Overcoming Challenges in Information Integration
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The necessity of information integration in multi-center clinical trial operation management

The Need and Challenges
The Differing Systems

One Central Application?

- Clinical Trial Data
- Safety Reporting
- Study Management
The Necessity

- Decrease in available funds but an increase in expectations
- Manage risk by reducing redundancy and reconciliation for the ultimate goals of:
  - Protect the safety of the subject data
  - Guarantee quality of the study
  - Decrease retrospective activities
  - Reduce human effort to manage human errors
- Ensure rapid trial execution to ensure availability to those in need
- Increase the need to be green
The Necessity (2)

- Centralization of information for greater access
  - Globalization of efforts
  - Early assessments of trial progress
- More effective communication
- The demand is here to stay
  - Immediate gratification is our culture
  - The need to know as soon as possible
Challenges

- Complexity of integration dependent upon
  - Differences in trial workflows
  - System flexibility
    - Regulations change
    - Protocols change
  - Financial resources
- EDC data has differing challenges
  - Multiple data sources
  - Cost to receiver or sender?
  - Enforce data standards or not?
Challenges (2)

- Technology integration can be costly upfront
- The need for drugs and therapies for critical needs
- Immerging technologies - how do we keep up with them?
- Browsers’ continual upgrades
- End user configuration issues
  - Institutional standards
- Can one system meet all of our needs?
- Vendor versus home grown