eNotebooks
A Perspective from the Field

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eNotebooks

• Very common in today’s GLP Research
• Companies using eNotebooks
• Overview of eNotebooks currently in use
• General eNotebook advice
• Issues you will encounter
• Other experiences
Companies Using eNotebooks

- Monsanto – eStudy / others?
- Bayer – FARM / eStudy
- BASF – FREDDY or PISAR / paper
- Syngenta – FERN / paper
- American Ag Service – iAdvantage / eStudy
- Valent – Field Trial Summary / paper
Advantage Field Trial Manager

- Computer-based
- Must be validated on each computer
- Updates sent manually
- Good flow and good guidance documents
- Version used by Syngenta for many years
- Used for 2016 studies
- Being replaced by eStudy
- Multiple users
eStudy

- Internet-based, no validation
- Requires an internet connection
- Mobile edition
- No manual updates required
- Very customizable
- Paper guidance available
- Multiple users
FERN

• Similar to Advantage
• Must still be validated but is automated
• Automatic data transmission
• Long, but excellent SOP with details explaining exactly what should be included
• Very easy for multiple users to access
ARM

- Computer-based
- Used for efficacy trials
- Trials can be conducted under GLPs
- Audit trail
- ARM training is available at NAICC
FARM

- Virtual machine-based (safe environment)
- Uninstall / reinstall each year
- No validation required at field level
- Useful tools for copying data between plots / trials
- Requires manual download / upload
- Guidance with screenshots available
FREDDY

- Software loaded from website
- No validation required at field level
- Originally used as a fully-compliant GLP notebook
- Recently used as a monitoring tool
- System prompt to upload new data
- Replaced by PISAR
PISAR

- Internet-based
- Full release in 2017
- Should be used with Internet Explorer
- Used as a monitoring tool
Valent

- Field Trial Summary
- Protected Excel spreadsheet
- Paper notebook is first point of entry
- Paper notebook and Field Trial Summary subject to QA review
- Updates sent manually by email
General eNotebook Advice

• Get trained
• Become familiar with SOPs or other guidance documents
• Make sure requirements listed in eNotebook match the protocol and SOPs
• Test software functionality
• Maintain close communication with SD / tech support
Issues You **Will** Encounter

- eNotebooks will fail
- Auto-filled cells will malfunction
- Batteries will go dead
- You will need to know your conversion equations
Other Experiences

- Test substance receipt/use/return
- Recording notes or other protocol required information
- Sample label generation
- Audit trails
- Generating deviations/GLP statements/QA statements
Conclusion

• Love – Hate relationship
• Gets easier with experience
• Pros / Cons
• Remember to attend training sessions regularly
• Communicate with PI / SD / tech support