



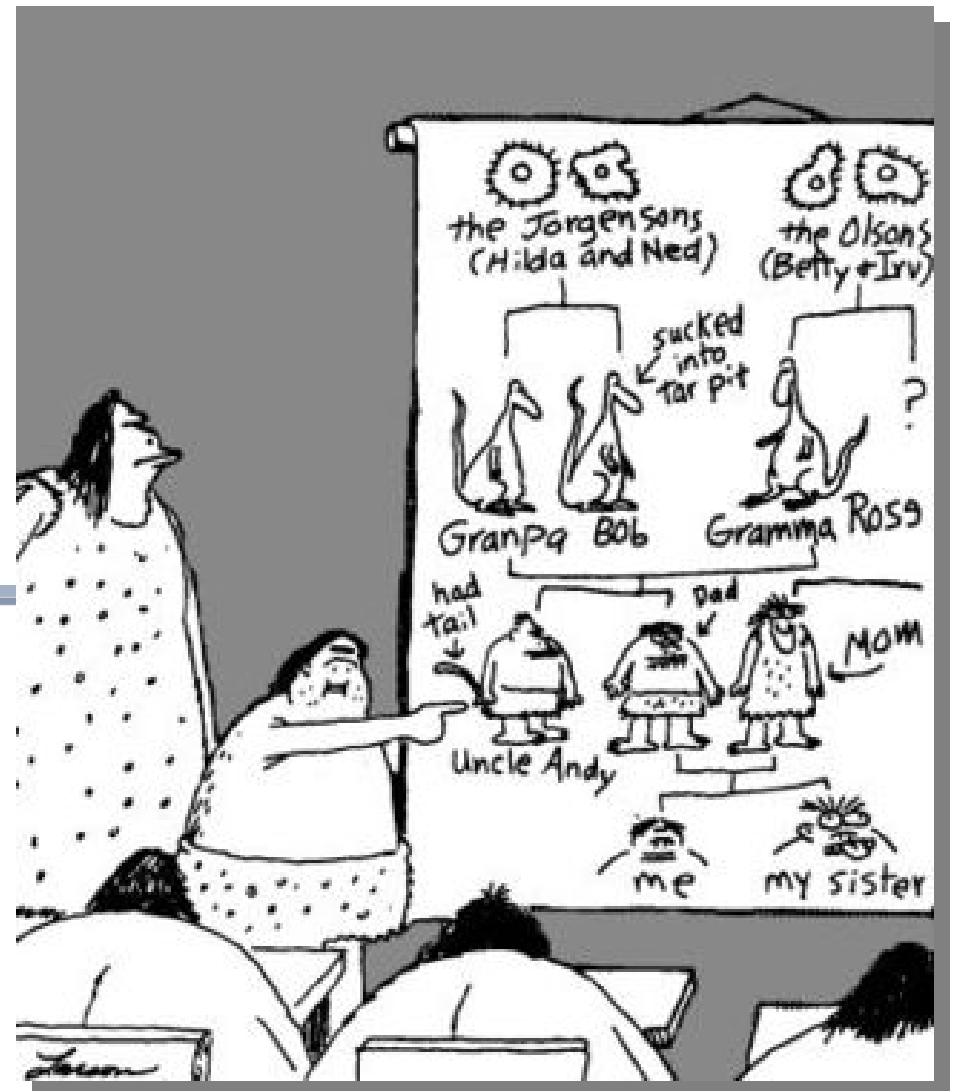
# What Does the Future Hold?

## *The Evolution of ELN*

*Michael H Elliott*

*CEO*

*Atrium Research & Consulting*



# About Atrium Research

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Atrium Research is an independent, vendor-agnostic market research and strategy advisory practice specializing in scientific informatics

Our clients include biopharmaceuticals, F&B, CPG, chemical, and government agencies

Edition IV of *Electronic Laboratory Notebooks: A Foundation for Scientific Knowledge Management* released in June 2009





The takeaway message....

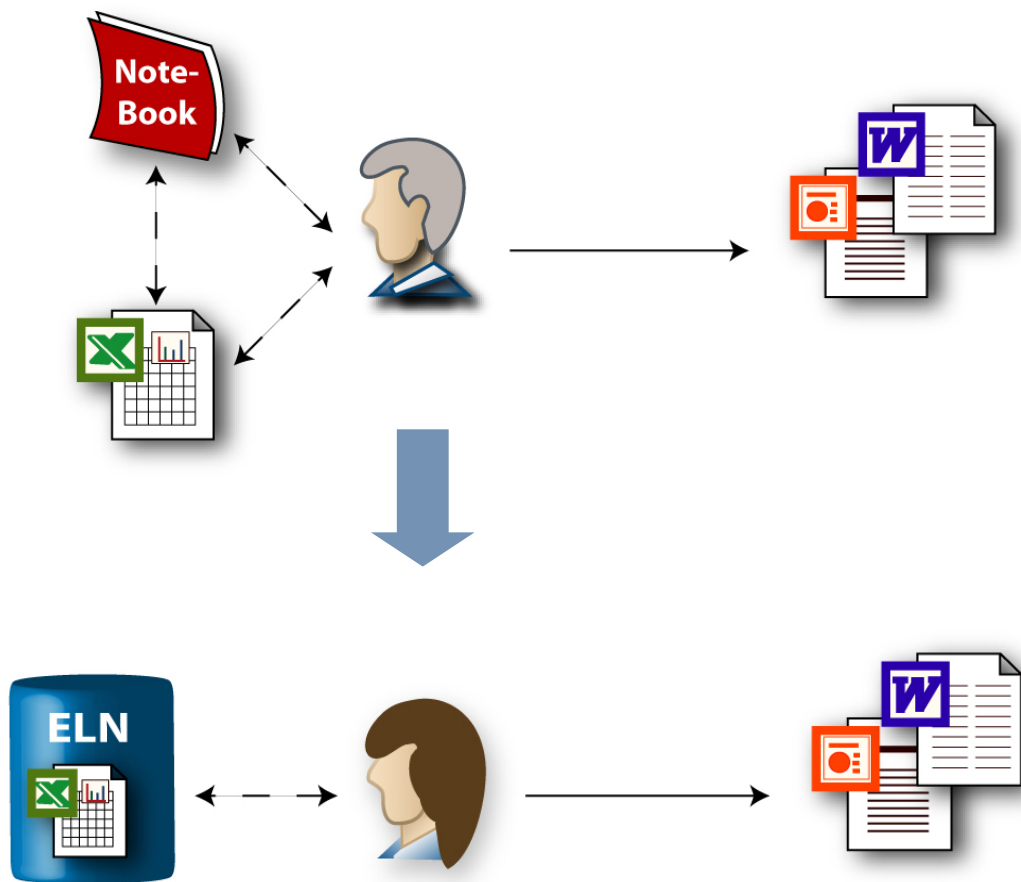
ELN is Dead....

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... Long Live ELN!

# Ah, the ELN as We Knew it....

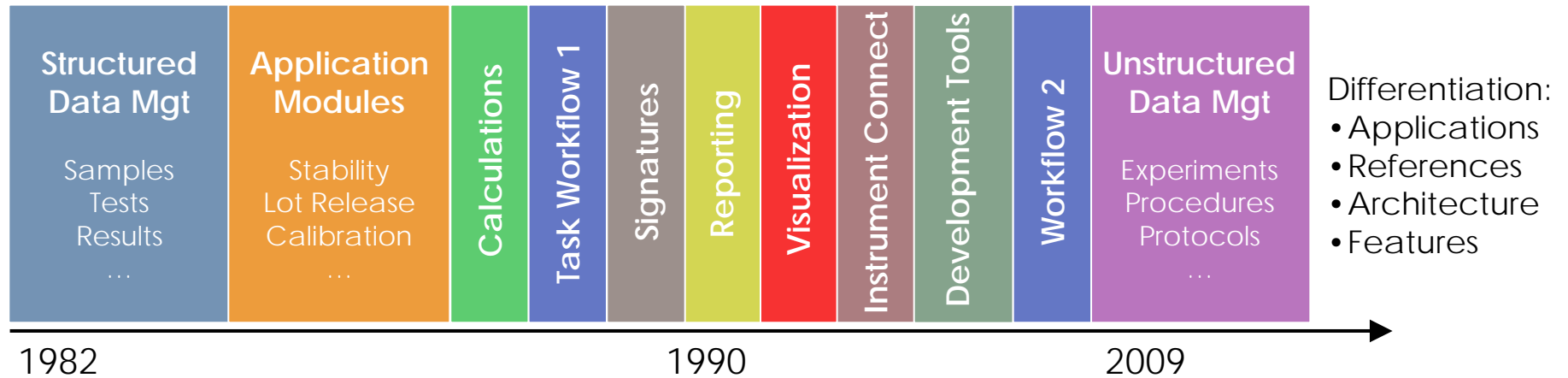
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...as a tool for *just* the support of patents

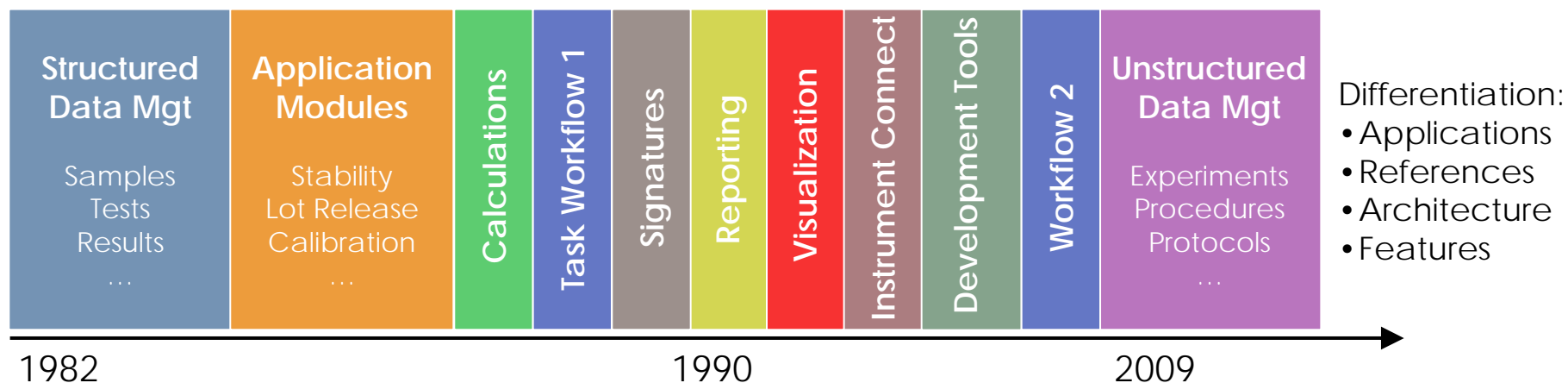
# A Look Back – The Evolution of LIMS

## LIMS

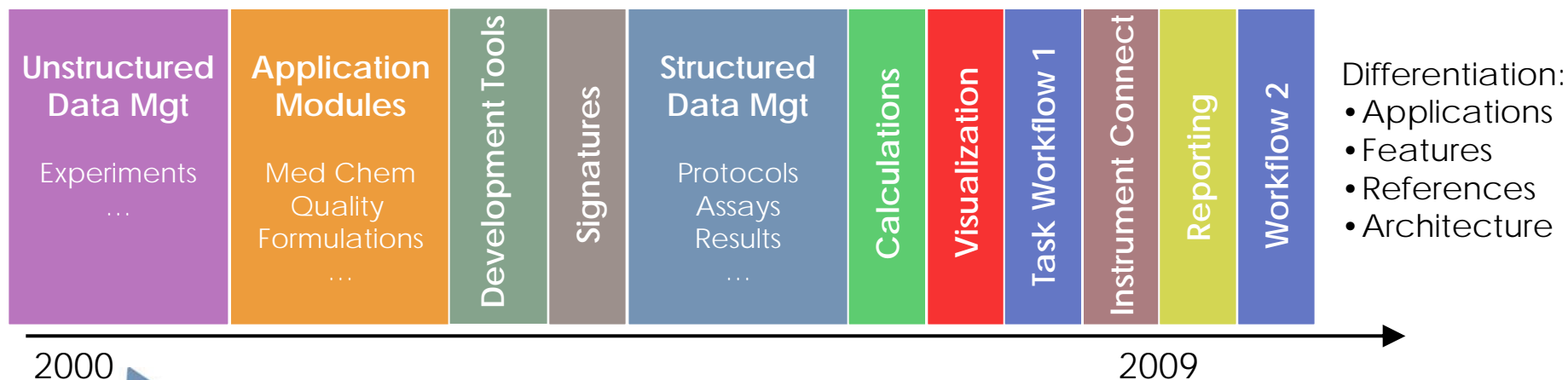


# ELN Evolution ... Look Familiar?

## LIMS

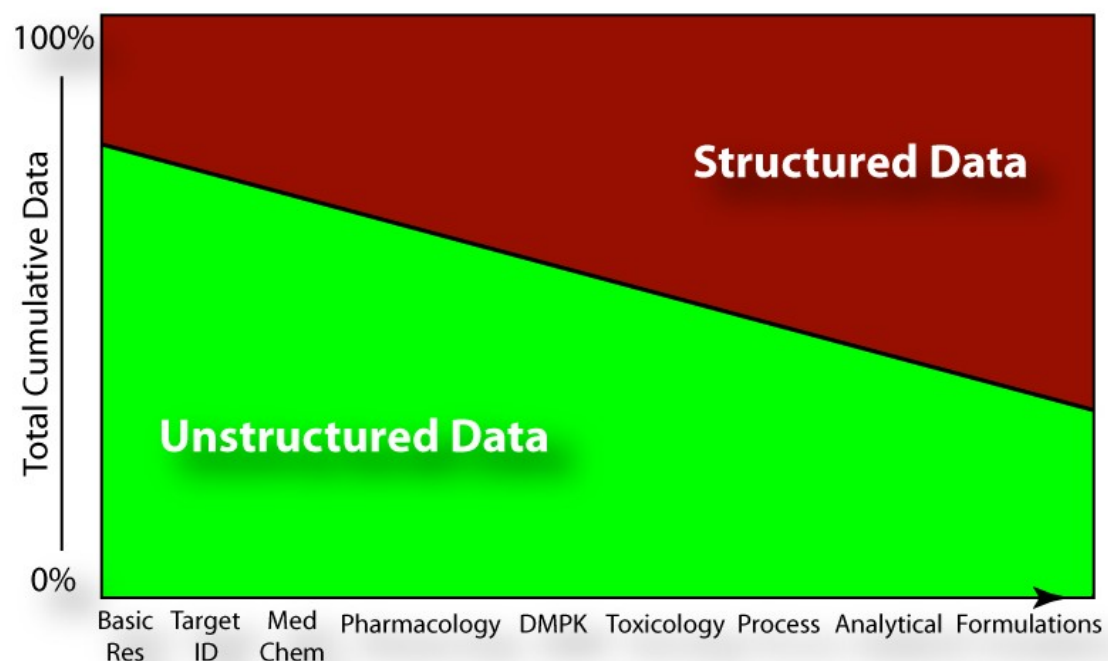


## ELN



# There is a Reason for ELN Evolution...

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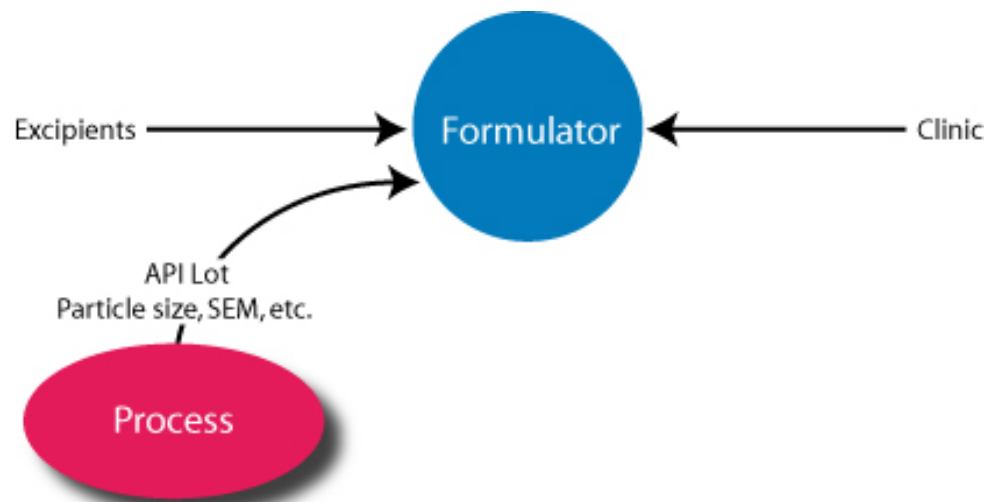
*... Customers expect holistic "whole product" solutions to their specific process and efficiency challenges*

*... ELN is pushing farther downstream into areas of increasingly defined workflows and structured data*

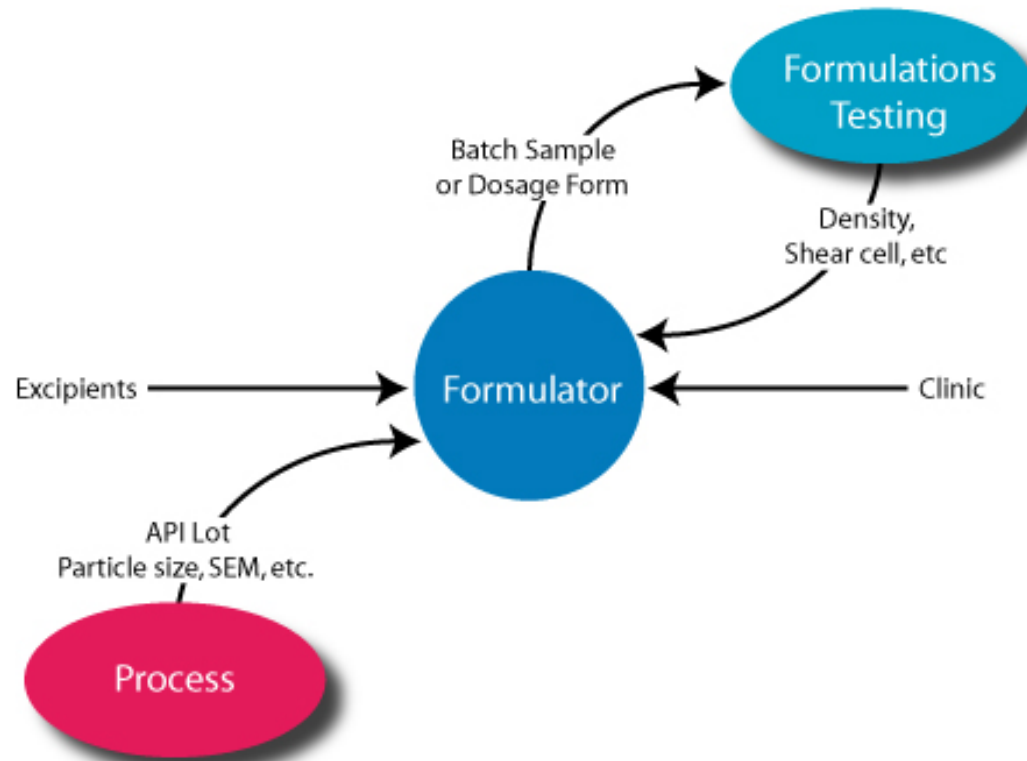


# Example: Consider the Formulation Data Integration Challenge...

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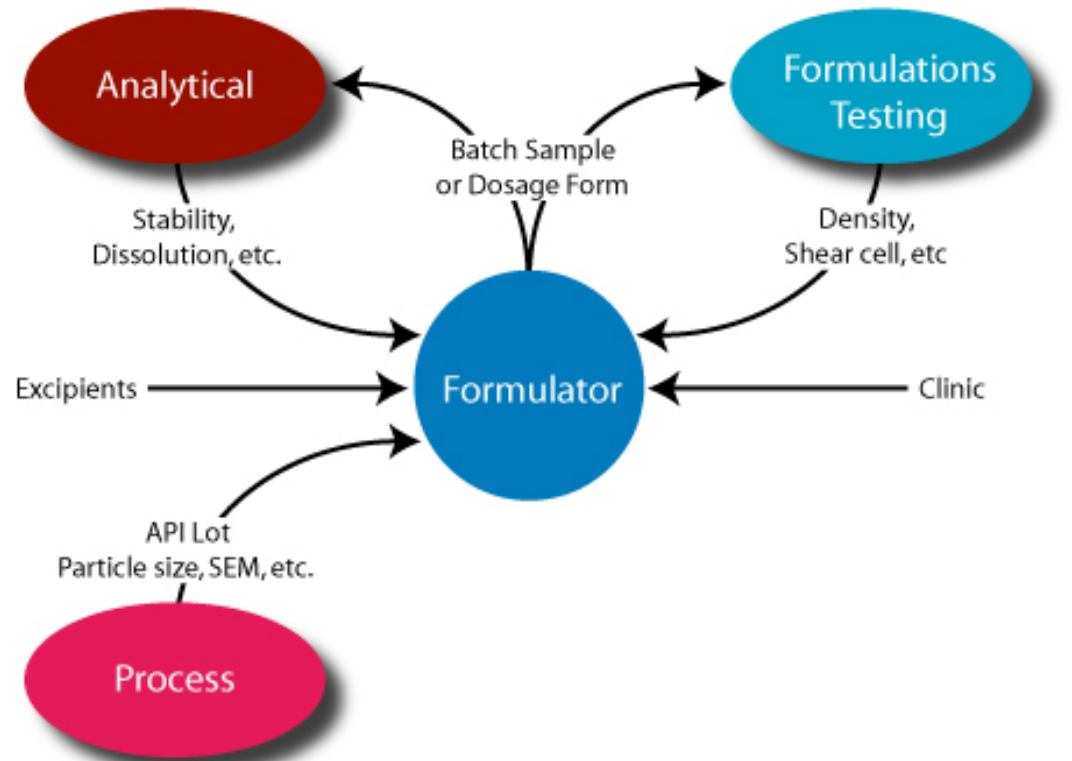
# The Formulator's ELN is Tuned to the Creation of Formulation Batches and Dosage Forms



## Formulation ELN

- ▶ Formulation Composition
- ▶ Creation of formulation batches and dosage forms
- ▶ Procedure documentation
- ▶ Managing materials
- ▶ Formulation calculations
- ▶ In-process testing
- ▶ Batch record generation
- ▶ ...

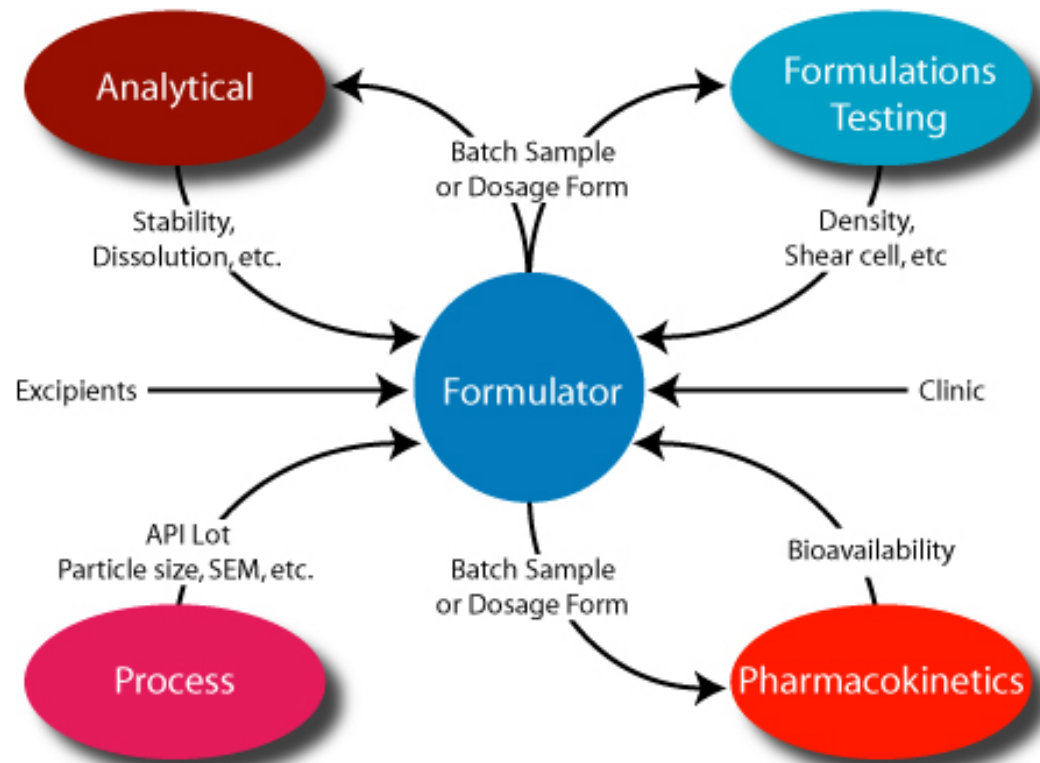
# Analytical ELN's is Used in Conjunction with LIMS for Procedures and Method Development



## Analytical ELN

- ▶ Method development and validation
- ▶ Documentation of procedures (balance checks, sample prep, ...)
- ▶ Experimental stability (non-GMP)
- ▶ Passes data to LIMS (e.g., standard concentrations, sample weights, ...)
- ▶ ...

# PK's ELN is Tailored to Management of their *in vivo* Studies and Data Analysis

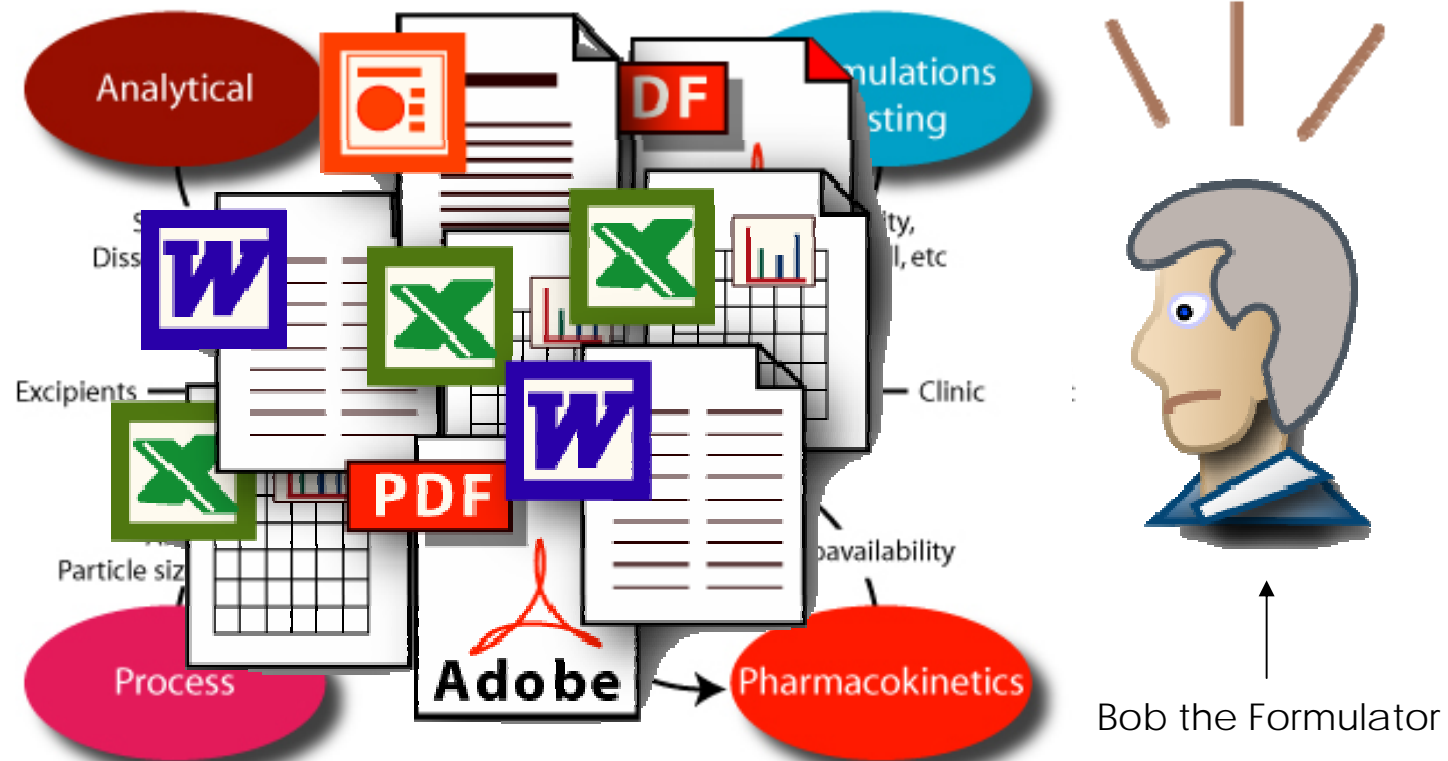


## Pharmacokinetic ELN

- ▶ Protocol/Study design
- ▶ Subjects, Treatment Group, recording
- ▶ Work scheduling
- ▶ Animal weights
- ▶ Dose schedules
- ▶ LC-MS plate creation
- ▶ LC-MS data import
- ▶ Data analysis
- ▶ Data visualization
- ▶ Reporting
- ▶ ...

... each group focused on their own departmental workflow needs

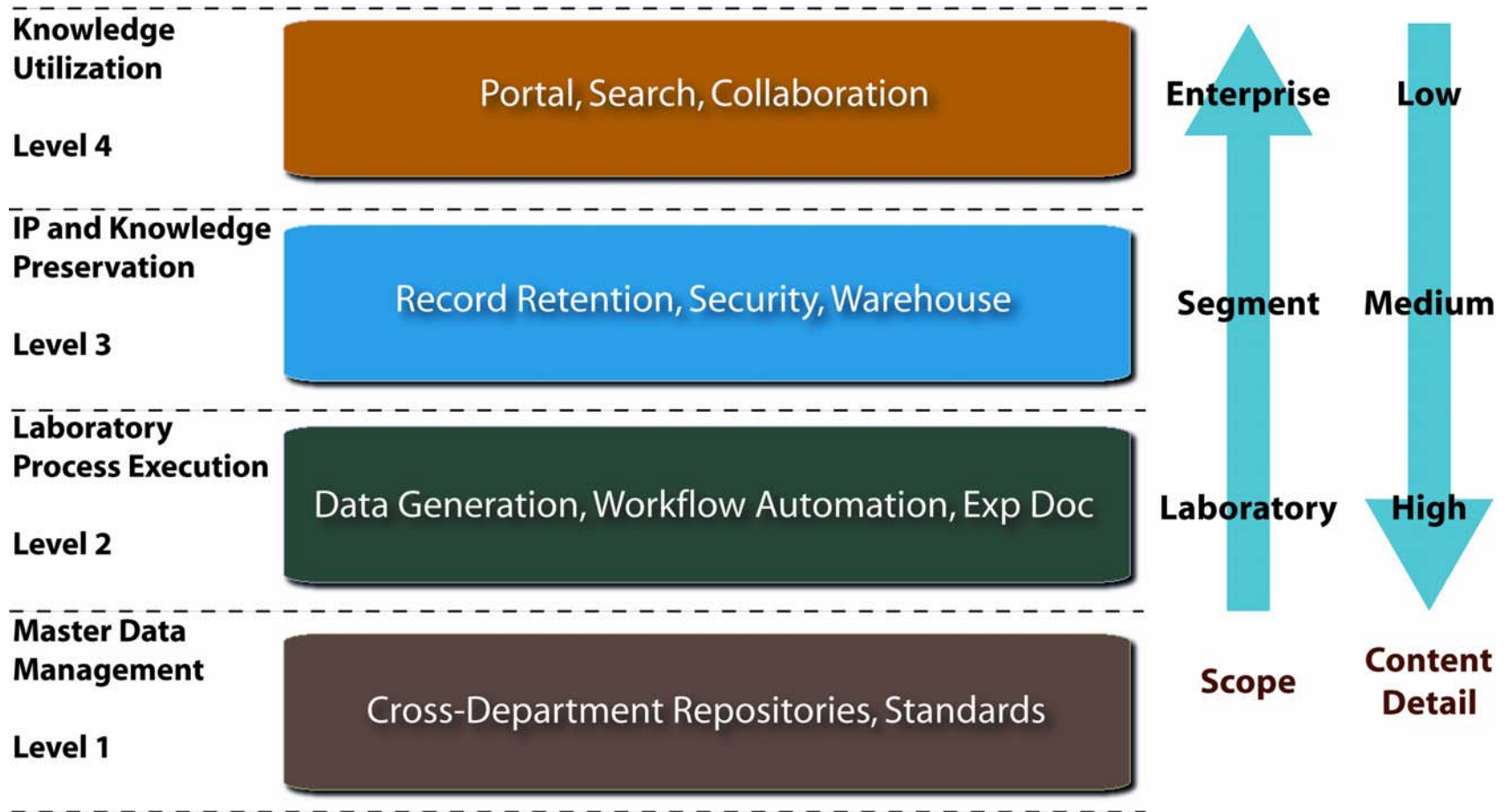
# Poor Bob, the Formulation Scientist



Bob has to manually aggregate data for analysis of dissolution v. bioavailability, particle size v. BA, stability v. particle size, ...

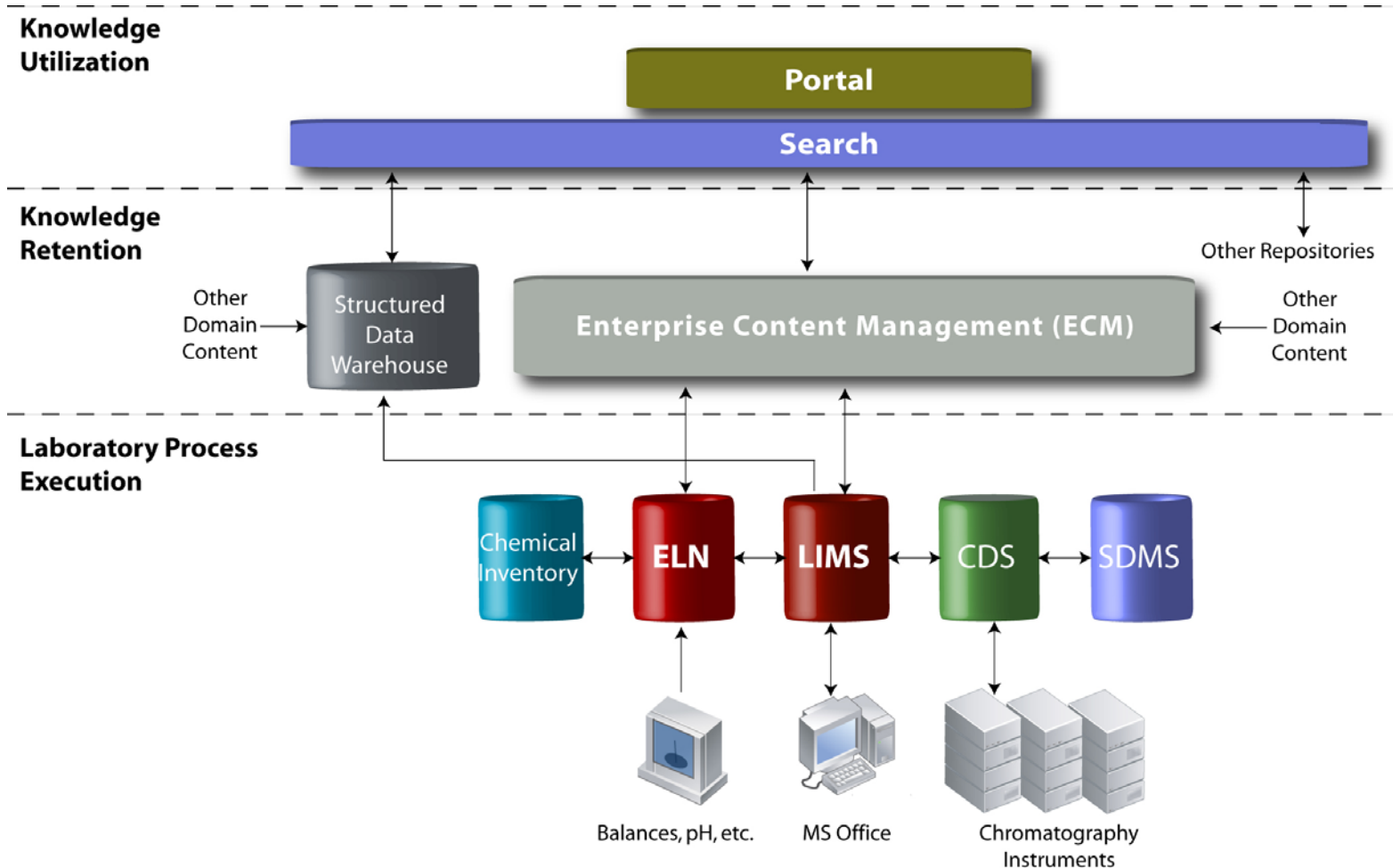
*Different formats, Different descriptors – from each department*

# The *Informatics Architecture Model*

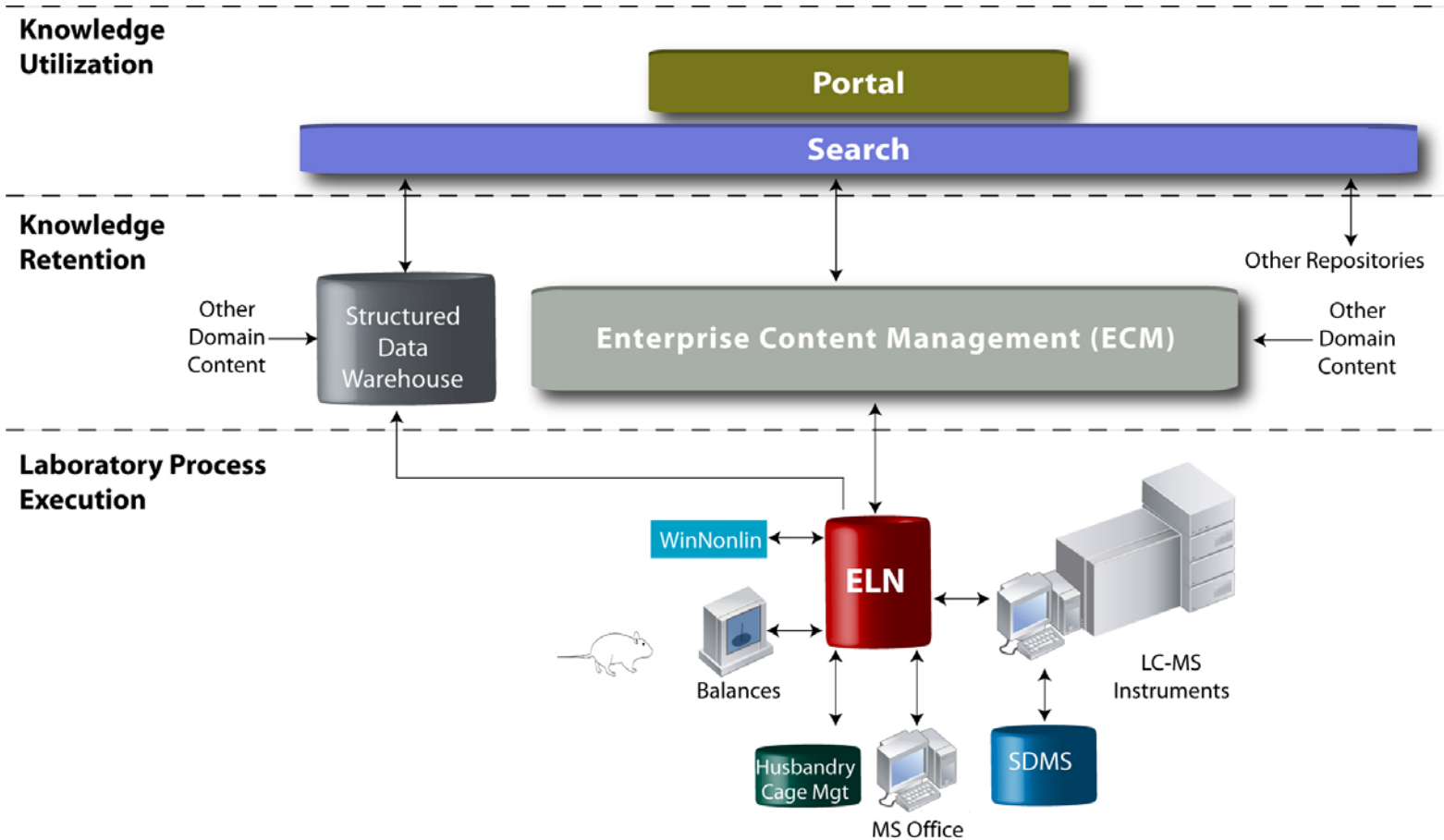


*A reference architecture to balance the needs of the department with the broader data and information requirements of the corporation*

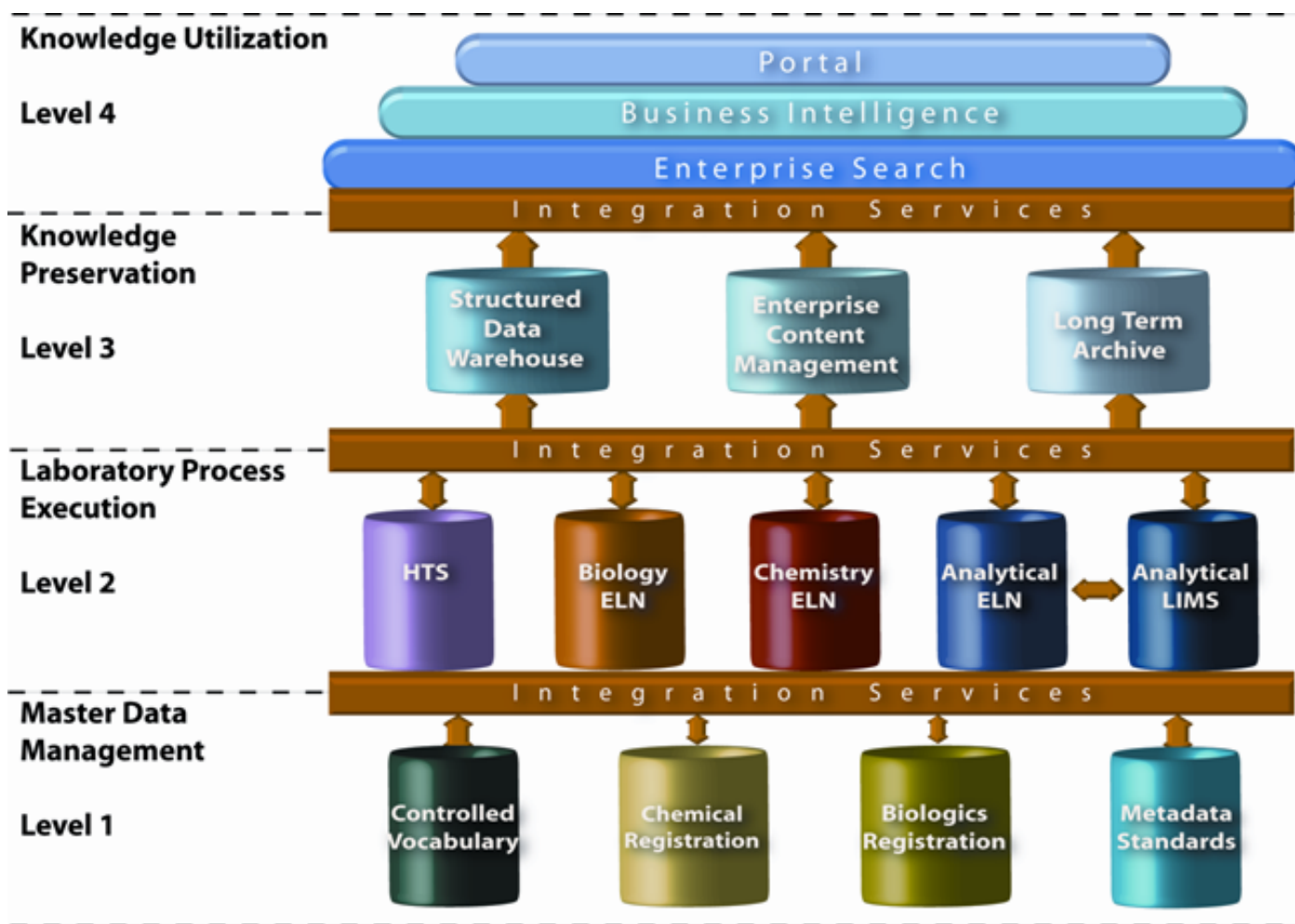
# Analytical and the Informatics Architecture Model



# Pharmacokinetics and the Informatics Architecture Model



# Bridging Perspectives: *Criticality of Master Data Management*

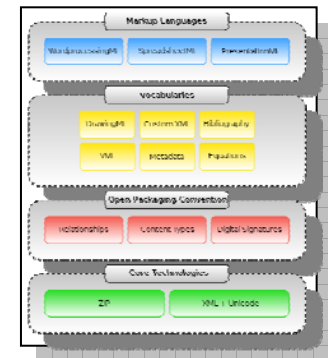


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*MDM provides consistent reference data to all laboratory process systems*

# Enabling the Future: *Information Island Avoidance*

- ▶ Leverage of *Existing* Document Format Standards?
  - **Open Document Format** (ODF, ISO/IEC 26300:2006)
    - Default format for OpenOffice
  - **OpenXML** (OOXML, ISO/IEC 29500:2008)
    - Default format for MS Office 2007 and beyond
  - Both can encapsulate unstructured and structured data
  - For content creation, data transactions, repurposing and consolidation
    - Not a static format for long term archiving like PDF/A
  - Why suffer vendor proprietary formats?
- ▶ A “**Dublin Core**” for Biopharma?
  - A *minimal* set of standard metadata terms for interoperability
    - E.g., project, study, experiment, compound, formulation, lot, batch,...



# Summary

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- ▶ There has to be a balance with the rush to become “paperless” and effective use of data and information on a broader scale
- ▶ Consideration of ELN as a component of a larger informatics puzzle, particularly in downstream areas (which have a greater number of potential users)



Questions!

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