## Abandoned in the Middle of Clinical Trials, Because of a Trump Order

The stop-work order on U.S.A.I.D.-funded research has left thousands of people with experimental drugs and devices in their bodies, with no access to monitoring or care.



Asanda Zondi, a participant in a research study to test a new device to prevent pregnancy and H.IV. infection. A U.S.A.I.D.-funded trial shut down, leaving a medical device in her body that needed to be removed right away. Credit... Sandile Ndlovu for The New York Times

By Stephanie Nolen

Stephanie Nolen has reported on U.S.A.I.D.-funded clinical trials in more than a dozen countries in Africa, Asia and Latin America.

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Asanda Zondi received a startling phone call last Thursday, with orders to make her way to a health clinic in Vulindlela, South Africa, where she was participating in a research study that was testing a new device to prevent pregnancy and H.IV. infection.

The trial was shutting down, a nurse told her. The device, a silicone ring inserted into her vagina, needed to be removed right away.

When Ms. Zondi, 22, arrived at the clinic, she learned why: The U.S. Agency for International Development, which funded the study, had withdrawn financial support and had issued a stop-work order to all organizations around the globe that receive its money. The abrupt move followed an executive order by President Trump freezing all foreign aid for at least 90 days. Since then, the Trump administration has taken steps to dismantle the agency entirely.

Ms. Zondi's trial is one of dozens that have been abruptly frozen, leaving people around the world with experimental drugs and medical products in their bodies, cut off from the researchers who were monitoring them, and generating waves of suspicion and fear.

The State Department, which now oversees U.S.A.I.D., replied to a request for comment by directing a reporter to <u>USAID.gov</u>, which no longer contains any information except that all permanent employees have been placed on administrative leave. Secretary of State Marco Rubio has said that the agency is wasteful and advances a liberal agenda that is counter to President Trump's foreign policy.

In interviews, scientists — who are forbidden by the terms of the stop-work order to speak with the news media — described agonizing choices: violate the stop-work orders and continue to care for trial volunteers, or leave them alone to face potential side effects and harm.

The United States is signatory to <u>the Declaration of Helsinki</u> that lays out ethical principles under which medical research must be conducted, requiring that researchers care for participants throughout a trial, and report the results of their findings to the communities where trials were conducted.

Ms. Zondi said she was baffled and frightened. She talked with other women who had volunteered for the study. "Some people are afraid because we don't know exactly what was the reason," she said. "We don't really know the real reason of pausing the study."

The stop-work order was so immediate and sweeping that the research staff would be violating it if they helped the women remove the rings. But Dr. Leila Mansoor, a scientist with the Centre for the AIDS Programme of Research in South Africa (known as CAPRISA) and an investigator on the trial, decided she and her team would do so anyway.

"My first thought when I saw this order was, There are rings in people's bodies and you cannot leave them," Dr. Mansoor said. "For me ethics and participants come first. There is a line."

#### <u>Image</u>

# <u>Vulindlela, where the CAPRISA clinical research took place, in rural South</u> Africa.Credit...Sandile Ndlovu for The New York Times

In the communities where her organization works, people have volunteered for more than 25 years to test H.I.V. treatments, prevention products and vaccines, contributing to many of the key breakthroughs in the field and benefiting people worldwide.

That work relied on a carefully constructed web of trust that has now been destroyed, Dr. Mansoor said. Building that trust took years in South Africa, where the apartheid regime conducted medical experiments on Black people during the years of white rule. Those fears are echoed in a long history of experimentation by researchers and drug companies in developing countries and in marginalized populations in the United States.

### Stephanie Nolen

Global health reporter, covering access to medicines and health care

"The guiding principle of my work is 'go there.' I want to hear directly from the people who are affected by disease, or lack of access to a new drug. I've been writing about global health for 30 years and have reported from more than 80 countries."

<u>Learn more about how Stephanie Nolen approaches her work.</u>

The Times identified more than 30 frozen studies that had volunteers already in the care of researchers, including trials of:

- malaria treatment in children under age 5 in Mozambique
- treatment for cholera in Bangladesh
- a screen-and-treat method for cervical cancer in Malawi
- tuberculosis treatment for children and teenagers in Peru and South Africa
- nutritional support for children in Ethiopia
- early-childhood-development interventions in Cambodia
- ways to support pregnant and breastfeeding women to reduce malnutrition in Jordan
- an mRNA vaccine technology for H.I.V. in South Africa

It is difficult to know the total number of trials shut down, or how many people are affected, because the swift demolition of U.S.A.I.D. in recent days has erased the public record. In addition to the disabled website, the agency no longer has a communications department. And the stop-work order prohibits any implementing agency from speaking publicly about what has happened.

In England, about 100 people have been inoculated with an experimental malaria vaccine in two clinical trials. Now, they no longer have access to the clinical trial staff if that vaccine were to cause an adverse reaction in their bodies. The trial is an effort to find a next-

generation vaccine better than the one now used in Africa; that shot protects children against about a third of malaria cases, but researchers hoped to find a vaccine that offered much more protection. Malaria remains a top global killer of children; 600,000 people died of the disease in 2023, the latest figure available.

Had the trial not been frozen, the participants would be coming to a clinic routinely to be monitored for adverse physical effects, and to have blood and cell samples taken to see whether the vaccine was working. The participants are meant to be followed for two years to assess the vaccine's safety.

A scientist who worked on the trial said she hoped that partners at the University of Oxford, where it was being conducted, were shuffling staff to respond if any participant fell ill. But she was fired last week and no longer has access to any information about the trial. She spoke on condition of anonymity because she feared jeopardizing her ability to work on malaria research the U.S. might conduct in the future.

"It's unethical to test anything in humans without taking it to the full completion of studies," she said. "You put them at risk for no good reason."

Had the stop-work order come later this year, the newly-vaccinated volunteers might have been in an even more precarious position. They were scheduled to be deliberately infected with malaria to see if the experimental vaccine protected them from the disease.

### <u>Image</u>

Ms. Zondi leaving the Vulindlela clinic. "Some people are afraid because we don't know exactly what was the reason. We don't really know the real reason of pausing the study," she said. Credit... Sandile Ndlovu for The New York Times

Dr. Sharon Hillier, a professor of reproductive infectious diseases at the University of Pittsburgh, was until this week director of a five-year, \$125 million trial funded by U.S.A.I.D. to test the safety and efficacy of six new H.I.V. prevention products. They included bimonthly injections, fast-dissolving vaginal inserts and vaginal rings.

With the study suspended, she and her colleagues cannot process biological samples, analyze the data they have already collected, or communicate findings to either participants or the partnering government agencies in countries where the trials were conducted. These are requirements under the Helsinki agreement.

"We have betrayed the trust of ministries of health and the regulatory agencies in the countries where we were working and of the women who agreed to be in our studies, who were told that they would be taken care of," Dr. Hillier said. "I've never seen anything like it in my 40 years of doing international research. It's unethical, it's dangerous and it's reckless."

Even trials that were not funded in whole or part by U.S.A.I.D. have been thrown into turmoil because they were using medical or development infrastructure that was supported by the agency and is no longer operational. Millions of dollars of U.S. taxpayer funds already spent to start those trials will not be recouped.

The shutdowns have business consequences as well. Many of those trials were partnerships with U.S. drug companies, testing products they hoped to sell overseas.

"This has made it impossible for pharmaceutical companies to do research in these countries," Dr. Hillier said.

Another H.I.V. trial, called CATALYST, has thousands of volunteers in five countries testing an injectable drug called long-acting cabotegravir. Participants were receiving bimonthly injections to maintain a sufficient level of the drug in their bodies to prevent H.I.V. infection. Without regular injections, or a carefully-managed end to use of the drug, the participants will not have enough cabotegravir to stop a new infection, but there will be enough in their systems that, if they were to contract the virus, it could easily mutate to become drug-resistant, said Dr. Kenneth Ngure, president-elect of the International AIDS Society.

This is a significant threat to the trial volunteers and also to the millions of people living with H.I.V. because cabotegravir is closely related to a drug that is already used worldwide in standard treatment of the virus. Development of resistance could be catastrophic, Dr. Ngure said: "It's wrong on so many levels — you can't just stop."

A clinical trial run by the development organization FHI 360, which implemented many U.S.A.I.D.-funded health programs and studies, was testing a biodegradable hormonal implant to prevent pregnancy. Women in the Dominican Republic had the devices in their bodies when U.S.A.I.D. funding was cut off. A spokeswoman for the organization, which furloughed more than a third of its U.S.-based staff this week, said that it had pulled together other resources to ensure that participants continue to receive care.

Another trial, in Uganda, was testing a new regimen of tuberculosis treatment for children. The stop-work order cuts those children off from potentially lifesaving medication.

"You can't walk away from them, you just can't," a researcher in that trial said