Meeting Outline (~40 min)

- Weida Tong (DBB/NCTR) (Introduction, 2 min)
- Hong Fang (OSC/NCTR) (Overview of FDALabel, 15 min)
- Reagan Kelly (DBB/NCTR) (FDALabel demo, 10-15 min)
- Open to Questions (Discussion, 13-18 min)

FDALabel – A Web Based Database for FDA Drug Labels

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What is FDALabel?

- http://ncsvmweb01.nctr.fda.gov/druglabel

- Free web-based database for drug labels (currently with 43,000 FDA approved drug labels)
  - developed by NCTR in 2012
  - user-friendly interface with searches against the entire text of drug labels
  - a secure three-tier platform with an Oracle database as a sever

- Source : FDA Structured Product Labeling (SPL) archived by DailyMed and maintained by the National Library of Medicine (NLM).

Why FDALabel (1)?

- Rapid growth of drug label data requires a timely updating and repeated use of complex queries
  - about 400-500 new or updated drug labels weekly

- Complex structure of drug labels require a flexible, powerful, and fast searching engine against the entire text
  - drugs labels (average about 20 pages) contain >80 sections and hundreds data standard code sets and codes (HL7)
  - querying text within any specific or combination of the product, generic name, document types, sections, dosage forms, routes, marketing information etc.
  - summary statistics and count total labels by specific section.
  - a user account can be created to save queries for later viewing.

- No publicly available tools have such a robust and flexible mechanisms offered by FDALabel for mining and querying drug labels

Why FDALabel (2)?

- Comparison of FDALabel with **DailyMed**

Both FDALabel and DailyMed are **free to users and use SPL data**

	FDALabel	DailyMed
Full Text Search	✓	
Sections Search with Keywords	**All sections (>80)**	Limited to 10
Logical Search (Boolean logic and combined section search)	✓	Limited to 10
Marketing Categories, Status and Date search	✓	
Export Summary Results to Excel	✓	
Query Saved in Database and Reused	✓	

Statistics from FDALabel in 2012
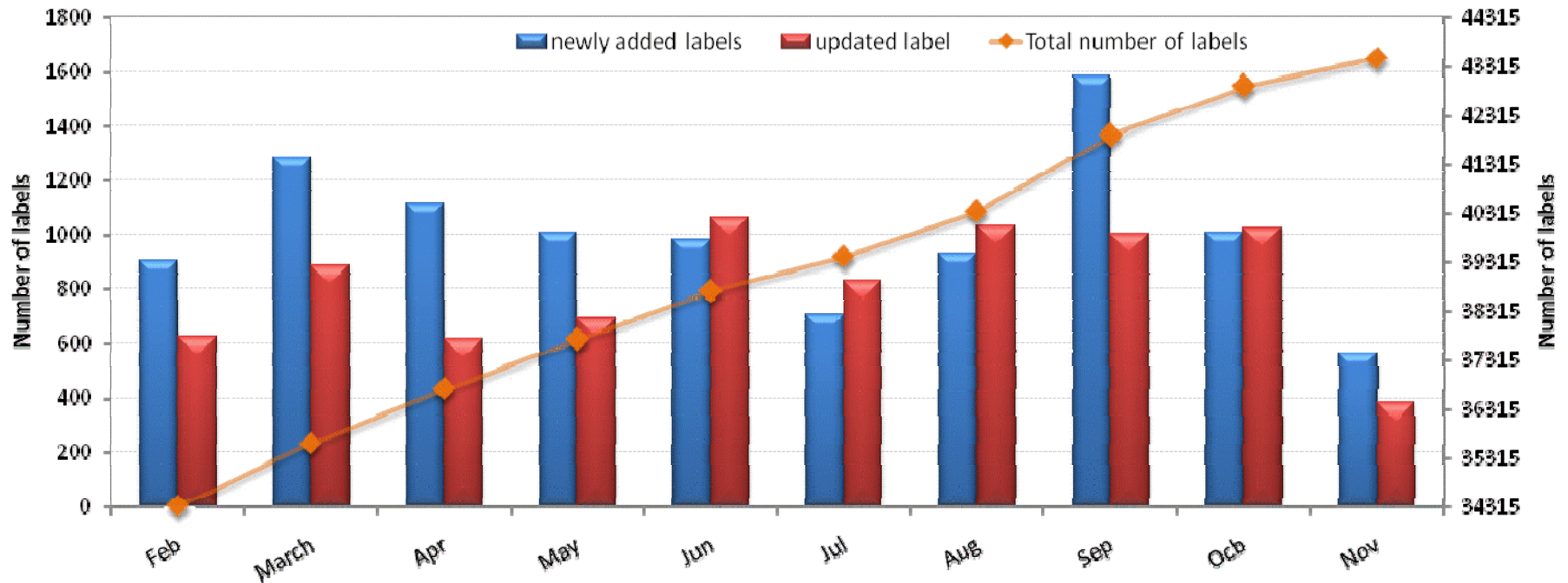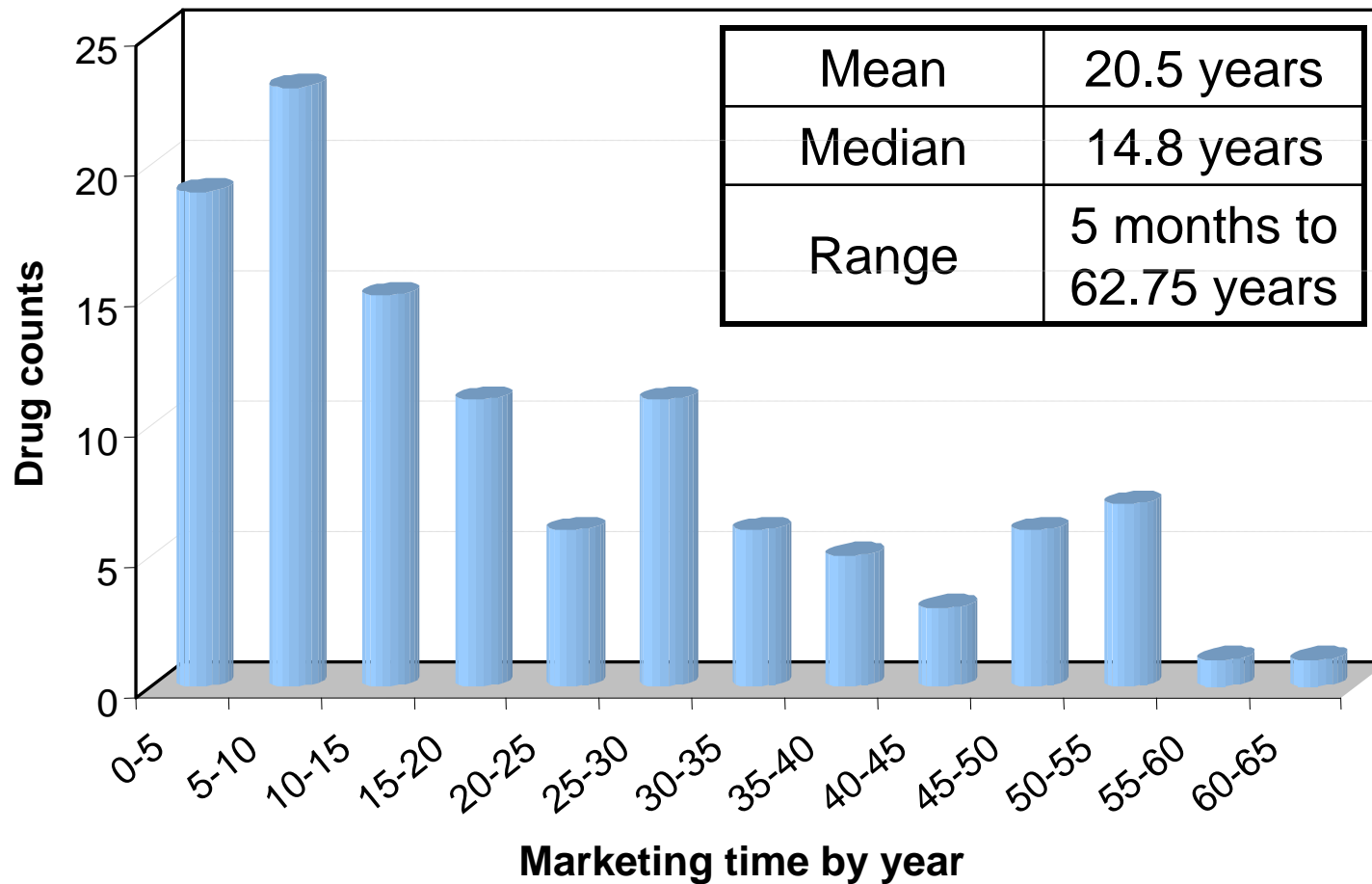

Monthly update statistics (Average)

newly added labels = 1055
updated label = 861

The total number of labels has been increased about 10,000 within 10 months

User Cases

Specific Organ Toxicities in Boxed Warning Drugs

Distribution of Organ Toxicities

The finding is consistent with the report: cardiac toxicity is also the leading cause of drug withdrawal from market in the past decade.
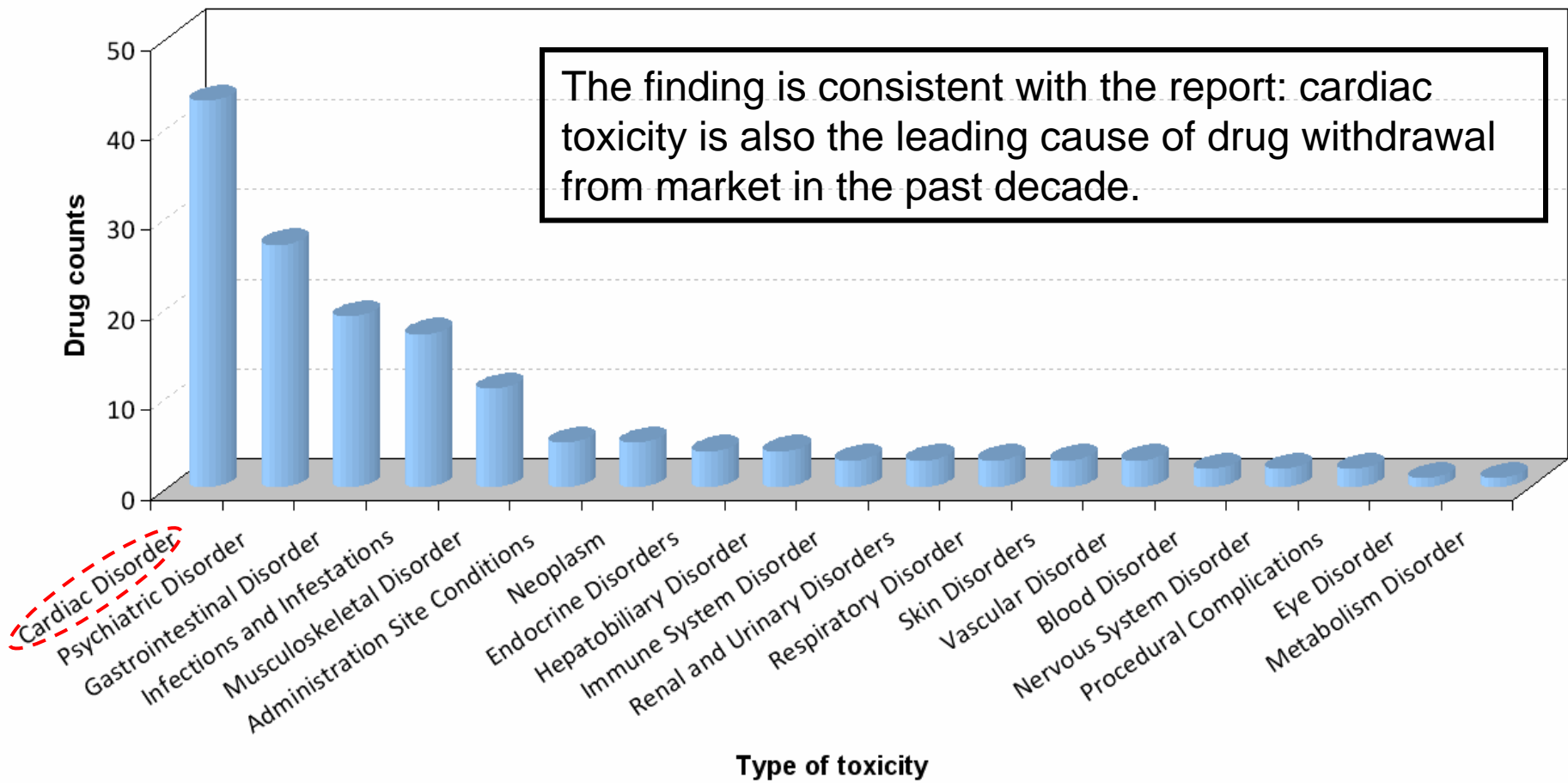
Therapeutic Categories in Boxed Warning Drugs

NSAIDS is the leading drug class for BW due to severe cardiovascular events and serious, potential life-threatening gastrointestinal (GI) bleeding
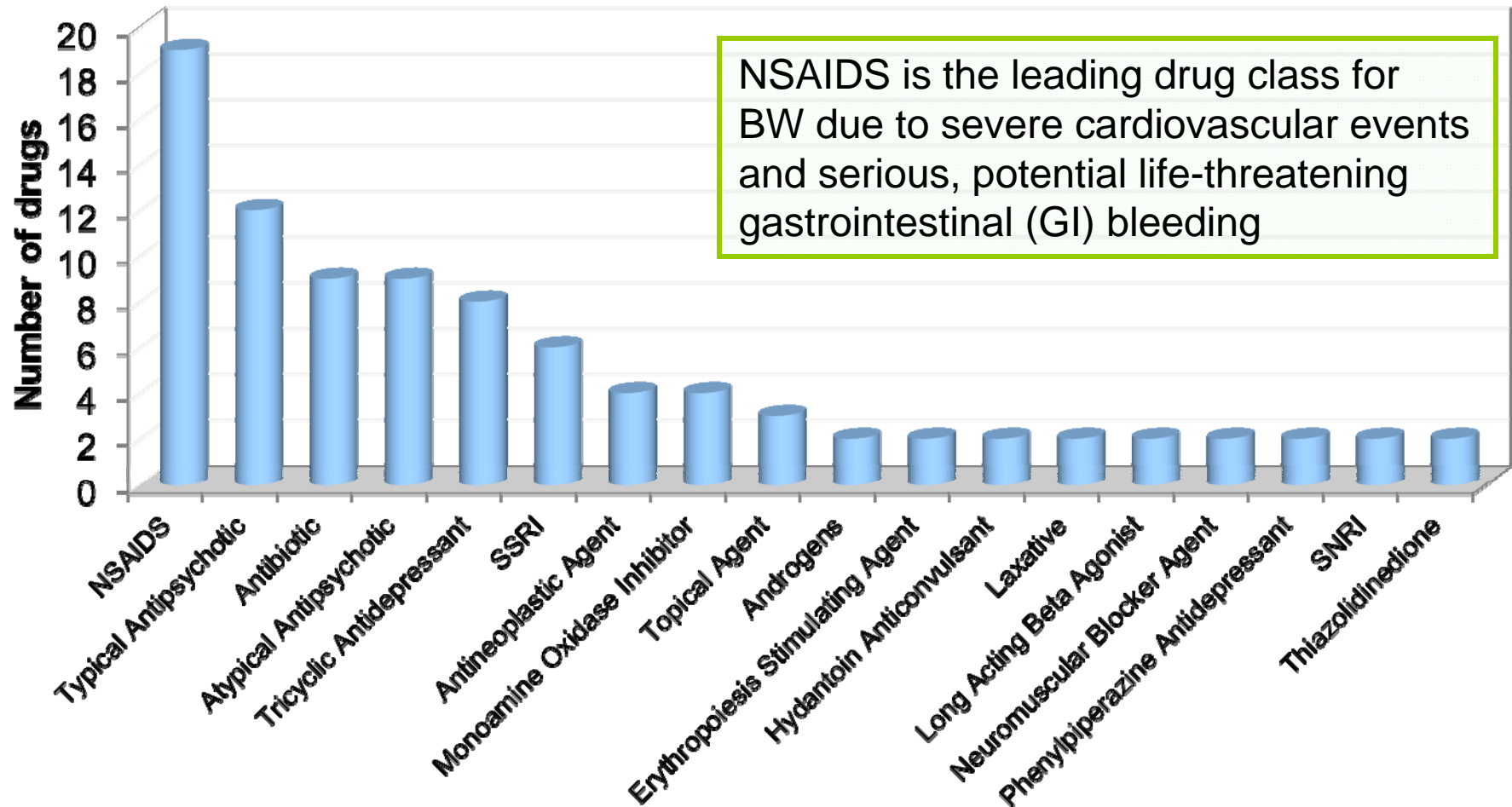
Existing and Potential Application in FDA

- Used in the Division of Pharmacovigilance, Office of Surveillance and Epidemiology in CDER (with about 50~60 medical officers)
 - Finding drug-drug interaction information
  - Capturing new medical terms that are not in MedDRA (Medical Dictionary for Regulatory Activities)

- Collaborating with Dr. Callahan (OCS/ORSI/DSCMI)
  - Integrating FDALabel with the FDA Substance Registration System (SRS)
  - Will allow chemical structure search of drug labels

- Identify pharmacogenomics biomarkers for personalized medicine
  - Drug metabolism variability
  - Risk for adverse events
  - Mechanism of drug action/drug efficacy

Pharmacogenomics Biomarkers Associated with Adverse Effects in Drug Labels
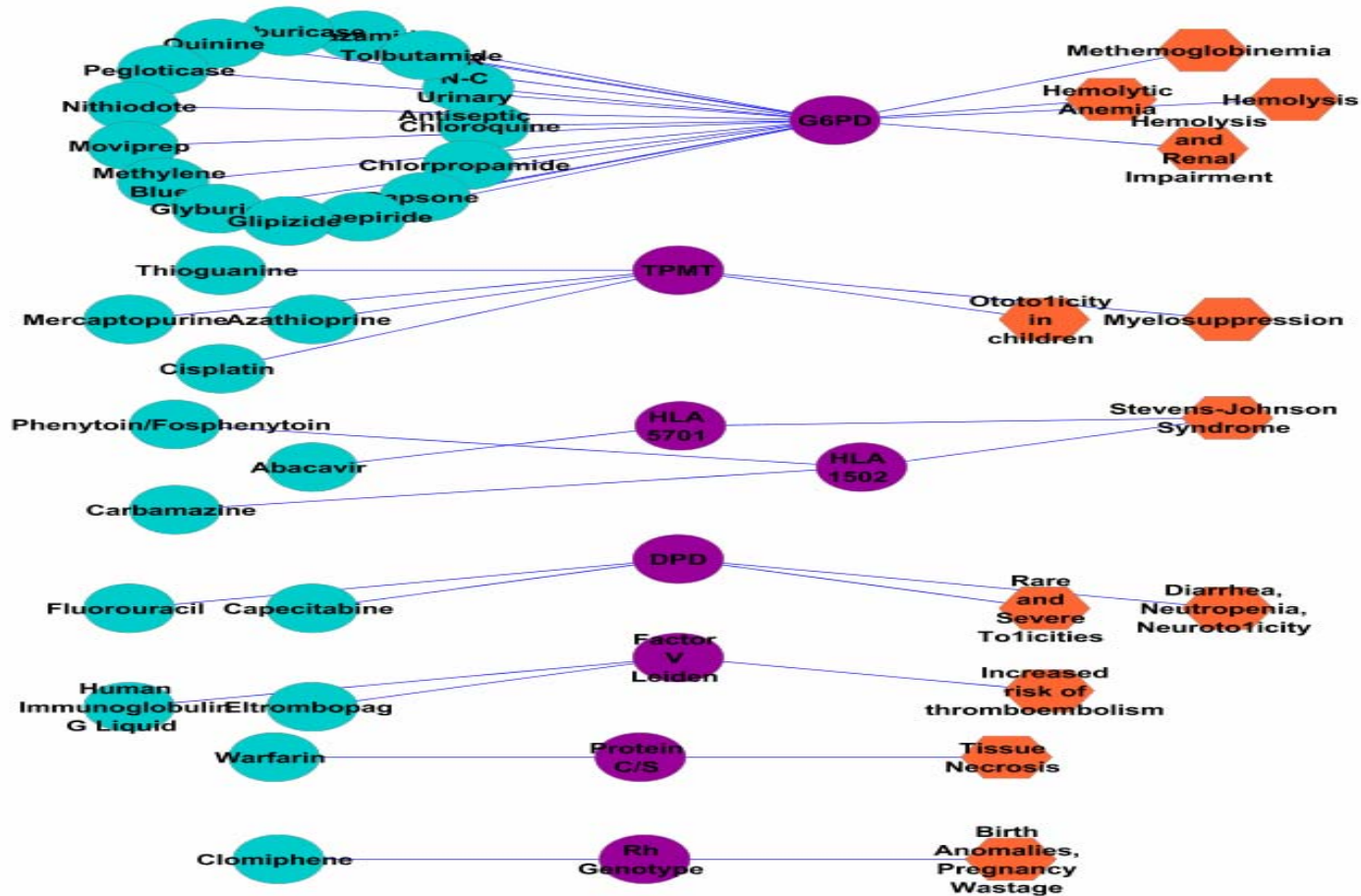
| Drug | Biomarker | Adverse Effect |

Summary

FDALabel can be used by researchers, FDA medical officers, pharmaceutical companies, physicians, and consumers

- Speed up monitoring ADR and studying of ADR for drug safety and health surveillance (e.g., black boxed warning, DILI, pharmacogenomics biomarkers).

- Serves as a bridge for transparent knowledge exchange among the public, pharmaceutical companies, and government regulatory agencies

- Up to date drug information and statistics of drug products to help FDA regulation and decision-making.

- Integrating information with other publicly available drug databases to promote public health.

FDALabel Future Direction

FDALabel is functional with good performance and speed. Further improvements based on user feedback from both FDA and non-FDA users:

- Add a "drug view" in the user interface; using Reference Listed Drugs (RLD) labels to reduce the duplicates in FDA labels (i.e., there are currently 40,000 labels for 2000 drugs, which contain a large number of repeating labels).

- Integrate FDALabel with the FDA Substance Registration System (SRS) to allow chemical structure and active ingredient search of drug labels.

- Move the FDALabel version 2 to Amazon Cloud and open the database to a large audiences and the public domain.

How to Access FDALabel

- Google search "FDALabel" or "bioinformatics tools"
- Home page: http://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm
- FDA User Database: http://ncsvmweb01.nctr.fda.gov/druglabel
- Non-FDA User Database (enclave): https://rm2.scinet.fda.gov/druglabel
- User Support: NCTRBioinformaticsSupport@fda.hhs.gov

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