Facilitating Clinical Trials with Content Based Authorization

Introduction

Providing the right stakeholders with unobstructed access to sensitive data is essential in any industry. Within the pharmaceutical and biotech industries, inefficient data sharing and collaboration slow down the research process and delay the launch of new products. However implementing an effective data share approach can be extremely complex through a combination of business, security, privacy and regulatory concerns. It involves not only providing secure access to the data sets that an end user is entitled to view, but also limiting access to specific pieces of information within the data sets.

This scenario is best exemplified by the need to protect sensitive clinical trial data. There are many issues that expose data to risk; most notably the protection of patient privacy, compliance with regulatory rules and regulations, and the protection of intellectual property.

Clinical trial data sets can span multiple layers of information such as:

- Research results
- The types of action taken upon drug targets
- Patient health data
- Clinical trial design and methodology
- Clinical laboratory data
- Trial analysis and summary reports

To provide a more secure way to access these data sets, one leading pharmaceutical manufacturer developed the concept of Content Based Authorization – which has virtually the same characteristics as Attribute Based Access Control. In its application to clinical trial data, Content Based Authorization is utilized based upon the following assumptions:

- Policy Structure: Data about multiple compounds, studies, trial designs and trial results need to be compliant with the regulatory and business access control policies.
- Real Time Access: Multiple data sources can be integrated into a data mart for quick and easy access.
- User Attributes: Descriptions about the data can come from multiple sources.
- Content Annotation: The content of the data also includes attributes that can be utilized in the access control process. These include such items as the trial stage, compound, or the sensitivity of the data.

Advantages

One of the biggest advantages of Content Based Authorization is that the representative data sets can be accessed efficiently and securely with fine-grained access control. This translates into a distinct value proposition for the business. Advantages include the following:

- **Agility:** Any changes to the authorization policies take place immediately as new attributes evolve and are added.
- **Visibility:** The ability to carry out random security audits to the authorization policies is fully supported.
- **Scalability:** As the quantity of data and sources grow over time, the relevant authorization policies will be equally consistent, controlled, and managed.
- **Accessibility:** Granular control over access to the needed data sets can be given to each user depending upon what his or her job requirements dictate.

Content Based Authorization also brings with it other strategic advantages. First, the authorization policies can be defined, created, and managed from one strategic location. The same authorization rules and policies can be applied to a potential new drug as it progresses through the various stages of research and development. As a result, authorization policies need to be only crafted once, and can be applied to all of the different steps in the drug development pipeline.

Second, with the use of Content Based Authorization, the creation of the access control rules (which are related to data set retrieval) can be accomplished at the business end, rather than having to rely solely on IT. This is achieved through the use of Attribute Based Access Control (ABAC), which allows for the creation of authorization policies utilizing business level attributes.

Finally, any changes which are made to the attribute data are automatically resolved by the runtime authorization service.

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Key Drivers

Because Content Based Authorization is applied to enterprise wide level applications, there are a number of key drivers involved:

- Corporate Governance: Because business entities are often prone to security threats and attacks, corporate governance directives are used to define the appropriate security posture.
- Regulatory Compliance: The pharmaceutical industry is highly regulated by federal standards in order to protect critical information and the drug development process.
- Business Requirements: A feature of utilizing Content Based Authorization is that the authorization policies can be converted to machine interpretable models, and can be reused throughout many business processes.

For more information

For more detail on this approach in practice, take a look at the full paper co-authored with Axiomatics and Eli Lilly: *Increasing the Value of Information with Fine-grained Security for Data Marts :* http://www.axiomatics.com/resources/case-studies-white-papers/white-papers/383-white-paperincreasing-the-value-of-information-with-fine-grained-security-for-data-marts.html

Paper Summary: Knowledge intensive industries, such as Pharma, Banking, Insurance, Media and Energy, increasingly rely upon timely access to integrated information for innovation and product development, as well as the marketing of new products and services. Critical decision making processes within these industries are based, at least in part, upon the value proposition that providing more stakeholders with greater information access drives more effective business outcomes.

The associated paradigm shift from “need to know” to “responsibility to share” holds the promise of increasing the value of information that is currently locked in corporate or application-specific silos. However, this integration of enterprise data poses new challenges for information security.

Key takeaways:

- How ABAC can increase agility for handling policy changes, consistency of adjudication decisions and comprehensive auditing of information access
- How the XACML standard works when applied to a SQL database