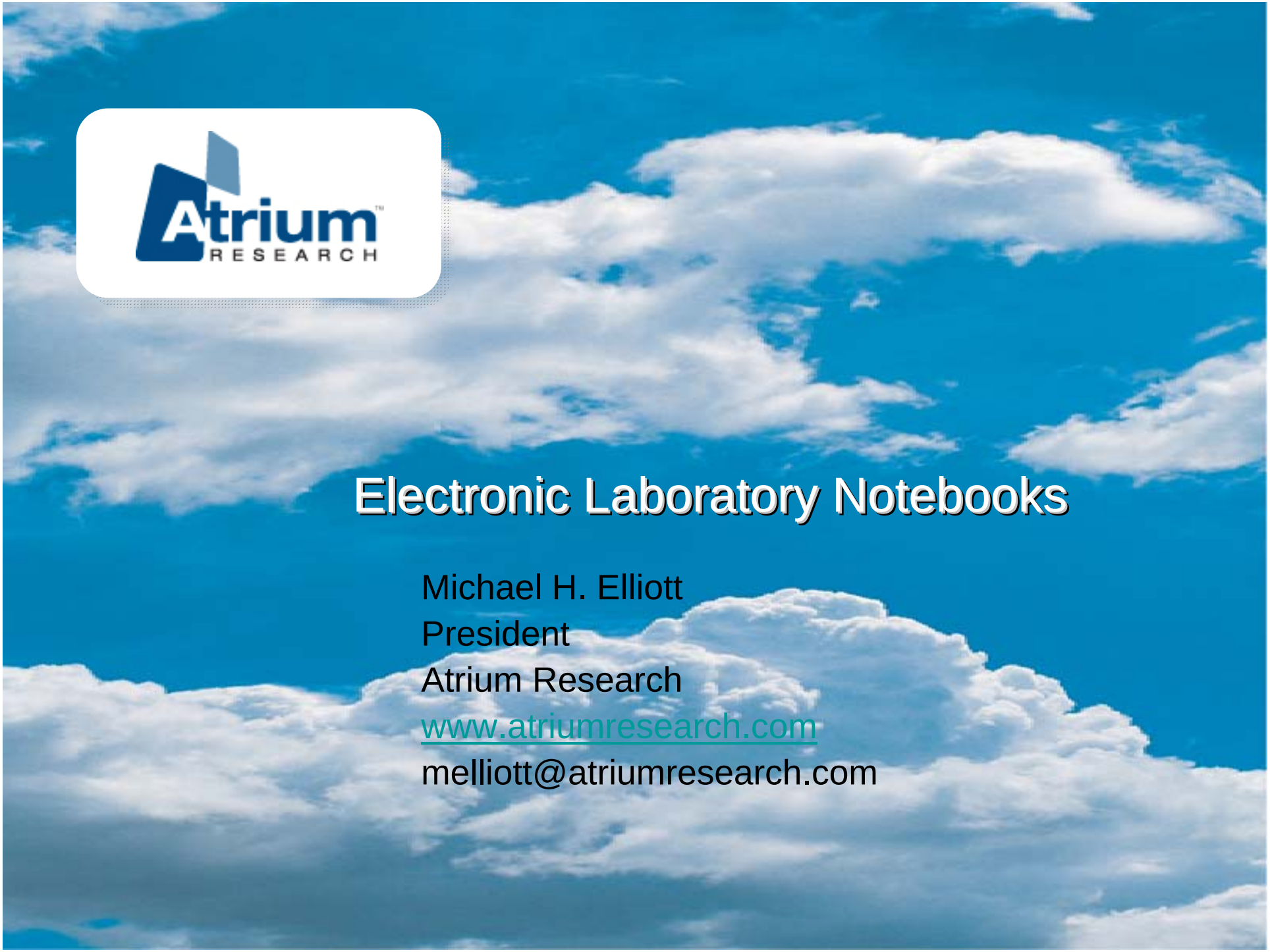

Electronic Laboratory Notebooks

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Agenda

- Overview
- What is an ELN?
- Types of ELNs
- Legal and Adoption issues
- Benefits


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ELN Overview

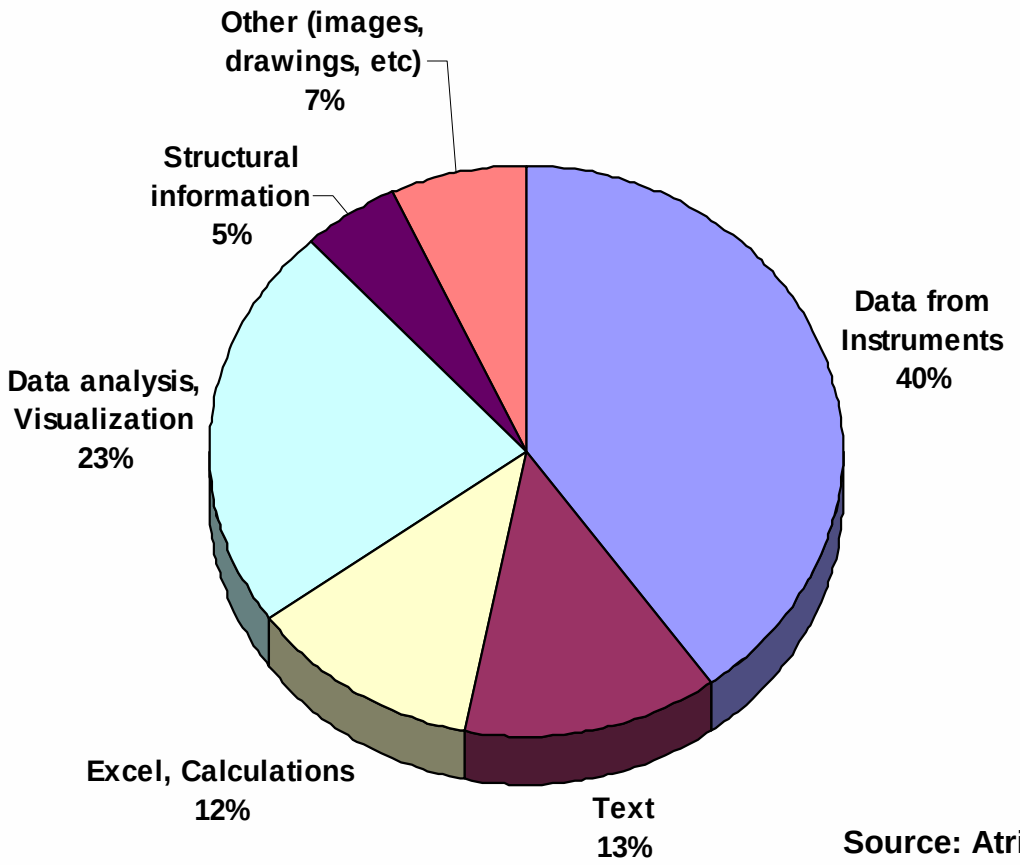
Overview of ELN Market

- Early growth market (>30% annual growth)
- New players with new capabilities
- There are ELNs for IP protection only and ELNs tied to a specific application(s)
- Market growth is being driven by the life sciences sector
- Legal and adoption concerns are primary restraints
- ELN users are experiencing multiple benefits

Why a Laboratory Notebook?

- It is a complete record of why experiments were initiated and how they performed
- Central repository to collect data from unrelated sources to collate them into contextual relevance
- It encourages sound thinking and a scientific process
- It allows for sharing of information
- It is required for patents and/or regulatory compliance

Notebooks Contain a Variety of Content



Source: Atrium Research

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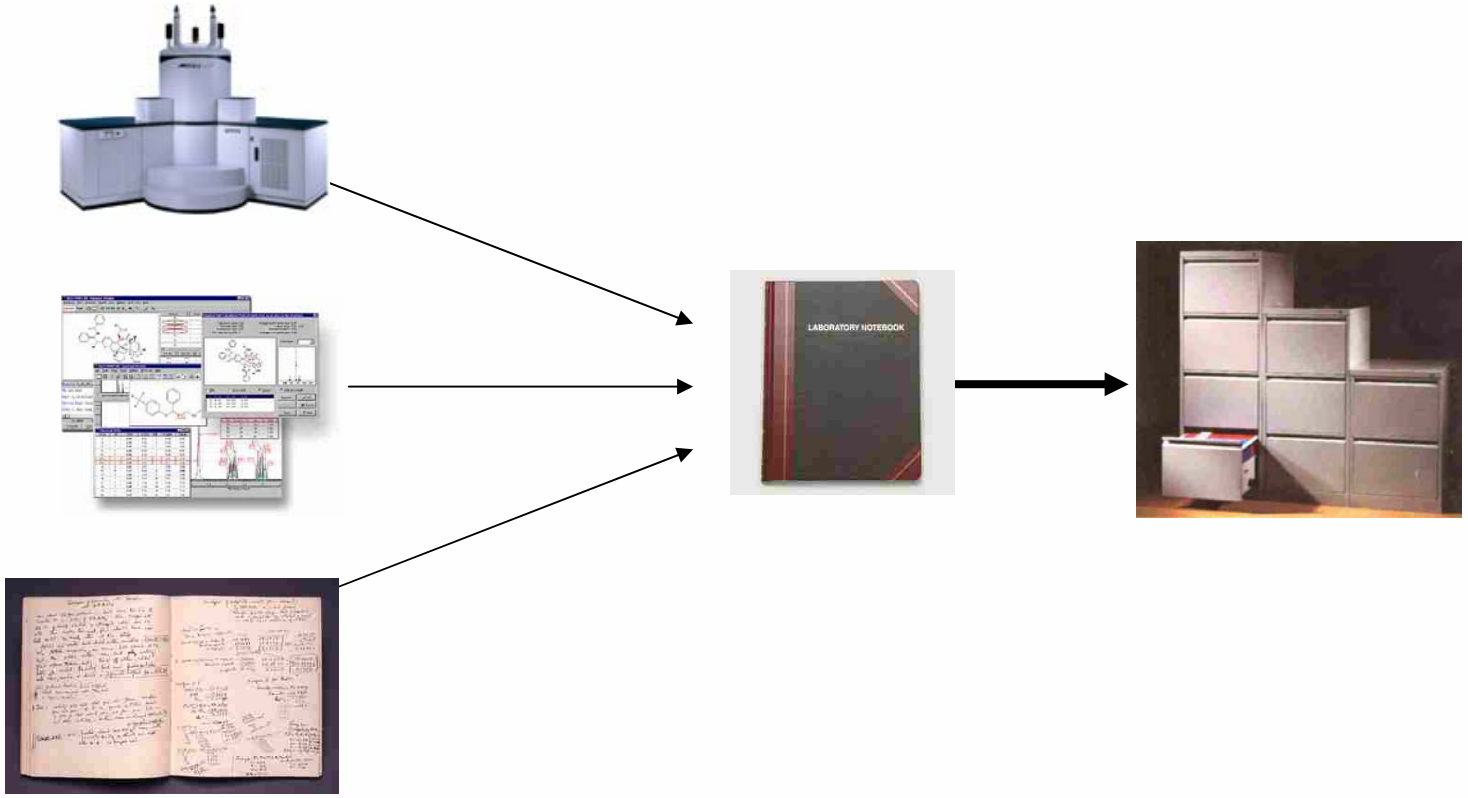
Critical Experimental Information is Buried in Filing Cabinets



Billions of Dollars of Research Are Lost Every Year

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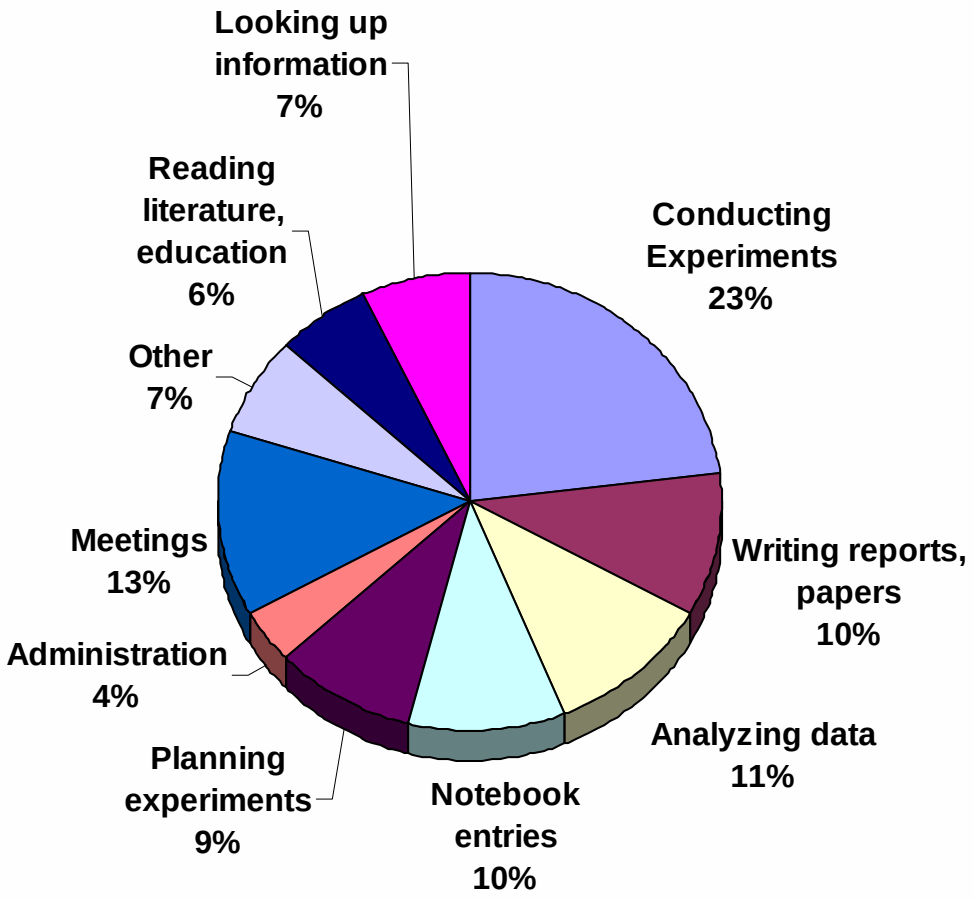
Shortcomings of a Laboratory Notebook

- Poor communicator
- Often illegible
- Traps company knowledge capital in a filing cabinet
- Expensive to manage and maintain
- Cannot easily re-purpose or re-analyze data
- Barrier to team building

Companies Need to Improve the Efficiency of Scientific Resources



Typical Scientist Time (Source: Atrium Research)

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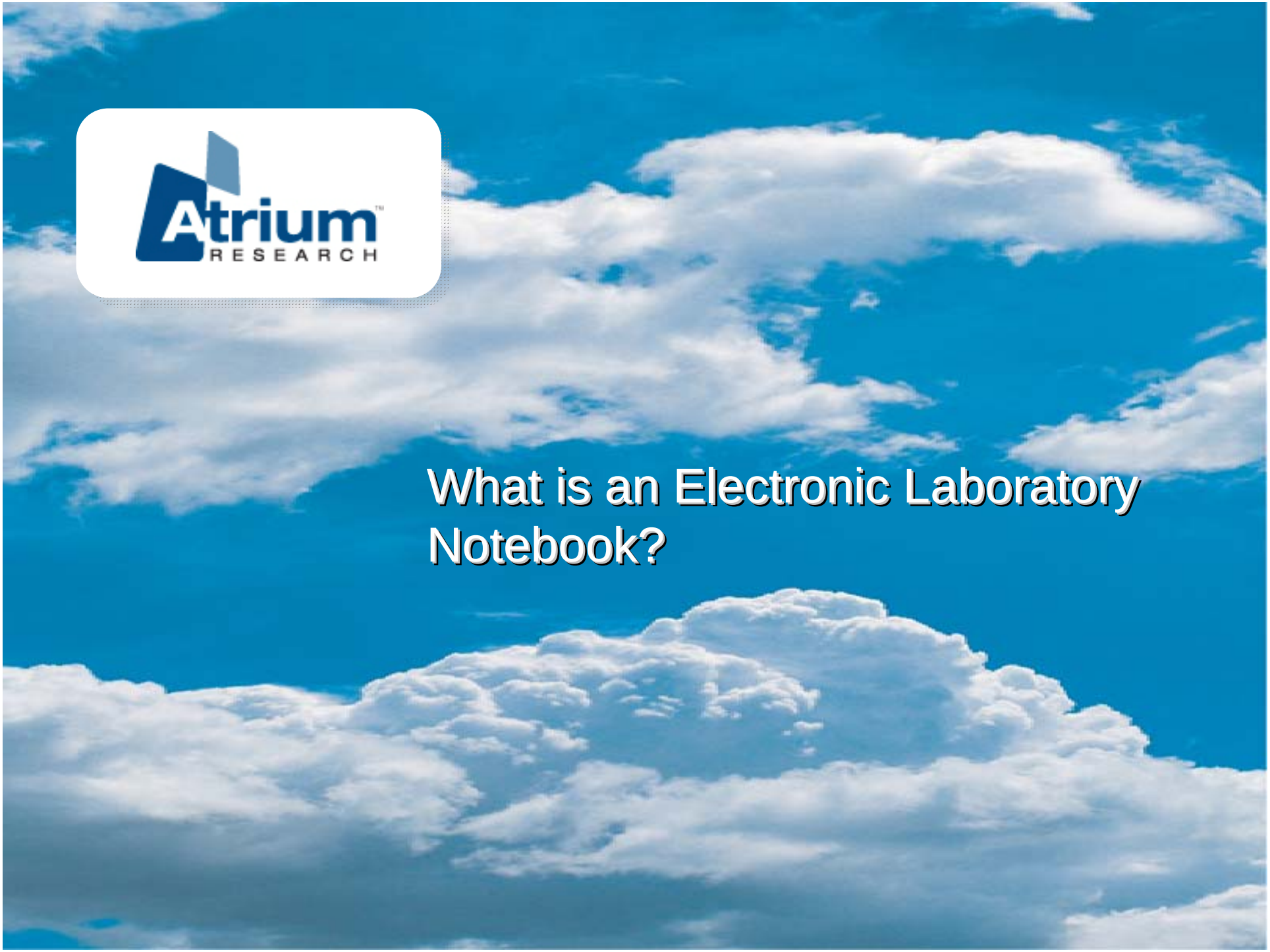
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What is an Electronic Laboratory Notebook?

An ELN….

- IS NOT just a digital version of a paper notebook
- IS a tool for securing intellectual property
- IS a knowledge repository that allows for collaboration and sharing of explicit and tacit knowledge
  - Explicit Knowledge – information that is easily written down
  - Tacit Knowledge – experiences, learned concepts, ideas, viewpoints
- Provides tools to improve the efficiency of resources
- Meets legal and regulatory requirements

R&D Director of a Top Ten Pharma Says…

"An ELN is a secure system that assembles content from multiple sources that are related to each other, allows for annotations, and packages it in a legally acceptable document which can be searched, mined and collaborated."

ELN Need and Use Varies by Area

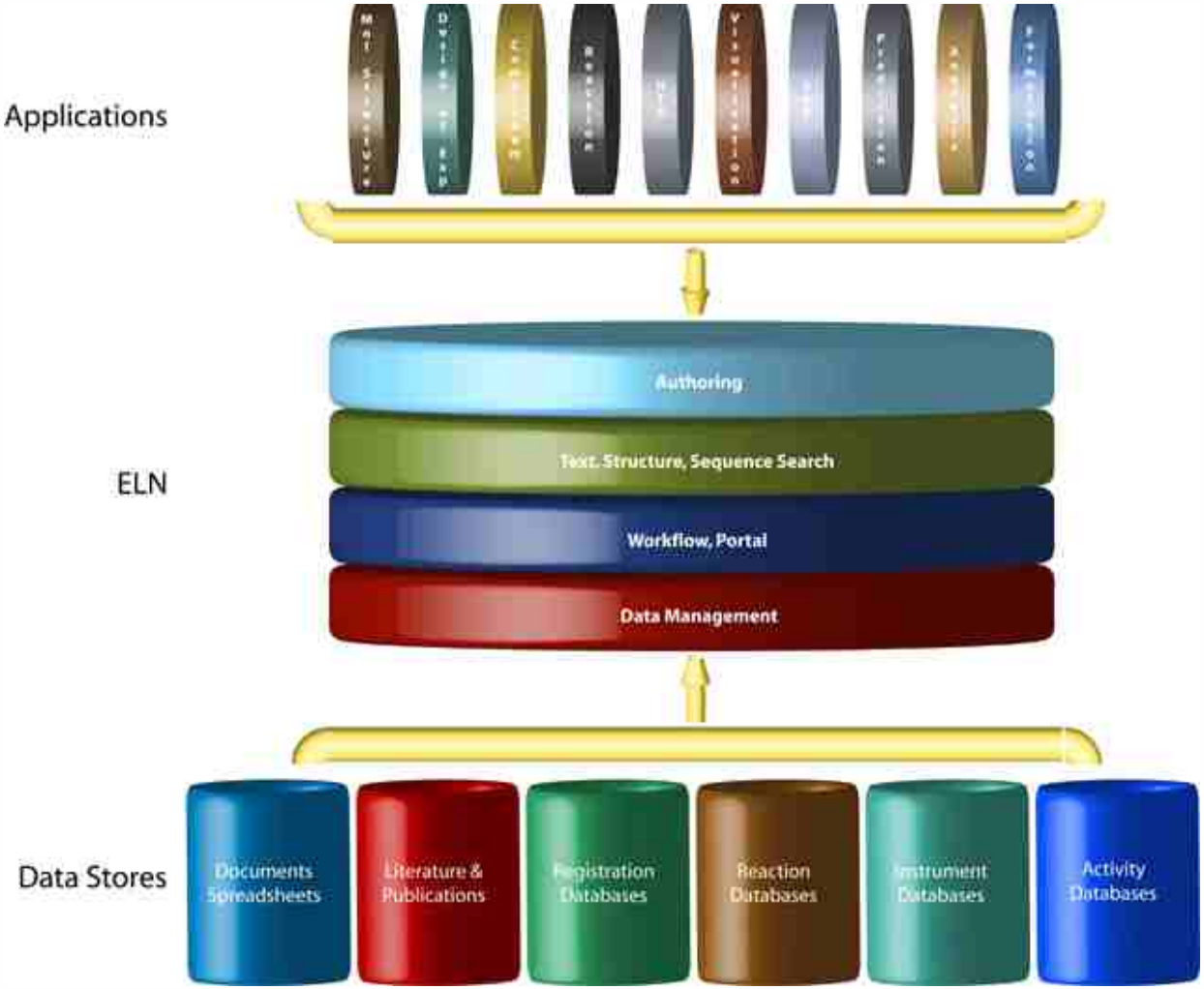
Research

- Aggregates related data in a legally defensible document to support a patent
- Tool for collaboration and team research

Manufacturing

- Records that experimental protocols were followed in accordance with established procedures ensuring compliance with governmental regulations.
- Tool for the support of Six Sigma and other quality initiatives

An ELN as a Content Aggregator



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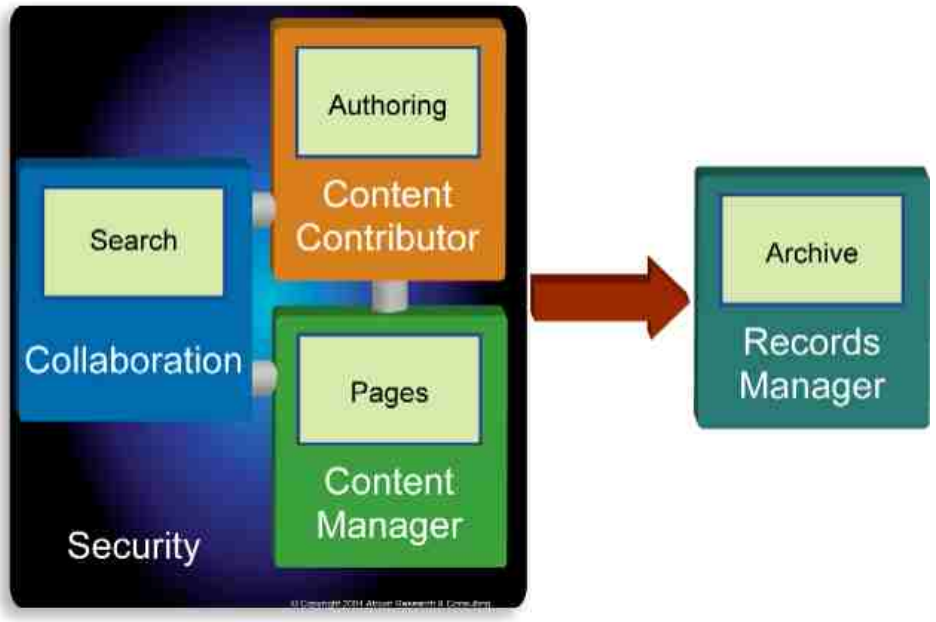
Basic Components of an ELN

Three basic components:

- Content Contributor
- Content Manager
- Collaboration

All wrapped in a security layer



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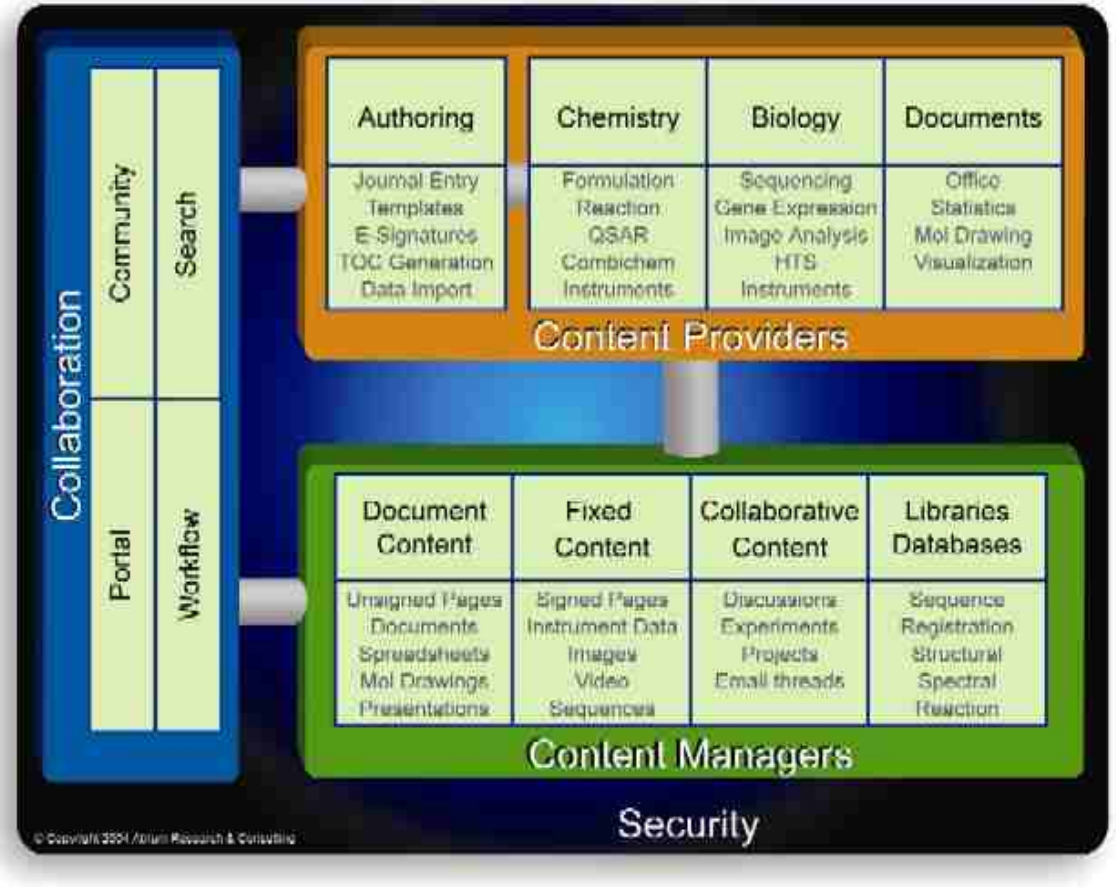
An Enterprise View of an ELN

Synonymous with eR&D, Collaborative R&D, Digital R&D, etc.



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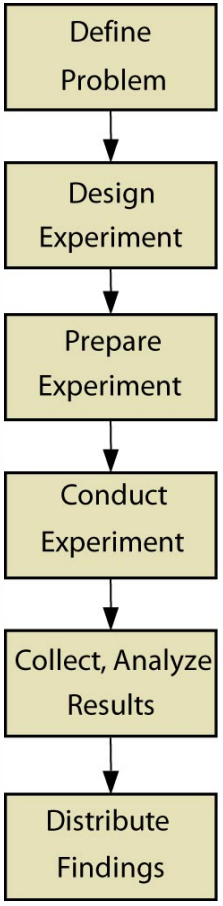
Requirements of an ELN



Scientific Workflow
Source: Myers 2000

- Supports the scientific workflow
- Permits entry of structured data
- Permits entry of unstructured data
- Allows for annotations
- Is secure and has an audit trail
- Digital signatures for data authentication
- Has authenticated e-signatures
- Is searchable and provides collaborative workspaces

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Types of ELNs

Two Types of ELNs

Non-specific

- Designed for multiple markets
- Generic authoring tool
- Focused primarily on intellectual property protection and patent support
- Personal, workgroup, or enterprise

Specific

- Designed for a single market
- Feature rich for one or two application areas (i.e. synthetic chemistry)
- Focused on improving efficiencies in niche area
- Targeted at enterprise, primarily life sciences

ELN Suppliers

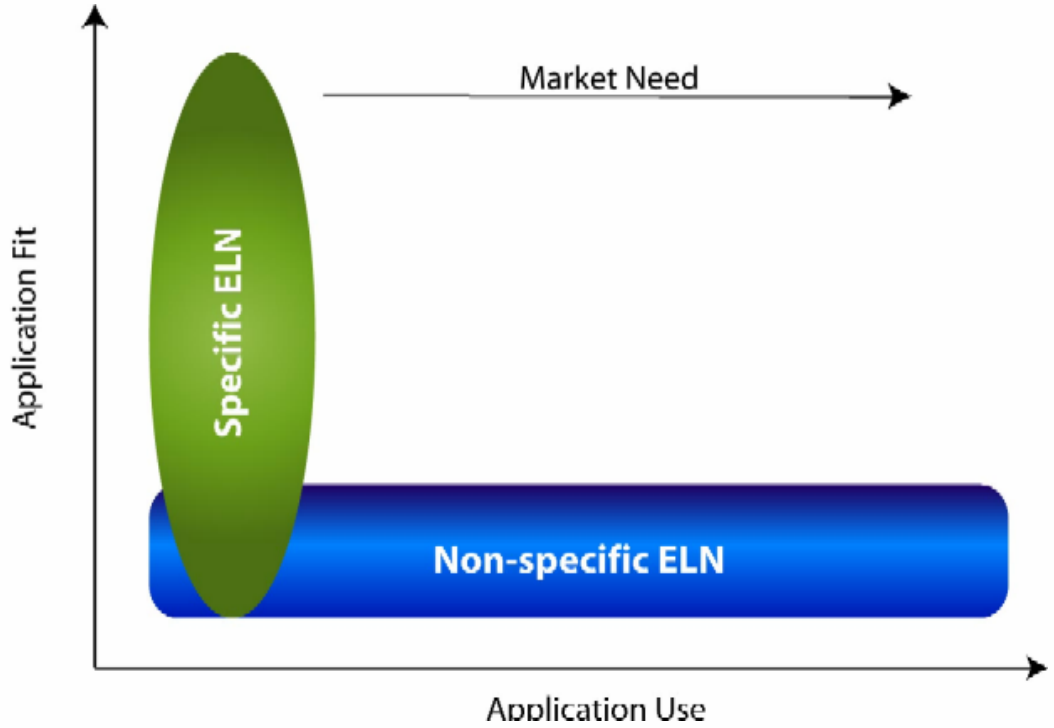
Non-specific ELNs:

- Amphora Research Systems
- CambridgeSoft
- Contur
- GenSys
- IntelliChem
- Kalabie
- Kinematik
- Knowligent
- LABTrack (EKM)
- NoteBookMaker
- Quattro Research
- Rescentris
- Waters

Specific ELNs:

- Array Genetics
- CambridgeSoft
- Chemexper
- Cheminnovation
- DeltaSoft
- Digipharm
- Ingenovis
- Invent
- IntelliChem
- Labtronics
- MDL
- Tripos
- VelQuest

Vertical vs. Horizontal Fit



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Common ELN Features

- Scientist “friendly” UI
  - “Portal” to show them what they are working on, what needs signing, etc.
- Authoring Tool
  - Allows text entry in a secure environment
- Security
- Searching
  - Full text
  - Structure (full, substructure, similarity)

Common ELN Features

- Templates / Protocols
- Workflow
  - Routing, witnessing, procedural
- Electronic Signatures
  - Author and witness
- Integration
  - registration databases, inventory systems, data management systems, etc.
- Experiment, Project Tracking
  - By scientists, group, or enterprise

Common ELN Features

- Messaging
  - Alerts for what needs to be signed, projects with new data, etc.
- Ability to add links for outside research or data stored on other systems
- Reporting and Publishing PDF generation
  - Hybrid ELN
  - Publishing to long term archive
- Regulatory compliance features
  - Part 11
  - Procedure management


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Legal and Adoption Issues

Legal Issues Regarding Electronic Records

- USPTO operates on a “first inventor” basis
- USPTO accepts electronic records if they meet Federal Rules of Evidence
- There is current no case law for defending a patent with fully electronic records
  - Bound paper notebooks have a long history of patent defense
- Most companies save IP records for 15-100 years
- Because of this, the majority of companies are implementing hybrid ELNs

Legal Issues Regarding Electronic Records

- Several biotechs have gone fully electronic
- Two major pharmaceutical companies will be pursuing fully electronic
  - The majority of the data in a paper notebook is originally electronic, so what is the difference how you ultimately store it?
  - E-Records (esp under Part 11) can be more secure than paper records
- Many lawyers would prefer not to keep all or too much raw data
  - Leaves them exposed for reanalysis and new findings

Cultural Adoption Barrier

- An ELN affects processes, procedures and ways of working more than any other system
- The lab notebook is ingrained in the scientific culture
- Resistance can be high, but specific ELNs have a higher adoption rate due to the end user benefits
- To successfully implement an ELN, the human and cultural impact must be carefully managed
  - Pragmatists and technology conservatives make up the majority of the users
  - People must see “what’s in it for them”


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Benefits of an ELN

Benefits of an ELN

- Improved effectiveness
  - Seeing what has been done before
  - Not repeating failed experiments
  - Idea and tips from others
  - Sharing and collaborating
  - Tools for more effective science
  - Workflow automates manual processes
- Improved data quality
  - Readable!
  - Templates enforce data capture
  - Reduction in transcription errors
  - Data verification
  - Error checking

Benefits of an ELN

- Enabling knowledge management
  - Capturing of explicit and tacit knowledge
  - Data not lost to filing cabinets
  - Data mining now possible
  - Expert locators
- Improved intellectual property protection
  - Better security around IP
  - No “coffee spill” worries
  - Authentication through digital signatures
  - Don’t have to worry about employees leaving
- Improved regulatory compliance
  - Helps to meet Part 11
  - Procedure automation demonstrates compliance

Summary

- ELN market is growing with many new suppliers
- Paper notebooks create inefficiencies
- An ELN is more than a digital replacement of a paper notebook
- There are two types of ELNs – Specific and Non-specific
- There are legal and cultural adoption barriers that can be overcome
- Companies who implement ELNs are experiencing tangible benefits