

endTB Clinical Trial **Research Adult Consent Form**

Version 3.3 Version Date: 14 February 2019

Subject Identification

Protocol Title: endTB (Evaluating Newly approved Drugs for multidrug-resistant TB)

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 form

Please read this form, called research consent form, carefully. It tells you important information about this study, called endTB. A member of our research team will also talk to you about taking part in this study. People who agree to be in the study are called “participants” in this consent form. Recruitment of participants for this study has been approved by the [Research Center Ethics Committee] [and the applicable national regulatory authority].

If you have any questions about the study or about this form, please ask us. Taking part in this study is up to you. You do not have to be in the study if you do not want to. If you decide to take part in this study, we will ask that you sign this form to confirm that you want to take part. We will give you a signed copy of this research consent form to keep. You can decide not to take part in this study at any time if you do not want to, even after signing this form.

If you are not able to sign the consent form, but you would like to participate, you can ask someone you know to sign for you and you can make a thumbprint to show that you understand the study and would like to take part.

Introduction

You have been asked to join a study called endTB clinical trial. Researchers want to know what combinations of drugs work better for people who have multi-drug resistant tuberculosis (MDR-TB). Drugs work differently in different people, and it is not clear what combination of drugs is best for any one person. The new combinations of drugs used in this study are called “experimental”; they have been used before but we do not know how well they work together.

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We are asking you to take part in this study because you are at least [18] years old and have tuberculosis that is affecting your lungs. You completed the screening process of this study and are eligible to take part. During the study, we will do some more tests to make sure that you may safely take part. 750 participants in 7 countries will participate in this study. About [number to be locally adapted] participants will take part at [Research Center Name].

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

Why is this study being done?

Current treatment for MDR-TB has 5-9 drugs taken daily for 18 to 24 months. During at least six months, treatment includes a daily needle shot. 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 containing at least one of these drugs may be shorter for example, 9 months and/or simpler (without injection). Such treatments must be tested to see if they are safe and work well for people with MDR-TB. We are asking you to take part in this study to compare new experimental treatment regimens to the current treatment for MDR-TB.

How long will I take part in this study?

It will take you between 1.5 to 2 years (73 to 104 weeks) to complete this study. During this time, we will ask you to make 26 to 30 study visits to [Research Center Name]. All study visits will take place at [Research Center Name].

What will happen in this study?

If you choose to take part in this study, we will ask you to sign this consent form before we start the study with you. If you are currently taking any medications that can't be taken with your study drugs, you may need to stop these medications before you can start taking the study drugs. Your doctor may give you new drugs instead of your current medications. This could make you feel bad. If this happens, please tell the study doctor. If your medication cannot be replaced by other treatment or needs to be stopped for more than 2 weeks before taking study drugs, you may not be able to take part in this study.

At the beginning of the study, you will be assigned by chance (like rolling a dice) to one of 6 treatment groups described below. Most patients will get one of the experimental treatments. A smaller number will get the regular treatment for MDR-TB. We don't know exactly how many patients will get each treatment because, as we learn how the different treatments are performing, more patients will be assigned to the treatments that are helping more patients. You and the study doctor cannot choose your study treatment group.

If you are assigned to an experimental treatment, you will get 4 or 5 study drugs that will be taken by mouth. You will take the study drugs for 39 weeks (9 months).

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If you are assigned to the control treatment, you will get the treatment used for MDR-TB according to current practice in your country and to international guidelines from World Health Organization. You will receive medications by mouth and by needle shots. The treatment will last for [18 to 24 months to be adapted if short regimen accepted].

If you are receiving an experimental regimen with linezolid, one of the drugs used for MDR-TB, we will change your linezolid dose after about 4 months of treatment or earlier if you are having important side effects that might be caused by linezolid. We are looking at two ways to lower the total dose of linezolid: in one, we reduce the daily dosage (dose still daily but lower - for example, 1 pill instead of 2 pills every day) or by giving it less often (same dose but not every day; for example, 2 pills every 2 days instead of 2 pills every day). We do not know if one way is better than the other.

If you are receiving an experimental regimen with linezolid, one of the ways of lowering the linezolid dose will be assigned to you by chance. You and the study doctor cannot choose how your linezolid dose will be reduced.

For all your study drugs at all times during treatment, your study doctor will tell you how many pills of each drug you will take. Study staff will teach you how, how often and where you should take your medications and for how long. You must follow these instructions carefully and should not stop taking the study drugs without telling the study workers. A study worker [to be adapted locally based on the setting for DOT/treatment support] will be with you every time you take your study drugs and bring all the unused study drugs back to the [Research Center].

If you miss doses or a study visit, a study worker may call you or go to your home to check if you are well and discuss with you ways to help you keep taking your study drugs and go to your study visits. [to be adapted locally based on the site set-up]

With your agreement, the study doctor will inform your regular doctor or other doctors who may be treating you, of your participation in the study.

You will go to the [Research site name] for study visits until at least 73 weeks (17 months) and possibly as late as 104 weeks (24 months) after you start your study treatment. The exact time you spend in the study will depend on the overall progress of the study. You might still be on treatment at the end of the study; if so, we will help you talk to the regular TB doctors to make sure you can finish your treatment.

Visit procedures

All participants have the same visits. What happens at each visit is explained here:

Visit before starting treatment

At this visit, we will:

- Answer all your questions and get your consent to take part in the study.

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- Ask about your job and schooling.
- Ask about any changes in your medical history or medicines being taken since the screening visit. The study doctor might change some of your medications and will discuss and recommend birth control methods so you can avoid pregnancy (yourself or your partner) while taking study medications.
- Ask about smoking or alcohol use. *[to be moved to screening consent if applicable]*
- Perform a brief exam and ask you about TB symptoms.
- Check your vision, hearing, movement, mental health status, and ask about your daily activities.
- Collect ½ tablespoon of blood samples for laboratory testing (we might not do some of these tests if you have had these tests recently); and for a pregnancy test if you are woman who can get pregnant. The pregnancy test might be repeated if the study medications are started a few days after the first test.
- Do an electrocardiogram to check if your heart is working normally.
- Depending on what tests you have had recently, we might:
 - Collect ½ tablespoon of blood sample for CD4 and HIV viral load testing if you are HIV-infected.
 - Ask you to cough up a sputum specimen if you do not already have one test result from the study laboratory to show the TB germ is resistant to rifampin and susceptible to fluoroquinolone.
 - Perform a chest X-ray.

Follow-up Visits (Week 1 to Week 73-104)

After you start taking the study drugs, you will return to [Research site name] for your follow-up visits every week during the first 3 months, then approximately every month until the end. At each visit, our study worker will schedule the next visit and write the date on your study identification card. If you need to change a visit date, please let the study worker know as early as possible. Each visit will take about 1 ½ hours including waiting time.

If needed, your study doctor might call you for additional examinations.

Doctor's exams:

At each visit, we will:

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- Ask about any changes in your medical history and any change in medicines you are taking since the last visit. The study doctor may change some of your prescriptions if you are taking medicines that can have interactions with drugs in your TB regimen.
- Perform a brief exam and ask you about TB symptoms and how you are feeling.
- Check if you are taking your study medications correctly and answer all your questions.
- If you are a woman who can get pregnant, we will ask you about your last menstrual period and use of birth control methods. The study doctor might do a pregnancy test.
- The study doctor will discuss and recommend birth control methods so you can avoid pregnancy (yourself or your partner) while taking study medications.
- If you are affected by other diseases, for example hepatitis C, we might collect the exam results that your doctor will prescribe according to clinical routine practice.

Other special exams

- An electrocardiogram will be done to check your heart at every visit until Month 12, then once again at Month 17 (25 times).
- Your vision, hearing, and movement status will be checked every 4 weeks until Month 8, then at Months 9, 10, 11, 17, and 24* (up to 15 times).
- Your ability to carry out your daily activities will be reviewed at Months 9, 17, and 24*.
- Your mental health status will be checked at Months 17 and 24*.
- A chest X-ray will be done at Months 2, 9, 17 and 24*.

Collecting your sputum samples

- You will provide 2 sputum samples to our study workers every 2 weeks for the first month for the study, then at Month 2, and then at every visit after Month 3 until study completion.
- You must follow our study workers' instructions on how to collect and pack your samples properly.

* Exams after Month 17 will be conducted only if your study follow-up is still ongoing.

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Collecting your blood samples

- One tablespoon of blood will be collected at the clinic to check for possible side effects approximately every 4 weeks until Month 11.
- 1/2 tablespoon of blood will be collected for CD4 and HIV viral load at Months 6, 11 and 17 if you are HIV-infected.
- 1/2 tablespoon of blood will be collected to check blood sugar at Months 6, 11, and 17 if you have abnormal blood sugar level at screening/baseline visit.

Stopping or withdrawing from the study early

If you start the study and decide you want to stop, you should tell us. We will make sure that you stop the study safely. We will ask you to make a termination visit. At this visit, we will:

- Ask about changes in your medical history and in medicines you are taking since the last visit.
- Perform a brief body exam and ask about TB-related symptoms and how you are feeling.
- Check your vision, hearing, movement, functional and mental health status.
- Obtain 2 tablespoons of blood for laboratory testing.
- If you are a woman who can get pregnant, we will ask you about your last menstrual period and use of birth control methods. The study doctor might prescribe you a pregnancy test.
- Collect 2 sputum specimens.
- Do an electrocardiogram to check your heart.
- Do a chest X-ray (unless recent results are available).

We will talk to you about follow-up care, if needed.

Also, the study doctor might decide to take you out of the study before you finish it. This might happen because:

- You are a female participant and become pregnant.
- The study doctor thinks it is best for you to stop taking the study drug.
- You can't make the required study visits.
- We stop doing the study for any reason.

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If this happens, the study doctor will explain why you need to stop taking part in the study. We will invite you to come in for the termination visit as described above. We will also help arrange other care for you, if needed.

If your study termination occurs before Week 39 (Month 9) or before Week 73 (Month 17), we will ask to come back for follow-up visits at the time of Week 39 and Week 73.

At this/these visit(s), we will:

- Ask about changes in your medical history and in medicines you are taking since the last visit.
- Perform a brief body exam and ask about TB-related symptoms and how you are feeling.
- Collect 2 sputum specimens.
- Unless recent results are available, we will:
 - Do a chest X-ray,
 - Collect up to 1/2 tablespoon of blood sample to measure your sugar level if it was abnormal when you started the study,
 - Collect up to 1/2 tablespoon of blood sample for CD4 and HIV viral load testing if you are HIV-infected.

The termination visit or the Week 73 follow-up visit will be your last visit for the study.

What will happen to me after the end of the study?

Once you complete your participation in the study, any follow-up of your disease will be done by your regular doctor.

If you complete the study with side effect(s) that are not yet resolved, your study doctor may contact you until the side effect goes away or is stable.

If you decide to leave or are taken out of the study early, and you still have ongoing side effect(s) at this time, your study doctor may contact you until the side effect goes away or is stable. You might also be contacted by your study doctor if you experience a new side effect.

Please let your study doctor know if you do not want to be contacted even for updates on the ongoing side effects. You do not have to give any information that you don't want to.

Managing your Samples and Health Information in the Study

We will label all your samples and health information with a code instead of your name to keep all your information private. The key to the code connects your name to your samples and health

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information. The study doctor will keep the key to the code in a password-protected computer and/or locked file.

The samples and bacteria isolates obtained from your sputum samples might be tested for drug resistance confirmation and further analyses on the bacteria in a specialized laboratory in Belgium.

Storing Isolates (strains) and Health Information for Future Research

We would like to store some of the bacteria isolates (TB bug) and health information for future research related to TB, which will be collected during this study. All your health information and bacteria isolates will be handled in a way to keep all your information private. Any use of stored bacteria isolates and your health information for other research inside your country or in other countries will be approved by the ethics committee of your country.

This future research is independent from your participation in the endTB study and your decision to participate in the future research will not affect your participation in the study. The bacteria isolates found in your sputum samples and your health information may be stored for up to 20 years in a special place (bank or repository) created to safely store them. The stored isolates and your health information will be used only to help future research in TB and to improve diagnosis (including resistance testing) and treatment of TB. During your participation in the endTB study, and the following storage period of 20 years after completion of the study, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your health information and bacteria isolates.

Do you agree that your health information and bacteria isolates found in your sputum samples may be stored for 20 years and used only for future TB research? You are free to refuse such storage and further use for TB research of your health information and bacteria isolates and you will still be able to take part in the study.

☐ Yes ☐ No [Initials or signature, to be adapted locally]_____

You have the right to change your mind, and to later want your health information and/or bacteria isolates destroyed. In that case, during your participation in the endTB study, and the following storage period of 20 years after completion of the study, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your health information and bacteria isolates and/or their destruction.

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Will anything bad happen to me from being in this study?

Risks of Taking Study Drugs:

You will take a combination of MDR-TB drugs when you are on this study, whether you get an experimental treatment or the control treatment. The drugs used in the control are the nation's standard MDR-TB medications, according to international guidelines from World Health Organization. Experimental treatments will use together 4 or 5 of the following drugs: bedaquiline, delamanid, clofazimine, linezolid, moxifloxacin, levofloxacin, and pyrazinamide.

Medications for MDR-TB have different side effects. We do not know which of the combinations is the easiest to take. Your doctor will tell you the most common side effects that you may have while taking study treatment and you will be given a document entitled "participant information leaflet" that summarizes the main side effects. There may be other risks of the study drugs that are not known yet. You will be closely followed through clinical, laboratory and other examinations (hearing test, heart test) in order to detect and treat promptly possible side effects. And, your doctor will explain more in detail when you should get in touch with him/her.

As with any drug, an **allergic reaction** can happen. Allergic reactions can be mild or more serious, and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing.

Some of the drugs may have an effect on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant. It is possible that this effect is unknown and may be harmful. Because of these unknown risks, women cannot start this study if they are:

- known to be pregnant;
- trying to become pregnant;
- unwilling or unable to stop breastfeeding an infant.

If you are a menopausal woman and have not had a menstrual period for the past 12 months or more, you will not need to have a pregnancy test. Also, if you have had any well-documented method of surgical sterilization, you will not need to have a pregnancy test. Methods of surgical sterilization include having had a hysterectomy (removal of the uterus), bilateral oophorectomy (removal of both ovaries), a tubal ligation (having your tubes tied), and transvaginal occlusion (plugging the opening of the tubes with a coil). All other women must have a negative pregnancy test before starting the study drugs.

Regardless of your sex, if you are sexually active and able to become pregnant or father a child, you must agree to abstain from sex (have no sex) or to use two of the birth control methods listed below while taking study drugs. Your doctor may also discuss with you the use of birth control after you finish taking your study drugs.

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Acceptable female birth control methods for use in this study are:

- Hormonal methods, such as birth control pills, patches, injections, vaginal rings, or implants.
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm).
- Intrauterine device (IUD).

Acceptable male birth control methods for use in this study are:

- Condoms with spermicide (a foam, cream, or gel that kills sperm).

For female participants, if you miss a period, or think you might be pregnant during the study, you must tell the study doctor immediately. *[to be adapted locally]* If you become pregnant, your treatment might be changed and you might stop taking part in the study. The study doctor will ask for permission to collect information about the outcome of your pregnancy and the condition of your newborn.

For male participants, if your female partner becomes pregnant, we would like to follow the outcome of the pregnancy. You should let us know immediately if your partner becomes pregnant. You will not have to stop taking the study drugs or stop taking part in the study if your partner becomes pregnant.

Risks of Taking the Study Drugs with Other Medications

Some drugs are not safe to be taken together with the study medications, or may not work when taken with the study medications. Please inform and consult your study doctor if, at any time of the study, you are prescribed or begin using any other medications.

For your safety during this study, call your study doctor BEFORE you take any:

- new medications prescribed by another doctor;
- other medications sold over-the-counter without a prescription;
- dietary or herbal supplements.

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 in this study?

By participating in the study, you may receive a shorter all-oral treatment compared to the current treatment recommended for MDR TB. There is no guarantee that any of these shorter

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treatments will work better than the current [18 to 24 – *to be adapted if short regimen available*] months standard treatment. During this study, we will learn more about the treatments and use the information to assign more patients to treatments that are helping other patients. When you receive the study drugs, we expect your medical condition/symptoms to improve. It is also possible that the TB bacteria are or become too strong to be killed by the study drugs you receive. If that happens, your study doctor will change your treatment. You will have more tests that allow the doctors to know what kind of anti-TB drugs they should use. The study doctors can also take care of your side effects sooner and better by having those extra tests. However, it may be harder for you to be cured if very few drugs work against your TB bacteria.

You will receive greater treatment support from the study team throughout the study than during regular MDR-TB treatment. Others with MDR-TB may benefit in the future from what we learn in this study.

What other treatments or procedures are available for my condition?

You do not have to take part in this study to be treated for MDR-TB. Other treatment is available to treat MDR-TB in your country through [local TB care provider/entity]. This treatment is similar to that in the control arm in the study [18-24 months *to be adapted if short regimen accepted*] of combination therapy, including about 6 months of a daily shot). Talk with the study doctor if you have questions about the other treatment.

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

Yes. Taking part in this study is up to you. You can decide not to take part. You will receive treatment through [local TB care provider/entity] if you do not take part in this study. There will be no penalty, and you will not lose any benefits you receive now or have a right to receive. The treatment outside the study is also free of charge.

What should I do if I want to stop taking part in the study?

If you take part in this study and decide you want to stop, you should tell us. We will make sure that you stop the study safely.

Also, it is possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why.

We will tell you if we learn any new information that could make you change your mind and choose to leave the study.

If any of these happens, we will talk to you about follow-up care, if needed, and you will be encouraged to come back at least for one additional visit (“termination visit”).

Information collected during your participation will be used to help answer study questions. When you leave the study, your health information, and information obtained from sputum samples and bacteria isolates previously collected may still be used and stored for 20 years for

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the study and future TB research. However, if you prefer this information is not used and that it is destroyed, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org.

Will I be paid to take part in this study?

You will not be paid to take part in this study. We will pay the transportation costs for study visits. You will also receive [local arrangement for monthly food supplements] when you take part in the study. In sum, you will be reimbursed [local currency] _____ for transportation for the baseline visit, [local currency] _____ for each follow-up visit, for any unscheduled visits, and [local currency] _____ for your final visit.

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

You will not have to pay in order to take part in this study. You also will not have to pay for the study drugs, or for any study-related procedures and visits.

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

The sponsor has made insurance arrangements to pay for an injury you suffer due to your participation in the study.

If you suffer physical injury from this study please inform your doctor and seek medical attention right away, _____ will ensure that you receive appropriate medical treatment.

[Research site name] will not pay to treat a medical condition or disease you had before joining this study or expenses for injury, treatment, or hospitalization you may require that are not the result of your participation in the study.

In an emergency, the study sponsor has made plans to pay for your visit to see a specialist, the related treatment, and/or your stay in the hospital. For non-urgent situations, the sponsor may pay for your visit to see a specialist. The study team will review your situation and decide whether the sponsor will pay for the resulting treatment if your condition is not the result of your participation in the study.

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

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

[PI Name and title] is the person in charge of this study. You can call him/her at [PI telephone number]. You can also call [Clinical Investigator] at [CI number] with questions about this study. If you have questions about the scheduling of appointments or study visits, call [Study Coordinator] at [SC number].

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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 this study, please contact the **[Research Center IRB]** office. You can call them at **[Research Center IRB number]**.

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

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

For the study, 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 this study will be used for the following purposes:

- For the purpose of this study. The sponsor, the study doctor, or other doctors involved in the study may publish reports or articles on the study or present the study findings to scientific groups. After the study is completed you may see your records, and you may be told the results of the study.
- Secondary use for TB research; your coded information may be used and shared with other institutions only for the purpose of further TB research during and after completion of the study and notably with the World Health Organization.

In all cases your identity will never be disclosed.

Your coded information may be sent electronically to other researchers or institutions, If sent, it will be encrypted (scrambled so it cannot be read by people who should not see it).

We guarantee that, when we send your coded information, it will be protected according to European Economic Area standards.

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Informed Consent and Authorization

Your signature on this document means the following:

I have read this consent form. This study 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 participant. I will receive a complete, signed, dated copy of this research consent form.

By signing below, I agree to take part in this study.

Signature of Participant

Signature or thumbprint of participant

Date (DD/MMM/YYYY) and Time

Name of participant, printed in capital letters

Witness (if applicable):

Signature of witness

Date (DD/MMM/YYYY) and Time

Name of witness, printed in capital letters

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Study representative who obtained informed consent:

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 study.

Signature of study representative

Date (DD/MMM/YYYY) and Time

Name of study representative, printed in capital letters

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Schedule of Visits

Visit	Consent	Doctors' Exam	Nurses' Interview	Blood Collection	Sputum Collection	ECG	Chest X-ray
Baseline	✓	✓	✓	(✓)	(✓)	✓	(✓)
Week 1		✓	✓			✓	
Week 2		✓	✓		✓	✓	
Week 3		✓	✓			✓	
Month 1		✓	✓	✓	✓	✓	
Week 5, 6, 7		✓	✓			✓	
Month 2		✓	✓	✓	✓	✓	✓
Week 9, 10, 11		✓	✓			✓	
Month 3, 4, 5, 6, 6.5, 7, 8		✓	✓	✓	✓	✓	
Month 9		✓	✓	✓	✓	✓	✓
Month 10, 11		✓	✓	✓	✓	✓	
Month 12		✓	✓		✓	✓	
Month 13.5, 15		✓	✓		✓		
Month 17		✓	✓	(✓)	✓	✓	✓
Month 19, 20, 22*		✓	✓		✓		
Month 24*		✓	✓	✓	✓		✓