How do I use AI to accelerate trials at my center?

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DISCLOSURES

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Personal fees: ConcertAI, Cancer Study Group, Biofourmis, Archetype Therapeutics, CreditSuisse, G1 Therapeutics, Humana, Nanology, Optinosis

Stock Options: Counsel Health, Scaled Insights

Honoraria: Flatiron and Medscape

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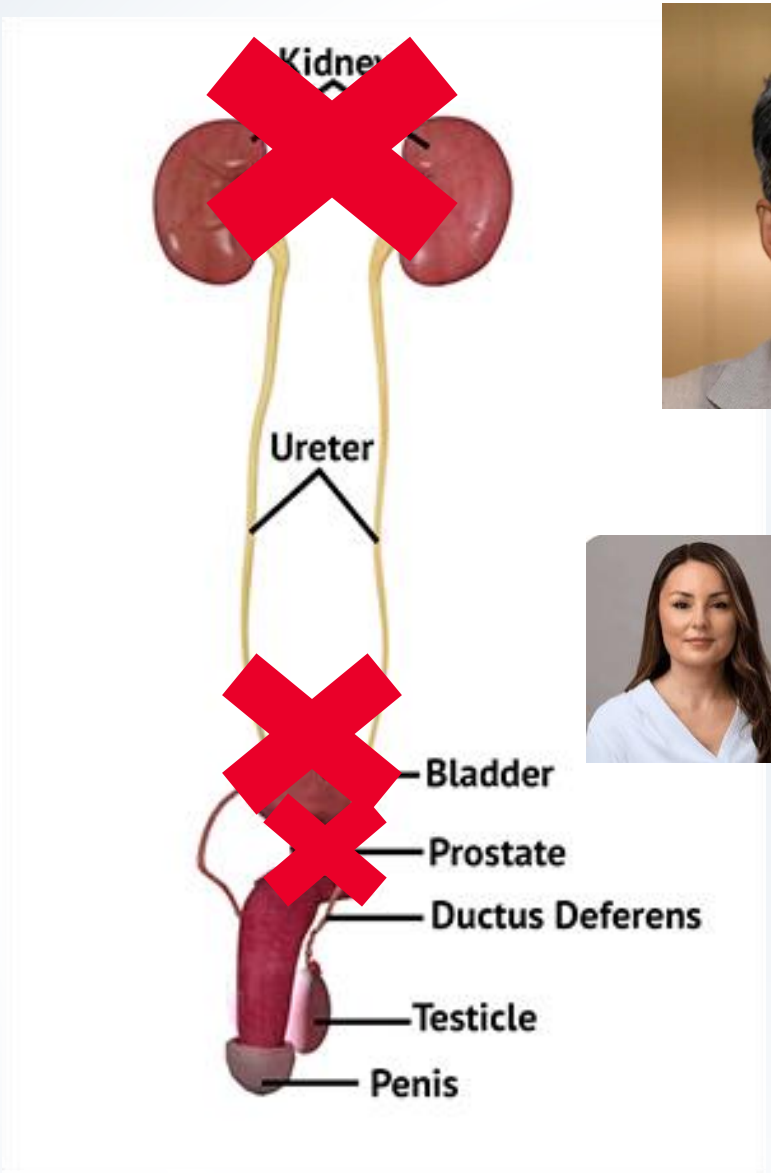
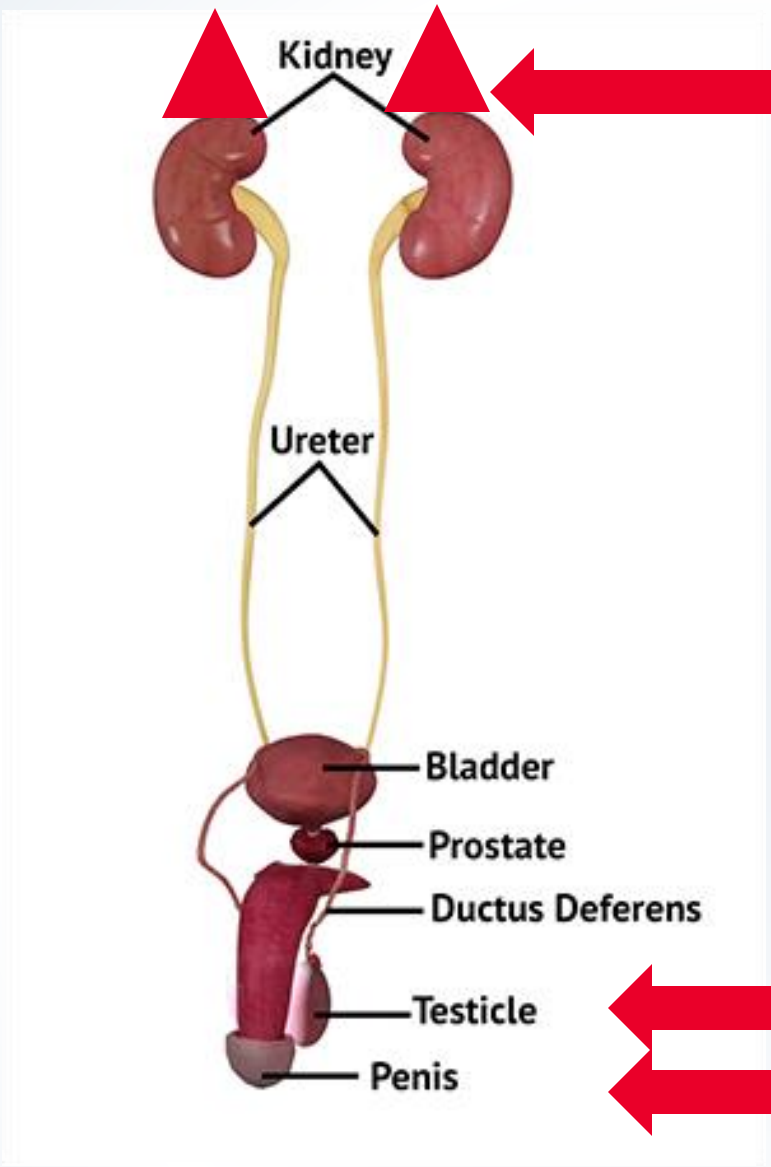
Editor: Journal of Clinical Oncology


Ureter
Bladder
Prostate
Ductus Deferens
Testicle
Penis


Kidney
Ureter
Bladder
Prostate
Ductus Deferens
Testicle
Penis

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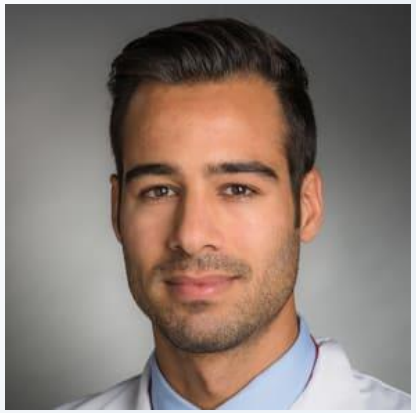


Most of you are using more AI this year than last year

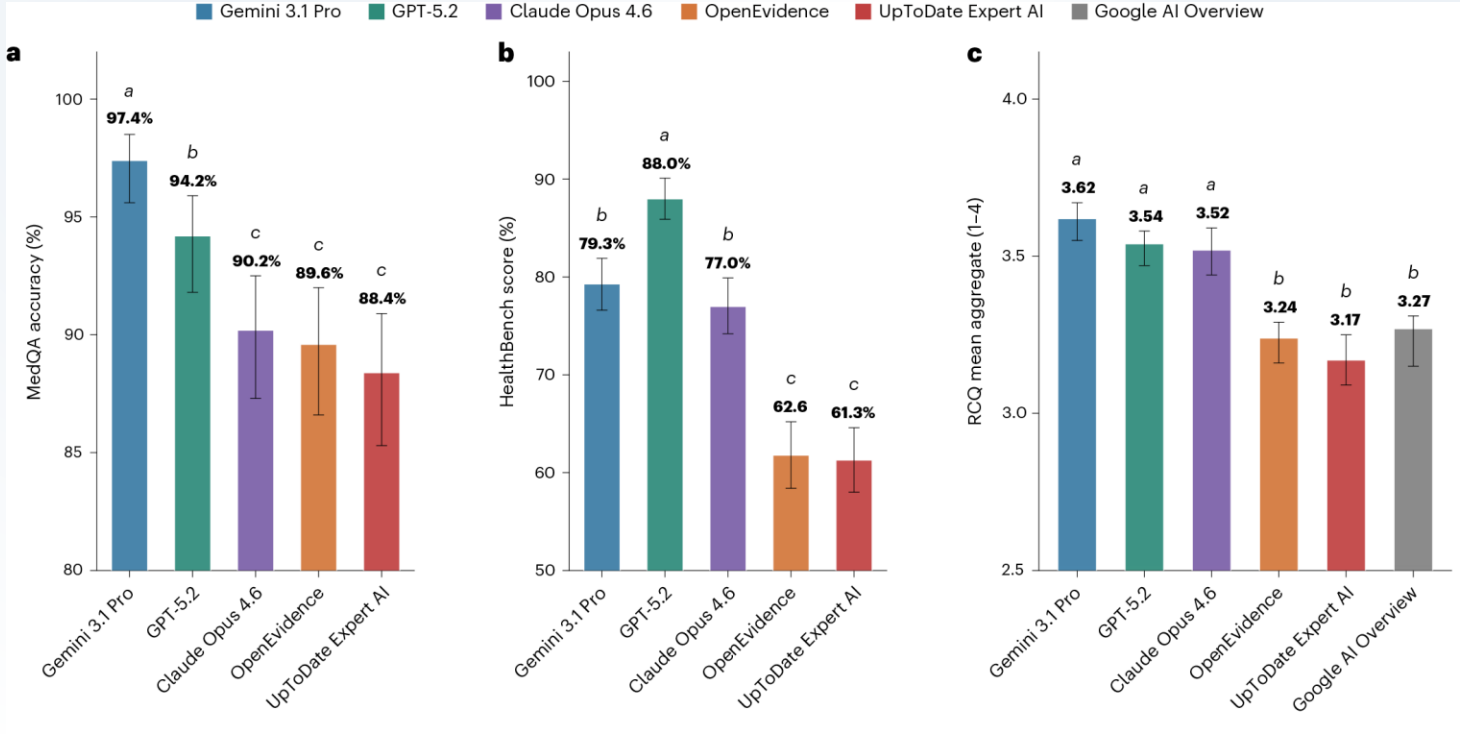
ABRIDGE

OpenEvidence®

HealthcareHuddle
UpToDate Expert AI

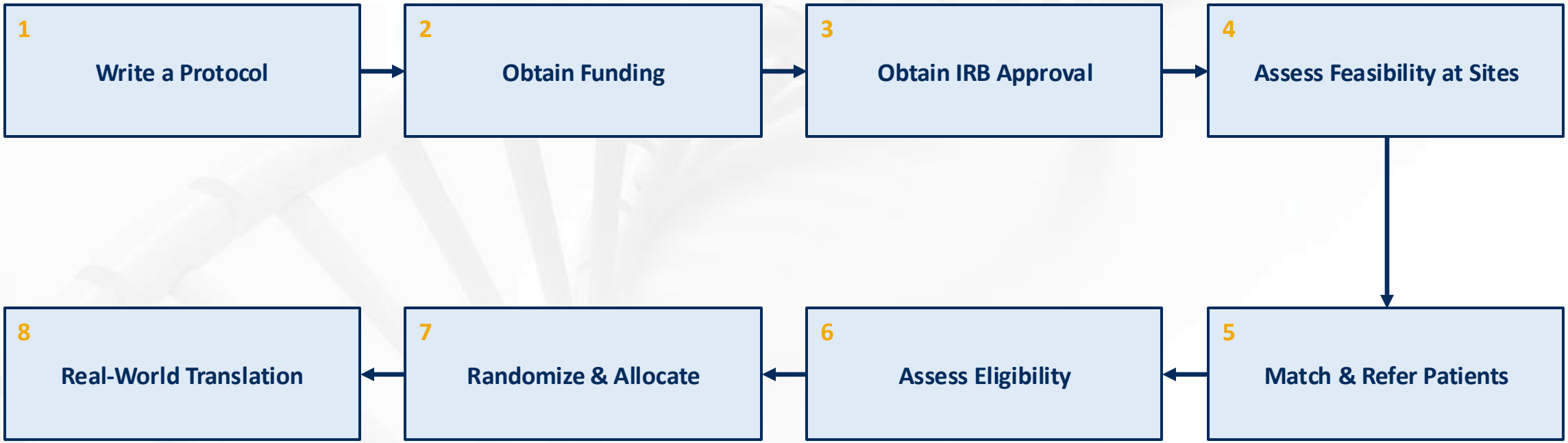
Nuance®
DAX™ Copilot

DeepScribe



Vishwanath et al, Nat Med, 2026

CLINICAL TRIALS ARE SLOW. EVERY STEP IS AN AI OPPORTUNITY.



AI is already at work in clinical trials

PATIENT-TRIAL MATCHING

Match & screen

NLP and LLMs read records and match patients to trial eligibility criteria.

110 → 24 min screening · 91.6% accuracy

DATA CAPTURE

EHR → EDC (eSource)

Automated transfer of EHR data into trial databases, cutting manual re-entry and query cycles.

Less transcription, fewer errors

PLANNING

Site feasibility & recruitment

Platforms forecast enrollment and rank sites using real-world and historical trial data.

Faster site selection

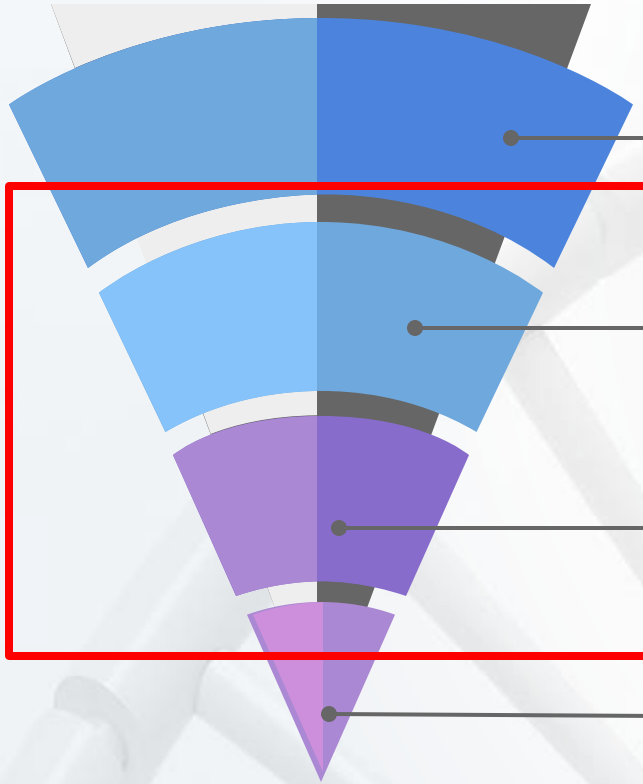
These work [illegible] after the protocol exists. Authoring it — the upstream [illegible] still done by hand.

Beck et al., JCO CCI 2020; Alexander et al., JAMIA Open 2020; von Itzstein et al., JAMA Oncol 2021

Human-AI Workflows to Improve Trial Prescreening

Problem: Trial Prescreening is Inefficient and Inaccurate

- Only <10% of adult cancer patients participate in trials, with many subpopulations underrepresented.
- Yet 55% of adult cancer patients do participate when offered a trial (Unger et al., *JNCI* 2021).



70% — 70% of adults would be "very willing" or "inclined" to participate in a cancer trial if asked to do so (Comis *JCO* 2003)

44% — 44% of cancer patients have a relevant trial available for their cancer type at local treating center (Unger *JNCI 2019*)

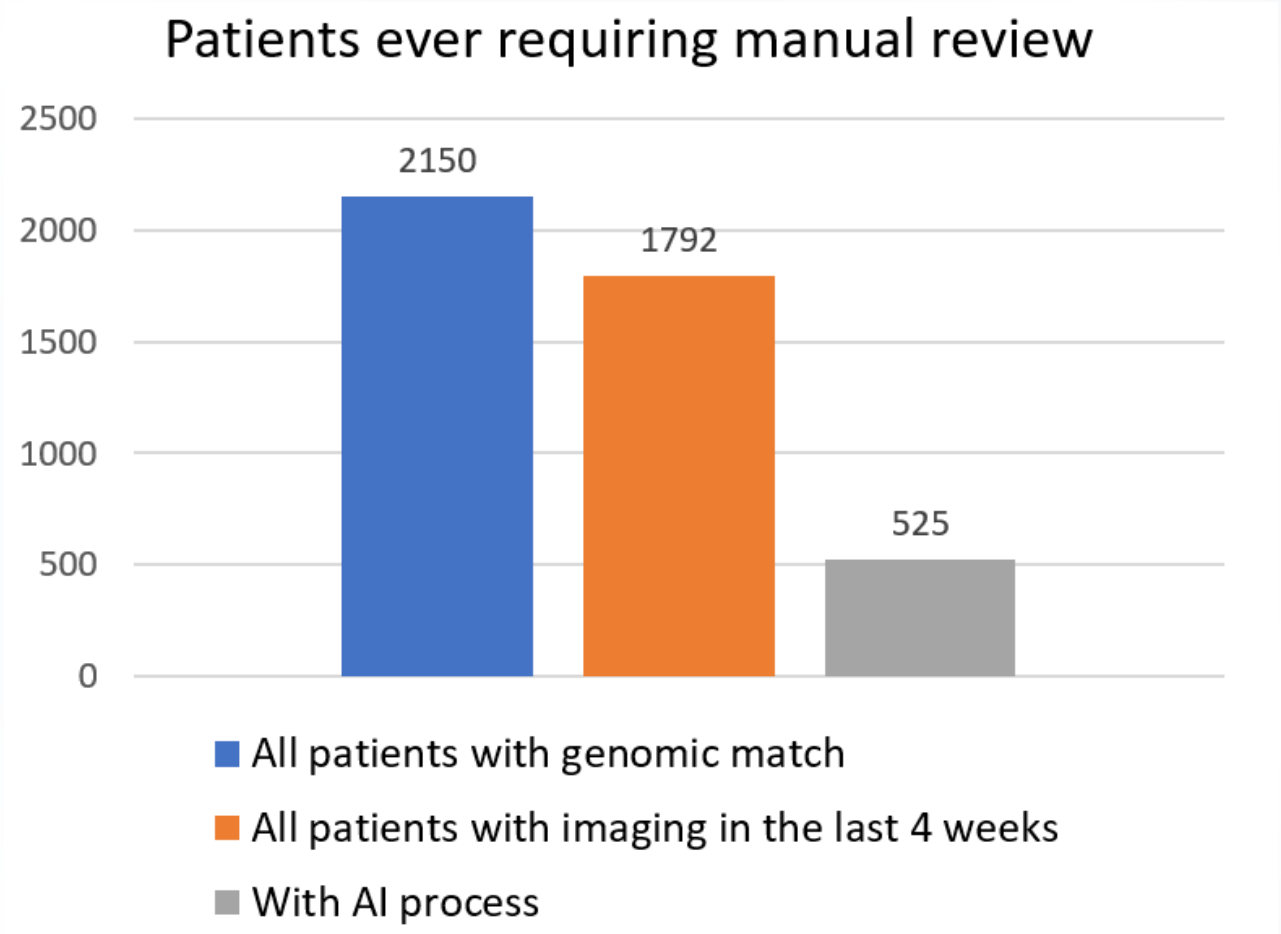
10% — 10% of cancer patients are offered participation in a trial (NCI 2022)

5-8% — 5-8% of cancer patients participate in trials (Unger ASCO 2016; Unger *JNCI 2019*)

Why is trial prescreening inefficient?

- Manual screening is **time-consuming** (and labor-intensive)
- Manual screening is **inaccurate**
- Manual screening is **random**, failing to account for eligibility likelihood
- Manual screening fails to prioritize **diverse populations**

Trial prescreening is more efficient with AI-driven curation



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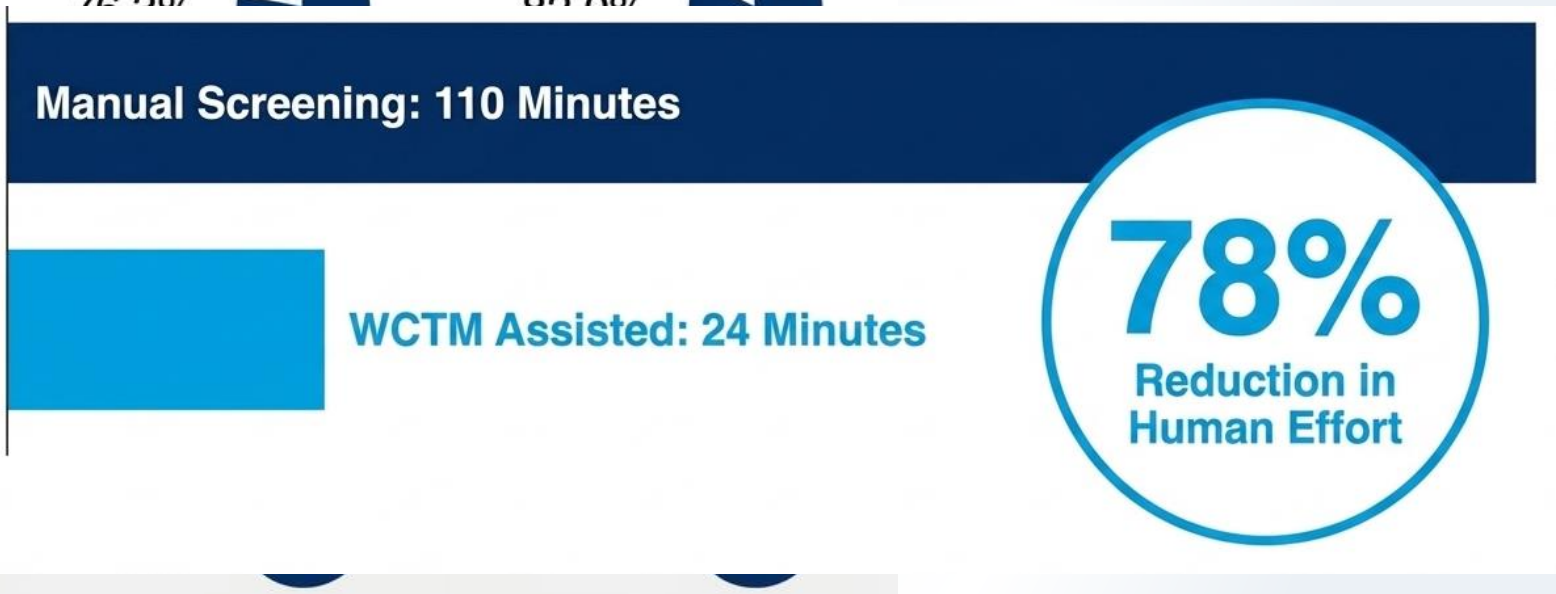
Kehl et al. JCO Precis Oncol. 2024 Mar;8:e2300507.

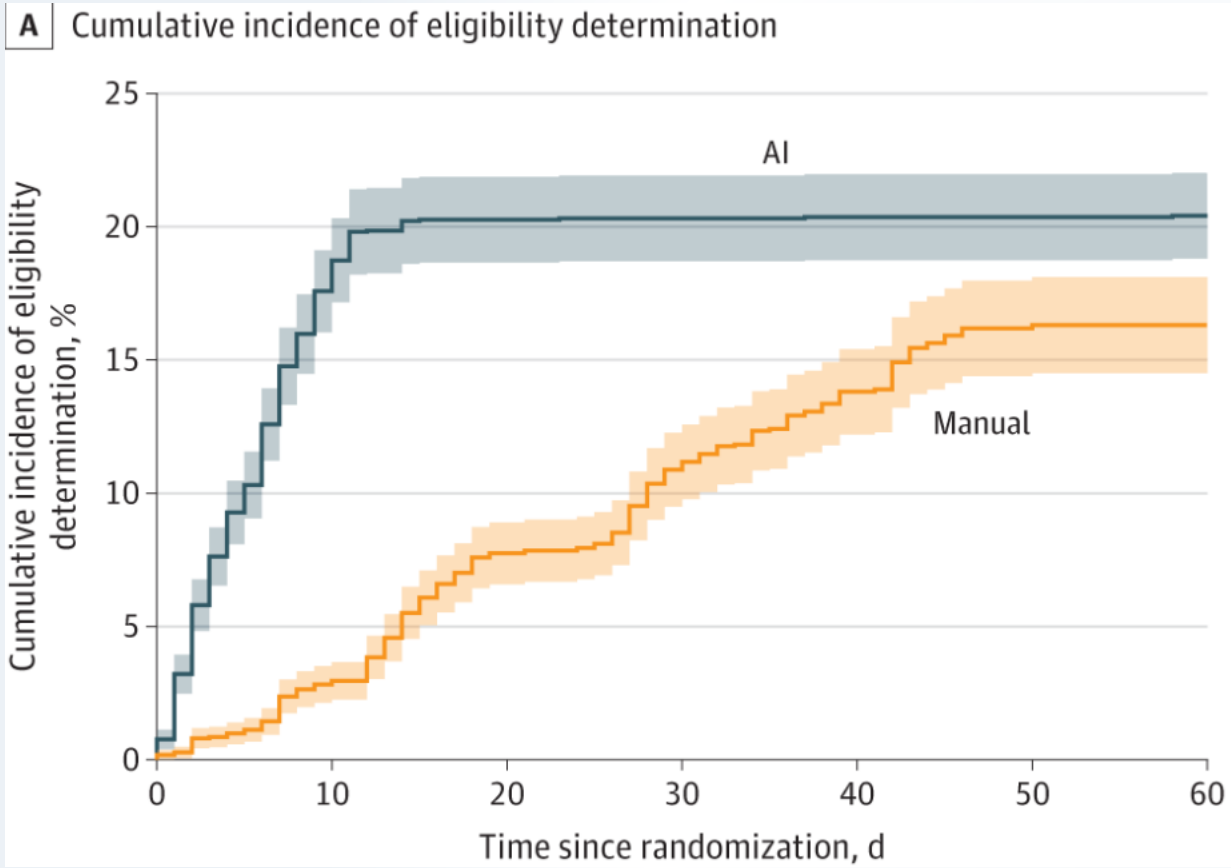
“Old” AI looks pretty good in retrospective evaluations

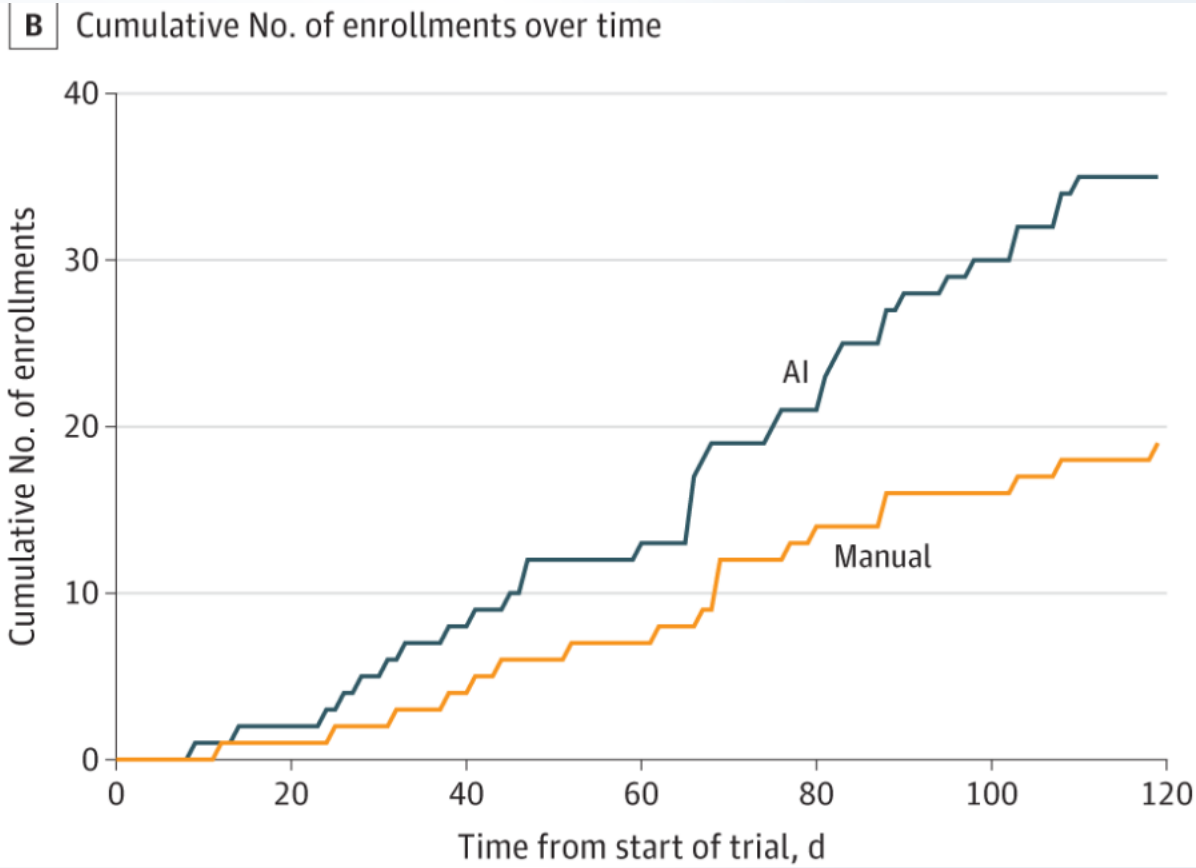
Trial	Sensitivity	Specificity	Overall Agreement
Trial 1 (NCT02437318)	93.7%		
Trial 3 (NCT01633060)	94.9%		
Trial 4 (NCT02422615)	91.1%		
Trial 2 (NCT01923168)	46.7%		



Beck et al, JCO CCI, 2020

PRIOR PROSPECTIVE DEPLOYMENTS OF AI-BASED PRESCREENING HAVE MIXED SUCCESS

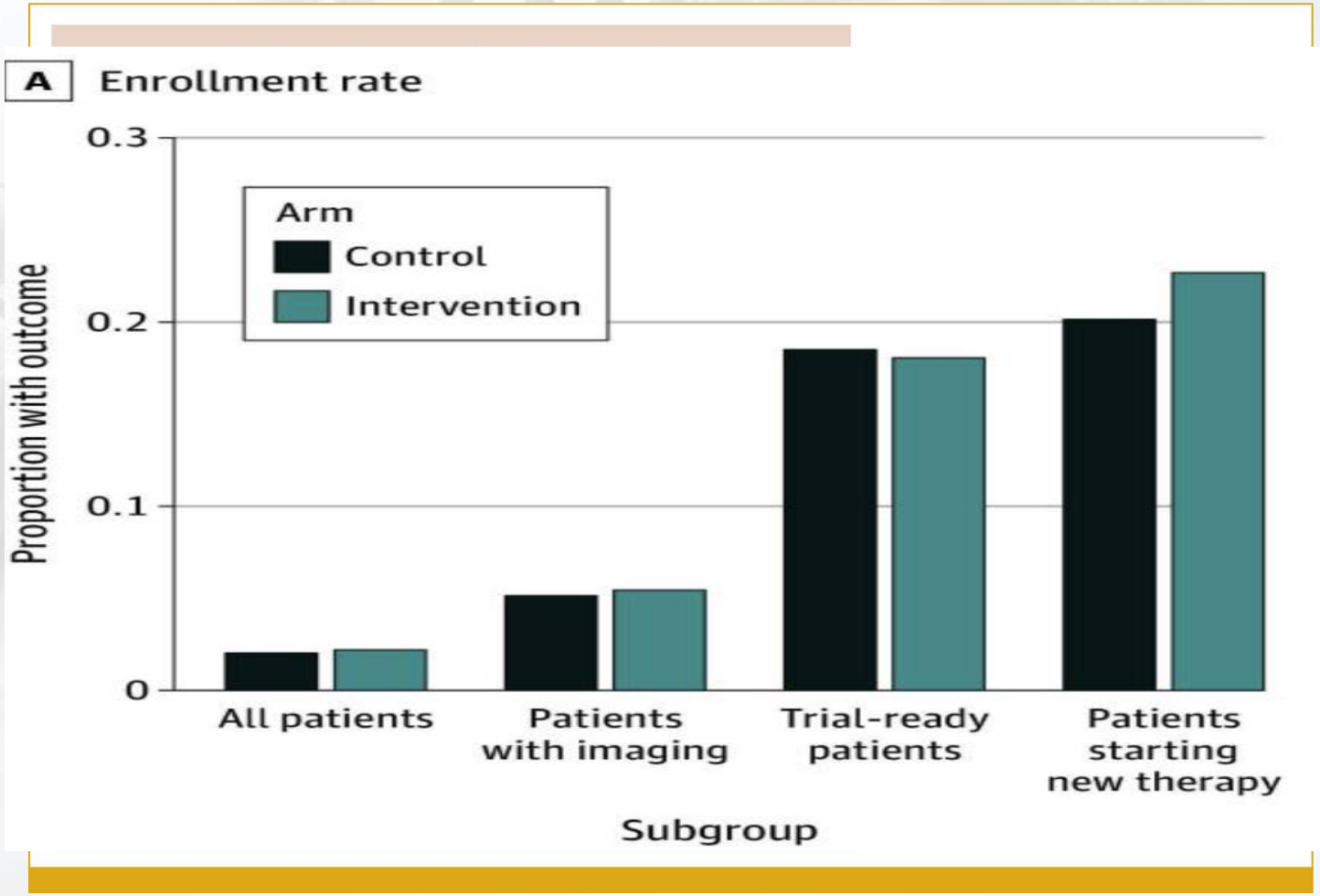




Unlu et al, JAMA, 2025

PRIOR PROSPECTIVE DEPLOYMENTS OF AI-BASED PRESCREENING HAVE MIXED SUCCESS

- Usually limited to natural language processing
- Trial-specific
- Only assessed an AI vs. human workflow, not an AI-guided human workflow



Kehl et al, JCO PO, 2024

How Natural Language Processing extracts clinical attributes from unstructured notes.

61-year-old female presents with ER-positive, HER2-negative metastatic breast cancer. Prior lumpectomy performed.

Attribute	Value
Age	61
ER Status	Positive
HER2 Status	Negative
Setting	Metastatic
Prior Surgery	Lumpectomy

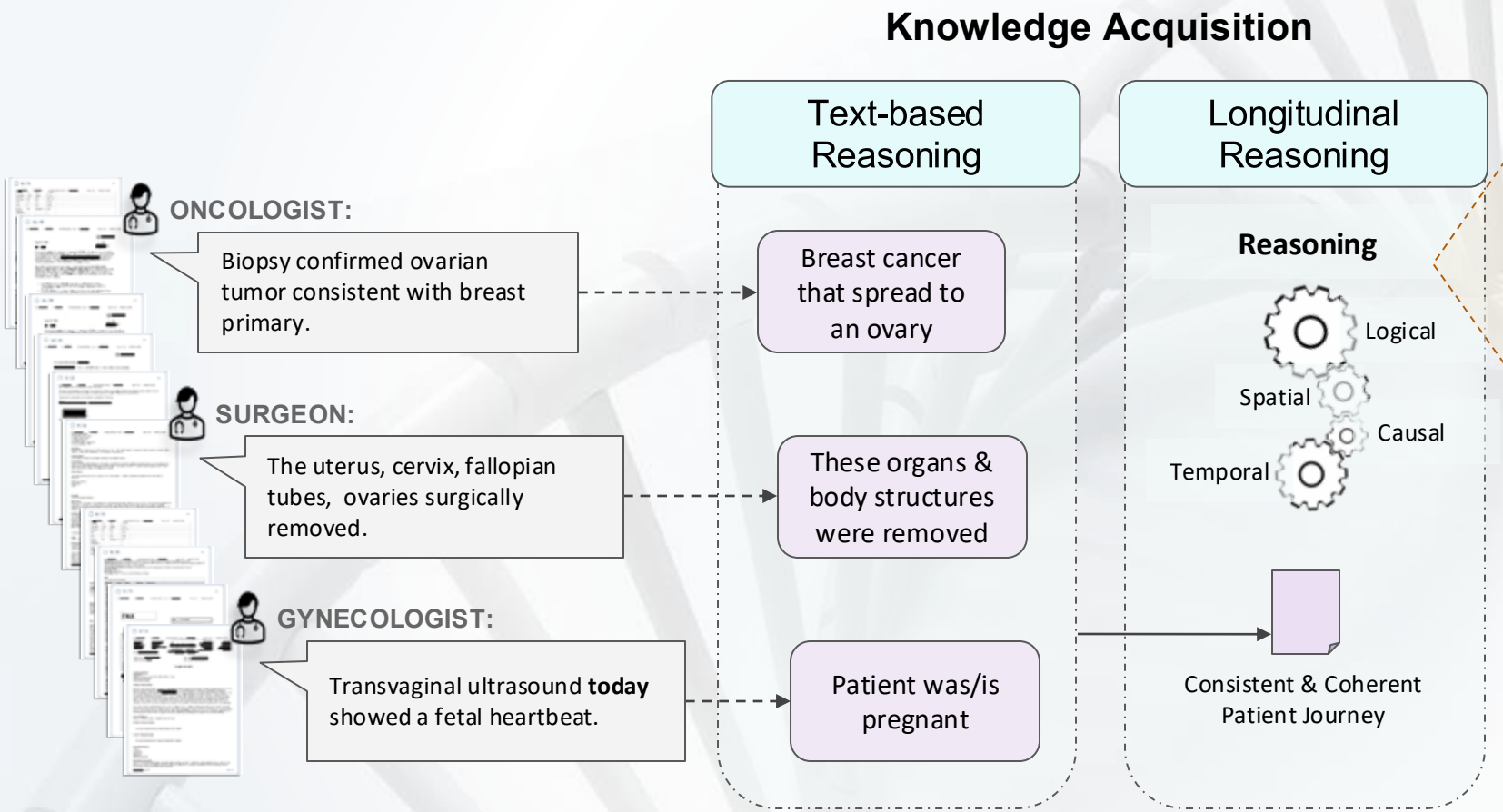
THE ELIGIBILITY-CRITERIA PROBLEM

Inclusion Criteria (abbreviated):

- Histologically- or cytologically-confirmed adenocarcinoma of the prostate without small cell histology
- Progression while on ADT (or post bilateral orchiectomy) within 6 months before Screening
- Current evidence of metastatic disease by bone scan and/or CT/MRI
- Disease that progressed during or after treatment with 1 novel hormonal agent (NHA)
- 1 but no more than 2 taxane-based chemo regimens for mCRPC with PD during or after
- Ongoing ADT with serum testosterone <50 ng/dL (<1.7 nM)
- Tumor tissue from a fresh core or excisional biopsy of soft tissue not previously irradiated
- ECOG performance status 0 or 1 assessed within 7 days of randomization
- Prior PARPi treatment, or deemed ineligible, or refused PARPi
- Prior 177Lu-PSMA-617, or deemed ineligible, or refused 177Lu-PSMA-617
- If first-gen anti-androgen, evidence of progression >4 wks since last flutamide and >6 wks since last bicalutamide or nilutamide
- Bone-resorptive therapy on stable doses for at least 4 wks before randomization
- HIV positive: well controlled on ART
- HBsAg positive: HBV antiviral therapy at least 4 wks with undetectable HBV viral load before randomization

14 criteria. 1 trial. The bottleneck in clinical research is translating the protocol

How does AI read a chart?



Detects & resolves a logical paradox in event order.

Options:

1. **Reorder events:** Surgery last to treat the cancer ⇒ pregnancy first:
   ⇒ Coherent Journey
1. **Discard events:** One or more events are wrong, delete:
   ⇒ Consistent Journey

Reordering options:

- `Pregnancy → Cancer → Surgery(treating)`
- `Cancer → Pregnancy → Surgery(unrelated)`

Discard 1 event options:

- `Cancer & Surgery ;` ~~`NO Pregnancy`~~

Study Design (NCT#06561217)

Document Preprocessing

Unstructured note aggregation

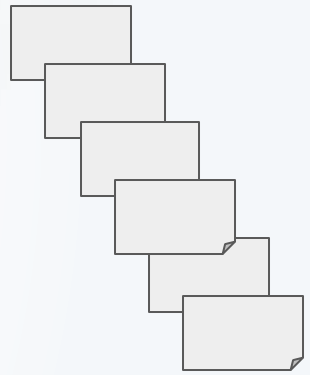
↓

De-identification

Trial Element Annotation (Paired-Design)

Interrater reliability check: 86%

CRC 1		CRC 2
Human + AI	[Charts #1-20]	Human alone
Human alone	[Charts #21-40]	Human + AI
Human + AI	[Charts #41-60]	Human alone
... (n= 356 charts)		*... (n= 356 charts)*

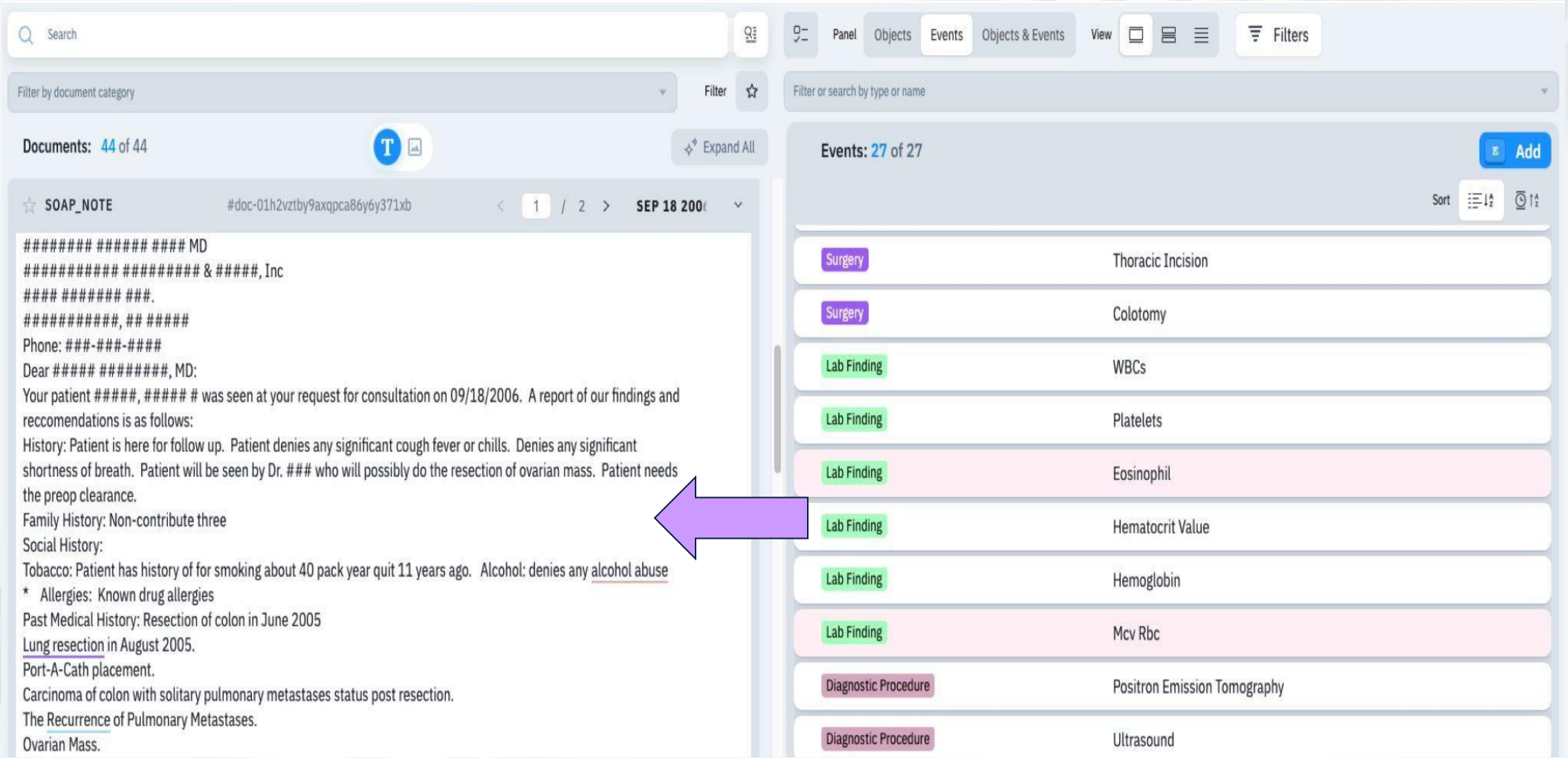


Outcome Assessment

- Chart-level accuracy
- Event-level accuracy
- Timeliness

Parikh et al, Nat Comm, 2026

Abstraction Interface: Human + AI ("Right → Left")

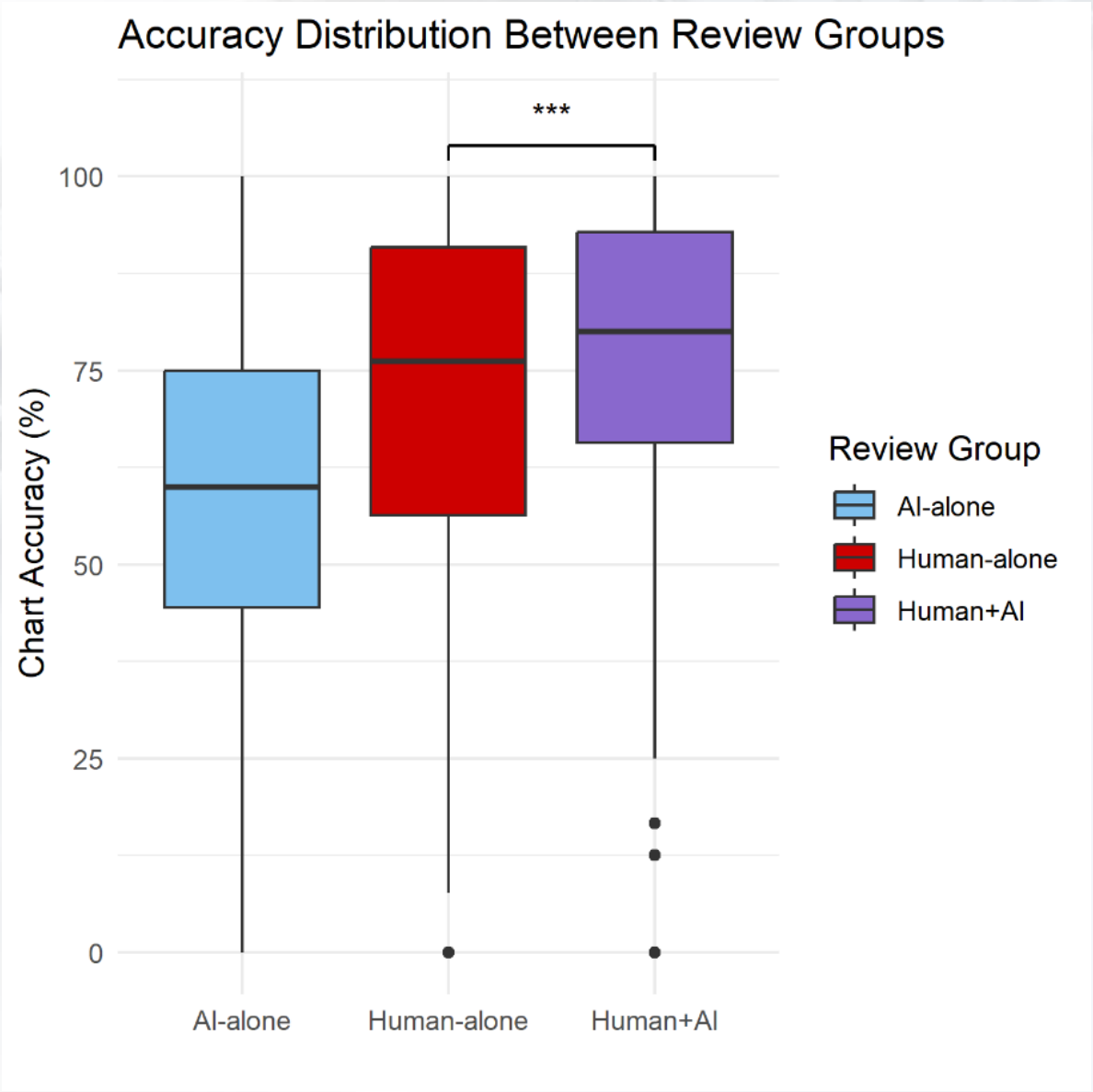


Parikh et al, Nat Comm, 2026

Overall Accuracy

*Overall accuracy for Human+AI was **noninferior** and **superior** to Human-alone*

Both were superior to AI-alone



Parikh et al, Nat Comm, 2026

Criteria-Specific Accuracy

	Criteria	N	Accuracy (%)			p-value
			Human-Alone	Human+AI	AI-Alone	
Neoplasm	Cancer Type	360	86.9	86.4	73.3	0.80
	Stage Group	237	71.7	73.4	57.0	0.57
	M Stage	221	43.9	57.0	**60.2**	<0.001*
	N Stage	196	50.5	66.3	52.6	<0.001*
	T Stage	197	56.3	71.6	54.3	<0.001*
Biomarker	Biomarker Tested	454	84.6	93.2	88.1	<0.001*
	Categorical Value	452	67.9	79.0	32.5	<0.001*
	Interpretation	381	80.8	91.3	35.7	<0.001*
Other	Outcome	181	23.7	35.9	**55.2**	0.004*
	Response	346	47.1	51.7	**60.4**	0.20
	ECOG Status	183	84.7	78.1	34.4	0.10
	Medications	525	89.0	89.1	59.4	0.92

Accuracy >= +5%

Accuracy >= +10%

Parikh et al, Nat Comm, 2026

Timeliness

Kolmogorov-Smirnov Test:

Adjusted P-Value: 0.05

	Human-alone	Human+AI	Total
Duration in mins			
Mean (SD)	48.08 (25.54)	41.85 (29.89)	44.97 (27.88)
Median	43.90	34.05	39.40
Q1, Q3	29.67, 63.00	21.25, 58.83	24.48, 61.20

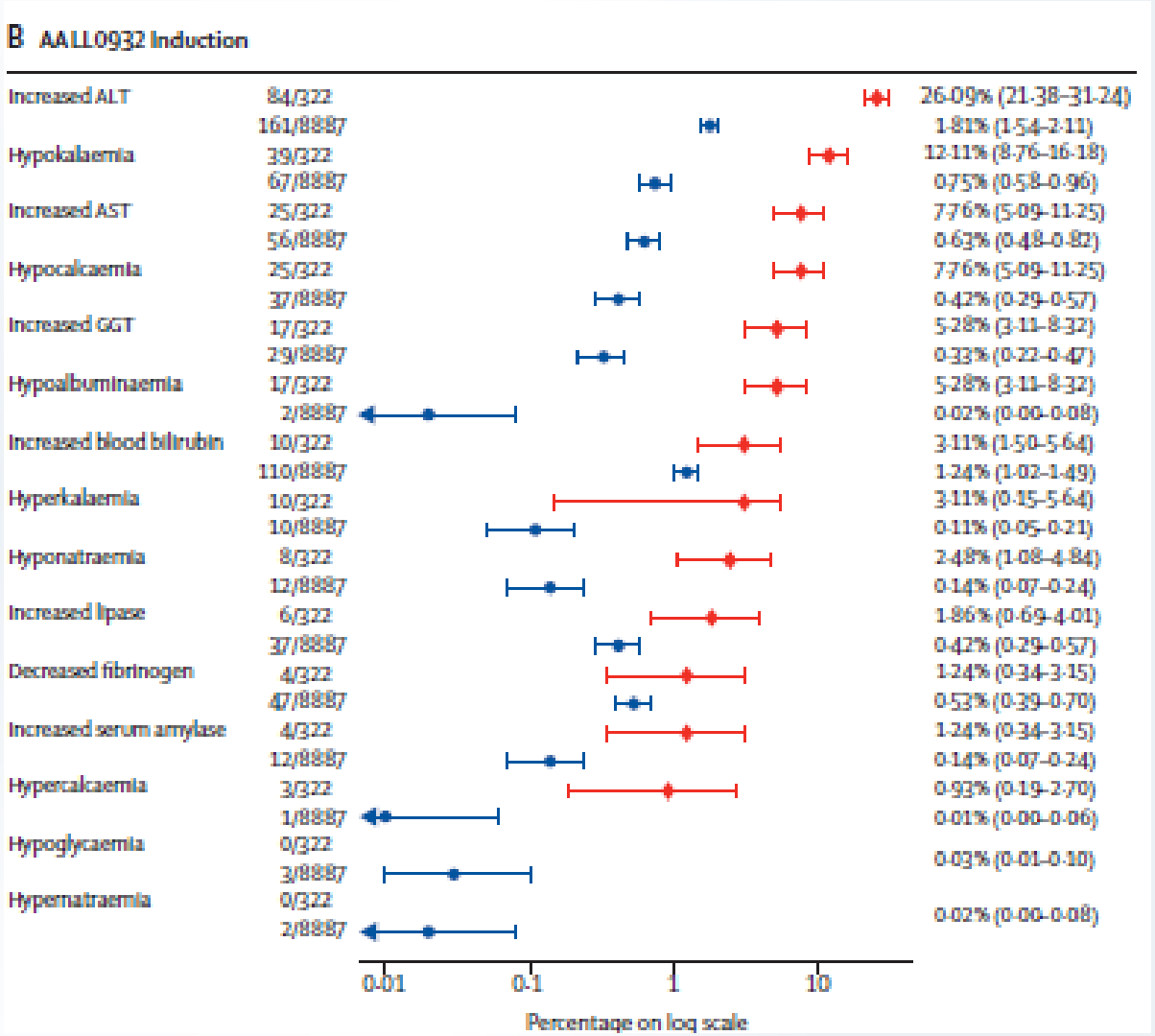
Parikh et al, Nat Comm, 2026

Other applications: Augmenting EHR extraction of Adverse Events

Automated Typhlitis Detection (2022): 81% sensitivity vs. 44% for manual COG reporting; reduced manual review burden by 96%

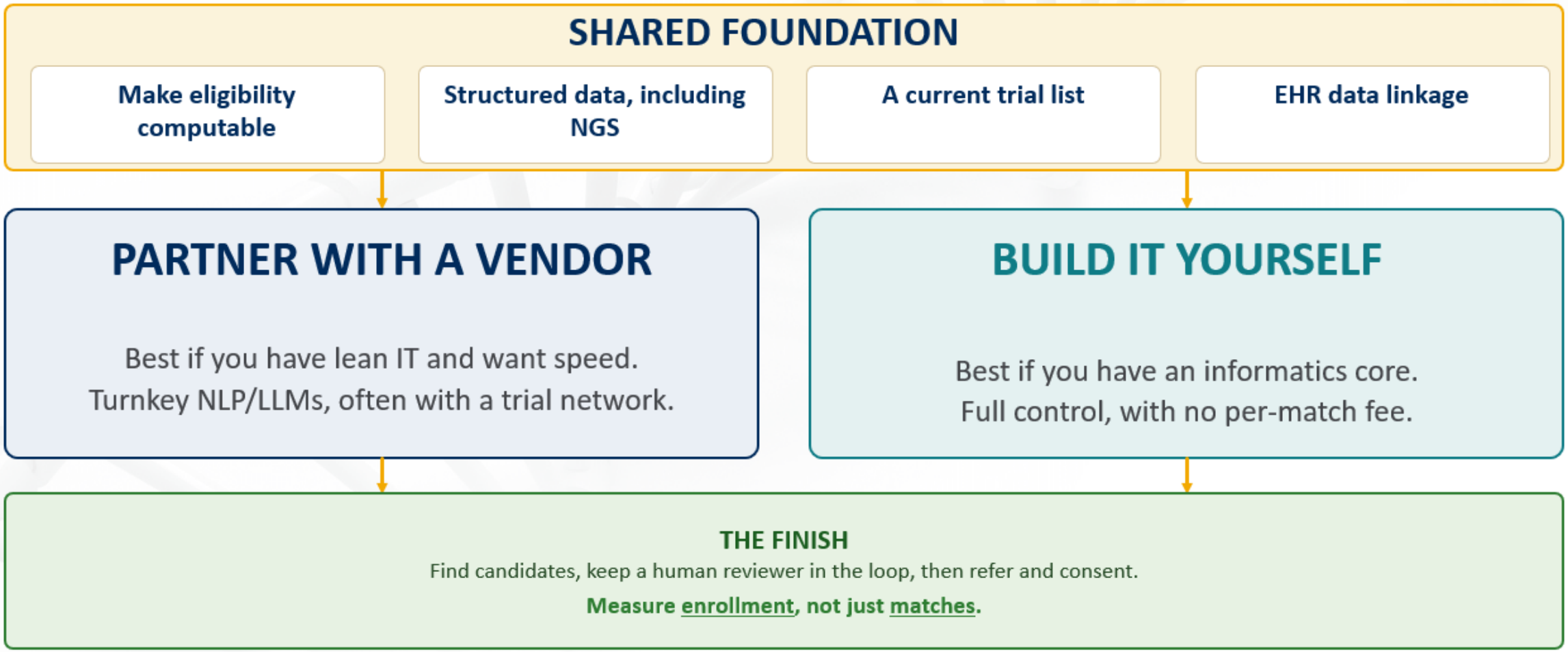
Multi-site Implementation via ExtractEHR (2024): Successfully deployed automated extraction across 4 major pediatric centers, supporting 5+ clinical studies

Superior Detection of Laboratory AEs (2022): ExtractEHR identified 2-100x higher rates of laboratory adverse events compared to manual COG trial reporting



Miller et al, Lancet Hem, 2022; Miller et al., JCO CCI, 2022; Miller et al, JCO CCI, 2024

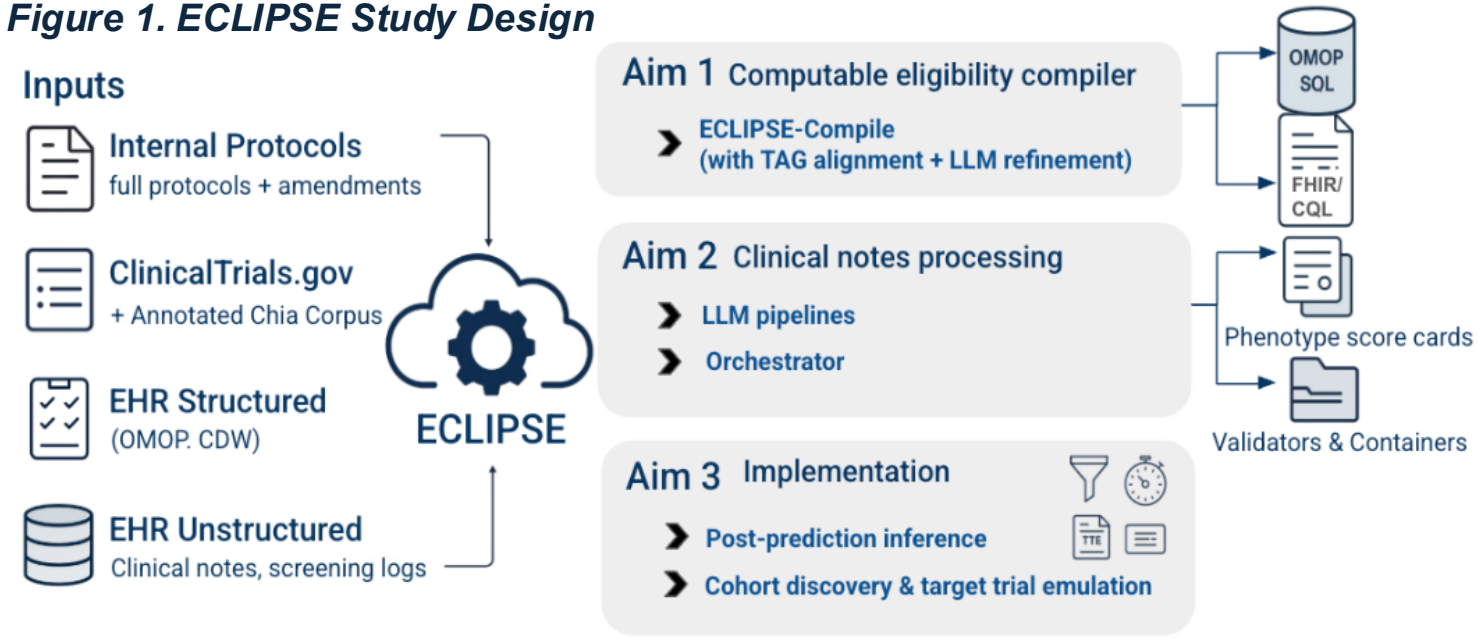
How do you stand up trial matching at your site?



Where are we going? Beyond trial matching

TRIAL FEASIBILITY ASSESSMENT

Figure 1. ECLIPSE Study Design

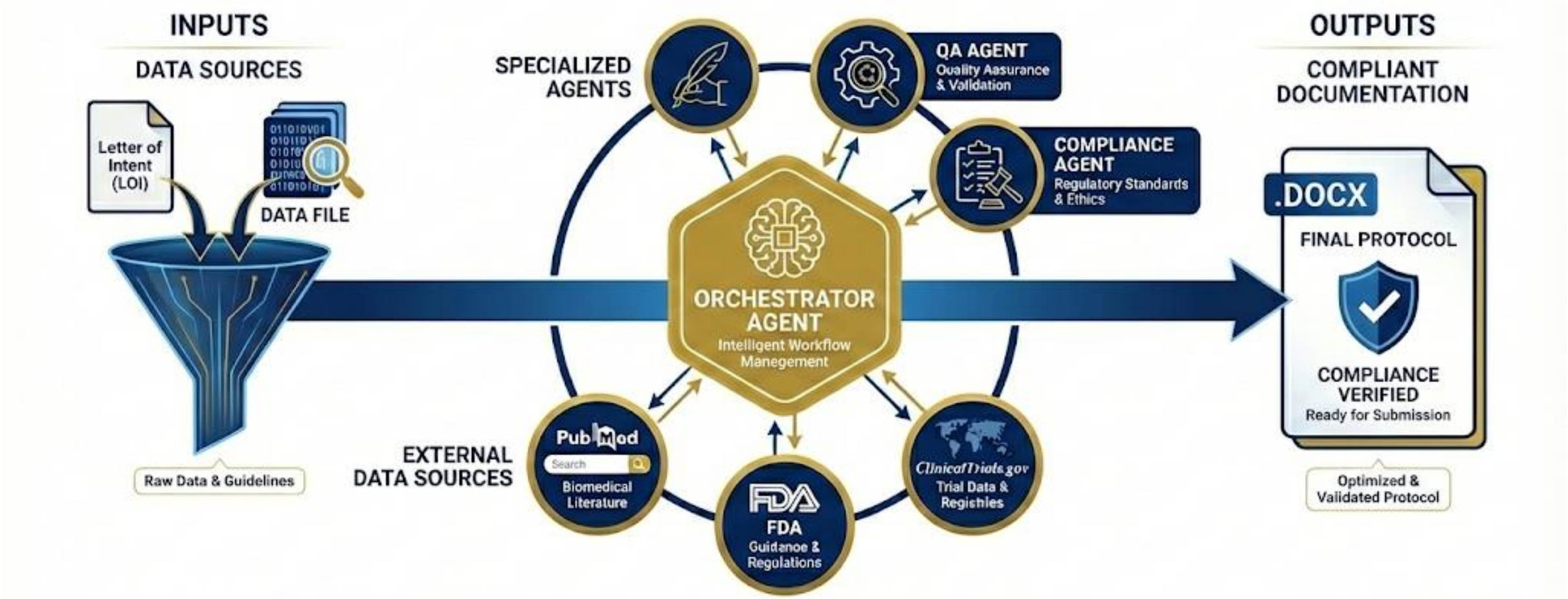


Aim 1. Define and validate computable trial eligibility phenotypes on structured EHR data.

Aim 2. Develop flexible LLM pipelines to extract trial eligibility variables from clinical notes.

Aim 3. Implement ECLIPSE for cohort discovery and trial emulation.

AI ASSISTED TRIAL DESIGN



Key takeaways

READY NOW

CAN USE AT YOUR SITE TODAY

- AI-assisted prescreening to shortlist candidates
- Human + AI: Keep a reviewer in the loop
- Cuts chart-review time and screening burden

EMERGING

PROMISING: VALIDATE LOCALLY

- Real-world prospective results still mixed
- Computable eligibility limited by EHR data
- AI-drafted protocols: good drafts, review pending

NOT YET

DON'T RELY ON IT

- Unsupervised AI screening or matching
- Off-the-shelf tools without local validation