Being Part of Tuberculosis Vaccine Clinical Trials

Deelname aan kliniese navorsingstudies vir 'n vaksien teen tuberkulose

BEING PART OF TUBERCULOSIS VACCINE CLINICAL TRIALS

ENGLISH - AFRIKAANS

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Advancing Tuberculosis Vaccines for the World

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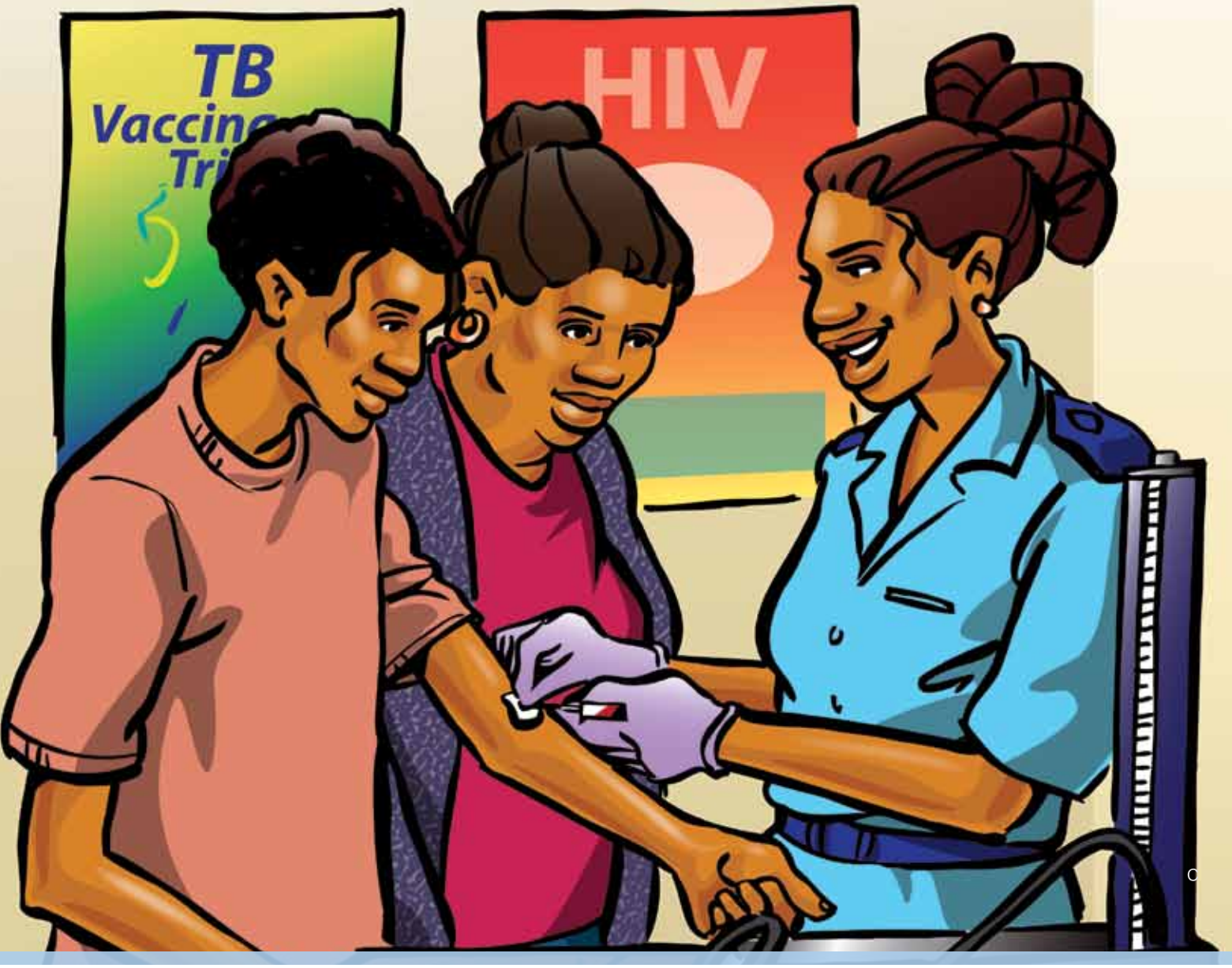
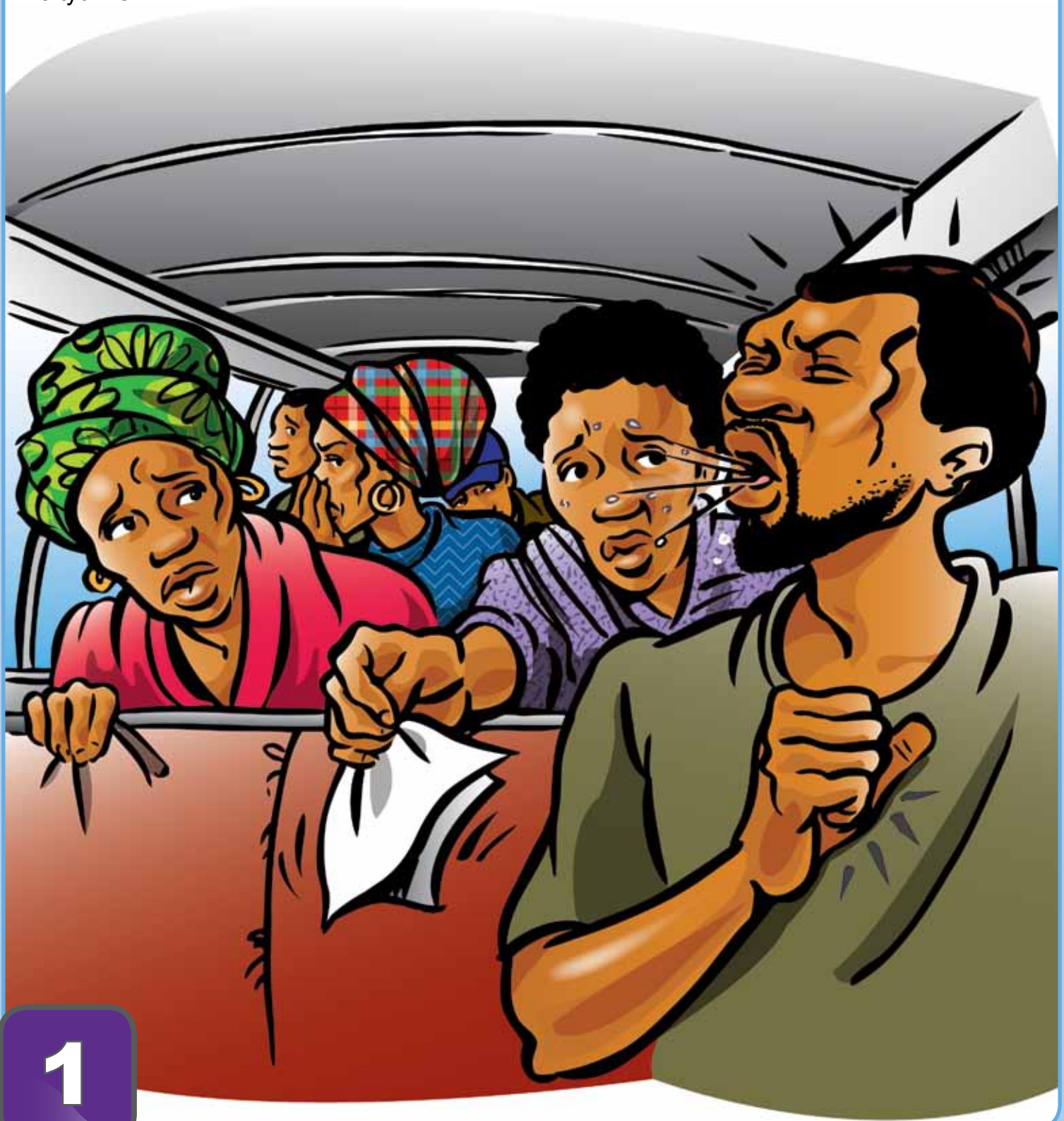


Press the buttons to listen to “Being Part of Tuberculosis Vaccine Clinical Trials” in English and Afrikaans.

Tuberculosis – TB - is caused by bacteria that mostly affect people's lungs. TB is spread through the air when people with TB cough, sneeze or spit. Coughing, chest pains, fever, night sweats, and weight loss can be signs of TB. Without treatment, many people with TB die. There are medicines that can treat and cure TB, but these do not always work.

Tuberkulose (TB) word deur bakterieë veroorsaak wat hoofsaaklik die longe affekteer. TB word in die lug versprei wanneer mense wat TB het hoes, nies of spoeg. Hoes, borspyn, koors, nagsweet en gewigsverlies kan tekens van TB wees. Sonder behandeling gaan baie mense met TB dood. Daar is medisyne wat TB kan behandel en genees, maar dit werk nie altyd nie.



Vaccines keep you healthy by helping your body fight germs. A vaccine for TB is given to babies, but it doesn't protect older children, teenagers or adults very well. A better vaccine to prevent TB is needed. Before a vaccine can be used by the public or general community, the vaccine developer must do a lot of research and tests to make sure the vaccine is safe and it works. These tests are called "clinical trials." A new vaccine for TB is being tested. William would like to take part in the clinical trial. He will be called a "participant."

Vaksiene hou 'n mens gesond deur jou liggaam te help om kieme te beveg. Daar word 'n vaksien teen TB aan babas gegee, maar dit bied nie goeie beskerming aan ouer kinders, tieners of volwassenes nie. 'n Beter vaksien is nodig om TB te voorkom. Voordat 'n vaksien deur die publiek of breë gemeenskap gebruik kan word, moet die vaksienontwikkelaar baie navorsing en toetse doen om seker te maak dat die vaksien veilig is en dat dit werk. Hierdie toetse word "kliniese navorsingstudies" genoem. 'n Nuwe vaksien teen TB word op die oomblik getoets. William wil graag aan die kliniese navorsingstudie deelneem. Hy sal 'n "deelnemer" genoem word.

The study team in the clinical trial has to follow a document called a “Protocol” which tells them exactly what to do and how to do it. This protocol is agreed to by a Health Authority and Ethics Committee before the vaccine is tested in people. These committees are separate from the study team and the vaccine developer. Their job is to make sure participants like William are protected from unnecessary risks and their rights are respected.

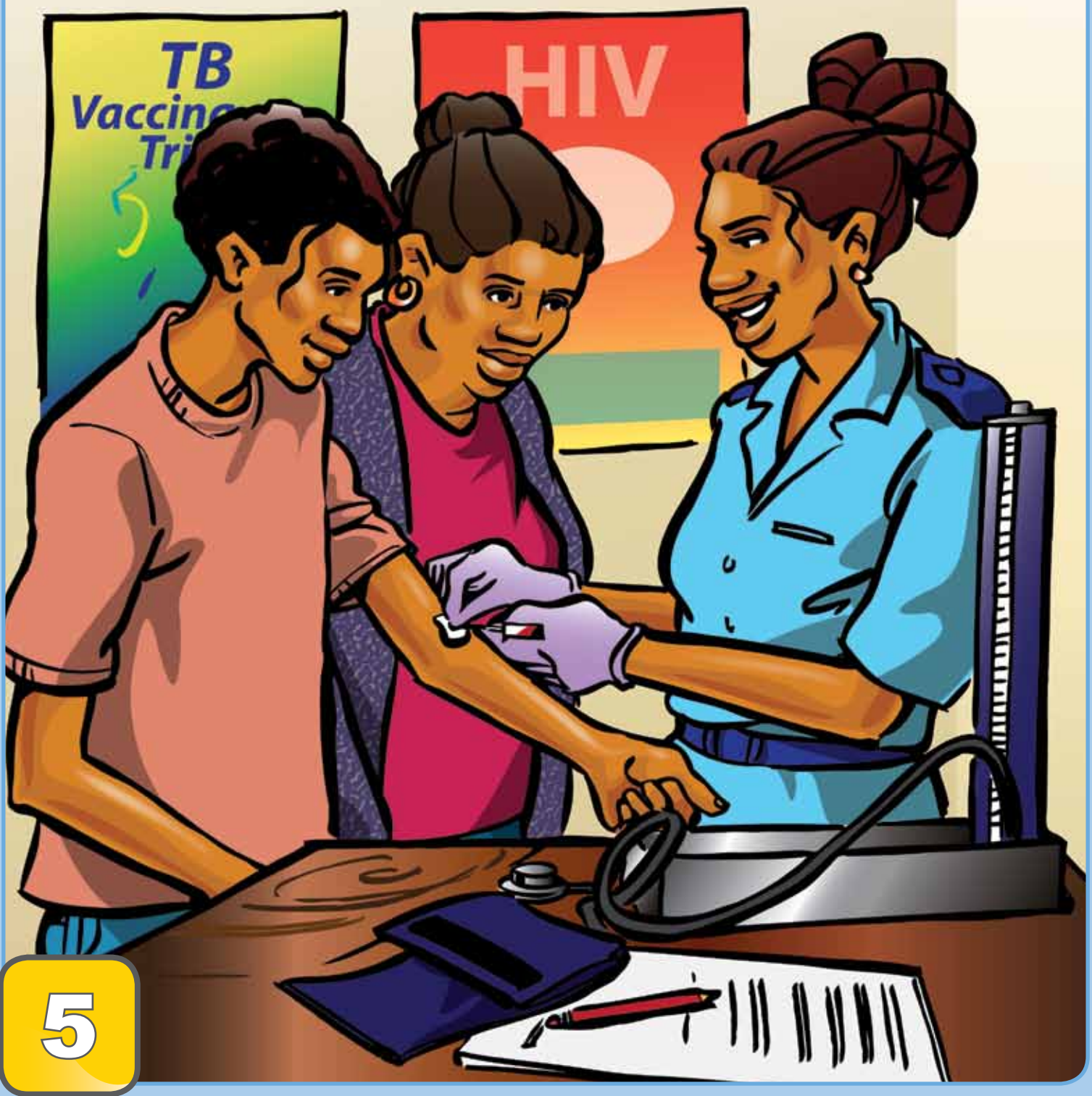
Die studiespan in die kliniese navorsingstudie moet by ’n dokument hou wat ’n “protokol” genoem word en wat vir hulle voorskryf presies wat hulle moet doen en hoe dit gedoen moet word. Daar word op hierdie protokol ooreengekom deur ’n gesondheidsowerheid asook ’n etiekkomitee voordat die vaksien op mense getoets kan word. Hierdie komitees staan onafhanklik van die studiespan en die vaksienontwikkelaar. Dit is hul werk om seker te maak dat deelnemers soos William beskerm word teen onnodige risiko’s en dat hul regte gerespekteer word.

Before William decides to be part of this clinical trial, the study team must explain everything in the approved protocol to him. This also includes how his blood will be used. This is called the “Informed Consent Process.” William can then decide if he wants to be in the trial or not. No-one can force him to participate. William can ask as many questions as he wants, at any time before and during the trial. He can discuss everything with his family before he decides.

Voordat William besluit of hy aan hierdie kliniese navorsingstudie sal deelneem, moet die studiespan alles in die goedgekeurde protokol aan hom verduidelik. Dit sluit ook in hoe sy bloed gebruik sal word. Dit word die “Ingeligte Instemmingsproses” genoem. William kan dan besluit of hy aan die navorsingstudie wil deelneem of nie. Niemand kan hom dwing om deel te neem nie. William kan te eniger tyd soveel vrae vra as wat hy wil, voor of gedurende die navorsingstudie. Hy mag alles met sy gesin bespreek voordat hy ’n besluit neem.

William will be told why the research is being done, what tests will be done (like blood or urine tests), and what his responsibilities are. He'll also be told of any risks or possible difficulties, like getting a bruise after giving blood, or any serious risks noted in the protocol. He'll be told how many months the trial will last, and how many times he will be seen by the study team.

Daar sal aan William verduidelik word waarom die navorsing gedoen word, watter toetse gedoen sal word (soos bloed- of urientoetse), en wat sy verantwoordelikhede is. Hy sal ook ingelig word oor enige risiko's of moontlike probleme soos enige kneusplekke nadat bloed getrek is, of enige ernstige risiko's wat in die protokol genoem word. Hy sal ingelig word oor hoeveel maande lank die navorsingstudie sal duur en hoeveel keer hy deur die studiespan gesien sal word.

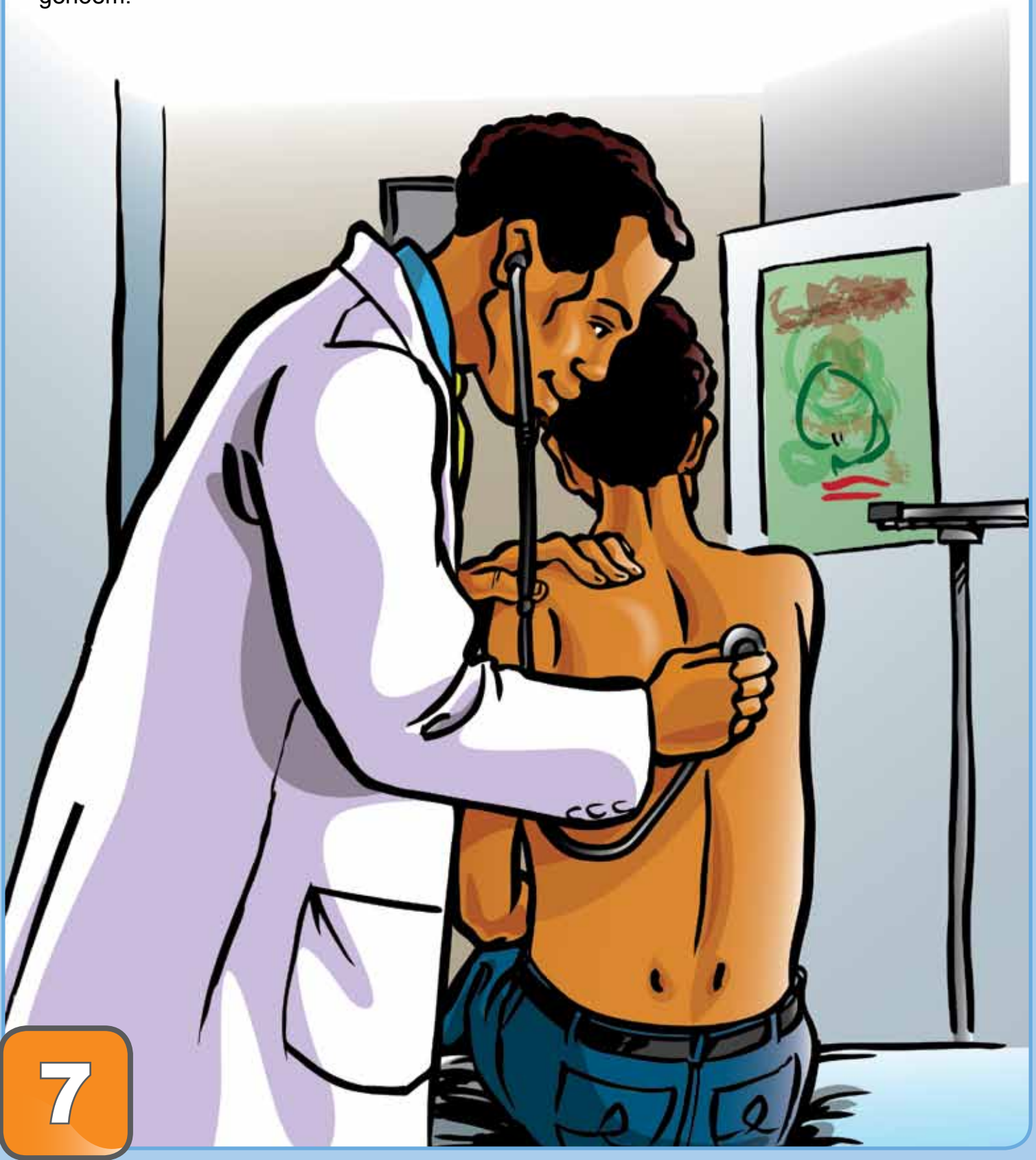


If William decides to take part in the trial, he'll sign the Informed Assent Form to show that he understands and agrees to everything that has been discussed. He'll sign the form with the study team, and will be given a copy to keep. Parents and Guardians of underage participants need to agree to the trial by also signing the consent form.

Indien William sou besluit om aan die navorsingstudie deel te neem, sal hy die Ingeligte Instemmingsvorm onderteken om aan te dui dat hy alles verstaan en instem met alles wat bespreek is. Hy sal die vorm saam met die studiespan onderteken en sal 'n afskrif daarvan ontvang wat hy kan hou. Die ouers en voogde van minderjarige deelnemers moet ook toestemming vir deelname aan die navorsingstudie verleen deur die toestemmingsvorm te onderteken.

If William decides that he wants to be part of the clinical trial for the test TB vaccine, the study team will do some tests and a medical check-up to make sure he is able to participate in the study. This is called the “Screening Process.”

Indien William sou besluit dat hy aan die kliniese navorsingstudie vir die ondersoekende TB-vaksien wil deelneem, sal die studiespan ’n paar toetse en ’n mediese ondersoek doen om seker te maak dat hy aan die navorsingstudie kan deelneem. Dit word die “siftingproses” genoem.

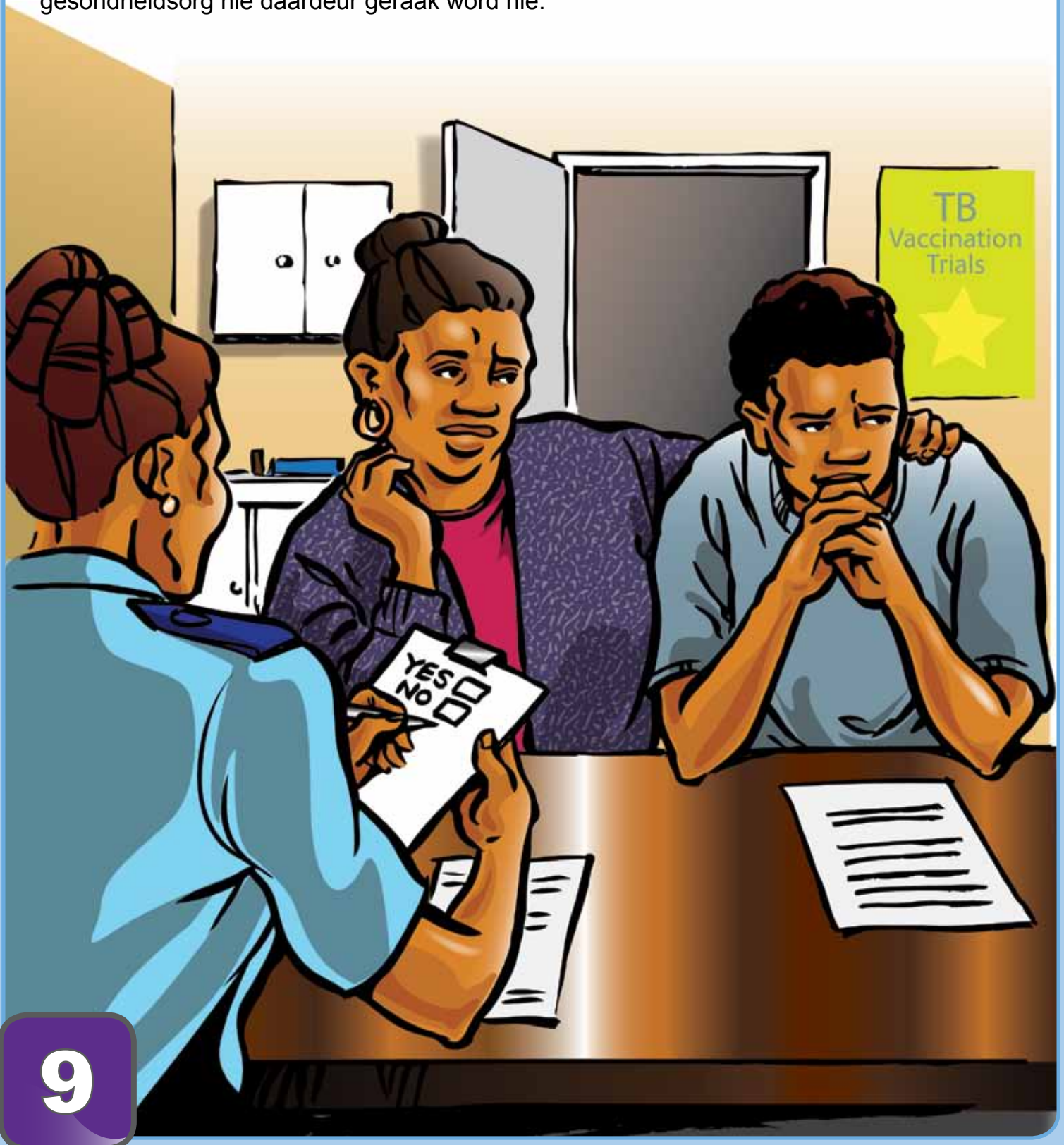


The doctor tells William that his personal information (like his name and his test results) will stay private. Only approved people will be able to see his personal information. All his information will be kept in a locked cabinet. William will be given an identification number if he joins the trial so he can't be identified by name.

Die dokter verduidelik vir William dat sy persoonlike inligting (soos sy naam en sy toetsuitslae) privaat gehou sal word. Slegs goedgekeurde persone sal sy persoonlike inligting mag sien. Al sy inligting sal in 'n kabinet gehou word wat toegesluit sal word. Daar sal 'n identifikasienommer aan William toegeken word indien hy by die studie aansluit sodat hy nie by die naam geïdentifiseer sal kan word nie.

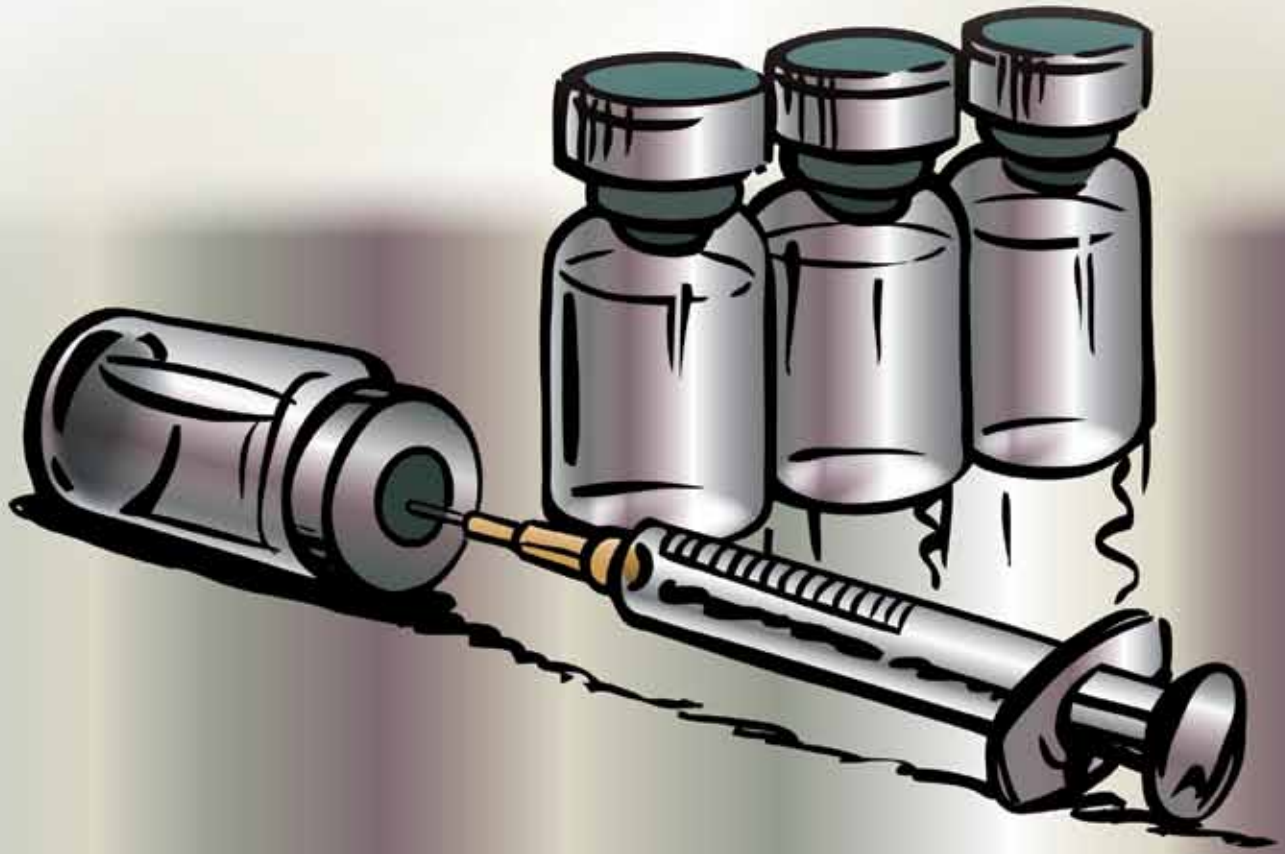
As a participant, William has rights and responsibilities. He has the right to know why the trial is being done, and the right to say “NO.” Even if he has joined the trial, he may change his mind – all he has to do is tell the study team. If William decides not to take part, his future medical care won’t be affected.

William het regte en verantwoordelikhede as deelnemer. Hy het die reg om te weet waarom die navorsingstudie gedoen word asook die reg om “NEE” te sê. Selfs al het hy by die navorsingstudie aangesluit, mag hy van plan verander. Al wat hy moet doen is om die studiespan daaroor in te lig. Indien William besluit om nie deel te neem, sal sy toekomstige gesondheidsorg nie daardeur geraak word nie.



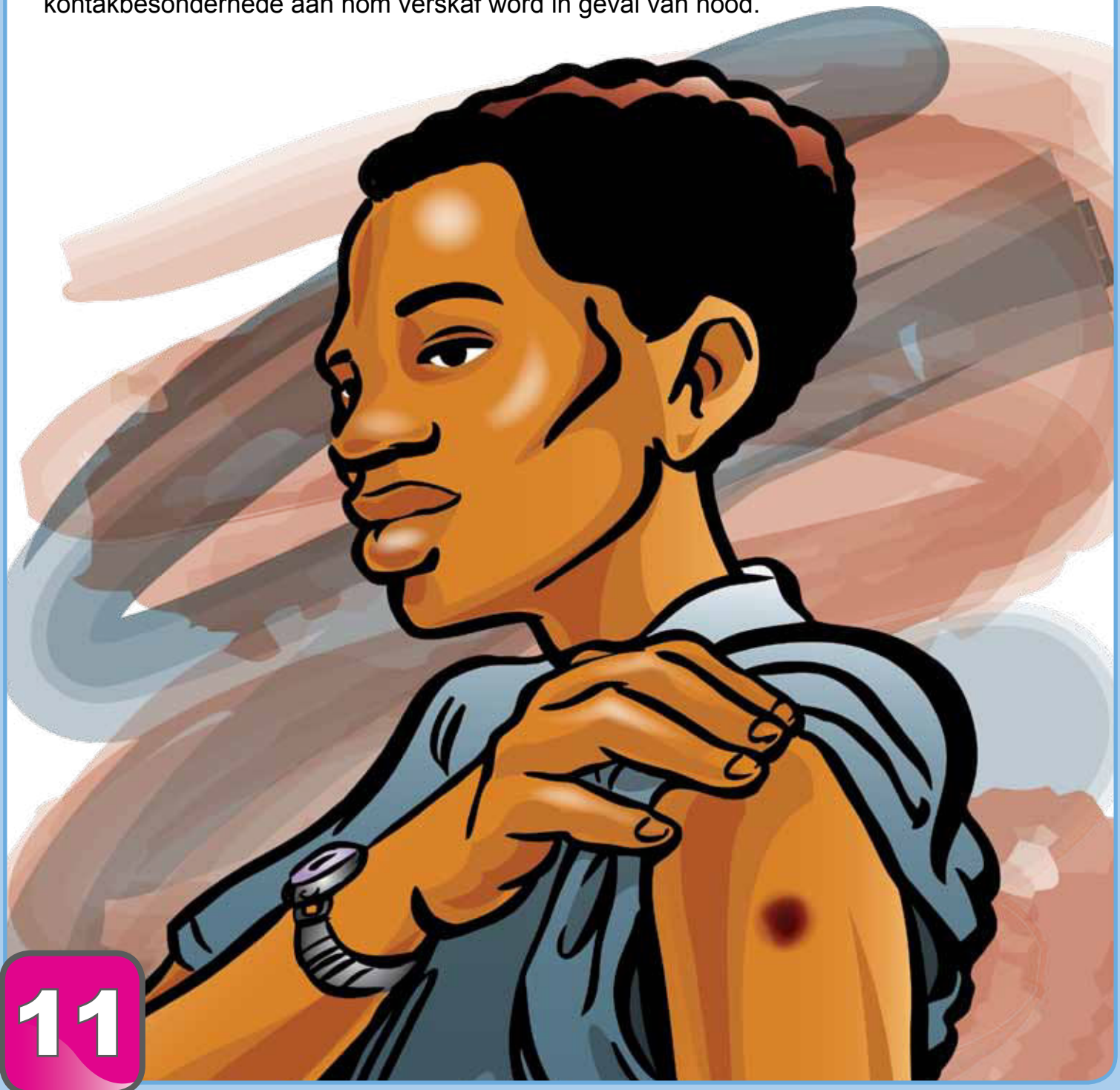
If William decides to take part in the clinical trial, he may receive the test vaccine, a vaccine that the clinics already use, or a placebo. Sometimes a “dummy” or “pretend” injection such as salt water is given to some of the participants instead of the real vaccine. This is called a “placebo”. A placebo is like a fake vaccine - it looks like the real vaccine, but is usually made of salt water. Usually, no-one knows which one he will get until the trial has finished. This is so that the researchers can compare how the body reacts differently to the vaccine than to the placebo.

Indien William sou besluit om aan die kliniese navorsingstudie deel te neem, kan hy dalk die ondersoekende vaksien, ’n vaksien wat reeds deur die klinieke gebruik word, of ’n plasebo ontvang. Soms word ’n “fopinspuiting” soos soutwater aan ’n paar van die deelnemers gegee in plaas van die regte vaksien. Dit word ’n “plasebo” genoem. ’n Plasebo is soos ’n fopvaksien: dit lyk soos die regte vaksien, maar word gewoonlik van soutwater gemaak. Gewoonlik weet niemand watter een hy/sy sal ontvang totdat die navorsingstudie afgehandel is nie. Die rede hiervoor is sodat die navorsers kan vergelyk hoe verskillend die liggaam op die vaksien reageer in vergelyking met die plasebo.



Some people have side effects after a vaccine like redness and swelling where the vaccine was given. They may get tired or don't feel like eating. This is normal and usually only lasts a few days. Serious side effects don't happen often, but there may be risks that the vaccine developer and the study team don't know about. If William gets sick because of the test vaccine, he'll be treated for free. If he joins the trial, he'll be given the clinic's contact details in case there is an emergency.

Sommige persone ervaar newe-effekte na 'n vaksien, soos rooiheid en swelling waar die vaksien toegedien is. Hulle mag dalk moeg voel of geen eetlus hê nie. Dit is normaal en duur gewoonlik net 'n paar dae lank. Ernstige newe-effekte kom nie dikwels voor nie, maar daar mag dalk risiko's wees waarvan die vaksienontwikkelaar en die studiespan nie bewus is nie. Indien William siek sou word as gevolg van die ondersoekende vaksien, sal hy gratis behandeling ontvang. Indien hy aan die navorsingstudie sou deelneem, sal die kliniek se kontakbesonderhede aan hom verskaf word in geval van nood.



William may be asked to keep a Diary Card. He will need to write how he feels after each vaccination: if he had any pain or swelling, if he had a fever, or if he felt sick in any way after the vaccine. This helps the study team make sure that William is doing well, and it is ok for him to stay on the trial.

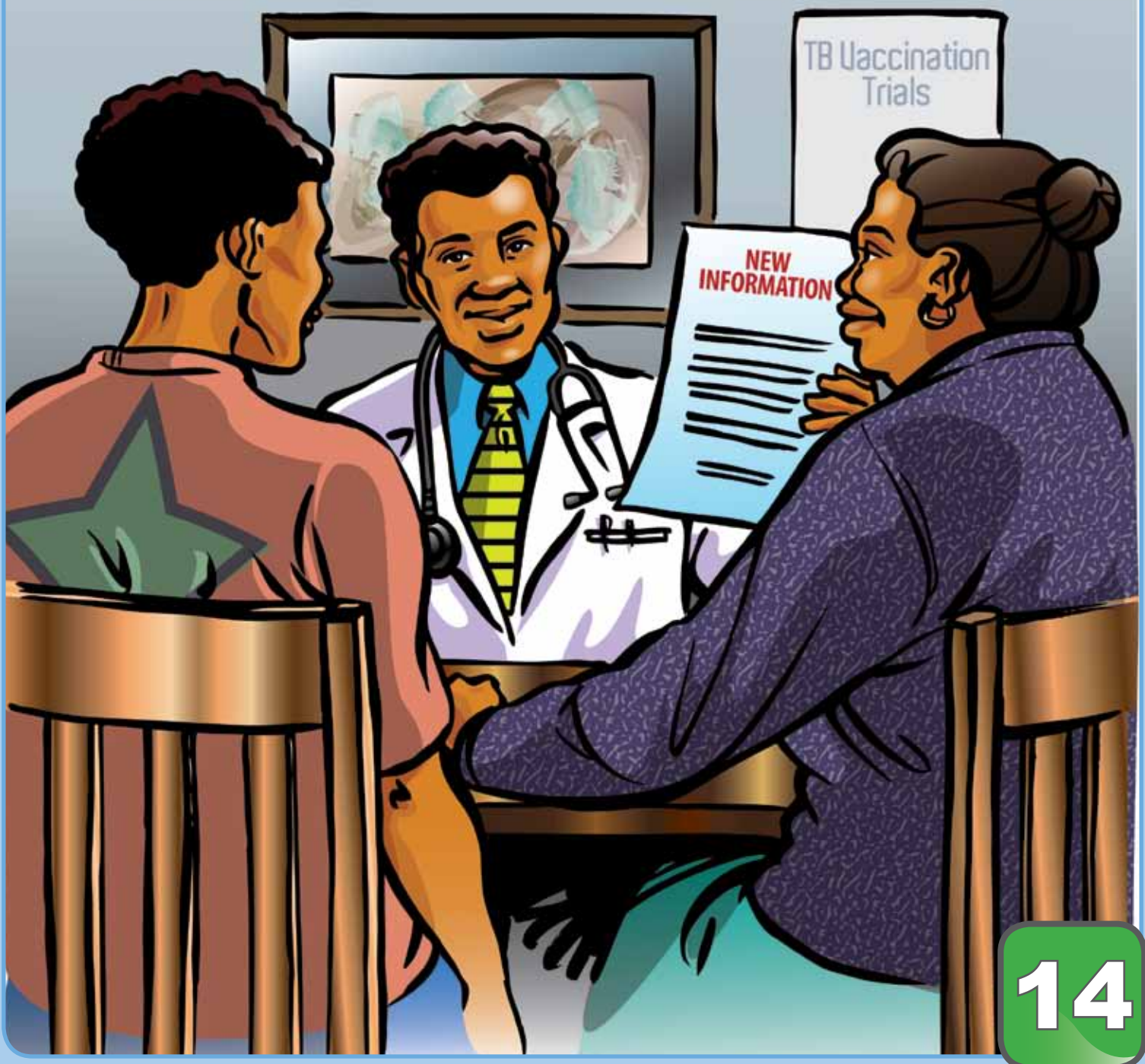
William kan dalk gevra word om ’n dagboekkaart te voltooi. Hy sal dan moet neerskryf hoe hy na elke vaksinering voel: of hy enige pyn of swelling ervaar het, of hy enige koors ervaar het, en of hy enigsins siek gevoel het nadat die vaksien toegedien is. Dit help die studiespan om seker te maak dat dit goed met William gaan en dat hy kan voortgaan met sy deelname aan die studie.

William has rights but also responsibilities. This means there are things he needs to do if he decides to take part in the trial. He must go to the clinic for all his appointments, tell the clinic immediately if he does not feel well and always tell the clinic if he takes any medicines – even aspirin or herbal medicine.

William het regte, maar ook verantwoordelikhede. Dit beteken dat daar dinge is wat hy sal moet doen indien hy besluit om aan die studie deel te neem. Hy sal na die kliniek toe moet gaan vir al sy afsprake, die kliniek dadelik in kennis stel as hy sleg voel en die kliniek altyd inlig as hy enige medisyne drink – selfs al is dit net aspirien of kruiemedisyne.

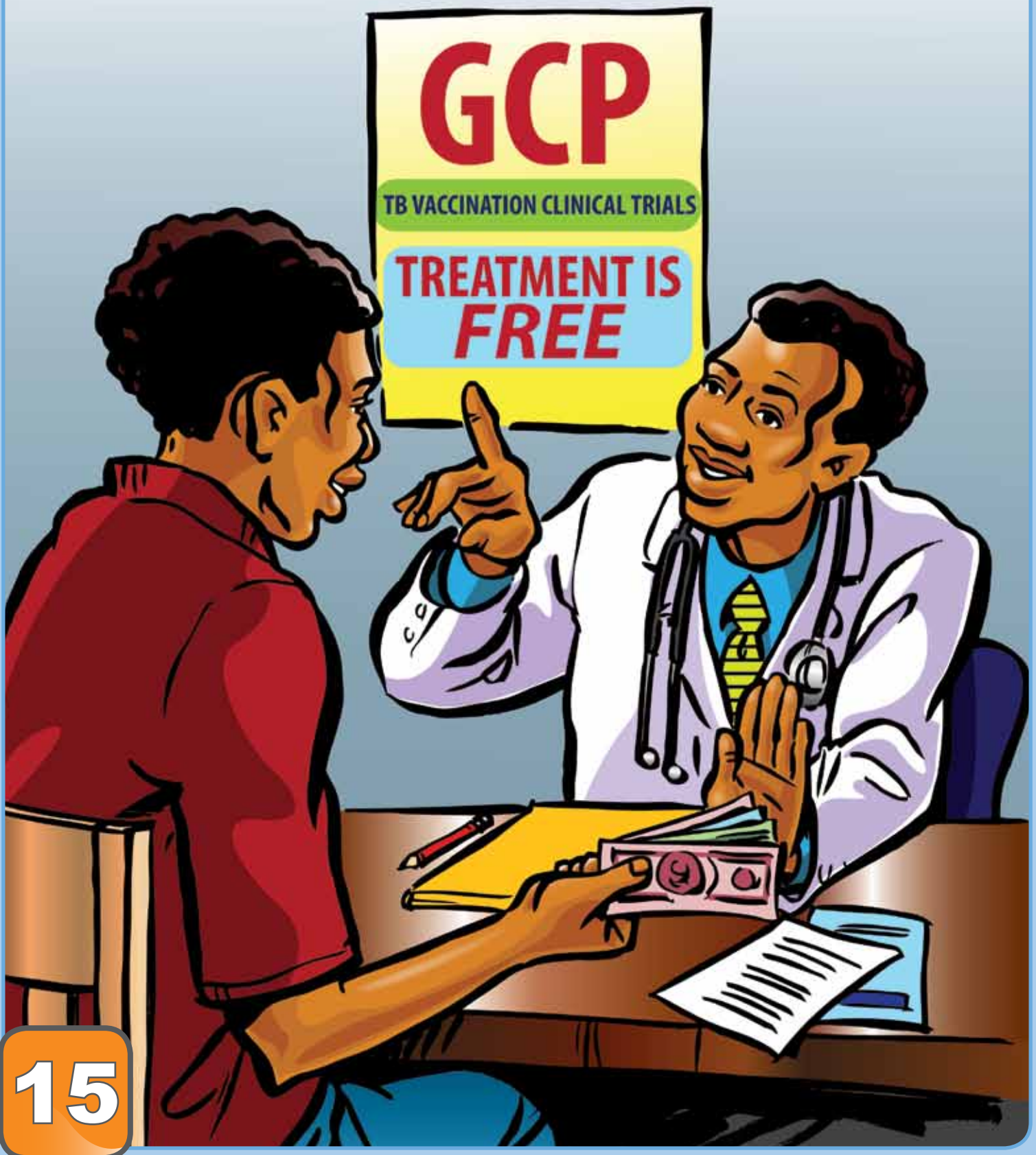
The doctor and study team have a responsibility to take good care of William's health and give him any new information about the test TB vaccine. These responsibilities are in guidelines used across the world for participants in clinical trials. William may be taken off the trial if the study team decides this would be best for him or if he does not follow the trial rules. The vaccine developer, the Authority, or the Ethics Committee could decide to stop the trial.

Die dokter en die studiespan het 'n verantwoordelikheid om goed na William se gesondheid te kyk en om vir hom enige nuwe inligting oor die ondersoekende TB-vaksien te gee. Hierdie verantwoordelikhede verskyn in riglyne wat wêreldwyd gebruik word vir deelnemers aan kliniese navorsingstudies. William kan dalk aan die studie onttrek word indien die studiespan sou besluit dat dit in sy beste belang is of indien hy nie die reëls vir die navorsingstudie volg nie. Die vaksienontwikkelaar, die Owerheid of die Etiekkomitee kan besluit om die studie te staak.



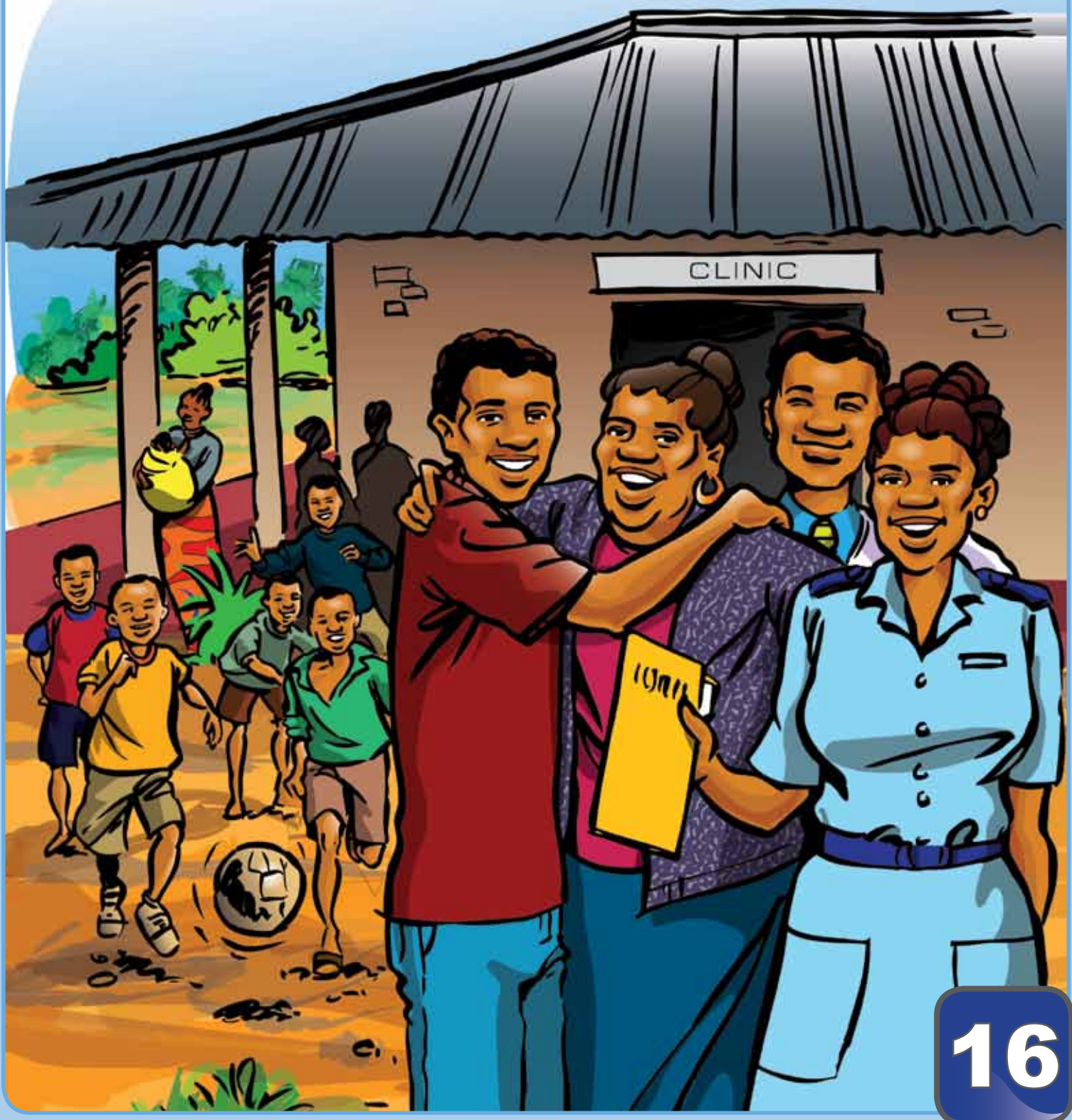
William doesn't have to pay for any of his trial visits, vaccines or tests. The study team reminds him that he can choose to leave the trial at any time.

William hoef nie vir enige studiebesoeke, vaksiene of toetse te betaal nie. Die studiespan herinner hom daaraan dat hy die besluit mag neem om die navorsingstudie te eniger tyd te verlaat.



Tuberculosis kills millions of people every year but TB can be stopped. This test TB vaccine may be very important to the health of people around the world. Through this clinical trial, we may learn important information about how to prevent TB. Let's all work together to stop TB, for the safety and health of us all.

Tuberkulose veroorsaak elke jaar die dood van miljoene mense, maar TB kan gekeer word. Hierdie ondersoekende TB-vaksien kan dalk baie belangrik wees vir die gesondheid van mense wêreldwyd. Deur hierdie kliniese navorsingstudie kan ons dalk belangrike inligting inwin oor hoe om TB te voorkom. Kom ons werk almal saam om TB te keer, vir elkeen van ons se veiligheid en gesondheid.



Our mission is to develop new TB vaccines that are affordable and accessible to all who need them.

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