Introduction to Protocols





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Powere

In this video, we introduce the first component of an experiment – the protocol.



In ARM, a protocol is a plan for an experiment. Essentially it is a *template* containing the design and instructions to perform trials.

The protocol is then used to create a trial, which is the *realization* of the plan. Multiple trials can be created from a single protocol, for different trial locations in the study.



A protocol primarily consists of:

- treatments to test,
- planned assessments, and
- study rules to enforce requirements.

All of the information entered in the protocol is copied and used in the trial.



It may be tempting to throw together a quick protocol in order to generate a trial and start entering data, but an incomplete protocol will lead to inconsistent results.

Instead of setting up the protocol to *create trials*, you should set up your trials *by filling out* the protocol.



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Enter Treatment and Application details to communicate exactly how the treatments should be formulated and applied. Clear descriptions can eliminate follow-up questions or miscommunications - which could ruin a trial!

(The Protocol Product Amount Totals report can calculate the amount of product needed across all trials planned for the study.)

Entering planned assessments will communicate to the trialist what data must be recorded for this experiment. Having this information pre-filled in the trial also ensures that data is entered consistently.

Here is an example of a simple % control assessment that was entered 3 different ways by 3 different people. Spending just 1 more hour to add assessment headers can save 10 hours of standardizing trial data that was entered in different ways. (Selecting terms from the ARM dictionaries also cuts down on this "diversity" in entering information.)

Leveraging study rules also improves consistency of trial data, and protects critical information. Study rules communicate important data fields that should be completed, define requirements, restrict trialists from changing key information, and can even hide confidential information when necessary.