Using Artificial Intelligence to Optimize Known Use Problem Analyses

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Background

Overall Goal: Creation of Known Use-Related Problem Analysis (KUPA) Tool

Proof of Concept: Eliminate human review of all retrieved cases by identifying if events are use-related

Why? KUPA are:

Required	FDA requires consideration of all known use-related issues
Tedious	Long hours of event/data review due to inconsistent, messy data
Box to be checked	Manufacturers often complete near end of development to meet requirements rather than when it is most valuable

Overall Approach

Phase 1. Data Retrieval
Type the type of device you are developing into an AI-based tool

- **1a** Identify similar devices based on typed description
- **1b** Identify all relevant data entry variants that may be present in data sources
- **1c** Iterate all possible data entry variants and **retrieve data from all FDA-recommended sources**

Phase 2. Data Analysis
Retrieve a comprehensive report of publicly available Use-Related Problems with similar and comparable devices

- **2a** **Analyze data to identify which reports are use-related**
- **2b** Identify and describe use-related problem
- **2c** List out the use-related problem and the device/data source it is associated with.

Database Retrieval Tool

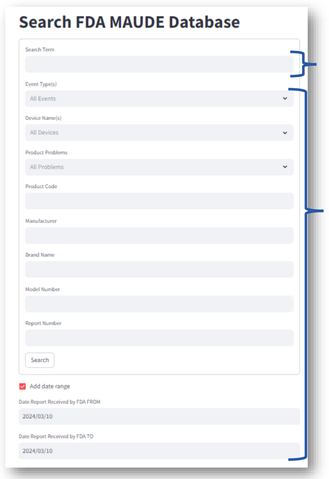
Method

- Identify data source for Proof of Concept

FDA-Recommended Sources

Public		Mixed	Private
Open Format	*Database*	*Open*	*Open*
FDA Safety Communications	MAUDE	Journal Articles	Training/Sales staff
ECRI	MedSun	Professional Meeting Proceedings	Previous HF Studies
ISMP Alert Newsletters	CDRH Recalls	Newsletters	*Database*
Joint Commision Sentinel Events		Current users	Customer Complaints

- Develop tailored search fields and dynamically construct API queries to call FDA's MAUDE database



Open form text field similar to FDA's Simple Search

Includes all advanced filtering options provided by FDA's Advanced Search option

- Bypass max retrieval limits by iterating through subsequent URLs until all available results are aggregated

Improvements over existing options

- Retrieves complete dataset – no capacity limitations
- Combines best of FDA's Simple and Advanced Search options
  - Provides open search field to query database for open terms such as "Pen Injector"
  - Range of dates, rather than choosing between a single year or all years

Next Steps

- Retrieve data from other API-based databases
- Iterate through plausible variants of open text search fields

Analysis Tool

Modeling Task

- Multi-class text classification: automatically assign a category or 'class' to text by training models on labeled data

General Method

Data collection
Retrieve data using tool and annotate

Preprocessing
Clean text

Tokenization
Split text into individual tokens

Fine-tune
Train model on annotated data

Control Model
Develop comparator model

Evaluate
Accuracy, Precision, Recall

Proof of Concept Model Notes

- Data limited to a single device type
- Labeled events as use-related, not use-related, or Insufficient info

Leveraged PubMed BERT, a tokenizer trained on domain-specific language/patterns

- Dataset split into training and validation sets
- Stratified 5-fold cross-validation strategy
- 5 epochs used for training

Always predicts majority class: Insufficient Info

Next Steps

- Increase annotations and fine tune model further
- Incorporate data from other sources
- Expand to other product types
- Develop model that can identify and describe the use-related problem

Reference for PubMedBERT:

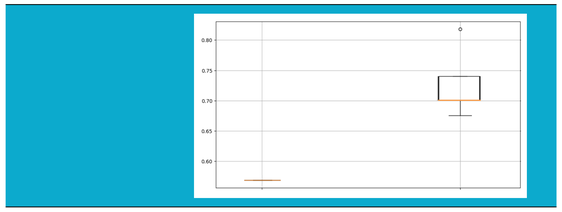
Gu, Y., Tinn, R., Cheng, H., Lucas, M., Usuyama N., Liu X., Naumann, T., Gao J., Poon H. (2020). Domain-Specific Language Model Pretraining for Biomedical Natural Language Processing. *ACM Transactions on Computing for Healthcare, 3*(1). arXiv:2007.15779

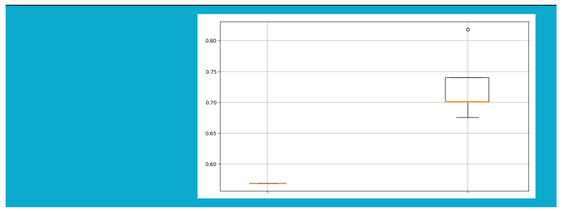
Findings

Results

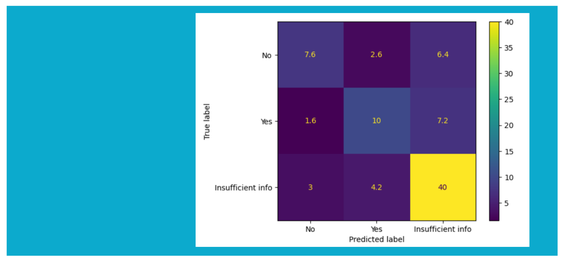
- Our model outperformed the baseline model on all metrics: accuracy, precision, and recall across the validation folds.

	Baseline	PubMedBert
Accuracy	.56	.73
Precision	.32	.71
Recall	.56	.73





Confusion Matrix for PubMed BERT



Discussion

- This tool has the potential to save HFEs hundreds of hours of data review
- Although some reports may be missed, savings gained from eliminating review of irrelevant data enables HFEs to identify **more** applicable use-related issues
- Results will only continue to improve as more data is annotated.
- This tool development process can be leveraged to develop internal complaint analysis tool searching for usability trends