



Writing Those Pesky Deviations

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- Do's and Don'ts
 - Well written vs. Ambiguous/Obtuse
 - All “errors” are not created equal
 - Oops vs. Oh SHI&%^\$&*#(
 - Significant vs. Insignificant
 - But all require documentation
 - Help the Study Director
 - Needs to determine impact on the study
 - Provide sufficient information clearly so the SD can do their job

Don't...

- Put it off
 - I'll do it tomorrow



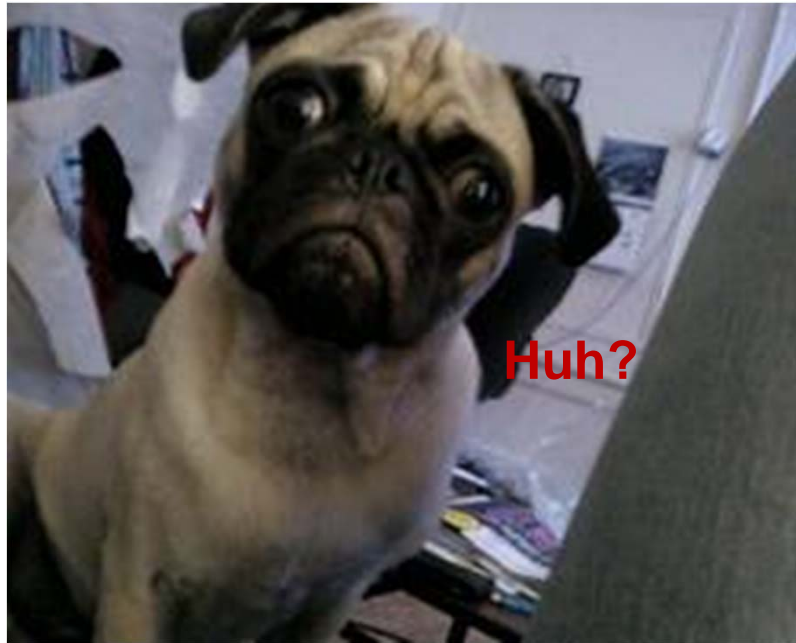
Don't...

- Make excuses
 - It wasn't my fault...



Don't...

- Be vague



Don't...

- Write too many words with no pertinent information



Don't...

- Write as if the reader has the notebook in front of them, because they won't.



Do...

- Write brief and clear statements
- Take responsibility (you can write “I...”)
- Communicate with SD
 - provide a draft if necessary
 - get your deviation “pre-approved”
- Note what is required:
 - Brief description of deviation
 - Explain why the deviation occurred

Do...

- Provide details
 - Actual number of fruit collected
 - Moisture percentage of hay or hops
 - Actual weight of samples
 - Number of days the application interval or PHI differed from the protocol

Some examples

- You decide
- Put on your Study Director hat
- Can you do your job (as SD)?
- What would make it easier to make the call on study impact?

Example Deviations



A well-written deviation

Provides all the information needed for the Study Director to determine the impact on the study

When it all goes South?

- Procedures for cancelling trials
 - Trial must have been initiated
 - Test substance applied
- Good news it doesn't happen very often
- First things first – SD must decide (hopefully with guidance)

When it all goes South?

- Are we starting another trial right away
 - Can we?
 - Time left in the season
 - Test Substance available
- Are we moving the trial
 - Another place or next year



When it all goes South?

- Starting another trial
 - Need a new field ID number
 - New protocol – signed amendment in hand
 - New notebook
 - Make copies of pertinent info for replacement trial
 - Generally TS information
 - New notebook out to FRD ASAP
 - “Old” notebook returned to Regional Field Office



When it all goes South?

- Call
 - Study Director
 - Regional Field Coordinator
- Put a plan in place
 - Immediate ASAP
 - Next Season
 - Different Location
- Unfamiliar – we'll walk you through it
- Ready, Aim, Fire NOT Ready, Fire, Aim



Questions?

- Deviations
- Replacement Trials
- Other stuff