

Data Integration for the Life Sciences Industry

Regulatory, Compliance and Operational Challenges and Best Practice Solutions

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Agenda

- **IdealNet Corporate Overview**
- **Compliance Challenges: Past, Present, & Future**
- **Regulation – Ramifications for Non Compliance**
- **Data required to Maintain Compliance**
- **Existing and Historical Data Integration Approaches**
- **Common Pain Points with Existing Approaches**
- **Introduction to Data Virtualization**
- **Data Virtualization – Enable Business Intelligence (BI)**
- **Easy Data Integration and Ongoing Data Management (Harmonization) thru MDM**



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IdealNet Corporate Overview

- Ideal Systems, Inc. was formed in 1994 : provided Enterprise Software and consulting
- IdealNet, Inc. was formed in 2002 and absorbed the Ideal Systems, Inc. consulting practice
- Provides expert Business and Technical consulting services to Life Sciences customers
- Clients include all of the top 10 Tier 1 Pharmaceutical Manufacturers as well as numerous Tier 2 Manufacturers and Biotech, Medical Device, Hospital Group Purchasing Organizations (GPOs), and Distributors
- Areas of expertise include Commercial and Regulatory Contracting, Finance, Business Intelligence & Analytics, and Sales Force Automation
- Many years of experience in implementing, integrating, and upgrading Enterprise Software solutions for Life Sciences customers
- Based on the East Cost in a Philadelphia, PA suburb with clients throughout the world



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IdealNet Partial Client List





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Compliance Challenges: Past, Present, and Future

The Past (and ongoing)

- **Food and Drug Administration (FDA) regulations**
- **Centers for Medicare & Medicaid Services (CMS)**
 - Medicaid
- **Commercial Contracts**
 - Chargebacks



The Present (and ongoing)

- **Centers for Medicare & Medicaid Services (CMS)**
 - Government Pricing
 - Deficit Reduction Act (DRA)
 - Medicare Part D



The Future (and ongoing)

- **The Healthcare Reform Act (HCA)**
- **Aggregate Spend**



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Regulation – Ramifications for Non Compliance

- **Products temporarily or permanently pulled from the market by the FDA**
- **Large Fines and Settlements for violations**
 - For example, Best Price violation settlements in excess of \$100 million each
- **Office of Inspector General (OIG) Audits**
- **Expanded powers to pursue charges directly against corporate executives**
 - Direct fines
 - Incarceration
- **Market effects of bad publicity**



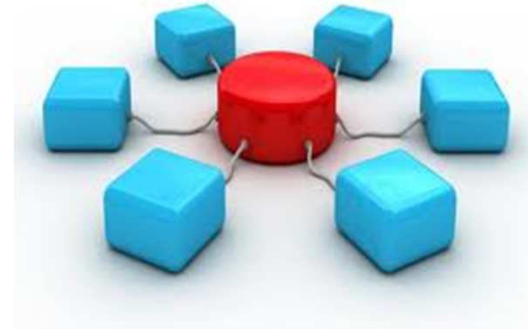


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Data required to Maintain Compliance

- **Enterprise Resource Planning (ERP)**
 - SAP, JDEdwards, Oracle
- **Clinical Trial Systems**
- **New Drug Application (NDA)**
- **Internal Data Warehouse**
- **Custom, “Home Grown” Systems**
- **Supply Chain Systems**
 - Contract Management
 - Sales Tracing
- **Warehouse & Distribution Management Systems**
- **Document Repository Systems**





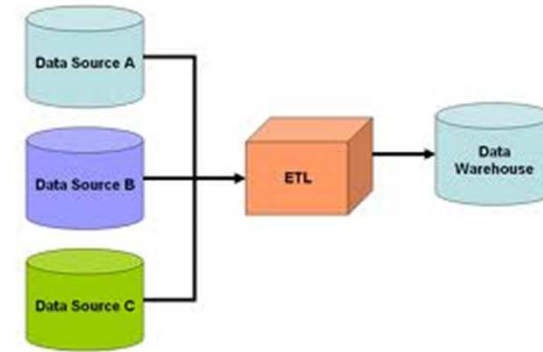
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Existing and Historical Data Integration Approaches

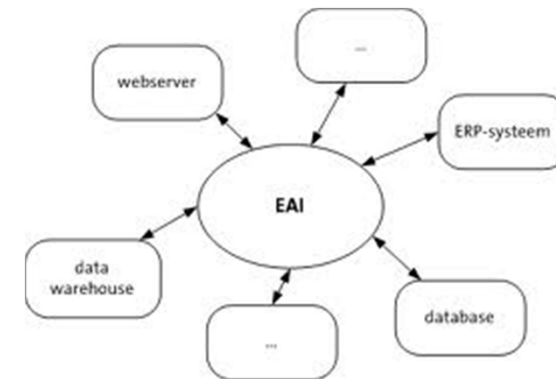
Extract, Transform, Load (ETL)

- Informatica®
- Talend®
- SAP Business Objects Data Integrator™
- Etc...



Enterprise Application Integration (EAI)

- Microsoft BizTalk®
- Apache Camel®
- Guaraná DSL
- Etc...



Home grown

- SQL (Oracle PLSQL, Microsoft SQLServer, etc...)
- 3G Programming Languages (C++, J2EE, etc...)



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Common Pain Points with Existing Approaches

- **Numerous segments of custom vendor or internal code**
 - Easily breaks when any underlying data structure or associated technology changes
 - Requires constant, expensive maintenance
 - Often, proprietary development technologies are involved which raises cost
- **Setup and Deployment of Tools is Cumbersome**
 - Non intuitive or only partially intuitive User Interfaces
 - Requirements for intermediary data warehouse structures
 - Significant synchronization issues
 - Low performance due to movement of massive data sets
 - High price consultants with expertise in the specific tools are required to implement and often for subsequent changes
- **Closed or Obsolete Architectures**
 - The technology is not scalable for future needs
 - Connectivity to new database technologies or data source objects is severely limited or non-existent





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Introduction to Data Virtualization

Queplix

- **Provides immediate and comprehensive visibility to all data (tables, fields, etc...) across all data sources**
- **Automatically integrates with underlying security models for each data source**
- **Empowers business users as well as IT like No Other tool or option**
 - Easy to use and uniform User Interface allows users to setup and control all aspects of data integration
 - Automatically uses vendor approved APIs within Software Blades for all data sources
 - Non invasive approach via Metadata layer does not disrupt underlying data sources
 - Very flexible while simultaneously providing class leading performance





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Data Virtualization – Enable Business Intelligence (BI)

- **Users can rapidly design and build meaningful BI reports and dashboards**
- **No requirement for IT or outside consultants to modify a “data catalog” to add, change, or delete fields**
- **No intermediary Data Warehouse means : no performance drain via large movements of data, elimination of dangerous data synchronization issues, any BI tool can access the Queplix model as opposed to some which require proprietary, intermediary data stores**
- **Underlying data source changes are automatically reflected within Queplix in a manner which does not “break” any usage at any level**





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Easy Data Integration and Ongoing Data Management (Harmonization) thru MDM

Master Data Management



- **Unlike existing ETL or EAI tools, Queplix both connects data easily And Harmonizes it**
 - Rules are controlled by the User
 - Straightforward User Interface with no coding required
 - Underlying rules within each data source are also automatically accommodated
- **Legacy, custom data integration and harmonization code can be completely replaced**
- **Internal, home grown relational database sources can also be accessed and harmonized via Queplix. Again, No coding required**
- **As data sources are virtual, Queplix then allows for ease of movement for underlying local data sources to migrate to the Cloud or SaaS model**

Thank You

Talk to a Queplix or IdealNet representative now to schedule a demo or Proof of Concept initiative

Contact Christopher C. Biddle at cbiddle@idealnetinc.com



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