

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



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)

1. Name of the medicinal product

2. Qualitative and quantitative composition

3. Pharmaceutical form

4. Clinical particulars

4.1 Therapeutic indications

4.2 Posology and method of administration

4.3 Contraindications

4.4 Special warnings and precautions for use

4.5 Interactions with other medicinal products and other forms of interaction

4.6 Fertility, pregnancy and lactation

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

4.9 Overdose

5. Pharmacological properties

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. Pharmaceutical particulars

6.1 List of excipients

6.2 Incompatibilities

6.3 Shelf life

6.4 Special precautions for storage

6.5 Nature and contents of container

6.6 Special precautions for disposal and other handling of the product

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 inRegister



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

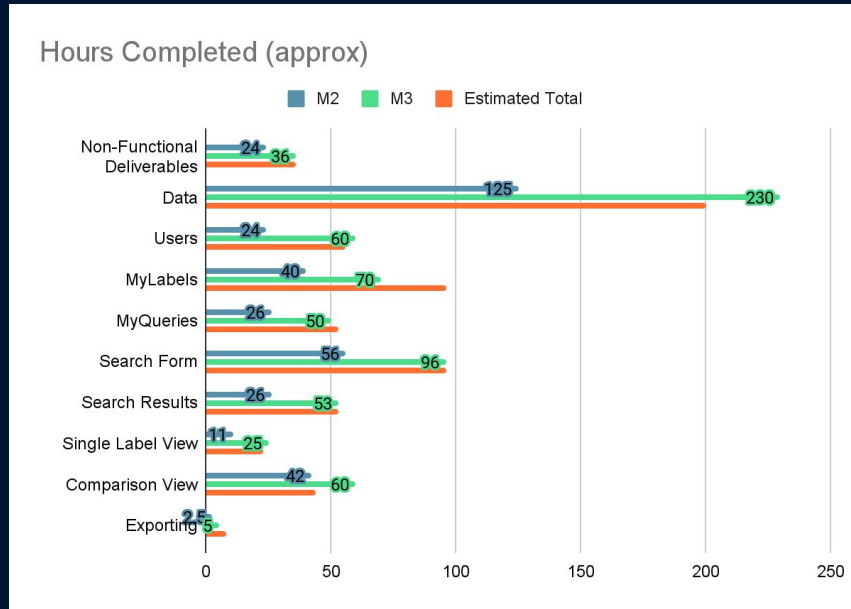
Line item deliverables

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

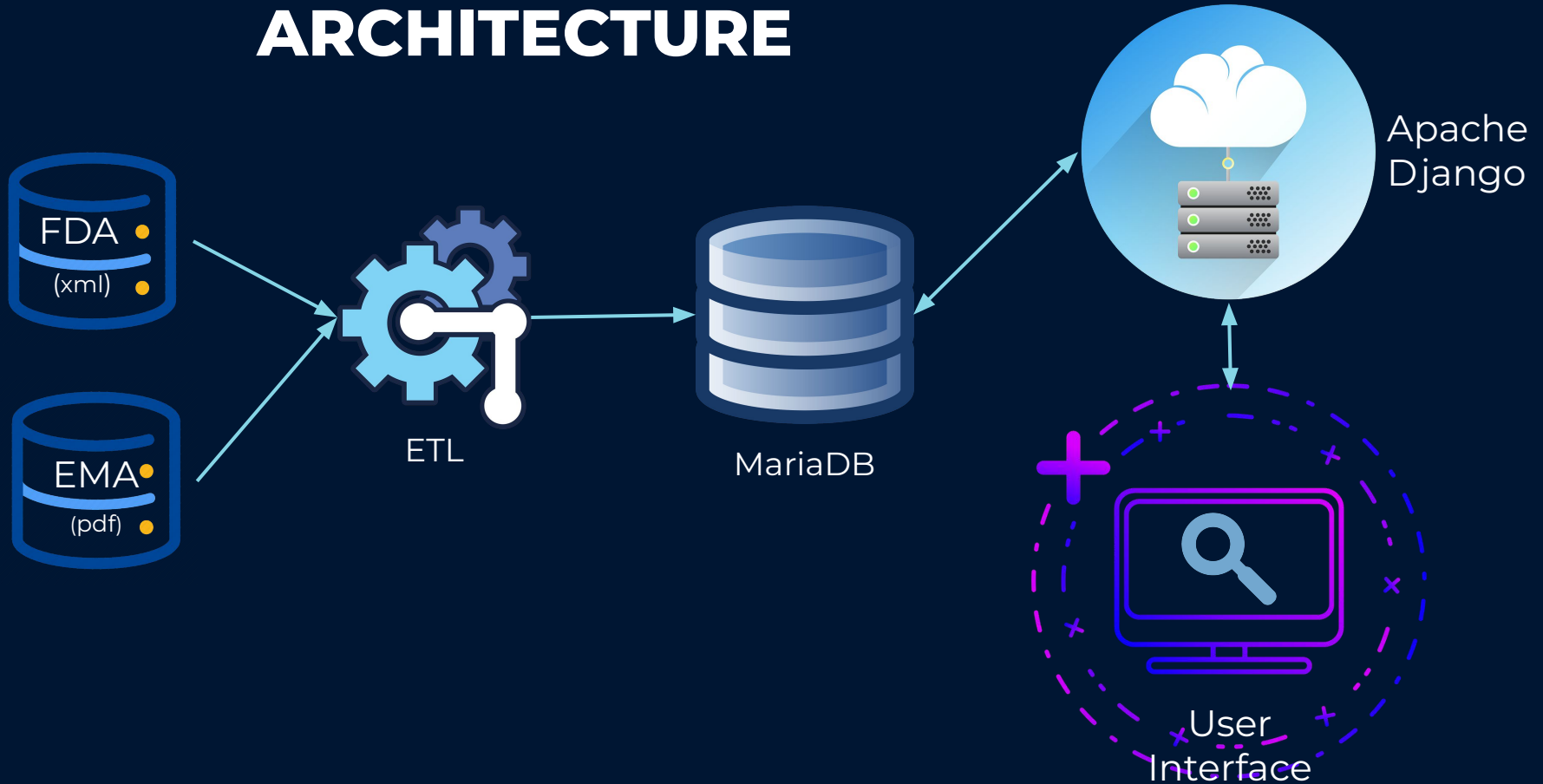
<input type="radio"/> 1 Open	<input checked="" type="radio"/> 42 Closed	Author ▾	Label ▾	Projects ▾	Milestones ▾	Assignee ▾	Sort ▾
<input type="checkbox"/>	<input checked="" type="checkbox"/>	fix sigle label highlighting	enhancement				
#102 by samNson was closed 5 hours ago  Milestone 3							
<input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

ESTIMATES

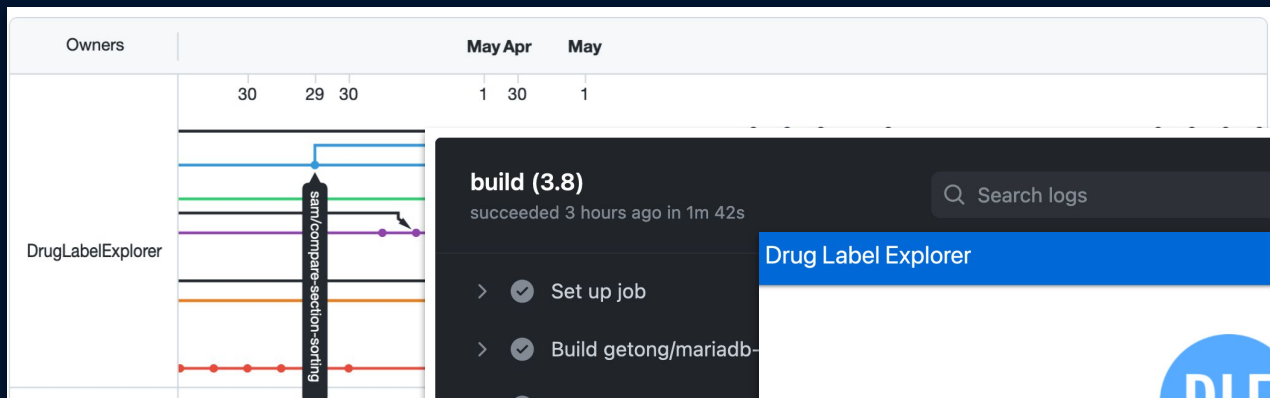


- Most estimates were very close to actual amount of time needed
- Largest amount of unplanned work came from emergent feature requests

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](#)

STRUCTURED DATA

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<?xml version="1.0" encoding="UTF-8"?><?xml-stylesheet href="https://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" type="text/xsl"?>
<document xmlns="urn:h17-org:v3" xmlns:xsl="http://www.w3.org/2001/XMLSchema-instance" xsl:schemaLocation="urn:h17-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <id root="8a4bb6df-63b8-41ed-bdc9-837bd8afab5e"/>
  <code code="34391-3" codeSystem="2.16.840.1.113883.6.1" displayName="HUMAN PRESCRIPTION DRUG LABEL"/>
  <title>
    <content styleCode="bold">Methocarbamol Tablets USP</content>
    <br/>
    <content styleCode="bold">Rx Only</content>
  </title>
  <effectiveTime value="20200501"/>
  <setId root="18aw354f-44a4-4d4e-bccc-ea189726b7ce"/>
  <versionNumber value="8"/>
  <authors>
    <time/>
    <assignedEntity>
      <representedOrganization>
        <id extension="079196022" root="1.3.6.1.4.1.519.1"/>
        <name>Proficient Rx LP</name>
      </representedOrganization>
      <assignedEntity>
        <assignedOrganization>
          <assignedEntity>
            <assignedOrganization>
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            </assignedOrganization>
            <performance>
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                <product>
                  <manufacturedProduct classCode="MANU">
                    <manufacturedMaterialKind>
                      <code code="63187-019" codeSystem="2.16.840.1.113883.6.69"/>
                    </manufacturedMaterialKind>
                  </manufacturedProduct>
                </product>
              </actDefinition>
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          </assignedOrganization>
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                    <code code="63187-019" codeSystem="2.16.840.1.113883.6.69"/>
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                </manufacturedProduct>
              </product>
            </actDefinition>
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      <actDefinition>
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      </actDefinition>
    </assignedEntity>
  </authors>

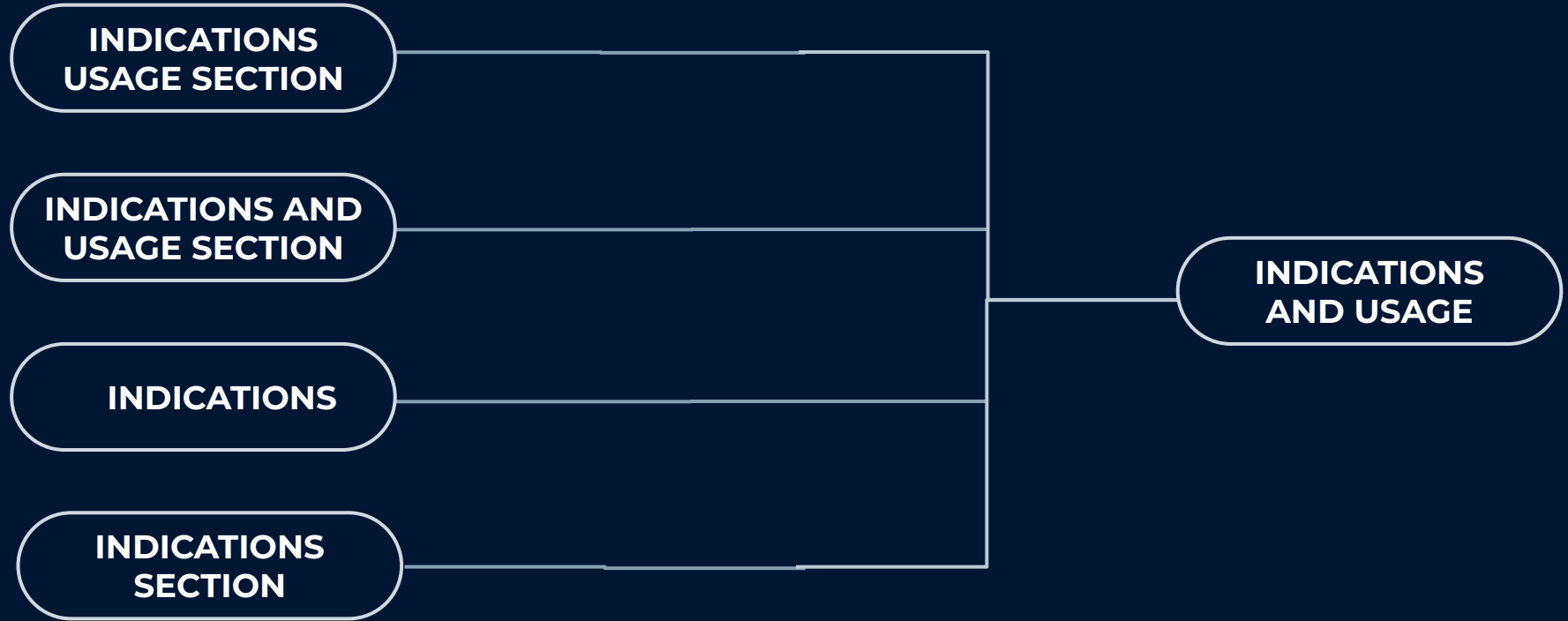
```

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 templated 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 druglabeexplorer.org**

QUESTIONS?



DLE



THANK YOU
