

Drug Label Explorer

DIGI-TECH PHARMA & AI 2022

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OUTLINE

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



*DEMO

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

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

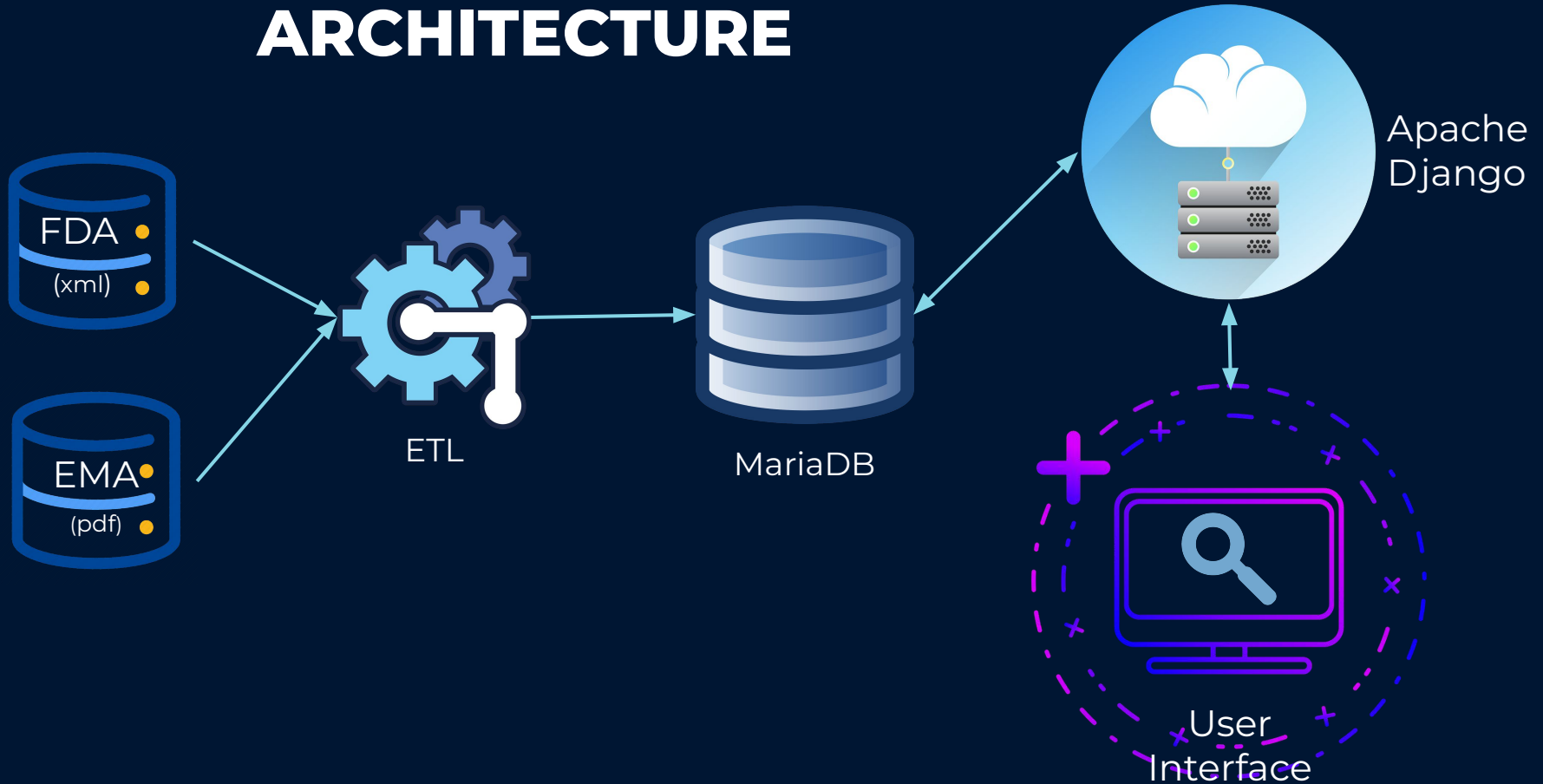
How we built this



63

Line item deliverables

ARCHITECTURE



STRUCTURED DATA

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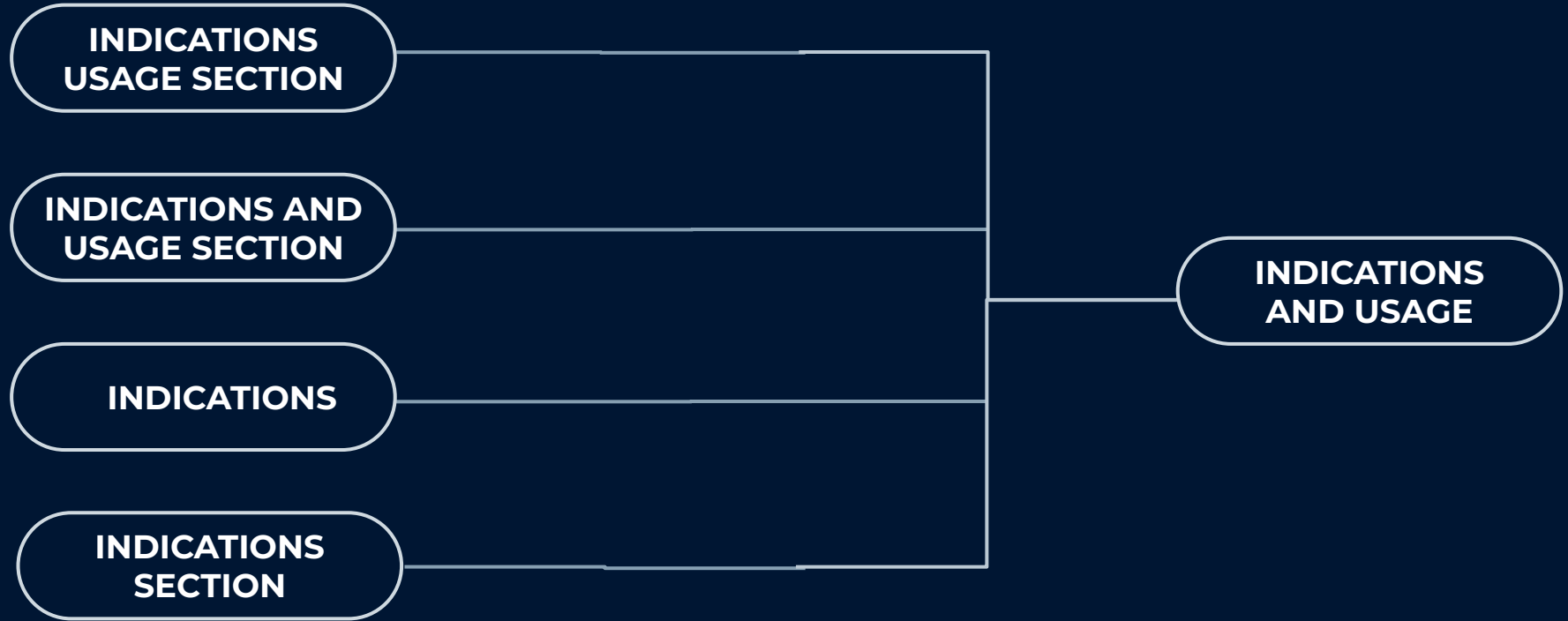
```

46,000 XMLs from FDA

2000 lines each

1,200 PDFs from EMA

TEXT SIMILARITY



POTENTIAL IMPROVEMENTS

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



SUMMARY



- **Open Sourced**
<https://github.com/DrugLabelExplorer/dle>
- **Powerful search tools**
- **Side-by-Side comparisons**
- **Sections linked across labels**
- **Live druglabeexplorer.org**

QUESTIONS?





THANK YOU
