

Did you know that...

- 'anniversary' means different things to different people?
 - For most people it means the recurrence of a date marking a notable institution was founded, e.g. a wedding-anniversary
 - In some countries it is linked to remembering an important national event
 - In some languages it means the equivalent of a birthday

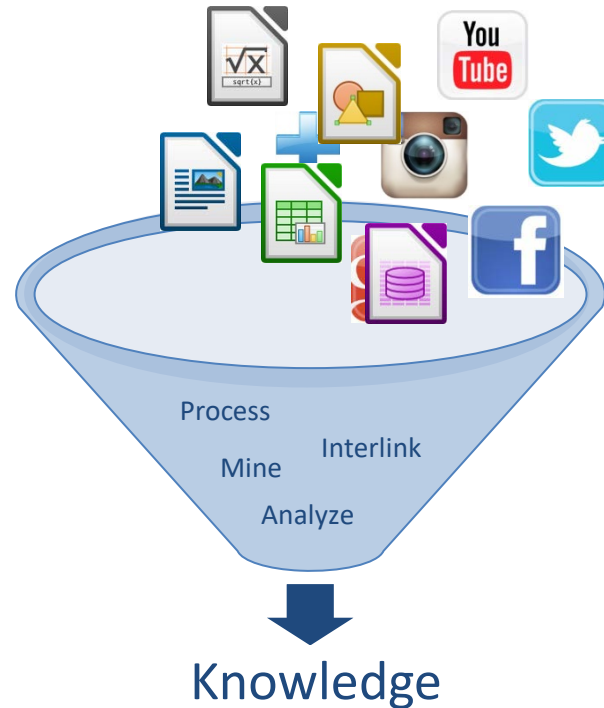


Have you ever...

- Tried to explain to somebody what you are currently working on?
- Organizations face the same issue when they are looking to combine:

data collected for
regulatory
requirements

with Real-world Data

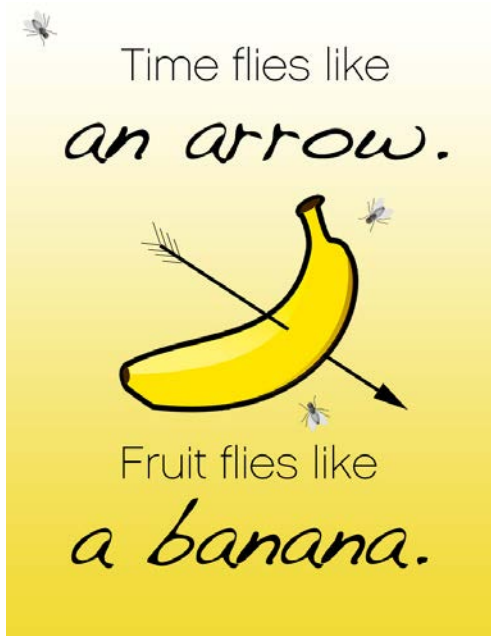


It's like....

- speaking a foreign language

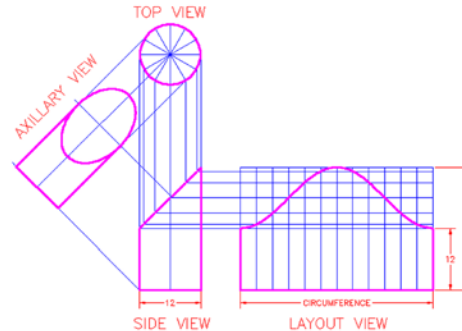
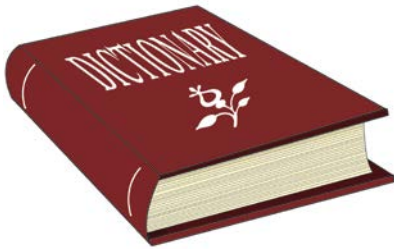


- Let's at the following sentences:

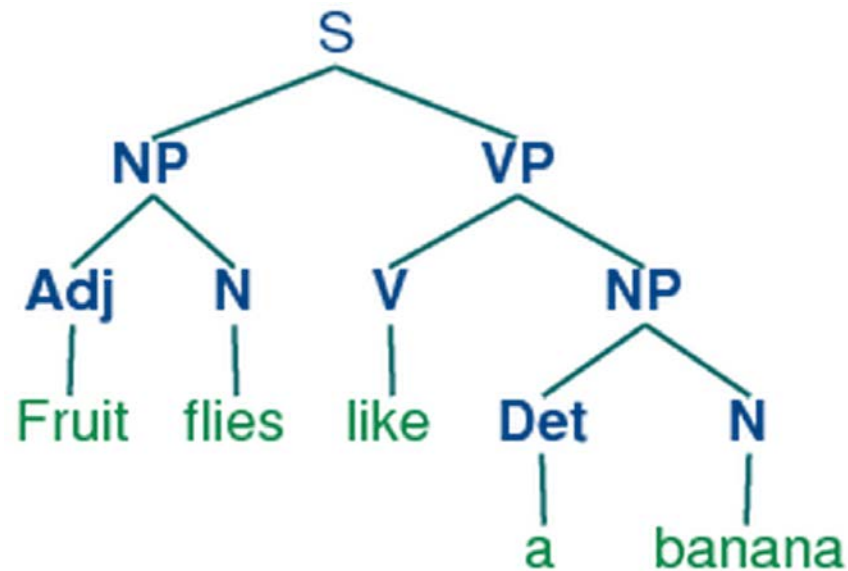
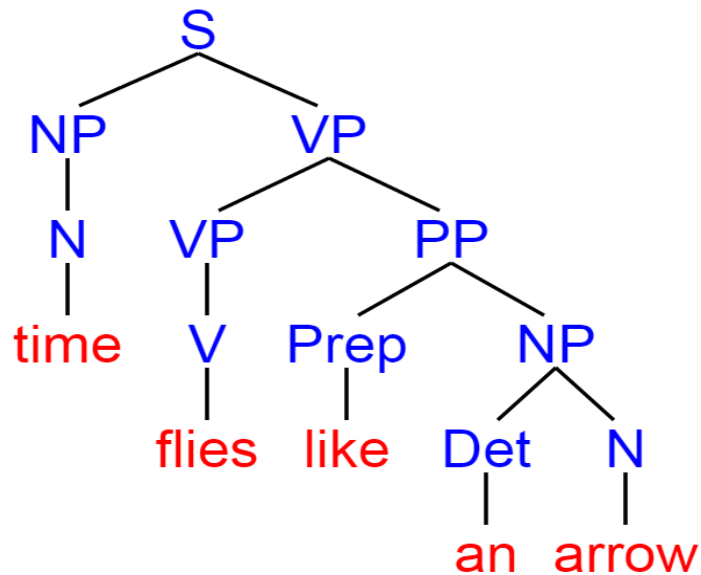


Semantics

- Semantics is defined as ‘the study of meaning’, independent from structure
- First introduced by a linguist
- Semantic theory consists of two parts:
 - (1) a dictionary, and
 - (2) a ‘distinctive set’ of ‘projection rules’



Back to the sentences...



ISO/IEC 11179

- Semantics principle implementation:

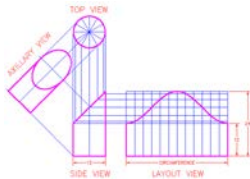
- Dictionary



- Thesaurus type combination of a wide 'concept' with an 'object class' to form a more specific 'data element concept'

e.g. 'hair color' + 'person' ➡ 'hair color of person'

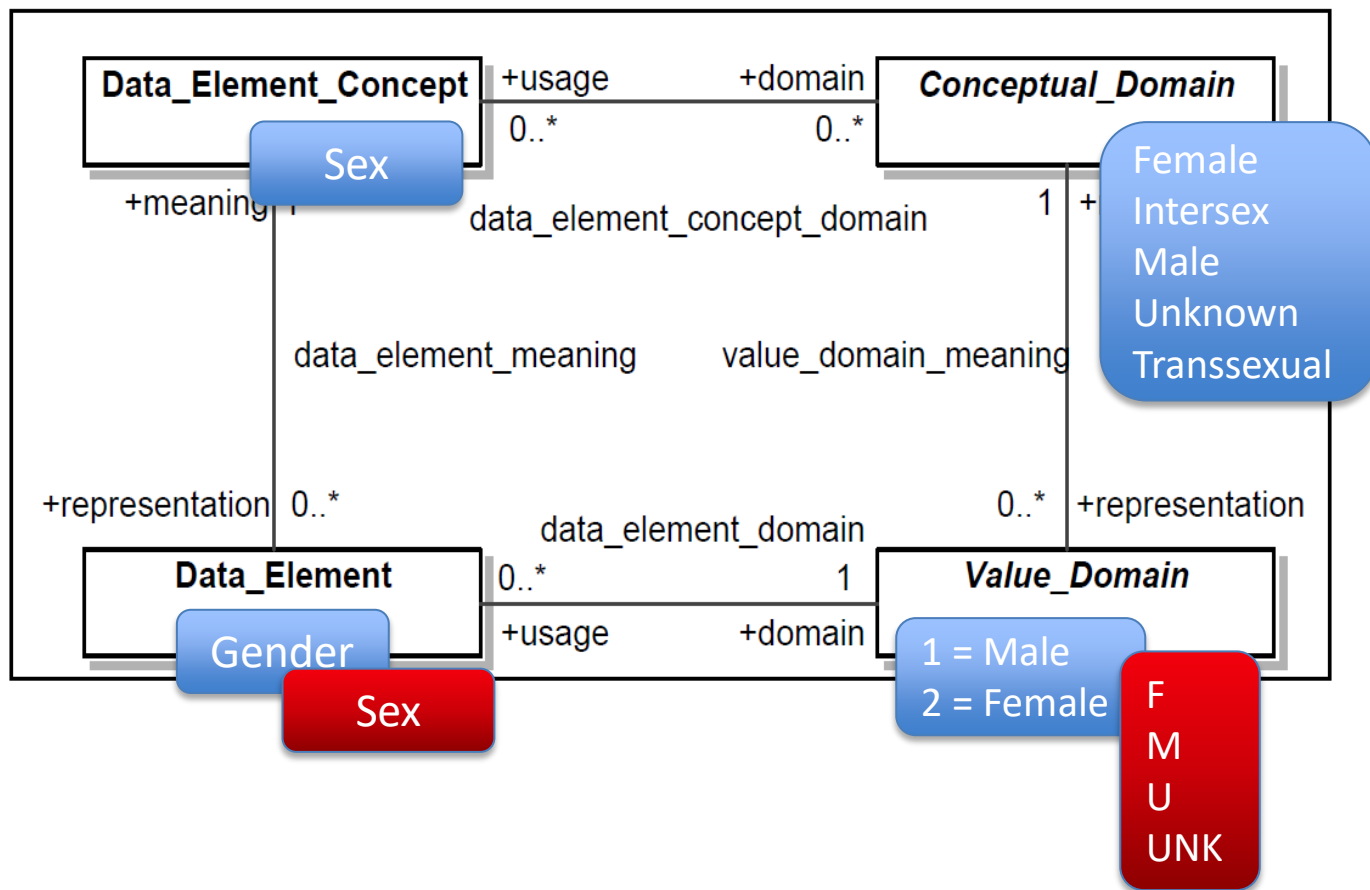
- Projection rules



- Relationship between a concept and its representation

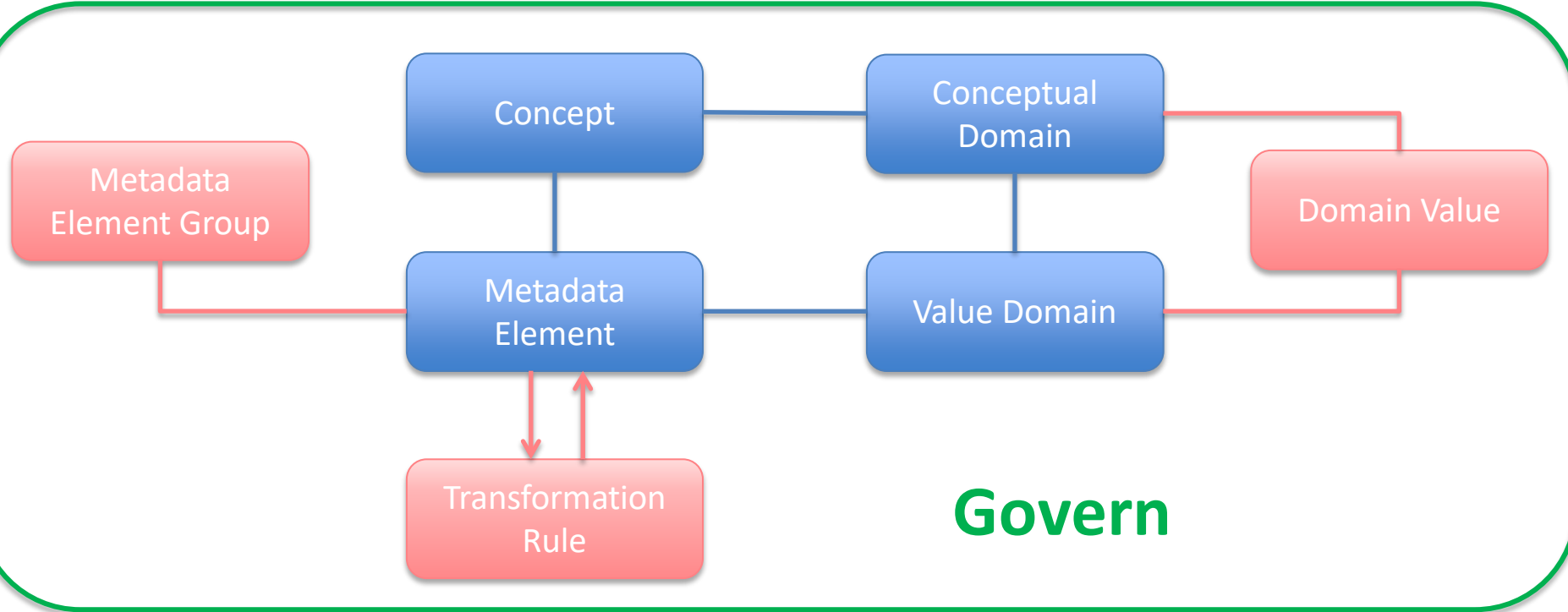
e.g. 'sex of person' is represented as gender in one system and sex in another system

ISO/IEC Metamodel



Implementation

- Use ISO/IEC 11179 metamodel to register/manage metadata
 - Granularity facilitating maximum reuse of existing data elements
 - Binding to industry definitions and terminologies



How does that help BioPharma?

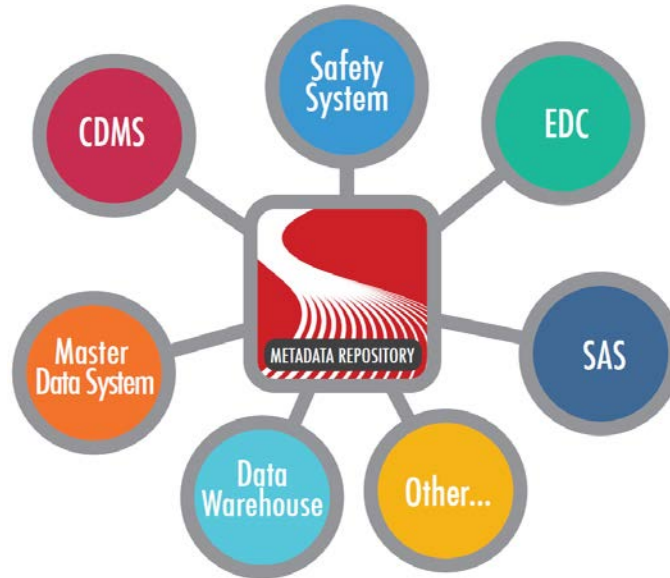


Linking elements from clinical research and real-world data to the same definition (= concept) enables:

- faster oversight
- easier analysis
- more innovation
- better patient care

Benefits

- Managing metadata based on the ISO/IEC 11179 metamodel enables to:
 - Create, maintain, govern and use standards in a consistent manner
 - Get maximum reuse out of existing data assets
 - Implement standards to improve processes
 - Know the impact of changes on other people, processes, or systems
 - Minimize human intervention and interpretation when exchanging data



Conclusion

- The ISO/IEC 11179 Data Description model offers a platform for managing the definitions including their associated implementations across systems and organizations
- Managing metadata in an ISO 11179-based repository will support knowledge development by:
 - Creating, maintaining, governing and using data definitions consistently and associating them with specific implementations,
 - Maximizing reuse of existing artifacts and data assets, and
 - Knowing data retrieved from/exchanged with other systems (like social media) is being used or interpreted correctly.

