

# FDA Label: A Tool to Facilitate Regulatory Application of Drug Labeling at FDA

**Hong Fang, Ph.D.**

National Center for Toxicological Research (NCTR)/FDA

[GSRS23](#), Sept. 27-28, 2023, EFSA, Parma, Italy  
Session 3 “**Regulatory Applications**”

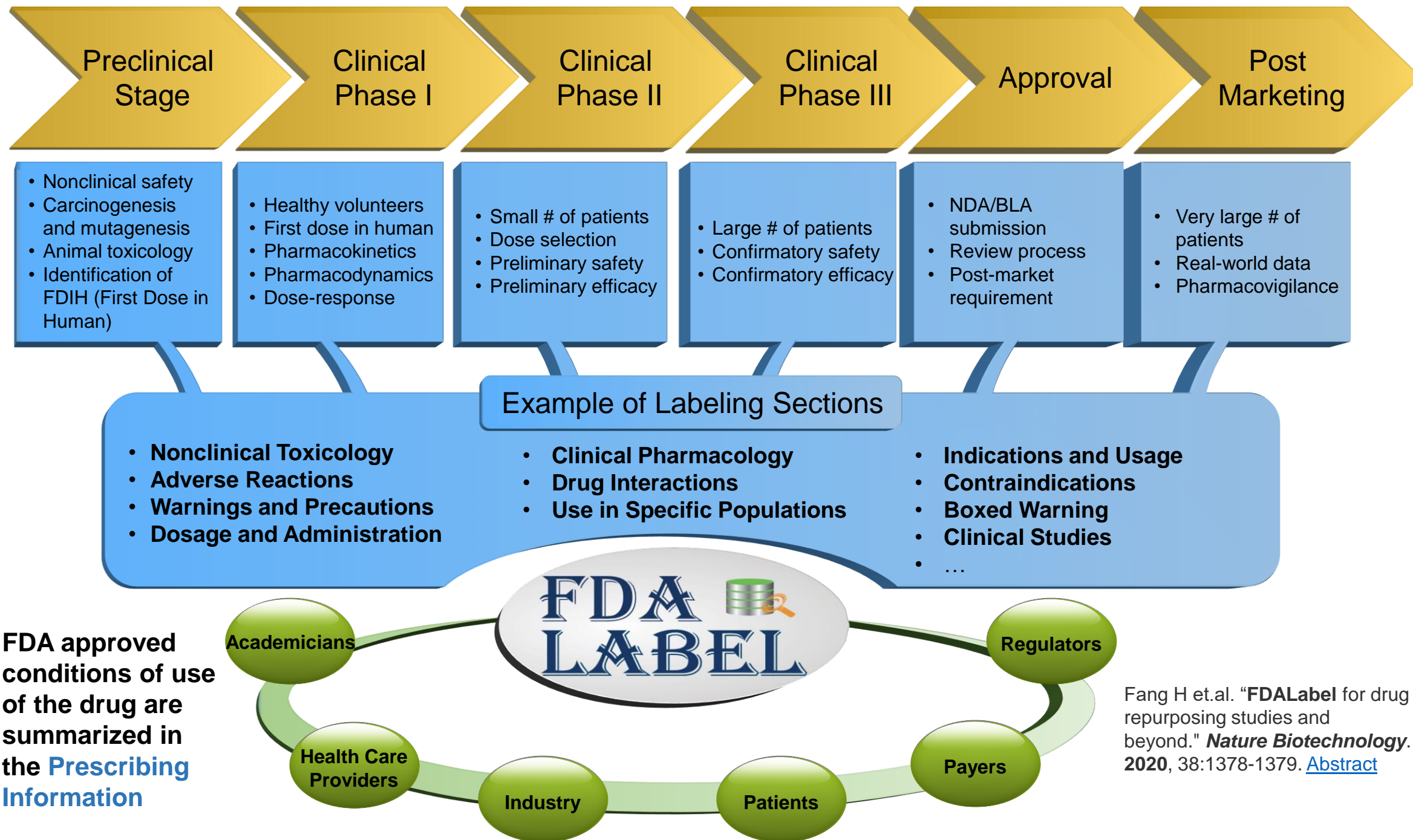


**Disclaimer**

*This presentation reflects the views of the author and does not necessarily reflect those of the US Food and Drug Administration. Any mention of commercial products is for clarification and is not intended as an endorsement.*

# What is Prescription Drug Labeling?

- Prescription drug labeling (e.g., PI: Prescribing Information) contains a summary of the essential scientific information needed for the safe and effective use of the drug
- Includes the FDA approved conditions of use of the drug. For example: its indication(s), dosage(s), safety information, and other information
- The number of sections/subsections and length of the Prescribing Information vary (e.g., 4 to 100 pages in length)



Fang H et.al. "FDALabel for drug repurposing studies and beyond." *Nature Biotechnology*. 2020, 38:1378-1379. [Abstract](#)

# **Table of Contents: VITRAKVI** **(Larotrectinib, Initial US approval in 2018)**

## **FULL PRESCRIBING INFORMATION: CONTENTS\***

### **1 INDICATIONS AND USAGE**

### **2 DOSAGE AND ADMINISTRATION**

- 2.1 Patient Selection
- 2.2 Recommended Dosage
- 2.3 Dosage Modifications for Adverse Reactions
- 2.4 Dosage Modifications for Coadministration with Strong CYP3A4 Inhibitors
- 2.5 Dosage Modifications for Coadministration with Strong CYP3A4 Inducers
- 2.6 Dosage Modifications for Patients with Hepatic Impairment
- 2.7 Administration

### **3 DOSAGE FORMS AND STRENGTHS**

### **4 CONTRAINDICATIONS**

### **5 WARNINGS AND PRECAUTIONS**

- 5.1 Neurotoxicity
- 5.2 Hepatotoxicity
- 5.3 Embryo-Fetal Toxicity

### **6 ADVERSE REACTIONS**

- 6.1 Clinical Trial Experience

### **7 DRUG INTERACTIONS**

- 7.1 Effects of Other Drugs on **VITRAKVI**
- 7.2 Effects of **VITRAKVI** on Other Drugs

### **8 USE IN SPECIFIC POPULATIONS**

- 8.1 Pregnancy
- 8.2 Lactation
- 8.3 Females and Males of Reproductive Potential
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Hepatic Impairment
- 8.7 Renal Impairment

### **11 DESCRIPTION**

### **12 CLINICAL PHARMACOLOGY**

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics

### **13 NONCLINICAL TOXICOLOGY**

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
- 13.2 Animal Toxicology and/or Pharmacology

### **14 CLINICAL STUDIES**

### **16 HOW SUPPLIED/STORAGE AND HANDLING**

### **17 PATIENT COUNSELING INFORMATION**

\* Sections or subsections omitted from the full prescribing information are not listed.

# Example of Highlights in Drug Labeling

## Remdesivir (VEKLURY®), Initial US approval in 2020

### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VEKLURY safely and effectively. See full prescribing information for VEKLURY.

VEKLURY® (remdesivir) for injection, for intravenous use

VEKLURY® (remdesivir) injection, for intravenous use

Initial U.S. Approval: 2020

### INDICATIONS AND USAGE

VEKLURY is a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor indicated for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. VEKLURY should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. (1)

### DOSAGE AND ADMINISTRATION

- Testing: In all patients, before initiating VEKLURY and during treatment as clinically appropriate, perform renal and hepatic laboratory testing and assess prothrombin time. (2.1)
- Recommended dosage in adults and pediatric patients 12 years of age and older and weighing at least 40 kg: a single loading dose of VEKLURY 200 mg on Day 1 followed by once-daily maintenance doses of VEKLURY 100 mg from Day 2 infused over 30 to 120 minutes. (2.2)
- For patients not requiring invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days. (2.2)
- For patients requiring invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days. (2.2)
- Administer VEKLURY via intravenous (IV) infusion over 30 to 120 minutes. (2.2, 2.4)
- Renal impairment: VEKLURY is not recommended in patients with eGFR less than 30 mL/min. (2.3)
- Dose preparation and administration: Refer to the full prescribing information for further details for both formulations. (2.4)
- Storage of prepared dosages: VEKLURY contains no preservative. (2.5)

### DOSAGE FORMS AND STRENGTHS

- For injection: 100 mg of remdesivir as a lyophilized powder, in a single-dose vial. (3)
- Injection: 100 mg/20 mL (5 mg/mL) remdesivir, in a single-dose vial. (3)

### CONTRAINDICATIONS

VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any components of the product. (4)

### WARNINGS AND PRECAUTIONS

- Hypersensitivity including infusion-related and anaphylactic reactions: Hypersensitivity reactions have been observed during and following administration of VEKLURY. Slower infusion rates, with a maximum infusion time of up to 120 minutes, can be considered to potentially prevent signs and symptoms of hypersensitivity. If signs and symptoms of a clinically significant hypersensitivity reaction occur, immediately discontinue administration of VEKLURY and initiate appropriate treatment. (5.1)
- Increased risk of transaminase elevations: Transaminase elevations have been observed in healthy volunteers and have also been reported in patients with COVID-19 who received VEKLURY. Perform hepatic laboratory testing in all patients before starting VEKLURY and while receiving VEKLURY as clinically appropriate. Consider discontinuing VEKLURY if ALT levels increase to greater than 10 times the upper limit of normal. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation. (5.2)
- Risk of reduced antiviral activity when coadministered with chloroquine phosphate or hydroxychloroquine sulfate: Coadministration of VEKLURY and chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments demonstrating a potential antagonistic effect of chloroquine on the intracellular metabolic activation and antiviral activity of VEKLURY. (5.3)

### ADVERSE REACTIONS

The most common adverse reactions (incidence greater than or equal to 5%, all grades) observed with treatment with VEKLURY are nausea, ALT increased, and AST increased. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Gilead Sciences, Inc. at 1-800-GILEAD-5 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 02/2021

# FDA-Approved Prescription Drug Labeling

- **Prepared by manufacturers and approved by FDA**
  - Data from preclinical and clinical trials and updated with post-market case reports (e.g., FAERS)
  - The wording in the approved prescription drug labeling is ordinarily based on an agreement between the FDA and the drug company.
- **Format and Content of Prescribing Information specified by Code of Federal Regulations, Title 21 (21 C.F.R. § 201.56, 201.57 and 201.80)**
  - In 1979, FDA established a Final Rule “Old” labeling format (non-PLR) (currently 21 C.F.R. §201.80)
  - In 2006, the Physician Labeling Rule (PLR) (see 21 C.F.R. §201.56) amended regulations regarding format and content of the Prescribing Information.
  - All drugs approved (under NDAs/BLAs) since June 2001 and certain drugs approved (under NDAs/BLAs) before June 2001 (e.g., those approved for new uses after June 2001), must have Prescribing Information in PLR format.
    - The amount of information captured in drug labeling has grown rapidly; labeling is updated (e.g., with new essential scientific information for the safe and effective use of the drug, to meet statutory/ regulatory requirements).
    - Additional [prescription drug labeling resources](#) including specific recommendations for sections of labeling are available.

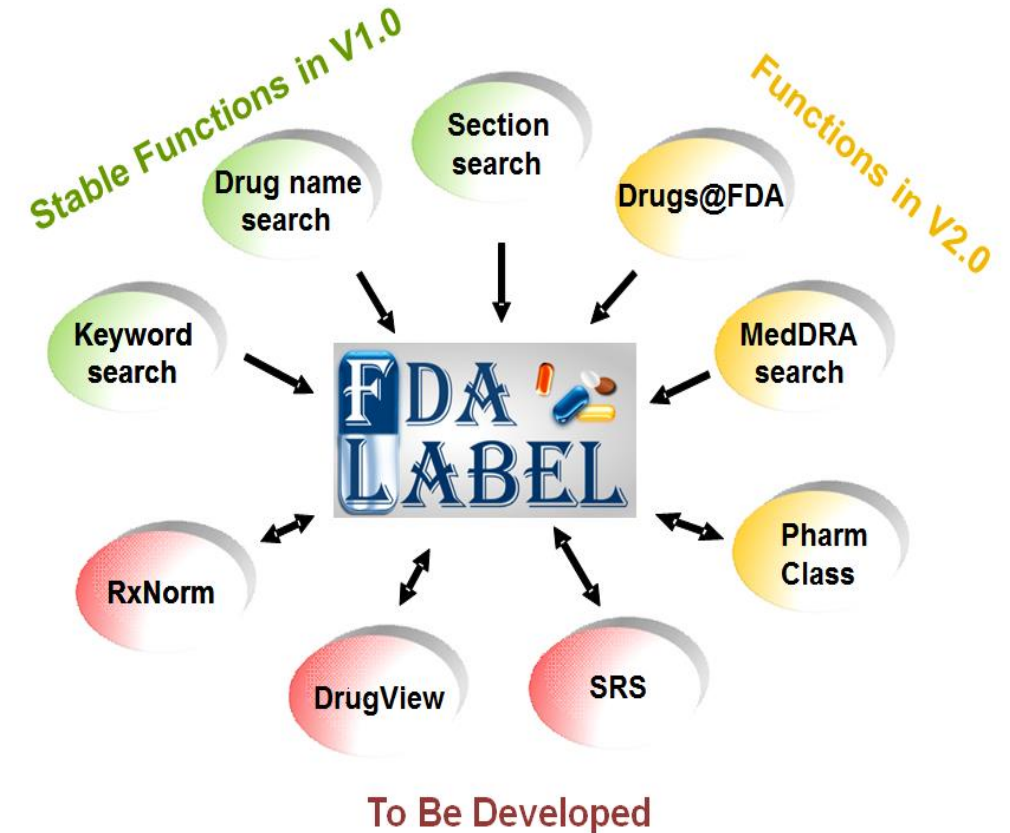


# FDA Label Tool Features for Searching Drug Labeling Documents

- **Complex structure of drug labeling requires a flexible, powerful, and fast search engine to search against the entire text**
  - Query text within any specific or combination of product names (e.g., generic or trade), labeling types (e.g., Rx and OTC), sections/subsections (e.g., Indications and Usage, Dosage and Administration, Warnings and Precautions), Pharmacologic Class information, etc.
  - Export labeling results to a summary spreadsheet to open in Excel
  - Direct links to the SPL document, DailyMed, Drugs@FDA, and Orange Book for the product
- **Repeat and reproduce the same complex queries**
  - Customized queries and results can be created, saved, and shared with other users for later viewing and updating

# FDA Label Overview

- **Web-based database** for managing, querying and organizing drug labeling and other product labeling
  - Data source: FDA's SPL (Structured Product Labeling - Electronic Drug Labeling): for human and animal prescription and nonprescription drugs and biological products downloaded from DailyMed
  - Currently with >146,000 labeling, updated weekly
  - User-friendly interface that searches against the entire text of drug labeling
  - Publicly available at AWS
- Advanced future query features for **Translational and Regulatory Science**
  - Integrate with Drugs@FDA and Orange Book
  - Integrate with MedDRA
  - Integrate with Pharmacologic Class
  - Integrate with GSRS (Global Substance Registration System)





# FDALabel User Interface (Version 2.7)

The screenshot displays the FDALabel User Interface (Version 2.7) with four main search criteria sections, each separated by an ampersand (&):

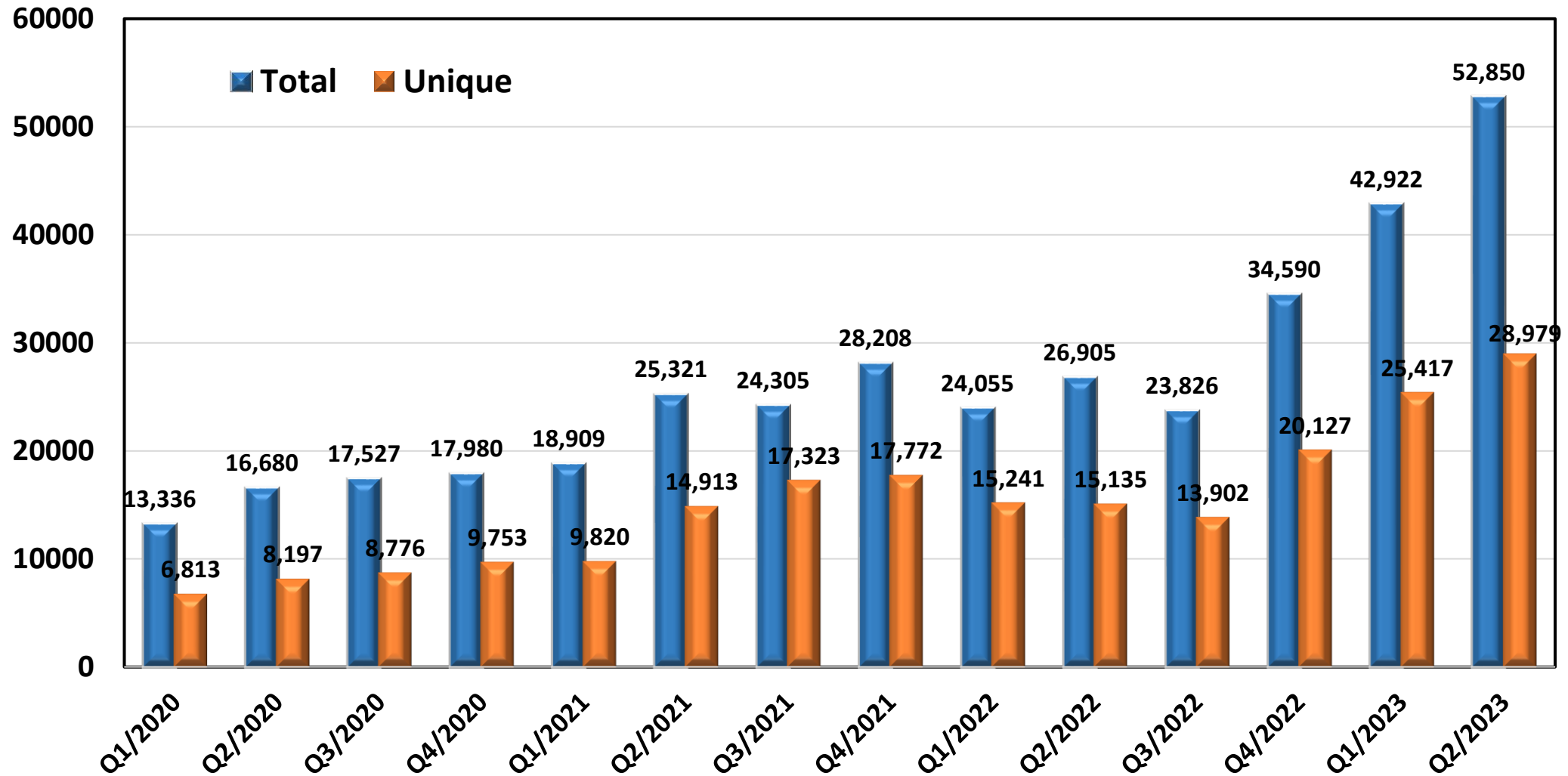
- Labeling Types:** Includes buttons for "Animal Rx", "Animal OTC", "Human Rx", "Human OTC", "Medical Device", "Medical Device Rx", and "Vaccine". Below these is a text input field with a dropdown arrow, preceded by the text "or choose one or more from the list:". A close button (x) is in the top right corner.
- Product Name(s):** Features a dropdown menu for "Trade or generic/proper nam", a dropdown for "contains", and a text input field with the placeholder "Enter any part(s) of product name". A close button (x) is in the top right corner.
- Labeling Full Text Search:** Includes a dropdown for "Simple Search" and a text input field with the placeholder "Enter text (e.g., search for NAUSEA OR VOMITING retrieves labeling containing the phrase 'nausea or vomiting')". Below the input field are two lines of text: "Simple Search: Search for exact text using complete words/phrases (ignores non-alphanumeric characters, e.g., ignores '-', '%')" and "Advanced Search (from drop-down menu): Conduct a Boolean and/or partial word search". A close button (x) is in the top right corner.
- Labeling Section(s):** Includes a dropdown for "Simple Search", a text input field with the placeholder "Enter text (may leave blank to check for presence of a labeling secti", and a dropdown for "within". Below the input field are two lines of text: "Simple Search: Search for exact text using complete words/phrases (ignores non-alphanumeric characters, e.g., ignores '-', '%')" and "Advanced Search (from drop-down menu): Conduct a Boolean and/or partial word search". A close button (x) is in the top right corner.

At the bottom, there is a section titled "Add more criteria:" followed by a series of links: "Labeling Full Text Search", "Product Name(s)", "Labeling Section(s)", "Labeling Types", "Pharmacologic Class(es)", "Application Types or Marketing Categories", "Market Status", "MedDRA Terms", "Chemical Structure", and "Labeling, Product and Ingredient Identifiers".

FDALabel on Amazon Cloud:  
<https://www.fda.gov/fdalabeltool>

Fang H., ... Tong W. "FDALabel for drug repurposing studies and beyond." *Nature Biotechnology*. 2020, 38:1378-1379.

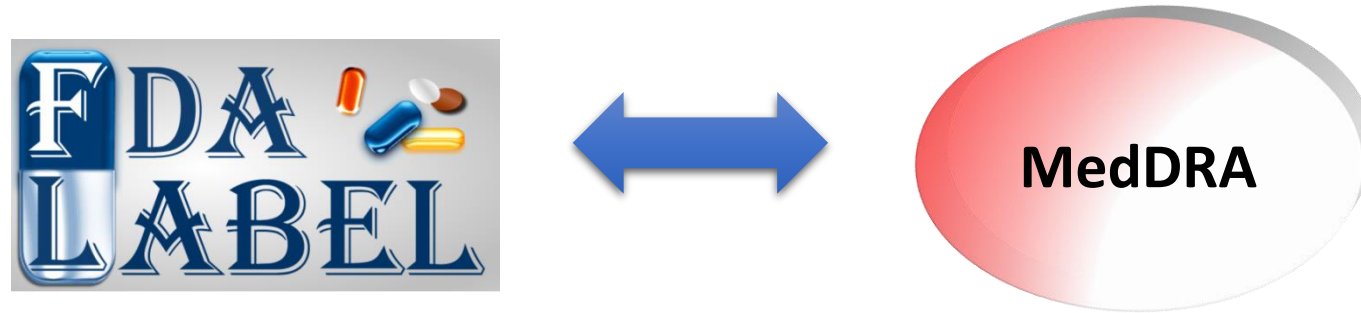
# FDA Label Public User Access Statistics (2020-2023)



# **Applications of FDALabel in Translational and Regulatory Science**

# FDA Label Integrated with MedDRA

## (Medical Dictionary and Standard Terminology)

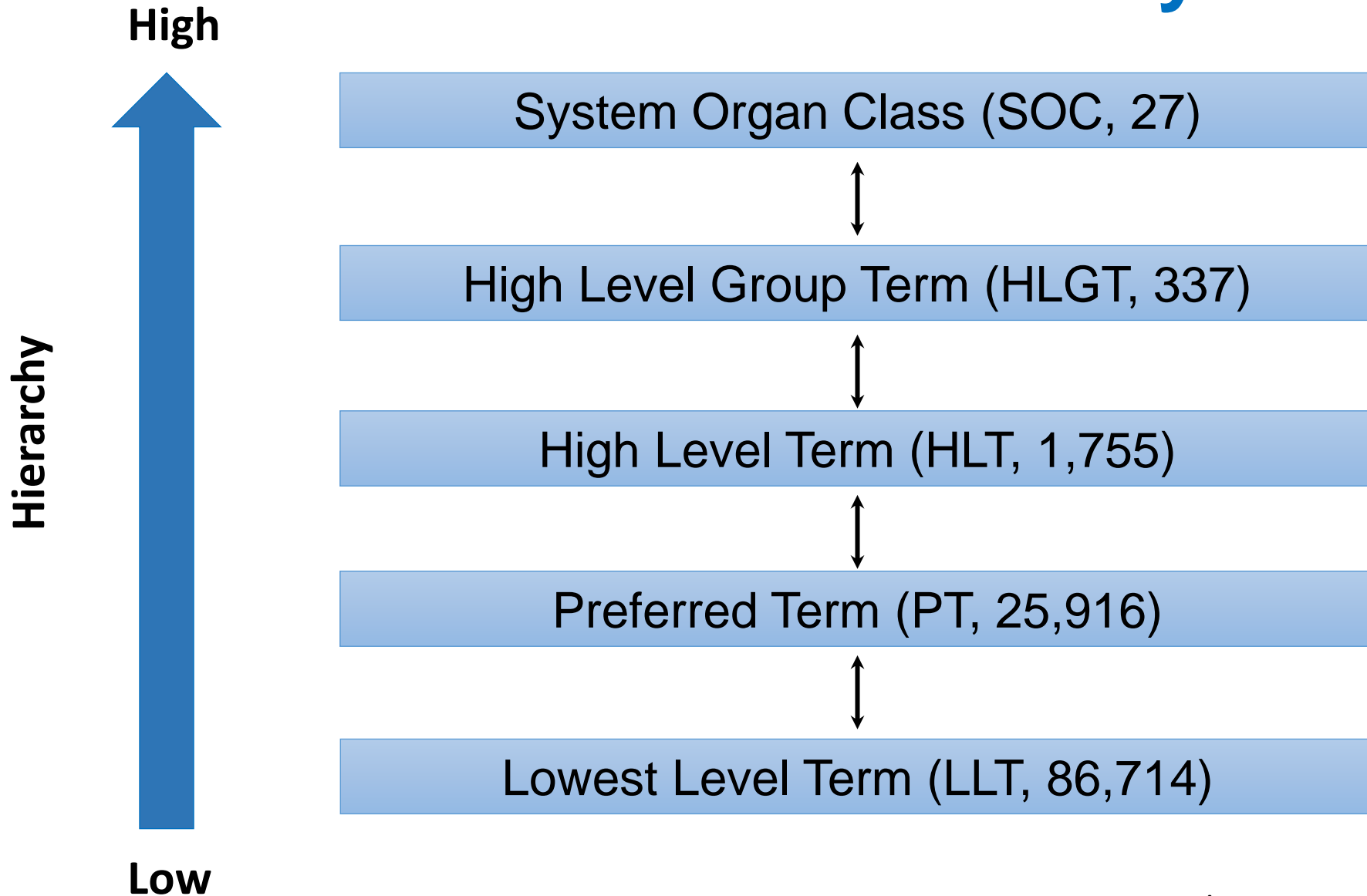


### **Medical Dictionary for Regulatory Activities (MedDRA):**

The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.

- FAERS codes adverse events using MedDRA.
- MedDRA is widely used internationally, including in the United States, European Union and Japan.
- Originally available in English and Japanese, MedDRA is now also translated into Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese and Spanish.
- Its use is currently mandated in Europe and Japan for safety reporting.
- Standardized MedDRA Queries (SMQs) will allow computer automation.

# MedDRA Hierarchy



# Distribution of MedDRA (PTs) in Some Safety Related Labeling Sections

Labeling Section	Number of Drugs	Number of LLTs (86,714)	Number of PTs (25,916)
BOXED WARNING	367	601	463
WARNINGS & PRECAUTIONS	1148	3206	2023
ADVERSE REACTIONS	1152	5300	2961
Whole Labeling Document	1164	7287	3819

Wu L., Ingle T., Liu Z., Zhao-Wong A., Harris S.C., Thakkar S., Zhou G., Yang J., Xu J., Mehta D., Ge W., Tong W., and Fang H. "Study of serious adverse drug reactions using FDA-approved drug labeling and MedDRA." *BMC Bioinformatics*. 2019, 20(97). [Abstract](#)



# Hierarchical Clustering Analysis (HCA) of Drug Class (ATC) and MedDRA for Adverse Event Study (Boxed Waning Drugs)

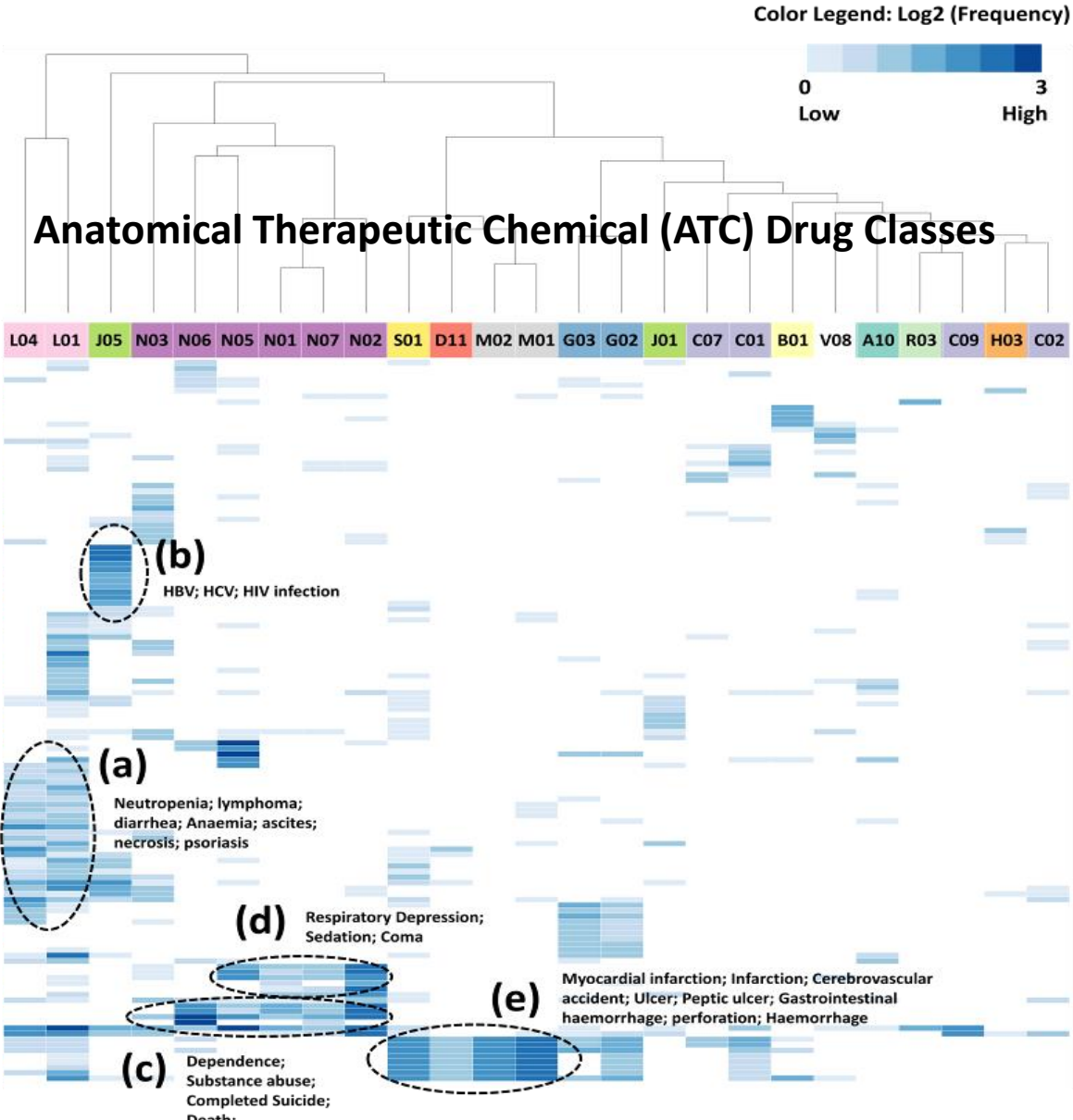
**ATC classes**

A	ALIMENTARY TRACT AND METABOLISM
B	BLOOD AND BLOOD FORMING ORGANS
C	CARDIOVASCULAR SYSTEM
D	DERMATOLOGICALS
G	GENITO URINARY SYSTEM AND SEX HORMONES
H	SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS
J	ANTIINFECTIVES FOR SYSTEMIC USE
L	ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
M	MUSCULO-SKELETAL SYSTEM
N	NERVOUS SYSTEM
R	RESPIRATORY SYSTEM
S	SENSORY ORGANS
V	VARIOUS

**SOC Labels**

Blood
Card
Cong
Ear
Eye
Gastr
Genrl
Hepat
Immun
Infec
Metab
Musc
Neopl
Nerv
Preg
Psych
Renal
Repro
Resp
Skin
Vasc

PT/SOC Association

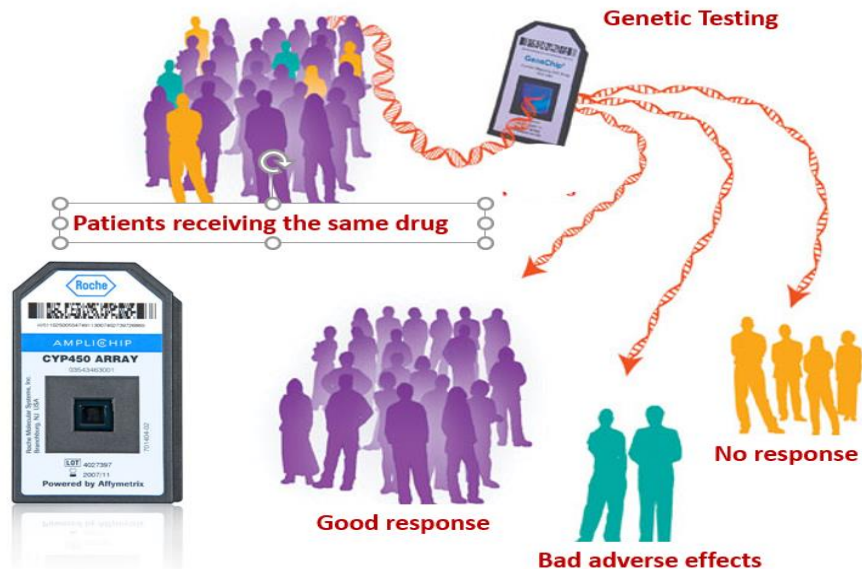


# Application in Pharmacogenomics

## (Precision Medicine)

- Pharmacogenomics (PGx) is a field of research that studies the relationship between drug response and genetic makeup of an individual/population.
- Patients Respond Differently to the Same Drug Treatment
- **Right Drug, Right Dose, Right Patient (Precision Medicine)**

**Example: VITRAKVI** (Larotrectinib, initially approved in 2018) is a kinase inhibitor indicated for the treatment of adult and pediatric patients with certain solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion (FDA Companion Diagnostic).



### FULL PRESCRIBING INFORMATION: CONTENTS\*

#### 1 INDICATIONS AND USAGE

#### 2 DOSAGE AND ADMINISTRATION

- 2.1 Patient Selection
- 2.2 Recommended Dosage
- 2.3 Dosage Modifications for Adverse Reactions
- 2.4 Dosage Modifications for Coadministration with Strong CYP3A4 Inhibitors
- 2.5 Dosage Modifications for Coadministration with Strong CYP3A4 Inducers
- 2.6 Dosage Modifications for Patients with Hepatic Impairment
- 2.7 Administration

#### 3 DOSAGE FORMS AND STRENGTHS

#### 4 CONTRAINDICATIONS

#### 5 WARNINGS AND PRECAUTIONS

- 5.1 Neurotoxicity
- 5.2 Hepatotoxicity
- 5.3 Embryo-Fetal Toxicity

#### 6 ADVERSE REACTIONS

- 6.1 Clinical Trial Experience

#### 7 DRUG INTERACTIONS

- 7.1 Effects of Other Drugs on **VITRAKVI**
- 7.2 Effects of **VITRAKVI** on Other Drugs

#### 8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.2 Lactation
- 8.3 Females and Males of Reproductive Potential
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Hepatic Impairment
- 8.7 Renal Impairment

#### 11 DESCRIPTION

#### 12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics

#### 13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
- 13.2 Animal Toxicology and/or Pharmacology

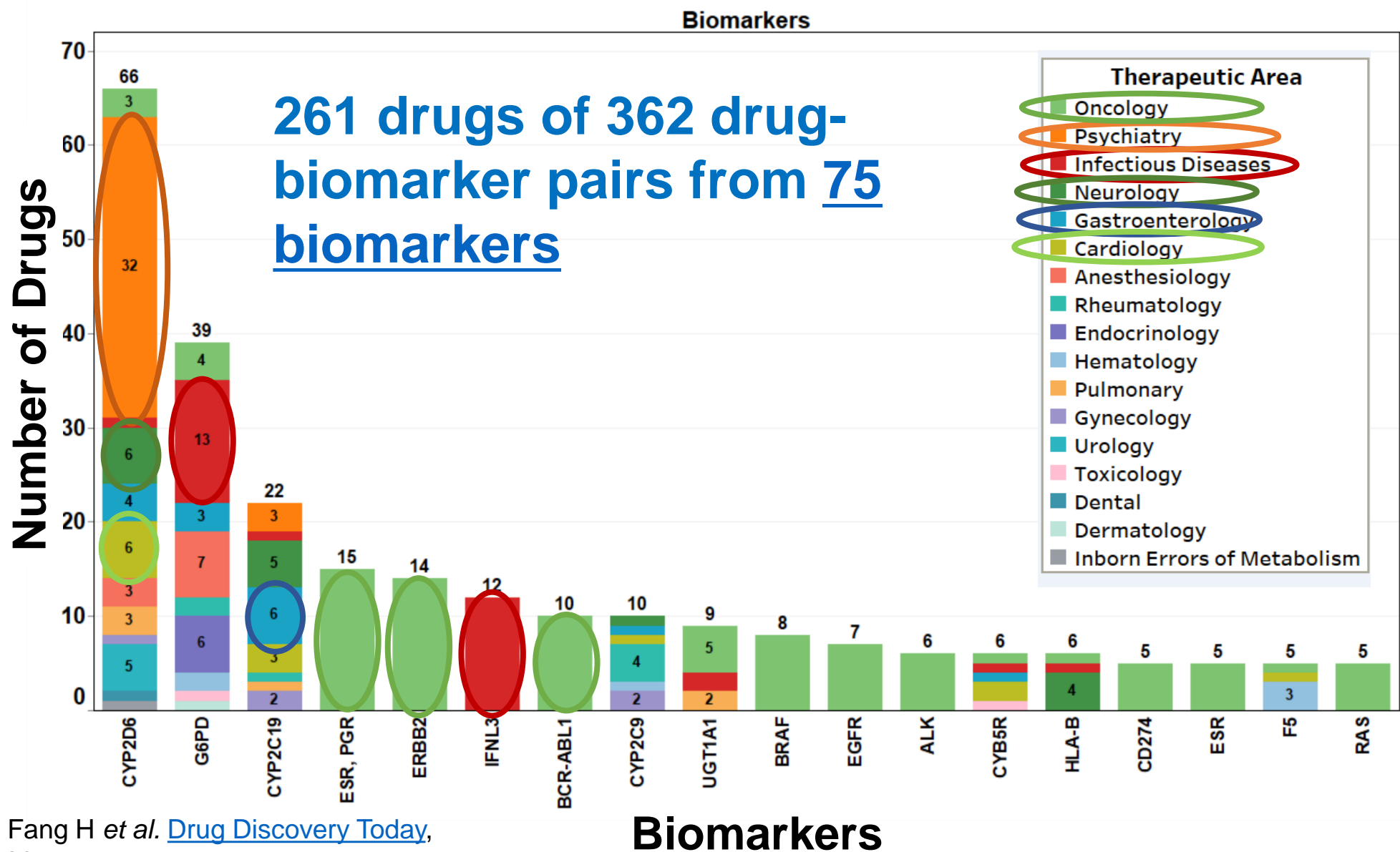
#### 14 CLINICAL STUDIES

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

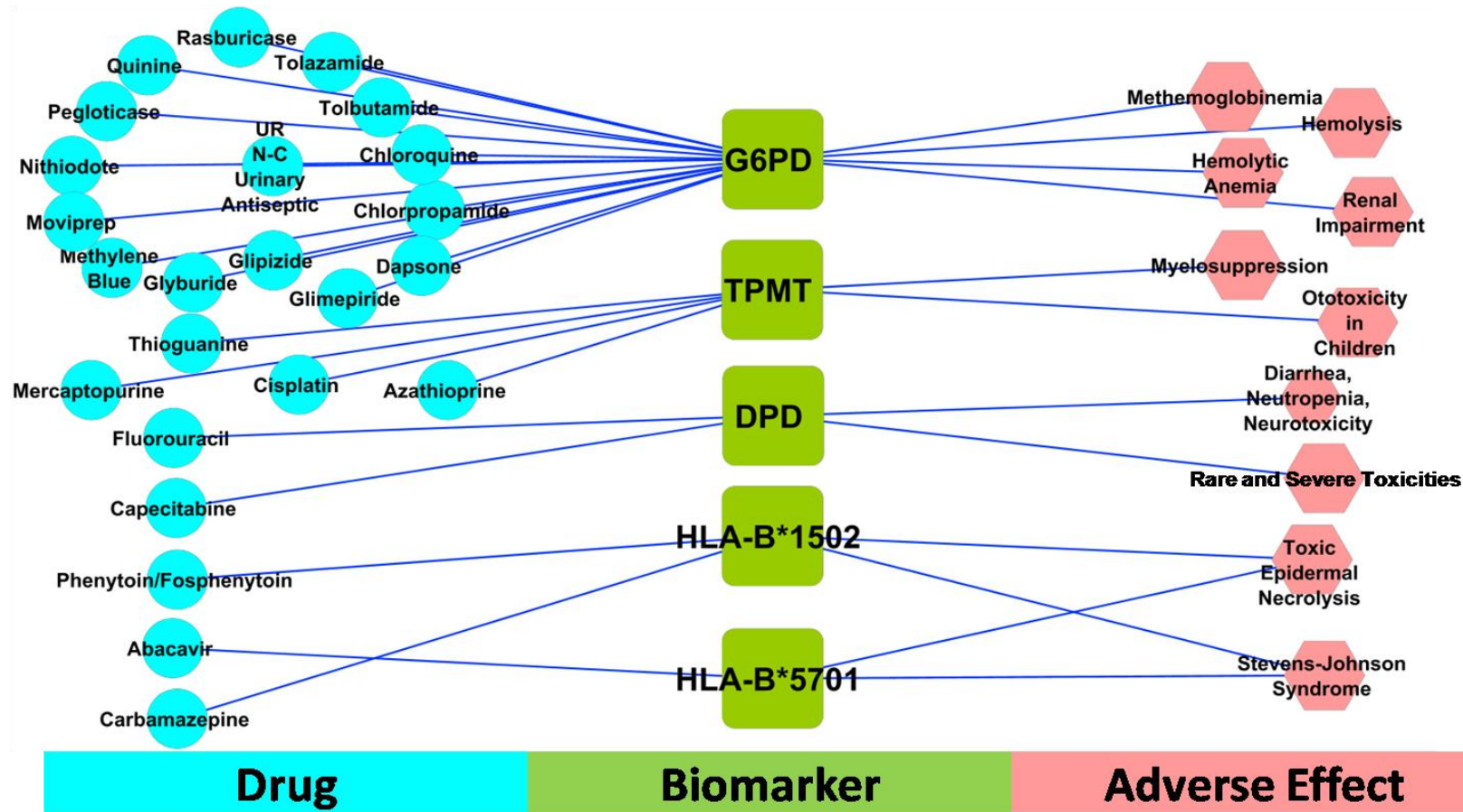
#### 17 PATIENT COUNSELING INFORMATION

\* Sections or subsections omitted from the full prescribing information are not listed.

# Drug-Biomarker Pairs with Therapeutic Classes



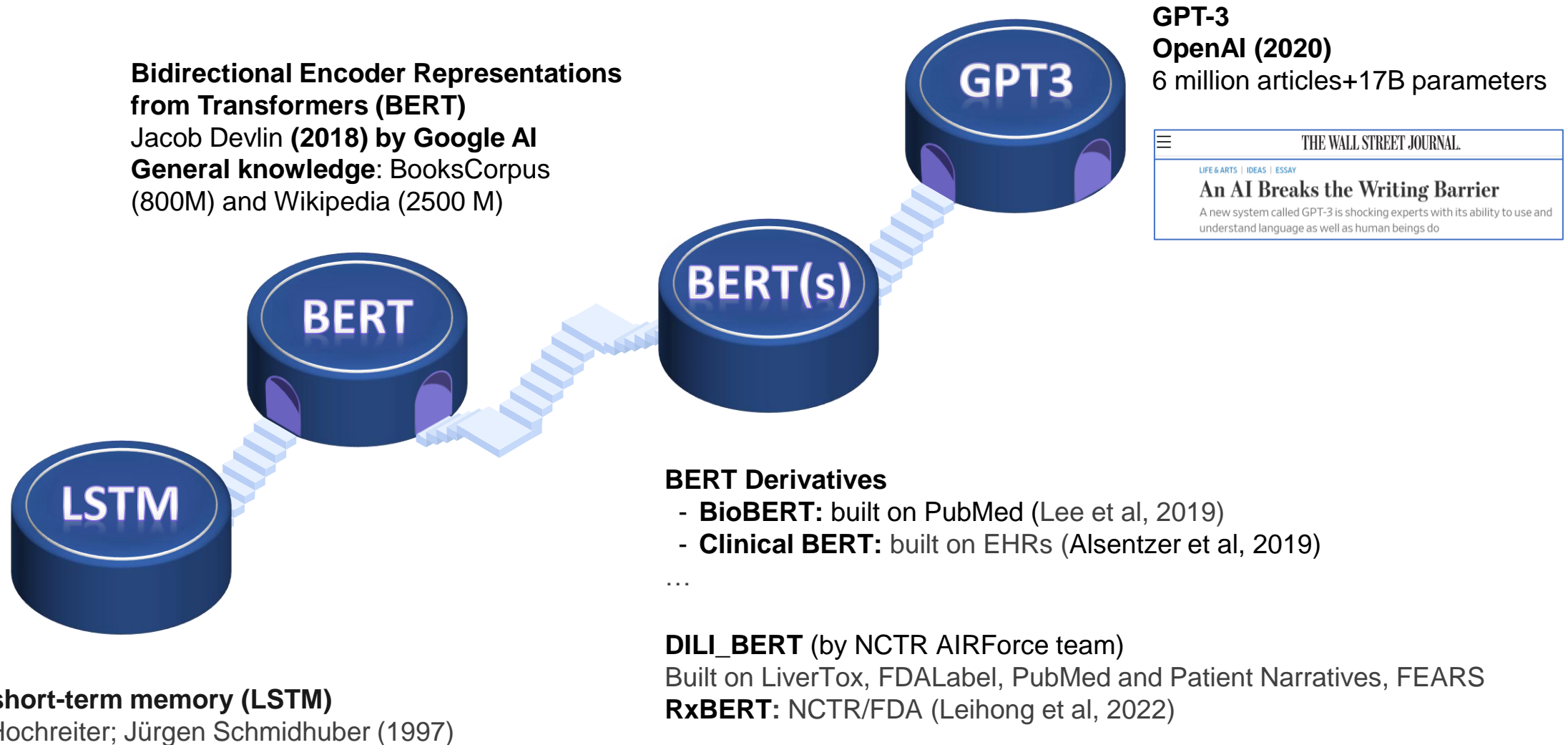
# PGx Biomarkers for Adverse Effects



**Patients who carry the HLA-B\*5701 allele are at a higher risk for experiencing a hypersensitivity reaction (HR) to Abacavir®.**

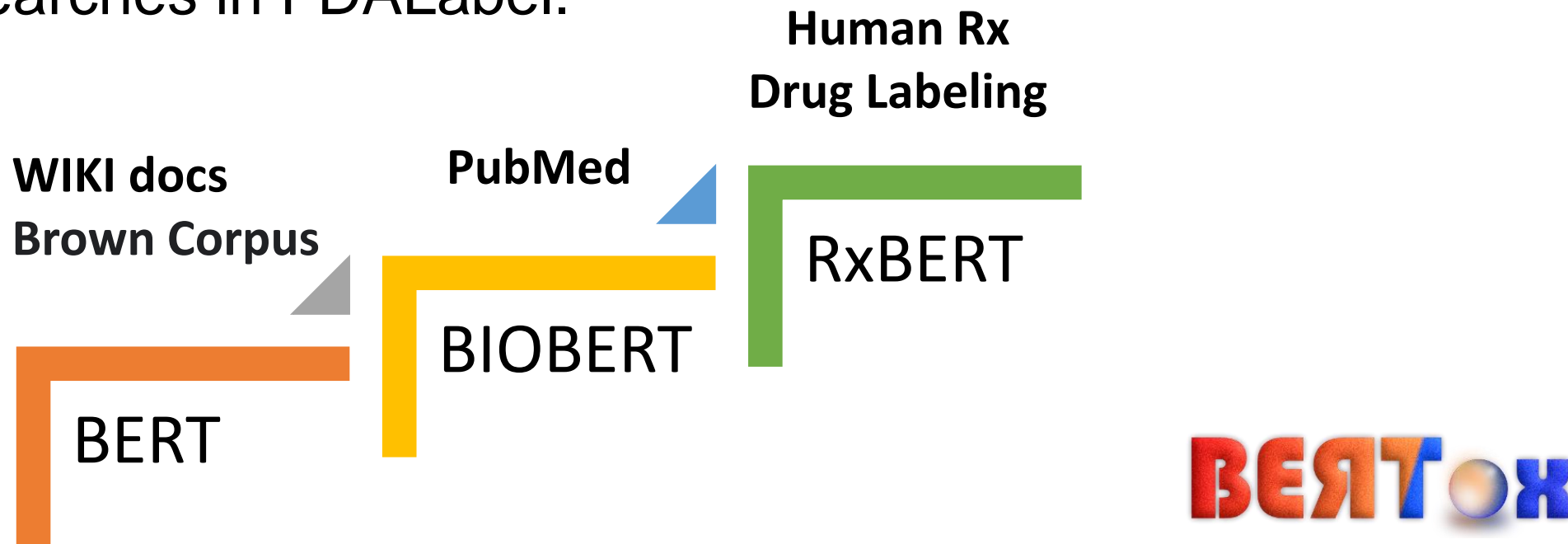


# Evolution of AI Language Models for NLP



# RxBERT Model In Exploring Drug Labeling Documents

**RxBERT** is a customized domain-specific BERT model that was trained using human prescription drug labeling documents. RxBERT was developed by NCTR/FDA to achieve Google/AI-like searches in FDALabel.





# RxBERT Search Results for “Taken with Food”

## Top 10 most similar phrases of “Taken with food” in drug labeling

- **Take** with **food**
- May take with or without food
- **Mix** with food or **beverage**
- **Give** with food
- Take with **meals**
- Take (*GEODON capsules*) with food
- Take with or without food
- **Administration** with Food
- You can take (*Jakafi*) with or without food
- Take (*Adempas*) with or without food

RxBERT is capable of understanding synonyms/similar verbiage used in drug labeling

# A Possible AI/AE Tool With Visualization

## Annotation result

- **RxBERT**: RxBERT Predicted terms
- **MedDRA**: MedDRA LLT terms

Combination of adverse events (AE) identified from **RxBERT** and **MedDRA Standard Rule-Based** models

### 5 WARNINGS AND PRECAUTIONS

#### 5.1 Hypersensitivity Reactions

Serious and sometimes **fatal hypersensitivity reactions** have occurred with ZIAGEN (abacavir). These **hypersensitivity reactions** have included **multi-organ failure** and **anaphylaxis** and typically occurred within the first 6 weeks of treatment with ZIAGEN (median time to onset was 9 days); although abacavir **hypersensitivity reactions** have occurred any time during treatment [see Adverse Reactions (6.1)]. Patients who carry the HLA-B\*5701 allele are at a higher risk of abacavir **hypersensitivity** reactions; although, patients who do not carry the HLA-B\*5701 allele have developed **hypersensitivity reactions**. **Hypersensitivity** to abacavir was reported in approximately 206 (8%) of 2,670 patients in 9 clinical trials with abacavir-containing products where HLA-B\*5701 screening was not performed. The incidence of suspected abacavir **hypersensitivity reactions** in clinical trials was 1% when subjects carrying the HLA-B\*5701 allele were excluded. In any patient treated with abacavir, the clinical diagnosis of **hypersensitivity** reaction must remain the basis of clinical decision making.

Due to the potential for severe, serious, and possibly **fatal hypersensitivity reactions** with ZIAGEN:

- All patients should be screened for the HLA-B\*5701 allele prior to initiating therapy with ZIAGEN or reinitiation of therapy with ZIAGEN, unless patients have a previously documented HLA-B\*5701 allele assessment.
- ZIAGEN is contraindicated in patients with a prior **hypersensitivity** reaction to abacavir and in HLA-B\*5701-positive patients.
- Before starting ZIAGEN, review medical history for prior exposure to any abacavir-containing product. NEVER restart ZIAGEN or any other abacavir-containing product following a **hypersensitivity** reaction to abacavir, regardless of HLA-B\*5701 status.
- To reduce the risk of a life-threatening **hypersensitivity** reaction, regardless of HLA-B\*5701 status, discontinue ZIAGEN immediately if a **hypersensitivity** reaction is suspected,

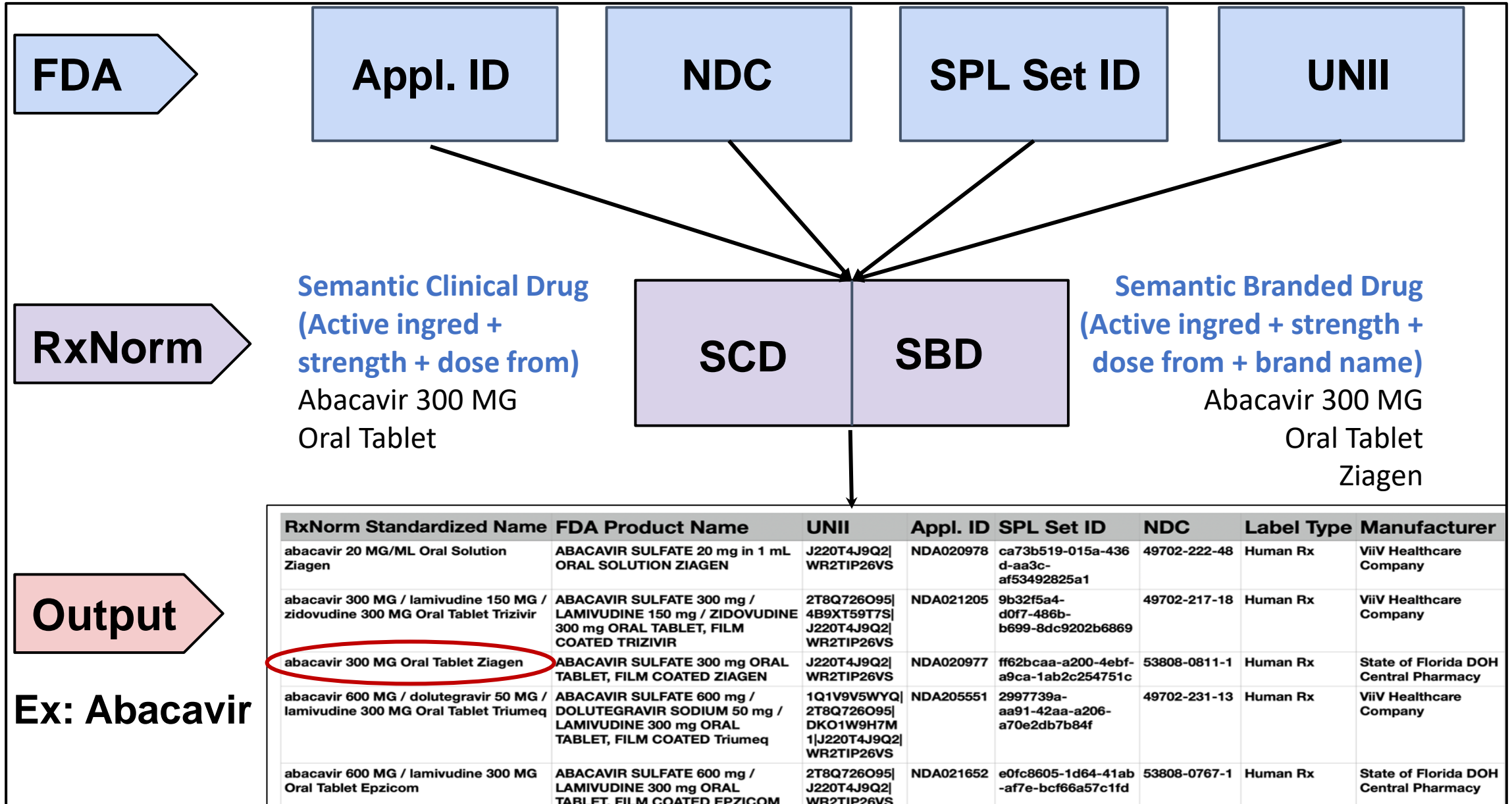
## Statistics:

Export ▾

Search:

Counts	Term Found	RxBERT?	MedDRA?	MedDRA-PT	SOC
15	hypersensitivity	No	Yes	Hypersensitivity	Immun
7	hypersensitivity reaction	No	Yes	Hypersensitivity	Immun
6	hypersensitivity reactions	Yes	No		
3	fatal	Yes	No		
3	acidosis	No	Yes	Acidosis	Metab
2	steatosis	Yes	No		
2	hepatomegaly	Yes	Yes	Hepatomegaly	Hepat
2	lactic acidosis	No	Yes	Lactic acidosis	Metab
1	multi-organ failure	Yes	Yes	Multiple organ dysfunction syndrome	Genrl
1	anaphylaxis	Yes	Yes	Anaphylactic reaction	Immun
Counts	Term Found	RxBERT?	MedDRA?	MedDRA-PT	SOC

# FDA Label IDs Mapped to RxNorm Drug Name Standard



# Take-Home Messages

**FDALabel Applications: pharmaceutical companies for drug development, researchers for study of efficacy and drug safety, FDA for drug review, etc.**

- Prescription drug labeling contains a summary of the essential scientific information needed for the safe and effective use of the drug.
- **FDALabel** is a powerful web-based database tool that allows flexible and customizable searches of human prescription drug, biological, and over-the-counter (OTC) labeling documents.
- Using **FDALabel**, information and resources can be powered by data standard (e.g., MedDRA, RxNorm) and AI/NLP text mining applying drug labeling sections (e.g., Indication & Usage, Boxed Warnings, Warning and Precautions, Adverse Reactions).
- **FDALabel** is freely available to the public, including healthcare professionals, patients, researchers, and regulatory agents to support and advance public health.

# Acknowledgements



## NCTR FDALabel Team:

- Weida Tong
- Stephen Harris
- Joshua Xu
- Junshuang Yang
- Taylor Ingle
- Steve Turner
- Zhichao Liu
- Leihong Wu
- Joe Meehan
- Minjun Chen
- Baitang Ning
- Qiang Shi
- Ted Bearden
- Amber Dedman
- Bradley Schnackenberg
- Tucker Patterson (NCTR, Director)

## CDER FDALabel Team:

- Lilliam Rosario (OTS/OCS, Director)
- Eric Brodsky (LPT/OND)
- Farrokh Sohrabi (LPT/OND)
- Isaac Chang (OTS/OCS)
- Charles Pastel (OTS/OCS)
- OCS Service Desk
- Robert Dorsam (OGD/OB)
- Miyoung Yang (OGD/OB)
- Wan Lee (OGD/ORO)
- Shannon Hill (OGD/ORO)
- ShaAvhree Buckman-Garner (OTS, Director)

## CDER:

- Lonnie Smith (ODT/ODAR)
- Laurence Callahan (ODT/ODAR)

## MedDRA MSSO

- Anna Zhao-Wong

## CBER:

- Lisa Lin (ORO/DIIT)
- Lisa Stockbridge (RMCC Labeling Subcommittee)

## CVM:

- Tina Burgess
- Tong Zhou
- Karen Sussman
- Charise Kasser



## Previous Contributors:

- William Slikker, Jr. (NCTR, Former Director)
- Paul Howard (NCTR)
- Madhu Lal-Nag (OTS)
- Guangxu Zhou (NCTR)
- Shraddha Thakkar (NCTR)
- Crystal Allard (OTS/OCS)
- Catherine Li (OCS/OTS)
- Darshan Mehta (NCTR, ORISE)
- Ryley Uber (Summer Student)
- Lawrence Lesko (UF)
- Guoping Zhang (NCTR, ORISE)
- Roger Perkins (NCTR)

# FDALabel Webpage and User Support

- **Public:** [www.fda.gov/FDALabelTool](http://www.fda.gov/FDALabelTool)
- **Tool Launch:** <https://nctr-crs.fda.gov/fdalabel/ui/search>
- **User Support :** NCTR Bioinformatics Support:  
[NCTRBioinformaticsSupport@fda.hhs.gov](mailto:NCTRBioinformaticsSupport@fda.hhs.gov)



# Thank you!

