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Aligning RxNorm with the SNOMED CT drug model and IDMP

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International drug standards

- Identification of medicinal products (IDMP)
  - Set of ISO standards for
    - substances (ISO 11238)
    - pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO 11239)
    - units of measurement (ISO 11240)
    - regulated pharmaceutical product information (ISO 11616)
    - regulated medicinal product information (ISO 11615)
  - Used by the European Medicines Agency (EMA)

SNOMED CT aims to be compliant with IDMP

International drug standards

- ISO/TS 19256:2016
  - Health informatics - Requirements for medicinal product dictionary systems for health care
  - “provides information to MPD-system developers, to help them design MPD-systems which are better able to meet the ISO IDMP standards and the needs of multiple use cases”
- EDQM Standard Terms
  - European Directorate for the Quality of Medicines
  - Standard terms for
    - Pharmaceutical dose form
    - Route or method of administration
    - Packaging items (Container, Closure, Administration device)

SNOMED CT drug model

Previous model

- Substance/product duality
- Most products are primitive concepts
- Limited set of attributes
  - Has_active_ingredient
  - Has_dose_form
  - No explicit BoSS information
  - No explicit strength information

Current model

- Substance/product duality
- All products are fully defined concepts
- Extensive set of attributes
  - Has_active_ingredient
  - Has_manufactured_dose_form
  - Has_BoSS
  - Has_presentation_strength_*
    - Numerator (value, unit)
    - Denominator (value, unit)

RxNorm vs. SNOMED CT

RxNorm

- Substance/product implicit duality
- Not based on description logics
- Attributes
  - Has_ingredient
  - Has_dose_form
  - No explicit BoSS information
  - Strength (attribute)
    - Normalized (not presentation*)
    - Combines value and unit, numerator and denominator
- Generic + branded drugs

SNOMED CT

- Substance/product explicit duality
- All products are fully defined concepts
- Extensive set of attributes
  - Has_active_ingredient
  - Has_manufactured_dose_form
  - Has_BoSS
  - Has_presentation_strength
    - Numerator (value, unit)
    - Denominator (value, unit)
- Generic drugs only

RxNorm vs. SNOMED CT

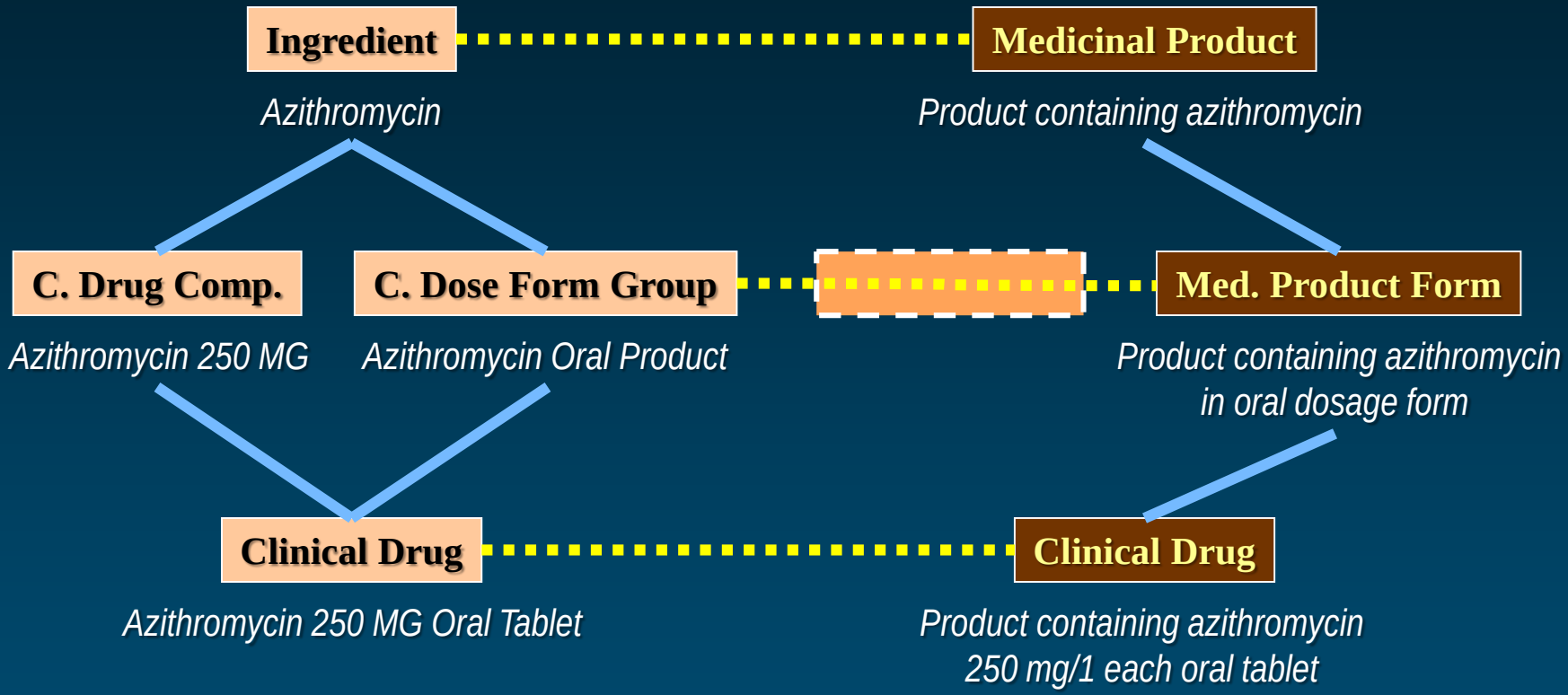
RxNorm

- Clinical drug (SCD)
  Atorvastatin 10 mg oral tablet
- Ingredient (IN) and Precise ingredient (PIN)
  Atorvastatin; Ergotamine tartrate
- Multi-ingredient (MIN)
  amLODIPine / atorvastatin
- Clinical dose form group (SCDG)
  Atorvastatin Oral Product

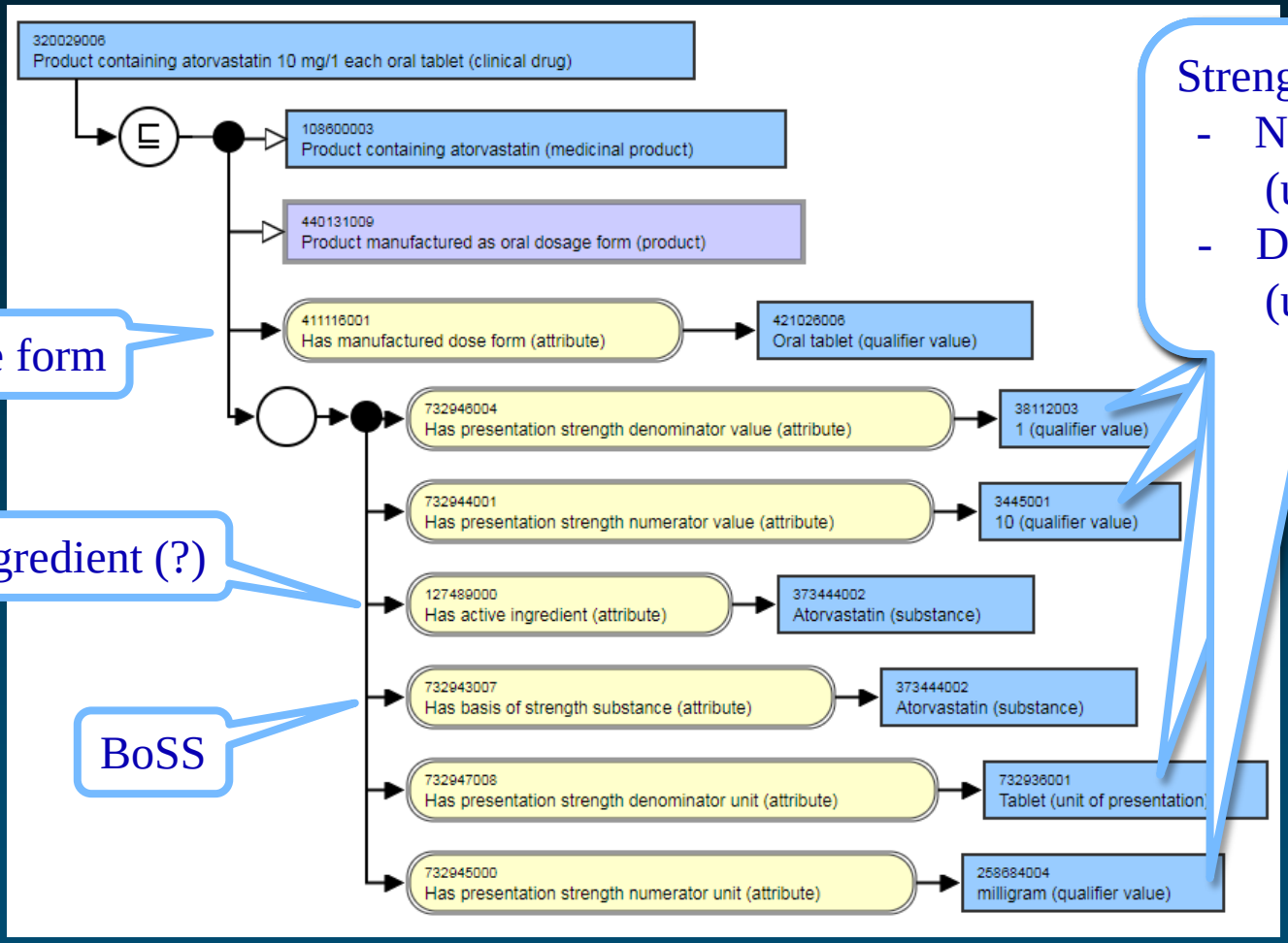
SNOMED CT

- Clinical drug
  Product containing atorvastatin 10 mg/1 each oral tablet
- [Single] Medicinal product (or Substance)
  Product containing atorvastatin
  Product containing ergotamine tartrate
- [Multi] Medicinal product
  Product containing amlodipine and atorvastatin
- Medicinal product form
  Product containing atorvastatin in oral dosage form

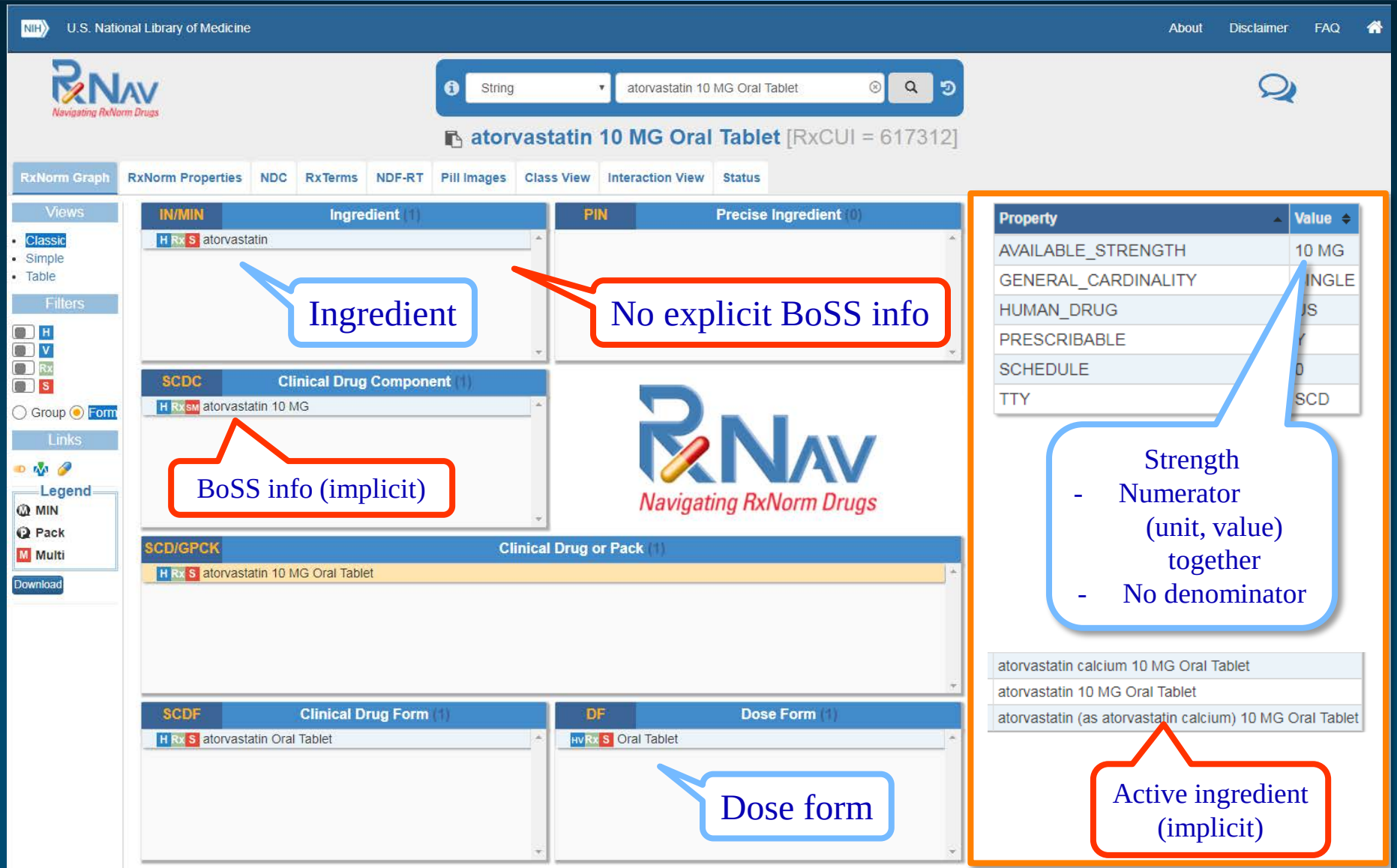
RxNorm vs. SNOMED CT



Atorvastatin 10 mg oral tablet



Atorvastatin 10 mg oral tablet



Atorvastatin 10 mg oral tablet

INGREDIENTS AND APPEARANCE

ATORVASTATIN CALCIUM
atorvastatin calcium tablet, film coated

Dose form

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42291-143(NDC:62175-890)
Route of Administration	ORAL		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
Atorvastatin Calcium (UNII: 48A5M73Z4Q) (Atorvastatin - UNII:A0JWA85V8F)	Atorvastatin	10 mg

Active ingredient

Active moiety

BoSS

Atorvastatin 10 mg oral tablet

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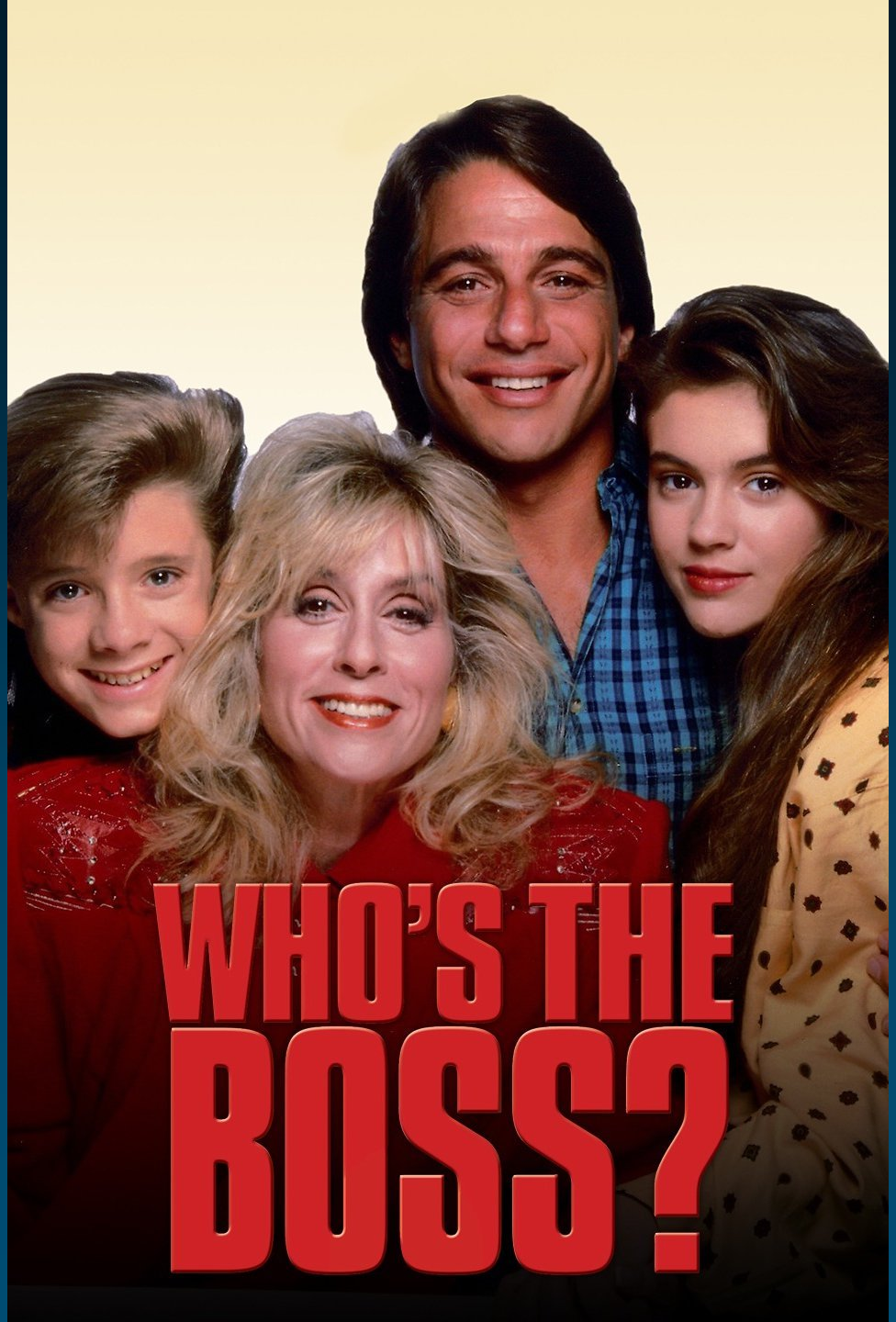
Dose form

Strength, split into
- Numerator (unit, value)
- Denominator (unit, value)

BoSS=Active moiety

Active ingredient

Active moiety


WHO'S THE
BOSS?

Extracting BoSS and presentation strength information

- From SPLs whenever available (XML) [~2/3]
  - <manufacturedProduct> tag
    - <quantity> → presentation strength (numerator + denominator; value + unit)
    - <ingredientSubstance> → active ingredient
    - <activeMoiety> → active moiety
    - classCode attribute (<ingredient>) → BoSS
      - ACTIB → BoSS = active ingredient
      - ACTIM → BoSS = active moiety
      - ACTIR → BoSS = other (specified) reference substance
- From similar SPLs or other reference information sources otherwise [~1/3]

BoSS inconsistencies in SPLs

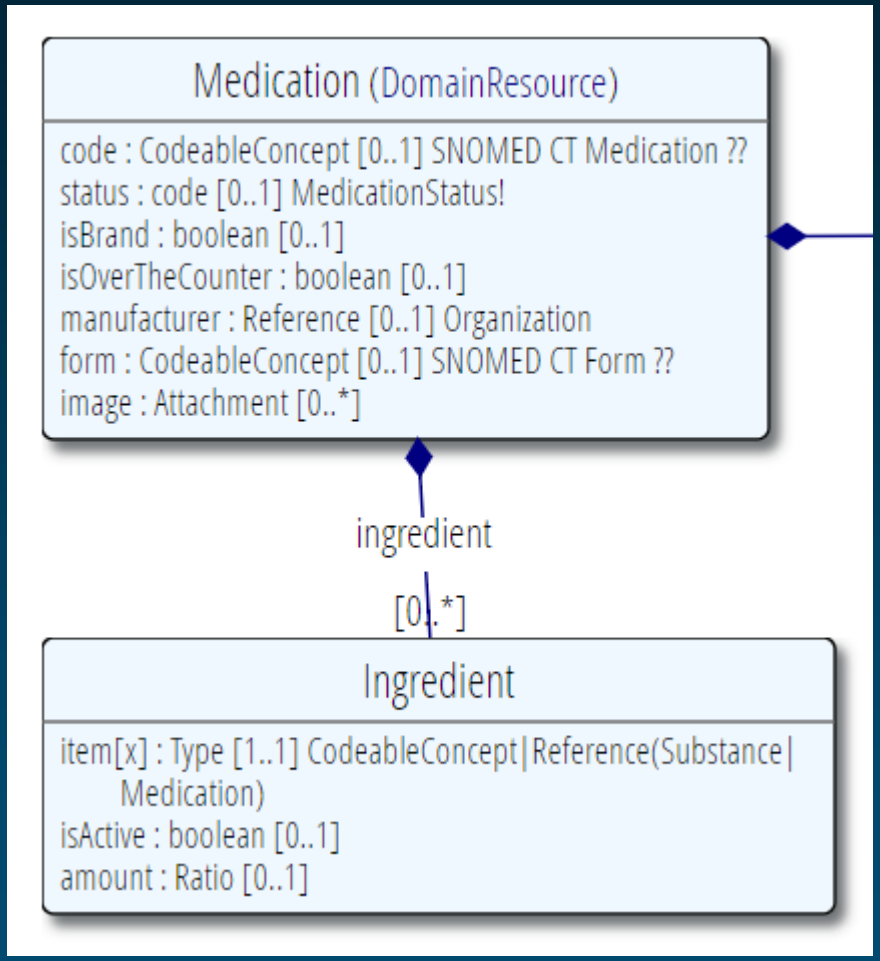
- A given RxCUI (SCD) is linked to multiple NDCs
- These NDCs are associated with multiple SPLs
- BoSS or presentation strength information is sometimes inconsistent across labels
  - Different, but functionally equivalent
    - Units are different, but values reflect equivalent strengths
    - ACTIB vs. ACTIM when AI = AM
    - ACTIR points to a reference that is the AI or AM (as opposed to another reference substance)
  - Different and not equivalent
    - Require manual review
    - Not all SPLs are high-quality

Summary

- Some information had never been recorded explicitly in RxNorm
  - BoSS (+ active ingredient and active moiety)
  - Presentation strength [except through PSNs]
- Extracted from Structured Product Labels whenever possible
- Future work
  - Harmonization of dose forms with EDQM's
- This information will be made available in RxNorm after completion of the project

Summary

- Opportunity for alignment with
  - New SNOMED CT drug model
  - International standards for medicinal products
- Contribution to SNOMED CT
  - RxNorm drug content will be converted to and loaded in SNOMED CT
- Opportunity for quality assurance
  - Comparison with DM+D (UK) and AMT (Australia) once also converted to and loaded in SNOMED CT
- Will also facilitate the publication of RxNorm as a set of FHIR medication resources

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Acknowledgments

- RxNav team (development)
  - Lee Peters
  - Richard Rice
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  - Tammy Powell
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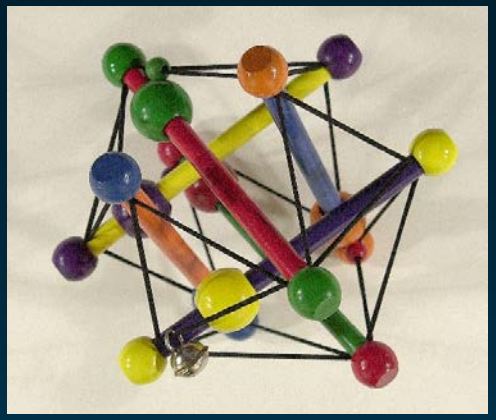
  - RxNorm editors



Medical Ontology Research

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