Use of NLP to Augment Real-World Data (RWD) and Identify Eligible Patients at Scale for Oncology Studies

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Background and Objectives

- The substantial volume of unstructured data contained within electronic health records (EHRs), with estimates as high as 80% (Li et al., 2022), represents a rich and untapped source of insights for real-world evidence studies.
- Practical examples of the application of natural language processing (NLP) approaches are needed to assess their performance in generating fit-for-purpose real-world studies from unstructured EHR data.
- We evaluated the application of NLP technologies to support feasibility assessments of real-world studies and the implementation of complex inclusion/exclusion criteria to identify eligible patients.

Methods

- The primary data sources are large sets of text-based clinical notes from iKnowMed[SM], an oncology-specific EHR system.
- Pretrained healthcare NLP models from John Snow Labs, Inc. as well as internally-developed models were utilized to identify patients meeting complex clinical criteria across 20 feasibility assessments for varying cancer types.
- Prior to utilization, the models were evaluated using internal validation datasets to measure precision, recall, and F1 scores to ensure model accuracy and reliability.
- Once the NLP models generated results, a randomly selected sample (5-10%) of the results were validated by clinical annotators for each assessment to further validate the model.
- A workflow illustrating the end-to-end production NLP process for the feasibility assessments is shown in Figure 1.

Reference:
Li, I., Pan, J., Goldwasser, J., Verma, N., Wong, W. P., Nuzumlalı, M. Y., Rosand, B., Li, Y., Zhang, M., Chang, D., Taylor, R. A., Krumholz, H. M., & Radev, D. (2022). Neural Natural Language Processing for unstructured data in electronic health records: A review. *Computer Science Review*, *46*, 100511. https://doi.org/10.1016/j.cosrev.2022.100511

Methods

Figure 1. Feasibility assessment NLP workflow

Step 1 – Clinical notes: Clinical notes are extracted for the patient cohort and timeframe of interest.

Step 2 – Clinician guidance: A clinician provides guidance on the keywords to use to find the desired variables.

Step 3 – Note excerpt selection: Clinical notes are filtered for the keywords provided by the clinician.

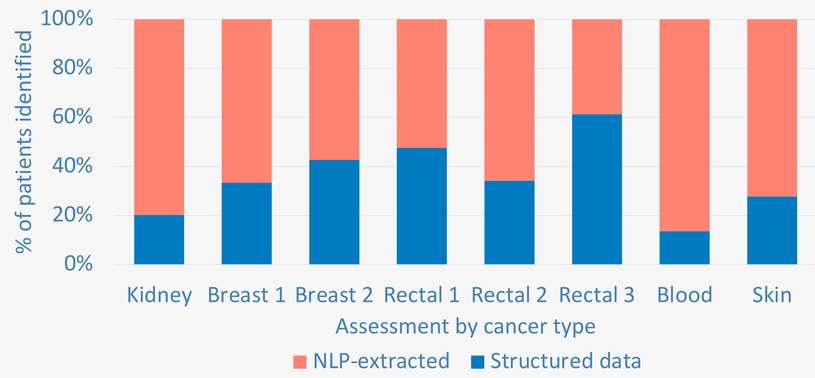
Step 4 – Model execution: A validated NLP model is executed to extract the values of the clinical variables of interest.

Step 5 – Subject Matter Expert validation: Clinical annotators validate a sample of the model results.

Step 6 – Result presentation: Aggregated counts are shared with the client to determine if the sample size is sufficient to propose a real-world evidence study.

Results

Figure 2. Structured vs. NLP-extracted data source distribution for feasibility assessments



- In 8 of the 20 assessments conducted, comparable structured data was available. NLP increased the desired patient population by an average of a 3.5-fold (range 1.1-7.4). The median sample size pre-NLP was 110 patients, and post-NLP, it was 315 patients. Figure 2 illustrates the percentage of patients identified by data source (structured vs. NLP).
- In another 9 of the same 20 assessments, NLP identified a patient cohort when comparable structured data was not available. The median number of patients identified in such assessments was 244 (range 40 – 1482 patients).
- In the remaining 3 assessments, NLP significantly narrowed down the population for manual chart review, resulting in a mean reduction of 80% (range 69-89%).

Conclusions

Augmentation of feasibility exercises with NLP can boost sample sizes by significant margins, increasing the statistical power and clinical generalizability of proposed studies.

This approach offers a scalable solution for conducting real-world evidence studies and supplements high-effort and costly activities such as manual chart abstraction.