A world-first clinical trial of a gene drive malaria parasite to control disease.

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Malaria is on the rise. Existing tools are failing to control disease. Gene drives offer the capacity to repress, perhaps even eradicate, problem organisms like the parasite that causes malaria[1]. But do gene drives work, and are they safe?

We are building and testing a variety of gene drives in *Plasmodium* spp. Our gene drives aim to reverse drug resistance, ameliorate malaria-in-pregnancy, prevent spillover of *P. knowlesi* into humans, restore the efficacy of rapid diagnostic tests (RDTs), and collapse *falciparum* malaria transmission.

Deploying gene drive parasites entails considerable safety, ethical, social, and compliance considerations. We have been funded for in-human safety and efficacy trials of a homing, sex biasing *falciparum* gene drive. Exploration of ethics, economics, social licence, and regulatory frameworks for a field trial of our gene drive in a malaria endemic region are also built into the project. Our team thus has the first chance to assess the utility and acceptability of a new malaria control tool. I will present our progress-to-date in building and testing malaria parasite gene drives. I will also weigh the pros and cons of these powerful and innovative tools.

1. Wilde, M-L *et al*. (2025) *Novel techniques for disrupting malaria transmission*. Trends in Parasitology **41**: 657-9