

Strategies for Success

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Strategies for Success

- Electronic Lab Notebooks sound like a wonderful idea... I want one!
- ...Now what?
- Question: what you need to make your ELN dreams a reality?

Strategies for Success

- Making things happen - some caveats
- What's special about ELNs
- Hybrid or totally Electronic?
- Cultural issues
- Building the momentum internally
- Business justification
- Running your project

Making things happen

- Every organization is different
 - Current drivers
 - History
 - Processes
- The most important thing is to do what works in your organization
- Believe it or not, a lot of what vendors do (often invisibly) is helping you make things happen

Making things happen

- Generalizations are dangerous, but necessary
- These lessons from my experiences
- Mix this with your experience of your organization
- And adjust in the light of events!

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Paper Lab Notebooks

- Since the very first “experiment”, people have been recording scientific activity in Paper Lab Notebooks
- A common (paper) Lab Notebook integrates all the different kinds of “Science” in one place
 - Work is done by different people, supported by different systems
 - So the PLN forms an important (and often invisible) systems integration role

Paper Lab Notebooks

- These records are used for a number of purposes
 - Scientific record
 - Regulatory compliance
 - To support future patent claims
 - Personal productivity of the scientist
 - Collaboration between scientists

Paper... to Electronic

- Computers have become more and more a part of scientific work
 - Organizations have already purchased and deployed a significant number of other computer systems to support R&D
 - As a result, Paper Lab Notebooks have become increasingly anachronistic
- Most people are now looking to replace the Paper Lab Notebook with an Electronic one
 - But any replacement must
 - Adequately perform the functions of the Paper Lab Notebook
 - Work with the systems that are already deployed
- This is a time of opportunity... and of threats

ELNs - Opportunities

- There are tremendous potential benefits in moving to ELNs
 - Productivity (and happier scientists)
 - Cycle time reduction
 - Better records
 - For science
 - For patenting
 - For compliance
 - Increased collaboration, especially across departmental and geographical boundaries
 - Efficient searching means Lab Notebooks are no longer "Write only"
 - etc....
- In short, it's a pretty compelling vision

ELNs - Threats

- The Paper Lab Notebook and associated processes have been around for years
 - Longer than all of us have been around
 - Longer than most of our companies have been around
- This can make it very difficult for us to stand back and examine and understand what Paper Lab Notebooks actually do for us

ELNs - Threats

- At the very least we aren't going to make the best of the opportunity to replace them...
- ...at worst
 - We won't create adequate records
 - We will lose the "lubrication" that Paper Lab Notebooks provide in a diverse scientific environment
 - We'll seriously mishandle the change

ELNs - What to do?

- What to do?
 - Be aware that ELNs are different, and that you need to be very conscious of the special considerations that apply
 - Attend more conferences in exotic locations!
 - Learn and benefit from others' experiences
 - Work with people who have done it before
- Aspects to consider
 - Record keeping
 - Technical/IT/Project Management
 - Commercial
 - Cultural

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Hybrid or totally Electronic?

- “Electronic Lab Notebook”
 - Sounds exciting (for users)
 - Sounds scary (for lawyers)
- “Paper”
 - Sounds boring (for users)
 - Sounds safe and predictable (for lawyers)

Hybrid or totally Electronic?

- Electronic Records
 - Are still an evolving discipline
 - In a patent situation, will be subjected to adverse scrutiny, unlike other areas (e.g. 21CFR11)
- Some organizations will be able to safely run an Electronic Records Programme
- Most won't
- Over time, the skill level required will reduce

Hybrid or totally Electronic?

- Unless you *know* you can run an ER programme safely, adopt a Hybrid approach
- This will deliver
 - 90% of the benefits of ELNs
 - With minimal risk
- Over time, your dependence on paper, and trust in Electronic Records will increase
- Until someone asks "Why are we keeping all this paper?"

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The cultural issues of ELNs

- The main obstacles to deploying ELNs are not technical, but cultural
- Most companies know that ELNs can solve big problems
- Deploying them is another matter
- ELNs are new systems with few precedents
- Lab Notebooks are very important to scientists
- Scientists are unusual people to work with

Scientists and their work

- Your company pays scientists to do things differently - to innovate the way they work
- This will often involve a high level of expertise and involvement in the tools they use to support their work

Influencing Scientists

- Peers are the most important influence on scientists
- For a significant proportion of scientists, their allegiance is to their art, not to your company

Scientists and Procedures

- Scientists will follow any procedure to the letter - as long as it is helping them
- If the procedures need "improvement", they will "improve" them

Scientists and record keeping

- The people who think the wackiest things
- Are the people the company needs to write stuff down
- But these are also the people whose record keeping processes are often “lacking”

The Lab Notebook in the scientist's world

- Your scientists will have been using a Paper Lab Notebook ever since school
- Often, they aren't really clear *why* they use a Lab Notebook
- Amusing exercise - get a bunch of scientists in a room and ask them to come up with
 - A definition of a Lab Notebook
 - A description of what purpose(s) a Lab Notebook serves

With a Paper Lab Notebook

- They have a high degree of privacy and control over their information (because they have the book)
- They can “reconfigure” the layout of their work to suit the task, without too much trouble
- It’s actually a very convenient form factor
- (It’s a bit of a pity that paper is increasingly hard to use, and indeed becoming irrelevant, in today’s R&D environment)

Cultural implications of ELNs

- The nature of scientists, and their relationship with their existing Paper Lab Notebook processes, means that any effort to introduce an ELN will have a major cultural component
- So, there are serious risks in deploying an ELN, which arise from:
 - The nature of scientists
 - The intimacy of Lab Notebooks
 - The longevity of the existing Paper Lab Notebook process
 - The wide scope of ELNs
- The strategy for selecting, evaluating and deploying an ELN is therefore crucial

If you remember one thing

- People don't know what they want until they see it
- People don't know what they want until they see it
- People don't know what they want until they see it
- People don't know what they want until they see it

This means

- When talking to users, paper specifications are not a reliable method of capturing the detail
- High-level specifications are necessary and valuable
- For the detail, get something in place as quickly and cheaply as possible

What users will do for you

- Tell you what's right and wrong with your proposed solution
- Evangelize the project to their colleagues
- Train their colleagues
- Feed you formal and informal cost justifications
- Convince their immediate management
- Act as an internal reference

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The importance of people

- The most important component for the early stages is one or more enthusiasts
- Later, you'll need a project manager
 - This is the person who will lay awake at night
 - Their career will be affected by the outcome of the project
 - Experience not necessary but useful
 - Flexibility and willingness to learn essential
 - If they aren't already well connected to the necessary parts of the organization, they will be

The Project Manager

- Every project manager I have worked with has found the ELN project the most challenging and enjoyable project they have worked on
- The Project Manager is the single most important component of the project's success
- (the second is probably the vendor's personnel and product)

Building the momentum

- Early on, you need to build a “map” of the people you need to help you
- These will be
 - People with money
 - People you need to say “Yes”
 - People you need not to say “No”
- You need to get inside everyone’s head

Typical players in the game

- Scientists
- Scientific middle management
- Scientific senior management
- IT
- Legal/Patents
- Records
- Regulatory
- Finance

Characterizing the players

- Its common to generalize about the different disciplines
- I've found every attitude in every role

General hints with stakeholders

- Make sure your Legal people know how broken the Paper process is
 - They may be in blissful ignorance
 - And think they are getting good records
 - Don't get into a situation where they compare a "ideal" Paper notebook to an unknown Electronic one
- Don't spook your IT people
 - They are often under severe resource pressure
 - Find an advocate and work with them

Users

- Users are key
- Without a user constituency
 - You'll build a useless solution
 - You'll get a negative cultural reaction
- Its always more fun initially if its skunkworks
- Don't drown them in process ceremony

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Making your case

- Intuitively, ELNs make sense
- But that's not enough to get the project approved
 - Unless you can find some very high level sponsor
- You need to
 - Figure out the best way to frame the ELN
 - Be the solution to a mission critical problem (legal, regulatory etc.)
 - Connect to a theme (KM, Quality, Cycletime, Records)
 - Pure financial cost/benefit
 - Then gather evidence
 - External evidence is always nice
 - Nothing beats internal evidence
 - Pilot is absolutely essential

Typical benefits seen

- Remove the productivity burden of Paper Lab Notebooks
- The contents of the ELN can be searched and shared
- Efficiency gains
 - Less re-work, because people can find work from other people
 - Better workflow between functions
 - Cyclic time reduction because process information flow is now electronic
 - All parties have a common view of the work

Typical benefits seen

- Collaboration can now be supported
 - Across departmental boundaries
 - Within groups of scientists
 - Across time & space
- Happier scientists
 - More time on science, less time on admin
- Better records for patents
- General KM benefits – but these are often hard to measure

Specific customer anecdotes

- Productivity gains
 - Without factoring in the business advantage of the cycletime reduction
 - One of our customers valued this at \$250 per person per week
 - CENSA estimates ~\$30,000 per year
- R&D/Engineering/Manufacturing Collaboration
 - Reduction in time & costs associated the the introduction of 1 product paid for the whole project

Specific customer anecdotes

- Geography becomes less of an issue in collaboration
 - Reduction in travel time & costs
 - Increasing multi-site teamwork
 - Expertise and capability of specific sites and people easily available to all
- Cycletime reduction generally, especially for interactions which cross departmental boundaries

Why now?

- R&D is currently crippled by the Paper Lab Notebook process
 - Lots of manual cut & paste
 - No possibility for collaboration
- Products are available in the market now, and legal issues have been resolved
- There are real concerns around most organization's Paper Lab Notebook processes
- The move to ELNs is a question of "When" not "If"
- Delay only means paying the Paper Lab Notebook tax for longer, with a deteriorating records process

Good candidates for ELNs

- Computers are used in the scientist's work
 - The more your current Lab Notebook consists of print outs, the bigger the instant productivity benefit
- Large groups which need to collaborate, often in ad-hoc ways
 - With small groups (everyone in one room) informal mechanisms keep everyone up to date
 - With bigger organizations, "Knowing what you know" is a big challenge
- Cross-site and Cross-discipline collaboration important

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The project: Expectations

- “ELN” technology isn’t perfect
 - There are probably perfect ELN solutions but no one can afford to implement them
 - Obviously software and hardware will improve over time
- We view the ELN as bringing a choice to the users
 - A Lab Notebook for the computerized world
 - Expect your users to use both the Electronic LN and the Paper LN
 - This is about making R&D more effective/productive, whilst continuing to create good records
 - It isn’t a project to force change without clear business benefit

Typical user adoption

- 40% of users will embrace the ELN with open arms
- 40% of users will use the ELN to a greater or lesser extent depending on the specific project/task
- 20% are unlikely to ever use an ELN, due to
 - The nature of their work or working environment
 - Their natural work style

Running your project

- The project team
- Pilots
- Implementation and roll out
- Training
- Long term

The project team

- A core team, with representation from all essential groups, is essential
 - Scientists (from the different departments)
 - Legal, regulatory, quality
 - IT
 - Records Management
 - Management
- Each group will have a particular slant on the ELN
- Each member of the project team will need to “Sell” the ELN to their colleagues

The need for Flexibility

- You will be re-visiting some long-standing assumptions about how R&D works
- Expect each member of the team to explain their perspective and understand others
- Try to make sure people explain the underlying principles behind requirements not parrot the procedure of the day
- Creativity and flexibility will be needed

Ideal team member

- Experienced
- Well connected
- Respected
- Flexible
- Creative
- Patient

The scientists on your project team

- The scientists on your core team are your best method of communicating with users - cherish them
- You'll get a better reception if it's viewed as an R&D project

If asked, the people in the pilot group should perceive it as **their** project that has assistance from IT, but not an IT project (and the IT people in this project are so much more helpful than in other projects, and are actually interested in what happens in research) - *a pilot team member*

Scientists and problems

- Scientists are also very good at solving problems
- These problem solving skills don't evaporate just because its "A computer system"
- When a difficulty comes up, ask them to help you find a solution - you'll be glad you did

Running the project

- Involve people from outside research
 - Product development cycle is a good place for cycle-time wins
 - Once manufacturing are demanding access, you're in a good position
 - Although this will bring problems
 - But they are the problems of success
- Avoid getting captured by special interests
 - Have a keen awareness of how many potential users an individual represents

Running the project

- Sometimes, having an external person involved helps the cultural issues
- The most important things
 - Stay flexible and expect surprises - you will learn new things
 - Involve every group that will be affected by an ELN
 - Stick close to the users
 - Opinion "on the street" will be the major determinant of your project's success
 - Collect and respond to user feedback

The project: Pilots

- Pilots are a “safe” first step towards deployment
 - They provide compelling internal evidence (reference material only goes so far)
 - They don't involve dramatic upheaval or costs
- You can see how a system would be used for real and whether it would deliver desired benefits
- Pilots provide a real system for your lawyers to inspect and approve
- Outcomes
 - Detailed evidence to make the case internally
 - Based on your organizations experience
 - Understanding of what ELNs mean in your organization
 - Understanding of what you'll need to do to go live
 - Skills required to rollout the ELN

Implementation and Roll Out

- Divide your scientists into groups, with like toolsets and work practices
- Profile each group and do a gap analysis of your existing abilities vs. their needs, making sure the ELN works well with other key IT systems
- Start with the easiest group first and work down the list. Expect the first group(s) to take significant time.

Adoption should be voluntary

- Ideally, at least until you have the majority of your users on board
- This forces you to make sure you are delivering genuine value to the business, and won't lull you into a false sense of security
- If they don't want to use it, the reason is an opportunity to improve the system
- Work with human nature: provide incentives, not rules
- Work with your scientists' natural communication mechanisms
- Avoid standard internal PR; word of mouth is far more powerful

Training

- A large part of “How to use the ELN” is really “How we will use the ELN in our work, with our tools”
- Training is most effective when given by scientists, to scientists
- Scientists are busy people and seldom have time for ceremony (the “Toddler principle”)

Training

- Train the core team in the ELN
- Core team members develop customized training for their specific area
- This training is most often delivered in the lab itself
- Keep training sessions to 20 minutes or so
- For our ELNs
 - Initial training ~15 minutes
 - One follow-up session of about 15 minutes
 - User fully integrates the ELN into their work within 4-6 weeks

Long term

- Your business requirements will change
 - The technical environment will evolve
 - Custom and practice will develop
 - Your comfort with Electronic Records will improve
-
- Expect to evolve your ELN to deal with these changes
 - Make sure your project, sponsors, and solution can gracefully deal with evolution

Misconceptions & death magnets

- Sharing and ownership
- ELNs and other initiatives
- Beware enthusiastic, unconscious adoption of regulations
- Existing processes
- “Technology” as saviour

Sharing and ownership...

- Scientists, by nature, share their work in progress with only a small group of collaborators - typically the people they lunch with
- Some scientists aren't ready to share their information with everyone

Although scientists claim they embrace the electronic age, deep in every scientist there is an alchemist clutching a lab book in their grubby little hands screaming "Me, Mine"

- a scientist on one of our project teams

Implication

- The scientist needs to have at least as much control and autonomy in an ELN as they do with their Paper LN
- They need to be able to have some influence over who can see what, and to keep things private
- Otherwise you'll only get things after they are tidy and proven

ELNs and other initiatives

- There can be a temptation to use the introduction of an ELN as an opportunity to do other things
 - Improve record keeping
 - Introduce a new way of measuring and managing people
- This seriously increases the risk of your ELN project failing
 - People's perceptions of the ELN will get mixed up with their feelings about the other change
 - It will make what's going on with the ELN less visible because there's another variable at work
- Implication
 - If you want a successful ELN project, resist the temptation to "piggy-back" other initiatives ;-)

“Technology” as saviour

- When confronted with hard, novel problems, “Technology” can often appear to be a saviour
- Vendors will position their tool as solving all sorts of problems
- Unfortunately, life is rarely that simple, and technology often comes with problems of its own

“Technology” as saviour

- For example, “Digital Signatures” are good solutions, but need to be implemented with care, and their quality depends primarily on your procedures
 - “Whoever thinks his problem can be solved using cryptography, doesn’t understand his problem and doesn’t understand cryptography” - Roger Needham/Butler Lampson
- Implications
 - Keep it simple
 - You cannot abdicate responsibility to a particular technical solution or vendor
 - Be prepared (and able) to get into detail. Do not accept things at face value.

Conclusion

- Paper lab notebooks are a long-standing artefact in your organisation
- Be sensitive to cultural issues
- Keep stakeholders on side
- Initially, adopt a hybrid record keeping approach unless you really know what you are doing
- Be prepared to evolve your lab notebook over time
- Pilots are an important first step, both for planning and detailed business case

DISCUSSION

Strategies for Organizing and Piloting an ELN Program

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Notebook Stages

- Overcoming tradition
 - How is “change” viewed?
- Current lab notebook practices
 - Manual entry with pen and ink
 - Computer with cut and paste
- Exploring ELN options
 - Hybrid notebook system
 - Advanced ELN

Key ELN Considerations

■ Internal

- Cultural
- Political
- Resource Assessment
- Long-term Expectations
- Technical capabilities
- Organization's risk environment

■ External

- Competitive Issues
- Legal issues
- Available technology options

Building the Business Case

- Develop a detailed business assessment:
 - As seen through the eyes of notebook users and stakeholders
 - Legal, records, R&D, scientists, etc.
 - Recognize obstacles and resolutions
 - Identify potential solutions
- Formulate a business strategy
- Establish Milestones
- Create Evaluation Criteria

Building the Corporate Team:

- Focus on notebook users
 - Their complaints, expectations, etc.
 - Accomplishing a user "buy-in"
- Focus on management
 - Are they "cost" or "result" driven?
 - Do they understand the issues?
 - Technology Risks/Benefits/Costs
- Focus on stakeholders
 - IP/Patent issues
 - Records management
- Focus on suppliers
 - Are they in tune with "your" goals, not just their product?

Develop a Benefit Assessment: Shared Expectations

- Improve scientific output
- Guaranteed long-term record availability
- Increase scientific collaboration and cross-referencing
- Eliminate redundant research
- Improve notebook integrity
- Protect intellectual property

Minimizing Internal Opposition

- Expectations of Key Beneficiaries
 - Scientific Users
 - Records & Archiving
 - Intellectual Property
 - Management
 - Business Unit
 - Functional Area
- Corporate ELN Strategies
 - Start now or wait for “The Perfect Risk-free System”
 - How far before getting approval?
 - Who must approve ELN project?

Importance of a “Champion”

- Function: takes control and drives the process forward
- Requirements:
 - A visionary/believer in ELN
 - Possesses sufficient organizational power
 - Controls/influences funding for projects
 - Capable/experienced in making things happen

The BMS Case

- First ELN application-adoption of unbound LNBS to eliminate cutting and pasting
 - e.g. e-data printed on secure paper and stored in binders
 - Initial buy-in from specific research group
 - Favorable opinion from patent attorney
 - desire to implement by records group representative

The Experience

- Over a year from presentation to beta testing
- Causes of the delay
 - Lack of a suitable champion
 - Researchers had numerous other objectives and concerns
 - Attorney favorable but not a process driver
 - Records group enthusiastic but without sufficient power/influence

The Results

- Favorable experience by beta test group
- Evolving awareness of ELN options by other research departments
- Gradual implementation by osmosis
- Current status
 - Formation of multidisciplinary ELN team
 - Still no consensus champion

Internal Preparations

- Notebook Pilot Team Meetings
 - Establish Core Team (Stakeholders)
 - Formalize the Pilot Process
 - Keep Decision-makers in Loop
- Approve Final Requirements
 - Communicate Additional Requirements
 - Find High Level Decision-maker/s as the ELN Champion/s with budget to spend

Identifying Supplier/s

- Review Notebook Expectations
 - Interview Prospective Suppliers
 - Discuss “Must” and “Should” Requirements
 - Request for Information (RFI)
 - Evaluate Responses
 - Determine Short List
 - Single source supplier
 - Multiple source suppliers

Selecting Supplier/s

- Understands notebook requirements
- Offers viable products
- Knowledgeable sales staff
- Staff easy to work with
- Proven willingness and ability to work with other suppliers
- Systems integration expertise
- History of good product support
- Provides product references
- Conducts a "successful" product demonstration

Initiating the Pilot Process

- Select Solution/s to Pursue
- Establish and Maintain Effective Communications with Management and Participants
- Outline Expectations for Defining the Process
- Develop Pilot Plan With Supplier

Launching the Pilot

- Internal Preparations Performed by Core Team
 - Select key members, including scientists, IP, IT, records management
 - Identify notebook pilot manager
 - Finalize hardware requirements
 - Understand software requirements
 - Constantly review goals and measure progress toward

Bureaucratic Process

- Budget Financial Resources
- Finalize Agreement between Supplier and Company
 - Management Review
 - Legal Review
 - IT Review

Concurrent Activities

- Software Installation
- Training
 - Train System Administrator
 - Train the End Users
- Actual Notebook Pilot
 - 3 month Period
- Continue to Evaluate Performance
 - Milestones & Measurements
 - Adjustments

Results

- Review Notebook Trial Results
 - Supplier/Product Evaluation
 - Internal Evaluation
 - Users
 - System Administration
 - Management
- Communicate Results-Written
 - Internal
 - External

Continuous Evaluation

- Determine & Assess Results
 - Review Successes
 - Admit Failures and Adjust
 - Ascertain Next Steps
- Re-evaluate Initial Business Case
- Embrace Evolutionary Development
- Continue involvement of high level "champion"

DISCUSSION