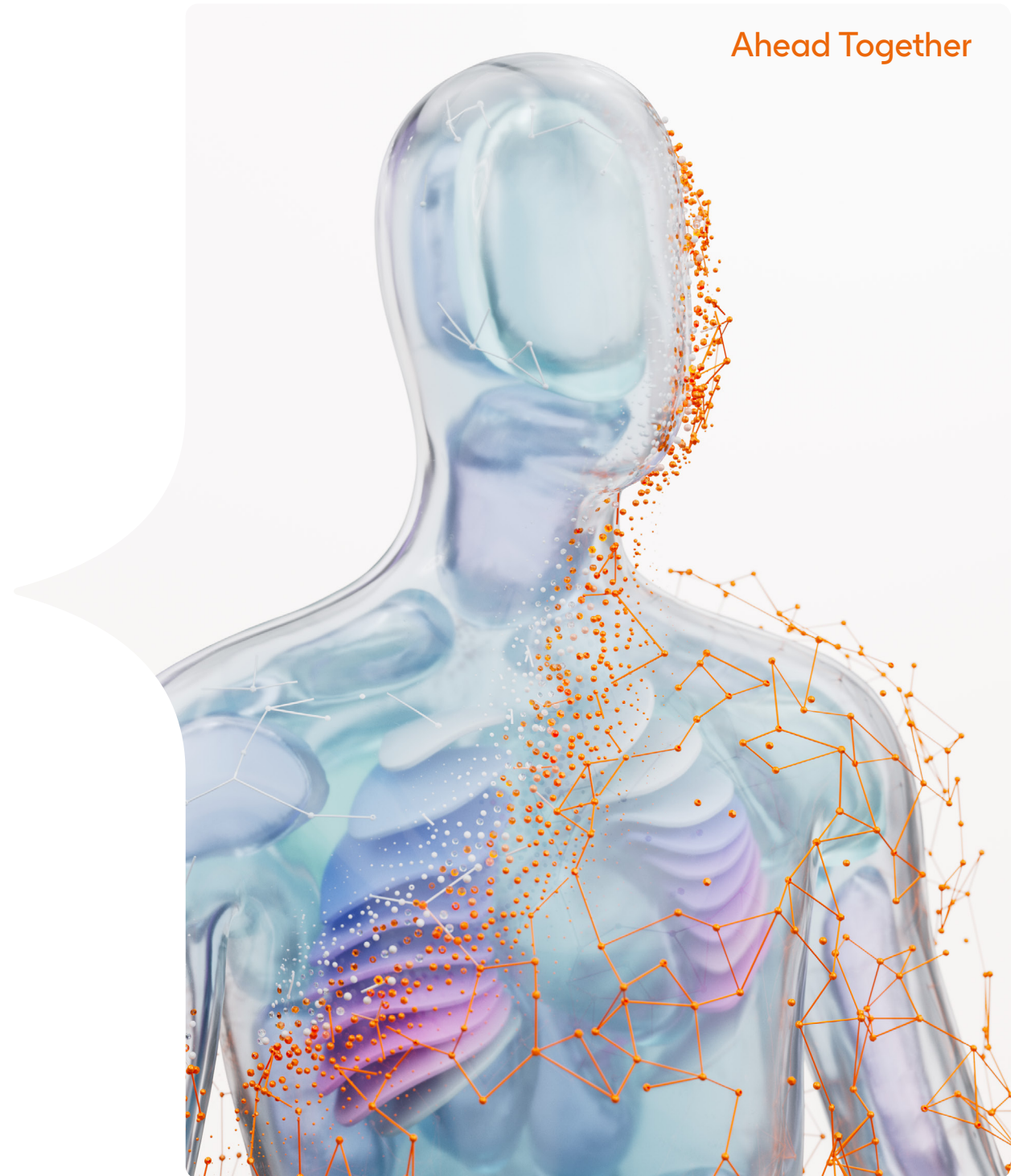




GSK's Global Health commitment: Our approach to delivering sustainable and equitable access

February 2024

Ahead Together



The Global Health challenge and GSK's ambition

Infectious diseases continue to be some of the leading causes of death in lower income countries. People living in lower income countries continue to be disproportionately impacted by infectious diseases (IDs), and amongst the biggest drivers of morbidity and mortality are tuberculosis (TB), malaria, HIV, anti-microbial resistance (AMR),

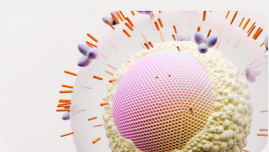
as well as other IDs. Neglected Tropical Diseases (NTDs) affect the poorest and most marginalised in lower income countries and when left untreated result in poor health outcomes and morbidity, higher mortality in coinfections with other infectious diseases, stigma-related mental disorders, and exacerbated social inequalities.



TB: 10.6m people fell ill with TB and 1.3m people died from TB in 2022, with south-east Asia experiencing the highest burden. Although TB should be preventable and curable, it is the second leading infectious disease killer after COVID-19; multi-drug resistant TB is a growing public health and security threat.



Malaria: With almost half the global population at risk of malaria and 249m cases and 608,000 deaths annually, children under the age of five bear the burden of disease, accounting for 80% of malaria mortality in Africa.



HIV: In 2022, 39m people were living with HIV, 1.3m people acquired HIV and 630,000 died from HIV-related causes. Almost three quarters of people living with HIV live in low and middle income countries, with a significant proportion in the Africa region – but there are major vulnerabilities right across the world.



Anti-microbial resistance (AMR): Is one of the top health threats. Accountable for 1.27 million deaths worldwide. AMR is particularly prevalent in low-resource settings – deepening existing health inequities and risking the efficacy of current medicines and vaccines to fight diseases. Left unchecked, by 2050, up to 10 million deaths could occur because of AMR annually. AMR could take US\$ 3.4 trillion off GDP annually and push 24 million more people into extreme poverty in the next decade.



Neglected Tropical Diseases (NTDs): Ever year, 200,000 people die from neglected tropical diseases (NTDs), and 19m disability adjusted life years (DALYs) are lost. Women and children, and poorer communities are at particular risk, with 16 low-resource countries bearing 80% of the total burden.

GSK believes that focusing on prevention and treatment of infectious diseases is a critical part of the global response to address health challenges in lower income countries. Alongside improving health outcomes, providing sustained access to health products that prevent and/or treat these infectious diseases also has an impact on wellbeing, education, and economic outcomes.

This is why GSK has laid out a bold ambition to positively impact the health of more than 2.5 billion people worldwide, including more than 1.3 billion people in lower income countries. It is also why GSK's Global health organisation aims to change the trajectory of high burden diseases in lower-income countries with a focus on infectious diseases. **In order to achieve this, we focus on malaria, TB, and AMR, as well as HIV through ViiV Healthcare.**

This document outlines our Global Health Access Model, which guides our approach to achieving sustainable, and equitable access to our products.

GSK's Global Health Access Commitments

Access to health products is complex and multifaceted.

As innovative health products for treatment and prevention are brought to market, a deeper understanding of both the supply factors (including manufacturing processes, costs and investments) and demand factors (including service delivery models, and novel implementation approaches) by all stakeholders will increase the acceptability and global impact of promising new interventions. The pricing of health products is important. There are also many other significant barriers including availability of healthcare resources, lack of medical facilities, fragile distribution networks, limited numbers of trained healthcare providers, low levels of health literacy, significant stigma and discrimination, a lack of political will and inadequate prioritisation of immunisation and disease programmes in government budgets.

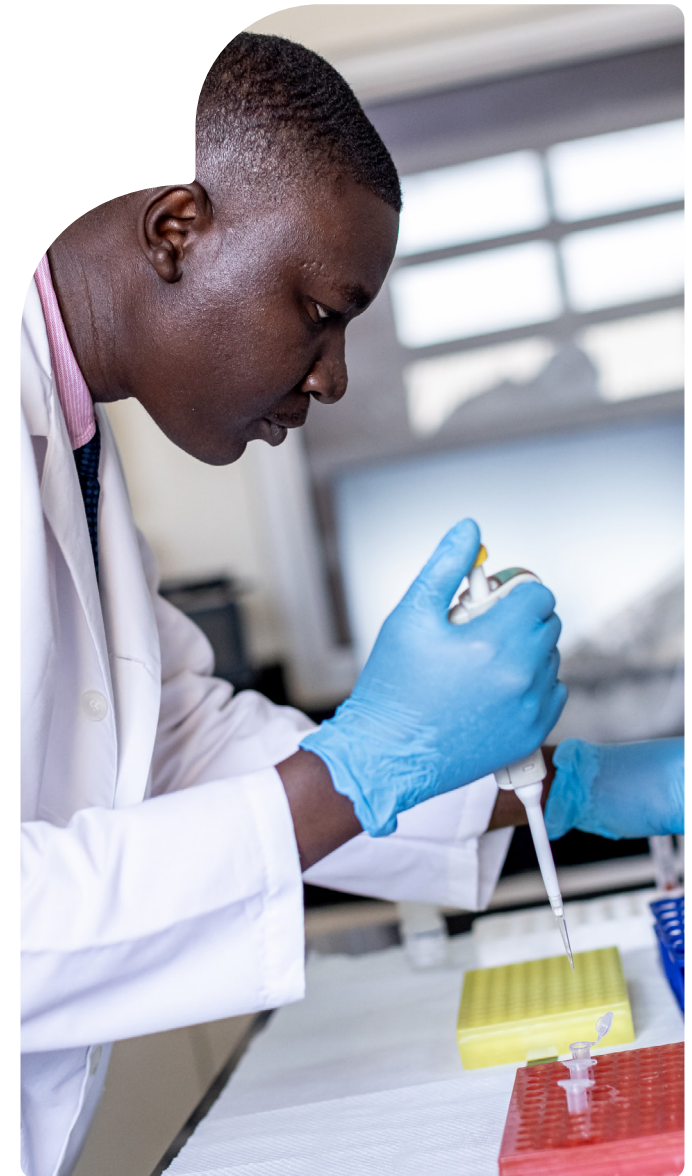
GSK is working to address some of these challenges. They can only be effectively addressed if all sectors of society – governments, international agencies, civil society, academic institutions, the pharmaceutical industry, regulators and the wider private sector, among others – work collaboratively to tackle them.

GSK Global Health works along the product development-access to patient pathway, from R&D to implementation at scale. We invest in infectious disease R&D that responds to and is tailored to lower income countries' needs, starting access planning early and developing **product access strategies** focusing on accessibility, availability and affordability, and we support **health system strengthening and capability building initiatives**.

We are renewing our commitment to expand access to vaccines and medicines from both GSK Global Health assets – which are developed to respond to high burden disease in lower income countries, like malaria and TB, as well as relevant GSK commercial products – which are selected because of their potential high health impact in lower income countries, like rotavirus, pneumococcal and cervical cancer vaccines. We are [systematically evaluating our pipeline and portfolio](#), in consultation with global health partners, to focus on opportunities for sustainable impact in lower income countries.

We take a partnership approach and work with organisations who bring complementary capabilities every step along the way, from early research to product introductions, to ensure that our innovations are fit for purpose and achieve maximum health impact at scale in lower income countries.

We believe that multi-stakeholder engagement and early planning and coordination across partners are critical to ensuring access. Together, we work on priorities that are aligned to and support global priorities and targets set by organisations including WHO, Gavi, and Global Fund and integrated into the Sustainable Development Goals (SDGs). Our strategy is also informed by feedback and input from communities and patient groups at the country level.



Research

New tools are required to reach the global goals for key infectious diseases like HIV, TB, and malaria and diseases driving AMR. Through our two dedicated Global Health R&D centres in Tres Cantos, Spain, and Siena, Italy, we are committed to researching and developing new global health vaccines and medicines.

During the Global Health R&D process we **align product development priorities to high burden unmet medical needs in lower income countries, R&D priority setting** processes for global bodies such as WHO and Africa CDC, and WHO preferred product characteristics (PPCs), as well as guidance from key policy setters such as PDVAC and SAGE for vaccines. We start **access planning** while projects are still in early R&D phase and **work with researchers and listen to patient groups in the most affected regions, countries and communities to listen to the local needs and priorities and ensure our products are relevant, tailored to local needs and appropriate for target populations**, particularly in the Global South.

To sustain our ambition to change the trajectory of infectious diseases in lower income countries, we are continuing to invest in infectious disease R&D. In 2022 GSK announced an **investment of £1 billion over the next decade in Global Health R&D**. This investment will help to develop 30+ potential new vaccines and medicines across 13 high-burden

infectious diseases, including next generation vaccines and medicines for malaria, TB, HIV, and an industry-leading pipeline for vaccines against pathogens driving AMR.

To bring this ambition to life, we are also committed to a variety of **R&D partnerships and collaborations with a range of stakeholders** including healthcare professionals, research networks, academic institutions, global health organisations (such as Carbex, BMGF, Gates MRI, Wellcome Trust, WHO, Unite4TB). We also engage in partnerships to share risks in R&D and encourage innovation including Product Development Partnerships (PDPs), such as the Medicines for Malaria Venture (MMV), the TB Alliance and the Drugs for Neglected Diseases Initiative (DNDi).

In addition to developing specific products for lower income countries, we invest in innovations that help make our relevant commercial GSK products more accessible in lower income countries, for example by developing appropriate modes or formulations or administration (e.g., vaccines, tablet, patch, liquid medicine, as well as 10-dose vial Vs 1-dose vial) that help either to lower the cost and/or facilitate the product delivery and acceptability to patients.



GSK's Global Health Access Commitments continued

GSK and ViiV commitments to developing paediatric formulations

We are committed to the **development of paediatric formulations** of our global health medicines in accordance with global health priorities. By GSK and ViiV working together, pooling resources and knowledge, we accelerate the development of innovative treatments and consider the development of paediatric formulations in a parallel rather than sequential way.

ViiV is fully committed to the **development of paediatric formulations of medicines** in accordance with global health priorities which are shared by the Paediatric ARV Drug Optimisation (PADO) Working Group led by the World Health Organisation (WHO).

ViiV received FDA approval for an integrase inhibitor in 2013 and by 2016 also received approval for a paediatric formulation. A collaborative partnership significantly accelerated development and registration of generic, paediatric dispersible products with the gap between FDA approval of innovator and generic products reduced from years to months. The generic paediatric version was launched at an affordable and sustainable price and is enabling greater access for children living with HIV in low- and middle-income countries.

In GSK we are working to ensure that our new global health products have paediatric formulations and regulatory approvals – including for tafenoquine, our single dose radical cure for *P.vivax* malaria. Tafenoquine was co-developed by GSK and MMV and was first approved by the US FDA for the radical cure of *P. vivax* malaria in July 2018 for use in adults and adolescents. In 2021, the Australian regulatory authority (TGA) accepted the extension of the indication of tafenoquine to paediatric populations for a lower dose dispersible tablet.¹



¹GSK, MMV filing for Kozenis (tafenoquine) in paediatric populations with *Plasmodium vivax* malaria accepted by Australian Therapeutic Goods Administration | GSK



Product access strategies

Ensuring more equitable access (i.e., access to products in lower income countries at the same time as in high income countries) can save lives, prevent disease, and improve health outcomes.

We take several tailored approaches to support product access through strategies including: tiered pricing; donations; NGO supply; voluntary licencing; and technology transfers agreements. We partner with those who have the right capabilities, reach and local knowledge to ensure our products reach people who need them.

We enable access to products in lower income countries by focusing on the following areas: **accessibility, affordability, and availability.**

Product access strategies continued

Accessibility

We are committed to making impactful GSK products more accessible in lower income countries by contributing to a supportive global and national policy environment and ensuring awareness and evidenced based decision making for our products. We will also pursue WHO prequalification for products where there is a high burden of disease in lower income countries and to ensure access at scale. WHO prequalification is a mandatory prerequisite for procurement and supply through United Nations agencies, such as UNICEF.

We are committed to **systematically evaluate 100% of our current and pipeline global health and commercial assets** to identify products that have potential global health impact (i.e., that are appropriate and will benefit lower income settings e.g. have a high burden of disease, high unmet medical need, a feasible path to patients and are a priority to global health stakeholders). For products that are identified to have global health impact, we will develop and implement access plans for products in late development (starting in Phase II). Early end to end access planning takes into consideration clinical development strategies; potential clinical sites in lower income countries; regulatory, manufacturing, pricing and partnering strategies.

To help accelerate product access, we will **register our impactful products in lower income countries with a high burden of disease**, where health care systems are able to support programme implementation.



Product access strategies continued

Availability

For global health and prioritised commercial assets, we commit to **developing manufacturing strategies to ensure sufficient supply for lower income countries.**

Strategies may include in-house manufacturing or assess alternative business models and manufacturing strategies that may include voluntary licensing – and are based on demand forecasts that are developed in consultation with countries and partners.

We deploy a range of manufacturing strategies. We manufacture many products in-house. This is the model we mostly use for assets we supply on a global scale. This allows us to achieve efficiencies and economies of scale – which in turn enables lower prices for lower income countries. We also use voluntary licences for the manufacture and supply of products to lower income countries, e.g., ViiV for some HIV products.

For Global Health products, our model is to work in partnership with emerging market manufacturers (e.g. products supplied exclusively to lower income markets or for diseases predominantly in lower income countries). We have long-term partnerships that enable the **transfer of technology to emerging market manufacturers** for instance as with vaccines for malaria and typhoid, which are licensed for endemic countries. GSK's typhoid conjugate vaccine was out-licensed to the Indian pharmaceutical company Biological E in 2013. As part of this partnership, Biological E ran the Phase III trials, and now manufactures and distributes the vaccine. It has so far been administered to more than 23 million children.

For global health products that we have transferred or licenced, we continue to play an active role in ensuring access in areas where GSK is well positioned to do so.

We believe in the impact of our products and want to support their successful introduction and implementation in long term sustainable programmes.

Intellectual property and Voluntary Licences

We believe that intellectual property (IP) stimulates and underpins continued investment in research and development for new and better medicines and vaccines. Therefore, improving access to treatments in developing countries requires a flexible and multifaceted approach to intellectual property (IP) protection. In March 2016, [GSK and ViiV, evolved our graduated approach to filing and enforcing patents so that IP protection reflects a country's economic maturity.](#) We therefore no longer file patents for our medicines, or enforce historic patents, in Least Developed Countries (LDCs) and Low Income Countries (LICs).

Generic companies can manufacture and supply generic versions of our medicines in those countries. For non-G20 Lower Middle-Income Countries (LMICs), we may file for patents but we are open to offering licences to allow supplies of generic versions of our medicines where we believe this will enable access. For other countries, our approach to seeking patent protection will be in accordance with our commercial strategy.

While Voluntary Licences (VLs) may not enable broader access in all circumstances, they have clearly demonstrated a significant and sustainable impact in tackling the global HIV epidemic in appropriate settings. ViiV Healthcare is committed to providing VLs for ARVs where it can be established that they will improve affordability and supply of our medicines in LICs, LDCs, LMICs and SSA countries. ViiV Healthcare utilises direct VL approaches with generic manufacturers as well as partnering with the United Nations-backed Medicines Patent Pool (MPP). In situations where VLs are not viable, we are committed to exploring alternative mechanisms and working through partnerships to enable clinical need-driven access determined by global public health priorities.



Product access strategies continued

Affordability

As part of our Global Health ambition, we are committed to price our assets to support broad access and impact in lower income countries. We do not expect to make a profit from sales in lower income on our global health products, but to ensure sustainable long-term access and reliable supply. In some specific cases we have made commitments to donate products, for example we have a long standing albendazole donation programme through which we have supplied more than 11 billion tablets to help treat and eliminate lymphatic filariasis and treat soil-transmitted helminths.

We support equitable access to impactful GSK products by implementing **responsible pricing strategies** based on a country's ability to pay. For example:



[GSK has a tiered pricing policy for our vaccines that address public health needs in low and middle income countries sold through public and private channels.](#)

This means that we offer countries prices based on their income levels (measured by Gross National Income and World Bank income classifications) rather than a single flat rate. Today, the lowest income countries such as those countries supported by Gavi, the Vaccine Alliance, have access to our lowest prices. As the Gross National Income (GNI) of countries increase and they transition away from Gavi support, we have committed to a price freeze that ensures they continue to access the lowest price for ten years from the time of transition.

We believe government-led programmes offer the best opportunity for implementing long term and sustainable vaccination programmes. However, humanitarian emergencies may limit a government's ability to deliver health services. In these circumstances, we work with partner organisations to help coordinate, manage and respond to vaccine supply requests from Civil Society Organisations (CSOs) and international organisations such as MSF and International Organisation for Migration (IOM). This includes the WHO Humanitarian Mechanism, which facilitates access to affordable vaccines in humanitarian emergencies.

Case study Gavi partnership

GSK has also been a partner of Gavi, the Vaccine Alliance, since its creation two decades ago. GSK science underpins our relationship with Gavi and our ability to supply needed vaccines for the world's poorest children. GSK is one of the largest suppliers of vaccines to Gavi: we have supplied Gavi with more than 1 billion doses of vaccines since 2010. As a Gavi partner, we are proud to have played an important role in swiftly introducing and rapidly scaling up access to new vaccines, such as pneumococcal, rotavirus and HPV vaccines, that might otherwise have taken years to reach children in low-income countries.

Gavi has dramatically expanded the global reach of immunisation by building reliable markets for vaccines in lower income countries by providing visibility on demand and ensuring secure financing for the procurement of large volumes of vaccines. In turn, GSK and other pharmaceutical companies have risen to the challenge, investing extensively in capacity to supply those vaccines at scale over the long term. This is exactly how a public-private partnership is meant to work — each partner plays a unique, complementary and critical role, and working together we can sustainably achieve better health worldwide.



Health system strengthening and capability building

Global health impact requires health services and products reaching people who need them – but significant inequities in access to health services and prevention and treatment products continue. **That is why work with partners on health systems and community capacity strengthening activities to catalyse community and locally led solutions for better access to services and more effective healthcare delivery and uptake including delivery of primary care services, uptake of products, healthcare worker training, research, and surveillance and beyond.** We help to create a supportive environment for patients to improve health outcomes, we also focus on reducing human rights and gender-related barriers, including stigma, discrimination and criminalization, which increase vulnerability and limit access to products and services.

Health system strengthening and capability building continued

Community health services capacity building

GSK has worked for many years in partnership with NGOs, community based organizations, local leaders and governments. In the last two decades, we have trained over 175,000 community health workers recognising their importance as part of a functioning health system and reaching over 17 million people. Our partners include:

For over 35 years, GSK has been a prominent supporter of Amref's mission to make lasting health change in Africa by working closely with the full ecosystem from communities to governments to international organisations. In the last decade, GSK has partnered with Amref and Ministries of Health to support the training of frontline health workers in the prevention and treatment of infectious disease, immunisation, maternal and child health and hygiene.

GSK's partnership with Save the Children has reached the 10 year milestone where together we want to bring us closer to a world where no child suffers from a disease that could be prevented by vaccines.

GSK and ViiV Healthcare are supporting the Positive Action programme and the Global Fund for AIDS, TB and Malaria to catalyse community engagement for gender equality by empowering women, girls and gender-diverse communities impacted by HIV, TB, and malaria. This builds upon ViiV's Positive Action programme that has supported communities affected by HIV and AIDS since 1992, creating strategic partnerships and offering community grants the enable organisations to create long term change for communities affected by HIV.

Research and clinical capacity strengthening

Through the Project Africa Genomic Research Approach for Diversity and Optimising Therapeutics (GRADIENT), GSK and Novartis are supporting quality scientific research investigating the link between genetic diversity across different regions in Africa and its potential impact on the treatment of malaria and TB.

Through the Africa Open Lab programme, we back early career researchers with grants and capability strengthening, supporting the next generation of African scientific leaders working innovative infectious disease research on the African continent.





Case study TB vaccine

GSK has developed a tuberculosis vaccine candidate (M72) which has demonstrated in a phase IIb trial the potential to reduce active pulmonary TB by half in adults with latent TB infection. M72 was developed by GSK in collaboration with IAVI. Funding for research which uncovered the potential of M72 was provided by the United Kingdom's Department for International Development (DFID), the Directorate-General for International Cooperation (DGIS) in the Netherlands, the Australian Department for Foreign Affairs and Trade (DFAT), the European Commission and the Bill & Melinda Gates Foundation.

GSK awarded the Bill and Melinda Gates Medical Research Institute (Gates MRI) a non-exclusive license to continue the development of the TB vaccine M72/AS01E, for lower income countries with high TB burdens. Together with the Wellcome Trust, they will invest approx. \$550 million to fund the Phase 3 trial. If proven effective, M72 could potentially become the first new TB vaccine that meets the WHO target product profile for over 100 years.

Case study

RTS,S/AS01 Malaria vaccine

During more than 35 years, GSK, in partnership with many organisations including PATH, researched and developed the malaria vaccine, RTS,S/AS01, the first vaccine to help protect children against the deadliest form of malaria, *P. falciparum*, licensed for use in endemic countries.

As part of the Phase III trial conducted with African research partners at 11 research centres in 7 sub-Saharan African countries, we worked closely with African research centres and supported in-country research capacity. The involvement of African research partners has been important for countries' evidenced-based decision making for the introduction and implementation of the vaccine.

The vaccine was recommended for use by WHO in 2021 after Malaria Vaccine Implementation Programme (MVIP) studies in Ghana, Kenya and Malawi and has been shown to be well tolerated in severe malaria and a fall in child death. Since 2019, Ghana, Kenya and Malawi have been delivering the malaria vaccine through the MVIP, implemented by Ministries of Health and coordinated by WHO and funded by Gavi, the Vaccine Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Unitaid. The RTS,S/AS01 vaccine has been administered to more than 1.7 million children in Ghana, Kenya and Malawi since 2019. Today the

vaccine is prequalified by WHO, a prerequisite for financing and procurement by UN agencies such as Gavi and UNICEF. The introduction of Gavi funded doses of the vaccine will begin across 12 countries during 2023-2025, including Benin, Burkina Faso, Burundi, Cameroon, Democratic Republic of the Congo, Ghana, Kenya, Liberia, Malawi, Niger, Sierra Leone and Uganda.

We worked with MedAccess and Gavi to develop a new innovative finance instrument to manage risk and allow for the on-going manufacture of RTS,S. This was needed because of the long time-lag between when GSK anticipated finished producing doses for the MVIP pilots, and the uncertainty around if and when RTS,S would be introduced to Gavi programmes. This de-risking tool could be adapted for other vaccines going forward.

To ensure longer term sustainable and affordable supply and reach even more children in malaria endemic areas, a tech transfer is underway with Bharat Biotech of India. The acceleration of this tech transfer will increase supply of the vaccine, with GSK continuing to supply the AS01 adjuvant to Bharat. This tech transfer illustrates our model of sharing the responsibility of bringing innovative medicines and vaccines to patients.

Case study

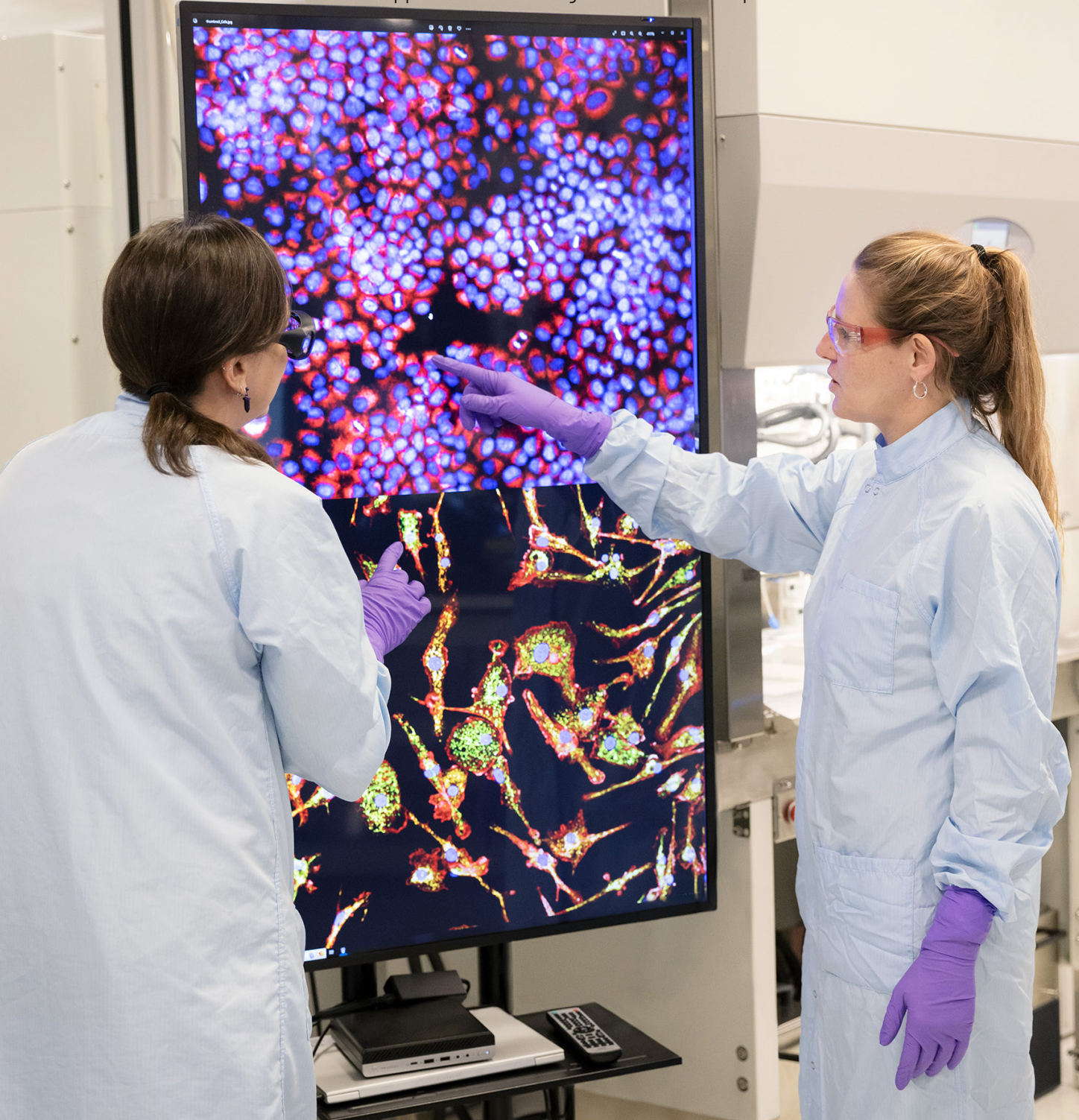
Albendazole donation to help eliminate lymphatic filariasis (LF) and treat soil-transmitted helminths (STH)

The impact of Neglected Tropical Diseases (NTDs) is devastating. 1 in 5 people in the world are at risk of these diseases, which predominantly impact the most underserved communities in the world. They are debilitating, disfiguring, and disabling, and drive inequality by perpetuating cycles of poverty. But many of them can be prevented or treated if those affected can access the medicines they need.

We've been working with the global community to end NTDs since 1999, reaching over 935 million people with our medicines. To date, 18 countries have eliminated LF as a public health problem and 7 countries have eliminated morbidity because of STH.

Albendazole, our medicine used to help eliminate lymphatic filariasis and treat soil-transmitted helminths is our biggest access programme. To date we have donated over 11 billion doses of the medicine. In early 2023 we committed to extend our donation commitment for soil-transmitted helminthiasis (STH) and will donate up to 100 million doses of our medicines for STH per year from 2026 to 2030. This commitment sits alongside our commitment to donate medicines until LF has been eliminated as a public health problem everywhere. We are now beginning to work with WHO and partners to evolve to a hybrid model once donations for public health programmes are no longer needed in countries where the disease is under control.





Conclusion

We are proud of GSK's leadership in Global Health and access, and our commitment to Global Health has been recognised by the Access to Medicines Foundation with our number 1 ranking in the ATMI in all 8 editions..

Achieving universal access to global health treatments and prevention tools is an evolution in which countries will progress at their own pace given domestic needs, capacities and specific disease burden. To succeed, countries must be at the centre of the process, taking the lead in setting the direction needed to develop and execute strategies as well as monitor progress and adapt each national response, where necessary.

GSK is committed to ongoing infectious disease R&D and to enabling the scale-up of access to medicines, treatment, and care. We recognise that achieving universal access to treatments and prevention tools requires collaboration across all parts of society – public, private, and not-for-profit sectors – working together to ensure that global and national goals are met, the SDGs are achieved, and to ensure that no one is left behind. As a world leading infectious disease company with the purpose of getting ahead of disease, we will continue to drive access to our vaccines and medicines to change the trajectory of high burden diseases in lower-income countries with a focus on infectious diseases.