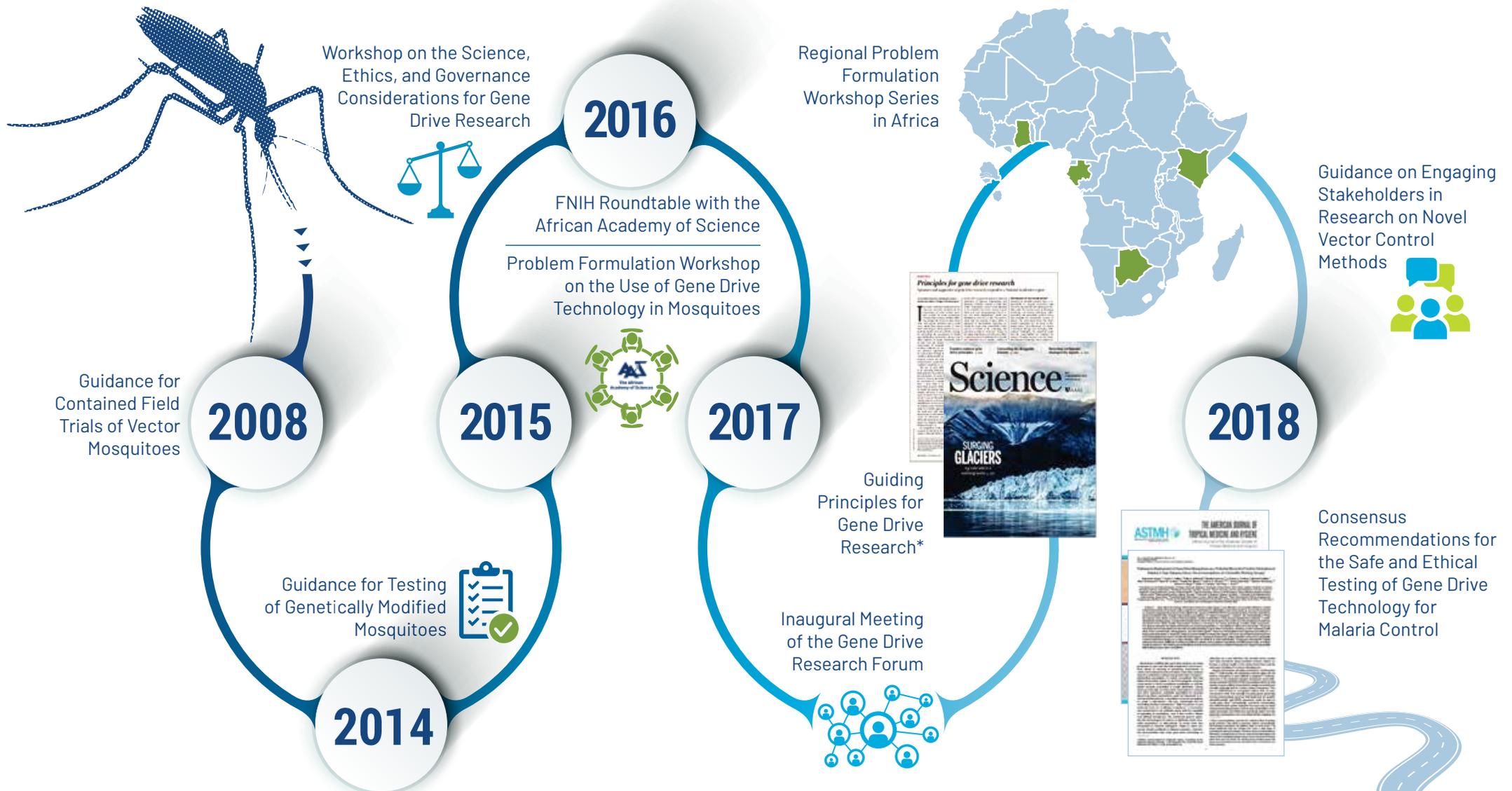


ESTABLISHING BEST PRACTICES IN GENETIC BIOCONTROL TECHNOLOGY

The Foundation for the National Institutes of Health (FNIH) has been at the forefront of scientific developments in genetic biocontrol technology, including the development of gene drive mechanisms to address challenges such as the eradication of insect-borne diseases, since 2005.

Following FNIH's initial involvement in research to reduce the burden of mosquito-borne diseases, the FNIH soon recognized the need to establish guiding principles and standards to underpin responsible research, development and, if warranted, implementation of genetic biocontrol technologies.

Today, the FNIH plays a leading role as a neutral convener to facilitate alignment among stakeholders involved in this field and the development and dissemination of consensus best practices guidance.



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2008

Guidance for Contained Field Trials of Vector Mosquitoes: The FNIH organized a scientific working group to create guidance that will aid researchers, government authorities and community leaders as they consider the design and implementation of confined field trials to assess the safety and efficacy of genetic strategies for reducing the transmission of diseases by mosquito vectors. The guidance was published in *Vector-Borne and Zoonotic Diseases* www.liebertpub.com/doi/pdf/10.1089/vbz.2007.0273.

2014

Guidance for Testing of Genetically Modified Mosquitoes: The FNIH collaborated with the World Health Organization (WHO) to publish a guidance framework www.who.int/tdr/publications/year/2014/Guidance_framework_mosquitoes.pdf that aims to foster quality and consistency among processes for testing and regulating genetic technologies by proposing standards of efficacy and safety testing comparable to those used for trials of other new public health tools.

2015

Report on the Science, Ethics, and Governance Considerations for Gene Drive Research: The FNIH and NIH commissioned the National Academies of Sciences, Engineering, and Medicine to convene a consensus committee to summarize current understanding of the scientific discoveries related to gene drives and their accompanying ethical, legal and social implications. The committee's report, *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values* www.nap.edu/catalog/23405/gene-drives-on-the-horizon-advancing-science-navigating-uncertainty-and, was published the following year.

2016

FNIH Roundtable with the African Academy of Science: The African Academy of Sciences and FNIH co-convened a roundtable discussion on the potential of gene drive technology for malaria control, October 2016 in Nairobi, Kenya. The roundtable brought together scientists from across Africa with expertise in infectious diseases, entomology and public health.

Problem Formulation for the Use of Gene Drive Technology in Mosquitoes: The FNIH hosted a workshop with global scientific, biosafety and regulatory experts to systematically evaluate the potential risks associated with the use of gene drive mosquitoes intended to reduce the burden of malaria in Africa. The workshop consensus points were later published in the *American Journal of Tropical Medicine and Hygiene* www.ajtmh.org/content/journals/10.4269/ajtmh.16-0726.

2017

Inaugural Meeting of the Gene Drive Research Forum: The FNIH helped organize and support a confederation of organizations and individuals involved or interested in the various potential applications of gene drive technologies. Participants meet regularly to discuss issues relevant to the safe and ethical conduct of gene drive research.

Problem Formulation Consultations for Testing and Use of Gene Drive-Modified Mosquitoes in Africa: The FNIH helped facilitate a series of workshops held by the New Partnership for Africa's Development (NEPAD) in Accra, Nairobi, Gaborone and Libreville. Representatives from regional biosafety and health regulatory authorities came together to discuss the concept of gene drive mosquitoes as a public health tool for reducing transmission of vector borne diseases.

Stakeholder Engagement Best Practices for Novel Vector Control Methods: The FNIH sponsored a three-day workshop for bioethicists and stakeholder engagement practitioners to develop guidance related to best practices for stakeholder engagement and informed consent for interventions intended to operate at the community level. The group's recommendations were published in *PLoS Neglected Tropical Diseases* www.journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007286 in 2019.

Guiding Principles for Gene Drive Research: With leadership from the FNIH, participants in the Gene Drive Research Forum developed guiding principles for sponsors and supporters of gene drive research, www.fnih.org/news/announcements/guiding-principles-for-sponsors-supporters-gene-drive-research, which were published in *Science*. The principles have been endorsed by 13 founding signatories representing leading public and private institutions around the world.

2018

Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: The FNIH established a multi-disciplinary international scientific working group to develop consensus recommendations for the safe and ethical testing of gene drive technology for malaria control. The proposed pathway, published in the *American Journal of Tropical Medicine and Hygiene* www.ajtmh.org/content/journals/10.4269/ajtmh.18-0083, defines steps to be taken from initial discovery research through implementation.