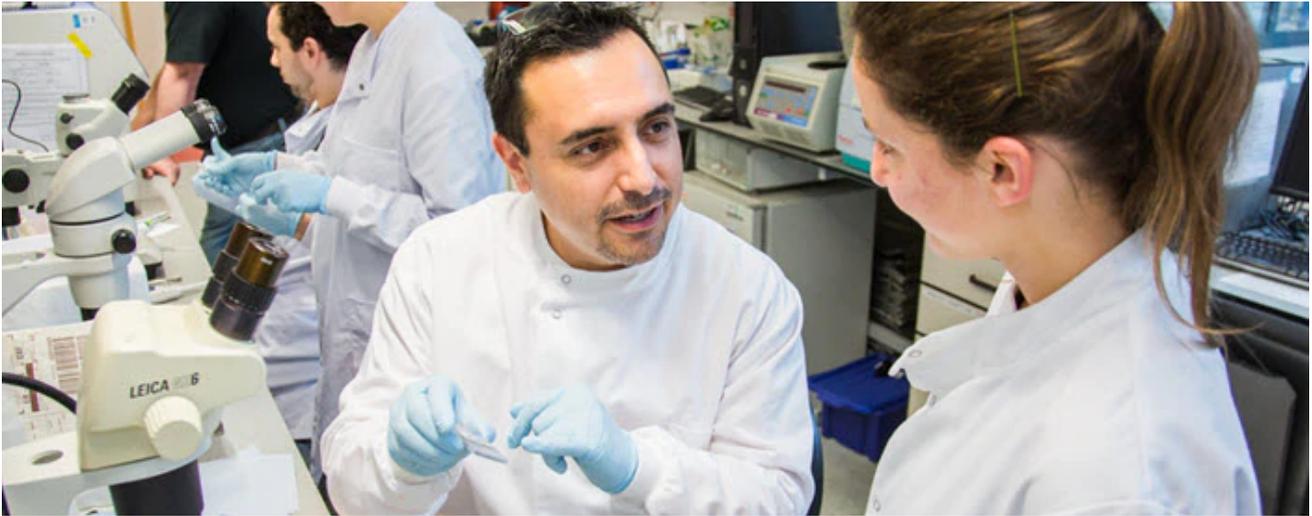


— What We Do —

VACCINE DEVELOPMENT AND SURVEILLANCE

STRATEGY OVERVIEW



Researchers collaborate as part of a team focused on improving vaccines for malaria, HIV and tuberculosis.

OUR GOAL: Advance public goods for global health through technological innovation. We do this by accelerating the development and commercialization of novel vaccines and the sustainable manufacture of existing vaccines, defining the global disease burden through better primary data and world-class modeling, and reducing the threat of epidemics through the development and use of innovative tools.

The Challenge

In global health, the focus we've put on fighting individual diseases has had enormous impact, yet many of the most stubborn challenges we face are shared across disease areas. Whether it's accelerating the development of new vaccines, forecasting the global health challenges of tomorrow, or preparing for epidemics, we must work beyond the scope of one disease area and create durable public goods whose benefits permeate global health.

Vaccines are some of our most powerful tools in combating diseases. Yet despite substantial scientific advances and investment, bringing vaccines to market affordably and reliably remains a challenge. Promising candidates can fail late in development, and existing vaccines can face supply shortages, resulting in wasted time, investments, and missed opportunities to improve human health. The diseases of low-resource settings—whether they are entrenched, like malaria and HIV, or they are the next outbreak pathogen—are often

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AT A GLANCE

Tackling diseases individually won't solve many global health challenges. Working across disease areas allows us to identify the public goods that can accelerate global health impact and reduce the threat of epidemics.

some of the hardest to address scientifically. They are also often the least attractive commercially. These challenges mean vaccine development for low-resource settings will only be successful if we use innovation in technologies, platforms, processes, and business models to accelerate timelines and reduce costs.

Because developing new vaccines is a lengthy and expensive undertaking, it is particularly important that we understand how to prioritize our efforts. Some diseases lend themselves to vaccine intervention. Others, like the neglected tropical diseases, are best tackled through better deployment of existing interventions. And others, like noncommunicable diseases, require non-vaccine approaches. Unfortunately, because the quality of our primary data is so poor, it is difficult to answer questions such as how many deaths a malaria vaccine could prevent. Parents who experience the tragedy of losing a child may never know the true cause of death. The mystery behind these individual tragedies are then accumulated into a public health conundrum, making it impossible for product developers, governments, and funders to effectively prioritize the resources of global and public health.

We believe technical innovation has a critical role to play in the design, development, and deployment of these public goods.

We invest in deep technical expertise and novel platforms in vaccine development and manufacturing to accelerate innovation for better, faster, and cheaper vaccines.

We also invest in building high-quality modeling and forecasting capabilities informed by trustworthy primary data. We make this information public to allow all experts to better prioritize our collective global health resources.

The Opportunity

We believe we can accelerate the impact of vaccines in low-resource contexts by cultivating deep expertise in the vaccine-manufacturing process, quality control, and clinical evaluation. This expertise allows us to advise on more effective vaccine development programs and identify new areas of innovation to benefit multiple disease programs.

In addition to technical expertise, we also need to know which problems are the most important to tackle. Trustworthy primary data and high-quality modeling and forecasting allow us to better prioritize the collective resources of global health. By improving the methods for primary data collection, we can give parents the peace of knowing what caused a child to pass away. We can also enhance the aggregated data that policymakers, health workers, funders, and product developers use to make decisions about innovation and implementation.

Finally, we know we need to address the time it takes to develop and deliver vaccines for epidemics. The urgency of epidemics requires solutions in months or even weeks, whereas traditional vaccine development can take years. Addressing this challenge will take innovation. We need to reimagine the way we use our immune systems to combat disease, allowing us to develop both “just-in-time” vaccines for unknown epidemics as well as a store of “just-in-case” vaccines for the next outbreak.

Our Strategy

We invest in expertise and platform technologies that help us make vaccines faster, better, and cheaper. We also invest in education and training to ensure that knowledge around vaccine development and manufacturing is created, shared, and retained. Some examples of this include:

- adaptive trial design;
- streamlining the schedule and dosing of vaccines;
- novel delivery formats for vaccines; and
- modular, automated manufacturing platforms enabling small-batch vaccine production.

Better data help us prioritize products, which increases our ability to make a meaningful impact. To that end, we fund institutional capacity of world-class modeling to provide critical information about the changing nature of disease in time and space. We also invest in improving the underlying primary data feeding into these models. In some cases, this requires changing how we collect information. For example, the gold standard in assessing cause of death is an autopsy. However, when traditional autopsies are conducted, parents may be unable to preserve their child's body. To address this, our grantees pioneered the minimally invasive tissue sampling (MITS) methodology. We believe MITS, when combined with other elements of a national surveillance system, can dramatically improve the accuracy of investigations on the cause of death. This, in turn, will improve the aggregated data used by public health institutions and industry.

Areas of Focus

The Vaccine Development and Surveillance team is organized into four domains:

Vaccine Clinical domain

Our **Vaccine Clinical domain** provides advice to all of our disease areas on the clinical evaluation of vaccines. It is also the home of our product-development investments on human papillomavirus (HPV)—most notably a series of trials funded to help our partners determine the health impact and cost effectiveness of giving just one dose of vaccine versus the existing schedule of two doses.

Chemistry, Manufacturing, and Control (CMC) domain

To ensure a sustainable supply of high-quality, affordable biologics and vaccines, our **Chemistry, Manufacturing, and Control (CMC) domain** provides advice to all of our disease areas on improving the cost and manufacturability of their vaccines. This domain also invests in a number of platforms to increase manufacturing flexibility, reduce the number of injections through long-acting and slow-release formulations, increase the simplicity of giving injections through novel devices, decrease the cost of vaccine containers, and increase vaccine quality.

Surveillance domain

Our **Surveillance domain** invests to improve the world's understanding of the causes of mortality and disability through three activities: 1) unprecedented pathology-based surveillance through MITS in child deaths; 2) the extrapolation of that data nationwide through Countrywide Mortality

Surveillance for Action (COMSA); and 3) improving the modeling and mapping of global mortality and disease data through the University of Washington’s Institute for Health Metrics and Evaluation (IHME).

Epidemic Preparedness domain

Our **Epidemic Preparedness domain** aims to reduce the threat of epidemics by investing in novel vaccines and rapid-response platforms, innovative surveillance methods, and accountability systems to improve country-level preparedness.

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