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# Developing a Computable Highlights Section

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# Not for All Products

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- Highlights section exists only in “PLR format” labels
- PLR format applies to
  - New products or efficacy supplements:  
beginning June 30 2006
  - Older products: Approved or efficacy  
supplement June 30, 2001, or later  
(7-year transition period)

# Most Important Use Cases

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- Clinical Decision Support
  - Comparison of coded label information with coded data in electronic health records
  - Triggers alerts and points to label text if label has to say something about the individual patient
- Data Base

Over time, the library of PLR labels will form an enormous product data base enabling, e.g., automated searches for potential interactions

# More than SNOMED CT Coding

Developing a computable Highlights section is more than coding terms in SNOMED CT.

- Coding terminologies include:
  - SNOMED CT subset\*
  - Lab LOINC
  - VA NDFRT
- Structuring:
  - Capturing relationships between coded concepts (preconditions etc.)
  - Simplified computable grammar

\*Companies can propose addition of SNOMED CT term to subset

# Current Limitations

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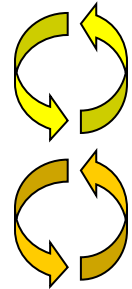
- Restricted to what is stated in the Highlights section (few exceptions)
- Does not (yet) cover complete Highlights content (e.g. no dosage recommendations, except max dose)
- Coding depth (still) very limited - data model permits more than what is currently enabled by the Implementation Guide

# What We Can Talk About ...

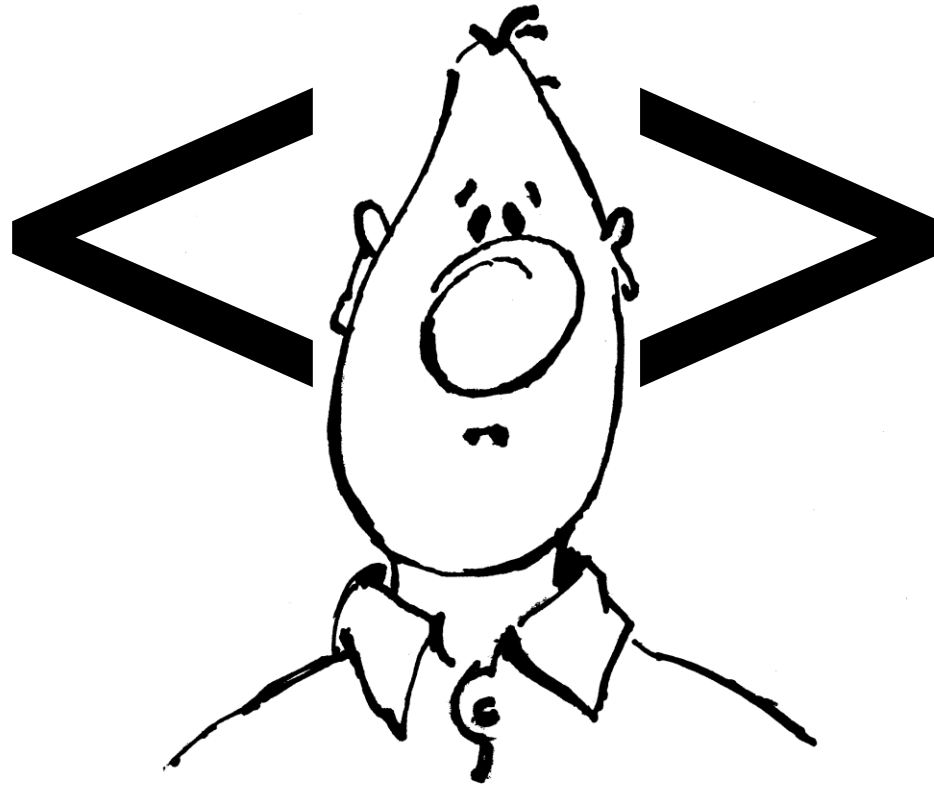
- Indication key concept
  - Intent of use
  - Maximum dose
  - Interaction
  - Adverse reaction
- CoU: Medical condition
  - CoU: Age, Gender, Race
  - CoU: Use as adjunct
  - CoU: Test (screening or monitoring)
  - LoU: Dose modification
  - LoU: Duration of use
  - LoU: Conditional approval
  - LoU: Contraindication
  - LoU: Limited or no information
  - LoU: Second line treatment
  - LoU: Use with caution

# Process

1. Text analysis [and improvement]  
(essence, ambiguities)
2. Syntactic and semantic transformation
3. Verification of codability
4. Element assembly to reflect relationships
5. Coding
6. XML Tagging
7. QC



Puzzled?



# Example

1. Text analysis [and improvement]  
(essence, ambiguities)
2. Syntactic and semantic transformation

## 3. Breast Cancer (1.2)

- After failure of combination chemotherapy for metastatic disease or after relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. PRODUCT has not been shown to be beneficial in patients with estrogen and progesterone-receptor-positive tumors.

*From FDA's fictitious IMDICON example label*

## 6. 1<sup>st</sup> Indication: Key concept = Breast cancer

- Intent of use: Treatment
- Only if: Tumor NOT estrogen receptor positive
- Only if: Tumor NOT progesterone receptor positive
- Only if: Patient has breast cancer metastases
- Only as: Second line after combination chemotherapy, which should have included anthracycline unless clinically contraindicated

## 7. 2<sup>nd</sup> Indication: Key concept = Breast cancer

- Intent of use: Treatment

Ex

Simplified  
Not in authentic "SPL jargon"

1. Text analysis [and improvement] (essence, ambiguities)
2. Syntactic and semantic transformation

3. **Breast Cancer (1.2)**

- After failure of combination chemotherapy for metastatic disease or after relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. PRODUCT has not been shown to be beneficial in patients with estrogen and progesterone-receptor-positive tumors.

From FD

sample label

6. **1<sup>st</sup> Indication: Key concept = Breast cancer**

- **Intent of use:** Treatment
- **Only if:** Tumor NOT estrogen receptor positive
- **Only if:** Tumor NOT progesterone receptor positive
- **Only if:** Patient has breast cancer metastases
- **Only as:** Second line after combination chemotherapy, which should have included anthracycline unless clinically contraindicated

7. **2<sup>nd</sup> Indication: Key concept = Breast cancer**

- **Intent of use:** Treatment

Interpretation correct?

How to capture this?

# Example

1. Text analysis [and improvement]  
(essence, ambiguities)
2. Syntactic and semantic transformation

## 3. Breast Cancer (1)

- After fail

## 4. Eled

## 5. C

## 6. B

## 7. -

Remember:

This is to enable patient record searches.

In case of a “match”, the prescriber’s brain is “activated” to make decisions based on the full label text.

The computer does not prescribe.

2<sup>nd</sup> Indication: Key concept

- Intent of use: Treatment

months of

estosterone-

tetracycline

# MedDRA and Highlights Coding

- Highlights section wording may contain MedDRA terms (most likely under Adverse Reactions and Warnings and Precautions)
- If these PTs need to be coded, they will be coded in “Subset SNOMED CT” or “Lab LOINC”
- No reason to change MedDRA terms in Highlights to SNOMED terms
- The computable metadata set will contain the SNOMED and LOINC codes and – to permit easy QC - SNOMED and LOINC “display names”
- A MedDRA→SNOMED mapping table that covers >95% of the ADR terms found in labeling would be helpful to achieve consistent SNOMED coding

# Human Readable Rendition

Header & Root E

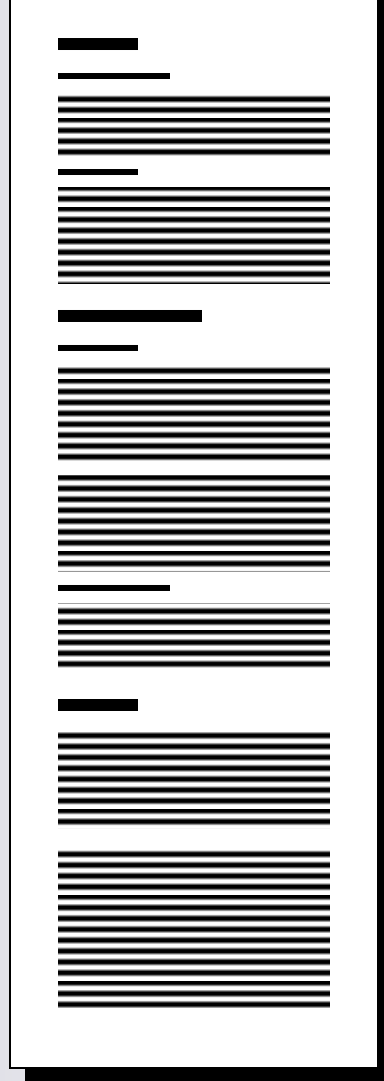
SPL Data Elements Section

Highlights Text Element

Computer Processable Clinical Content



Highlights

A section titled 'Highlights' enclosed in a blue bracket. It contains two columns of horizontal lines representing text, with orange bars above each line to indicate highlighting.

oversimplified

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# **Question & Answer Period:**

## **Open Forum - Attendee Topics of Interest**