Judi
by AG Mednet

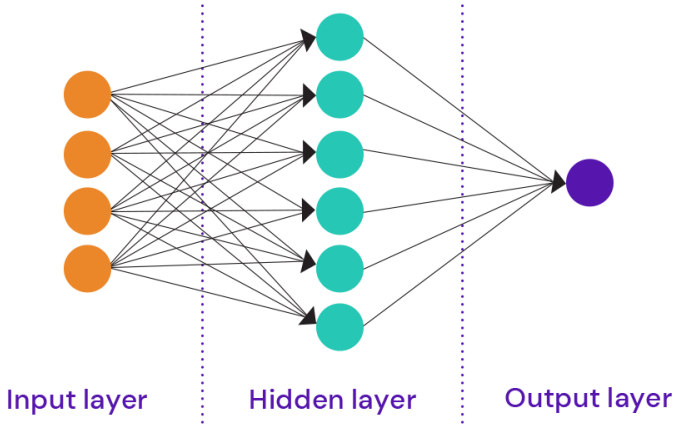
Harnessing AI for Clinical Trial Workflow Management

Large Language Models and Neural Networks for Redaction, Endpoint Adjudication and Central Eligibility Reviews

Large Language Models (LLMs)

Large language models (LLMs) such as Bard, Transformer and GPT have begun to permeate many areas of business and everyday life. The way most people experience them is as Bot implementations where the systems exhibit an almost-human ability to answer questions using prose as opposed to providing links to answers. It is important to know how these systems work to understand their capabilities.
LLMs are trained by taking in massive amounts of text as input and enabling internal machine learning algorithms to perform complex statistical analysis around the occurrence of individual words or phrases, and the frequency with which these words or phrases occur in proximity of others. With a sufficiently sized set of training texts, these systems create the equivalent of relationship graphs (e.g., Vector Spaces, Neural Networks) that connect words or phrases to other words or phrases. These graphs become very complex networks of connections that computer scientists have likened to those of neurons in human brains. (It is for this reason that these learning systems are often referred to as "Neural Networks".)
A simplified way to think about how they work, is that when an LLM is presented with a question, it looks at the words that make up the question, derive the meaning of the question and then use some methodology (e.g., Beam Search) to generate possible answers which are then ranked before presenting the best one(s).

AG Mednet has been exploring the use of LLMs in the areas of redaction, endpoint adjudication and central eligibility reviews.



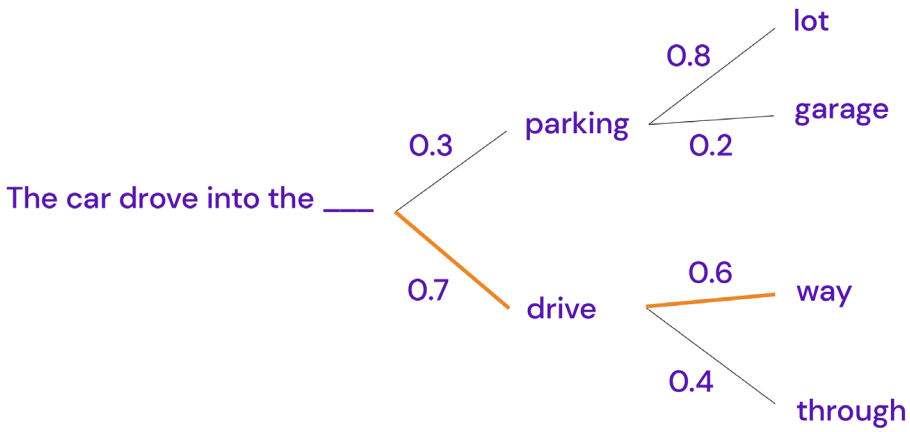
To learn more about Judi by AG Mednet, visit www.judi.io, or contact the company at info@agmednet.com.

Click here to read why Frost & Sullivan selected AG Mednet as winner of the Global Customer Value Leadership Award for 2023.

Redaction and De-Identification

In targeting redaction and de-identification requirements in clinical trials existing LLMs present interesting opportunities. Well trained systems like the ones mentioned above have good representations of parts-of-language that make up the definition of PII. Machine learning can be used to classify PII and remove it from text. These methodologies can help organizations to comply with regulations such as the General Data Protection Regulation (GDPR), while reducing the burden on investigator sites and CROs to catch every PII instance in extensive document sets.

There are a number of challenges to overcome in order to enable robust, automated redaction/de-identification:



1. **Scanned Paper Documents**: A large number of documents provided by investigator sites are pdf versions of scanned physical documents. Most often these paper scans are done without applying Optical Character Recognition (OCR), thus making the resulting files sub-optimal for most operations including simple things such as search-and-replace, and more complex ones such as automated redaction. For those sites where the trial coordinator is actually generating the required documents, simply asking that they print-to-pdf as opposed to printing to paper and then scanning, can dramatically change this equation. For those sites where paper documents are scanned, requesting that OCR be enabled on their scanners can also have a very positive effect in enabling powerful functions to reduce PII escapes and increasing data quality.
2. **Regulatory Compliance**: Country regulations require that document redaction occur prior to data being uploaded by investigator sites. We are exploring a number of approaches to this problem. They include:
    a. **Ability to Run LLM Locally**: The possibility to running a constrained environment (an "embedding" in NN parlance), fine-tuned to recognize the common elements of PII, that could be served through browser-based code.
    b. **Cloud-Based Redaction as Quality Control Mechanism**: Utilize cloud-based LLMs to automatically check the work submitted by site senders and reducing both CRO burden and possible GDPR violations.

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Endpoint Adjudication and Eligibility Reviews

Endpoint adjudication and central eligibility reviews are areas ripe for AI system approaches. One of the reasons is that, in both cases, we have access to an extremely rich set of curated data that can be used to train ML models. Adjudication and eligibility data in Judi has been collected using very specific charters, and it has been reviewed and quality controlled (QC'd). Available data analyses are the product of multiple reviews by independent experts under a controlled environment, and in the case of expert disagreement (i.e., discordance) CECs are able to produce final outcomes.

At a very high level, adjudication and eligibility processes are the same: An investigator site gathers required documents which they redact and/or de-identify. These documents are then presented to a trial administrator at the CRO who verifies that all the required data are present, and all redactions have been completed. In those cases where additional PII is detected, the CRO completes the redactions and creates a dossier. The next and final step is the evaluation of the dossier to produce a conclusion.

AG Mednet believes there are significant benefits to creating LLMs trained on the above data and consider applying it in the following scenarios:

1. **Computer-Aided Adjudication/Eligibility**: Utilize the trained LLM to extract key data from medical histories and other documents and suggest possible analyses to individual adjudicators
2. **Autonomous Initial Adjudication/Eligibility with CEC Backstop**: Utilize the trained LLM to adjudicate endpoints or events, forwarding to a CEC those that don't reach a particular level of reliability
3. **Retrospective Adjudication/Eligibility from Source Documents**: Utilize the trained LLM to perform retrospective adjudication on failed trials that have not been adjudicated and on selected participant data to look for possible endpoints that could lead to discovery

Proposed Approach

AG Mednet, under the direct guidance of its CEO, has initiated a robust research project in the area of redaction. We have begun to train ML models to recognize names, addresses, patient IDs, dates and titles and our early results are extremely promising. We have also begun to explore the possibilities and requirements for running such models in our Judi platform, thus enabling local redaction within regulatory constraints. Additionally, we are exploring various OCR capabilities to understand accuracy and runtime options.

AG Mednet is also actively identifying partnerships and collaboration models with leading clinical development entities for the goal of introducing Artificial Intelligence (AI) technology to optimize redaction, endpoint adjudication and central eligibility review processes in clinical trials. AG Mednet believes that the time is right to first experiment and then implement a series of capabilities within the Judi platform to enhance three specific areas: (1) Document redaction; (2) Dossier creation; and (3) Adjudication/Eligibility reviews.