DAIDS Applied Research Training (DART) Essential Documents (ED)

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National Institute of Allergy and Infectious Diseases

DART

Essential Documents Activity

What is it?

The objective of the following activity is to facilitate and generate group work and discussion by sorting and identifying documents that meet the Essential Documents (ED) criteria per clinical trial phase (Before, During and After Completion or Termination of the clinical trial). In addition, participants will be asked to identify and correct errors to demonstrate adherence to Good Documentation Practices (GDP). 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
- 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?

- Essential Documents Facilitator Instructions 15Nov2019
- Essential Documents Slide Deck 15Nov2019
- Essential Documents Activity 15Nov2019
- Essential Documents Label List 15Nov2019
- Essential Documents Label List 15Nov2019
- Essential Documents Activity Rubric 15Nov2019
- Essential Documents Activity Rubric Answer Key 15Nov2019
- Essential Documents Quick Reference Guide 15Nov2019

How long does it take?

Allow approximately sixty 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: ED Slide Deck 15Nov2019. 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: ED Activity 15Nov2019. There are 10 documents included in this file (Eight of these documents are ED, the other two are Source Documents, these are meant as distractors for the activity). Some of the documents are intended to print double-side (for example, the Form 1572). Determine if you want to use just one or two of the essential documents of if you will use all 10 in the activity. Print on standard size paper according to your printer specifications.
- Open File: ED Label List 15Nov2019. These are the labels that will be used in the activity. Print ED Label List on Avery File Folder Labels (optional) or on cardstock, or standard paper (cut to size).
- Open the file: ED Activity Answer Key 15Nov2019 and print according to the size of your audience (There are eight answer key documents included on the file which are associated with ED). Some of the documents are intended to print double-side (for example, the Form 1572).
- Open the file: ED Activity Rubric 15Nov2019 and print on standard paper and distribute individually or by group table.
- Open the file: ED Activity Rubric Answer Key 15Nov2019 and print on standard paper and distribute individually or by group table.

How do I do it?

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

- Distribute a set of 5 or 10 Essential Documents to each table.
- Ask participants to individually, review document selected and match label document title with the correct label document description.
- Verify participant are identifying document type and title.
- Direct participants to read assigned documents and identify/highlight Good Document Practices (GDP) errors. They will need to identify the number and nature of the errors found in each document.
- Remind participants to correct errors according to GDP guidelines.
- Distribute Essential Documents Rubric for participants to complete individually or as a group based on the documents completed by table.
- Once the participants have completed the activity, distribute the final and correct version of each document by group table.

- Verify participants review their previous answers based on document final version and answer sheet and rubric answer key.

How can I modify this activity?

Don't want to sort and identify these documents? That will be perfectly fine! The beauty of this activity is that you have multiple ways to go about it. For example, you can use your study Essential Documents and examine if they all meet the critical elements. You can look at your site's Form 1572 and compare it to the one included in this activity and examine if yours meet the appropriate criteria.

Or, you can have your staff review the Essential Documents at your site to get ready for a monitoring visit. 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).

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

Also, during a meeting, training or event provide your staff with existing Essential and Source Documents and have them articulate, identify the nature and purpose of Essential Documents and its importance and relevance to clinical trials.