



**AUDA-NEPAD**  
AFRICAN UNION DEVELOPMENT AGENCY

***Strengthening AU Member  
States' Regulatory Capacities for  
Responsible Research Towards  
Elimination of Malaria in Africa***



POSITION PAPER ON  
INTEGRATED VECTOR MANAGEMENT

© African Union Development Agency – NEPAD (AUDA-NEPAD)  
230 15th Road, Randjespark, Midrand, Johannesburg, 1686, South Africa  
+27 11 256 3600  
www.nepad.org  
Twitter @Nepad\_agency  
#TheAfricaWeWant

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# Summary

Africa continues to bear a heavy brunt of the malaria which is a disease transmitted by the female *Anopheles* mosquito. Thousands of lives, mostly of young children, are lost every year; which undermines efforts deployed at various levels for increased life expectancy and improved wellbeing for the socio-economic transformation of the continent. Accelerated changes and complementary tools are urgently needed to ensure effective elimination of malaria on the continent. Genetic engineering has been identified as one of such promising tools when applied to mosquito populations to reduce the transmission of the malaria parasite.

The African Union Development Agency – NEPAD (AUDA-NEPAD), based on recommendations from the African Union High-Level Panel on Emerging Technologies (APET), continues to provide African Union Members States with the necessary support to ensure that research on and development of new genetically-based vector control tools are conducted in a responsible manner and in full compliance with safety requirements for human health and the environment for the benefit of African communities.

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# *Africa has a high burden of malaria cases and deaths*

According to the WHO 2019 Global Malaria Report, sub-Saharan Africa accounted for 94% of the 405 000 global mortality cases linked to malaria in 2018. Children aged 5 years and under were the most vulnerable group, accounting for 67% of all malaria deaths worldwide. The WHO report also noted that the West and Central African subregions recorded the highest prevalence of exposure to malaria infection.

The economic impact of malaria is estimated to cost Africa \$12 billion every year while the WHO African Region absorbs around 75% of the total amount of US\$ 2.7 billion invested globally by governments of malaria endemic countries and international partners in malaria control and elimination efforts. The WHO/RBM Action and Investment plan to defeat malaria estimates that if malaria were eliminated, the return on investment for Africa would be as high as 60:1<sup>1</sup>, effectively unlocking extensive human and economic development on the continent.

For decades several methods have been used to control malaria globally and these include the use of anti-malarial drugs, use of insecticides to control the vectors, use of mosquito nets among others.

Though noticeable progress in malaria reduction has been experienced globally over the last decades, the WHO notes that progress in reducing new malaria cases has levelled off. It is understood that without accelerated changes, the “Global technical strategy for malaria 2016–2030 (GTS)” milestones for morbidity in 2025 and 2030 will not be achieved.

In recognition of these developments, the African Union through the Assembly/AU//Dec.642-664(XXIX) requested the Commission, WHO and AUDA-NEPAD (previously NEPAD Agency) to support initiatives and investments in the development and regulation of the gene-drive technology as well as other new innovations for the elimination of malaria.

***AUDA – NEPAD takes note of the need to accelerate change in malaria investment efforts in order to achieve the AU target of eliminating malaria by 2030***

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1 <https://endmalaria.org/sites/default/files/Frequently-Asked-Questions.pdf>

# Gene drive technology - a promising complementary tool for malaria elimination

## What are Gene drives?

Gene drives are genetic mechanisms that exist naturally and allow for accelerated transmission of characteristics from parents to their offspring. This allows for new characters to quickly spread within a given population, in a manner faster than under natural conditions. Gene drives function only in sexually reproducing species and several organisms are known to possess such phenomena.

Since the 1940s, scientists have explored applying this natural mechanism to suppress populations of insects that are vectors of diseases<sup>2</sup>, for instance mosquitoes. This also includes the use of sterile tsetse flies to control disease sleeping sicknesses of cattle or nagana for humans.

Recent advances in the field of genetic engineering have provided new tools that make it easier to apply the gene drive mechanism; thus, affording great opportunities to suppress or alter insect populations that transmit diseases or reduce crop yields. Currently, gene drive-based technologies to suppress or modify populations of malaria-transmitting mosquitoes have been tested in the laboratory and have proved effective and will soon be tested in the experimental field.

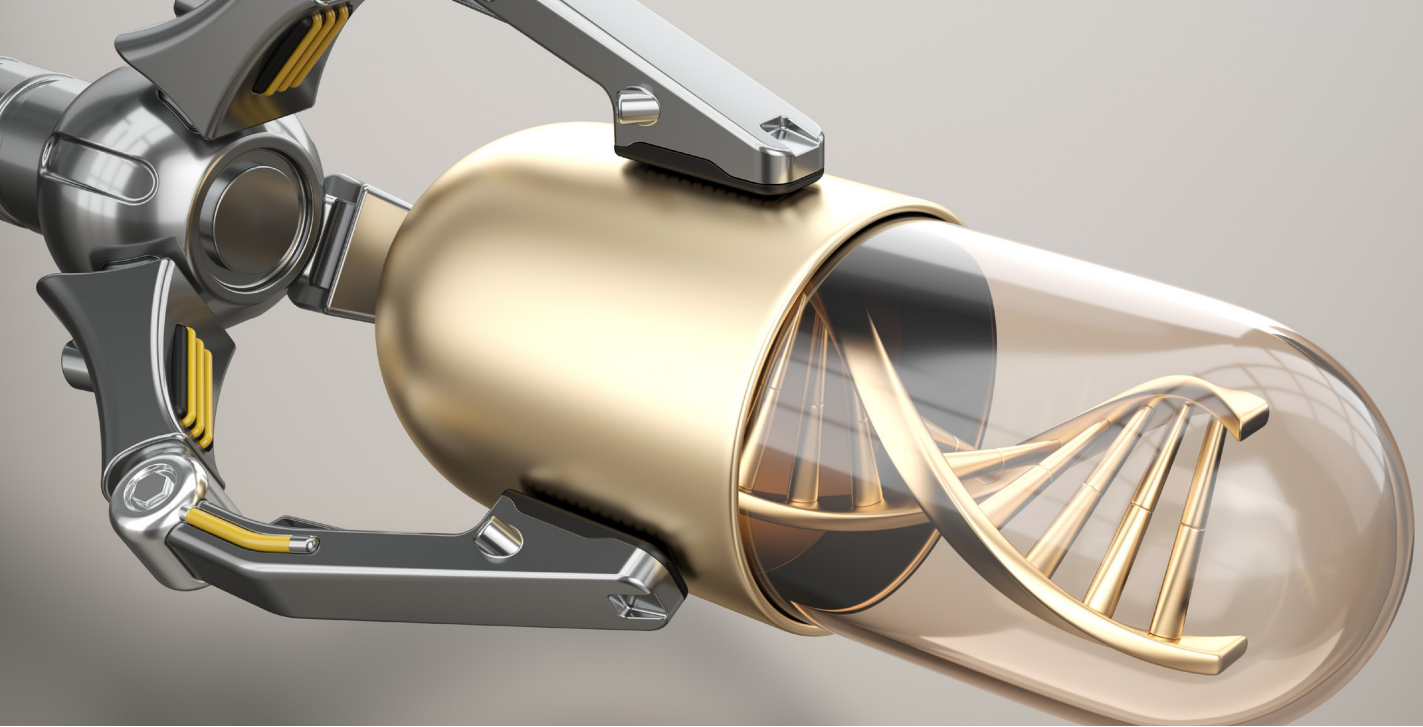
## What are the concerns raised about gene drives technology?

Concerns are being raised about the safety of gene drive applications, especially regarding safety to the environment in general and biodiversity in particular. The recurrent question is what happens if a gene drive containing organism escapes? And the concern also is whether this could lead to irreversible alterations or eradication of natural populations.

***AUDA - NEPAD and her development partners are committed to assisting African Union Member States build sound regulatory capacities to safely harness gene drive opportunities for malaria elimination***

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2 <https://wyss.harvard.edu/technology/gene-drives/>



Based on such legitimate concerns, priority must be given to building sound regulatory systems that can assess every stage of the technology development process to ensure safety to the environment and biodiversity.

Gene drive technology development targeted at malaria elimination occurs in phases as recommended by the WHO guidance for testing genetically modified mosquitoes. Functional regulatory systems define required safety measures and ensure that these are fully adhered to at every development stage before the research progresses to the next. No gene drive technology will be released into the environment without ensuring first its effectiveness against mosquitoes and its safety to humans and the environment including biodiversity.

However, it is critically important that any such assessments of potential environmental risks associated with gene drive applications for malaria elimination are properly balanced with considerations of anticipated health benefits.

Noting that a lot of real and perceived concerns, myths and misperceptions abound with the science of genetic engineering or modification and which must be appropriately addressed

through a sound communication policy and strategy, AUDA-NEPAD assists national regulatory agencies and regional bodies in developing and implementing communication and knowledge engagement plans. This way, stakeholders would give the necessary support to institutions engaged in research and product development efforts and those that regulate these efforts.

***AUDA -NEPAD considers evidence-based communication as a key driver in building science-trusting communities in Africa to accelerate the socio-economic transformation of the continent through the realization of the aspirations encapsulated in the AU Agenda 2063***

## ***What is the major guiding principle for decision-making on gene drive technology for malaria vector control?***

The reduction in deaths, morbidity and other disease-related burdens from malaria being the end goal of gene drive application on mosquito populations, the whole IVM concept is underpinned by the Risk/Benefit Analysis (RBA) principle. Here, potential risks with respect to safety to the environment especially on its biodiversity component are assessed against improved public health as the expected benefit.

***AUDA-NEPAD advocates that health value is considered as the primary driver for decision-making on gene drive applications, taking into account potential environmental risks***





## **What are the policy references for AUDA-NEPAD's engagement in building regulatory capacity for gene drive researches in the continent?**

The 2007 African Union High-Level Panel on Modern Biotechnology's call for a co-evolutionary approach – Early in the twenties, a few years after the first biotechnologically improved crop was commercialized, the African Union Commission established a high-level panel to guide the continent's position on the then-emerging technology. The Panel called on African leaders to adopt a co-evolutionary approach that would allow for the development of biosafety regulatory systems while enabling effective development of biotechnology products so that the continent can safely harness the unprecedented potentials offered by the emerging gene revolution.

The African Ministerial Council on Science and Technology (AMCOST) directed that regulatory frameworks for modern biotechnology for effective biosafety regulatory systems in the continent be developed. In 2009, AUDA-NEPAD established the African Biosafety Network of Expertise (ABNE) with the mandate to build functional regulatory systems among Member States. Functional regulatory systems are required to assess biosafety applications and make regulatory decisions for facilitating access to the safe use of emerging biotechnology including gene drive.

Agenda 2063 - This strategic framework for inclusive growth and sustainable development was adopted in 2015 by the 24th African Union (AU) Assembly

of Heads of State and Government and places science, technology and innovation (STI) at the centre of Africa's socio-economic transformation.

The Science, Technology and Innovation Strategy for Africa STISA-2024 -The was adopted in order to respond to the African peoples' demand to access science and technology for sustainable impact in critical sectors such as agriculture, energy, environment, health, infrastructure, mining, security and water.

***AUDA-NEPAD's  
commitment to building  
sound regulatory  
systems for modern  
biotechnology stems  
from the 2007 AU High  
Level Panel on Modern  
Technology's call for  
a co-evolutionary  
approach***

**Renewed needs and interest in harnessing emerging technologies** – The AU recognises the fast-evolving nature of science, technology and innovation, and the need for the continent to remain competitive as an active player in the global



economy. Therefore, the Assembly/AU/Dec.618 (XXVII) in 2016 “Further directs the AUDA-NEPAD to establish a system for obtaining expert contribution on the matters of technology development, acquisition and deployment for economic development”.

The AU High Level-Panel for Emerging Technologies (APET) – Further to the Assembly/AU/Dec.618 (XXVII), the

AU Commission and AUDA-NEPAD jointly established the AU High-Level Panel on Emerging Technologies (APET) in order to provide technical support to AU Member States to harness high impact emerging technologies. APET comprising of eminent independent scientists conducted intensive consultations and detailed analysis and made recommendations for three priority technologies comprising 1) Gene drive technology for malaria vector control and malaria elimination; 2) usage of drones’ technology for agriculture transformation; and 3) dissemination of micro-grids to improve power supply in the continent.

At its Thirty-Second Ordinary Session in January 2018 in Addis Ababa, the Executive Council through its Decision EX.CL/ Dec.986-1007(XXXII) endorsed APET’s report and its recommendations on gene drive technology along with the two other priority technologies. The same Executive Council “further requests the African Union and Member States to harness these emerging technologies for development initiatives”.

***AUDA-NEPAD refers to the African Union Agenda 2063, its subsequent STISA 2024 and the AU High-Level Panel on Emerging Technologies’ report and recommendations on gene drive to provide support to African Union Member States in their effort to harness gene drives for malaria. elimination***

# The APET's recommendations as drivers to AUDA-NEPAD interventions in strengthening regulatory capacity on gene drive technology:



**Political support** -The panel calls for African policymakers and leaders to advocate and support decisions on emerging technologies including gene drive technology to ensure socio-economic development.



**Risk / Benefits** – The panel calls for regulations that consider the weight of the health benefit when balancing with potential risks, to create an appropriate enabling regulatory environment for the adoption of the gene drive technology for malaria elimination.



**Capacity building** - The panel calls for the development of strategies that can address the needs for increased competencies and skills, sound regulations including ethical considerations, to strengthen decision-making processes that deliberate on emerging technologies including gene drive technology.



**Harmonisation & Regional Approach** – The panel strongly calls for regional approaches and cooperation to harmonise policies that ensure acceptance and implementation across borders of gene drive technology as part of a malaria vector control strategy.



**Logistical Support** – The panel calls the African Union Member States to provide the necessary support for the conduct of laboratory studies, field and semi-field experiments that are necessary to properly assess the potentials of gene drive technology where it is needed in various African settings.



**Funding** – The panel calls for support from private-public and international partnerships to ensure funding for laboratory infrastructure, research and development activities as well as public engagement communication activities.



**Engagement** – The Panel calls for strong and early engagement with all stakeholders on the development of gene drive technology, in order to ensure that researches on gene drive and their outcomes and products meet expectations and therefore will have great chance to be accepted and supported.

*Based on the APET recommendations, AUDA-NEPAD is committed to working closely with the AU Member States and the Regional Economic Communities to ensure that informed political support and adequate funding are provided for the development of science-based regulations that consider health value and align with stakeholders' priority needs and acceptance when exploring gene drive technology potentials for malaria elimination in the continent.*

# What is the progress so far on APET recommendations implementation?

## **Establishment of the West Africa Integrated Vector Programme**

As West Africa is part of the sub-Saharan region that is hardest hit with malaria, AUDA-NEPAD, in collaboration with the West Africa Health Organization (WAHO), has established the West Africa Integrated Vector Management Programme (WA-IVM) to promote a multi-sectoral approach in building robust regulatory systems for genetically-based vector control applications. The programme brings together professionals from various fields including health, environment, biosafety and ethics to deliberate on concerns raised with genetically based vector control applications.

The governance structure of the programme comprises a steering committee which is led by a representative from the national medicine regulatory agencies, and several technical working groups specializing in critical aspects associated with gene drive technology development, i.e. environment safety (biosafety), ethics, vector control management, epidemiology, clinical trials.

The WA-IVM is the first step towards the establishment of a continental vector control programme in response to the need to foster continental cooperation and coordination for the elimination of malaria and other vector-borne diseases.

## **Continent-wide stakeholder consultations**

Following the adoption of the APET report, AUDA-NEPAD has conducted stakeholder consultations over the five

geographic regions of the continent. This has yielded broad consensus and a strong buy-in regarding the need to responsibly explore genetically based vector control applications towards the elimination of malaria in the continent.

## **Strengthening and unifying African's position at international negotiations**

At the international level, gene drive activities and other advanced biotechnology tools are regulated under the provisions of the Convention of Biological Diversity (CBD) and its associated protocols, mainly the Cartagena Protocol on Biosafety (CPB) to which most of the AU Member States are parties.

***Based on the APET report's recommendations, AUDA-NEPAD, in collaboration with the AU Commission, assists the African Group of Negotiators to build consensus and common positions during international negotiations***

At the last Conference of Parties (COP) serving as the 14th Meeting of Parties (MOP) held in December 2018 in Sharm el Sheikh, Arab Republic of Egypt, the African Group joined other parties in rejecting attempts to impose a moratorium on technologies including gene drive for malaria vector control.

***AUDA-NEPAD will continue to provide such support to AU Member States in subsequent meetings of Parties with the primary aim of ensuring African researchers and their partners are able to safely conduct research on gene drives and related technologies with the potential for malaria elimination.***

#### **Development of practical regulatory tools**

In 2014, the WHO published general guidance for testing genetically modified mosquitoes, which now serve as a basis to develop specific technical documents for guiding regulators and scientists engaged with the gene drive work.

As part of the WA-IVM programme activities, and in response to stakeholders' demand, AUDA-NEPAD provides support to the IVM Technical Working Groups to develop initial guidelines to enable

progress with research and development for gene drive technology. AUDA-NEPAD will provide the required assistance to develop, finalise, update or adapt those documents.

***AUDA – NEPAD takes note of the progress made so far in implementing the APET recommendations, mainly the establishment of the West Africa Integrated Vector Management Programme, the support provided to the African group at the COP-MOP meetings and the development of initial guidance documents on gene drive; and is encouraged to further engage with Member States and the Regional Economic Communities to fully implement all APET recommendations on gene drive for malaria elimination in the continent.***

## Final Statements

- As per her mandate, AUDA-NEPAD seeks to harness knowledge to deliver the Africa We Want, as outlined in the African Union's Agenda 2063.
- The Africa We Want will be free from malaria and other deadly diseases.
- AUDA-NEPAD recognises science, technology, and innovation as the engine of its delivery mechanism to realise the Africa We Want.
- The current advanced knowledge in biology has generated new technologies and tools with great potential to tackle malaria right at the roots, i.e. the mosquito species that spread the malaria parasites and disease among the populations.
- AUDA-NEPAD reaffirms her commitment to supporting AU Member States in building regulatory systems that are required to safely explore the usage of innovative tools for the elimination of malaria and other arthropod-borne diseases.
- Saving lives to sustainably augment the continent's capacities to address its socio-economic development needs remains a non-negotiable priority goal to the Agency .
- While striving to assist build sound regulatory frameworks, AUDA-NEPAD respects Member States' sovereign decisions and the RECs' coordinating mandates regarding emerging technologies including gene drives for malaria vector control.





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230 15<sup>th</sup> Road  
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[www.nepad.org](http://www.nepad.org)