Q&A
Clinical trials & scientific research

About Us

Right to Care

Right to Care is a non-profit organisation established in 2001 to help HIV-positive South Africans access life-saving antiretroviral treatment. We support the National Department of Health in South Africa with preventing HIV and TB and treating patients with these diseases to allow them to live full, productive lives. We also support the Department of Correctional Services by working with inmates to prevent and treat HIV and TB, and this year, we helped test inmates in correctional services facilities in Gauteng for COVID-19. We also work with governments outside of South Africa to help prevent and treat HIV, TB, HIV-associated conditions and to manage COVID-19.

Today, Right to Care employs 3,300+ staff across seven countries and supports 800,000+ patients living with HIV with antiretroviral treatment.

Right to Care is well regarded for putting patients first. We pioneered client-centred care. This approach has seen us get more people onto HIV and TB treatment, and we are now working to end HIV as a global pandemic and an international public health emergency. We work with each patient to understand their life circumstances and their challenges, to help them unblock these challenges, to get onto treatment, and to stay on their treatment.

In 2015, Right to Care helped Sierra Leone manage the Ebola epidemic and in 2017, we helped Zambia manage the Cholera outbreak.

With our 20-year track record, and our capacity to manage disasters in accordance with the World Health Organisation's public health emergency framework, we stepped up to support the National Department of Health with its COVID-19 response, and we are also supporting health departments in the Eastern Cape, the Free State and Mpumalanga to manage COVID-19.

Right Clinic's Esizayo Clinic

Cosmo City is a thriving multiclass, multiracial city situated 25 kilometres north west of Johannesburg, but there are not enough public healthcare facilities to serve the people living there. This is why Right to Care launched the Esizayo Clinic in Cosmo City in 2018. The clinic provides quality healthcare at affordable prices. Today, people living in and around Cosmo City pay just R350 for a consultation with a doctor, screening, testing and their medication.

Right to Care also has a mobile unit that reaches into the heart of communities living here to test and screen them for HIV, TB and cancer, and to help those that test positive access care and treatment. We have built strong relationships with communities living in Cosmo City and surrounding areas including Zandspruit.

The Esizayo Clinic is an initiative of Right to Care, and falls under its Right Clinic division. This division supports the Department of Health in providing fee-for-service primary healthcare in communities.

The clinic will soon open as another research site of the Clinical HIV Research Unit.

The Clinical HIV Research Unit

The Clinical HIV Research Unit (CHRU) was founded in 2001 and until 2020, has run clinical trials undertaking clinical research to prevent, treat and manage HIV/AIDS, TB and associated diseases. This year, we are participating in studies to help end the coronavirus pandemic.

CHRU is a division of the Wits Health Consortium, which is part of the Faculty of Health Sciences at the University of Witwatersrand (Wits) and affiliated to the Department of Internal Medicine at Wits. We have long-standing collaborations with the National Health Laboratory Services (NHLS), and in particular, its Department of Molecular Medicine and Haematology, and with the National Institute of Communicable Diseases (NICD).

Our research sites are situated at:

- The Helen Joseph Hospital, Westdene, Johannesburg, Gauteng
- The Sizwe Tropical Disease Hospital, Sandringham, Johannesburg, Gauteng
- The King DinuZulu Hospital, Sydenham, Durban, KwaZulu-Natal and
- The Empilweni TB Hospital, Port Elizabeth, Eastern Cape.

Internationally, CHRU is recognised as a multi-disciplinary research group that participates in major global multi-centre clinical trials, and as one of South Africa's leading research sites.

Our mission is to deliver excellence and quality in clinical research.

How do these organisations link together?

Right to Care supports the Clinical HIV Research Unit (CHRU) to recruit people and encourage them to participate in clinical trials. The Esizayo Clinic is part of Right to Care and is also a recruitment site for the Clinical HIV Research Unit. It will soon be launched as another CHRU clinical research site.

About clinical trials

What is a clinical trial?

Clinical trials are used to test new methods of diagnosing, treating or preventing health conditions. The goal of a clinical trial is to determine whether something is both safe and effective. A clinical trial involves research using human volunteers (also called participants) and is used to add to medical knowledge.

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the sponsor. A variety of interventions are evaluated through clinical trials, including: medications, medication combinations, new uses for existing medications, vaccines, medical devices and even behavioural changes, like diet.

Clinical trials may compare a new medical approach to either a standard one that is already available and in use, to a placebo that contains no active ingredients, or to no intervention at all. Some clinical trials compare interventions that are already available against each other to see which is best.

When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including no intervention at all).

The investigators first study the product or approach in the lab and in animal trials to determine safety and efficacy. Once they have met certain standards of safety in these early stages, they move onto different phases of the trial where they start testing the product or approach in humans. They first assess the safety of the intervention by observing and measuring the responses of the participants.

In later phases, they look at the effectiveness of the intervention by measuring it against certain outcomes. For example, investigators may give a drug or treatment to participants who have high blood pressure to see whether their blood pressure decreases.

Remember, no treatment is completely safe for everyone; however, a clinical trial helps make sure that the treatment is safe and effective for the vast majority of people. Without clinical trials we would have no medications or agents to fight illness or to prevent illness in our population.

Who runs clinical trials?

Clinical trials can take place in many locations, including hospitals, universities, doctors' offices, and community clinics. The location depends on who is conducting the trial and what is being tested.

Usually, trials are run at clinical research sites. Clinical studies can be sponsored, or funded, by pharmaceutical companies, academic medical centres, universities, voluntary groups, government agencies and a variety of other organisations.

Every clinical trial is led by a principal investigator, often a medical doctor. Clinical trials also have a research team that may include doctors, nurses, social workers, and other health care professionals.

Who benefits from clinical trials?

Everyone benefits from clinical trials. New medications and developments in the medical and health fields could not be found if it were not for clinical trials. Any medication that you take today, including something as basic as Panado, has come from clinical trials, and even science about lifestyle choices has been investigated using clinical trials.

Who participates in clinical trials?

Clinical trials have standards outlining who can participate. These standards are called eligibility criteria and are listed in the trial protocol. Some clinical trials seek participants who have the

illnesses or conditions that will be studied, while some are looking for healthy participants, and others are limited to a set group of people who are asked by researchers to enrol.

The factors that allow someone to participate in a clinical trial are called inclusion criteria, and the factors that prevent someone from participating are called exclusion criteria. They are based on characteristics such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

How long do they take?

The length of a clinical trial varies, depending on what is being studied. Participants are told how long the study will last before they enrol.

Do people that take part in clinical trials get paid?

This depends on the trial and the risks involved. However, in most instances participants will simply be reimbursed for any costs required to participate. They often also receive free high-quality medical care for the duration of the trial.

How do we know clinical trials are safe for people that participate in them?

It is worth remembering that no treatment, even 'natural' treatments, are guaranteed to be completely safe for everyone even after clinical trials have been performed. The medications we take every day all have side effects and risks.

A clinical trial is designed, however, to make sure that the benefits of the treatment, vaccine or drug outweigh the possible risks for most people.

In the early phases of the trial (Phases 0, 1 and 2) the focus is predominantly on the correct dose and the safety of the drug or treatment. From Phase 3 onwards, common side effects are more or less established, and the main question is then about how effective the treatment or drug is, although safety monitoring continues, even after registration of the new medication.

In South Africa, the following regulatory approvals are required before any trial can commence:

- Research Ethics Committee – This committee is independent of the sponsor and the clinical investigators. These committees are usually affiliated with a university scientist e.g. specialist, and also someone from the community e.g. pastors, lawyers and traditional healers.
- South African Health Products Regulatory Authority (SAHPRA) - SAHPRA is an entity of the National Department of Health, created by the South African Government to ensure that the health and well-being of human and animals is prioritised. SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines and medical devices.

Other regulatory approvals are also required, for example from the Department of Health and the hospital or clinic involved in the trial.

Internationally, there are research networks that provide oversight to trials taking place in South Africa, and all clinical trials are conducted in accordance with World Health Organisation regulations.

Additional safety factors for participants are that:

- Independent data safety monitoring boards (DSMB) monitor trial results and side-effects throughout the process, and will pause or halt the trial if they have any concerns regarding the safety of participants.
- The clinicians who take part in and run the trial also put the interests of the participants first. They work independently and are not dictated to by the sponsors of the trial. As locally trained doctors who are part of the local communities, they really do have the participant's best interests as their primary focus.
- All trial participants complete an informed consent form, which details exactly what the trial involves and any potential risks. All participants will therefore have all the aspects of the trial explained to them, and have all their questions answered in advance. Nobody is coerced into participating in a trial, and instead everything is done on a voluntary basis. Informed consent is only considered valid if the person fully understands what is required, and has voluntarily confirmed their willingness to participate.
- All participants have the option of withdrawing from a trial at any time.

What is a Phase 3 clinical trial?

Clinical trials used in drug development are described by phase once they reach the human stage of testing. These phases are pre-defined and provide structure to the process.

Phase 0 of a clinical trial generally involves fewer than 15 participants, and in this phase a very small dose is usually given to exclude that the agent causes harm.

Phase 1 normally has between 20 and 80 participants, who are all in good health. In this phase the dosing is tested, to establish the highest dose tolerable to people.

In Phase 2 there are several hundreds of participants. In this phase the safety of the agent continues to be evaluated, and commonly some people with underlying conditions are now involved, to again establish safety.

In Phase 3 there are commonly a few thousand participants. The aim of this phase is to evaluate the effectiveness of the agent being tested, with safety having been mainly established in phases 0-2. Side effects are monitored. The agent will be tested in the healthy population, as well as in those with underlying conditions and comorbidities.

Phase 4 trials occur after the drugs have been approved for use by the public. These trials look at long term safety data.

Are people coerced or forced to participate in a clinical trial?

No one is ever forced or coerced to participate. It is a decision every individual makes for him or herself. It is voluntary. People that are considering participating will be provided with comprehensive information about the clinical trial. If they choose to participate in the trial, they will sign a voluntary informed consent form. Voluntary informed consent is the cornerstone of health research ethics.

What is voluntary informed consent?

Voluntary informed consent is a procedure through which a competent volunteer, after having received and understood all the research-related information, can voluntarily provide his or her willingness to participate in a clinical trial. He or she is provided with information about the trial, its aims, benefits, and potential risks. Only after signing a voluntary informed consent form can a participant participate in the trial.

The Clinical HIV Research Unit (CHRU) ensures that all the ethical and legal requirements for voluntary informed consent for clinical research participation are fulfilled. It also adheres to the South African Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa.

If the study sponsor of a clinical trial just wants results, who looks out for the participants and protects their interests?

Research sites across the world have community advisory boards (CABs). A CAB is an independent body and acts as a watch dog to ensure that studies proceed properly and trial participants' concerns are accommodated and their rights are protected. Members of a CAB reflect a diverse mix of experiences, profiles and skills, and have cultural insight into the communities participating in the clinical trials. They are volunteers who are trained on good clinical practice. They educate people about clinical trials and about studies taking place at the research site, and they advocate for participants, give feedback on cultural and religious sensitivities and raise community concerns.

The research team, made up of doctors, nurses, social workers and other health care professionals also put the interest of trial participants first. They work independently and are not dictated to by the sponsors of the trial. As locally trained doctors who are part of the local communities, they really do have the participant's best interests as their primary focus.

Does a participant know what risks she or he will face?

Clinical trials are designed to improve the science of medicine. They are not designed to put people at risk. Everything about a trial is made clear to a participant before they sign the voluntary informed consent form:

- What is required from them
- How long they will be involved in the study
- How often they need to go to the research site
- The tests and procedures involved in assessing their health and response to the study

What happens if someone wants to stop half way through the trial?

Participants can withdraw from a study at any time. The informed consent process includes counselling which makes it clear that someone can withdraw at any time. The only thing the participant must do is inform the principal investigator of the study that she or he is withdrawing. They do not need to provide a reason.

What happens if someone on a trial gets sick or has a reaction?

When you enrol for the trial, you will be given a card with the names of your healthcare team at the research site, and their contact information. Contact them immediately and discuss your symptoms.

They may decide that they want to see you to assess you, in which case you will be assisted with transport, or, they may refer you to your healthcare facility.

Data safety monitoring boards monitor the safety of a clinical trial at regular intervals.

Should there be a signal that there is an increase in side effects, they will halt the trial while they investigate the issues and start-up the trial once they are satisfied with all safety aspects.

Remember that when a participant alerts the study team to a symptom or side-effect and the scientists respond quickly, it means that the safety protocols are working and that the safety measures are in place.

What is a vaccination clinical trial and how does it work?

The purpose of a vaccine/prevention clinical trial is to determine the efficacy (whether it works) and safety of an investigational vaccine for the prevention of a particular disease e.g. COVID-19.

In a vaccination clinical trial, the vaccine is given to volunteers who are followed up to see if they become unwell, or contract the illness being vaccinated against. This informs researchers as to whether the vaccine is safe and effective.

What past vaccination clinical trials have provided safe vaccinations that we use today?

All vaccines available today have been tested in clinical trials. All our life-saving vaccines such as those against smallpox, measles and polio were developed in clinical trials.

How do vaccines work?

Vaccinations all use different methods to produce an immune response. However, the immune response is similar. Therefore, when someone is injected with a vaccine, their body produces an immune response in the same way it would following exposure to a disease but without the person getting the disease. If the person comes in contact with the disease in the future, the body is able to make an immune response fast enough to prevent the person developing the disease or developing a severe case of the disease.

What do vaccines contain?

The active ingredients of a vaccine are made from viruses or bacteria (also called ‘antigens’). They challenge the immune system so that it fights the disease. Vaccines contain tiny quantities of active ingredients – just a few micrograms (millionths of a gram) per vaccine. To give some idea of how small these quantities are, one paracetamol tablet contains 500 milligrams of the drug, which is several thousand times more than the quantity of the active ingredient you would find in most vaccines. Hundreds of thousands of individual vaccines can be made from a single teaspoon of active ingredient.

Compared to the number of viruses and bacteria in the environment that our bodies have to deal with every day, the amount of active ingredient in a vaccine is very small.

In addition to the active ingredient in a vaccine, vaccines may also contain either a small amount of preservative or a small amount of an antibiotic to act as a preservative. Some vaccines may also contain a small amount of an aluminium salt, which helps produce a better immune response. Aluminium is one of the most common metals found in nature and is present in air, food, and water, and the aluminium contained in vaccines is similar to that found in a litre of infant formula.

About COVID-19 clinical trials in South Africa

Why do South Africans need to get involved in COVID-19 clinical trials?

At the moment many people's lives are on hold as we wait to be able to return to 'normal'. The COVID-19 virus is not going anywhere, with second waves of infection being seen across the globe. It is therefore imperative if we are to return to 'normal' that we find a way to prevent the virus, particularly in our most vulnerable populations. This would allow people to return to work and to go about their lives again as normal. Prevention of infection in our vulnerable populations is the only way of safely and responsibly returning to 'normal' and finding a vaccine is the best and most effective way of preventing spread and disease for those most at risk.

But South Africa has such a high recovery rate, so a COVID-19 vaccine isn't a huge priority?

Drugs don't necessarily work similarly across different populations. Africa has different needs and concerns compared to many other regions of the world. For example, we have had issues with Ebola, and our HIV and TB incidences are very high. It is therefore important that we test drugs on people here, as well as in other countries, to ensure that they work as well for us as they do for other populations.

The South African population has previously shown in research studies to have relatively unique responses to certain drugs and vaccines, e.g. the flu vaccine, certain antiretrovirals, and it is therefore vital that we take part in COVID-19 trials.

As an additional incentive, participating in clinical trials gives us the opportunity to get first access to medications that could prove to be life-saving. This avoids delays waiting for drugs to be fully registered and then marketed.

South Africa has benefitted hugely in the past from being involved in clinical research, in that access to expensive medications that would otherwise have been inaccessible to most of the population, were made available to those who needed them most through clinical trials.

We have many people in our country who are more vulnerable to COVID-19 and over 15000 people have died. These have included the elderly, diabetics, people with hypertension, overweight people and others. We have a responsibility to protect people whose immune systems may not be as strong as ours to fight the coronavirus.

Many say that big pharmaceutical companies in the US and Europe want to use Africans as guinea pigs to find a vaccine. Why should we support them?

Studies for new medications, vaccines, regimens and devices should always be done in countries that will use them. We know that there are genetic differences between people in different parts of the world, and the only way to know if there will be differences in side effects and effectiveness, is to do the trials in all relevant populations.

For example, the flu vaccine from 2009 was very effective in European and North American populations, but not in Africa. Another example is the antiretroviral drug nevirapine, which had very serious side effects in African women with high CD4 counts. Scientists would not have known this had the clinical trials not also been conducted in Africa. Clinical trials provide very controlled structures within which new interventions can be checked for side effects.

In addition, certain diseases are specific to certain areas, for example Ebola, and Ebola trials can only be done in areas affected by Ebola.

In terms of a COVID-19 vaccine, the pandemic affects all countries, and all countries have vulnerable populations that need to be protected. If South Africans don't come together to ensure that a vaccine is safe for our people, we won't be giving the vulnerable in our communities the protection they need.

Isn't there already a COVID-19 vaccination?

There is currently no vaccine against the coronavirus.

Is it true that sickness is raging in certain parts of the world directly as a result of Bill Gates-funded vaccines?

There is a fake news story doing the rounds concerning the oral polio vaccine. It was recently announced that wild type polio has been eliminated from Africa, which is a wonderful achievement. However, in areas with very low polio vaccination coverage with low levels of herd immunity, mutations can occur and lead to vaccine derived polio. These outbreaks occur from time to time, but the numbers are very small compared to the cases prevented by polio vaccine.

You can read more here: https://www.who.int/westernpacific/news/q-a-detail/what-is-vaccine-derived-polio.

The Bill and Melinda Gates foundation donate significantly towards many programmes. To note, websites that make outrageous claims and are trying to sell you something on their page, are often sources of fake news.

How do we know that a vaccine trial will be safe for participants?

Researchers who conduct the study are required to follow strict rules to keep participants as safe as possible. Although side effects can occur in any clinical trial, the study is designed to minimize the risk and participants are monitored very closely.

What happens if someone on a trial gets sick or has a reaction?

Large trials have data safety monitoring boards to monitor the safety of the trial at regular intervals. If there is any sign at any stage that there is an unacceptable rate of side effects, or that the severity

of side effects is high, the trial will be paused. Upon pausing the trial they will stop recruiting new participants, and investigate the causes of concern. They look at the safety issues and the side effects, and if they establish that the problems were completely unrelated or of such minor significance as to be tolerated, the trial is restarted. This should not be seen as something going wrong with the trial, but rather as the safety procedures being effective.