



# Electronic Lab Notebooks (ELN)

PLM World 2006

# Product Lifecycle Digital Transformation





# UGS Vision for pharma research data management

- ▶ Fragmented architecture, data and application silos
- ▶ Need for an integration platform
- ▶ Need for Generic templates for organizing experimental data
- ▶ Need for data structure enabling quick access and navigation
- ▶ Need for flexible way of managing data access rights
- ▶ Need for new concepts related to Research knowledge management



# Business Goals

- ▶ Increase researcher productivity by 20%
- ▶ Promote knowledge reapplication
- ▶ Eliminate paper and paper based microfilming
- ▶ Reduce legal response time
- ▶ Early identification of patentable ideas
- ▶ Streamline records management



# Business Processes

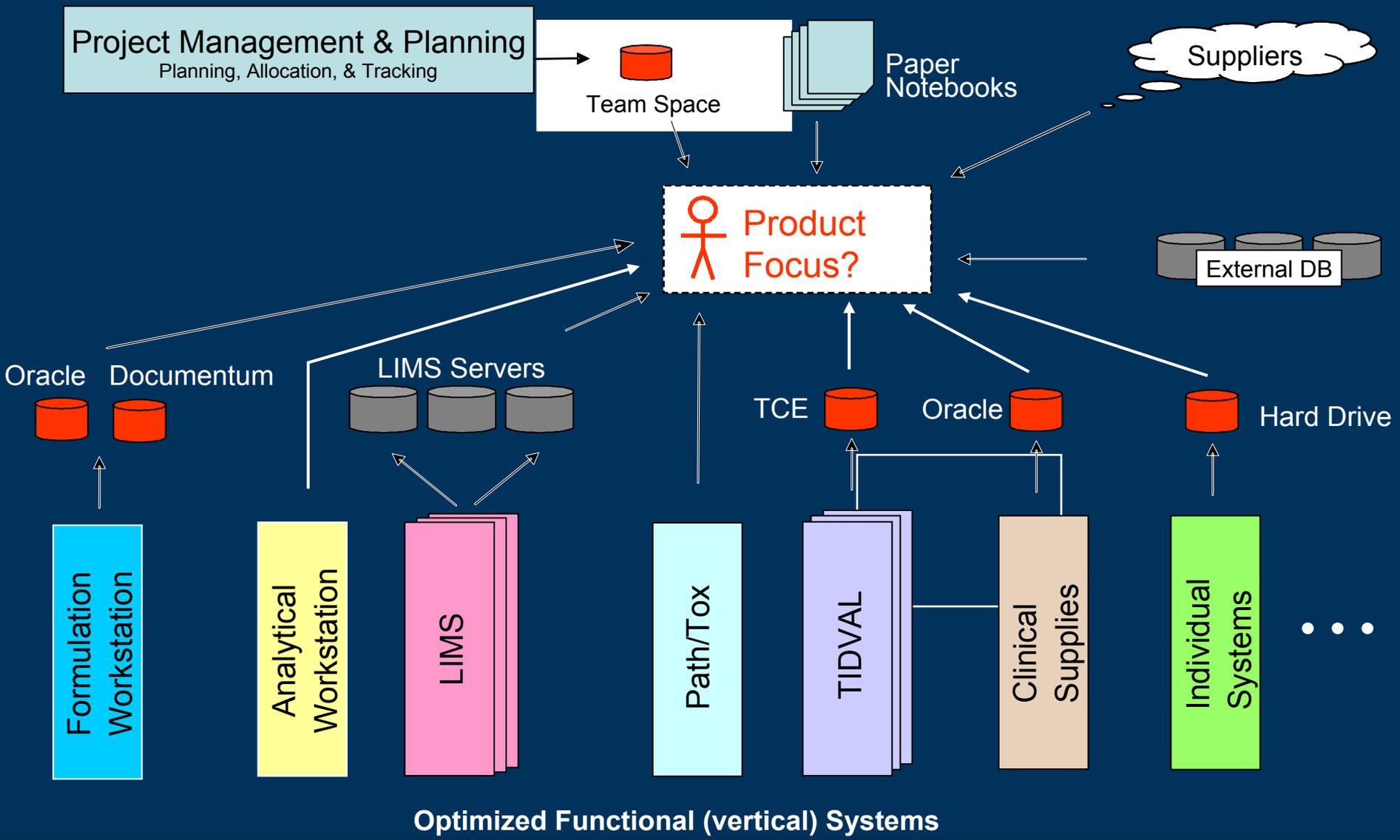
- ▶ Authoring and witnessing primary lab notebook records.
- ▶ Capturing instrument data as adjunct records and relating them to primary records.
- ▶ Record life cycle management.
- ▶ Identification of patentable ideas and initiation of patenting process.
- ▶ Litigation support



## Key Roles

- ▶ ELN Author
- ▶ Witness
- ▶ Research Supervisor
- ▶ Internal Records Administrator
- ▶ Records Manager
- ▶ Patenting Office
- ▶ Legal
- ▶ System Administrator

# Typical Environment - Fragmented Architecture



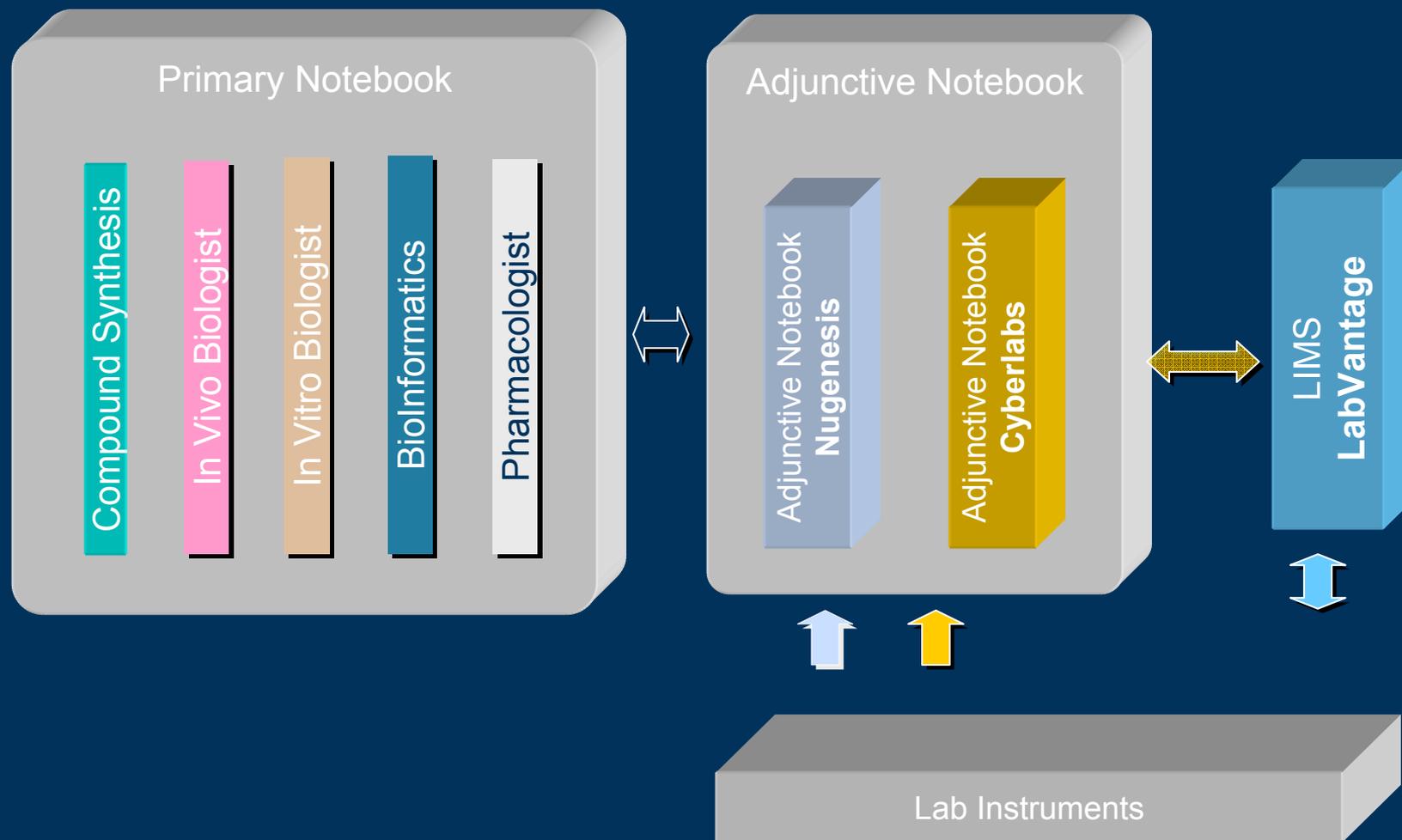


# Key Concepts

- ▶ Notebook
- ▶ Primary Record
- ▶ Adjunct Record
- ▶ Microfilm
- ▶ RMA Concepts (RMA Folder, File Plan, Audit Record, Disposition Phase, Disposition Schema)



# Solution Strategy: Typical Approach



U1

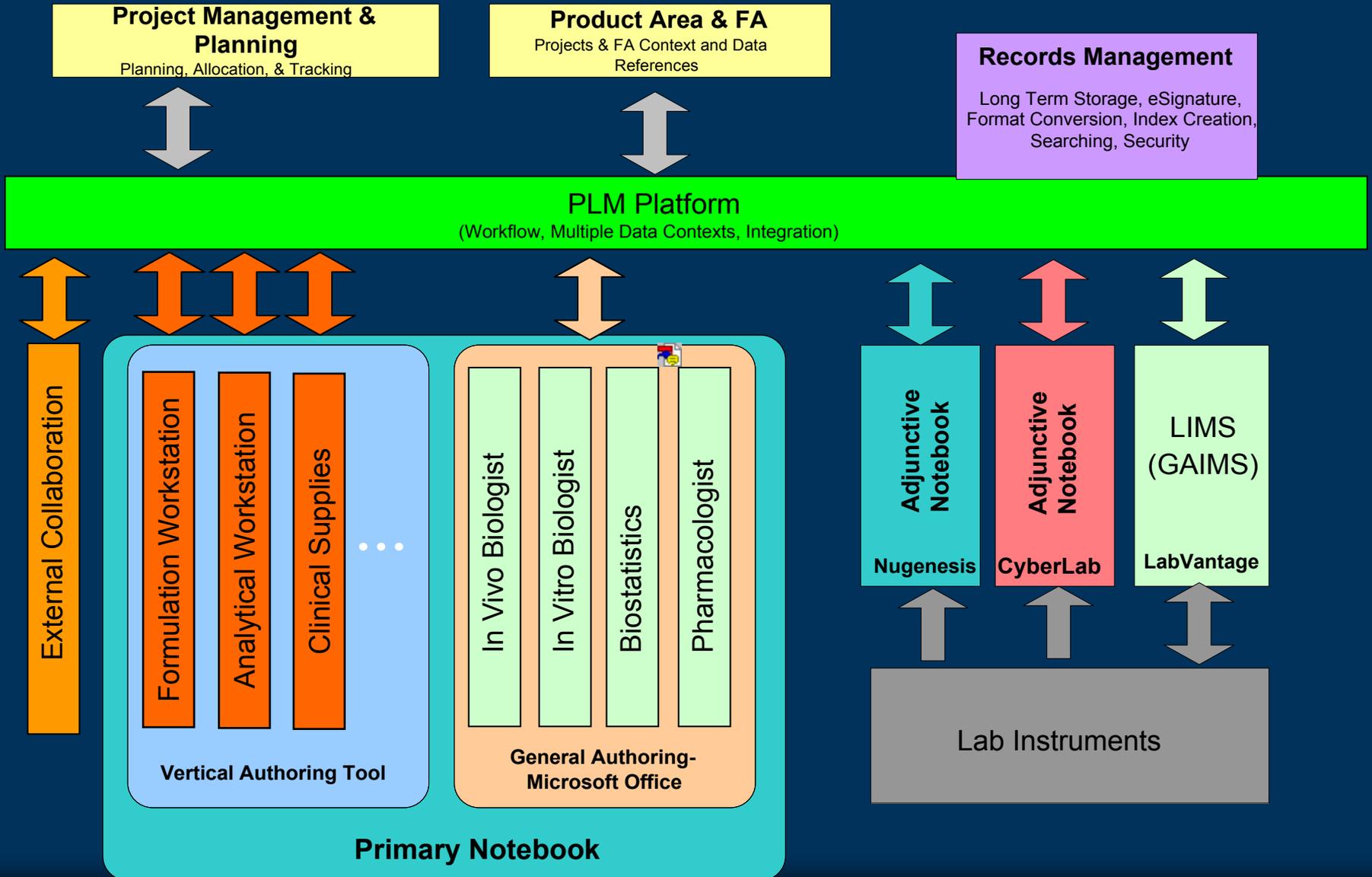
Add Odyssey as a functional bar.

Add as "New" or "Existing Function"?

UGS, 4/17/2006



# ELN/LIMS Architecture





# Records Management Perspective

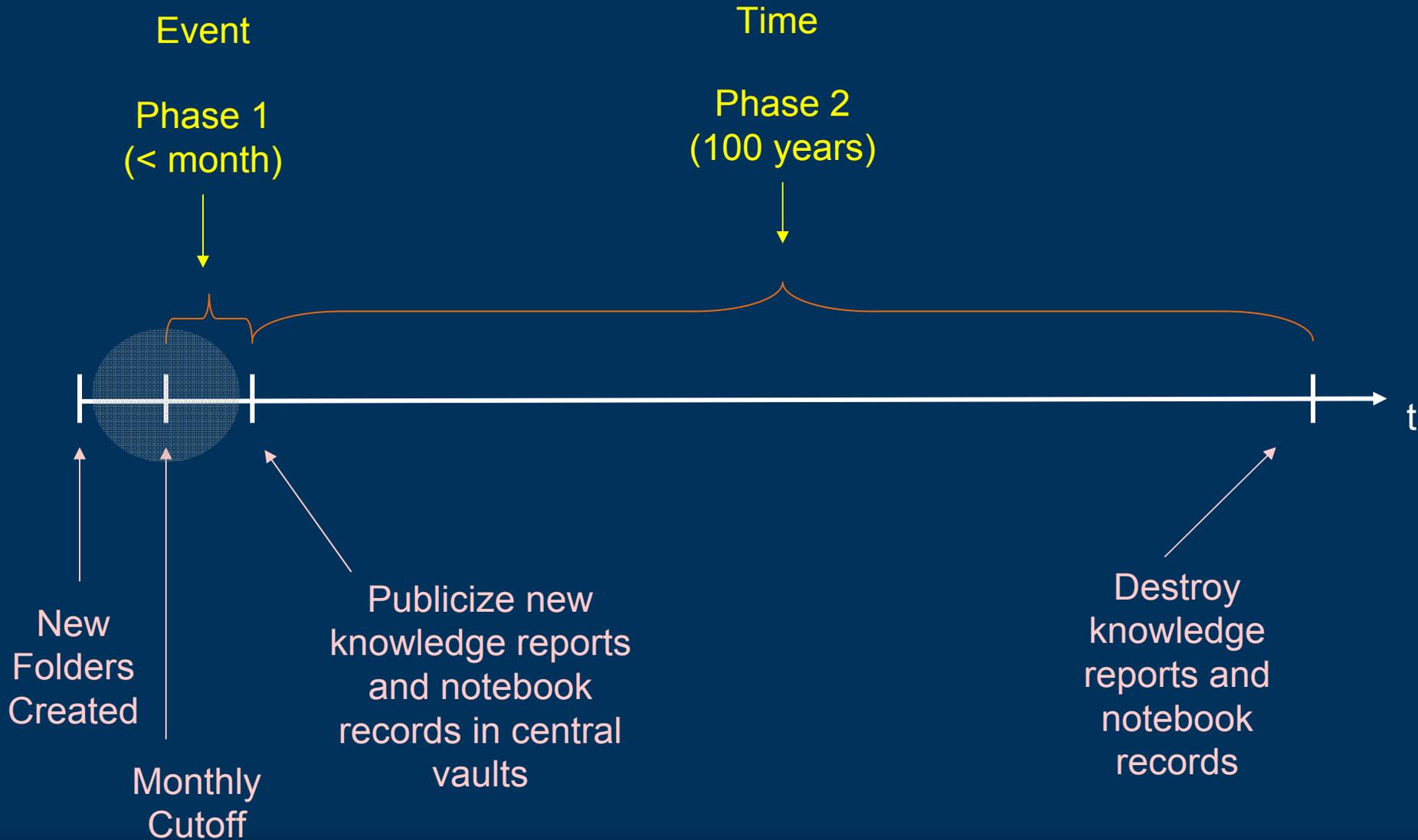


- ▶ **Records** – data/content to be managed (tax information)
  - Record Format (Form 1040)
  - Record Media (paper, electronic)
- ▶ **Record Folders** – organizers for records
- ▶ **Folder Cutoff** – collect and process annually
- ▶ **Disposition Schedule/phases**
  - collect annually
  - file by April 15<sup>th</sup>
  - retain returns & supporting information for 4 yrs
  - retain returns for 10 years



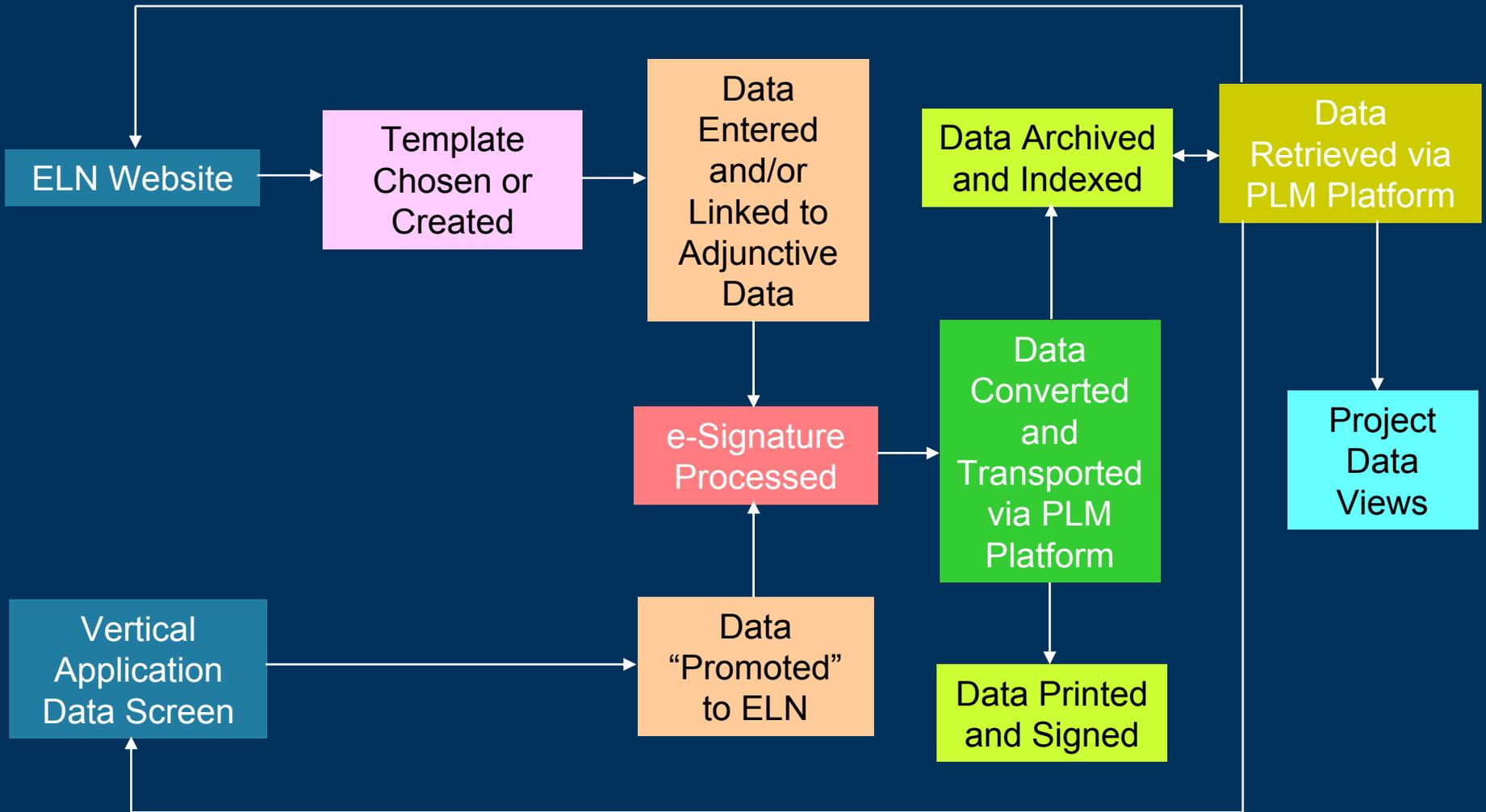


# Electronic Notebook Disposition Schedule





# ELN Simplified Process Flow





# Key Custom Features

- ▶ Notebook and Record Concepts
- ▶ Integration with adjunct data
- ▶ Digital signatures
- ▶ MS office Integration
- ▶ Acrobat Server Extension integration
- ▶ UI customization/configuration
- ▶ Records Management Configuration



# Research and Purpose

Objective Purpose  
(See inset Below)

IP

## ELN/PLM R&D Platform

Notebooking, Records, Management, Process, Search/Index, Reports, Regulatory

MS Office  
Word  
ppt  
xl

Chemistry  
Authoring  
e.g., Gensys,  
ChemPro,  
etc.

Genetics  
Application

Instruments  
NuGenesis  
LabVantage  
direct print

Other

## Logical Architecture

Objective Purpose  
(Context)

Project/Product

IP Mgt

Exploration

Function/Methods

Knowledge Push

Universal Hierarchy

Notebook

Primary Record

Adjunct Record



# ELN 2007 Features

- Record Authoring
  - Primary
  - Adjunctive
- Digital Signature
- Records Management / Retention
- Reports
- NuGenesis Integration
- CyberLabs Integration



# Electronic Laboratory Notebook

To leverage and protect our intellectual property

enterprise knowledge management

**Login** 

User ID:

Password:



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## In summary

- ▶ UGS provides :
  - A proven integration platform for all research applications
  - A system that is referencing and structuring all data
  - ELN capabilities integrated in this platform
  - An innovative approach validated in an industrial way