Drug Label Explorer

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OUTLINE

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

*DEMO

DIGI-TECH PHARMA & AI 2022

CORVUS
GLOBAL EVENTS

DRUG LABELS

- Communicate critical information on how a medication must be used.
- Regulations impact patient access.
- It is crucial to get drug labeling right by using clear and precise language.

FDA DRUG LABEL (US)

APPENDIX E —HIGHLIGHTS AND CONTENTS FORMAT SAMPLE

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

[DRUG NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol]
Initial U.S. Approval: [year]

WARNING: [SUBJECT OF WARNING]
See full prescribing information for complete boxed warning.
- **[text]**
- **[text]**

----------RECENT MAJOR CHANGES----------
[section (X.X)] [m/year]
[section (X.X)] [m/year]

----------INDICATIONS AND USAGE----------
[DRUG NAME] is a [name of pharmacologic class] indicated for:
- [text]
- [text]

----------DOSAGE AND ADMINISTRATION----------
- [text]
- [text]

----------DOSAGE FORMS AND STRENGTHS----------
- [text]

----------CONTRAINDICATIONS----------
- [text]
- [text]

----------WARNINGS AND PRECAUTIONS----------
- [text]
- [text]

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

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

----------DRUG INTERACTIONS----------
- [text]
- [text]

----------USE IN SPECIFIC POPULATIONS----------
- [text]
- [text]

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

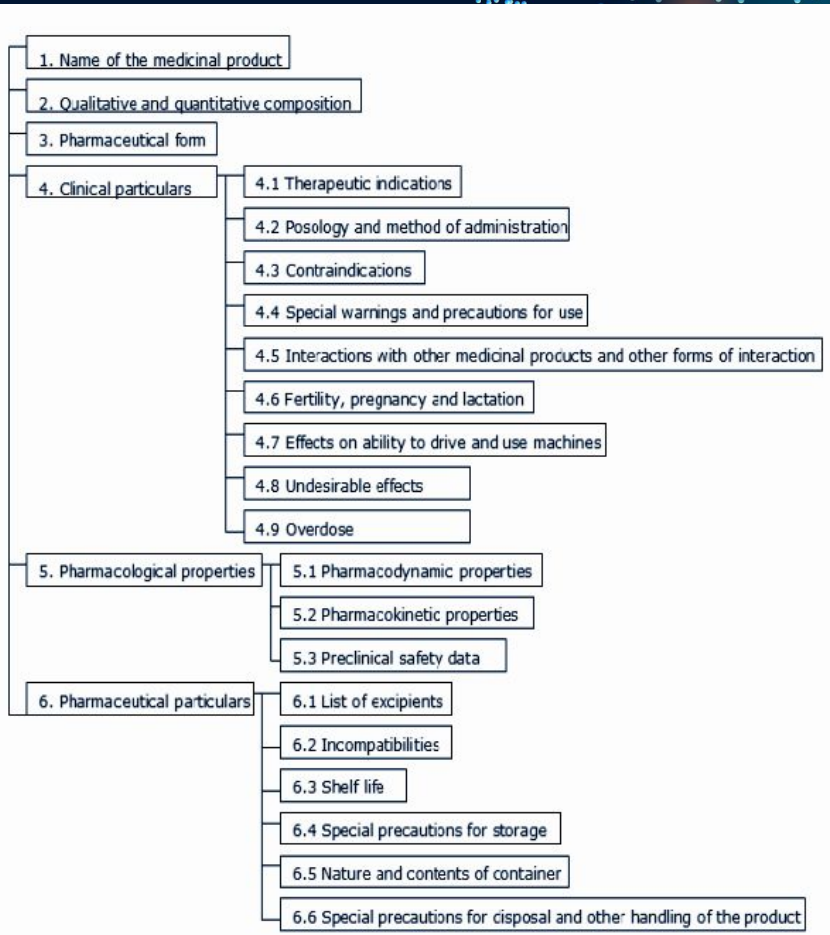
Revised: [m/year]

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: [SUBJECT OF WARNING]
1 INDICATIONS AND USAGE
1.1 [text]
1.2 [text]
2 DOSAGE AND ADMINISTRATION
2.1 [text]
2.2 [text]
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 [text]
5.2 [text]
6 ADVERSE REACTIONS
6.1 [text]
6.2 [text]
7 DRUG INTERACTIONS
7.1 [text]
7.2 [text]
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Labor and Delivery
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
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 [text]
14.2 [text]
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

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

EMA DRUG LABEL (EU)



DRUG LABEL USERS

PUBLIC HEALTH SPECIALISTS

- Scientists
- Compliance specialists
- Epidemiologists

ACADEMIC RESEARCHERS

- Life sciences
- Medical
- Interdisciplinary
- Public health

PHARMACEUTICAL COMPANIES

- Regulatory affairs
- Operations
- Compliance
- Labelling
- Medical affairs, etc

DRUG LABEL CHALLENGES

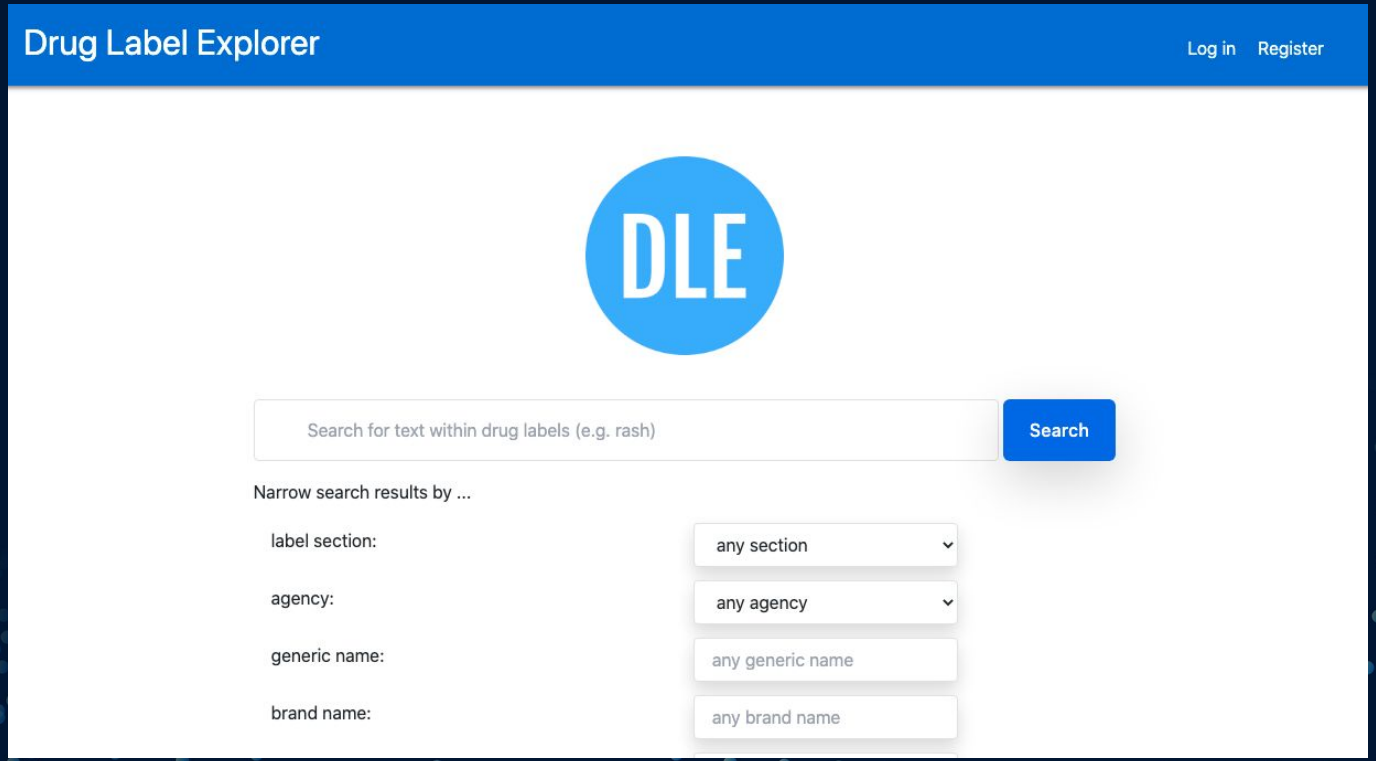
Multiple sources

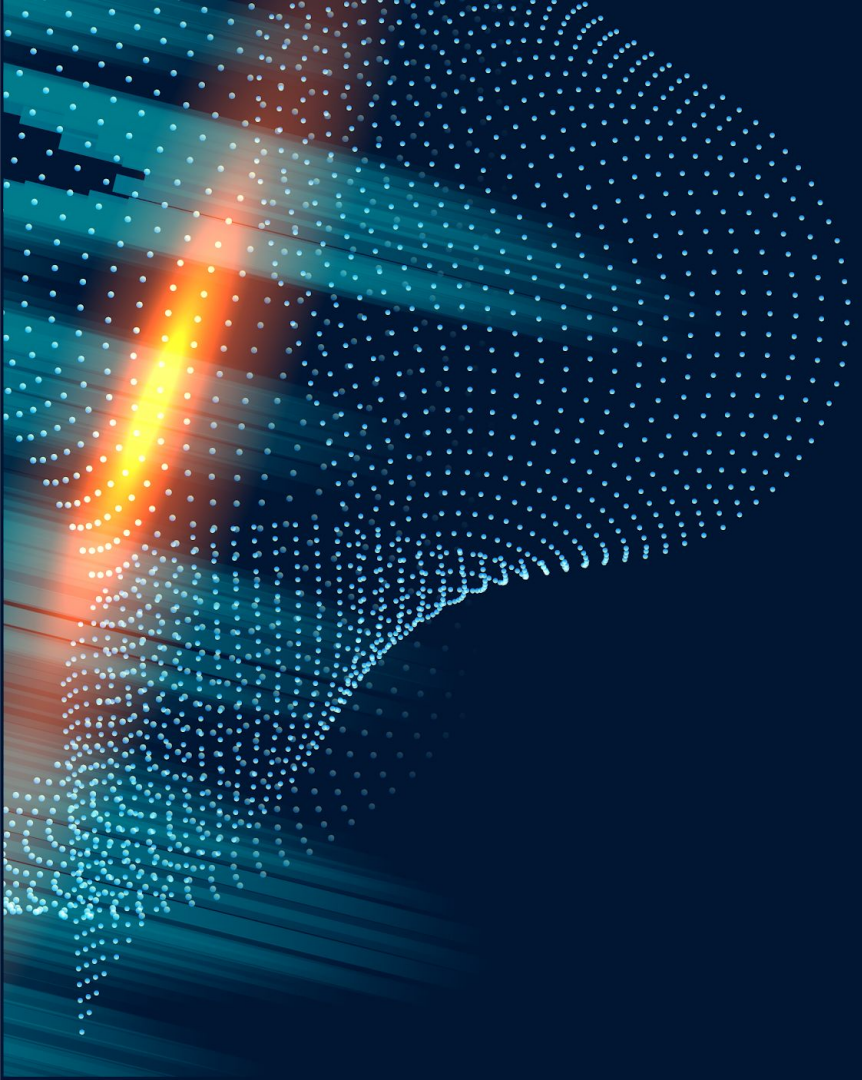
Lack of discoverability

Too manual and tedious

Improve custom labels

DEMO


Drug Label Explorer
Log in
Register
DLE
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



Methods

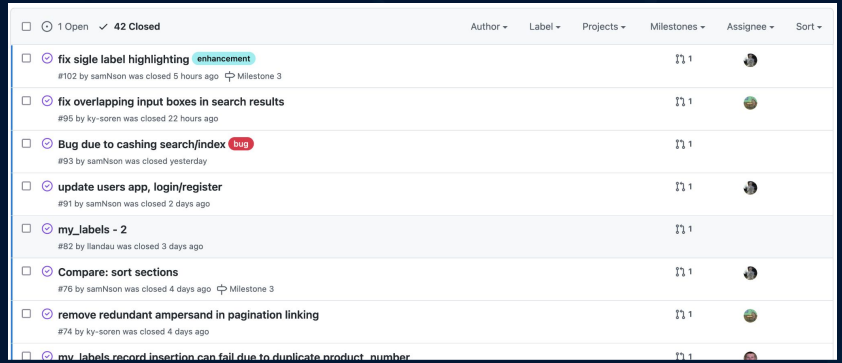
How we built this

63

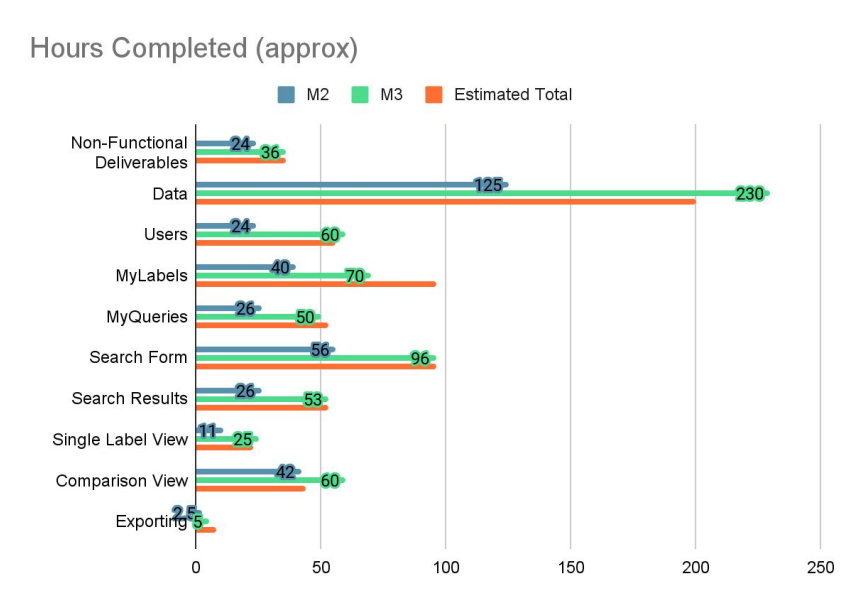
Line item deliverables

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

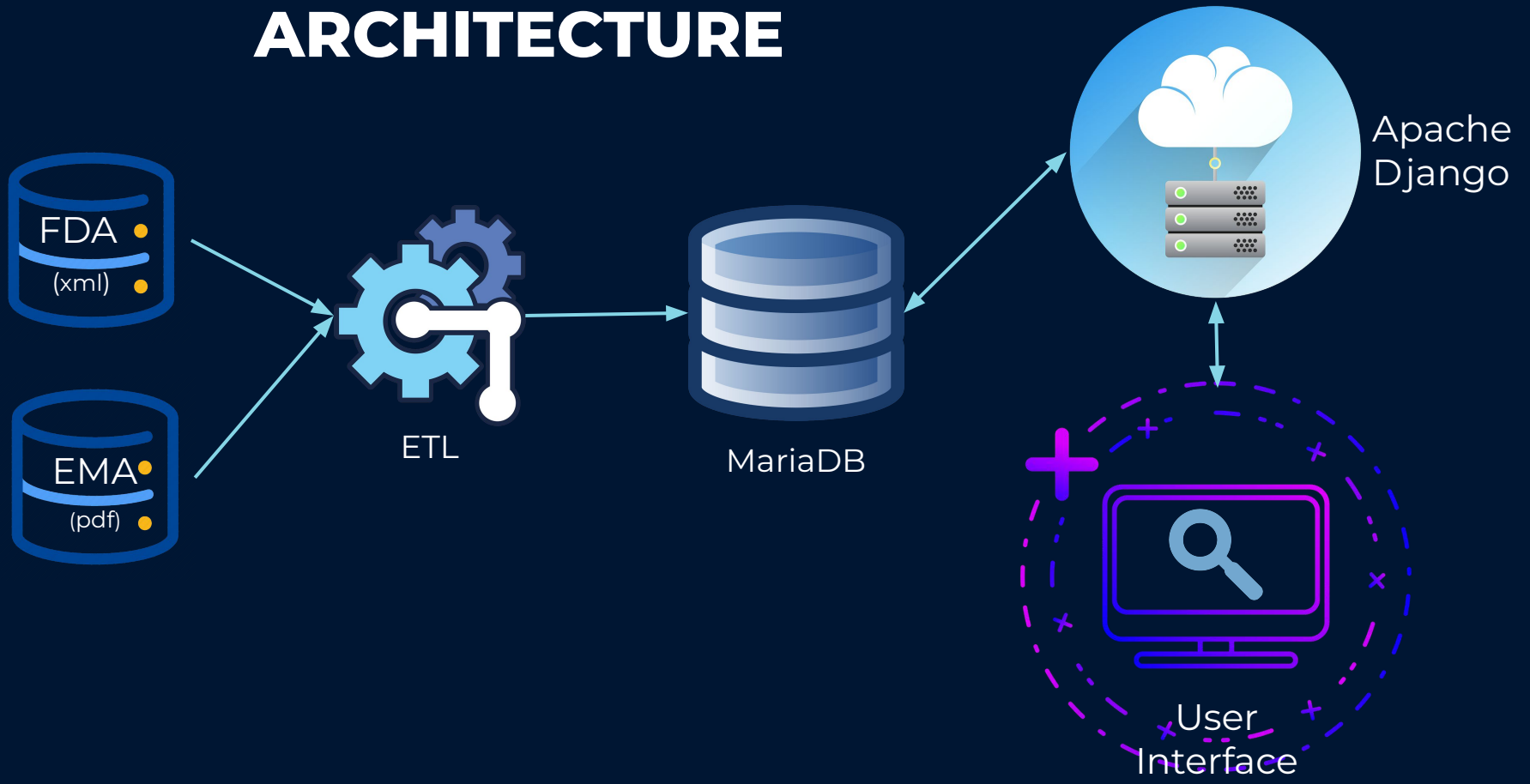


ESTIMATES

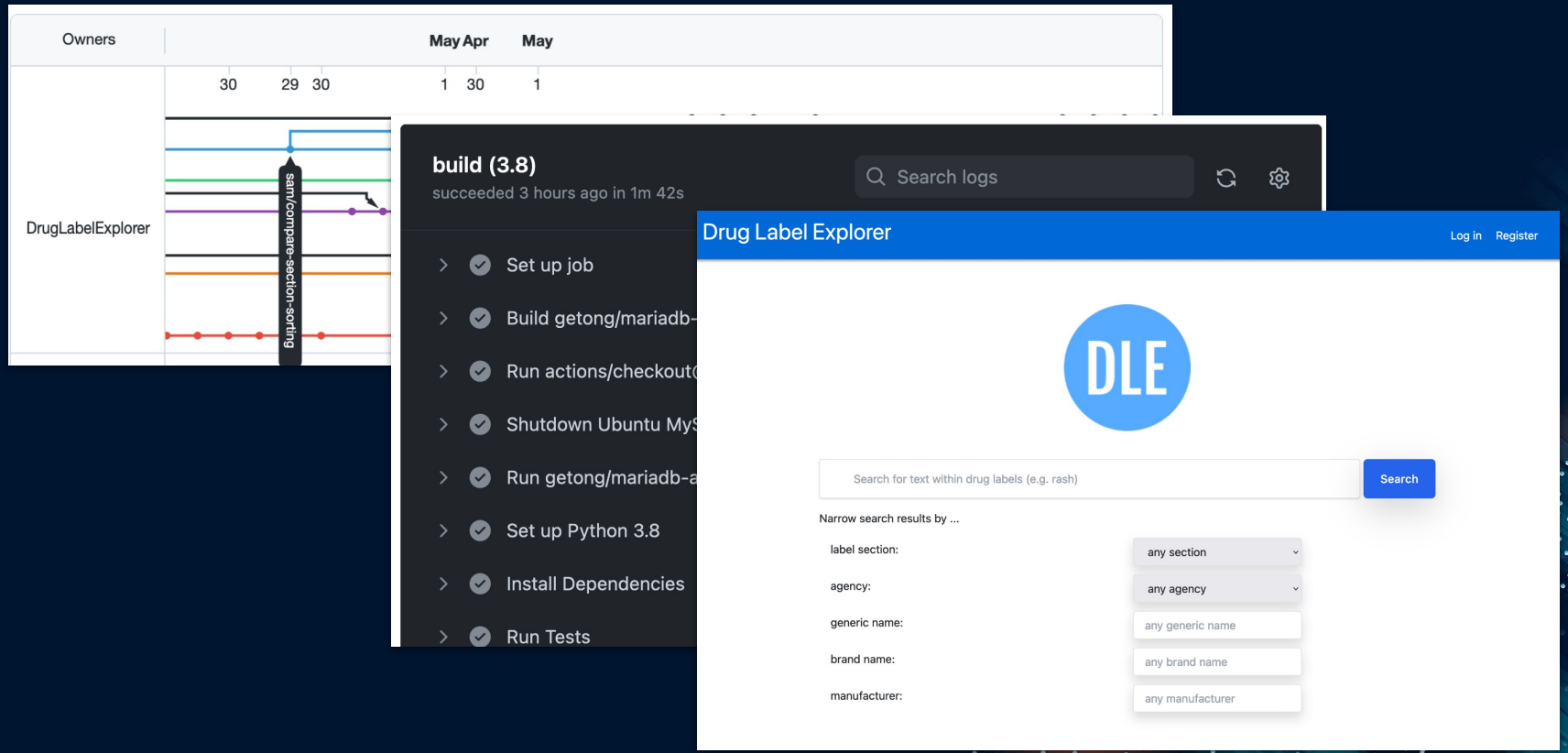


- Most estimates were very close to actual amount of time needed
- Largest amount of unplanned work came from emergent feature requests

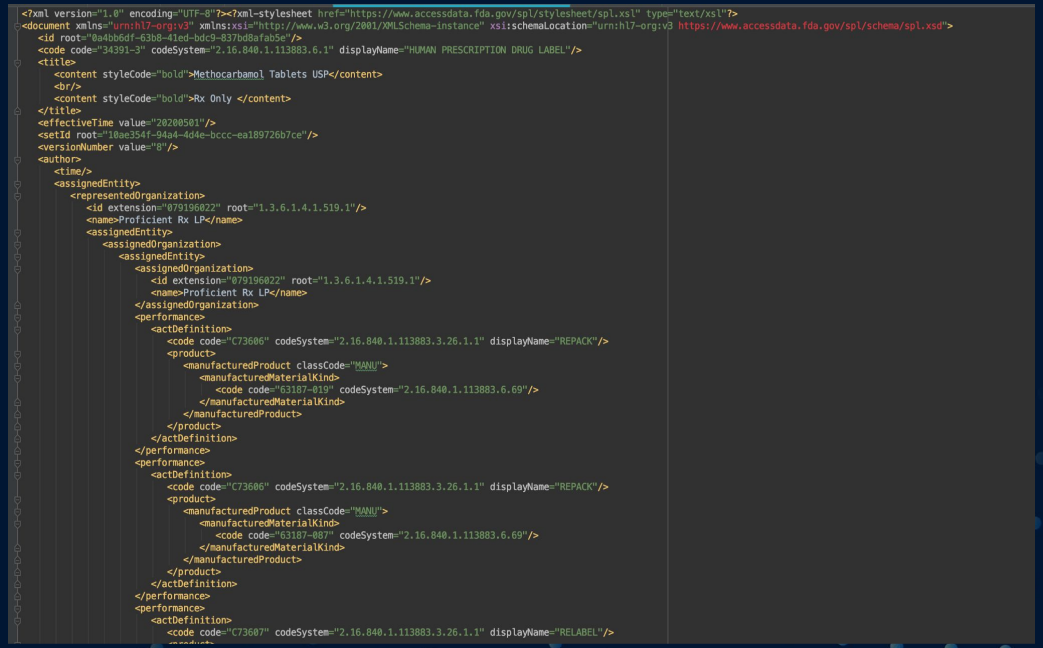
ARCHITECTURE



CI/CD


Owners
May Apr
May
30
29
30
1
30
1
DrugLabelExplorer
sam/compare-section-sorting
build (3.8)
succeeded 3 hours ago in 1m 42s
Search logs
Set up job
Build getong/mariadb-
Run actions/checkout
Shutdown Ubuntu My
Run getong/mariadb-a
Set up Python 3.8
Install Dependencies
Run Tests
Drug Label Explorer
Log in
Register
DLE
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

STRUCTURED DATA



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      <br/>
      <content styleCode="bold">Rx Only </content>
   </title>
   <effectiveTime value="20200501"/>
   <setId root="10ae354f-94a4-4d4e-bccc-ea189726b7ce"/>
   <versionNumber value="8"/>
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      <time/>
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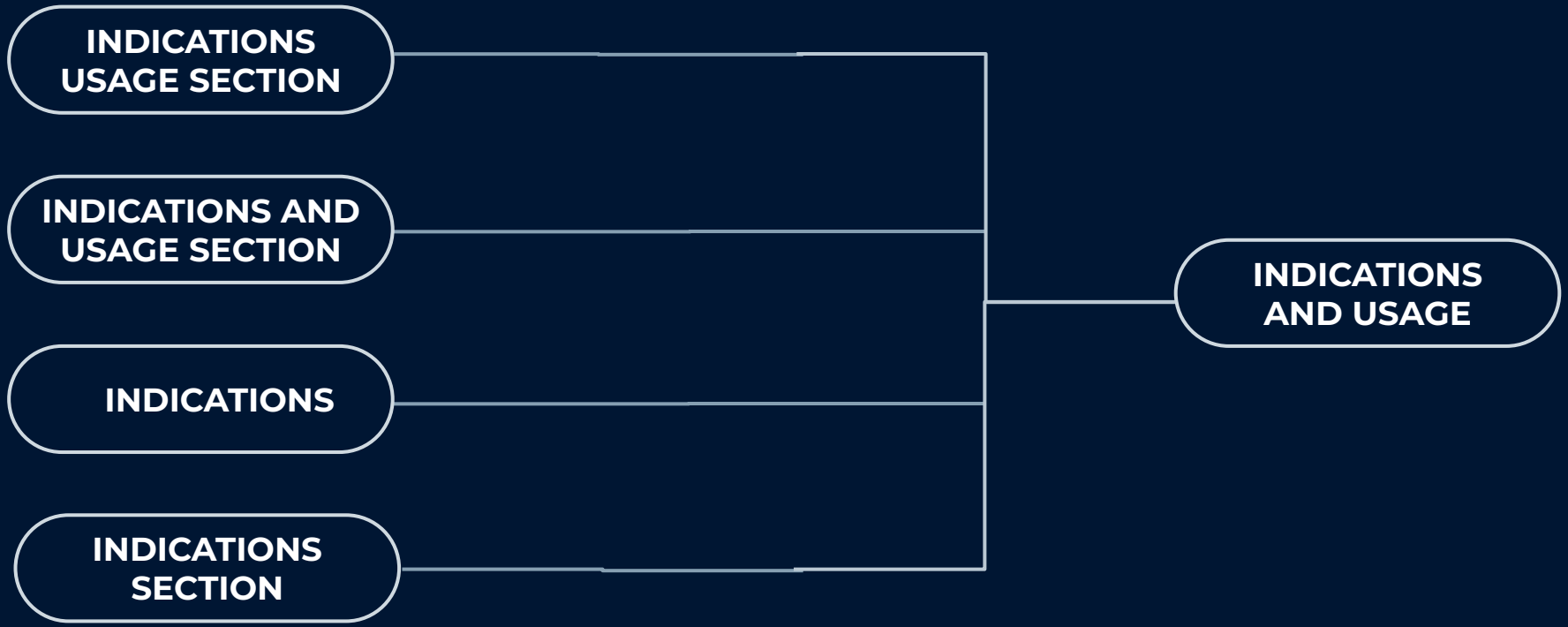
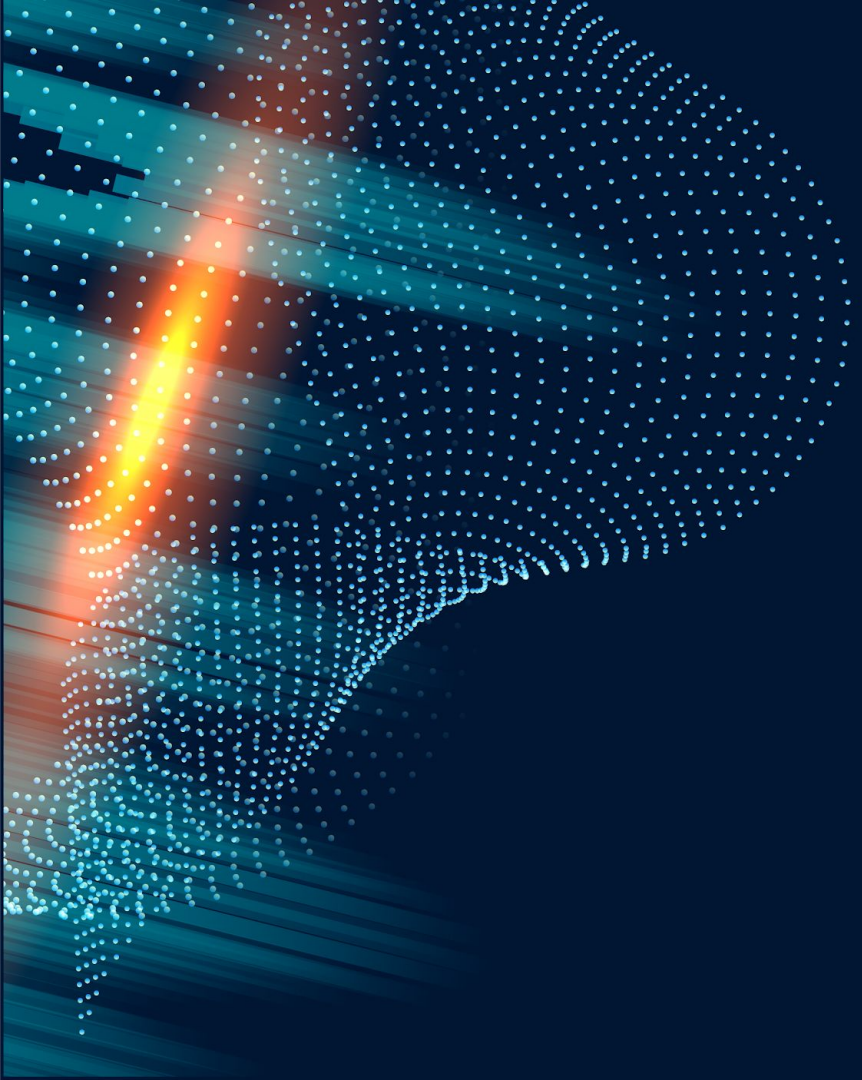
46,000 XMLs from FDA

2000 lines each

1,200 PDFs from EMA

TEXT SIMILARITY





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
- BERT Model
  (ML for NLP)
- Dedicated Semantic Search

SUMMARY

- Open Source https://github.com/DrugLabelExplorer/dle
- Powerful search tools
- Side-by-Side comparisons
- Sections linked across labels
- Live druglabelexplorer.org

QUESTIONS?

THANK YOU