

# **MASTER DATA MANAGEMENT: APPLICATIONS FOR CLINICAL TRIAL DATA**

PHUSE 2012 – SD06 – BILL GIBSON – SAS INSTITUTE





### Agenda

- Applying Master Data Management (MDM) techniques to clinical trial data
- Two example applications via DataFlux qMDM
  - Identification of participants and other individuals within and across trials
  - Higher quality and more standardized concomitant medications

# MDM IN LIFE SCIENCES CLINICAL TRIALS

DEFINITION AND KEY CONCEPTS



# MDM FOR CLINICAL DEVELOPMENT

## CONNECTING OPERATIONAL DATA SYSTEMS

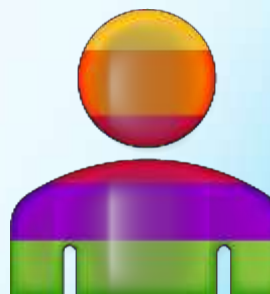


## MANUAL CONNECTION OF PARTICIPANTS TAKES TIME



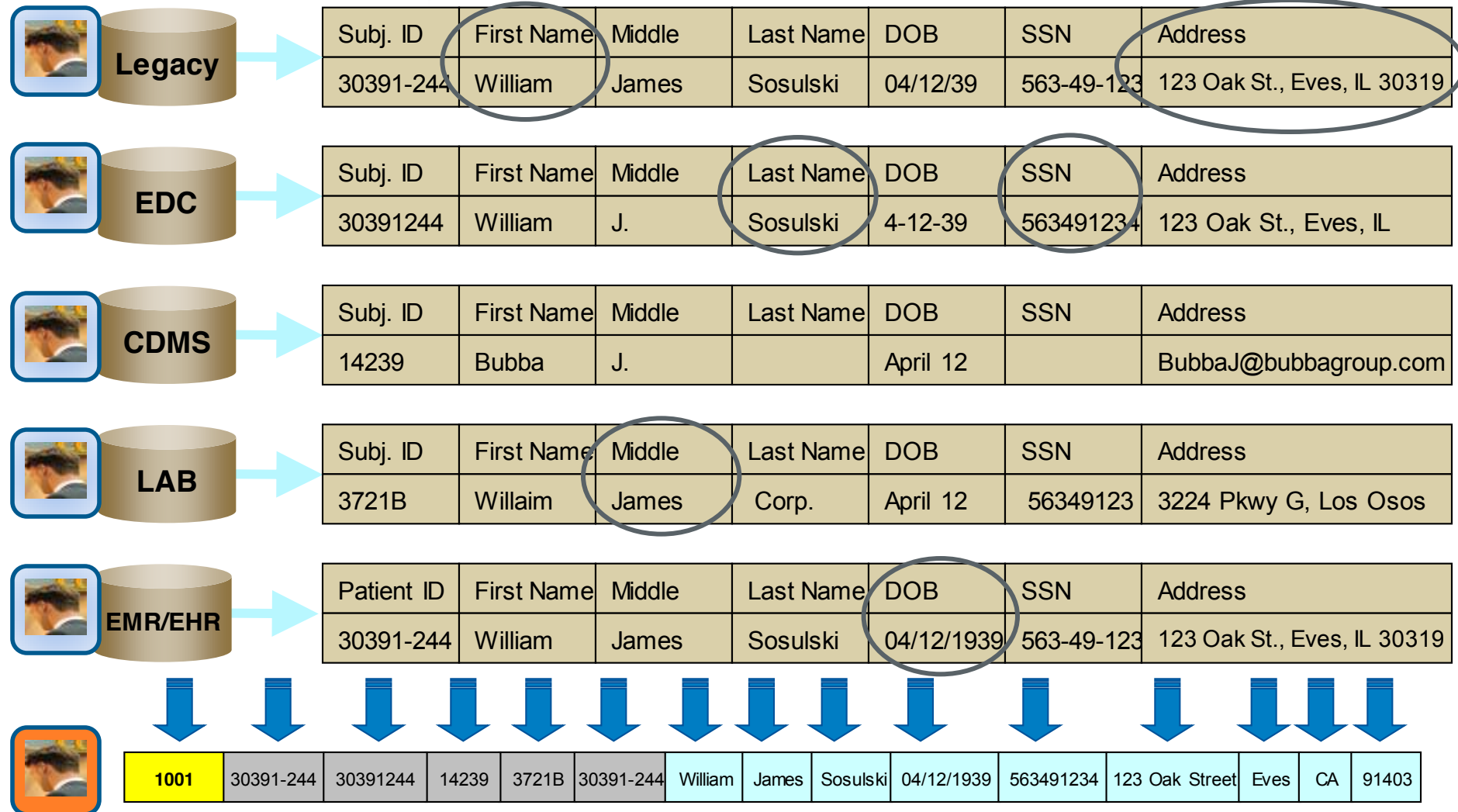
## Participant

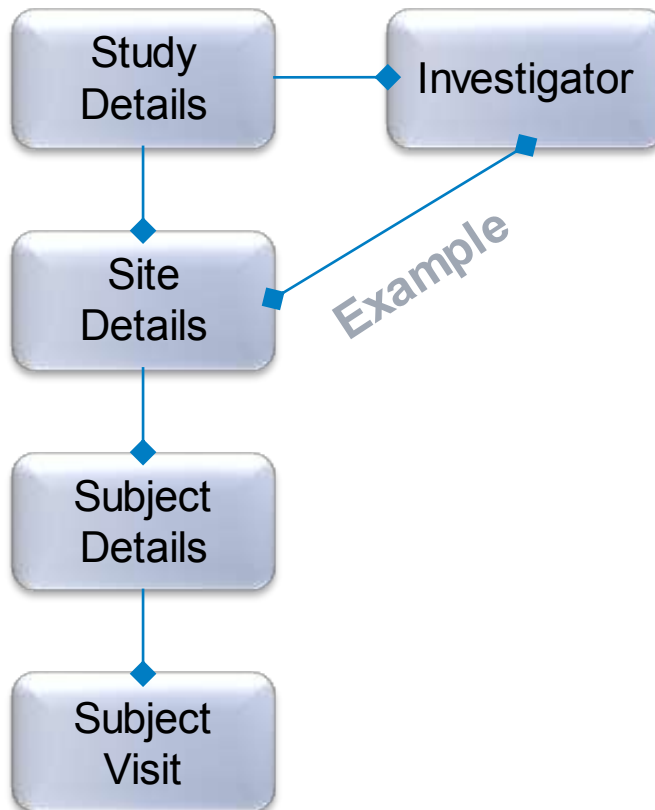
## WHAT IF WE HAVE A MASTER DECODER KEY RING?



# MDM FOR CLINICAL DEVELOPMENT

## THE MASTER RECORD VS. OPERATIONAL DATA SYSTEMS





- Support for binary relationships:
- Relationship modeling
  - Derived relationships based on keys in each entity record or manually authored

## MDM FOR CLINICAL DEVELOPMENT

### MDM IS DIFFERENT THAN DATA WAREHOUSING

|                               | Data Warehouse                                                                                                        | MDM                                                                                                                               |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| <b>Data Content</b>           | Historical content.<br>Multiple, disparate subject areas.<br>Integrated data.                                         | Single subject area.<br>Manages and maintains links to the authoritative source.                                                  |
| <b>Usage</b>                  | Analytics.<br>Reporting and provisioning of historical, multi-subject area content.<br>User-oriented; access via SQL. | Up-to-the-moment identification.<br>Retrieve and synchronize data from other systems.<br>System facing; SOA access.               |
| <b>Integration &amp; Load</b> | Batch loads typical.<br>Transactional if latency is an issue.                                                         | Integrate data upon creation.<br>Can be batch or real-time (online).                                                              |
| <b>Data Transformation</b>    | Standardization unique to each DW.<br>Code developed/maintained for each feed.                                        | Master data elements standardized.<br>Data manipulation is handled by centralized rules engine.<br>Dramatically less maintenance. |
| <b>Data Remediation</b>       | Data quality checking and cleansing recommended.<br>Infrequently occurs.                                              | Data cleansing and validation are core.<br>Data can be cleansed in a manner transparent to the source system.                     |

# IDENTIFYING PARTICIPANTS

TECHNOLOGY AND PROCESS



- FIELD1: Sosulski, William James
- FIELD2: 123 Oak St
- FIELD3: Eves, IL 30319
- FIELD4: 708.452.4252
- FIELD5: BubbaJ@bubbagroup.cm

- NAME: Sosulski, William James
- ADDRESS: 123 Oak St
- ADDRESS: Eves IL 30319
- PHONE: 708.452.4252
- E-MAIL: BubbaJ@bubbagroup.cm

Sosulski, William James, 123 Oak St, Eves, IL 30319, 708.452.4252, BubbaJ@bubbagroup.cm

Name Address City/State Phone E-mail

| NAME      |          | ADDRESS     |       | PHONE     |          | E-MAIL    |            |
|-----------|----------|-------------|-------|-----------|----------|-----------|------------|
| Prefix    |          | Street #    | 123   | Area Code | 708      | Mailbox   | BubbaJ     |
| Given Nm  | William  | Street Nm   | Oak   | Number    | 452.4252 | Subdomain | bubbagroup |
| Middle Nm | James    | Street Type | St    |           |          | Domain    | cm         |
| Family Nm | Sosulski | Adr. Ext #  |       |           |          |           |            |
| Suffix    |          | Adr. Ext    |       |           |          |           |            |
|           |          | City        | Eves  |           |          |           |            |
|           |          | State       | IL    |           |          |           |            |
|           |          | Postal Cd   | 30319 |           |          |           |            |

# MDM FOR CLINICAL DEVELOPMENT

## QKB BUILDING BLOCKS – CLEANSING

Sosulski, William James, 123 Oak St, Eves, IL 30319, 708.452.4252, BubbaJ@bubbagroup.cm

Name

Address

City/State

Phone

E-mail

| NAME      |          | ADDRESS     |        | PHONE     |          | E-MAIL    |            |
|-----------|----------|-------------|--------|-----------|----------|-----------|------------|
| Prefix    | Mr       | Street #    | 123    | Area Code | 708      | Mailbox   | BubbaJ     |
| Given Nm  | William  | Street Nm   | Oak    | Number    | 452.4252 | Subdomain | bubbagroup |
| Middle Nm | James    | Street Type | Street |           |          | Domain    | com        |
| Family Nm | Sosulski | Adr. Ext #  | 11A    |           |          |           |            |
| Suffix    |          | Adr. Ext    |        |           |          |           |            |
|           |          | City        | Eves   |           |          |           |            |
|           |          | State       | IL     |           |          |           |            |
|           |          | Postal Cd   | 30319  |           |          |           |            |

| NAME      |          | ADDRESS     |        | PHONE     |          | E-MAIL    |            |
|-----------|----------|-------------|--------|-----------|----------|-----------|------------|
| Prefix    | Mr       | Street #    | 123    | Area Code | 708      | Mailbox   | BubbaJ     |
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| Suffix    |          | Adr. Ext    |        |           |          |           |            |
|           |          | City        | Eves   |           |          |           |            |
|           |          | State       | IL     |           |          |           |            |
|           |          | Postal Cd   | 30319  |           |          |           |            |

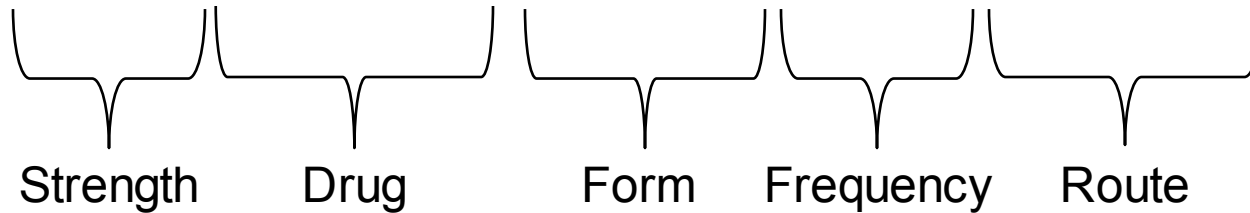
Mr. William James Sosulski  
 123 Oak Street  
 Eves, IL 30319  
 (708) 452-4252  
 BubbaJ@bubbagroup.com

# IDENTIFYING CONCOMITANT MEDS

SIMILAR PROCESS!



600mg ibuprofen capsules 2x/day by mouth



| Token           | Output    |
|-----------------|-----------|
| Drug            | ibuprofen |
| Frequency       | 2 x / day |
| Duration        |           |
| Form            | capsules  |
| Route           | oral      |
| Strength        | 600mg     |
| Additional Info |           |

# PARSING MEDICAL RECORDS

EXAMPLE PROCESS



Patient is 50-year-old male with spasms in left trapezius resulting from injury during ultimate frisbee game. CT scan revealed no additional injury. Treated with 350mg Soma 3x/day for three days followed by Motrin 600mg as needed for pain.

**Event**

**Age** **Gender** **Condition** **Location**

Patient is 50-year-old male with spasms in left trapezius resulting from injury during ultimate frisbee game. CT scan revealed no additional injury. Treated with 350mg Soma 3x/day for three days followed by Motrin 600mg as needed for pain.

**Drug** **Dosage** **Frequency** **Duration** **Procedure**

Patient is 50-year-old male with spasms in left trapezius resulting from injury during ultimate frisbee game. CT scan revealed no additional injury. Treated with 350mg Soma 3x/day for three days followed by Motrin 600mg as needed for pain.

| Identification | Value              | Identification | Value          |
|----------------|--------------------|----------------|----------------|
| Age            | 50 Years           | Gender         | Male           |
| Diagnosis      | Spasms, pain       | Location       | Left trapezius |
| External Cause | Ultimate Frisbee   | Procedure      | CT scan        |
| Treatment      | Soma               | Treatment      | Motrin         |
| Dosage         | 350mg              | Dosage         | 600mg          |
| Frequency      | 3x/day, three days | Frequency      | As needed      |

| Identification | Value              | Identification | Value          |
|----------------|--------------------|----------------|----------------|
| Age            | 50 Years           | Gender         | Male           |
| Diagnosis      | Spasms, pain       | Location       | Left trapezius |
| External Cause | Ultimate Frisbee   | Procedure      | CT scan        |
| Treatment      | Soma               | Treatment      | Motrin         |
| Dosage         | 350mg              | Dosage         | 600mg          |
| Frequency      | 3x/day, three days | Frequency      | As needed      |

Diagnosis (spasms) + Location (left trapezius) = ICD

- Left trapezius is a muscle
- Standardized as Left Trapezius Muscle Spasm
- ICD-9 Code 728.85 - Spasm of Muscle

| Identification | Value              | Identification | Value          |
|----------------|--------------------|----------------|----------------|
| Age            | 50 Years           | Gender         | Male           |
| Diagnosis      | Spasms, pain       | Location       | Left trapezius |
| External Cause | Ultimate Frisbee   | Procedure      | CT scan        |
| Treatment      | Soma               | Treatment      | Motrin         |
| Dosage         | 350mg              | Dosage         | 600mg          |
| Frequency      | 3x/day, three days | Frequency      | As needed      |

Procedure (CT scan) + Location (left trapezius) = CPT

- Left trapezius is a neck muscle
- Standardized as CT scan of Left Trapezius muscle
- CPT Code 7049 – CT soft tissue of neck

| Identification | Value              | Identification | Value          |
|----------------|--------------------|----------------|----------------|
| Age            | 50 Years           | Gender         | Male           |
| Diagnosis      | Spasms, pain       | Location       | Left trapezius |
| External Cause | Ultimate Frisbee   | Procedure      | CT scan        |
| Treatment      | Soma               | Treatment      | Motrin         |
| Dosage         | 350mg              | Dosage         | 600mg          |
| Frequency      | 3x/day, three days | Frequency      | As needed      |

External Cause (Ultimate Frisbee) = ICD

- Ultimate Frisbee is a sport/game
- ICD code E917.5 – Striking against or accidentally struck by objects of persons - In sports with subsequent fall

| Identification | Value              | Identification | Value          |
|----------------|--------------------|----------------|----------------|
| Age            | 50 Years           | Gender         | Male           |
| Diagnosis      | Spasms, pain       | Location       | Left trapezius |
| External Cause | Ultimate Frisbee   | Procedure      | CT scan        |
| Treatment      | Soma               | Treatment      | Motrin         |
| Dosage         | 350mg              | Dosage         | 600mg          |
| Frequency      | 3x/day, three days | Frequency      | As needed      |

Treatment (Soma) + Dosage (350mg) = NDC

- Soma is standardized to Carisoprodol
- Standardized name plus dosage = Carisoprodol 350mg
- NDC 0037-2250

| Identification | Value              | Identification | Value          |
|----------------|--------------------|----------------|----------------|
| Age            | 50 Years           | Gender         | Male           |
| Diagnosis      | Spasms, pain       | Location       | Left trapezius |
| External Cause | Ultimate Frisbee   | Procedure      | CT scan        |
| Treatment      | Soma               | Treatment      | Motrin         |
| Dosage         | 350mg              | Dosage         | 600mg          |
| Frequency      | 3x/day, three days | Frequency      | As needed      |

Treatment (Motrin) + Dosage (600mg) = NDC

- Motrin is standardized to Ibuprofen
- Ibuprofen 600mg
- NDC 0179-0115

# MDM FOR CLINICAL DEVELOPMENT



THE  
POWER  
TO KNOW<sup>®</sup>