Comments to the NIH Office of Dietary Supplements, May 20, 2005

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My name is Susan Moyers. I am a member of the Research Faculty at the University of South Florida, College of Medicine. First of all, I would like to express thanks to the organizers at the Office of Dietary Supplements for sponsoring today's session, and for permitting comments on a topic that may be somewhat different compared to other topics heard today.

Our organization, the Pediatrics Epidemiology Center, led by Dr. Jeffrey Krischer, functions primarily as a large data collection, management, analysis, and informatics center for a number ofNIH-funded prospective cohort and intervention studies. These studies involve conditions such as Type 1 diabetes, childhood cancers, and diseases under the jurisdiction of the NIH Rare Disease Network. It is in connection with our work among clinical trial participants that we are appearing today, with a recommendation that we hope will broaden the scope of services of the ODS, foster collaboration, and enhance opportunities to include dietary supplements in interdisciplinary research.

Weare proposing the creation of a common dietary supplement database that will allow researchers in NIH-sponsored trials to capture and code ingredient information using a central data source that is current, publicly-supported, and free of charge. This project will greatly improve data collection techniques and epidemiological methodologies in many clinical trials.

At the Pediatrics Epidemiology Center, we collect large amounts of data from food frequency questionnaires, dietary supplement questionnaires, food diaries, and other data collection instruments, that are largely based on self-reported intakes.

And, I am sure no one in this meeting will find it surprising to hear that increasingly, our study participants report the use of dietary supplements. **In** fact, some of our families report the use of off-the-shelf dietary supplements in infants as young as two and three months of age.

A large percentage of study participants, however, seem to be unable to identify their supplements beyond the brand name, or general product description. We ask them to bring to the clinic the supplement labels and bottles; but typically they do not. Research staff must often spend hours tracking down the ingredients of these loosely-identified dietary supplements, and then try to make a determination about how to code them in our data structures.

The accurate representation of dietary supplement intake in a clinical trial is vitally important, even if the clinical trial is not investigating the use of supplements *per se.* As is increasingly clear, dietary supplements are emerging as important variables in our analyses of the determinants and outcomes of many diseases.

At present, as you know, ODS has made important advances to create a supplementnutrient database in conjunction with datasets created by the National Center for Health Statistics (NCHS), and plans to merge these datasets with existing food composition databases. But thus far, planned efforts do not meet the data collection needs of our large clinical trials. One reason is that NCHS data are limited to those dietary supplements actually reported by study participants in CSFII-NHANES, and represent only a subset of products on the market.

There is a pressing need is for a database system that can facilitate the rapid capture, coding, and categorization of the products according to brand name and ingredients, with perhaps the added capability to include a grading system for authentication of product constituents and dose.

A dietary supplement database for use in clinical trials can be modeled after currently databases in existence to code medications. Each product is given a unique code that is never duplicated, even if the product is discontinued. Notice that this particular model (used by the National Library of Medicine for prescription and OTC medications) captures relationships between brand name, ingredient, ingredient strength, and product form, and enables a user to query from the specific to the generic and vice versa.
Accordingly, the dietary supplement database model needs to allow data entry and look up by varying levels of detail: (e.g., brand, ingredient, dosage, form, packaging). The ideal data model should have defined relationships between these constructs.

Whatever model is adopted for ODS, it is important to ensure that a central data source is made available, developed using good information management practices, that is accessible to researchers to share throughout the United States. Further detail, including data and resource requirements, are being submitted as addenda to this presentation.

We believe that a centrally accessible, free-of-charge, up to date data system for capturing product and brand information will enable research communities to better incorporate dietary supplement questions, will enable data sharing across all clinical trials, and will facilitate understanding of the role of dietary supplements in the determination of disease and health outcomes.

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Dietary Supplement Database for Use in NIH-Sponsored Clinical Trials

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Background:
USF Pediatric Epidemiology Center

- **Collection, management, analysis of large datasets**
  - **Self-reported data**
  - **Laboratory & clinically-measured data**
- **↑ DS use among trial subjects**
  - **"Sketchy" product identification**
  - **Costly, resource-intensive product searches**

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Dietary Supplement Database for Use in Clinical Trials

- **Central data source**
  - **Current**
  - **Publicly-supported**
  - **Free of charge**
- **Capture and code**
  - **Product brands**
  - **Ingredients**
  - **Product forms**
  - **Relationships & categories**
  - **Gradings *(when available)***
    - **Authentication of constituents**
    - **Doses**

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Importance & Relevance

- **Supplements may be associated with**
  - **Risk of disease**
  - **Treatment outcomes**
- **Even if a particular trial is not investigating supplement use *per se***

Current DS Data Sources

- **NCHS Datasets**
  - **Products reported by NHANES-CSFII respondents**
  - **~25% of products on market**
  - **Some supplement products obsolete**
- **Third party databases**
  - **Costly for subscribers**
  - **Unpredictable record and version control**

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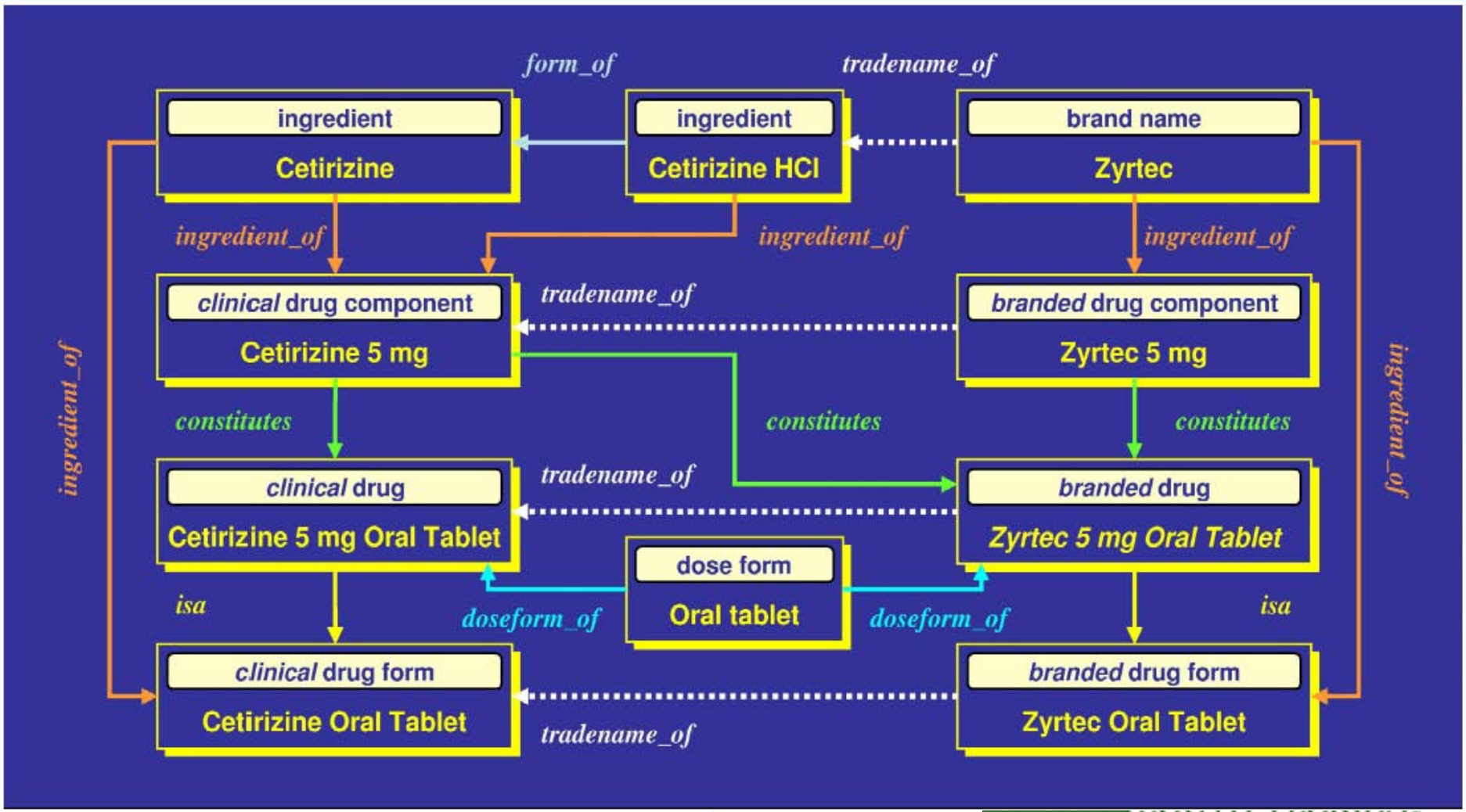
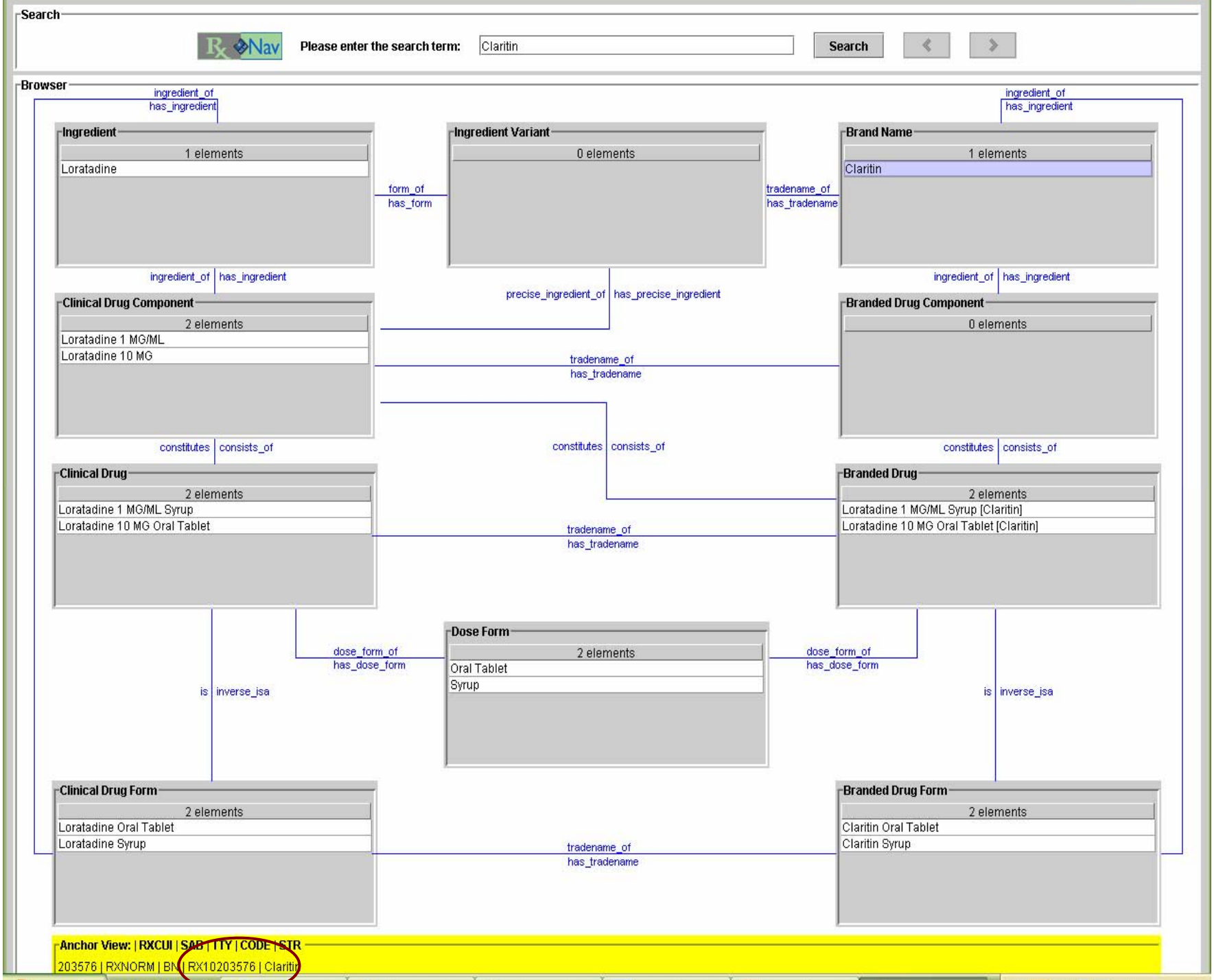
NLM Data Modeling

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Please enter the search term:
Claritin
Search
Browser
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Loratadine
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constitutes
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Loratadine 10 MG Oral Tablet
Branded Drug
2 elements
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Loratadine 10 MG Oral Tablet [Claritin]
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Loratadine Syrup
Branded Drug Form
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Summary of Benefits

- Improve data collection in clinical trials
  - techniques
  - epidemiological methodologies
- ↑ quality, quantity, and efficiency of data collection for DS
- Encourage researchers to extend DS parameters in “other” clinical trials
- ↑ accuracy, ↑ breadth in measuring health outcomes associated with DS usage
- ↑ data sharing among clinical trials

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