Overview and Benefits of Electronic Regulatory Documentation Systems

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Overview of Electronic Regulatory Documents

- Electronic Trial Master File (eTMF) vs Electronic Investigator Site File (eISF)

- St. Jude Children's Research Hospital
  - Unique that we're sponsor and site
  - eTMF: Veeva Clinical Vault
  - eISF: Veeva SiteVault

Previous Trial Documentation Storage

- Paper Binder
- Shared Drive
- Home Grown System
- PDMS (St. Jude)
- Desktop

St. Jude Children's Research Hospital

Benefits

Finding cures. Saving children.

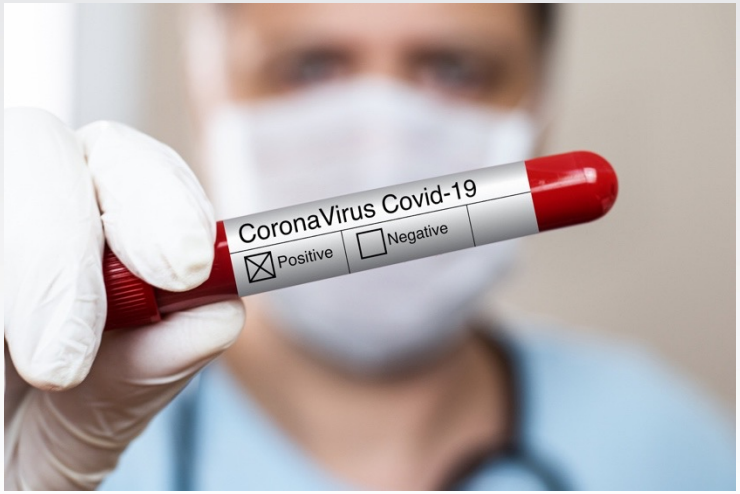
21 CFR Part 11 Compliant

- Validation
- Audit Trail
- Copies of Records
- Record Retention
- Enhanced Security

Remote Access

Veeva SiteVault is a Cloud Based Interface

- Study/Regulatory Coordinator
- Study Monitor/Auditor
- Essential in Time of a Pandemic



Real Time Benefits

- Tracking
- Viewing Documents
- Monitoring
- Data Exports
- Patient Safety

Ease of System

- Search and Find Documents
- Collaboration with IRBs/IECs
- Integration Opportunities
  - EDC
  - CTMS
  - E-Consent

Time and Money

- Shortened Clinical Trial Time
  - Speeding Startup and Closeout

- Cost Savings
  - Purchasing Paper
  - Storage of Paper Binders
  - Courier/Shipping Fees

Reporting and Analytics

- Visibility into Key Trial Performance Metrics
- Improved Audit and Inspection Readiness
- Custom Reporting
  - Documents
  - Studies
  - Persons

Stay Competitive

- Stay up to par with other Research Institutions
  - Many Institutions have already made the transition to Electronic Regulatory Documentation

- Deciding Factor from Sponsors for Site Selection

Conclusion

- Multitude of Benefits to having an Electronic Regulatory Document System
- Many Institutions are Moving Towards Electronic Regulatory Documentation
- In the Future, It Will Be Essential to Have an Electronic Regulatory Document System

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