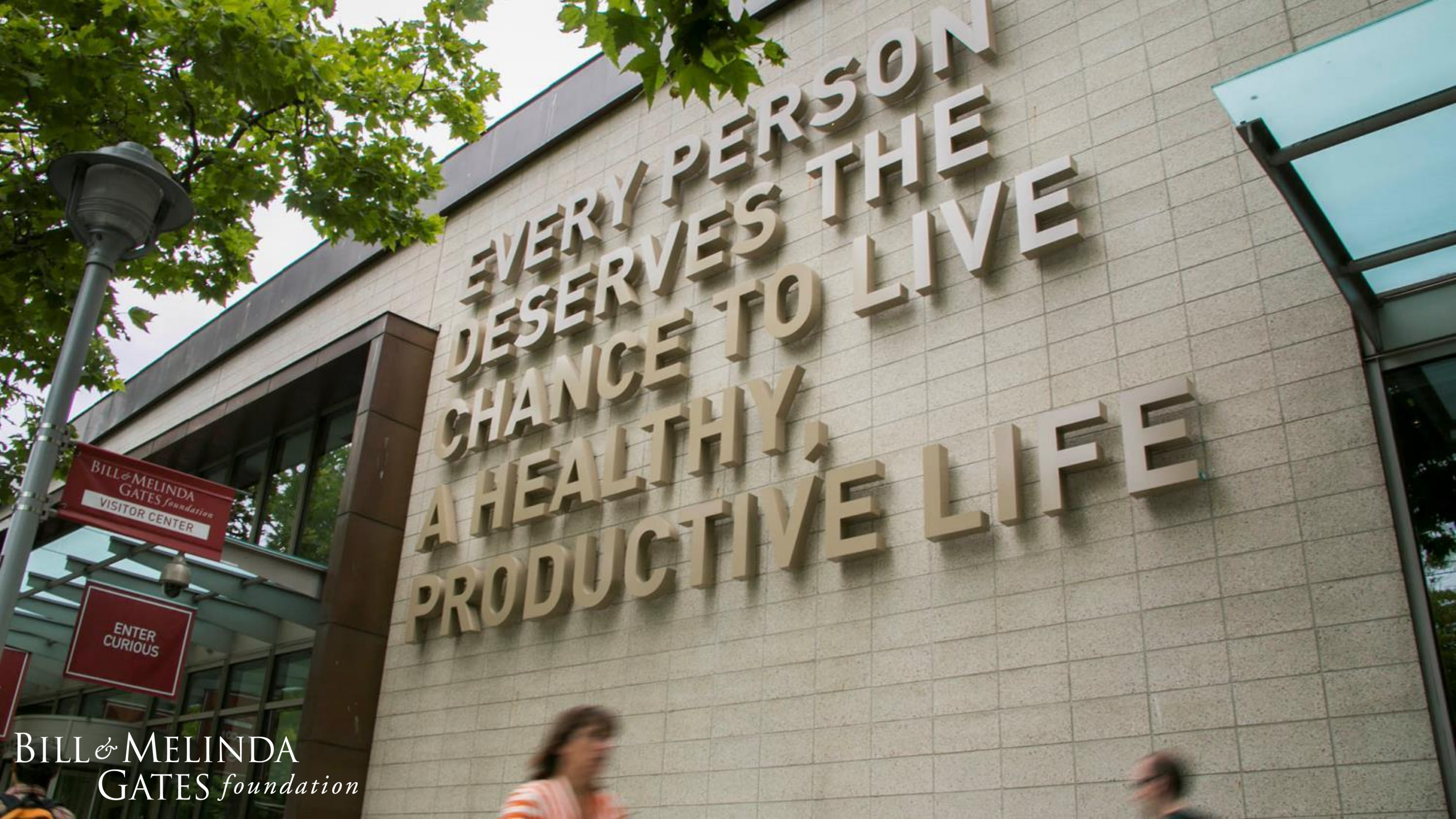

EVERY PERSON
DESERVES THE
CHANCE TO LIVE
A HEALTHY,
PRODUCTIVE LIFE
BILL & MELINDA
GATES foundation
VISITOR CENTER
ENTER
CURIOUS
BILL & MELINDA
GATES foundation

11NOV2022
PART 2

Funding strategy, grant process, and insights on how to contribute to the Bill and Melinda Gates foundation’s vaccine mission

THE FOUNDATION

IMPROVING PEOPLE'S LIVES NEEDS TO TAKE AN INTEGRATED APPROACH

IMPROVING SANITATION

HELPING FARMERS

ACCESS TO VACCINES

FAMILY PLANNING

STOPPING MALARIA

BETTER NUTRITION

WHERE WE WORK

From our headquarters in Seattle to our teams based in regional offices across four continents, we work with partners around the globe to improve people's lives.

THE SCOPE OF OUR WORK

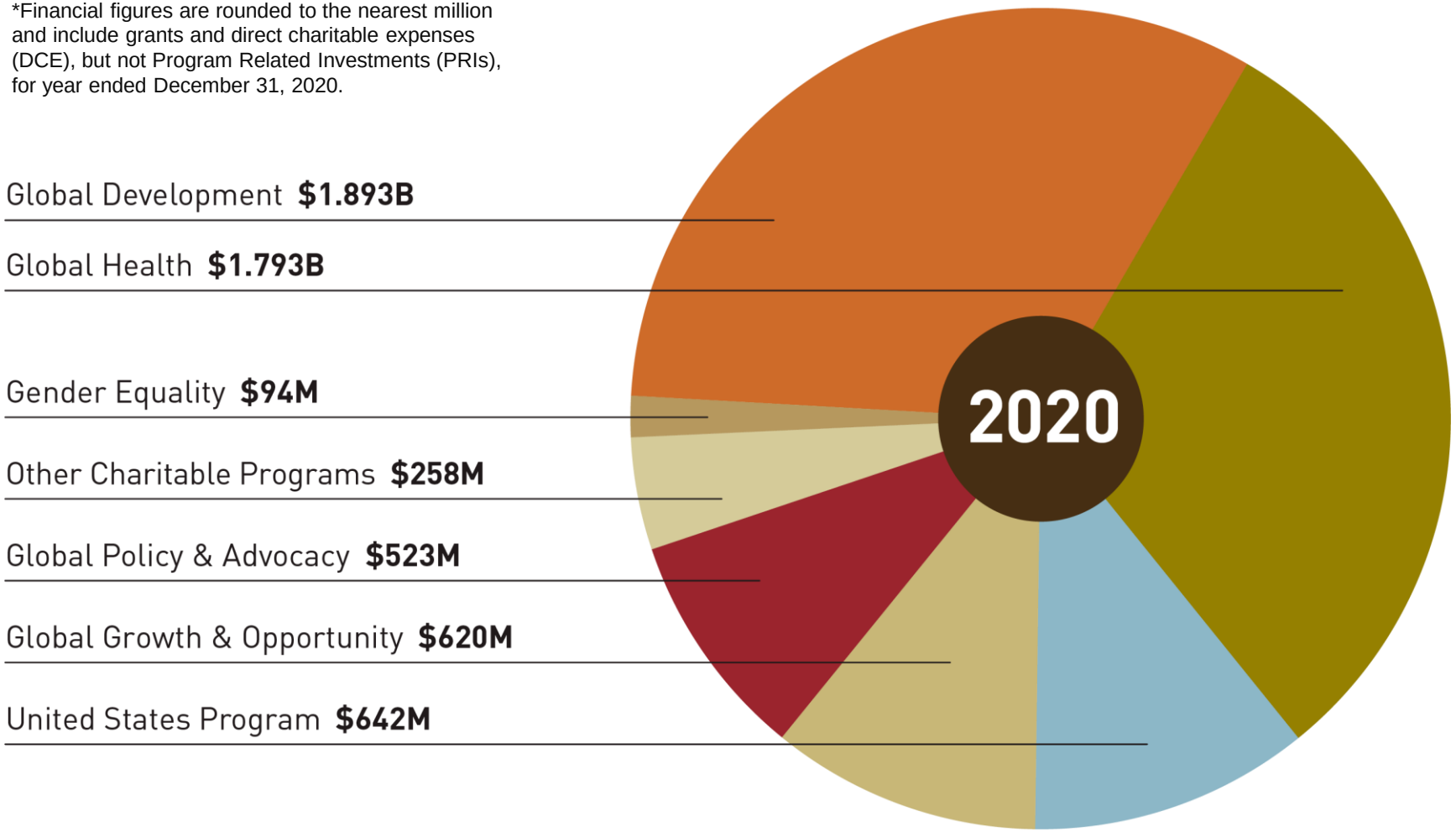
We work with partner organizations around the world to reduce inequity

For the Year ended December 31, 2020.

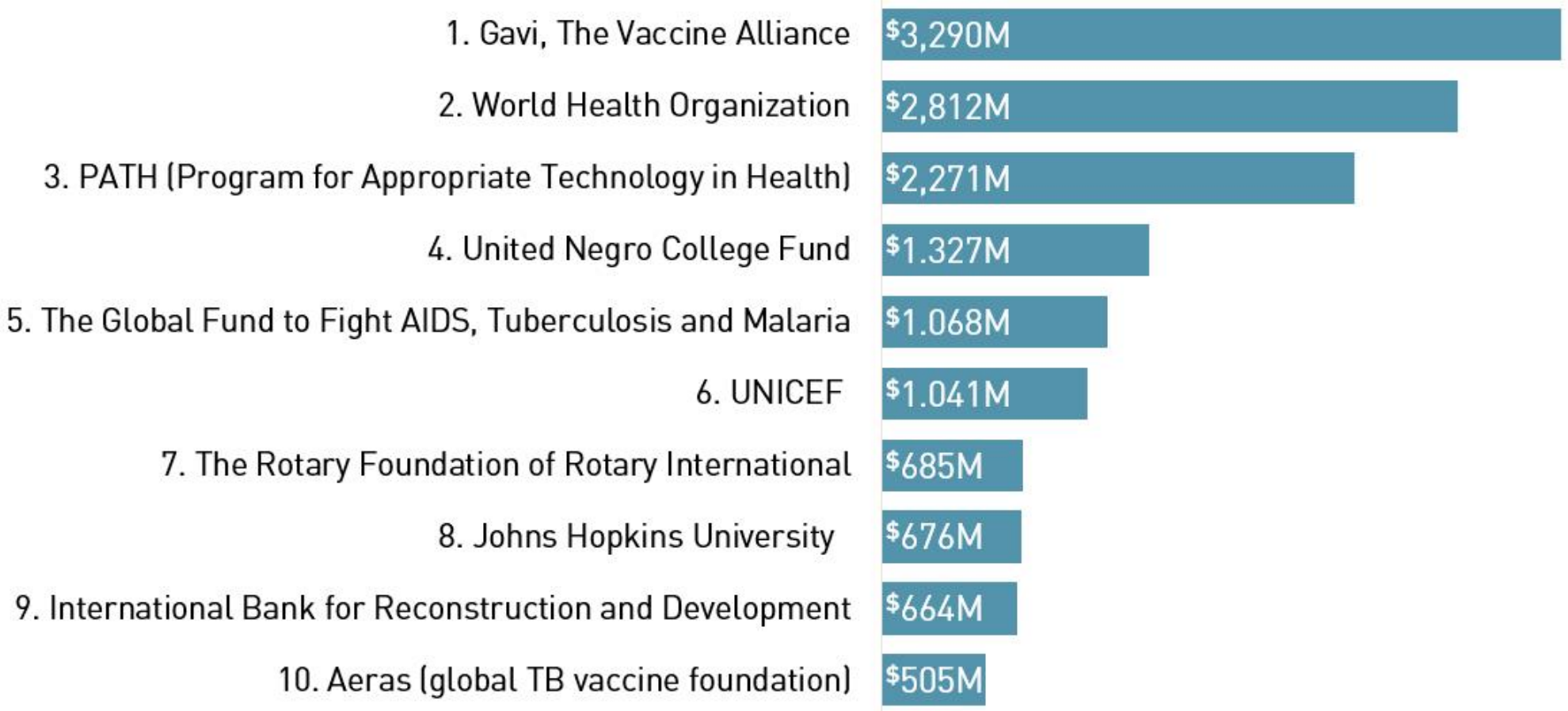
FOUNDATION FUNDING SUMMARY

In 2020, the foundation invested US $5.822 billion* in these areas

*Financial figures are rounded to the nearest million and include grants and direct charitable expenses (DCE), but not Program Related Investments (PRIs), for year ended December 31, 2020.



TOP 10 GRANT RECIPIENTS BY DOLLAR AMOUNT



Total amount of grants paid through the year ended December 31, 2017. Amounts in thousands of U.S. dollars.

ORGANIZATIONAL STRUCTURE

MARK SUZMAN, Chief Executive Officer

GENDER EQUALITY DIVISION
ANITA ZAIDI, President

GLOBAL DEVELOPMENT DIVISION
CHRIS ELIAS, President

GLOBAL HEALTH DIVISION
TREVOR MUNDEL, President

GLOBAL GROWTH & OPPORTUNITY DIVISION
RODGER VOORHIES, President

GLOBAL POLICY & ADVOCACY DIVISION
GARGEE GHOSH, President

UNITED STATES PROGRAM DIVISION
ALLAN GOLSTON, President

FOUNDATION STRATEGY OFFICE
ANKUR VORA, Chief Strategy Officer

COMMUNICATIONS
SUSAN BYRNES, Chief Communications Officer

OPERATIONS
CAROLYN AINSLIE, Chief Financial Officer
LISA ALVAREZ-CALDERÓN, Chief Human Resources Officer
CONNIE COLLINGSWORTH, Chief Operations Officer

FOUNDATION EXECUTIVE LEADERSHIP

Bill Gates
Co-Chair and Trustee

Melinda French Gates
Co-Chair and Trustee

Mark Suzman
Chief Executive Officer

Carolyn Ainslie
Chief Financial Officer

Susan Byrnes
Chief Communications Officer

Lisa Alvarez-Calderón
Chief Human Resources Officer

Connie Collingsworth
Chief Operations Officer

Christopher Elias
President, Global Development

Gargee Ghosh
President, Global Policy & Advocacy

Allan Golston
President, U.S.Program

Trevor Mundel
President, Global Health

Rodger Voorhies
President, Global Growth
& Opportunity

Ankur Vora
Chief Strategy Officer

Anita Zaidi
President, Gender Equality

GLOBAL DEVELOPMENT

Delivering health and development solutions that help people lift themselves out of poverty

Programs:

- Agricultural Development
- Water, Sanitation & Hygiene
- Nutrition
- Family Planning
- Maternal, Neonatal & Child Health
- Polio
- Financial Services for the Poor
- Global Libraries
- Emergency Response

GLOBAL HEALTH

Discovering and developing affordable vaccines, drugs, and diagnostics for people in the developing world

Programs:

- Enteric and Diarrheal Diseases
- Pneumonia
- Neglected Tropical Diseases
- Malaria
- HIV
- Tuberculosis

GLOBAL HEALTH DIVISION

TREVOR MUNDEL, President

OFFICE OF THE PRESIDENT

STRATEGY, PLANNING & MANAGEMENT

Trevor Mundel

President, Global Health

ENTERIC & DIARRHEAL DISEASES

HIV & TUBERCULOSIS

MALARIA

MATERNAL, NEWBORN & CHILD HEALTH DISCOVERY & TOOLS

NEGLECTED TROPICAL DISEASES

PNEUMONIA

DISCOVERY AND TRANSLATIONAL SCIENCES

INNOVATIVE TECHNOLOGY SOLUTIONS

INSTITUTE FOR DISEASE MODELING

INTEGRATED DEVELOPMENT

VACCINE DEVELOPMENT

Office of the President & SPM | Program | Function


TAKING
RISKS
THAT OTHERS
CAN'T OR WON'T
BILL & MELINDA
GATES foundation

VACCINES

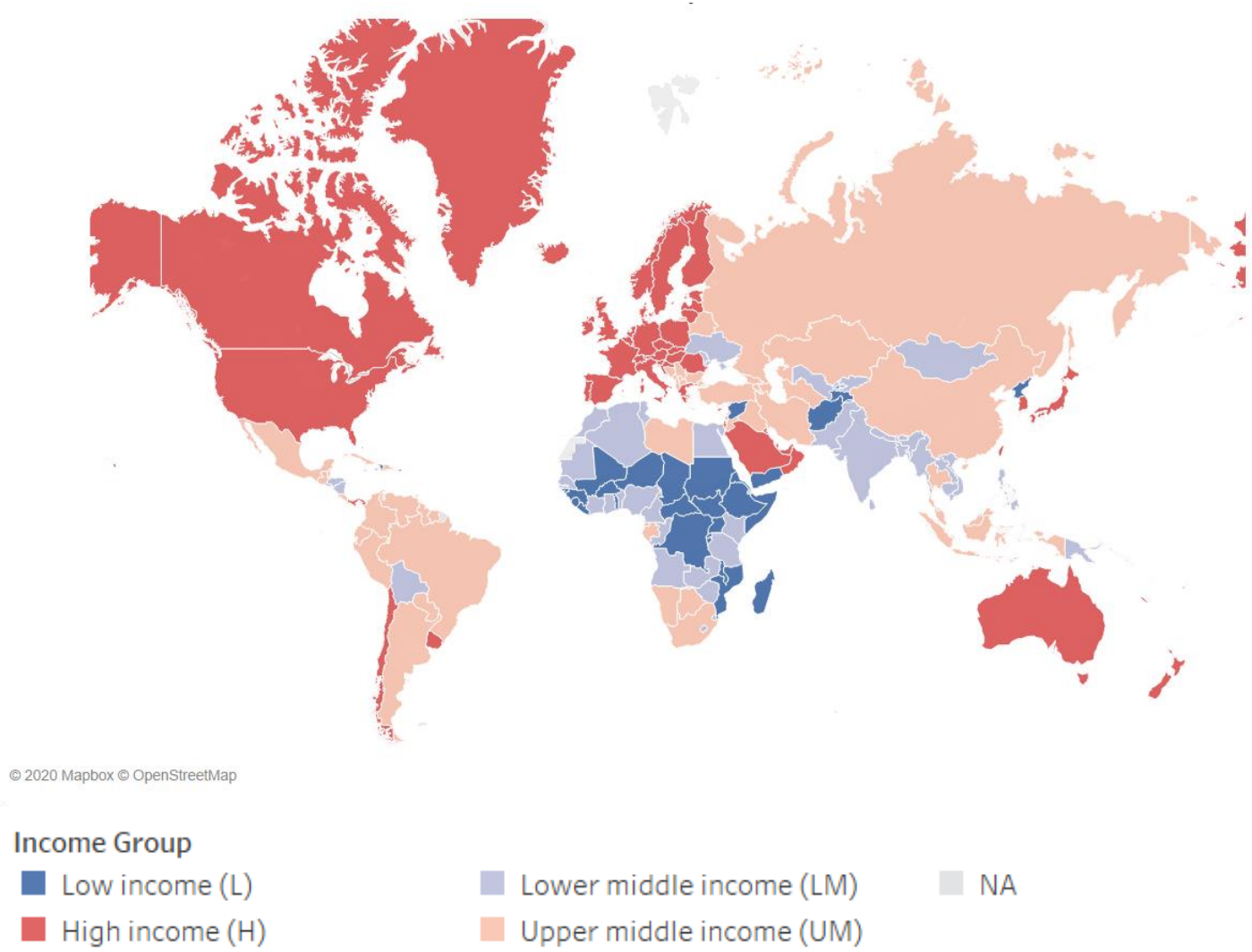
COMBAT INFECTIOUS DISEASES THAT PARTICULARLY AFFECT THE POOR

We believe we can save lives by delivering the latest in science and technology to those with the greatest needs.

Select examples of this work:

- Accelerate progress to eradicate malaria
- Reduce HIV infections and extend lives of people with HIV
- Deliver life-saving vaccines where they're needed most
- Work to eradicate polio

THE WORLD BY INCOME



The World Bank classifies economies for analytical purposes into four income groups: **low, lower-middle, upper-middle, and high income.**

For this purpose, it uses gross national income (GNI) per capita data in U.S. dollars.

These are often referred in an abbreviated format, for example:

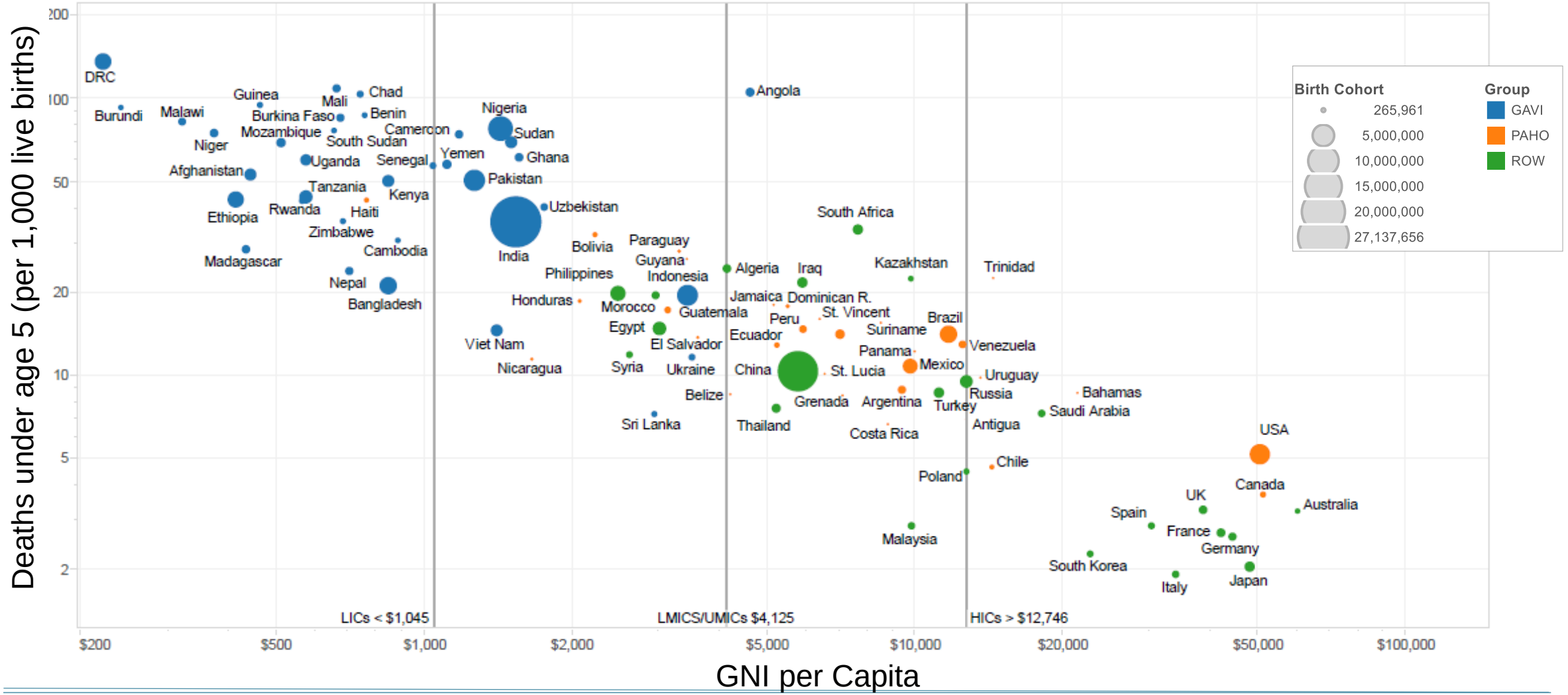
HIC = High income countries

LMIC = Low- and lower-middle- income countries

https://datatopics.worldbank.org/world-development-indicators/the-world-by-income-and-region.html; accessed 25OCT2020

THE WORLD'S REALITY IS THAT VACCINES ARE NEEDED MOST WHERE THERE IS LEAST ABILITY TO PAY

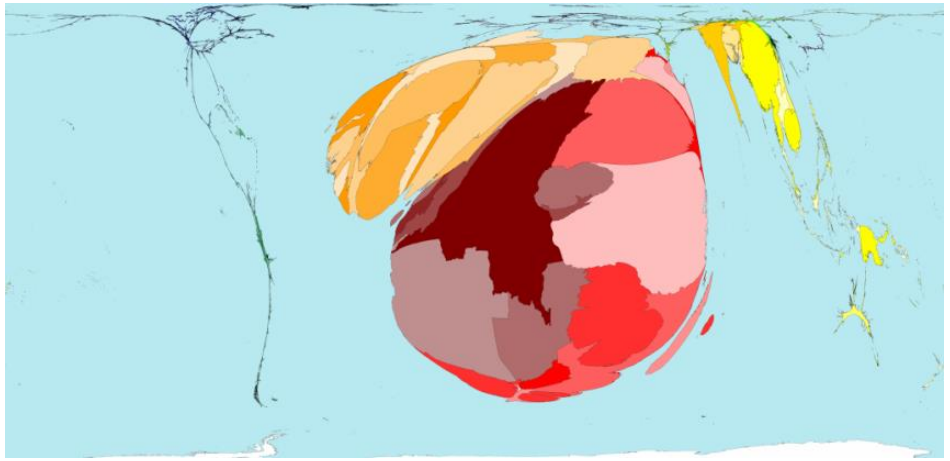
We share a common interest in achieving best possible access by developing countries to vaccines at lower prices



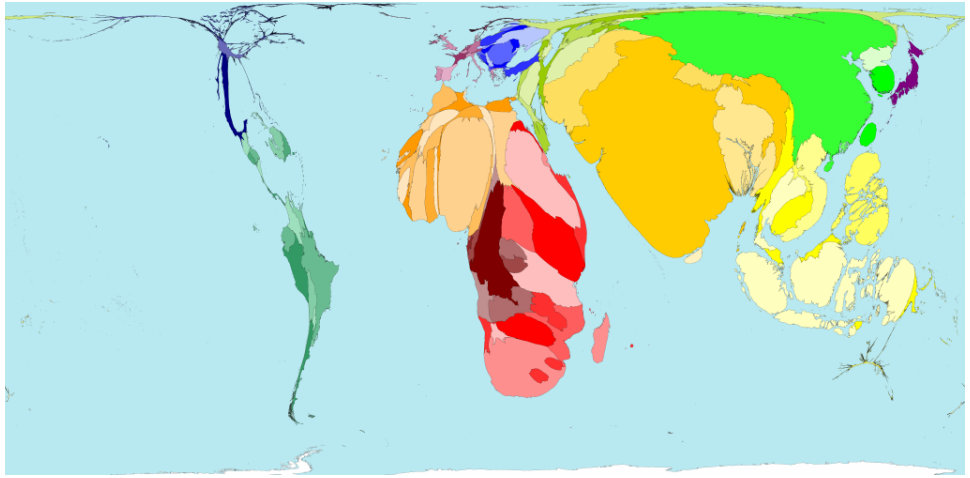
Note: Only non-PAHO countries with >250,000 annual birth cohort included. Source: World Bank GNI 2013, UNPD Population Prospects 2012 Edition, GAVI Website, September 2014

MISMATCH BETWEEN DISEASE BURDEN AND AVAILABLE MEDICAL CARE

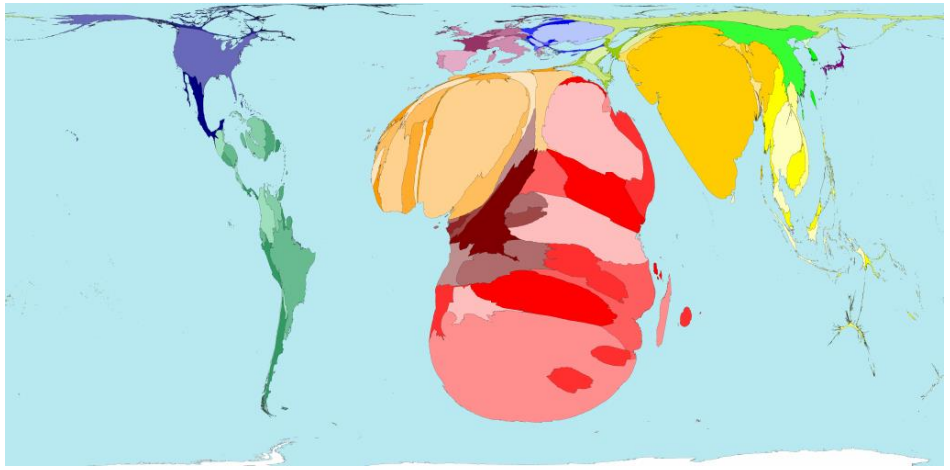
Malaria deaths



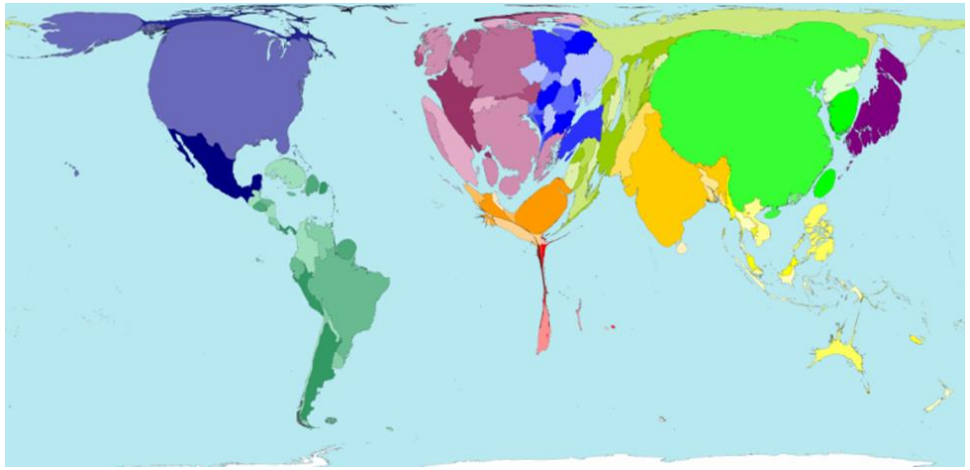
TB cases



HIV prevalence



Physicians

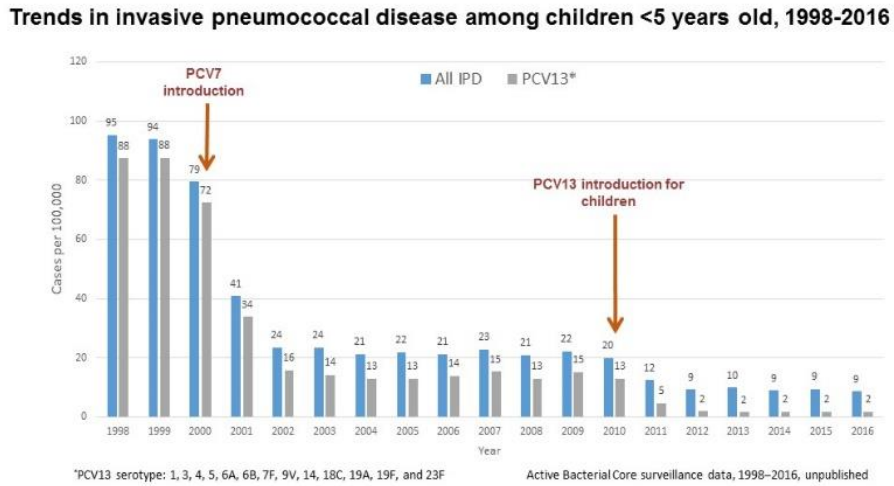


Source: http://www.worldmapper.org/

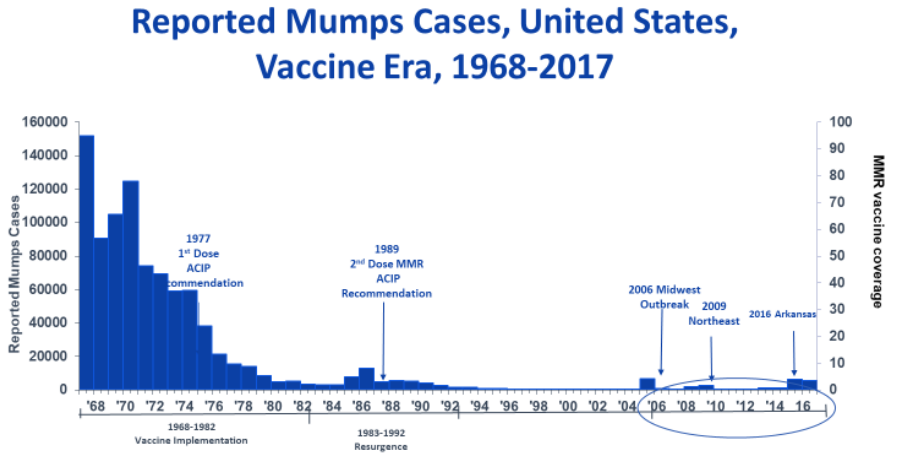
THE POWER OF VACCINES

Disease	20th Century Annual Morbidity†	2017 Reported Cases ††	Percent Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Measles	530,217	120	> 99%
Mumps	162,344	6,109	96%
Pertussis	200,752	18,975	91%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	7	> 99%
Congenital Rubella Syndrome	152	5	97%
Tetanus	580	33	94%
Haemophilus influenzae	20,000	33*	> 99%

† *JAMA*. 2007;298(18):2155-2163
†† CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book). Appendix E.
* *Haemophilus influenzae* type b (Hib) < 5 years of age. An additional 10 cases of Hib are estimated to have occurred among the 203 reports of *Haemophilus influenzae* (< 5 years of age) with unknown serotype.

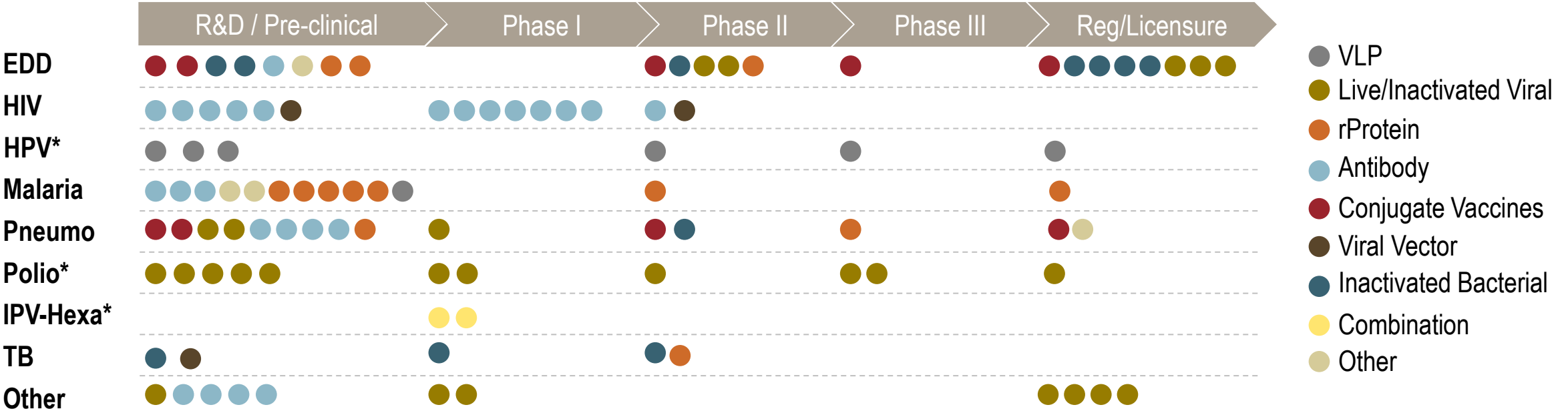


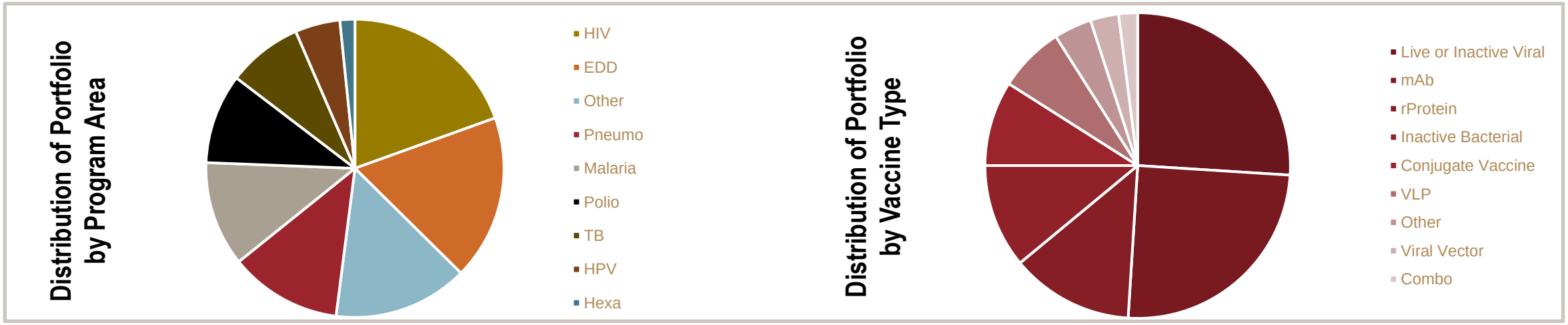
Source: Pneumococcal Disease Surveillance and Reporting. https://www.cdc.gov/pneumococcal/surveillance.html



www.cdc.gov; accessed 19OCT2020

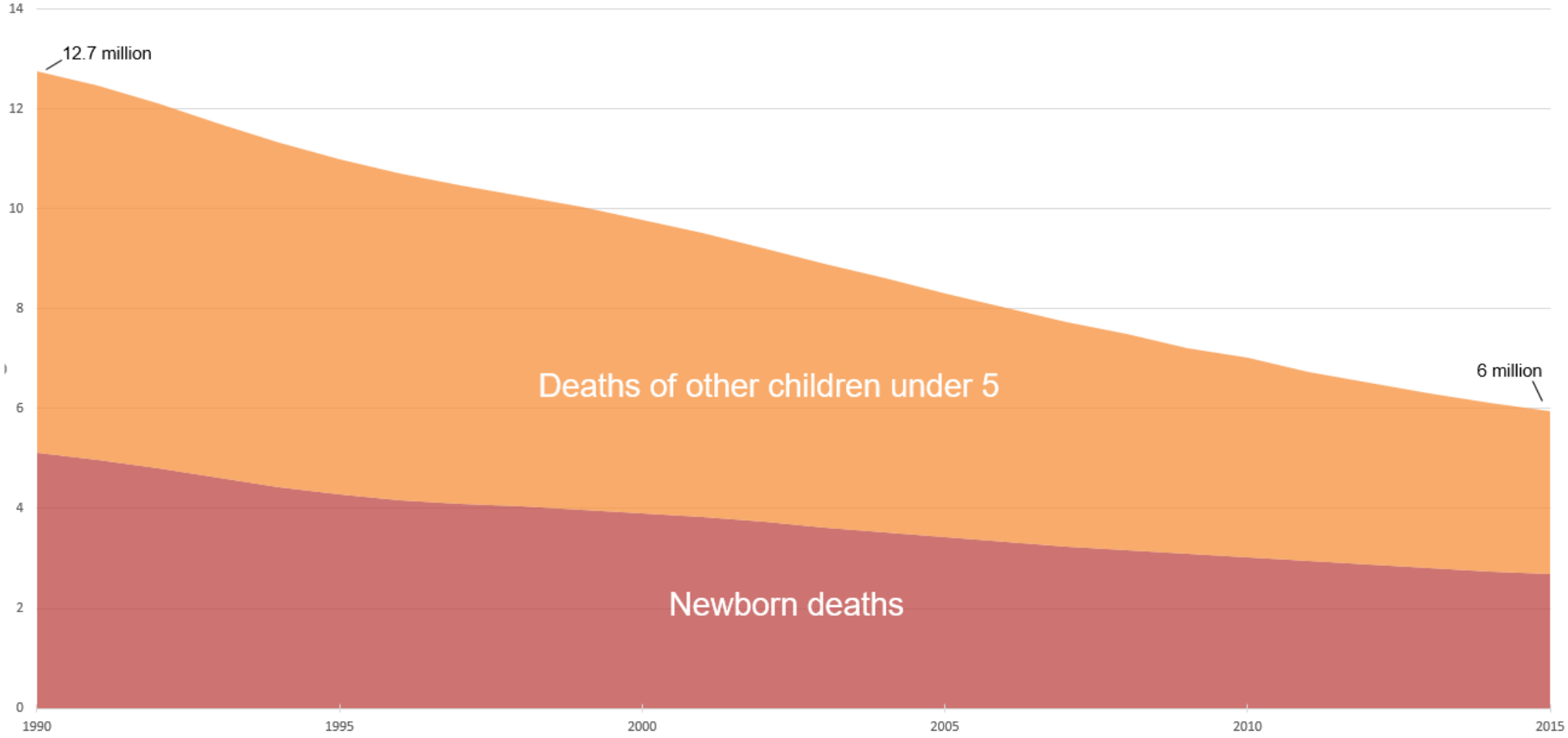
Our Vaccine and Antibody Portfolio – Supporting Over 80 Candidates in Development and another 15 Post-Licensure





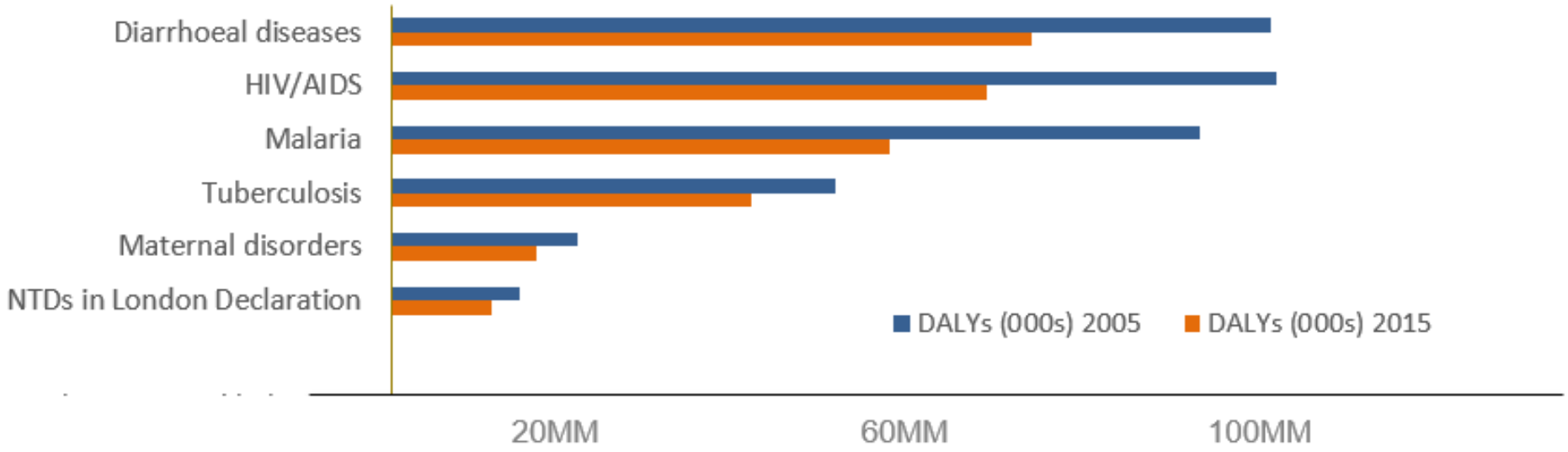
CHILDHOOD DEATHS DECLINING WORLDWIDE

Vaccines, malaria prevention, and improved newborn health care have helped reduce child mortality. But newborn deaths have plateaued and now make up 45% of the total.



Source: UNICEF

THERE HAS BEEN BOTH PROGRESS AND CHALLENGES WITH DALYS CAUSED BY LEADING DISEASES

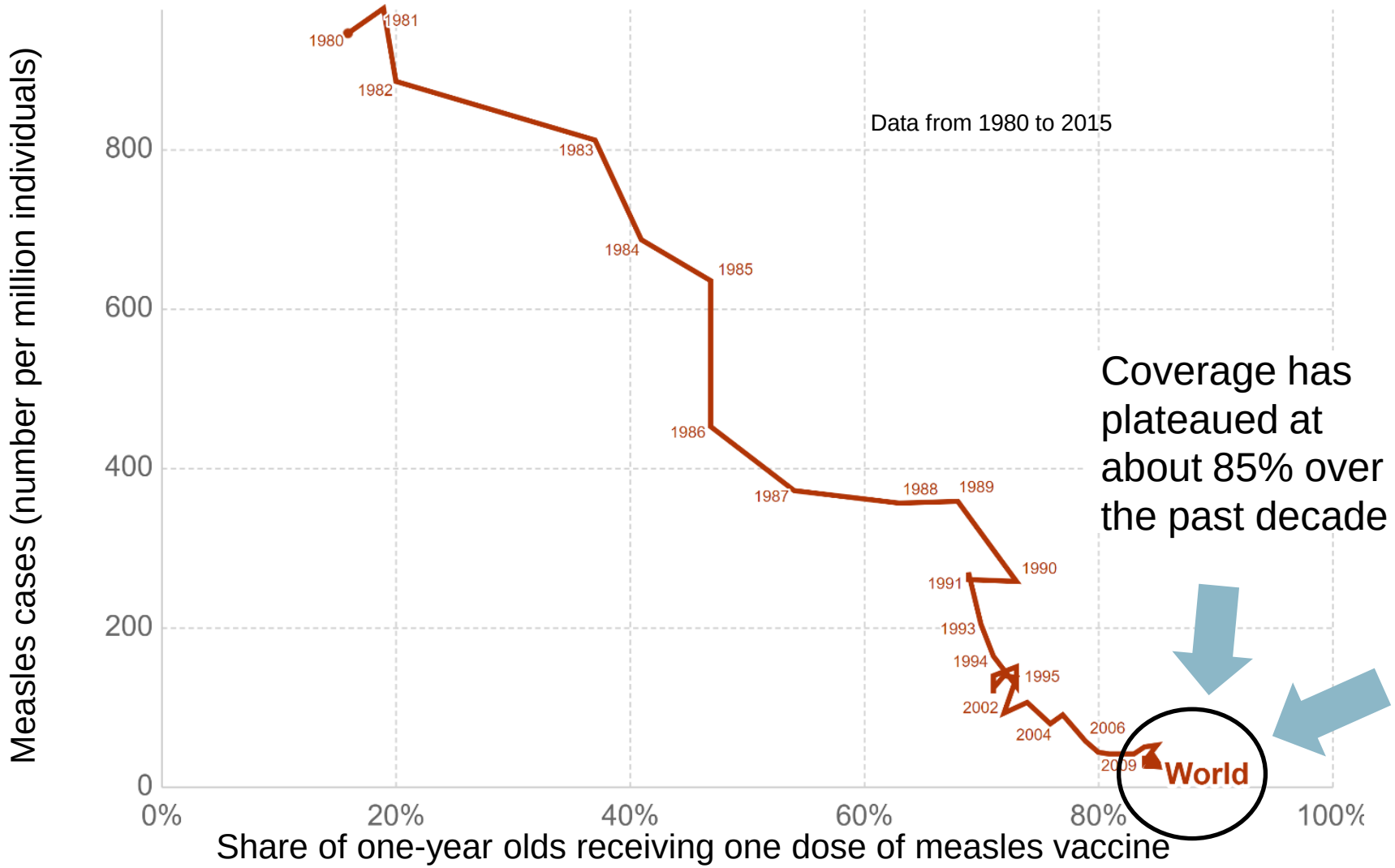


Progress in global health since 2005 has been strong, but there are still 1.5MM deaths each year from both HIV and TB, and 530K deaths from malaria

https://www.who.int/healthinfo/global_burden_disease/metrics_daly/en/

THE POWER OF VACCINES – IMPACT OF COVERAGE

Measles vaccine coverage worldwide versus measles cases worldwide



Coverage has plateaued at about 85% over the past decade

Still results in 100,000 infant deaths each year of unvaccinated children

Data source: World Health Organization (WHO), UNICEF, UNPD

OurWorldinData.org/vaccination; accessed 25OCT2015

 |


MAKING MARKETS
WORK FOR
THE POOR
BILL & MELINDA
GATES foundation

VACCINE TECHNOLOGY INNOVATION

GLOBAL HEALTH GEOGRAPHIES OFTEN HAVE DIFFERENT NEEDS THAT HIGH-INCOME MARKETS

- **Low-cost** required to ensure affordability by key populations
- **Regulatory** challenges due to diversity of markets
- **Delivery challenges** to reach those in need
- **Data accuracy** in understanding what are the disease of highest burden

VACCINE INNOVATION PORTFOLIO

GOAL: Develop and implement innovative technologies to accelerate development timelines, lower cost of manufacturing, secure supply for GAVI, ensure appropriate product profiles for our geographies, including new combinations and novel vaccine & biologics platforms

- **Platform manufacturing technologies**
- **Delivery/Injection Technologies**
- **Combination-enabling technologies**
- **New formulations & preservatives**
- **New modalities (i.e. RNA vaccines, monoclonals)**
- **Fill/Finish and lyophilization technologies**
- **Assays, Correlates & new analytical methods**
- **Programmatic Delivery-enabling technologies**

THE FOUNDATION HAS MADE INVESTMENTS IN MULTIPLE MODULAR PLATFORMS

Viral Vx

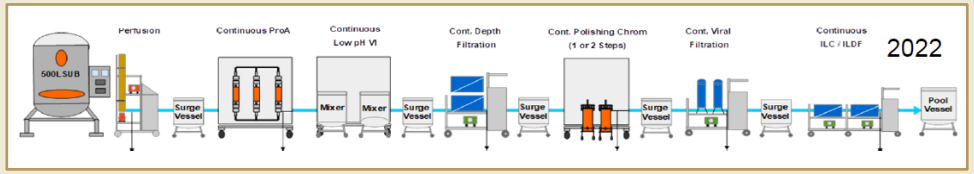
Integrated unit combining cell culture, purification and further processing (inactivation if required)

- Fixed bed reactor for attachment cell lines (Vero, MRC5)
- Can be modified for use with suspension cells (HEK293, CHO)
- Can be completely contained for use with live infectious agents

mAbs

Combines cell culture and purification for monoclonal antibody production

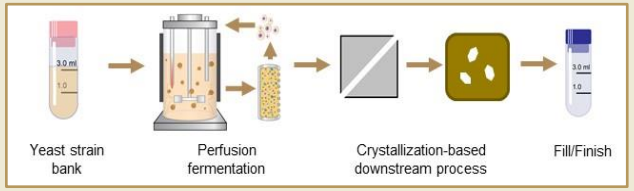
- Used in semi-continuous or continuous operation
- Can be integrated with antibody design for manufacturability



rProtein

Combines fermentation and purification for recombinant protein production

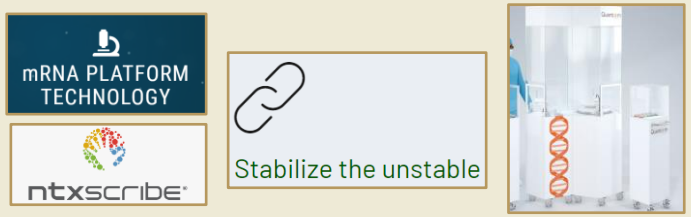
- Can be integrated with strain development
- Demonstrated using Pichia (yeast) for recombinant protein and antigen



mRNA

Small footprint manufacturing, COGS reduction and thermostability

- Continuous flow mRNA vaccine manufacturing
- Solutions for COG reduction for critical reagents and thermostability



https://www.univercellstech.com/; https://just-evotecbiologics.com/; https://sunflowertx.com/; https://elarexinc.com/; https://ntxbio.com/technologies/ https://providencetherapeutics.com; https://www.quantoom.com/; accessed 06DEC2021

ADDRESSING DELIVERY NEEDS

- **Shortage of highly skilled healthcare workers**
  - What if you had a simpler way to administer vaccines that didn’t require training on how to use a needle-and-syringe?
- **Cold-chain storage**
  - What if you could use refrigerated instead of frozen storage or take a vaccine completely out of the cold chain?
- **Need to multiple doses in a series (prime-boost)**
  - What if you could give a child, or an adult, a single-injection of a vaccine and have them fully immunized?
- **Need to deliver and administer so many different vaccines**
  - What if you had an easier way to combine different antigens into a single-shot?

TAKING RISKS

THAT OTHERS CAN'T OR WON'T

GRANT PROCESS

WHAT KINDS OF INVESTMENTS DO WE MAKE?

We listen and learn so we can identify pressing problems that get too little attention. Then we consider whether we can make a meaningful difference with our investments.

We are committed to information sharing and transparency, and we believe that published research resulting from our funding should be promptly and broadly disseminated

We make 3 major kinds of investments:

1. **Grants**
   Funding for projects, products, and infrastructure
2. **Direct Charitable Expenses**
   Support for activities that benefit the public or charitable sector
3. **Program-Related Investments**
   Tools to stimulate private-sector innovations, encourage market-driven efficiencies, and attract external capital to priority initiatives

Our investments are made in the form of:

Fund Investment

Loans

Guaranties

Direct Equity Investments

HOW WE MAKE GRANTS

- **Generate Ideas**
- **Identify Applicants**

- **Develop**
- **Analyze Proposal**

- **Determine Funding Decision**
- **Develop Grant Agreements**

- **Manage Grant**
- **Measure Progress**

OUR APPROACH: STRATEGIES AND PARTNERSHIPS

- Grantees and partners are at the center of our work
- Our program strategies are reviewed and approved on an annual basis by leadership
- We work on initiatives that align with our strategic priorities and tap the expertise of others.
- To achieve greater impact, we continually improve how we work with others.

STRATEGY LIFECYCLE

- **Develop Strategy**
  Plan for execution
- **Execute**
  Make grants and create partnerships
- **Measure**
  Track progress
- **Review**
  Reflect on execution
- **Adjust**
  Refine execution and strategy

FRAMEWORK FOR A DECISION-FOCUSED MINDSET

DECISION GUIDE	TPP	Describes what the product should be, helping us align with our partners to accelerate the process
DECISION MAP	IPDP	A comprehensive end to end development plan identifying the areas required to generate the data
DECISION POINT	Stage Gate Reviews	The point where we make Go/No Go funding decisions

INTERVENTION TARGET PRODUCT PROFILE iTPP

Primary Owner:

- Initiative Lead Responsible PST Director Accountable

Purpose:

- Establishes clear **alignment** on PST strategy**,** desired outcomes & measures for success
- Facilitates early **dialogue** with grantee
- Describes **the medical need, use case and desired attributes** of a potential intervention using **specific & quantitative** language
- Drives thinking, dialogue, alignment and linkage with partners
  - speak a common language around product development

Best Practice:

- The iTPP should be viewed as **part of PST Strategy**, it is separate from the grant-making process.
- iTPP is **a living document** and should be updated when there are *significant* changes to the clinical landscape, new data or other information.
- **Annotations** are a critical part of the document. These should describe clearly the rationale for the recommendations so that the thinking is clear years after the document is developed.

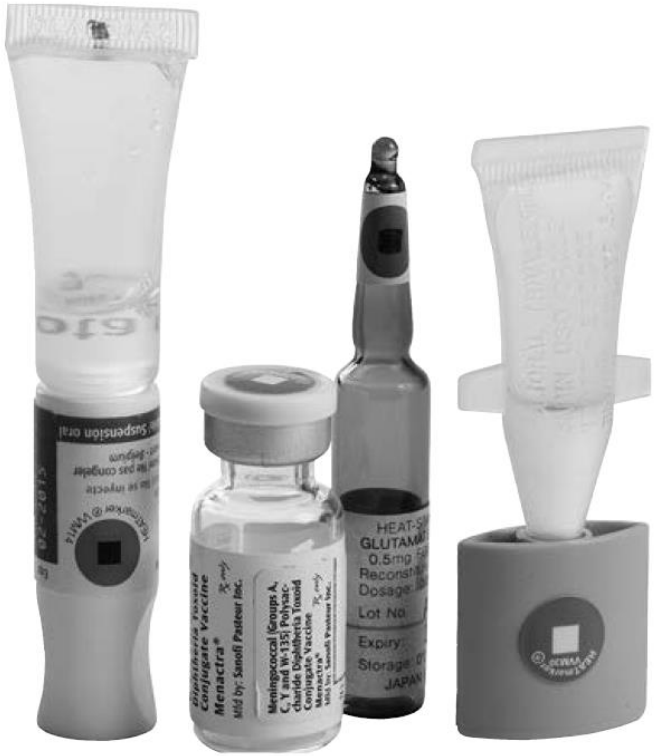
1 Executive Summary

Variable	Minimum	Optimistic
Indication*		
Product *(Candidate TPP only)*		
Target Population*		
Target Countries		
Efficacy*		
Duration of Protection		
Onset of Immunity		
Indirect (Herd) Protection		
Safety*		
Co-administration		
Presentation		
Dosing Schedule and Route of Administration*		
Vaccine Volume (cm^3/dose)		
Stability / Shelf Life		
Product Registration Path		
WHO Prequalification Date		
Primary Target Delivery Channel		
COGS		
Manufacturing Capacities *(Candidate TPP Only)*		

Drug – iTPP Template / Vaccine – iTPP Template

BROADENING YOUR TARGET PRODUCT PROFILE

- Include higher temperatures in real-time stability studies
  - Include 37°C (2, 7, 14 and 30 days) and 40°C (3 days)
- Leave space on primary container for a vaccine vial monitor
- Minimize the physical size of required for storage



https://www.who.int/immunization/documents/IIP2015_Module2.pdf

CANDIDATE TARGET PRODUCT PROFILE: cTPP

Primary Owner:

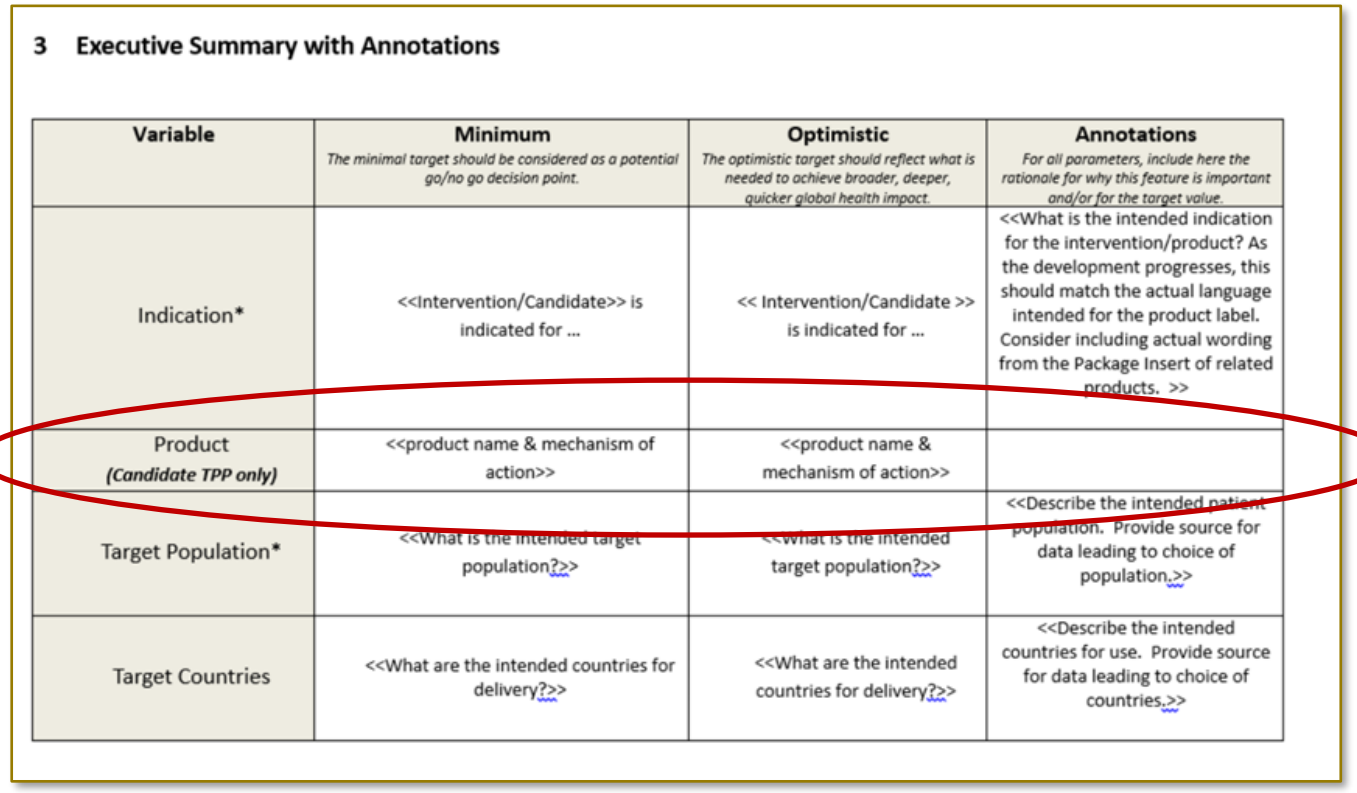
- Grantee

Purpose:

- Reflection of the product that the Grantee would like to develop
- Contains specific & quantitative language to define the medical need and desired attributes of the proposed product

Best Practices:

- cTPP will be able to drive the creation of an IPDP
- cTPP will have sufficient clarity to guide decisions
- PO, PPL, and Investment Team ensure alignment and consistency with program strategy and iTPP
- Updated through the life of the product by the Grantee and reviewed at Stage Gate meetings.
- Annotations are a critical part of the document. Describe the data and the rationale for the criteria described.



3 Executive Summary with Annotations

Variable	Minimum *The minimal target should be considered as a potential go/no go decision point.*	Optimistic *The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.*	Annotations *For all parameters, include here the rationale for why this feature is important and/or for the target value.*
Indication*	<<Intervention/Candidate>> is indicated for …	<< Intervention/Candidate >> is indicated for …	<<What is the intended indication for the intervention/product? As the development progresses, this should match the actual language intended for the product label. Consider including actual wording from the Package Insert of related products. >>
Product ***(Candidate TPP only)***	<<product name & mechanism of action>>	<<product name & mechanism of action>>	
Target Population*	<<What is the intended target population?>>	<<What is the intended target population?>>	<<Describe the intended patient population. Provide source for data leading to choice of population.>>
Target Countries	<<What are the intended countries for delivery?>>	<<What are the intended countries for delivery?>>	<<Describe the intended countries for use. Provide source for data leading to choice of countries.>>

Drug – iTPP Template / Vaccine – iTPP Template

INTEGRATED PRODUCT DEVELOPMENT PLAN IPDP

Primary Owner:

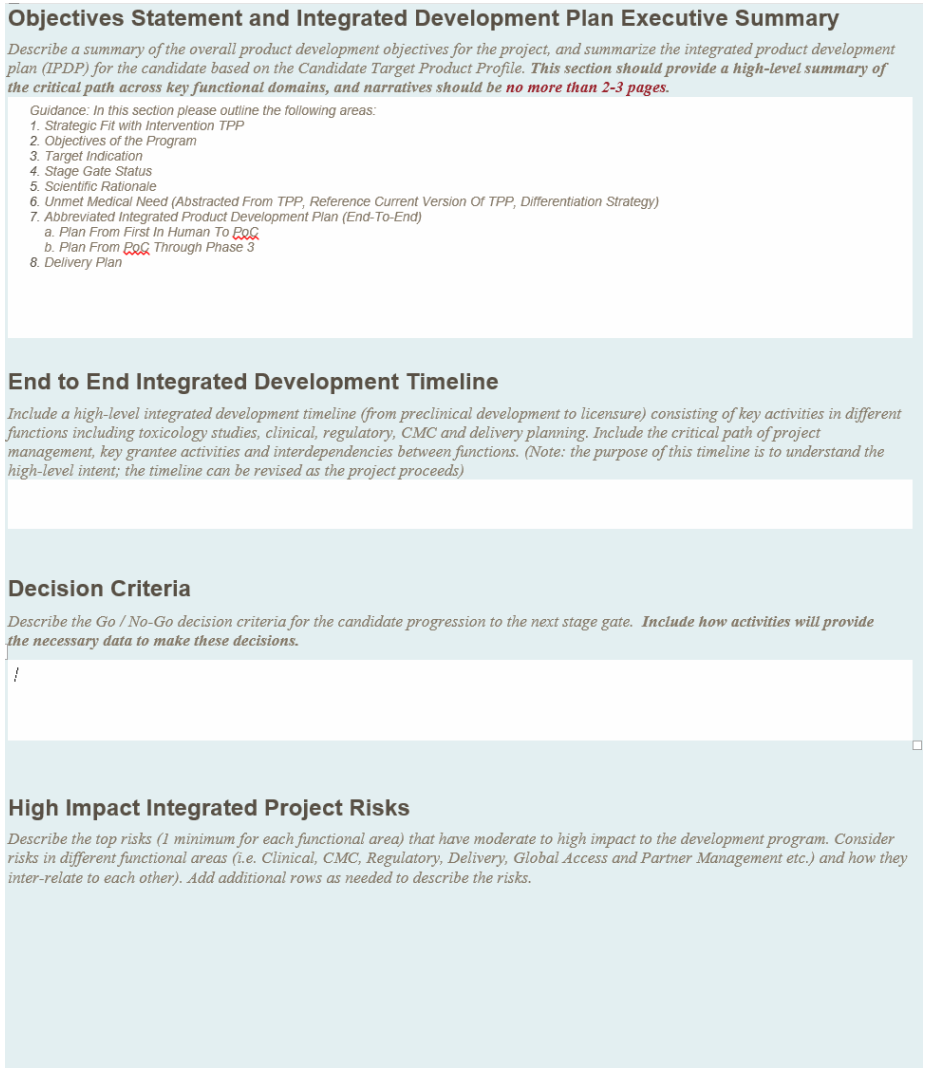
- Grantee

Purpose:

- Describes the end-to-end plan that guides project execution to increase the probability of success. Defines expected outcomes and go-no go decision criteria.
- Contains detailed strategies in the areas of research, regulatory, clinical development, CMC (chemistry, manufacturing & controls) development, global access, partner management, and delivery and how they are connected.
- Facilitates alignment on the plan, supports effective management of the investment and focuses on key decision points/criteria and the plan to collect data necessary to inform these decisions

Best Practices:

- Reflects end to end planning, even if the grant only covers a certain phase of development. It is a “decision map” for the program
- Focuses on critical decisions during the course of product development. Activities described in the IPDP create the necessary data required for decision making.
- Update throughout the development process at stage gates and/or if course-corrections in the plan are required



Objectives Statement and Integrated Development Plan Executive Summary

Describe a summary of the overall product development objectives for the project, and summarize the integrated product development plan (IPDP) for the candidate based on the Candidate Target Product Profile. ***This section should provide a high-level summary of the critical path across key functional domains, and narratives should be no more than 2-3 pages.***

Guidance: In this section please outline the following areas:
1. *Strategic Fit with Intervention TPP*
2. *Objectives of the Program*
3. *Target Indication*
4. *Stage Gate Status*
5. *Scientific Rationale*
6. *Unmet Medical Need (Abstracted From TPP, Reference Current Version Of TPP, Differentiation Strategy)*
7. *Abbreviated Integrated Product Development Plan (End-To-End)*
   a. *Plan From First In Human To PoC*
   b. *Plan From PoC Through Phase 3*
8. *Delivery Plan*

End to End Integrated Development Timeline

Include a high-level integrated development timeline (from preclinical development to licensure) consisting of key activities in different functions including toxicology studies, clinical, regulatory, CMC and delivery planning. Include the critical path of project management, key grantee activities and interdependencies between functions. (Note: the purpose of this timeline is to understand the high-level intent; the timeline can be revised as the project proceeds)

Decision Criteria

Describe the Go / No-Go decision criteria for the candidate progression to the next stage gate. ***Include how activities will provide the necessary data to make these decisions.***

High Impact Integrated Project Risks

Describe the top risks (1 minimum for each functional area) that have moderate to high impact to the development program. Consider risks in different functional areas (i.e. Clinical, CMC, Regulatory, Delivery, Global Access and Partner Management etc.) and how they inter-relate to each other). Add additional rows as needed to describe the risks.

Integrated Product Development Plan (IPDP)

How We Develop Ideas/Grants

Channels for developing partnerships for funding

- Connection through our employee networks and current grantees
- Request for Proposals
- Grand Challenges grant opportunities https://gcgh.grandchallenges.org/
- BMGF staff attends a presentation
- Connections at a conference
- Direct outreach from organizations

CMCInnovations@gatesfoundation.org

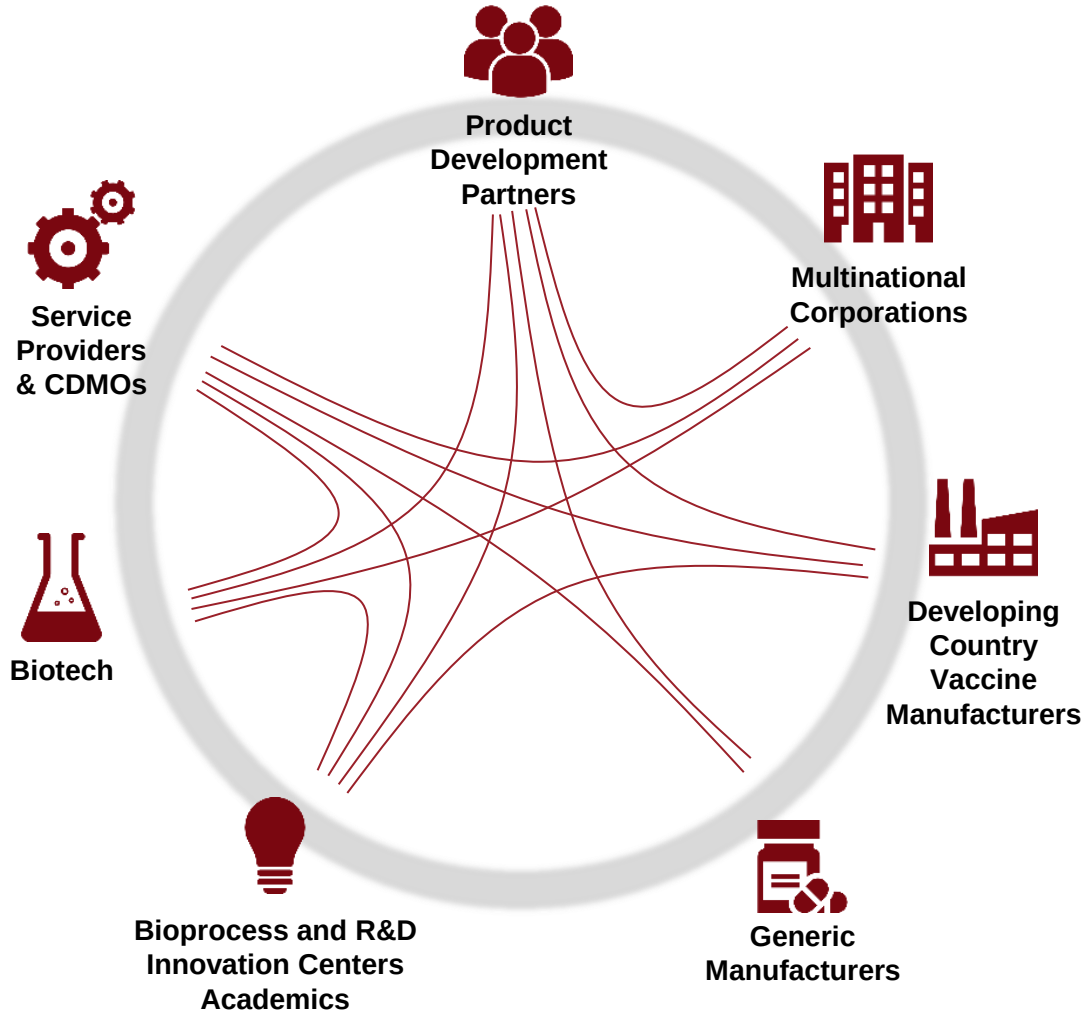
Main factors we assess for funding innovations

- Does it make vaccines lower-cost, easier to use, easier to transport or offer superior protection at the same price point?
- Does it impact WHO disease areas and LMIC populations?
- Is it scalable?
- Is there a unique role for the foundation to play?
- If already a funded area, is the foundation underinvested in that area?
- **Global Access is critical – requires funded developments to be made available & accessible to our target populations**

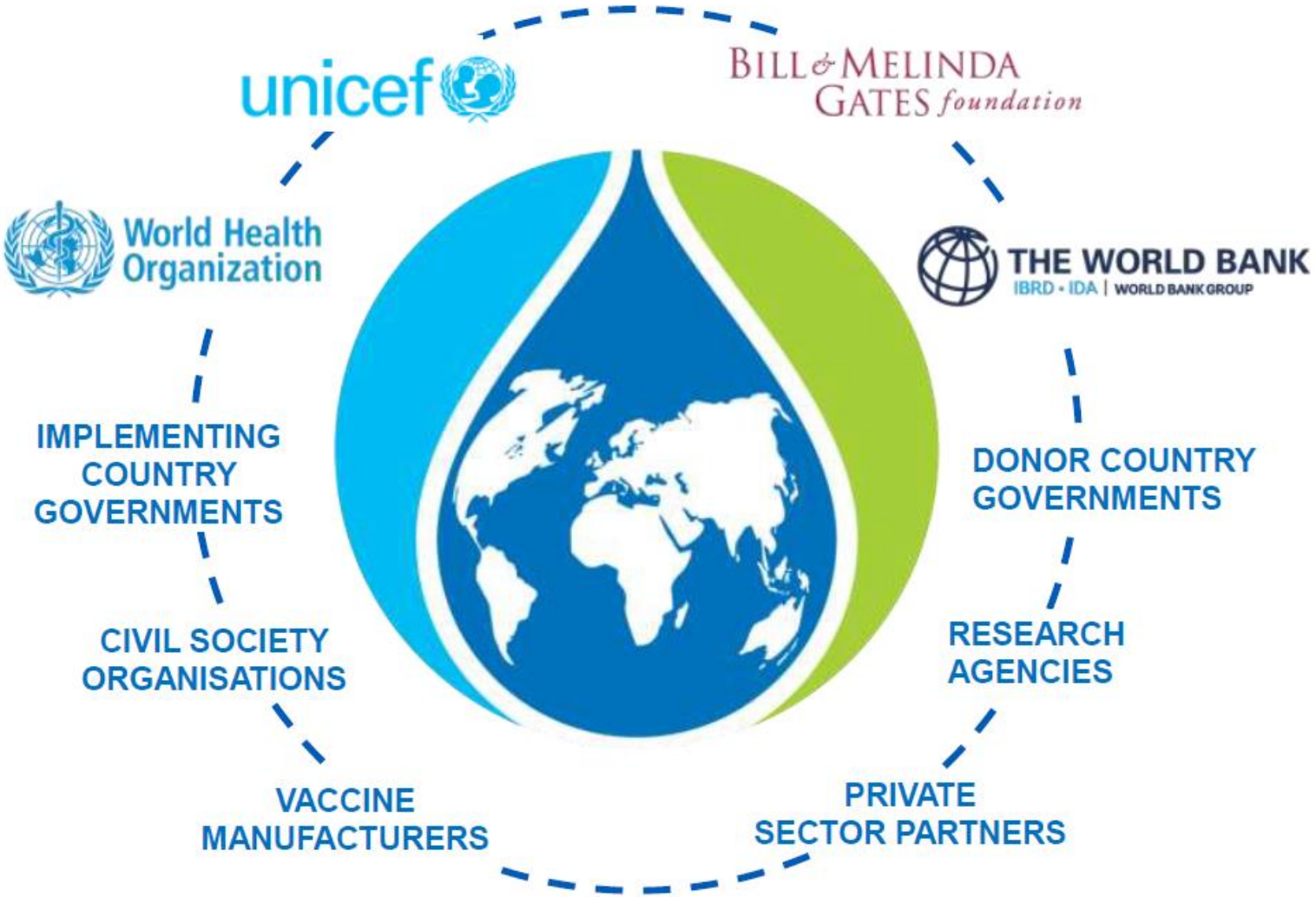

TAKING
RISKS
THAT OTHERS
CAN'T OR WON'T
BILL & MELINDA
GATES foundation

PARTNERSHIP

OUR ABILITY TO ACHIEVE IMPACT IS DEPENDENT UPON PARTNERSHIPS



Vaccine Alliance partners



Gavi
The Vaccine Alliance

World Health Organization

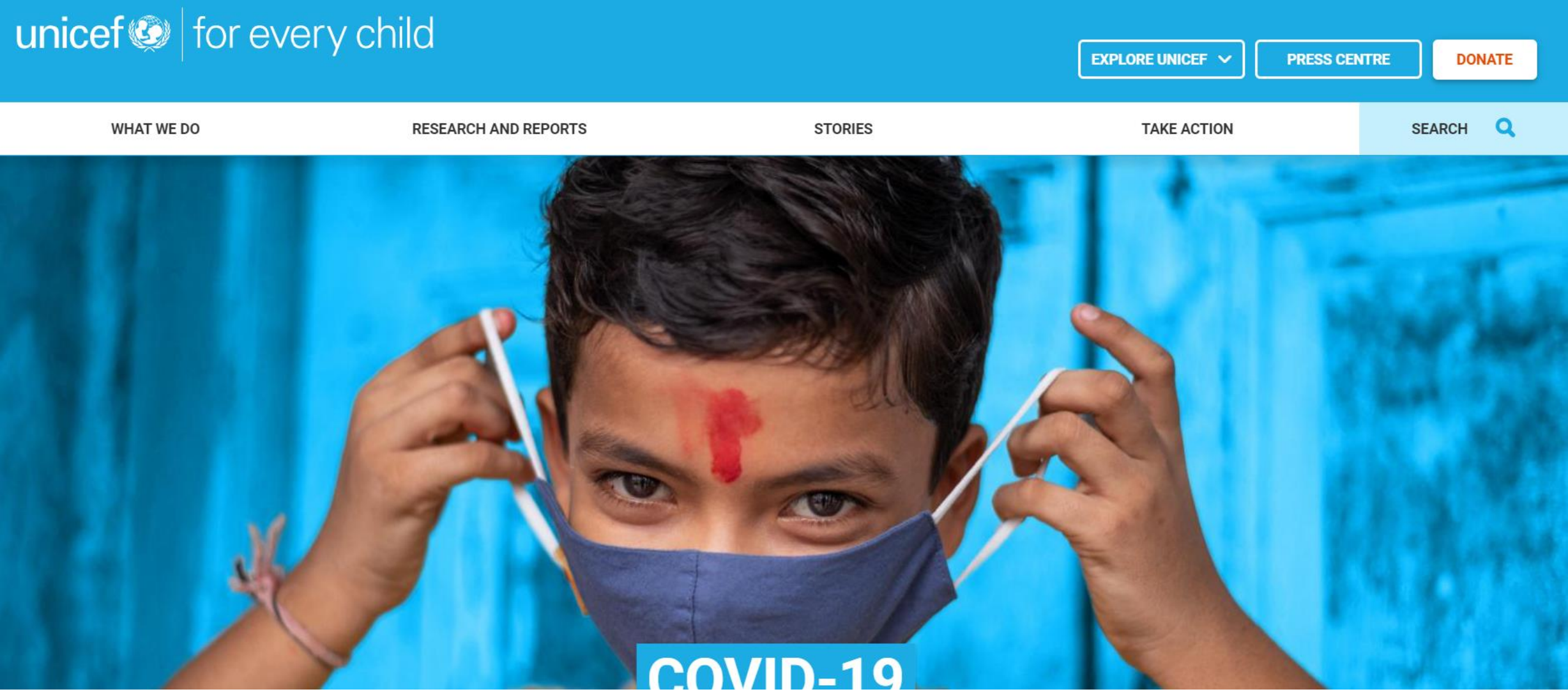
Health Topics | Countries | Newsroom | Emergencies | Data | About Us

Home / About WHO / Who we are

WHO works worldwide to promote health, keep the world safe, and serve the vulnerable.

Our goal is to ensure that a billion more people have universal health coverage, to protect a billion more people from health emergencies, and provide a further billion people with better health and well-being.

WHO began when our Constitution came into force on 7 April 1948



UNICEF is the largest single vaccine buyer in the world. UNICEF will use its market shaping and procurement expertise to coordinate the procurement and supply of COVID-19 vaccines for the COVAX Facility. This could potentially double the agency's overall vaccine procurement throughput volume in 2021 alone.

https://www.unicef.org/press-releases/unicef-lead-procurement-and-supply-covid-19-vaccines-worlds-largest-and-fastest-ever

CEPI (Coalition for Epidemic Preparedness Innovations) was founded in 2017 with initial investments by the governments of Norway and India, the Bill & Melinda Gates Foundation, the Wellcome Trust and the World Economic Forum

THE FOUNDATION HAS PARTNERED WITH NIIMBL TO SET UP A COLLABORATION FOR GLOBAL HEALTH

The National Institute for Innovation in Manufacturing and Biopharmaceuticals was developed under the US National Institute of Standards and Technology

How we want to work together:

- Collaborate to de-risk technologies of mutual interest to global health and broader biopharmaceutical industry
- Introduce global health challenges to NIIMBL membership of academics, pharmas and biotech
- Joint funding of priority programs through RFP call
- Partner on solutions for workforce development and regulatory engagement

WE UTILIZE A PARTNER NETWORK TO ACCELERATE TECHNOLOGIES THROUGH TWO VALLEYS OF DEATH

Discovery | Phase 1 | Phase 2 | Phase 3 | Commercialization

Pre-clinical to Proof of Concept
Valley of Death

Commercialization
Valley of Death

Examples of Foundation Partnerships

BILL & MELINDA GATES MEDICAL RESEARCH INSTITUTE

CEPI
New vaccines for a safer world

NIMBL

PATH

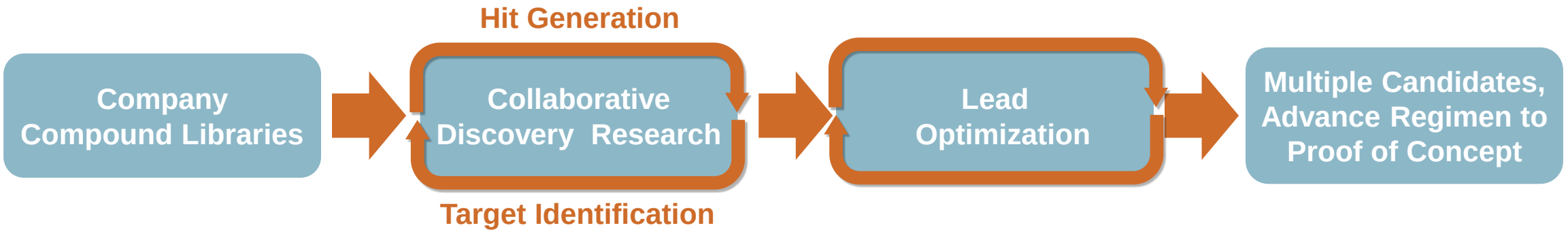
unicef

Gavi
The Vaccine Alliance

World Health Organization

Pharmas, Biotechs and DCVMs

PARTNERSHIP IN ACTION: TB DRUG ACCELERATOR



RESEARCH INSTITUTIONS:

Cornell University Founded A.D. 1865

Texas A&M

NIH National Institute of Allergy and Infectious Diseases

Drug Discovery Unit

Rutgers Biomedical and Health Sciences

IDRI Infectious Disease Research Institute

University of Cape Town · iYunivesithi yaseKapa · Universiteit van Kaapstad

Colorado State University

Calibr California Institute for Biomedical Research

TB ALLIANCE Global Alliance for TB Drug Development

PHARMACEUTICAL COMPANIES:

Bayer

Lilly

Eisai

AstraZeneca

MERCK

SANOFI

abbvie

gsk GlaxoSmithKline

UNPRECEDENTED BREADTH OF RESPONSE

Responses across the globe from all players

- Vaccine developers
  - Academic, government institutions, public-private partnerships, biotechnology, developing country vaccine manufacturers and multinational corporations
- Supply chain
  - Contract manufacturing organizations, glass manufacturers, medical equipment providers, engineering firms, beverage industry
- Funders
  - Billions donated by major funding organizations
    - Philanthropic organizations, official development assistance (ODA), government finance and health ministries, private foundations and individuals

PRODUCT DEVELOPMENT PARTNERS HAVE LAUNCHED MORE THAN 20 PRODUCTS IN THE LAST DECADE

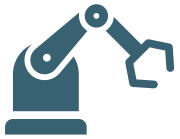
Drugs
ASAQ (DNDi with Sanofi)
ASMQ (DNDi with Farmanguinhos)
Pediatric Benznidazole (DNDi with Brazil lab)
Paromomycin (iOWH)
Coartem® Dispersible (MMV with Novartis)
Injectable artesunate (MMV with Guilin Pharmaceuticals)
Eurartesim® Dihydroartemisinin-piperaquine (MMV)
Pyramax® (pyronaridine-artesunate) (MMV with Shin Poong)
Sayana Press (PATH with Pfizer)
Sino-Implant (II) (FHI-360 with Shanghai Dahua Pharma)
Vaccines
MenAfriVac (MVP with Serum Institute)
Shancol(IVI with Shantha)
JE Vaccine India (PATH with CNBG)
Rota Vac 20C (PATH with Bharat)
Euvichol (IVI with Eubiologics)

Diagnostics
Xpert MTB/RIF (FIND with Cepheid)
Liquid culture & DST (FIND with BD)
Rapid speciation for MDR TB (FIND with Tauns, Co)
LPA line probe assay (FIND with Hain Lifescience
Fluorescence microscopy (FIND with Carl Zeiss)
CareHPV (PATH with Qiagen)
KalazarDetect (IDRI with InBios)*
2nd Generation HAT diagnostics (FIND with Standard Diagnostics)
SD Bioline Oncho 1gG4 RDT (PATH with Standard Diagnostics)
New Regimens
NECT (Nifurtimox Eflornithine Combination Therapy) (DNDi)*
SSG & PM VL combination therapy (DNDi)
Four combination therapies based on AmBisome®, miltefosine, and paromomycin (DNDi)

BASED ON 20 YEARS OF EXPERIENCE WORKING WITH DCVMS, WE HAVE LEARNED LESSONS THAT CAN HELP INFORM INITIATIVES

Challenge to sustain sites

- Great risk of the falling into a **"panic/neglect" cycle**
- Any new effort must **move from a build and decay to build and sustain response** capable of sustaining operations outside long-term donor / government support



Need latest, flexible technology

- **Facing competition from more technically advanced and cost-efficient methods**
- Programs should be designed with the flexibility needed to accommodate future innovation (e.g., mRNA, modular manufacturing)

Lack of governance can lead to inequity

- Lack of **clear rules and governance protocols** for pandemic times can lead to chaos
- need to establish protocols in non-pandemic times to ensure pandemic product changeover processes

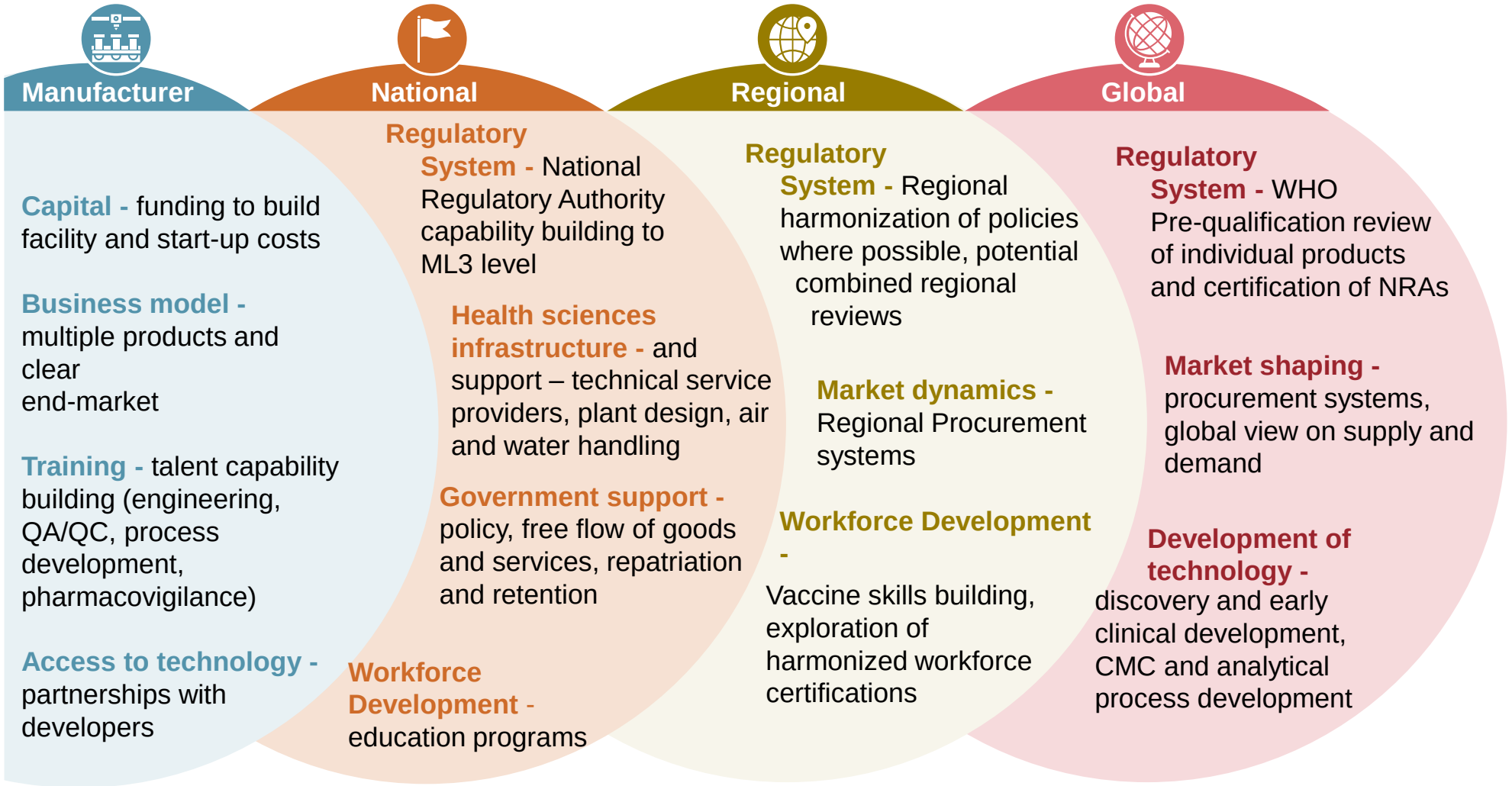
Need everyone at the table

Involvement of multiple and different stakeholders including international organizations, national governments, and private sectors groups

Strong capabilities and commitment are needed

When there were capability gaps at the manufacturer, creating a **product development partnership** to augment expertise led to success

MULTIPLE COMPONENTS OF A VACCINE MANUFACTURING ECOYSTEM ARE NEEDED FOR SUCCESSFUL REGIONAL MANUFACTURING



- Each component of the ecosystem is required for a functioning manufacturing ecosystem that delivers high quality vaccines
- **Coordination among donors is essential to achieve this ecosystem**


If you want to go fast,
go alone.
If you want
to go far,
go
together.
- african proverb

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WE ENVISION A
WORLD WHERE
EVERY
PERSON
HAS THE OPPORTUNITY
TO LIVE A HEALTHY,
PRODUCTIVE LIFE

THANK YOU

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