

# Drug Label Explorer

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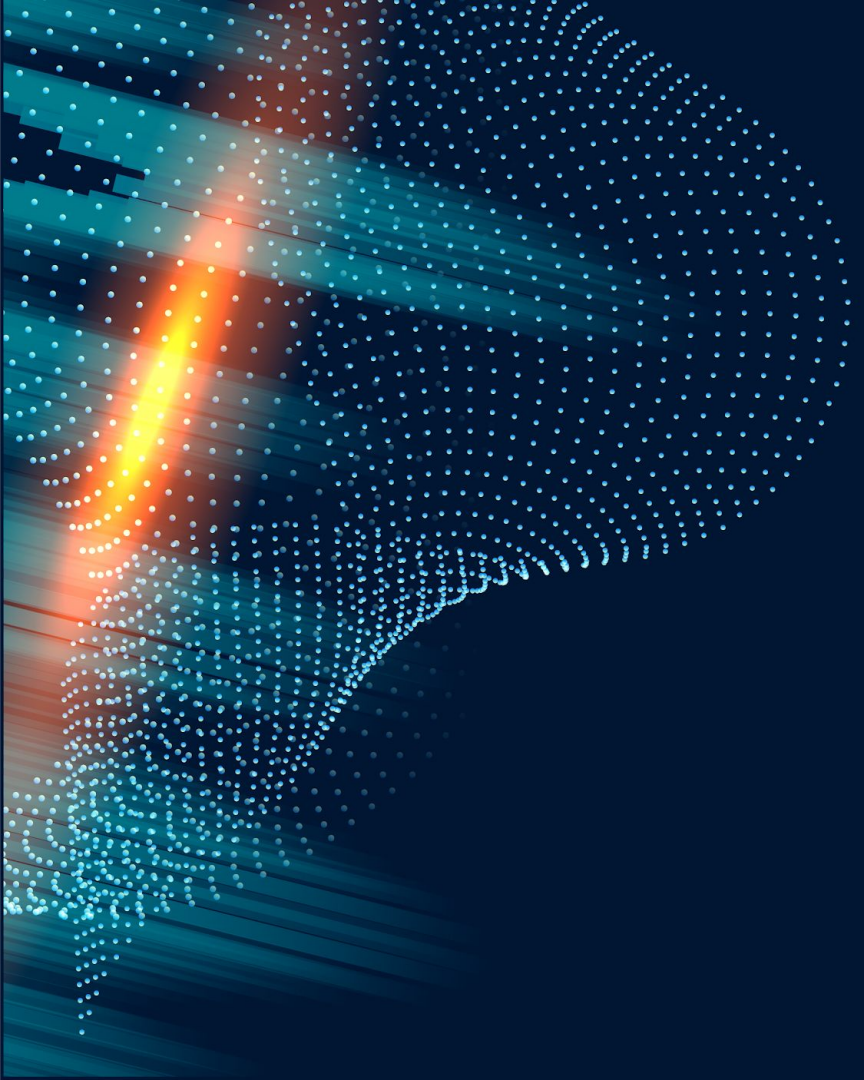
Ken Brown, Agi Kajanaku, Leo Landau,  
Sam Negassi, Ky Nguyen

# 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**  
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: YYY

**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) MYYYY  
Section Title, Subsection Title (x.x) MYYYY

**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)

**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

**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

**DOSAGE FORM**

(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 > 5%) 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](http://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 [Q&A](#) and Medication Guide.

Revised: M/YYYY

## Table of Contents

**9 DRUG ABUSE AND DEPENDENCE**

9.1 Controlled Substance

9.2 Abuse

9.3 Dependence

**10 OVERDOSE**

**11 DESCRIPTION**

**12 CLINICAL PHARMACOLOGY**

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

12.4 Monitoring

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

**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**

(no contraindications are known, this drug is not for use in children)

## Full Prescribing Information

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# DRUG LABEL USERS



## PHARMACEUTICAL INDUSTRY

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



## ACADEMIC RESEARCHERS

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Life sciences,  
medical,  
interdisciplinary,  
public health



## PUBLIC HEALTH SPECIALISTS

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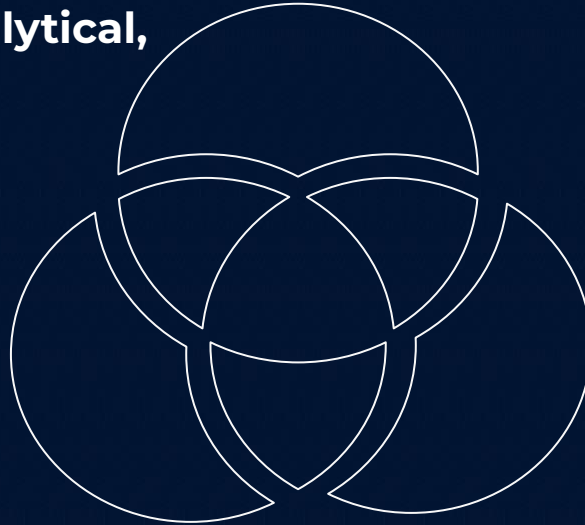
Scientists,  
compliance  
specialists,  
epidemiologists



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# DRUG LABEL USE CASES

**Research (Analytical,  
Exploratory)**



**Improve  
decision-making  
process in developing  
custom labels**

**Case Studies**

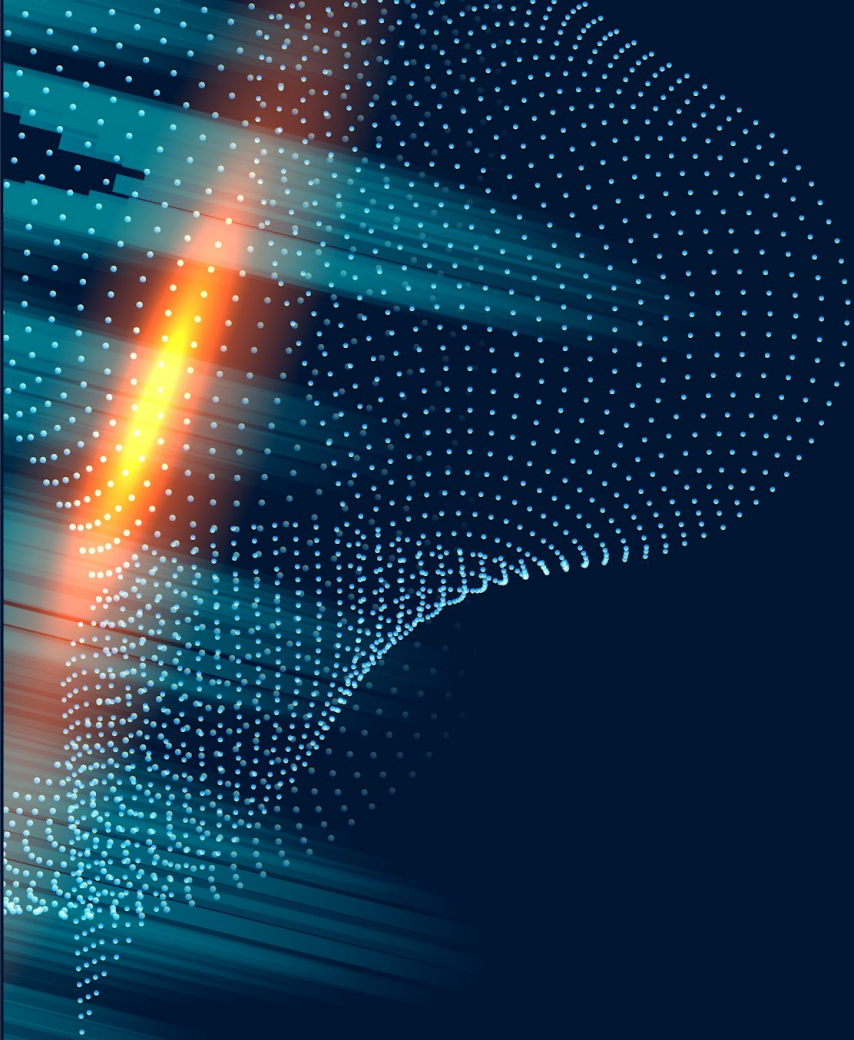
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# DRUG LABEL CHALLENGES

**Manual and tedious**

**Multiple agencies/sources**

**Noisy data**



# DLE

Our site



# Demo

- Drug Label Search
- Data: EMA & FDA
- Comparisons
- History
- My Labels
- Content Shareable (via direct links)





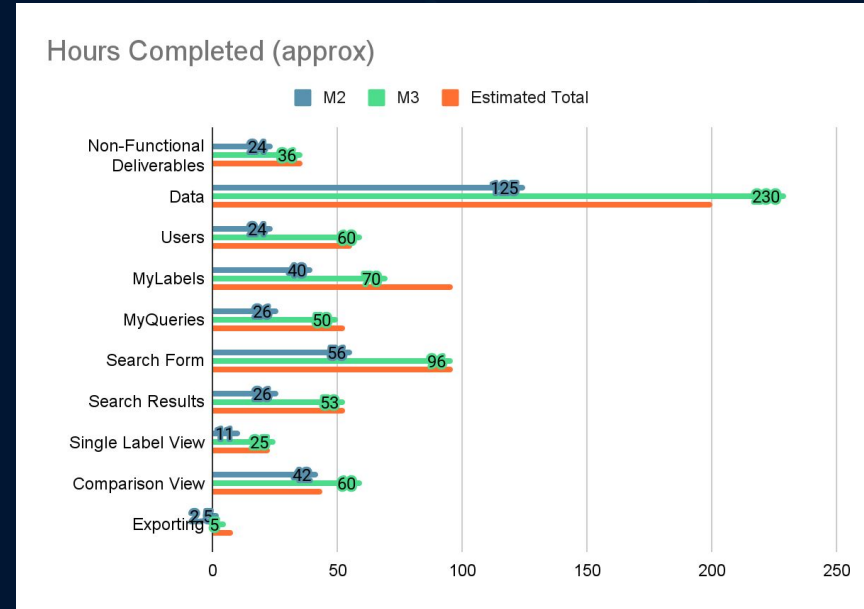
# Methods

How 5 strangers built this in 4 months

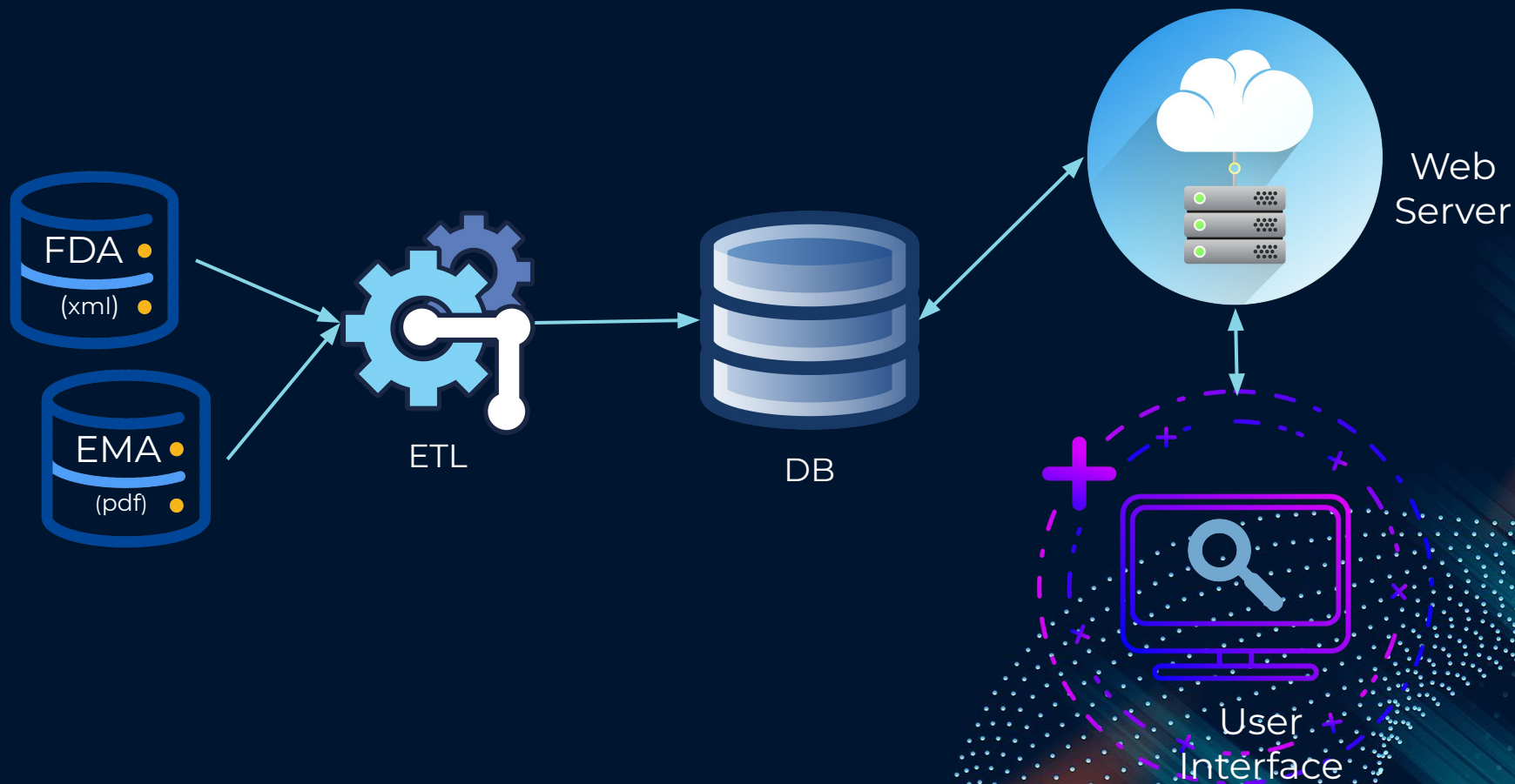
# 63

Line item deliverables

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



# Architecture







# Future

What's next for DLE?

## Transfer of ownership

- App is templated via CloudFormation
- Client can deploy to private Pfizer cloud



## Potential improvements

- MedDRA ontology
- Dedicated Semantic Search



**MedDRA**  
Medical Dictionary  
for Regulatory Activities

*APACHE*  
**LUCENE**™

 **meilisearch**

 **elasticsearch**

# 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!

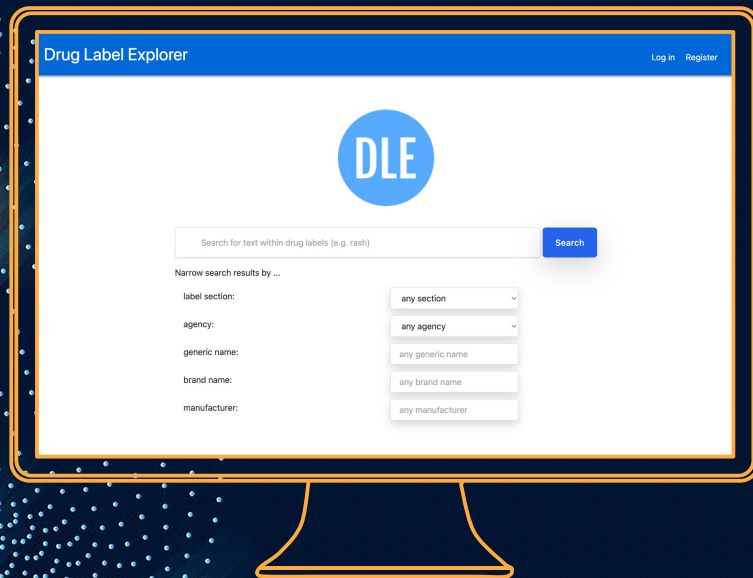
**Questions?**







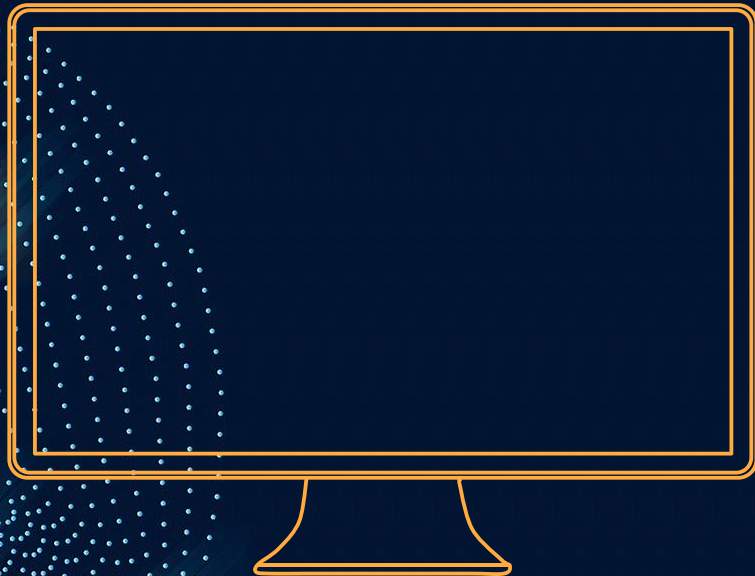
# SLIDE IDEA #1



Placeholder text -  
landing page

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Placeholder text -  
landing page