Real World ELN Case Study: Documented Productivity Gains and Using Them to Justify the Purchase of an ELN.

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Today’s Presenter

Richard Stember

- CEO Scientific Division, EKM Corporation
- Lead developer and inventor of the LABTrack ELN product.
- Developing ELNs since 1997.
- Over 25 years product marketing, sales, and engineering of scientific software.

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Presentation Outline

• What makes an Electronic Lab Notebook?
• Medtronic Case Study
• Indiana University Productivity Study
• Return on Investment Analysis
What is a lab notebook?

• To a Researcher - "a place to do science"
  • primary lab data & experimental observations.
  • references to external data and literature sources.
  • interpretations, distill data & final experimental conclusions - reports for other researchers or management.

• Convenient, easy to use, portable
  • Merit with legal and regulatory authorities.
  • Non-reputable, courts consider to be standard business records (exception to hearsay rule).
  • US PTO issues patents based upon date of invention.
Why Replace Paper Notebooks?

- Used for hundreds of years.
- Not a Collaborative Tool
- Do not facilitate searching, mining, reporting
- Not the best tool to support science, the researcher or the corporation.

Leonardo da Vinci’s Lab Book (circa 1478)
An “Ideal” Day in the Life of a Research Scientist

• Research & review science literature
• Plan & outline experiments
• Discuss ideas w/ colleagues & res. staff
• Execute experiments
• Analyze data, draw conclusions plan next experiments
• Write reports, document findings, file IP
• Present research findings at meetings
A “Typical” Day in the Life of a Research Scientist

- Literature piled-up, reports due, meetings
- Experiment takes longer than planned or fails.
- Data & supplements from past week’s experiments still not in notebook.
- Incomplete data, partial analysis, inconclusive.
- Coffee spills, misspelling & miss-entries in notebook, forgot details.
- Can’t find data in old notebook for a figure in a publication or an IP filing.
A Better Mirror on the Paper Notebook

**Paper Notebook**
- Fixed order, pre-blocked pages, non-contiguous entries, use several notebooks.
- Multiple projects & loose field notes & supplements.
- Possession by researcher, difficult to share work, potential loss or inaccessibility
- R&D complex with global cross-functional teams & collaborators

**ELN**
- Pages reordered & reorganized virtually to support multiple projects “Loose leaves” never lost.
- Remote access, always available to researcher and collaborators.
- Individual notebooks contribute to virtual group notebook, contributions tracked.
Saving User’s Time

**Paper Notebook**

- Manually enter repetitive tables or SOP’s
- Remember cross references & SOPs.
- Manual cut & paste, data entry; binding limit inserts
- Review & sign by hand
- Slow retrieval of archived notebooks.
- Copy pages or call to respond to requests from Legal, Clinical, Regulatory or Business units.

**ELN**

- Download, search and reference templates & SOPs
- Automate data entry & embedding of any file type of any size.
- Notarized & electronically sign.
- Instantly retrievable, searchable & transmittable
- Provide “perfect copies” to Legal, Clinical, Regulatory & Business units
Improving Accuracy & Compliance

**Paper Notebook**
- Poor penmanship & poor grammar
- Incorrect or incomplete entries, cross-outs
- Little or no GLP training or adherence to guidelines
- Lag in witnessing & corroboration
- Notebooks lost or improperly maintained

**ELN**
- Legibility, grammar & spelling checked automatically.
- Audits incomplete, unusual entries & changes, guides and automates data entry.
- Maintains compliance
- Enforces e-signature, witnessing, approval.
- System maintains “perfect copies” for IP, legal & reg.
Facilitating Timely Decisions

- **Research**
  - Evaluate Progress, Performance, Results

- **Business**
  - Aids valuation of IP & knowledge for M&A
  - Tracking R&D knowledge & value productivity

- **Legal**
  - Aids patent filing, prosecution & defense
  - Enables liability response filings

- **Regulatory**
  - Compliance
  - Document generation & delivery
The Hidden Costs of Using Paper

• A Scientist may spend 10% of time Manually Cutting, Pasting, Transcribing & Indexing
  – $MMs for 100 FTE lab/yr

• Searching Notebooks Is Very Time Consuming
  – Experiments are repeated unnecessarily.
  – Knowledge Lost – Not Retained

• Managers may spend 1-5% signing paper notebooks
  – Shutdown on notebook signing day.

• Notebook Administration
  – Manual Microfiche Procedure
  – Retrieving notebook from storage takes 1-3 days
LABTrack Enterprise ELN

- **Web based.**
  - Page Paradigm
  - Built-in Word Processor
  - Real Time Collaboration
  - Automated Communications
  - Virtual Views for browsing and searching notebooks

- **Templates support**
  - Forms, SOPs, Protocols
  - Automated calculations
  - Interfacing to other databases and Apps
  - XML Import & Export

- **Table of contents**
  - Dynamically organizes pages
  - Projects, Titles and User Defined Bookmarks/Folders.
Combining the functions of a Word Processor & Document Management system.

Many types of objects can be embedded on a page including chemical drawings, spreadsheets, Word documents, etc. embedded on the page picture such that toolbar gives the user and below objects

The drawing to the right is a .bmp file that was placed on the page.

The chromatogram below is a .bmp file that was embedded on the page using the embed object button.
Complex Requirements

• Longevity
  – Each page is stored as an HTML record in a RDBMS.

• Ease of Use

• Searching
  – Searching on page text, embedded object contents, projects, titles, meta data, keywords, etc.

• Security
  – Supports multiple views & privileges (rights).
  – Virtual Notebooks – Views
  – Electronic Signature (21 CFR Part 11)

• Legal & Compliance
  – Digital Notarization, PKI
  – cGMP, GLP, GAMP
ELN Case Study

Medtronic, Inc.
Heart Valve Division, Santa Ana California

- Conducts research on prosthetic heart valves, performs biochemical, biomechanical, immunological and hydrodynamic tests on porcine valves that have been chemically treated to prevent rejection in human patients. With current technology, such valves last about 15 years in patients. Medtronic’s goal is to enhance the tissue treatment technology to ensure that these valves last at least 30 years.
Medtronic’s Objectives

• Replace paper laboratory notebooks with secure and easier to search database.
• Comply with cGMP and FDA 21 CFR Part 11.
• Capture data from a diverse variety sources (microscopy images, wave form files, analytical test result files, etc).
• Better secure Intellectual Property (IP)
Medtronic Implementation

- Dozens of users at Santa Ana, CA Research Facility.
- Researchers use Tablet PC’s with docking station at each desk.
- LABTrack Enterprise
- Custom Templates.
Medtronic Success

“Adopting this new system decreases the risk of losing data and decreases the risk of repeating experiments.”

- Chris Coppin M.D., PhD, Senior Research Manager, Medtronic Heart Valve Business Unit.
Indiana University Productivity Study

• Graduate Student Masters Thesis
• Studied implementation of lab operations before and after LABTrack was implemented.
• University Biomedical Research Lab
• Employed “Work Sampling” method over two 7 week periods.
• Measured proportions of time spent on specified tasks.
Measured Tasks

- Computer Work
- Non-computer Work
- Experimentation
- Computer Data Management
- Non-computer Data Management
- Reporting
- Other/Meetings
**Work Sampling Results**

<table>
<thead>
<tr>
<th>Category</th>
<th>Before</th>
<th>After</th>
<th>Diff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comp Work</td>
<td>42 %</td>
<td>33 %</td>
<td>- 9 %</td>
</tr>
<tr>
<td>Non-comp Work</td>
<td>5 %</td>
<td>5 %</td>
<td></td>
</tr>
<tr>
<td>Experiment</td>
<td>16 %</td>
<td>23 %</td>
<td>+ 7 %</td>
</tr>
<tr>
<td>Comp Data Mgt</td>
<td>5 %</td>
<td>4 %</td>
<td></td>
</tr>
<tr>
<td>Non-comp Data Mgt</td>
<td>3 %</td>
<td>4 %</td>
<td></td>
</tr>
<tr>
<td>Reporting</td>
<td>5 %</td>
<td>4 %</td>
<td></td>
</tr>
<tr>
<td>Other/Mtgs</td>
<td>24</td>
<td>27 %</td>
<td>+ 3 %</td>
</tr>
</tbody>
</table>

* N Vinukonda; Implementation of an Electronic Laboratory Notebook in a University Based Biotechnology Laboratory, masters thesis, School of Informatics, Indiana University, Dec 2002
Survey Comments from Users

- “There wouldn’t be loose papers laying around that you don’t know where they belong”
- “Easier to locate experiments”
- “An asset to the lab”
- “Convenience, security, organization”
- “Saves time and effort”
- “Easy tracking, easy organization, easy presentation”
Return on Investment

\[
\text{ROI (yrs)} = \frac{\text{Cost of ELN}}{\# \text{FTEs} \times \text{PPG} \times \text{FTE Cost / Yr}}
\]

- Cost of ELN = $60,000 (typical 20 user license plus services for installation and training.)
- # FTEs = 20
- FTE Cost / Yr = $65,000
- PPG (Projected Productivity Gain) = 10%

\[
\text{ROI} = \sim 6 \text{ months}
\]
Value Justification
What is the value of a lab notebook?

Cost of PN vs ELN

- **Cost-PN**
- **Value-PN**

Years

- 0
- 3
- 6
- 9
- 12

Cost

- 0
- 5
- 10
- 15
- 20
- 25
- 30
Value Justification
What is the value of a lab notebook?

Value of PN vs ELN

Years

0 3 6 9 12

Value-ELN
Value-PN
Presentation Summary

• ELN’s can work the way scientists work.
• Reduces the drudgery of documentation.
• Reduces burden of supporting needs of Legal, Regulatory, Research, Clinical and Business units.
• Allows scientists to focus on what they do best - solving problems, creating knowledge.
• Retains instead of losses knowledge.
• ELN’s are easily justified based upon real productivity gains and data valuation.