

Your SCE is Only as Good as Your Data: The Central Role of Information Governance in Clinical Research

Michelle Chen, Senior Sales Executive



Data governance provides a formal framework that standardizes the means for managing the clinical data

Description

Data governance provides a formal framework that establishes and monitors data standards, processes, and policies. The governance components provide a proactive approach to ensuring the quality and accessibility of data that will optimize insights and influence key decisions



Benefits

- **Improve Data Quality**
Ensure data is managed in standard, consistent, and consumable format across systems
- **Increase Accessibility of Data**
Provides direct and efficient path from business to data
- **Reduce Cost and Resources**
Provides opportunities for reuse of data and eliminate redundant data capture activities
- **Increase Agility**
Reduce cumbersome processes required to increase interoperability of source systems

Who touches the data?

Collection



Cleansing



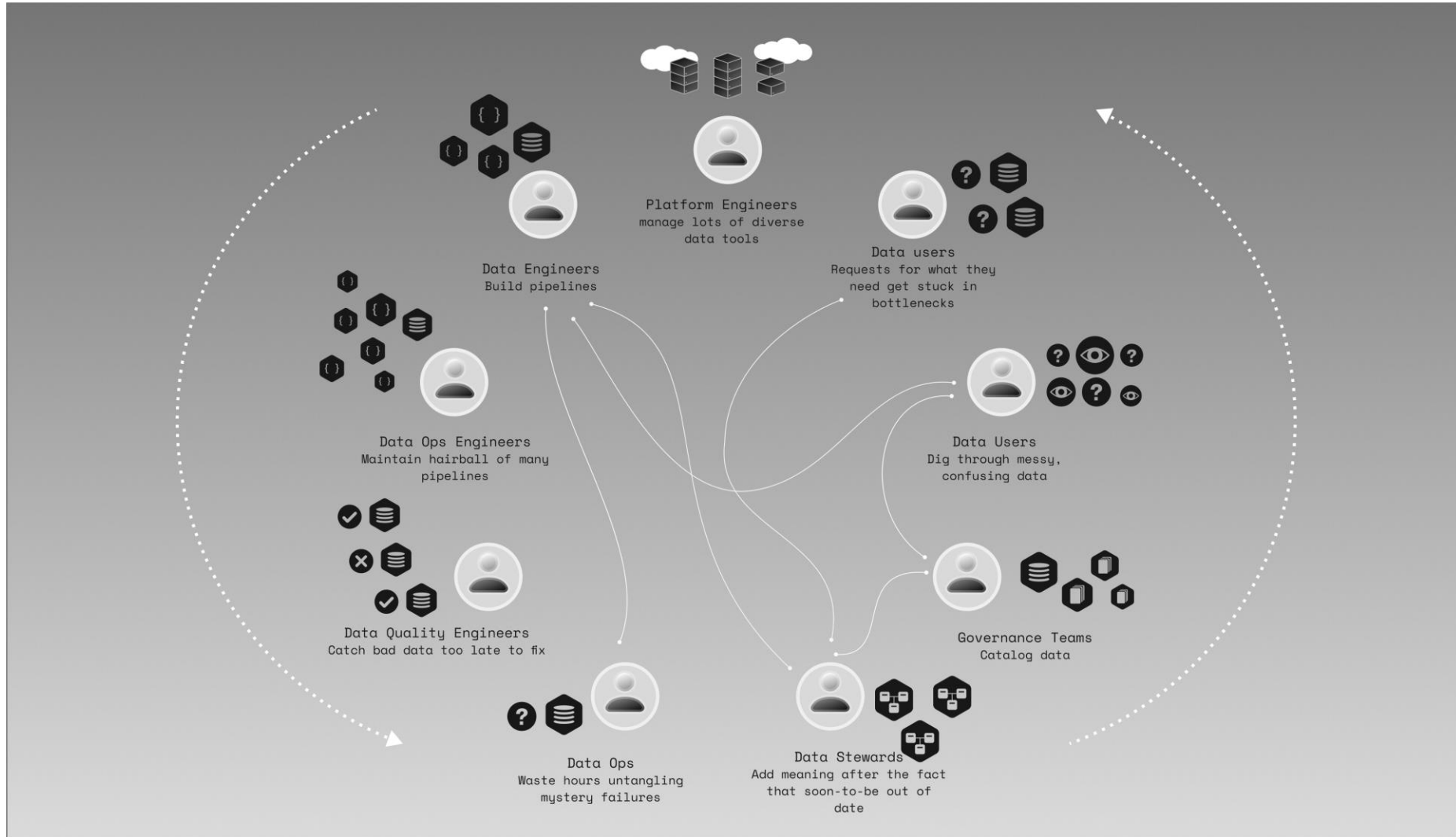
Analysis



Presentation

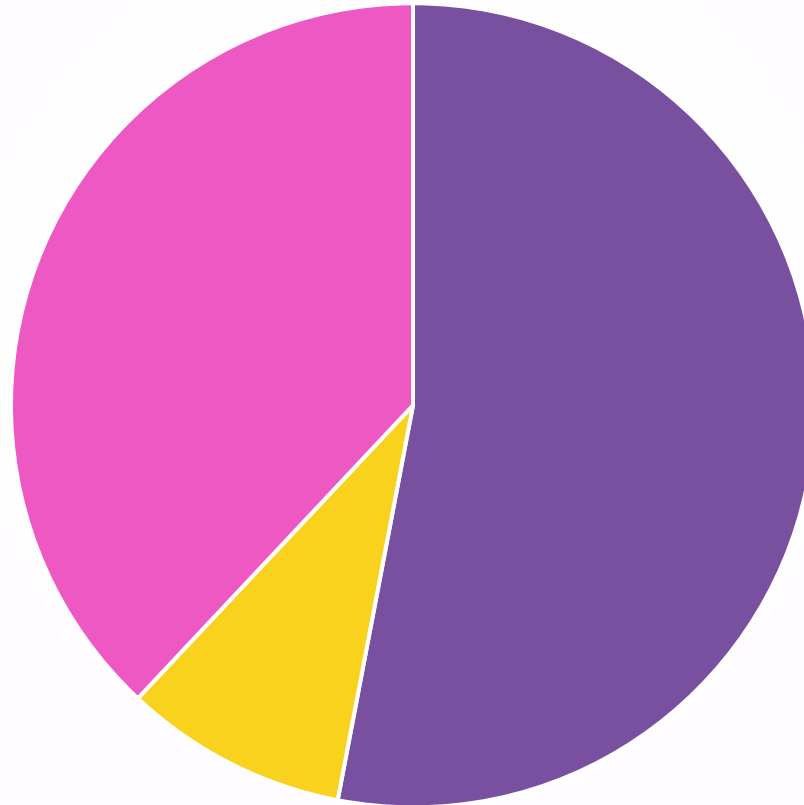


But what really happens?

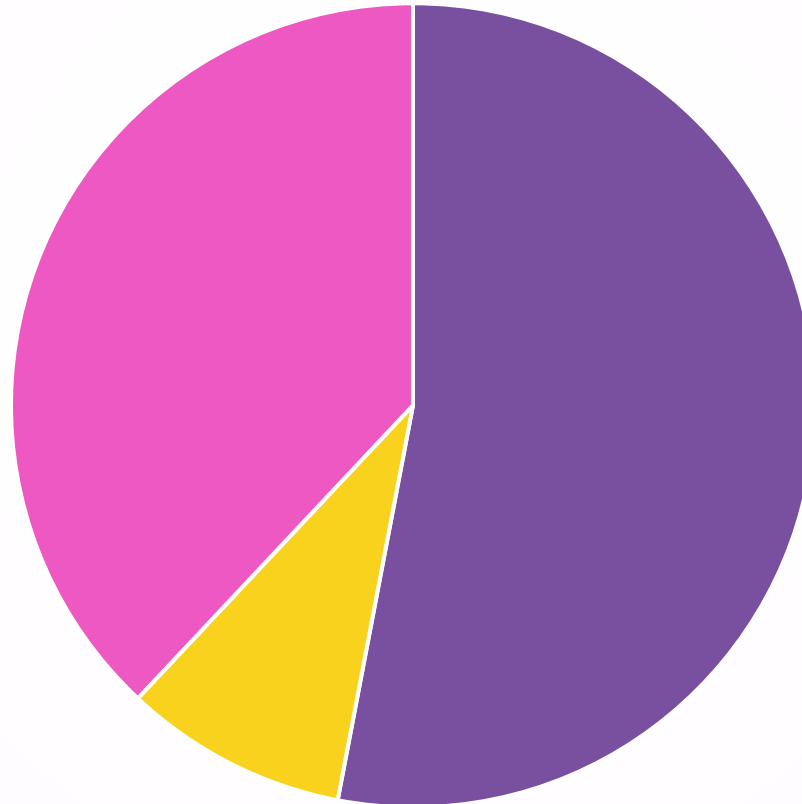


“IT is responsible for leading data management solutions.”

Survey says...



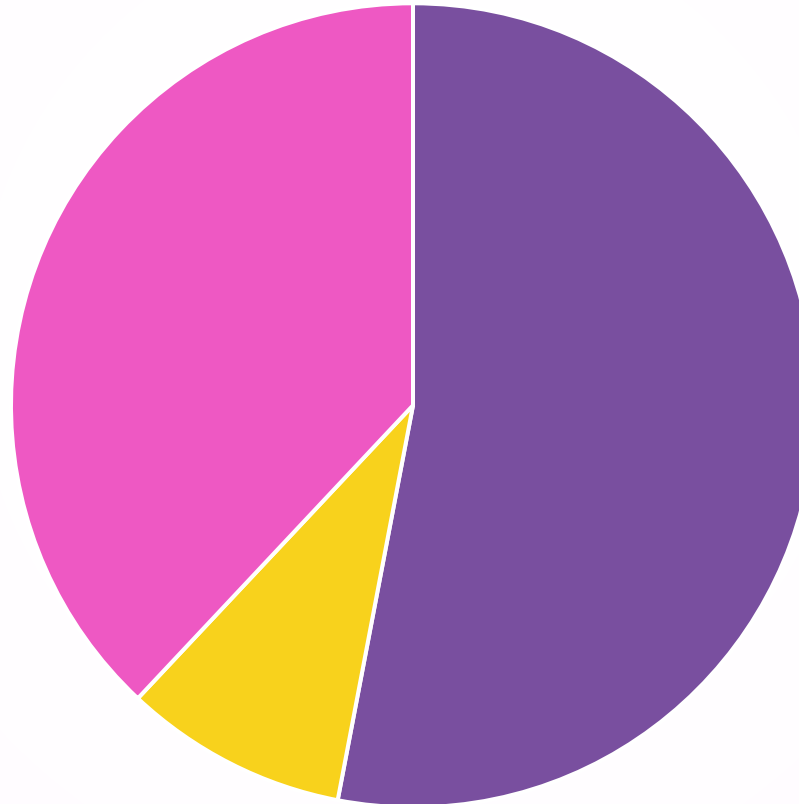
Survey says...



53%

**"IT should lead data
management
solutions"**

Survey says...



8%

"Biometrics and other teams should lead data management solutions"

53%

"IT should lead data management solutions"

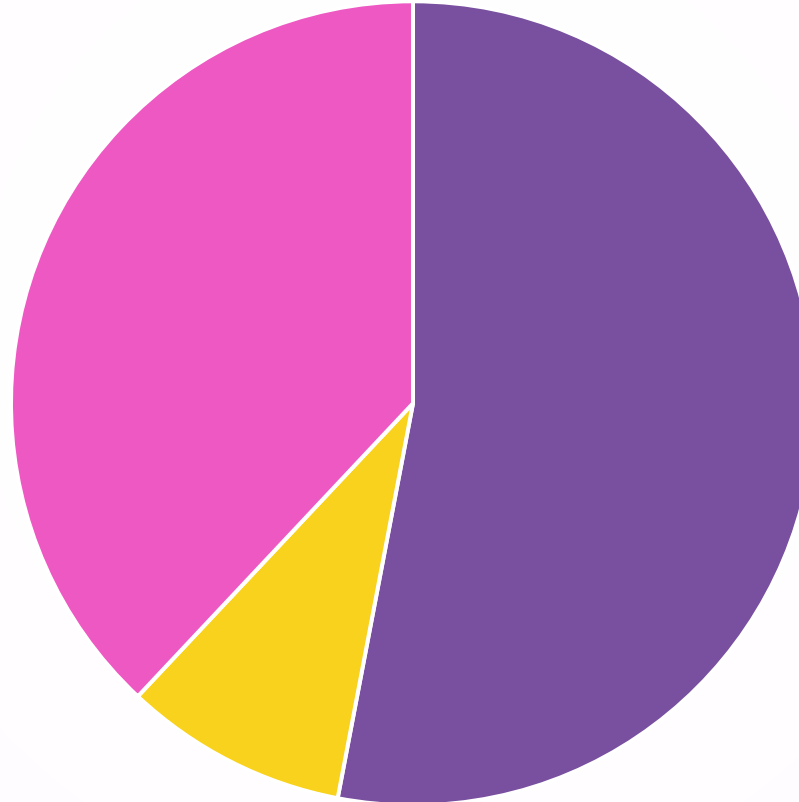
Survey says...

38%

"IT and other business users should lead data management solutions"

8%

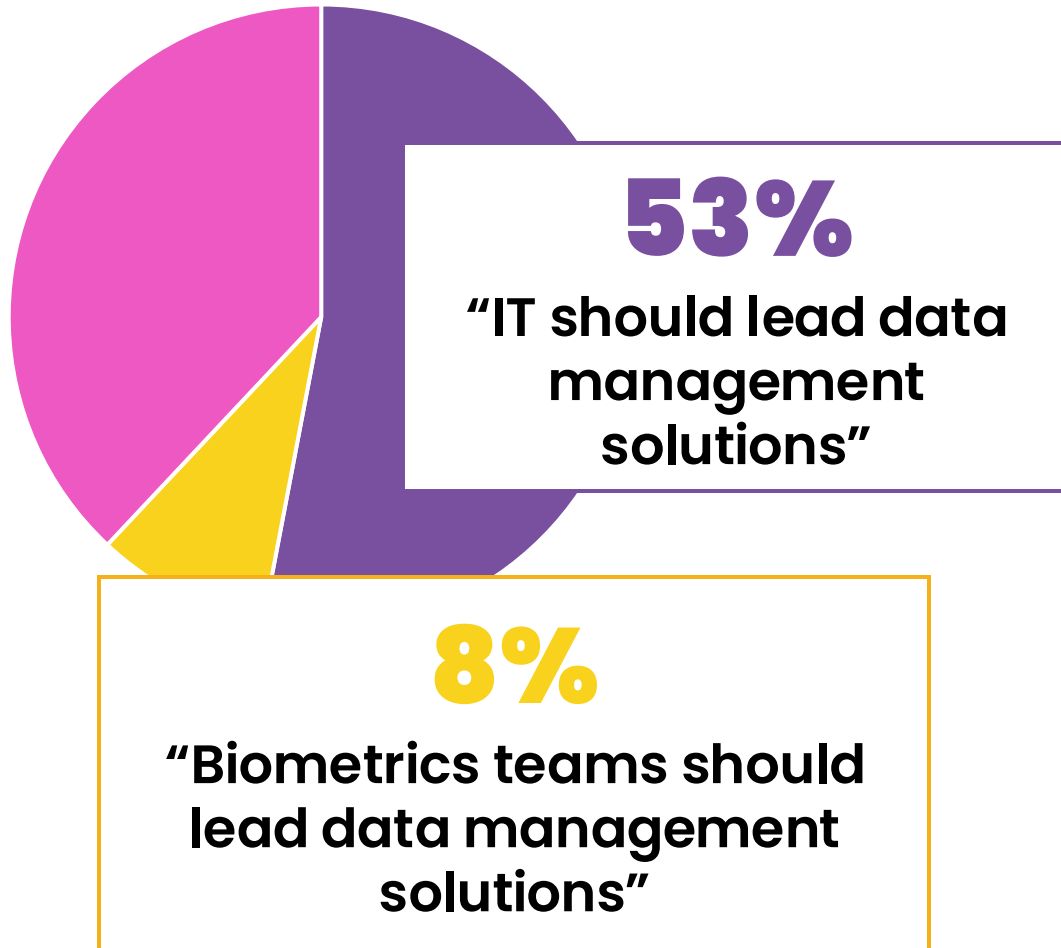
"Biometrics teams should lead data management solutions"



53%

"IT should lead data management solutions"

What ends up happening?



- Technologies / solutions are put in place without clear understanding of objectives
- Difficulty to implement data-driven decisions
- “Source of Truth” – redundancy
- Traceability

Avoid these common mistakes

- Sell data management as an infrastructure project
- Recommend a complete data management solution REPLACEMENT
- Big bang approach
- Technology-focused, NOT value-focused
- Don't fix what's not broke

So, what needs to happen?

- Long-term commitment for creation, capture, access and delivery of information
- Data Governance Committee that includes both business users and IT users

Story Time: Modernizing SCE To Close Data Compliance Gap

Context

- Client had received an FDA 483 letter identifying major quality gaps in their processes
- Siloed business units following disparate processes causing inefficiencies and negative audit findings
- Legacy technology causing performance and usability issues
- Manual process and technical limitation supporting transfer of data from vendors to client impacting data integrity

❖ Top 30 PHARMA

Approach

Gap Analysis

- Conducted detail stakeholder interviews to understand the quality findings and siloed groups
- Created a current state workflow and identified most critical gaps

Recommendations and Future State

- Built an aligned end to end process across all business units
- Created future state platform architecture and automation requirements
- Generated a detailed timeline to develop, deploy and adopt the new platform

Build and Deployment

- Built an SCE foundation that including compute, workflow and data
- Built Study management toolkit as tool within their SCE to support automated study set-up, file transfer, and controlled code and production execution
- Managed process adoption throughout the project

Testing, Training, and Adoption

- Developed comprehensive OQ and UAT testing protocol
- Developed and delivered business user specific training
- Implemented a change management plan to optimize adoption

Solution & Outcomes

Instem drove an aligned business model and developed a solution to realize the process and ensure data integrity

- Enforced standard directory and security model focusing on data integrity
- Role-based execution to ensure the right person is performing the right task
- Immutable centralized source of raw data, code, & outputs throughout the lifecycle
- Traceability of data and programs through the system

Imperative to align siloed business units on a common workflow and designed, built, and deployed a Data Review and Analysis Environment in a private cloud to support workflow, programming, and automation ensuring data integrity and process efficiency

Thank you.

Michelle Chen

michelle.chen@instem.com

