
There is no Participant Guide page for this slide.

Welcome participants to the course. Tell participants to sit down anywhere they will be comfortable. Thank participants for coming to the workshop, if appropriate. Remind participants that the course will be more interesting and fun if they ask questions and share their experiences.

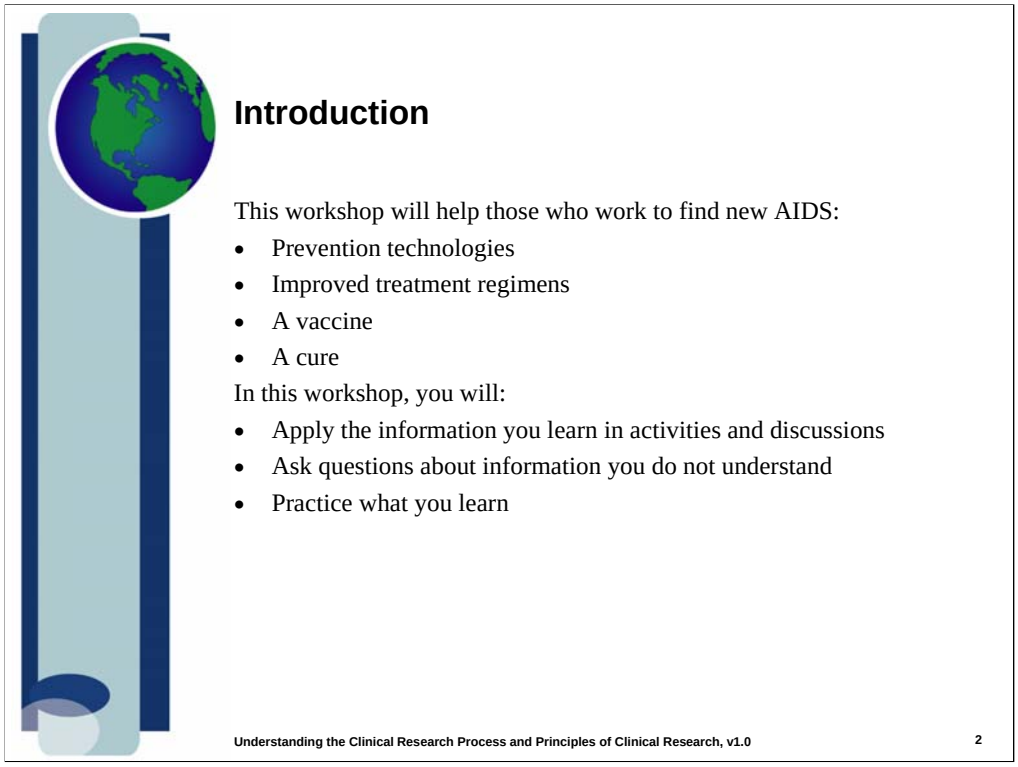
Tell participants to write their names on the Participant Guides. These Participant Guides are for them to keep and write notes in.

Explain that the Participant Guide contains a lot of information. Go through the Table of Contents to show participants what the course is about. Then show participants the Glossary at the end of the Participant Guide.

After everyone is settled, introduce a whole group activity (approximately 5 minutes): Introductions. Go around the room and ask each person to stand up and state his/her name, what they do, and why he/she is taking this workshop. Begin the introductions to provide an example. Feel free to use your own introductions activity ("ice breaker"), if desired.

This module will last approximately 50 minutes.

*This project has been funded in whole with a grant from the United States Government Department of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases (UO1 AIO68614).*




Participant Guide, page 1

The Introduction should take approximately 50 minutes.

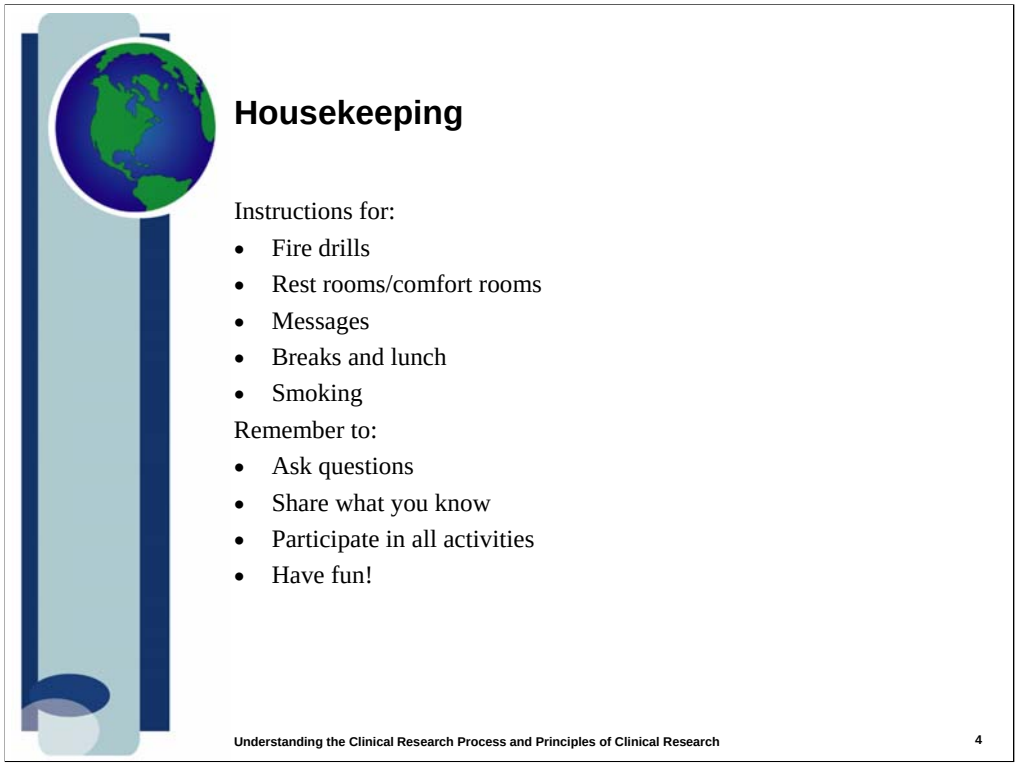
Review the content in the Participant Guide.

Tell participants they will see a lot of abbreviations in this course. The first time an abbreviation is used, there will be an explanation of what it stands for. The abbreviations are also included in the Glossary.


There is no Participant Guide page for this slide.

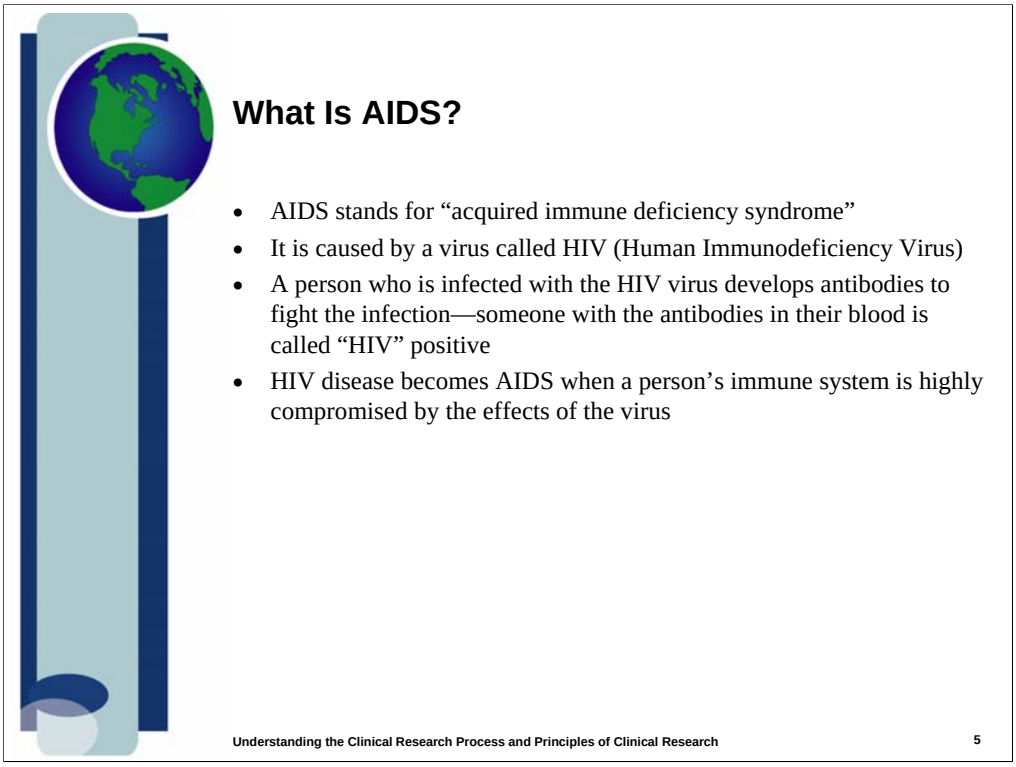
Review the agenda for the workshop. Be prepared to change this slide if the workshop is given with a different time structure.

Review the logistics of breaks and lunch, depending on the location.




There is no Participant Guide page for this slide.

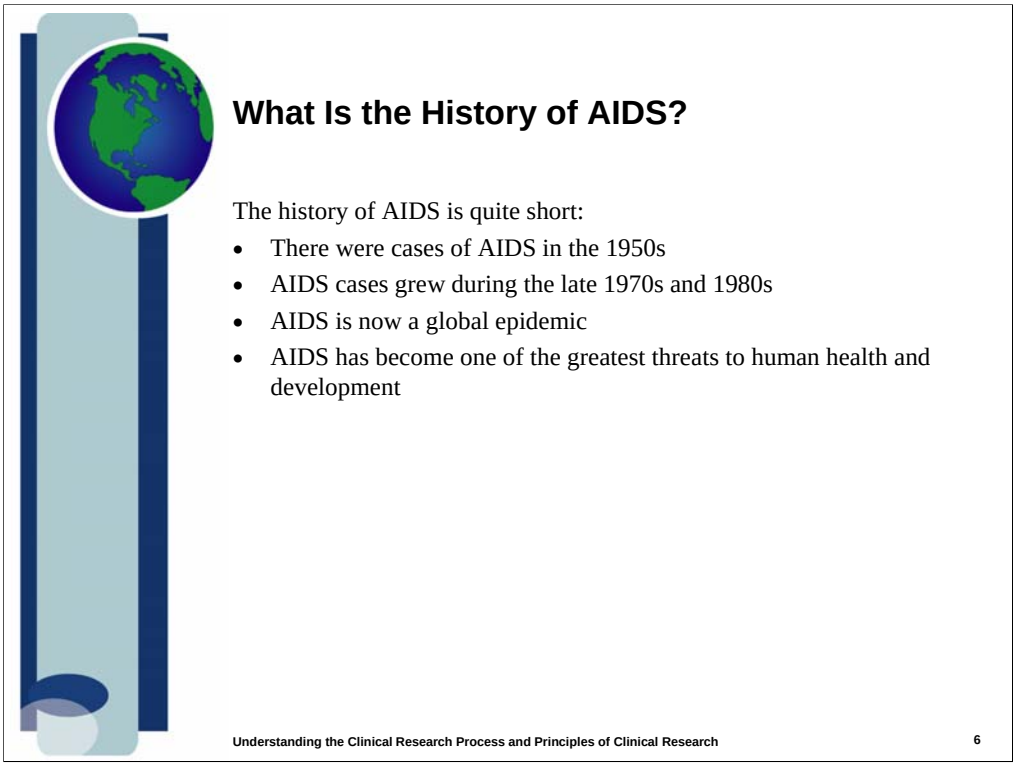
Review housekeeping for the workshop. Be prepared to change this slide if the workshop location has specific housekeeping issues.




Participant Guide, page 1

Review the content in the Participant Guide and on the slide.

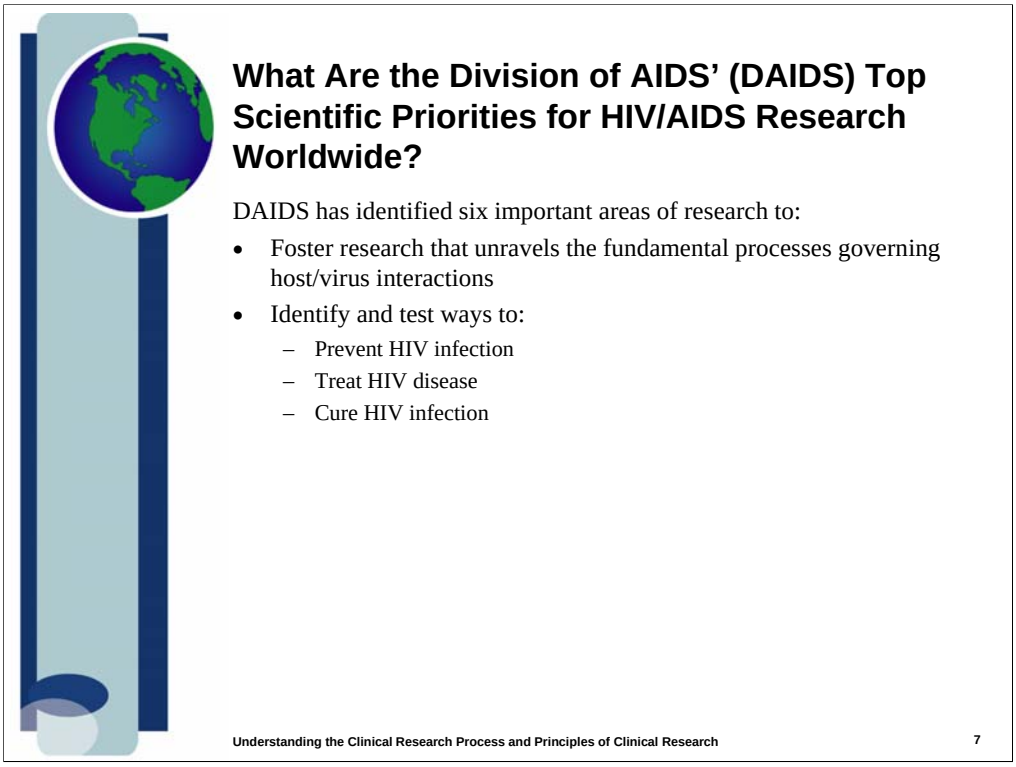
Allow for questions and discussion.




Participant Guide, page 2

Review the content in the Participant Guide and on the slide.

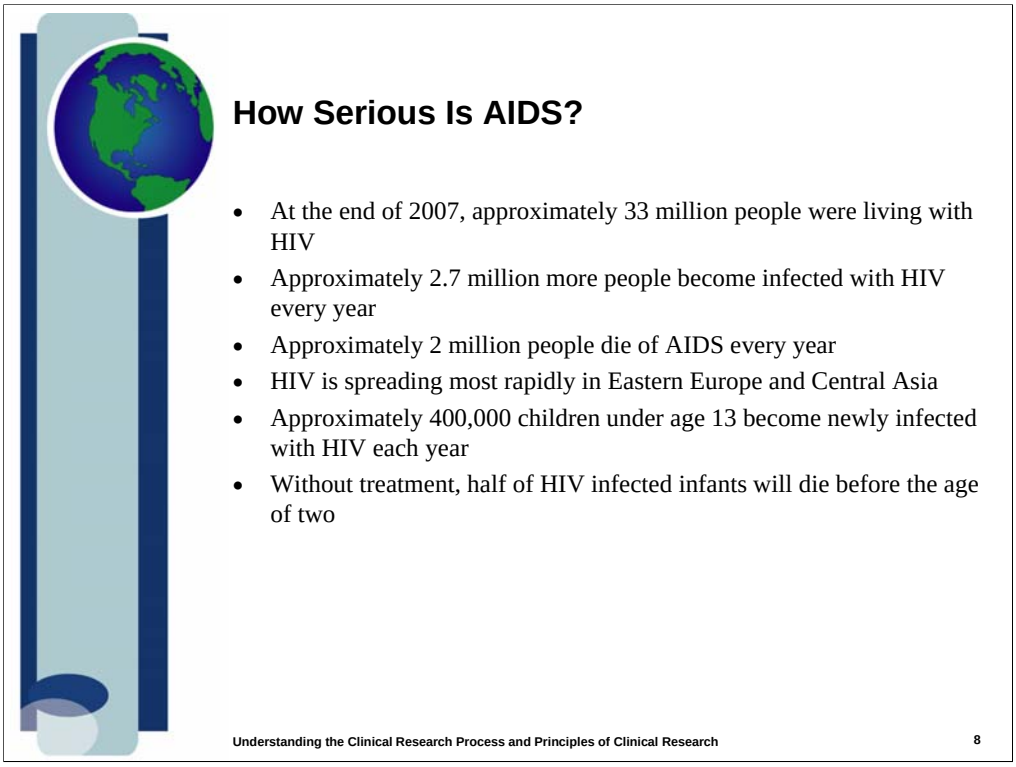
Allow for questions and discussion.



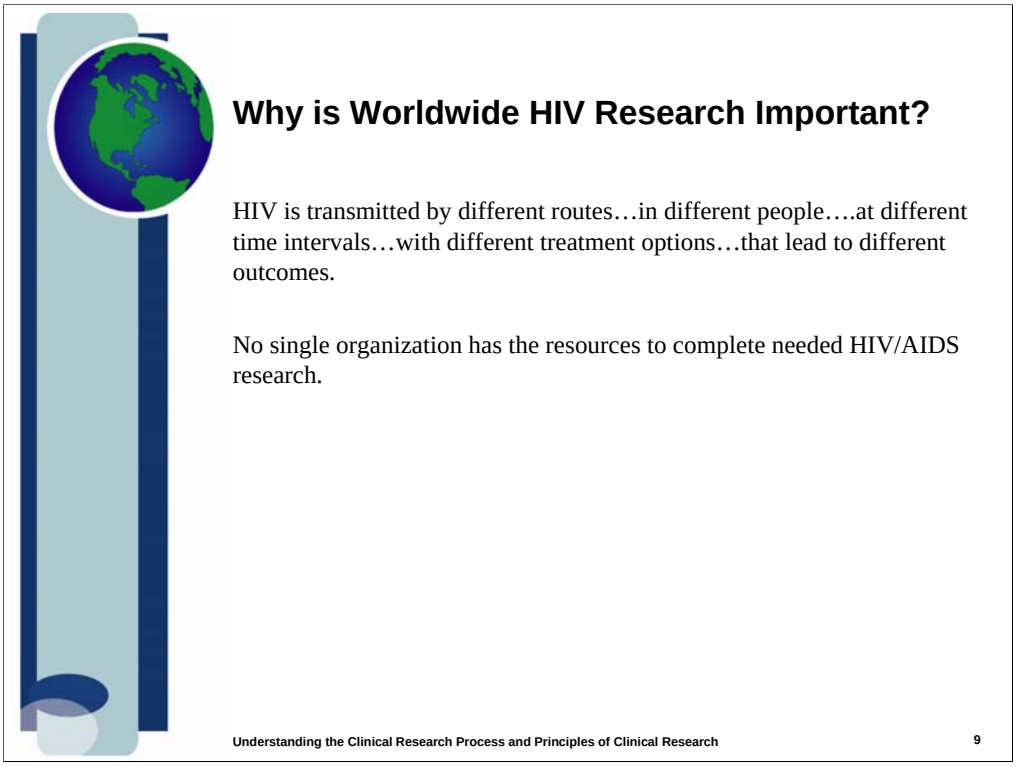

Participant Guide, page 2

Review the content in the Participant Guide and on the slide.

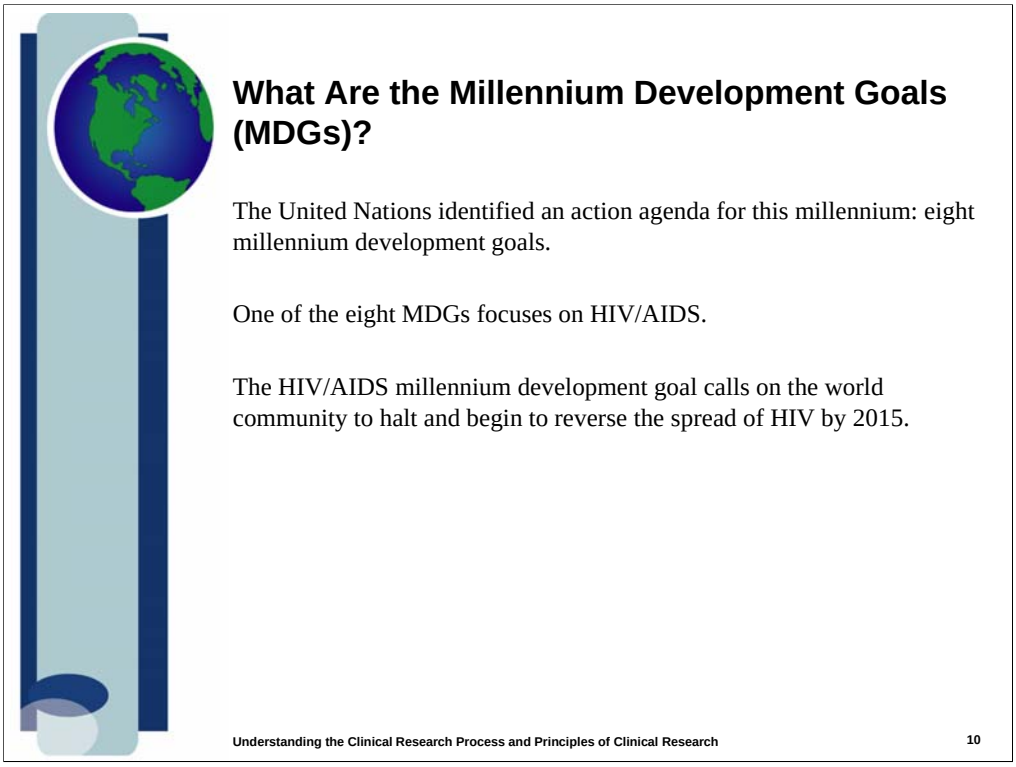
Depending on the experience level of participants, review the content in the table.



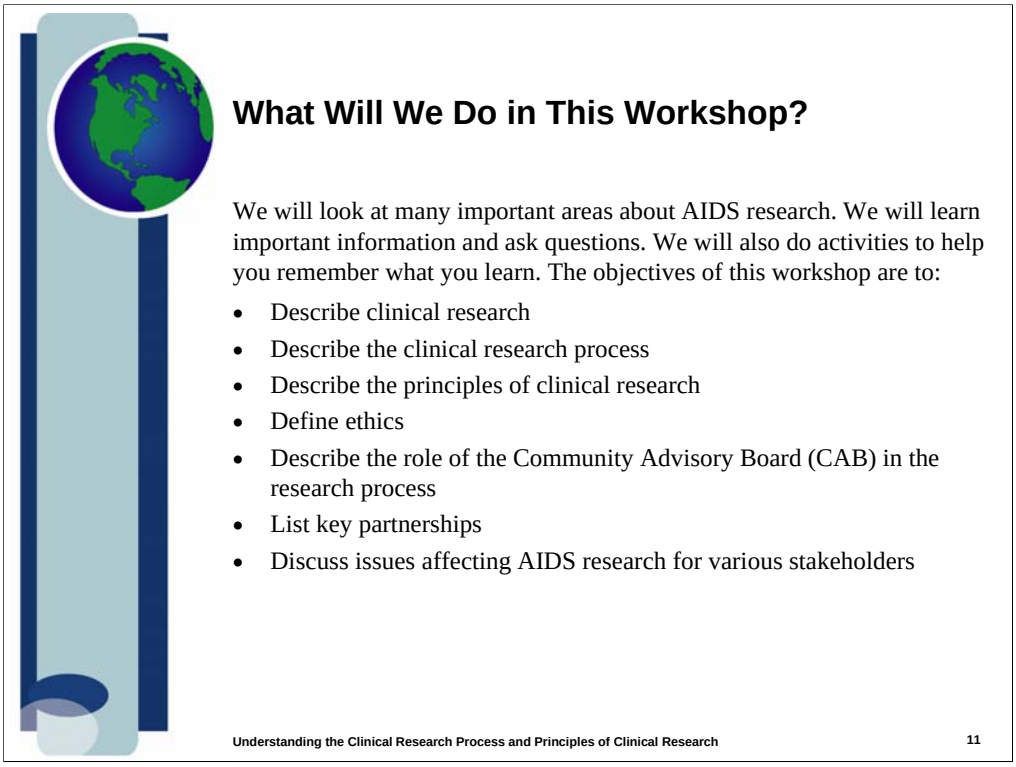

Participant Guide, page 3



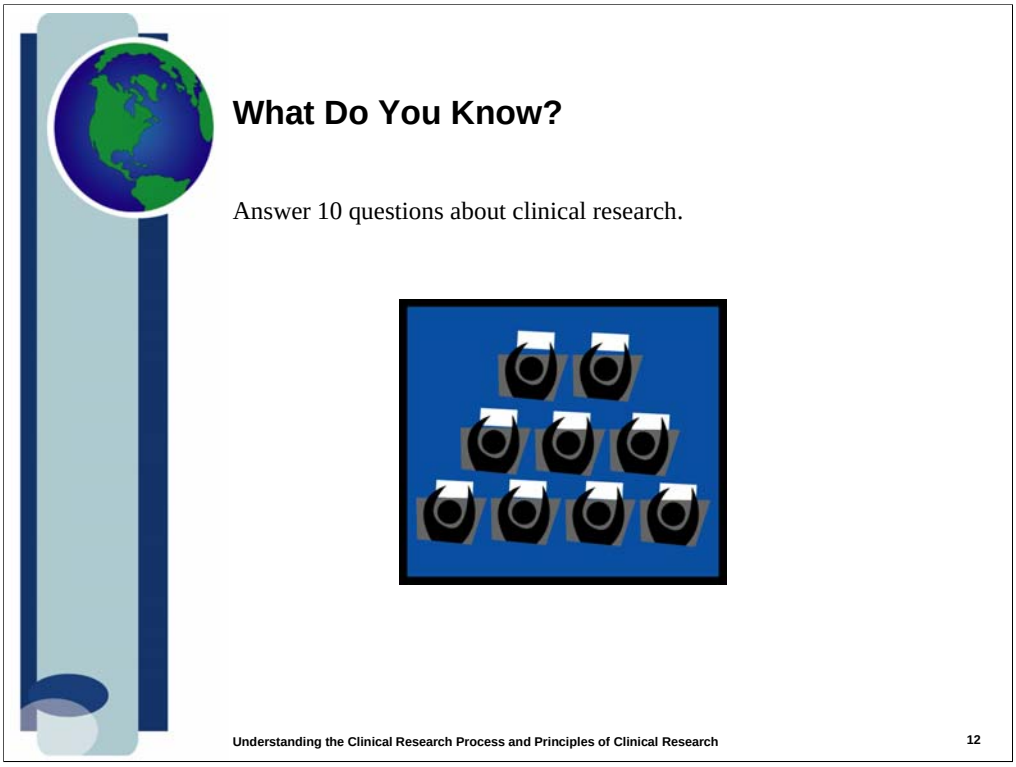

Participant Guide, page 4




Participant Guide, page 4




Participant Guide, page 5




There is no Participant Guide page for this slide.

This activity functions as a pre-test to find out how much participants already know about the information presented in this workshop.

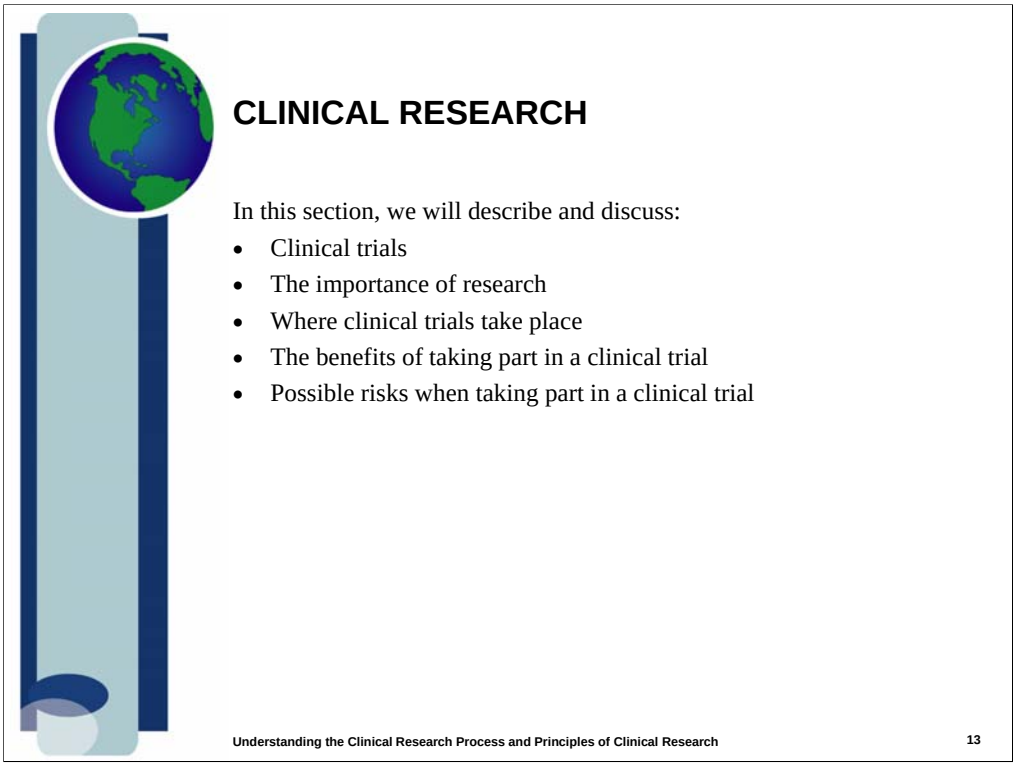
Avoid mentioning the word “test” so participants do not become stressed. This activity should be a low-key method of getting to know the participants, what each is capable of, and find out how much they know in a non-threatening way.

See the Instructor Guide for various options to deliver this activity. It can be delivered by using a handout or reading aloud the questions and asking for participant’s to provide the answers.

As specific questions are covered in the workshop materials, there will be a reminder inserted in these notes to remind participants of the questions and answers. This technique helps participants remember answers for the post-test at the end of the workshop.

Answers to the questions are:

1a, 2a, 3c, 4b, 5g, 6a, 7a, 8a, 9e, 10c



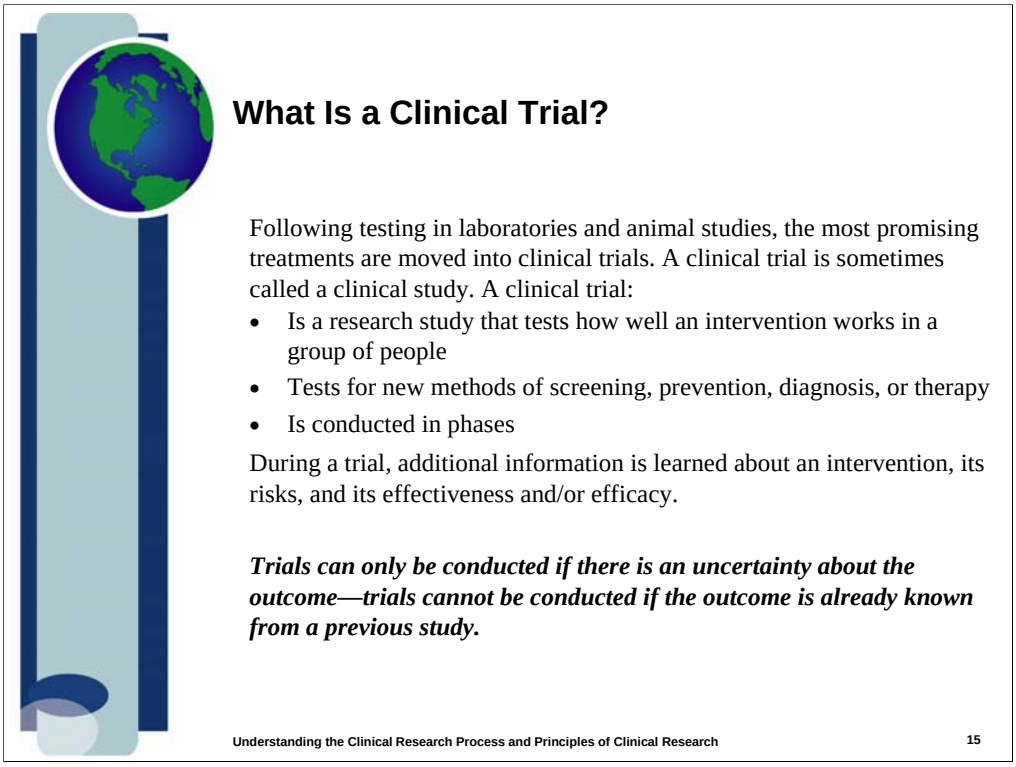

Participant Guide, page 6

This module will last approximately 50 minutes.


Participant Guide, page 6

Note: Depending on the level of knowledge of the workshop participants, a discussion of cohort studies (as prospective clinical trials) vs. clinical trials can be discussed.

Allow for questions and discussion.




Participant Guide, page 6

Note: Emphasize the text in italic on the slide: "…trials cannot be conducted if the outcome is already known from a previous study."

Allow for questions and discussion.


Participant Guide, page 7

Allow for questions and discussion.


There is no Participant Guide page for this slide.

See the instructions in the Instructor's Guide for leading whole group discussions.

Read the first question on the slide. Allow time for participants to think about some examples.

Because this is the first discussion in the workshop, participants may be reluctant to speak up for fear of saying the wrong thing. Be prepared to provide an answer to the first question yourself.

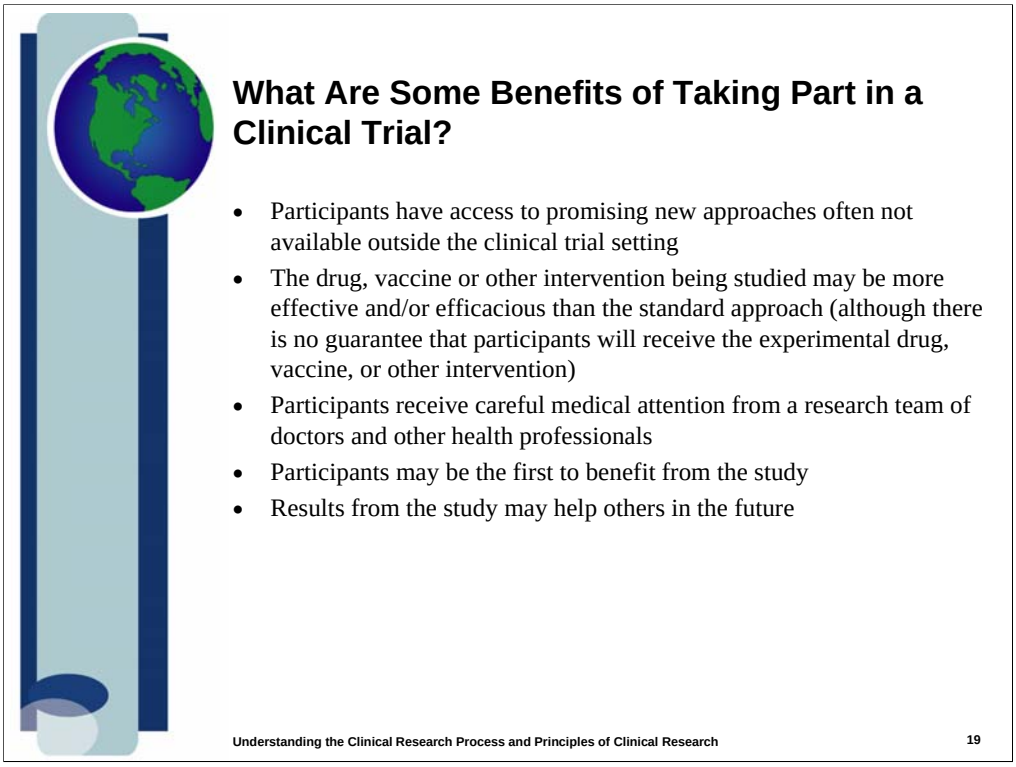
Possible answers for these questions:

1. Medical approach: vaccine
2. Behavioral approach: education program with adolescents to use condoms during intercourse
3. Management approach: population-based surveillance of HIV-related risk behaviors


Participant Guide, page 7

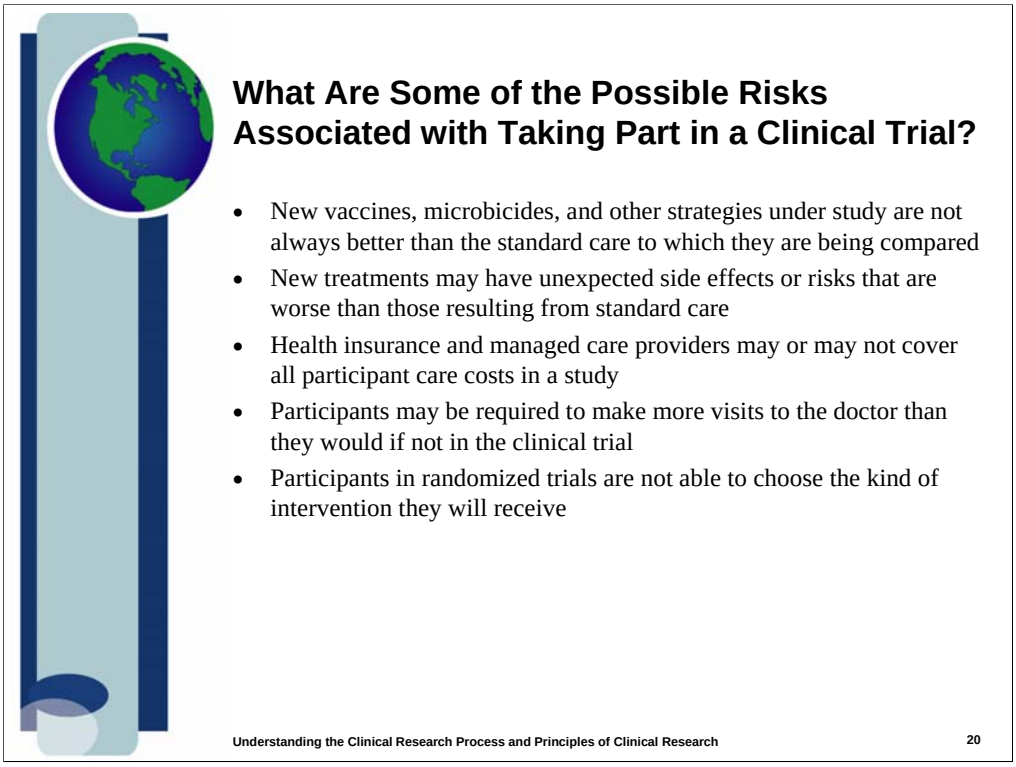
Be sure to discuss the Good Clinical Practice (GCP) stand and the good clinical laboratory practice standards. Emphasize the importance of the same, thorough requirements throughout the world. These standards and guidelines protect people.

Allow for questions and discussion.



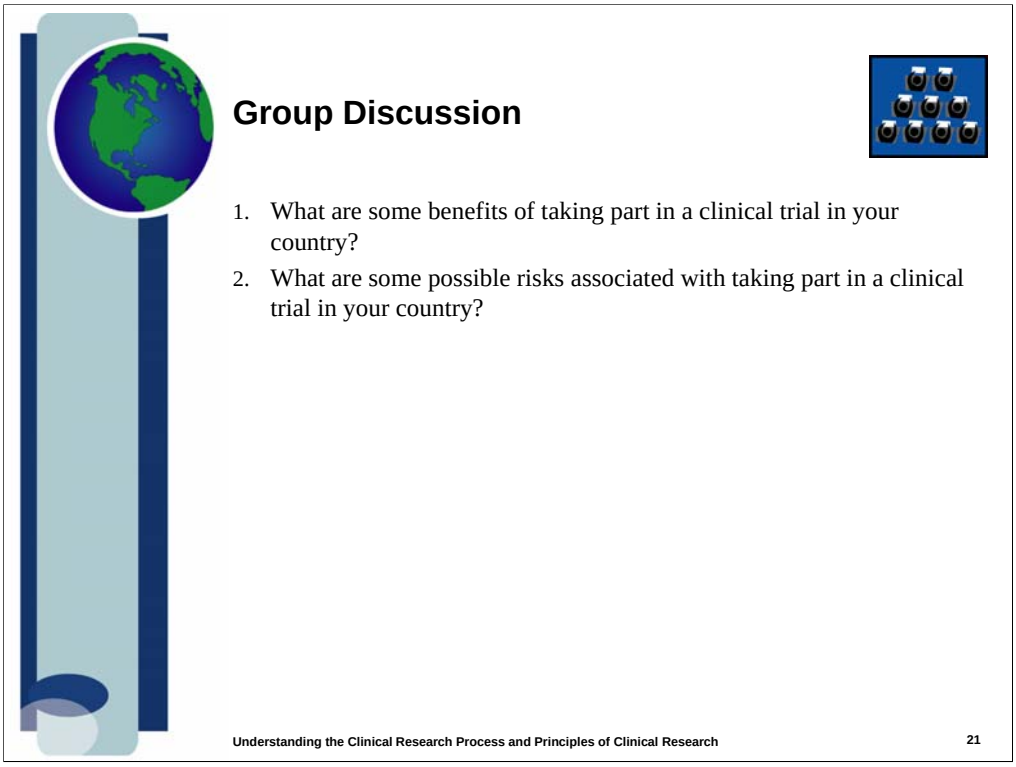

Participant Guide, page 8

Allow for questions and discussion.




Participant Guide, page 8

Allow for questions and discussion.




There is no Participant Guide page for this slide.

Please review the section of the Instructor's Guide about leading "Small Group Activities."

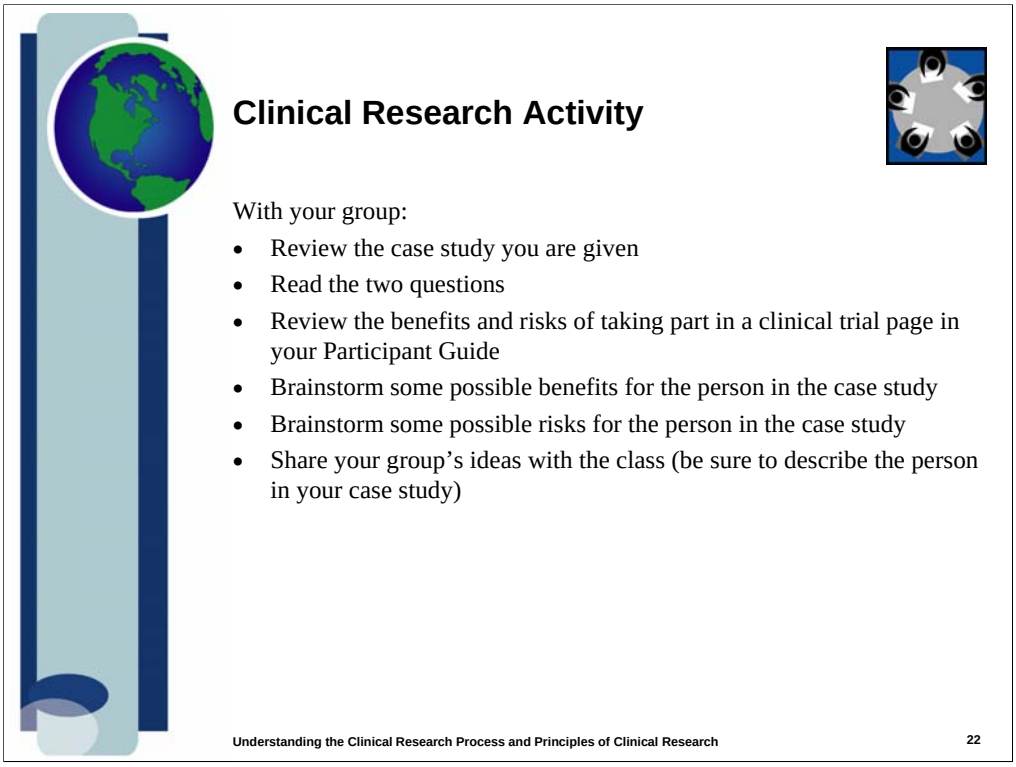
Answers to these questions will vary considerably among different locations. For these questions, look for location-specific answers.

If possible, research the activities in the location where this workshop is being delivered to have some answers available.

Provide an example, if necessary, to get participants started. Examples for the questions are:

1.A 25-year-old University of Botswana student, is participating with BOTUSA in the TDF2 Trial. Benefits for him are free medications, a free check-up, health advice from a doctor once a month, and free transportation to his appointments.

2.Possible side effects of experimental vaccines could include fever, chills, rash, aches and pains, nausea, headache, dizziness, and fatigue. Injections can cause pain, soreness, redness, and swelling on the part of the body where the vaccine shot is given.




There is no Participant Guide page for this slide.

Please review the section of the Instructor's Guide about leading "Small Group Activities."

Distribute the case study handouts for this activity: Clinical Research Activity. Each person in a group should receive a copy. Remember that there are four different case studies.

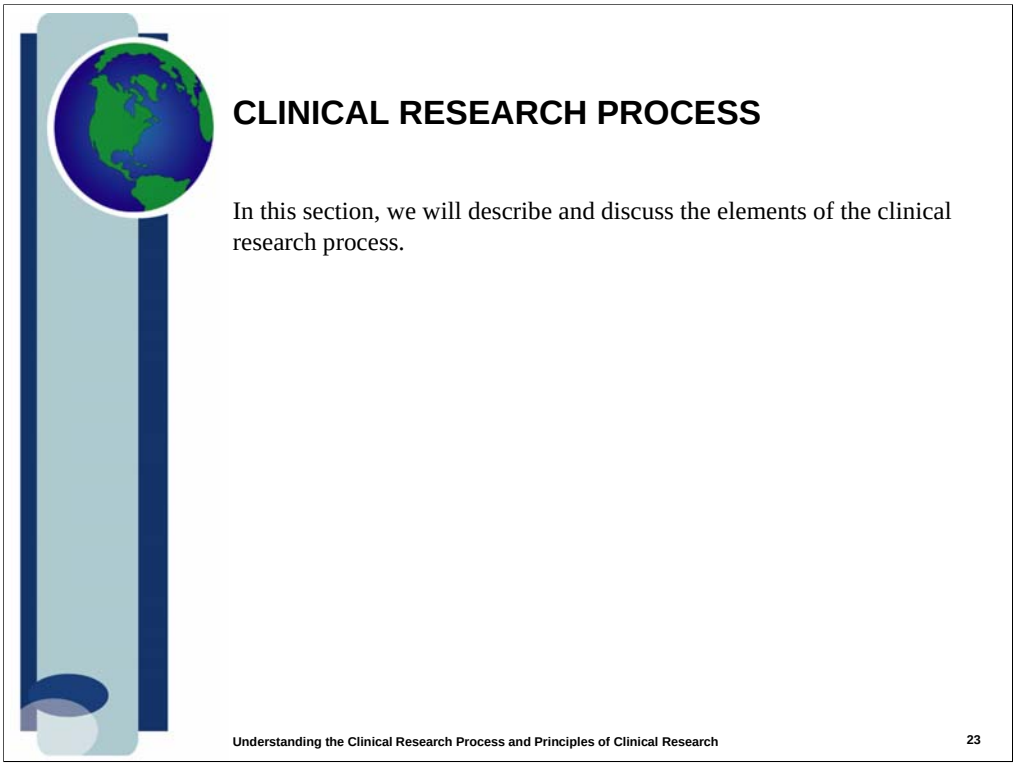
Note: Most small groups will have similar answers for this activity. The main purpose of the activity is to build confidence to work together and share experiences. Be prepared to offer specific examples and ask open questions to encourage independent thinking.

Before going to the next section of this workshop, stop to:

-Review what was learned in this section (there is no PowerPoint slide for this review)

-Ask for questions and allow for questions

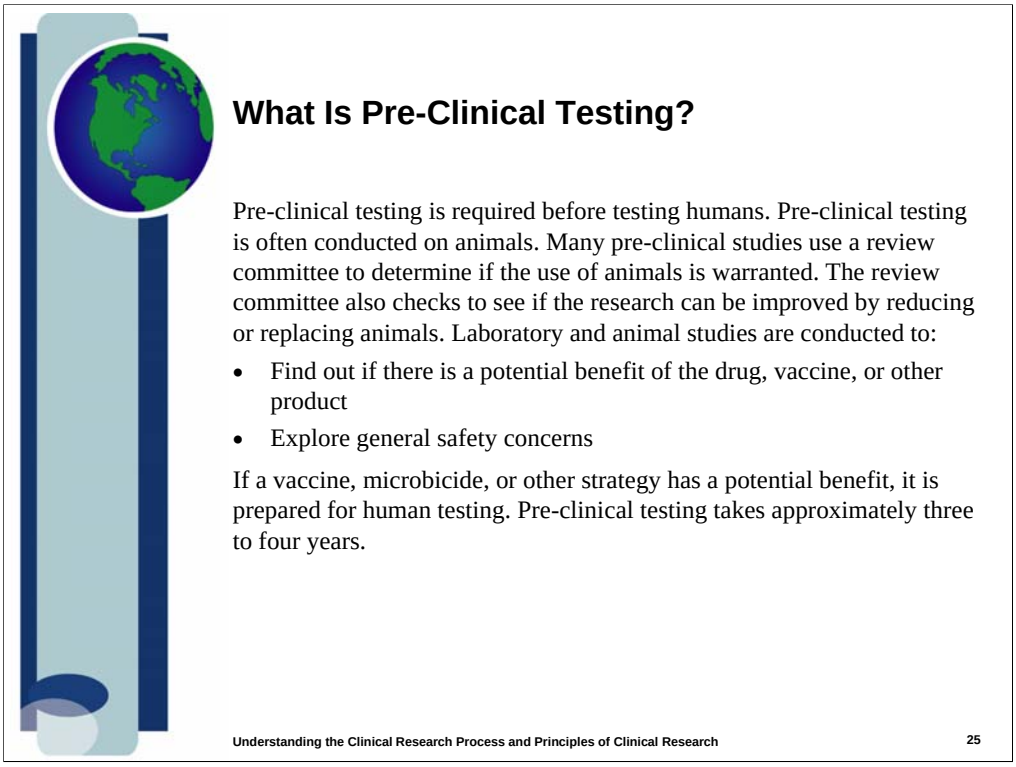
-Write any "parking lot" issues or information you need to come back to on a blank flip chart (a parking lot is where we capture all questions we may not necessarily have an answer during the workshop. Write these questions on a flip chart and follow up with the participants. Parking lot items are also good reminders for instructors to consider including in future workshops.




Participant Guide, page 9

This module will last approximately 65 minutes.


Participant Guide, page 9

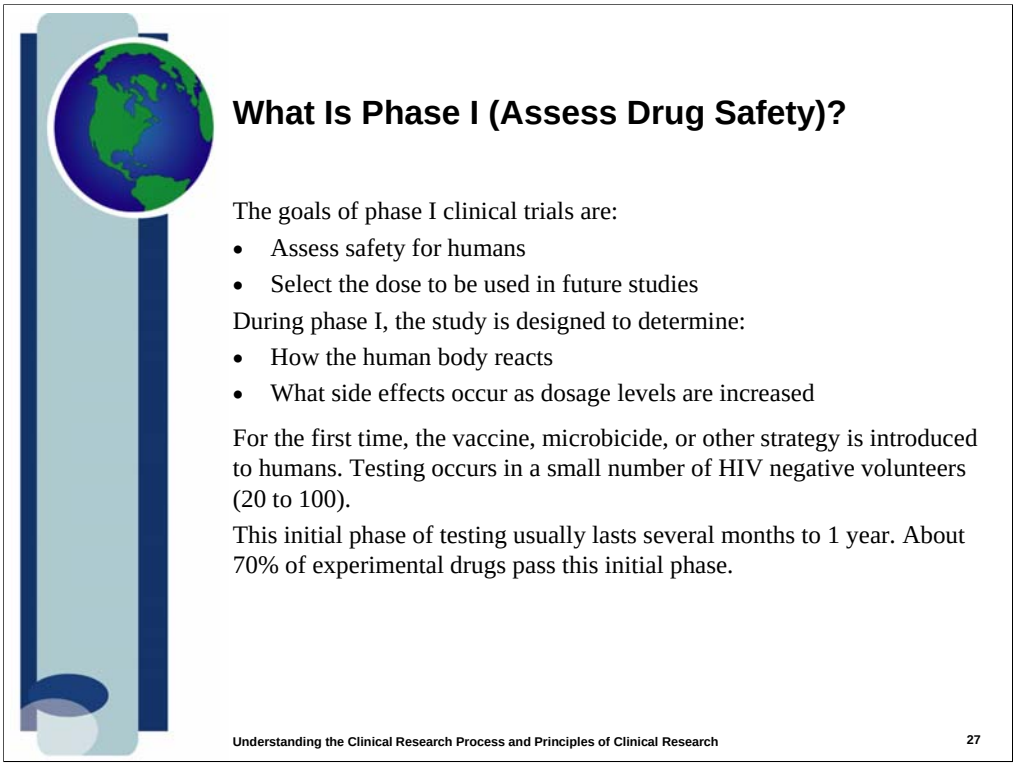



Participant Guide, page 9

Allow for questions and discussion.

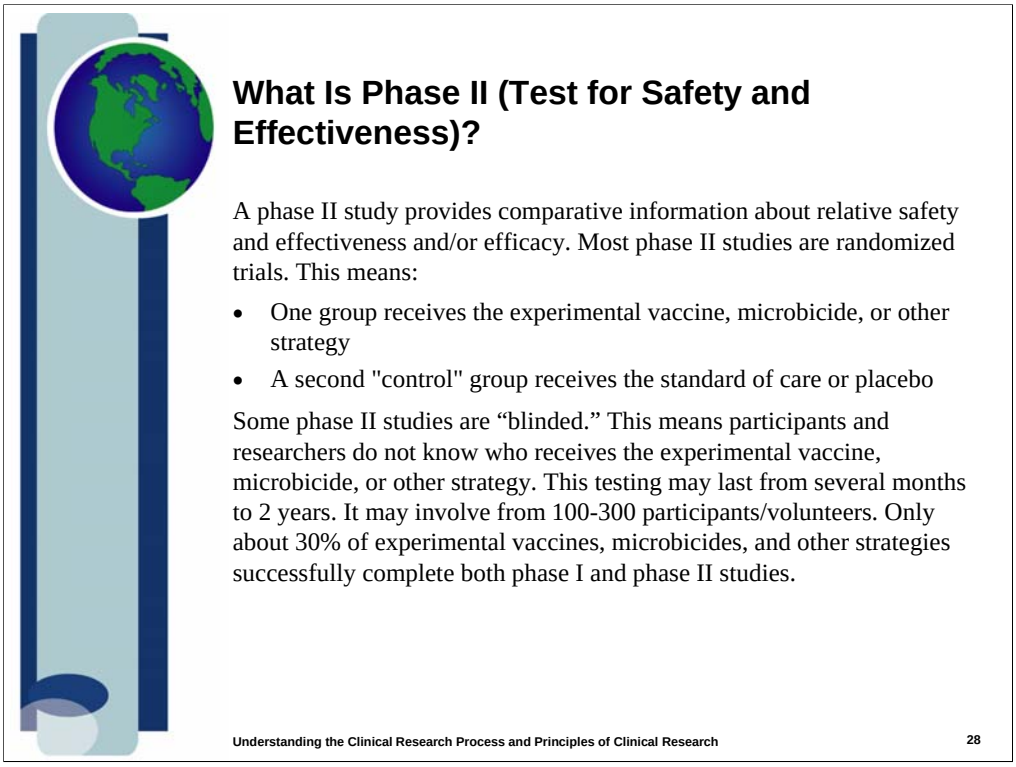

Participant Guide, page 10

Allow for questions and discussion.



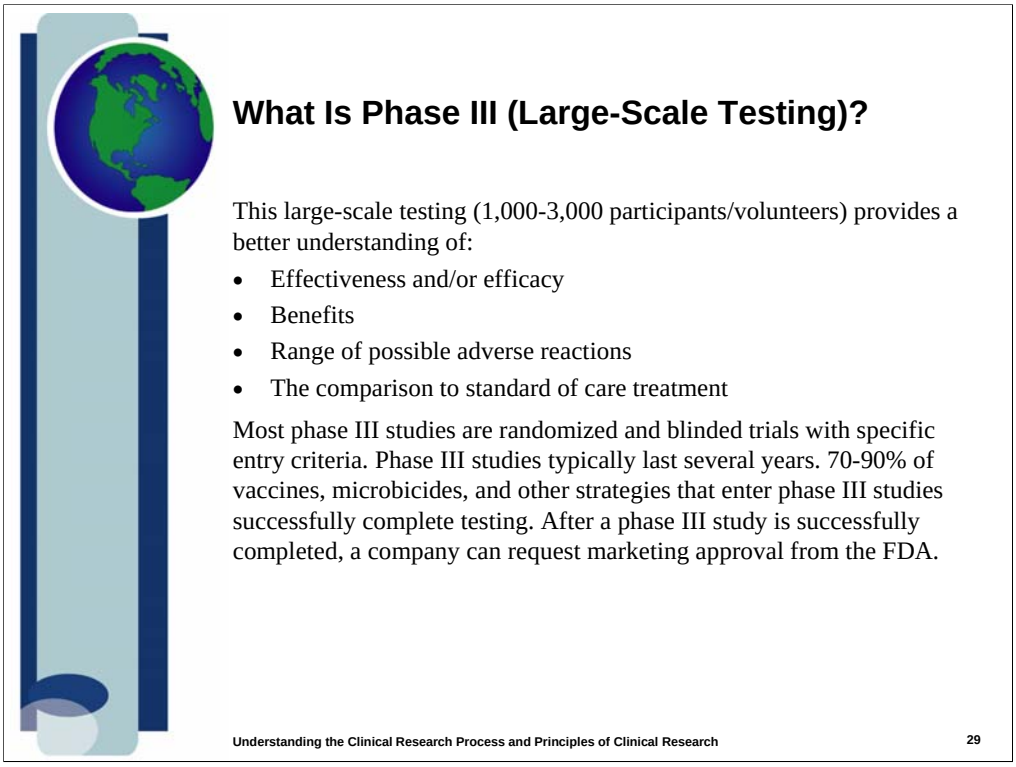

Participant Guide, page 10

Allow for questions and discussion.



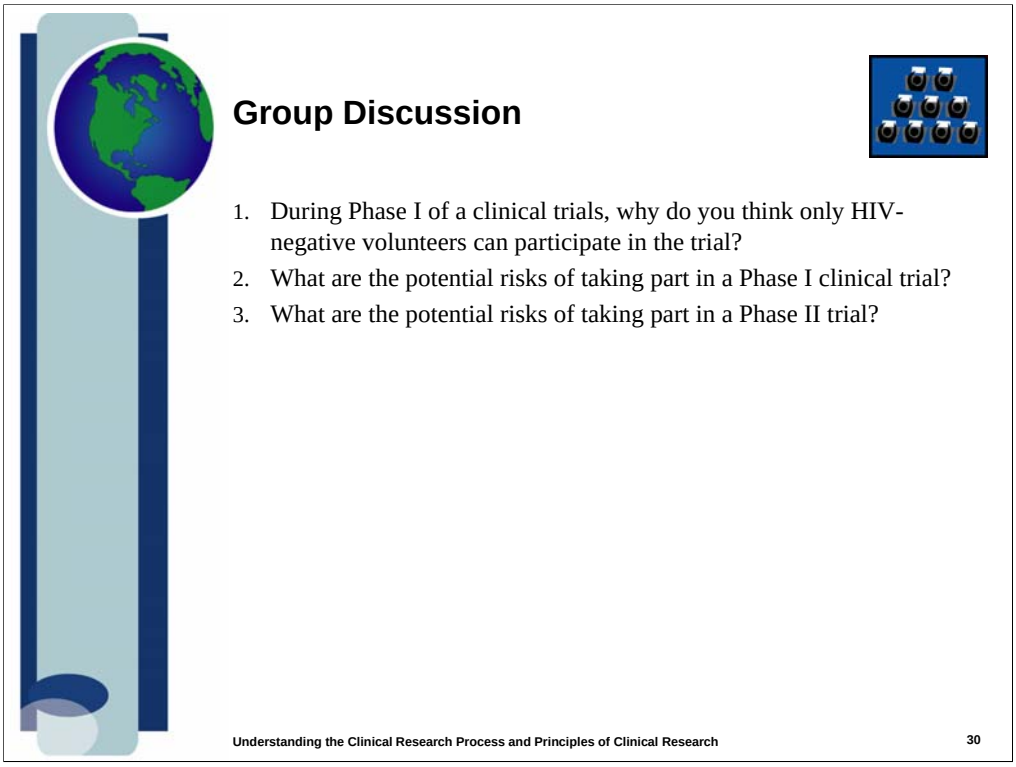

Participant Guide, page 11

Allow for questions and discussion.




Participant Guide, page 11

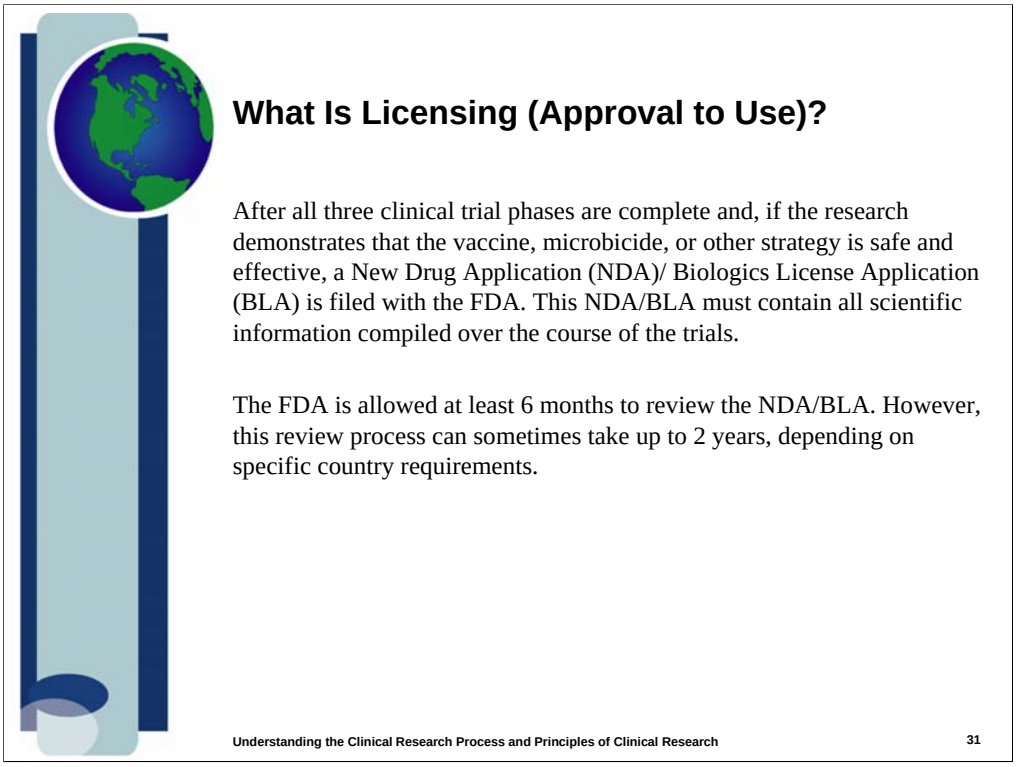
Allow for questions and discussion.




There is no Participant Guide page for this slide.

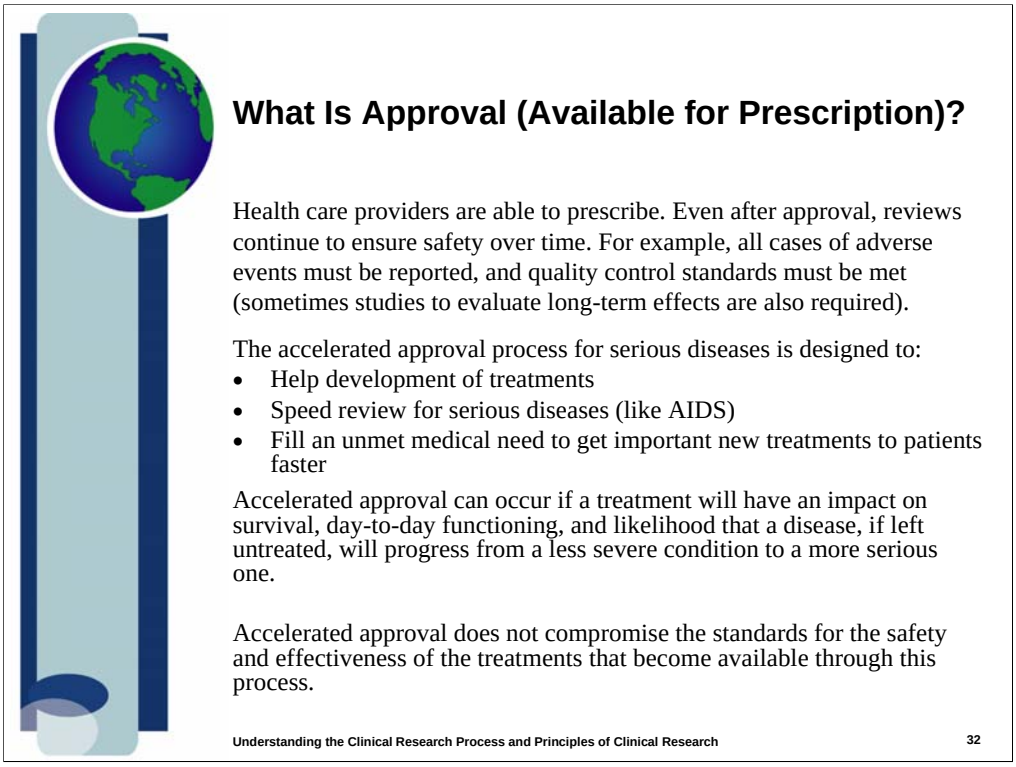
Possible answers for these questions:

1. HIV-negative participants provide a more-accurate picture of how safe the vaccine, microbicide, or other strategy is and what side effects occur at specific dosage levels.
2. Some risks might be: 1) the severity of the side effects that might occur; 2) the potential for a participant to become HIV-positive during the trial (not as a result of the trial/treatment), which may impact responses to the dosage/treatment.
3. One important risk might be that the control group receiving the placebo may delay treatment options, if needed.




Participant Guide, page 11

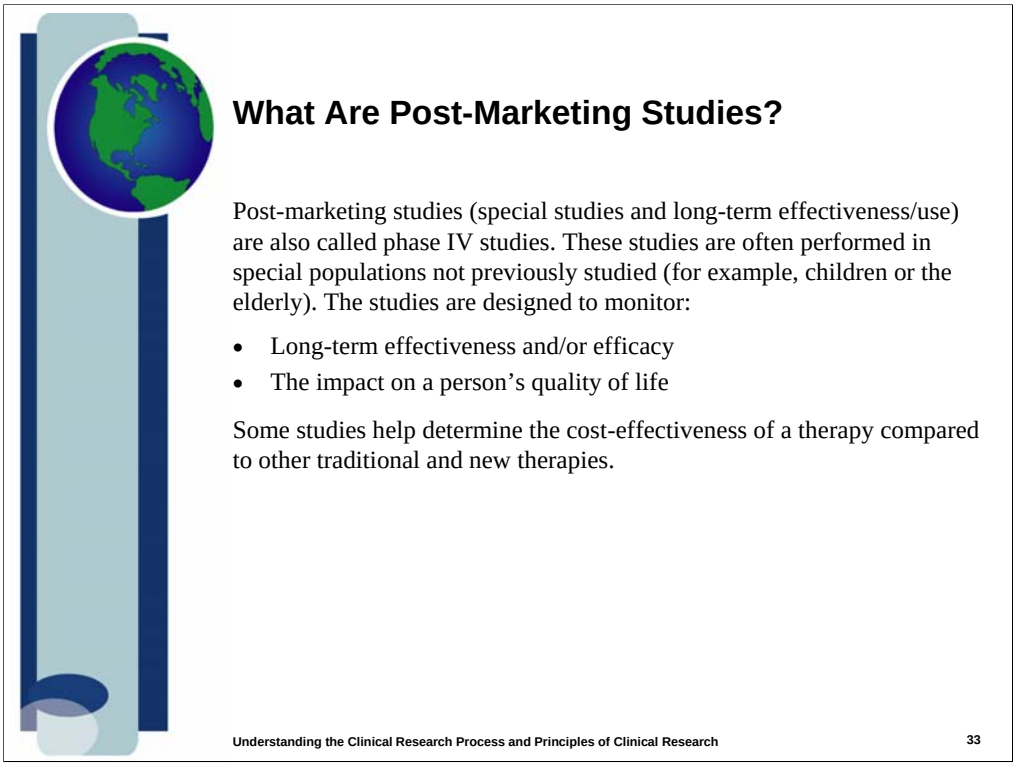
Allow for questions and discussion.




Participant Guide, page 12

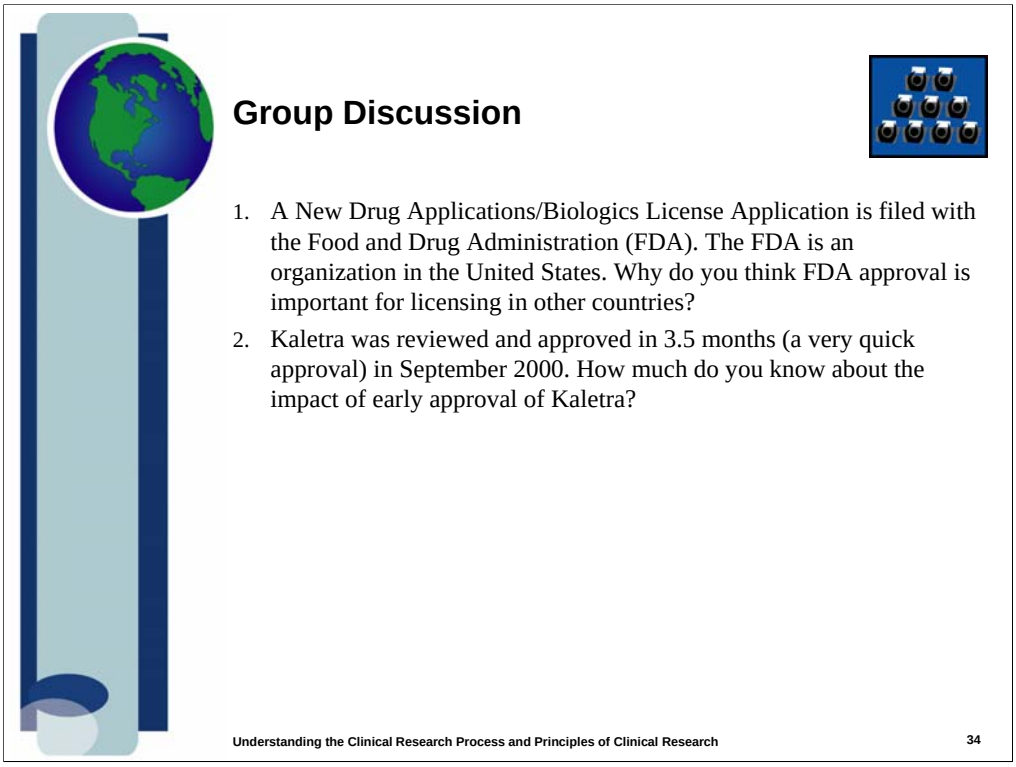
Note: Be sure to mention Kaletra during the discussion of this slide because a discussion question at the end of this section refers to Kaletra. Kaletra for the treatment of HIV/AIDS was reviewed and approved in 3.5 months (a very quick approval) in September 2000.

Allow for questions and discussion.




Participant Guide, page 12

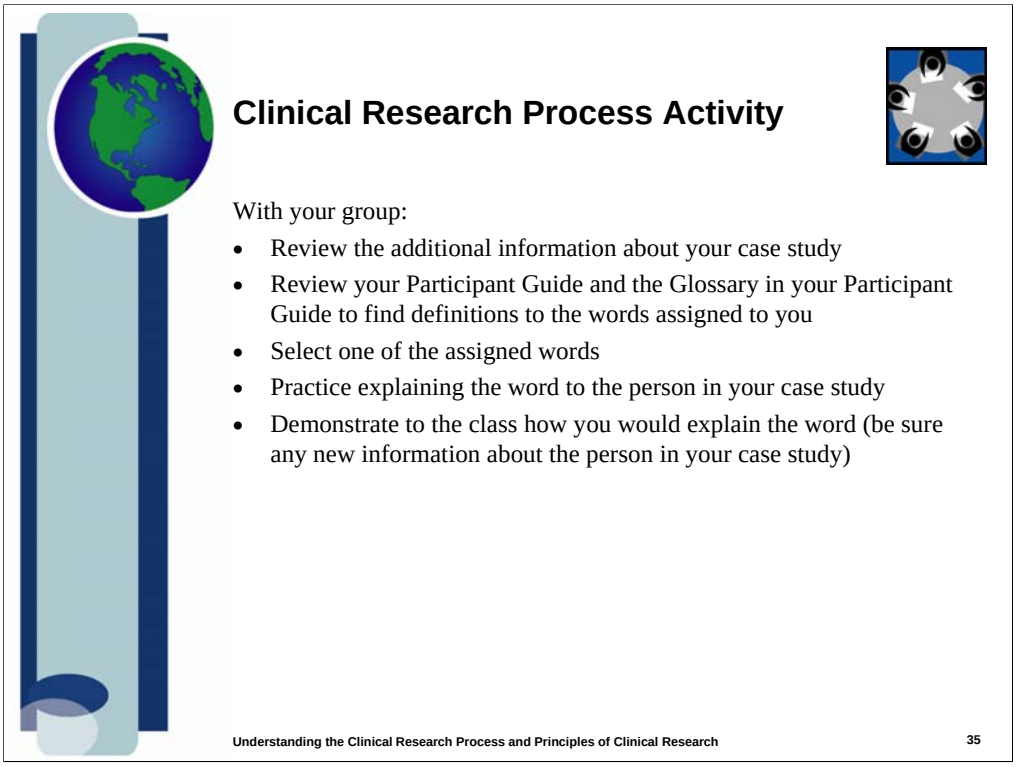
Allow for questions and discussion.




There is no Participant Guide page for this slide.

Possible answers for these questions:

1. THE FDA maintains high standards for safety and effectiveness. The FDA evaluates products developed outside the United States and assures that the quality of non-U.S. products meets the same standards as U.S. products. Products not approved by the FDA may be substandard. Substandard products might not be effective and might worsen the situation by stimulating the development of drug-resistant strains of the virus that causes HIV/AIDS.
2. Early approval of Kaletra provided treatment to more people much more quickly. Some features of Kaletra make it important for a variety of reasons: 1) Kaletra can be taken with or without food; 2) refrigeration is not necessary, which is important in some countries; 3) children between ages 6 months and 12 years can take it and a liquid formulation is available for babies and children who can't swallow pills; 4) Kaletra is listed as a recommended treatment in the federal guidelines on treating HIV-positive pregnant women.




There is no Participant Guide page for this slide. See the instructions for conducting small group activities in the Instructor's Guide. Distribute the case study handouts for this activity: Clinical Research Process Activity. Each person in a group should receive a copy, and each group should get the same person's case study. Allow each table group to select the person who will pretend to be the case study person(s) and doctor. Before asking participants to demonstrate (role play) the person and doctor, provide an example. If possible, ask one of the non-participants in the room to help you. Select a glossary item (for example, "HIV" or "AIDS"). Take the role of doctor/clinic person, and explain (in simple terms) what the word is that you selected. Practice the role play with the non-participant while the table groups are working. At the end of the role play, be sure to say "Do you have any question?" to model the correct role play techniques for the participant role plays. Encourage thoughtful questions and responses. Debrief notes after a group has role played the situation in front of the class:

1.Encourage the workshop participants to ask questions about the word and definition after seeing the role play

2.Encourage participants to ask for examples (be prepared to provide examples, if needed)

3.Summarize the activity by reminding participants how:

a. Difficult it is to describe difficult subjects and words in simple terms

b. Important it is to make sure people understand what is explained to them

c. Difficult it is for some people to communicate they might not understand what is being said

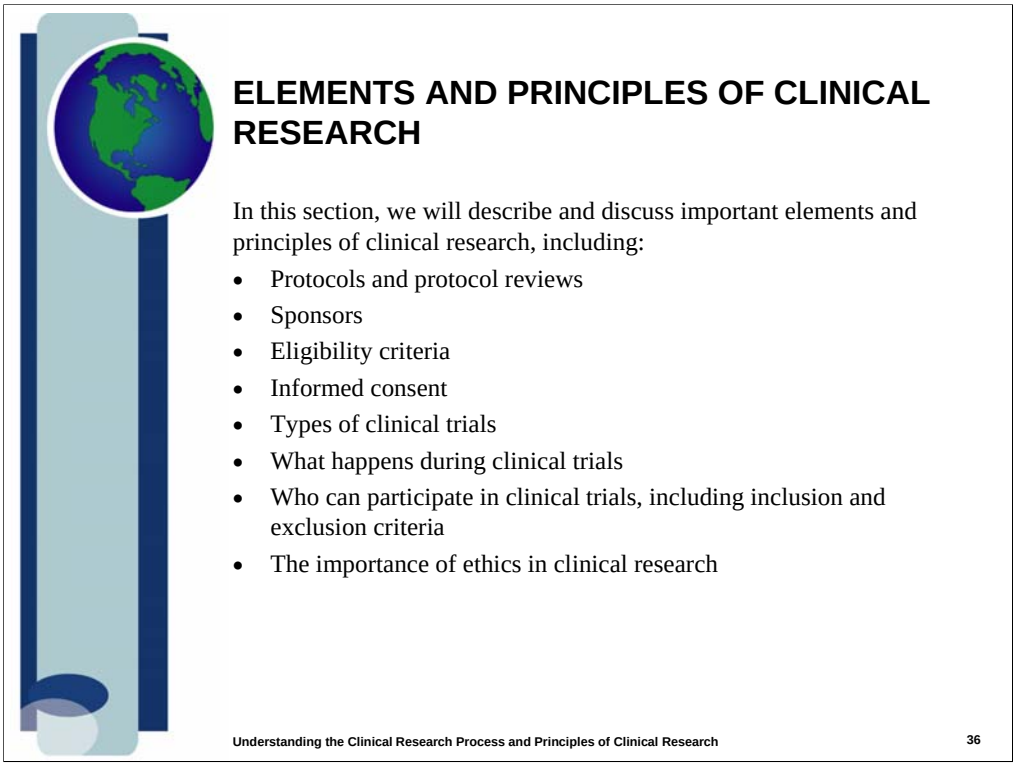
Before going to the next section of this workshop, stop to:

-Review what was learned in this section (there is no PowerPoint slide for this review)

-Ask for questions and allow for questions

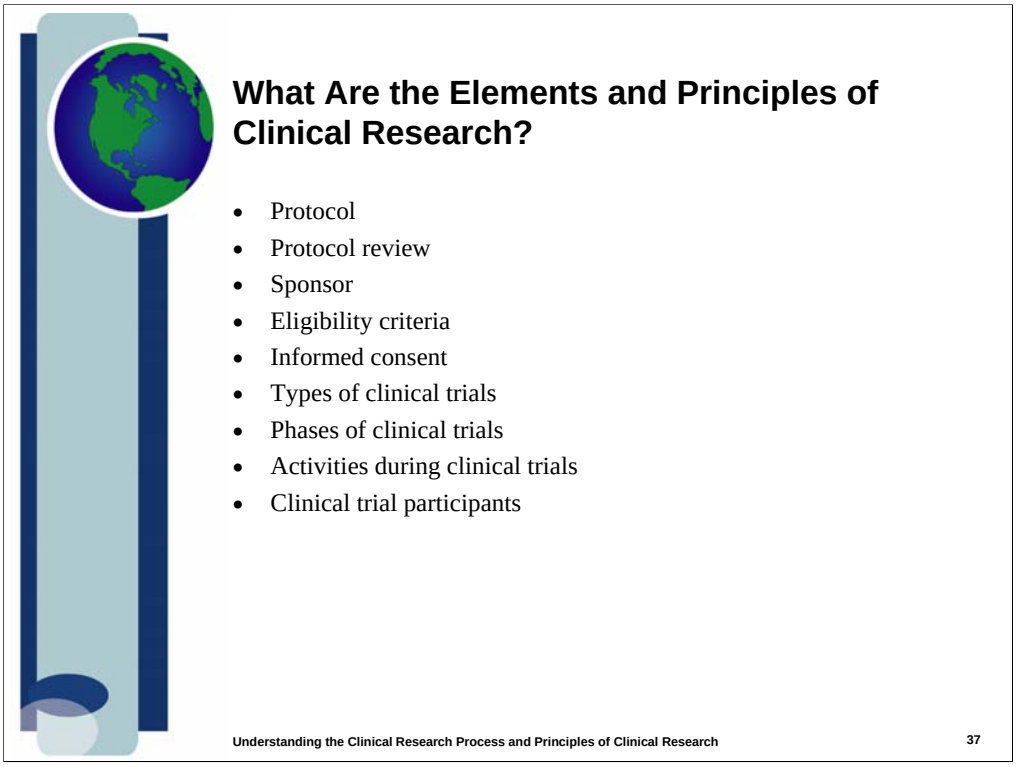
-Write any "parking lot" issues or information you need to come back to on a blank flip chart

Break for lunch.



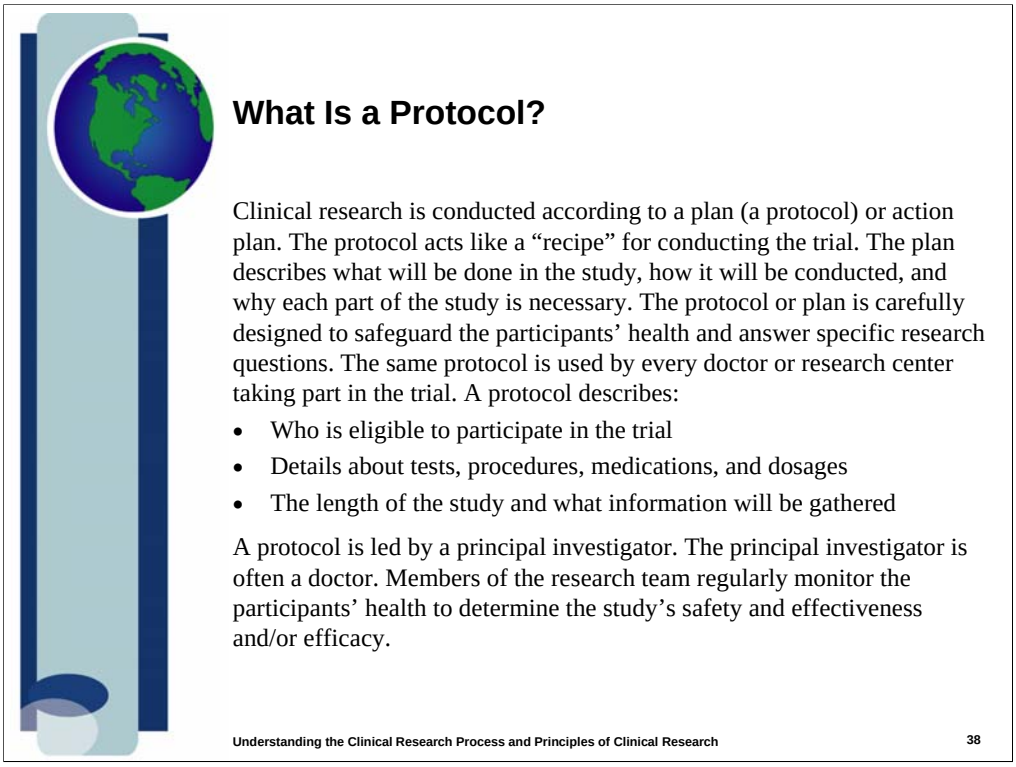

Participant Guide, page 13

This module will last approximately 130 minutes.



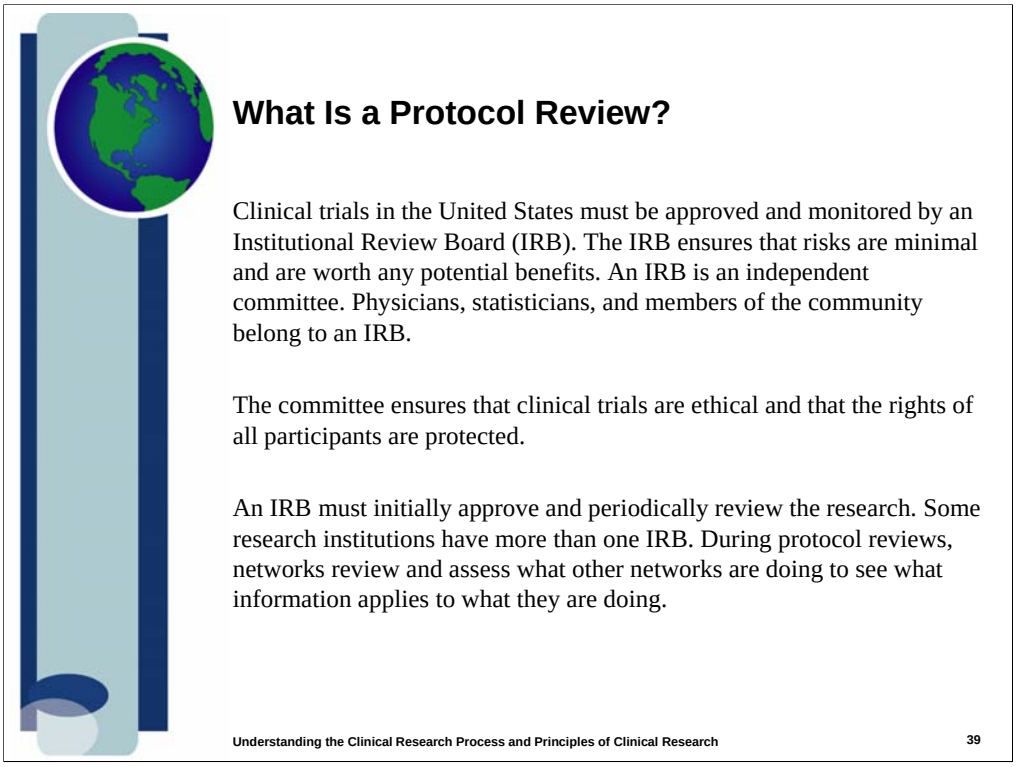

Participant Guide, page 13

Briefly review the items in the list. Each of the items will be covered in depth shortly.




Participant Guide, page 14

Allow for questions and discussion.

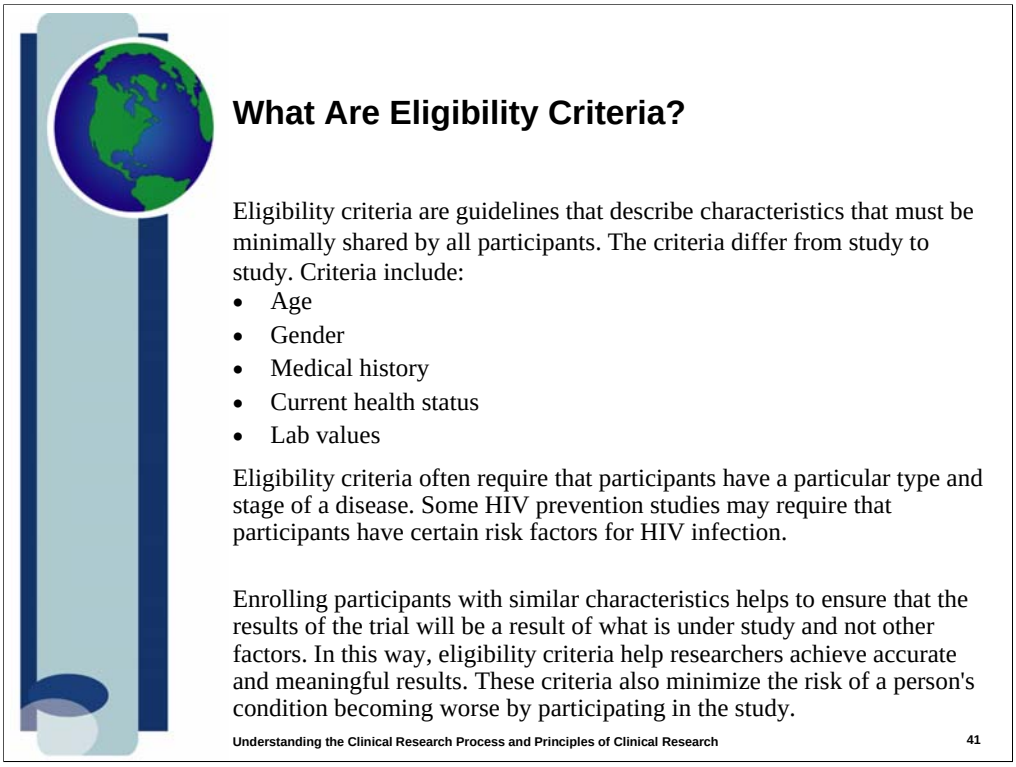



Participant Guide, page 14

Allow for questions and discussion.

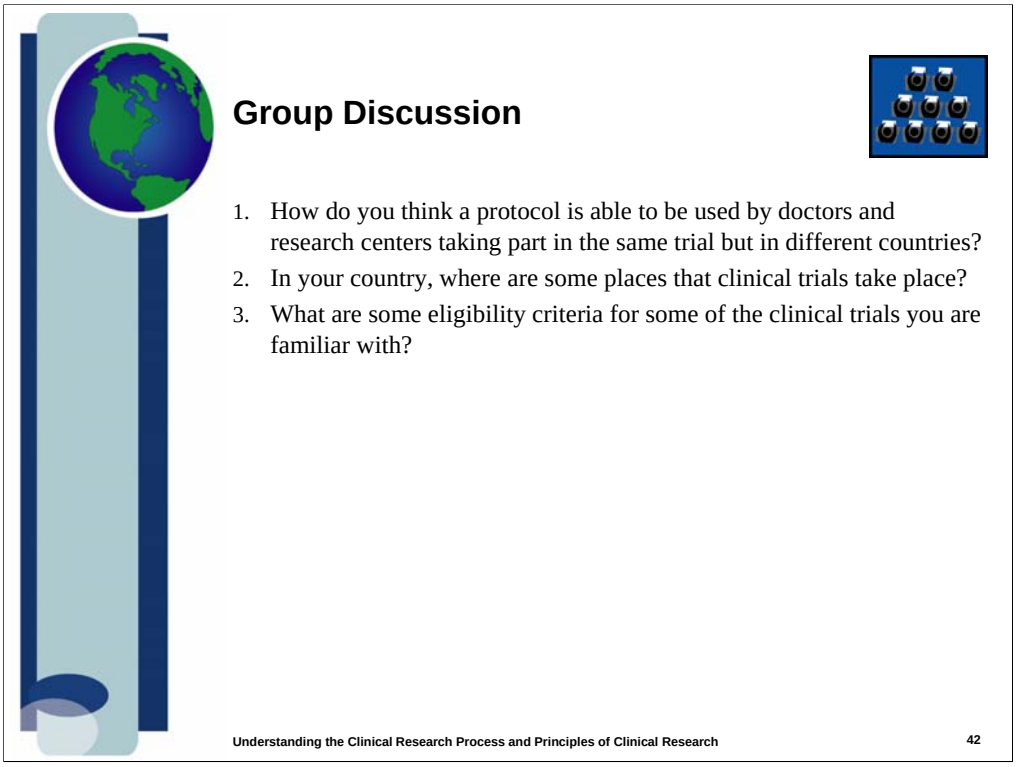

Participant Guide, page 15

Allow for questions and discussion.




Participant Guide, page 16

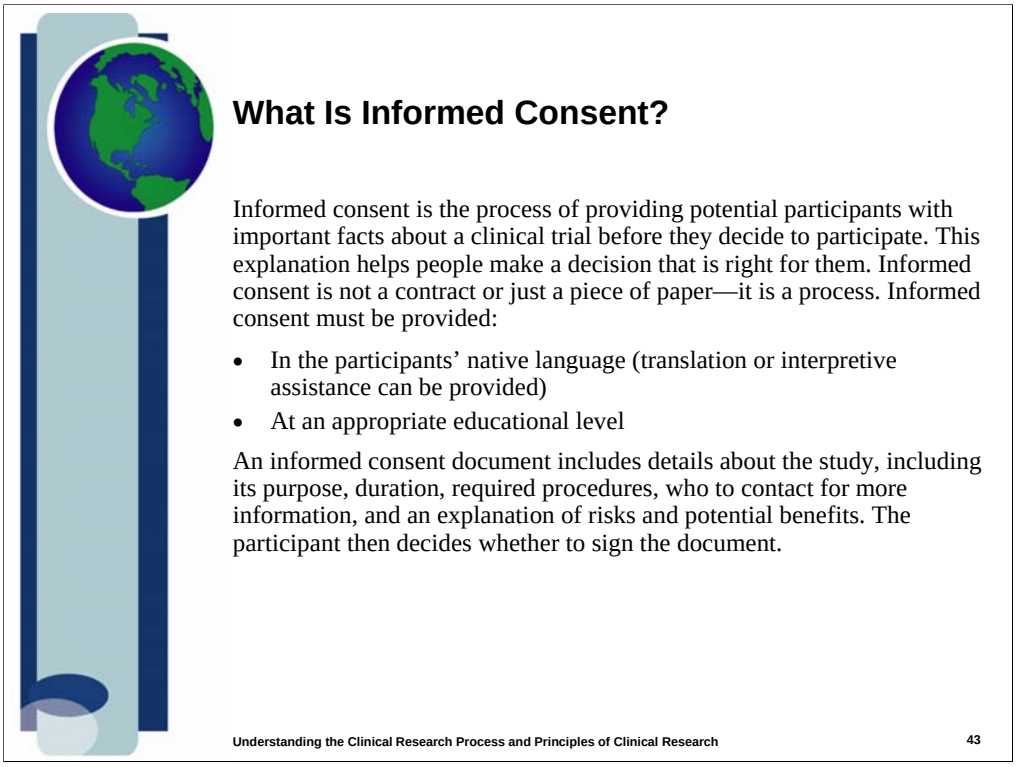
Allow for questions and discussion.




There is no Participant Guide page for this slide.

Possible answers for these questions:

1. A protocol defined the process for systematic collection, description, analysis and interpretation of data. Key attributes of good research are proper planning, accuracy in data collection, and proper unbiased interpretation. A principal investigator works with the members of the research team to make sure the study is administered consistently in all its locations.
2. Possible answers may include: doctor's office, clinic, and hospitals. There may be others, depending on the location of the workshop.
3. Answers should include age, gender, medical history, current health status, and lab values. There may be others.

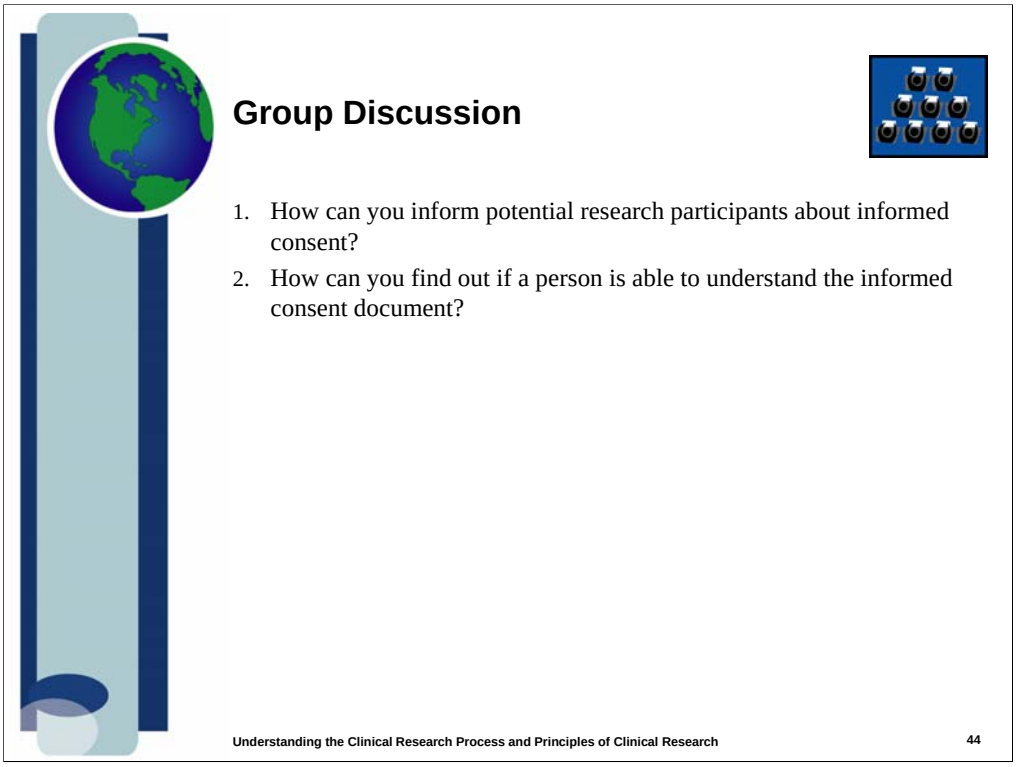



Participant Guide, page 17

Instructor note: In many communities, illiteracy and mistrust exist toward anyone who asks for a signature as a commitment. Sometimes people fear their signatures may lead to unexpected obligations, because they attach great importance to legal formalities.

Volunteers are free to withdraw from a study completely or to refuse particular treatments or tests at any time (sometimes, however, this will make them ineligible to continue the study).

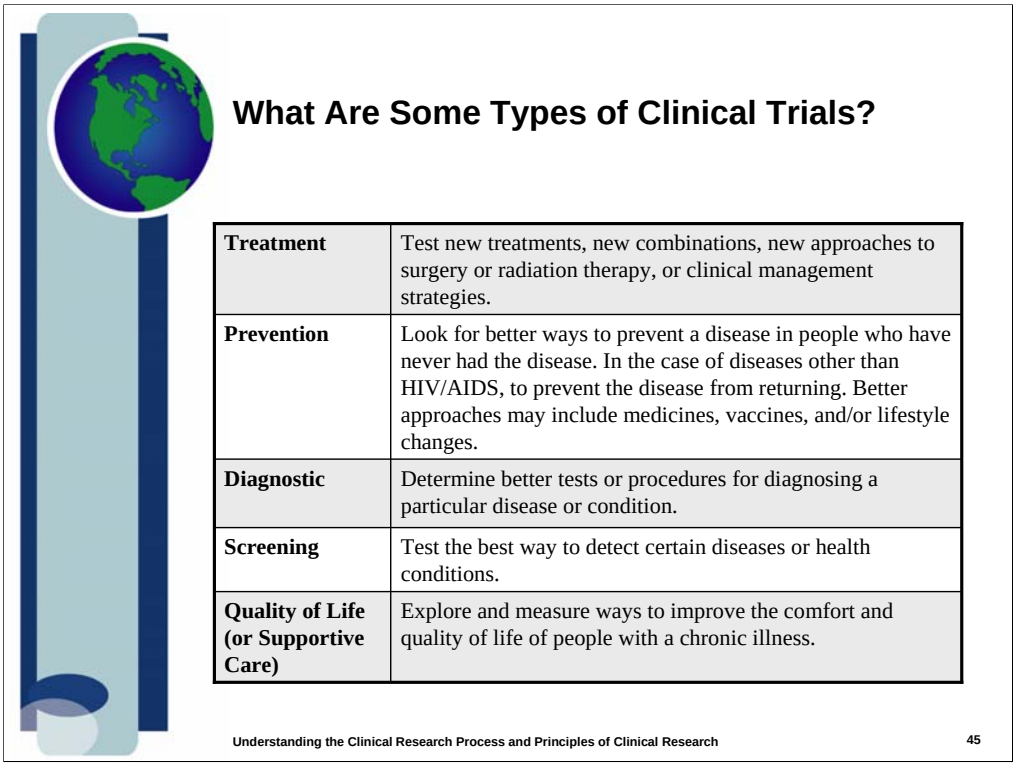
Allow for questions and discussion.




There is no Participant Guide page for this slide.

Possible answers might include:

1. Answers will vary based on the workshop participant's experience. Encourage discussion about making sure that potential research participants actually have an opportunity to hear about what their rights are.
2. Answers will vary, but should include: ability to read; ability to see; ability to speak,; ability to hear; ability to read the consent document before signing; ability to answer questions with more than a "yes" or "no."
3. There is an optional third question for this discussion. Use your discretion about asking this question, depending on the makeup of the workshop participants, other observers who might be in the room, and available time for what might turn out to be a lengthy discussion. The optional third question is: "What would you do if you found that informed consent was not practiced in your community?"




Participant Guide, page 18

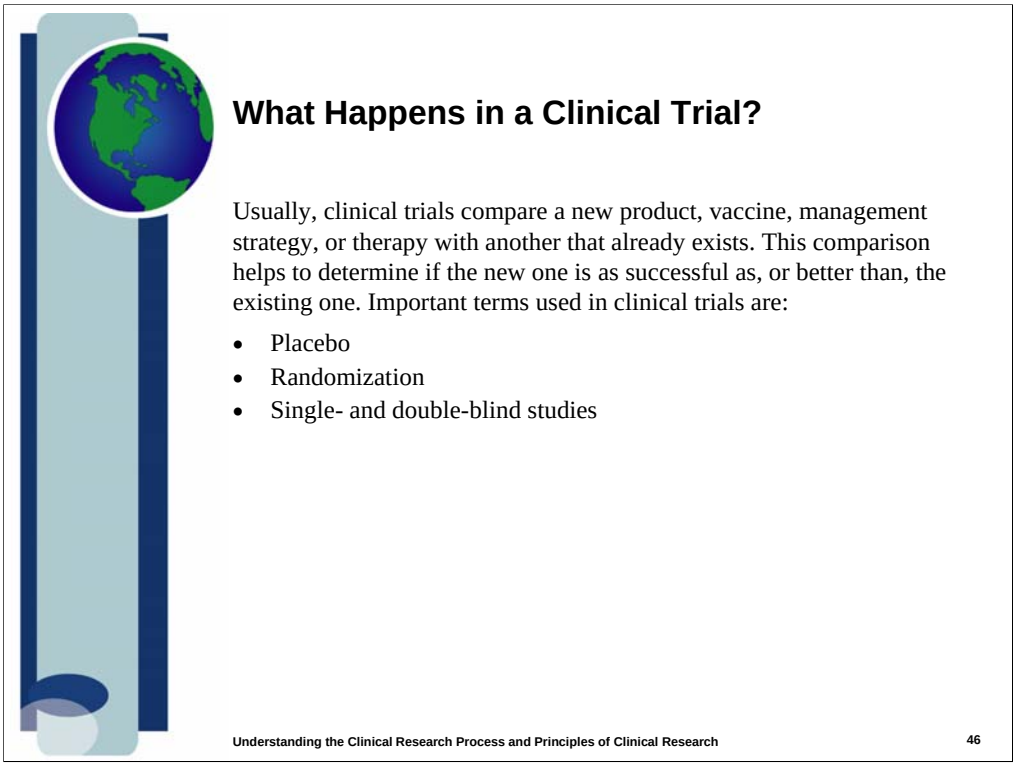
Review the examples in the Participant Guide:

•Anti-retroviral drugs (ARVs) are used to lower the risk of transmission of HIV from an HIV+ pregnant woman to her infant. Clinical trials have proven that ARVs are both safe and effective for this purpose.

•In a retrospective study, children known to be taking ARV treatment are enrolled. The researcher then reviews the medical record of each participant, checks the type of treatment received, and records information from the point of enrollment and looking backward at the 5 years *before* enrollment.

•In a prospective study, children enroll in the study and then started on ARV treatment. From the first visit, data are collected for 5 years going forward.

Allow for questions and discussion.




Participant Guide, page 19

Note: There is a lot of very important content in the Participant Guide that does not appear on the slide. Be sure to direct participants to this page of the Participant Guide and review the page with them.

Allow for questions and discussion.


Participant Guide, page 20

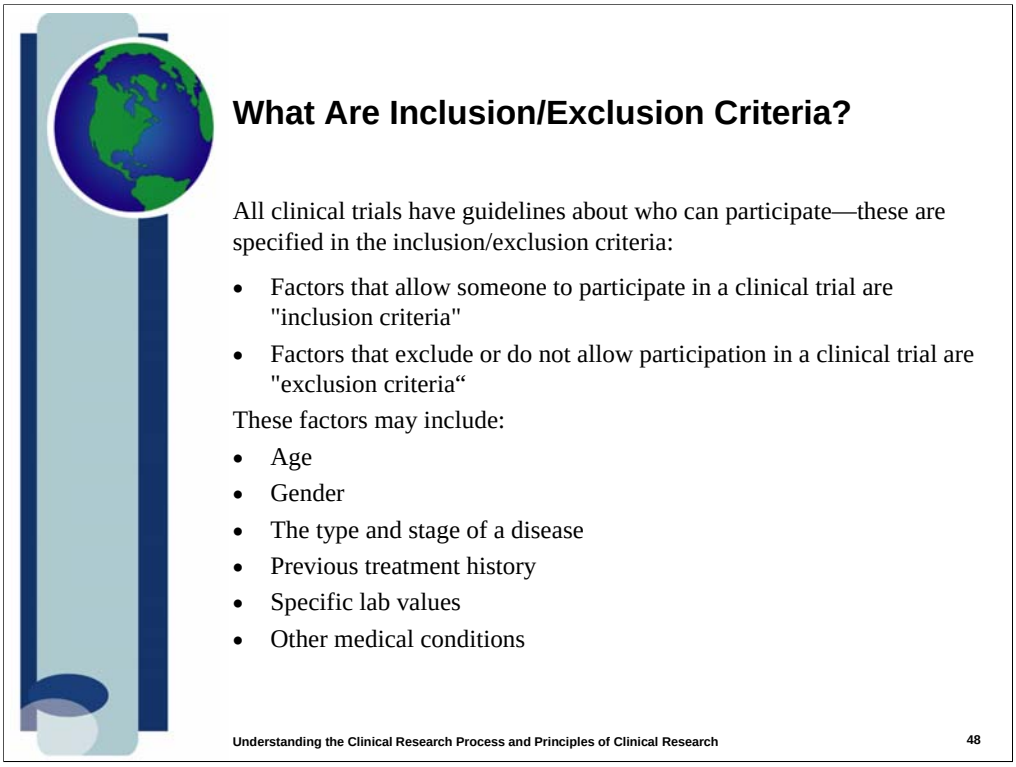
Note: There is a lot of very important content in the Participant Guide that does not appear on the slide. Be sure to direct participants to this page of the Participant Guide and review the following information with them:

•Definition of patient volunteer

•Definition of control

•The last paragraph about consent

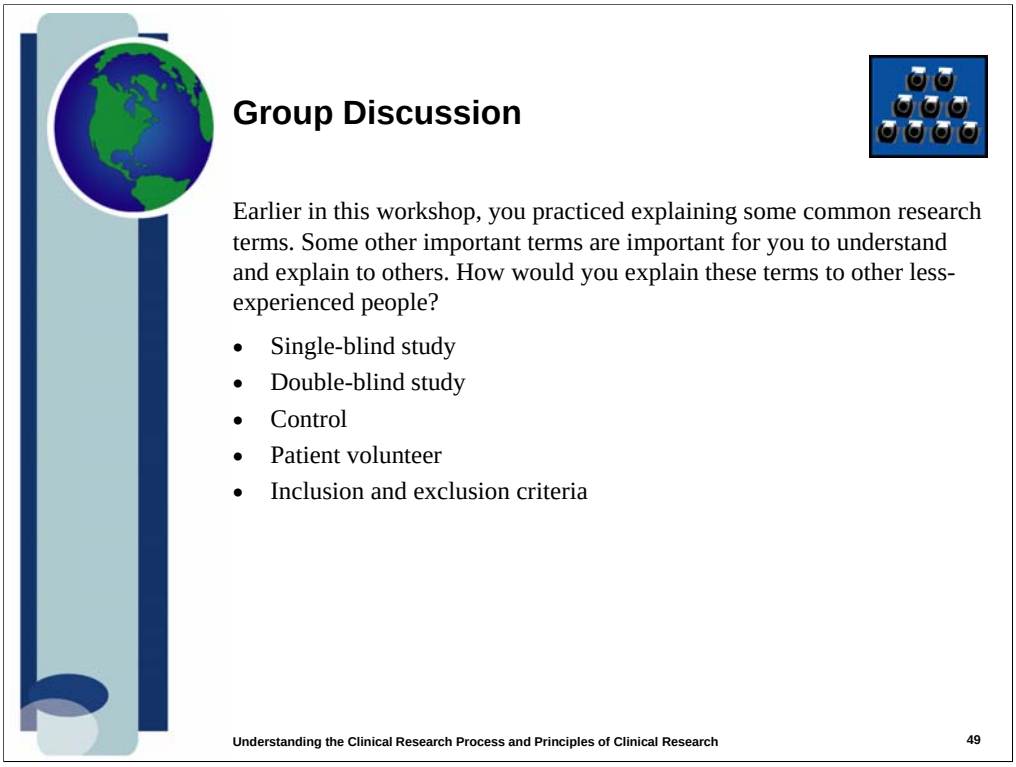
Allow for questions and discussion.




Participant Guide, page 21

Note: Be sure to review the last paragraph and bullet points in the Participant Guide.

Allow for questions and discussion.

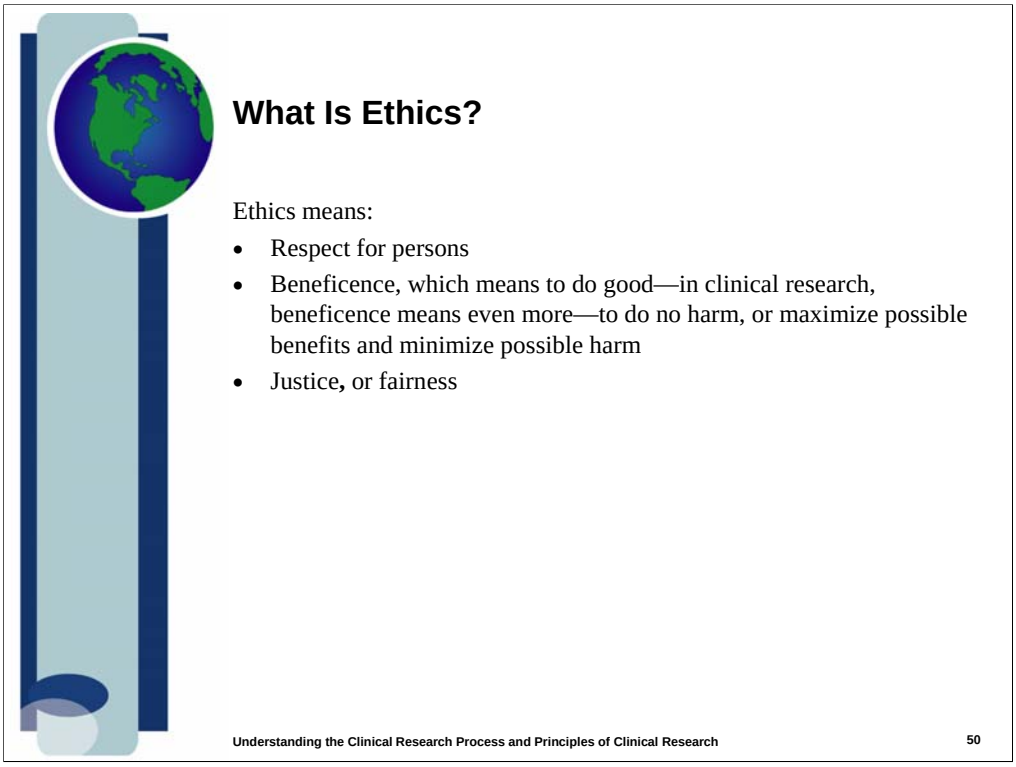



There is no Participant Guide page for this slide.

Definitions for these words can be found on Participant Guide pages 19, 20, and 21 and in the glossary.

Ask participants to provide examples from their own experience, if possible. Provide your own location-specific examples, if possible.

Note: Be careful this discussion does not drift into real-life negative examples where the study activities were inappropriate and/or personal.




Participant Guide, page 22

Note: Be sure to review all sections on this page.

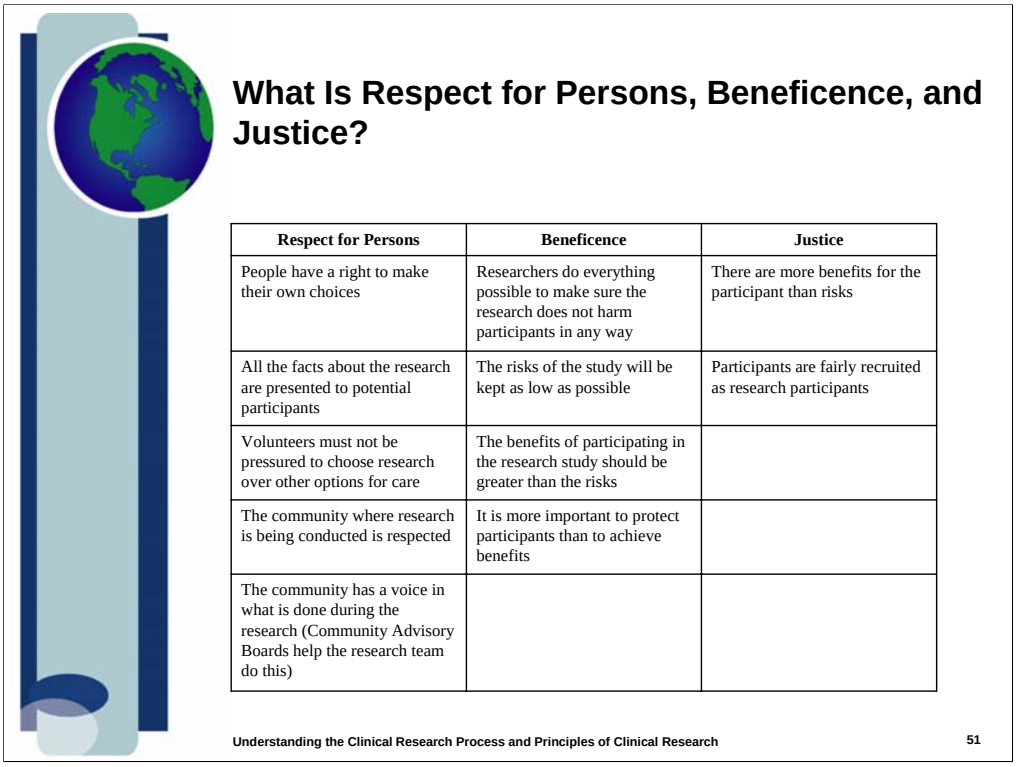
This is a good point to show a 9-minute video about the Belmont Report, depending on the location and experience of the participants. The video is in English. This video was developed for the 25th anniversary of the Belmont Report. The video provides the context for the original report for those who are not familiar with the report's principles and uses. Instructions for locating and downloading the video are provided in the Instructor's Guide.

Before showing the video, tell participants you are showing a 9-minute video. They should just watch and listen. After the video they will have an opportunity to ask questions and talk about what they just saw.

Show the video.

Debrief the video by asking anyone if they have questions about what they heard and saw. One common question may be how the Belmont Report affects research ethics outside the United States. Remind participants that research ethics applies to everyone, and everyone is responsible.

Allow for questions and discussion.




Participant Guide, page 23

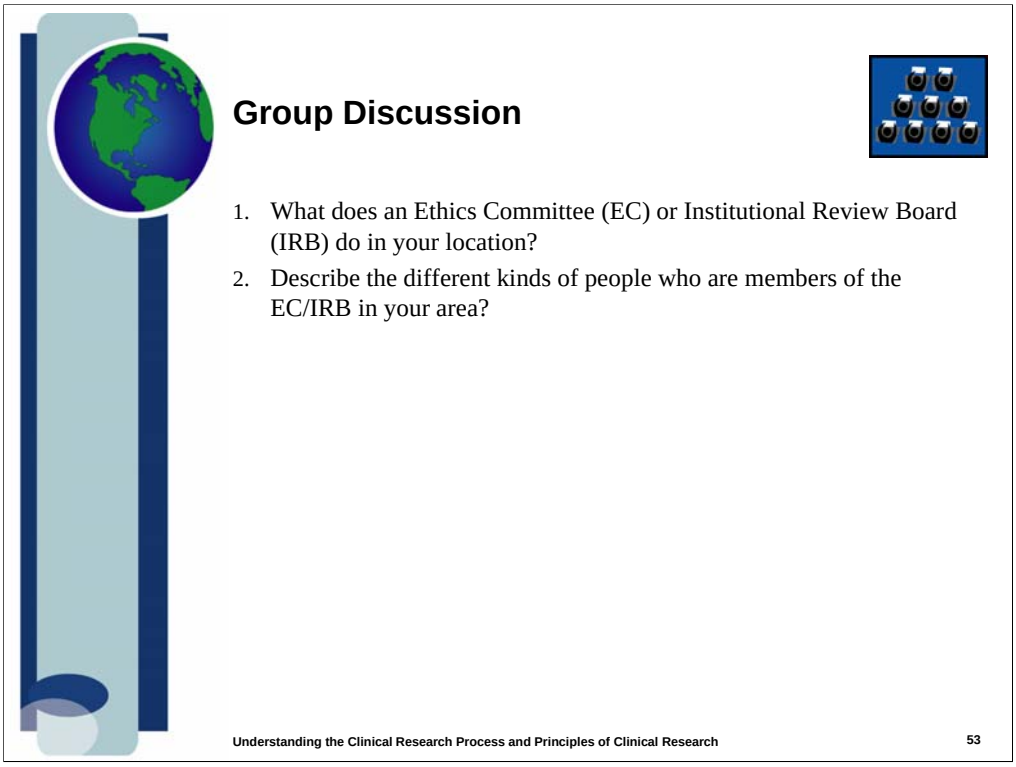
Allow for questions and discussion.


Participant Guide, page 24

Note: Be sure to review all sections on this page.

Note: Before showing the next slide, introduce the slide with this statement: “In an earlier discussion, we talked about how trials can be conducted in a variety of locations. We discussed how important it is for researchers to define protocols so they can be used in the same way, no matter where they are conducted. The Ethics Committee or Institutional Review Board is responsible for making sure the research is conducted correctly, accurately, and ethically. On the next slide, there are two questions about the Ethics Committee and Institutional Review Board in your community.”

Allow for questions and discussion.



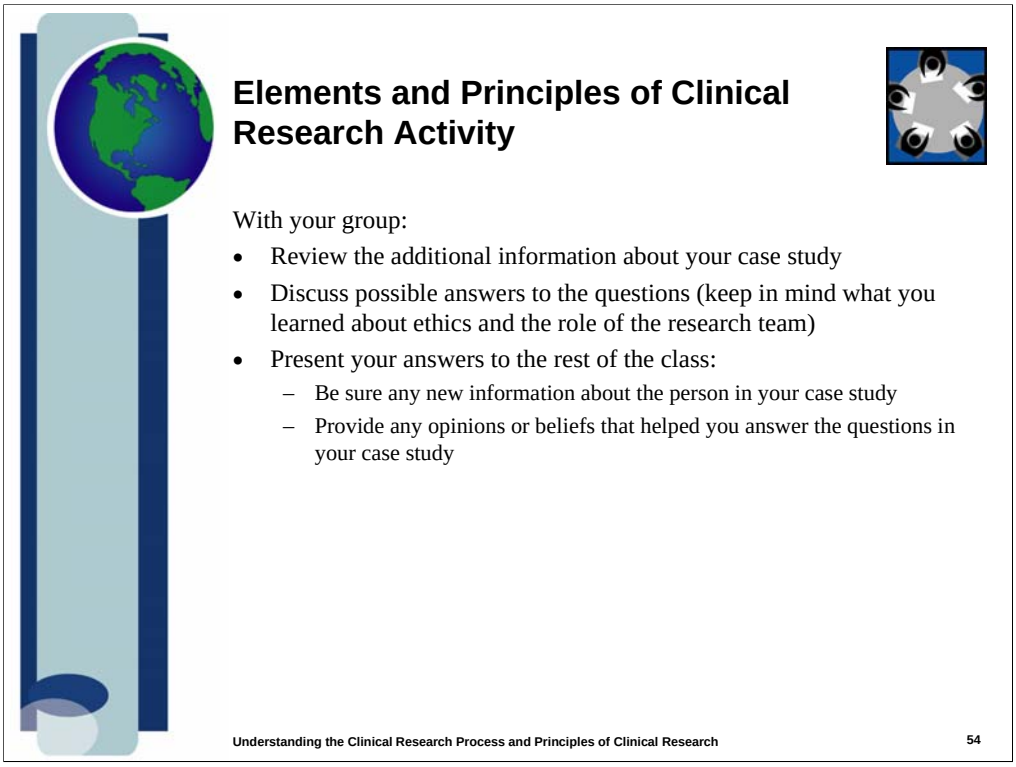

There is no Participant Guide page for this slide.

Be sure to introduce this group discussion by saying: “In an earlier discussion, we talked about how trials can be conducted in a variety of locations. We discussed how important it is for researchers to define protocols so they can be used in the same way, no matter where they are conducted. The Ethics Committee or Institutional Review Board is responsible for making sure the research is conducted correctly, accurately, and ethically.”

Then ask the questions on the slide.

Answers will vary considerably for this discussion, depending on the location. If participants are unable to answer these questions, lead a group discussion about the items on page 24 of the Participant Guide. As you review the bullet points on the page, ask open questions such as “Why do you think this is important?.”

The key point to take away from this discussion is that EVERYONE is responsible for protecting human rights in research activities.




There is no Participant Guide page for this slide.

Distribute the case study handouts for this activity: Elements and Principles of Clinical Research Activity. Each person in a group should receive a copy, and each group should get the same person's case study.

Note: Walk around and listen to the table groups as they discuss the questions in their case study. Depending on the experience level, they should be able discuss specifics about what is and is not allowed by the research team during a first appointment with a potential research participants. Important, too, is to seek examples of workshop participant empathy toward the case study person. For less-experienced groups, "human" issues will probably become more important and focus on how people are treated during the first appointment. While working with individual table groups, ask open questions like, "Have you thought about how the research team feels?" and "Have you thought about why interviewees might not want to share information they think might make them ineligible?," etc.

Prior to delivering the workshop, try to get a clear understanding of how participants are selected and treated in that location. Also seek to include a local member of a research team or EC/IRB member to offer specific insights.

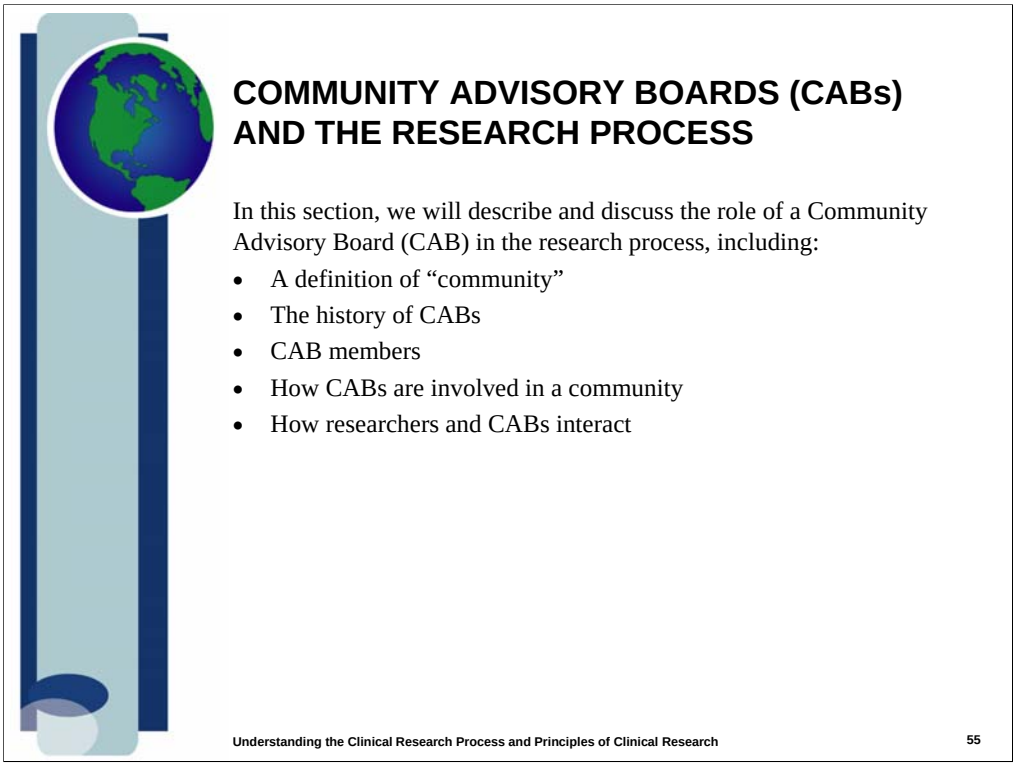
Before going to the next section of this workshop, stop to:

-Review what was learned in this section (there is no PowerPoint slide for this review)

-Ask for questions and allow for questions

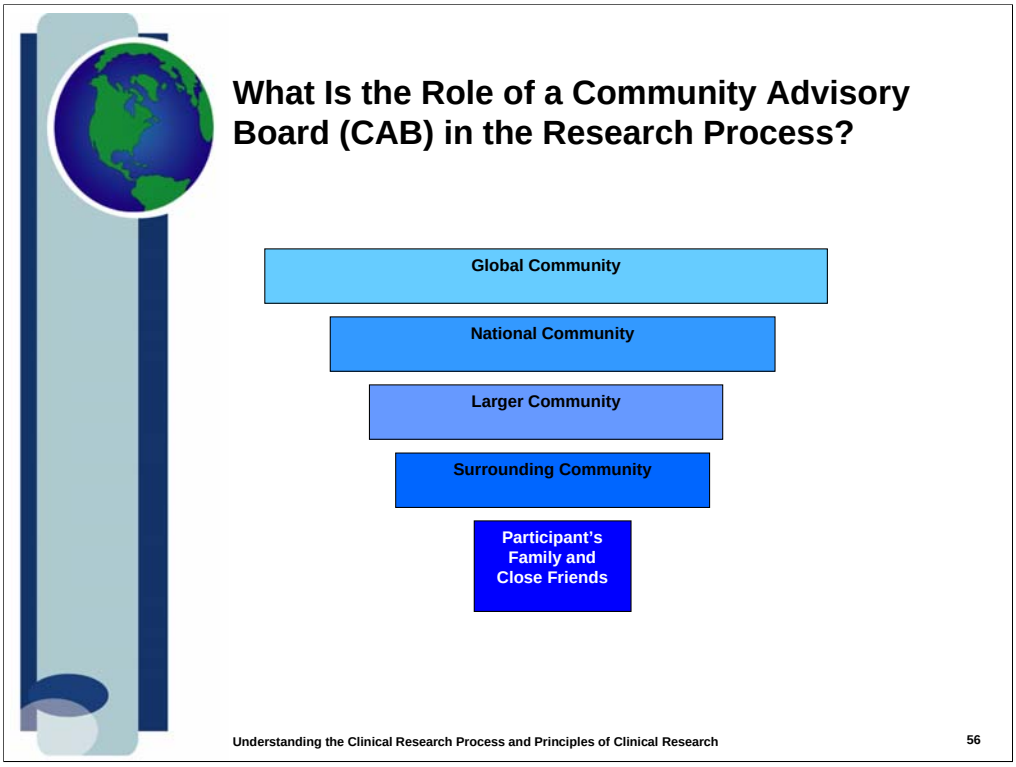
-Write any "parking lot" issues or information you need to come back to on a blank flip chart

Break for 15 minutes.




Participant Guide, page 25

This module will last approximately 90 minutes.



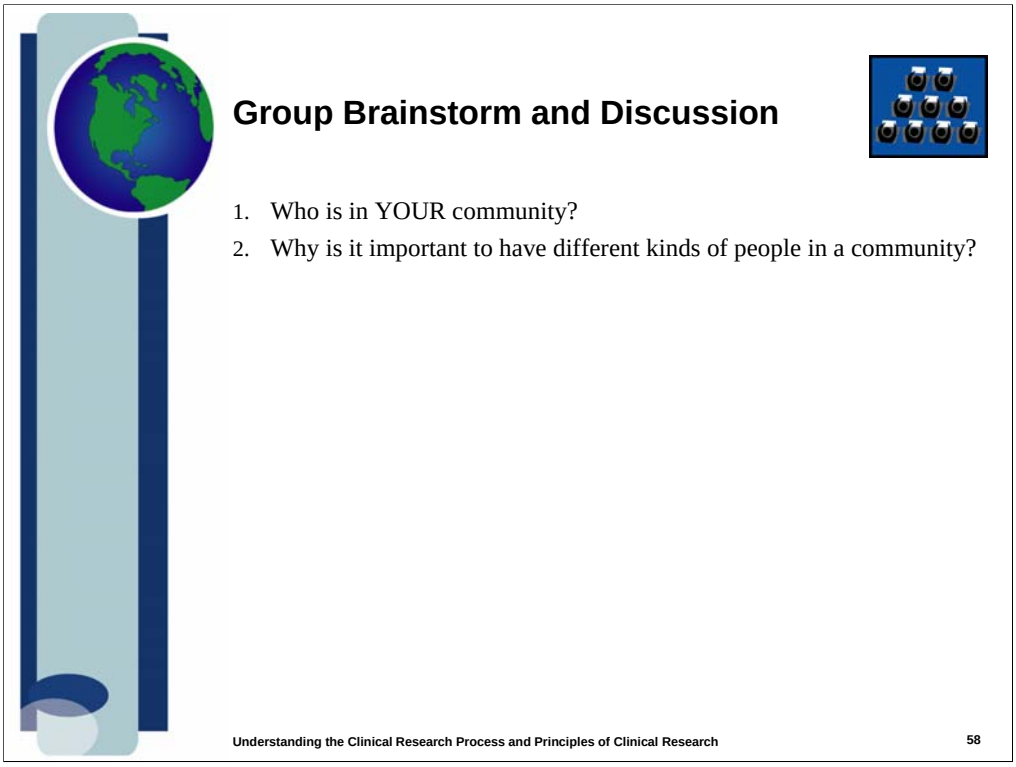

Participant Guide, page 25

Note: In the graphic, note that these are external influences. The graphic is not meant t o imply that each of these "communities" is aware of an individual's clinical trial.

Allow for questions and discussion.


Participant Guide, page 26

Allow for questions and discussion.




There is no Participant Guide page for this slide.

Note: At this point in the workshop, participants are probably ready for a break and something different more energetic. Consider asking everyone to stand up for this discussion (they are also free to move around). That will get people out of their seats, which will likely also spark some new brain activities. The instructor's responsibility is to write what participants share on a flip chart or whiteboard.

Introduce this activity by saying, "We're now going to do some brainstorming. Brainstorming is a fun way to collect new ideas…no idea is a bad idea in brainstorming. In fact, in brainstorming, these new ideas can be silly and even wrong! But there are a few rules for brainstorming:

•Think of as many ideas as possible

•Say each idea as it comes to you

•Build on other people's ideas

•Think of absurd, humorous, crazy ideas

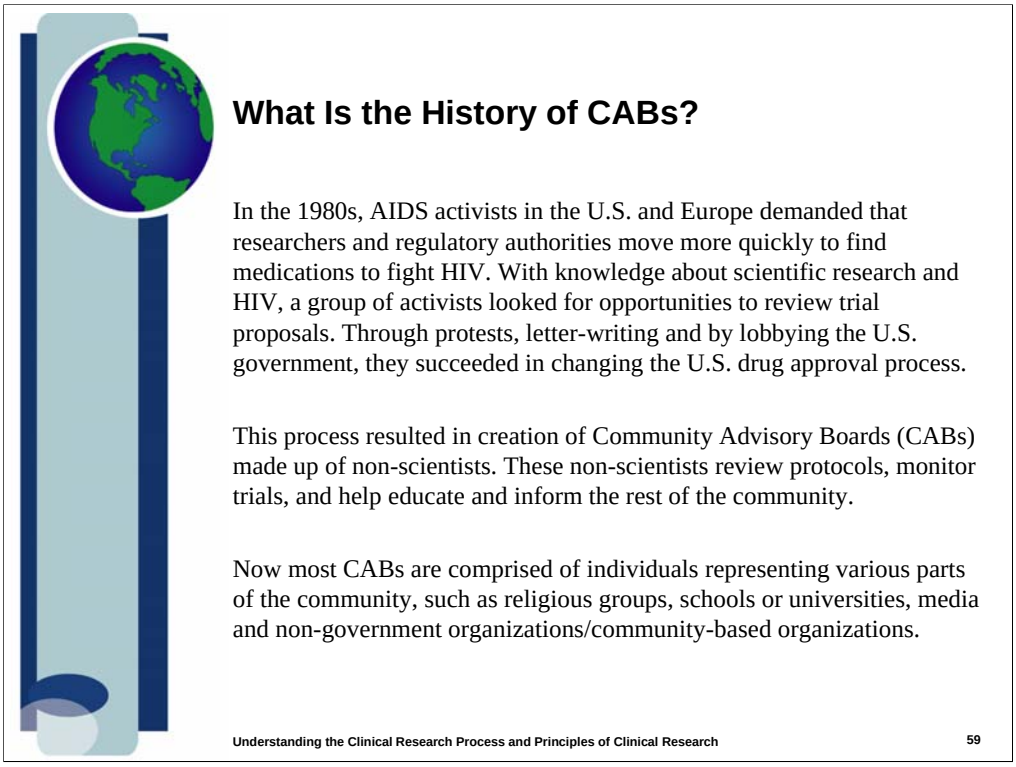
•Keep up a rapid pace

•Be positive

•Do ***not*** question, criticize, or challenge other people's ideas

Brainstorm the first question on the slide. Allow approximately 5 minutes for participant ideas. Encourage creativity and spontaneity. Write the brainstorm ideas on a flip chart or board.

Then lead a discussion about the importance of having different people in a community. Answers might include: variety, experience, empathy, understanding, skills, comfort, etc. If time permits, ask how community members are important to HIV/AIDS research. Answers should include all of the same answers.

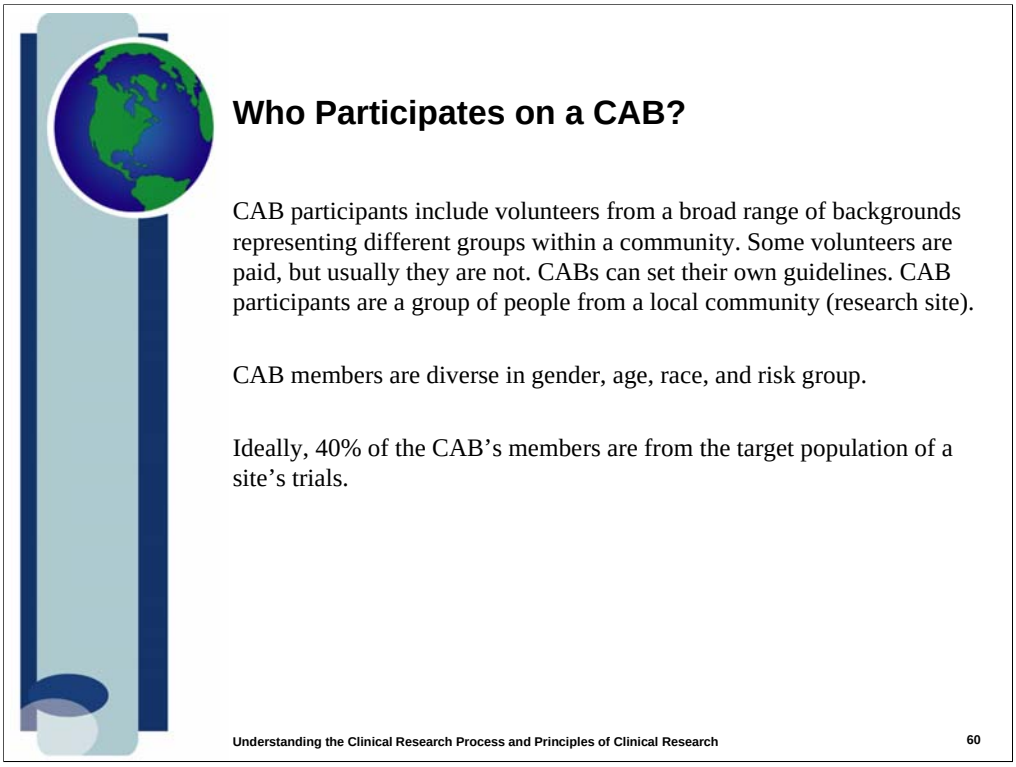



Participant Guide, page 26

Note: Review all paragraphs in the Participant Guide.

Note: The Uganda effort was not U.S. based.

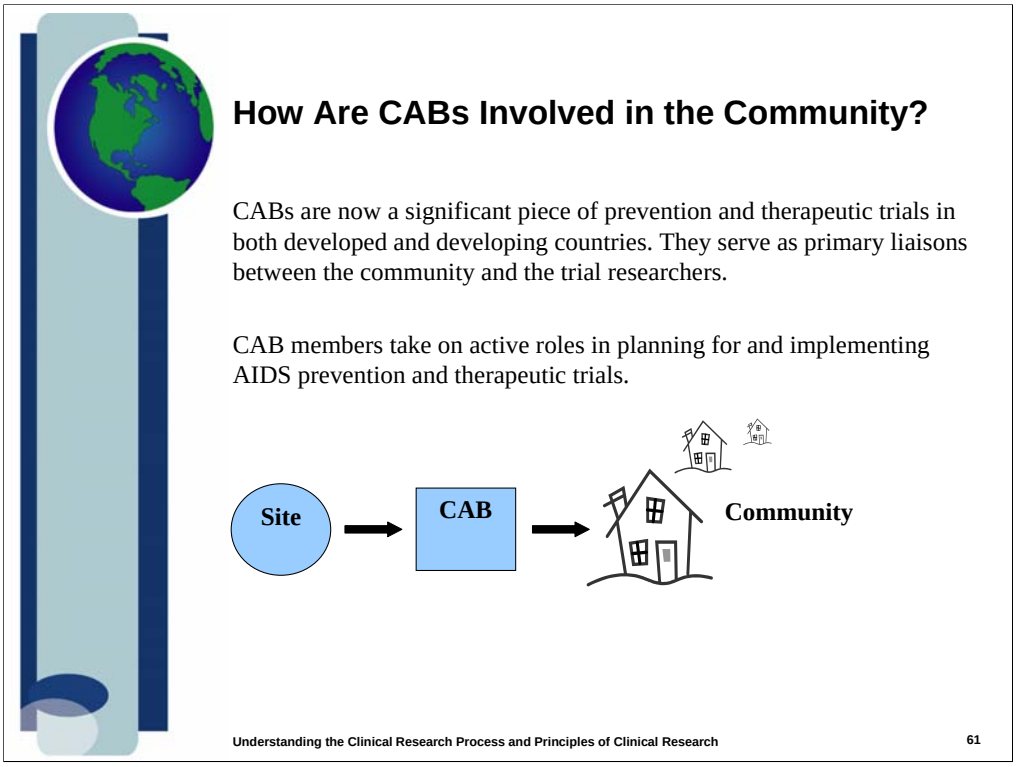
Allow for questions and discussion.




Participant Guide, page 27

Note: review the bullets on this page: they have not been included in the PPT.

Allow for questions and discussion.

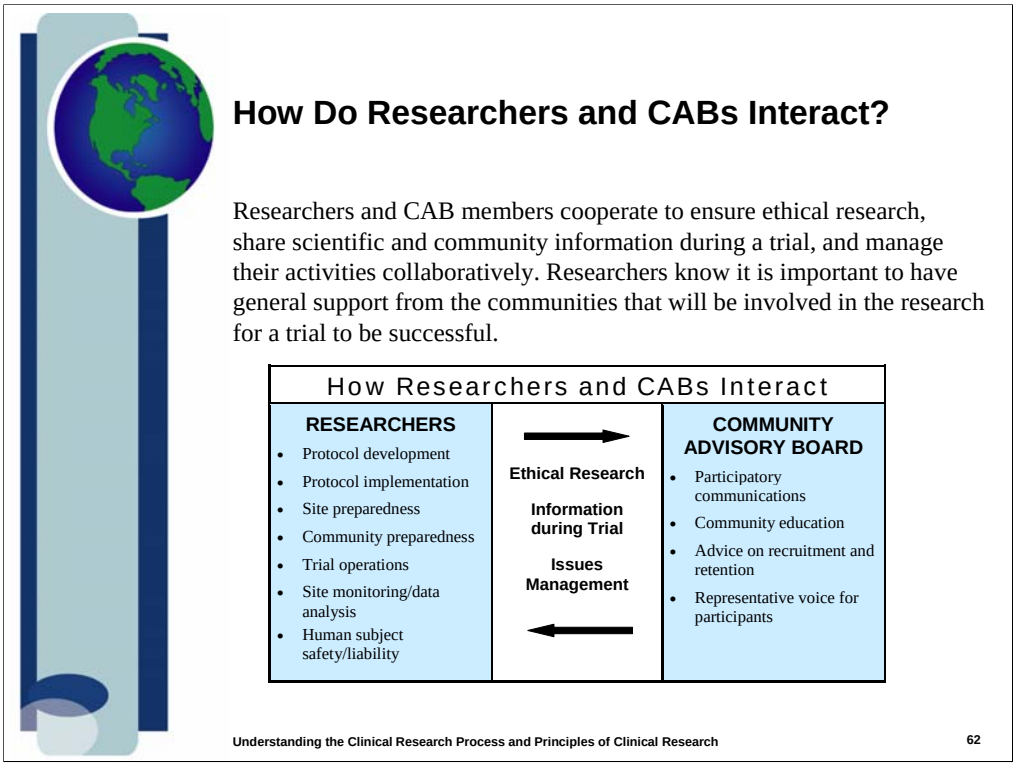



Participant Guide, page 28

Note: Review the bullets in the Participant Guide.

Note: In some locations, other sites and groups may be involved with a CAB to link the site with the community.

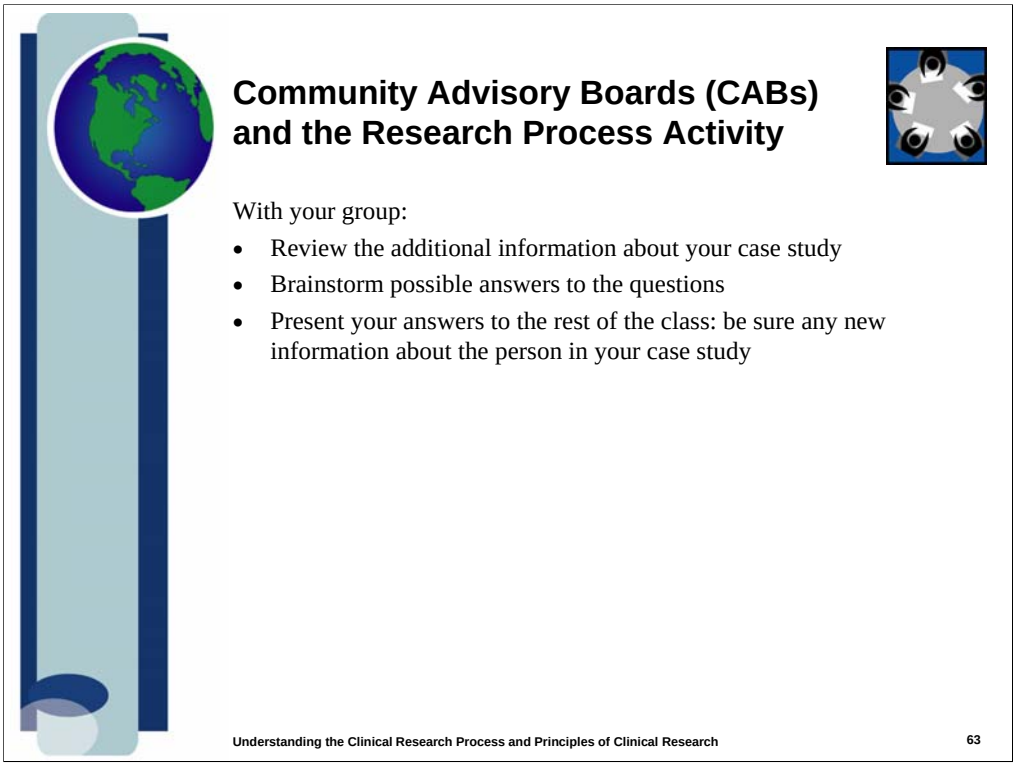
Allow for questions and discussion.




Participant Guide, page 29

Note: Review the additional material in the Participant Guide.

Allow for questions and discussion.




There is no Participant Guide page for this slide.

This is the final activity of the workshop. Allow extra time for this activity because the topics covered here are important and meaningful. By the time this activity is conducted, the workshop participants will likely be working well together and willing to share ideas. This interaction is an important conclusion to tie together the focus of the workshop.

Distribute the case study handouts for this activity: Community Advisory Boards (CABs) and the Research Process Activity. Each person in a group should receive a copy, and each group should get the same person's case study.

Refer participants to the graphic on page 25 of the Participant Guide to understand how large a community can be.

Note: Walk around and listen to the table groups as they discuss the questions in their case study. While working with individual table groups, ask open questions like, "Have you thought about how a person's community might affect his/her health options and accessibility to research opportunities?" and "Have you thought about how CAB members can help within the bounds of confidentiality?," etc.

After all the presentations are complete, lead a whole group discussion about:

•The definition of confidentiality

•The importance of confidentiality

•What might happen if confidentiality is breached to the people in the case studies

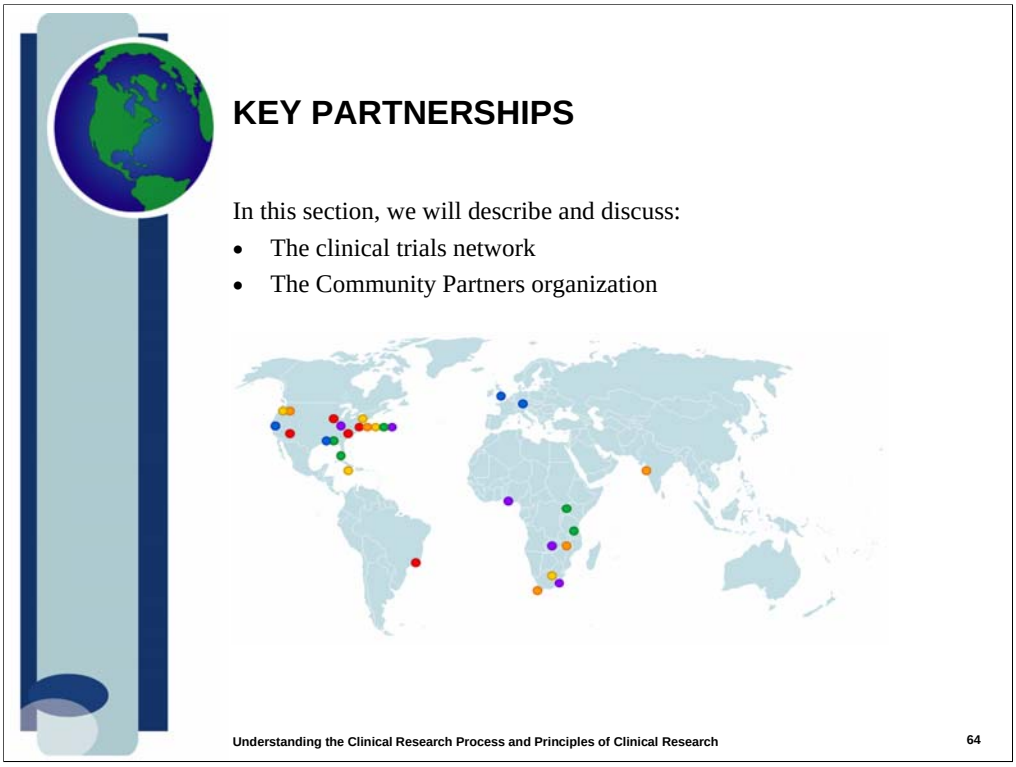
•How clinical research is affected if there is a breach of confidentiality by the research team or CAB members

Before going to the next section of this workshop, stop to:

-Review what was learned in this section (there is no PowerPoint slide for this review)

-Ask for questions and allow for questions

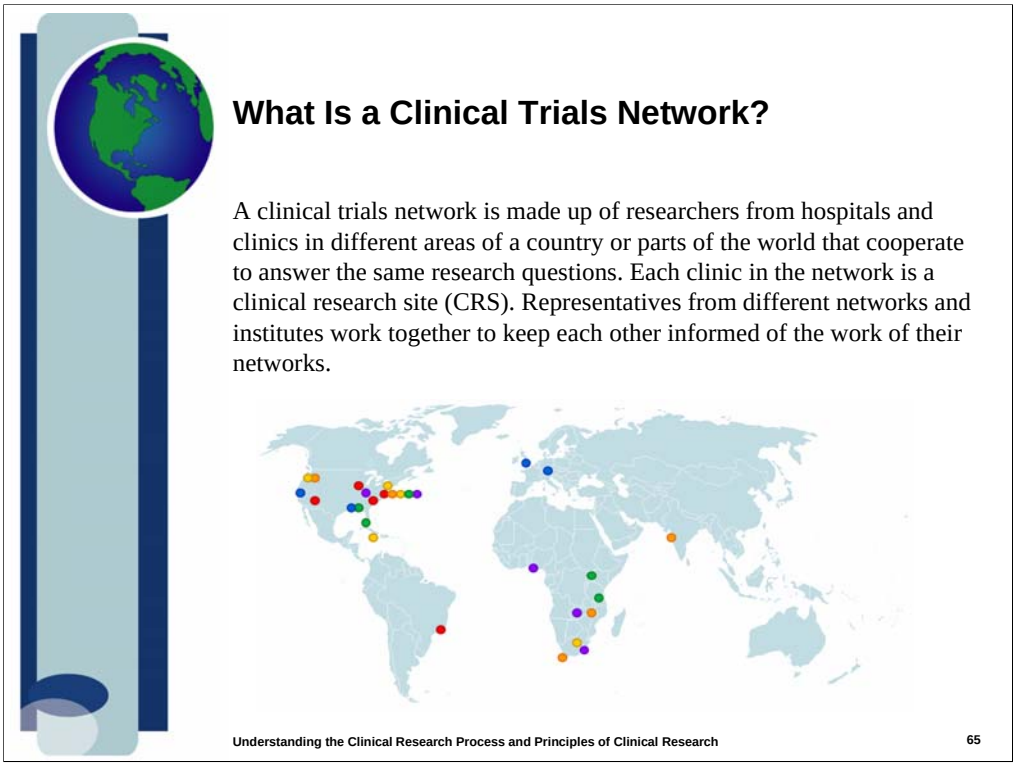
-Write any "parking lot" issues or information you need to come back to on a blank flip chart




Participant Guide, page 30

Note: Carefully review the content in the paragraph above the graphic in the Participant Guide. Emphasis the six clinical trials networks. Tell participants you will explain what the colored circles mean in a minute. The important point for this slide is that the networks supported by Community Partners are found throughout the world.

This module will last approximately 15 minutes. There are no activities or discussions for this module, so be sure to allow participants to ask questions. At this point in the workshop, participants will be ready to finish.




Participant Guide, page 31

Note: Review the information in the table in the Participant Guide. The graphic shows the six network locations:

Red circles: AIDS Clinical Trials Group (ACTG)

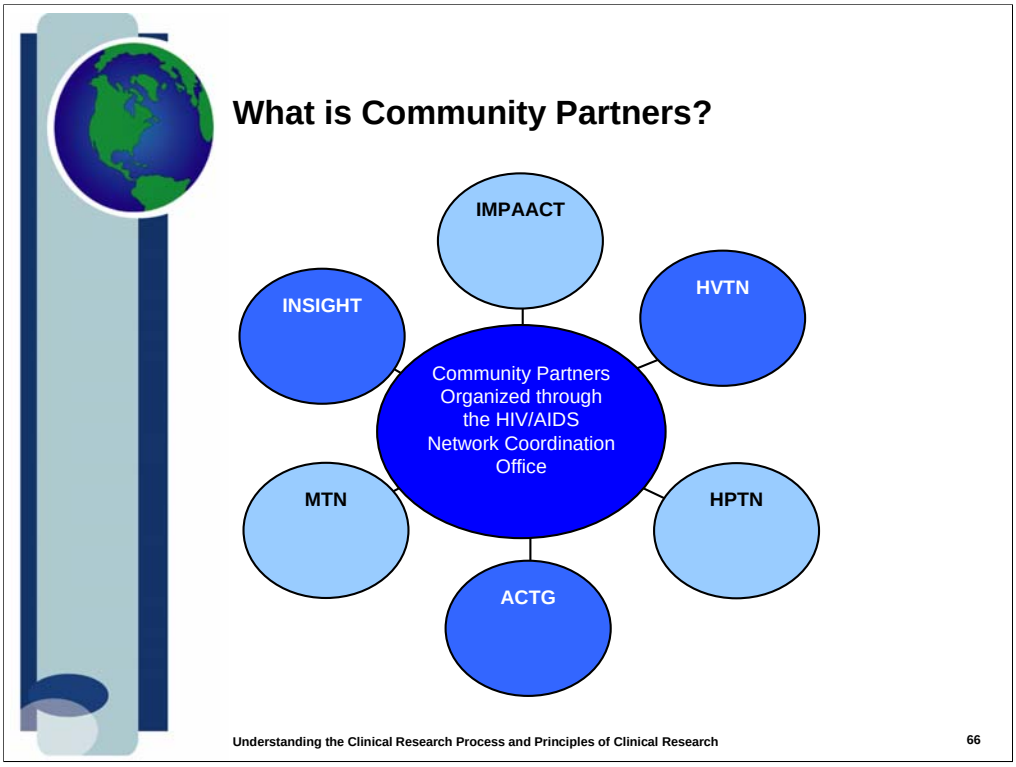
Orange circles: HIV Prevention Trials Network (HPTN)

Yellow circles: HIV Vaccine Trials Network (HVTN)

Green circles: International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT)

Blue circles: International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)

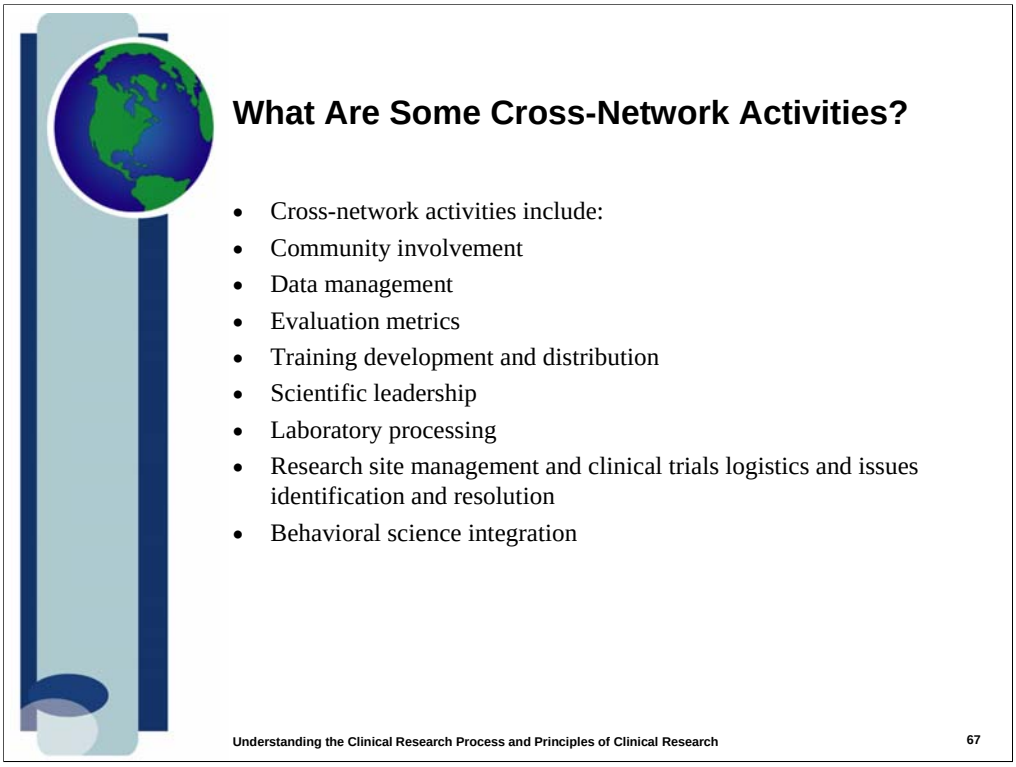
Purple circles: Microbicide Trials Network (MTN)




Participant Guide, page 32

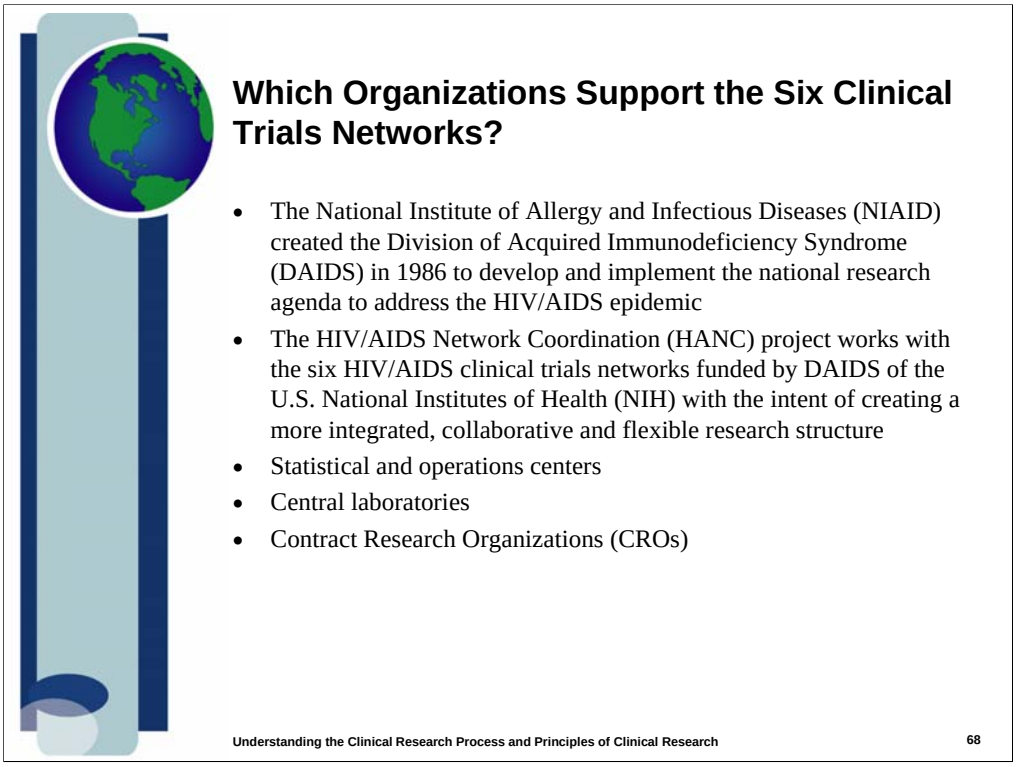
Note: Read the introductory paragraph before discussing the graphic. Tell participants this graphic shows how the networks come together and work through Community Partners.

Allow for questions and discussion.



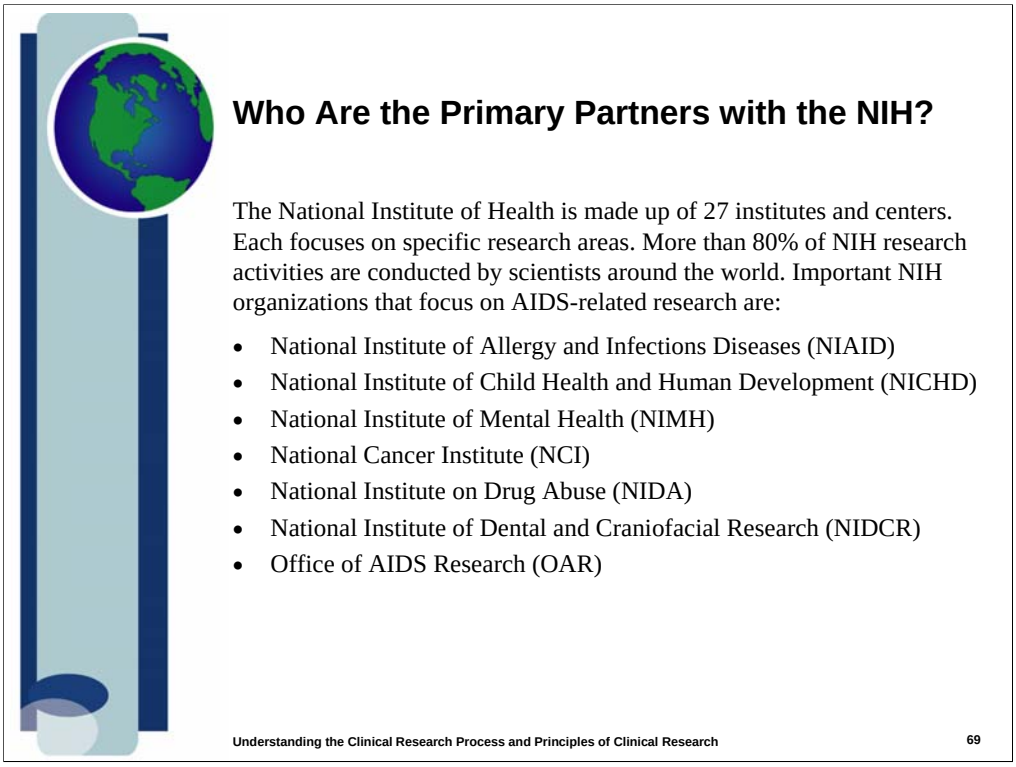

Participant Guide, page 33

Note: be sure to review the specifics of each bullet in the Participant Guide.

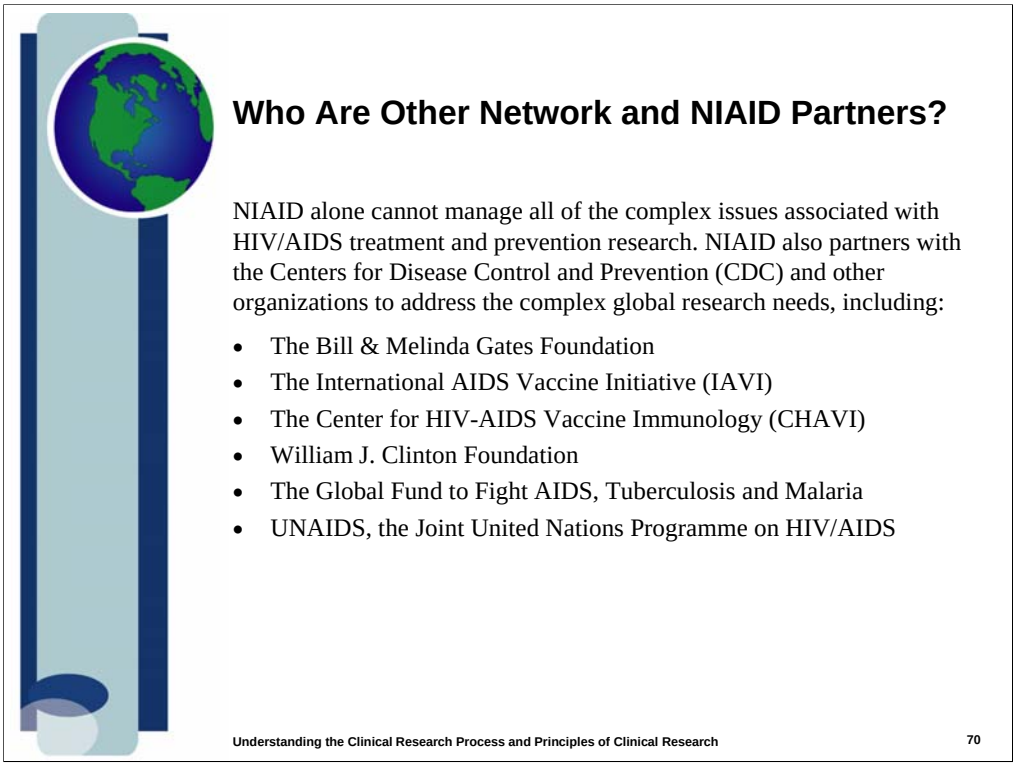



Participant Guide, page 34

Allow for questions and discussion.




Participant Guide, page 34

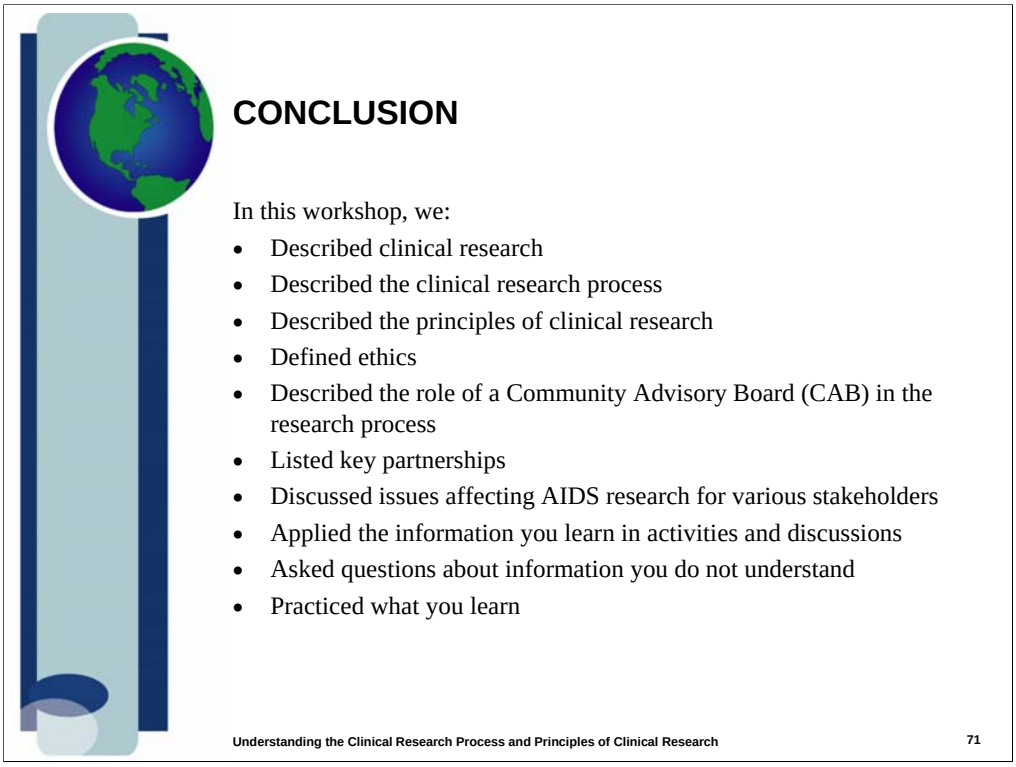



Participant Guide, page 35

Review the details of the bulleted items in the Participant Guide. Also review the last paragraph on the page to emphasize the importance of collaboration and the efforts of all.

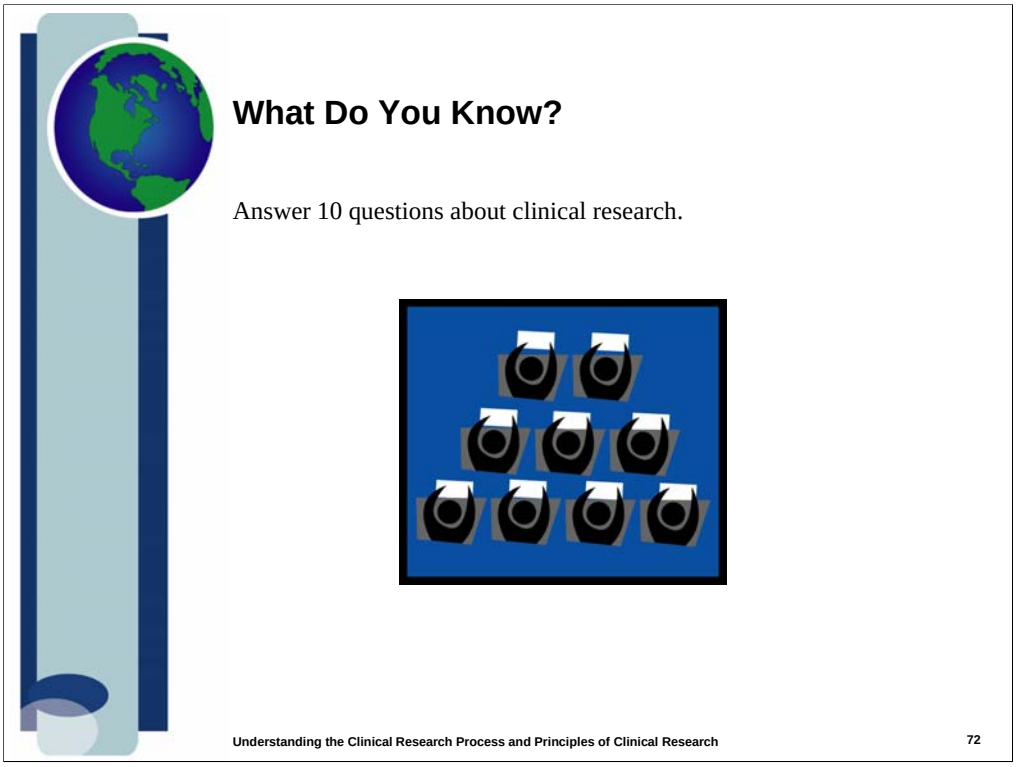
Allow for questions and discussion.

Summarize the module before going to the conclusion.




Participant Guide, page 36

This module will last approximately 20 minutes.




There is no Participant Guide page for this slide.

This activity functions as a post-test to find out how much participants learned about the information presented in this workshop. Avoid mentioning the word “test” so participants do not become stressed.

See the Instructor Guide for various options to deliver this activity. It can be delivered by using a handout or reading aloud the questions and asking for participant’s to provide the answers.

Answers to the questions are:

1a, 2a, 3c, 4b, 5g, 6a, 7a, 8a, 9e, 10c

If possible, ask participants to see if they received more correct answers now that they have attended the workshop:

•Congratulate participants who improved their scores

•Ask any non-improving participants if they learned new information after taking the workshop and emphasize that learning new information is most important.

After reviewing the answers:

• Review any items on the parking lot

•Allow for any final questions and discussions

•Ask participants to complete the Workshop Evaluation form at the end of their Participant Guides and turn it in to you before leaving

•THANK PARTICIPANTS for their contributions, energy, and attendance