



# Study Rules

## Overview:

1) **Overview** - Study Rules are a method for the protocol writer to:

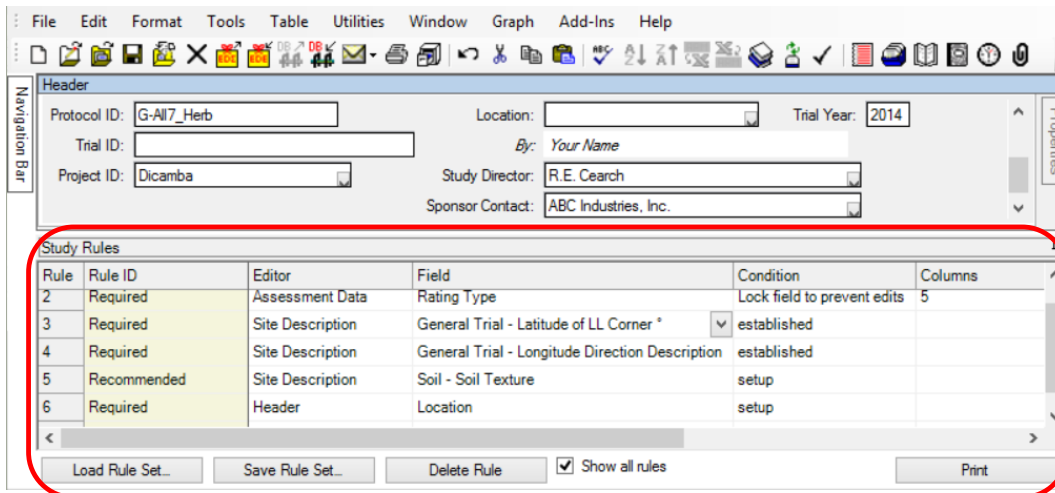
- Identify for trialists the important data entry fields that should be completed.
- Define additional requirement for trials conducted from the protocol.

Study rules:


- Are defined using Study Rules panel in a protocol, and are carried automatically to trials created from the protocol.
- Only the owner of a protocol can define study rules (or trial owner, to create rule sets).
- "Belong" to the protocol writer, and cannot be changed or deleted by anyone else.
- Can be saved into rule sets for easy portability of rules between protocols.
- Are enforced in trials by "required field" validation, which identifies blank data entry fields where information must be entered.

2) **Example:** A protocol writer can use study rules to identify information requirements that *should* (Recommended) or *must* (Required) be fulfilled in the trial. For example, as displayed on the screen below, a protocol writer may specify that:

- GPS location information *must* be entered into a trial when trial status is "Final" (a "Required" rule):
- Fertility Level and Overall Moisture Conditions *should* be entered when trial status is "Final" (a "Recommended" rule).




3) When rules are defined for a study, the Study Rules panel displays automatically. To display the Study Rules panel in a new protocol or when rules are not defined, select "Study Rules" from the Tools menu. Use the study rules panel to define new study rules. (The Study Rules menu command is disabled for any ARM licensed user who does not own the current study.)

4) **Note:** To *determine study ownership*, open the study and click the About Study toolbar button  (or select Tools - About Study from menu). The ARM license GDM ID code of the study owner displays here:



To determine the ARM license GDM ID code *of the current ARM login*, select Help - About ARM from the ARM menu. The license information displays here:

This product is licensed to:  
 Steven R. Gylling  
 Gylling Data Management, Inc.  
 Serial number: 2948  
 GDM ID code: GYGYST

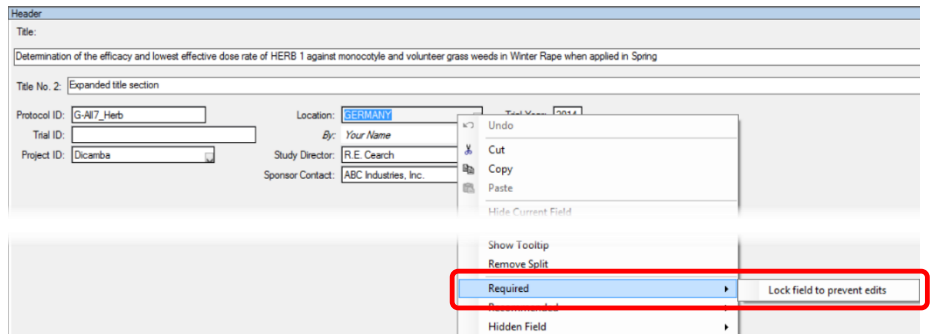
- 5) Validation - select Tools - Validate Trial or click the Validate Trial icon  to validate a trial that is open. Validation also occurs automatically when a trial is exported (File - Export - EDE or Database), or when sent by email (File - Send To).

Following is the process to define and use study rules.

- 1) Study Rules Panel. New study rules can only be defined by the owner of the current protocol or trial. To display the Study Rules panel in a protocol, either:
  - a) Create a new protocol (of which the current ARM licensee is automatically the study owner).
  - b) Open a protocol that was previously created by the current ARM licensee.
- 2) Defining Rules. While study rules are defined in protocols, the simplest way to create Header and Site Description field study rules is by using right-click menus in a trial for which you are the owner (create protocol, then create trial from that protocol).

For example, to define Location field in Header of a G-All7 trial, first display Study Rules panel by selecting Tools - Study Rules, then:

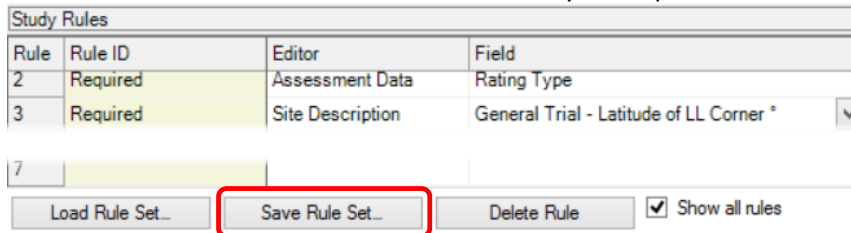
- a) Right-click in Location field.
- b) Select 'Required', then choose 'Lock field to prevent edits'. Notice that Location field is now highlighted with a special background color that identifies the field as one that requires an entry.



Change the 'Condition' to set the timing of the rule.

By linking to status, when trial status is set to 'established' by trialist, if location is not entered, the trial will fail validation.

- c) Continue adding additional Header and Site Description study rules.
- d) Select 'Save Rule Set' button at bottom of Study Rules panel.



- e) Name the rule set with an appropriate name for purpose of the study rules. For example, 'All efficacy trials.rls', or 'Post-emergence weed trial.rls'.
- f) Create or open protocol that should contain study rules, and select Tools - Study Rules to add rules panel.
- g) Select 'Load Rules Set', and select the appropriate rule set such as 'All efficacy trials.rls'.

h) Continue adding additional rules as appropriate for that protocol by selecting 'Load Rules Set' button and choosing additional relevant rule sets.

3) Assessment Rules. Use assessment rules to: **Required** Assessment Data Rating Type

Lock field to prevent edits  
 With assessment data  
 Modify SE Name if entry changed  
 Lock field to prevent edits  
 Consistent entries across SE Name

a) Require that assessment header fields to be filled when assessment data is entered.

b) Lock an assessment header field to prevent or restrict changing an existing field entry. The purpose is to notify trialist about key assessment description fields that should not be change.

c) Automatically fill an assessment header field with the same field entry in a series of linked assessment columns. For example, consider a SE (Standard Evaluation) with two data columns: a disease severity column plus an Abbott transform of the severity. The same pest, crop, and assessment date should be entered in both data columns. The SE is entered into data columns 2 and 3 of a protocol.

Column Number	2	3 (Calculated)
Pest Type		
Pest Code		
Crop Code		
Part Rated	LEAF3 P	LEAF3 P
Rating Date		
Rating Type	PESSEV	PESSEV
Rating Unit	%	%UNCK
Number of Subsamples	1	1
SE Group No.	2	2
SE Name	disease seve	disease seve
ARM Action Codes		TAB[2]

Notice that "SE Group No." field is 2 for both linked data columns which is how ARM tracks the linked column relationship:

These study rules define the automatic linkage of field entries between the two data columns.

Study Rules					
Rule	Rule ID	Editor	Field	Condition	Columns
24	Required	Assessment Data	Rating Date	Consistent entries across SE Name	2 3
25	Required	Assessment Data	Crop Code	Consistent entries across SE Name	2 3
26	Required	Assessment Data	Pest Code	Consistent entries across SE Name	2 3

d) Change the SE Name field entry when a key assessment header field entry for that SE is modified. ARM changes SE Name by adding parentheses around the name, showing the SE has been changed in a way (different Assessment Type or Assessment Unit) so assessments from the modified SE should not be combined with assessments from the original SE. Sponsors use this linkage to prevent combining assessments that are different than were planned in the original protocol.

**How to:**

- 1) Prevent trialist from changing Trial ID defined in protocol by protocol owner.
  - a) Use 'Condition' of 'Lock field to prevent edits'
  - b) Use the 'Permissions' of 'All protocol owners'

Study Rules							
Rule	Rule ID	Editor	Field	Condition	Columns	Permissions	Owner ID
1	Required	Header	Trial Number	Lock field to prevent edits		All protocol owners	GYSTRE
2	Limit validation list	Assessment Data Header	Crop & Pest in Site Description	Always		All protocol owners	GYSTRE
3	Lock Trial ID as position 1	Assessment Data	Image Attachments	Always		All protocol owners	GYSTRE
4	Strict Validation	Treatments				All protocol owners	GYSTRE
5	Recommended	Trial	Image Attachments	One or more Plots	1	All protocol owners	GYSTRE
6	Hidden Field	Protocol Description	Trial Establishment Guidelines - Responsible	If not in my company		All protocol owners	GYSTRE
7							

Show all rules

- 2) Ensure that every crop and pest in assessment header has been described in the trial site description.
  - a) Use 'Rule ID' of 'Limit validation list'
  - b) Denote the appropriate 'Editor' of 'Assessment Data Header' and 'Field' of 'Crop and Pest in Site Description'
  - c) Use 'Condition' of 'Always'

Rule	Rule ID	Editor	Field	Condition	Columns	Permissions	Owner ID
1	Required	Header	Trial Number	Lock field to prevent edits		All protocol owners	GYSTRE
2	Limit validation list	Assessment Data Header	Crop & Pest in Site Description	Always		All protocol owners	GYSTRE
3	Lock Trial ID as position 1	Assessment Data	Image Attachments	Always		All protocol owners	GYSTRE
4	Strict Validation	Treatments				All protocol owners	GYSTRE
5	Recommended	Trial	Image Attachments	One or more Plots	1	All protocol owners	GYSTRE
6	Hidden Field	Protocol Description	Trial Establishment Guidelines - Responsible	If not in my company		All protocol owners	GYSTRE
7							

Show all rules

- 3) Enforce that trial ID is always the first portion of plot pictures.
  - a) Use 'Rule ID' of 'Lock Trial ID as position 1'
  - b) Select 'Editor' of 'Assessment Data' and 'Field' of 'Image attachments'
  - c) Use 'Condition' of 'Always'

Rule	Rule ID	Editor	Field	Condition	Columns	Permissions	Owner ID
1	Required	Header	Trial Number	Lock field to prevent edits		All protocol owners	GYSTRE
2	Limit validation list	Assessment Data Header	Crop & Pest in Site Description	Always		All protocol owners	GYSTRE
3	Lock Trial ID as position 1	Assessment Data	Image Attachments	Always		All protocol owners	GYSTRE
4	Strict Validation	Treatments				All protocol owners	GYSTRE
5	Recommended	Trial	Image Attachments	One or more Plots	1	All protocol owners	GYSTRE
6	Hidden Field	Protocol Description	Trial Establishment Guidelines - Responsible	If not in my company		All protocol owners	GYSTRE
7							

Show all rules

- 4) Ensure trialist selects only information in the associated validation list.
  - a) Use 'Rule ID' of 'Strict Validation'

Rule	Rule ID	Editor	Field	Condition	Columns	Permissions	Owner ID
1	Required	Header	Trial Number	Lock field to prevent edits		All protocol owners	GYSTRE
2	Limit validation list	Assessment Data Header	Crop & Pest in Site Description	Always		All protocol owners	GYSTRE
3	Lock Trial ID as position 1	Assessment Data	Image Attachments	Always		All protocol owners	GYSTRE
4	Strict Validation	Treatments				All protocol owners	GYSTRE
5	Recommended	Trial	Image Attachments	One or more Plots	1	All protocol owners	GYSTRE
6	Hidden Field	Protocol Description	Trial Establishment Guidelines - Responsible	If not in my company		All protocol owners	GYSTRE
7							

Show all rules

- 5) Recommend trialist to take plot pictures for key assessment columns.
  - a) Use 'Rule ID' of 'Recommended'
  - b) Select 'Editor' of 'Trial' and 'Field' of 'Image Attachments'
  - c) Denote in 'Column' which column in assessment data image should be attached.

Rule	Rule ID	Editor	Field	Condition	Columns	Permissions	Owner ID
1	Required	Header	Trial Number	Lock field to prevent edits		All protocol owners	GYSTRE
2	Limit validation list	Assessment Data Header	Crop & Pest in Site Description	Always		All protocol owners	GYSTRE
3	Lock Trial ID as position 1	Assessment Data	Image Attachments	Always		All protocol owners	GYSTRE
4	Strict Validation	Treatments				All protocol owners	GYSTRE
5	Recommended	Trial	Image Attachments	One or more Plots		All protocol owners	GYSTRE
6	Hidden Field	Protocol Description	Trial Establishment Guidelines - Responsible	If not in my company		All protocol owners	GYSTRE
7							

Show all rules

- 6) Hide confidential protocol information from trialists who receive the protocol.
  - a) Use 'Rule ID' of 'Hidden Field'
  - b) Denote the appropriate 'Editor' and 'Field'
  - c) Select 'Condition' of 'If not in my company'

Rule	Rule ID	Editor	Field	Condition	Columns	Permissions	Owner ID
1	Required	Header	Trial Number	Lock field to prevent edits		All protocol owners	GYSTRE
2	Limit validation list	Assessment Data Header	Crop & Pest in Site Description	Always		All protocol owners	GYSTRE
3	Lock Trial ID as position 1	Assessment Data	Image Attachments	Always		All protocol owners	GYSTRE
4	Strict Validation	Treatments				All protocol owners	GYSTRE
5	Recommended	Trial	Image Attachments	One or more Plots	1	All protocol owners	GYSTRE
6	Hidden Field	Protocol Description	Trial Establishment Guidelines - Responsible	If not in my company		All protocol owners	GYSTRE
7							

Show all rules