What Can I Expect During the Trial?
Your research doctor and his/her staff will determine if you meet the entry requirements for the study. Remember, the study protocol includes detailed information of who can and cannot enter the study. The staff will ask if you are interested in the study. If you are, they will explain the study to you and answer all of your questions. It is important that you determine if you are able to make the return visits, take the investigational drug as ordered, and follow any other study directions. If you are still interested, you will then be given a study consent to read and sign. A copy of the completed consent will be given to you. Any tests or procedures required by the study will only be performed once you have read and signed the study consent. You will then make return visits to the research staff so they can evaluate your health and progress in the study. Once you have completed the study, you are free to discuss other treatment options with your doctor.

What Is a Placebo?
Some studies are designed to determine if the investigational product is as good if not better than another product. Other studies test if it is better than receiving no treatment at all. In these studies, volunteers who are not receiving the investigational product are given a placebo.

Placebo is made of inactive substances so it has no effect on you. It is also designed to look the same and be packaged the same as the investigational product. You may be assigned to the investigational drug, the approved drug or to the placebo. Neither you nor your research doctor knows if you are getting the investigational product or placebo. This avoids volunteers and researchers from showing a preference for one of the drugs in the study while collecting study information.
What is a Clinical Trial?
Medications, vaccines, some medical devices such as heart pacemakers or artificial joints are thoroughly studied before being allowed for use by doctors for their patients. While these products are being studied and before being approved, they are considered “investigational products.” There are many research studies, or trials, that must be done on an investigational product to determine if it is safe and if it works or is effective.

How Does the Trial Work?
Every study follows a specific written plan or “protocol.” The protocol explains how the trial is to be done and describes the goal of the study, how many volunteers are needed, the types of tests required, how many study visits are needed, and what information is collected by the doctor and his staff from the study volunteers.

Once the protocol is done for all of the volunteers, all of the information is put into a report and sent to a government agency such as the Food and Drug Administration (FDA) in the United States or Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom. These agencies review the results and decide if the investigational product should be approved to treat people.

How Is My Safety Monitored?
There are country and international guidelines and laws that study doctors and drug companies must follow for every clinical trial they do. Every country has a national government agency, such as the FDA and MHRA, who oversee clinical trial activities. Additionally, the protocol must be reviewed and approved by an Institutional Review Board, Ethics Committee, and sometimes other local or country groups. These groups must give approval for a research doctor to begin the study. Their main concern is the safety of the volunteers.

Some protocols also have a further independent safety monitoring committee. The safety committee reviews information at regular intervals during the study for potential safety issues.

Lastly, your study doctor and his team will see you during return visits. They will assess how you are doing and if you are having any problems. You will have a person at the study site to contact should you have any problems between visits.

Why Should I Participate in a Clinical Trial?
The purpose of a clinical trial is to determine if the investigational product is safe for use in people in general, safe for people with the disease it will treat, and if it works. Volunteers are needed to complete this testing. Participation in a clinical trial helps researchers potentially discover a treatment for a new or existing disease, or improve treatments currently available.

What Is Informed Consent?
Informed consent means the study has been explained to you, all of your questions have been answered, and you have given your consent (permission) freely. No study procedures can be completed until you sign the informed consent.

Informed consent is your right to receive information about the trial and to have as much time as you need to consider this information before you agree to participate. All of this information will be in a written document called a consent form. The study doctor or his staff will explain the study to you and give you this document to review. They will tell you about the investigational product, risks, how to use the investigational product, how long you will be in the study, how often your study visits are, and the various tests and examinations that will be done.

After discussing the study, you will have the opportunity to ask the study staff any questions you may have. You should read and understand all of the information in the study consent form and have all of your questions answered before agreeing to participate in the trial.

Once your questions are answered and you decide to participate in the study, you will sign the consent form. The study staff will also sign to confirm they have explained the study to you. You will be given a copy of the signed consent to take with you.