DAIDS Applied Research Training (DART)
Safety/Safety Oversight

Table of Contents

Safety / Safety Oversight Activity

What is it?

The objective of the following activity is to facilitate and generate group work and discussion for participants to be able to understand the importance of safety oversight and reporting, differentiate between different types of safety occurrences during clinical trials as well as identify different safety events.

During this activity participants will work in two (2) team-based exercises. First, they will listen to a Case Study narration followed by a role play re-enactment. Second, they will read a case study. In both instances, as a group table, participants will discuss and answer a set of guided questions and report to the larger audience their responses. In the subsequent sections you will find the instructions and materials needed in order to complete this activity.

When can I use this Activity?

This activity is good for a variety of events and purposes. The following list shows alternatives ways to use it:

- Self-Reflection and reviewing concepts learned during an event
- New Employee Training
- Cooperative Learning
- Team Building
- Critical Thinking
- Refresher Training
- Risk Analysis
- Individual self-assessments
- Training Meetings/Events
- Conferences
- Group Annual Retreat
- Office/Departmental Meetings

What Materials / Resources do I need?

- Safety Oversight Facilitator Instructions 16Dec2019
- Safety Oversight Slide Deck 16Dec2019
- Safety Oversight Role Play Activity 16Dec2019
- Safety Oversight Role Play Activity Guiding Questions 16Dec2019
- Safety Oversight Role Play Activity Answer Key 16Dec2019
- Safety Oversight Case Study Activity 16Dec2019

- Safety Oversight Case Study Activity Answer Key 16Dec2019
- Safety Oversight Quick Reference Card 14Aug2019

How long does it take?

Allow approximately Forty (40) minutes for the entire activity.

How do I prepare?

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

- Open the file: Safety Oversight Slide Deck 16Dec2019. Review the Power Point presentation and determine if you will want to use this during your activity. Feel free to add information or customize for the needs of your site.
- Open the file: Safety Oversight Role Play Activity 16Dec2019 (there is a narration and a dialog section in the document). Print four (4) copies, one for you and three (3) to distribute to the those participating in the role play.
- Select three (3) volunteers where one will be a Narrator and Principal Investigator and the remaining two (2) will do the role play. Make sure that the volunteers have time to become familiar with the script prior to beginning the activity.
- Open the file: Safety Oversight Role Play Activity Guiding Questions 16Dec2019 and print on standard paper and distribute individually during the activity.
- Open the file: Safety Oversight Role Play Activity Answer Key 16Dec2019 and print on standard paper and distribute individually after the activity.
- Open file: Safety Oversight Case Study Activity 16Dec2019 and print enough to distribute to all participants.
- Open the file: Safety Oversight Case Study Activity Guiding Questions 16Dec2019 and print on standard paper and distribute individually during the activity.
- Open the file: Safety Oversight Case Study Activity Answer Key 16Dec2019 and print on standard paper and distribute individually after the activity.
- Open file: Safety Oversight Quick Reference Card 14Aug2019. Print quick reference card on cardstock (optional), or standard paper according to your printer specifications and cut to size for distribution to the participants.

How do I do it?

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

- Make sure every table nominates a writer and a speaker to document each group response.
- The speaker will report answers to the other groups when called upon by the facilitator.
- Have narrator and role play volunteers come up to the front of the room to read their respective' s scripts.

- Make sure all learning participants are actively paying attention to the role play.
- Distribute individually during the activity the role play activity guiding questions.
- Make sure table groups discuss the role play activity questions and answer the activities guided questions as a group.
- Remind group of their time frame for reporting answers per activity. (Suggested time period to report per activity five (5) minutes. Adjust a needed).
- Once the participants have completed the activity, distribute individually the Safety / Safety Oversight Role Play Activity Answer key.
- Distribute individually during the activity the Safety Oversight Case Study.
- Distribute individually during the activity the Safety Oversight Case Study activity guiding questions.
- Ensure all participants are reading individually the assigned case study. As they read, remind them to take notes in their activity sheet to use during group discussion.
- Make sure table groups discuss the case studies and answer the activities guided questions as a group.
- Once the participants have completed the activity, distribute individually the activity the Safety Oversight Case Study Answer Key.
- Remind group of their time frame for reporting answers per activity. (Suggested time period to report per activity four (4) to five (5) minutes. Adjust a needed).
- Distribute to each participant a copy of the Safety Oversight Quick Reference Card.

How can I modify this activity?

Don't want to use the provided role play and case study? That will be perfectly fine! The beauty of this activity is that you have multiple ways to go about it. For example, you can create you a new role play, and a case study activity based on real and prior cases / studies you and your staff might have experienced or worked on.

Or, you can review what are the Principal Investigator's responsibilities with regards to safety, such as protect safety of subjects, assess causality, review and file Expedited Safety Reports (ESRs) to mention a few.

Another alternative is to have your staff differentiate between the different types of safety events that occur during clinical studies, identify safety events and verify they are fully documented and are reported in accordance with protocol and case report form.

Also, during a site meeting, training or event, provide your staff with existing or past safety events and determine whether all these safety events were reported within the timeliness required by Good Clinical Practices (GCP), Institutional Review Board/Independent Ethics Committee (IRB/IEC), sponsor, and applicable regulatory requirements.

In addition, you can review all safety events at your site to get ready for a monitoring visit.