European Commission

HERA HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

#HealthUnion

HERA Industry days

Health Emergency Preparedness and Response Authority

2 & 3 June 2025, Brussels

European Commission

Side session

MCMs for vector-borne diseases: industry challenges and funding opportunities

European Commission

MCMs for vector-borne diseases: industry challenges and funding opportunities

Ana BURGOS
HERA 02

Anna-Bella FAILLOUX
Head of the Arbovirus and Insect Vectors Unit, Institut Pasteur

Isabela RIBEIRO
Viral Diseases Cluster Director, DNDi

Lisa GOERLITZ
Head of Advocacy DSW, voucher for Dengue and Chikungunya industry partnerships

Olivier JANKOWITSCH
Vice President Governmental Affairs Valneva

Vector borne diseases: the invasive mosquito species, *Aedes albopictus*

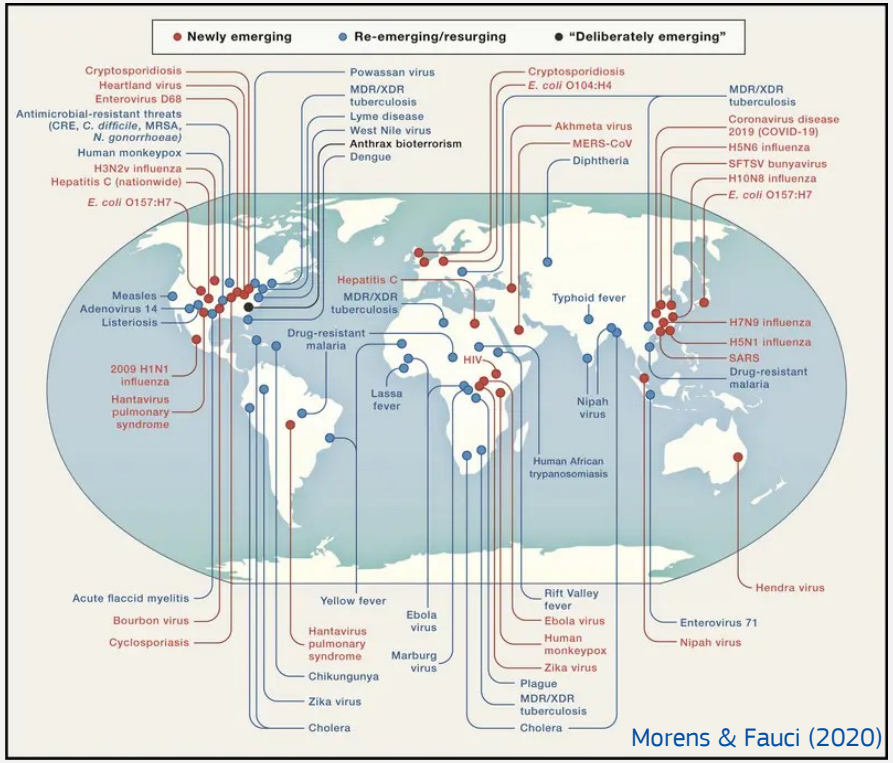
Prof. Anna-Bella FAILLOUX, Institut Pasteur, Unit of Arboviruses and Insect Vectors, Department of Virology (anna-bella.failloux@pasteur.fr)

ARBOVIRUSES
& INSECT VECTORS

INSTITUT
Pasteur

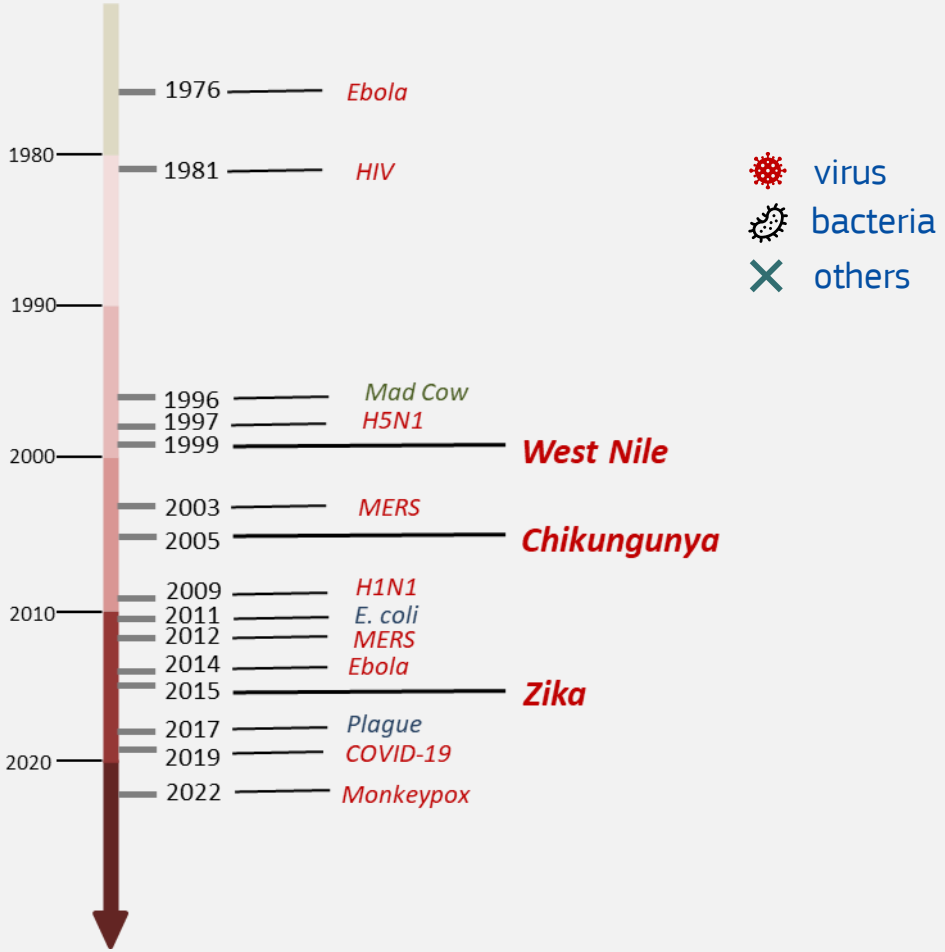
2 & 3 June 2025,
Brussels

Vector-borne diseases



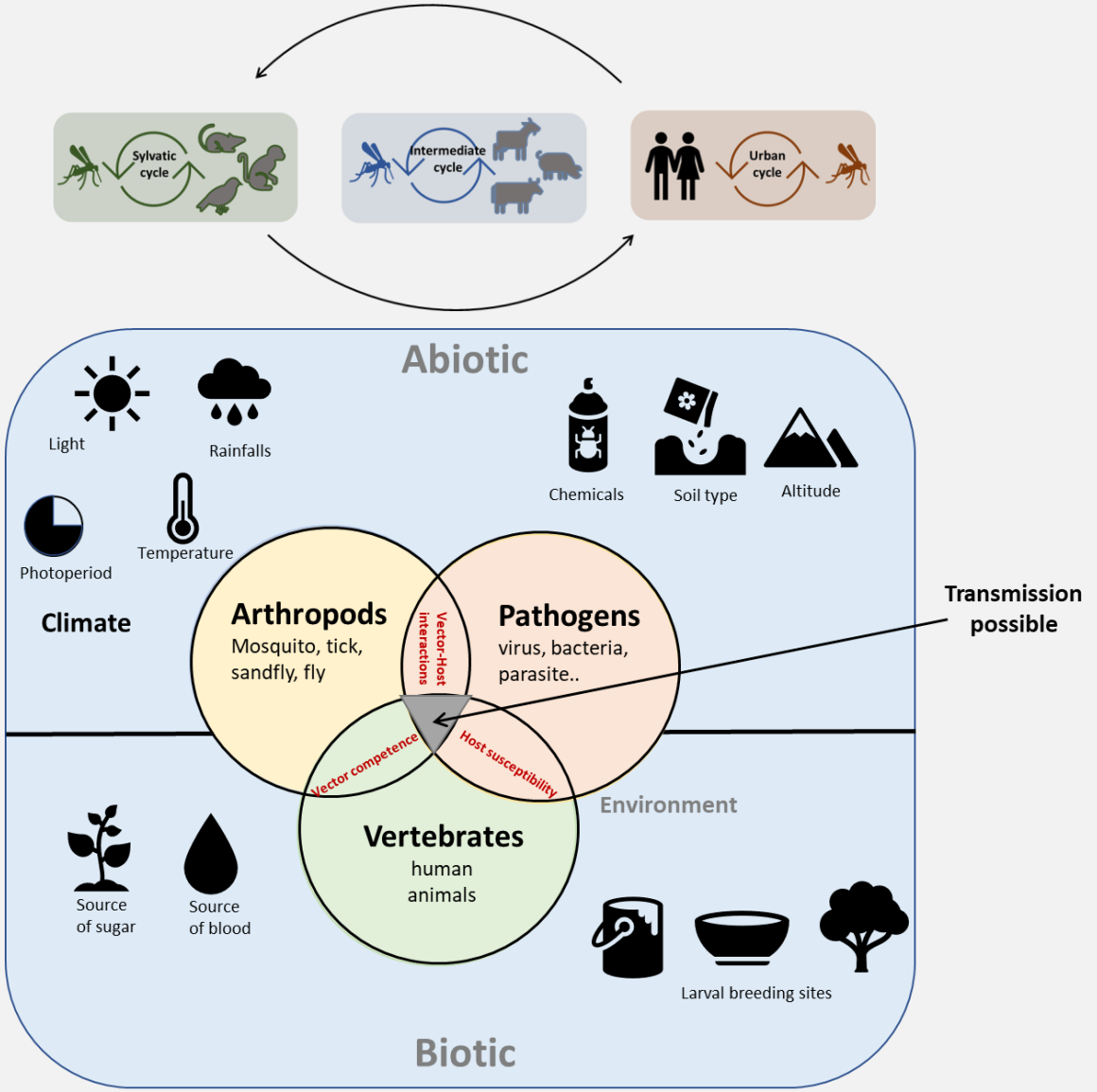
Morens & Fauci (2020)

- Since 1940: 60.3% of EIDs are caused by zoonotic pathogens
- VBD are responsible for 22.8% of EID events



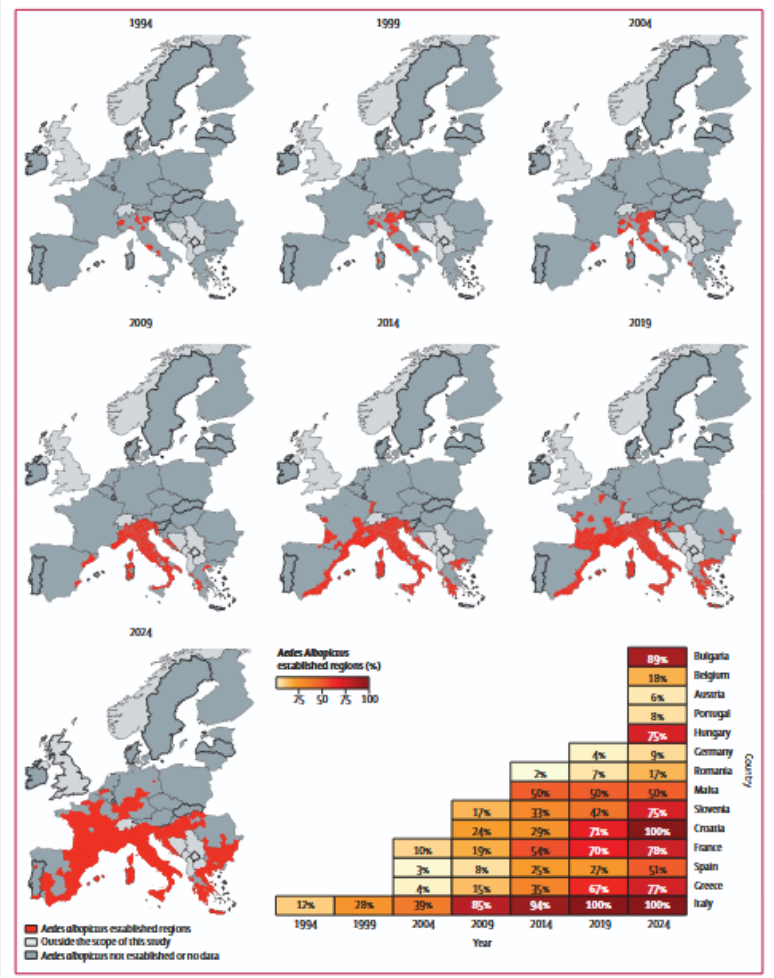
Functioning of the vectorial system

Zoophilic mosquitoes



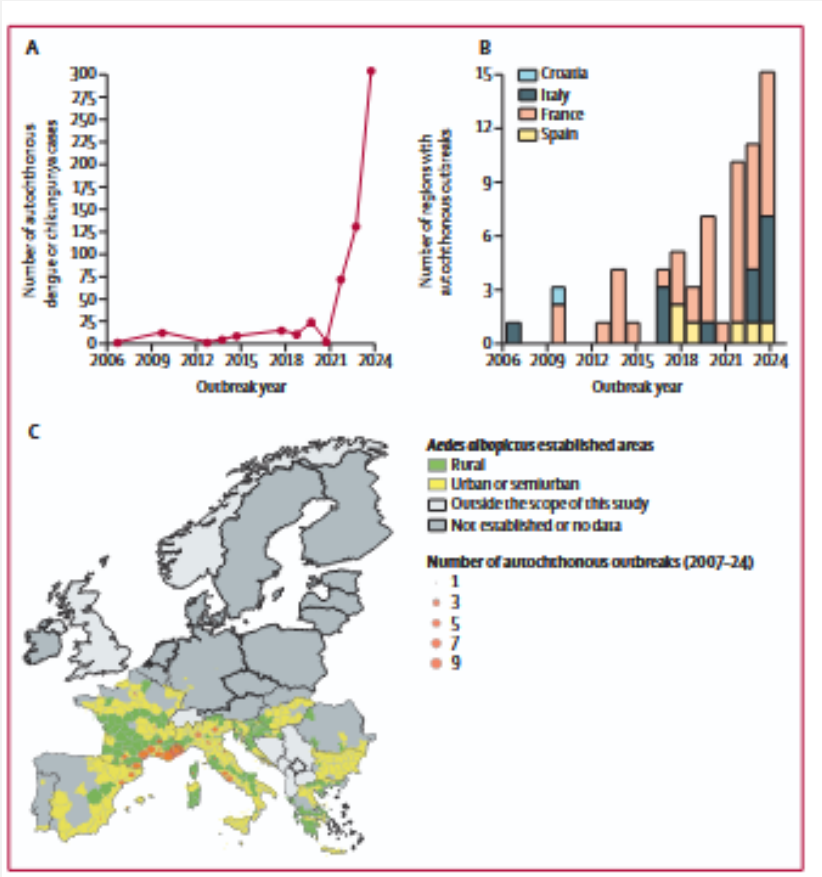
Human-biting mosquitoes

The tiger mosquito, *Aedes albopictus*



Expansion of *Aedes albopictus* in EU (1990-2024)

Zia-Farooq et al. (2025)

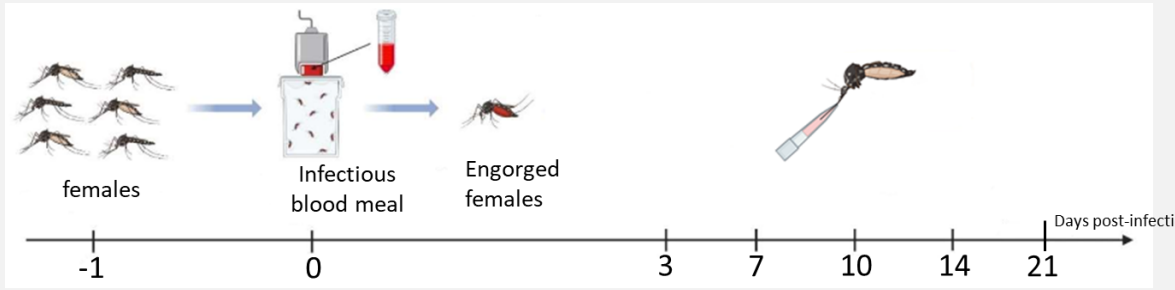


Autochthonous cases of dengue and chikungunya (2007-2024)

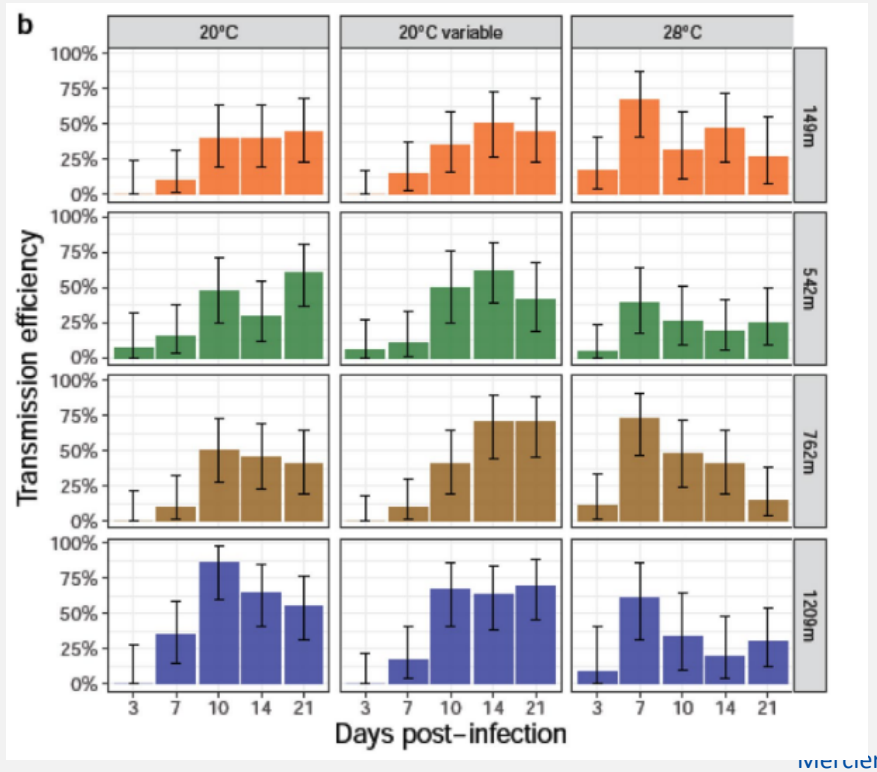
Zia-Farooq et al. (2025)

Aedes albopictus and chikungunya

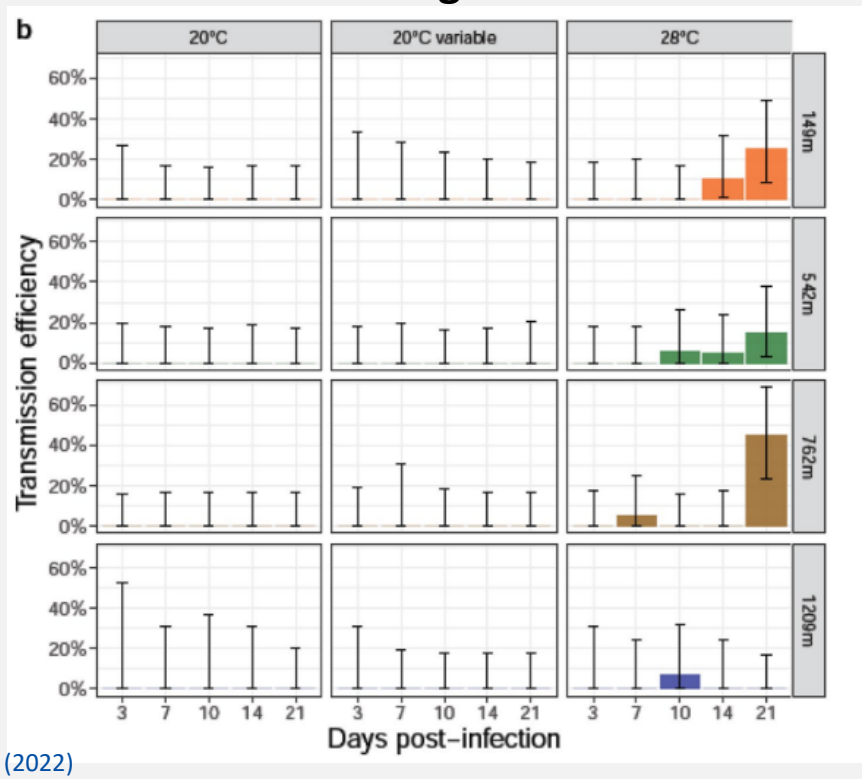
Experimental infections in BSL-3



Chikungunya

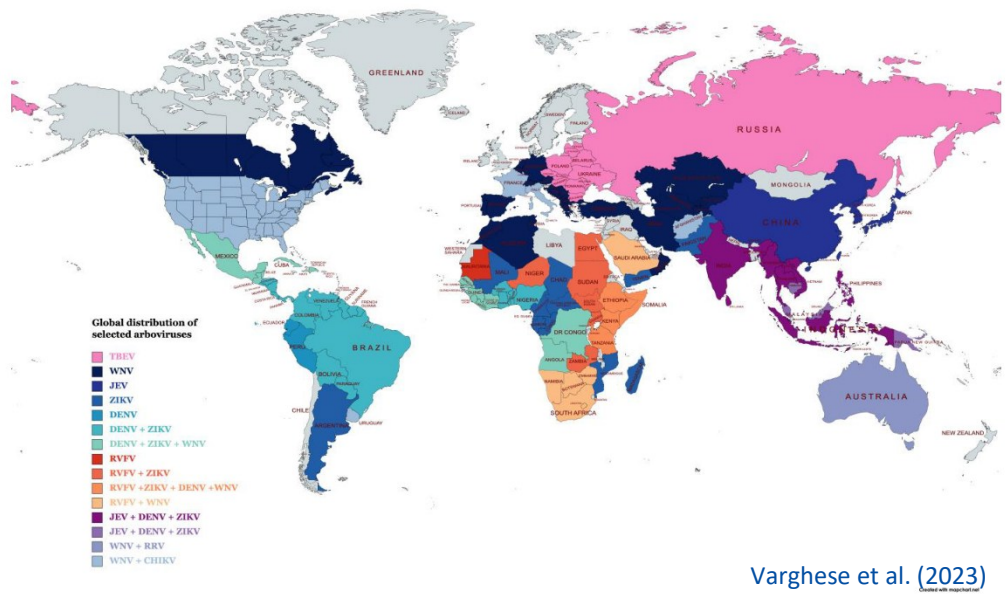


Dengue

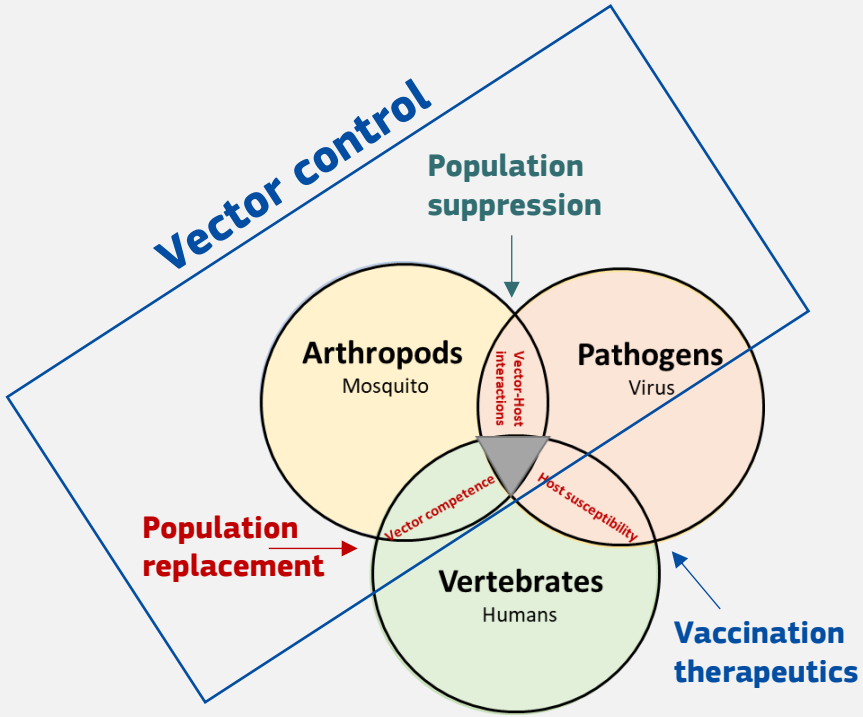


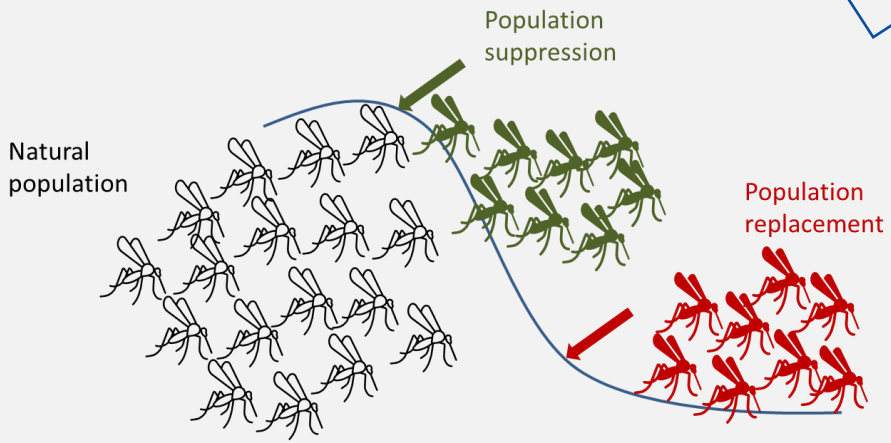
Mercier et al. (2022)

Global distribution of arboviruses



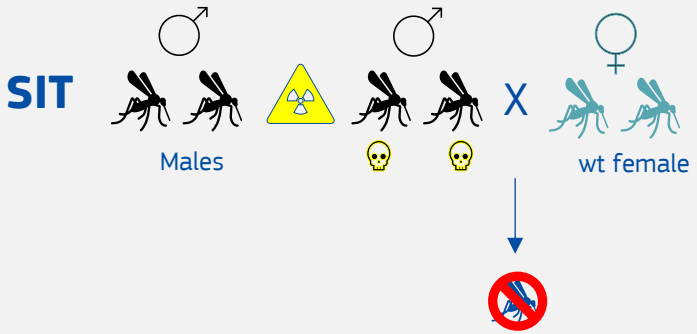
Varghese et al. (2023)

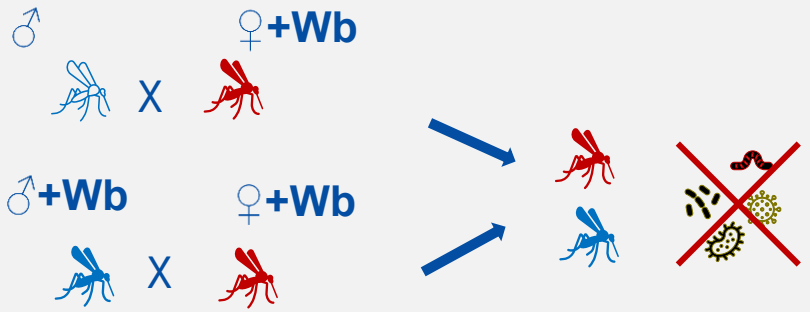




Self-limiting and self-sustaining systems

Population suppression	Population replacement
Self-limiting	Self-sustaining
Sterile Insect Technique (SIT) Release of Insects carrying a Dominant Lethal genetic system (RIDL) Incompatible Insect Technique (IIT)	**Wolbachia**





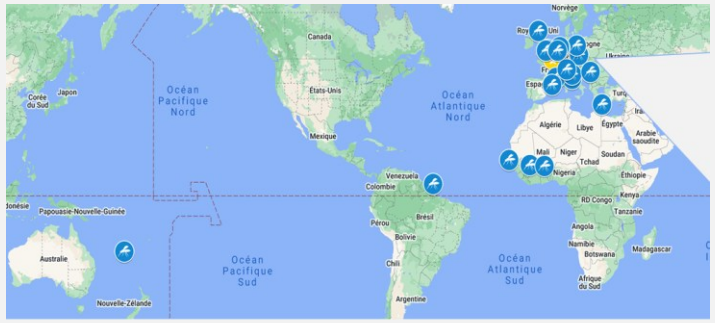
Infravec2 (2017-2021)

Europe (20 sites)

Africa (3)

Americas (1)

Pacific (1)



13 countries and 9 EU member states

Infravec2 users

Vectors (Live)

- Mosquitoes
- Culicoides
- Tsetse flies
- Sandflies
- Ticks

Access to facility

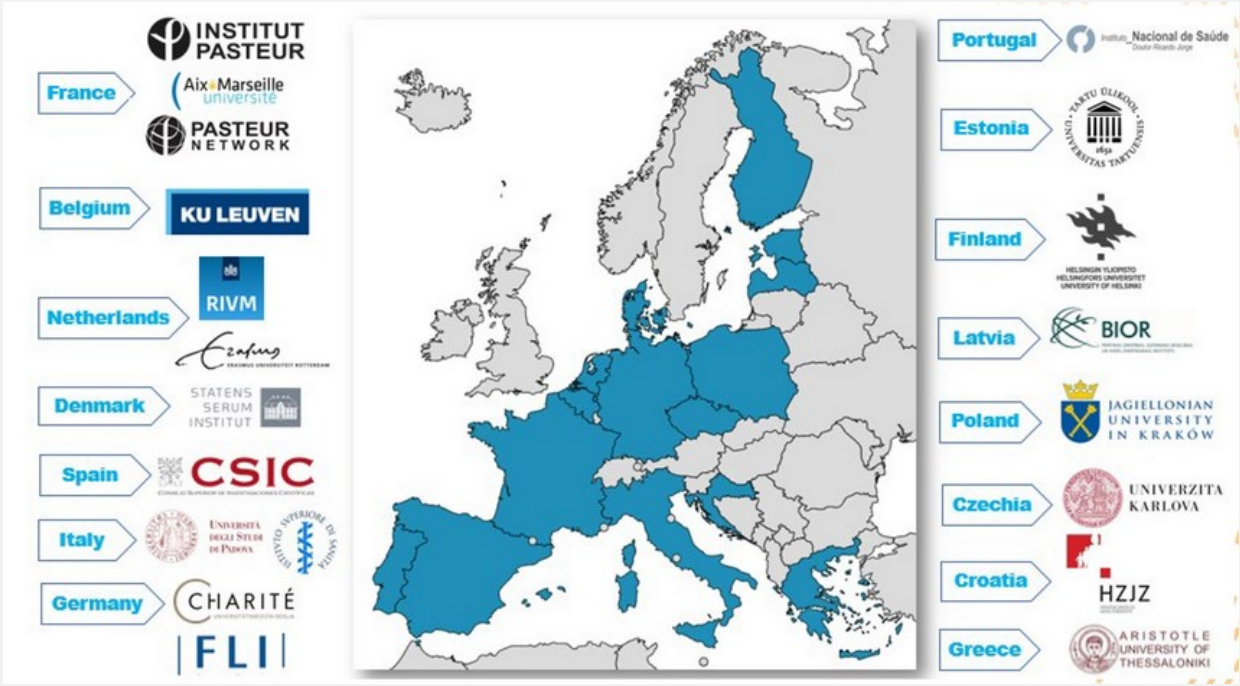
- Infections with CL2/3 agents
- Conduct mosquito behavioural assays
- Conduct Insecticide resistance tests

Derived products

- Infected mosquitoes (*Aedes*, *Culex*) with arboviruses
- Infected mosquitoes with *Plasmodium*
- Infected sandflies with *Leishmania*
- Construction of transgenic lines (*Aedes*, *Anopheles*)
- NGS genotyping
- Bioinformatic analysis of transcriptional profiles

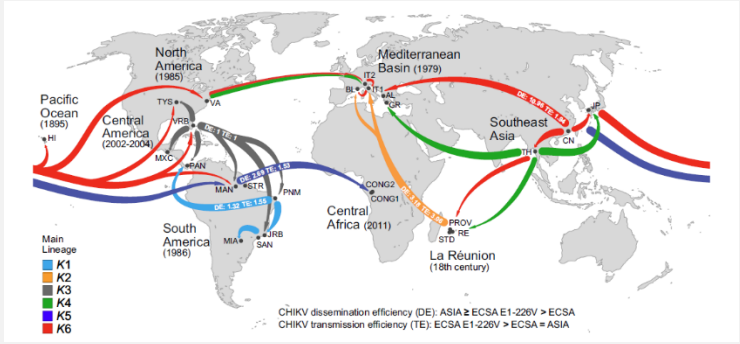
DURABLE
Research Network against Epidemics

Objective: develop a one-stop-shop for emerging disease laboratory preparedness
Diagnostics, research, response, preparedness
Duration: 4 years
Budget: 30 M€ (25M€ funded by HERA)
Institutions: 19 (15 in EU countries)
Individuals: 170



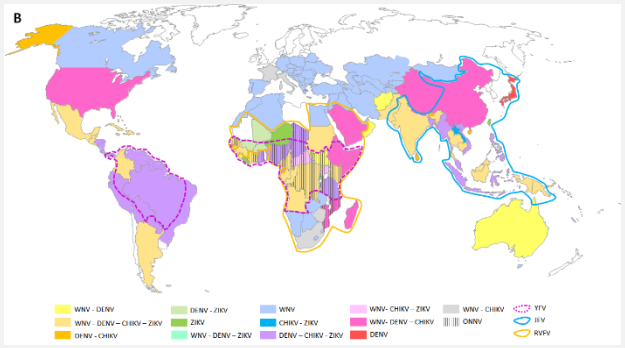
Emergence of VBD in two steps

1. Adaptation of the vector to a new biotope



Vega-Rua et al. (2020)

2. Adaptation of a new virus to a local vector



Viglietta et al. (2021)

HERA Industry days

Medical Countermeasures for Vector-Borne Diseases: Industry Challenges and Funding Opportunities

BEST SCIENCE FOR THE MOST NEGLECTED

Our mission: Innovation and equitable access to drugs for neglected populations

DNDi

DRIVEN BY THE NEEDS OF NEGLECTED PEOPLE AND COMMUNITIES

ACTIVITIES

- R&D and treatment access
- Inclusive partnerships
- Capacity strengthening
- Advocacy for policy change

OUTCOMES

- Shared knowledge and expertise
- **NEW TREATMENTS** adapted to the needs of patients and health systems
- Public leadership and accountability

IMPACTS

- Disease control and elimination
- Better health for neglected populations
- Universal Health Coverage
- Equitable R&D ecosystems

Growing threat of neglected and climate sensitive diseases with pandemic and epidemic potential

- **Recent global emergence** of dengue affecting numerous high- and low-middle income countries
- Dengue introduction is associated with **high morbidity and mortality among elderly** – learnings from Southern Brazil to regions at risk of disease introduction
- Emerging drivers such as climate change and migration are intensifying the burden, including within the EU, and highlight the **urgent need for proactive investment and preparedness**
- **Despite advances in vector control (e.g., Wolbachia) and vaccines (e.g., QDENGA, Butantan), an integrated approach including dengue treatments is urgently needed**. Current tools have coverage gaps and limitations, and case numbers are expected to rise in the coming years.
- Developing dengue treatments and other medical countermeasures today for patients in endemic regions **serves the future needs of patients in Europe**

Emergency Dengue Treatment Unit, Belo Horizonte, Brazil – one of many field hospitals established by the military to cope with the huge increase of dengue cases in 2024.

DNDi

Prioritizing end-to-end therapeutic research and innovation

Therapeutics play a critical role in responding to health emergencies.

Yet, the clinical pipeline is bare, with major therapeutic developments limited to a few diseases like COVID-19, Ebola Zaire, and Lassa.

The pre-clinical pipeline for many other viral threats is limited or nonexistent—highlighting a critical gap in global preparedness.

- **Prioritize therapeutic research and innovation** to reinvigorate the antiviral pipeline and accelerate the evaluation of leading candidates.
- **Leverage synergies and collaborate with existing initiatives**—such as the Dengue Alliance and the Therapeutics Development Coalition—which aim to:
  - Advance therapeutic innovation and platform technologies
  - Establish pre-agreed pathways for clinical trials, regulatory approval, manufacturing, and procurement
  - Ensure equitable access as a core commitment
- These efforts are closely aligned with, and can significantly complement, the objectives of the EU Strategy.

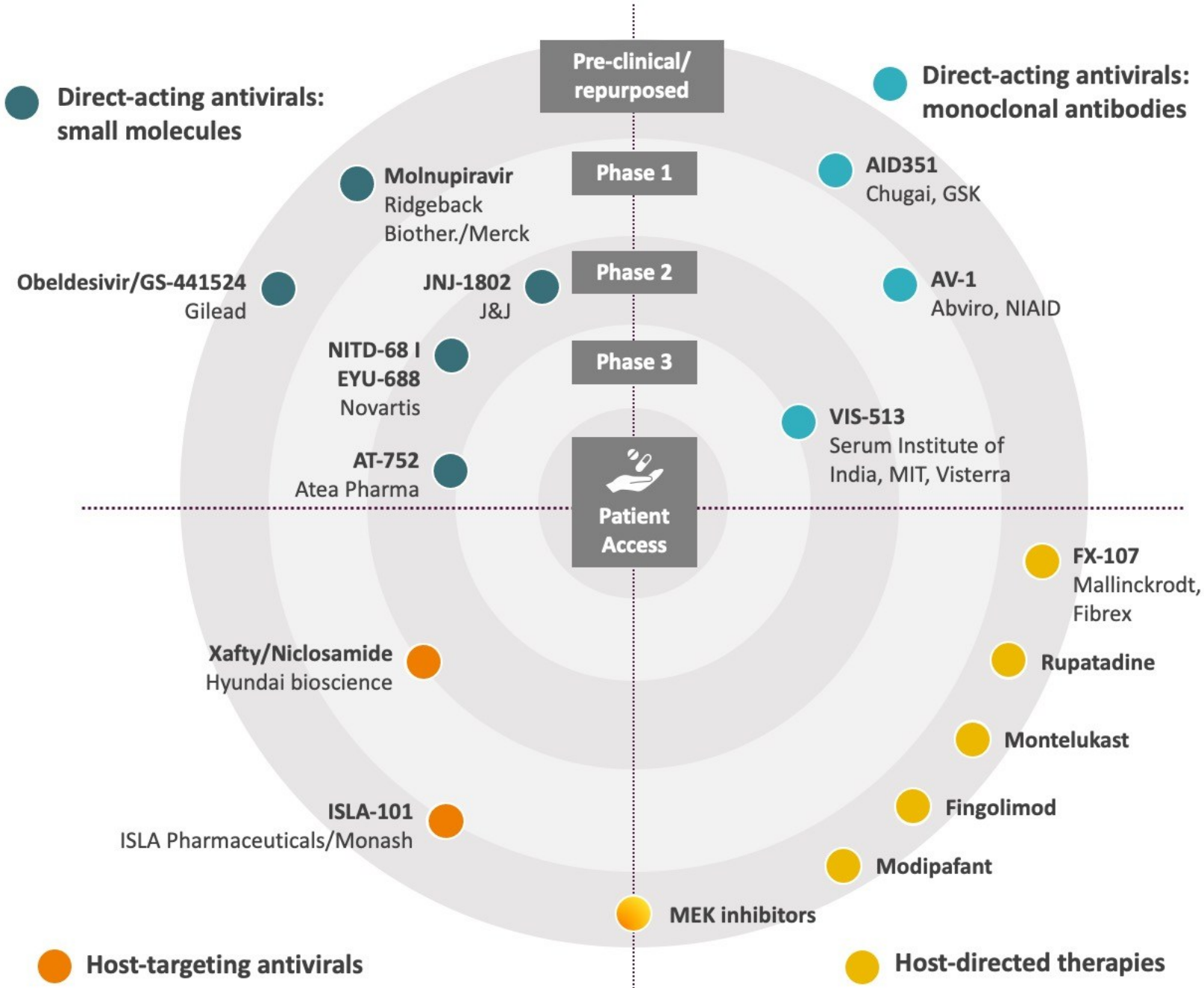
DNDi

The case of dengue

Candidates ready for Phase II and III assessment:

- Novel DENV antivirals in clinical development
- Clear opportunities for partnering and advancing novel antiviral products for Phase II/III clinical evaluation
- Pre-clinical evaluation of potential host-directed therapies ongoing
- Licensing at affordable cost, registration, tech transfer & local manufacturing opportunities in LMICs

DNDi



Dengue Alliance and supporting ecosystem accelerating innovation in dengue

Siriraj hospital, Mahidol University, Thailand

Translational Health, Science & Technology Institute (THSTI), India

FIOCRUZ Oswaldo Cruz Foundation, Brazil

Universidade Federal de Minas Gerais (UFMG), Brazil

Ministry of Health, Malaysia

Drugs for Neglected Diseases initiative

Pre-clinical working group

25 members

Focusing on *in vitro* and *in vivo* testing of compounds
AI-guided HDT screening

Clinical working group

34 members

Discussions on endpoint selection and study design
Working on study protocols and site selection

Translational working group

Diagnostics and biomarkers

Establishing diagnostic protocols for trials and potential treatments
Scoping review and embedding biomarkers in clinical studies

Epidemiology and Access working group

Being established

Burden of disease assessment
Use-case scenario for treatment access

Key component:
Placing equitable access and affordability at the core of response

Pro-access conditions can ensure that public investments yield tangible health gains and long-term cost savings and should be consistently applied across all funding streams.

- Embedding access, affordability, and equity throughout the entire R&D process to ensure a more effective and inclusive response to future emergencies, translating public investments into public benefit.
- Guiding the development of policies that tie EU incentives and funding to pro-access conditions, ensuring that medical countermeasures are accessible to all populations, including those beyond EU borders. Such an approach would support the EU's commitment to implementing Article 9.5 of the WHO Pandemic Agreement.

Dr Wanatpreeya is a Dengue Physician and Paediatric Infectious Disease Specialist at Siriraj Hospital in Bangkok, Thailand. Here, she visits with 7-year-old Pholtara, who has severe dengue but is recovering. Dengue presents a significant burden to health systems and society.

Supporting research and innovation for neglected and climate sensitive diseases with pandemic and epidemic potential

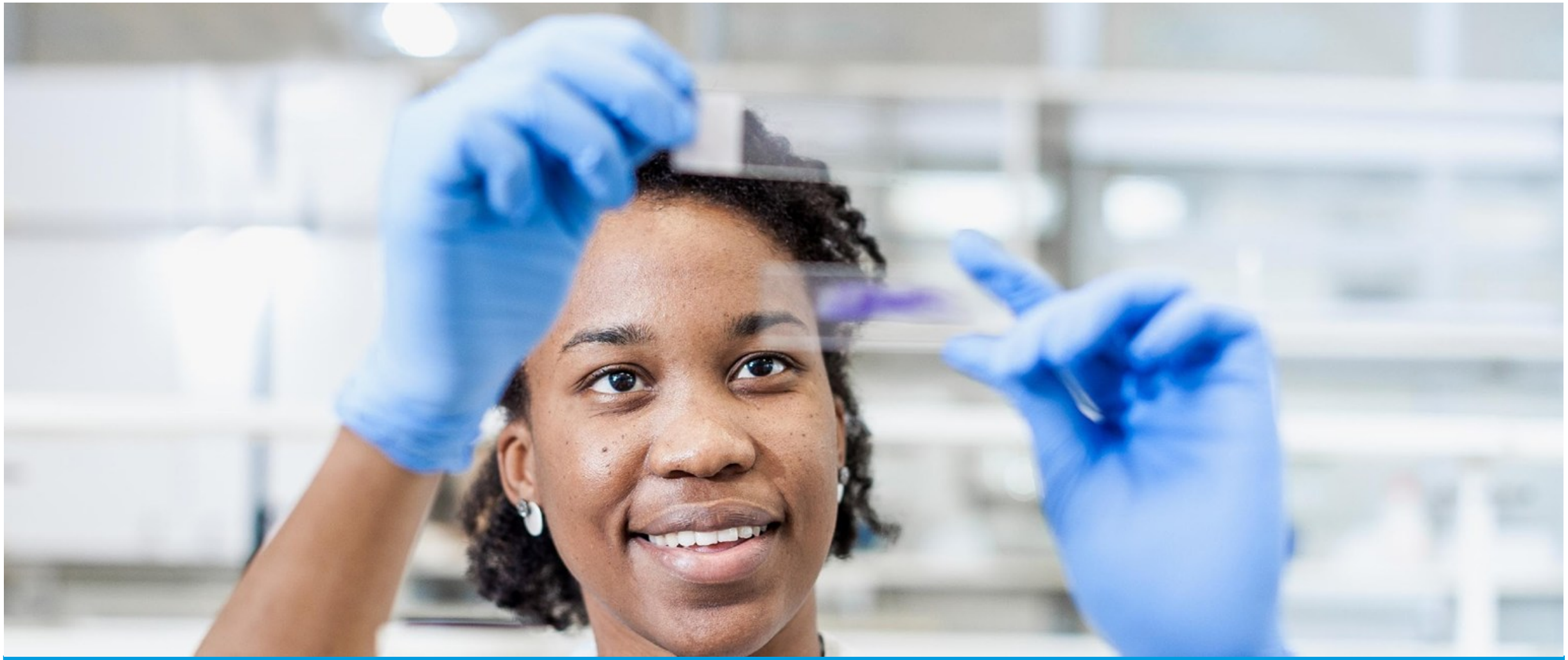
Medical ward at peak Dengue season in Sri Lanka.

- **Introduce targeted incentives and sustained funding** for research and innovation addressing poverty-related and neglected diseases, which are increasingly linked to epidemic potential.
- **Secure dedicated funding streams** to develop health solutions—including vaccines, treatments, and diagnostics—that respond to the impacts of climate change on infectious diseases, build resilient health systems, and meet the evolving needs of patients in Europe.
- **DNDi stands ready to provide strategic and technical expertise and to drive the development of medical countermeasures,** ensuring that the EU and the global community are equipped to respond to future health crises.

DNDi

European Commission

Thank you

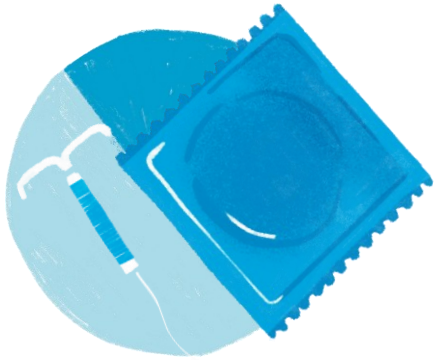


HERA INDUSTRY DAYS

MCM For Vector-borne diseases: industry challenges and funding opportunities

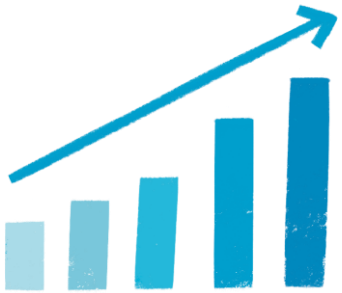
DSW Deutsche Stiftung Weltbevölkerung youth car

About DSW



DSW is an international development organisation that addresses the challenges faced by youth to exercise their **sexual and reproductive health and rights (SRHR)** and to meet their need for health services.

Our colleagues in **offices in Ethiopia and Tanzania**, and close partners in Kenya and Uganda (formerly DSW offices) contribute to our **evidence based advocacy**.



We advocate towards policy-makers to ensure political and financial support for SRHR and youth-friendly services, and for c**ritical investments into global health and research & innovation for poverty-related and neglected diseases (PRNDs) and women's health.**

We work in close collaboration with research-based organisations, academia, and product development partnerships on PRND advocacy.

A global lens for MCM for vector-borne diseases: a strategic necessity

- The development, production, and distribution of MCMs depend on **interconnected global supply chains**
- Many COVID-19 MCMs were based on knowledge and infrastructure built through global networks, often focused on **poverty-related and neglected diseases** (PRNDs)
- Ensuring **global access** to MCMs—especially in LMICs —helps suppress outbreaks, reducing the risk of variants and future waves.

- **The Union Preparedness Strategy**'s Action Plan, calls to embed preparedness in EU external investments", but
- **but an external dimension also needs to be integrated into all other EU preparedness measure, including importantly MCMs!**

General pharmaceutical legislation: an opportunity for increased support

European Parliament

European Parliament legislative resolution:

"...Union Pharmaceutical legislation has a role to play in the realisation of global public health objectives by promoting the development of efficacious, safe, accessible, and affordable innovations for antimicrobial resistance, poverty-related, emerging and re-emerging health threats, and neglected diseases, and other conditions of global public health interest. The Commission should continue to encourage research, development and innovation in areas of major global health interest, in line with its international commitments".

Proposal to include neglected diseases within HERA's scope

"...However, in the future with increasing capacity, the Authority should expand the scope of its agenda, specifically to tackle other areas of unmet medical need such as rare and neglected diseases. The Authority should have adequate resources to fulfil its mandate".

Expanding R&I support for neglected and vector-borne disease MDCs

EU R&I framework programme Horizon Europe (HEU)

HEU Health Cluster work programmes

European Innovation Council

EDCTP

innovative health initiative

EU ODA/ development cooperation funding programme (NDICI)

Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies ('MAV+')

Explore novel pull funding mechanisms that can incentivise vector-borne disease R&I

"PUSH" funding mechanisms

incentivise R&D by reducing or covering the research and development costs

e.g. grants

"PULL" funding mechanisms

incentivise R&D by rewarding results or by creating market demand for final products

e.g. priority review vouchers

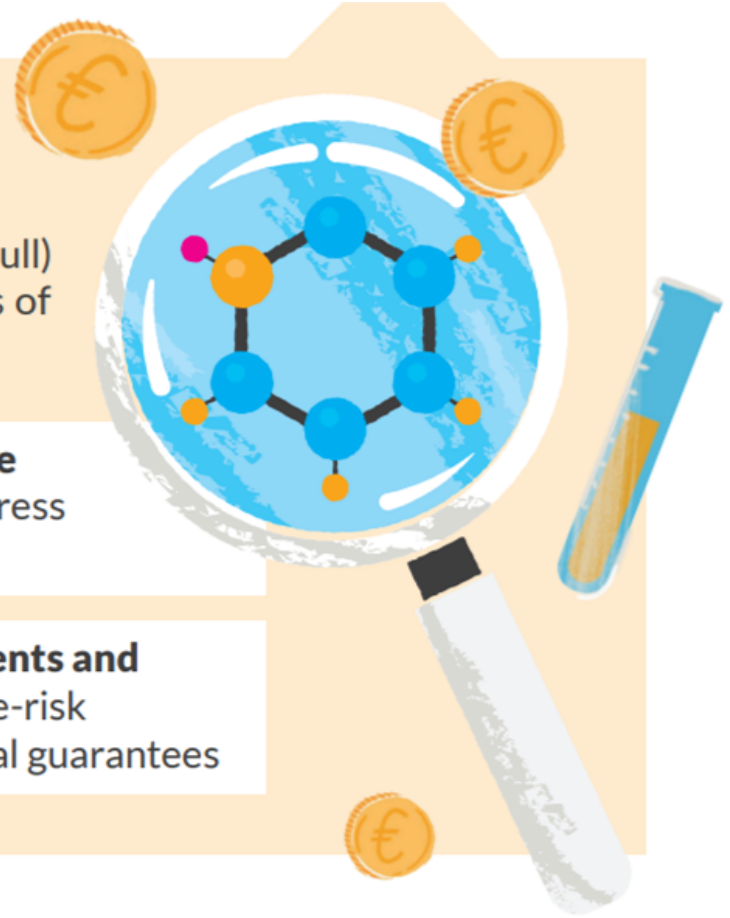
DSW Deutsche Stiftung Weltbevölkerung youth car

Explore novel pull funding mechanisms that can incentivise vector-borne disease R&I

PULL funding mechanisms can provide R&D support in different ways

There are different pull mechanisms, and some have mixed (push and pull) features. Some have been implemented (in other geographies or fields of research), whereas others have only been theorised so far:

- **Innovation hubs** promote portfolio funding and equitable partnerships
- **Impact bonds and milestone prizes** reward research progress and outputs
- **Priority review vouchers** reward regulatory approval and product launch
- **Advance market commitments and minimum revenue/prices** de-risk investments through financial guarantees



DSW Deutsche Stiftung Weltbevölkerung youth car

Introducing a PRV programme in the EU

Product development
Drug or vaccine developed for a priority disease.

PRV awarded
A PRV is given as a 'prize' to the drug maker for the approval of a drug or vaccine for a priority disease.

It can be redeemed
by its recipient to expedite the review of any one of its new health products.

It can be sold
to another company that wants to expedite the review of any one of its health products.

Reinvestment or pay-out
The voucher seller can reinvest money received from voucher sale into further research and innovation or pay out investors who pre-financed the development of the first product.

DSW Deutsche Stiftung Weltbevölkerung youth car

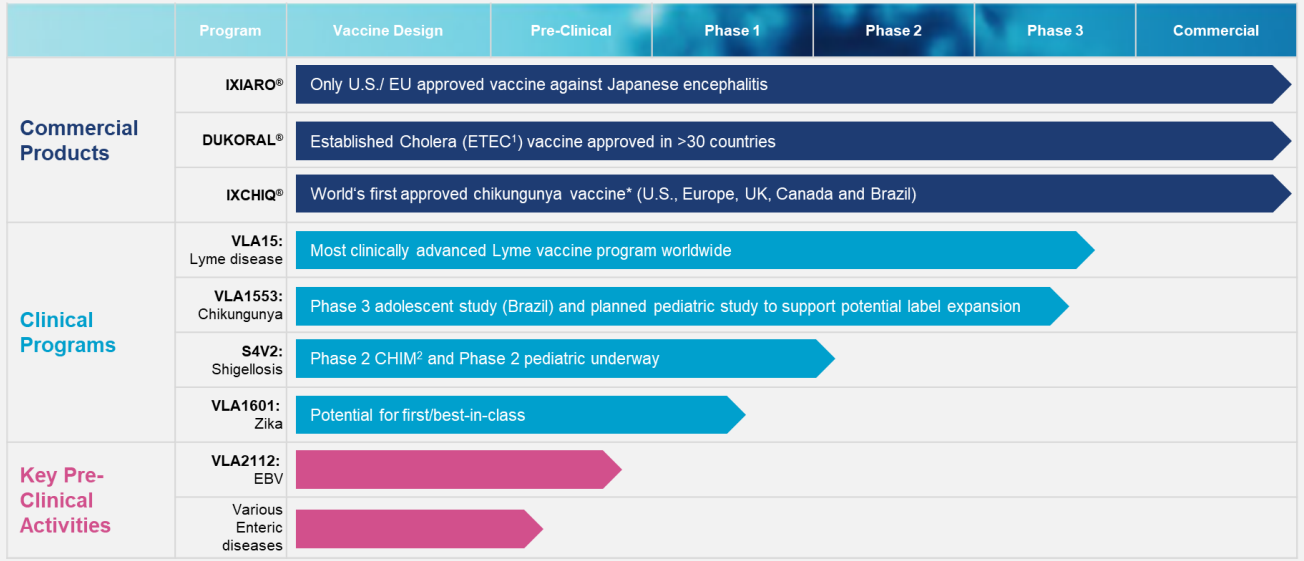
Medical Countermeasures for Vector-Borne Diseases: Industry Challenges and Funding Opportunities

Valneva: A Leading Specialty Vaccine Company

Focused on vaccines that make a difference

We **develop, manufacture, & commercialize** prophylactic vaccines for infectious diseases addressing unmet medical needs

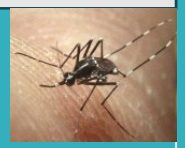
- **Proven Expertise:** Three in-house vaccine approvals; three proprietary commercialized travel vaccines
- **Focus on Innovation:** Advancing first-, only- or best-in-class vaccine candidates; Experience across multiple vaccine platforms
- **Key Value Driver** – De-risked blockbuster lead program: Lyme disease vaccine candidate partnered with Pfizer



1 ETEC indication in some markets only; 2 Controlled human infection model * since approval of IXCHIQ, another vaccine has been approved by several regulators, and may further be approved by certain regulators

Chikungunya: A Major Public Health Threat
IXCHIQ® Chikungunya Vaccine

Chikungunya – a mosquito-borne outbreak disease



- Often causes large, explosive outbreaks
- Affecting up to 75% of the local population[1]
- Substantial quality-of-life and health-economic impact[2]
- Nearly half (43%) of those infected develop chronic symptoms[3]
- ~460,000 cases and 170 deaths associated with chikungunya disease worldwide in 2024[4]

IXCHIQ® – Valneva's chikungunya vaccine

- Approved for adults by the U.S. FDA*, EMA*, UK's MHRA, Health Canada, and ANVISA (Brazil); for adolescents as well by EMA.
- Filed for additional adolescent label extensions and including two-year persistence data

Private development with public support

- **Priority Review Voucher** granted upon approval by US FDA (Nov 2023), resold for $103m in 2024 to finance its R&D
- **CEPI funding** (with support from EU Commission)
  - 2019: US$23.4m for late-stage development, incl. tech transfer to LMIC partner (Instituto Butantan)
  - 2024: US$41.3m to support broader access, incl. tech transfer to Asian LMIC partner (Serum Institute India)

1. Staples et al. CDC Yellow Book 2020, Chapter 4; 2. The global health and economic burden of chikungunya from 2011 to 2020: a model-driven analysis on the impact of an emerging vector-borne disease; 3. Bettis et al, PLOS Neglected Tropical Diseases 16(1): e0010069. 4. As of September 30th; https://bluedot.global/vaccines-on-the-table-as-chikungunya-outbreak-intensifies-in-india/

* While investigations in SAEs are ongoing, FDA and CDC recommend IXCHIQ® for use in individuals aged 18 to 60 years and EMA recommends IXCHIQ® for individuals aged 12 to 64 years

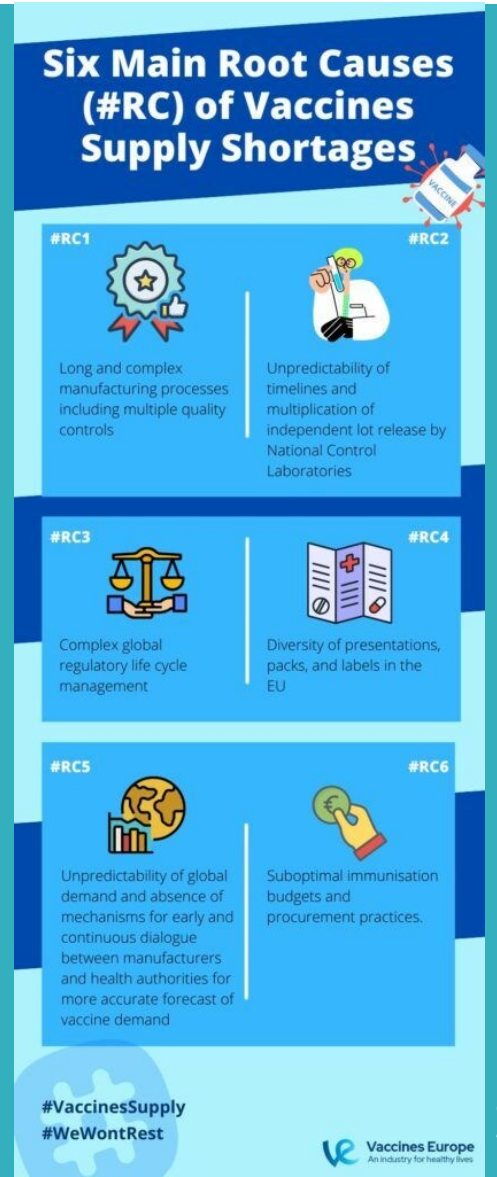
Developing a novel Zika virus vaccine candidate

- Zika: Flaviviral disease transmitted by *Aedes* mosquitoes[1]
- Devastating effects[2]:
  - Microcephaly & severe brain defects in newborns
  - Guillain-Barré syndrome in adults
- No vaccines or specific treatment available
- Zika remains “high” on WHO’s list of Public Health Emergencies of International Concern[3] – but funding has dried up

1. https://www.cdc.gov/zika/transmission/index.html; 2. http://www.who.int/mediacentre/factsheets/zika/en/;
3. https://cdn.who.int/media/docs/default-source/consultation-rdb/prioritization-pathogens-v6final.pdf?sfvrsn=c98effa7_7&download=true (last accessed 22 May 2025)

Manufacturing and supply of vaccines[1]

- Vaccines are very complex biological products with lengthy manufacturing, control and release processes
- Production of vaccines usually takes from 12 to 36 months, with 70% of that time dedicated to quality control
- How to prepare for future outbreaks?
- How to fund and stockpile MCMs in Europe?



1. https://www.vaccineseurope.eu/vaccines-ecosystem/vaccine-manufacturing-and-supply/ (last accessed 22 May 2025)

SLIDO Question: What is the cost for the development of a vaccine to market?

100-300m€

400-600m€

700-900m€

Source: A Sertkaya et al, New Estimates of the Cost of Preventive Vaccine Development, 8 Jan 2025, https://aspe.hhs.gov/reports/cost-preventive-vaccine-development, (last accessed 22 May 2025)

European Commission

Thank you

European Commission

MCMs for vector-borne diseases: industry challenges and funding opportunities

Ana BURGOS
HERA 02

Anna-Bella FAILLOUX
Head of the Arbovirus and Insect Vectors Unit, Institut Pasteur

Isabela RIBEIRO
Viral Diseases Cluster Director, DNDi

Lisa GOERLITZ
Head of Advocacy DSW, voucher for Dengue and Chikungunya industry partnerships

Olivier JANKOWITSCH
Vice President Governmental Affairs Valneva

European Commission

Thank you