

endTB-Q Clinical Trial

Research Screening Adult Consent/Assent Form

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SUBJECT IDENTIFICATION

Protocol Title: endTB-Q (Evaluating Newly Approved Drugs in Combination Regimens for Multidrug-Resistant TB with Fluoroquinolone Resistance)

Sponsor: Médecins Sans Frontières (Doctors Without Borders) – France

Principal Investigators: Carole Mitnick, Sc.D. and Lorenzo Guglielmetti, M.D.

Site Principal Investigator: [Insert PI Name]

Research Center: [Insert Research Center Name]

Participant Name (please print): _____

Study Subject ID: _____

About this consent/assent form

You have been diagnosed with multidrug-resistant tuberculosis (MDR-TB) with fluoroquinolone (FQ) resistance. We are conducting a study, called endTB-Q, to see if we can find a better treatment for MDR-TB with FQ resistance. We would like to ask if you agree to be interviewed and examined to see whether you could be in our study.

This research screening consent/assent form is written to help you understand this screening and decide whether to participate. A member of our study team will talk to you about what it means to do the study screening. There may be words that you do not understand or information that is unclear or confusing. Please ask us questions so we can help you understand better. You may take some time to think about and discuss your participation with others.

Introduction

TB is a disease caused by bacterium (or germ) that usually affects the lungs. It is passed from person to person through the air by droplets that come from the lungs of a person who is sick with TB. When the sick person coughs, sings, shouts, or spits, the TB bacteria can make others sick. Most people with TB can be treated and cured, if they complete all their treatment. Some types of TB bacteria can't be treated with drugs that are commonly used to treat TB, rifampin and fluoroquinolones. This is known as multi-drug resistant tuberculosis (MDR-TB) with fluoroquinolone (FQ) resistance. People sick with MDR-TB with FQ resistance need different drugs for their treatment.

Around 650 people with TB in 6 countries will be screened for this study. We expect that about [number to be adapted locally] people will be screened at [Research Center Name].

This study has been approved by the [Research Center Ethics Committee] [and the applicable national regulatory authority].

Médecins Sans Frontières (Doctors Without Borders) – France is the sponsor of this study.

Taking part in the study screening is completely up to you; you do not have to be screened if you do not want to. After you have had time to ask questions and think about your participation, we will ask you to sign the consent/assent form if you agree to participate. We will give you a signed copy of this research screening consent/assent form to keep.

Screening is the first step. If you agree to be screened and are eligible to be in the study, we will give you more information about the study and ask you to sign another form if you agree to be in the study.



Why is this study being done?

Current treatment for MDR-TB with FQ resistance includes 5-9 drugs taken every day for 20 to 24 months. Treatment may be oral or include daily shots. This treatment may cause many mild and some serious side effects, for example: feeling sick to the stomach, throwing up, hearing loss, numbness/tingling in fingers and toes, kidney damage, mental illness/feeling sad, etc. Two new drugs (delamanid and bedaquiline) have recently become available. New treatments with these drugs may be shorter and/or simpler (no injection). Such treatments must be tested to see if they are safe and work well for people with multidrug-resistant TB with FQ resistance. The endTB-Q study will compare new shorter, injection-free treatments to the current treatment for MDR-TB with FQ resistance.

How long will the screening process take?

The complete screening process for this study could take 4 to 5 hours. It is possible that this will take more than one visit. All visits should be done within 2 weeks.

What will happen during screening?

We will ask you to come to [Research Center Name]. We will ask you to sign a consent/assent form before you start the study screening. Then, we will do some tests and procedures to see if you are eligible to take part in the study. The study doctor will review the results of these tests and procedures. If you cannot participate, the study doctor will tell you why and might ask if you would like to participate in another study.

Specifically, during screening, we will:

1. Answer all your questions and get your permission for screening.
2. Ask for your full name, contact information, sex, and age.
3. Review your medical history, including past or present illnesses, and information on drugs you are currently taking.

The treatment you will receive for your TB may interact with some of the drugs that you are currently taking. The study doctor may review with you if some of your drugs need to be stopped or changed prior to receiving any MDR-TB treatment.

4. Perform a complete check-up and ask about your TB symptoms.
5. Collect 2 tablespoons of your blood for laboratory testing to check if your body is functioning well.
6. Unless recent results are available, we will also ask you to use the collected blood to test for viruses like hepatitis B and C, which affect your liver, and HIV, which affects your body's ability to fight infection. These might affect your treatment for TB. All test results will remain confidential. You have the right to refuse these tests. Refusing a test will not affect your participation in the study or any access to usual treatments that do not depend on knowledge of the test result. If the test result(s) is (are) positive, you will be referred to appropriate care. If you have HIV infection, we will test CD4 count and HIV viral load to see if the disease is well controlled.
7. Ask you to cough up 3 sputum (phlegm) samples. These will be used to test whether the TB bacteria can be treated with regular drugs and/or drugs in the study treatment. This is called testing for drug resistance.

8. Do a test, called an electrocardiogram, to check if your heart works normally.
9. Because we don't know if some of these medicines are safe in pregnancy:
 - The study doctor will discuss birth control to avoid pregnancy (yourself or your partner) if you are eligible and agree to participate in the study.
 - Pregnant patients cannot enter the study. So, if you are a woman who can get pregnant, we will collect a urine or blood sample for a pregnancy test. Your study doctor will refer you for TB treatment outside of the study if the test shows you are pregnant.

Depending on your test results:

- your study doctor may prescribe medicines, for example to balance the level of salts in your blood, when possible;
- some of these tests may need to be repeated within the 2-week period, your study doctor will let you know which ones.

Managing your Samples and Health Information in the Study

To keep all your information private, we will label all your samples and health information with a code instead of your name. The study team will keep a key that connects your name to the code. The study doctor will keep the key to the code in a password-protected computer and/or locked file.

In a special lab in Belgium, sputum samples and TB bugs from your sputum might be tested to see if drugs work against the bug.

What are the risks and possible discomforts from being screened for this study?

Risks of Blood Draws

You may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of infection, light-headedness, and/or fainting.

What are the possible benefits from being screened for this study?

This screening evaluation has not been planned to give you direct benefits but it may help you to get treatment within the study, or get other appropriate treatment more quickly. Others with MDR-TB with FQ resistance may benefit in the future from what we learn in this study.

Can I still receive TB treatment if I do not take part in this screening?

Yes. You will receive treatment through [local TB care provider/entity] if you do not take part in this screening. Taking part in this screening is up to you. You can decide not to take part. You will not lose any benefits you have the right to receive.

What should I do if I want to stop taking part in this screening?

If you decide you want to stop the screening, we will talk to you about follow-up care you might need.

Information collected during your screening will be used to help answer study questions. When you leave the screening, your information may still be used for the study. If you do not want this information to be used, and you want it to be destroyed, please contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org.

Will I be paid to be in this screening?

You will not be paid to be in this screening. We will pay transportation costs for visiting the research center(s). We will pay or you will be reimbursed [local currency] _____ for transportation to and from the screening visit.

What will I have to pay for if I take part in this screening?

All screening procedures will be free of charge to you.

What happens if I am injured as a result of taking part in this screening?

If you suffer injury from the screening, [] will give you immediate medical treatment.

The sponsor will not pay to treat a medical condition or disease you had before screening or expenses for injury, treatment, or hospitalization that are not the result of your participation in the screening.

You do not waive any of your legal rights by signing this consent/assent form.

Who can I speak to if I have questions, concerns or complaints?

If you have questions about this screening, you can contact [PI Name and title] at [PI telephone number]. You can also call [Clinical Investigator] at [CI number] with questions. If you have questions about the scheduling of appointments or study visits, call [Study Coordinator] at [SC number].

For medical emergencies outside business hours, please contact [Must include 24/7 phone number of licensed site physician investigator here].

If you want to speak with someone not directly involved in the screening or study, please contact the [Research Center IRB] office. You can call them at [Research Center IRB number].

If I take part in this screening, how will you protect my privacy?

We are careful to protect the identities of people who are screened in this study to the extent permitted by law. We will also keep your information secure and confidential. Study information kept on a computer will be password-protected, and paper files will be stored in a locked office at [Research site]. Your screening records will be kept at the clinic/hospital for [XX] years [to be adapted locally] following the study completion. As needed to monitor the study quality, your screening records may be looked at by institutions responsible for quality and privacy, such as the sponsor, Ethics Committee and other Authorities.

For the screening, we will store some non-medical information about you, such as your date of birth and city of residence. You can ask us to access, modify, complete, update, or delete this information. If you have any complaints about the protection of your data, you could contact your local/national Data Protection Authority [Name and contact to be adapted locally].

The information collected for screening will be used:

- For the purpose of this study: the sponsor, the study doctor, or other doctors involved in the study may share reports on the screening with scientific groups. After the study ends, you may see your records, and you may be told the study results.
- To make new recommendations about treatment of MDR-TB with FQ resistance: your coded information may be used and shared with other institutions, during and after completion of the study, notably with the World Health Organization.

In all cases your identity will never be disclosed.

If your coded information will be sent electronically to other researchers or institutions, it will be encrypted (scrambled so it cannot be read by unconcerned people) and will be protected according to European Economic Area standards.

endTB-Q Screening Informed Consent/Assent and Authorization

We are asking you to be in the screening because you are:

☐ at least 18 years old. We seek your **consent** to participate in this screening.

☐ between 15 and 17 years old (minor). We seek your **assent** to participate in this screening. Because you are younger than 18 years of age, we will also ask your parent(s) or someone else who takes care of you (legal guardian) to give permission for you to take part in this screening, by signing a parental consent. We will need permission from both you and your parent(s)/legal guardian before you can take part in this screening. If you decide not to participate, nobody else can make you participate. Your parents may be informed of results of the screening process [*to be adapted locally*].

Your signature on this document means the following:

I have read this consent/assent form. The screening process has been explained to me, including risks and possible benefits, other possible treatments or procedures, and other important things about the study. I have had the opportunity to ask questions. I understand the information given to me. I recognize that my participation is voluntary and that I can refuse or end my participation at any time, without any loss of benefits that I would otherwise have.

I recognize that by signing this document, I do not lose any of my legal rights as a patient. I will receive a complete, signed, dated copy of this research screening consent/assent form.

By signing below, I agree to take part in the screening.

Signature or thumbprint of participant

Date (DD/MMM/YYYY) and Time

Name of participant, printed in capital letters

If applicable, Signature of witness

Date (DD/MMM/YYYY) and Time

Name of witness, printed in capital letters

Study representative who obtained informed consent/assent:

I have explained this study to the participant and have answered all of his/her questions. He/she understands the information described in this document and accepts voluntary participation in the screening.

Signature of study representative

Date (DD/MMM/YYYY) and Time

Name of study representative, printed in capital letters

**endTB-Q Screening Adult Informed Consent/Assent Form Addendum
Storing Isolates (strains) and Health Information Future Use**

Your health information and bacteria isolates (TB bug) collected during the screening can be useful for other research in TB. We are asking permission to store your health information and bacteria isolates for future use in research on better treatment and diagnosis of TB, for up to 20 years after the study ends. The endTB-Q study sponsor will control access to this information and will share it only for research on better TB treatment or diagnosis. We do not know yet what these studies will be but they will be on better TB treatment or diagnosis (including resistance). Your coded health information will be handled according to the European regulation for the protection of personal data.

Your health information contains a code instead of your name. To further protect your privacy, we will change this code before your information is shared for other research.

Your bacteria isolates and health information will not be sold for profit.

You can be in the endTB-Q screening if you do not agree to store your bacteria isolates or health information for future use.

Any use of your coded health information or bacteria isolates in your country or in other countries for other research will be reviewed by an Ethics Committee in your country.

Results from this future TB research can be made public. Your identity will never be shared. No one will share individual findings with you or anyone else about you or your health.

Even after signing this consent/assent addendum for future use of bacteria isolates and health information, you have the right to change your mind. Anytime during the storage period of bacteria isolates and your health information, you can contact your study doctor or send an email to endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your coded health information and bacteria isolates and/or their destruction.

Informed Consent/Assent and Authorization - Storing Isolates (strains) and Health Information Future Use

We are asking to use your health information and bacteria isolates because you gave your consent/assent to be screened for endTB-Q and you are:

☐ at least 18 years old. We seek your **consent** to store your health information and bacteria isolates for future use.

☐ between 15 and 17 years old (minor). We seek your **assent** to store your health information and bacteria isolates for future use. Because you are younger than 18 years of age, we will also ask your parent(s) or someone else who takes care of you (legal guardian) to give permission, by signing a parental consent. We will need permission from both you and your parent(s) or legal guardian. If you decide not to participate, nobody else can make you participate.

Your signature on this document means the following:

I have read this consent/assent form. The purpose of the future use of my health information and bacteria isolates has been explained to me.

I understand that this future use is separate from the endTB-Q screening and my decision to allow future use of this information will not affect my participation in endTB-Q.

I have had the opportunity to ask questions. I understand the information given to me. I recognize that my participation is voluntary and that I can refuse or end the storage of my health information and bacteria isolates for future use at any time, without any loss of benefits that I would otherwise have.

I agree to have my health information and bacteria isolates stored for future use: ☐ Yes ☐ No

I recognize that by signing this document, I do not lose any of my legal rights as a patient. I will receive a complete, signed, dated copy of this future use of health information and bacteria isolates consent/assent form.

Signature or thumbprint of participant

Date (DD/MMM/YYYY) and Time

Name of participant, printed in capital letters

If applicable, Signature of witness

Date (DD/MMM/YYYY) and Time

Name of witness, printed in capital letters

Study representative who obtained informed consent/assent:

I have explained the future use of bacteria isolates and health information to the participant and have answered all of his/her questions. He/she understands the information described in this document and accepts voluntary participation.

Signature of study representative

Date (DD/MMM/YYYY) and Time

Name of study representative, printed in capital letters