ELN SIG

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Presentation Outline

- ELN Drivers
- Definitions
- Requirements
- Benefits
- Challenges
- Current approaches
- ELN options
- Architecture
- Way forward
- Conclusions

Electronic Laboratory Notebooks

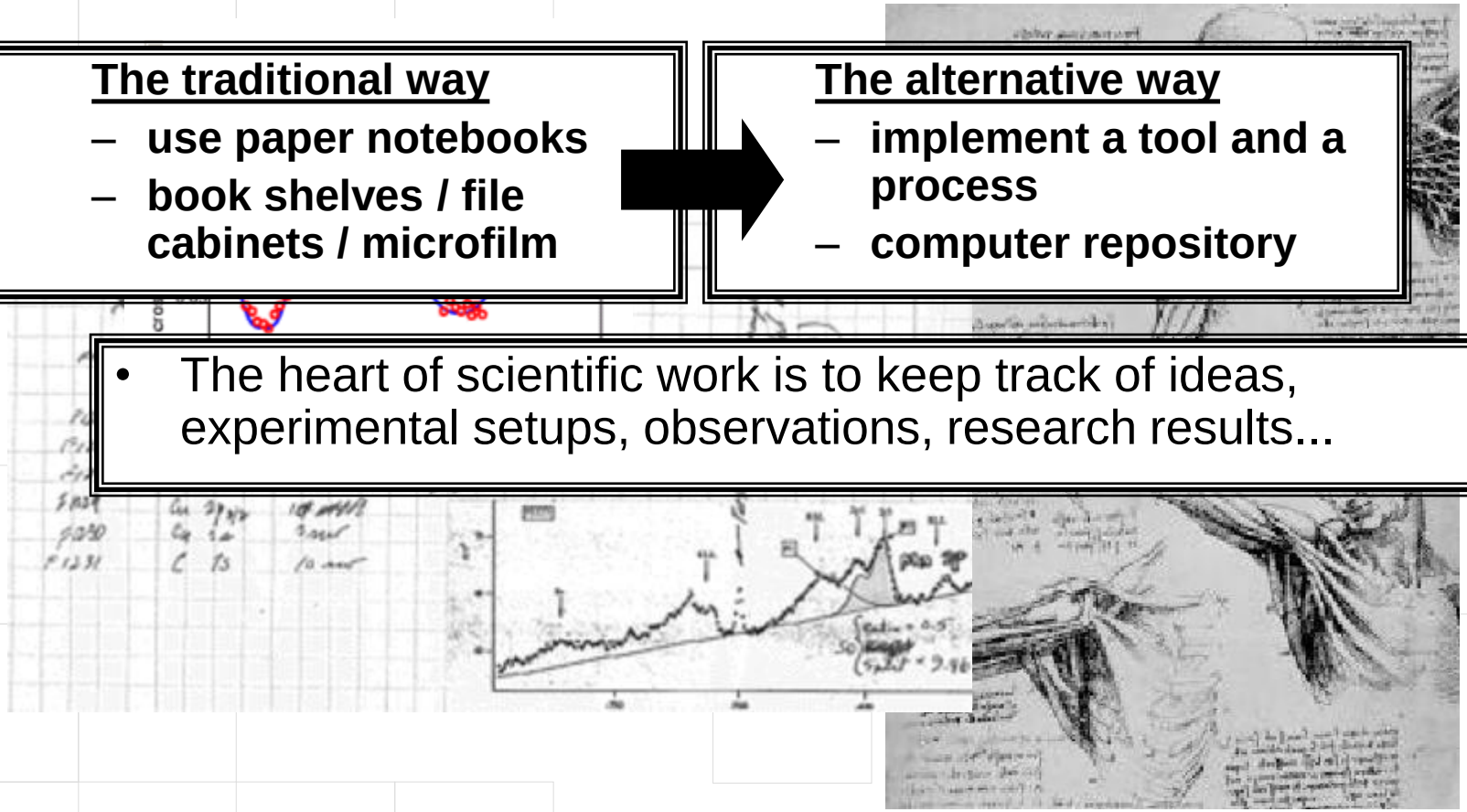
The traditional way

- **use paper notebooks**
- **book shelves / file cabinets / microfilm**

The alternative way

- **implement a tool and a process**
- **computer repository**

- The heart of scientific work is to keep track of ideas, experimental setups, observations, research results...



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ELN Drivers

- Improve IP protection
  - Completeness and compliance
- Knowledge sharing
  - Reduce repetition of failed activities
  - Capture best practice
  - Identifying new opportunities
- Efficiency
  - Personal efficiency
  - Information flow
- Data capture and information management

ELN Definition

- A fully electronic notebook is a system to create, store, retrieve and share fully electronic records in ways that meet all scientific, legal, regulatory, and technical requirements.
- A hybrid electronic laboratory notebook is a system to create, store, retrieve and share electronic records, which uses printed copies with handwritten signatures for archiving and IP protection.
- Records are the collection of information or data associated with an experiment to enable a suitably skilled person to repeat it. records also contain a time and date-stamp.

Key Requirements: Scientists

- capture information independent of source and format
- clearly associate a record with the originator
- import/export data
- supports scientists' working practices (including reuse)
- fully searchable
- link to other systems
- retrieve and share records over time
- support document life cycle stages – private / in progress, public / finalized, and archived
- supports element referencing within experiments
- user acceptance; better than the paper counterpart

Key Requirements: Other Stakeholders

- LAWYERS/REGULATORY
  - ability to show in court records, & audit-trail
  - support for due diligence
  - IP protection
  - validated records when applied in regulated situations
  - Completed records, non-deletable
- ARCHIVISTS
  - compatible with corporate archiving and retention strategy
  - longterm retrievability of records
  - human readability over time
- MANAGEMENT
  - ability to generate business process metrics
  - improve quality
  - facilitates collaboration and share information
  - provide the ability to use, mine, extract and compile information
  - be compatible with corporate strategies
  - drive process improvement

Benefits (company perspective)

- IP protection
  - Capture ideas, and creative process
  - Completeness of records
  - Reduce litigation cost by improved access to the data
  - Establish an earlier priority date
- Quality
  - Records are complete
  - Quality of information recorded improved
  - Structured information
  - Easier to be more verbose and capture additional information
  - Improved calculation
  - Readable
  - Audit trail
  - Metrics
- Disaster recovery

- Productivity increase
  - Easier to capture varied data types (don't glue things into lab notebook)
  - No need to manage paper lab notebooks
  - Use of forms and templates (iconic, reusable text, etc) makes data entry easier
  - Drives improved workflow
  - Integrating other components enables more rational use of other components and services
  - Avoid duplication of failed assays and synthesis
  - Avoid reinventing protocols
  - Better design of experiments
- Sharing
  - Sharing information among different business components (e.g. Disc to PD)
  - Packaging of information for 3rd parties

Benefits (scientist perspective)

- Productivity increase
  - Same as above
- Searchable
  - Access to previous experimentation => reuse of experimental methods, ideas, outcomes, equipment evaluations
  - Ability to understand results of experiments
  - Support for legal requirements
  - Organizational productivity enhancement
- Sharing
  - reuse of experimental methods, ideas, outcomes, equipment evaluations
  - Information about running the experiment and the conclusions derived from the data
- Integration of systems
  - Compound registration
  - Analytical systems
  - Compound management
  - Workflow management
  - Image systems (fMRI, gene expression)
  - Analysis tools

ELN Challenges

- **Cultural aspects**
  - Sharing information
  - New SOPs / work practices
  - Computer literacy
  - Part of the workflow
  - Need strong management champion
  - Acceptance of electronic paradigm across the business
  - Workflow Inertia
    - Slow Adoption
    - Root-cause of Resistance
    - Workplace Disruption
- Security
  - Electronic Signature Standard
  - Repository Security
  - Archival Records Format
  - Inter-application Credentials
  - Records with Open & Restricted Data
  - Third Party Access
- **Integration**
  - Custom Applications / other ELNs
  - Compound Registration & Request
  - Experimental Request & Data Systems
  - Vendor Databases
  - LIM Systems
  - Tight integration for robust information sharing with loose coupling with other systems
  - Must have a clear business strategy and IT architecture
- **Managing scope and expectations**
  - Establishing ROI and commitment to funding
  - Phased implementation
- Scalability
  - Growing User Population
  - Variable Loading
  - Potentially Highly Integrated
  - Frequent Data Mining Target

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ELN Challenges

- **Persistence**
  - Indefinite (~50 yrs) Retention Policy
  - Platform Neutral Record Format
  - Separable Record Elements
  - (for Searching and Accessing)
- Flexibility
  - Diverse Workflows
  - Continually Changing Workflows
  - Centralized & Personal Styles
  - Variable Software Environment
- Logistics; Practical implementation in the lab
- Change
- Politics
  - Strong Leadership Required
  - Inter-departmental Cooperation
  - Proprietorship of Data
  - Perceived Productivity Monitoring
- **Immature Products**
  - Unstable Base
  - Frequent Releases
  - Changeable Marketplace
  - Incomplete Understanding of Science
- Ease of adoption
  - Easy to learn
  - How to make a complex system easy to use

Top ELN Challenges

- Cultural aspects
- Managing scope and expectations
- Integration
- Evolving products
- Persistence

? CHANGE

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Current Approaches

Company Name	Current Stage	Description
BMS	Evaluation	requires multiple solutions to meet different user requirements
Syngenta	Early stage	Scanning, non-GLP paper records to enable people to view online at some sites
AstraZeneca	Planning/evaluation	Working on the implementation roadmap for discovery chemistry and undertaking multiple evaluations of potential solutions.
Biovitrum	Implementation	Capture work electronically, lock completed experiments and print to secure printers for wet signature and paper archive
Lilly	Implementation /Evaluation	Intellichem for process chemistry, solutions being evaluated for discovery chemistry. Decision on discovery chemistry Q3 2004.

Current Approaches

Company Name	Current Stage	Description
Johnson & Johnson	Planning/evaluation	ELN is not currently funded, but high on list of priorities. Planning to target solutions to specific business needs.
GSK	Project approval	Seeking one system to satisfy all users in discovery. Preferred system identified, and seeking funding approval
Wyeth	Early stage	ELN not part of the strategic plan yet. Current expectations 2006
Roche	Planning, implementation next year	Harmonization of ELN across discovery research. Architecture that leverages investment in key components.

ELN Options

Scope

- Build
  - Risk management
  - A chance to fit requirements exactly and control future
  - Plan for integration
  - Requires resource and skills
- General or Discipline specific

- Buy
  - Risk management
  - Does not fit all requirements
  - Integration challenges
  - Immature products
  - Future vendor viability
- Hybrid or fully electronic

Fit with wider IT Architecture Considerations

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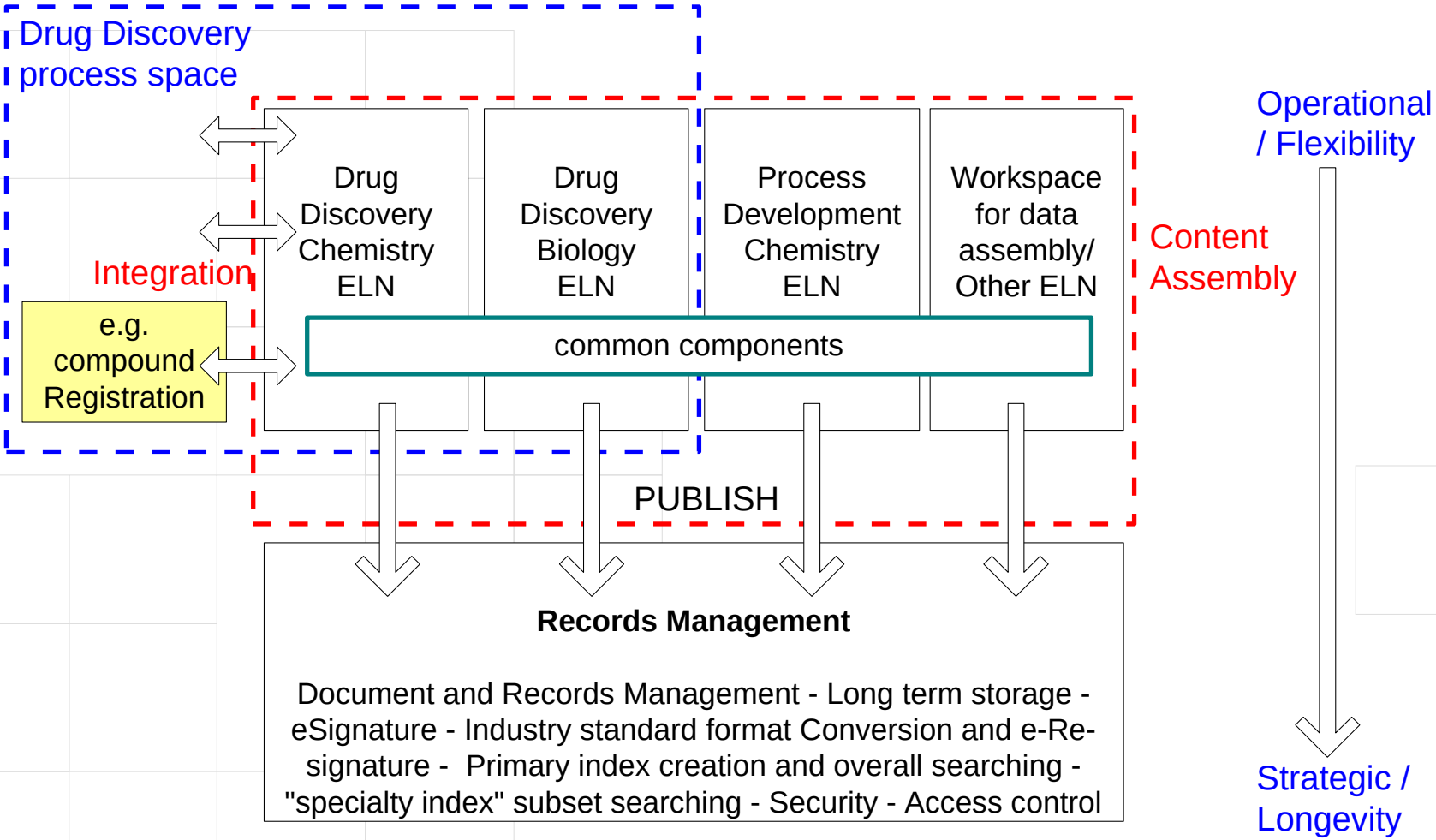
Architecture

- ELN is primarily a workspace for data assembly and record creation
- Separate ELN interface from records management function
  - ELN Workspace/GUI for content assembly
  - Publish records
  - Record management is a corporate service
    - Paper/electronic/hybrid
- ELN becomes an enabler/ productivity tool for investigators
- application integration with other tools
- data integration

Architecture



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Steps towards an ELN installation

- Define what other systems exist or should be created first
  - Avoid wrong expectations. ELN may not be your biggest problem.
  - e.g. Compound registration, sample logistics, chemical inventory
- Define the IT architecture for data sharing
  - Use this as requirements for any purchasing or in-house development project
- Create a master plan for desired final system
  - Start with component architecture
  - Applications, meta-data, database and records management
- Set realistic scope for pilot implementation
  - Avoid solving all problems at once
  - Identify driving forces, allow iterative improvements
  - Keep final architecture in mind and don’t deviate from it

Conclusions

- Business drivers support implementation in near future
- Requires a ELN strategy now
- Challenging but mission critical