

Drug Label Explorer

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Overview



Today we're going to talk about:

1. **Defining the Problem**
2. **Developing our Solution***
3. **How does DLE work?**
4. **Next steps!**

***DEMO**

DRUG LABELS

- Definition: contain critical information on any prescription or over-the-counter medication
- Purpose: to inform healthcare providers of relevant information on dispensing and administering medication to patients

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 (6)
- Text (5.x)

RECENT MAJOR CHANGES
Section Title, Subsection Title (x.x) MYYY
Section Title, Subsection Title (x.x) MYYY

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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation (If not required to be in PLR format use Labor and Delivery)

8.3 Females and Males of Reproductive Potential (If not required to be in PLR 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 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.

Highlights of Prescribing Information

CONTRAINDICATIONS

- Text (4)
- Text (4)

WARNINGS AND PRECAUTIONS

- Text (5.x)
- Text (5.x)

ADVERSE REACTIONS
Most common adverse reactions (incidence > 1%) 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 [Q8](#) and Medication Guide.

Revised: MYYY

Table of Contents

Full Prescribing Information

DRUG LABEL USERS



PHARMACEUTICAL COMPANIES

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



Case Studies

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

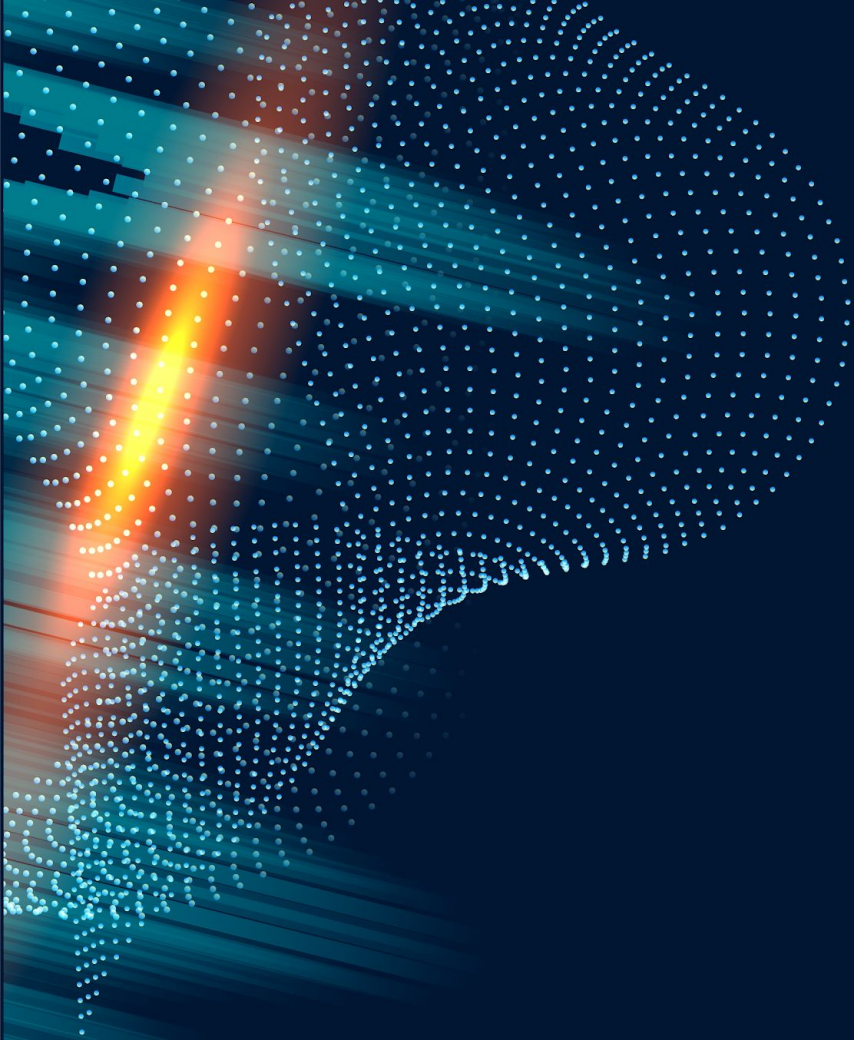
DRUG LABEL CHALLENGES

**Lack of
discoverability**

**Multiple
sources**

**Too manual
and tedious**

**Storage of
custom labels**



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

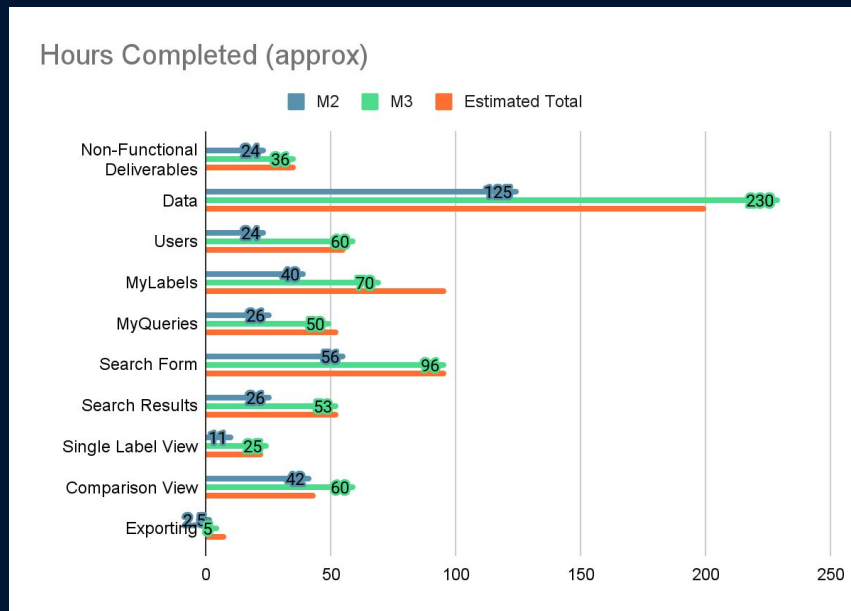
Line item deliverables

Agile Framework

- 665 estimated hours of work
- 10 Functional Areas
- 9 Week-long Sprints
- Gitlab Task Tracking
- 1, 2, and then 3 synchronous meetings weekly
- Retrospective after Milestones

<input type="checkbox"/> 1 Open <input checked="" type="checkbox"/> 42 Closed		Author	Label	Projects	Milestones	Assignee	Sort
<input type="checkbox"/>	<input checked="" type="radio"/> fix sigle label highlighting	enhancement				11, 1	
	#102 by samNison was closed 5 hours ago Milestone 3						
<input type="checkbox"/>	<input checked="" type="radio"/> fix overlapping input boxes in search results					11, 1	
	#96 by ky-soren was closed 22 hours ago						
<input type="checkbox"/>	<input checked="" type="radio"/> Bug due to cashing search/index	bug				11, 1	
	#93 by samNison was closed yesterday						
<input type="checkbox"/>	<input checked="" type="radio"/> update users app, login/register					11, 1	
	#91 by samNison was closed 2 days ago						
<input type="checkbox"/>	<input checked="" type="radio"/> my_labels - 2					11, 1	
	#82 by llantau was closed 3 days ago						
<input type="checkbox"/>	<input checked="" type="radio"/> Compare: sort sections					11, 1	
	#76 by samNison was closed 4 days ago Milestone 3						
<input type="checkbox"/>	<input checked="" type="radio"/> remove redundant ampersand in pagination linking					11, 1	
	#74 by ky-soren was closed 4 days ago						
<input type="checkbox"/>	<input checked="" type="radio"/> my_labels record insertion can fail due to duplicate product_number					11, 1	

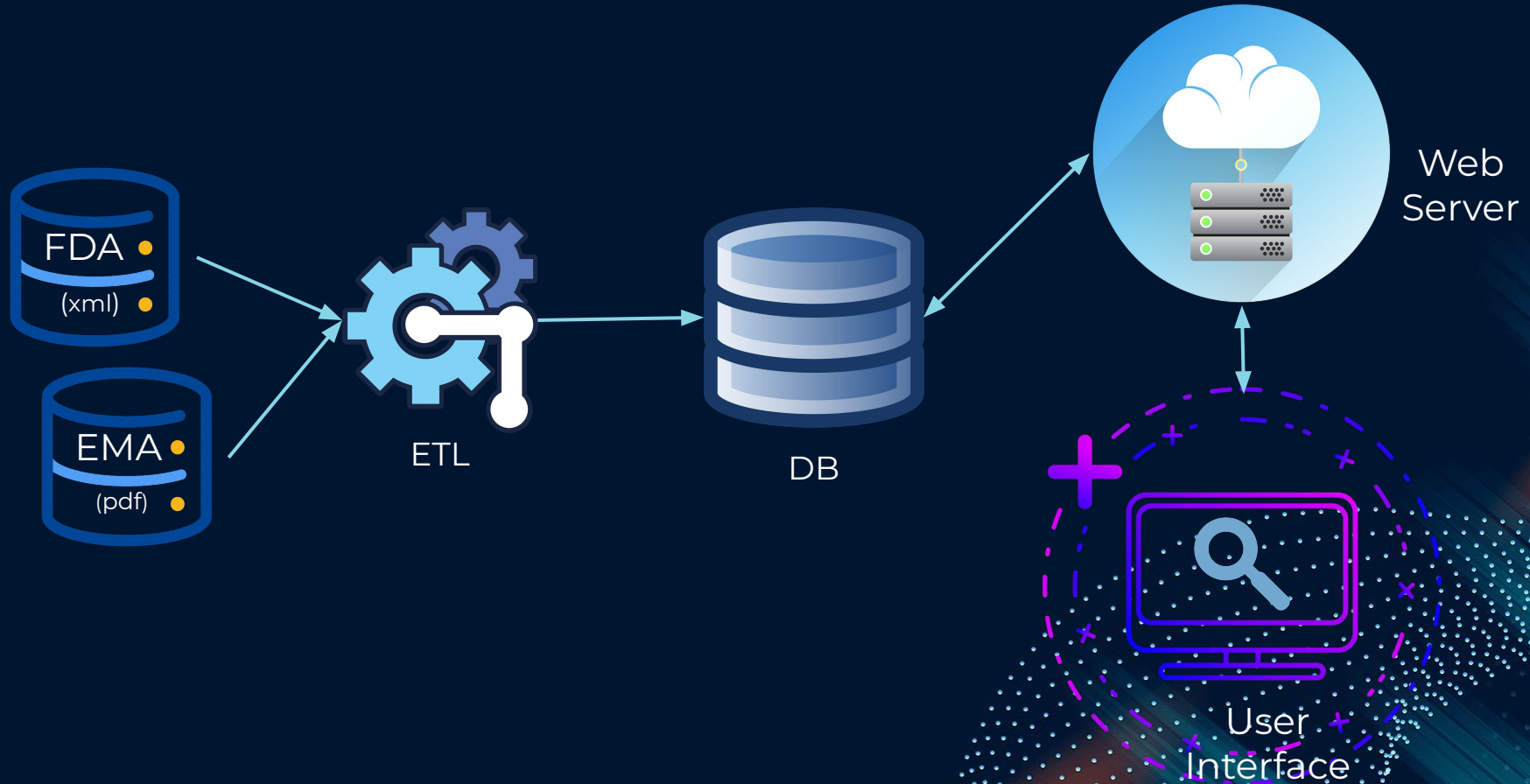
Estimates



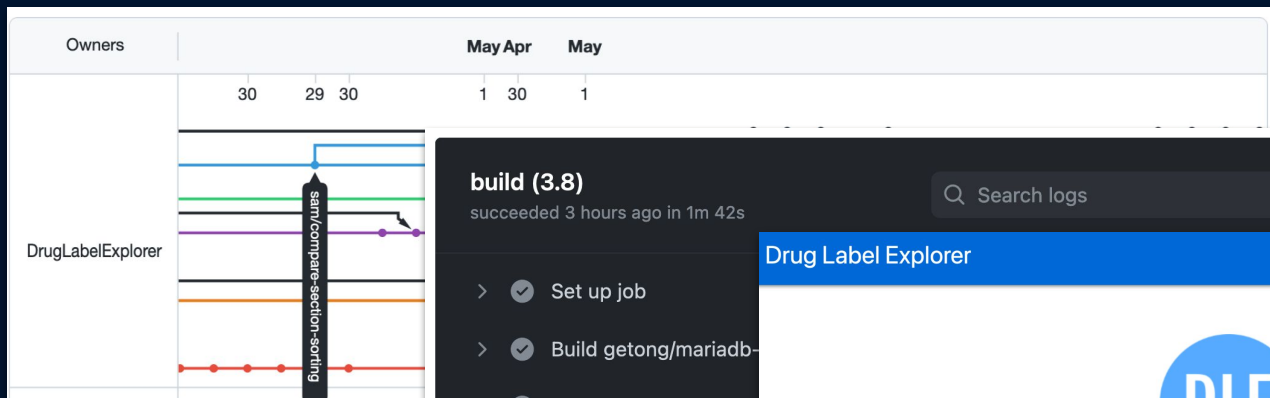
Most estimates were very close to actual amount of time needed

Largest amount of unplanned work came from emergent feature requests

Architecture



CI/CD



build (3.8)


succeeded 3 hours ago in 1m 42s

Search logs

- > ✓ Set up job
- > ✓ Build getong/mariadb-
- > ✓ Run actions/checkout
- > ✓ Shutdown Ubuntu Mys
- > ✓ Run getong/mariadb-a
- > ✓ Set up Python 3.8
- > ✓ Install Dependencies
- > ✓ Run Tests

Drug Label Explorer

Log in Register



Search for text within drug labels (e.g. rash) Search

Narrow search results by ...

label section:	any section
agency:	any agency
generic name:	any generic name
brand name:	any brand name
manufacturer:	any manufacturer



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
- BERT Model
(ML for NLP)
- 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?

