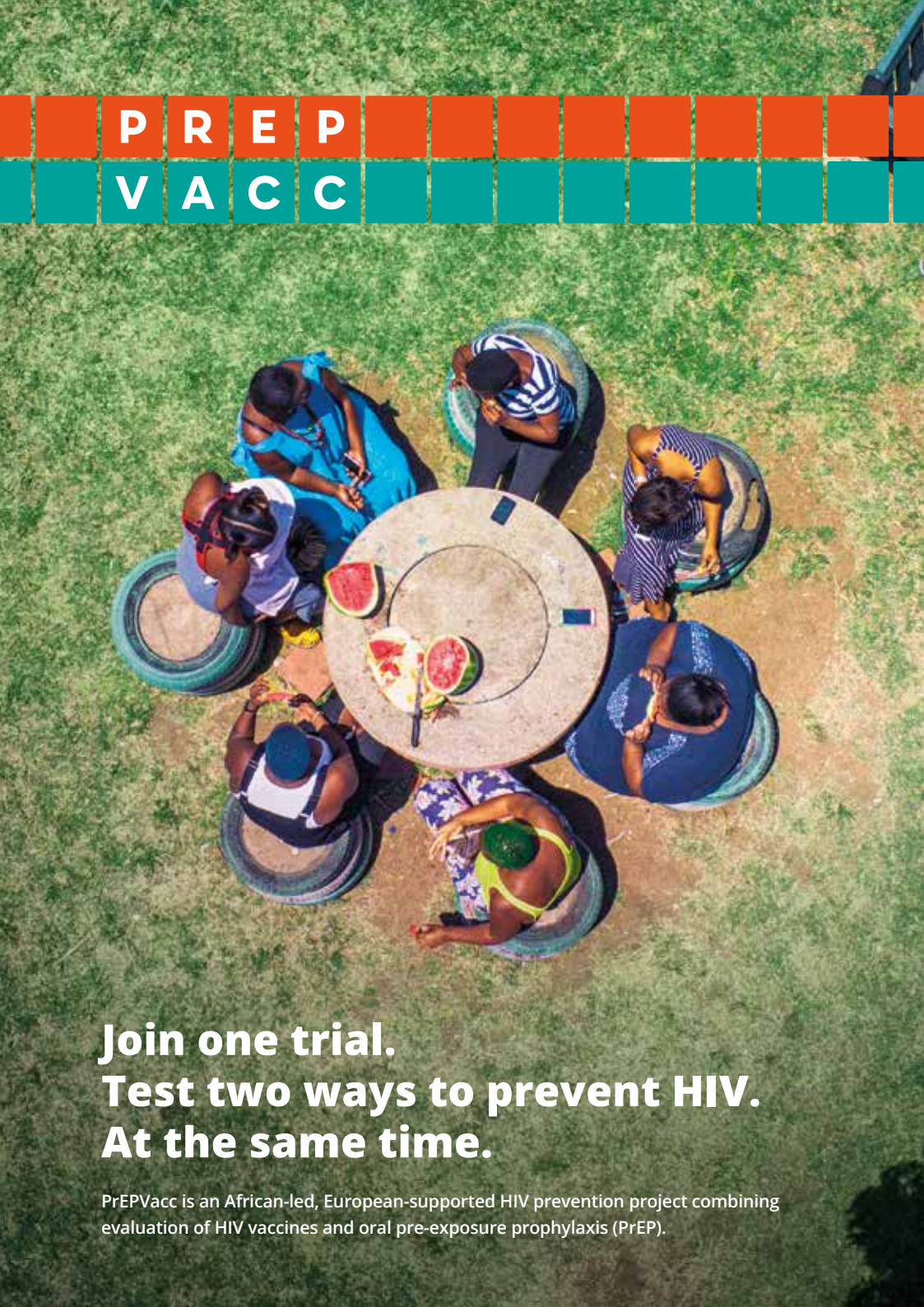
PREP
VACC



Join one trial.
Test two ways to prevent HIV.
At the same time.

PrEPVacc is an African-led, European-supported HIV prevention project combining evaluation of HIV vaccines and oral pre-exposure prophylaxis (PrEP).

What is the PrEPVacc study?

PrEPVacc is two things:

It is testing whether two experimental vaccine combination regimens can protect against HIV. Both these regimens have already been tested in clinical trials and have demonstrated their safety.

And at the same time it is testing a new form of PrEP against the existing standard for PrEP.

Where is the study?

It is planned to run at five sites in four countries: in Masaka, Uganda; Mbeya, Tanzania; Dar-es-Salaam, Tanzania; Maputo, Mozambique and Durban, South Africa.

What is an HIV Vaccine?

A vaccine teaches the body's immune system to prevent a particular infection or fight a disease, to keep you healthy. The world does not yet have a licensed vaccine to prevent HIV. In order to develop an HIV vaccine, researchers need to test it in people, to find out if it might help prevent or fight HIV. It is given as an injection.

What is oral PrEP?

PrEP is the use of antiviral drugs by HIV-negative individuals to reduce their risk of HIV infection. PrEP has been shown to prevent HIV and is available globally as a tablet.

What contribution will you make by taking part?

There are many ways to prevent HIV, but each year new infections continue to be reported. Your participation and efforts will be helping to answer two questions with information that could help prevent new infections in your community.

- We will be able to say whether developing either of the two different combination vaccine regimens for preventing HIV is worthwhile or not.
- We will be able to say whether a new form of PrEP is as acceptable, safe, and effective as the available oral standard PrEP, in women as well as men.

Men and women are being invited to take part in the PrEPVacc study who are aged 18–40 and likely to be at risk of HIV.

You can take part if:

- You are a healthy individual
- You are aged 18–40 years old on the day of screening
- You are willing and able to give informed consent to be part of the study
- You are willing and able to come to all the visits and undergo HIV testing and provide blood, urine and other samples at the required time points.

How will the health and the rights of participants be protected?

We will always give study participants full information about the study before they join, so they can give us informed consent to take part.

Participants have the right to leave the study at any time.

During the study, the clinic staff will monitor participants to make sure the vaccines and PrEP are not causing any health problems.

The clinic staff will also assist participants who report any social problems they may experience from being in the study.

Participant safety is managed by a study safety review team and an independent safety monitoring board that regularly look at the health information from the study participants to decide whether it is safe to continue giving the vaccines and PrEP.

An institutional Ethics Committee reviews and monitors the study plan for each site doing the study, including the information that is given to people about the study, study progress, and health problems in participants. The Ethics Committee also looks at whether participants' rights are being respected.

Each study clinic has a Community Advisory Board. Its members are local people who advise the researchers and bring the concerns and interests of the community and study participants to the researchers.

What if I don't want to take part?

Your participation is entirely voluntary, and it is up to you to decide whether or not to take part. If you do decide to take part you can withdraw at any time without giving a reason. If you decide not to take part or withdraw after you have joined, you will not be treated differently by the clinic or lose any other benefits or rights you would otherwise have.

What are the possible side effects?

Like most available medications and vaccines that we take, we know that there can be reactions or side effects. This may include fever, headaches, nausea, aches and pains and fatigue.

In some people PrEP can cause minor side effects like nausea, bloating, diarrhoea and headache. These side effects usually disappear over time.

Will I be protected from HIV if I join the study?

We do not know yet if the vaccines in this study will protect participants from HIV. People who take PrEP correctly are extremely unlikely to catch HIV.

All participants will be counselled on how to prevent HIV infection and will be encouraged to use the available prevention methods through the study.

How long will it take to find out if the study products work?

We expect the study to be completed by March 2023 and to learn whether the study vaccines and the new PrEP are preventing HIV infections by that time, but it is possible that we may know sooner. Whenever this information becomes available, it will be shared with the study participants and relevant stakeholders.

Does participation in the study affect my personal life in some way?

We ask women to use contraception during the vaccination period of the study (from screening until 18 weeks after the last injection) to prevent a pregnancy, as we don't know the effects of this vaccine on the developing baby. We ask men to avoid making their female partners pregnant during the vaccination period of the study for the same reason.

Can the vaccines give you HIV?

No. It is absolutely NOT POSSIBLE to get HIV infections from the vaccines used in this study. The vaccines do not contain any live HIV, killed HIV, parts taken from HIV or HIV-infected cells. The vaccines are made up of safe chemical components.

What will I need to do if I take part?

Your involvement in the PrEPVacc study will last at least 17 months from the first vaccine injection. There will be at least 15 clinic visits during the study. Visits will involve various procedures, counselling, learning from your experiences, updating on your health, answering questions about your sexual practices and behaviour, as well as taking blood and urine samples. They will typically last 1–3 hours each.

You will be given a detailed breakdown of what happens at each visit so you know what to expect. Your travel expenses to the clinic will be reimbursed.

The Vaccines

One regimen combines DNA with protein based vaccine, and the other combines DNA, MVA and protein based vaccine. Some participants will receive a placebo that does not contain vaccine, which will be a sterile liquid called saline.

PrEP

PrEPVacc will test whether a new form of oral PrEP, Descovy, taken daily, is equivalent or more effective than Truvada taken daily. Participants will be offered PrEP during the vaccine immunisation phase (6 months) in order to prevent HIV.

Who is running PrEPVacc?

PrEPVacc is led by African researchers from Entebbe in Uganda, at the MRC/UVRI and LSHTM Uganda Research Unit. They are supported by 14 partners, six from Africa, six from Europe and two from the US. The Sponsor of PrEPVacc is Imperial College London.

What do I do next?

If after reading this leaflet you have questions or are potentially interested in taking part in PrEPVacc, please contact your local site as follows:

PrEPVacc investigators from all sites.

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