

Informed consent form: Evaluation of *Novartis Access* in Kenya

Background

You are being asked to take part in this research study because you work at a health facility that dispenses medications for non-communicable diseases (NCD).

In Kenya, NCDs account for 27% of deaths (about 370,000 per year) among people between 30 and 70 years old. NCDs limit economic growth through increased expenditure on treatment of disease sequelae such as increased hospitalization. Out-of-pocket spending can result in catastrophic health expenditure and increased poverty.

Novartis recently launched *Novartis Access*, initiative corporate social responsibility program aiming to provide a basket of 15 medicines for the treatment of NCDs, in Kenya in 2016. The portfolio of 15 medicines will be sold to local public sector and not-for-profit purchasers, including the Mission for Essential Drugs and Supplies (MEDS) at a cost of US\$1 per monthly treatment (excluding costs for transportation, duties and expenses, VAT related to the distribution, import and sale of the products in the territory.)

Purpose

The purpose of this study is to evaluate the impact of *Novartis Access* on the availability and price of NCD medicines at health facilities and households using a cluster-randomized trial design.

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What Happens In This Research Study

You will be one of approximately 400 health facility-workers to be asked to participate in this study. The research will take place in 8 districts throughout Kenya.

The included districts and the health facilities in these districts have been put in two groups. Health facilities included in one group will receive the *Novartis Access* medicines to sell to their patients. Health facilities in the other group will continue to receive and sell the medicines they are currently selling right now.

If you agree to be in this study, we will ask you some questions about the medicine availability at your facility, your perceptions about the affordability and quality of medicines, what happens when medicines are not available, and how you learn new information about medicines. At the beginning of the study, 12 months later, and 12 months after that, a data collector will visit your facility and conduct a survey. We may also ask to call you on the phone once a month to ask you a few questions about the medicines available at your facility. Each survey will take approximately 15-20 minutes of your time.

Risks and Discomforts

The visits may take time to complete and this may cause you some inconvenience. You

may also feel uncomfortable answering the questions in the presence of other people at your place of work. You do not have to answer questions that make you feel uncomfortable. There is a risk of loss of confidentiality. We explain measures taken to ensure your confidentiality below.

Potential Benefits

You may not receive any direct benefits from participating. The information that this study will generate will help evaluate a program that aims to increase access to affordable medications for non-communicable diseases.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

There are no costs to you for participating in this research study. You will be provided with a small amount of cell phone air for each survey visit you complete.

Confidentiality

We will only collect identifying information one time and we will then keep this information separate from all other information that you provide. All of your identifying information will be kept strictly confidential through the use of unique identifying numbers on all paper forms and computer-based files, with the exception of an initial form that will include name, study number, and address information to allow for follow-up activities, including surveillance and follow-up surveys. The file linking names and study numbers will be password-protected, maintained on computers in locked offices or hotel rooms (when collecting data in the field), and only accessible to authorized study personnel. It will be destroyed within 6 months after the study is completed. All study results presented in written form will be aggregated, with no individual identifying information. Information collected during this study may be reviewed and photocopied by agencies such as the Institutional Review Board of Boston University Medical Center. Information from this study may be used for research purposes and may be published; however, your name will not be used in any publications.

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep. If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by contacting:

Amina Salim (asalim@strathmore.edu)

Telephone number: +254 703 034 000

Fax Number: +254 020-607498



Physical address

Strathmore University Ole Sangale Road Nairobi KENYA

Postal address

P.O. Box 59857-00200 Nairobi KENYA

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your job. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

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Subject (Signature and Printed Name) Date

Person Obtaining Consent (Signature and Printed Name) Date

Subject's Thumb Print