

# Classifying Texts into Organized Drug Label Sections Using BERT Language Modeling

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## Introduction

- Structured data formats are critical for accessing and processing text data in regulatory science.
- Despite the FDA's guidelines for regulatory submissions in Structured Product Labeling (SPL) format<sup>[1]</sup>, many labeling documents are still not well formatted, which hinders their information from being accessed and used.
- This study focuses on developing a language model that can classify texts/sentences into organized drug labeling sections.

## Related Work

- Several studies have shown promising results with regard to predicting the section label for a given sentence.
- In 2017, Deroncourt and Lee<sup>[2]</sup> aimed to predict the section (i.e., background, objective, method, result, or conclusion) of a given sentence for 200,000 medical abstracts, and their trained artificial neural network achieved an accuracy of over 90%.
- In 2020, researchers used BERT-based classification models to predict whether a sentence is propaganda (as well as the propaganda technique) or non-propaganda with 55-80%+ accuracy for various classification tasks.<sup>[3]</sup>

## Methodology

- Over 17 million sentences were extracted from 45,626 drug labeling documents obtained from DailyMed's full release of human prescription labels.<sup>[4]</sup>
- Using Logical Observation Identifiers Names and Codes (LOINC)<sup>[5]</sup>, the documents were separated into Physician Label Rule (PLR) Format (n=29,709) and Non-PLR Format (n=15,917).
- A series of BERT-based models were trained using datasets composed of 10,000 sentences per label from the "golden standard" PLR-format drug labeling documents.
- In addition to testing these models on PLR and Non-PLR datasets, an external dataset was assembled to further measure the models' performance.
- 9,580 Summaries of Product Characteristics (SmPCs), which are akin to U.S. prescription drug labels, were obtained from the UK medicine database, Electronic Medicines Compendium.<sup>[6]</sup>

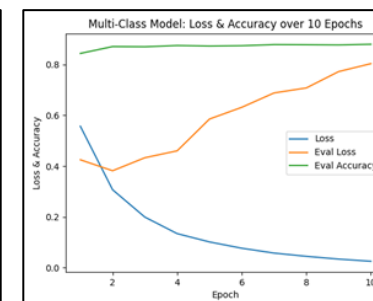
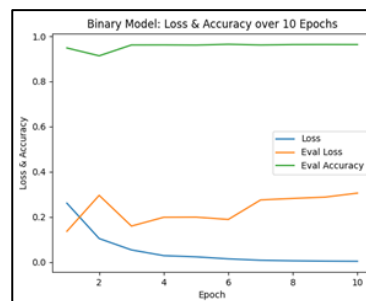
## Results

- The tables below show the prediction accuracies and precision produced by fine-tuned binary and multi-class models for three testing datasets, each of which contained 10,000 records per label.

		Overall	Indications & Usage	Warnings & Precautions
Binary (96% Training Accuracy)	PLR	95%	94%	96%
	Non-PLR	89%	91%	88%
	UK SmPC	89%	93%	85%

		Overall	Indications & Usage	Warnings & Precautions	Adverse Reactions	Other / Unknown
Multi-Class (88% Training Accuracy)	PLR	84%	90%	85%	86%	77%
	Non-PLR	74%	82%	47%	86%	80%
	UK SmPC	67%	79%	58%	71%	59%

- The results above show that the BERT-based model excels at differentiating sentences between two distinct categories and that model performance only slightly drops off when more categories are introduced.
- Furthermore, it is noted that the results for the Non-PLR and SmPC datasets are similar, showing that the model works well for the external UK dataset.



- The graphs above, showing the models' loss and accuracy over the course of fine-tuning, mostly display the expected behavior; however, the additional labels led to more evaluation loss in the multi-class model.

## Discussion

- To explore how a different input-level would affect the results, the same experiments were conducted again, but with paragraphs as inputs rather than sentences.
- Typically, the paragraph-input models had better training accuracies and worse testing accuracies, indicating that overfitting was much greater in these models.
- Furthermore, the paragraph-input models were worse at sentence-label prediction than the sentence-input models.

## Conclusion

- In an effort to make unstructured text information more accessible to researchers, this study focused on developing a language model that can classify texts into organized drug labeling sections.
- The results showed that automatically classifying free-texts into appropriate drug label sections is possible to an extent.
- Moreover, this research could be used to process other unformatted (e.g., scanned or photographed) drug labeling documents and their contents.

## Acknowledgment

- Special thanks to ORISE – your support is appreciated.

## References

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