Electronic Laboratory Notebooks

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Agenda

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

- Data from Instruments: 40%
- Data analysis, Visualization: 23%
- Excel, Calculations: 12%
- Text: 13%
- Structural information: 5%
- Other (images, drawings, etc): 7%

Source: Atrium Research
Critical Experimental Information is Buried in Filing Cabinets

Billions of Dollars of Research Are Lost Every Year
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)
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
“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

Applications

ELN

Data Stores

- Documents
- Literature & Publications
- Registration Databases
- Reaction Databases
- Instrument Databases
- Activity Databases

Authoring
Text Structure, Sequence Search
Workflow, Portal
Data Management
Basic Components of an ELN

Three basic components:

- Content Contributor
- Content Manager
- Collaboration

All wrapped in a security layer
An Enterprise View of an ELN

Synonymous with eR&D, Collaborative R&D, Digital R&D, etc.
Requirements of an ELN

- 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

Scientific Workflow
Source: Myers 2000
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

Application Fit

Specific ELN

Non-specific ELN

Application Use

Market Need
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
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**
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.”
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