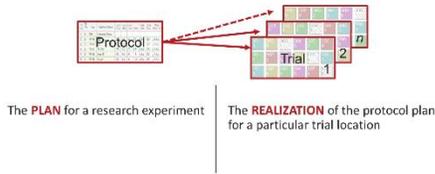


## Elements of a study



In this video, we introduce ARM trials, and demonstrate the process of creating one from an existing protocol template.

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

## Trial Components

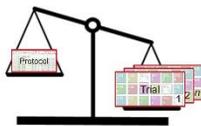
- Treatment Randomization
- Site Description
- Assessment Data



A trial primarily consists of: the treatment randomization, site information, and data from assessments.

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.

## Incomplete Protocol → Inconsistent Trial



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

Note that this does not just apply to sponsors sending out many trials in a given year. A complete protocol from last year is an excellent starting place for a similar study the following year! See our video series on the basics of setting up a protocol to start off on the right foot.

**Trial Location**  
Insert row with Shift+F7, Delete current row with Shift+F8

Trial ID	Responsible	Site	Number of Trials	Site Requir
Create Trial	Name	1		
Edit TrialMap	Trialist2	2		
MakeAnApplication	Trialist3	1		
RecordSiteInfo	Trialist4	1		
EnterData	Trialist5	1		

Total Trials:

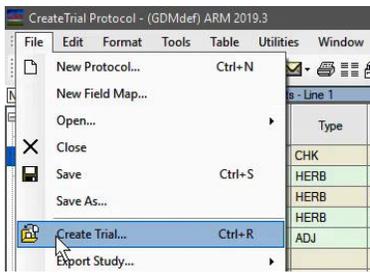
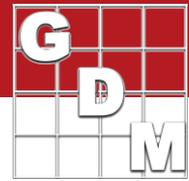
- Show Validation List...
- Accept All Changes
- Create this Trial
- Merge Protocol Description
- Show Tooltip
- Remove Split
- Required
- Recommended
- Hidden Field
- Delete Study Rule
- Save Rule Set...

To create a trial, first open the protocol in ARM. You can follow along by using the tutorial protocol 'CreateTrial'.

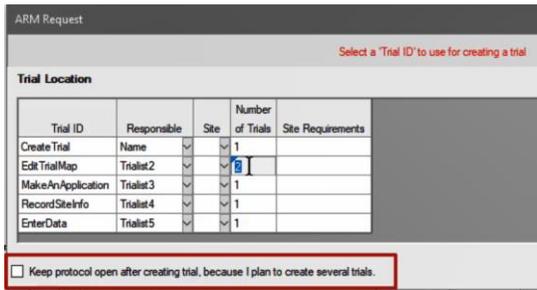
You can use the Trial Location table in the Protocol Description to plan out the trials that will be created from this protocol. This includes the Trial ID, the investigator responsible, and even the number of trials to create for that person.

Right-click on the planned trial you wish to create, and select 'Create this Trial' to begin the process.

# Creating a Trial

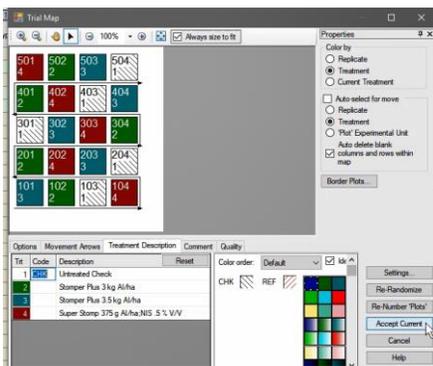


Alternatively, you can create a trial from any editor by selecting File > Create Trial. If you have filled in the Trial Location table, it is presented now. Otherwise if the table is empty, ARM skips this step of the process.

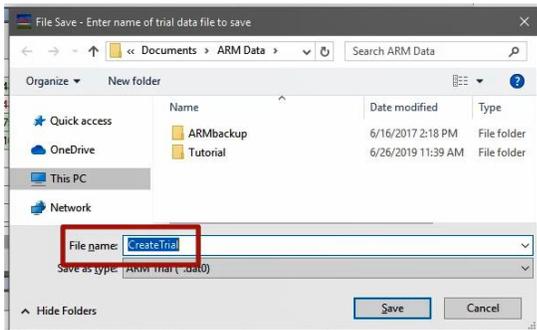


It is easy to create multiple trials in a row, when choosing a location with several trials and selecting this option. ARM opens each trial in a new window, so the protocol remains open for additional trials to be created.

We will keep it simple this time, and just choose to create one trial.



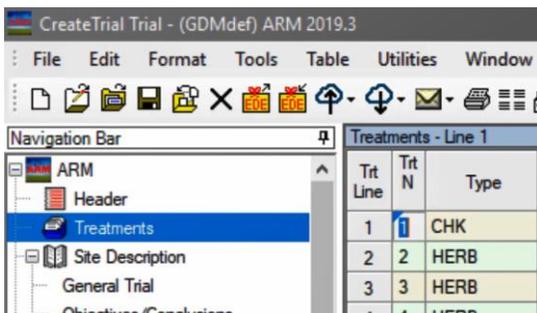
Next, the Trial Map dialog opens, to edit the treatment randomization. We cover this dialog in more detail in another video. For now, let's accept the randomization that ARM gives us.



Now save the trial file. The Trial ID is the default file name, but the file can have a different name if desired.

Trials are saved with the d-a-t-zero extension, and can be stored on a cloud drive, network drive, or your local PC.

We will just save this file in the default location – the 'ARM Data' folder in the Documents folder.



Now the trial has been created and opened. Note that the top Title bar has been updated to list the trial name, the type of file opened, and the study definition of the file (chosen when we first created the protocol).