



# R&D for Emerging Infectious Diseases

## How new tools can transform the fight

In a world experiencing increasing human mobility and ecological change, emerging infectious diseases (EIDs) pose a growing threat to health security. An outbreak in a remote corner of the world can quickly become a global crisis with devastating economic and human costs. New vaccines, treatments, diagnostics, and other tools are urgently needed to outsmart epidemics. However, research and development (R&D) for EIDs is particularly challenging.

The market potential for tools against EIDs is too uncertain to drive commercial investment and testing these products is especially difficult. Strong government support and smart collaboration between nations is vital to overcome these barriers and develop the tools needed to prevent, detect, and respond to these threats when we need them most.

**\$570** billion  
projected average annual cost of  
pandemics over coming decades

**11,310** lives  
human loss from 2014 West Africa  
Ebola outbreak

**3x** increase  
in annual disease outbreaks since 1980

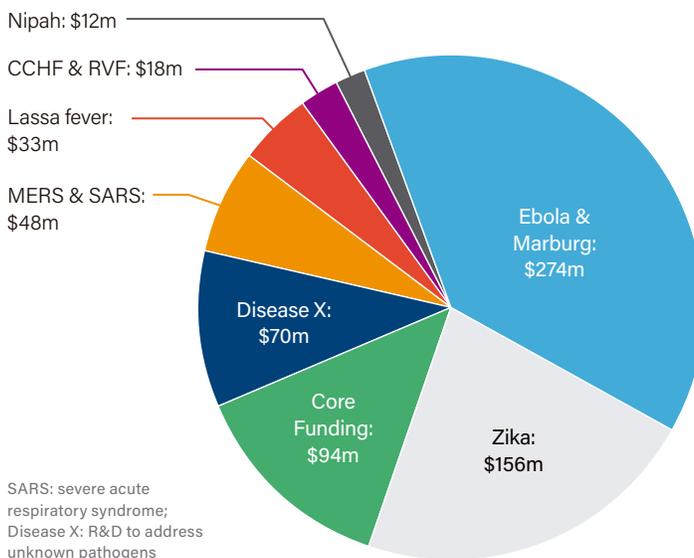
### Key missing tools We are without essential tools to combat many EIDs considered most likely to cause the next epidemic:

	Vaccines	Treatments	Diagnostics
<b>Crimean-Congo Haemorrhagic fever (CCHF)</b>	No FDA-approved vaccine is available. A Bulgarian-licensed vaccine exists, but its efficacy is unclear. Most advanced other candidate is in early human trials.	No specific licensed treatment is available. An existing antiviral has been used during outbreaks, but its efficacy remains unclear, and an experimental Ebola drug has shown initial promise.	Commercial tests are available but require sophisticated lab infrastructure. <b>Rapid, point-of-care (POC) tests are needed.</b>
<b>Ebola Zaire</b>	<b>One vaccine</b> , VSV-ZEBOV, is approved by the FDA and European regulators, while a second is being used on an emergency basis. Additional vaccines are in early development stages.	<b>Two experimental treatments</b> have been found highly effective and are being used on an emergency basis, but neither has full regulatory approval.	<b>One rapid test is FDA-approved</b> , while additional diagnostics, including rapid and portable tests, have been approved for emergency use with further validation studies needed.
<b>Marburg &amp; Ebola Sudan</b>	No licensed vaccine is available. Most advanced candidate is in early human trials.	No specific licensed treatment is available. Most advanced candidate is in early human trials.	Confirmatory tests are available but require sophisticated lab infrastructure. <b>Rapid POC tests are needed.</b>
<b>Lassa fever</b>	No licensed vaccine is available. Most advanced candidate is in early human trials.	No specific licensed treatment is available. The antiviral ribavirin is effective if used in early disease stages, but more robust assessment is needed.	Confirmatory tests are available but require sophisticated lab infrastructure. <b>Rapid POC tests and tests to distinguish symptomatic stages are needed.</b>
<b>Middle East respiratory syndrome coronavirus</b>	No licensed vaccine is available. Most advanced candidate is in early human trials.	No specific licensed treatment is available. Most advanced candidate is in early human trials.	Confirmatory tests are available at a laboratory level and rapid tests are FDA-authorized for emergency use. <b>POC tests for humans and animals are needed.</b>
<b>Nipah</b>	No licensed vaccine is available. Most advanced candidate is in preclinical research.	No specific licensed treatment is available. Most advanced candidate is in early human trials.	Confirmatory tests are available but require sophisticated lab infrastructure and could benefit from further validation. <b>Rapid POC tests are needed.</b>
<b>Rift Valley fever (RVF)</b>	No licensed human vaccine is available, though animal vaccines are used. Several candidates are in early stages of development.	No specific licensed treatment is available.	Confirmatory tests are available but require sophisticated lab infrastructure. <b>Rapid POC tests for humans and animals are needed.</b>
<b>Zika</b>	No licensed vaccine is available. Several candidates are in development, including ones in late-stage human trials.	No specific licensed treatment is available. Several therapies are in clinical development	<b>Commercial tests are available</b> with additional tests authorized under emergency use protocols.
<b>Pandemic influenza</b>	No licensed universal flu vaccine is available. Most advanced candidate is in late-stage human trials.	Existing antivirals may be effective. <b>Additional broad-spectrum antivirals are needed.</b>	<b>Rapid, POC tests will be needed.</b>

## Research progress

- The VSV-ZEBOV **Ebola vaccine**, which is now approved by the FDA and European regulators, demonstrated a 97% protection rate during the 2018/2019 outbreak. The development of this vaccine, as well as a second deployed vaccine and other candidates in early stages of development, are supported by partnerships with NIH, DoD, and BARDA.
- Two **experimental Ebola treatments** were found to dramatically improve survival rates during a NIH-funded trial during the 2018/2019 outbreak. One was developed by scientists at DoD and NIH, while the other was advanced through a partnership with BARDA.
- A candidate **vaccine for Marburg**—a deadly cousin of the Ebola virus—which was developed by NIH, entered first-in-human trials led by the DoD Walter Reed Army Institute of Research (WRAIR) in 2018. Development of this vaccine is now being continued with BARDA support.
- A candidate **vaccine for Middle East respiratory syndrome coronavirus (MERS-CoV)**, a severe respiratory disease, completed first-in-human studies in July 2019 and will progress to phase 2 studies in the Middle East. DoD funded the study which was conducted at WRAIR.
- The most advanced **universal flu vaccine** candidate, which was developed with support from NIH, began phase 3 clinical trials in 2018. Additional candidates supported by NIH are in clinical development with the goal of achieving a vaccine that is highly effective against multiple strains of influenza.
- Over a **dozen Zika vaccine candidates** are in clinical development, including candidates developed with support from NIH, DoD, and BARDA.
- Numerous **diagnostic tools for EIDs** have been advanced, including 1 test for Ebola and 2 tests for Zika that have FDA approval, as well as additional tests authorized by the FDA for emergency use including 10 tests for Ebola, 2 for MERS-COV, and 16 for Zika.

Global funding for R&D for World Health Organization R&D Blueprint EIDs, 2017



### US Government R&D efforts

The US government is developing tools to improve health security through a whole-of-government approach:

- **Biomedical Advanced Research and Development Authority** supports advanced development of vaccines, drugs, diagnostics, and other medical countermeasures against EIDs considered a threat to national security and has authority to add them to the US Strategic National Stockpile.
- **National Institutes of Health** conducts basic and clinical research to advance new treatments, vaccines, diagnostics, and vector control products to combat EIDs.
- **Department of Defense** supports R&D to create vaccines, drugs, and other tools for EIDs considered a threat to US service members or to national security.
- **Centers for Disease Control and Prevention** works to develop new and improved diagnostics and surveillance tools to improve global capacity to prevent, detect, and respond to outbreaks.
- **US Agency for International Development** has supported development of select tools to combat EIDs designed for low-resource settings, primarily through the Grand Challenges for Ebola and Zika programs.
- **Food and Drug Administration** administers the Tropical Disease Priority Review Program to incentivize industry investment in products for select EIDs and grants emergency use authorization to permit use of unapproved products during an emergency.

