# Keeping the Promise:

## Product Development Partnerships' Role in the New Age of Health Research and Product Development

# New Report from coalition of PDPs details significant recent achievements and critical success factors for continued success

- PDP products and innovations have improved health and saved lives by addressing unmet needs
- Investing in PDPs is a cost-effective way to drive global development and public health preparedness
- Increased investment and political will is needed to realize the full promise of PDPs

DNDi Drugs for Neglected Diseases *initiative*
FIND Because diagnosis matters
EVI
IVCC Building Partnerships Creating Solutions Saving Lives
INTERNATIONAL PARTNERSHIP FOR MICROBICIDES
iavi
International Vaccine Institute
Medicines Development for Global Health
MMV Medicines for Malaria Venture
PATH
TB Alliance
TBVI TuBerculosis Vaccine Initiative

# How PDPs work

Product Development Partnerships (PDPs) develop new products for people suffering from diseases and health threats underserved by traditional markets. This is accomplished by building partnerships between the public, private, academic, and philanthropic sectors.

# The PDP model, history, impact, and future potential in 10 bullets

**PDP products and innovation have improved health and saved lives by addressing unmet needs:**

1. PDPs are the global leaders in developing new health technologies where lack of traditional market incentives have stalled progress.
2. PDP pipelines are robust and poised to deliver a significant number of innovative technologies in the near-term.
3. PDPs achieve impact by developing products appropriate for the people and contexts in which they will be used.

**Investing in PDPs is a cost-effective way to drive global development and public health preparedness:**

4. PDPs save money and are a cost-effective way to save lives and grow economies.
5. PDPs build local capacity to perform research and strengthen health systems.
6. The products that PDPs develop are essential to achieve universal health coverage and the United Nations 2030 Sustainable Development Goals.
7. PDPs are equipped to help prevent and respond to urgent emerging and future health threats.

**Increased investment and political will is needed to realize the full promise of PDPs:**

8. PDPs need sustained, diverse, and flexible funding to increase their impact on global health and development.
9. Regulatory harmonization is needed to accelerate the global availability of PDP-developed products.
10. Increased investment and cross-sector collaboration are needed to ensure the widespread adoption, delivery, and implementation of new health technologies.

# 1. PDPs are the global leaders in developing new health technologies where lack of traditional market incentives have stalled progress

- Since 2010, this coalition of PDPs has delivered 66 new health technologies—treatments, vaccines, diagnostics, vector controls, and devices
- Products have reached more than 2.4 billion people, mostly in LMICs
- Highlights include:
  - First ever drug approved for treatment of highly drug-resistant forms of tuberculosis
  - Single dose treatment to prevent relapse of *P. vivax* malaria
  - First all-oral cure for all stages of sleeping sickness
- Advances are concentrated in diseases of poverty where investment and innovation have long been stagnant; market forces don't drive innovation in these fields

**PDPs DELIVER INNOVATION**

Many PDPs were established around the turn of the century. This past decade has seen the fruits of previous investment.

**Products developed and marketed by PDPs featured in the report**

# 2. PDP pipelines are robust and poised to deliver a significant number of innovative technologies in the near term

- PDPs featured in the report have more than 375 potential new technologies in their pipelines
  - Approximately 25% of those products are in late-stage development
- Portfolios are built through diverse partnerships—across sectors and geographies
- Products in development stand to impact some of the world's oldest and deadliest diseases, including those that disproportionately impact women and children

**PDPs FEATURED IN THE REPORT HAVE MORE THAN**

**375**

**POTENTIAL NEW TECHNOLOGIES IN THEIR PIPELINES**

# 3. PDPs achieve impact by developing products appropriate for the people and contexts in which they will be used

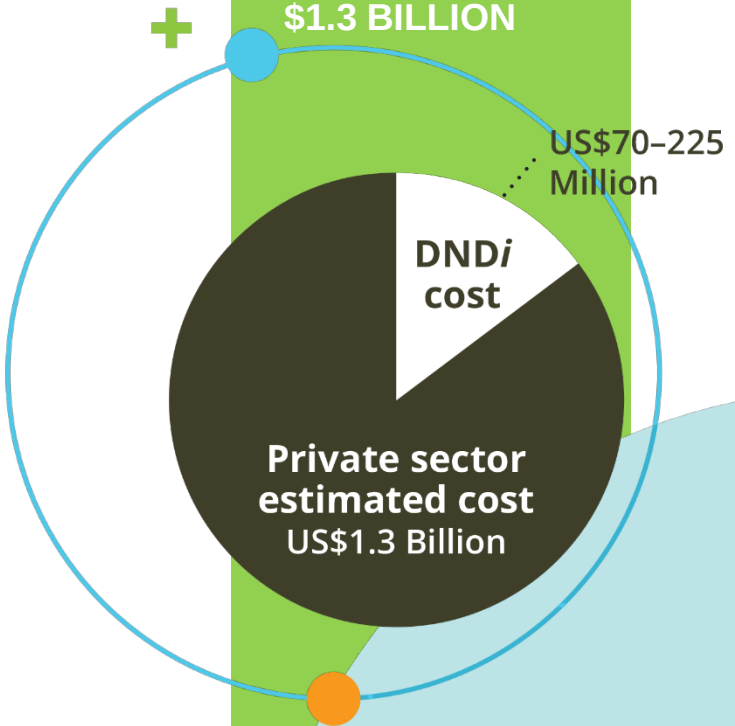
- PDPs closely engage with local communities, care providers, researchers, and policy makers to ensure they are designing products for use in the settings where they are most needed
- Attributes to enable use in low-resource settings are prioritized
- This is the first step to driving widespread and equitable access to PDP-developed products

**PRODUCTS DEVELOPED BY PDPs FEATURED IN THE REPORT HAVE REACHED 2.4+ BILLION PEOPLE AROUND THE WORLD**

# 4. PDPs save money and are a cost-effective way to save lives and grow economies

- PDP-developed products provide tremendous value for money and a strong return on investment
- PDPs are consistently able to develop products at costs below that of the private sector
- By pooling and leveraging funding from multiple sources, PDPs spread risk across multiple investors and research programs

**FULL COSTS OF R&D OF A NEW CHEMICAL ENTITY BY DNDI: $70–225 MILLION**
**ESTIMATED COST OF PRIVATE SECTOR BRINGING NEW CHEMICAL ENTITY TO MARKET: $1.3 BILLION**



# 5. PDPs build local capacity to perform research and strengthen health systems

- PDPs have built scientific capacity through research partnerships at 550+ sites in 80+ countries mostly in LMICs
- PDPs build sustainable research capacity in these countries by developing:
  - Partnerships
  - Training programs
  - Infrastructure improvements
  - Next generation researchers, disease experts & scientific leaders
- LMIC infrastructure currently operationalized to combat COVID-19 has been substantially developed through previous PDPs collaboration
- PDP products often relieve burden on health systems—i.e, faster, easier, therapies and diagnostics; preventive medicine

**COUNTRIES IN WHICH PDPs BUILT CAPACITY THROUGH RESEARCH PARTNERSHIPS**

# 6. The products that PDPs develop are essential to achieve universal health coverage and the United Nations 2030 Sustainable Development Goals

- The development of products in PDPs' portfolios are necessary to achieve universal health coverage and several United Nations Sustainable Development Goals, including:
  - **SDG #1:** End poverty in all its forms everywhere
  - **SDG #3:** Ensure healthy lives and promote well-being for all at all ages
  - **SDG #5:** Achieve gender equality and empower all women and girls
  - **SDG #8:** Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all
  - **SDG #10:** Reduce inequality within and among countries
  - **SDG #17:** Strengthen the means of implementation and revitalize the global partnership for sustainable development

# 7. PDPs are equipped to help prevent and respond to urgent emerging and future health threats

- Capabilities of PDPs are not limited to poverty-related diseases.
- PDPs have mobilized to contribute to the global response to the COVID-19 pandemic by:
  - Developing vaccine and monoclonal antibody candidates
  - Providing chemical libraries to be tested for potential efficacy against SARS-CoV-2
  - Applying drug discovery techniques to aid in COVID-19 product research
  - Staging large-scale adaptive platform trials in Africa
  - Convening novel partnerships to accelerate the development, production, and broad, equitable access to COVID-19 tests, treatments, and vaccines that meet the needs of resource-limited contexts
- PDPs are also developing products and coalitions to address looming health threats, such as:
  - Antimicrobial resistance
  - Pandemic preparedness

# 8. PDPs need sustained, diverse, and flexible funding to increase their impact on global health and development

- PDPs require stable, long-term funding and investment across every stage of the research process. An ideal funding landscape would be characterized by:
  - Increased investment by governments, including those of BRICS and LMICs
  - Independence to shift funding across pipelines to prioritize most promising programs
  - Diverse menu of innovative financing mechanisms—both push and pull
  - Increased engagement and investment from the private sector

# 9. Regulatory harmonization is needed to accelerate the global availability of PDP-developed products

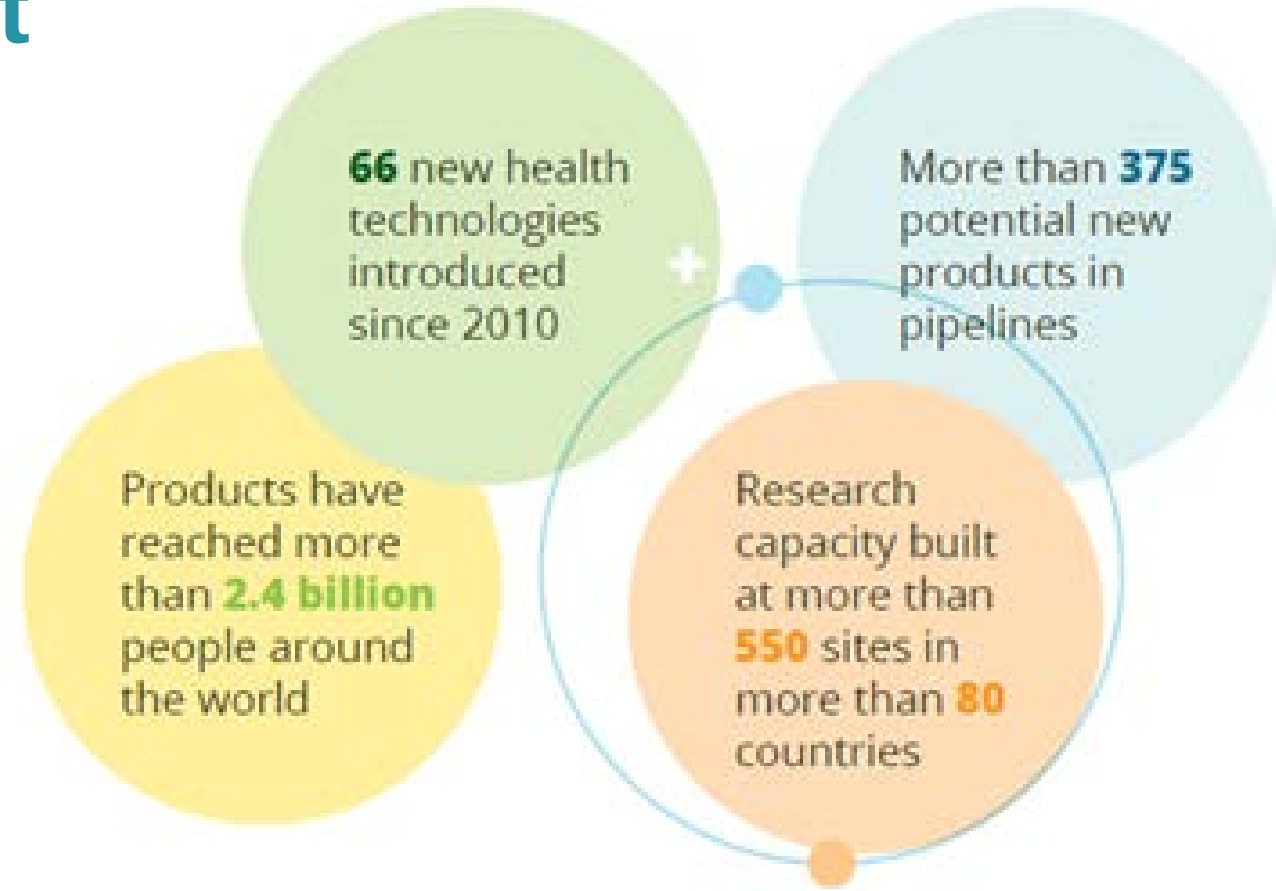
- Inconsistent, complex, and slow processes for earning approval of new products globally is a challenge to widespread and equitable access to new health solutions
- Relieving regulatory barriers results in quicker and larger health impact and return on investment
- National and regional efforts to streamline and harmonize regulatory processes can accelerate the availability of life-saving new health technologies
    - Example: IAVI‘s collaboration with the East African Health Research Commission (EAHRC) to standardize the research ethics review process helped ensure trial safety and reduced approval times by 30% for IAVI-sponsored protocols in Kenya, Uganda, and Zambia

# 10. Increased investment and cross-sector collaboration are needed to ensure the widespread adoption, delivery, and implementation of new health technologies.

- Achieving health impact requires an end-to-end approach; impact isn't achieved until new products reach those in need
- New products must be affordable, rapidly available, and widely and equitably accessible
- Challenges must be addressed in manufacturing, market competition, affordability, forecasting and training health of service providers
- Accelerating and expanding access to new products requires dedicated investment and creative and multi-sectored partnerships
- With more products reaching and approaching the market than ever before, the need to invest in access is increasingly critical and urgent

# PDPs Will Continue to Thrive with Sustained Support and Investment

- With sustained support and investment, PDPs will realize the promise of their growing pipelines and continue to improve global health, development, and security through the development of new and impactful global health innovations



# CASE STUDIES

# TB Alliance: New TB Drug Approved to Treat the Deadliest Forms of TB

- Tuberculosis is the deadliest infectious disease in the world—kills 1.4 million per year.
- Drug-resistance is on the rise; Extensively Drug-Resistant TB (XDR-TB) is highly deadly and difficult to treat.
- Treatment previously consisted of 18 months of therapy, including injections and 14K+ pills.
- TB Alliance developed new, 6 month, all-oral therapy—approved by US FDA, European Commission, and Drug Controller General of India.
- A McKinsey investment case study estimated new therapy will reduce cost of successful treatment by 65–80% and save health systems US$0.7–1.1 billion from now until 2023.

TB Alliance

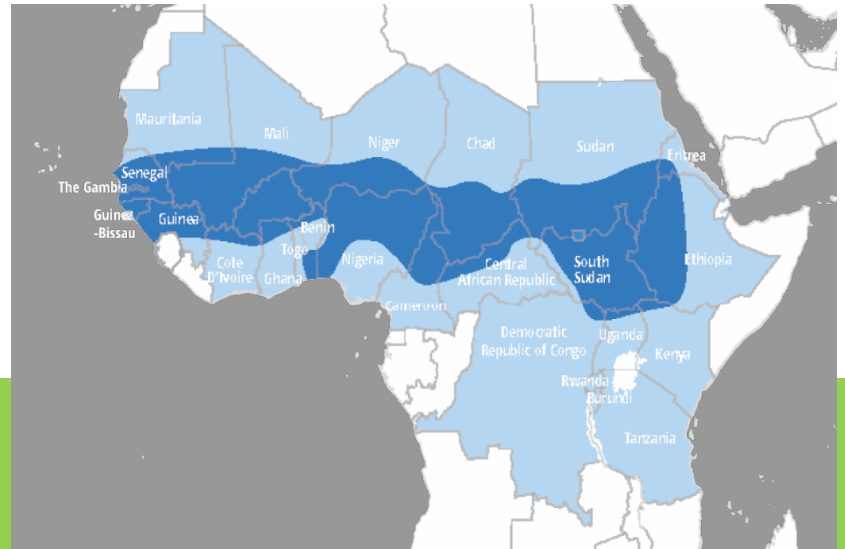
# DND*i*: Development of First All-Oral Cure for all Stages of Sleeping Sickness

- Sleeping sickness occurs primarily in the poorest regions of Africa, with 8.5 million people at risk. It is usually fatal without treatment.
- Just over a decade ago, the only treatment available for sleeping sickness was melarsoprol, an arsenic derivative, killing 1 in 20 patients.
- In 2009, DND*i* and partners developed NECT. While less toxic, it is complex, difficult to ship and store, and requires hospitalization.
- In 2018 DND*i* and Sanofi developed **fexinidazole**—a 10-day *all-oral treatment* for most common form of sleeping sickness (*T.b. gambiense*).
- DND*i*'s partnerships with the National Control Programmes for the trial and screening contributed significantly to national disease control and to a better understanding of sleeping sickness prevalence.
- Fexinidazole was approved by the European Medicines Agency in 2018 and was added to the WHO Essential Medicines List in 2019.
- An oral treatment will radically change the management of the disease and support global sustainable elimination efforts.

DNDi
Drugs for Neglected Diseases *initiative*

# PATH: First Vaccine Developed Specifically for Africa Virtually Eliminated Meningitis across Majority of African Meningitis Belt

- Meningitis affects the thin lining surrounding the brain and spinal cord; in Africa, 80%+ percent of epidemics have been caused by Neisseria meningitidis group A.
- Without treatment, 50 percent of those infected can die within days. Survivors often suffer severe, lifelong disabilities.
- In 2001, PATH and WHO formed the Meningitis Vaccine Project (MVP). Together, PATH and partners created a new group A meningitis vaccine in record time.
- MenAfriVac® was the first vaccine to be developed for meningitis specifically for Africa. It has low cost and can be delivered outside of the cold chain.
- By end of 2019, MenAfriVac® had been delivered to ~340 million people in 24 of 26 “meningitis belt” countries, virtually eliminating meningitis A where used.



# MMV: Preventing Malaria Relapse with a Single-Dose Treatment

- *Plasmodium vivax* malaria causes between 5.9 and 7.1 million clinical infections annually; in the Americas, it is responsible for more than 75% of malaria cases.
- This form of malaria can lie dormant in the liver, reactivating weeks, months, or even years after initial infection, leading to periodic and debilitating relapses.
- Due to this relapsing nature, the human and economic cost of *P. vivax* malaria is high.
- Previously, primaquine was the only available treatment for preventing relapses, but length of treatment resulted in compliance challenges.
- MMV and GSK developed and gained marketing authorization for tafenoquine (*Kozenis/Krintafel*)—the first new treatment for relapse prevention in more than 60 years and the first ever single-dose treatment for the indication.
- MMV is actively working with partners to expand access to *P. vivax* treatment and supporting countries to accelerate progress toward their elimination goals.

MMV
Medicines for Malaria Venture

# MDGH: Innovative Financing Enables Development of Moxidectin, Yielding Returns for Social Impact Investors

- Moxidectin was approved by the US FDA in 2018 for "river blindness." It is also being developed for lymphatic filariasis, soil transmitted helminths, strongyloides, and scabies. More than 1.5 billion people suffer from diseases potentially treatable with moxidectin.
- MDGH licensed moxidectin from the WHO in 2014. MDGH was the sole sponsor of regulatory filing, but partnerships with TDR and regulatory scientists were critical.
- MDGH accomplished registration with just a six-person team.
- MDGH leveraged FDA's priority review voucher (PRV) to raise capital from social impact investors to support product development and registration, demonstrating capabilities of social impact investing to yield both financial and humanitarian returns on investment when paired with PDPs.

Medicines Development for Global Health

# FIND: Self-Administered Tests for Hepatitis C Could Ease and Broaden the Reach of Testing

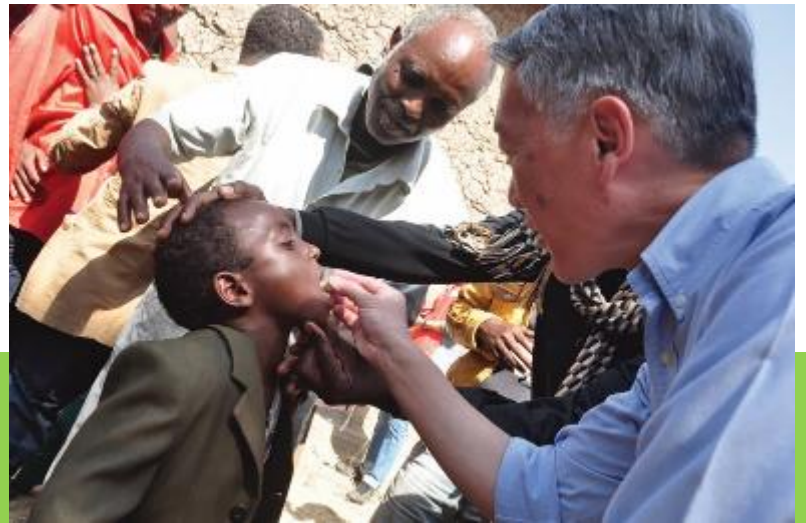
- With support from UNITAID and the Dutch government, FIND and DND*i* partnered with Malaysia Ministry of Health to make Hepatitis C (HCV) diagnosis more affordable and widely available, especially among those who are HIV+—the program is known as HEAD-Start.
- Before HEAD-Start, diagnostic tools were expensive and slow. Screening in Malaysia typically took 6 months.
- HEAD-Start introduced HCV rapid diagnostic tests at primary health centers, returning results in 15 minutes.
- FIND and Clinical Research Malaysia (CRM) continue working to further simplify and expand HCV diagnosis. Efforts to earn WHO prequalification are ongoing.

FIND
Because diagnosis matters

# IVI: Affordable Oral Cholera Vaccine Goes Beyond Outbreak Response; Enables Mass-Scale Prevention

- Cholera affects more than 2.5 million annually, killing nearly 100,000.
- Oral cholera vaccine (OCV) has been available since 2001, but cost prevented wide use in endemic countries. Lack of commercial incentive stalled new cholera vaccine development.
- In response, IVI developed Euvichol® and Euvichol-Plus®—low cost OCVs, in partnership with EuBiologics, a South Korean bioventure company. IVI trained them in vaccine production.
- IVI earned WHO prequalification of Euvichol® and Euvichol-Plus® < 7 years, at development cost of only US$19.7M.
- More than 42 million doses of Euvichol® and Euvichol-Plus® have been released globally as of November 2019.
- Creation of a global stockpile of OCVs enabled mass-scale preventative Campaigns.

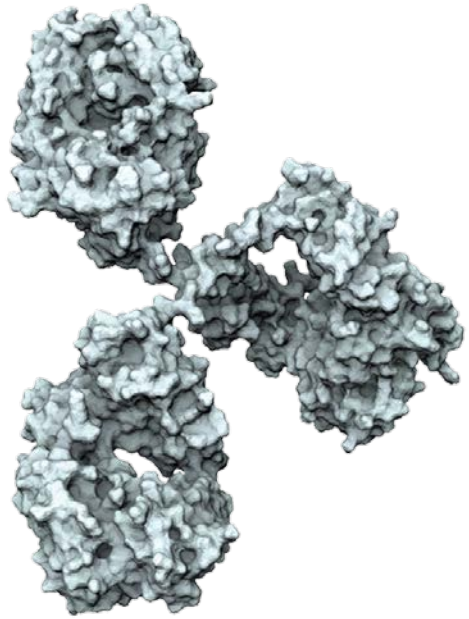
International Vaccine Institute



# IAVI: Applying Cutting-Edge HIV Research to Develop Novel Affordable Prevention and Treatment and Modalities for Many Diseases Including COVID-19

iavi Translating **science** into **global** health impact

- Donor investments and an extensive partner network led to the discovery of broadly neutralizing antibodies (bnAbs), which present promising strategies for preventing and potentially treating HIV. Clinical studies are expected to begin in 2021.
- IAVI is also utilizing its antibody capabilities to develop affordable, globally accessible antibodies to combat COVID-19, snakebite, and drug-resistant infections.
- In parallel, IAVI is applying a viral vector technology developed for HIV to vaccines for emerging infectious diseases, including an investigational COVID-19 vaccine in collaboration with Merck and Co. (USA).
- Such advances are enabled by IAVI's PDP model, which fosters unique partnerships between researchers, product developers, and funders.



# IPM: Dapivirine Ring Would Offer Women in Sub-Saharan Africa First Long-Acting HIV Prevention Option

- Every day, nearly 1,400 women in Sub-Saharan Africa acquire HIV.  Existing HIV prevention tools like condoms and the daily oral antiretroviral (ARV) pill known as PrEP are essential, but not all women as are to use them.
- IPM developed the dapivirine ring—the first long-acting HIV prevention product—to help address women's unmet need for new methods of HIV-prevention.
- Received a positive opinion from the European Medicines Agency, facilitating national regulatory approvals. Submissions to African national regulatory authorities and US FDA are being pursued.
- Received WHO prequalification, which will facilitate procurement decisions, pending regulatory approvals.
- Dapivirine ring reduced women's HIV risk by 35% and by 27% in two Phase III trials; no safety concerns.

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

# IVCC: Dual-Active Ingredient Bed Nets Combat Insecticide Resistance and Help Preserve Hard-Fought Progress against Malaria

IVCC
Building Partnerships
Creating Solutions
Saving Lives

- WHO report 229 million cases of malaria and 409,000 deaths in 2019, mostly in sub-Saharan Africa.
- Vector control tools, such as Long-Lasting Insecticidal Nets (LLINs) and Indoor Residual Spraying (IRS) have helped halve malaria cases since the turn of the century, but resistance to pyrethroids, the most commonly used insecticide, poses a real threat to the future efficacy of these tools.
- IVCC is working with its funders and industry partners to develop new insecticides that can be used across LLINs and IRS.
- As part of the New Nets Project, IVCC is supporting the introduction of two dual active ingredient bed nets: BASF's Interceptor G2® and Royal Guard® into 10 endemic countries.
- Through a combination of a randomized controlled trials, and pilot net deployments, the New Nets Project will produce efficacy evidence for WHO, along with effectiveness and operational learnings that will help to optimize future deployments of dual-active ingredient bed nets.

# EVI: Maintaining a Robust Vaccine Portfolio to Combat Diseases of Poverty

EUROPEAN VACCINE INITIATIVE

- Vaccination is a successful and cost-effective health intervention; however, vaccine development is lengthy, costly and difficult.
- EVI has supported the development of ~40 different vaccine candidates for a variety of diseases/pathogens, including malaria, leishmaniasis, diarrheal diseases, and emerging infectious diseases.
- EVI is currently evaluating ChAd63-KH as a vaccine for visceral leishmaniasis (VL; kala azar) and post kala azar dermal leishmaniasis (PKDL), a skin disease that follows treatment for VL.
- Leishmaniases are poverty-related diseases present in nearly 100 countries that account for more than 1 million cases per year.
- No vaccines are currently licensed for any form of human leishmaniasis.
- ChAd63-KH is currently in Phase 2B clinical development.

# TBVI: Pursuing a Vaccine to Prevent the World's Deadliest Infectious Disease

- Tuberculosis is the world's deadliest infectious disease, killing 1.4 million each year.
- The only vaccine against TB in use today, Bacille Calmette-Guerin (BCG), is administered at birth and ineffective at preventing pulmonary TB—the most common and transmissible form in adults.
- The global portfolio of new TB vaccine candidates has been significantly advanced in the last 20 years by PDPs.
- TBVI supports multiple TB vaccine candidates, including MTBVAC, which is scheduled to begin a Phase 3 trial in 2021. If trials are successful, MTBVAC could reach the market for infants as early as 2026 and for adults by 2028–2030.
- Support for MTBVAC development comes from multiple public funders and foundations; research partners span universities, industry, and research institutions.

TBVI
TuBerculosis Vaccine Initiative