


# Acquisition, Use, and Reuse of Study Meta Data



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## Acknowledgements

RU CCTS BERD

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OCRe

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Industry

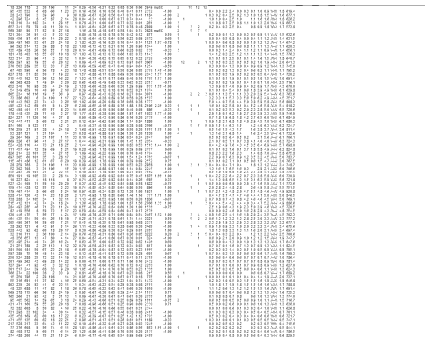
- Claudia Peissert (Scopeland\*)
- James Raddock (Door3\*)

**Conflict of Interest: None**

**\* ARRA**

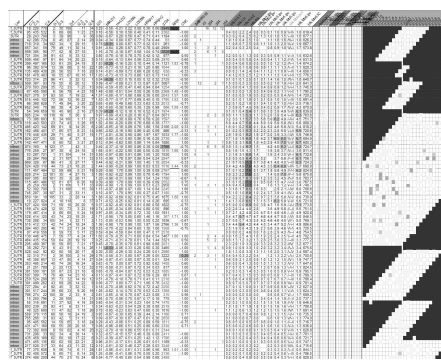
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## Data



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## Data & Metadata



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## Study Metadata

Beefeaters  
Vegetarians  
LowFat:LowCarb  
Leptin:Placebo

- Study Population: Patients (20)
  - Demographics
  - Consent
  - Screening
  - Diets (2)
    - Phases
  - Stabilization
    - Treatment: Hormones (2)
      - Periods (5)
        - Visits
          - Visit 1
            - Biological Response
            - Dx, Lab, Tx
            - Medications
            - Expected Outcome
          - Visit 2
          - Visit 3
          - Visit 4
        - Bicycle: Energy Level (3)
          - Duration (3)
          - Positions (2)

Massloss

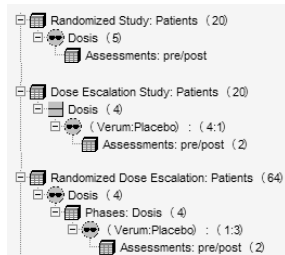
## Study Metadata

Low Fat :  
Low Carb  
Leptin:Placebo

- Study Population: Patients (20)
  - Demographics
  - Consent
  - Screening
  - Diets (2)
    - Phases
  - Stabilization
    - Treatment: Hormones (2)
      - Periods (5)
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          - Visit 4
        - Bicycle: Energy Level (3)
          - Duration (3)
          - Positions (2)

BMI

## Placebo + 4 Doses

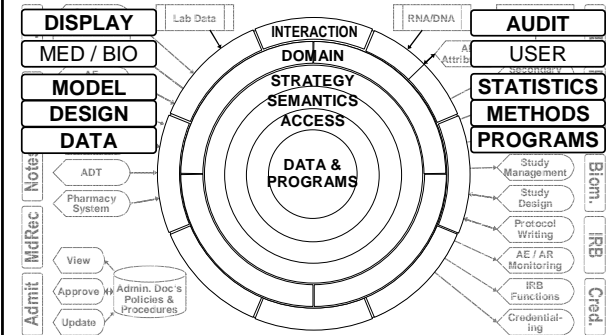


- (Concurrent) Randomized Study (Dose 0:1:2:5:10)
- Dose Escalation Study (Any Dose : Placebo)
- (Delayed Treatment) Randomized Study (Dose 0:1:2:5:10)

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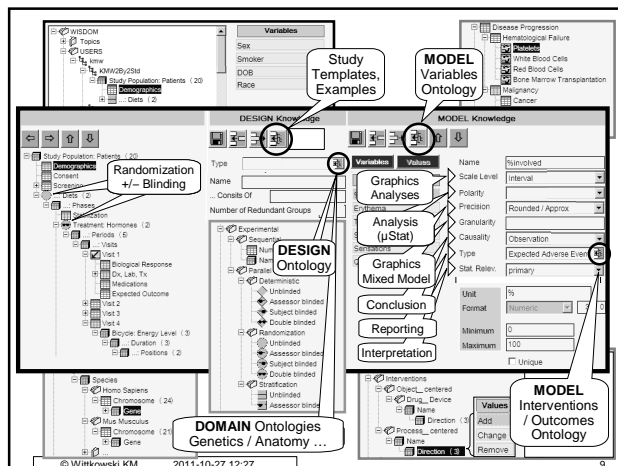
## Layers of Meta-Data



WITTKOWSKI KM (1968) KB support for statistical databases LN Comp Sci 339:62

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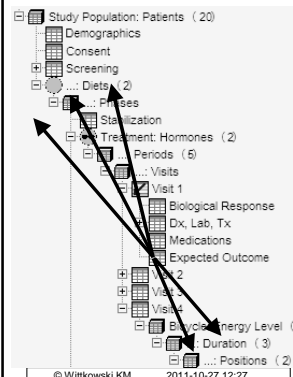
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## Study Search Language



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## Meta Data for Data Sharing

"To ensure that others can use" data, meta-data is needed that documents

- "definitions of variables, details about codes"
- the methodology and procedures used to collect the data,
- variable field locations, [...].

MODEL

DESIGN

DATA

The precise content of only the DOMAIN documentation will vary by the

- scientific area,

DOMAIN

- type of data collected,

MODEL

- study design, and

DESIGN

- characteristics of the dataset."

DATA

[http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)

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## Summary

- Knowledge acquisition is the bottleneck preventing data from being shared effectively.
- Entering metadata into WISDOM provides additional benefit to the investigator: automatic generation of study data base (mySQL,...), case report forms (REDCap), registration (clinicaltrials.gov), AE reporting (DSMB), statistical analysis, ...
- The layered meta data structure enables novel techniques for selection of data.

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