Electronic Laboratory Notebooks

The Role of Paper – Is This the End?

John Trigg

phaseFour Informatics Limited

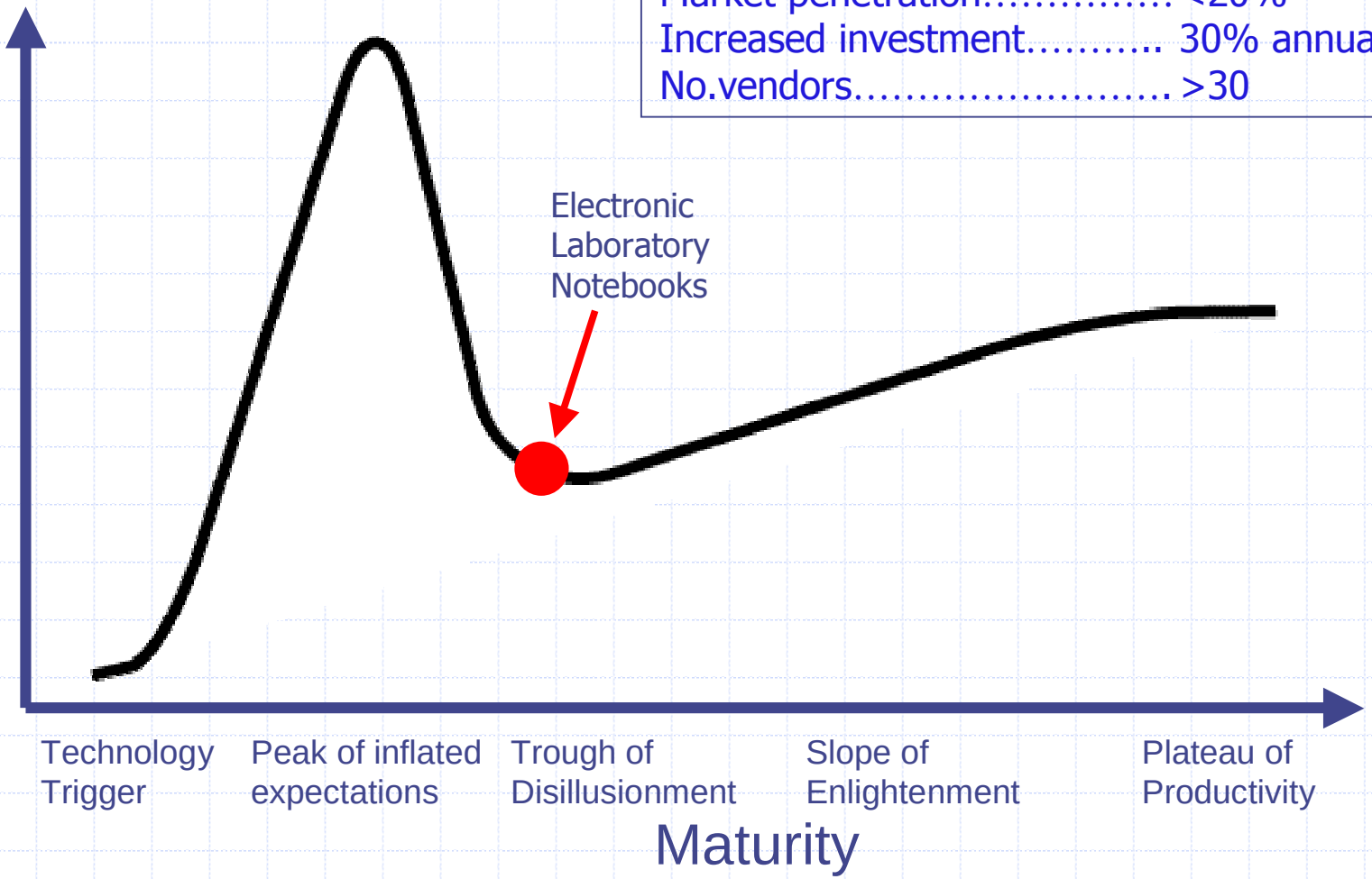
www.phasefour-informatics.com

Hype Cycles

Source : Gartner

Current ELN Market Status

Market penetration…… <20%
Increased investment……. 30% annually
No.vendors…….. >30



The Case for an ELN

The Benefits

- Easier to share
- Accessible knowledge repository
- Easier patent evidence creation
- Improved R&D productivity
  - By eliminating some mindless paper-based processes
  - Elimination of wheel re-invention
  - Re-use of information

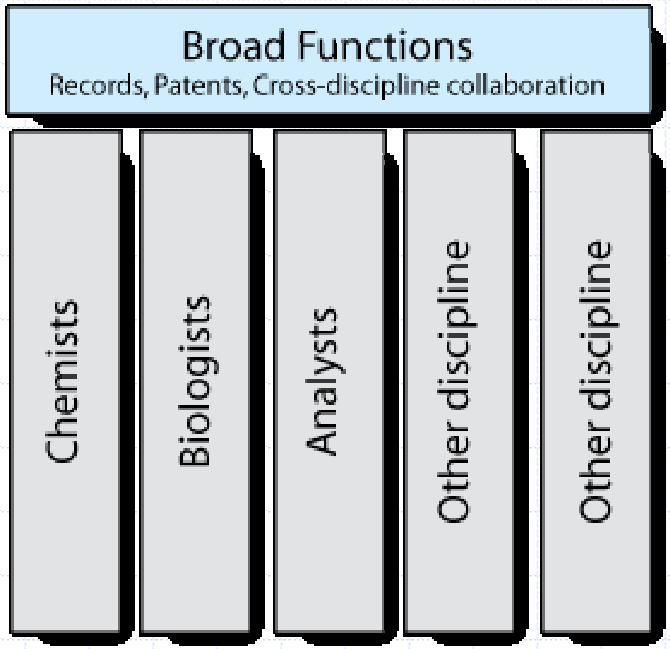
The Barriers

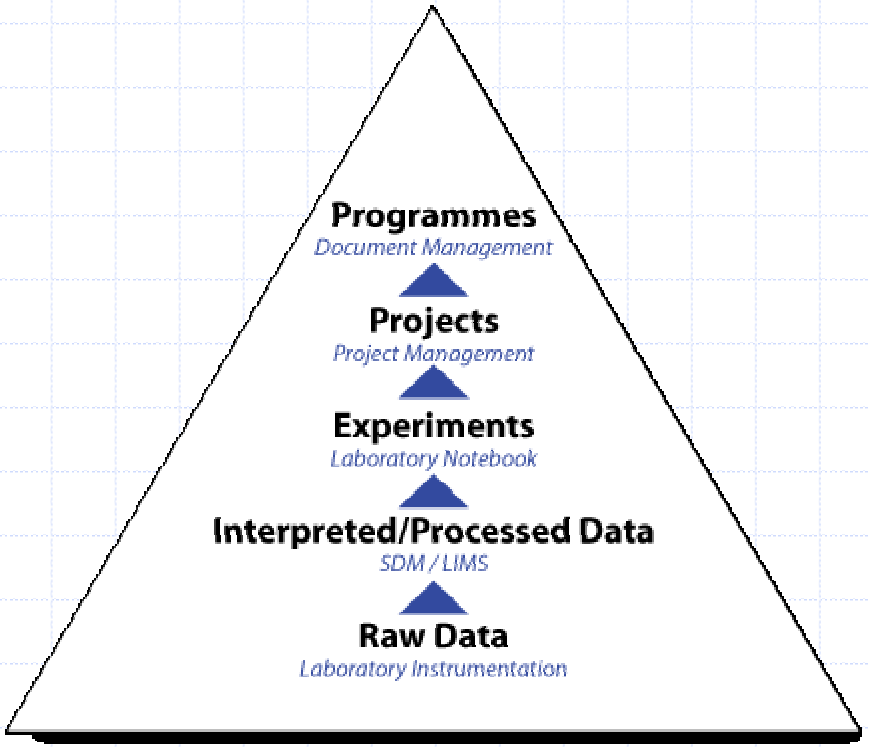
- Functionality
- Legal/Patent considerations
- Long term data preservation
- Costs
- User adoption

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*

Are electronic records admissible?

- Records are not automatically admitted
- Admissibility governed by 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.

U.S. Constitution - Article 1 Section 8
To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

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.

The Business Rule Exception to Hearsay

Records of regularly conducted activity are not excluded by the hearsay rule. Therefore an Electronic Business Record is admissible if:

1. It was made at or near the time of the event being recorded by (or from information transmitted by)
2. A person with knowledge
3. In the course of a regularly conducted business activity
4. And it was the regular practice to make the records
5. As shown by the testimony of custodian or qualified witness
6. Unless the source of information or method of preparation indicate lack of trustworthiness

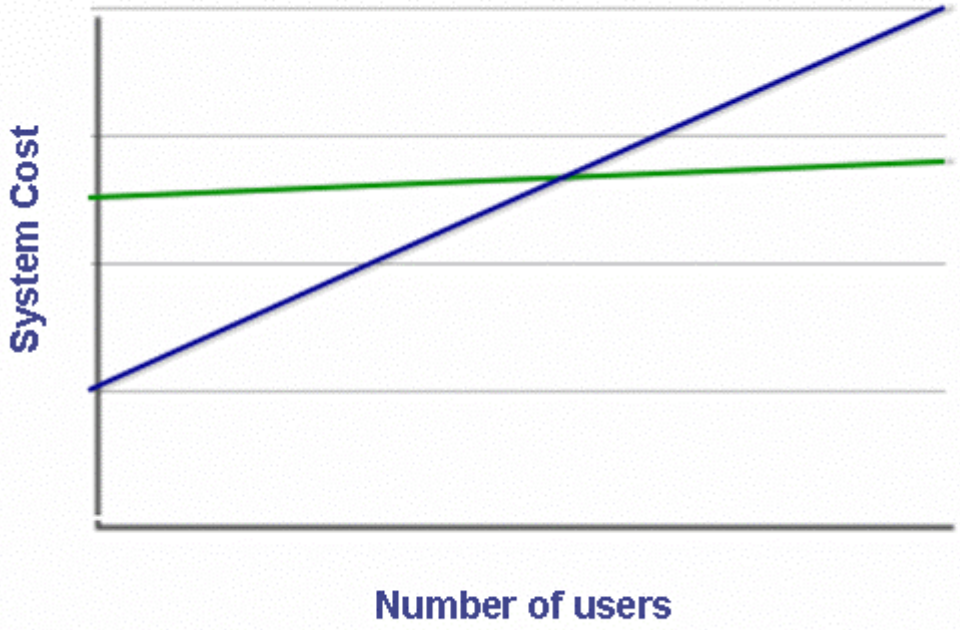
Are your records trustworthy?

- The court will assign weight on a case-by-case basis
- 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.
- 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

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?

Costs – Paper vs. Electronic



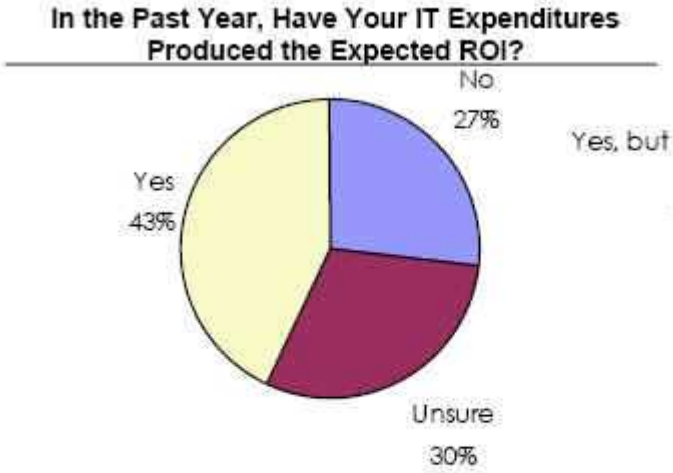
Cost Elements
- Media
- Storage
- Management Process

ROI issues

- Some companies have a formal ROI process, which is painful.

  ROI = (gains – costs)/costs

  - It is often based on faith, not data
  - Time savings are "soft" dollars
- Phasing
  - Split the ELN project into a series of smaller investments, possibly purchased & deployed by an individual budget holder.
  - Move forward as you demonstrate ROI at each stage to build credibility.



Fixing the System

"Almost invariably, it's simply made-up numbers to justify a project."

CFO
Food Company

Source: Scott Leibs, "One Way Or Another," *CFO IT* Magazine, 15 November 2004.

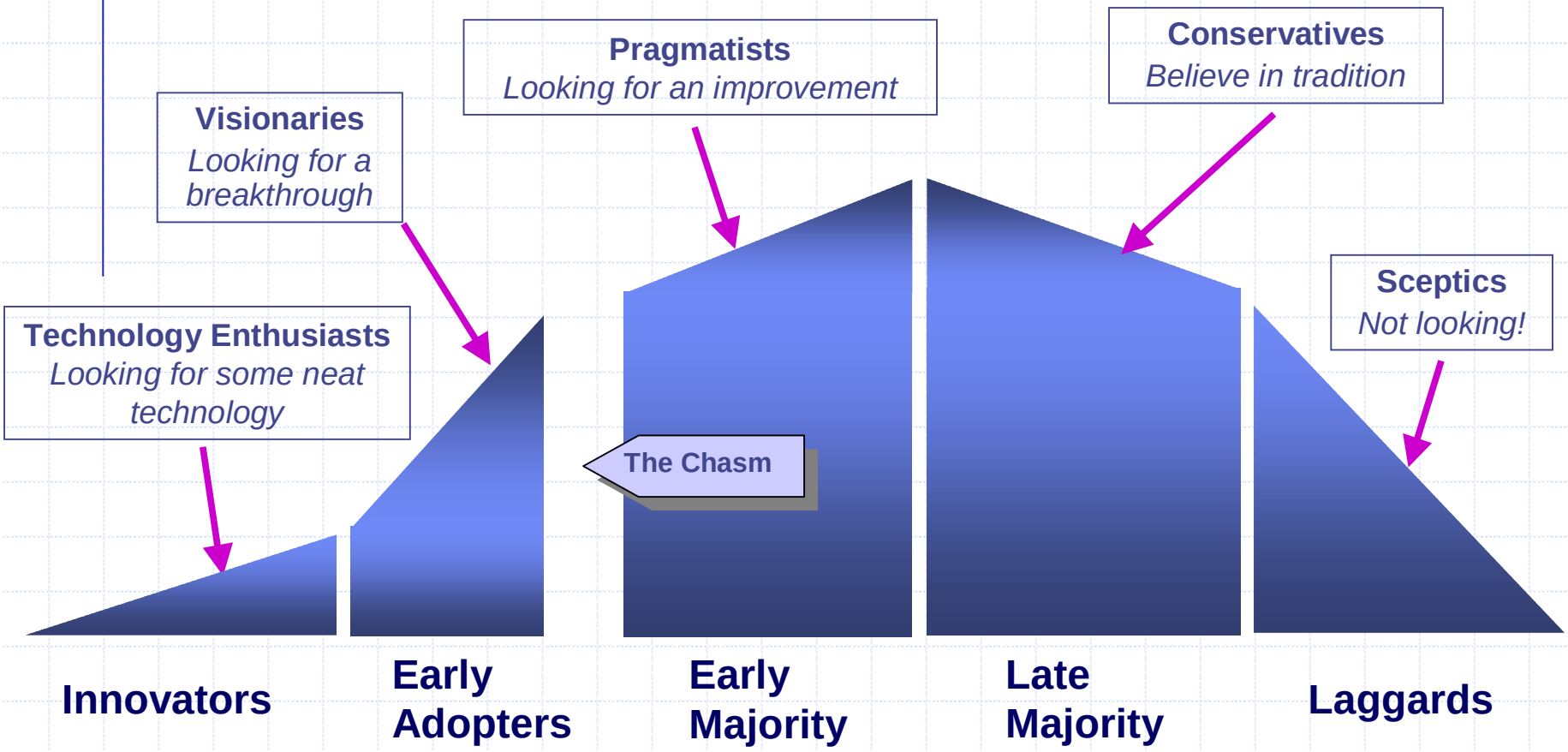
Case Studies

- Most organisations that have implemented an ELN claim to be making time savings in the order of 10 - 15%.
- Improvement in operational efficiency ~20%
- Anecdotal evidence points to additional, non-quantifiable benefits.
  - More time in the lab
  - Easier write-ups
  - Improved IP protection
  - Searchable archive
  - Increased efficiency
  - Improved data quality

Users - the Problem

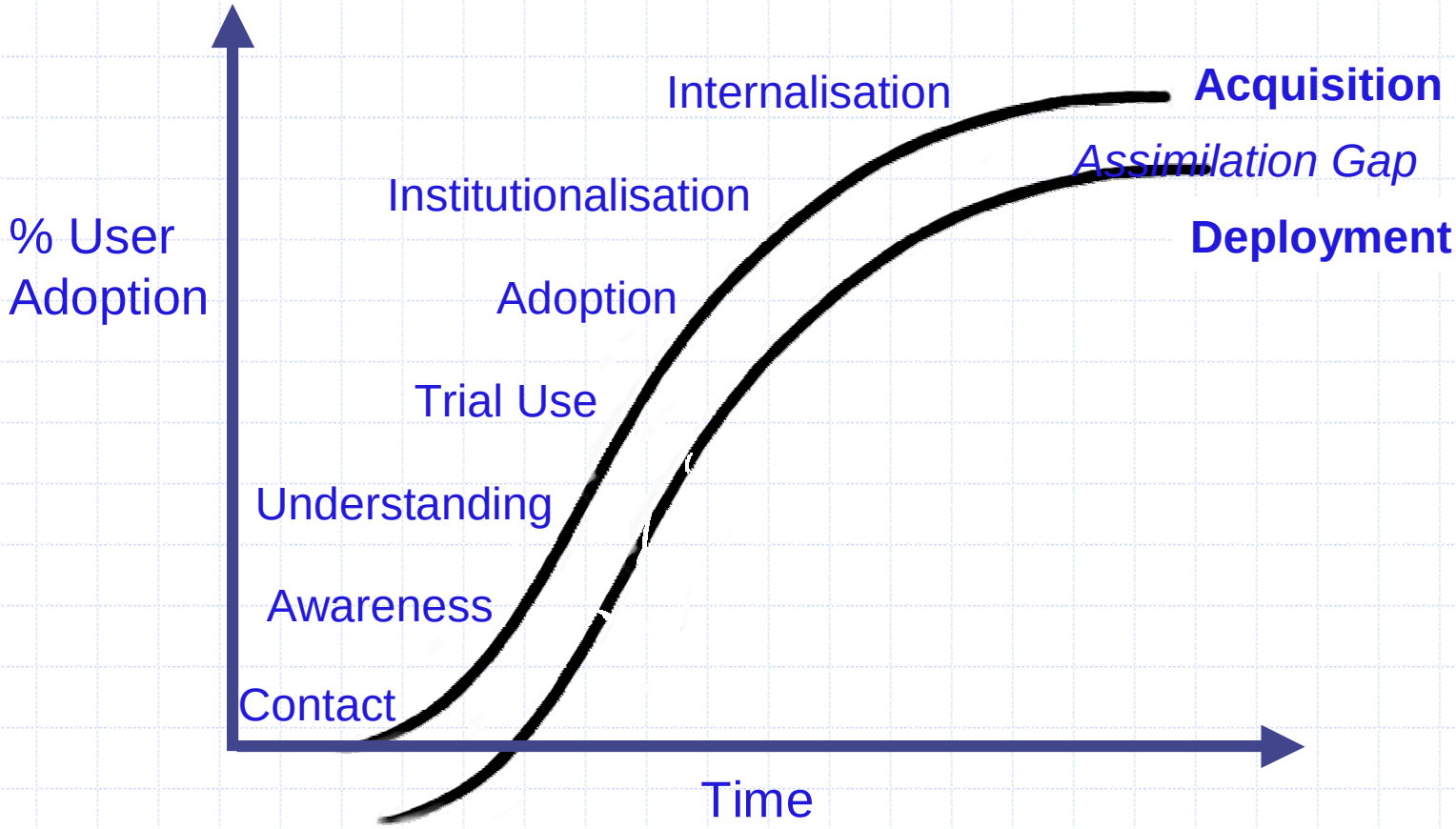
- The essential problem is that people have enough complexity in their lives.
- Peripheral activities need to be simple - we really don't have the "brain space" to handle too much complexity in non-core areas.
- People are quite literally turned off as soon as they see lots of options:
  - "It must be complicated to use"
  - "I don't have time to look at this right now"
- 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

Technology Adoption Life Cycle



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

Technology Adoption S-curve and the Assimilation Gap

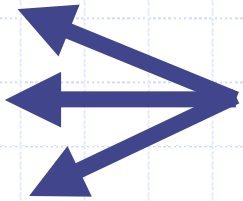


Robert G. Fichman, Chris F. Kemerer, "The Illusory Diffusion of Innovation : An Examination Of Assimilation Gaps", Working Paper Series No.746, Katz Graduate School of Business, University of Pittsburgh, November 1995.

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.
- Concentrate on real task activities, ease-of-use and low risk of failure.
- Target and involve the pragmatists (Early Majority).
- Avoid the big bang; target a niche area to start.
- Think about project leadership as well as project management.
- Engage a Management champion.
- Implement a vertical support structure (local peer support).

People will change when they want to, or when they see the value in doing so (or see the punishments of not doing so).

Is the ELN the last piece of the e-lab jigsaw?

A structured and systematic approach to managing scientific knowledge may conflict with the creative and innovative approach we look for amongst our research scientists. Historically, so many major scientific breakthroughs have come about by accident and by mistake, rather than by design and by strategy. We still need to consider whether our laboratory systems can therefore fully support or stifle innovation. And do they also stifle discussion and debate?

Do we want a string quartet or a jazz band?