

e-Data Working Group Update

Kim Hill, RQAP-GLP

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Topics

- e-Data Working Group Background
- White Paper Content
- Next Steps

e-Data Working Group Background

- January 2024 NAICC Meeting
 - ▶ Discussion during presentations about e-data
 - Possible for industry alignment for handling e-data?
 - Possible for Sponsors to align on what facility data to include in study files?
 - ▶ Those interested invited to first meeting
- NAICC is sponsoring the paper
- Participants
 - ▶ QA (Sponsor, Field, Consultant)
 - ▶ Analytical Lab Personnel
- EPA GLP Regulations
 - ▶ OECD GLP perspective

e-Data Working Group Background (continued)

■ Frequency of Meetings

- ▶ Every two weeks for most of 2024
- ▶ Every three weeks for 2025

■ Scope of the White Paper

- ▶ Any Testing Facility in the US, working under EPA GLPs, who use e-signatures and/or generate electronic data.

■ Purpose of the White Paper

- ▶ Provide practical guidance for QA, IT, study directors, and management teams responsible for ensuring compliant electronic data practices in agricultural research operations.

White Paper Content

■ Definitions

- ▶ Electronic file
- ▶ Electronic raw data
- ▶ Human Readable Format
- ▶ Certified Digital Copy
- ▶ Metadata
- ▶ Verified Copy
- ▶ PDF vs. PDF-A

White Paper Content (continued)

- General Information for instruments/computer systems
 - ▶ Validation should confirm system is fit for use; no need to validate unused functionality
 - Access permissions
 - User roles
 - ▶ Validate creation of human readable format, certified digital copy, or verified copies
 - ▶ Software updates
 - Backwards compatibility?
 - ▶ System retirement
 - Data migration?
 - ▶ Password or biometrics to access system
 - ▶ Unique ID

White Paper Content (continued)

■ e-Signatures

- ▶ Validate system used
- ▶ SOP for use of e-signatures and platform(s) used
- ▶ Statement that e-signature is equivalent to and as legally binding as a wet-ink signature
- ▶ Workflows
 - Include audit trail in study file, not as part of downloaded, signed document
 - Certificates

White Paper Content (continued)

■ Generating e-data

▶ Instruments

- Data file generated is considered raw data; no changes without means of tracking
- Follow prescribed naming convention for data files
- May be saved on instrument-specific computer and locked within the application; back-ups
- Typically archived at facility generating the data

▶ e-Notebooks/e-Forms

- Web-based or direct computer installation
- May be saved on test site servers and locked within the application; back-ups
- Typically archived at facility generating the data

▶ LIMS

- Saved within the LIMS and locked within the application; back-ups
- Archived at facility generating the data

White Paper Content (continued)

■ e-Data File Conversion

▶ Human Readable Format

- From proprietary format to human readable format without need of the system
- Include metadata, if possible; otherwise, maintain electronic raw data in archives
- QC review

▶ Certified Digital Copy

- Marked as such
- All pages are checked for clarity and legibility
- Verification statement, before distribution

White Paper Content (continued)

■ File Naming

- ▶ Indexing and retrieval
- ▶ Avoid proprietary information
- ▶ QA reports

■ Security

- ▶ Computers or systems that access internet or other sources
- ▶ Protect from unauthorized changes – password, encryption, permissions
- ▶ Changes to file

White Paper Content (continued)

- Archiving
 - ▶ Secure server or external device; data back-up
 - ▶ Same requirements as for paper data
 - Archivist control
 - Expedient retrieval
 - Archive log
 - Retention period
 - ▶ Password protection removed or provided to Archivist
 - ▶ If needed, copy provided
 - ▶ Changes to file

Next Steps

- Study Management companies and CROs to review (approved by the NAICC Board)
- NAICC Board to review
 - ▶ High-level overview to EPA in February 2026



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