# **Best Practices for Companies using ARM**

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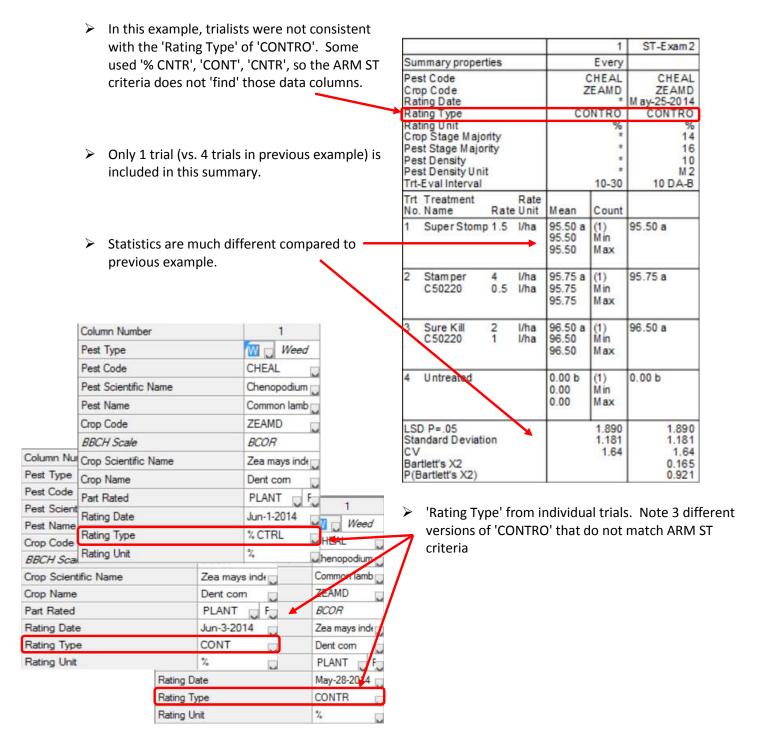
# **ARM ST Examples**

A well-defined ARM protocol vs. a textual Word document that only provides generalities can make a large difference in the efficiency of summarizing results across a trial series. This is especially applicable when trials are completed by multiple trialists with a company, or by external contract researchers or CROs (Contract Research Organizations).

# Example ST Summary with consistent data headers

CONTRO defined as			j		1	ST-E xam1	ST-Exam2	ST-Exam3	ST-Exam5
'Rating Type' and used	Summary prope	rties			Every				
consistently across									
multiple trials - 4 in this	Pest Code				CHEAL	CHEAL	CHEAL	CHEAL	CHEAL
•	Crop Code Rating Date			2	EAMD	ZEAMD	ZE AMD May-25-2014	ZE AMD	ZEAMD May-28-2014
example	Rating Date Rating Type			co	NTRO	CONTRO	CONTRO	CONTRO	CONTRO
	Rating Unit				%	%	%	%	%
	Crop Stage Maj	ority			*	16	14	16	16
	Pest Stage Majo	rity				16	16	16	12
	Pest Density				*	12	10	12	12
	Pest Density Un Trt-Eval Interval				10-30	17 DA-B	10 DA-B	15 DA-B	13 DA-B
	Trt Treatment No. Name	Rate	Rate	Mean	Count				
	1 Super Stom	p 1.5	I/ha		(4)	54.50 c	95.50 a	89.25 a	65.75 b
Statistics show summary —				54.50 95.50	M in M ax				
across the 4 experiments	2			19.35	StDev				
' ·	2 Stamper	4	I/ha	85.56 a	(4)	75.75 a	95.75 a	92.00 a	78.75 a
	C50220	0.5	I/ha		M in				
				95.75 9.80	Max StDev				
	3 Sure Kill	2	I/ha	80.34 b	(4)	66.00 b	96.50 a	93.25 a	65.63 b
	050220	1	I/ha		M in	00.00 D	50.50 a	53.23 a	03.03 0
	5.5225		,,,,,		Max				
				16.83	StDev	ξ.			
	4 Untreated			0.00 d	(4)	0.00 d	0.00 b	0.00 b	0.00 c
				0.00	M in				
					M ax StDev				
	LSD P= .05			0.00	2.569	5.504	1.890	4.139	8.964
	Standard Deviat	ion			3.582	3.441	1.181	2.587	5.604
	CV				5.92	7.01	1.64	3.77	10.67
	Bartlett's X2					0.317	0.165	5.523	5.192
	P(Bartlett's X2)					0.853	0.921	0.063	0.075

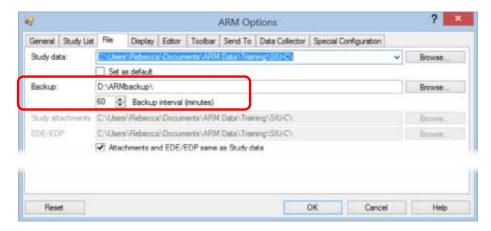
# Example ST Summary with inconsistent data headers



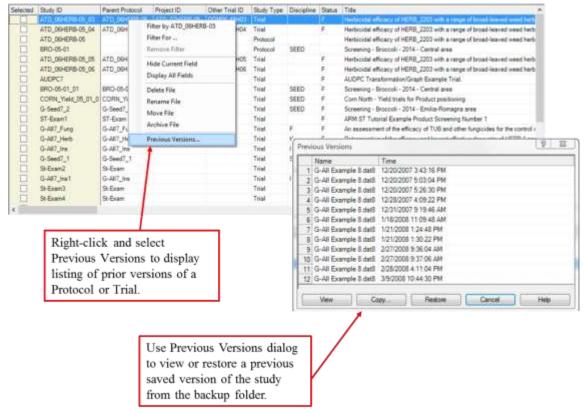
# **Prepare ARM**

# Use SD card to backup ARM

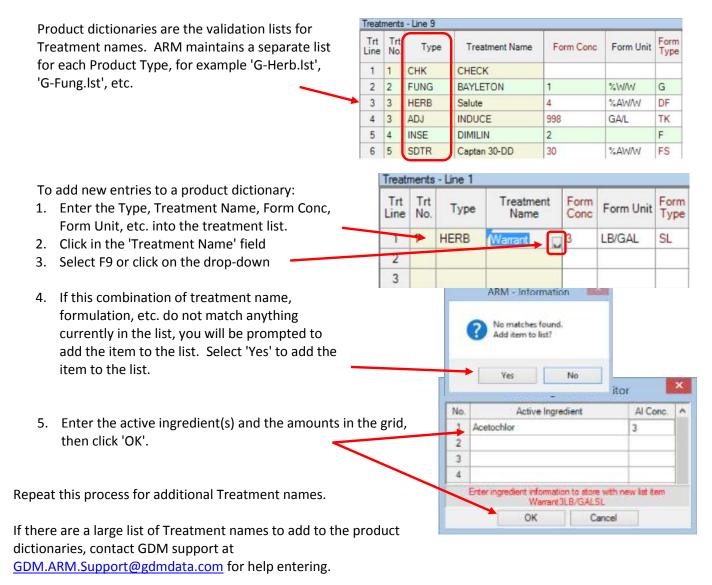
- ➤ Use SD card as ARM backup device to ARM can keep automatic previous versions of all protocol and trial changes.
  - 1. Go to Tools Options, File tab. In this example, 'D' is an SD card.
  - Set the 'Backup interval'.
  - 3. Click OK



This feature maintains a history of all saved ARM study versions, providing security against losing information from mistakes or hardware failures.



# Prepare ARM product dictionaries



GDM can also provide an optional Access database for maintaining and distributing product updates within a company.

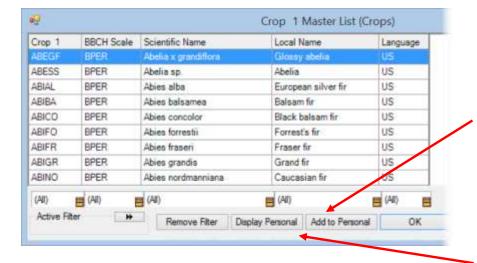
# Build personal lists for key master lists

Similarly, personal lists can be created from key master lists, such as Crop, Pest, Part Rated, etc., by adding to the personal list.

To add items to a person list:

 In ARM, go to the field that a personal list is to be built, for example, Crop (in Protocol Description, Crop/Pest Description tab).





- 2. Select F9 to open the validation list for Crop.
- 3. Begin typing the first few letters of the crop to display.
- 4. Once the crop of interest is found, select the 'Add to Personal' button.
- 5. To add additional crops to person list, continue searching for crops and selecting 'Add to Personal' button.
- 6. To view items added to Personal list, select 'Display Personal' button.

# Distribute product dictionaries and personal lists

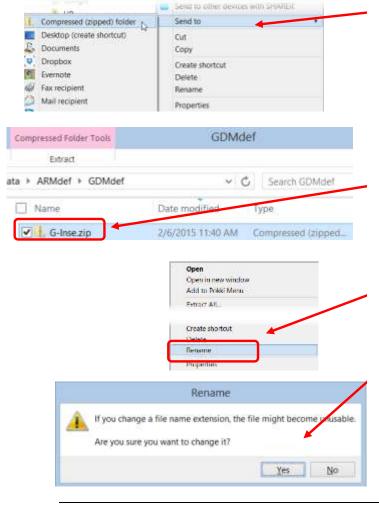
Once product dictionaries and personal lists have been updated, distribute them to other users in your

organization. To do this, follow these steps:

 In Windows Explorer, go to C:\ProgramData\ARMdef\GDMdef folder.

Select the updated dictionary (list) files to be distributed to others.





3. Right-click and select 'Send to - Compressed (zipped) folder'.

- 4. A 'ZIP' file is created that contains the list files.
- 5. Re-name the file by right-clicking on the file and selecting 'Rename'. Rename to 'GDMdef.a7z'.
- Select 'Yes' to Rename.
  Note: The 'GDMdef' tells ARM where to place the list files, and the 'a7z' file extension requires simply double-clicking for ARM to apply the lists.
- 7. Distribute the 'a7z' file to other users in your organization.

# The Importance of a well-designed Protocol

#### Header

#### Protocol ID

- Identify an ID system the company will use for all protocols, such as 2016-XYZ-Soy-FR
  - Year
  - Project or product
  - Sometimes crop or pest
  - Location code such as country or region

## Trial ID

- ldentify a similar ID system the company will use for trials. Typical components:
  - Year
  - Project or product
  - o Sometimes crop or pest
  - Location code such as country or region
  - Trialist

#### Title

A brief statement of trial objectives, including crop, product and goal

# Example Header below:

Header					
Title:					
Test STRA_	15 as insecticide in brassica against Brev	vicoryne brassicae			
	[		lo		T. 13
Protocol ID:	Example Best Practice PRT	Location:	Central and South EU	~	Trial Year: 2015
Trial ID:		Ву:	Dr. Bernd Stratmann		
Project ID:	Example PRT Best Practice	Study Director:	Dr. Bernd Stratmann		U
		Sponsor Contact:	Sponsor name		U

# **Detailed Treatment List**

#### **Product names**

> Entered consistently with accurate formulation concentration

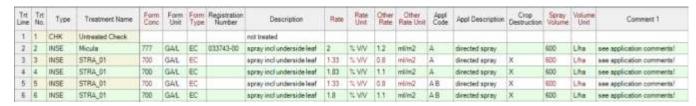
# Application rates and timings

> Include for all products

# **Application Codes**

- > Use to identify treatments with repeated applications
- Identify what each code means
- > This also helps ensure Protocol Product Amount Totals report includes product for each planned application

#### Example Treatments below:



## **Key Assessments**

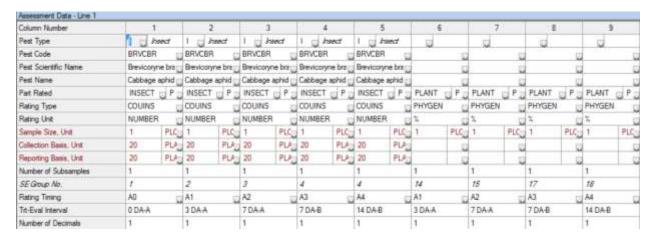
# Identify fields at minimum for key assessments:

- Part Rated
- Rating Type
- Rating Unit

# Others may include:

- Pest
- Pest Density Unit
- Evaluation timing

#### ARM Action Code

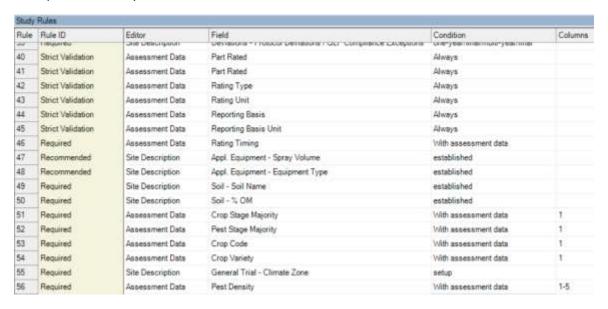


# **Use Study Rules**

# Clearly identify key trial information fields to complete

- Required fields
- Recommended fields
- > Timing of the rule

#### Example set of Study Rules below:



# Use well-written protocol to identify other key information for conducting the trial

When preparing protocol, be aware that frequently the person who is actually performing trial work is **not** the person with whom the sponsor contact is typically working. The trialist is often a technician who is instructed by the primary contact in the contractor organization. The better that requirements are

described in a protocol, the better the actual trialist is equipped to know and understand how to conduct and describe the trial.

# **Objectives**

- Clearly state the objectives of the trial.
- May include background information on the purpose of the study.

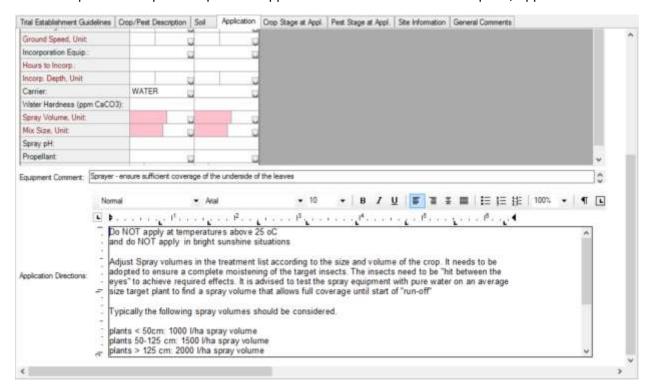
An example of a desirable objective is listed below:

In the past few years, generic alternatives to name brand herbicides have begun to appear on store shelves in Anywhere, USA. These generic herbicides usually have the exact same active ingredient as the name brand product, although the "inerts" as described on the label may differ. "Inerts" are simply additives to the herbicide that may help the products solubility, stability over time, tolerance to cold temperatures, etc. Generic herbicides often differ as compared to their name brand counterparts in terms of these additives. Generic herbicides also may differ in the solvent used. An example would be the name brand using vegetable oil as a solvent as compared to a generic herbicide using petroleum based solvent. Differing inerts and/or solvents can impact performance of herbicide in the field. Finally, generics may differ in the quantity of active ingredient contained within the product. This is easily checked by referring to the label. GenericHerbicides, Inc. is a company that produces many generic alternatives to common name brand herbicides. Examples include HerbiSyde which is similar to the herbicide CLAIM1, and their herbicide SilverSyde which is similar to the herbicide CLAIM2. Both HerbiSyde and SilverSyde contain the same active ingredient, at the same concentration, as their name brand counterparts, but the "inerts" are probably not the same, although it is impossible to know from the information presented on the herbicide label. The objective of these herbicide trials is to compare the effectiveness of HerbiSyde and SilverSyde to their trade name competitors CLAIM1 and CLAIM2, when applied as individual plant leaf sprays or stem sprays to weedy place.

## Application details

- Special equipment
- > Timing of applications
- > Type of application

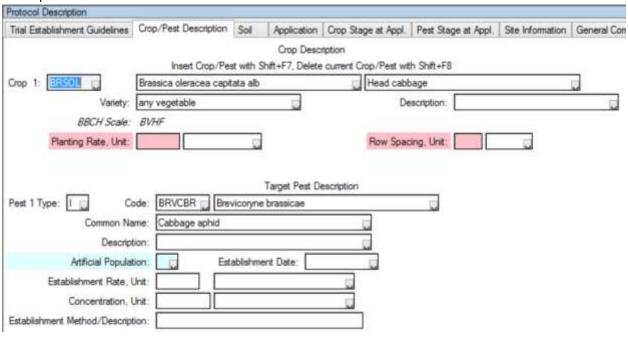
#### Below is a partial example ARM protocol Application details in Protocol Description, Application tab:



# **Crop Information**

- > Specific variety or hybrid to plant
- Seeding depth
- Seeding rate
- Seed size
- Use of seed treated seed or 'naked' seed

Below is an example of Crop information from an ARM protocol, Protocol Description, Crop/Pest Description tab:



# Site Requirements

- Crop rotation details
- > Irrigation requirements
- Drainage
- ➤ Soil types, texture, pH range

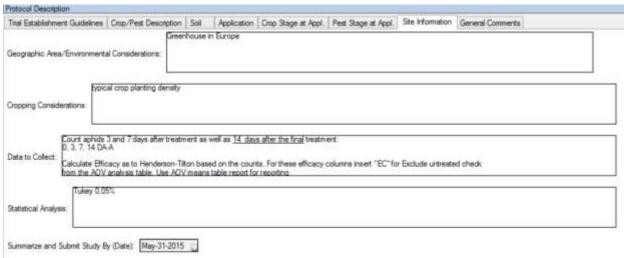
## Soil Sampling

- > Timing of sampling
- > Handling of samples
- > Types of analysis to be completed on soil samples

#### Date for Final results

- > Date final results are needed.
- > If interim results, dates as well.

Below is an example of Site requirements from an ARM protocol, Protocol Description, Site Information tab:

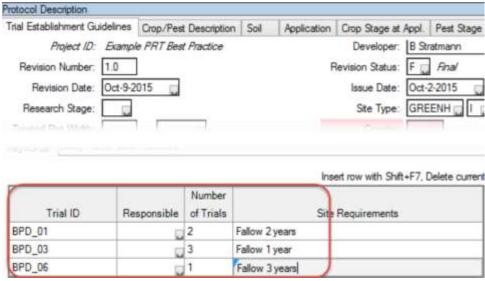


# Clearly identify expectations of what information the trialist must provide

- Photographs
- Raw data
- Whether trialist should provide interim results (or next day results posted on a cloud site such as Dropbox)
- Whether to notify the Sponsor Contact immediately if trialist observes something "unusual or noteworthy"
- ➤ Whether trialists' conclusions are expected as part of the finalized trial

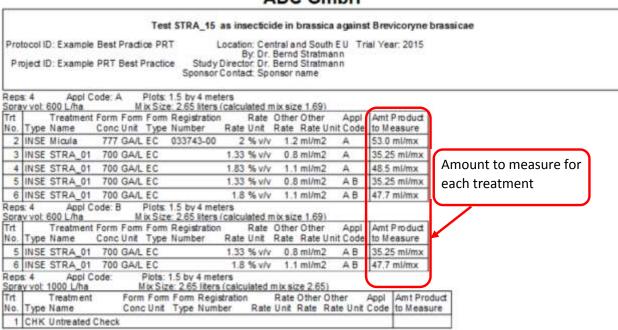
## Product planning

Complete the trial distribution table in Protocol Description, Trial Establishment Guidelines to calculate and fill Total Trials (or at least manually enter the expect Total Trials).



Print a Protocol Spray/Seeding Plan to get details for all applications for one protocol.

# ADC GmbH



Sort Order: Application Code, Treatment

> The Protocol Amount Totals Report lists total product requirements for all planned trials (Total Trials Is a multiplier).

Product quantities required for listed treatments and applications of trials included in this table:

Amount*	Unit	Treatment Name	Form Conc	Form Type	Lot Code	Amount of each
66.250	mi	Micula -	777	EC		product needed for
312.038	ml	STRA_01	700	EC		one trial

- \* 'Per area' calculations based on spray volume= 1000,600 L/ha, mix size= 2.65 liters (mix size basis).
- \* Product amount calculations increased 25 % for overage adjustment.
- \* 'Per volume' calculations use spray volume= 1000,600 L/ha, mix size= 2.65 liters.
- \* Adjusted for multiple applications in treatment list.

Product quantities required for listed treatments and applications across multiple studies:

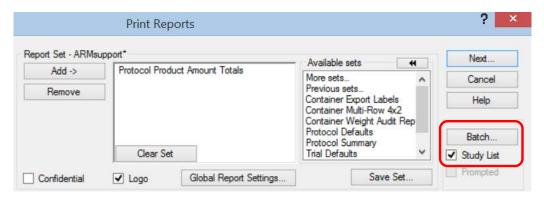
Amount*	Unit	Treatment Name	Form Conc	Form Type	Lot Code
397.500	ml	Micula	777	EC	
1,872.225	ml	STRA_01	700	EC	

Amount of each product needed for entire protocol (6 trials)

C:\U sers\Rebecca\Documents\ARM Data\Example Best Practice.prt

- \* 'Per area' calculations based on spray volume= 1000,600 L/ha, mix size= 2.65 liters (mix size basis).
- \* Product amount calculations increased 25 % for overage adjustment.
- \* 'Per volume' calculations use spray volume= 1000,600 L/ha, mix size= 2.65 liters.
- \* Adjusted for multiple applications in treatment list.
- \* Product amounts adjusted for the 6 trials planned for this protocol.

> To obtain product amount totals across several protocols, use Select Batch to choose the group of protocols, and use Protocol Product Amount Totals report. Product amount totals are across all protocols for all planned trials.



# Validate protocol

- Validate the protocol to ensure consistency in spelling and the use of proper terms from validation lists.
- ➤ The keyboard shortcut: CTRL + A performs checks of the current protocol, and refreshes field entries for copy default fields. ARM may also perform additional checks depending on which study definition the current protocol uses.
- The keyboard shortcut: CTRL + E performs the same checks as validate, but does not stop at the first error. This option displays a log of all validation errors when validation is completed.

#### Best Practice - Merge - From ARM Study

- ➤ Use Tools Marge From ARM Study to include information from previously written similar protocols, rather than attempting to remember what information to include, or copy/pasting the information.
- > See this detailed document for instructions and examples of using the Merge feature.

# Use 'Send To - External Sponsor/Cooperator'

- ➤ Use the 'Send to External Sponsor/Cooperator' to provide CROs with protocols.
  - o Include a protocol report set that is printed as a pdf
  - In the email created by ARM, open the report pdf and verify that all needed information is included, and that the information is correct and complete.
- See this website link for details
- It is risky to send a PRT file attached to an email message, because the protocol may not have been validated, and thus the CRO may be prevented from using it to create a trial.

## CROs should use 'Send To - External Sponsor/Cooperator'

- CROs should use the 'Send To External Sponsor/Cooperator' to provide sponsors with interim or final trial results.
- See this website link for details

- CROs should send interim or next-day results to sponsor in order for sponsor to track progress of each trial.
- CRO sends actual ARM trial, and sponsor overwrites previous interim trial and opens in study list. Previous versions of the past interim trials are kept automatically in the ARM backup folder.

# Sponsor receives trial from CRO

- When the sponsor receives a trial from the CRO, either interim of final:
- Open Zip file from email and save files to an ARM data directory, such as My Documents\ARM Data.
- 2. In ARM, open the trial. You may need to use the 'Browse...' button in the Study List to direct ARM to the newly saved trial.
- 3. Use Data Assessment Column Properties to review the data in each column.

 Use a ST criteria to check consistency of data entries in assessment headers and/or treatments.

