

## **EDUCATION MODULE**

# **Clinical Trials: What Women Need to Know**



Sponsored by Boston Scientific

To access the *Clinical Trials: What Women Need to Know* video online:

Downloadable link: <https://vimeo.com/248465382>

To watch online: <https://youtu.be/ZpES1-vkCKM>



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Clinical Trials: What Women Need to Know

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# AGENDA

## Clinical Trials: What Women Need to Know

### 1. Introduction and overview approximately 5 minutes

- ♥ Welcome participants to the support group session
- ♥ Introduce yourself and ask participants to introduce themselves
- ♥ If there are new members to the group, introduce them to WomenHeart
- ♥ Conduct basic “housekeeping”
  - ♥ Tell them the timeline for the meeting (educational presentation, Q&A, regular support meeting business)
  - ♥ Introduce the topic of today’s educational presentation: Clinical trials

### 2. Show video 5 minutes

To access the *Clinical Trials: What Women Need to Know* video online:

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### 3. Objective 1: Discuss the value of women’s participation in clinical trials 7 minutes

### 4. Objective 2: Describe your role in clinical trials 5 minutes

### 5. Ask participants if they have any questions or concerns. Give time to discuss.

Thank everyone for coming and announce time and place for future meetings.



# Clinical Trials: What Women Need to Know



## Purpose

This module is designed to provide an instructional framework for WomenHeart Support Network Coordinators to discuss the topic of clinical trials research with support network participants



## Time

25 minutes (This is an estimate of total time.) We encourage you to complete the module at your own pace.



## Preparation

Familiarize yourself with the subject matter by reviewing the entire module, including the video, informational handouts, and infographic cards before the meeting.

The information in this module is organized into two objectives and begins with the module **video**. Each objective has materials to deliver the educational content.

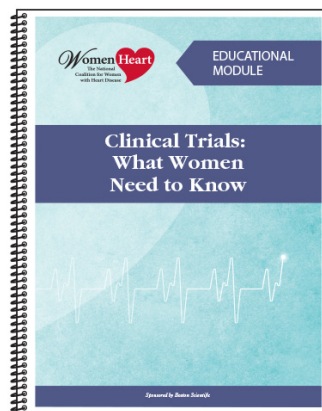
The module contains the video and the **handouts** for each attendee on the resource flash drive called *Clinical Trials: What Women Need to Know*. Please print copies of the handouts for each attendee.

To access the *Clinical Trials: What Women Need to Know* video online:

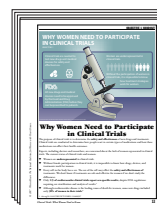
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## Module Contents



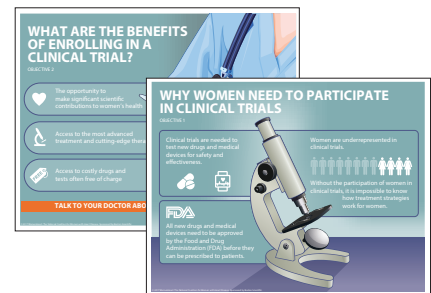
Module



Handouts



Flash drive with video and resources



Infographics





# Education Module

## Video Presentation



Time: 5 minutes

Materials: Flash drive — *Clinical Trials: What Women Need to Know*

To access the *Clinical Trials: What Women Need to Know* video online:

Downloadable link: <https://vimeo.com/248465382>

To watch online: <https://youtu.be/ZpES1-vkCKM>



### 1. Introduce the video

This patient education video features an interview with a *WomenHeart Champion* and a well-respected cardiologist who has authored hundreds of academic research studies and led many clinical trials. They share what women need to know about clinical trials and why clinical trials are important to advancing women's heart health.

### 2. Assign writing task

Ask attendees to write down at least two things they learned from the video.

### 3. Show and discuss the video

Gather any reactions.

Ask for volunteers to share at least one important thing they learned about clinical trials in women.

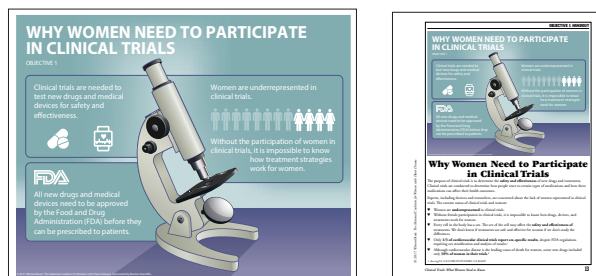




## Objective 1: Discuss the value of women's participation in clinical trials

Time: 7-10 minutes

### Materials



### 1. Discuss the meaning of medical research

Ask participants to explain what they know about medical research and clinical trials. Summarize the discussion and make sure the following points are clear:

- ♥ Medical research refers to studies conducted by professionals designed to test the efficacy of drugs, devices or treatments, provide information on health or disease, and to find new ways to treat or prevent disease.
- ♥ Without medical research, the safety or effectiveness of new drugs, vaccines, or medical devices could not be scientifically demonstrated.

### 2. Why and how is medical research done?

Pass out the **Why Women Need to Participate in Clinical Trials** handout and display the infographic. Explain that medical research helps save lives by identifying cures for diseases, as well as improving and developing treatments to relieve symptoms. The federal government has a responsibility to assure safety and effectiveness of new drugs and treatments:

- ♥ All new drugs, vaccines, or medical devices need to be approved by the Food and Drug Administration (FDA) before they can be prescribed to patients.
- ♥ The FDA requires data to demonstrate safety and effectiveness of the product.

Medical research is conducted in many different ways. All of these methods are carefully scrutinized to assure the safety of participants. Methods include:

- ♥ Survey or questionnaires
- ♥ Experiments in laboratories using tissues, cells, or animals
- ♥ Clinical trials with human participants

Clinical trials with human participants are conducted after promising experiments in laboratories with animals. The clinical trial results are analyzed to determine the effectiveness in human patients.

### 3. Discuss the representation of women in clinical trials

- ♥ In 1993, the NIH Revitalization Act was passed which required inclusion of women and minorities as subjects in each clinical research project funded by NIH. Prior to this, women were excluded from clinical trials. Now that they are involved, there are still concerns that they are underrepresented.

The current status of clinical trials and women:

- ♥ Women **representation** in clinical trials does not reflect the disease prevalence in women.
- ♥ Without female participation in clinical trials, it is impossible to know how treatment strategies work for women.
- ♥ Every cell in the body has a sex. The sex of the cell may affect the **safety and effectiveness** of treatments. We don't know which treatments are safe and effective for women if we don't study the differences.

Differences between men and women are observed for a number of diseases including cardiovascular disease. These sex differences need to be studied and reported in the data analysis of medical research.

However:

- ♥ Only **1/3 of cardiovascular clinical trials report sex-specific results**, despite FDA regulations requiring sex stratification and analysis of results.<sup>1</sup>
- ♥ Although cardiovascular disease is the leading cause of death in women, some new drugs included **30% or less women in their trials**.<sup>1</sup>

1. [doi.org/10.1161/CIRCOUTCOMES.110.868307](https://doi.org/10.1161/CIRCOUTCOMES.110.868307)

# WHY WOMEN NEED TO PARTICIPATE IN CLINICAL TRIALS

## OBJECTIVE 1

Clinical trials are needed to test new drugs and medical devices for safety and effectiveness.

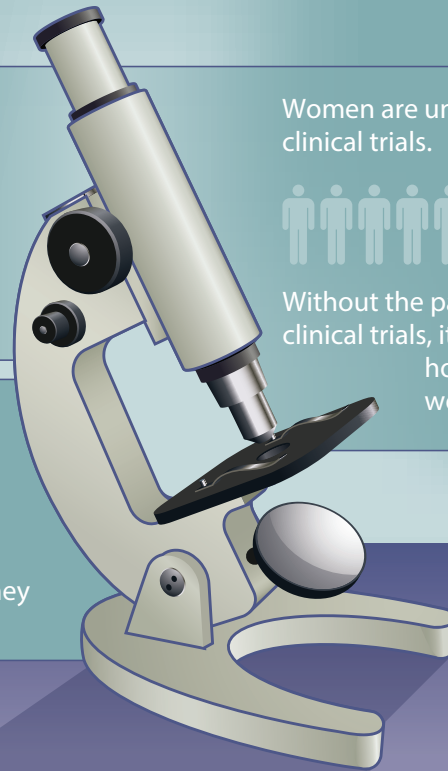


All new drugs and medical devices need to be approved by the Food and Drug Administration (FDA) before they can be prescribed to patients.

Women are underrepresented in clinical trials.



Without the participation of women in clinical trials, it is impossible to know how treatment strategies work for women.



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## Why Women Need to Participate in Clinical Trials

The purpose of clinical trials is to determine the **safety and effectiveness** of new drugs and treatments. Clinical trials are conducted to determine how people react to certain types of medications and how these medications can affect their health outcomes.

Experts, including doctors and researchers, are concerned about the lack of women represented in clinical trials. The current status of clinical trials and women:

- ♥ Women are **underrepresented** in clinical trials.
- ♥ Without female participation in clinical trials, it is impossible to know how drugs, devices, and treatments work for women.
- ♥ Every cell in the body has a sex. The sex of the cell may affect the **safety and effectiveness** of treatments. We don't know if treatments are safe and effective for women if we don't study the differences.
- ♥ Only **1/3 of cardiovascular clinical trials report sex-specific results**, despite FDA regulations requiring sex stratification and analysis of results.<sup>1</sup>
- ♥ Although cardiovascular disease is the leading cause of death for women, some new drugs included only **30% of women in their trials**.<sup>1</sup>

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## Objective 2: Describe your role in clinical trials

Time: 5-7 minutes

### Materials



### 1. Explain clinical trials

Clinical trials are one of the best ways to determine how to treat diseases and often lead to critical advances in medical therapy.

Clinical trials are essential in order to determine if a new treatment is **safe and effective** for certain illnesses and groups of people. It is important for women like you to participate in medical research, which can include surveys and clinical trials, in order for scientists to reach accurate conclusions regarding both the risks and benefits of drugs, devices, and therapies.

Ask if anyone has been involved in a clinical trial and would like to share. Do not pressure anyone to share.

### 2. Discuss benefits and barriers to participating in a clinical trial

Pass out the handout **What Are the Benefits of Enrolling in a Clinical Trial?** and display the infographic. Explain that this medical research depends on the willingness of volunteers to take part in clinical trials, which can test new ways to prevent, diagnose, or treat various diseases and conditions.

By participating in a clinical trial, you can gain access to new treatments before they're widely available and usually at no cost. With most clinical trials, participants have the support of a team of health care providers who closely monitor their health. And, even if you don't directly benefit from the results of a clinical trial, the information gathered can help other women and add to scientific knowledge.

#### Benefits to joining clinical trials:

- ♥ Participants have the opportunity to make significant contributions to the science of women's health
- ♥ Participants have access to the most advanced treatment and cutting-edge therapies
- ♥ Participants have access to costly drugs and tests often free of charge

#### Possible barriers to joining clinical trials:

- ♥ Lack of awareness regarding clinical trial availability
- ♥ Lack of information about appropriate trials

- ♥ Uncertainty about the risks and benefits of each specific trial
- ♥ Logistical difficulties regarding time/place/convenience
- ♥ Misconceptions and fear about what a clinical trial entails

Ask participants to think about reasons to get involved in a clinical trial. Ask, “Why might you want to enroll?”

Then ask for volunteers to provide suggestions. Reasons may include:

- ♥ To improve my own health
- ♥ To advance the evidence base for the care and treatment of women with heart disease

### **3. Discuss how to enroll in a clinical trial**

Explain that there is a great deal of information about clinical trials online. They can read about different types of studies from credible sources such as government and research hospitals websites and the WomenHeart website: [www.womenheart.org](http://www.womenheart.org)

The most comprehensive site for patients and families is [www.clinicaltrials.gov](http://www.clinicaltrials.gov). It provides current information about clinical research studies to patients, their families and caregivers, health care professionals, and the public. Information on [clinicaltrials.gov](http://clinicaltrials.gov) is provided and updated by the sponsor or principal investigator of the clinical study. [Clinicaltrials.gov](http://clinicaltrials.gov) is a free service of the National Institutes of Health (NIH) and is maintained by the National Library of Medicine (NLM).

How do you enroll?

- ♥ Talk to your doctor about available clinical trials
- ♥ Find out the risks and benefits of a particular trial
- ♥ Volunteer for a study if you meet the inclusion criteria

Find more information at: [clinicaltrials.gov](http://clinicaltrials.gov)



# WHAT ARE THE BENEFITS OF ENROLLING IN A CLINICAL TRIAL?

OBJECTIVE 2



The opportunity to make significant scientific contributions to women's health



Access to the most advanced treatment and cutting-edge therapies



Access to costly drugs and tests often free of charge

**TALK TO YOUR DOCTOR ABOUT ENROLLING IN A CLINICAL TRIAL.**

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## What Are the Benefits of Enrolling in a Clinical Trial?

Clinical trials are essential in order to determine if a new drug, device or other therapy is **safe and effective** for treating cardiovascular disease. It is particularly important for women to become a part of a clinical trial to gather data specifically about women.

### What are the benefits of enrolling in a clinical trial?

- ♥ Participants have the opportunity to make significant contributions to the science of women's health
- ♥ Participants have access to the most advanced treatment and cutting-edge therapies
- ♥ Participants have access to costly drugs and tests often free of charge

### Where do I get information about clinical trials?

The most comprehensive site for patients and families is [clinicaltrials.gov](http://clinicaltrials.gov). It provides current information about clinical research studies to patients, their families and caregivers, health care professionals, and the public. [Clinicaltrials.gov](http://Clinicaltrials.gov) is a free service of the National Institutes of Health (NIH) and is maintained by the National Library of Medicine (NLM). You can also visit [www.womenheart.org](http://www.womenheart.org) to learn more and view the *Clinical Trials: What Women Need to Know* video.

**Talk to your doctor about enrolling in a clinical trial.**

