

# HOW PARTNERSHIPS ACROSS SECTORS CAN REINVIGORATE THE VACCINE PIPELINE



In association with





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Wellcome, an independent charitable foundation, supports research to improve health across the world. We support researchers, take on big health challenges, campaign for better science, and help everyone get involved in science and health research. Wellcome funds thousands of scientists and researchers around the world at every step of the way from discovery to impact through our funding schemes.

We also identify priority areas in which we want to see, lead and be accountable for significant change to transform the global response to some of today's biggest health challenges. One of these is Wellcome's Vaccines Programme. Vaccines are among the most successful and cost-effective healthcare interventions in human history, freeing people and entire populations from the fear of many infectious diseases.

But there are many life-threatening diseases that we don't have vaccines for – and some of the vaccines we do have are not as effective as they should be.

That's why Wellcome is working to support more effective ways to develop new vaccines and to enable better, broader use of the vaccines that already exist. We are working with partners to speed vaccine development, ensure it is relevant to vulnerable populations and that new and existing vaccines reach all those who need them.

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**“ALL KEY PLAYERS IN THE FIGHT AGAINST INFECTIOUS DISEASES MUST MOVE BEYOND BUSINESS-AS-USUAL APPROACHES AND FIND WAYS TO COME TOGETHER TO DEVELOP AND DELIVER NEW VACCINES.”**

## HOW PARTNERSHIPS ACROSS SECTORS CAN REINVIGORATE THE VACCINE PIPELINE

We have made enormous progress over the last few decades, but the scale of vaccine innovation, production and delivery needed to achieve global immunization goals by 2030 is significant. Building on the World Health Organization's [Global Vaccine Action Plan](#), which promotes equitable access to vaccines and runs up to 2020, the [UN Sustainable Development Goal for health](#) commits the world's governments to making sure everyone has access to essential vaccines that are safe, effective and affordable by 2030.

To achieve this, there are numerous regional and national immunization plans up and running. But there is potential to save many more lives and we can do much more. No one organization or sector can address this huge public health need alone. Partnerships can play a vital role in maintaining our momentum to achieve the goals the international community has set itself in relation to eradicating disease and promoting immunisation.

All key players – whether governmental, non-profit, philanthropic, academic or industrial – must move beyond business-as-usual approaches and find ways to come together to develop and deliver new quality vaccines. If common ground can be found between organizations in different sectors, then partnerships can be hugely successful and could reinvigorate the vaccine pipeline and advance global immunization efforts.



## INCENTIVE PROBLEMS IN THE VACCINE PIPELINE

Over the last few decades, many vaccines have been developed, saving millions of lives. Since its inception in 2000, [Gavi, the vaccine alliance](#), has contributed to the immunization of nearly 700 million children and prevented more than 10 million future deaths.<sup>2</sup>

The majority of death and illness caused by infectious diseases could be prevented, either through the broader use of existing vaccines or through the development of new vaccines, such as for TB or malaria.<sup>3</sup> However, the global vaccine pipeline as it currently works is unable to fully meet the vast global need for vaccines.<sup>4</sup> This is because of the limited, or sometimes total lack of, economic incentives for companies involved in vaccine manufacturing.

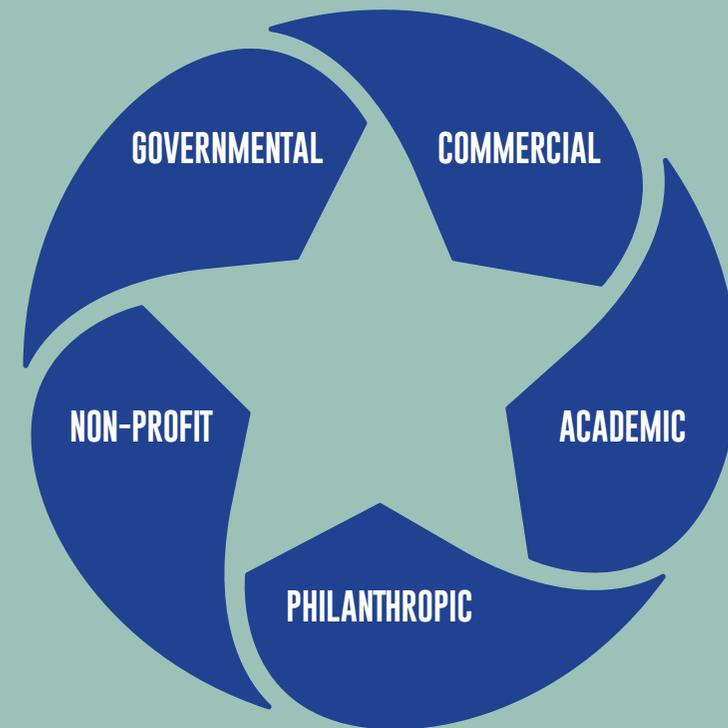
Firstly, for many diseases, the major burden is in low- and middle-income countries (LMICs) where there are limited commercial markets.<sup>5</sup> This is in contrast to diseases that are more of an issue in countries with larger commercial markets, such as seasonal flu or rubella, for which licensed vaccines exist, or respiratory syncytial virus (RSV), for which vaccines are being developed. Secondly, the most feasible vaccines have already been developed and now the biggest vaccine

priorities are more difficult pathogen targets, including HIV and malaria. In such cases, it may be harder to identify which pathogen component to target or to find a population suitable for carrying out trials, or the likely protection achievable may only be partial. Such obstacles mean that the costs of R&D may be higher and the eventual market may be less clear.

Thirdly, global vaccine manufacturing is based on tightly scheduled and well refined processes to maximize effectiveness. When responding to an urgent threat like an epidemic or a vaccine shortage, companies must make tough decisions on whether to change profitable production lines and move people and resources onto projects with an uncertain commercial market and no guarantee of success. MSD stepped up during the West Africa Ebola outbreak in 2014-16, giving the world an effective vaccine that has saved many lives and strengthened the international response to this deadly disease, but we cannot expect businesses to work purely on goodwill.

To overcome these problems, and to develop and deliver the much-needed vaccines of the next few decades, we need a new system that incentivizes partnerships across sectors – commercial, governmental, non-profit, philanthropic and academic. Working together, we need to find new approaches to research, development and production, approaches that can leverage the expertise and resources of a wide range of organizations.

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## **SUCCESSFUL NEW PARTNERSHIPS FOR VACCINE R&D**

Thankfully, models of collaboration have been evolving that bring together the strengths and expertise of key players. These partnerships are demonstrating ways to work towards a supply of vaccines for public health needs that is more systematic and sustainable.

At Wellcome, our experience in recent years has shown us the value of cross-sector partnerships. Different types of organization offer different sets of expertise and different ways of thinking and working. By collaborating, we can take on problems that we could not solve alone.

**“ BY COLLABORATING, WE CAN TAKE ON PROBLEMS THAT WE COULD NOT SOLVE ALONE. ”**

One example of this is the [Coalition for Epidemic Preparedness Innovations](#) (CEPI), which brings together governments, industry, philanthropic organizations and academia to catalyze vaccine R&D for epidemic diseases where there is a limited commercial market.

CEPI was set up following the West African Ebola epidemic, which exposed serious flaws in the world's capacity to prepare for, and respond to, outbreaks. That epidemic stimulated unprecedented ad-hoc collaboration to develop and test vaccines within a year. But even this was too slow to prevent the loss of thousands of lives, and it cost billions of dollars. It is also an unsustainable approach.

What CEPI aims to do is to get Phase 1 and Phase 2 clinical studies completed before any outbreak occurs. The ultimate goal is that a vaccine could be mobilized much more quickly in an outbreak, as seen in DRC for the Ebola VSV vaccine. CEPI demonstrates how partners from different sectors can collaborate when they have a shared goal, and as its work progresses it will support and coordinate activities to improve our collective response to epidemics, strengthen capacity in countries at risk, and advance the regulatory science that governs product development.

It is still early days for CEPI, but it has already galvanized public and private sector investors to work together to tackle unmet public health needs, by mobilizing investment in early-stage research and development for epidemic diseases such as Nipah, Lassa and MERS-CoV. There are likely many more successes to come, and this collaborative model has the potential to be used for other diseases where there is a limited commercial market.

Another model of partnership is demonstrated by the Hilleman Laboratories, based in India. It is an equal joint-venture partnership between MSD and Wellcome, carrying out vaccine R&D focused on the needs of LMICs. Hilleman's scientific teams are working to create new vaccines in areas of unmet need as well as adapting existing and novel vaccines for more effective delivery in these countries.

Current R&D programs include developing an easy-to-administer oral cholera vaccine and a variety of conjugate vaccines targeting invasive bacterial diseases. Through Hilleman, two organizations have come together with a common goal, combining their strengths to think about new, innovative ways in which vaccines can be developed for those who most need them and can least afford them.

## **COLLABORATING TO DELIVER VACCINES TO THOSE MOST IN NEED**

While the stories of CEPI and Hilleman Laboratories highlight the value of working together at the early stages of development, the later stages of the vaccine pipeline can also benefit when organizations pool expertise and align resources.

A case in point is the MenAfriVac<sup>6</sup> vaccine for meningitis A, the result of a partnership initiated in 2000 between the Bill & Melinda Gates Foundation, the World Health Organization and the Serum Institute of India. Together, they developed an affordable, effective vaccine based on the specifics of the disease and the people and countries most in need, and got it into widespread use across the target population.

To achieve this, the partnership engaged with governments and citizens in the African meningitis belt early in the process, to understand how local populations perceived the issues surrounding meningitis vaccination and to identify their unmet needs. Then they made sure that the policies needed to use the vaccines would be developed and implemented; this included finding a manufacturer (the Serum Institute of India) that could meet

the price needs. And they involved the target population in the vaccine rollout, for example by working with local communities and investing in local communications to spread the word.

Underpinning the success of the partnership was a shared focus on developing a vaccine that worked for the local communities. Another collaboration that has supported progress in later stages of the vaccine pipeline is the International Vaccines Initiative's (IVI) oral cholera vaccine.

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The development of this vaccine was made possible due to a public-private partnership that worked to bring manufacturers in LMICs on board to lower the cost of vaccine production. IVI worked with Shantha Biotechnics to perform clinical trials to demonstrate safety and efficacy, but also to develop a global access agreement to ensure the vaccine could be affordable in LMICs. Shantha agreed to provide the vaccine at an affordable price to the public sector. As with MenAfriVac, it was beneficial to shift the center of gravity for vaccine production away from high-income countries.





## **REIMAGINING HOW WE WORK TOGETHER**

Partnerships across sectors can allow everyone involved to play to their strengths in a way that advances progress on global health goals. In CEPI, for example, each partner plays a specific role, bringing together the skills and resources of industry, academia and the public health sector.

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Some technical and creative differences will be inevitable, as different partners come from different directions and operate in different styles. Good communication between partners is key, to develop a shared goal and agree which partners will do what, along with how and why, when and where, and at what cost. By accepting from the start that there are bound to be tensions, partners can build resilience and understanding so that they can overcome these tensions constructively.

Progress made by recent partnerships is encouraging. Reimagining and redesigning how we can work together is vital if vaccines are to be developed and delivered to the people who most need them.

New types of partnership become even more important as the future of public health initiatives move into more challenging areas where coordination and combination of multiple interventions needs to be considered, such as the use of bed nets and other therapeutics alongside malaria vaccines.

This growing set of new approaches to partnerships is timely, as global health actors discuss how resources and strategies can be aligned for maximum impact and what should form part of post-2020 global vaccines strategy development. There is more work to do and everyone has a role. Arguably, there is no unmet vaccine need where cross-sector collaboration would not be beneficial.



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## IMAGES

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