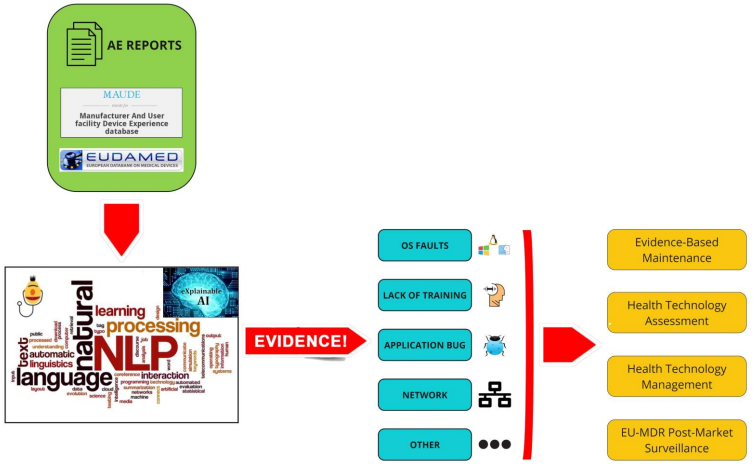
AIIC 2024 AWARDS

Università degli Studi di Firenze
Dipartimento di Ingegneria dell'Informazione

Università degli Studi di Siena
Dipartimento di Biotecnoligie Mediche

Designing and developing a dedicated Natural Language Processing framework for Healthcare Information Technology Management and Assessment



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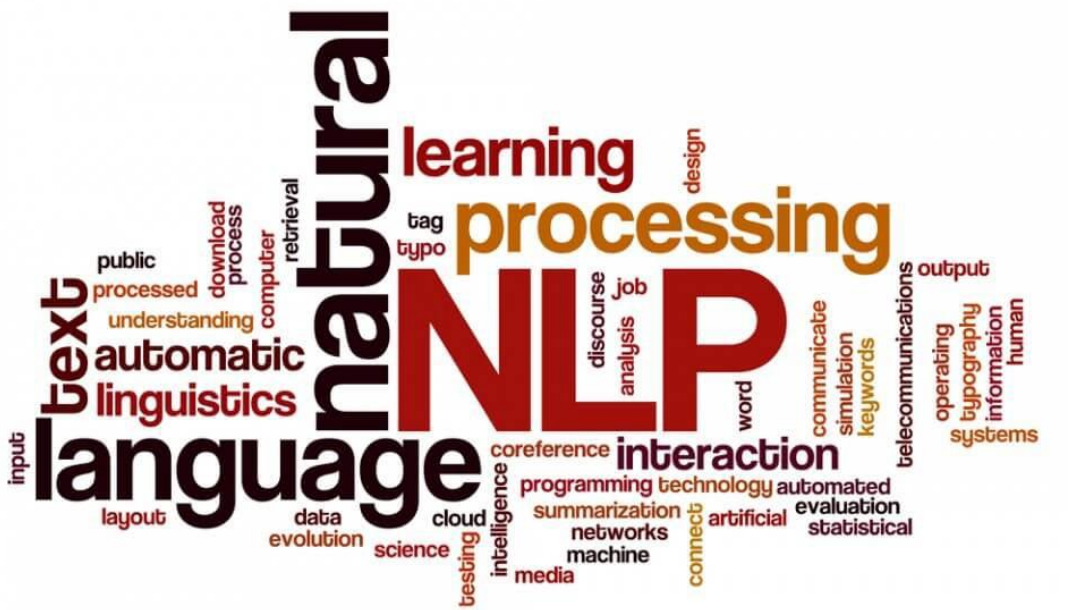
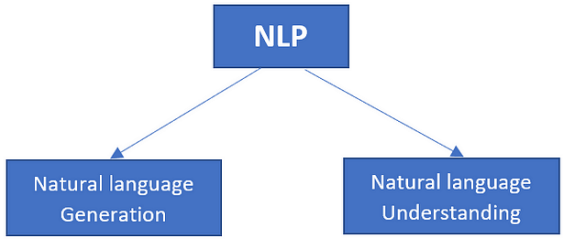
NLP
Natural
Language
Processing



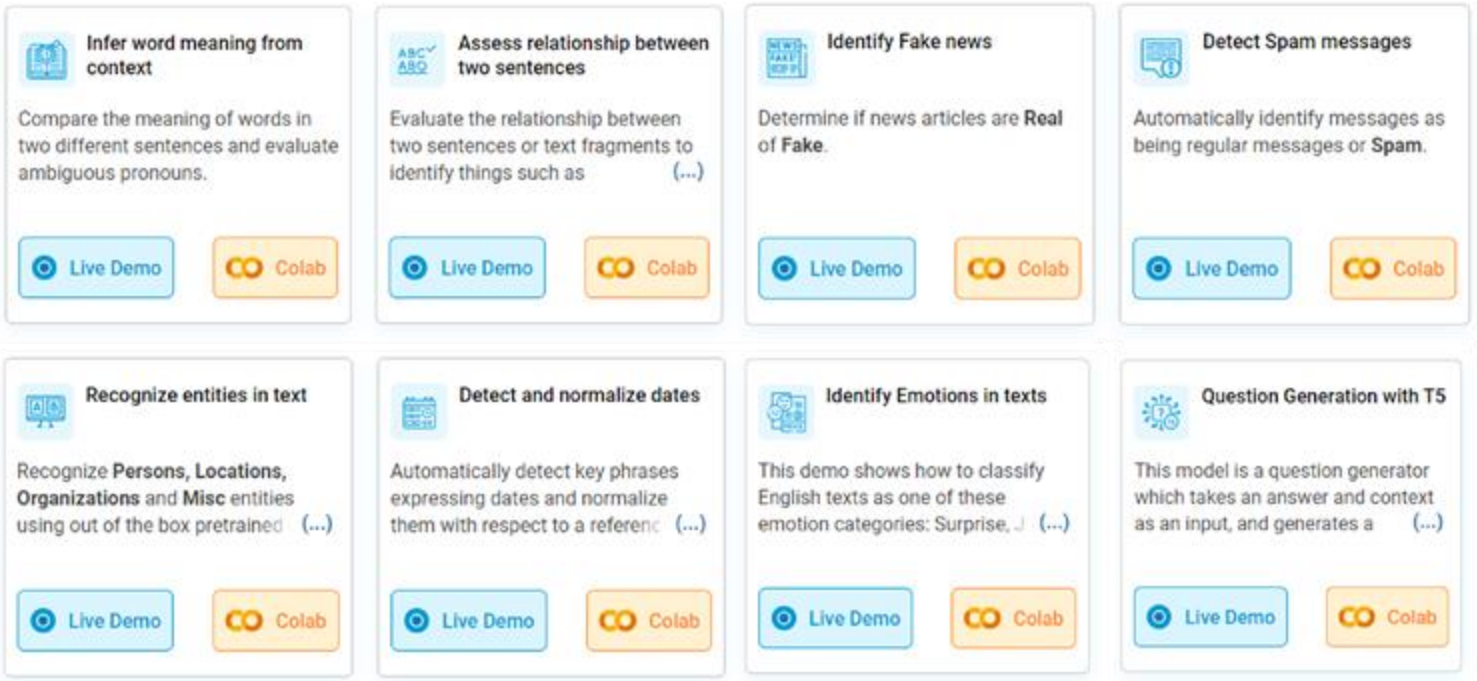
Natural language processing (**NLP**) is a subfield of artificial intelligence with the main goal to help programs understand and process natural language data. The output of this process is a computer program that can "understand" language.

NLP has primarily two aspects:

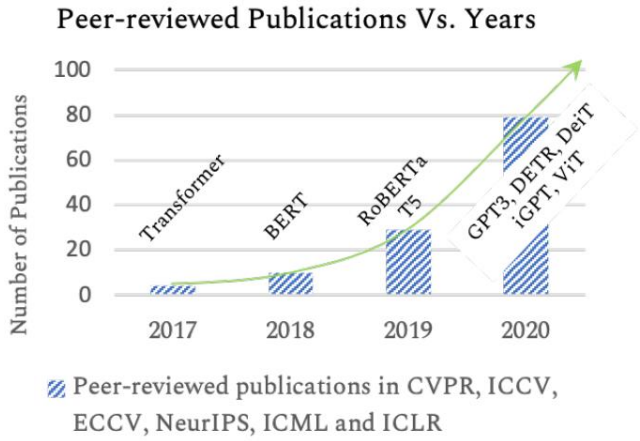
- **Natural Language Understanding** (NLU)
- **Natural Language Generation** (NLG)

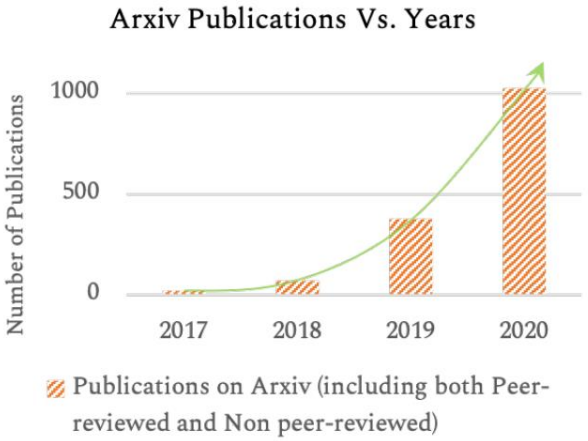


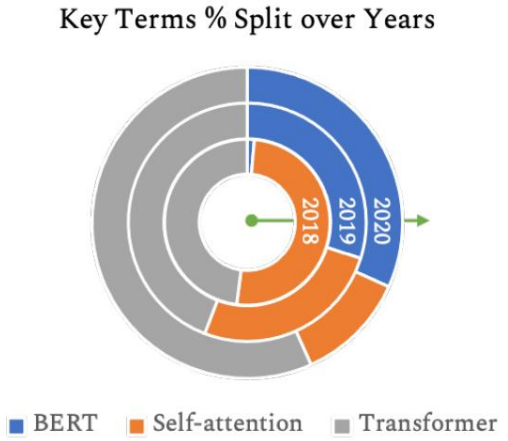
NLP tasks (examples)

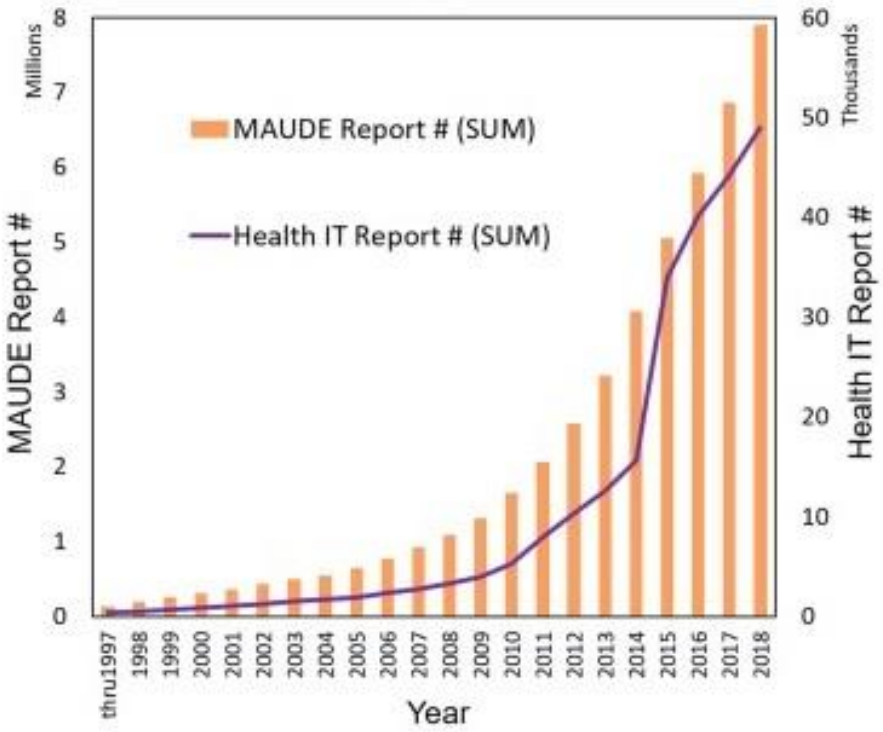


Transformer-based models over the years

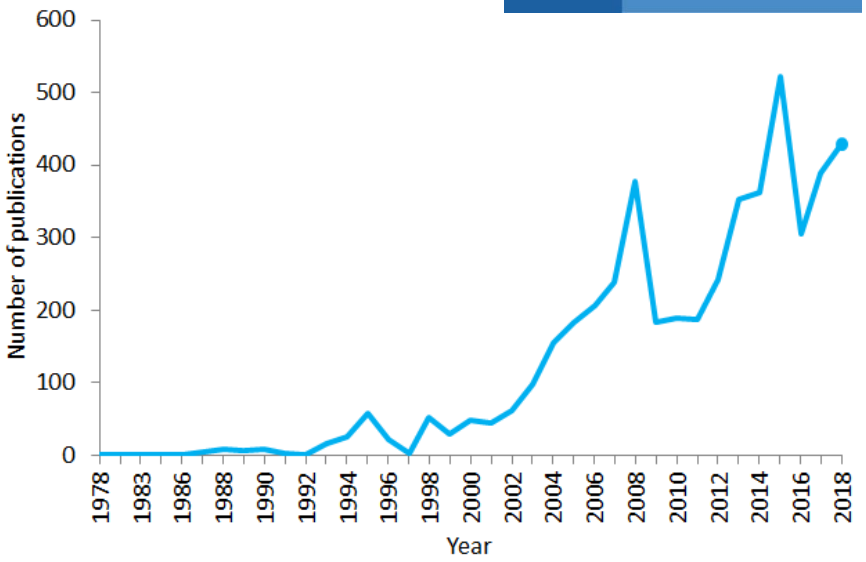








Kang, H., Gong, Y., Creating a database for health IT events via a hybrid deep learning model, Journal of Biomedical Informatics, vol. 110, 2020.



Number of publications containing the sentence “natural language processing” in PubMed in the period 1978–2018. As of 2018, PubMed comprised more than 29 million citations for biomedical literature

NLP in Healthcare and Health Information Technologies

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Top 10 Health Technology Hazards for 2023

Executive Brief

ECRI is providing this Executive Brief describing its 2023 Top 10 list of health technology hazards to inform the healthcare community about key safety issues involving the use of medical devices and systems.

The List for 2023

1. Gaps in Recalls for At-Home Medical Devices Cause Patient Confusion and Harm
2. Growing Number of Defective Single-Use Medical Devices Puts Patients at Risk
3. Inappropriate Use of Automated Dispensing Cabinet Overrides Can Result in Medication Errors
4. Undetected Venous Needle Dislodgement or Access-Bloodline Separation during Hemodialysis Can Lead to Death
5. Failure to Manage Cybersecurity Risks Associated with Cloud-Based Clinical Systems Can Result in Care Disruptions
6. Inflatable Pressure Infusers Can Deliver Fatal Air Emboli from IV Solution Bags
7. Confusion Surrounding Ventilator Cleaning and Disinfection Requirements Can Lead to Cross-Contamination
8. Common Misconceptions about Electrosurgery Can Lead to Se
9. Overuse of Cardiac Telemetry Can Lead to Clinician Cognitive (Missed Critical Events
10. Underreporting Device-Related Issues May Risk Recurrence

ECRI MEMBERS: LOG IN TO ACCESS THE FULL REPORT

Detailed descriptions of the hazards outlined in this Executive Brief, alor by-step recommendations for addressing them, are provided in the 202 Technology Hazards Solutions Kit. Members of ECRI programs can acce through their membership web pages. For more information, contact cl or call +1 (610) 825-6000, ext. 5891.

ECRI The Most Trusted Voice in Healthcare

e DeviceEvaluatior

Underreporting Device-Related Issues May Risk Recurrence

10

TEN

Reporting medical-device-related problems is crucial for keeping patients and staff safe. Unfortunately, problems aren't always reported through appropriate channels, if at all. The reasons for this can vary:

- Device users may be focused on patient care and unable to interrupt a time-sensitive task to submit a report.
- They may be unfamiliar with the method for reporting.
- They may see little benefit to reporting, particularly if no harm was observed.
- They may fear disciplinary action or other personal consequences.

As a result, broken, malfunctioning, poorly manufactured, or poorly designed devices may remain in use.

Attempting to use faulty devices can, at the very least, waste clinician time as users try to effect workarounds or to quickly locate replacement equipment. More significantly, continuing to use deficient equipment can lead to patient harm.

In contrast, when problems are reported as soon as they are noticed, they can often be remedied before patient care is affected. To achieve this goal, healthcare organizations need to identify and eliminate barriers to reporting. Most importantly, they must make the reporting process as easy as possible in order to minimize disruptions to patient care tasks. Other measures include building a culture of safety (to encourage reporting), educating staff about how to identify device-related hazards, providing feedback to keep staff informed about the status of a report, and promoting the "wins"—that is, instances in which a report prevented significant harm or led to meaningful improvements.

> Continuing to use deficient equipment can lead to patient harm.

Top 10 Health Technology Hazards for 2023

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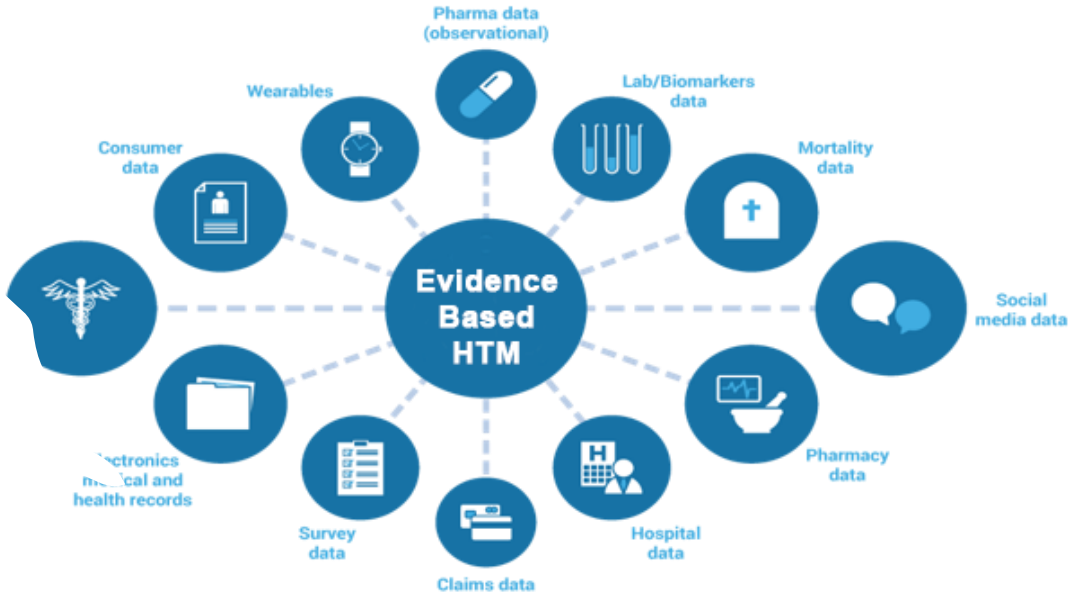
Evidence-Based Maintenance and Real-World Data

Evidence-Based Maintenance consists of the continuous performance monitoring of equipment, starting from the evidence (i.e., the current state in terms of failure history) and improvement of its effectiveness by making the required changes.



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Spontaneous Reporting System

Table 2.1: Publicly Available Vigilance Databases.

Country	National Regulatory Authority	Database
United States	FDA Center for Devices & Radiological Health	Manufacturer and User Facility Device Experience (MAUDE)
European Union	European Commission	European Databank for Medical Devices (EUDAMED)
Australia	Therapeutics Goods Administration	Database of Adverse Event Notifications (DAEN)

MAUDE

stands for

Manufacturer And User facility Device Experience database

VAERS

stands for

Vaccine Adverse Event Reporting System

FAERS

stands for

FDA Adverse Event Reporting System

EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES

Database of Adverse Event Notifications (DAEN)
Australian Government
Department of Health
Therapeutic Goods Administration

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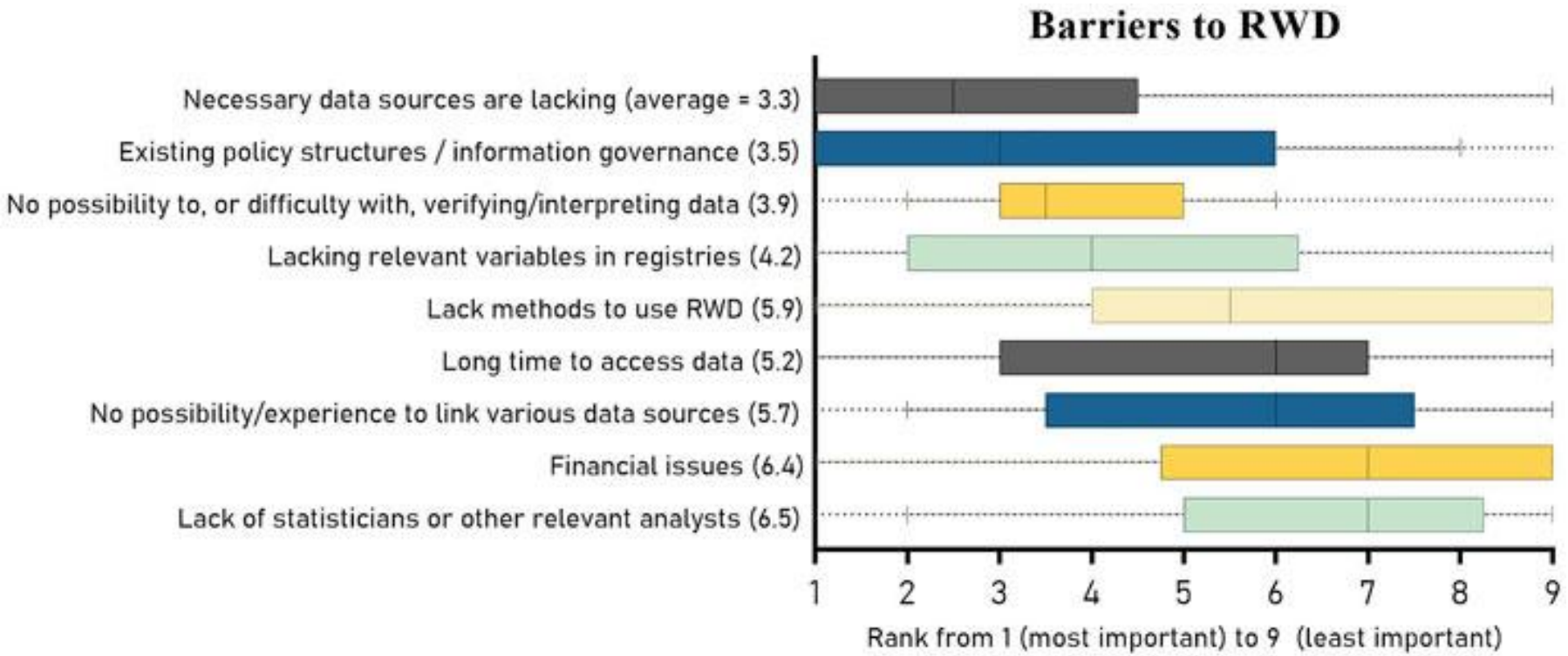

Hogervorst MA, Pontén J, et al. Real World Data in Health Technology Assessment of Complex Health Technologies. Front Pharmacol. 2022 Feb 10;13:837302. doi: 10.3389/fphar.2022.837302.

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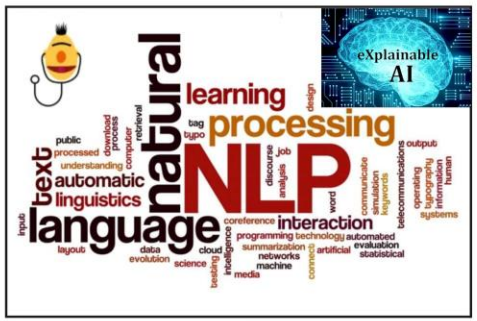
AE REPORTS

MAUDE
stands for
Manufacturer And User facility Device Experience database

EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES



EVIDENCE!

- OS FAULTS
- LACK OF TRAINING
- APPLICATION BUG
- NETWORK
- OTHER

- Evidence-Based Maintenance
- Health Technology Assessment
- Health Technology Management
- EU-MDR Post-Market Surveillance

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Results and Explainable AI applied to the model

The developed model (**HITClinicalBERT**) has an overall classification run-time of:

- 9.73s ± 21.5ms for 1,000 reports.

The classification run-time of one report is:

- 9.48ms ± 5.6µs.

Results show better metrics than other existing HIT adverse events reports text classifiers based on non-BERT NLP models

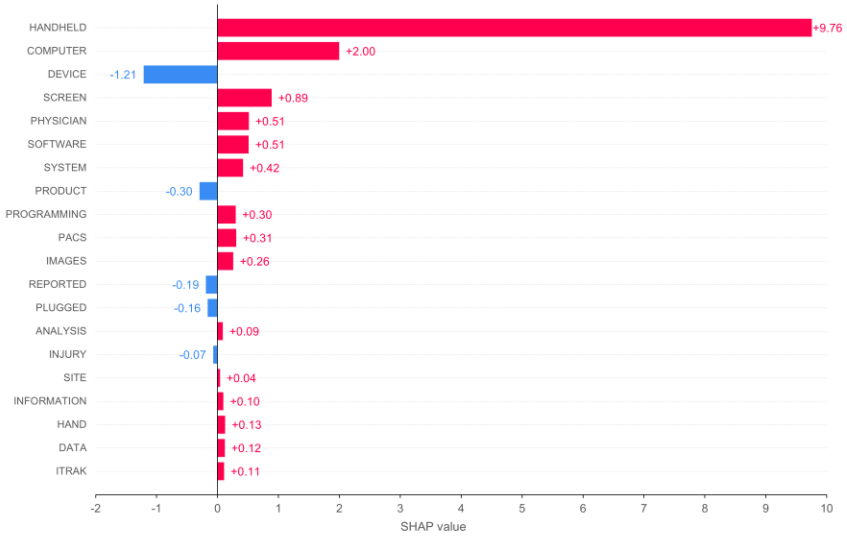
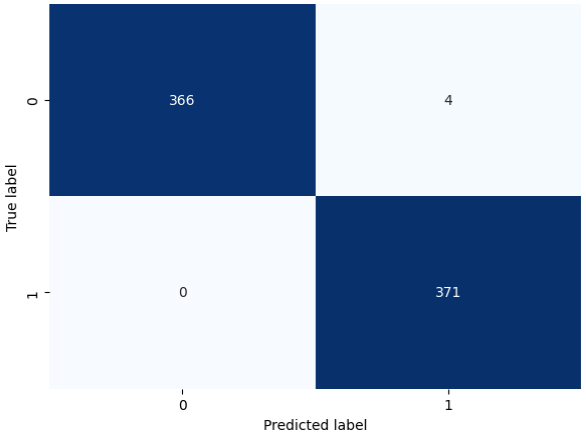


Table 4.2: Comparison of performances of the proposed NLP model (fine-tuned ClinicalBERT) and other non-BERT models. LR - Logistic Regression. SVM - Support Vector Machine. CNN - Convolutional Neural Network. HRNN - Hierarchical Recurrent Neural Network.

Model	Accuracy	Precision	Recall	F1 score
ClinicalBERT	**0.9946**	**0.9893**	**1.0000**	**0.9946**
LR [15]	-	0.9670	0.9420	0.9540
LR [32]	-	0.6940	0.8040	0.7450
SVM+LR+CNN [116]	0.9012	0.8796	0.8606	0.8700
LR+CNN+HRNN [62]	0.9030	-	-	0.8760



[15] K. Chai, S. Anthony, E. Coiera, and F. Magrabi, "Using statistical text classification to identify health information technology incidents," Journal of the American Medical Informatics Association : JAMIA, vol. 20, 05 2013.
[32]A. Fong, K. Adams, M. Gaunt, J. Howe, K. Kellogg, and R. Ratwani, "Identifying health information technology related safety event reports from patient safety event report databases," Journal of Biomedical Informatics, vol. 86, 09 2018.
[62]H. Kang and Y. Gong, "Creating a database for health it events via a hybrid deep learning model," Journal of Biomedical Informatics, vol. 110, p. 103556, 2020.
[116]E. Wang, H. Kang, and Y. Gong, "Generating a health information technology event database from fda maude reports," Studies in health technology and informatics, vol. 264, pp. 883–887, 08 2019.

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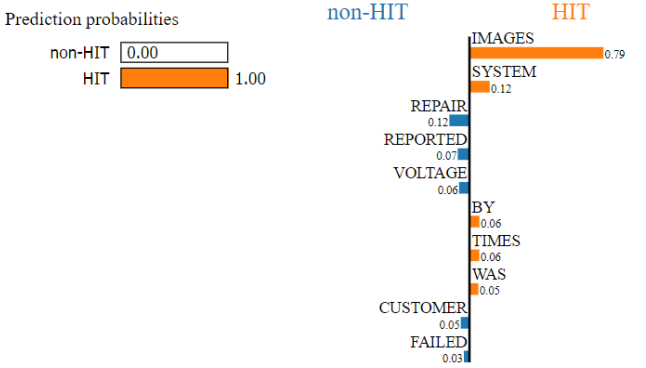
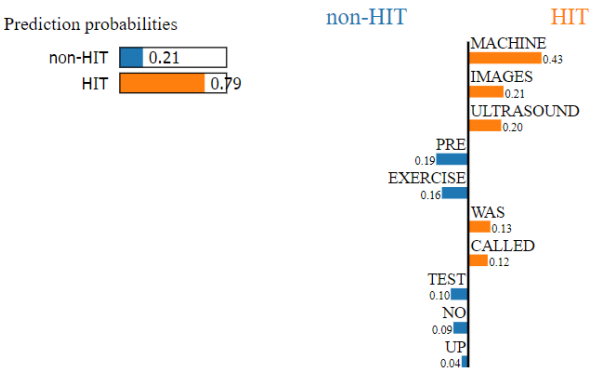
Results and Explainable AI applied to the model



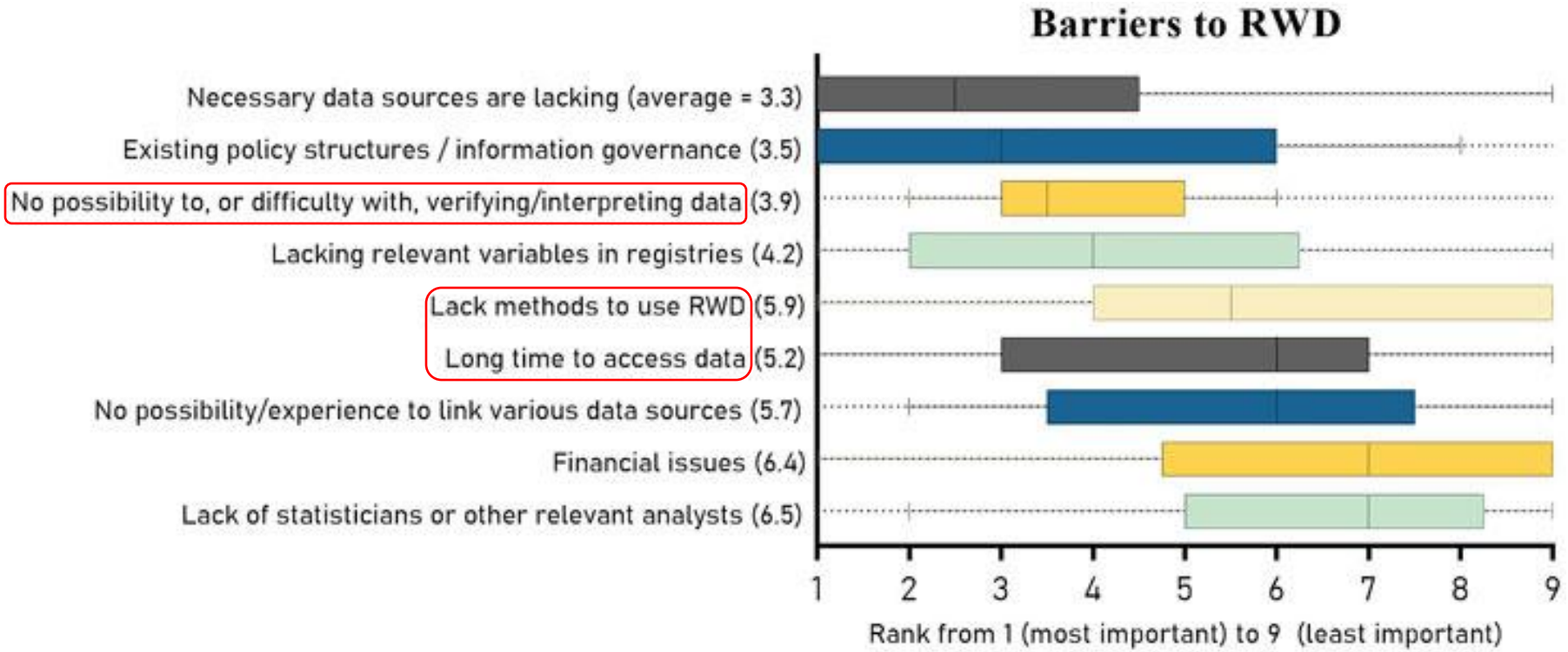
Text with highlighted words

THE CUSTOMER REPORTED THAT THE SYSTEM WAS DISPLAYING A COMMUNICATION FAILED ERROR MESSAGES. THE SYSTEM DID NOT HARM THE PT. THE WORKSTATION POWER SUPPLY WAS WITHIN ITS VOLTAGE SPECIFICATION. THE GE SERVICE REP REPLACED THE SBC CPU BOARD AND VERIFIED THE C-ARM FOR PROPER OPERATION BY REBOOTING 20 TIMES AND USING THE C-ARM. DURING THE COURSE OF THIS REPAIR, HE FOUND A PROBLEM WITH THE IMAGES BEING MIXED UP BETWEEN THE THUMBNAILS AND THE IMAGES. SO ANOTHER CASE WAS OPENED. SYSTEM OPERATES AS INTENDED.



Text with highlighted words

WHILE ACQUIRING PRE-EXERCISE IMAGES, THE ULTRASOUND MACHINE FROZE UP. THIS MACHINE WAS THEN TAKEN OUT OF SERVICE AND ANOTHER MACHINE USED TO COMPLETE THE TEST.========== MANUFACTURER RESPONSE FOR ULTRASOUND MACHINE, BIOMED ULTRASOUND - ECHO MACHINE==========SIEMENS ENGINEER WAS CALLED IN TO CHECK ULTRASOUND UNIT. COMPLETED LEVEL ONE AND LEVEL TWO DISGNOSTICS. SYSTEM PASSED. ACCORDING TO SIEMENS, UNIT WAS OPERATING PROPERLY. NO SOLID EXPLANATION WAS GIVEN FOR FREEZING UP.



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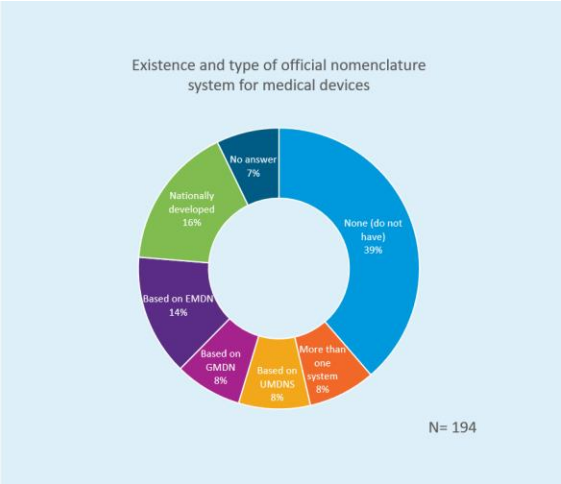
Existence and type of official nomenclature system for medical devices by country

The data for this graph was collected by WHO during 2021 and 2022.

The data is part of the up-date of the 2022 Global Atlas of Medical Devices.

None (do not have)	75
More than one system	15
Based on UMDNS	16
Based on GMDN	15
Based on EMDN	27
Nationally developed	32
No answer	14

World Health Organization



Code	Description
NPF	No problem found
BATT	Battery failure
ACC	Accessory failure (including supplies)
NET	Failure related to network
USE	Failure induced by use (i.e., abuse, accident, environment conditions)
UPF	Unpreventable failure caused by normal wear and tear
PPF	Predictable and preventable failure
SIF	Induced by service (i.e., caused by a technical intervention not properly completed or premature failures of a part just replaced)
EF	Evident failure (i.e., evident to the user but not reported)
PF	Potential failu
HF	Hidden failure
	measurement

Code	Description
Accessory or Disposable Failure	Failure of device accessory or disposable, not a failure of the device itself.
Calibration Failure	Failure of a device to meet calibration parameters, requiring recalibration.
Component Failure (Battery)	Failure of the battery that provides power for device operation.
Component Failure (Not Battery)	Failure of a device component other than the battery.
Failure Caused by Maintenance	Failure of a device resulting from maintenance activities.
Failure Caused by Abuse or Negligence	Failure of a device resulting from damage caused by intentional misuse or negligent use.
Network or Connectivity Failure	Functional failure external to device from failure of network or connectivity.
Software Failure	Functional failure of a device resulting from malfunctioning software.
Use Error (Use Failure)	Failure of a device to support achievement of a clinical objective.
Failure Caused by Utility System	Functional failure of a device resulting from failure of or access to a utility system.
Failure Cause by Environmental Factor	Functional failure of a device resulting from an environmental factor.
Failure Could Not Be Identified	Reported failure could not be reproduced or identified by testing.
Failure Not Diagnosed—Device Not Repaired	Reported failure indicated that testing or repair was unwarranted.
No Failure Associated with the Work Orders	There was no failure associated with the work order (included for completeness).

Nomenclature of Medical Devices and Standardization of Failure Code for maintenance

World Health Organization: **International Classification and Nomenclature of Medical Devices** (ICMD), implemented in the ICD-11.

https://www.who.int/teams/health-product-policy-and-standards/

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Iadanza, E., Luschi, A. (2024). Standardization of Failure Codes and Nomenclature of Medical Devices for Evidence-Based Maintenance. In: IFMBE Proceedings, vol 94. Springer, Cham. https://doi.org/10.1007/978-3-031-49068-2_19

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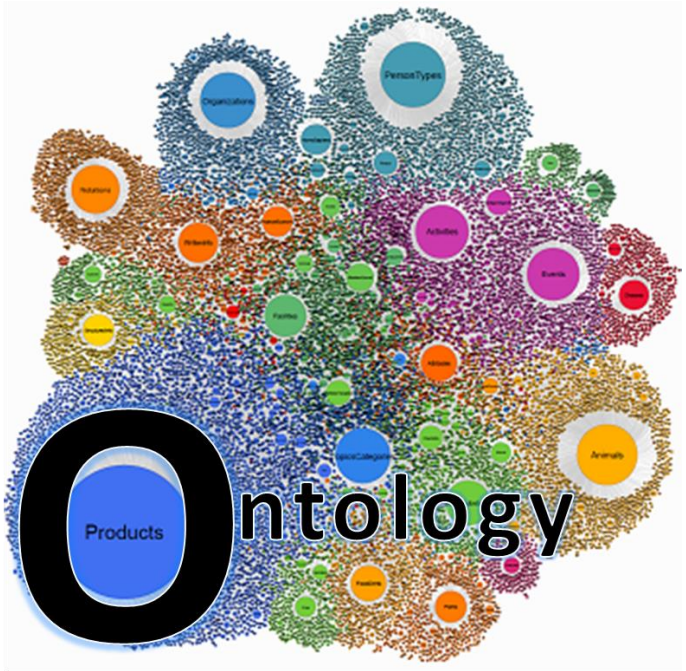

A comprehensive review of existing literature has revealed a notable absence of an up-to-date global standard for naming and coding medical devices and their associated fault codes in maintenance work orders. This deficiency poses significant challenges when attempting to collect data from diverse systems, as mapping across disparate nomenclatures becomes exceedingly difficult due to the unique internal organization of each nomenclature and CMMS software.

Semantic ontologies offer the potential to establish a suitable level of abstraction for sharing and reusing concepts in a standardized manner. This ensures that data from diverse sources can be provided with a common nomenclature, facilitating communication among stakeholders and **streamlining the integration of the proposed NLP framework for Health Technology Management and Assessment, and Post-Market Surveillance in line with the EU Medical Device Regulation (EU-MDR) 2017/745**.

NCIT Ontology (National Cancer Institute Thesaurus)

SCTO (SNOMED-CT Ontology)

CORA Ontology (Core Ontology for Robotics and Automation)

BOT (Building Topology Ontology)

WoT (Web Of Things) Ontology

ICD9CM Ontology

The Organizational Ontology

The **OdinEMDN** (European Medical Device Nomenclature Semantic Ontology)

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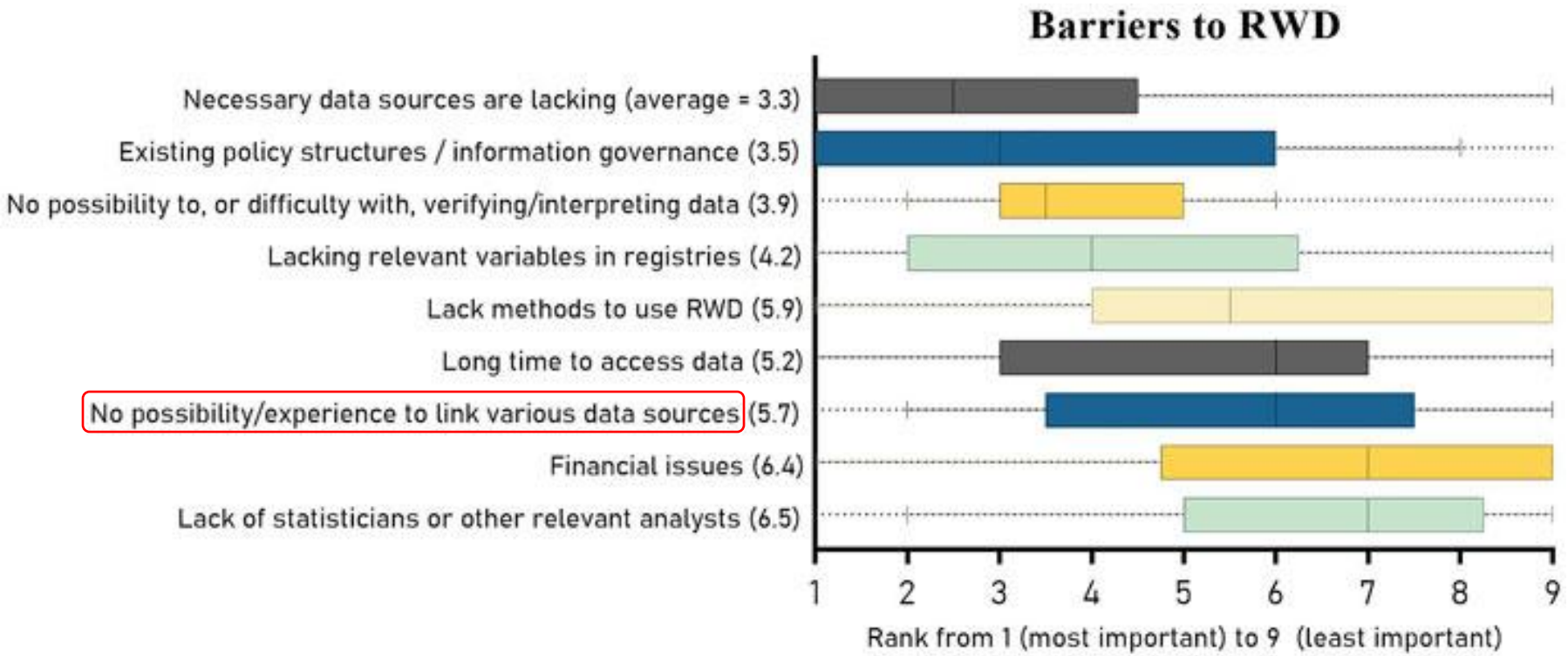

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Final thoughts

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