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Intellectual Property Protection

## Electronic Laboratory Notebooks Remarkable KM Tools!!

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## Electronic Records Standards and Guides

- **CENSA Legal Acceptability Guide for Electronic Records (LAGER) (2001)**
- **Electronic Records Lifespan Specification (ERLS) 180 page reference model for entire lifespan of a record. (2003 & 2006)**
- **Litigator's Guide for Electronic Records (LitiGER) 150+ pages of processes, case law, and research to help attorneys during litigation (2003 & 2006)**
- **Validation Guide for Electronic Records (ValiGER) 350+ pages with checklists to help with validation and audits of eRecords programs, policies, procedures, and training (2003 & 2006)**

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## Other CENSA Publications

- **“Moving to Electronic Records, While Meeting the Legal, Regulatory, and Quality Standards” - Report**
- **Corporate Enterprise Electronic Records Master Policy Template - 2005**
- **Electronic Notebooks State of the Art - Market Research Study – 2006**
- **eNotebook Product Certification Toolkit – 2004**
- **eNotebook Product Technical Specification - 2003**
- **eRecords & eArchives Product Technical Spec – 2001**

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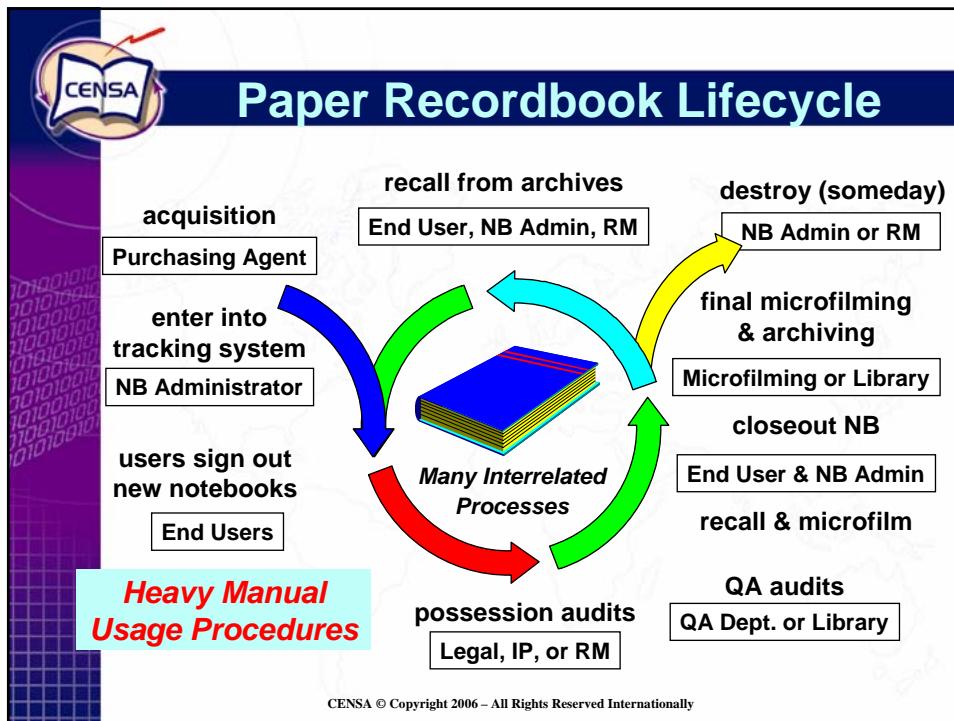
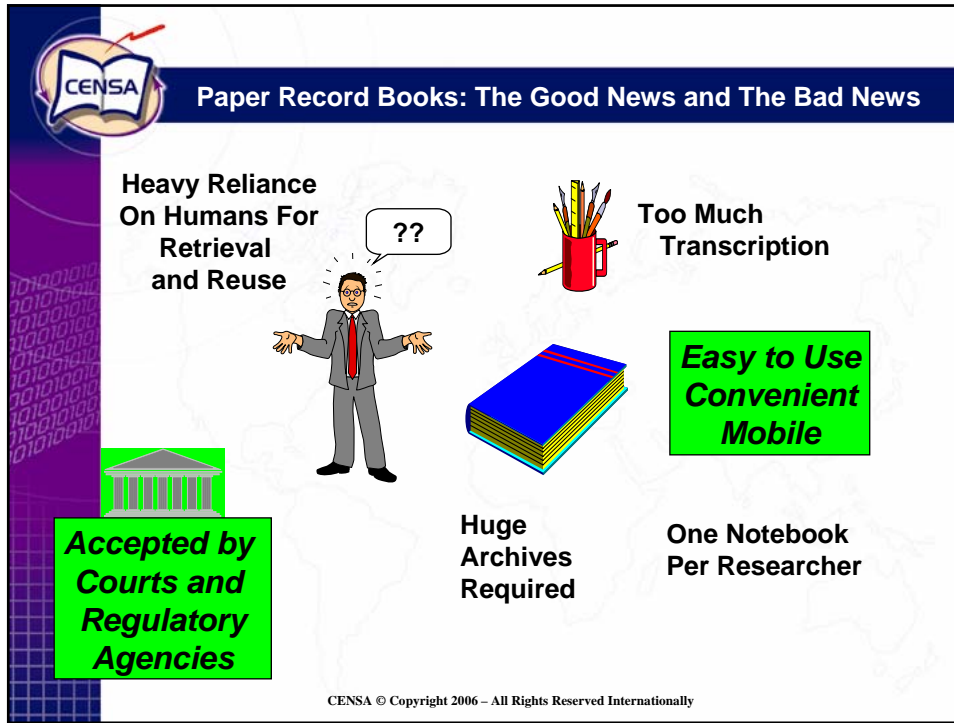
## Workshop Outline

- **ELNs: what they're; what they're not**
- **Foster Collaboration - Get ROI**
- **Legal Wins with eRecords**
- **Considerations - getting ready**
- **Considerations - picking systems**
- **Succeeding with Quality Practices**

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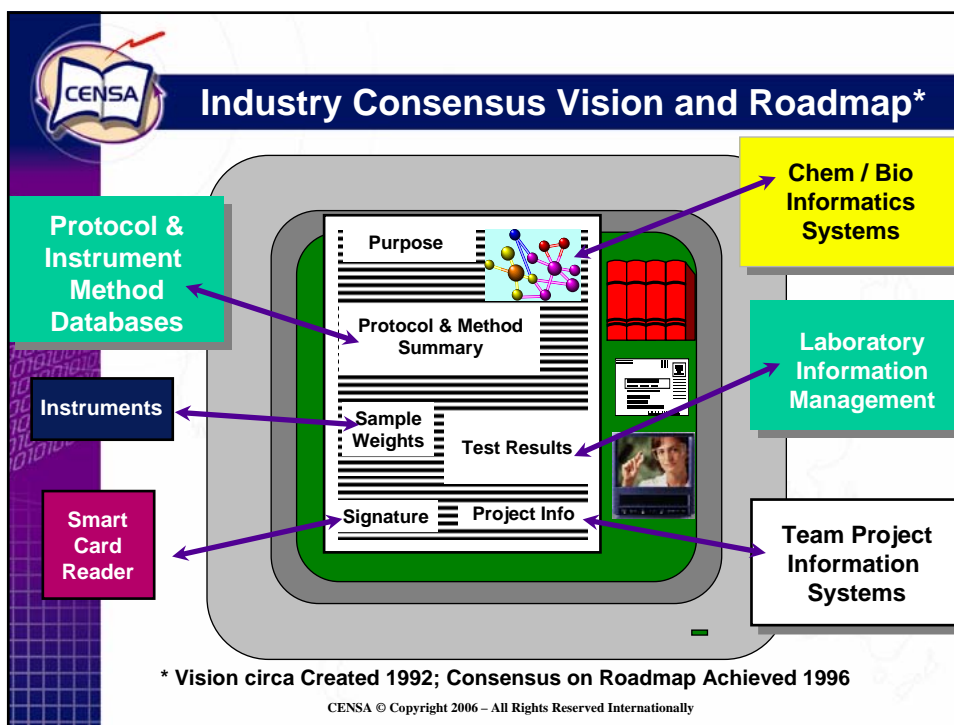
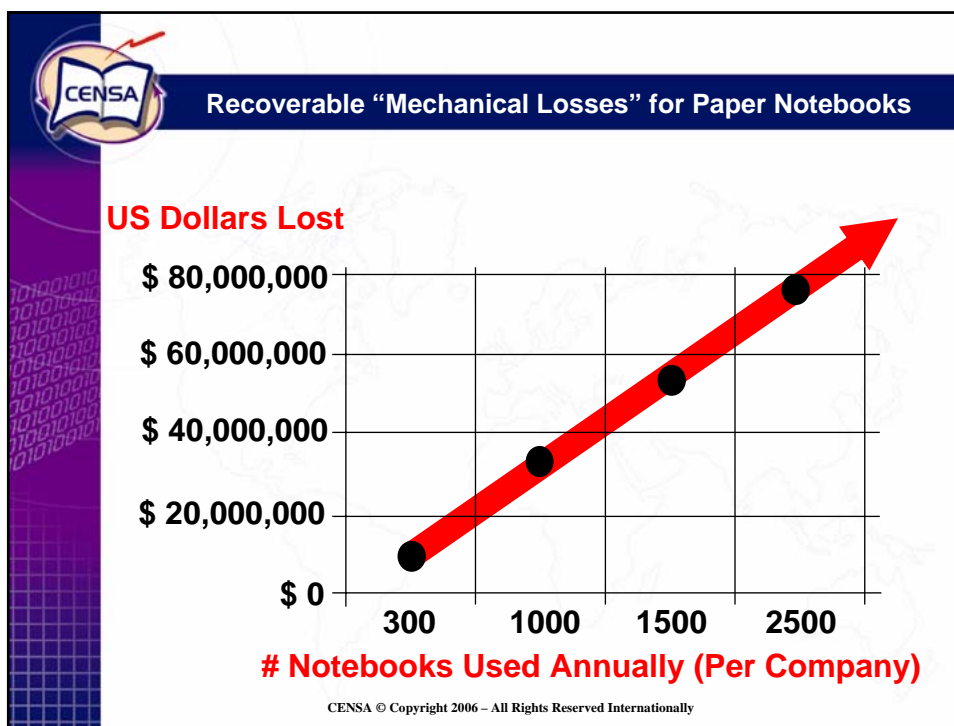
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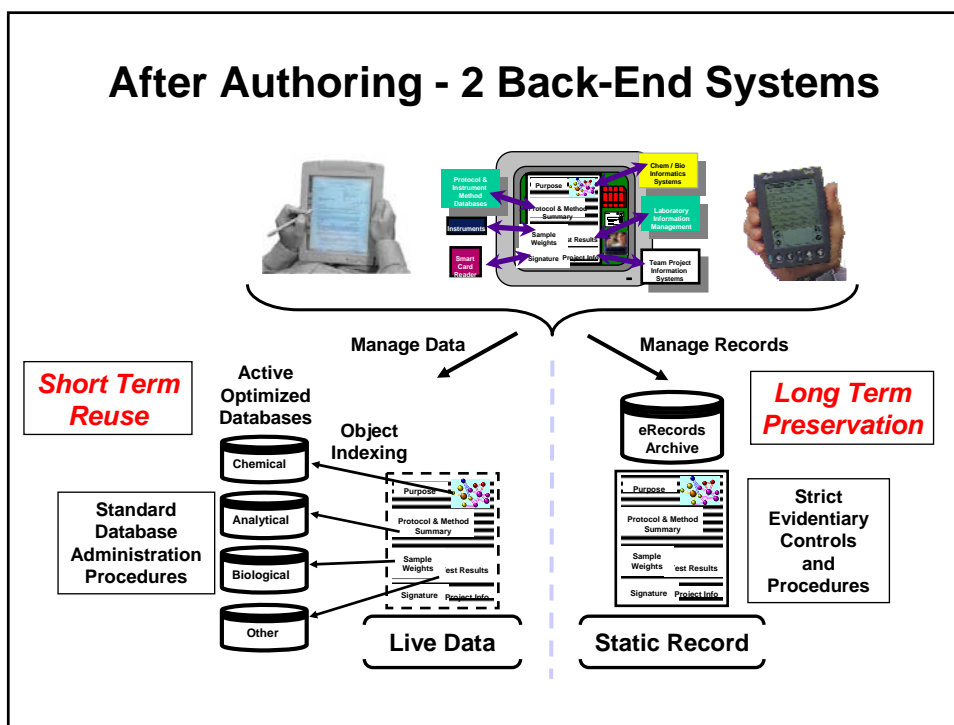
## What ELNS are...

**CENSA 1997 Consensus Layman's Definition:**  
 "An *electronic notebook* is a system to create, store, retrieve and share *fully electronic records* in ways that meet all, legal, regulatory, technical and scientific requirements."

**CENSA 2005 Practitioners Definition:** articulated and agreed upon as a useful working definition of functional needs:


- Experimental planning and information setup
- Tool for documenting results from the "Scientific Method"
- Records creation tool and management system interface
- Connectivity tool for LIMS, CDMS, statistics, chem/bio informatics, materials inventory, and all other data sources.
- Organization, annotation, curation, and management tool for doing better science in a distributed environment
- Tool used to create "the record of copy" for legal, regulatory, business, and archival purposes.

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## What ELNs will not do...

- **Replace other RDM tools**
- **Cure poor recordkeeping practices**
- **Fix poorly done science**
- **Manage electronic records**
- **Manage institutional knowledge**

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## “I’ll Take Care of Your Records”



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## Dead ELN Players

**In olden days...**

- ForeFront Group's Virtual Notebook System
- Helix Systems ResearchStation
- ChemExper+ React
- Mathematica – Nat-InstruLab


**In recent times...**

- ACDNote
- Beckman LAO's eNotebook
- Thermo Lab Systems eRecords Manager

***and the beat goes on...***

RIP

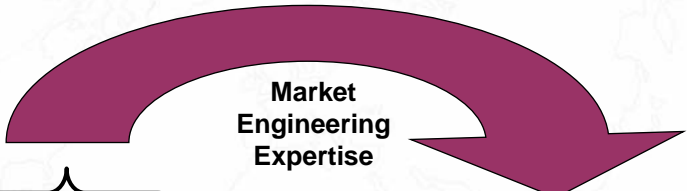
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## CENSA =

### Market Development Association

***Mission: Catalyze Evolution of RDM Automation Markets***



**Market Engineering Expertise**

**Legal  
Regulatory  
Business  
Technology  
Requirements**

**Buyer-Supplier  
Program  
Implementation  
Teams**


**“The Right Products”  
To Market Faster**

**More Effective  
Automation Markets**

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## CENSA's Strategic Programs

- **Protecting Intellectual Property**
- **Demonstrating Regulatory Compliance**
- **Improving Automation Markets & Products**
  - Intelligent Infrastructure and Integration Tools
  - Create Fast-Track Standards Where Badly Needed

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## Market Engineering

**Focus on “Market Development”**

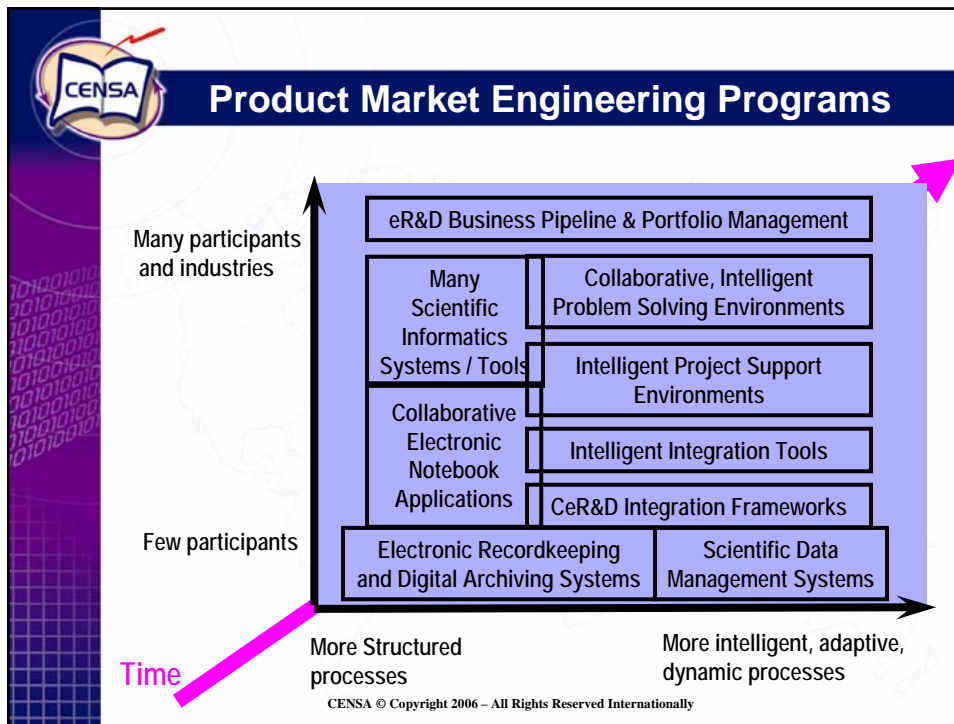
**and**

**“The Right Products” will Emerge**

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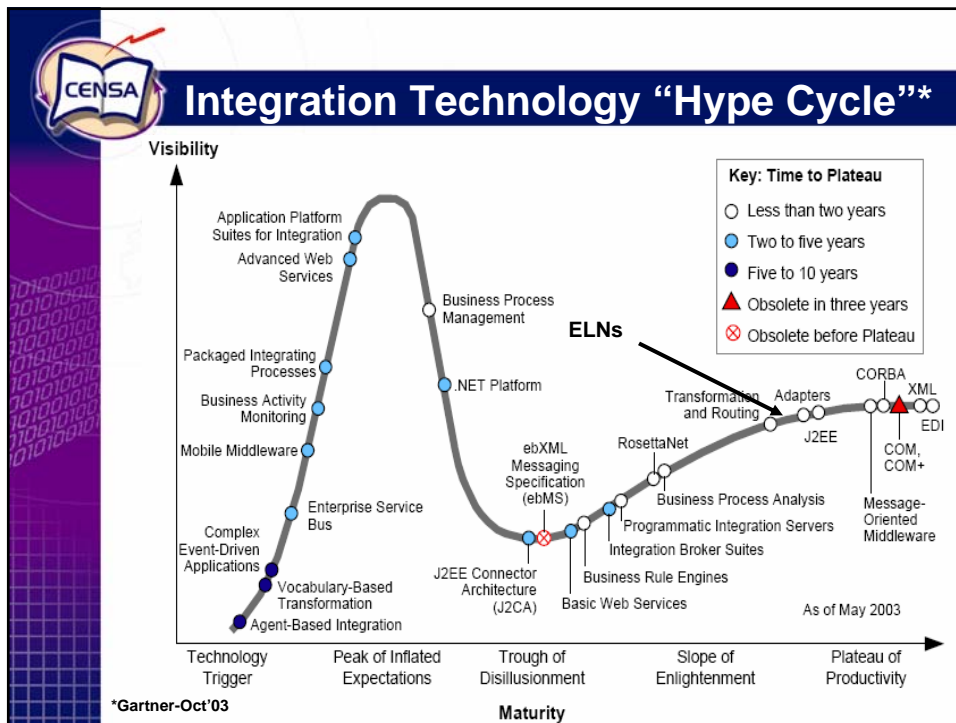
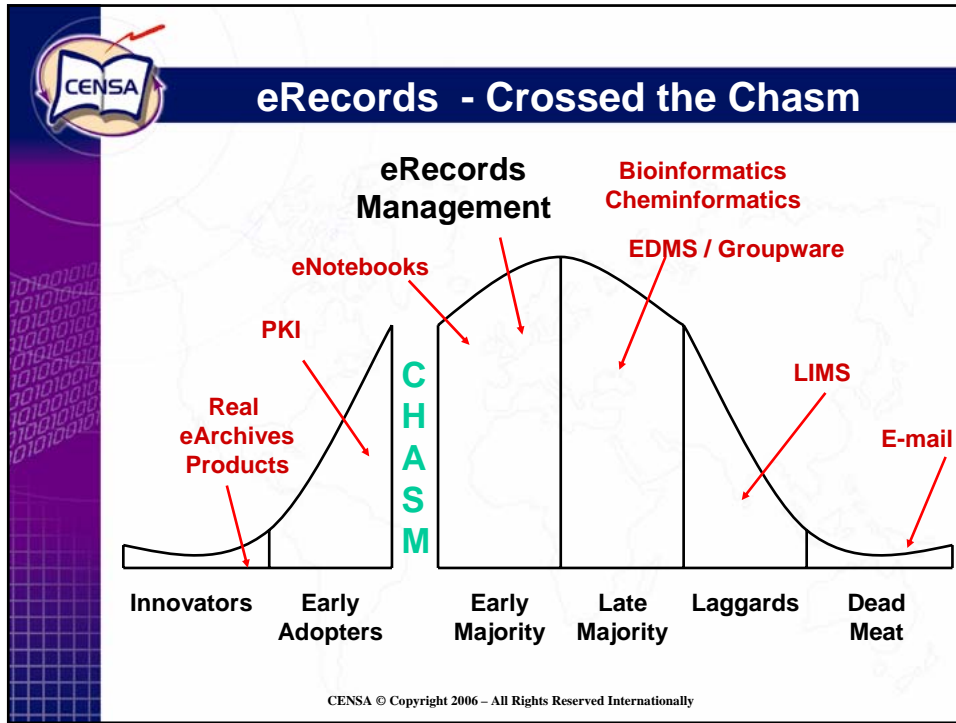
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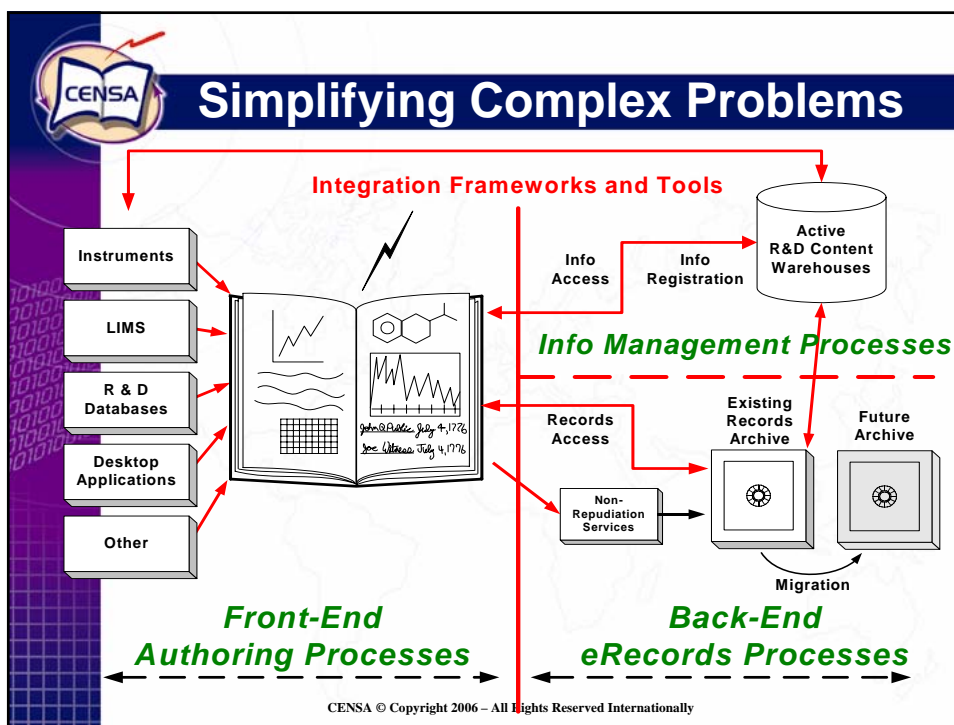
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# Technical and Legal Aspects and Future Plans

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## Whose Long-Term Perspective?

- **Government**
  - several decades to centuries
- **Industry – End Users (IT Buyers)**
  - 7 to ~15 years for eCommerce & eBusiness
  - 7 to 75+ years for R&D & historical records
- **Industry – IT Suppliers**
  - 6 months to 3 years

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## CENSA Achievements

- **Created and drove vision, requirements, markets, and products for:**
  - eNotebooks™
  - eRecordkeeping Tools and Systems
- **Created key metrics, standards, and education resources for ELNs, eRecords, Leg/Reg (via meetings & development teams)**
- **Contributed to crucial standards R&D (ISO PDF-Archive, InterPARES)**

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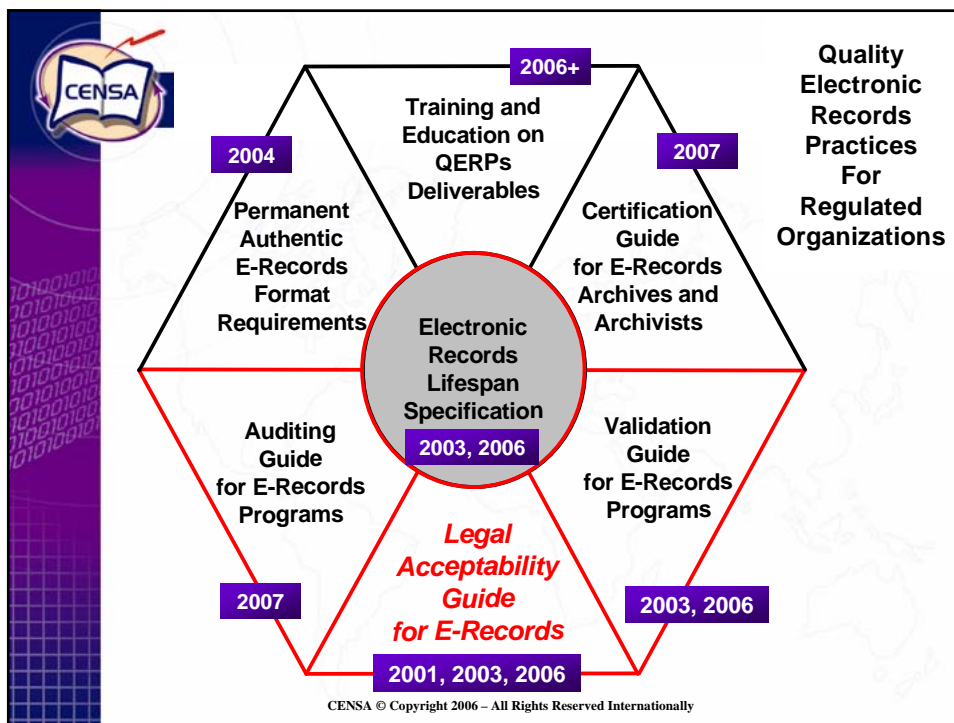
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## CENSA Legal & Regulatory Achievements


- Addressed issues with 21CFR Part 11 and EPA CROMERR regulations
- Comprehensive solutions for legal issues of eRecords for IP protection
- **Quality Electronic Records Practices:**
  - “Electronic Records Lifespan Specification”
  - “Legal Acceptability Guide for Electronic Records”
  - “Litigation Guide to Electronic Records”
  - “Validation Guide for Electronic Records”
- **Model Policy for eRecords Programs**

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**Electronic Records – Are they Admissible In Courts?**

**Welllll... That Depends...**

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**The US PTO Position and Practices on eNotebooks, Records, and eSubmissions**

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## ELN Records acceptable to PTO?

- **Steve Kunin did 5/21/2003 Official Gazette “pre-notice”**
- **June 2003 Target for internal use of eRecords for patent applications**
- **All submissions converted from paper**
- **Manage all patent case review and storage in ERM systems**
- **Includes full use history (audit trail)**

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## USPTO Official eRecords

- **To make [USPTO] eRecords official, [USPTO] systems must:**
  - **(a) satisfy OMB Circular No A-130 requirement especially the Records Management standards**
  - **b) satisfy both the requirements for GPEA (Pub.L.No. 105-277, Title XVII; 44 USC § 3105) and (36 C.F.R. § 1234) - Standards for the Creation, Use, Preservation, and Disposition of Electronic Records.**

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## USPTO uses eRecords Internally

- Got NARA to accept patents eRecords
- June 2002 - defined reqts/tasks for entire ERM life cycle – “Tech. Std. IT 212.03-15”
- Nov 2002 – piloted “ePhoenix” (no paper)
- July 2003 - instituted “ePhoenix”
- Mandates internal use of eRecords over paper
  - 1) Scan all paper patent applications to eRecord format [TIFF (fax4) image & XML
  - 2) Toss paper after 2 months or final review
  - 3) “paper copies of documents are no longer official records”

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## Unofficial PTO View


“Chances are *vanishingly small* that you will get caught up in a patent interference of any kind. And even in such cases, the question of the records being in electronic format is NOT the primary material question at issue, it is the quality of the recordkeeping policies, procedures, and evidence thereof.”

→ Judge Bruce Stoner, Former Chief APJ, PTO

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## Bottom Line With Attorneys

- **Use conservative policies (Quality eRecords Practice Standards)**
- **Use Long-term reliable standards (PDF-A and XML data formats)**
- **Make core preservation standards paramount; force vendor compliance**
- **Educate attorneys on problems and solutions with secure systems.**

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## Trends Underway Now

## Trends On the Horizon

## Trends Over the Horizon

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## Trends on The Horizon (for most)

- Integration Offerings Expanding & Easier
- Standards will keep easing integration
- Intelligent interfacing products will emerge
- Intelligent Collaborative Problem Solving Environments for RDM will emerge
- Certification will strengthen confidence in products and automation professionals

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## Things to Consider When Choosing New Systems

- RM-AS-IT-QA, business expertise shall overwhelm legal dept concerns
- YOU must protect your vital records – *not* ELN or eRecords Vendors
- XML data format standards policies and support are crucial to covering your assets
- Let vendors compete above standards

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## Ultimate Stakeholders for Success

- **Scientists**
- **R&D Managers and Executives**
- **Lawyers**
- **Regulatory personnel**
- **Archivists**
- **Management**
- **Quality Assurance**
- **Others**

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## Key Trends Underway

- **ELN and eRecords markets are maturing**
  - ELNs are being widely deployed
  - ELN visions being widely realized & extended
  - “ELN” Suppliers base maturing (35+ & growing)\*\*
  - PDF/Archive V1.0 done & being used
  - IP / Regulatory risks being addressed with standards, knowledge, experience
- **Some Issues Taking Center Stage**
  - Many hitting big integration “bottlenecks”
  - Next-gen eRecords “whole products” missing

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## Milestones in 2003-2008

### Tactical (2003-2008)

- Universally apply eNotebooks
- Create complete eRecords Systems for short-term reuse and long-term archives
- Design and implement agent-based “programmerless” RDM solution assembly
- Create consensus on eRecords Standards (via Q-ERPs Standards, PDF/Archive, expML™ )
- Create standardized architectures and tools for Strategic RDM Knowledge Mgmt & Reuse

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## Milestones in 2004-2007 (cont.)


### Tactical (2004-2007)

- Advance long-term data / record preservation, access, ownership, and interoperability goals:
  - Apply Quality eRecords Practice Standards
  - Build consensus for standards:
    - experiment Markup Language (expML™)
    - eRecords CollectionML (ala VERS)
    - eRecord Audit Trail ML

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## 2006/2007 – “A difference of degree”

*Problems On the Horizon- solutions from today*

- **Integration problems solved more broadly**
  - Integrating data from many more sources
  - Integrating data from different ELNs
  - Service Oriented Architectures (SOA) and Open Source
  - Shallow integration based on point-to-point services
- **Incremental additions to ELN products, each covering more disciplines, blurring vendor foci**
- **Quality eRecords Practices applied more deeply**

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## 2006-2010 – ““A difference of kind” ”


*Problems Over The Horizon - Solutions from the future*

- **“Heavyweight” Integration Shifts:**
  - Integration across the RDM value chain
    - Web service-based designed for loose external app. integration
    - Tightly-coupled application routines optimized for performance
    - Programmerless integration with standardized vocabularies
    - Deep data integration based on standards
- **Intelligent Problem Solving**
  - Problem-solving environments using autonomous agents
  - Large-scale data spaces using semantic webs fitting science
  - Pattern recognition and advanced mathematics used across eNotebooks and informatics bases

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### eRecords Will Soon Be Required by All US Agencies

- US FDA 21 CFR Part 11 was first (very expensive) regulation imposed on industry (April 1998)
- US Patent Office permits eRecords in lieu of paper (March 1999)
- US Patent Office moved to electronic patent application filing, management, and archiving in 2002
- US EPA had the first stages in place in 2002
- FDA mandated electronic Product Application filing in 2003
- GPEA required ALL US govt. agencies to use eRecords by 2003
- eSIGN – mandates usage of e-signatures US government-wide
- Dept. Of Labor – mandated pension plans use eRecords 2003
- US Bankruptcy Courts mandated the use of PDF in 2004
- NARA permitted the use of ISO PDF / Archive in 2004
- FDIC requires use of XBRL; SEC will soon follow.
- And the rest will follow... (ISO PDF/Archive and XML)

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