Better Data, Better Studies: Software Solutions for Clinical Data Management

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Agenda

- Challenges Around Study Data

- Software Solutions

- How to Evaluate and Choose

Vocabulary to Know

- CDMS - Clinical Data Management System

- CTMS - Clinical Trial Management System

- CDR - Clinical Data Repository

- CRF / eCRF - Case Report Form / Electronic Case Report Form

- EDCS - Electronic Data Capture System

- "Study"

Common Challenges

- **Siloed data:**
  - data in different systems and formats

- **Data cleaning, analysis, and reporting:**
  - Cleaning, validation and QC
  - Aligning different data types, participant info, and time points
  - Reproducibility - knowing where a report came from

- **Secure data sharing and collaboration:**
  - Proper access control
  - Getting data publish-ready - de-identification
  - Providing audit trails
  - Regulatory Compliance

Benefits of a CDMS

- **Improved Data Quality**
    - Entry enforcement checks and QC monitoring
    - Minimize manual entry
    - Common data entry method for remote sites

- **Improved Data Structure**
    - Better analysis and reporting
    - Avoids many issues that can develop latter

- **Enhanced Collaboration**
    - "One source of truth" - a single access point for teams
    - More efficient coordination and workflows

- **Better foundation for regulatory compliance**
    - Rigorous auditing
    - Precise picture of who has seen what, and why

What to Look for in a CDMS

1. Support for diverse data types and formats

2. Easy data capture

3. Easy to work with different data types

4. Orientation toward clinical concepts and challenges

5. Rich reporting, querying, and data analysis

6. Support for external data analytics systems

7. Actively developed and supported

8. Robust security and regulatory compliance

Support for Diverse Data Types and Formats

- Diverse data: samples, multiple assays, clinical, demographic, and other data types.

- Support for many file formats: Excel, TSV, TXT, novel instrument formats, etc.

- The system must conform to your data, not vice versa

HOW LABKEY HELPS:

- LabKey has different data types for different scientific domains

- Flexible, easy to design, data tables

Easy Data Capture

- Many modes of capture:
  - Manual
  - Surveys / EDC
  - File import / bulk import
  - Pulling in data from other systems and DBs
  - Automated without human intervention

- Data validation, input enforcement rules

- Provide post-acquisition QC validation & annotation

- Support for correcting mistakes, and tracking corrections

HOW LABKEY HELPS:

- Diverse toolkit for data input

- Diverse toolkit for QC

Joining Heterogeneous Data

- The ability to join diverse data in ways that further your scientific inquiry

  Clinical Trial Example: sample, assay, & clinical data joined and aligned via participant and visit

HOW LABKEY HELPS:

- Easy joining of datasets with a graphical user interface

Orientation toward Clinical Concepts

- Does the system have built-in concepts?
  - Participant
  - Time point
  - Sample/Specimen
  - Cohort

- Ability to constrain and harmonize data based on clinical ontologies

HOW LABKEY HELPS:

- LabKey parses your data for participant ids, cohort information, time points, etc.

- Support for clinical ontologies of your choice

Reporting & Analytics

- Built-in visualizations, statistics, querying, and reporting

- Support for external data analytics systems, like Spotfire, Tableau, Excel, Access, MATLAB, R, SAS

- Standard data access methods, like JDBC & ODBC

- Direct integration with popular programming languages. R, Python, Java, JavaScript, etc.

HOW LABKEY HELPS:

- Rich built-in reporting tools

- Support for many popular external tools and languages.

Actively Developed and Supported

- **Look for actively developed, modern systems**
  - Is the software regularly updated?
  - Is the UI modern and easy to use?

- **Look for a vendor *partner***
  - Frequent upgrades, support, training, hosting
  - Customer-driven enhancements and fixes
  - Simple, transparent pricing

HOW LABKEY HELPS:

- Our product roadmaps are based on closely tracked customer requests

- Direct engagement with the LabKey service and dev teams

- Support for co-development with your development team

Robust Security and Compliance

- Integrate with existing institutional authentication systems

- Support different forms of access for users: Readers, Editors, Admins.

- Ability to partition the data easily & control access to each partition

- Support regulatory compliance controls: HIPAA, FISMA, CRF Part 11

HOW LABKEY HELPS:

- Special handling for patient data

- Intensive logging and audit trials

- Access control that records who saw what and why.

Evaluating and Choosing a CDMS

Steps to take:

1. Gather requirements
2. Survey the product options
3. Short list of options - deep dive
4. Choose and Implement

Gathering Requirements - Some Considerations

- What are your needs and priorities?

- What are your pain points?

- Be open to evolving requirements:
  - Initial assessments may be incomplete
  - As you become better acquainted with options, your reqs may evolve

- Good vendors will help you refine these requirements.

Evaluating Solutions - User Experience

- **Is the software easy to use?**
  - Is it relatively self-explanatory and discoverable?
  - Or do you need to constantly consult the docs?

- **What about the implementation effort?**
  - Weeks, months, years?

- **Is the software easy to learn and adopt?**
  - Does the vendor provide assistance?
  - Is training provided? What is the state of the documentation?
  - Is there an active client community that shares information?

Evaluating Solutions - Vendor Experience

- Does the vendor demonstrate engagement in the evaluation process?

- Is the vendor focused on *your* needs and goals?

- Will the vendor provide references?

- Does the vendor have transparent pricing?

- Note the evaluation relationship is a preview of the customer relationship!

Evaluating Solutions - Hands On Experience

- **Get hands on with products.**
  - Load your data and run the critical analyses & reports. Does this product meet your requirements? Is it easy to use?

- **"Guided Trials"**
  - Get access to trial product with training and vendor support.

- **Enter in a pilot engagement**
  - System design or proof-of-concept engagement with promising systems where appropriate
  - "POC" or "SDE" (Solution Design Engagement)

What's next?

Let's talk, schedule a meeting with us!

- Share information about your requirements and begin planning

- Learn about our solutions and how we can help

Questions?

(Please use Zoom Q&A)

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Evaluating Solutions - Communication with Vendors

- **RFPs - "Requests for Proposal"**
    - Can be a good first exercise for gathering requirements
    - Can be misleading if there is no follow up conversation with vendor

- **Demos**
    - Great way to get a sense of the product offering

- **Real Conversations**
    - Great way to get a sense of the product offering and the vendor demeanor.

Questions?

- Add your questions to the Chat function in Zoom

Next Steps

- Dedicated suite of study data management tools

- Robust security: data partitioning, institutional authentication, role-based access, compliance controls

- Designed with scalability and flexibility at the core

  - Automated data acquisition and multiple QC mechanisms

  - Ability to integrate large volumes and diverse data types

  - Clinical ontology support for import and annotation

- Supports all popular data analytics systems, APIs, languages

- Continuous enhancement

- Supported trial, pilots

- Our training and world-class support

- A great vendor experience, great evaluation experience

- We want you to make the right decision for your long term advantage