

# Evaluating an NLP-Based Approach to Modeling Computable Clinical Trial Eligibility Criteria

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## Abstract

*One area of active research and development within the clinical research informatics domain is the design and use of clinical trial participant recruitment tools. Such tools require the definition of clinical trial eligibility criteria in a computable format. This abstract describes a pilot study employing a natural language processing-based approach for abstracting generic query patterns that are representative of eligibility criteria as found in a corpus of clinical trial protocol documents.*

## Introduction

Numerous recent reports have outlined the benefits and advantages afforded by the use of information technology to support clinical research<sup>1</sup>. One active area of research and development within this domain has focused upon the semi-automated or automated identification of clinical research participants<sup>2</sup>. Such identification can be either prospective (e.g., at the point of care) or retrospective (e.g., based upon data collected from patients during previous encounters). The specific criteria needed to formulate such queries are defined in terms of eligibility criteria statements, such as “Ejection fraction less than or equal to 35% by echocardiography”. Current tools used to automatically identify potential study participants usually require the definition of protocol-specific rules<sup>2</sup>. However, we hypothesize that a knowledge collection of generic inclusion or exclusion criteria query patterns could be used as the basis for expediting the deployment of fully-automated clinical trial participant identification platforms.

## Methods

Our pilot study focuses upon the evaluation of a natural language processing (NLP) based approach to parse clinical trial eligibility criteria statements in order to derive generic query patterns. We collected a corpus of 195 eligibility criteria statements from Phase I-III cardiology clinical trials. These statements were then parsed using the MedLEE NLP engine<sup>3</sup>. A random sample of 50 of the parsed statements was then subjected to a consensus-based evaluation conducted by two experts according to two axes. **Axis 1** was concerned with the completeness of coverage and accuracy of the semantic concepts parsed by MedLEE as compared to the statement used as input. For those criteria

where all relevant concepts were deemed to have been correctly parsed, **Axis 2** evaluated the accuracy of the set(s) of relationships between semantic concepts as compared to the input statement. It is important to note that MedLEE had not been previously trained for this specific domain.

## Results

Our results indicated that for 14% of statements, the parsing results completely and correctly represented all concepts and relationships, and that for 62% of statements the parsing results correctly represented some but not all concepts and/or relationships. In the case of 24% of statements, some aspect of the parsed concepts or relationships was incorrect. We found that the majority of the parsing errors were due to abbreviations, mathematical comparisons (e.g., greater/less than), and clinical research-specific concepts (e.g., informed consent, study). Such issues can be addressed through pre-processing of the documents and further training of the employed NLP engine. Manual inspection of the parsing results indicated that numerous candidate query patterns can be derived from the result set.

## Conclusion

A heuristic review of the previously described parsing results yielded several candidate eligibility criteria query patterns. Given that MedLEE was naïve to the lexicon and semantic patterns present in the eligibility criteria being parsed, we were encouraged by these initial results. However, additional work is needed to improve MedLEE’s performance in this domain, with an emphasis on addressing the previously described common parsing errors.

## References

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