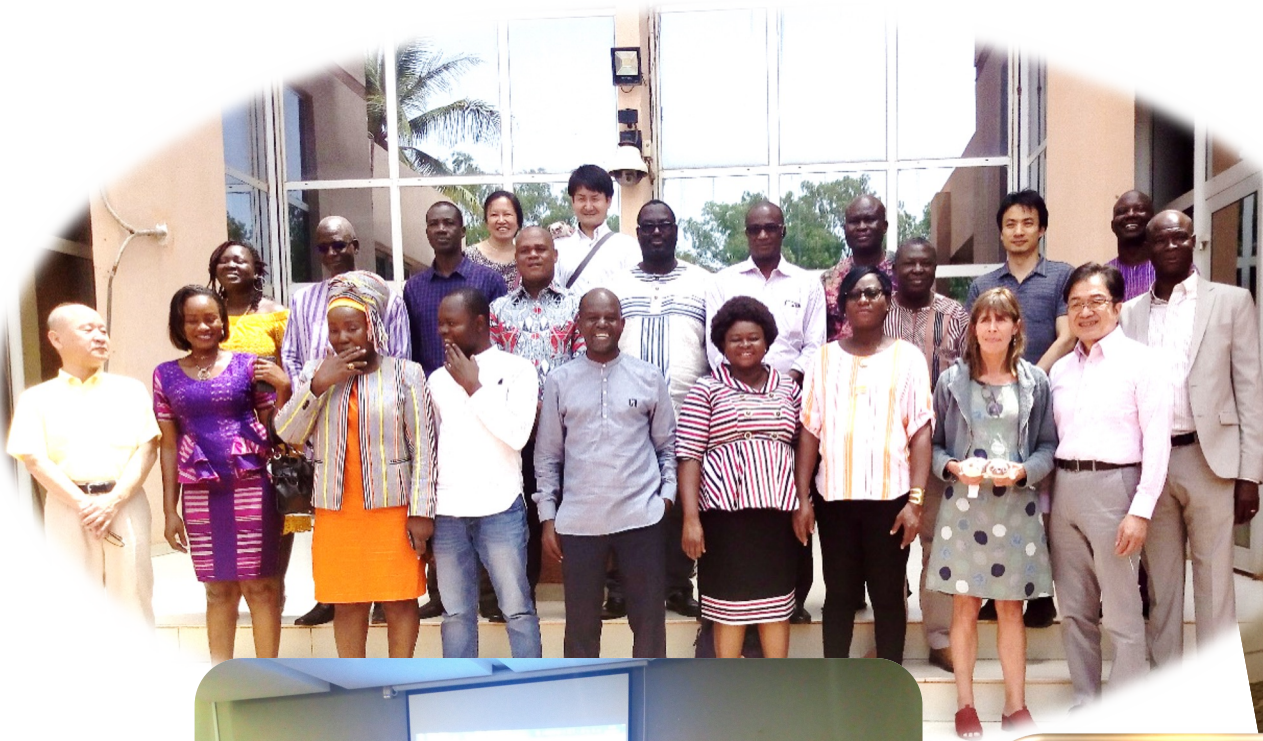
Ongoing epidemics of disease with similar symptoms (febrile illnesses) makes the detection of new pathogens with pandemic potential more difficult, hence increasing the risk of a next pandemic.

**GHIT Fund investment and partnership with Japanese R&D entities are vital to developing innovative tools to tackle these diseases and enhancing global health security.**





## Annual meetings SE36 vaccine partners 2015----2019





# European Vaccine Initiative



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