



Electronic R&D: Opportunities and Risks

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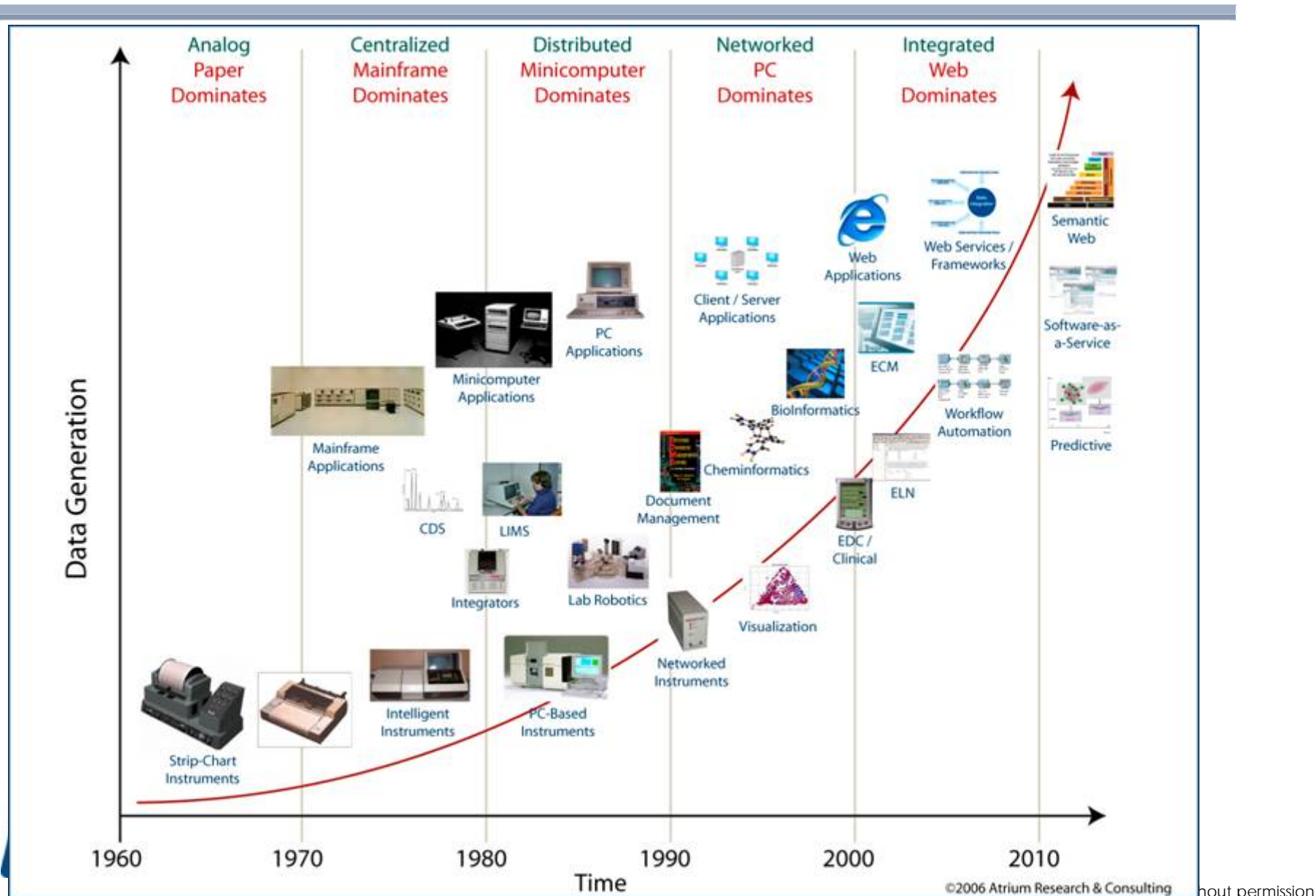
About Atrium Research

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

Our clients include pharmaceutical, biotech, F&B, CPG, chemical, and government organizations



The Evolution of Laboratory Computing



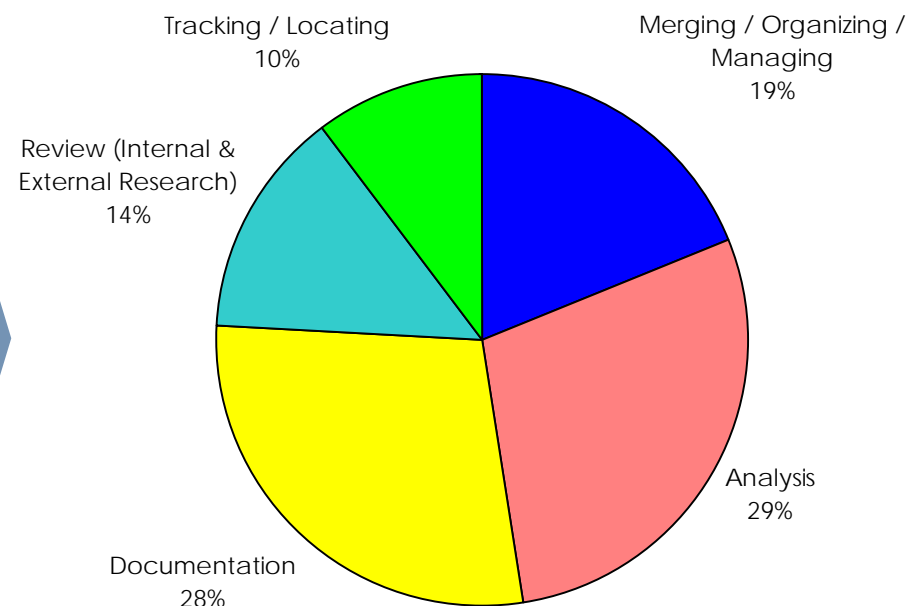
Increasing Time for Data Tasks Takes Away from Effective Use of Talent

Medicinal Chemist Study

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

Biologist Study

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



Source: Atrium Research Market Research

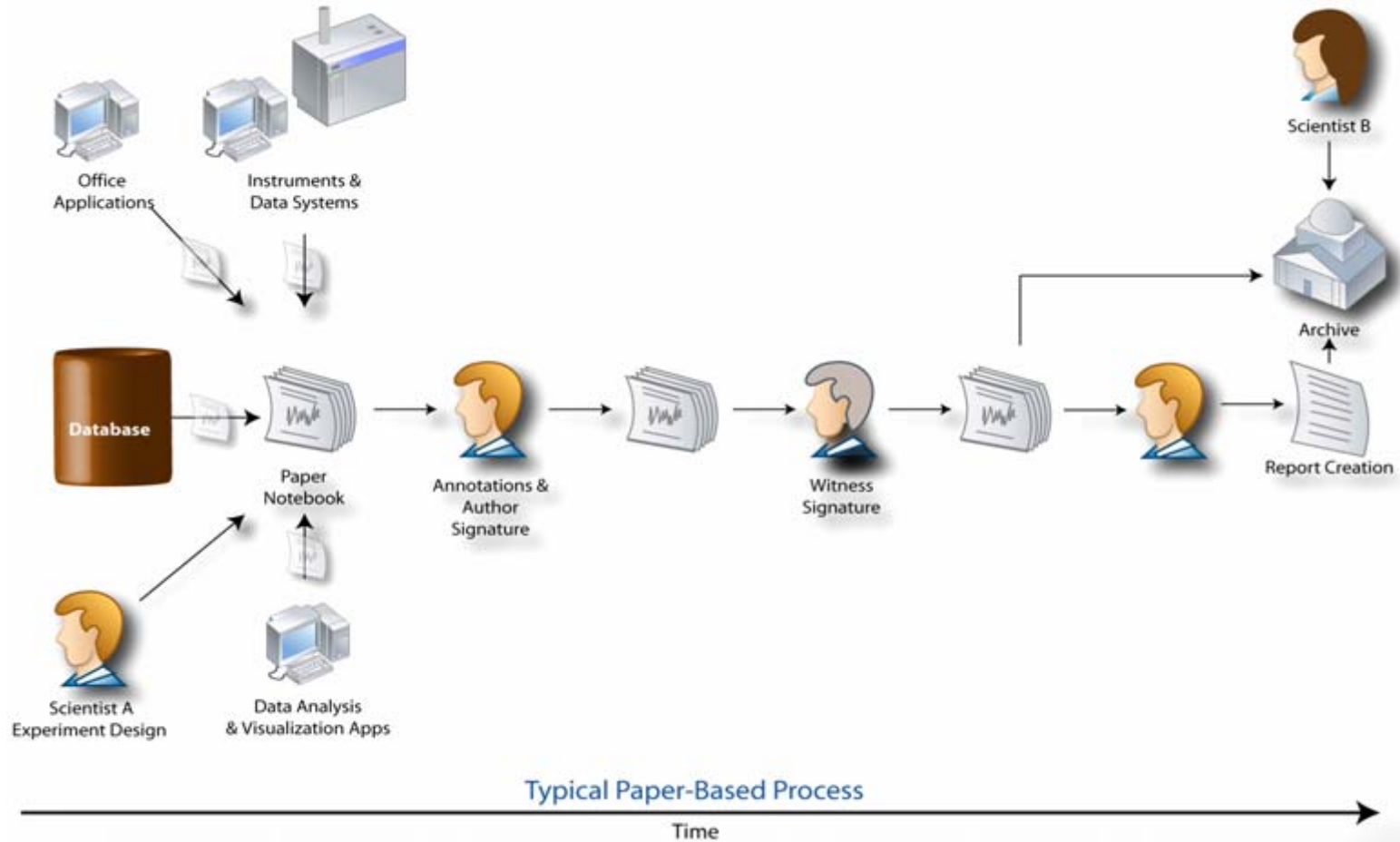
Data Management Challenges Persist in the Laboratory

1. Finding what I need when I want it
2. Storing and organizing data and information
3. Sharing data and information
4. I have to use too many systems and databases
5. I have to consolidate data from multiple sources
6. Keeping up with all the data being generated

Source: Atrium Research Market Research



For Intellectual Property Protection, the Paper Notebook Continues



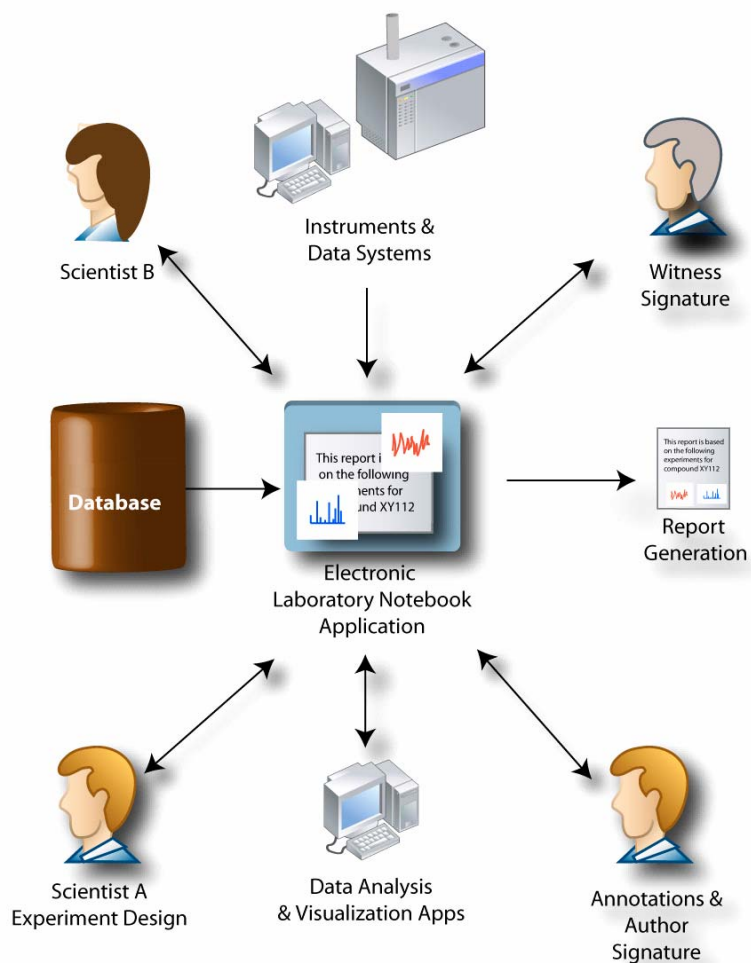
Results:

- The Scientist as the Data Integrator
- Excel as the Data Manager
- Historical Knowledge Lost to Archives



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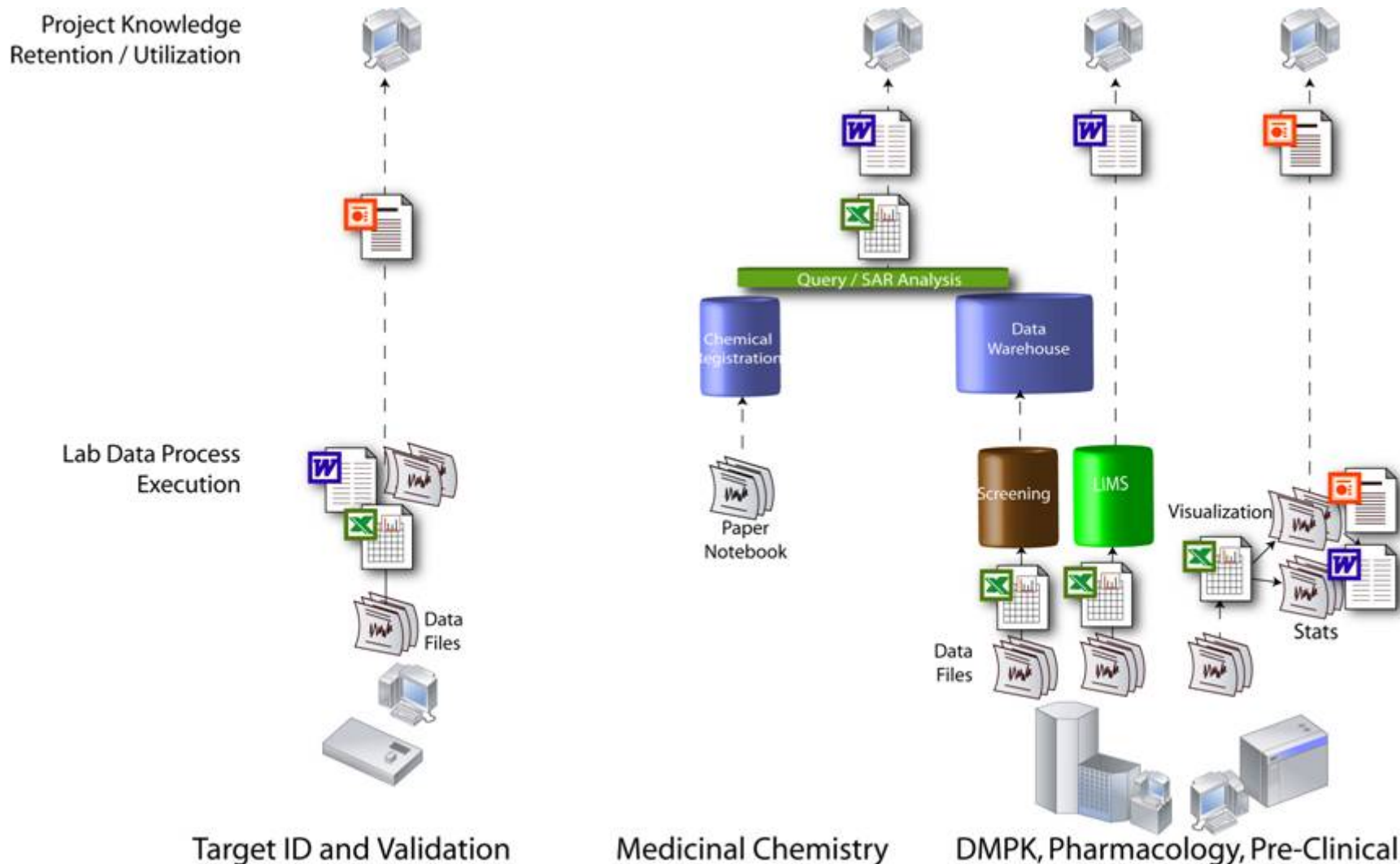
Enter Electronic Laboratory Notebooks (ELN)



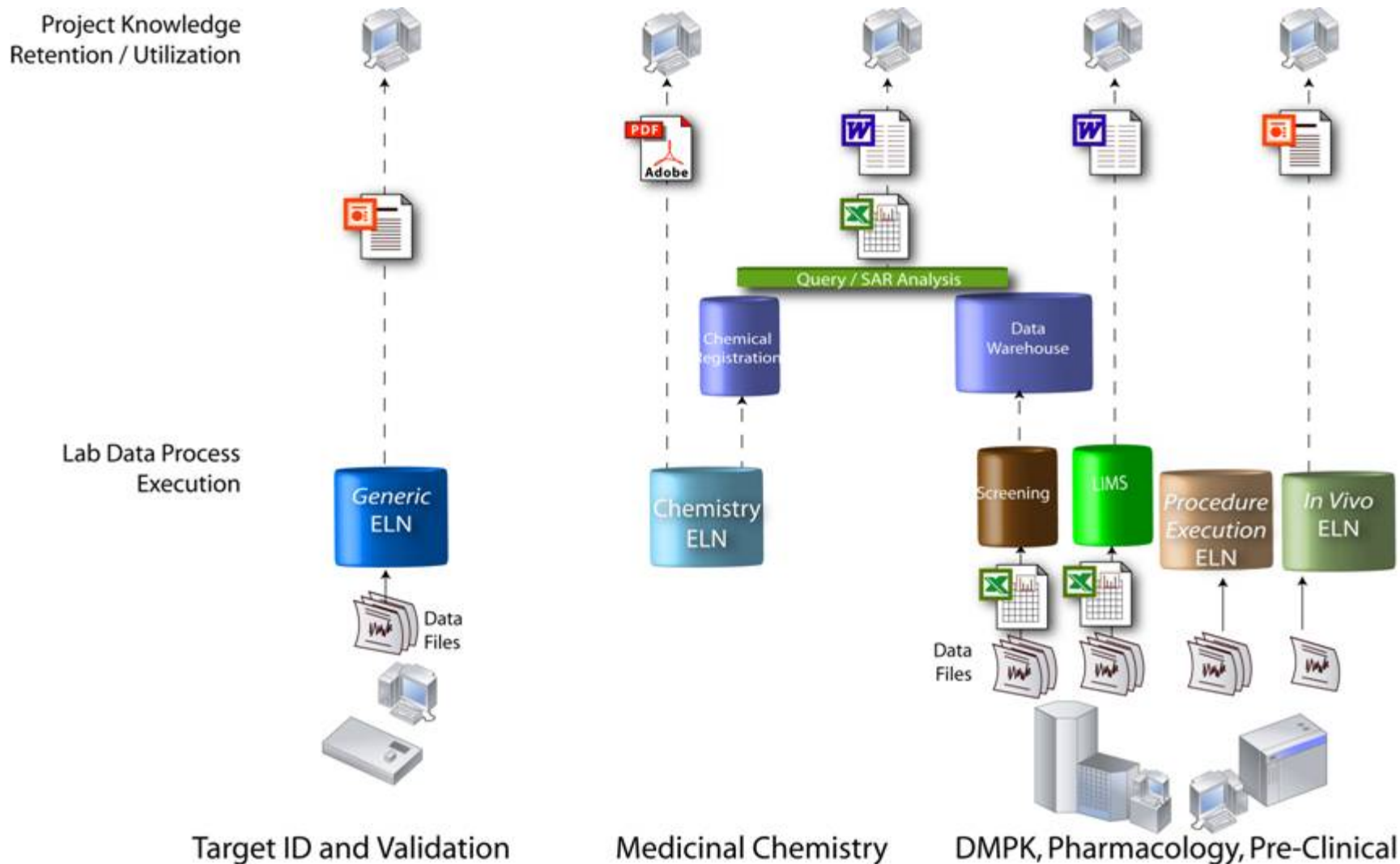
- ▶ *One* option available for documenting experimentation and IP management
- ▶ A secure repository for primary and select secondary data
- ▶ Market accelerated in 2003 to now 20%+ market penetration
 - Over 30 suppliers
- ▶ Common features:
 - Application/Domain-specific modules
 - Synthetic chemistry, DMPK, formulations, etc.
 - Search
 - Collaboration
 - Electronic signatures
 - Workflow
 - Authoring
 - Tools Integration (e.g., Office)
 - Report writing
 - Templates and Forms
 - Data dictionary



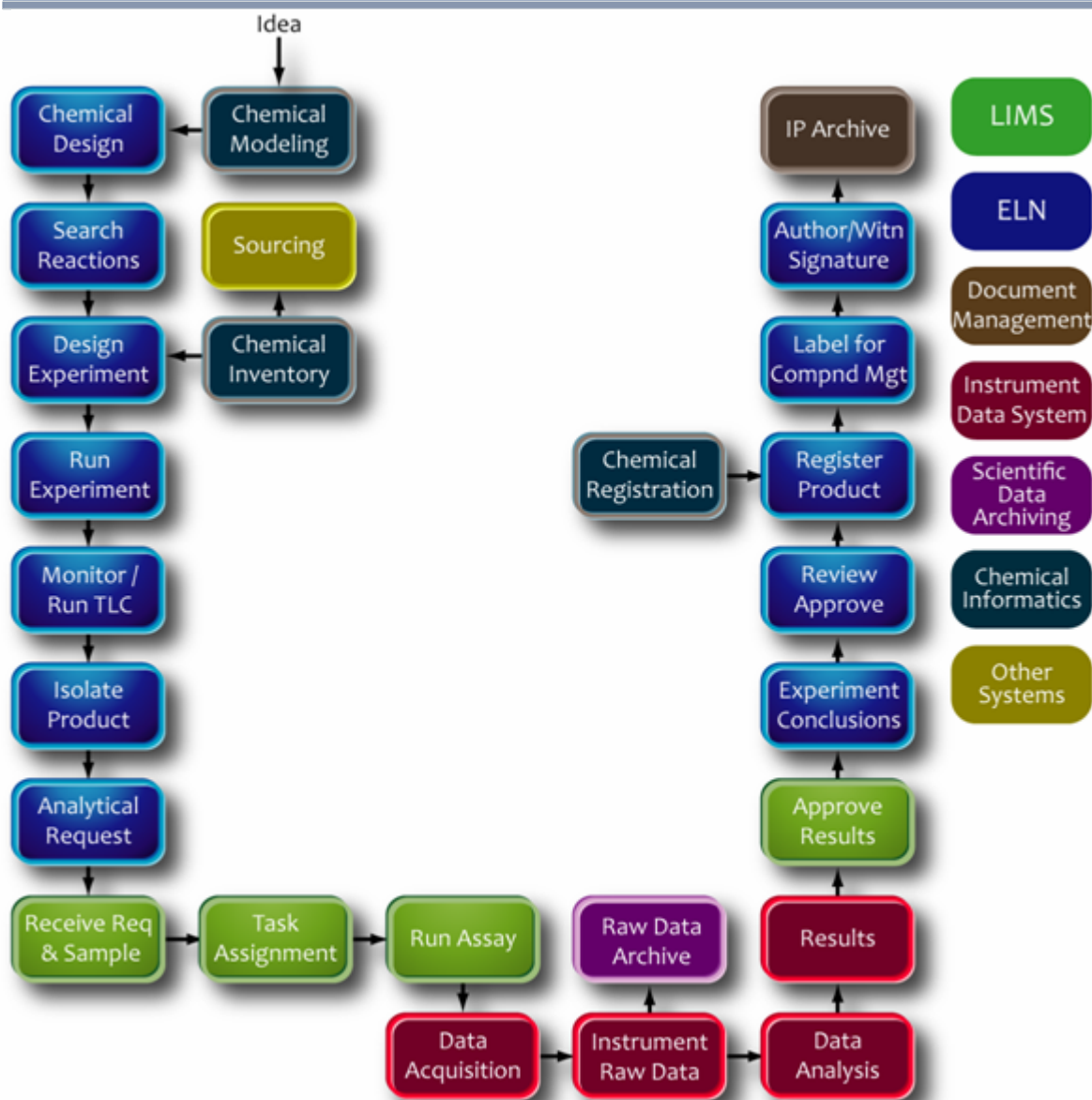
Let's Examine a Typical Small Molecule Drug Discovery Environment



Analysis Often Results in Domain-Specific Solutions



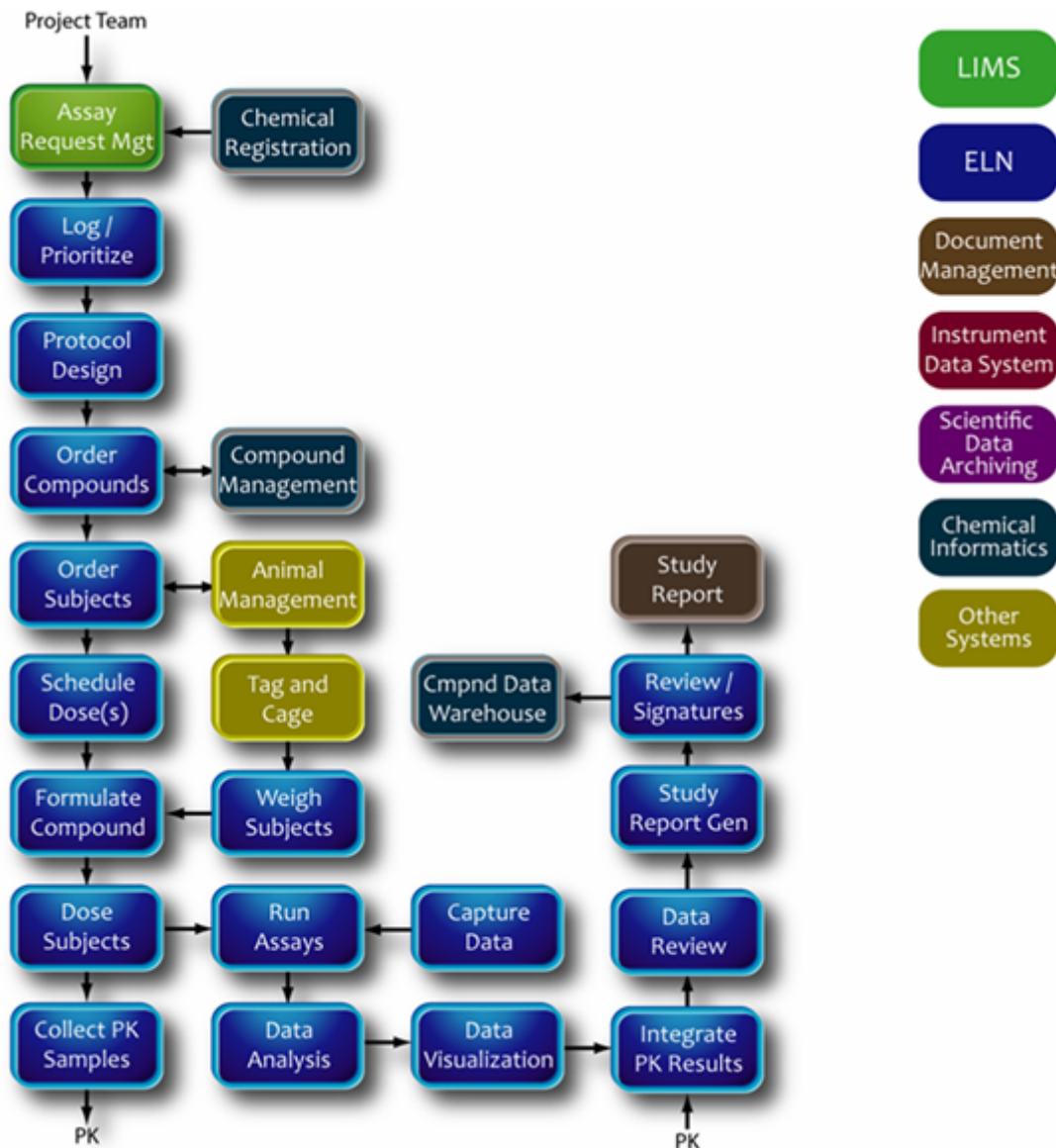
Where the ELN Lives Defines Its Use



Medicinal Chemistry ELN Example Workflow

- ▶ Reaction planning
- ▶ Stoichiometry
- ▶ Analytical data capture
- ▶ Integration with registration and inventory

ELN in Biology Domains Differ Greatly in Use from those in Chemistry

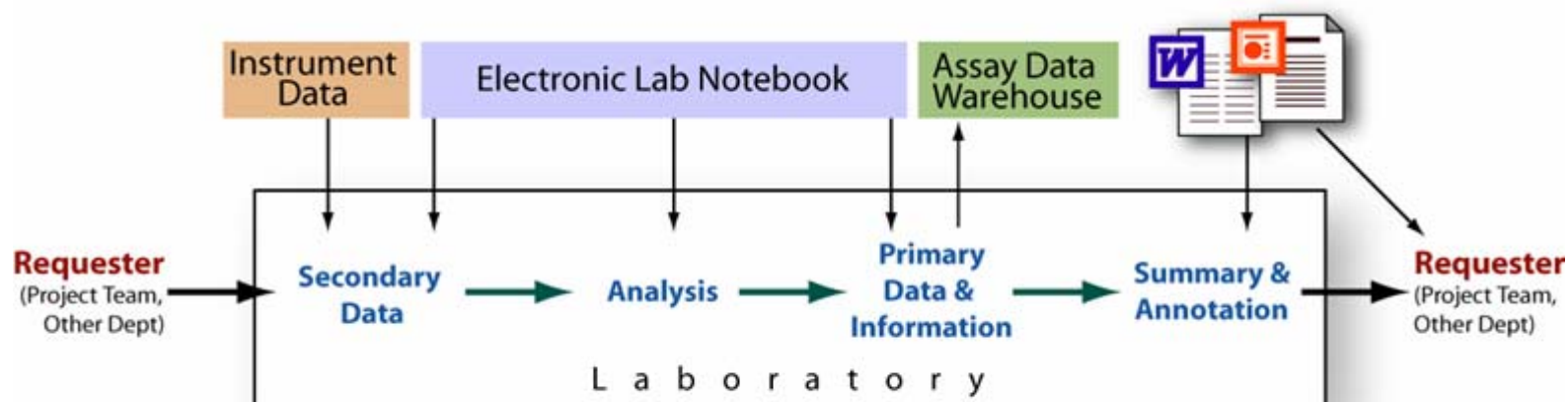


Pharmacology Example ELN Workflow

- ▶ Protocol design
- ▶ Study execution,
- ▶ Assay support,
- ▶ Analysis
- ▶ Reporting

eRecord Intellectual Property Challenges

- ▶ Often, there are multiple ELN solutions across an organization with different security, electronic signature, and record authentication capabilities
- ▶ ELN is *not* the be-all and end-all of IP protection. Discoverable records are contained in summary project team PowerPoint presentations, reports, data warehouses, e-mails, and raw data



Bear in Mind...

- ▶ US patents versus the rest of the world are based on “first to invent” rather than “first to file”
 - Cases can occur in the US Patent and Trademark Office or in the Federal Courts
- ▶ Electronic evidence creates unique challenges
 - Difficult to determine authorship and time of creation
 - Detection of alteration
- ▶ Records must be proven to be authentic, relevant and not hearsay (or business rule exemption) to be admissible into court
- ▶ US Federal Rules of Civil Procedure (FRCP) guides cases – the USPTO follows them



2006 Changes to FRCP Explicitly Address Discovery of Electronic Records

“Except in categories of proceedings specified in Rule 26(a)(1)(E), or to the extent otherwise stipulated or directed by order, a party must, without awaiting a discovery request, provide to other parties:....

*(B) a copy of, or a description by category and location of, **all documents, electronically stored information, and tangible things that are in the possession, custody, or control of the party** and that the disclosing party may use to support its claims or defenses, unless solely for impeachment”*



Source: US FRCP

ELN Records are Not the Only Discoverable Electronic Records!

*“Any party may serve on any other party a request (1) to produce and permit the party making the request, or someone acting on the requestor’s behalf, to inspect, copy, test, or **sample any designated documents or electronically stored information** — including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations **stored in any medium from which information can be obtained** — translated, if necessary, by the respondent into reasonably usable form”*



Source: US FRCP

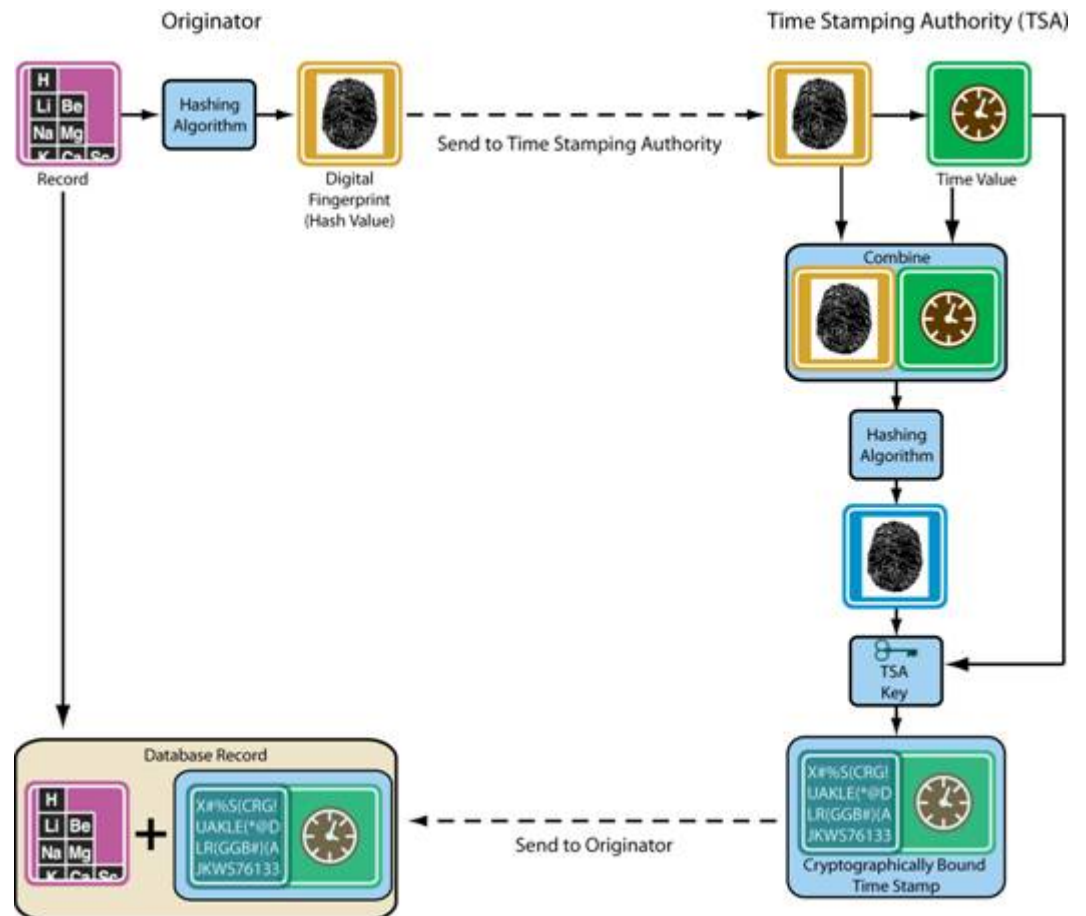
There is a a Need for User *and* Record Authentication that is Consistent Across Systems

▶ Record and Authentication

- SHA256, 512 REPMD160 hashes
- Message authentication code (MAC)
- X9.95 Trusted Time Stamping Authority

▶ User Authentication

- Digital Signatures - Public Key Infrastructure (PKI)



Summary

- ▶ R&D organizations are quickly adopting technologies to enable electronic R&D environments to improve efficiency and cycle time
- ▶ There are many components to an informatics architecture with Electronic Laboratory Notebooks playing a major role
- ▶ In the age of e-Discovery, all records can be discoverable, not just those contained in the ELN
- ▶ A consistent approach to record authentication and integrity is needed to minimize risks



Finally....

*"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 W. Grimm
Lorraine v. Markle*

