# STUDY DIRECTOR PERSPECTIVE ON GLP ELECTRONIC NOTEBOOKS - REALITY IN REAL TIME

Laura Seastrum

Global Agricultural Development Corporation

Electronic notebooks can be a powerful tool for tracking and reporting field trial and study progress in real time. The benefits that electronic notebooks can provide regarding efficiency and the quality of trial data are often impacted by how the system is used. Following a few simple steps can improve the way electronic notebooks are utilized and facilitate communication between field researchers, laboratory personnel, project managers and sponsors that is crucial to the success of a study.



#### ADVANTAGES OF REAL-TIME NOTEBOOK MANAGEMENT



#### FIELD SITE

Lower risk of transcription errors.

Increased efficiency if data is entered directly.

Notebooks completed and submitted quicker.

Less time spent sending data via email.



#### LABORATORY

Aids in planning for sample receipt and scheduling for sample analysis.



#### STUDY MANAGEMENT

Potential issues that could result in deviations can often be avoided.

Facilitates timely updates to the sponsor on study progress.

Field phase of the final report can be written while waiting for completion of the analytical phase.



#### SPONSOR

Allows the sponsor to download real-time status reports.

Data can be used to make decisions about marketing strategy for the product.

# TYPICAL DETAILS NEEDED FOR A SPONSOR UPDATE

Trial coordinates
Test material receipt and lot number
Application/planting schedule
Crop variety and planting date
Application dates
Application rates
Sampling dates
Shipping dates
Sample receipt





#### COMMON CHALLENGES

## APPLICATION/PLANTIN G SCHEDULE

The schedule should be filled out and the notebook transmitted as soon as you get the protocol. Even if your trial will not start for several months, or the date is not certain, please add an estimated date. You can update it later as needed.

#### CRITICAL UPDATES

Notebooks should be updated as soon as possible after critical events.

Communication is key: things happen, but the study director needs to know what is going on.

#### MISSING DATA

PHI

Weather Data (absolute max)
Details on test substance
disposal.

Plot diagram – check to make sure all details are included.

# TIPS FOR SUCCESS!

### READ THE PROTOCOL CAREFULLY!

Always read the entire protocol, not just the tables. Check the protocol again before applications and sampling.

#### TIMELY ENTRY IS KEY!

Update and transmit electronic notebooks as soon as you have the information, not at the end of the season. Transcription from paper forms is not preferred, but if needed, should be done within a few days of the critical event.

#### CHECK YOUR ENTRIES

Take a moment to look over what you have entered into the forms. This is your best chance to catch errors while the details are fresh in your mind.

#### PROMPT QA REPORTING

Audit reports should be submitted to the study director no more than 30 days after the audit event.

#### ASK FOR HELP

If something in the protocol is not clear, or if you are having technical issues with the software, reach out to the study director.



### THANK YOU

Laura Seastrum

919-469-3600, x137

lseastrum@trustglobalag.co m

www.trustglobalag.com

