

Clinical Trial Phases

Number
of people

Purpose

Duration

Pre-
clinical
Phase



Preliminary testing of the investigational drug/intervention in a lab before any testing in humans is done.



several
years

Phase
1



20 - 80



Test safety
of the drug



Test for side
effects



Determine the
right dose



12 - 18
months

Phase
2



100 - 300



Test for the
drug's effects
in the short
term



Compare the new drug
against an existing
drug or placebo



Monitor
side
effects



2 years
or longer

Phase
3



1000 - 3000



Compare the new
drug against an
existing drug or
placebo



Test for side
effects



See if it's
better



3 - 5
years

If successful in phase 3:



Application
submitted at
the Food and
Drug Administration



Application
reviewed



Application
approved



Drug awarded
marketing
licence and
made available
to public

Phase
4



1000+



Monitor its
safety



Monitor it's
side effects



Monitor its
effectiveness



ongoing



Will be continuously studied while
it's being used in practice.



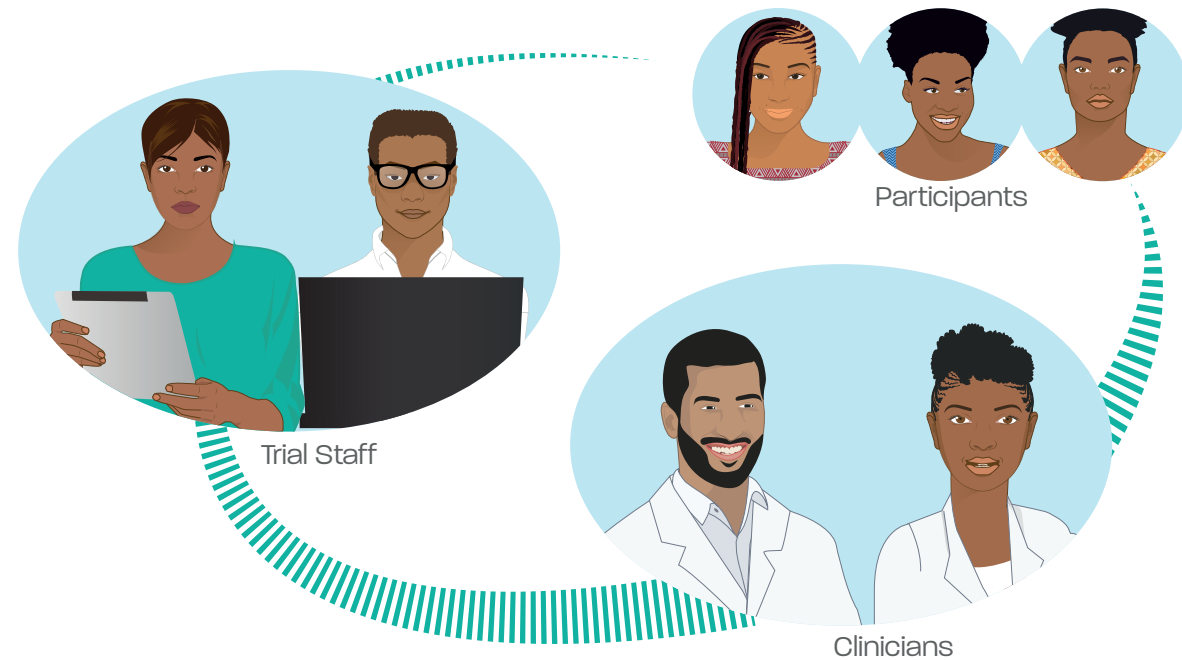
University of the Witwatersrand

WITS RHI

TYPES OF BLINDING IN A RANDOMISED CONTROLLED TRIAL

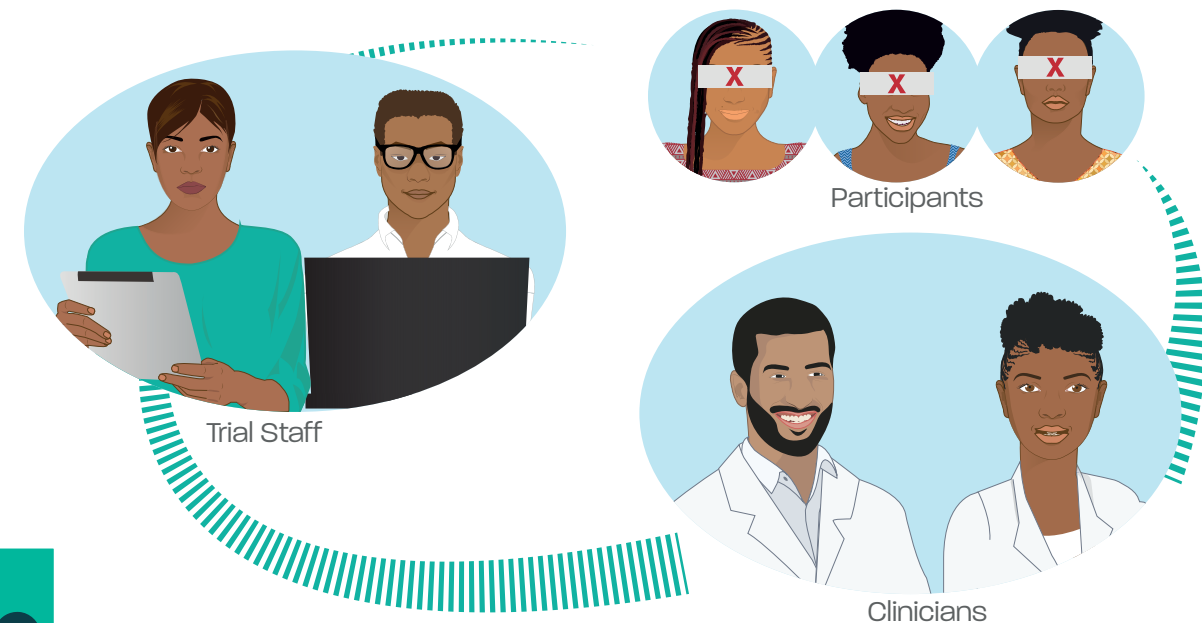
Unblinded or Open Label

All parties are aware of the treatment the participant receives.



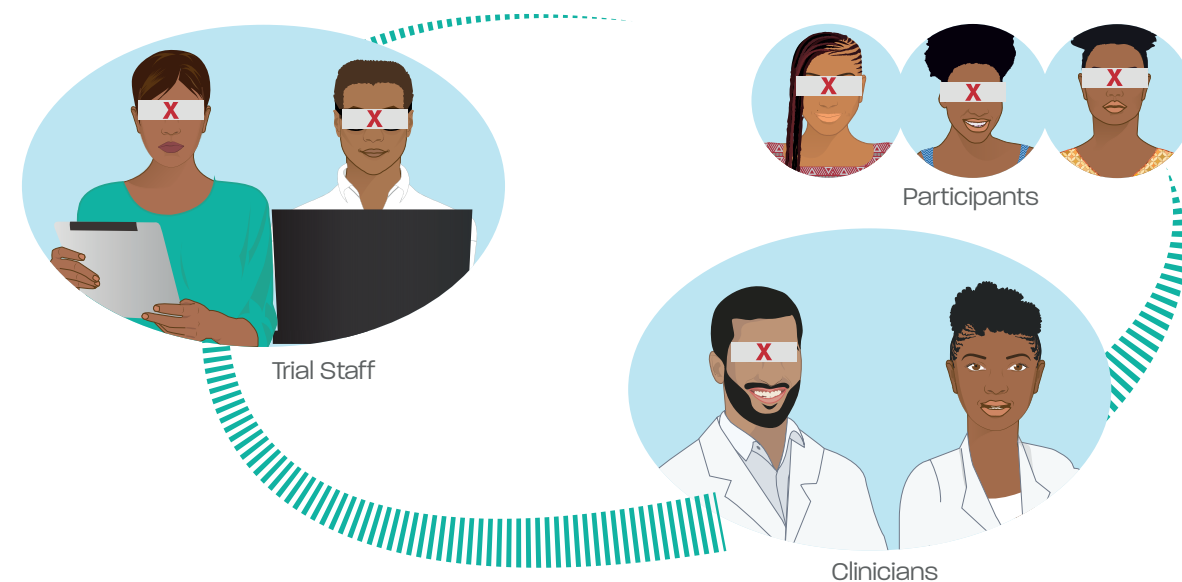
Single Blind

Only one party, usually the participants, does not know whether they are taking the placebo or the active drug/medicine.



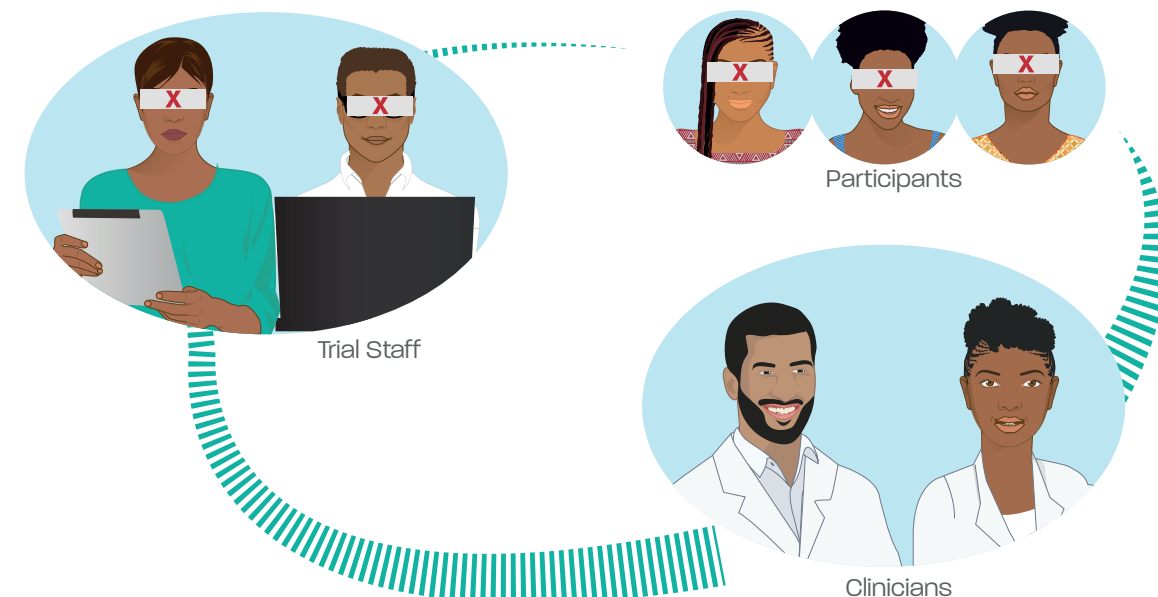
Double Blind

Neither the participant nor the trial staff knows who is receiving the placebo or the active drug/medicine until the trial is finalised. In some studies only one group of trial staff will be partially blinded.

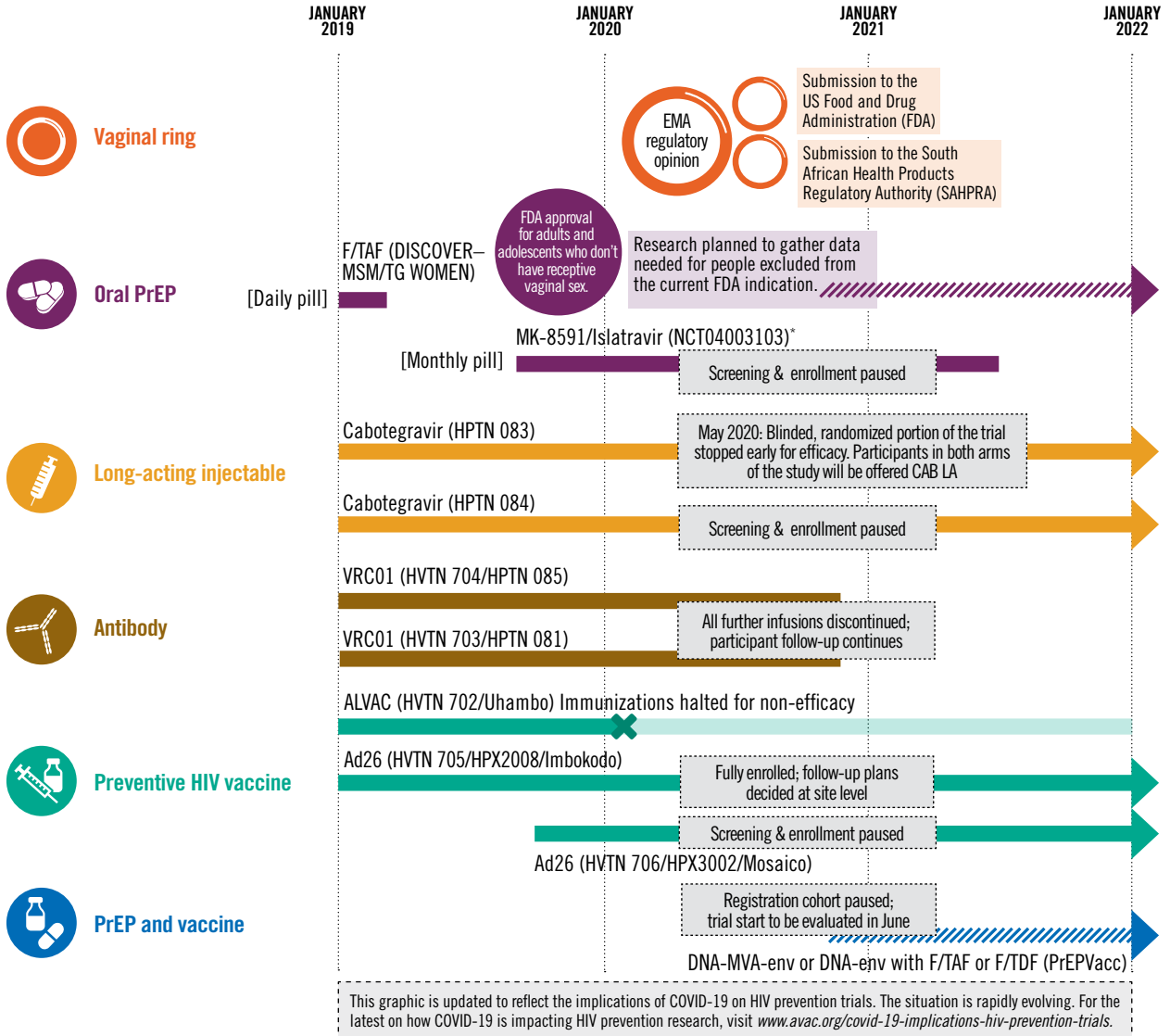


Triple Blind

The participants, clinicians & statisticians who conduct the analysis of the data are all unaware of who is receiving the placebo or active drug/medicine.



Biomedical HIV Prevention Trials: Results, milestones and more



This graphic is updated to reflect the implications of COVID-19 on HIV prevention trials. The situation is rapidly evolving. For the latest on how COVID-19 is impacting HIV prevention research, visit www.avac.org/covid-19-implications-hiv-prevention-trials.

