

# *The Life Sciences Database: An Foundation for Regulated Information in Healthcare & Life Sciences*



What Are Regulated Information Systems



# Market & Needs



# What Are Regulated Systems

- Regulated systems are information systems that require certification and validation by an enterprise.
- Examples of regulated systems are:
  - US HHS HIPAA 1996-2002
  - US FDA 21 CFR Part 11
  - EU EMEA eCTD New Drug Applications
  - Country specific software validation



# What is the Life Sciences Repository?

The Repository is a database software product that stores financial, clinical and personal healthcare information (PHI) for enterprises, physicians, hospitals and managed care “covered entities” using HIPAA PHI standards and 21 CFR §11 for the life sciences in one database.

It allows the storage and retrieval of standard transactions plus clinical, administrative and financial data on a patient, consumer, medical device either directly from a workstation or through systems integration.

It uses standard transactions and also allows the enterprise to define and immediately capture new information on a patient or consumer in minutes because it is uniquely vocabulary-driven.



# What are the Needs?

- Store related transactions and documents and unstructured clinical and relationship data
- Form financial, clinical and operational relationships for all “covered entities”
- Improvement in financial systems and cash flow through all electronic document management
- Helps compliance with regulated systems (FDA, EMEA eCTD, 21 CFR 11, HIPAA, HL7, etc.)



## For the Systems Integrator: What Problems Does It Solve

- Systems Integrator needs a single standard database to support a healthcare, insurance or provider entity that is HIPAA certified
- One architecture serves all PHI data and a *local vocabulary*
- Provides extensive data dictionary of thousands of data elements
- SI can focus on loading and tracking data and not designing databases
- Also enables a generalized repository for all enterprise healthcare or financial data
- Moves the project quickly to loading and analyzing data
- The vocabulary-driven architecture allows great flexibility in design



# What are the Enterprise Solutions

- All electronic financial management
- Clinical repository linked to financial data
- HIPAA
- Application integration
- Data warehouse construction
- Security model for the enterprise
- Document management



# Contact:

Contact: Bernard P. Wess, Jr.

(781)453-2351

[www.perseidsoftware.com](http://www.perseidsoftware.com)

[BWess@perseidsoftware.com](mailto:BWess@perseidsoftware.com)

Needham, MA, USA

