

1. What is Ebola Virus Disease?

Ebola virus disease (EVD) or simply Ebola, is a disease of humans and other primates caused by ebola viruses. Signs and symptoms typically start between two days and three weeks after contracting the virus.

Symptoms include fever, sore throat, muscular pain, and headaches.

The disease kills between 25 and 90 out of every 100 persons who get infected.

2. What are measures in place to treat the Ebola Virus disease?

No specific treatment or vaccine for the virus is currently available, although a number of potential treatments are being studied. The following basic interventions, when used early, can significantly improve the chances of survival:

- Providing intravenous fluids (IV) and balancing electrolytes (body salts).
- Maintaining oxygen status and blood pressure.
- Blood transfusions
- Treating other infections if they occur.

A number of experimental treatments are being considered for use in the context of the recent outbreak. Treatments which will prevent people from getting the disease are also undergoing experiments. These kinds of treatments are known as vaccines.

A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as a threat, destroy it, and keep a record of it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters.

3. What is a clinical trial?

The experiments being conducted on the treatments and vaccines are known as clinical trials. Clinical Trials are researches that are conducted to determine whether a medicine, medical strategy, treatment, or device is safe and effective for humans. Clinical trial is defined by section 166 of the Public Health Act 2012, Act 851 as an “investigation consisting of a particular description by, or under the direction of a medical practitioner, dentist or veterinary surgeon to the patient or animal where there is evidence that a medicine, medical device or procedure or herbal medicine of that description has effects which may be beneficial to and safe to the patient or animal, and the medicine, medical device or procedure or herbal medicine is for the purpose of ascertaining beneficial or harmful effects”.

Clinical trials may be conducted on volunteers who have a disease or are healthy, depending upon the purpose of the research.

Clinical trials produce the most reliable data for justifying any health care decision. A trial is only conducted if existing evidence does not provide an answer to:

- Whether a new approach works well in people and is safe
- Which treatments or strategies work best for certain illnesses or groups of people

An Ebola Vaccine trial is therefore a clinical trial that will test the safety of experimental vaccines that may protect against the Ebola Virus Disease and determine if the vaccine induces an immune response to the virus.

Ebola Vaccine trials will therefore help determine the safest and most effective vaccine for treating or preventing EVD.

4. Which vaccines are in development?

http://www.who.int/medicines/emp_ebola_q_as/en/ provides a summary of some ongoing clinical trials for Ebola vaccines. As indicated in the table Ghana will participate in trials that will test the safety and immunogenicity of two of the vaccines that has been developed against the disease.

The vaccines that will be tested in Ghana do not treat EVD but rather prevent EVD.

5. Can the vaccine(s) cause Ebola outbreak?

No, the Ebola vaccines to be tested cannot cause disease.

The vaccines to be tested in Ghana are made using a common cold virus called an adenovirus that does not make people sick. The vaccines contain extracts that do not cause the disease from the Ebola virus. It is expected that the body will recognize this extract as a foreign body and develop substances to fight it. These substances developed by the body against the extract may protect humans from the disease. In animals, such the vaccines have been shown to stimulate immune response against Ebola virus.

6. Why is Ebola trial being conducted in Ghana when the country is not affected?

Although Ghana has not yet recorded any case of EVD, Ghana is neighbours to the epidemic areas in West Africa and people living in Ghana are at risk of contracting the disease due to high passenger flow and risk of animal transmission.

Participation in the clinical trials is also the only way that can assure that people living in Ghana can benefit from the vaccines. Participation in the trials will give crucial information about whether the tested vaccines are safe, well tolerated and capable of stimulating adequate immune responses in people living in Ghana. If it works, it could help alter the dynamic of this epidemic by interrupting transmission.

Participation of Ghana in the Ebola trials will also contribute to worldwide public health.

7. Why does it seem that the Ebola Vaccine trials are being rushed?

Ebola's infected more than 8,000 people and killed about half of them, and the World Health Organization says the true toll is likely even higher. If it is eventually shown to work and if this information can be generated fast enough, it could become a public health tool to bring the current, and future, Ebola virus disease epidemics under control.

8. Who will authorize conduct of the clinical trials in Ghana?

The Government of Ghana gives the Food and Drugs Authority (FDA) the power to authorize and monitor clinical trials in Ghana (Part 8 of the Public Health Act 2012, Act 851). The trial protocols are being reviewed for approval both the FDA and the experts from various Independent committees responsible for the ethical review of the trials. The Technical Advisory Committee on Clinical Trials is also reviewing the trial protocols and will provide expert advice for conduct of the trials when required.

9. Should the FDA give approval, will they still monitor the clinical trials?

Yes, The FDA monitors all approved trials in Ghana and especially with a sensitive clinical trial like this; the FDA has already conducted pre- trial inspection of the sites and trained the study team to ensure that both the site and personnel are all in good position for effective work as per international and national standards.

10. Can the Ebola vaccines to be tried in Ghana cause side effects in people who will be vaccinated?

Just like any vaccination, it may come with certain common side effects like fever, chills or headaches, or feel fatigue or muscle pain. These reactions usually last no longer than a few hours and disappear with medication to bring the fever down. Some volunteers may also experience joint pain, beginning in the first two weeks after vaccination and generally lasting no more than a few days.