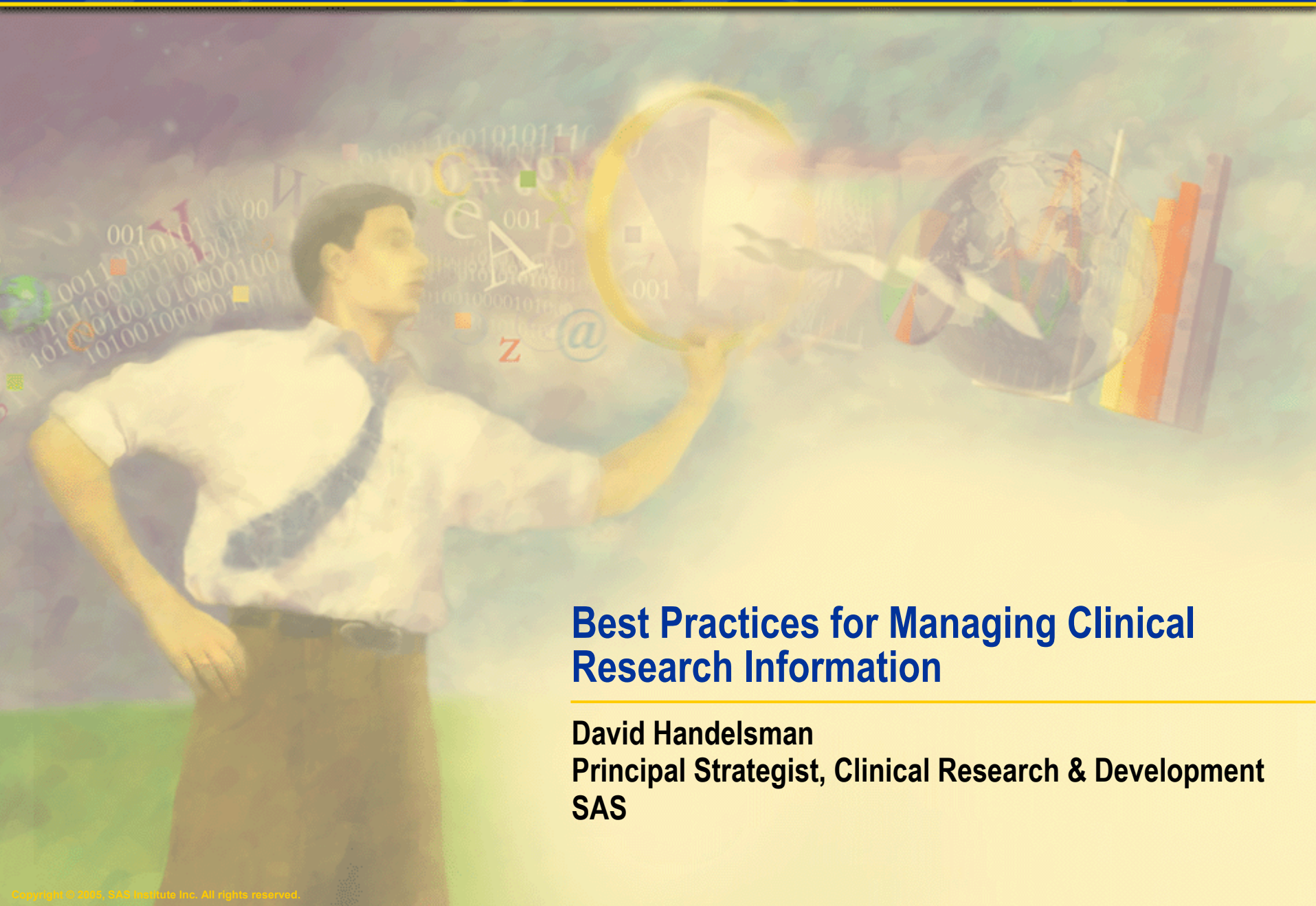

Best Practices for Managing Clinical Research Information

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This talk is not about….

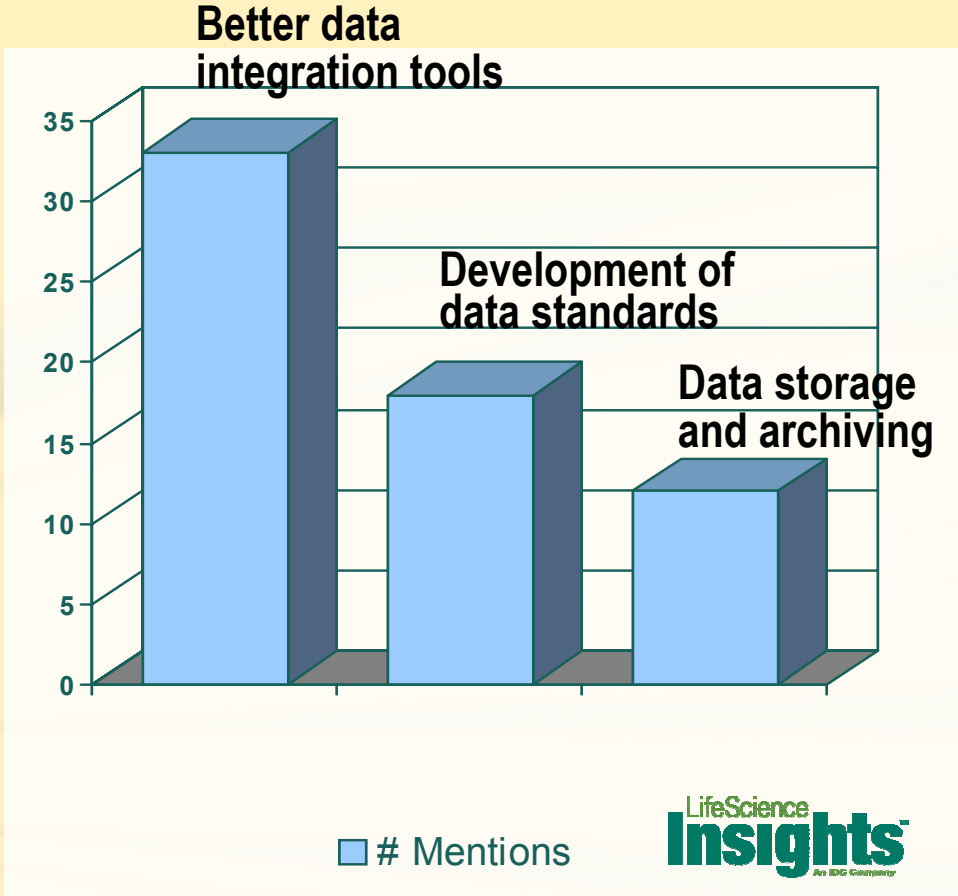
- How to process queries
- Choosing between EDC / CDMS options
- Choosing between paper diaries and ePRO
- Why you should outsource / insource

Issues & Initiatives in Life Sciences

- Bring safe and effective therapies to market more quickly and at lower cost
- Restore consumer / investor confidence and perception
- Optimize product portfolio to patient population
- Address the FDA's Critical Path Initiative

Issues & Initiatives in Life Sciences

Q: What are the most pressing technology issues facing life sciences?



How do you develop Best Practices? Start with the end in mind

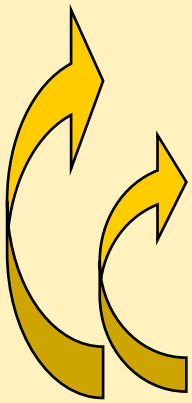
- What's not the final goal?
  - Minimizing query turnaround time
  - Locking the database in some pre-determined number of days after last visit
  - Cleaning data to some pre-determined accuracy

The final goal is demonstrating safety and / or efficacy by proving the protocol's hypotheses

Organizational Metrics Will Be Met

- What's necessary to demonstrate the protocol's hypotheses?
  - Determine the fields needed for the analyses
  - Capture only what's needed
  - Clean only what's needed to prove the hypotheses
- If you collect only what's needed
  - Queries, and query turnaround time, will be reduced
  - Time to lock database will be reduced
  - Quality goals will be easier to achieve

What happens after data is collected?



- Data is transformed to analysis-ready structures
- Figures, tables and listings are generated
- Quality control reviews content
- Study report is written and reviewed

Transformations

- Within the Clinical Data Management / Electronic Data Capture systems, all data updates are automatically documented and audit-trailed
- Downstream from clinical data management
  - Data can be freely transformed
  - Documentation is typically manual and process-based
  - QC spends extensive time reviewing and validating

Transformations should be …

- Automatically documented and audit-trailed
  - Which data sets (dates? versions?) were transformed by
  - Which transformation programs and produced
  - Which new data sets
- Reproducible
- Easily QC'ed

The production of Figures, Tables and Listings should be …

- Automatically documented and audit-trailed
  - Which data sets (dates? versions?) were used by
  - Which analysis programs and produced
  - Which figures, tables and listings
- Reproducible
- Easily QC'ed

The clinical research information value chain should be fully controlled.

Clinical research data should …

- Be accessible to authorized consumers
  - Data management
  - Medical writing
  - Clinical
- Be consumable by less-technical users
  - Data management
  - Medical writing
  - Clinical
- Be maintained in a compliant environment for all consumers

Data standards provide enormous value

- True libraries become the routine
  - Data entry modules
  - Data cleaning modules
  - Data transformation modules
  - Data analysis modules
- Using CDISC brings additional value
  - Data transfers between sponsor, development partners, CROs and regulatory agencies become much more efficient
- If you don't standardize on CDISC, standardize on something

Leverage Organizational Intelligence: The Best Practice of All

Bring all associated research information together in one location.

Assess safety and efficacy on a per-trial basis, or across trials.

Find hidden opportunities within the body of knowledge you've already built.

Critical Path Initiative: Process Opportunities

- Tighter integration between Discovery and Development
- Stronger support for alternative trial designs
  - Group sequential testing
  - Adaptive design
  - Adaptive randomization
- Predictive models for clinical research operations
  - Site recruitment and success
  - Patient recruitment
  - Project timelines

EDC provides the key enabling mechanism

Best practices lead to….

- Improved operational metrics
- Safe and effective therapies available more quickly and with lower development costs
- Restored confidence across the organization, with consumers, and with shareholders

Questions?

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