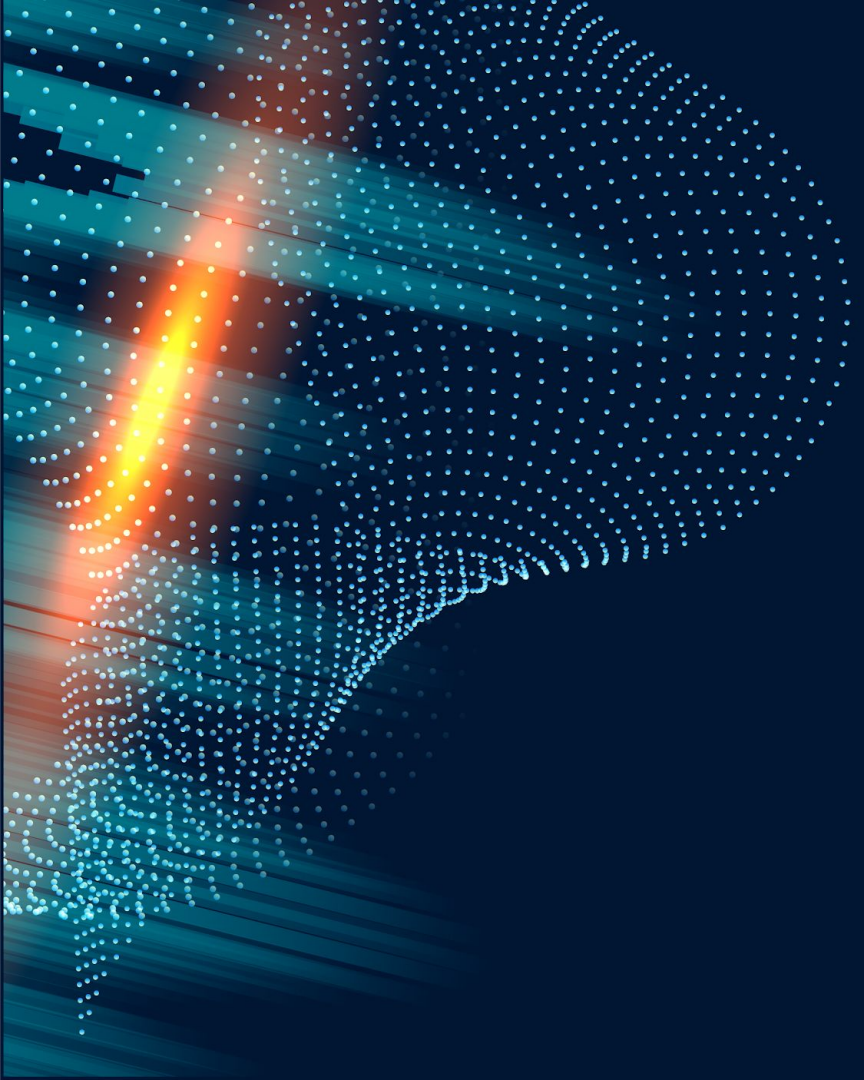# Drug Label Explorer

Ken Brown, Agi Kajanaku, Leo Landau, Sam Negassi, Ky Nguyen

Overview

Today we're going to talk about:

1. **What is a Drug Label for?**

2. **What does DLE do?**

3. **How did we do it?**

4. **What's next?**

Drug Labels

What are they?

DRUG LABELS

Highlights of Prescribing Information

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.

PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol
Initial U.S. Approval: YYYY

---WARNING: TITLE OF WARNING---
See full prescribing information for complete boxed warning.
- Text (4)
- Text (5.x)

------------RECENT MAJOR CHANGES------------
Section Title, Subsection Title (x.x)   M/YYYY
Section Title, Subsection Title (x.x)   M/YYYY

------------INDICATIONS AND USAGE------------
PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for … (1)

Limitations of Use
Text (1)

------------DOSAGE AND ADMINISTRATION------------
- Text (2.x)
- Text (2.x)

------------DOSAGE FORMS------------
Dosage form(s): strength(s) (3)

------------CONTRAINDICATIONS------------
- Text (4)
- Text (4)

------------WARNINGS AND PRECAUTIONS------------
- Text (5.x)
- Text (5.x)

------------ADVERSE REACTIONS------------
Most common adverse reactions (incidence > x%) are text (6.x).

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

------------DRUG INTERACTIONS------------
- Text (7.x)
- Text (7.x)

------------USE IN SPECIFIC POPULATIONS------------
- Text (8.x)
- Text (8.x)

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

Revised: M/YYYY

Table of Contents

FULL PRESCRIBING INFORMATION: CONTENTS*
WARNING: TITLE OF WARNING
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
  2.1 Subsection Title
  2.2 Subsection Title
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
  5.1 Subsection Title
  5.2 Subsection Title
6 ADVERSE REACTIONS
  6.1 Clinical Trials Experience
  6.2 Immunogenicity
  6.2 or 6.3 Postmarketing Experience
7 DRUG INTERACTIONS
  7.1 Subsection Title
  7.2 Subsection Title
8 USE IN SPECIFIC POPULATIONS
  8.1 Pregnancy
  8.2 Lactation (if not required to be in PLLR format use Labor and Delivery)
  8.3 Females and Males of Reproductive Potential (If not required to be in PLLR format use Nursing Mothers)
  8.4 Pediatric Use
  8.5 Geriatric Use
  8.6 Subpopulation X
9 DRUG ABUSE AND DEPENDENCE
  9.1 Controlled Substance
  9.2 Abuse
  9.3 Dependence
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
  12.1 Mechanism of Action
  12.2 Pharmacodynamics
  12.3 Pharmacokinetics
  12.4 Microbiology
  12.5 Pharmacogenomics
13 NONCLINICAL TOXICOLOGY
  13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
  13.2 Animal Toxicology and/or Pharmacology
14 CLINICAL STUDIES
  14.1 Subsection Title
  14.2 Subsection Title
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

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

Full Prescribing Information

FULL PRESCRIBING INFORMATION

WARNING: TITLE OF WARNING

- Text *[see Contraindications (4)]*
- Text *[see Warnings and Precautions (5.x)]*

1 INDICATIONS AND USAGE
PROPRIETARY NAME is indicated for …

Limitations of Use
Text

2 DOSAGE AND ADMINISTRATION

2.1 Subsection Title (e.g., Recommended Dosage)

2.2 Subsection Title (e.g., Administration Instructions)

3 DOSAGE FORMS AND STRENGTHS
Dosage form #1: strength(s)
Dosage form #2: strength(s)

4 CONTRAINDICATIONS

Source: FDA https://www.fda.gov/about-fda/fda-organization

DRUG LABEL USERS

PHARMACEUTICAL INDUSTRY

Regulatory affairs, operations, compliance, labelling, medical affairs, etc

ACADEMIC RESEARCHERS

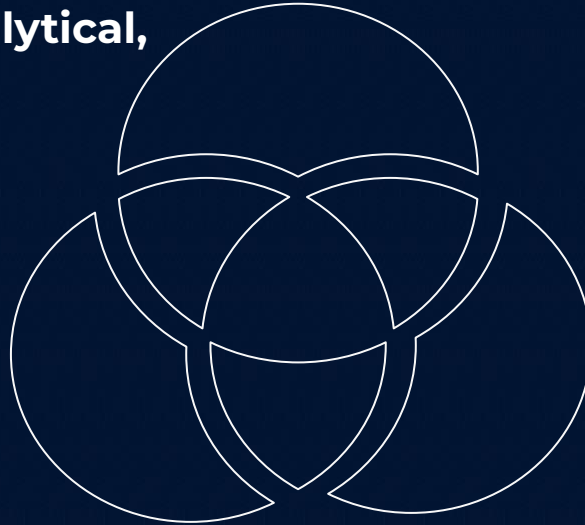Life sciences, medical, interdisciplinary, public health

PUBLIC HEALTH SPECIALISTS

Scientists, compliance specialists, epidemiologists

DRUG LABEL USE CASES

Research (Analytical, Exploratory)

Improve decision-making process in developing custom labels

Case Studies

DRUG LABEL CHALLENGES

Manual and tedious

Multiple agencies/sources

Noisy data

DLE

Our site

Demo

https://youtu.be/t8XdRJmkTL0

- Drug Label Search

- Data: EMA & FDA

- Comparisons

- History

- My Labels

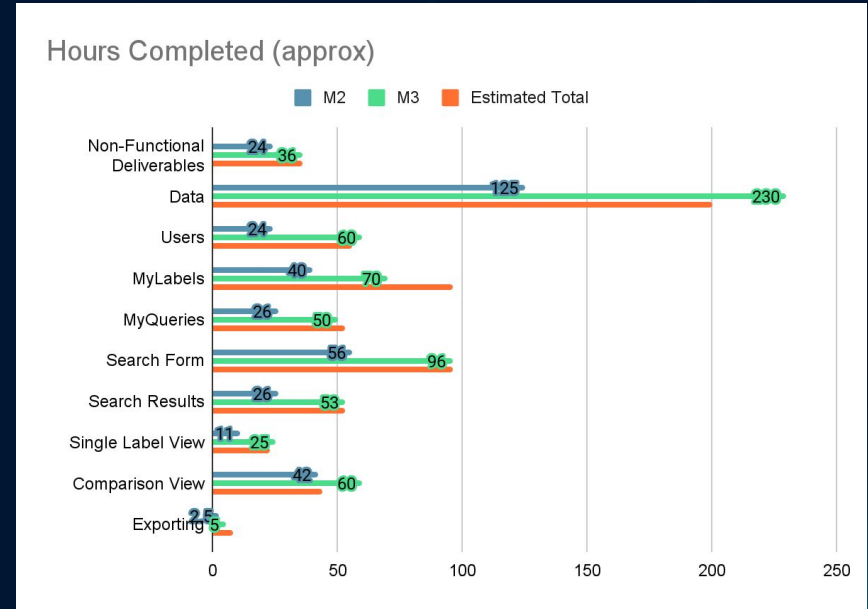**- Content Shareable (via direct links)**
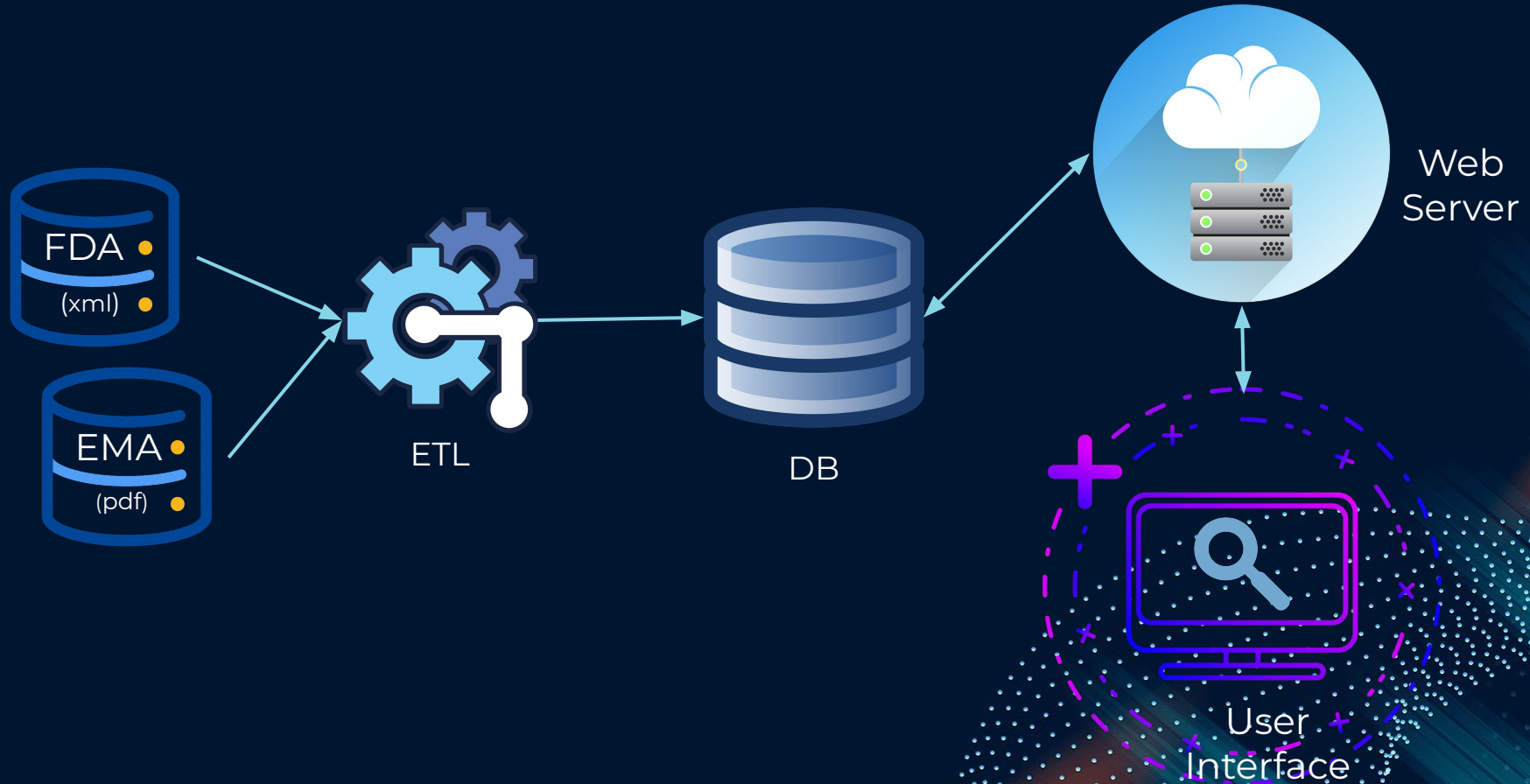
Methods

How 5 strangers built this in 4 months

63

Line item deliverables

- 10 Functional Areas
- 9 Week-long Sprints
- Gitlab Task Tracking
- Code Reviews with automated CI/CD

Hours Completed (approx)

Legend: M2, M3, Estimated Total

Functional Area	M2	M3
Non-Functional Deliverables	24	36
Data	125	230
Users	24	60
MyLabels	40	70
MyQueries	26	50
Search Form	56	96
Search Results	26	53
Single Label View	11	25
Comparison View	42	60
Exporting	2	5

Architecture

FDA (xml)

EMA (pdf)

ETL

DB

Web Server

User Interface

Future

What's next for DLE?

Transfer of ownership

- App is templatized via CloudFormation

- Client can deploy to private Pfizer cloud

Potential improvements

- MedDRA ontology

- Dedicated Semantic Search

Thank you!

We could not have done this without the incredible support from our client David Edelen, our professor Peter Henstock, and our TA Roman Burdakov. Thank you so much!

Questions?