Data Analytics Framework for Identifying Relevant Adverse Events in Medical Software

Md Moin Uddin and Mouzhi Ge
European Campus Rottal-Inn, Deggendorf Institute of Technology, Deggendorf, Germany

Keywords: Clinical Evaluation, Adverse Event, Medical Software, Natural Language Processing, Machine Learning.

Abstract: The clinical evaluation process is an ongoing and iterative process. Through clinical evaluation, the clinical performance and effectiveness of the medical device will be monitored. While the clinical evaluation process requires clinical data, these relevant data may come from different sources. One of the recommended sources is "medical device adverse event report database", which is mentioned in several guidance documents, since the adverse event reports are useful to identify hazards caused by substances or technologies used in medical devices. They also contain signals on the new or unknown risks associated with medical devices. As the use of medical devices is increasing, new adverse event reports are being updated in a daily manner, thus, the size of the adverse event database is also increasing. It is difficult and time-consuming to collect and process data from multiple adverse event data sources and feed the data into the clinical evaluation process needs special consideration. In this paper, the feasibility of adopting a data analytic ecosystem to deal with a large amount of adverse event data is studied. As an output, a data analytics framework is proposed to process and classify adverse event texts. The whole process will significantly facilitate the clinical evaluation process for medical image analysis software.

1 INTRODUCTION

The healthcare industry is being transformed by technological advancement. The use of software in the health sector is significantly increasing over the last decade. On the one hand, it is making health services efficient and on the other hand, it is, however, creating various types of risks. The use of Artificial Intelligence (AI) in the medical decision-making process has created new challenges for us. For example, the "Threac -25" incident (Leveson, 1995) is caused by software errors that pose risks to patients. In addition, heterogeneous medical device regulations and approval procedures across the world also create various challenges for medical device manufacturers. Since the application of better data analytics and making data-driven decisions may solve some of these challenges (Chen et al., 2017), this paper be exploring how medical device adverse event data can be used to make medical software safe and effective.

The complexity of medical device regulations has been increasing over time (Agyei et al., 2022). The goal is to make medical devices safe and effective. Also, the application of AI technology in medical software makes the product even more complex. Medical device regulation plays an important role in the maintenance of the safety and performance of the medical device. As part of medical device regulatory requirements, manufacturers have to conduct different tasks such as clinical evaluation, and post-market surveillance activity. Most of these activities take place in both the pre-and post-marketing stage of a medical product's life cycle and often rely on clinical data (Nadakinamani et al., 2022).

The term "Clinical Data" has been defined and mentioned in different medical device regulatory guidance documents(Astapenko, 2019; Commission, 2007) and refers to "Safety, clinical performance and/or effectiveness information that is generated from the clinical use of the medical device." Clinical data may come from multiple sources (Astapenko, 2019; Kessler, 2007; GHTF, 2012) and reside in different forms and locations. This data may include relevant published literature, post-market surveillance data, adverse event databases, and recall databases. As per regulatory guidance documents, the manufacturer is the responsible entity to identify relevant clinical data. However, it is a very time-consuming process to collect clinical data as the source of clinical data is diverse. In fact, most of the clinical data lives

Uddin, M. and Ge, M.
Data Analytics Framework for Identifying Relevant Adverse Events in Medical Software.
DOI: 10.5220/0012038900003476
In *Proceedings of the 9th International Conference on Information and Communication Technologies for Ageing Well and e-Health (ICT4AWE 2023)*, pages 81-90
ISBN: 978-989-758-645-3; ISSN: 2184-4984

in text format. A considerable amount of effort is required to appraise and utilize this data for a medical device regulatory task such as clinical evaluation.

This paper, therefore, aims to build a text classifier that would classify clinical data based on relevancy to the medical software in question. It will be focused on medical image analysis software and the goal is to identify relevant adverse event data to support the clinical evaluation process for this software. According to European Medical Device Regulation (MDR), "Clinical Evaluation" is, a systematic and planned process to continuously generate, collect analysis and assess the clinical data pertaining to a device in order to verify the safety and performance including clinical benefits, of the device when used as intended by the manufacturer (European Parliament and Council of the European Union, 2017). The key objectives of clinical evaluation include periodically monitoring safety, and performance, also assessing the risk-benefit of medical devices. Figure 1 illustrates a conceptual workflow to conduct a clinical evaluation for medical software. The box in the middle shows the steps involved in the clinical evaluation process. In this work we consider medical device adverse event data as clinical data sources.

To find relevant adverse events to the software in question text classification can be useful. (Chai et al., 2013) shows, by using statistical text classification it is possible to identify health information technology incidents from the FDA MAUDE database. The authors also emphasize using a semi-supervised machine learning approach to big data analysis of medical incidents. Apart from the study (Chai et al., 2013), there is a lack of research that focuses on the concept of big data and machine learning when it deals with a large amount of medical device adverse event data from multiple sources.

The main contributions in this paper are: a) adopting a modern data ecosystem to deal with the massive amount of medical device adverse event data, and b) using text classifiers to classify adverse event data as per business requirements.

The rest of the paper is organized as follows. Section 2 reviewed related works, especially various important adverse event databases. Based on the review, Section 3 proposes an adverse event data analytic framework to organize the workflow of the data analysis for the clinical evaluation procedure. An integral part of the proposed framework is an adverse event text classifier. In order to validate the framework, Section 4 conducts experiments to evaluate the classification accuracy. Finally, Section 5 concludes the paper and outlines future research directions.

2 RELATED WORKS

The required important regulatory standards for medical software depend on the country and type of device in question. In the USA, the Food and Drug Administration (FDA) is the regulatory authority whereas in Europe, the European Medicines Agency (EMA) is the main regulatory authority for medical devices in Europe. The EMA works closely with the European Commission, national competent authorities, and other stakeholders to ensure that medical devices are safe and effective for patients in the EU and EEA. For medical software some key standards are (1) ISO 13485: Medical devices – quality management system (Lie et al., 2020) (2) ISO 14971: Application of risk management to medical devices (Flood et al., 2015), (3) IEC 62304: Medical Device software-system life cycle process (Kim et al., 2019), (4) IEC 62366: Medical devices- application of usability engineering to medical devices (Costa et al., 2015), (5) ISO 9001: Quality management systems (Golas, 2014).

As part of the regulatory standards, medical device manufacturers use different conformity assessment procedures to demonstrate the performance, efficacy, and safety of the medical devices. Proving the safety of medical devices is an ongoing process and it continues throughout the life cycle of medical devices. Once the device is in the market it starts generating data regarding safety and performance. Since medical decisions increasingly depend on data provided by different medical software, the volume of data for the safety and performance of medical devices is accordingly increasing over time. For instance, the type of data generated after a medical device is brought to market may include safety reports, adverse event reports, and clinical investigations reports. This data can be useful for different conformity assessment procedures such as clinical evaluation. In addition to that, this data may contain information on unknown risks from medical devices. Also, the post-market adverse event data can be useful, however, one needs to carefully process the data since the adverse event reporting system varies among countries (Kessler, 2007). According to many medical device regulations, it is medical software manufacturers' responsibility to generate evidence through different mechanisms mentioned in the regulatory process to support the intended purpose of a medical device in normal use. Clinical evaluation is one of the processes which can be used to generate evidence for medical software in both pre-market and post-market stages. To conduct clinical evaluation procedures, medical device adverse event data can be

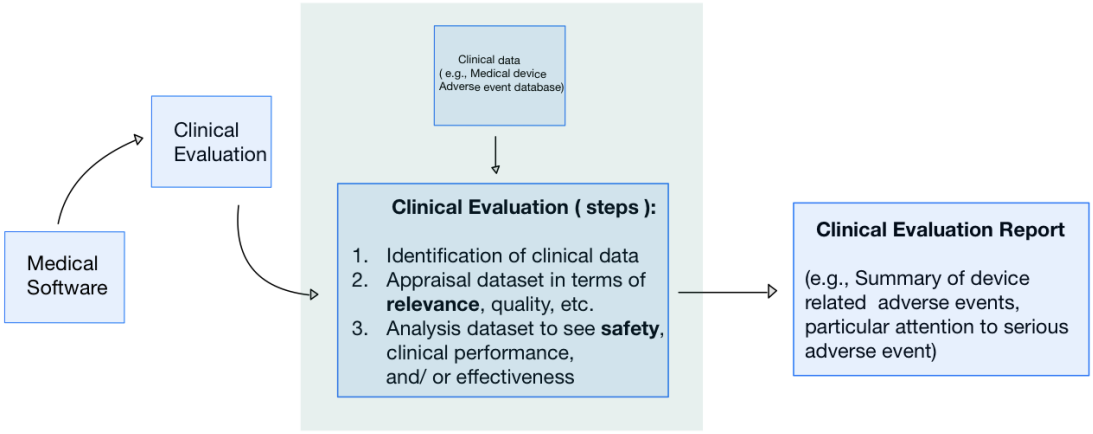


Figure 1: Conceptual Workflow for Conducting Clinical Evaluation for Medical Software.

used(Astapenko, 2019; Commission, 2007; European Commission, 2020).

This work will focus on collecting clinical data from desired sources and processing the data to feed into the clinical evaluation report preparation tasks. Preparing a clinical evaluation report is out of the scope of this work. The desired data source may vary, it depends on the degree of evidence required for the clinical evaluation report. In this work, adverse event databases are considered as a desired clinical data source.

2.1 Adverse Event Databases

Medical device Adverse Event (AE) databases are reliable sources for medical software manufacturers to conduct both pre- and post-market surveillance activity. Usually, these databases contain adverse event reports submitted by medical device manufacturers, patients, physicians, and nurses. For example, the FDA MAUDE database (Manufacturer and User Facility Device Experience) contains information on medical device adverse event reports (MDRs) submitted to FDA by mandatory and voluntary reporters (FDA, 2022). This database represents feedback from different stakeholders when a product was brought into the market. FDA MAUDE represents two kinds of reports voluntary and mandatory. The mandatory reports are submitted by manufacturers, importers of medical devices, and device user facilities. The voluntary reports are submitted by healthcare professionals, patients, consumers, etc. These reports represent information on suspected device-associated deaths, injuries, malfunctions, etc. MAUDE database is publicly available and provides adverse event data since 1991. These reports support FDA to monitor, and detecting medical device-related issues and assessing the risk-benefit of medical devices. The search option on the MAUDE database has some limitations. (Lisa Garnsey Ensign, 2017) explains how the MAUDE database only shows a maximum of 500 records and restrict the search result within the past 10 years for a specific search query. Due to such restrictions, only a subset of the available record against a query can be retrieved.

Another database maintained by the FDA is Recall. The purpose of the recall database is different than the MAUDE database. FDA Recall database provides information on recalled devices to the user of the device (e.g., Patient, Physician). This database can be a good source for medical device manufacturers. (Fu et al., 2017) shows that between 2012-2015 a total of 913 recall data was found related to user interface (UI) software error. To make medical software safe and effective such information is useful. When manufacturers acknowledge an issue associated with their medical device, they usually take either corrective measures or remove the medical device where it was sold. FDA provides a recall class based on the degree of risk associated with the medical device in question. This information may also be important for the manufacturer to see how serious the event was. The database is publicly searchable and search results can be downloaded in CSV format.

Apart from MAUDE and Recall, in the UK the Medicines and Healthcare products Regulatory Agency (MHRA) provides data on alerts, recalls, and safety information about medical devices and drugs. In Switzerland, the Swiss Agency for Therapeutic Products (Swissmedic) is a responsible authority to conduct surveillance on medicines and medical devices available in the Swiss market. In Australia, the Therapeutic Goods Administration (TGA) is a regulatory authority that regulates different therapeutic goods such as medicine, and medical devices available in the Australian market. All these data sources can be useful for the clinical evaluation process for

medical software. As these sources contain information on medical device safety and effectiveness in clinical settings.

2.2 Collection of Adverse Event Data

As far as we know, the adverse event data sources have no uniform layout to collect the desired information. Data reside in semi-structured/ unstructured form on those sources. Some of them provide search results in downloadable files which contain semi-structured data, others show the search result on an HTML table on their the web-page. In this context, collecting data from dynamic sources and preparing it for further analysis requires more effort.

Study (Zhang Y, 2019) shows how to collect and analyze data from FDA Recall database to see user interface (UI) software error. Authors use keywords to search data from FDA Recall database, a total of 7,771 records obtained from the database. After that, data were normalized with two phases to identify potential software errors related to the user interface. In phase 1, FDC (FDA-determined causes) and keywords are used to filter out a non-software-related recall. Here noted that the FDC information is provided by the recall database. In phase 2, the authors use a manual approach to analyze the remaining data to identify potential UI-related software errors. During this phase, FDA RES (Recall Enterprise System) database was used to identify relevant information. This study observed, one quarter (25 %) of total identified UI software errors associated with medical imaging. Although the outcome shows a well-categorization of UI software errors; however, the downside is, this work only focused on a single data source. Especially when it is necessary to collect data from multiple sources and analyze them to produce clinical evaluation reports, such an approach could take a long time.

Another study (Fu et al., 2017) shows a slightly different approach to identifying software-related issues present in medical device recall data. The authors use a set of pre-defined software-related keywords and a data element named “Reason” which available on the FDA Recall database. FDA Recall database provides information on “Reason” of recall. It is a piece of free text that explains why the medical device was recalled. Authors use this text data and tag the textual data with the parts of speech (POS) tagging technique. POS tagging is a technique that provides a tag (e.g., noun, adjective, verb, etc.) to each word in the text/document. Such representation of text is useful and prepares textual data for further analysis (e.g., syntactical analysis of text). In the next step, a comparison was made between the most relevant nouns /adjectives and pre-defined software-related keywords to find the most relevant data. After that, the TF-IDF algorithm was used to rank the most relevant recall data.

Moving on to another publication (Chai et al., 2013) that explores the feasibility of using statistical text classification to automatically identify health information technology incidents in the FDA MAUDE database. This work is a preliminary work that has shown the use of statistical classification and the potentiality to adopt big data concepts to process a large amount of adverse event data.

A recent work (Ceross et al., 2021) has shown how Access Global Unique Device Identification Database (AccessGUDID) and Global Medical Device Nomenclature (GMDN) can be used to analyze medical device adverse events. The AccessGUDID is a medical device data database that offers key device identification information and is maintained by FDA. On the other hand, GMDN is a collaborative effort to standardize terms used in the medical device industry. Compared with other studies this study has shown a new way to analyze adverse event data.

Several studies, for example, (Liebel et al., 2020), also those mentioned previously have shown a common approach to analyzing adverse event data that is using relevant keywords. For instance, to find the user “interface-related” or “software-related” issues they considered relevant words such as “software”. This seems to be a reliable approach to mining adverse event databases.

3 ADVERSE EVENT DATA ANALYTICS FRAMEWORK

This section will discuss a data analytics framework and an adverse event text classifier. Based on adverse event data type and sources we propose a data analytics framework that would support collecting adverse event data, processing it, analyzing it, and finally preparing data to support clinical evaluation procedure. In this context, image analysis software is taken into account that is built on AI technology. As shown in Figure 2, based on the lessons learned from (Macák et al., 2020), the framework contains 5 stages, which are data source, data ingestion, data preparation, intermediate data storage, and data analysis.

3.1 Data Sources

The data source component represents different adverse event data sources useful for medical software.

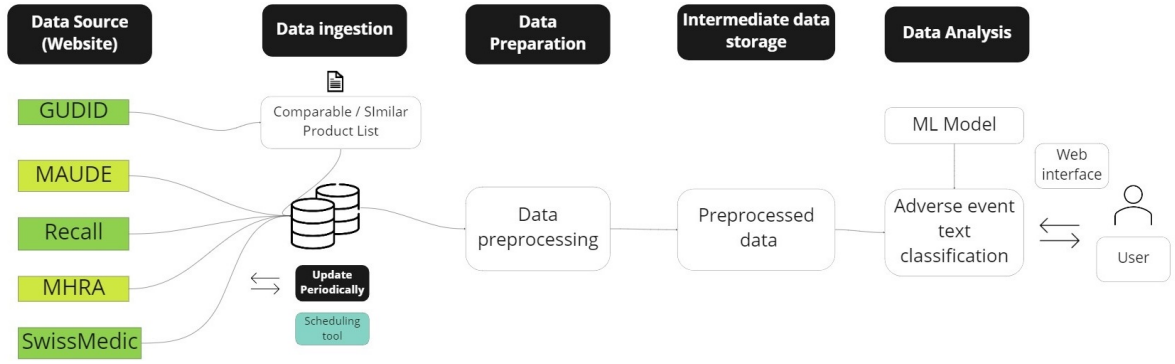


Figure 2: Adverse event data analytics framework.

Some medical device regulatory guidelines that mentioned potential clinical data sources which can be considered for the clinical evaluation process are- (1) GHTF/SG5/N7:2012 Clinical Evidence for IVD medical device – Scientific Validity and Performance Evaluation (Appendix A) (GHTF, 2012), (2) IMDRF MDCE WG/N56 FINAL: 2019 Clinical Evaluation – (Appendix B) (Astapenko, 2019). In addition to that, the International voluntary group "International Medical Device Regulators Forum (IMDRF) also provides a list of websites where country-specific medical device safety information / adverse event data can be found (IMDRF, 2022). Consulting with those sources only four adverse event data sources are considered those are FDA MAUDE, FDA Recall, MHRA, and SwissMedic. Access Global Unique Device Identification Database (GUDID) provides important information to identify medical devices. Specifically, this database provides product-specific FDA code which is used by other databases such as FDA MAUDE and Recall. AccessGUDID database is used to find similar/comparable products in the first place. Based on this list FDA MAUDE and Recall database will be mined. It is worth mentioning that, not all of the chosen data sources provide a uniform layout to access data. Table 1 shows different options to access data from desired sources.

3.2 Data Ingestion

As it is shown in Table 1, the targeted data sources have diverse options to access data. To download the data from those sources individualized approach has been taken. For instance, the MAUDE database provides an option to download data text files whereas updated data from the Recall database can be accessed through RSS feed. Both FDA MAUDE and Recall databases have API (Application Program Interface) to access data (U.S. FDA, 2023). In contrast, data from MHRA and SwissMedic need to be accessed through RSS (Really Simple Syndication) feed and web-scraping technology respectively. Thus, a combination of different approaches needs to be considered to access targeted data from those sources. It is important to mention that, in the framework, the similar or comparable product code list will be reviewed and selected by the user manually. To collect data periodically a scheduling tool can be considered.

After data collection, data need to be stored. The term "Data Repository" is commonly referred as a central location where data is collected, organized, and managed so that it can be used for further business operations. The types of data repositories include databases, data warehouses, and big data stores. At the time of writing this paper, FDA MAUDE holds more than 15 million records, and FDA Recall holds more than 100 thousand records. The other two databases, MHRA, SwissMedic hold more than 9 hundred and 9 thousand records respectively. Thus, managing this large amount of data and bringing them into a common format is important for analysis.

3.3 Data Preparation

Data integration is important for gaining a unified view of data. Usually the data integration refers to a process that combines and transforms data from multiple sources. As the adverse event data is in semi-structured or unstructured form ETL/ELT tool can be chosen to achieve data integration. Both ETL (Extract, Transform, and Load) and ELT (Extract, Load, Transform) processes serve the purpose to move data from source to destination systems and prepare raw data into an analysis-ready form. The difference between ETL and ELT is when the loading step would take place. Compared with ETL, the ELT offer more flexibility and raw data will be immediately available to serve other purposes such as exploratory data analysis.

Table 2 shows, some useful data elements available on the adverse event databases. On the table, the FOI TEXT, Reason, Description, and Summary data fields provide descriptions of the adverse events. To analyze adverse events these fields are important. Not all of them have a uniform structure, text length, or reporting style. This data contains noise like white space, punctuation, numbers, etc. To feed data into a machine learning model some pre-processing is required. As a result, the model could pick the right signal from the data. Some basic text pre-processing steps such as removing punctuation, tokenization, and removing stop words, are used. Based on the use case, other advanced pre-processing techniques like stemming, lemmatization, and part-of-speech tagging (POS) can be considered. After pre-processing, data needs to be stored in intermediate storage. So that, the original data will remain intact.

3.4 Intermediate Data Storage

The next component in Figure 2 is intermediate data storage. Intermediate data storage is considered in the pipeline to keep the original raw data intact. Adverse event text data may contain noise, such as punctuation, stop words, unwanted characters, etc. So this data needs to be cleaned before going for further analysis. After pre-processing data is transformed and the step is irreversible. If we operate on raw data there is no way to go back, once data is transformed. So it would be a good idea to keep raw data as it is and consider saving transformed data in a separate location. The intermediate storage can be thought of as a data lake where data will write once and read many times for analytic purposes. Another advantage of having intermediate storage is cleaned and pre-processed data can be used for other analytical purposes without doing repetitive pre-processing. Different file formats can be considered such as Parquet, or Pickle to achieve space-efficient storage.

3.5 Data Analysis

Turning now to the data analysis component which contains the machine learning model to classify adverse event data. The model would take pre-processed data from the previous step. Then it will predict each adverse event record whether it is relevant for an image analysis software or not and finally provide the output in an excel format. Building a text classifier requires some labeled data set. To the best of our knowledge, no publicly available labeled data set is available to build a text classifier on medical device adverse events. Thus, we need to prepare some data sets with specific labels. In this work, we use two labels, those are “Relevant” and “Not relevant”. The “Relevant” label represents an adverse event record that is relevant to image analysis software. On the other hand, the “Not relevant” label represents an adverse event record that is not relevant for image analysis software. To build an adverse event text classifier supervised machine learning approach is considered. Two different supervised machine learning algorithms with different vectorization approaches are tested. The algorithms include Support Vector Machine (SVM) and Random Forest Classifier and the vectorization techniques are TF-IDF and word2vec.

4 EVALUATION

This section represents the outcome of applying commonly used matrices to find which algorithm performs well to classify adverse events text. The evaluation matrices are - Accuracy, Precision, Recall, and Cross-validation.

4.1 Evaluation Setting

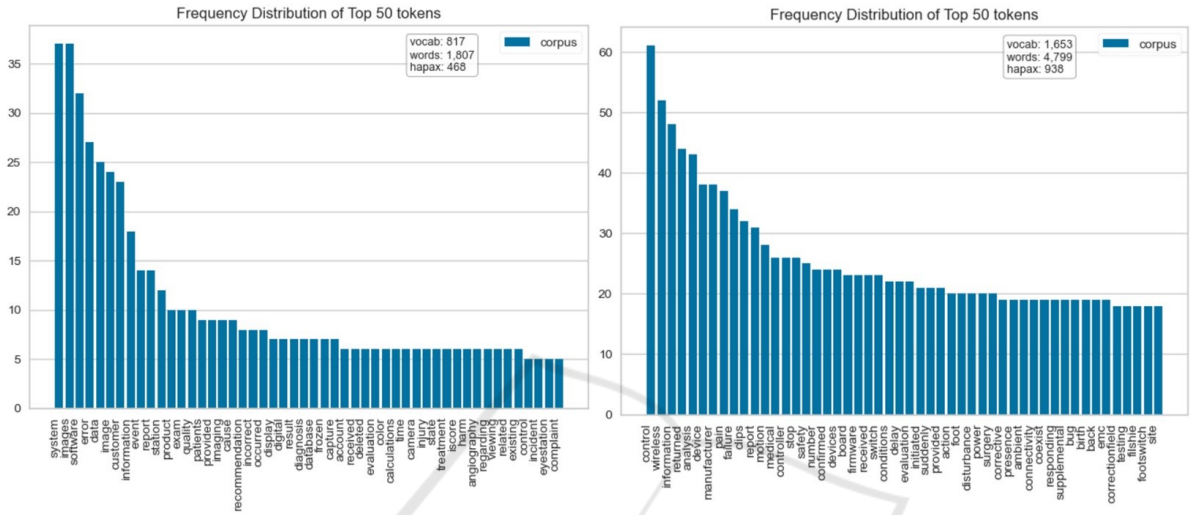
The accuracy is compared with a simple baseline. The goal is to validate whether the trained model works better than the baseline. We use DummyClassifier class from scikit-learn. It provides strategies like “most frequent” where the method returns the most frequent class label. We applied this for LinearSVC model only.

The whole labeled data set is split into 80-20 ratio. Twenty percent data set is used as a test set. For cross-validation, the whole data set is considered and split into k-subsets (k=9) and the holdout method is repeated k times. Each time, one of the k-subsets is used as the test set and other k-1 subsets are put together to be used to train the model. Cross-validation allow to use the whole data set and it helps the model to learn on more data. As it is shown in Table 3 and Table 4, the Support Vector Machine (SVM) algorithm performs well in different matrices. Only LinearSVC with TF-IDF model is considered for cross-validation.

In the confusion matrix, the “Relevant” class is considered as true positive, and the “Not relevant” class is considered as true negative. Precision represents what proportion of predicted positive is positive or how good the classification model is at predicting the ”relevant” class. The recall represents what proportion of real positive values are identified by the classification model.

Table 1: Possible Ways to Access Data from Targeted Sources.

Website	URL Generation	Robots.txt	Sitemap.xml	RSS Feed	Downloadable file
MAUDE	x	x	-	-	x
Recall	x	x	-	x	x
MHRA	x	-	x	x	-
SwissMedic	x	-	-	-	x
GUDID	-	-	-	x	x

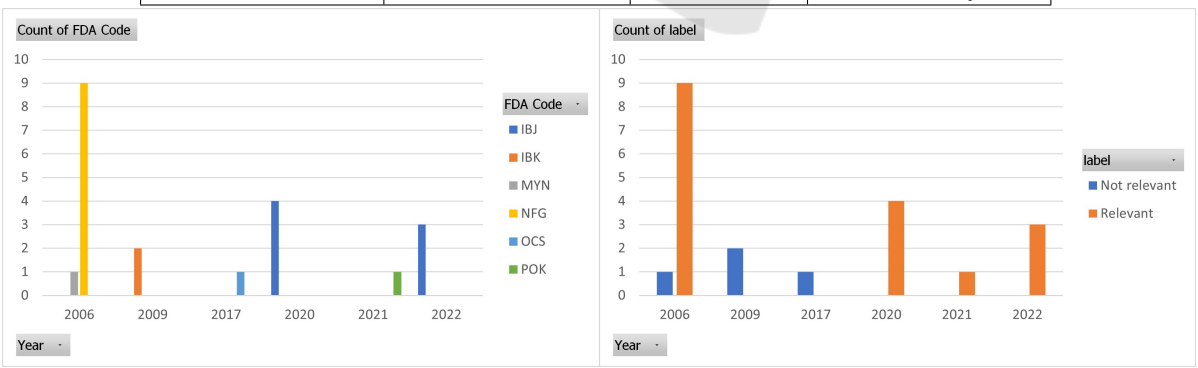


(a) Relevant (b) Not Relevant

Figure 3: Visualizing feature for both classes.

Table 2: Useful Data Elements Available on Adverse Event Databases.

FDA MAUDE	FDA Recall	SwissMedic	MHRA
Manufacturer	Product Description	Manufacturer	Title
Brand Name	Recall Class	Date	Issue Date
Date Received	Recall Posting Date	Brand Name	Alert Type
Adverse Event Flag	Manufacturer	Description	Medical Specialism
FOI TEXT	Reason	-	Summary



(a) Favorable adverse event records to image analysis software(b) Classification of adverse event data using the trained model

Figure 4: Use trained model on new adverse event data. Database: FDA MAUDE, Timeframe:(2000-2022).

4.2 Training Data

To the best of our knowledge, there were no existing publicly available datasets to train a model for adverse event data. Thus, data annotation has to choose to create some labeled data. Data annotation requires time and strong domain knowledge. There are several approaches that can be followed to annotate data. When no training data is available, manual annotation or bootstrapping can be chosen. Manual annotation is a time-consuming process. Also, it is ideal to have 3-5 annotators, who would work on the same dataset and annotate them individually. Later the annotated data will compare, if any disagreement occurs on any specific record, it should be further analyzed.

We have labeled 162 data with two classes. It is worth mentioning that all 162 records come from the MAUDE database. The reason is, during exploratory data analysis it was observed this database and also Recall database follow a structure in their reporting and explain the reason for the event. This is useful to capture intuition on adverse events. Figure 3 visualizes top-frequent terms in the labeled data. Here the label "relevant" means, the adverse event relevant to image analysis software and "not relevant" means the event is not related to image analysis software.

We take our 162 labeled data and count the word frequency, where the bag-of-words (BOW) model is used. The BOW model takes each adverse event description text and treats it as a bag of words, where the order of words is ignored. The adverse event terminology working group led by IMDRF, is working on improving, harmonizing, and standardizing terminology as regards medical device adverse event (IMDRF, 2019). To find the most informative terms within labeled data this resource was used. Furthermore, the technical report titled "IEC/TR 80002-1:2009 Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software" includes "Annex B", which provides additional guidance on software function areas and hazards(IEC, 2009) also used to find the most informative terms. It is worth mentioning that only adverse event/hazard definitions associated with image analysis software were considered.

4.3 Evaluation Results

We achieved 78 percent accuracy for the dummy classifier. The result of the dummy classifier indicates that the trained LinearSVC model adds some value. Table 3, lists the accuracy scores for different model combinations. The LinearSVC shows the highest accuracy (96 percent) compared with other models. In Table 4 shows, precision and recall scores for different model combinations. For precision and recall the best score was achieved with the SVM algorithm that was utilized with the TF-IDF model, employing a linear kernel function. In this case, for the "Relevant" class precision and recall were 1 and 0.89 respectively. In the test set, the total observation was 33, among them, 9 were "Relevant" class. The trade-off between precision and recall depends on the business use case. For instance, if the cost of not identifying an adverse event is high then we should consider improving the recall score. With the current recall score of 0.89, the model is able to capture most of the adverse event text that is relevant to image analysis software. Comparing the score with other kernel functions, it seems that the adverse event text data is linearly separable. Finally, cross-validation was applied to the same model. We achieved a 0.94 (mean) score where k=9. This score is close to what we achieved for other matrices. Thus, this score can be taken as the model's true potential.

Figure 4 shows an output of the proposed data analytics framework. The illustration represents the data based on the FDA MAUDE database and the trained model applied to new adverse event data. Between 2002-2022, a total of 21 adverse events have been identified. Among them, 17 records were assigned to a relevant class and 4 were assigned to a not-relevant class by our model. The similar/comparable FDA product code included IBJ, IBK, MYC, MYN, NFG, OCS, OEB, POK, QBS, QDQ, QJU, QNP. Based on these product codes a total of 35 records are stored in intermediate storage. To use the model on new data, we have taken those records that contain more than 50 words in the adverse event description.

4.4 Discussions

We found that the AccessGUDID, MAUDE, and Recall databases can be connected by using the FDA product code. This linkage is useful to find a specific subset of data from the adverse database. First, it is important to identify the most similar or comparable product code from AccessGUDID database to the device in question. Later the selected product code can be used to retrieve data from the other two databases MAUDE and Recall. During our data analysis, it was observed between 2000-2022 only MAUDE database contains more than fifteen million records and the Recall database contains more than one hundred thousand records.

By using specific product codes, it is possible to take a subset of data that represents adverse event data useful for specific medical products. Finding similar/comparable product not only helps to mine ad-

Table 3: Accuracy.

Algorithm	Vectorization technique	Accuracy	Note
SVM	TF-IDF	0.96	LinearSVC
		0.79	Polynomial, Degree 3
		0.87	RBF, Degree 3
	word2vec	0.67	LinearSVC
		0.67	Polynomial, Degree 3
Random Forest	TF-IDF	0.88	-
	word2vec	0.88	-

Table 4: Precision and Recall.

Algorithm	Vectorization	Precision	Recall	Class	Observation	Note
SVM	TF-IDF	1	0.89	Relevant	9	Linear
		0.96	1	Not relevant	24	
		1	0.22	Relevant	9	Polynomial, Degree 3
		0.77	1	Not relevant	24	
		1	0.56	Relevant	9	RBF, Degree 3
		0.86	1	Not relevant	24	
	word2vec	0.68	1	Not relevant	22	
		0	0	Relevant	11	LinearSVC
		0.68	1	Not relevant	22	Polynomial, Degree 3
		0	0	Relevant	11	
Random Forest	TF-IDF	1	0.64	Relevant	9	-
		0.85	1	Not relevant	24	-
	word2vec	0.85	1	Not relevant	22	-
		1	0.64	Relevant	11	-

verse event data but this knowledge can also be used for other purposes as well. For instance, market analysis, product differentiation, etc. This can be achieved by analyzing the AccessGUDID database. During the adverse event data analysis we dealt with large amounts of text data. It requires more computational power and resources. Long processing time was a key challenge. A multi-processing tool like Spark can be useful to resolve this problem.

5 CONCLUSIONS

This paper has proposed a data analytics ecosystem to analyze medical device adverse event reports for clinical evaluations. The proposed framework consists of collecting various data sources, via data ingestion, preparation, and data staging, and finally data analysis. We found that one of the important components in the framework is the adverse event text classifier. In order to validate the framework and adverse event text classifier, we have conducted an experiment to evaluate the accuracy of different machine learning algorithms.

The experimental result has shown that an adverse event text classifier can be an integral part of this ecosystem and it is feasible to achieve solid classification accuracy. Thus, the adverse event text classifier and the framework can support other medical devices' regulatory tasks such as active post-market surveillance activity. Also, this work has indicated a new research stream that is using knowledge from the data science domain to deal with different medical device regulatory affairs tasks and clinical evaluation tasks.

As future work we will focus on building an adverse event text classifier that would classify adverse event text at a more granular level. For example, what semantically the adverse event text means, and how to represent an issue related to a "software execution" or an "image orientation" related issue.

REFERENCES

Agyei, E. E. Y. F., Pohjolainen, S., and Oinas-Kukkonen, H. (2022). Impact of medical device regulation on developing health behavior change support systems. In Baghaei, N., Vassileva, J., Ali, R., and Oyibo, K., editors, *Persuasive Technology - 17th International Conference, PERSUASIVE 2022, Virtual Event, March 29-31, 2022, Proceedings*, volume 13213 of *Lecture Notes in Computer Science*, pages 1–15. Springer.

Astapenko, E. M. (2019). Clinical evaluation. *International Medical Device Regulators Forum. IMDRF MDCG WG/N56FINAL.*

Ceross, A., Bergmann, J., et al. (2021). Tracking the presence of software as a medical device in us food and drug administration databases: Retrospective data analysis. *JMIR Biomedical Engineering*, 6(4):e20652.

Chai, K., Anthony, S., Coiera, E., and Magrabi, F. (2013). Using statistical text classification to identify health information technology incidents. *Journal of the American Medical Informatics Association : JAMIA*, 20.

Chen, J. H., Alagappan, M., Goldstein, M. K., Asch, S. M., and Altman, R. B. (2017). Decaying relevance of clinical data towards future decisions in data-driven inpatient clinical order sets. *Int. J. Medical Informatics*, 102:71–79.

Commission, E. (2007). *Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC*. European Commission, Brussels, Belgium.

Costa, S. B. D., Beuscart-Zéphir, M., Bastien, J. M. C., and Pelayo, S. (2015). Usability and safety of software medical devices: Need for multidisciplinary expertise to apply the IEC 62366: 2007. In Sarkar, I. N., Georgiou, A., and de Azevedo Marques, P. M., editors, *MEDINFO 2015: eHealth-enabled Health - Proceedings of the 15th World Congress on Health and Biomedical Informatics, São Paulo, Brazil, 19-23 August 2015*, volume 216 of *Studies in Health Technology and Informatics*, pages 353–357. IOS Press.

European Commission (2020). Guidance on clinical evaluation (mdr) / performance evaluation (ivdr) of medical device software. [Accessed: March 11, 2023].

European Parliament and Council of the European Union (2017). Regulation (eu) 2017/745 of the european parliament and of the council of 5 april 2017 on medical devices.

FDA (2022). Maude - manufacturer and user facility device experience. *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm*.

Flood, D., McCaffery, F., Casey, V., McKeever, R., and Rust, P. (2015). A roadmap to ISO 14971 implementation. *J. Softw. Evol. Process.*, 27(5):319–336.

Fu, Z., Guo, C., Zhang, Z., Ren, S., Jiang, Y., and Sha, L. (2017). Study of software-related causes in the fda medical device recalls. In *2017 22nd International Conference on Engineering of Complex Computer Systems (ICECCS)*, pages 60–69.

GHTF (2012). Clinical evidence for ivd medical devices – scientific validity determination and performance evaluation. *Global Harmonization Task Force, Study Group 5 Final Document GHTF/SG5/N7:2012*.

Golas, H. (2014). Risk management as part of the quality management system according to ISO 9001. In Stephanidis, C., editor, *HCI International 2014 - Posters' Extended Abstracts - International Conference, HCI International 2014, Heraklion, Crete, Greece, June 22-27, 2014. Proceedings, Part II*, volume 435 of *Communications in Computer and Information Science*, pages 519–524. Springer.

IEC (2009). Medical device software — part 1: Guidance on the application of iso 14971 to medical device software. Technical report.

IMDRF (2019). Medical device problem codes. Accessed on: March 12, 2023. URL: https://www.imdrf.org/working-groups/adverse-event-terminology/annex-medical-device-problem.

IMDRF (2022). Imdrf -safety information. *https://www.imdrf.org/safety-information*.

Kessler, L. (2007). Ghtf sg5: Clinical evaluation.

Kim, D., Lee, B., and Lee, J. (2019). Building a rule-based goal-model from the IEC 62304 standard for medical device software. *KSII Trans. Internet Inf. Syst.*, 13(8):4174–4190.

Leveson, N. (1995). Medical devices: The Therac-25. *IEEE Computer*, 26(7):18–41.

Lie, M. F., Sánchez-Gordón, M., and Palacios, R. C. (2020). Devops in an ISO 13485 regulated environment: A multivocal literature review. *CoRR*, abs/2007.11295.

Liebel, T. C., Daugherty, T., Kirsch, A., Omar, S. A., and Feuerstein, T. (2020). Analysis: Using the fda maude and medical device recall databases to design better devices. *Biomedical Instrumentation & Technology*, 54(3):178–188.

Lisa Garnsey Ensign, K. B. C. (2017). A primer to the structure, content and linkage of the fda's manufacturer and user facility device experience (maude) files. *Egems (generating Evidence & Methods to Improve Patient Outcomes)*, 5(1).

Macák, M., Ge, M., and Buhnova, B. (2020). A cross-domain comparative study of big data architectures. *Int. J. Cooperative Inf. Syst.*, 29(4):2030001:1–2030001:27.

Nadakinamani, R. G., Reyana, A., Kautish, S., Vibith, A. S., Gupta, Y., Abdelwahab, S. F., and Mohamed, A. W. (2022). Clinical data analysis for prediction of cardiovascular disease using machine learning techniques. *Comput. Intell. Neurosci.*, 2022:2973324:1–2973324:13.

U.S. FDA (2023). Openfda. https://open.fda.gov/. Accessed March 11, 2023.

Zhang Y, Masci P, J. P. T. H. (2019). Research: User interface software errors in medical devices: Study of u.s. recall data. *Biomedical Instrumentation & Technology*, 53(3).