

Real-World Evaluation of AI-Assisted vs Manual Prescreening for Clinical Trial Eligibility

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Background

In 2025, the GUCRO enrolled 79 patients across more than 50 trials. Despite, several trials struggled with low enrollment. This challenge is not unique to our group. A 2024 survey of more than 50 cancer centers found that 52% identified limited staffing and high workload as major barriers to clinical trial enrollment¹. One study reported that AI-assisted prescreening reduced the time required to review the same patients for the same trials by 4.5 times² versus traditional manual prescreening.

Recent work also demonstrates that large language models (LLMs) can extract and interpret clinical information from unstructured EHR data with high accuracy, supporting their use in prescreening workflows

Addressing these barriers is essential for improving trial activation and increasing patient enrollment in clinical studies. However, few studies have evaluated AI-assisted prescreening in prospective, real-world clinical workflows using fully integrated electronic health record (EHR) systems³⁻⁴.

Goal

To compare the effectiveness of AI-assisted prescreening with traditional manual methods across four ongoing clinical trials over six months, with a focus on accuracy and efficiency.

Methodology

To accomplish our goal, we developed workflows specific to AI-assisted prescreening and manual screening. EHRs and the AI-prescreening tool served as the primary data sources. Time was collected automatically for AI-assisted reviews via a clock within the review page. Time was collected manually via a stopwatch for manual review.

Figure 1. Manual vs AI-Assisted Prescreening Method Comparison Workflow for Study

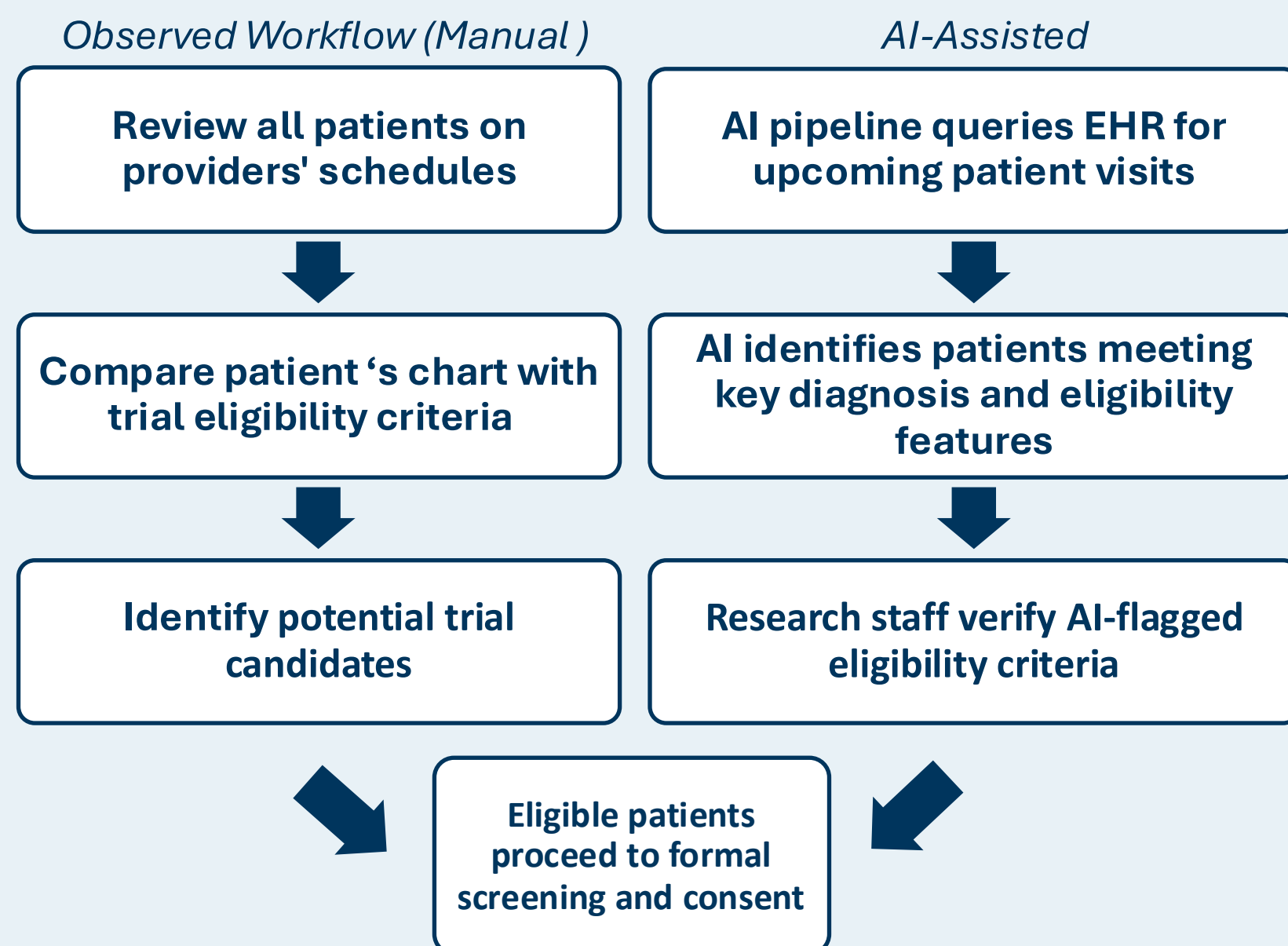


Figure 1. Observed prescreening workflows used during the study period. The manual workflow reflects prescreening practices observed during the study period and may vary across institutions.

Analysis

Accuracy Evaluation

Manual prescreening by trained staff served as the gold standard. AI-assisted prescreening outcomes were compared to manual review using:

- Sensitivity
- Specificity
- F1 score
- Youden Index

Efficiency Evaluation

Efficiency assessed by:

- time required to prescreen a patient
- reduction in the number of patients requiring manual chart review

Review times between workflows were compared using two-sample independent t-tests for each study.

Interventions

This project evaluated two prescreening approaches rather than implementing a new workflow intervention. AI-assisted prescreening integrated into the clinical workflow was compared with a traditional manual chart review process used for study comparison. Direct Epic integration enables real-time review of AI-generated outputs within standard workflows, improving efficiency, and reducing redundant patient reviews.

Figure 2. AI-Assisted Prescreening Implemented Workflow

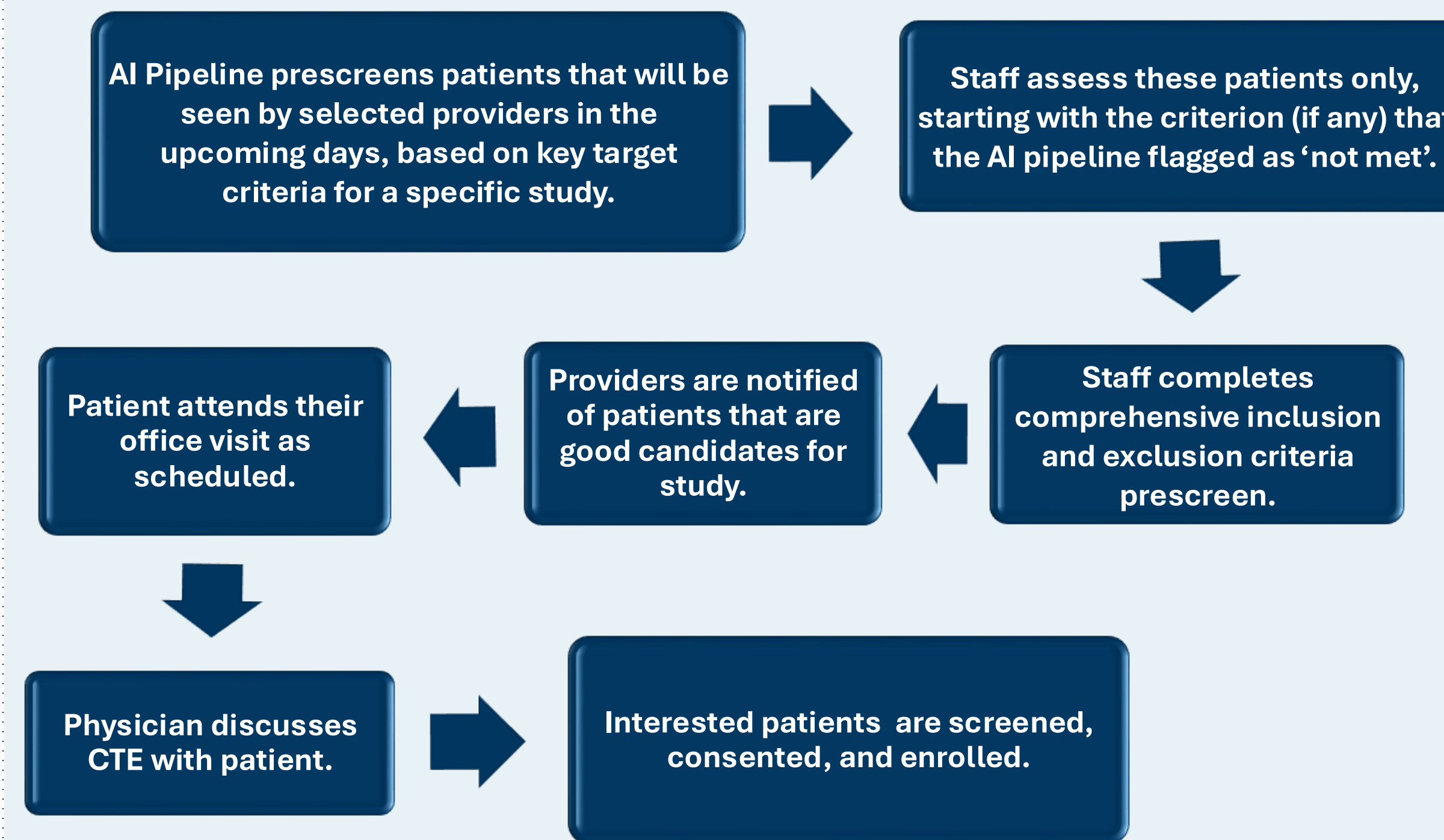


Figure 2. AI-assisted prescreening workflow implemented during the study period. The AI pipeline identifies potentially eligible patients based on predefined criteria, after which trained staff verify eligibility and notify providers of potential candidates.

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Results

Across four studies, AI-assisted prescreening reduced the number of patients requiring manual chart review, decreasing manual prescreening workload by 74–97% and cumulative prescreening time by 87–97%.

The AI prescreening model showed sensitivities of 96–100%, specificities of 61–99%, and F1 scores of 0.87–0.99 across four studies, indicating high concordance with the gold standard. Youden Index values ranged from 0.6 to 0.98, demonstrating the AI-assisted prescreening system's strong discriminative performance.

Table 1. Diagnostic Performance of AI-Assisted Prescreening

Study	Sensitivity	Specificity	F1	Youden Index
Study 1	0.97	0.70	0.96	0.66
Study 2	0.96	0.62	0.86	0.58
Study 3	1.00	0.93	0.98	0.93
Study 4	0.99	1.00	0.99	0.99

Table 1. Diagnostic performance of AI-assisted prescreening compared with manual review.

AI-assisted prescreening significantly reduced average time-to-prescreen in Study 1 (49.8 percent reduction, $p=2.83 \times 10^{-7}$) and Study 2 (64.0 percent reduction, $p=1.8 \times 10^{-7}$). No statistically significant difference was observed per patient in Study 3 ($p=0.93$) or Study 4 ($p=0.96$). However, total operational workload notably decreased across all trials.

Figure 3. Cumulative Prescreening Time: AI-Assisted vs Manual

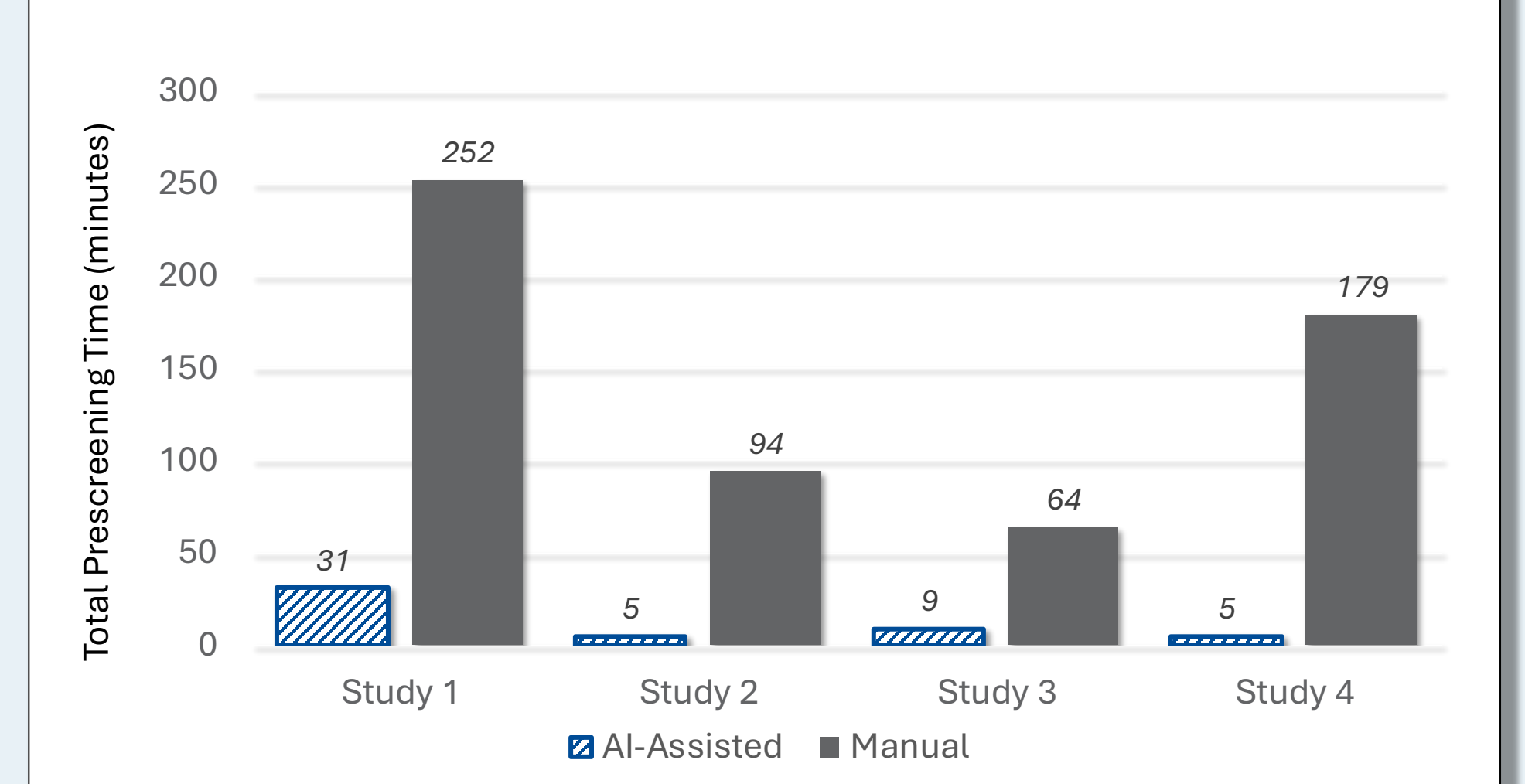


Figure 3. Cumulative prescreening time for AI-assisted and manual workflows across four studies.

Conclusion

AI-assisted prescreening maintained diagnostic accuracy while improving operational efficiency in clinical trial enrollment. Direct Epic integration enables real-time review of AI-generated outputs within existing clinical workflows, improving efficiency and reducing redundant patient reviews. This integration supports a strong capacity for translation into other high-volume oncology programs. The adoption of AI-assisted prescreening models has the potential to streamline clinical trial recruitment, reduce overall staff workload, and improve patient access to research opportunities.

Staff verification remains essential in confirming eligibility determinations and ensuring clinical accuracy. Future studies should evaluate downstream effects including screening success, enrollment rates, and time-to-accrual.