SESSION SPEAKER

JERRY XIAO (CQE, CQA, CSSBB, CRE)

RdQCC LLC

Using AI-Powered Application to Conduct Risk Assessment for Post market Data

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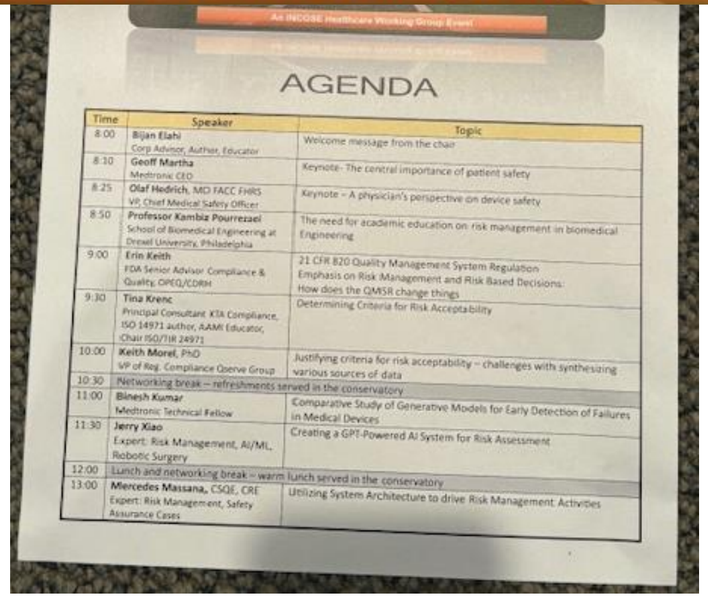
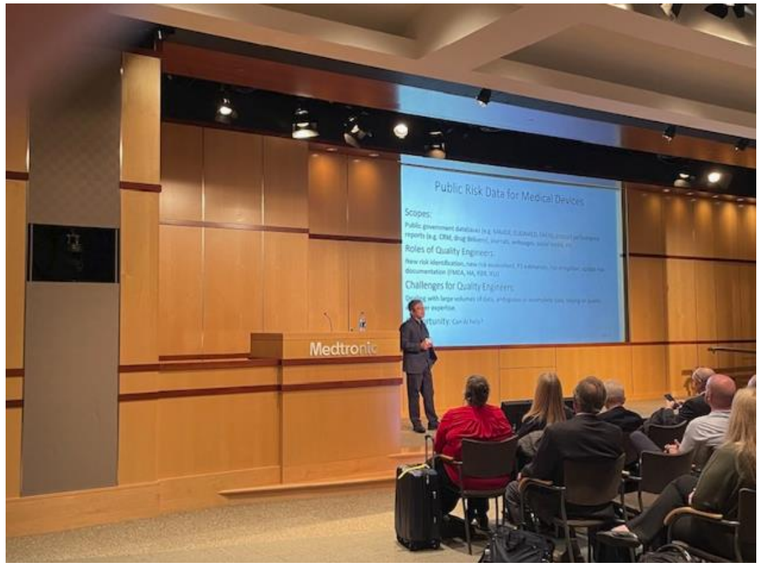
Minneapolis, Minnesota, USA

First International Conference on Medical Device Safety Risk Management



AGENDA

Time	Speaker	Topic
8:00	**Bijan Elahi** Corp Advisor, Author, Educator	Welcome message from the chair
8:10	**Geoff Martha** Medtronic CEO	Keynote- The central importance of patient safety
8:25	**Olaf Hedrich**, MD FACC FHRS VP, Chief Medical Safety Officer	Keynote – A physician's perspective on device safety
8:50	**Professor Kambiz Pourrezaei** School of Biomedical Engineering at Drexel University, Philadelphia	The need for academic education on risk management in biomedical Engineering
9:00	**Erin Keith** FDA Senior Advisor Compliance & Quality; CPEQ/CDRH	21 CFR 820 Quality Management System Regulation Emphasis on Risk Management and Risk Based Decisions: How does the QMSR change things
9:30	**Tina Krenc** Principal Consultant KTA Compliance, ISO 14971 Author, AAMI Educator, Chair ISO/TIR 24971	Determining Criteria for Risk Acceptability
10:00	**Keith Morel**, PhD VP of Reg. Compliance Qserve Group	Justifying criteria for risk acceptability – challenges with synthesizing various sources of data
10:30	Networking break – refreshments served in the conservatory	
11:00	**Binesh Kumar** Medtronic Technical Fellow	Comparative Study of Generative Models for Early Detection of Failures in Medical Devices
11:30	**Jerry Xiao** Expert: Risk Management, AI/ML, Robotic Surgery	Creating a GPT-Powered AI System for Risk Assessment
12:00	Lunch and networking break – warm lunch served in the conservatory	
13:00	**Mercedes Massana**, CSQE, CRE Expert: Risk Management, Safety Assurance Cases	Utilizing System Architecture to drive Risk Management Activities



Public Risk Data for Medical Devices

Scopes:

Public government databases (e.g. MAUDE, EUDAMED, DAEN), product performance reports (e.g. CRM, drug delivery), journals, webpages, social media, etc.

Roles of Quality Engineers:

New risk identification, new risk assessment, P1 estimation, risk mitigation, update risk documentation (FMEA, HA, RBR, IFU)

Challenges for Quality Engineers:

Dealing with large volumes of data, ambiguous or incomplete data, relying on quality engineer expertise.

Opportunity: Can AI help?

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Section 1:
Understanding human-driven Risk Assessment

Humans Use Top-Down Approach

Standard Requirements (e.g. 62304, 12052, 27001,17568)

Engineering Requirements (e.g. hardware, software, network)

Use Requirements (environment, patient, user)

Module A communicates with Module B

Failure Mode	* Inappropriate communication protocol * data breached	* Cable damaged * Network latency * Software corrupted	* Fail to link module * User error
Hazard	Data issue	application network issue	Use of device issue
Hazardous Situation	Application security issue	Loss of communication	Loss of operation
Harm	Patient privacy violation	Hypoxia, organ damage	Delay in therapy
Risk Mitigation	Compliance assessment	Upgrade bandwidth, backup	Training, usability studies

Human Cognitive Process

Cognitive psychology has revealed that:

- **Cognitive biases**: humans are subject to cognitive biases. By understanding these biases, each individual may deviate when conducting risk assessment.
- **Information processing Issue**: individuals may gather information differently, and risk mitigation can be inadequate due to technology availability.
- **Learning** from **experience**: experts often follow **distinct** cognitive processes when performing risk assessment compared to novices.
- **Mental models**: individuals often construct mental models or frameworks when dealing with complex risks.

Logical Thinking is a Hidden Strength of Humanity

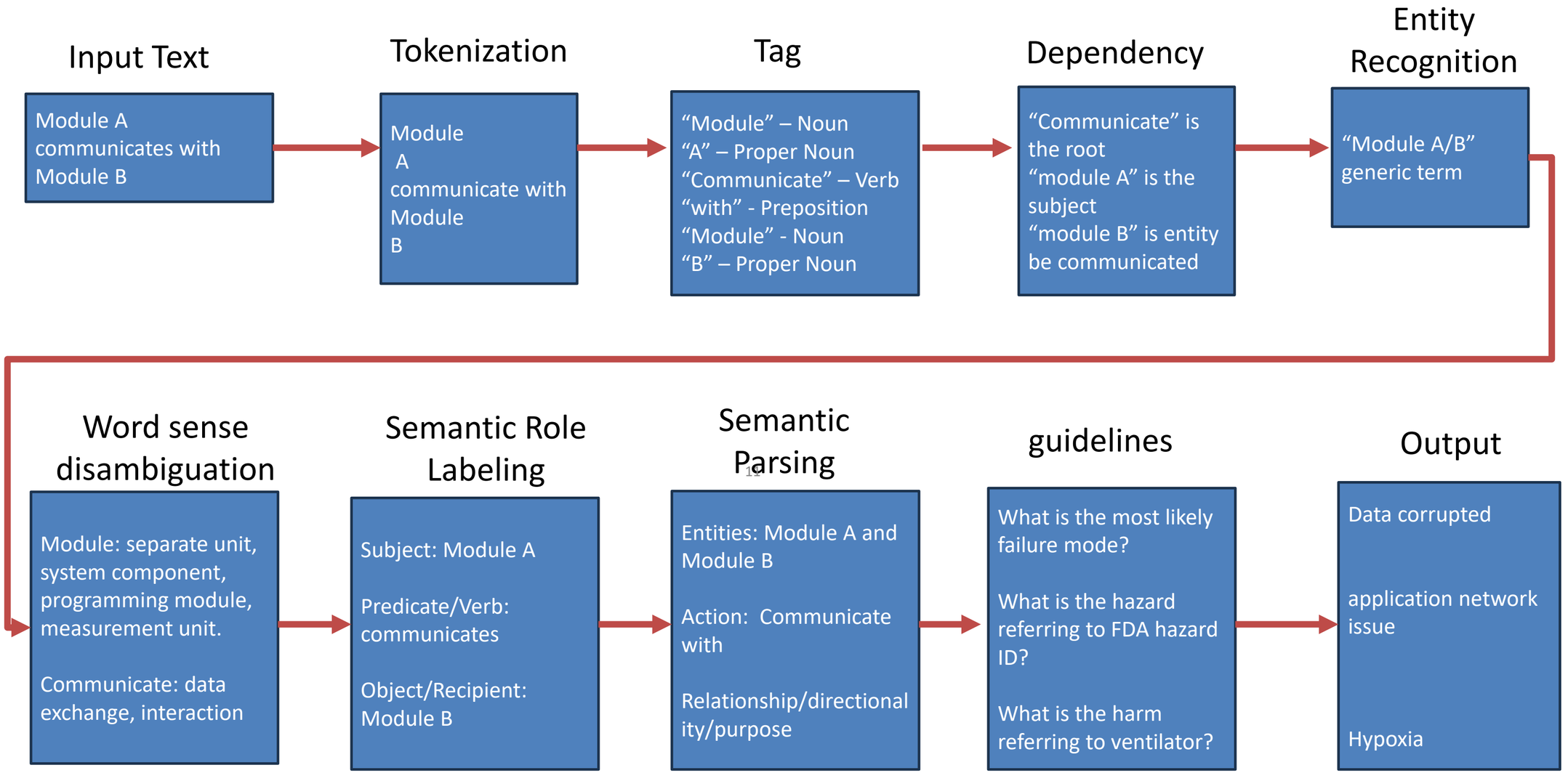
- **Structured and systematic approach**: This helps us to explore risks comprehensively, avoid common cognitive biases, and ensure risk assessments are grounded in sound reasoning.
- **Logical fallacy avoidance**: These include hurried generalization, false causality, confirmation bias, all of which can distort risk assessments.
- potential **risk factors:** Consideration of uncertainties, hazards, consequences, likelihood, events, scenarios.
- **Cause-effect relationships**: This allows us to understand how one factor may lead to or influence another, and construct relationship chains.
- **Risk probabilities:** This is done based on available data and evidence, rather than relying solely on intuition.

Section 2:
Introducing AI for data processing

Core of AI: Technique of Semantic Analysis

- **Understanding structured information**: databases, tables, user needs, product requirements, specifications, event reporting, patient data.
- **Understanding unstructured information**: documents, reports, customer complaints, images of product damage, and product failure videos.
- **Information extraction**: extract keywords, identify topic or themes, find similar risk terms within a document or conversation. (e.g. failure modes, hazards)
- **Contextual analysis**: analyze the surrounding text to understand the circumstances, causes, and potential consequences of each risk.(e.g. cause)

Example: Semantic Analysis



AI Uses Bottom-Up Approach

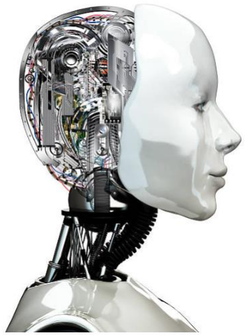
Risk Mitigation	Compliance assessment	Upgrade bandwidth	Training, usability studies
Harm	Patient privacy violation	Hypoxia	Delay in therapy
Hazardous Situation	Application security issue	Loss of communication	Loss of operation
Hazard	Data issue	application network issue	Use of device issue
Failure Mode	* Inappropriate communication protocol * data breached	* Cable damaged * Network latency * Software corrupted	* Fail to link module * User error

most likely F. M

second likely F.M.

third likely F. M.

Module A communicates with Module B



GPT-3.5: Trained on massive amounts of text data
(hundreds of gigabytes of text from the internet)

Entities
Action

Subject
Verb
object

ambiguity

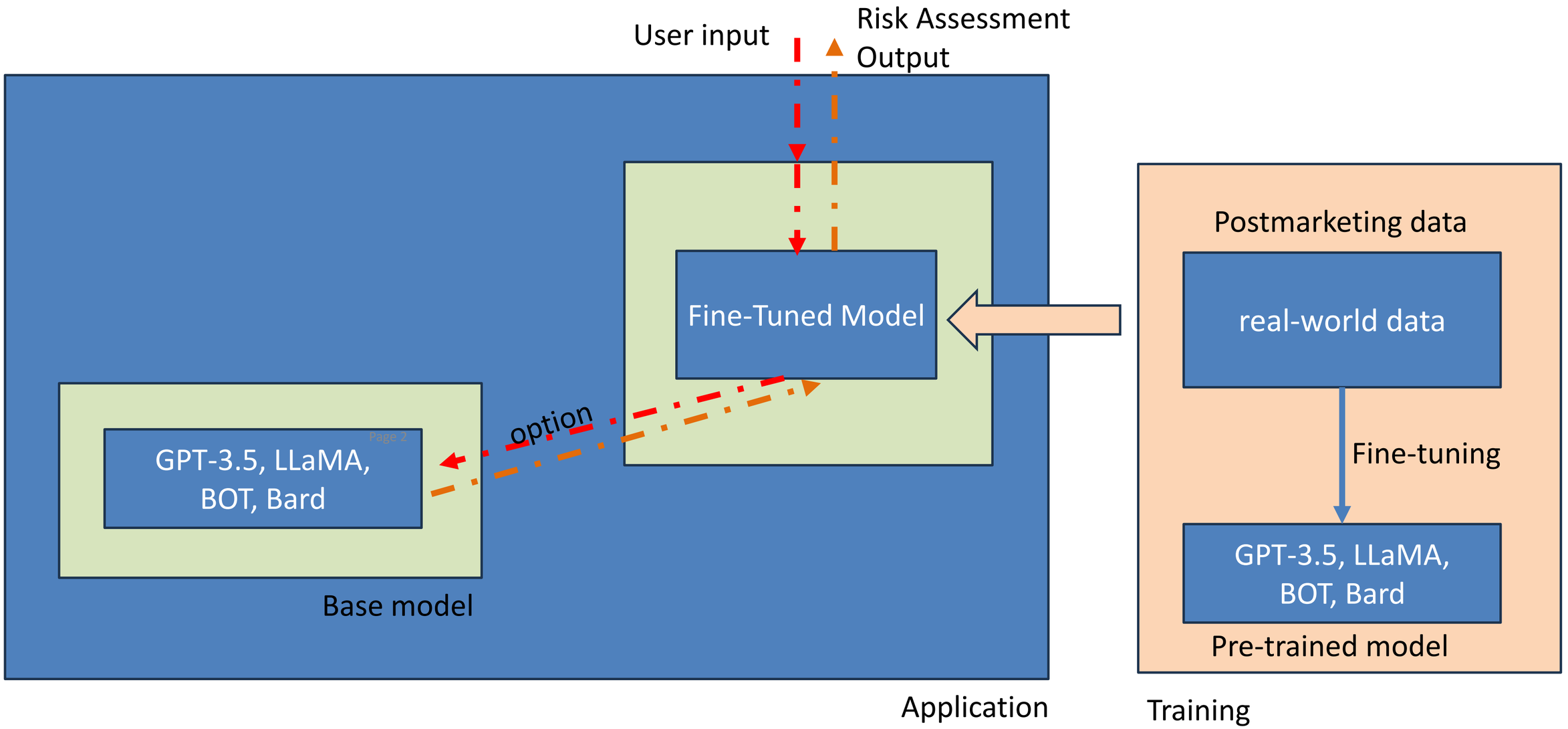
Relationship
Direction, dependencies

Functional interaction

Operational scenarios

Section 3:
Establishing AI-powered application to assess risks

Diagram of the AI-Powered Application



Benefits of Fine-Tuned Model

- **Task-specific performance**: GPT-3.5, like other pre-trained models, has a general understanding of language. Fine-tuned model allows to specialize on the risk knowledge and risk assessment tasks.
- **Control outputs**: fine-tuned model can control and guide the ChatGPT outputs to provide more relevant and appropriate responses.
- **Data privacy and security**: fine-tuned model is hosted on your own server to keep sensitive information and your visitation data within your organization.
- **Improved accuracy**: fine-tuned model can provide your unique Hazard Lists, Hazardous Situation Lists, and Harm Lists to achieve higher accuracy.

How to Create a Fine-Tuned Model

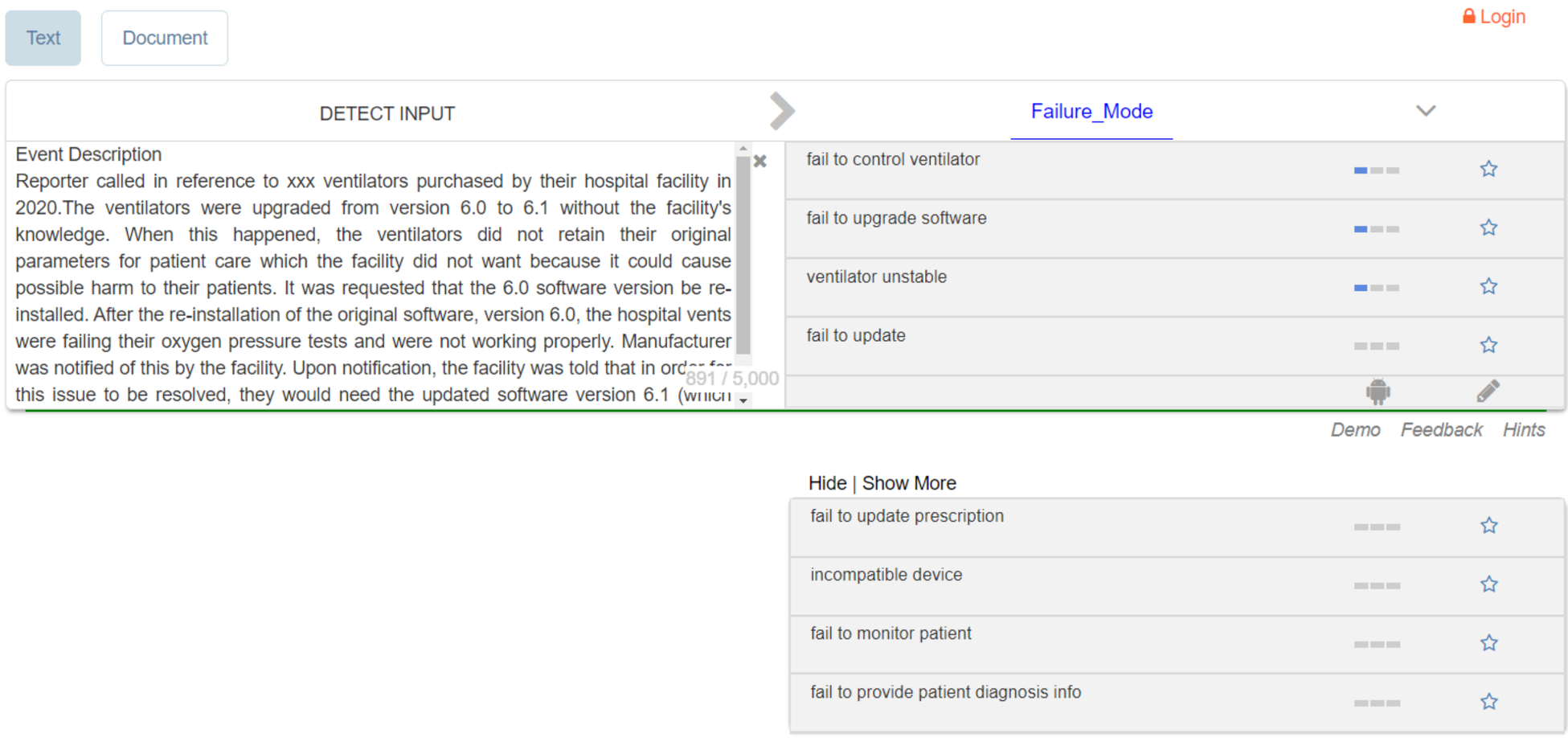
- The fine-tuned model is at the **core** of GPT-powered application.
- **Collect training data**: gather a comprehensive dataset that representative of real-world scenarios including requirements, post market data, risk documentations, field failure data, medical side events as possible.
- Data **pre-processing**: clean and standardize the text such as tokenization, lowercasing, punctuation removal, and stop-word removal.
- **Generate** a fine-tuned model: setup fine-tuning environment and configuration (e.g. epochs), access to powerful GPU resources.
- Model **validation**: ensure that all risk assessment satisfy your organization needs (e.g. accuracy, less biases).

Section 4:
Case study: risk assessment on public postmarketing data

Public Postmarketing Data in Medical Devices

- FDA Maude: manufacturer and user facility device experience https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
- Australia TGA DAEN: Database of adverse event notification https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx
- Health Canada: Canada vigilance adverse reaction online database (since 1965) https://cvp-pcv.hc-sc.gc.ca/arq-rei/index-eng.jsp
- EUDAMED: European database on Medical Devices (expect in Q3 2024) https://ec.europa.eu/tools/eudamed/#/screen/home
- German BfArM DMIDS: German medical devices information and database system. https://www.bfarm.de/EN/Medical-devices/Tasks/DMIDS/Public-databases/_node.html
- Etc.

Example of AI-Powered Application for Risk Assessment: www.risk-chat.com



Section 5:
Questions and Answers