



ELN Implementation Planning

John Trigg
phaseFour Informatics

Workshop
ELNS & Advanced Laboratory Solutions
Amsterdam, 27 Sep 2010

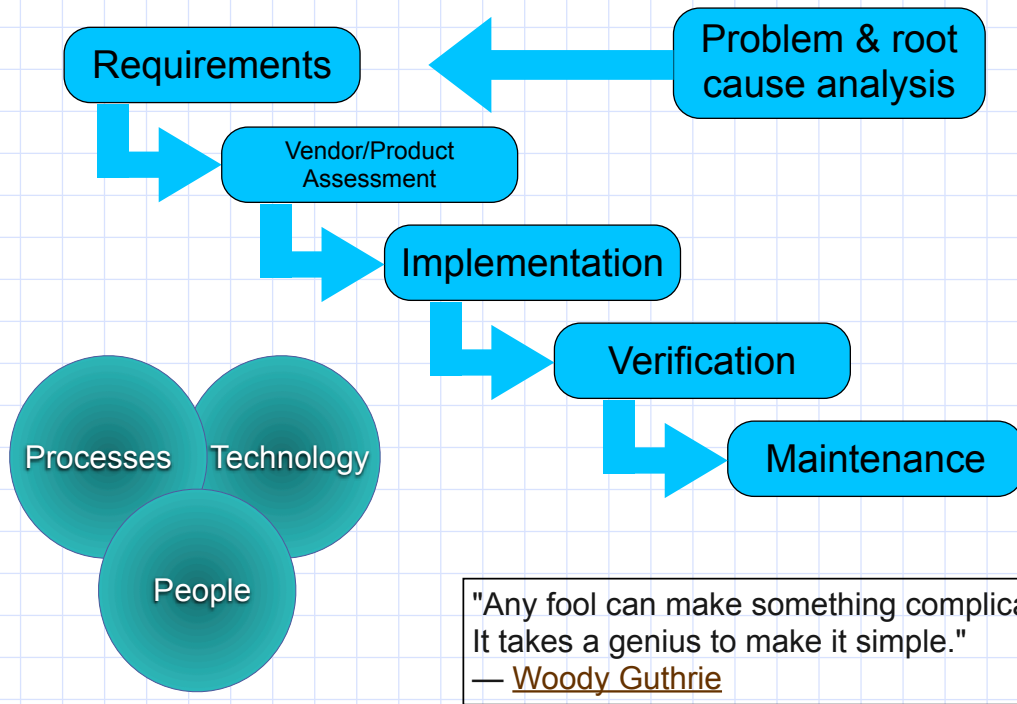


Agenda

- Welcome & Introduction
- Laboratory Notebook basics?
 - What is an ELN & why would I need one?
 - Electronic records
- Implementation strategy
 - Project management
 - Risk assessment
 - Technology adoption & getting user buy-in
- Summary

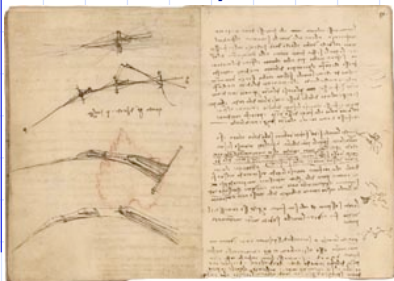


Project Methodology



Paper has worked for centuries, so why do we want an ELN?

15th Century



From Leonardo Da Vinci's Notebook (5000+ pages)

- Neat technology ?
- Paperless laboratory?
- Keeping up with competitors ?
- Seems like a good idea ?

- Business efficiency ?
- Knowledge management ?
- Patent evidence creation ?
- IP Protection ?

21st Century



The answer is an ELN.
What was the question?



Thinking about migrating to an ELN?

- What do you do with your paper lab notebook?
 - How well does the process work?
 - Is the process broken?
- Who cares about lab notebooks & why?
- What could an ELN do better (or worse) than paper?
- Who do you need to convince in order to buy one?



Traditional Functions of Lab Notebooks

- Record ideas
- Inventions
- Experimentation records
- Observations
- Work details
- Conclusions
- Demonstrates your adherence to the scientific method

The Laboratory Notebook can help you prove:

- Exact details and dates of conception
- Details and dates of reduction to practice
- Diligence in reducing your invention to practice
- Details regarding the structure and operation of your invention



What is an Electronic Lab Notebook?

Definition of an ELN (CENSA*)

"A system to create, store, retrieve, and share fully electronic records in ways that meet all legal, regulatory, technical and scientific requirements."

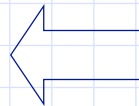
* Collaborative Electronic Notebook Systems Association

Definition of an ELN (Atrium Research)

"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."

Scientific Requirements

- Scientific Data Management
- Discipline-specific systems
- Experimental design
- Laboratory Automation
- LIMS
- Documentation of Experiments
- Electronic Record Keeping
- Patent Evidence Creation
- Evidence of Regulatory Compliance
- Document Management



Is this an Electronic Lab Notebook or an Electronic Lab?



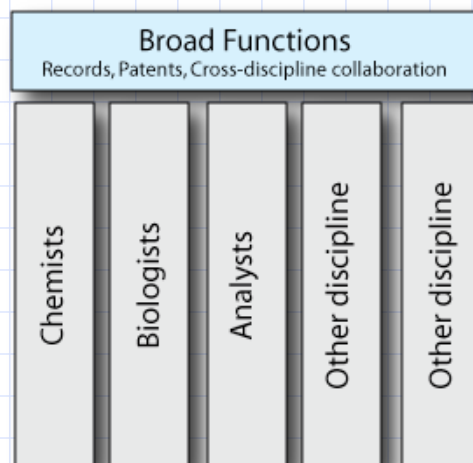
What is an ELN? - Broad vs. Deep

Broad (Generic)

- Support a wide variety of work across a company
- Enables collaboration & Knowledge Management
- Best achieved by deploying a "Thin" layer over other systems
- Budget & ROI generally found in a staff function

Deep (Specific)

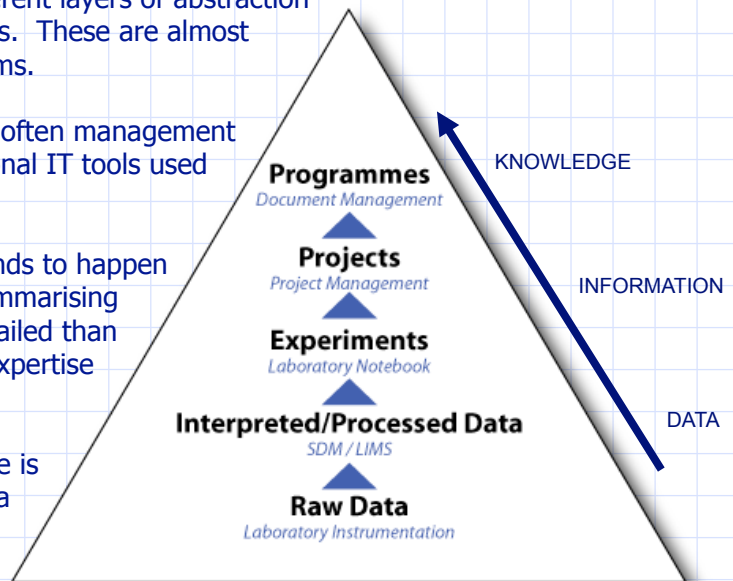
- Support for each individual scientific discipline or technology
- Generally involves specific data types
- Can involve significant product & implementation costs
- But delivers significant productivity benefits
- Budget & ROI found on a departmental basis





The Triangle

- The triangle represents the different layers of abstraction that exist in R&D information flows. These are almost always handled by different systems.
- Above the experimental layer is often management context, and is handled by traditional IT tools used elsewhere in the enterprise.
- Cross discipline collaboration tends to happen around experiment (or reports summarising experiments). Anything more detailed than the experiment requires specific expertise and tools to interpret.
- Below the experiment level there is an increasing specialisation of data types and tools, and only a few systems are comfortably deployed across workgroups.

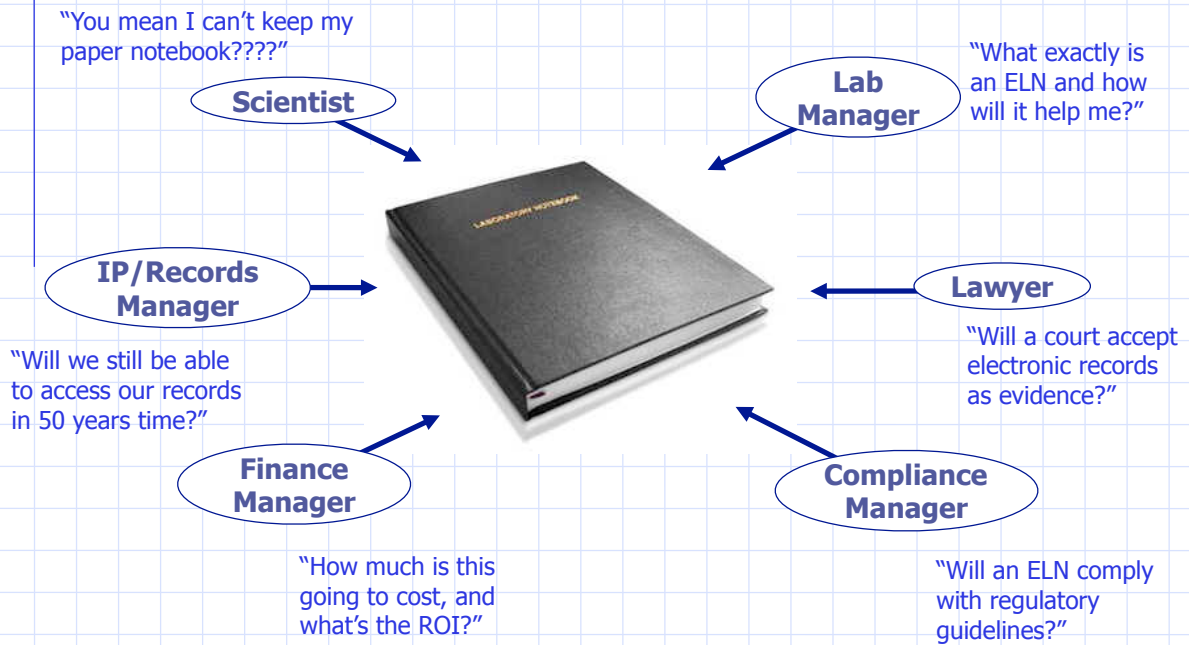


Laboratory data & information

Activity	Format	Application
Programmes / Studies	Documents	Enterprise tools (Doc.Mgt)
Projects	Documents / Files	Desktop tools (MS Office)
Experiments	Paper Notebook	
Samples	Data (Abstracted / collated)	LIMS
Tests	Raw Data / Processed Data	Instrument data systems (+ SDM?)



Who cares about Lab Notebooks?



Recap

- What business problem is the ELN going to solve?
- What quantitative data do you have to support the case?
- What will the 'solution' look like?



Questions

- What could be the use of an ELN for a QC laboratory already using a well implemented LIMS system?
- What is the best way to start the process of harmonising vocabulary/ nomenclature across large diverse groups who are doing similar things but currently have no consistency in vocabulary/nomenclature? How can this tremendous gap be filled when there are so many ways of doing things currently and it is quite difficult to get all parties engaged to make these types of harmonisation decisions?
- How do we get the balance right between rolling out something that is general enough for many diverse groups to use but specific enough, in terms of structured data, to ensure we get the searching / exploitation benefits? So it's about how much the configuration (in terms of fixed fields) should be tailored to particular groups.



Characteristics of trustworthy records

500 yrs <----- Paper | Electronic -----> ??? yrs

- Reliability
 - The content can be trusted as accurate.
- Authenticity
 - Proven to be what they purport to be and were created and transmitted by the person who purports to have created and transmitted them.
- Integrity
 - Complete and unaltered; physically and logically intact.
- Usability
 - Can be located, retrieved, presented and interpreted.



Are electronic records admissible?

- ◆ Admissibility is governed by the Federal Rules of Evidence
 - ◆ Relevant
 - ◆ Reliable record of events being examined
 - ◆ Created contemporaneously with events
 - ◆ Accurate representation.
 - ◆ Authenticated as to their source
 - ◆ Testimony of a qualified witness, either present at the time of creation or the custodian.

The 2006 amendments to the Federal Rules of Civil Procedure specifically address the admissibility of electronic records.

March 10 1998, Official Gazette

Admissibility of electronic records in interferences:

Pursuant to 37 CFR 1.671, electronic records are admissible as evidence in interferences before the Board of Patent Appeals and Interferences to the same extent that electronic records are admissible under the Federal Rules of Evidence. The weight to be given any particular record necessarily must be determined on a case-by-case basis.

Bruce H. Stoner Jr.,
Chief Administrative Patent Judge



Are your records trustworthy?

- The court will assign weight on a case-by-case basis
- The proponent should be able to show
 - Conception Date - the date that you conceived your invention.
 - Date of reduction to practice – the date that you made a working embodiment of your invention.
 - Diligence in reducing your invention to practice - diligence refers to your intent and conscious effort to make a working embodiment.
- Note: the inventor isn't trusted
 - They are assumed to have an interest
 - Hence the need for a witness
- The opposing side will attempt to discredit
 - The record
 - The record keeping system
 - The record keeping process
- ...and this all has to happen in front of a non-technical Judge/Jury



What does this mean for ELNs

- You can use Electronic Records for patent defence
- But you need to make sure your records are created and looked after in a way that means
 - You can introduce them into court
 - The court will give them maximum weight and credibility
- Remember: the other side will be seeking to spread fear, uncertainty and doubt.



System design guidelines

- Start in court and work back
- Keep it simple
 - Say what you do; do what you say.
 - Keep the system running properly - and prove it
- Ensure you can show
 - Who created it?
 - When was it created
 - What was its content when it was created
 - Whether it can be reproduced in human readable form?



Regulatory Compliance (21CFR part 11)

- System must be validated
- Human readable output
- Security/access control
- Audit trail
- Version control
- Data validity checks
- Electronic signatures
- Disaster Recovery
- Revision and Change Control procedures
- Training procedures



21 CFR Part 11 Best Practices

- Audit trail must be independently recorded.
- Ensure that system maintains "irrefutable link" between documents, metadata, and electronic signature.
- Establish a clear electronic signature process for all signed electronic records.
 - Printed name of the signer
 - Date and time of signature execution
 - Meaning of signature
- Validate the system.
- Establish role-based access and control.
- Establish password and identification controls.
- Avoid hybrid systems, where practical.
- Do not over-customise technology solutions.



Electronic signatures

- The signer must intend the signature to have the same force and effect as a signature affixed by hand.
- The signature must be unique to the person using it.
- The signature must be verifiable as belonging to the user.
- The signature must be under the sole control of the person using it.
- The signature must be attached or linked to the document in a way that authenticates the integrity of the electronic signature and document contents.
- Controls must be in place to prevent fraud.
- The system must be able to detect attempts of unauthorised access and notify the appropriate security/management staff.

See : SAFE-BioPharma Association (www.safe-biopharma.org)



General Requirements for Electronic Records

	Quality Criteria	Material to be preserved	Scrutiny	Timescale
Internal Use	Internal requirements	Scientific data, experimental write-up	Internal	Company defined
Regulatory	Published regulations, with comment	Primarily scientific data, some write-up	Regulatory inspection	Defined by regulations
Patents/Legal	Case law, Federal Rules of Evidence	Primarily experimental write-up.	Adversarial	~10yrs before they come under scrutiny. Retain for 50+ yrs.



Long Term Data Preservation

- File format
 - Standards, or lack of them
 - Open vs. Proprietary
- Media
 - Long term media life unproven/questionable
 - CDs – 5-100yrs
 - Magnetic Tape – 10-30yrs
- Application
 - How long will current applications be available or supported?
- Device
 - How long will current hardware and operating systems be available or supported?



File formats – Open vs. Proprietary

- Publicly documented
 - Legally unencumbered
 - No patents, copyright concerns etc.
 - Any patents or copyright must be in the public domain
 - Ideally, self documenting (e.g. XML)
 - Expect your suppliers to use open file formats
 - If there is an acceptable standard, use it
 - Make sure you are using the right kind of format for each purpose
- Good
 - For text: Plain ASCII, Unicode, HTML, possibly RTF
 - For graphics: PNG, SVG
 - For structured data: XML
 - To preserve appearance: PDF (ISO 32000) and PDF/A (ISO 19005-1:2005)
 - Be careful about
 - Storing files in databases
 - The database file format is probably undocumented
 - Store objects on the file system and use the database to point to them
 - Anything that is proprietary
 - 'Lossy' formats (e.g. JPG)
 - Binary files generally



Media

- Long term media life unproven/questionable
- 'Live' storage keeps getting easier
- CDs – 5-100yrs
- Magnetic Tape – 10-30yrs

- Life span depends on
 - The number of times the media is accessed over its lifetime
 - The care with which the media is handled
 - The storage temperature and humidity
 - The cleanliness of the storage environment
 - The quality of the device used to write to or read from the media



Electronic Records Management Best Practices

- Integrate electronic content/records management
- Understand the legal implications of electronic records
- Establish a file plan
- Establish an electronic records preservation file plan
- Establish a records management team
- Train the technical team
- Establish and communicate policies
- Avoid point solutions
- Don't keep electronic records forever

Refs.

DoD 5015.2 'Design Criteria Standard for Electronic Records Management Software Applications'

Digital Preservation Coalition (www.dpconline.org)



Questions

- Which kind of work did you initiate in the pre phase project implementation ?
- What was the changes between the initial Request for proposal document and the "purchase" document ?
- How to manage the performances in a global deployment?
- Do you have any suggested approaches that work for implementing to large groups?
- We are planning to implement a replacement to the paper notebook with familiar worksheets and templates in Phase I and then implement automatic transfer of data from instruments to the ELN, integration with LIMS and result value searching in Phase II. Is this a common approach?
- Where do I store the data?

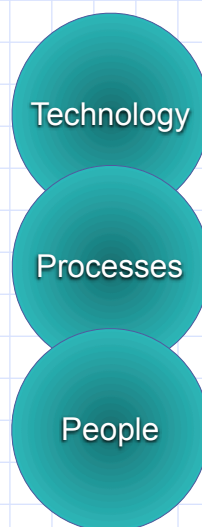


Implementation objectives

- ◆ Immediate
 - On time
 - On budget
 - Delivered in full
- ◆ Post Implementation
 - Return on investment
 - Productivity gain
- ◆ Longer term
 - Permanent benefits
 - Better science
 - Improved knowledge management



Increasing
user
engagement





Project Management

- The Ninety-Ninety Rule of Project Schedules
 - The first 90 % of the task takes 90 % of the time, and the last 10 % takes the other 90 %
- Murphy's Law
 - If anything can go wrong, it will.
 - If anything can't go wrong, it will go wrong.
 - If anything can't go wrong on its own, someone will make it go wrong.
- 6 Phases of a Project
 - Enthusiasm
 - Disillusionment
 - Panic
 - Search for the guilty
 - Punishment for the innocent
 - Praise & honour for those who did nothing



Ten Ways to Guarantee Project Failure

1. Abbreviate the planning process.
2. Don't ask "what if?"
3. Minimise customer involvement.
4. Select team members by the "hey, you" method.
5. Work people long and hard.
6. Don't inform management of problems.
7. Allow changes at any point.
8. Discourage questions from team members.
9. Don't give customers progress reports.
10. Don't compare project progress with project estimates.

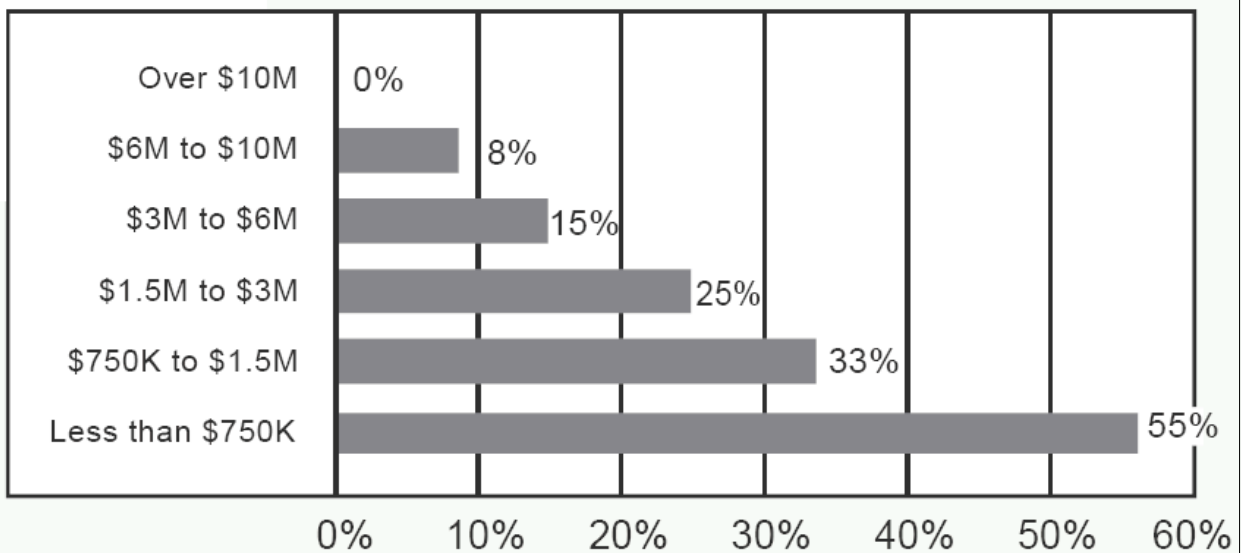


Project Management

- Why do projects fail?
 - Objective(s) not clear
 - Creeping scope
 - No user buy-in
 - Poor project management
 - Technology did not work
 - No change management process
- An IT project is more likely to be unsuccessful than successful.
- About 1 in 5 IT projects is likely to be fully successful.
- The larger the project, the more likely it is to fail.



Success by Project Size – small is beautiful



Standish Group International (1999)



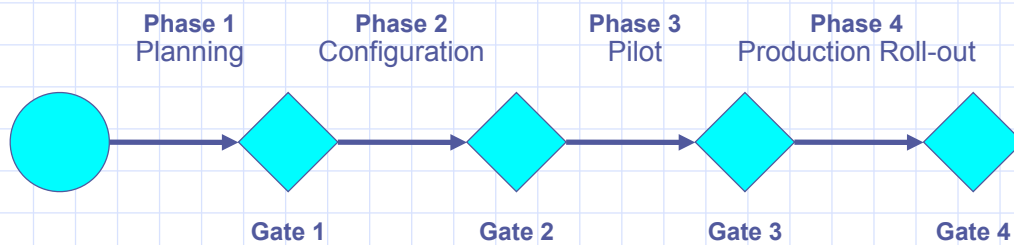
Project Success Factors

User Involvement	20%
Executive Support	15%
Clear Business Objectives	15%
Experienced Project Manager	15%
Small Milestones	10%
Firm Basic Requirements	5%
Competent Staff	5%
Proper Planning	5%
Ownership	5%
Other	5%

Standish Group International (1999)



Phases and Gates



Traditional model



Flexible model





Risk Management

- Avoidance
 - identifying and implementing alternative procedures or activities to eliminate the risk.
- Contingency (Mediation)
 - having a pre-determined plan of action to come into force as and when the risk occurs.
- Prevention
 - employing countermeasures to stop a problem from occurring or having impact on an organisation.
- Reduction
 - taking action to minimise either the likelihood of the risk developing, or its effects.
- Transference
 - transferring the risk to a third party.
- Acceptance
 - tolerating the risk when its likelihood and impact are relatively minor, or when it would be too expensive to mitigate it.



Risk Analysis

Likelihood	Severity		
	Low 10	Medium 50	High 100
High 1.0	Low $10 \times 1.0 = 10$	Medium $50 \times 1.0 = 50$	High $100 \times 1.0 = 100$
Medium 0.5	Low $10 \times 0.5 = 5$	Medium $50 \times 0.5 = 25$	Medium $100 \times 0.5 = 50$
Low 0.1	Low $10 \times 0.1 = 1$	Low $50 \times 0.1 = 5$	Low $100 \times 0.1 = 10$



Risk Assessment

Potential Risk	Likelihood	Severity	Risk Score
Vendor goes bankrupt	High	High	100
Users do not adopt	High	High	100
Need added functionality after purchase or deployment	Medium	High	50
Low long-term maintenance budget	High	Medium	50
Long term system admin load	Medium	High	50
Poor vendor relationship	Medium	Medium	25
Limited funding available	High	Low	10
System/Network failure	Low	High	10
Managing Roll Out	Medium	Low	5



Question

What are the main topics of your risk analysis before implementation, and what would you have to add now in the risk analysis you have forgotten ?



Project Team

- Ensure the team buys into a clear vision of the role of the ELN.
 - What's the problem the ELN is going to solve?
 - Use a 'flip' test to reinforce the message
- Select the Project Team carefully
- Get commitment (does everyone know which problem you are trying to solve?)
 - Users (early adopters)
 - Management (hard/soft)
 - Vendor
 - IT
 - Legal & Regulatory
- Communicate a clear and consistent message
- Be flexible; expect surprises



Implementation Tactics

- IT project or Lab project?
- Split into multiple phases, each with a very clear deliverable.
- Use gate reviews for go/no-go decisions for the next phase.
- Involve everybody with an interest.
- Keep it simple.
- Be flexible, expect surprises.
- Communicate, communicate, communicate.
- Have a sense of humour and humility.
- Avoid guerrilla warfare; think in terms of winning the war, not the battle.
 - Game Theory



Game Theory – The Prisoners' Dilemma

		Action of B	
		Cooperate	Defect
Action of A	Cooperate	Win/Win	Lose/Win
	Defect	Win/Lose	Lose/Lose



Technology questions

- What type of PC hardware is used to access eLN in the laboratory: use of stationary PCs, mobile PCs, carts, arms.
- Are folks allowing mobile PCs to move in and out of the laboratory?
- What are the safety policies with eLN PC hardware verses paper notebooks?
- For mobile PCs, is the responsibility to individual users or are folks implementing shared mobile PCs?
- Are there issues with theft, responsibility, damage, costs, maintenance?
- Devices in the labs - are users using their own laptops, tablets, common or instrument PCs?



Change Management

- *from Peter Senge:* "People don't resist change. They resist being changed!"
- *from Peter Drucker:* "Company cultures are like country cultures. Never try to change one. Try, instead, to work with what you've got."
- *from John Kenneth Galbraith:* "Faced with the choice between changing one's mind and proving that there is no need to do so, almost everyone gets busy on the proof."
- *from Charles Darwin:* "It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change."
- *from Buckminster Fuller:* "If you want to teach people a new way of thinking, don't bother trying to teach them. Instead, give them a tool, the use of which will lead to new ways of thinking."
- *from Kenneth F Murphy:* "Change is good. You go first."

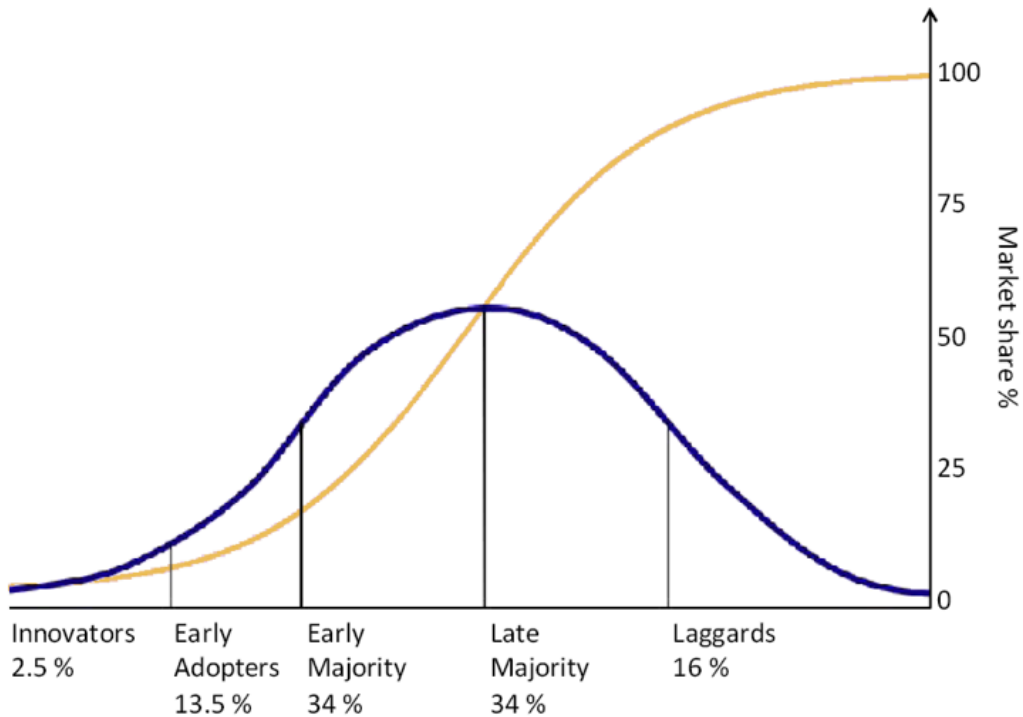


User Culture

Innovators	2.5%	Technology Enthusiasts : want to be first to try new technology; want one of everything.
Early Adopters	13.5%	Visionaries : able to align technology with strategic opportunities; willing to take risks; horizontally oriented.
Early Majority	34%	Pragmatists : cautious with risk and money; loyal; vertically oriented.
Late Majority	34%	Conservatives : opposed to discontinuous innovation; believe in tradition rather than progress.
Laggards	16%	Sceptics : negative attitude towards technology; identify discrepancies between what's promised and what's delivered.



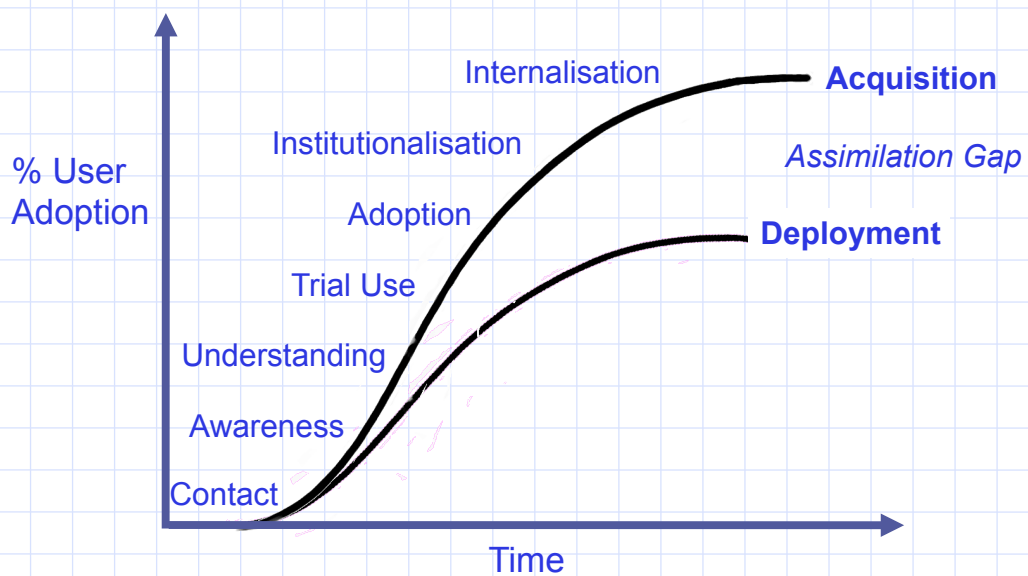
Diffusion of innovations/S-curve



5



Technology Adoption S-curve and the Assimilation Gap

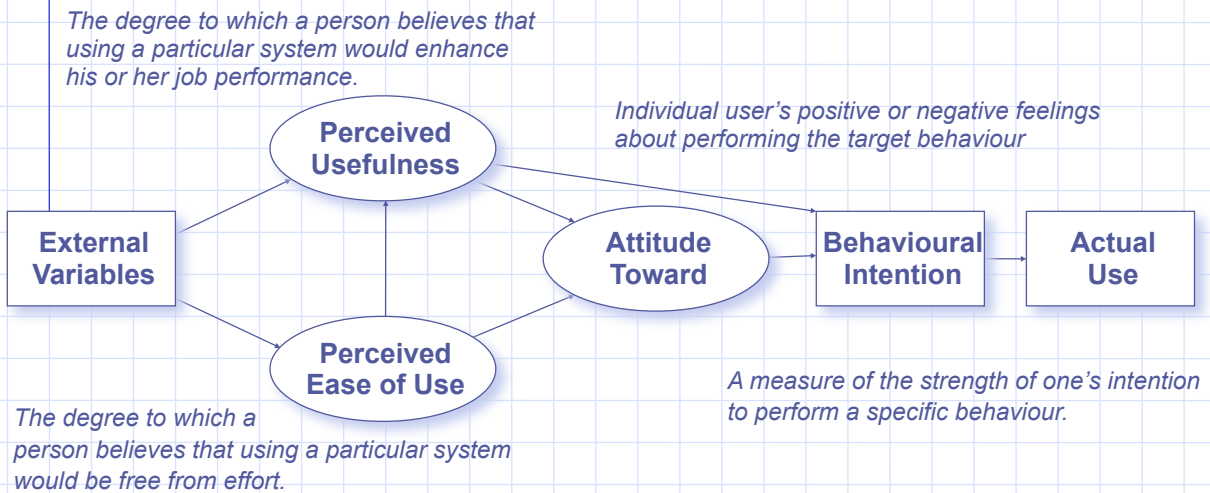


Robert G. Fichman, Chris F. Kemerer, "The Illusory Diffusion of Innovation : An Examination Of Assimilation Gaps", Working Paper Series No.746, Katz Graduate School of Business, University of Pittsburgh, November 1995.

46



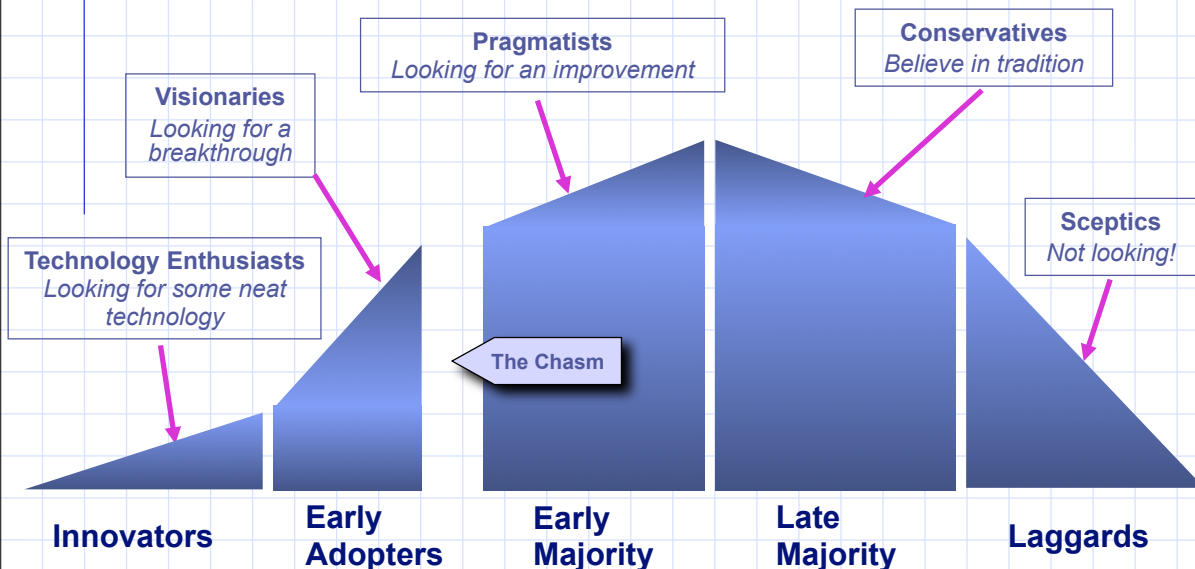
Technology Acceptance Model



Davis, F.D. "A Technology Acceptance Model for Empirically Testing New End-User Information Systems: Theory and Results", in *MIT Sloan School of Management*. Cambridge, MA; MIT School of Management. 1986.



Technology Adoption



Ref : 'Crossing The Chasm', G.A.Moore, Capstone Publishing



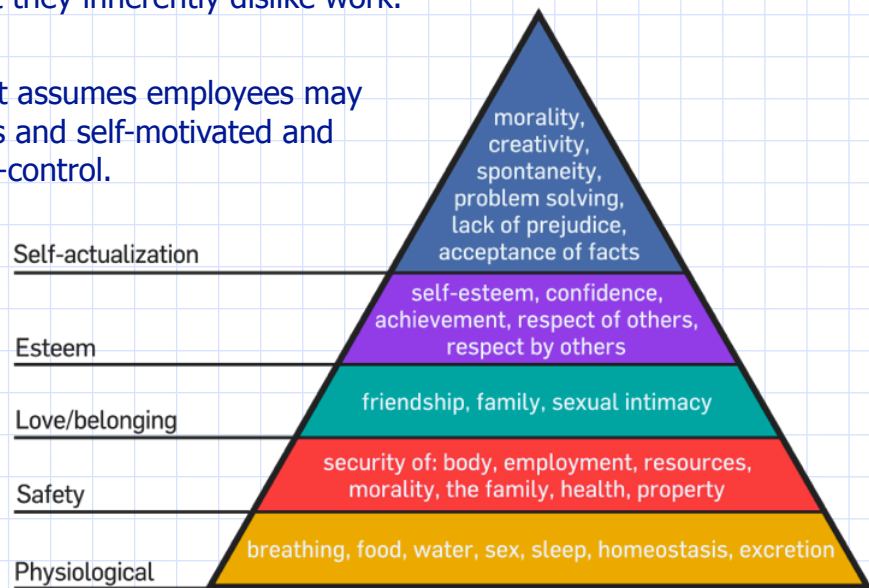
McGregor Theory X and Theory Y

◆ Theory X

- Management assumes employees are inherently lazy and will avoid work if they can and that they inherently dislike work.

◆ Theory Y

- Management assumes employees may be ambitious and self-motivated and exercise self-control.



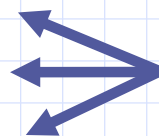
Maslow's hierarchy of needs 49



Closing the gap

Adoption process

- Contact
- Awareness
- Understanding
- Trial Use
- Adoption
- Institutionalisation
- Internalisation



What can we do to influence attitude in order to drive the 'right' behaviours?



- 'Market' the project.
- Establish and articulate a well-defined purpose and a compelling reason to adopt.
- Avoid the big bang; target a niche area to start.
- Concentrate on real task activities, ease-of-use and low risk of failure.
- Use the Early Adopters as local project champions, trainers, first-line support.
- Think about project leadership as well as project management.
- Engage a Management champion.
- Implement a vertical support structure (local peer support).

People are more likely to comply with a request when:

- A reason is provided
- There is give and take
- They see others complying
- The request comes from someone they respect or like
- The request comes from a legitimate source of authority

Robert B. Cialdini, "Influence: Science and Practice", HarperCollins, 1993.



Questions

- Can you speak to managing the significant cultural change that users experience going from paper to eLN?
- What is the best way to handle resistance?
- Do you force uptake or grow commitment through slow transition?



Why an ELN?

What is the problem that needs to be solved?	Clarify why the organisation thinks it needs an ELN. This is best achieved by developing a problem statement that quantifies a specific problem, or set of problems, about the laboratory's productivity and or knowledge management performance. The scope and scale of the problem (and hence, the solution) should be identified. The key decision makers/budget holders should also be identified, plus any other interested party who may have influence over a go/no-go decision. It is important to know what business level constraints may apply in terms of internal, legal or regulatory compliance.
Is there any quantitative data that illustrates the problem?	
Which laboratory areas will be involved in the project?	
Who makes the go/no-go decision?	
What are the issues relating to IP (internal/legal/patent)?	
Are there any regulatory compliance requirements?	



Laboratory/Company background

Use organisation charts to clarify roles and responsibilities and organisational relationships	Establish the way in which the laboratory is organised, the nature of the work it undertakes and identify any external organisations that it collaborates with.
Identify the nature and scientific disciplines of the laboratory work and how they relate to each other	
Are outsourced agencies (contract labs) involved?	

53



Current laboratory processes and systems

How is the paper lab notebook used (is there an SOP?)	Establish how the laboratory is currently working, paying specific attention to the use and effectiveness of the paper lab notebook. Also identify major 'electronic' systems used for the acquisition, processing and management of data, and what happens to this data; where is it stored and for how long?; is it communicated or transferred elsewhere – if so, how? Is it backed up and/or archived? Can it be found? Is laboratory data the responsibility of the laboratory, or does IT have any involvement. What level of involvement does IT have in the purchase and implementation of laboratory systems?
Which laboratory systems are already in use?	
What data acquisition systems are already in use?	
What teamwork/collaboration systems are already in use?	
What document management system(s) is already in use?	
Who is responsible for the management and support of these systems?	
Is there an (electronic) records management policy?	
Are there any specific policies and restraints relating to the introduction of IT systems?	

54



Future laboratory processes and systems

Based on interviews with laboratory managers and laboratory staff, formulate a model that illustrates the major relationships between laboratory data and information	Put together a high-level plan showing the relationships, processes and data flows that describe a future state for the laboratory. This should include an identified role for each of the laboratory systems and should clarify the specific function of the ELN. AN problems with laboratory terminology should be resolved. The plan should be tested by presentation and discussion with the interested parties.
Construct data workflow and laboratory process diagrams	
Identify any conflicts in nomenclature and establish an agreed taxonomy	
Identify the role (scope and scale) of existing laboratory systems in the model and diagrams	
Test the model and diagrams against each of the laboratory areas and other interested parties (IT, Legal, QA, Records Management)	

55



Business plan development

Quantify the benefits of the proposal, in particular productivity gains, ROI and Knowledge Management, and support these estimates with case studies	Quantitative benefits should be identified, along with all risks. An implementation plan should address known risks and/or potential problems, in particular the strategic approach to roll out, e.g. a progressive deployment, the composition of the project team, change management and user support.
Undertake a risk assessment, paying attention to process, technology and people-related risks. Align the risk assessment to the set of user requirements.	
Prepare, and include in the business case, a high-level implementation plan that addresses any specific requirements and/or risks that have been identified	

56



Human Factors

<p>What practical problems do laboratory workers experience with existing laboratory processes and data workflows?</p>	<p>Identify potential problems associated with the change from paper to electronic notebooks. This may be at an individual level (early adopters vs. laggards) or at an organisational level; R&D vs. legal, R&D vs. IT, etc.</p>
<p>How well will laboratory workers accommodate change?</p>	
<p>Are there any cultural, political or other internal relationships that could have an impact on the project?</p>	



Contact details and further reading

John Trigg websites: www.phasefour-informatics.com
www.theintegratedlab.com

email: john.trigg@phasefour-informatics.com
tel: +44 (0)20-8621-0389
mobile: +44 (0)7725-550041
skype: john.trigg

- **Getting Started with an Electronic Laboratory Notebook**, John Trigg, Scientific Computing World, Cambridge
- **Writing the Laboratory Notebook**, Howard M. Kanare, An American Chemical Society Publication
- **Laboratory Notebook Guidelines** : <http://www.bookfactory.com/> , BookFactory, LLC, 2302 S. Edwin C. Moses Blvd, Dayton, OH 45408
- **Diffusion of Innovations**, Everett M. Rogers, The Free Press. New York
- **Crossing The Chasm**, G.A.Moore, Capstone Publishing
- **Why Innovation Fails**, Carl Franklin, Spiro Press
- **Here Comes Everybody**, Clay Shirky, Allen Lane