



Electronic Laboratory Notebooks: Market and Technology Overview

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About Atrium Research

Atrium Research is an independent, vendor-agnostic market research and strategy consulting practice specializing in scientific informatics

Recent ELN publications:

- *Electronic Laboratory Notebooks: A Foundation for Scientific Knowledge Management Edition III*
- *2008 ELN Survey Report (to be released in July)*



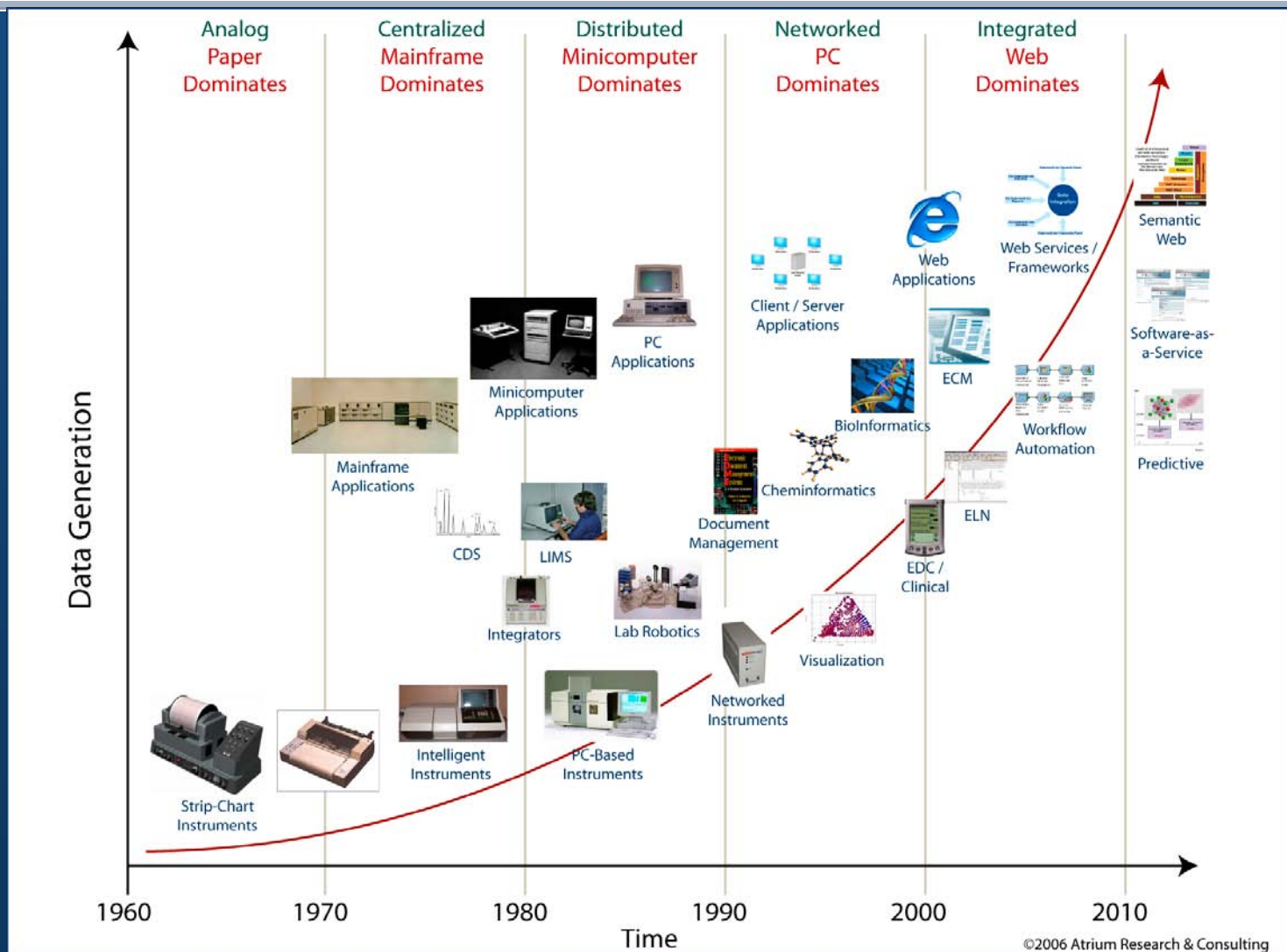
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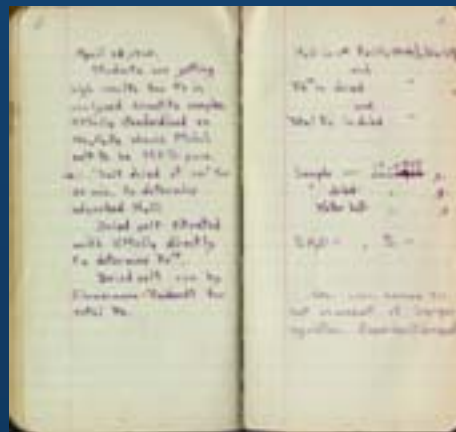
Agenda

- Why Electronic Laboratory Notebooks (ELN)?
- I say tomato, you say tomato. What is an ELN, really?
- The market for ELN technology
- Legal considerations
- ELN in academia
- Questions and discussion

The Evolution of Laboratory Computing



Despite Scientific Advances, the Paper Notebook has Survived...



1903



2003

@50% of Scientists' Time is Spent in Data and Information Related Tasks

2004 Medicinal Chemist Study

Data and Information Tasks:	45%
Exp Design and Execution:	33%
Admin / Meetings / Other:	24%

2006 Biologist Study

Data and Information Tasks:	48%
Exp Design and Execution:	36%
Admin/Meetings/Other:	16%



94% of Scientists Report Data Management Challenges



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Source: AR&C 2008 Survey
Confidence at 95% +/- 4%

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Why Are *Organizations* Turning to ELN?

- 1) Improve scientific efficiency
- 2) Provide easier access to information
- 3) Share knowledge between scientists
- 4) Improve the quality of data
- 5) Enable consistency across operations

Source: AR&C 2008,2006,2005 surveys



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Why Would a *Researcher* Use an ELN?

- 1) "If it has the tools to help me be more productive"

Prospective end users want to know: "What's in it for me?"

- 3) "If it helps me to better organize my data"

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The Obligatory Overly Broad Definition of an ELN....

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

- Atrium Research

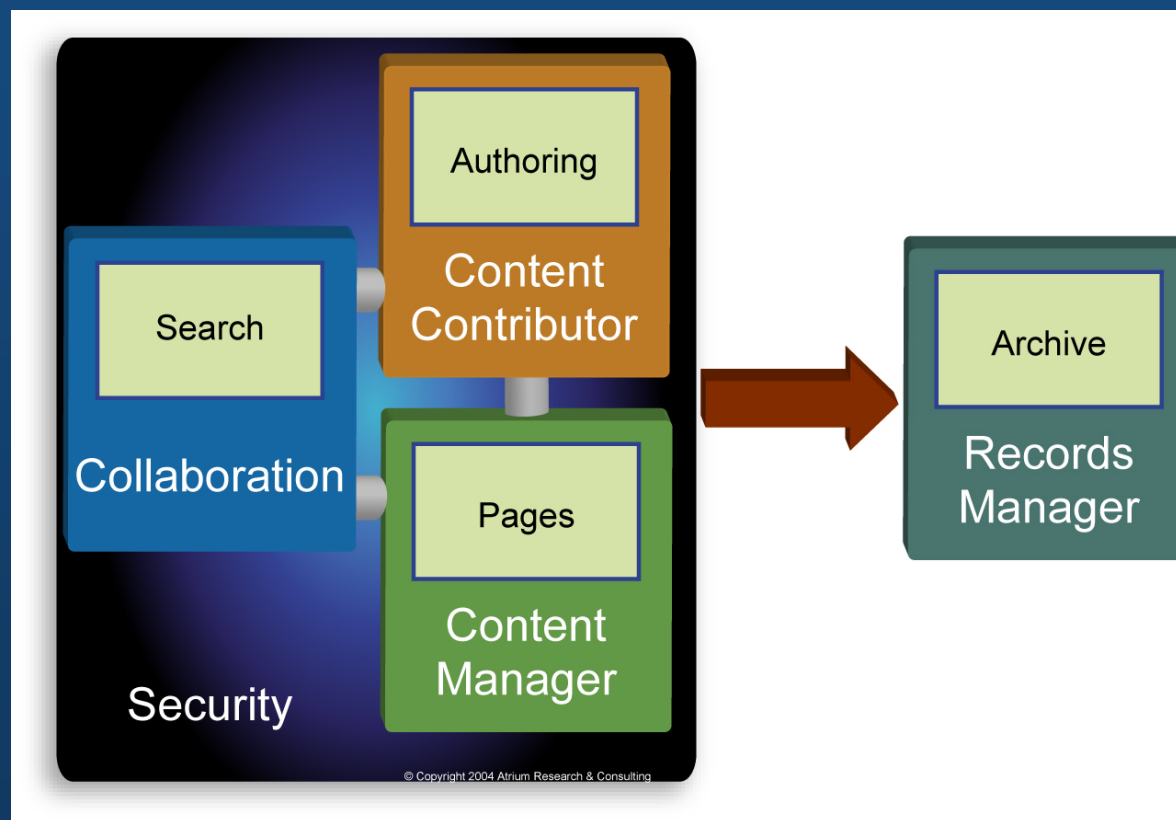
Product capabilities and definition vary by area!



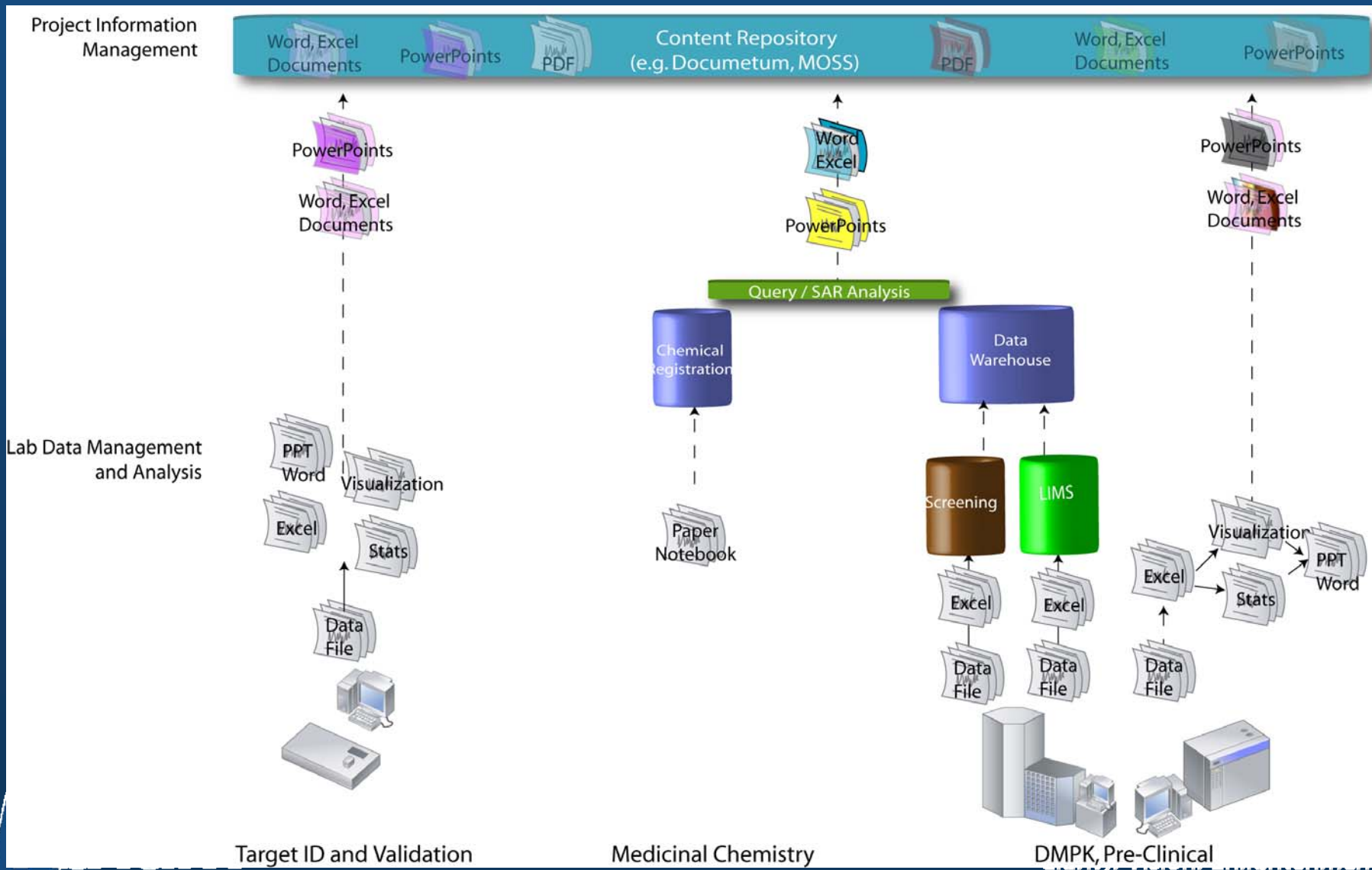
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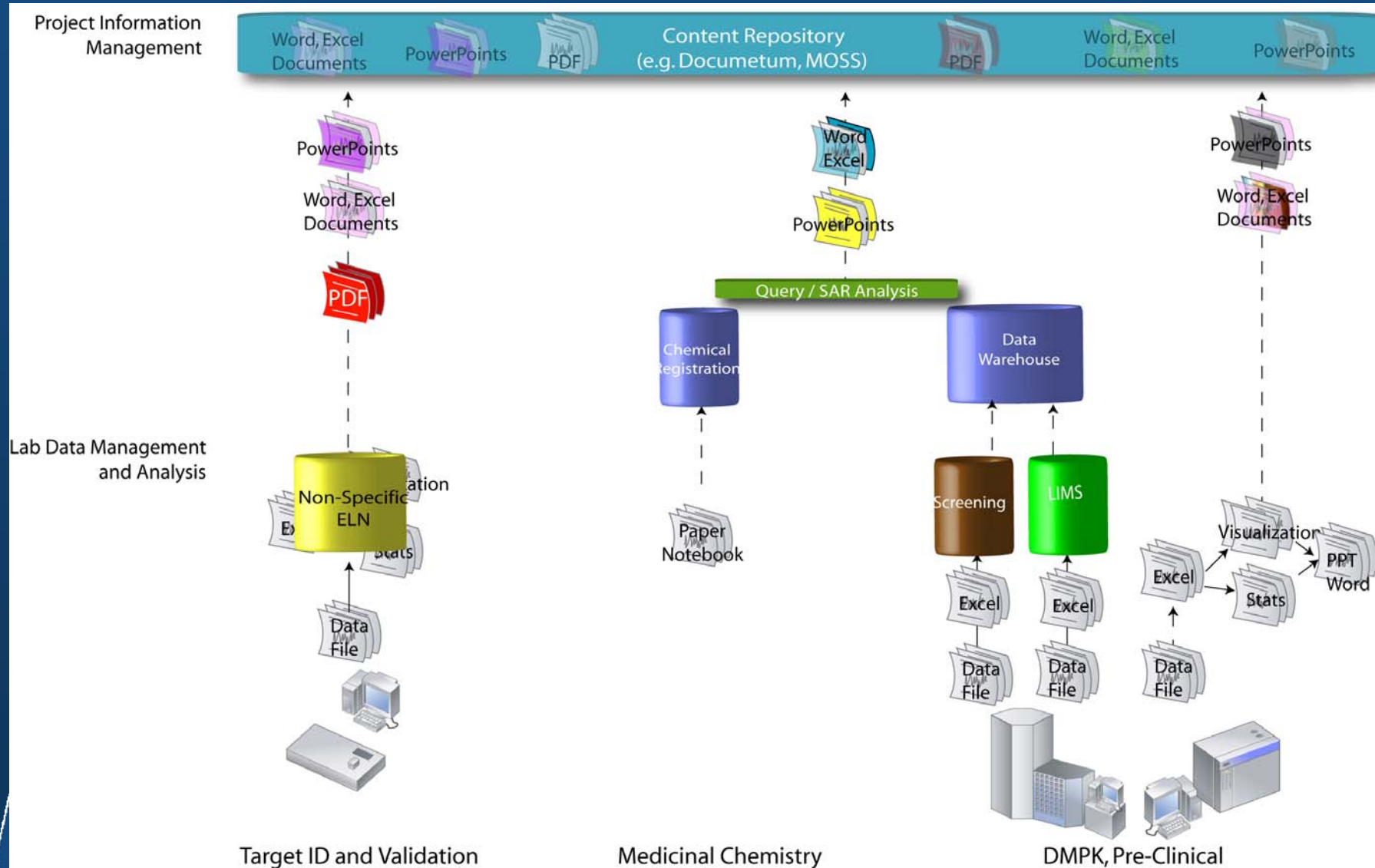
Fundamental Components of an ELN



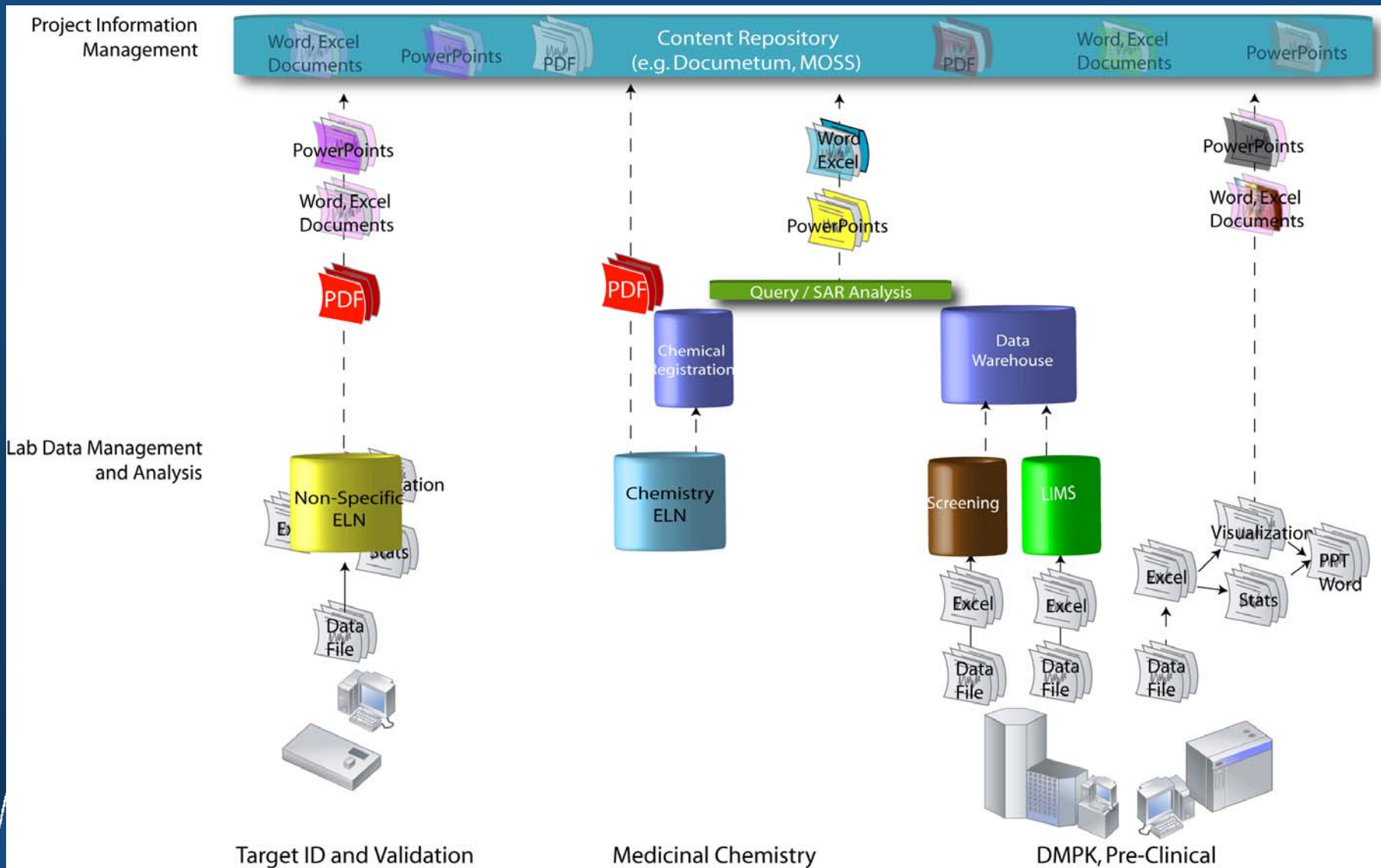
Let's Explore a Typical Drug Discovery Data Management Environment



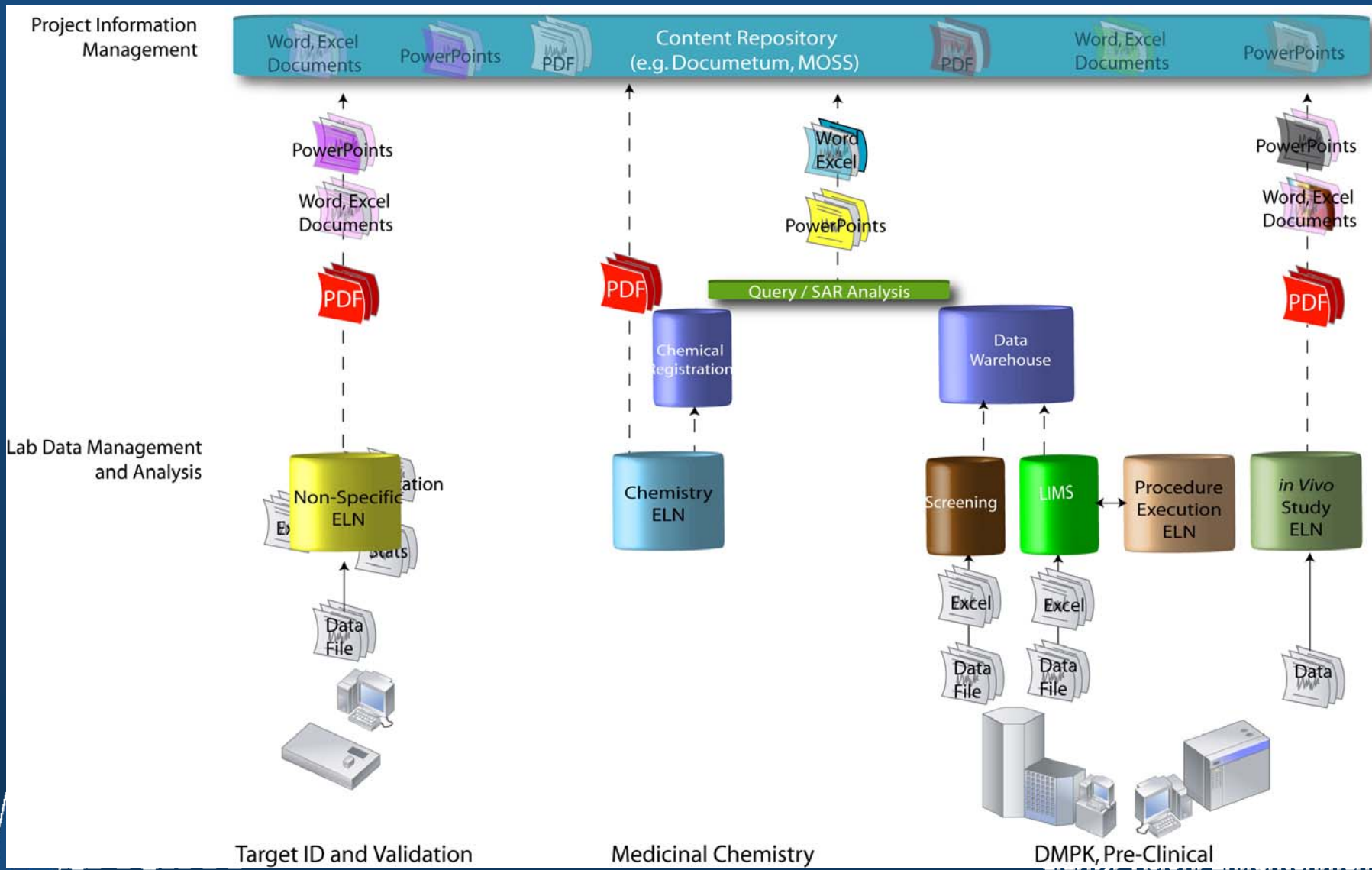
Target Biology May Just Need a Better Way to Manage Unstructured Content



Medicinal Chemistry May Want to Store and Search Chemical Reactions



Drug Metabolism and Pharmacology May Want to Automate Work Processes



ELN is Not...

...*just a replacement of a paper laboratory notebook*

...the savior for all data management woes in the laboratory

... a repository for *all* scientific data

...the final resting place for office files, emails, and other unstructured content

...going to make you more “productive” all by itself

... *the final archive* for your IP



However, ELN...

...is about *knowledge capture* and its *effective use*

...is a *component* of an informatics strategy

...*can* address multiple data management challenges

...*can help* protect intellectual property and/or improve regulatory compliance

... *can* increase collaboration between scientists and laboratory "efficiency"



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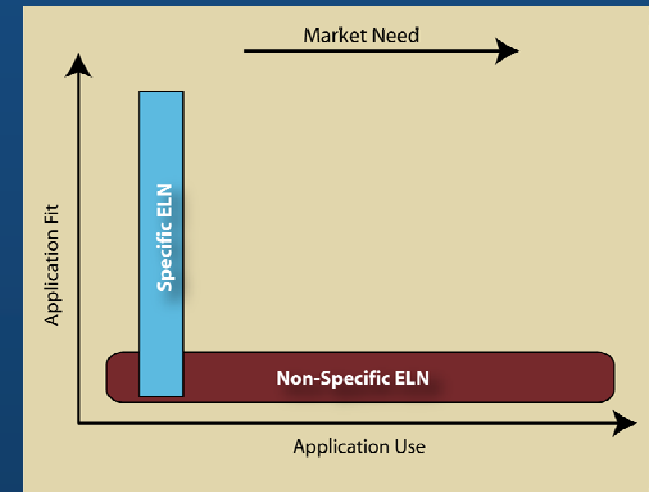
Types of ELN Products

Non-Specific ELN

- Also known as “generic” ELNs
- Strong IP protection and e-signature features
- Designed for multiple markets
- Competing against paper notebook consumption

Specific ELN

- Specific ELNs have integrated applications designed for end user productivity
- Designed for a single market or application area
- *Disruptive* - competing against non-consumption



Specific ELNs are experiencing the highest growth rate due to market disruption, user acceptance, and demonstrable ROI

ELN is a *Component* of an Informatics Architecture

Example Analytical Informatics Architecture

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Connection Level
"Collaborative"
Level 4

INTERNET / INTRANET

Portal

E-Mail

Enterprise Level
"Knowledge"
Level 3

External Archive

Long Term Archive

Document Management / Enterprise Content Management (ECM)

Submissions, SOPs, Training Records, IP Records, QA Reports, etc.

Operations Level
"Information"
Level 2

Analytical Data Mgt

Instrument Raw Data

ELN

Experiment Write-up,
Method Development

LIMS

Workflow
Sample Tracking
Results Mgt

CDS

Chromatography DM

Laboratory Level
"Data"
Level 1



Data
Analysis & Visualization



Balances, pH, etc.



Analytical Instruments



Example ELN Benefits

Maximize the effective use of information

- Creation of a *usable* repository of scientific knowledge
- Ability to search and share experimental information and data
- Elimination of work duplication
- Prevention of information loss on employee departure

Improve productivity

- Tools for experiment design and execution
 - 20% improvement in throughput from existing scientists
 - Enhance creativity and collaboration of ideas across sites
- Workflow automates manual processes

Enhance IP Protection and/or regulatory compliance

- Greater detail in write-up
- Security and audit trails



ELN Challenges

Lack of standardization for long term record preservation and interoperability

- PDF/A is as good as we have, but is too static
- Different XML schemas from suppliers

Most suppliers are relatively small organizations

- Active M&A activity changing landscape

"One size fits all" comes at a cost

- No vendor has best in class functionality across multiple domains
- Multiple system implementations exasperate IP retention but enhance adoption

Academia is slow to adopt ELN

- Creating challenges for future graduates



Managing Change is Critical for Project Success

An ELN project is about improving the way people work, not technology

- *Start small, show success and build from there*
- Leadership and project planning are essential as is management sponsorship and support
- A process and plan for change management
- Analyze, simplify, and document processes and requirements
- Communicate, communicate, communicate!!

Top Reasons for ELN Resistance

- 1) *General reluctance to change (62%)*
- 2) *Users don't understand benefits*
- 3) *Scientific culture*

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The US Rules Have Changed Toward Electronic Records in the Courts

- US patents versus the rest of the world are based on “first to invent” rather than “first to file”
 - Could change with patent reform act
- US patents can be overturned either via the USPTO (interference case) or as a civil suit
- Federal Rules of Evidence (**FRE**) - Records must be proven to be authentic to be admissible (avoid hearsay)
- Federal Rules of Civil Procedure (**FRCP**) – Guide civil cases
 - the USPTO follows FRCP

Good-Bye to the Hybrid ELN

- Until recently, the majority of ELN installations were deployed in a “**hybrid**” configuration with final records still printed to paper with a “wet” signature
- The December 2006 changes to the U.S. Federal Rules of Civil Procedure (FRCP) explicitly addressed *Electronic Record Discovery*
- This *significantly* changed perceptions about the need for paper-based records
- Potential change to U.S. patent laws still necessitate proper attention to records management

Every major pharmaceutical company has, or is in the process of, transitioning to a fully electronic ELN deployment



Recent U.S. Cases Involving Admission of E-Records into US Courts

"Focus is not on the circumstances of the creation of the record, but rather on the circumstances of the preservation of the record during the time it is in the file so as to assure that the document being proffered is the same as the document that was originally created"

In Re Vee Vinhnee Appellate Court (2005)

"If it is critical to the success of your case to admit into evidence computer stored records, it would be prudent to plan to authenticate the record by the most rigorous standard that may be applied."

Judge Paul Grimm *Lorraine et al v. Markel* (2007)



Often Overlooked ELN IP Considerations

Organizations *must have established business rules and policies* for IP protection

- *Must prove compliance*
- *We see companies getting "sloppy" after implementing ELN*

Electronic record preservation practices

ELN products *must have technology for record authentication and integrity*

- *Risk-based approach*

Even if US moves to first-to-file, these are still important considerations



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Academia – Only 4% have Adopted ELN

- Will be challenged by industry to adopt ELN for graduate programs, particularly for synthetic chemistry
- Majority of installations are chemistry related (60%)
- Many of academic installations are custom developed

Examples

- University of Southampton (U.K.) custom-developed system for chemistry laboratory using Semantic Web concepts
- Indiana University – Combined program with School of Informatics and biochemistry
- University of Cincinnati Biomedical Research Center

- Time for experiments increased 43.8%

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