

# R21/Matrix-M™ Malaria Vaccine Phase 3 Trial Results Published in The Lancet

February 2, 2024

Today, peer-reviewed results from a Phase 3 efficacy trial of the R21/Matrix-M™ malaria vaccine were published in [The Lancet](#). The trial was conducted across multiple sites in four African countries with 4,800 children aged 5-36 months.

Data from this trial served as the basis for the World Health Organization's (WHO) recent [prequalification](#) of the R21/Matrix-M vaccine, paving the way for a global rollout that is expected to commence in mid-2024 by Serum Institute of India. Availability of the R21/Matrix-M vaccine is expected to help close the gap for the vast demand for malaria vaccine doses to protect children against the disease.

The publication reported:

- Efficacy of 75% when administered prior to the high transmission season: In areas with highly seasonal malaria transmission (where malaria transmission is largely limited to four or five months per year), the R21/Matrix-M vaccine was shown to reduce symptomatic cases of malaria by 75% during the 12 months following a three-dose series.
- Efficacy of 68% when administered in an age-based schedule in regions where malaria is present perennially during the 12 months following the first three doses.
- The most common adverse events with the vaccine were fever (47%) and injection site pain (19%).

Developed by [University of Oxford](#) and [Serum Institute of India](#), the vaccine contains Novavax's saponin-based [Matrix-M™ adjuvant](#). The R21/Matrix-M vaccine is one of several ongoing [collaborations](#) involving Novavax's adjuvant technology, including additional research in malaria and other infectious diseases in both humans and animals.

According to the most current WHO data, almost 250 million cases of malaria were reported globally in 2022, causing upwards of 609,000 deaths. Most cases occurred in Africa, with children under the age of five accounting for the vast majority of deaths in the region.<sup>1</sup>

The vaccine has also been licensed by regulators in Ghana, Nigeria and Burkina Faso. More information about the R21/Matrix-M vaccine may be found [here](#).

<sup>1</sup> [WHO World Malaria report 2023](#)

## Forward-Looking Statements

Statements herein relating to the future of Novavax, its partners, operating plans and prospects, including the availability of the R21/Matrix-M™ malaria vaccine being licensed, developed and manufactured by Serum Institute of India, the possible effects of the prequalifications on meeting vaccine demands, and the timing of delivery and distribution of the vaccine are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; challenges or delays in obtaining regulatory authorization for its product candidates, including challenges or delays in clinical trials; manufacturing, distribution or export delays or challenges; Novavax's exclusive dependence on Serum Institute of India Pvt. Ltd. for co-formulation and filling and the impact of any delays or disruptions in their operations on the delivery of customer orders; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent Quarterly Reports on Form 10-Q, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at [www.sec.gov](http://www.sec.gov)

and [www.novavax.com](http://www.novavax.com), for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.