Study Title: A Phase 2 Randomized, Double-blind, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of PF-06252616 in Ambulatory Boys with Duchenne Muscular Dystrophy			
ICD	**Protocol ID:** B5161002	**Date Created:** 23 Aug 2016	
☒**Study-Level** or ☐**Country**	**Language:** English	**Center ID:** N/A	**Country:** N/A
Assent Derived From: Study level assent 26 Jun 2015			

Please take your time to read this. There is no hurry. Please ask the study doctor or someone who works with him/her to explain anything that you do not understand.

This is a research study:

My name is Dr. _____ and one of my jobs is to study new medicines. We want to find out if a new medicine called PF-06252616 is safe and if it can help children with Duchenne muscular dystrophy (DMD). This is called a "research study" or "study". You have DMD and the doctor wants to know if you want to be in the research study.

The Purpose of the Study: We want to see if this new medicine called PF-06252616 helps boys with DMD and see if it causes any problems.

If you want to be in this study, you will write your name on the last page of this paper to say that you understand what will happen and that you agree to take part in the study. Your parent (mommy or daddy or person who takes care of you) will sign another document to say that they understand what will happen and agree that you can take part in the study.

I will also give you a signed copy of this paper to keep for yourself. You can ask your parent to look after it if you want.

You do not have to be in the study. It is up to you and your parent to decide. If you do not want to take part in the study, you do not have to, even if your parent(s) says yes.

You may talk to your parents or friends or anyone else you want to, about the information in this paper. You can decide if you want to take part or not after you have talked it over. You do not have to decide immediately.

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About 105 boys around your age from around the world will be in this study.

There may be some words you do not understand or things that you want me to explain more about because you are concerned or worried. Please ask me to stop at any time and I will take time to explain. If you have a question later that you did not think of now, you can ask us next time. Or you can ask your parent(s) to call us and you can ask your questions over the telephone.

What you will be asked to do as part of the study:

You will have to visit the clinic many times during this study. Sometimes you may have to visit the clinic for two days in a row. You will be in this study a little over 2 years. Sometimes you may not want to come to the clinic. It is however important that you try to come.

If you decide that you want to be in this research study, this is what will happen:

When you visit the clinic, the study doctor will write down information about you so that other people can look at it too. Any information used for this study will have a number on it instead of your name. During the visits, some or all of the following things will be done:

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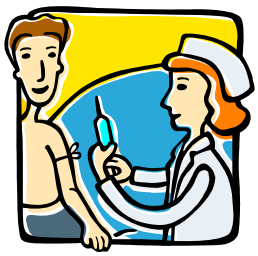
The study doctor will give you a physical examination (exam of your body), and see how tall you are and how much you weigh.

You will have to give urine (pee) samples for some tests. You will be asked to pee in a cup. You will also be asked to bring in bowel movement (poo) from home in a special container.

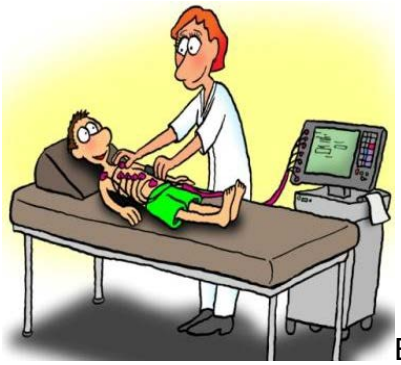


You will have to give blood samples for some tests. This will be taken from your arm with a needle. This may hurt a little.

The doctor will also listen to your heart beat and tell you to take deep breaths, take your blood pressure, and take your temperature to check if you have a fever.

The doctor will also ask you how you are feeling and about any other medicines or

vitamins that you may be taking.



Electrocardiogram (ECG). This is a test to see how well your heart is working. For this test, you will have wires taped to your chest while you're lying down. The machine will record your heart beats to see how well it is working. This does not hurt.

Echocardiogram (ECHO): This is a test that takes pictures of your heart beats. It uses your heart's sound waves to create a picture of your heart. This test does not hurt.

Magnetic Resonance Imaging (MRI). While you are lying on a table, the machine takes pictures of your body. For this test, you must lie inside the machine which is a little bit like a tunnel. This machine can make loud noises but it does not hurt. To help look at your heart, you may be given a dye (gadolinium) through a needle.

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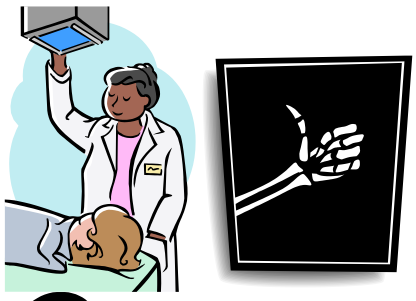

Dual-energy X-ray absorptiometry (DXA): While you are lying still on a table, a bone scan will be taken of your body. This test does not hurt.

X-ray: You will be asked to keep your arm still on a table while pictures are taken of the bones in your hand and wrist. This test does not hurt.

You will have tests to see how your muscles are working. You will also have breathing tests.

Your parent will be asked to answer questions about your disease and how your feeling.

You will be given either PF-06252616 or a pretend medicine called placebo. You will not know which medicine you are getting, but you will be given PF-06252616 for at least half the time you are in the study. These medicines are liquids that will be given to you as an intravenous (IV) infusion. IV infusion means you will have a plastic needle in your arm and the study drug will slowly drip through a tube into your arm.

Remember to tell your parents and the doctor what you are feeling while you are in the study especially if something makes you feel bad, afraid or uncomfortable. PF-06252616 could cause too much iron in your blood, sores in your stomach, nose bleeds, skin rashes, or your body to change into an adult (puberty) earlier than expected. During the study, your doctor will be watching carefully for these changes.

Your DMD could get worse if PF-06252616 doesn't work or while you are given the pretend medicine.

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You do not have to be in this research study if you do not want to. Your normal treatment will not be affected if you say no. Even if you say yes now and change your mind after you start doing this study, you can stop and no one will be upset or disappointed. Just tell the doctor or your parent(s) if you want to stop at any time. Your doctors will still take care of you if you don't want to be in this study.

You can ask questions about the study any time. You can call the doctor any time.

If you want to ask questions about what it means to be in a research study, you or your parents can call (name) IRB at (phone no.).

Be sure to ask Dr. _____ to tell you more about anything that you don't understand.

____Yes, I will be in this research study.

____ No, I don't want to do this.

Participant: _____ Date: _____ Time:_____

Parent(s) or legal representative: _____ Date: _____
Time:_____

CONSENT FOR PARENT/LEGALLY ACCEPTABLE REPRESENTATIVE WHO CANNOT READ

The study participant's parent/legally acceptable representative has indicated that he/she is unable to read. One or more members of the study team read the consent document to the study participant's parent / legally acceptable representative, discussed it with the study participant's parent / legally acceptable representative, and gave the study participant's parent/legally acceptable representative an opportunity to ask questions.

_____

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Printed name of impartial witness ‡

_____ _____

Signature of impartial witness Date of signature§

☐ Not applicable (*Check this box if the Signature of an impartial witness is not required. Signature of an impartial witness is required if the subject or subject's legal representative cannot read*).

§ Parent / legally acceptable representative / impartial witness must personally date their signature.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.

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ASSENT SECTION

Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the subject to the best of his ability to understand.
2. I have answered all the questions of the subject relating to this research.
3. The subject agrees to be in the research.
4. I believe the subject's decision to enroll is voluntary.
5. The study doctor and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Initials of Person Obtaining Assent: _____ Date: _____ Time: _____

Principal Investigator: _____ Date: _____ Time: _____

-- Please provide a copy of this assent to the minor, parent or legal representative --