



# DAIDS APPLIED RESEARCH TRAINING (DART) SOURCE DOCUMENTS (SD)

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# Source Documents Activity

## What is it?

The objective of the following activity is to facilitate and generate group work and discussion by having participants examine a source document verification case-based scenario. Participants will reflect, discuss, and answer a set of guided questions and report to the larger audience.

## 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
- Mock Monitoring/Audit visits
- Critical Thinking
- Identify Areas for Improvements
- Categorize Trends
- Refresher Training
- Risk Analysis
- Individual self-assessments
- Training Meetings/Events
- Conferences
- Group Annual Retreat
- Office/Departmental Meetings

## What Materials / Resources do I need?

- Source Documents Facilitator Instructions 15Nov2019
- Source Documents Slide Deck 15Nov2019
- Source Documents Activity 15Nov2019
- Source Documents Activity Answer Key 15Nov2019
- Source Documents Quick Reference Card 14Aug2019

## How long does it take?

Allow for approximately thirty minutes to complete 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: Source Documents Slide Deck 15Nov2019. Review the Power Point presentation and determine if you will use this during your activity. Feel free to add information or customize for the needs of your site.
- Open the file: Source Documents Activity 15Nov2019. Determine if you will be printing all 4 of the scenarios (there are 4 case-based scenarios in the document). You can distribute 1 scenario per table, or a combination depending on how many people are participating. Be sure that every participant has a copy so they can write their answers in the worksheet. Print the Activity worksheets on standard size paper according to your printer specifications.
- Open the file: Source Documents Activity Answer Key 15Nov2019 and print enough to distribute after the activity.
- Open File: Source Documents Quick Reference Card 14Aug2019. Print quick reference cards 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 speakers will report answers to the other groups when called upon by the facilitator.
- Distribute a set of 2 or 4 case-based scenarios to each table.
- 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 the group discussion.
- Make sure table groups discuss the case studies and answer the activity guided questions as a group.
- Remind group their time frame for reporting answers. (Suggested time period to report three to four minutes. Adjust as needed).
- Encourage participants to include additional commentaries from other groups in their individual activity answer sheet.
- Distribute the Source Documents Answer Key to all participants.
- Distribute a copy of the Source Documents Infographic to each participant.

## How can I modify this activity?

Don't want to use the provided scenarios? That will be perfectly fine! The beauty of this activity is that you have multiple ways to go about it. For example, you can ask participants to review the concept or define Source Documents, Electronic Source Documentation and its role on clinical trials. Also, you can ask participant to generate a list of Source Documents, (e.g. Progress notes, Subject's study, clinical, Subject diaries, or hospital charts (paper or entered into the Electronic Medical Record (EMR) to mention a few).

Or, you can conduct a Source Document verification activity at your site to get ready for a monitoring visit. Look at data discrepancy, revise the Source-Data Investigator Responsibilities, verify if your site's source documents are adhering to Accurate, Legible, Contemporaneous, Original, Attributable, and Complete, Consistent, Enduring and Available (ALCOA-C) principles and if staff/participants understand the importance of it in Source Documentation.

In addition, they can conduct their own Quality Control by identifying and correcting errors within their own documents and adhere to Good Documentation Practices (GDP) and identify any trends reflected on their findings

Another alternative is to have your staff to look at your site documents and to differentiate between Source Documents and Essential Document.