

# **DIA Document & Records Management SIAC**



**EDM Reference Model**

**22nd Annual DIA Conference for  
Electronic Document Management**

**Dedicated to your information and advancement.**

**DIA Document & Records Management SIAC**

***Shared Metadata and Terminology***

***Jim Averback, Life Science Integration Partners***

## Goals

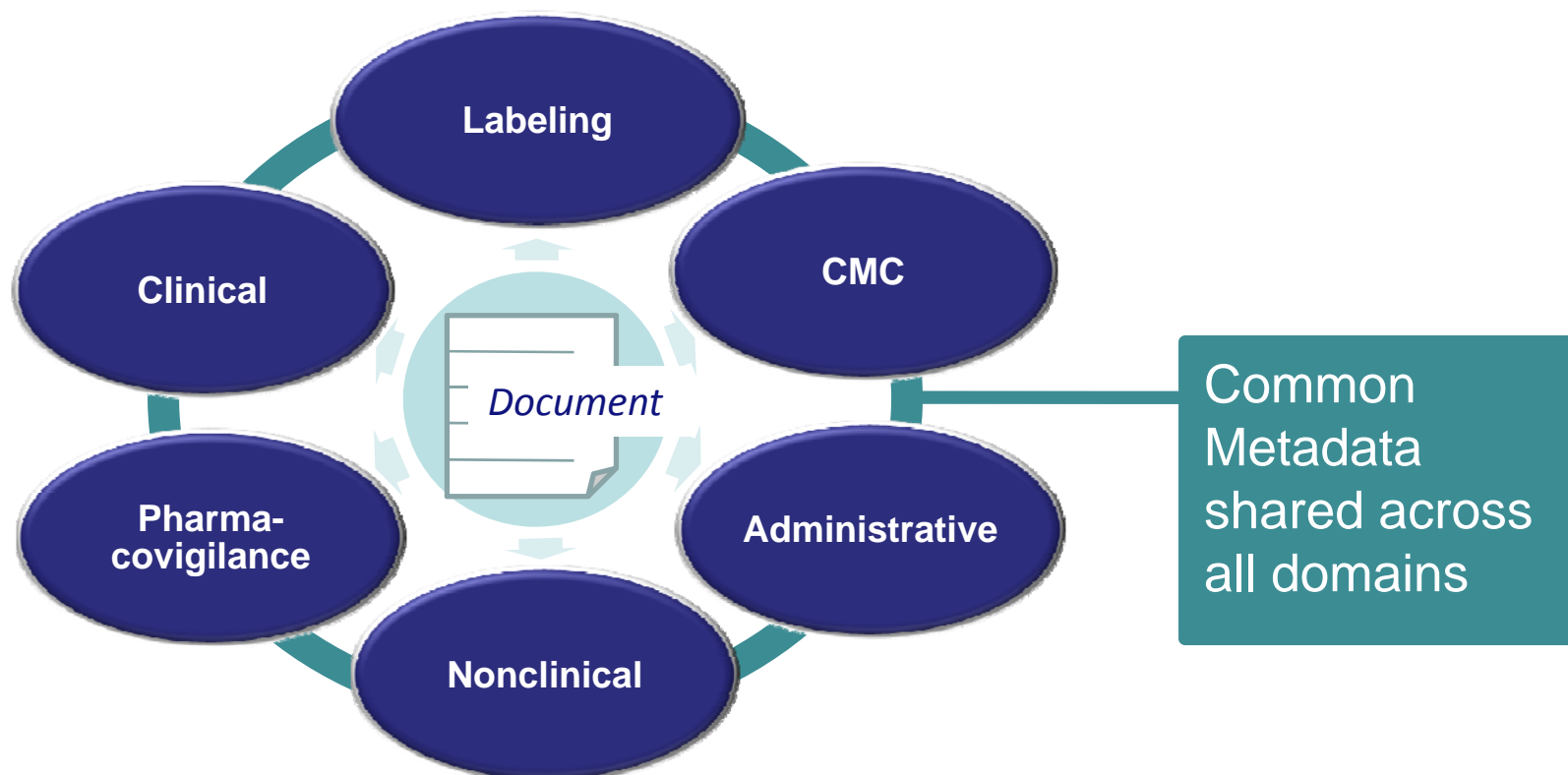
- Flexibility
  - Easy configuration for new products, co-development/co-promotion partners, new service providers (e.g., CRO's, Contract Labs)
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- Content models across the full spectrum of R&D documentation
- Easy interchange of documents for internal and external systems
  - Easy “long lasting” training
  - Consistent User Interface and function across companies

DIA DRM SIAC EDM Reference Model Working Group

# THE DOMAIN-BASED MODEL

## Functional Area Content Domains

*EDM Reference Model organized the content 6 major business domains*



## Common Attributes - Shared Across Documents

- Goals
  - Include ONLY attributes applied to every document
  - Technology neutral, address “business value” of metadata
  - Consider needs of content “Provider” and “Consumer” roles
  - Build on broad-based standards for metadata and terminology

Attribute Category	Sample of Attributes
Product Names	<i>Compound Number, Generic, Trade (Proprietary), Chemical Name, ATC Code</i>
Content Owners	<i>Author, Business Owner, Contributor, Component, Document Title</i>
Document Management	<i>Creation Date, Creator, Language, Modified Date, Status, Version</i>
Records Management	<i>Archive Location, Record Code, Originating Company</i>
Market	<i>Submission Country, Region</i>

## Challenge: Document Granularity Changes Metadata

- **Content Providers**

More granular documents become “topic based”, with each fragment written by a subject matter expert

*Problem:*

*Metadata for topics based content fragments is determined by the subject matter of the fragment, rather than the document*

- **Content Consumers**

*Opportunity:*

*“Topic based” metadata makes it easier to find product information*

*Research Paper*

**Relationship between Insulin Resistance and Serum Levels of Adiponectin and Resistin with Childhood Obesity**  
Chao Chun Zou, Li Liang and Fang Hong

*Objective:* The aim is to study the relationship between insulin resistance and serum adiponectin and resistin in obese children.

**I**NSULIN resistance (IR) with consequent hyperinsulinemia has a central role in the pathogenesis of many diseases including obesity, diabetes mellitus, hypertension and dyslipidemia. Recent investigations have been focused on a family of adipose derived cellular mediators (adipocytokines), including TNF- $\alpha$ , IL-6 and leptin. The importance of these agents is that they are produced by fat cells and are known to play a key role in the complex interorgan communication network, which appears to modulate intermediate metabolism and energy balance(1-3). Recently, another two adipocytokines (adiponectin and resistin) are described as secretory products of adipose tissue. Some animal model and several human studies suggested that resistin were related to obesity and glucose metabolism while some studies in human did not find such relationship(4-7). Some previous studies have investigated the role of adiponectin in obesity(7-9), but rare in insulin resistance. Here, we measured serum adiponectin and resistin levels in obese and nonobese children to study their role in obesity, especially in the mechanism of insulin resistance.

**Subjects and Methods**

A total of 113 obese children from our unit were enrolled in this study from January 1 2005 to November 31 2005. The criteria for obese diagnosis was defined that the body mass index (BMI) was over 95% percentile of the same gender and age. They included 35 girls and 78 boys aged from 6.0 to 16.0 years (mean 11.1  $\pm$  2.3 years). In obese group, 55 cases were prepubertal (Tanner I) and 58 were pubertal (51 of Tanner II and 7 of Tanner III) and the mean BMI was 27.71  $\pm$  3.88 kg/m<sup>2</sup>.

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## Challenge: Metadata for Content “Providers” and “Consumers”

### • Content Providers

- Document Managers
- Medical Writers
- Scientists

#### *Problem:*

*Tight timelines limit opportunity to provide rich metadata*

### • Content Consumers

- Scientists
- Physicians
- Regulatory

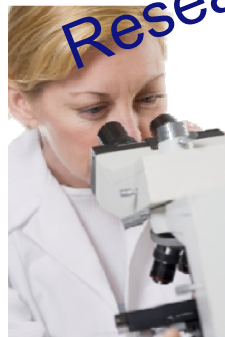
#### *Problem:*

*Thin metadata limits opportunity to find documents*



## Challenge: Metadata Evolves Through Stages of a Product's Lifecycle

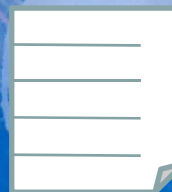
- Portfolio Management
  - As a product's "target profile" matures, document metadata evolves, i.e., indications, dosage form, ...
- Research
  - Align and /or enrich metadata for products acquired to fill the pipeline
- Manufacture
  - Increasing number of Formulations, Specifications, Recipes as a product matures
- Clinical Trials
  - Studies for product combinations
  - Metadata for Phase IV versus Phase I, II and III
- Market
  - Managing the product dossier for Medical Information



Research



Manufacturing



Clinical Trials



Market