Using artificial intelligence (AI) to accelerate vaccine development

PATH is exploring how AI could help identify immune biomarkers used to determine whether a vaccine candidate works

Demonstrating efficacy is critical to achieving regulatory approval of new vaccine candidates. The identification of immune biomarkers can help accelerate vaccine development by serving as a reliable indicator of protection with simple laboratory tests and eliminating the need for lengthy clinical trials. However, discovering and validating these immune biomarkers is a highly complex and time-consuming process.

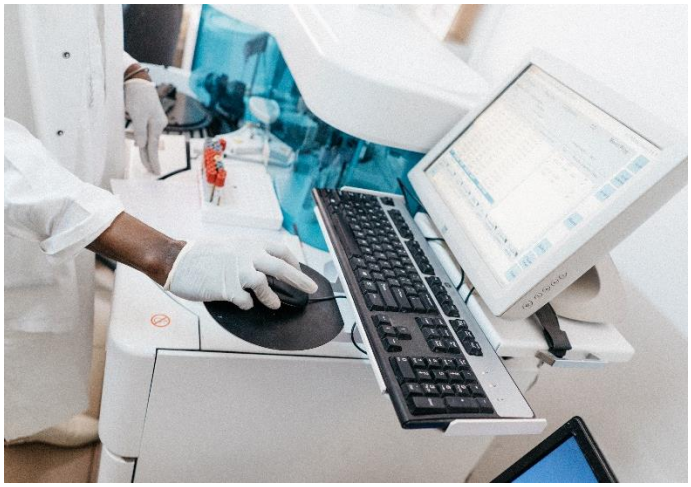
PATH is assessing how agentic AI tools—in which multiple AI agents can autonomously coordinate, plan, and take actions to achieve a defined goal—could be leveraged to speed the identification of immune biomarkers that may correlate with protection from disease. This could ultimately help bring new vaccines to market more quickly, shortening the often yearslong journey to regulatory approval and getting new vaccines to children and communities that need them sooner.

The opportunity

Bringing new vaccines to licensure can be a long and expensive process. The average vaccine candidate costs US$500 million and takes a decade to develop, with fewer than 10 percent of candidates making it to licensure after Phase 2 trials. But when researchers identify specific immune biomarkers that indicate protection against an infection or disease, they can more rapidly and reliably determine whether new vaccine candidates will be effective.

KEY TERMS

- **Agentic AI:** Artificial intelligence systems in which multiple AI agents can autonomously coordinate, plan, and take actions to achieve a defined goal.
- **AI co-scientist:** An AI tool designed for hypothesis generation and other critical research tasks.
- **Correlate of protection (CoP):** An immune biomarker that signals protection against an infection or disease.



PATH is assessing how agentic AI could be leveraged to speed the identification of immune biomarkers for use in vaccine development. Photo: PATH/Gabe Bienczycki.

During the COVID-19 pandemic, for instance, researchers were able to update COVID-19 booster shots more quickly because they determined that a simple antibody blood test was a reliable indicator of protection—eliminating the need for lengthy clinical trials of the updated vaccine.

These immune biomarkers are known as correlates of protection (CoPs). Identifying CoPs can help de-risk vaccine development by supporting the licensure pathway, accelerating decision-making, and informing clinical development plans. Using validated CoPs can help researchers identify and progress vaccine candidates that have the greatest likelihood of being effective.

These biomarkers can be identified in several ways, including studies of recovery from natural infection, animal immunogenicity studies, and human clinical studies. Scientific literature related to the development of vaccines against a given pathogen can cover decades of research and be highly diverse.

Given this complexity, AI tools have exciting potential to analyze large volumes of literature quickly and spot patterns that humans may have missed. This may provide insights about the potential value of biomarkers to serve as surrogates for efficacy.

PATH's approach

PATH is exploring how agentic AI tools can help identify potential CoPs. Using an "AI co-scientist" designed for scientific research, PATH is investigating potential immune biomarkers for several diseases. The AI-generated hypotheses will then be carefully reviewed by a team of experts and tested to assess their scientific validity.

This work is initially focused on testing the ability of an off-the-shelf AI co-scientist to identify potential biomarkers associated with infant protection following rotavirus vaccination and maternal respiratory syncytial virus (RSV) vaccination. PATH is also evaluating the co-scientist's (or other similar tools') ability to generate justifications for using a potential CoP in the vaccine authorization process, exploring ways to augment or enhance existing co-scientist tools for use in biomarker-focused research projects, mapping the evolving landscape of co-scientist models, and creating a benchmarking system to compare co-scientist tools.

In addition, a series of research and development sprints conducted in collaboration with academic and technology partners will focus on developing or enhancing components of agentic AI workflows. PATH may also then assess the ability of the augmented co-scientist to identify potential CoPs for an additional disease.

Leveraging AI for vaccine development

As new AI tools transform the landscape of vaccine research and development, evaluating and refining these tools is essential. PATH aims to build a stronger foundation for AI applications in CoP research, catalyzing more efficient development and approval of new vaccines.

References

1. King DF, Groves H, Weller C, et al. Realising the potential of correlates of protection for vaccine development, licensure and use: short summary. *npj Vaccines.* 2024;9(82). https://doi.org/10.1038/s41541-024-00872-6
2. Khoury DS, Schlub TE, Cromer D, et al. Correlates of protection, thresholds of protection, and immunobridging among persons with SARS-CoV-2 infection. *Emerging Infectious Diseases.* 2023;29(2). https://doi.org/10.3201/eid2902.221422

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Date Published
March 2026