



**DAIDS APPLIED RESEARCH TRAINING (DART)
INTRODUCTION TO CLINICAL RESEARCH
COURSE**

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Introduction to Clinical Research

What is it?

The following activity is a self-paced video course activity. It is meant to provide a concise introduction to Clinical Research. The objective of this activity is to get participants ready to take full advantage of the session by thinking ahead about the content and begin to formulate ideas for active and open participation in the real-time event.

In the subsequent sections, you will find the instructions and materials needed in order to complete this activity.

How can I use this Activity?

This activity is good for a variety of events and purposes. The following list provides suggestions for these:

- Increase participants investment in live sessions.
- Connect participants with others who will also attend the session.
- Build interest and preparedness for an interactive session.
- Result in a personal connection with the facilitator.
- Keep participants engaged.
- New Employee Orientation.
- Office / Departmental Meetings.
- Training Events / Workshops.
- Webinars
- On Line / Skype Meetings
- Short Video / Presentation clips.

What Materials / Resources do I need?

- Introduction to Clinical Research _ Course _ Facilitator Instructions _ 19Sep2019
- DART Pre-Work Video - Located on the DART Website at this location:
https://edjassociates.com/dart_presentation/story_html5.html
- Computer access
- Your Team

How long does it take?

Make the pre-work assignment available for participants at least one week prior to the event for them read and reflect. The course itself will take from 20 to 30 minutes to complete. Since it is designed as a self-paced activity, participants might use more time to complete the course.

How do I prepare?

First, access the DART website and verify you have access to the course, then proceed with the following steps:

- Launch the Introduction to Clinical Research Video (DART Pre-Work Video).
- Become familiar with the content.

How do I do it?

Now you are ready for the next steps. As a facilitator, do the following:

- Open the program located on the DART Website at this location: https://edjassociates.com/dart_presentation/story_html5.html
- Use the navigation keys (**Pre /Next**) at the bottom right of the slide to go **back** or **forward** as shown below.



- Click the **Yellow Button** (see the above and below pictures) on the right side of the slide to read additional information on the topic presented.



- Click the **Star Symbol** at the left side of the Additional Information text box to return to the main slide.

Non-IND Requi

Additional Information

A non-IND study would be an observational study that assesses if counseling, community education, and promoting safe, sexual practices would reduce the occurrence of HIV. In this study the Sponsor is not seeking regulatory approval.

- Institutional Rules/Regulations
- Local IRB/IEC Guidelines
- ICH E6(R2) GCPs

- Locate the **audio button** placed at the bottom of the left side of the slide. Use this to adjust the volume as needed (see the below picture). This video course has audio; unmute your speakers or use your headphones to be able to listen.

E6 Consolidated Guidelines (1996)

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Efficacy Guidelines

The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/ pharmacogenomics techniques to produce better targeted medicines.

IRB/IEC	Investigator	Sponsor	Protocols/Amendments	Investigator's Brochure	Essential Documents
Responsibilities	Qualifications	Medical expertise	Trial design	General considerations	Before a trial
Composition	Medical oversight	Investigator selection		Contents	During a trial
Procedures	Compliance with protocol	Monitoring			After a trial
	Informed consent	Reporting			

Click here to adjust volume

How to Change the Pre-Work Video Course?

This course is a self-guided interactive learning course that was developed for DART. It is not editable at this time.

How can I modify this activity?

Don't want to use this as a pre-work video activity? That will be perfectly fine! The beauty of this activity is that you have multiple ways to go about it. For example, you could share

portions of the training to your colleagues at a meeting or take screen shots of specific portions of the module and create a PowerPoint presentation.