Experience With AI in Pragmatic Clinical Trials

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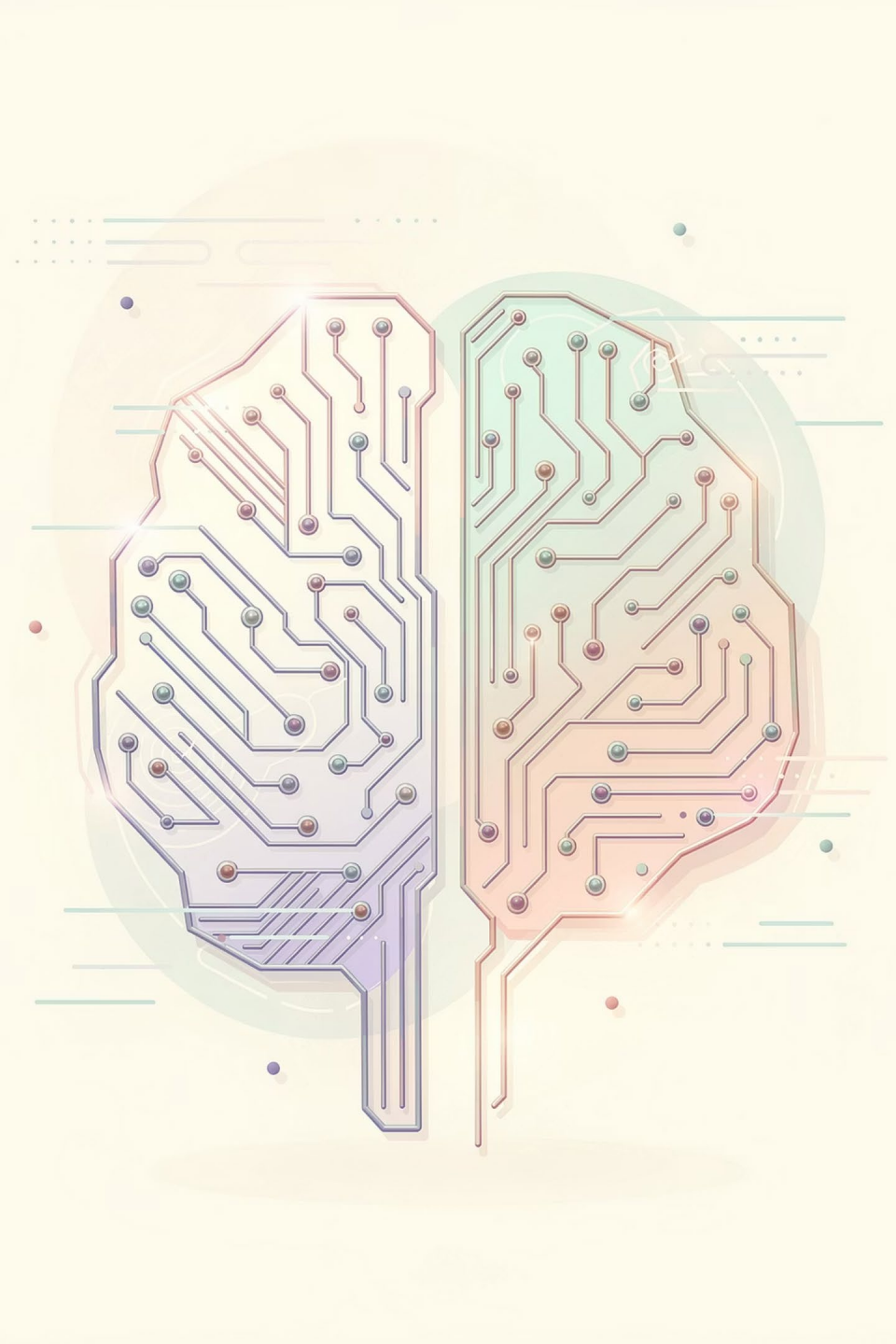

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Survey: Do You Have Experience With With AI in a PCT?

As Part of an Intervention

AI directly embedded into the intervention delivered to participants

To Improve a Process

AI applied to enhance trial operations (recruitment, data analysis, implementation, QI)

In the Background

AI operating within clinical systems that could influence trial conduct or outcomes outcomes without direct team involvement

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Survey Results

Survey sent to **35 active trials in September 2025**

7

Yes

Trials confirmed AI experience in their PCT

14

No

Trials reported no AI use or exposure

14

No Response

Teams did not reply to the survey

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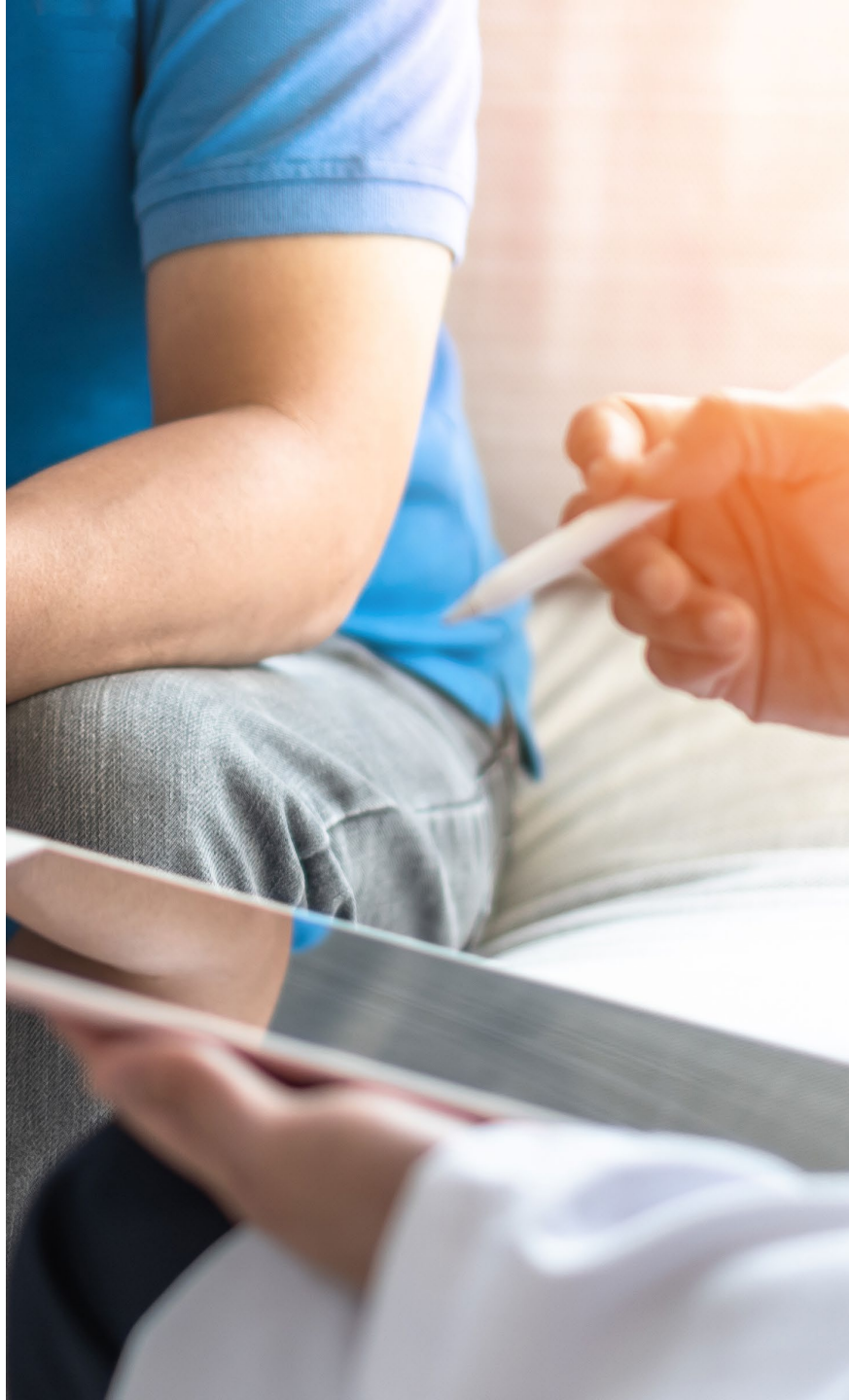
AI Used as Part of an Intervention

3 Trials

AI was a core component of what was delivered to participants or providers providers

- Chat 4 Heart Health
- iPath
- LungSMART



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Chat 4 Heart Health

AI chatbot used to:

Improve control of risk factors for cardiovascular disease

Improve adherence to cardiovascular medications

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iPath

SMART Patient-Centered Medical Home Manager tool used to:

Better stratify patients and assign them to appropriate workflows, such as a diabetes collaborative or a session with a health educator or nutritionist

Give providers better feedback on their practice via brief educational modules based on their performance in their clinic population

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LungSMART

AI tools used to:

- Generate content for messages in a rules-based chatbot (reviewed/edited by team)
- Testing LLMs for use in intervention chatbots; experts designing prompts to tailor knowledge base and conversation topics

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AI applied to improve a process

5 Trials

Trial	AI Use
ADAPT (follow-up to EMBED)	Identify patients in a registry for automated enrollment
ACP PEACE	Review charts for care concordant with patient wishes (validated vs. manual clinician review)
GRACE	Implementation data analysis to support trial monitoring and decision-making
iPATH & LungSMART	Apply findings to iteratively improve the intervention based on real-world performance data

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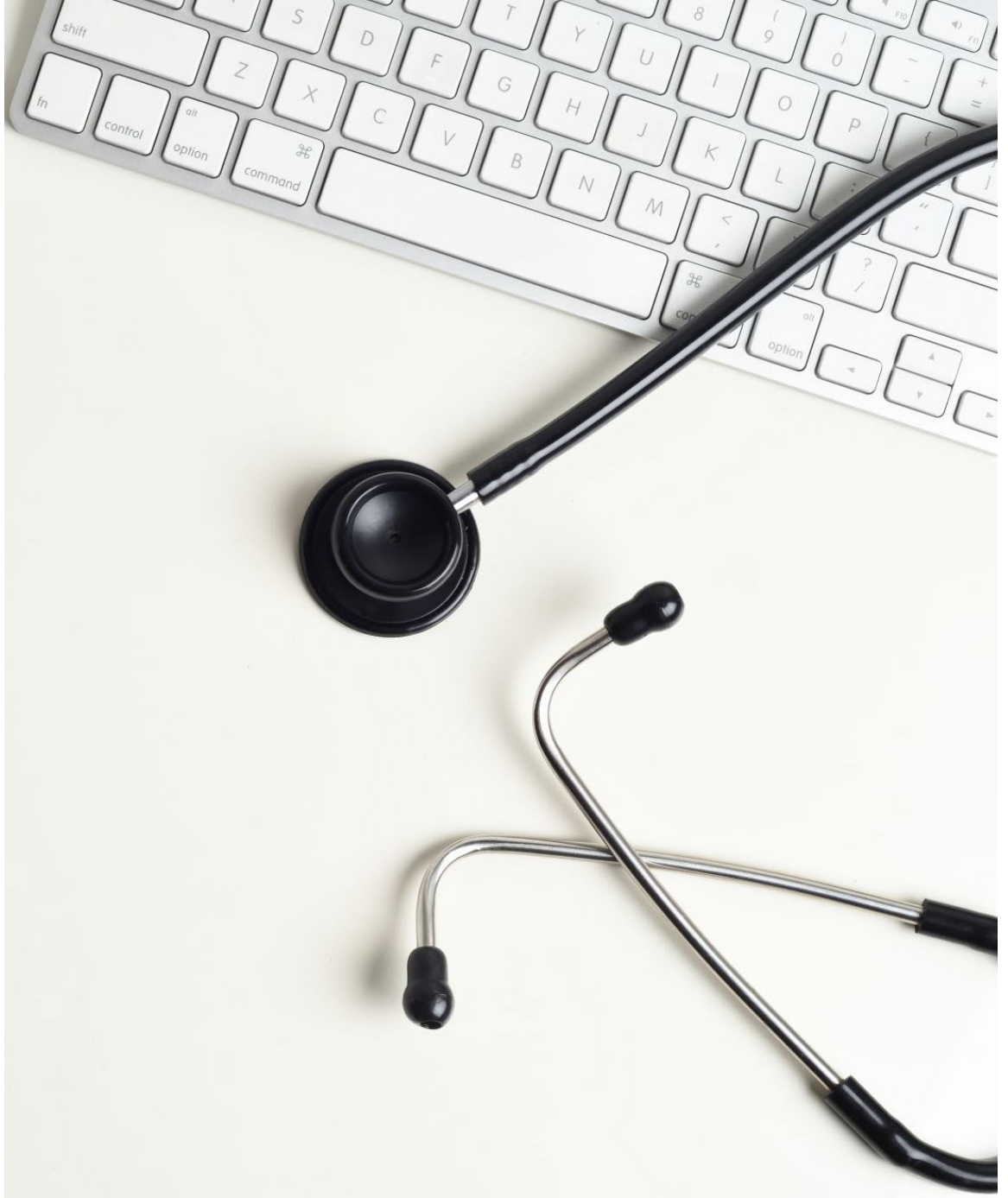
AI in the Background: Potential
Potential PCT Impact

2 Trials

ADAPT (Confirmed)

GRACE (Potential)



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Looking Forward: AI as a Problem-Solving Partner

Could AI help address the operational challenges our trials are facing?

We shared our Collaboratory issues tracker with an AI system and and asked it to assess whether & how AI tools could plausibly address address each logged problem

This exercise was exploratory. The goal was not to commit to AI solutions solutions but to open the conversation about where AI might help and help and where we should be cautious

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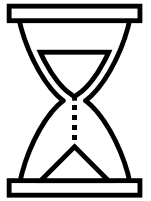
Addressing Slow Enrollment With AI



Enrollment delays are a major challenge in PCTs; AI can help with EHR searches, prediction + workflow support

Trial	AI Opportunity	Suitability	Potential Problems
MOMs Chat & Care	NLP to scan EHR notes for eligible patients; model to prioritize outreach	Uses limited recruitment resources resources efficiently	Misread notes; possible bias in prioritization
IMPACt-LBP	Dashboard for early enrollment alerts; ML to flag likely dropouts	Moves from reactive to proactive decisions	Alert fatigue; behavior models raise ethical questions
FM-TIPS	ML to predict high-yield clinics; EHR tool to flag patients between visits	Targets resources where impact is highest	May miss rural or diverse populations; EHR fatigue
HiLo	Predictive site onboarding; AI workflow tool for tracking	Scalable, data-driven support	May skew to high-performing sites; generalizability concerns

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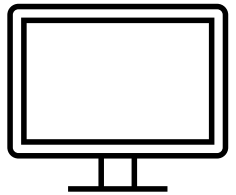
Addressing IT Issues With AI

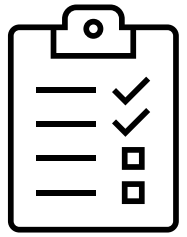


IT issues like fragmented EHRs and algorithm drift threaten data quality and trial fidelity

Trial	Issue	AI Opportunity	Suitability / Potential Problems
FM-TIPS	Data extraction across 9 EHRs	Map data to a common model; run run automated quality checks	Big manual savings, but mapping errors could corrupt datasets; human validation needed to separate noise from real issues
NOHARM	EHR updates may degrade the assignment algorithm	Use a "digital twin" synthetic cohort to test the algorithm after each update	Proactive for a changing IT environment, but the synthetic cohort is complex and raises security concerns
Nudge	Only next-day Surescripts data available	Use EHR-based predictive ML to flag medication gaps, bypassing Surescripts	Could avoid a multi-year delay, but it is not a substitute for real data; monitor accuracy and bias

Addressing Regulatory Issues With AI

Regulatory hurdles can slow enrollment and site activation; AI can help streamline compliance with strict oversight.



Chat 4 Heart Health

Issue: FAA opt-in rules → consent bottleneck

AI Opportunity: Predict the best channel and timing to improve opt-ins

Risks: Selection bias; consent must stay ethical/informed

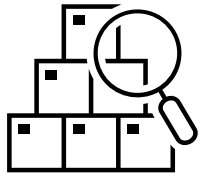
BeatPain Utah

Issue: Site-specific rules → complex clinic onboarding

AI Opportunity: LLM gap analysis against IRB requirements

Risks: Custom build is costly; errors need human review

Addressing Missing Data & Analysis Issues



AI can help preserve trial integrity by improving record linkage and catching analysis errors early

STEP-2: Patient Record Linkage

Issue: Missing IDs → deduplication challenges

AI Opportunity: Match records with ML; extract identifiers with NLP NLP

Risks: Wrong matches; strict privacy needed

EMBED: Automated Analysis Auditing

Issue: Coding errors -> distort outcomes

AI Opportunity: Compare code to the analysis plan + flag gaps

Risks: Misses some errors; human review still required

Addressing Communication & Staffing Issues With AI

Language barriers and staff turnover can undermine engagement and protocol fidelity; AI can help, if implemented carefully.

Trial	Issue	AI Opportunity	Suitability / Potential Problems
BeatPain Utah	Spanish-speaking follow-up gaps	Translated reminders; Spanish chatbot for chatbot for routine questions	Helps reduce biased attrition; may miss cultural/medical nuance, and some patients may avoid chatbots
NOHARM	Nurse turnover and onboarding strain	EHR-embedded AI assistant with protocol checklists and staff Q&A	Supports fidelity and data quality; must avoid workflow disruption and does not fix staffing shortages

AI can extend PCT capacity, but human oversight, equity, and readiness are still essential.

Next Steps

Manuscript submitted to *Contemporary Clinical Trials*

Actively discussing core-related opportunities

On to the discussion!

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