

Pre-Defined Randomization Files

Use a pre-defined randomization to quickly load preferred trial randomizations when creating trials in ARM. This approach is much faster than editing randomizations after creating a trial. Create a pre-defined randomization using File – Export Study – Data Export menu choice in ARM. The following examples display ARM 9 dialogs, and also apply for newer ARM versions.

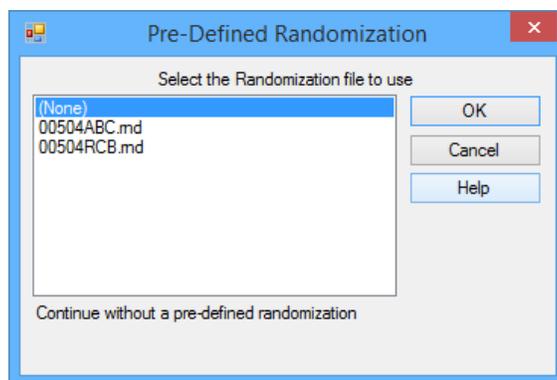
Introduction

Use randomization files (*.RND) to utilize saved preferred trial randomization plans when creating a trial. A valid .RND file must match the current protocol based on number of treatments and replicates. The number of treatments in the randomization file must exactly match number of treatments in the protocol.

During the process of creating a trial, ARM first identifies randomizations that match based on the number of treatments, and then discards ones with fewer replicates than are defined on General tab of Window - Settings for the protocol. Any randomization files for more replicates are preserved, since they may be valid for the protocol.

ARM displays the Pre-Defined Randomization dialog during the trial creation process when valid randomization files are available in the study definition directory. Select a pre-defined randomization from the list, or select "(None)" to create a new randomization. If at least one pre-defined randomization files exists but none are valid, a message box is displayed.

The following example illustrates the Pre-Defined Randomization dialog when two randomization files are available for a five treatment, four replicate protocol:



Creating Randomization Files

Create pre-defined randomizations (*.RND) using the Data Export command (File, Export Study, Data Export). The saved randomization contains the current trial randomization in a format used to supply a fixed randomization to use when creating a new trial. Randomizations must be stored in the study definition directory (in ARM, see Tools – Options – File Tab).

The file naming that must be followed for a randomization file is "TtRrXxx.RND" where:

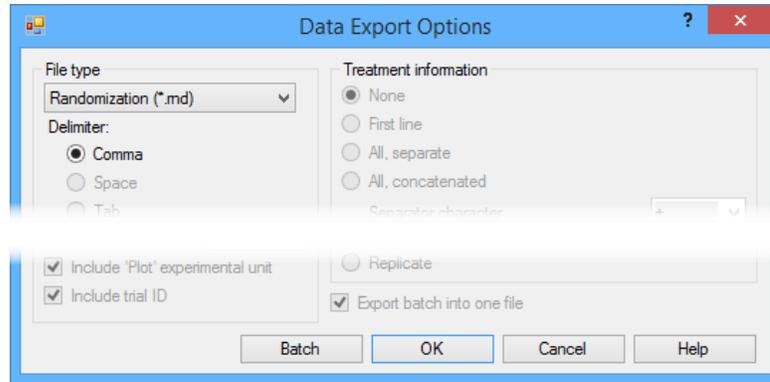
- "Tt" is the number of treatments (zero-padded)
- "Rr" is the number of replicates (zero-padded)
- "Xxx" is what the user wishes to add to define a unique name when more than one randomization file may be stored for a given combination of treatments and replicates.

For example, a 12 treatment and 3 replicate randomization file for a RCB experimental design could be named, "01203RCB.RND".

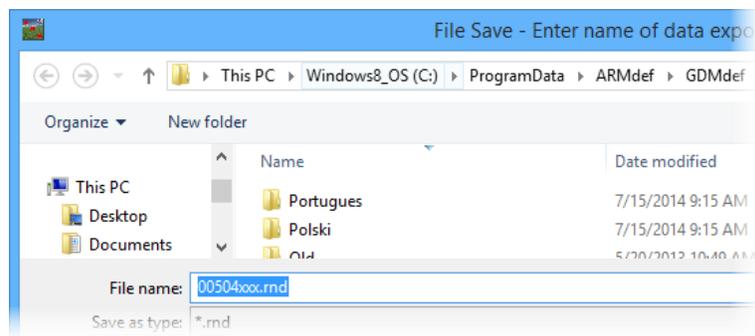
Follow the below steps to create a randomization file from an existing ARM trial:

1. Start ARM.
2. Select File – Open Trial and select the trial that contains the randomization you wish to save.
3. Display the Trial Map (Window – Trial Map) to verify the randomization, and then close the trial map before proceeding.
4. Select File – Export Study – Data Export.

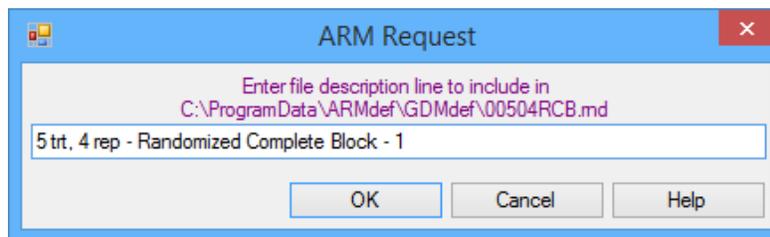
5. Select the File Type by clicking the down arrow and selecting Randomization (*.RND) from the list, and then select OK.



6. The File Save dialog displays next. Since our example trial contains 5 treatments and 4 replicates the file name defaults to 00504xxx.RND. Change the last three characters denoted by “x” to save the file with a unique file name.



7. Select the Save button to continue.
8. Enter a description for the randomization on the ARM Request dialog, then select OK.

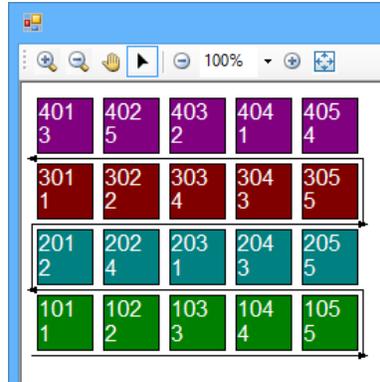


9. The randomization file 00504RCB.RND is created in the current study definition directory. To verify the current study definition directory path, select Tools – Options – File tab.

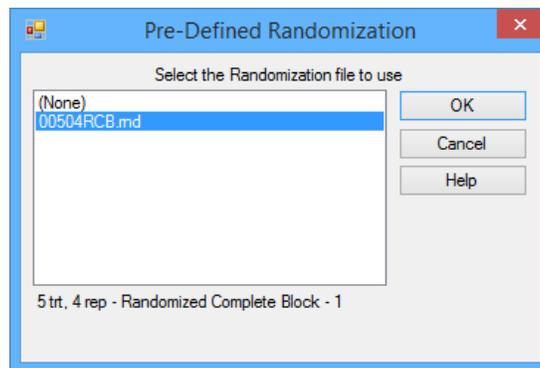
Using a Pre-Defined Randomization File

ARM displays the Pre-Defined Randomization dialog during the trial creation process when valid pre-defined randomization files are present in the current study definition directory. A valid randomization file matches the number of treatments in the current protocol, and at least the number of replicates for the protocol. Select a pre-defined randomization (*.RND) from the list, or select “(None)” to create a new randomization. If at least one .RND file exists but none are valid, a message box displays to notify that no pre-defined randomizations are available for the current protocol.

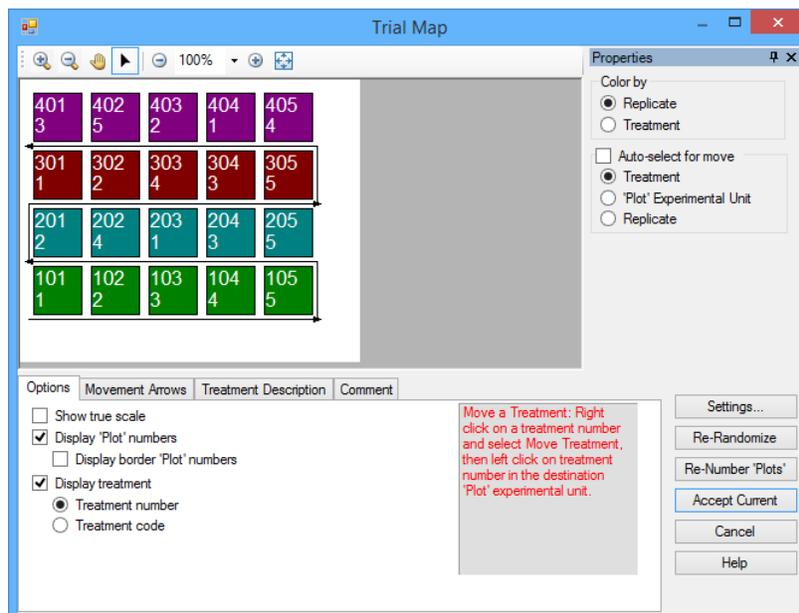
The following example uses the pre-defined randomization, 00504RCB.RND, for the five treatment four replicate trial example in the previous section on creating a randomization:



1. To use this example randomization file, first create a protocol with five treatments, and four replications defined in protocol Settings.
2. Select File – Create Trial. The Pre-Defined Randomization dialog displays:



3. Select 00504RCB.RND file and select OK.
4. The Trial Map dialog displays next. Notice the randomization matches the randomization saved in the previous section:



5. Select the Accept Current button to use the Pre-Defined randomization shown.