A guide to understanding
Clinical Studies

This guide is for patients and caregivers who want to learn more about clinical studies

How can this guide help me?

This guide explains key concepts about clinical studies (also referred to as clinical trials) to help you have meaningful conversations with your doctor.

How should I use this guide?

This guide is divided into **six chapters.** Each chapter is a complete story. You can start at whichever chapter you want.

Keep this guide for your reference. Space has been provided for you to take notes and write down any questions you may have as you read through it.

Chapter 1: Understanding clinical studies

Your doctor learns about investigational treatments by looking at results from clinical studies. They use this information to help decide if an investigational treatment may be appropriate for you.

What are clinical studies?

A clinical study is a type of research that involves human volunteers and looks at **investigational or study treatments,** such as medicines, vaccines, or medical devices, for benefits and risks. A clinical study is sometimes also called a *clinical trial*. Your doctor may have questions about the benefits and risks of an investigational treatment, and clinical studies help find answers about better ways to prevent, screen (or look) for, diagnose, or treat a disease. Before any investigational treatment is approved by the United States Food and Drug Administration (FDA) and becomes available to patients, it is carefully studied by a clinical study team.

It is important to know an investigational treatment is a treatment that is being studied and is not approved by the United States Food and Drug Administration (FDA)

Why are clinical studies important?

Clinical studies may help your doctor learn more about a disease and improve medicine. Joining a clinical study can make a difference in the care of future patients by providing important information such as if an investigational treatment works in a certain disease or explore ways to improve comfort and quality of life.

The main questions that clinical studies help answer are:

1. **What are the potential risks associated with the investigational treatment?**
2. **Does the investigational treatment work? How well does it work?**

You may hear the terms **benefits and risks** when learning about a clinical study. You and your doctor would talk about the potential pros and cons of an investigational treatment in detail before deciding if it would be right for you.

Benefits can be seen as something that potentially helps improve your health outcome or helps you feel better.

Risks can be any potential side effects that you might experience.

What types of clinical studies are there?

Clinical studies happen in a series of steps or phases and may take years to complete before an investigational treatment reaches the public. Once an investigational treatment is successful in one phase, it then moves on to the next phase. Most of the time, participants will only be in the phase of the study that they are taking part in. Investigational treatments move through the different clinical study phases, but participants do not.

There are 4 phases known as Phase 1, 2, 3, and 4. Each phase has a different purpose and helps answer different questions. Clinical study phases can go from early small Phase 1 studies to larger Phase 3 studies.

Phases of Clinical Studies

	Who can participate	Questions each phase tries to answer		
		What does the dosing* look like for the study treatment?	Does the study treatment work? How well does it work?	What are the potential risks associated with the study treatment?
Phase 1	Small group of healthy participants or patients with the disease/condition	●		●
Phase 2	Up to several hundred patients with the disease/condition	●	●	●
Phase 3	Larger group of patients who have the disease/condition		●	●
United States Food and Drug Administration (FDA) Review and Approval Treatment is now available to the public				
Phase 4	Several thousand patients who have the disease/condition		●	●

The information in the table above comes from the United States Food and Drug Administration (FDA)

*Dosing is the amount of medication or treatment given for a disease/condition.

How do I decide if enrollment in a clinical study may be right for me?

You and your doctor will work together with the goal of deciding if a clinical study may be right for you. Your doctor will give you information about different investigational treatments to help you decide what may be appropriate for you. This could include considering the impact on daily activities and possible side effects from the investigational treatment.

There may be times when you may have to start the conversation and ask your doctor if there are any available clinical studies for which you may be a good fit.

It is important to know you can always get a **second opinion** from another doctor to help you decide if a clinical study is right for you. The decision to enroll in a clinical study may not be an easy one to make. Getting a second opinion can help you feel more comfortable and confident with your decision.

In the next chapter, we will take a closer look at what to look for before making the decision to join a clinical study.

Chapter 2: Deciding if participating in a clinical study is an option for you

You may have questions as you think about participating in, or joining, a clinical study. It is important to get answers from your doctor so you can decide what is right for you.

What are some considerations if you are thinking about joining a clinical study?

There are many factors to consider and discuss with your doctor before joining a clinical study, including the potential benefits, risks, and safety measures put in place to protect you.

POTENTIAL BENEFITS

1. May feel like you are playing an active role in your own health by making an informed decision about clinical study participation
2. Have the opportunity to get an investigational treatment that may be available only for patients that join the study
3. Get more frequent checkups as part of the clinical study
4. May get payment for your time and any inconvenience while participating in the clinical study
5. May help others get a potential treatment for their disease or condition in the future

POTENTIAL RISKS

1. Have mild to serious side effects or feel uncomfortable due to the investigational treatment
2. Clinical studies may be an inconvenience; you may need more medical appointments and travel time
3. You may not be a part of the investigational group that gets the study treatment. You may be a part of the control group that either gets the standard treatment or inactive treatment, known as placebo
4. If you are in the investigational group and get the study treatment, the study treatment may not work for you or it may not be better than the current standard treatment

How does the clinical study team decide that a clinical study is right for me?

Before joining a clinical study, you must provide information that helps the clinical study team decide if you can join the study.

Every clinical study has detailed guidelines about who is and who is not able to take part. These guidelines are known as the *eligibility criteria*. The guidelines or criteria are based on many things including a participant's age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

The clinical study team looks at each participant as a whole to make sure that joining the study is right for them.

How are possible risks of an investigational treatment monitored in a clinical study?

A clinical study looks at if an investigational treatment is safe. Any possible study risks will be looked at during a clinical study. Laws have been passed to make sure every participant is protected. There are strict rules in place that the clinical study team must follow. There are also committees and processes designed to protect you.

An ethics committee known as the *Institutional Review Board (IRB)* helps to make sure that the study is ethical and that your well-being is protected. This ethics committee is made up of doctors, scientists, and patient advocates or other patients. The IRB must review and approve clinical studies in the United States before they start and then continue to regularly review them to make sure risks do not outweigh the potential benefits of the study.

In addition to the IRB, many clinical studies are monitored by a safety committee. The safety committee, known as the *Data and Safety Monitoring Board (DSMB)*, is made up of experts on a disease. If an investigational treatment is not working or is found to be harming clinical study participants, the study will be stopped early.

What is the informed consent process and informed consent form?

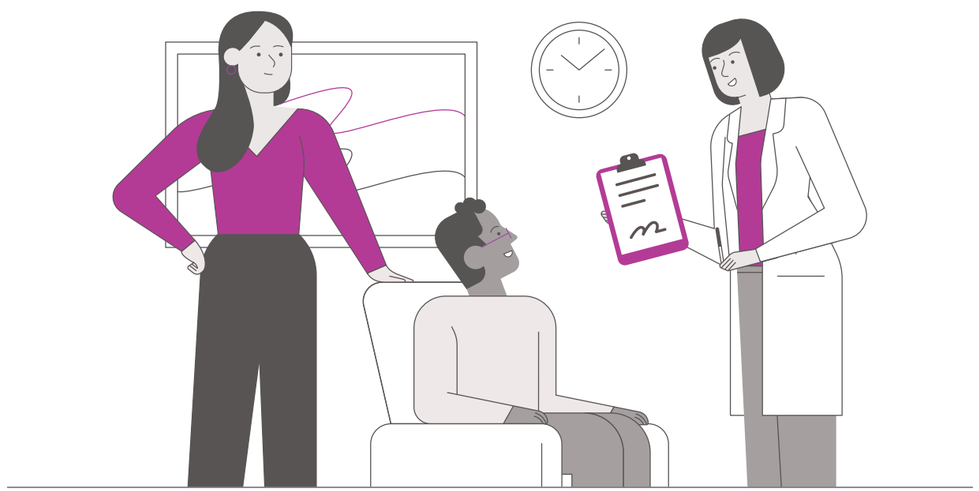
The **informed consent process** is used by your clinical study team to give you information about the study. During this process, you will learn the details of the clinical study, such as its goal, how long it will last, tests or procedures that will be done as part of the research, and who to contact for further information. You will also learn about the potential benefits and risks of the clinical study.

This is the time for you to learn about the clinical study.
You may want to:

- Bring your own notes and potentially record any conversations you have with your clinical study team
- Bring a family member or friend to help you keep track of information
- Go to question-and-answer sessions or other activities to help make sure you understand the information
- Ask your clinical study team about any support services offered to people who join a clinical study. This may help you decide if you want to join the clinical study

It is important to know that signing the informed consent form is **not a contract**. You can leave the study at any time without it affecting the medical care you receive. You and your doctor would discuss what to do next for your medical care if you decide to leave the clinical study.

The **informed consent form** provides information about clinical studies, including the potential benefits and risks. If you need more time to read through this form you can ask for a copy to bring home and review. If you decide to join a clinical study you must sign the informed consent form before starting the study to show that you understand the benefits and risks. During the clinical study, there may be a need to sign a new informed consent form based on any new research discoveries that could happen. In general, it is a good idea to keep a copy of the consent form for your reference.



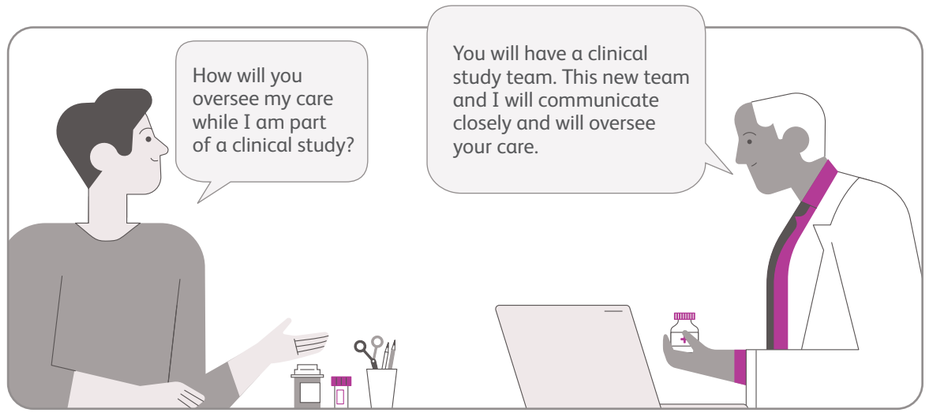
Why is diversity important in clinical studies?

It is important for clinical studies to have participants of different characteristics like race, ethnicity, age, sexual orientation, and physical ability, as the effect of study treatments can vary across these groups. Clinical studies should represent the people who use the investigational treatment if it is approved. By making studies more diverse, the findings from these studies may apply to or benefit a wider group of people.

In the next chapter, we will learn about who is on your clinical study team and some questions you might ask them.

Chapter 3: Communicating with your clinical study team

Your clinical study team is made up of a group of experts with experience in different areas. Each team may be set up differently based on the specific clinical study site.



Who may be on my clinical study team?

A clinical study team includes many different experts with different experience. Each clinical study site may set up teams differently, but most teams will include the following people:

You, the clinical study participant with the support from your family and friends

Principal investigator
oversees all aspects of a clinical study

Subinvestigator
helps the principal investigator carry out the clinical study. Subinvestigators may include physician assistants or nurse practitioners

Study doctor
helps take care of the patients during a clinical study according to the clinical study design. The study doctor records any responses and side effects

Research nurse
gives the study treatment and helps the principal investigator in monitoring for side effects

Clinical study coordinator
works closely with the principal investigator and manages day-to-day activities to make sure the study is running correctly and meeting requirements

Research pharmacist
makes sure the study treatment is given safely to each participant

Social worker
talks with you and your family about emotional or physical needs and finds support services

Data manager
manages the collection of data throughout the clinical study

What other information might be important to ask my study team about clinical studies?

When talking with your clinical study team, it is important to make sure you have all the answers you need to make the most appropriate decision about your health. Below are some questions about clinical studies you may consider asking to get the conversation started. If you have any questions not listed here, make sure you also share those with your clinical study team.

Questions to ask your clinical study team

The study

1. What is the purpose of this study?
2. How long will the study last? How long will I be expected to participate in the study?
3. How often will I have to visit the study site? What happens if I must miss or reschedule a visit?
4. How far will I need to travel to be a part of this study? If I must travel from far away, will there be somewhere for me to stay? If I am local, what options are available for transportation to and from the study site?
5. What kinds of tests, assessments, physical exams, or procedures will I undergo during the study?
6. What are the potential risks and benefits of the investigational treatment, and what happens if I am harmed?
7. What are the risks and benefits of this investigational treatment compared to the standard of care?
8. Will follow-up visits be done in person, by telephone, or virtually?
9. Have similar studies already been done and what were the results?
10. What are some different ways to address my disease/condition?

Participation and care

1. How will my medical information and privacy be protected?
2. How long do I have to make up my mind about joining the study?
3. How could joining this study affect my daily life, including going to work and being a caregiver?
4. Will I be able to take my regular medications while participating?
5. Will the study provide interpreter services or documents translated into other languages?
6. Is there a person I can contact at any time with questions or concerns I may have?

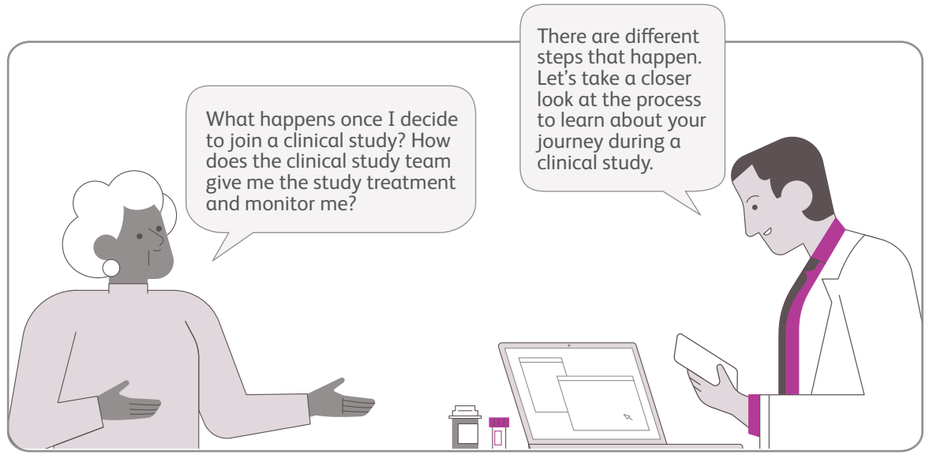
Costs

1. What costs do I have to pay and what costs will be covered by my health insurance?
2. Will I be paid back for expenses such as travel, parking, lodging, or meals?
3. What resources are available for me if I need additional assistance?
4. Will the cost of childcare be covered while I am in the study?

In the next chapter, we will go into detail about the process and flow of clinical studies.

Chapter 4: What to expect when participating in a clinical study

Your clinical study team will help guide you through each part of the process.



The clinical study investigators consider a lot of things before they start a clinical study. The written plan for the clinical study is called a *protocol*.

A protocol includes:

- Background scientific information about why more research is needed for this disease
- The reason for doing the study (the study objective)
- Who may participate in the study (the eligibility criteria)
- The number of participants needed
- The schedule of tests, procedures, and study medications or treatments
- How long a study will last
- What information will be gathered about the participants
- Statistical information about how the study responses are collected and analyzed

What does the general timeline of a clinical study look like?

A schedule or timeline of events can vary from study to study. A general timeline is explained below.

Screening period

Meet with study doctor to discuss the study details and to see if a participant qualifies to join the study based on the eligibility criteria. If the criteria are met and the participant is willing to consider joining the study, they will go through the informed consent process and sign the informed consent form. Once the informed consent form is signed, the clinical study can begin

Treatment period
participant in one of the clinical study groups

At the first visit:
- Measurements (physical exam, blood work, imaging, or scans) are taken
- Record how a participant feels and their daily activities
- This information is compared with what happens later in the study

Regular scheduled follow-up visits for new measurements (physical exam, blood work, imaging, or scans)

Throughout the treatment period:
- The clinical study team collects information about potential benefits and risks
- If a participant feels any change that is strange, worrisome, or bothersome, it will be recorded as a side effect
- You and your family members follow the study processes and report any issues or concerns to the clinical study team
- The information collected at follow-up visits will be different depending on the type of disease and the investigational treatment being studied

Follow-up period

Clinical study has ended and the participant will continue to be monitored for potential benefits and risks

How many and what sort of tests will I need to get during a clinical study?

The type of tests and measurements done during the clinical study will depend on the disease and investigational treatment being studied.

Many studies need participants to get tests, assessments, and procedures based on the protocol. This will be described in the informed consent form. If you have any questions or concerns, you should discuss them with your clinical study team.

Is there a cost to participating in clinical studies?

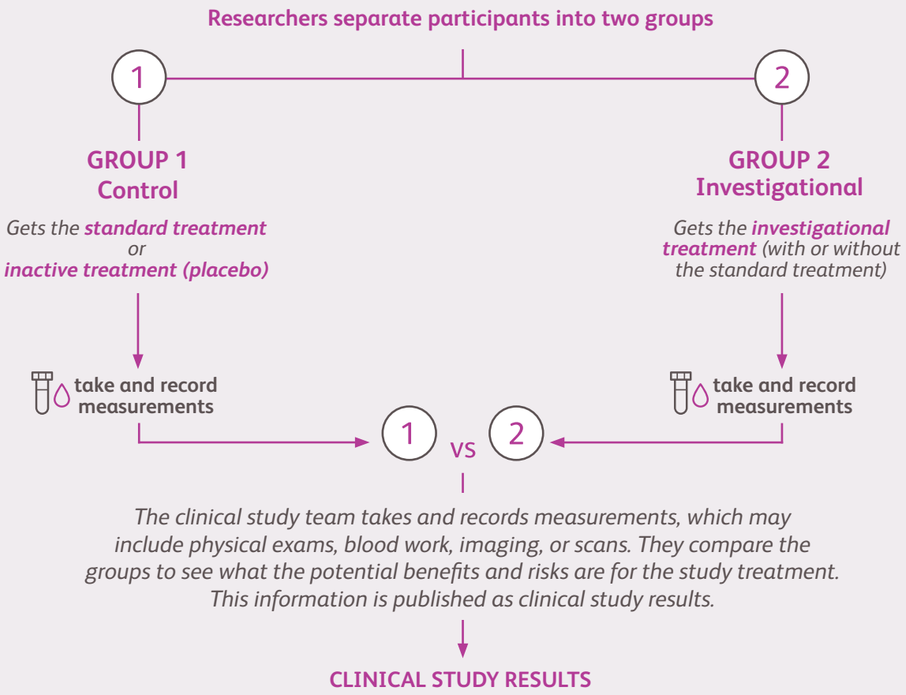
Patients generally do not have to pay for investigational treatments studied as part of a study. The sponsor of a clinical study may pay for research-related costs and any special testing. Every study is different, so it is important to ask the clinical study team about the cost.

Before you join a clinical study, you will receive an informed consent form that will tell you exactly what you may have to pay for. You may be asked to pay for any routine tests, treatments, or procedures through your insurance if these are needed as part of routine treatment in the clinical study.

How are treatment groups decided and what treatment will I get?

There are a few different types of clinical studies that you may hear about. The information covered below is specific to randomized clinical studies.

Randomized clinical studies put participants into two or more groups. Treatments are assigned to participants by chance rather than by choice. Randomization also helps make sure each group has a similar mix of people, in terms of age, gender, race, and other characteristics.



Information about treatment groups

Placebo treatment would not be given in a clinical study if it would put you at more risk and harm by not having active treatment. Before entering a study, you would know if a placebo will be used in one of the groups.

In some clinical studies, when a placebo is used, a participant would also receive the standard treatment for their specific disease. In some studies, a participant may be assigned to the placebo treatment and then be switched to the investigational treatment if the disease is getting worse. Sometimes switching to the investigational treatment happens if one group is doing much better than the other and it is unethical to keep the groups separate. This information would be explained to you before you start the clinical study.

It is important to know that the different phases of a clinical study may also have different study designs and number of treatment groups. Sometimes there may only be one treatment group, which would be the group getting the **investigational treatment**.

Will I know which treatment group I am in?

When learning about clinical studies, the term "blinded" or "masked" might come up. Many clinical studies are designed to prevent the clinical study team and study participants from affecting the study's scientifically accurate results. Blinding is a process used to prevent participants and/or the clinical study team from knowing which treatment group each participant is in.

In single-blind studies, you are not told what treatment is being given, but the clinical study team knows.

In a double-blind study, neither you nor the clinical study team are told what treatment you are given.

If needed for your medical care, it is always possible to find out which treatment you are receiving.

How does my clinical study team know if the study treatment is helping me?

The clinical study team will record measurements throughout the study. They will keep a close eye on the measurements and anything else you report. They will compare this information to the first visit measurements to see if there is a change and compare it to the information that is known about the standard treatment already approved.

The potential benefits and risks results are collected and evaluated to see if the study treatment is right for you.

What happens if the clinical study treatment is not helping my disease?

The clinical study team monitors you closely. If they find that an investigational treatment is not helping you, they may take you off of the investigational treatment and the clinical study may be stopped early.

It is important to know that participants in a clinical study have the right to stop participating at any time.

In the next chapter, we will review some key information about what happens after a clinical study is over.

Chapter 5: Learning what happens after clinical study participation

After a clinical study ends, you might have some questions about what happens next.

What happens after the clinical study is over?

Once a clinical study has ended, the clinical study team will collect and analyze the results. As a participant, you should be provided information before the clinical study starts about how long it will last, whether you will continue receiving the study treatment after the study ends, and how you will learn about the results of the clinical study.

Will I continue to see my clinical study team once the clinical study has come to an end?

After the clinical study has finished, there is a follow-up period where participants continue to be monitored. Your clinical study team will follow your progress for some time after study treatment. They do this to see if the study treatment works over a longer period and to find out more about the potential long-term side effects.

What treatment will I be on after the clinical study ends? Can I continue on the study treatment if it is working for me but is not yet approved by the United States Food and Drug Administration (FDA)?

The treatment you get after a clinical study ends may not always be the study treatment and may depend on the type of study. You may be put on the best available standard treatment instead of the investigational treatment based on your doctor's evaluation. You can ask your doctor about your options.

How does my doctor interpret the clinical study results to evaluate a treatment?

After a clinical study ends, the results are often published in a scientific journal. The results of a study may give important information about the benefits and risks of the study treatment.

One of the common ways clinical study teams look at clinical study results is by turning the results into tables or graphs. Your doctor will use these tables and graphs to compare the benefits and risks seen between different groups. In other words, the results may help see if the investigational treatment worked better than the standard treatment or placebo. Your doctor will also look at the safety of the investigational treatment when compared to the standard treatment or placebo to get a better idea of the risks.

In the next chapter, we will review resources available to you.

Chapter 6: Resources available to you

There are many ways to find a clinical study that may be right for you. The best place to start is to talk to your doctor. There are also resources available for you if you need other types of assistance during the clinical study.

- **ClinicalTrials.gov:** Searchable registry and results database of federally and privately supported clinical studies conducted in the United States and around the world

  https://clinicaltrials.gov/

- **National Institutes of Health (NIH) Clinical Research Studies:** Database of clinical research studies taking place at NIH's Clinical Center

  https://clinicalstudies.info.nih.gov/

- **Center for Information and Study on Clinical Research Participation (CISCRP):** Service that identifies the right clinical study for patients

  https://www.ciscrp.org/services/search-clinical-trials/

- **ResearchMatch:** ResearchMatch is a nonprofit program funded by the National Institutes of Health (NIH). It helps connect people interested in research studies with researchers from medical centers across the United States

  https://www.researchmatch.org/

- **findhelp.org:** Free tool to help find assistance for food, housing, goods, transit, health, money, care, education, work and legal

  https://www.findhelp.org/

- **United States Department of Health and Human Services:** Resource for social services and programs such as paying for child care, programs for seniors, and programs for persons with disabilities

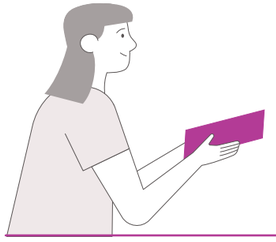
  https://www.hhs.gov/programs/social-services/index.html

- **Disease-specific patient advocacy organizations**
- **Pharmaceutical company websites**

Bristol Myers Squibb is not affiliated with and does not support the organizations/agencies in the list above.

This guide is intended to clarify key concepts about clinical studies to help you have a meaningful conversation with your healthcare team.

Talk to your healthcare team about how any investigational treatments may work for you and if you may be eligible for upcoming clinical studies.



What’s next?

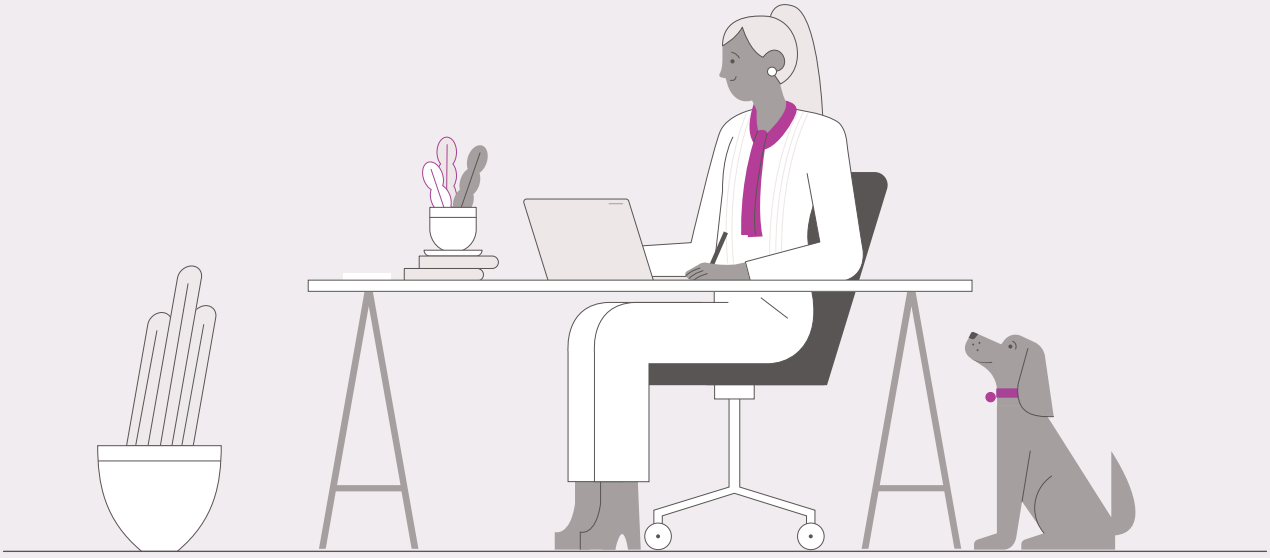
Write down any notes or additional questions you have about clinical studies. Please bring your questions to your next appointment with your healthcare team.

MY NOTES

Thank you for considering a clinical study

Want to learn more about clinical studies?

Study Connect is a starting point for patients that are considering taking part in clinical studies. The website has information about clinical studies for you, your loved ones, and your doctor. To learn more, please visit **www.bmsstudyconnect.com**



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