Development and Evaluation of a Community Navigator Intervention for Enhancing Diversity in Early Phase Clinical Trials

Deborah Doroshow, MD, PhD
Associate Professor of Medicine
Tisch Cancer Institute
Icahn School of Medicine at Mount Sinai

Mount Sinai

Early Phase Clinical Trials (EPCTs) in Advanced Cancer

- EPCTs translate findings from preclinical research into clinical practice
- EPCTs represent unique opportunities for patients to access potentially promising anticancer therapeutics otherwise not available to them
- The likelihood that a patient may benefit from participation in a phase 1 cancer CT is growing
  - 20% of unselected or 42% of biomarker-selected patients may have an objective response (more than 30% cancer shrinkage) on a phase 1 cancer CT
- Increasing the diversity of EPCT participants is critical from a social justice perspective to ensure equal access to high quality care and novel anticancer therapies

Adashek et al. Nat Rev Clin Oncol. 2019 December ; 16(12): 773–778

Diversity in Early Phase Clinical Trials

- Racial and ethnic minoritized groups (REMG) are significantly underrepresented in cancer clinical trials (CT)
- A recent study showed that White patients were enrolled in CTs at 98% of the expected proportion based on cancer incidence in the US, whereas enrollment for Black and Hispanic patients was only 22% and 44% of expected enrollment by cancer incidence

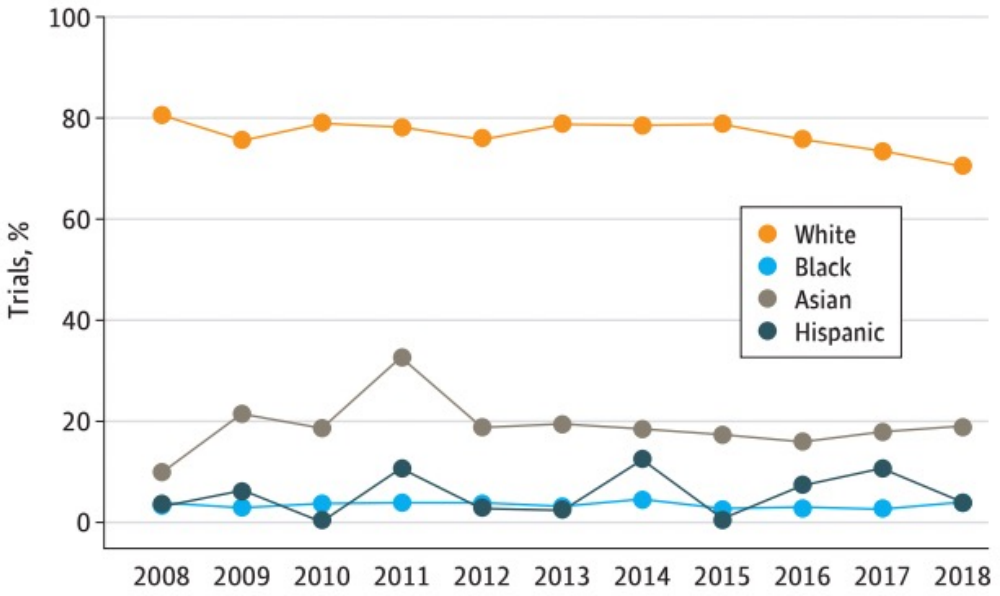


Figure 1. Percentage of patients enrolled in FDA drug approval trials by race

Loree JM, Anand S, Dasari A, et al. Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals From 2008 to 2018. JAMA Oncol. 2019;5(10)

Community navigation in cancer care

- Community navigators (CNs) are community partners who provide guidance to patients as they move through the health care system
- Potential roles can include:
  - Identifying and addressing barriers to care (finances, transportation)
  - Education about treatment options
  - Help with keeping track of appointments
  - Referrals to relevant professionals (social work, spiritual care)
- A few small studies suggest that CNs engage underserved patients and improve CT awareness, education, and recruitment among REMG populations

Ghebre et al. State-of-the-science of patient navigation as a strategy for enhancing minority clinical trial accrual. Cancer. 2014;120:1122-1130.

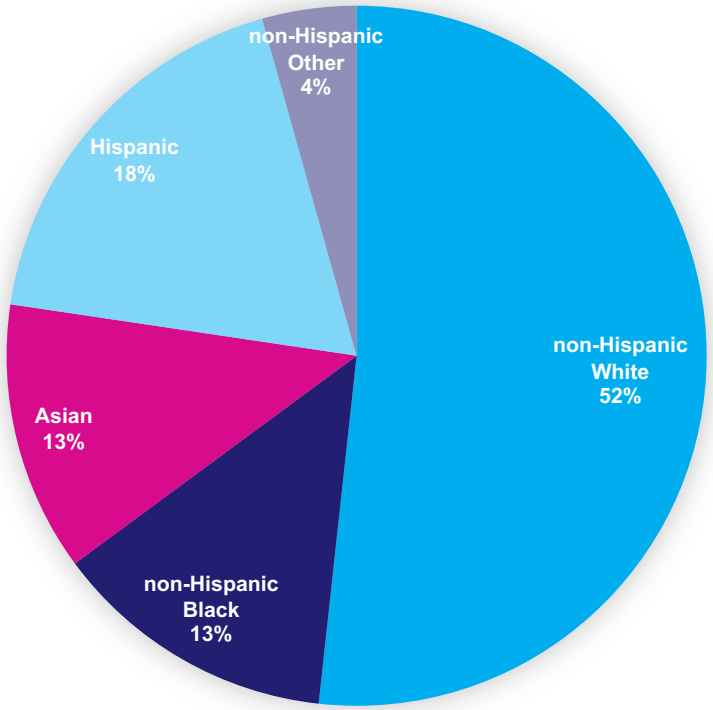
Mount Sinai Early Phase Trials Unit (EPTU)

- Cares for patients with advanced solid malignancies
- 4 doctors, 4 nurse practitioners, 5 research coordinators, 2 data specialists, 2 regulatory specialists, 1 start up manager, 2 trial managers
- Offers phase 1 and phase 2 trials of immunotherapies and targeted therapies
- Typically 20-30 trials open at any one time (31 as of 5/8/25)

Mount Sinai *The Tisch Cancer Institute*
Early Phase Trials Unit

Mount Sinai Early Phase Trials Unit (EPTU)

- From July 2018 to October 2023, EPTU received 499 referrals of patients with advanced solid cancers (some patients had >1 referral)
- 135 of those referrals ultimately resulted in EPTU trial participation
- 31% identified as Black or Hispanic
- No significant differences were found between trial (T) and non-trial (NT) pts in gender, race, ethnicity, language, or insurance status

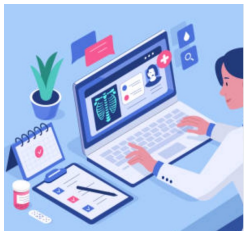


However – most patients (all demographics) have limited understanding of why they were referred to EPTU and little to no awareness of clinical trials or EPCTs in particular

Doroshow, unpublished data

Current EPTU referral process and workflow

Primary MD and patient discuss EPT option

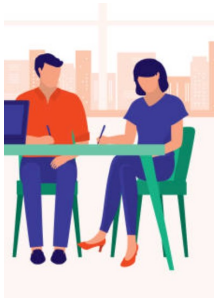


Primary MD emails EPTU

EPTU prescreens for available trials and sets up initial visit

Patient meets EPTU team and learns about early phase trials and about specific EPT

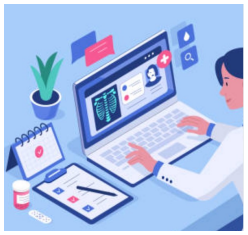
Patient and family/ friends discuss trial



If interested, patient returns to sign consent

Current EPTU referral process and workflow

Primary MD and patient discuss EPT option



Primary MD emails EPTU

EPTU prescreens for available trials and sets up initial visit

1

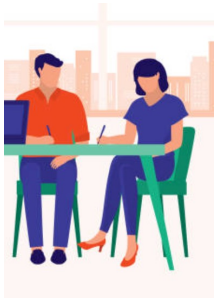
Patient meets EPTU team and learns about early phase trials and about specific EPT

2

Patient and family/ friends discuss trial

3

Community navigation intervention



If interested, patient returns to sign consent

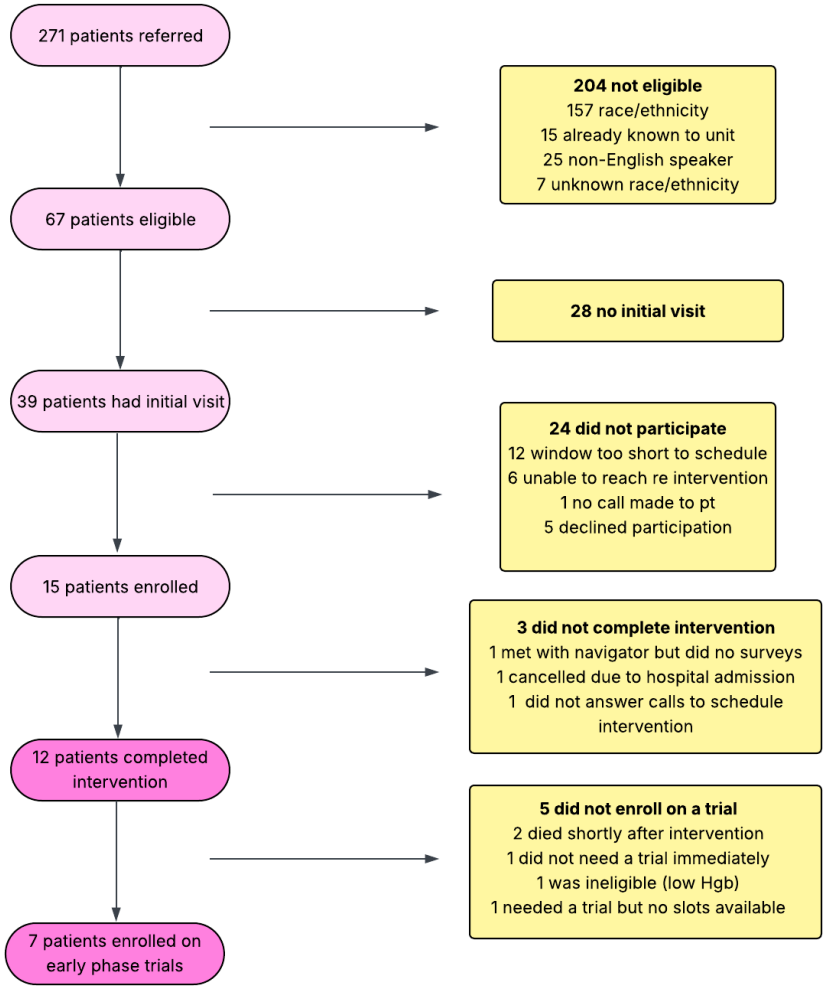
Ongoing pilot project

- Collaboration with Karen Peterson of Karen's Club
- From September 2023– May 2025
- Surveys regarding distrust, clinical trial awareness, mood given at baseline
- Meet with CN prior to EPTU initial visit and later as desired
- Post-intervention surveys regarding distrust and clinical trial awareness
- Patients provided with gift cards for participation

Ongoing pilot project

Modifiable reasons for intervention drop out:

- Non-English speaker (majority spoke Spanish)
- Window too short to schedule
- No call made to patient
- Patients who enrolled but did not complete navigation



Early lessons learned

- Complexities of coordinating among many team members including external CN
- Challenges of coordinating visits, surveys etc. in a short number of days
- Technical challenges – Zoom not feasible for many patients; often ended up doing last minute phone calls
- Challenges reaching patients for follow up surveys
- Patients have given strongly positive informal feedback
- Patients were often worried about, distrustful of, and unfamiliar with trials before visit
- In one case, CN meeting was after initial visit and patient had questions that had been addressed in visit – importance of assessing understanding

Research plan and goals:

American Cancer Society Cancer Health Equity Research Center (CHERC) Grant

- The goal of this proposal is to develop a CN-led intervention through community-engaged design to increase REMG enrollment in EPCTs by developing knowledge of EPCTs, overcoming barriers to enrollment, and enhancing trust

Aim 1: Develop the CN-led EPCT educational intervention

Aim 2: Iteratively refine the CN-led EPCT intervention through cognitive interviews with stakeholders

Aim 3: Conduct a pilot, single-arm trial of a CN-led EPCT educational intervention

Research plan and goals:

American Cancer Society Cancer Health Equity Research Center (CHERC) Grant

Aim 1: Develop the CN-led EPCT educational intervention.

Focus groups with EPCT stakeholders (patients, caregivers, clinicians)

Aim 2: Iteratively refine the CN-led EPCT intervention through cognitive interviews with stakeholders.

Cognitive interviews with a different group of stakeholders from these groups

Aim 3: Conduct a pilot, single-arm trial of a CN-led EPCT educational intervention.

Primary objective: assess feasibility

Secondary objectives: assess changes in EPCT knowledge, beliefs, and medical mistrust

Thank you!

deborah.doroshow@mssm.edu

Shaping Equitable Access to Cancer Clinical Trials through AI and Navigation

Mount Sinai

Society for Clinical Trials May 2025

Enhancing trial access through innovative screening approaches at The Tisch Cancer Institute, Mount Sinai Health System

Presenters

Therica Miller, MBA CCRP

Executive Director, Enterprise Cancer Clinical Research
The Tisch Cancer Institute

Associate Dean, Cancer Programs,
Icahn School of Medicine at Mount Sinai

Deirdre Cohen, MD, MS

Director of the Gastrointestinal Oncology Program for the Mount Sinai Health System

Associate Professor of Medicine, Hematology Oncology,
Icahn School of Medicine at Mount Sinai

Disclosures

Therica Miller serves as an advisor to Triomics, a company developing AI-driven solutions for clinical trial matching and trial optimization. This relationship is disclosed in the interest of transparency.

Dr. Cohen has no relevant financial relationships or conflicts of interest to disclose related to the content of this presentation.

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Background

- Fewer than **7% of adult cancer patients** participate in treatment trials, with **underrepresented groups** (i.e. racial/ethnic minorities, rural populations) facing even greater barriers to access.
- Increasing **protocol complexity and restrictive eligibility criteria** contribute to low accrual rates, with nearly **20% of trials failing** due to insufficient enrollment.
- **Biases and logistical barriers** (i.e. provider assumptions, transportations, finances) limit trial opportunities for underserved populations, perpetuating health disparities.
- Emerging solutions – such as **centralized pre-screening, AI-driven trial matching, and navigation programs** – are promising, but can they improve efficiency, increase participant diversity, and reduce staff burden and recruitment costs.

Source: JM Unger, et al. National Estimates of the Participation of Patients With Cancer in Clinical Research Studies Based on Commission on Cancer Accreditation Data. *JCO* **42**, 2139-2148(2024).
Mahmud A, et al. *Clinical Trials Accrual and Success Rates in Oncology.* J Clin Oncol. 2018;36(16):1554-1561.
Huang GD, et al. *Clinical Trials Recruitment Planning: A Proposed Framework from the Clinical Trials Transformation Initiative*. Contemp Clin Trials. 2018;66:74-79

Guiding Our Approach

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PARTIAL ACCESS | ORIGINAL CONTRIBUTIONS | January 11, 2023

An Assessment of the Feasibility and Utility of an ACCC-ASCO Implicit Bias Training Program to Enhance Racial and Ethnic Diversity in Cancer Clinical Trials

Authors: Nadine J. Barrett, PhD, Leigh Boehmer, PharmD, Janelle Schrag, MPH, Al B. Benson III, MD, Sybil Green, JD, RPh, MHA, Leila Hamroun-Yazid, Alexandra Howson, PhD, ... SHOW ALL ... , and Carmen E. Guerra, MD, MSCE | AUTHORS INFO & AFFILIATIONS

Publication: JCO Oncology Practice • Volume 19, Number 4 • https://doi.org/10.1200/OP.22.00378

Cancer / Volume 130, Issue 8 / pp. 1193-1203

COMMENTARY | Open Access

A call to action to advance patient-focused and decentralized clinical trials

R. Donald Harvey PharmD, Therica M. Miller MBA, Patricia A. Hurley MSc, Ramya Thota MBBS, Lora J. Black RN, MPH, Suanna S. Bruinooge MPH, Leigh M. Boehmer PharmD ... See all authors

First published: 09 January 2024
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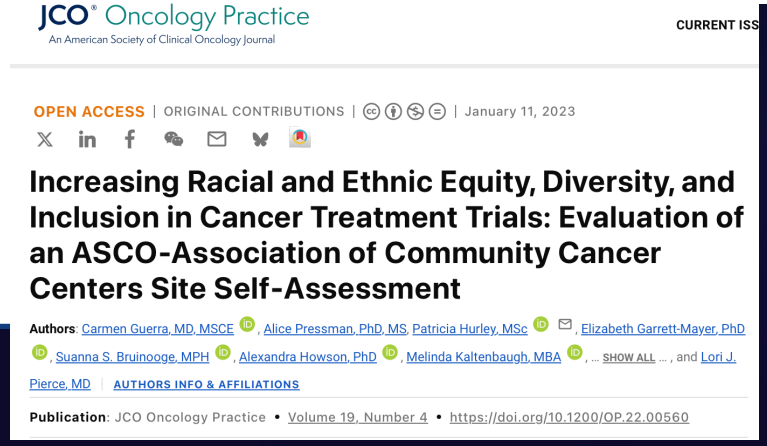
Citations: 1

R. Donald Harvey and Therica M. Miller contributed equally to this work.



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CURRENT ISS

OPEN ACCESS | ORIGINAL CONTRIBUTIONS | January 11, 2023

Increasing Racial and Ethnic Equity, Diversity, and Inclusion in Cancer Treatment Trials: Evaluation of an ASCO-Association of Community Cancer Centers Site Self-Assessment

Authors: Carmen Guerra, MD, MSCE, Alice Pressman, PhD, MS, Patricia Hurley, MSc, Elizabeth Garrett-Mayer, PhD, Suanna S. Bruinooge, MPH, Alexandra Howson, PhD, Melinda Kaltenbaugh, MBA, ... SHOW ALL ... , and Lori J. Pierce, MD | AUTHORS INFO & AFFILIATIONS

Publication: JCO Oncology Practice • Volume 19, Number 4 • https://doi.org/10.1200/OP.22.00560

Source: Harvey RD, Miller TM, Hurley PA, Thota R, Black LJ, Bruinooge SS, Boehmer LM, Fleury ME, Kamboj J, Rizvi MA, Symington BE, Tap WD, Waterhouse DM, Levit LA, Merrill JK, Prindiville SA, Pollastro T, Brewer JR, Byatt LP, Hamroun L, Kim ES, Holland N, Nowakowski GS. A call to action to advance patient-focused and decentralized clinical trials. Cancer. 2024 Apr 15;130(8):1193-1203
C. Guerra et al. Increasing Racial and Ethnic Equity, Diversity, and Inclusion in Cancer Treatment Trials: Evaluation of an ASCO-Association of Community Cancer Centers Site Self-Assessment. *JCO Oncol Pract* **19**, e581-e588(2023).
Barrett NJ, Boehmer L, Schrag J, Benson AB 3rd, Green S, Hamroun-Yazid L, Howson A, Matin K, Oyer RA, Pierce L, Jeames SE, Winkfield K, Yang ES, Zwicker V, Bruinooge S, Hurley P, Williams JH, Guerra CE. An Assessment of the Feasibility and Utility of an ACCC-ASCO Implicit Bias Training Program to Enhance Racial and Ethnic Diversity in Cancer Clinical Trials. JCO Oncol Pract. 2023 Apr;19(4):e570-e580.

Current Challenges in Clinical Trial Access

? Can centralized prescreening improve consistency, reduce burden on disease teams, and enhance trial access?

? Will AI-powered patient trial matching further boost efficiency and accuracy, accelerating enrollment and optimizing resource utilization?

Resource Constraints

High patient and trial volume overwhelms disease team staff, limiting chart review capacity.

Personnel Instability

High turnover among research personnel leads to inconsistent pre-screening workflows.

Systemic Limitations

Fragmented clinical data causes difficulties in identifying eligible patients efficiently.

Our project evaluates whether a systematic, navigator-driven, AI-supported screening process can enhance trial access while optimizing resource utilization.

Project Overview: Enhancing Clinical Trial Access

Project timeframe: August 2024 - April 2025 with an 8-week initial logistics period

Planning Phase

Partnership established between Tisch Cancer Institute and Triomics AI

Implementation

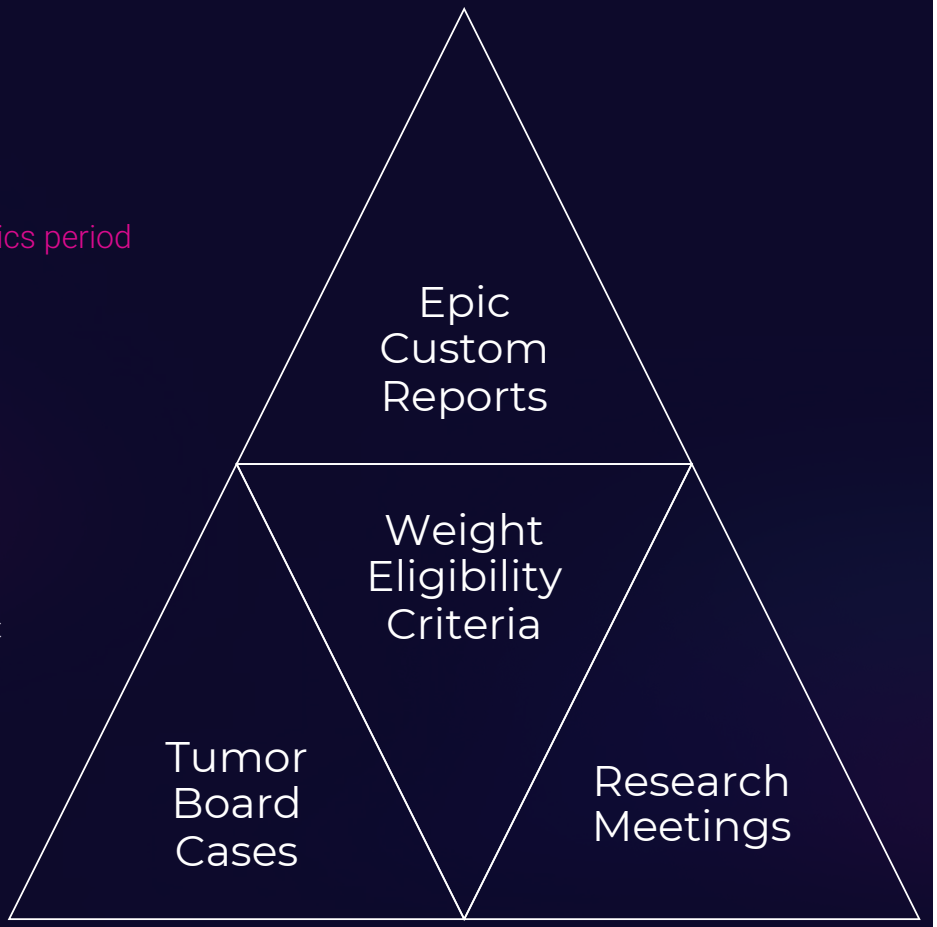
Dedicated navigator performs indication based pre-screening for GI and Lung cancer patients presenting for consultation or disease assessment

Evaluation

Plan-Do-Study-Act model enables continuous workflow refinement

Analysis

Assessment of impact on trial access, enrollment, and resource utilization



Clinical Research Navigator Qualifications

Strong Clinical Research Foundation

Experience across academic and community oncology settings

Oncology-Specific Expertise

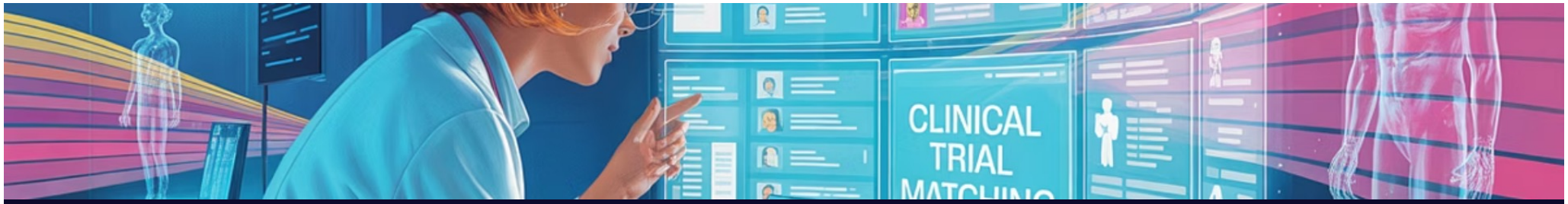
Skilled in interpreting imaging, pathology, and investigational protocols

Technical Fluency

Adept at navigating complex medical records and unstructured data sources

Research Credentials

Publication record demonstrating analytical rigor and scientific credibility



Pre-screening Process Flow

Epic Report Generation: Daily reports identify GI and lung patients with upcoming appointments

Chart Review: Navigator reviews medical history against Tier 1 protocol criteria

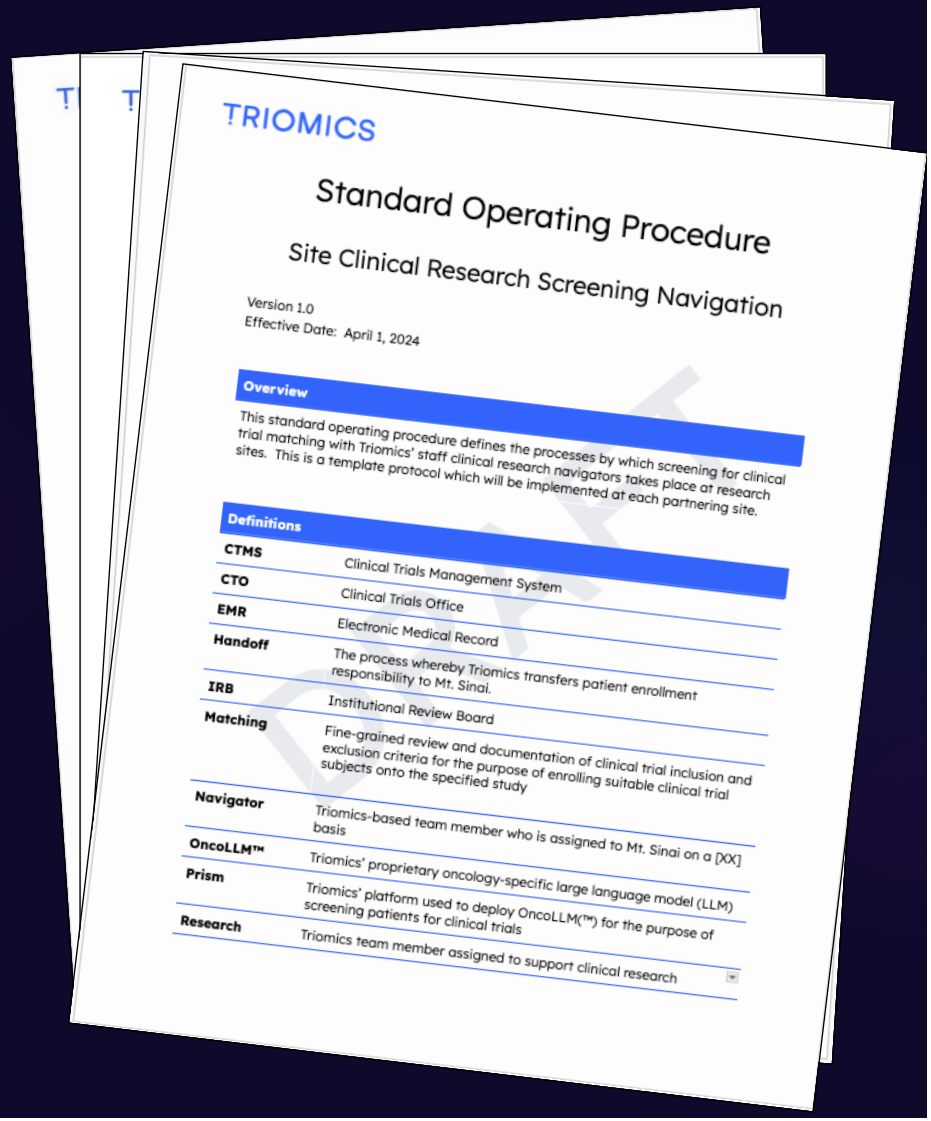
Team Discussion: Navigator attends weekly disease team meetings to present candidates

Patient Handoff: Approved candidates are approached for consent and deeper screening

Patient Waitlist: Patients not immediately eligible are placed on a watchlist for future consideration

Standard Operating Procedures

- Project specific SOPs were developed to ensure standardized workflows are followed throughout the duration of the pilot phase, where manual patient clinical trial screening is ongoing
- Based on weekly team meetings and provider feedback, workflows are routinely reviewed. Adjustments are made as needed to maximize efficiency and patient throughput
- For future work, Triomics has instituted a library of standard operating procedures pertaining to introducing AI into clinical workflows



TRIOMICS

Standard Operating Procedure

Site Clinical Research Screening Navigation

Version 1.0
Effective Date: April 1, 2024

Overview

This standard operating procedure defines the processes by which screening for clinical trial matching with Triomics' staff clinical research navigators takes place at research sites. This is a template protocol which will be implemented at each partnering site.

Definitions

CTMS	Clinical Trials Management System
CTO	Clinical Trials Office
EMR	Electronic Medical Record
Handoff	The process whereby Triomics transfers patient enrollment responsibility to Mt. Sinai.
IRB	Institutional Review Board
Matching	Fine-grained review and documentation of clinical trial inclusion and exclusion criteria for the purpose of enrolling suitable clinical trial subjects onto the specified study
Navigator	Triomics-based team member who is assigned to Mt. Sinai on a [XX] basis
OncoLLM™	Triomics' proprietary oncology-specific large language model (LLM)
Prism	Triomics' platform used to deploy OncoLLM(™) for the purpose of screening patients for clinical trials
Research	Triomics team member assigned to support clinical research

Project Connect: Research Communication Study

NIH-funded research led by Dr. Cardinale Smith investigating patient-provider communication

Study Objectives

Assess oncologist-patient communication quality regarding values and preferences in serious illness conversations.

Examine impact on patient satisfaction and psychological distress.

Design Parameters

Target: 325 patients with advanced solid cancer across Mount Sinai and Duke.

Criteria: Advanced solid tumor diagnosis with prognosis <2 years, English-speaking, age ≥21

Assessment Methods

Audio recording of clinical encounters to analyze communication patterns.

Evaluation of oncologist implicit bias and its effects on discussions.

Patient outcomes are collected.

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8	MS5288P	Female	GOEL, ANUPAM	DXA BONE DENSI	BLACK OR A	NON-HISPAN	3	4		5/22/2025	11:30
9	MS5289P	Female	KOZUCH, PETER	US THYROID	WHITE	NON-HISPAN	3	2		5/27/2025	10:00
10	MS5290P	Female	PINTOVA, SOFY	CT CHEST ABDOM	WHITE	NON-HISPAN	1	2		5/27/2025	7:55
11	MS5291P	Female	KOZUCH, PETER	CT CHEST ABDOM	OTHER	DOMINICAN	1	2		5/1/2025	12:00
12	MS5292P	Female	GOEL, ANUPAM	DXA BONE DENSI	WHITE	NON-HISPAN	3	4		5/16/2025	14:00
13	MS5293P	Female	KLEIN, PAULA	DXA BONE DENSI	CHINESE	NON-HISPAN	2	4		5/23/2025	13:00
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Project Connect: Implementation Challenges

Resource-Intensive Case Identification

Manual review of oncologist schedules required substantial coordinator time.

Complex Eligibility Assessment

Screening required evaluation of multiple criteria across fragmented data sources.

Workflow Integration

Coordinating scan appointments with patient visits necessitated careful timing.

4857 patients manually reviewed between July 2022 and August 2024, yielding 117 patients enrolled **(2.4% enrollment rate)**
2 eligible patients identified for every 50 reviewed **(4% identification rate)**

Non-Treatment Intervention Setting

Project Connect: Enhanced Screening Results

405

Patients Reviewed

Total patients evaluated between August 2024 and April 2025

6.7%

Enrollment Rate

Compared to 2.4% with traditional screening methods

20%

Identification Rate

Eligible patients found (vs. 4% with conventional screening)

The navigator-driven approach yielded 27 patient enrollments, demonstrating significant improvement over traditional methods.

Treatment Trial Intervention Results

Initial Program Context at Mount Sinai

Large Academic Medical Center

Complex patient populations, diverse catchment area and broad geographic footprint

Varied Practice Patterns

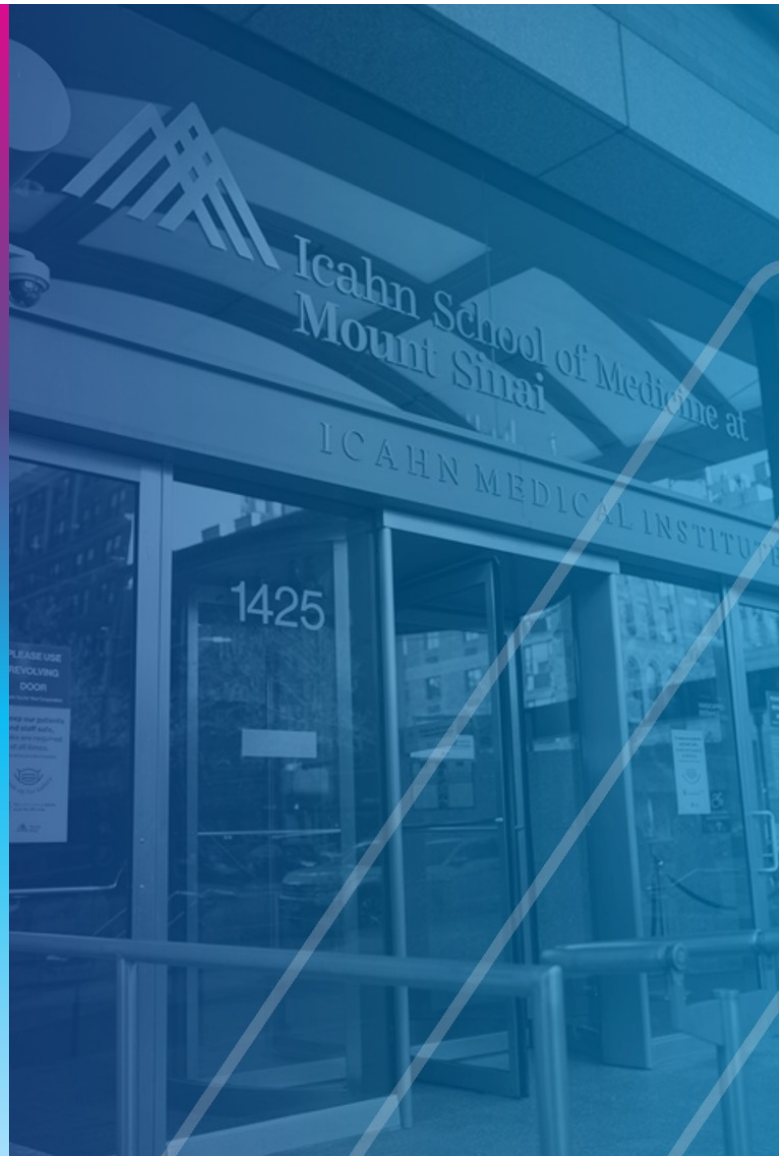
Investigators with diverse practice styles and research familiarity

Resource Constraints

Limited protected research time within RVU compensation model

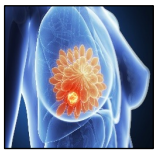
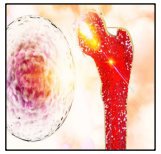
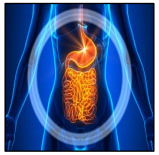
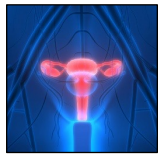
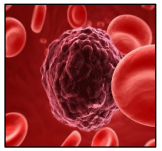
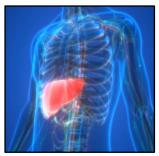
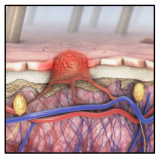
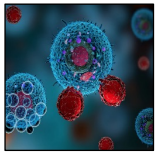
Clear Goal

Need to simplify trial participation for both providers and patients



Multidisciplinary Disease Team Leaders

Multidisciplinary leadership across 12 disease-focused teams ensures comprehensive oncology trial coverage

 **Breast** *Stephanie Bernik, MD* *Paula Klein, MD* *Amy Tiersten, MD*	 **BMT** *John Levine, MD* *Alla Keyzner, MD*	 **Gastrointestinal** *Deirdre Cohen, MD* *Karyn Goodman, MD* *Patricia Sylla, MD*	 **Genitourinary** *Matthew Galsky, MD* *Richard Stock, MD* *Ashutosh Tewari, MD*	 **Gynecologic Oncology** *Stephanie Blank, MD* *Monica Prasad, MD*	 **Hematology Oncology** *John Mascarenhas,MD* *Cesar Rodriguez, MD*
 **Head & Neck** *Richard Bakst, MD* *Bruce Culliney, MD* *Scott Roof, MD*	 **Lung** *Jorge Gomez, MD* *Fred Hirsch, MD* *Andrea Wolf, MD*	 **Liver** *Michael Buckstein,MD* *Joseph Llovet, MD* *Myron Schwartz, MD*	 Sarcoma, Melanoma, Neuro-Oncology *Phillip Friedlander, MD* *Bobby Liaw, MD* *Ray Yong, MD*	 Pediatrics *Kaylen Bailey, MD* *Oren Becher, MD*	 Phase I Developmental Therapeutics *Matthew Galsky, MD* *Thomas Marron, MD* *Joseph Sparano, MD*

Baseline Trial Portfolio Analysis

Pre-intervention baseline demonstrates the scale of clinical operations and existing trial activity across the two focus areas.
GI oncology had higher patient volume but comparable accrual rates to lung oncology.

Gastrointestinal Program

833 Analytic Cases (Mount Sinai Hospital)

23 Average 9-mo Accrual

18 Available Interventional treatment trials

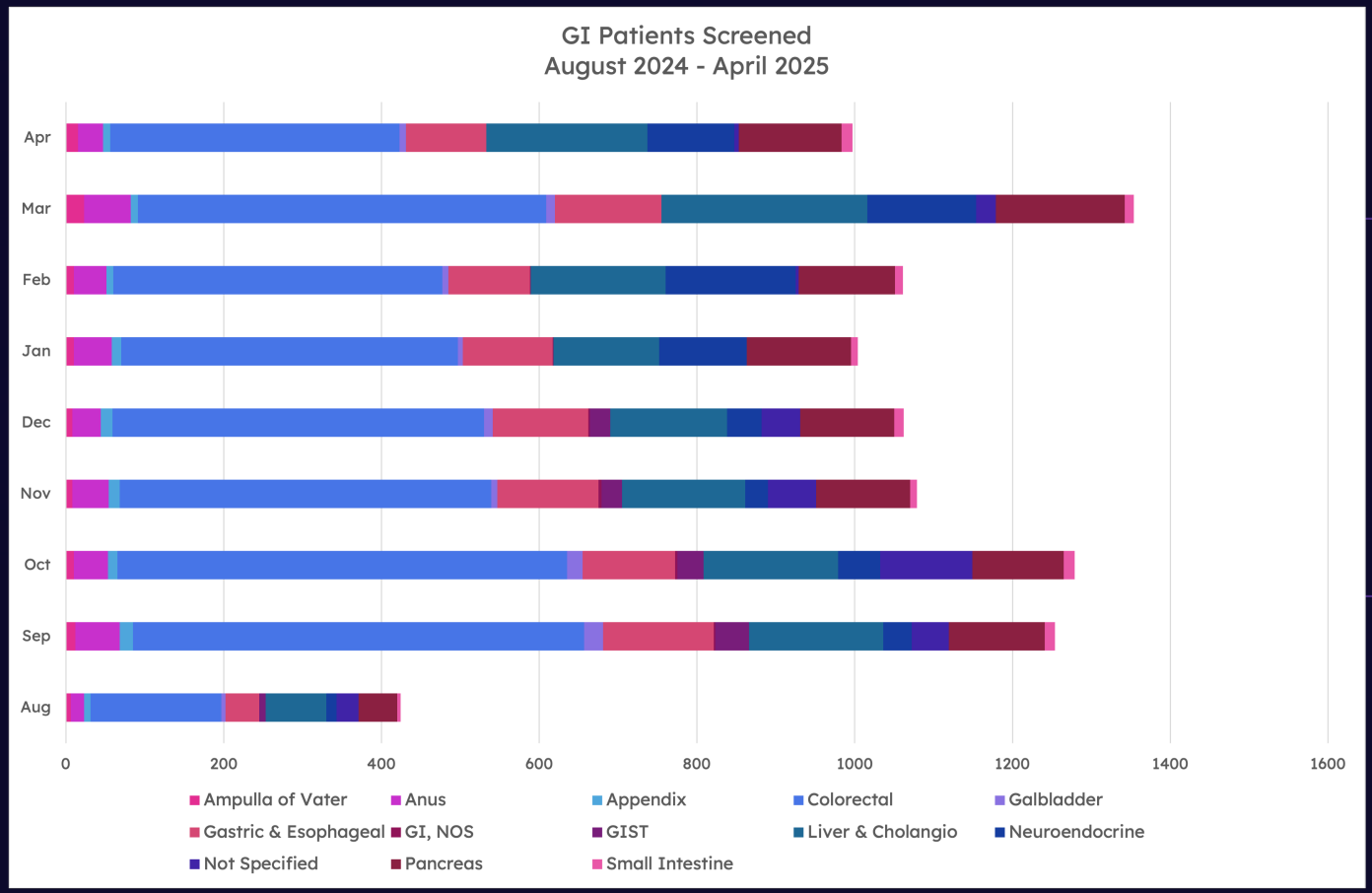
Lung Program

393 Analytic Cases (Mount Sinai Hospital)

20 Average 9-mo Accrual

7 Available Interventional treatment trials

Over 9,500 medical records reviewed over a 9-mo period



1.9 %

Potential Patients Identified

GI Oncology: Screening Results Summary

Comprehensive screening of GI oncology patients revealed a modest but important percentage of potentially eligible trial candidates.

9,514

Records Reviewed

Total medical records screened over 9-month period

7,838

Patients Screened

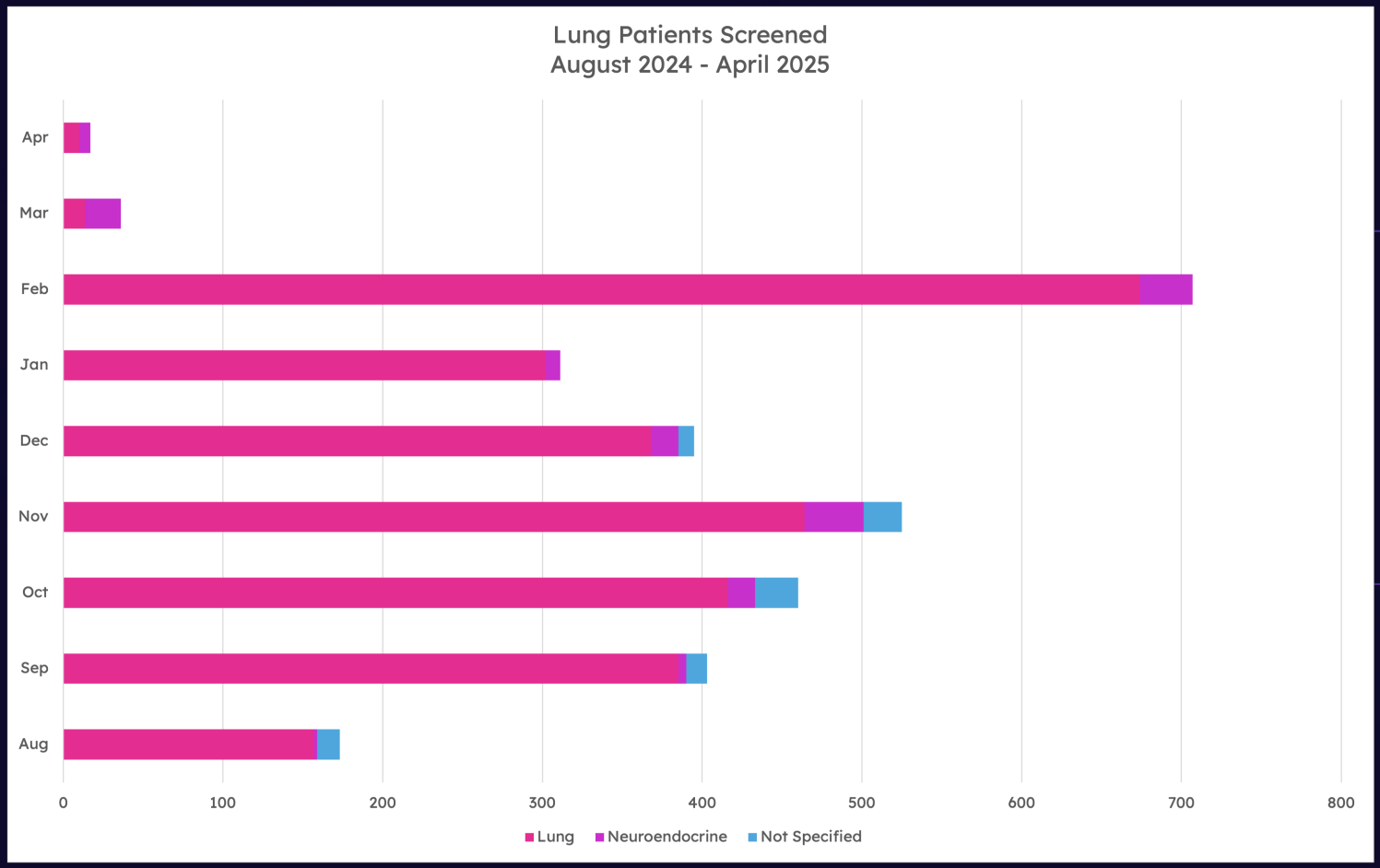
Unique patients evaluated for trial eligibility

145

Recommendations

Patients identified as potential trial candidates (1.9%)

Over 3,000 medical records reviewed over a 9-mo period



3.8 %

Potential Patients Identified

Lung Cancer: Screening Results Summary

Lung cancer screening efforts revealed a higher percentage of potentially eligible candidates compared to GI oncology.

3,027

Records Reviewed

Total medical records screened over 9-month period

2,370

Patients Screened

Unique patients evaluated for trial eligibility

91

Recommendations

Patients identified as potential trial candidates (3.8%)

Accrual Impact Analysis

The navigator-driven approach significantly contributed to overall accrual, accounting for 23% of GI and 18% of lung trial enrollments during the study period.

Disease Site	#Recommend	Approached	Consented (watchlist)	Enrolled	Total Accrual Aug 2024-Apr 2025	Baseline Accrual 9-month period
GI	145 (1%)	38	15 (6 pending)	**11**	**48**	**23**
Lung	91 (4%)	17	6 (4 pending)	**3**	**17**	**20**

Barriers to Trial Participation

Approach Barriers

- Limited information on new patients
- Undocumented social factors
- Appointment cancellations
- Delayed biomarker results
- Staffing limitations

Enrollment Barriers

- Patient preference
- Physician clinical judgment
- Patient compliance / resources / support system
- Trial suspensions
- Complex eligibility criteria

Patient Case Study: Enhanced Access

Initial Presentation

68-year-old patient with metastatic colorectal cancer after standard therapy progression

Navigator Intervention

Pre-screening identified potential eligibility for targeted therapy trial

Outcome

Successful enrollment and treatment response not otherwise available

This case illustrates how the navigator-driven approach can identify opportunities that might otherwise be missed, expanding treatment options for patients.

Investigator & Staff Survey

Centralized screening has shifted investigator and staff behaviors toward patient identification for clinical trials

71%

of investigators rated the centralized pre-screening approach as effective or very effective at increasing potential trial candidates.

42%

of investigators indicated the centralized pre-screening recommended trial(s) they were previously unaware of

55%

of staff agreed that the navigator recommended trials they previously lacked capacity to fully assess candidacy for

Qualitative Investigator Feedback

Awareness Enhancement

"Constant reminders about individual studies help our high-volume team maintain trial awareness across providers with varying familiarity."

Workflow Optimization

"The pilot narrows patients from very high to manageable volume, focusing weekly discussions on viable candidates scheduled for the upcoming week."

Future Improvements

"While avoiding overly narrow criteria, enhanced assessment of staging and pathologic features could further refine recommendations."

Investigator feedback indicates high value while suggesting targeted enhancements for future implementation.

Implementation Limitations

Addressing these limitations in future implementations could further enhance the effectiveness of the approach.

Communication Methods

Email and meetings could be enhanced with EMR flags

Local Expertise

Comprehensive screening still requires study team knowledge

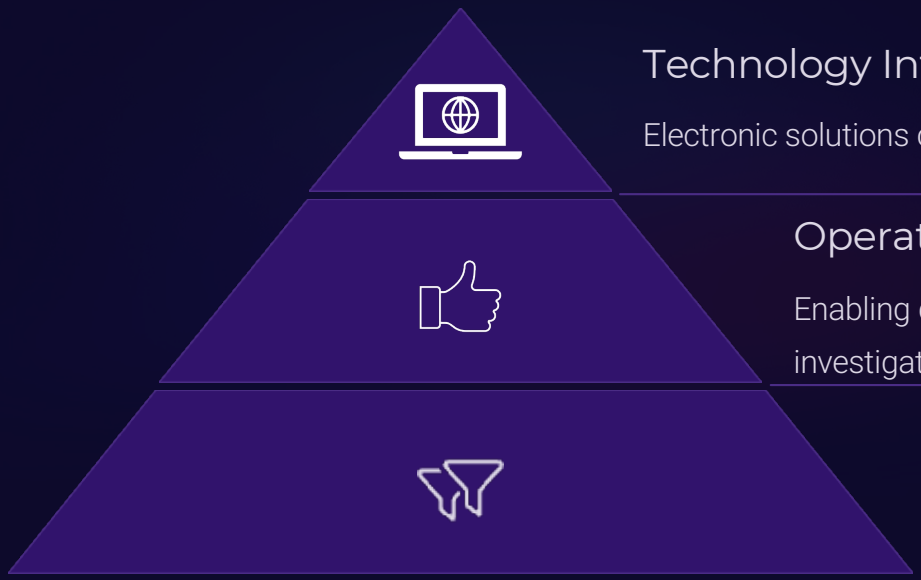
Facility Limitations

Trial location remains a perceived participation barrier

Timing Constraints

Weekly screening misses last-minute schedule additions

Key Insights from Pilot Implementation



Technology Integration

Electronic solutions critical for scaling and sustainability

Operational Insights

Enabling deep dive analysis of patient population and screening activity and investigator accountability

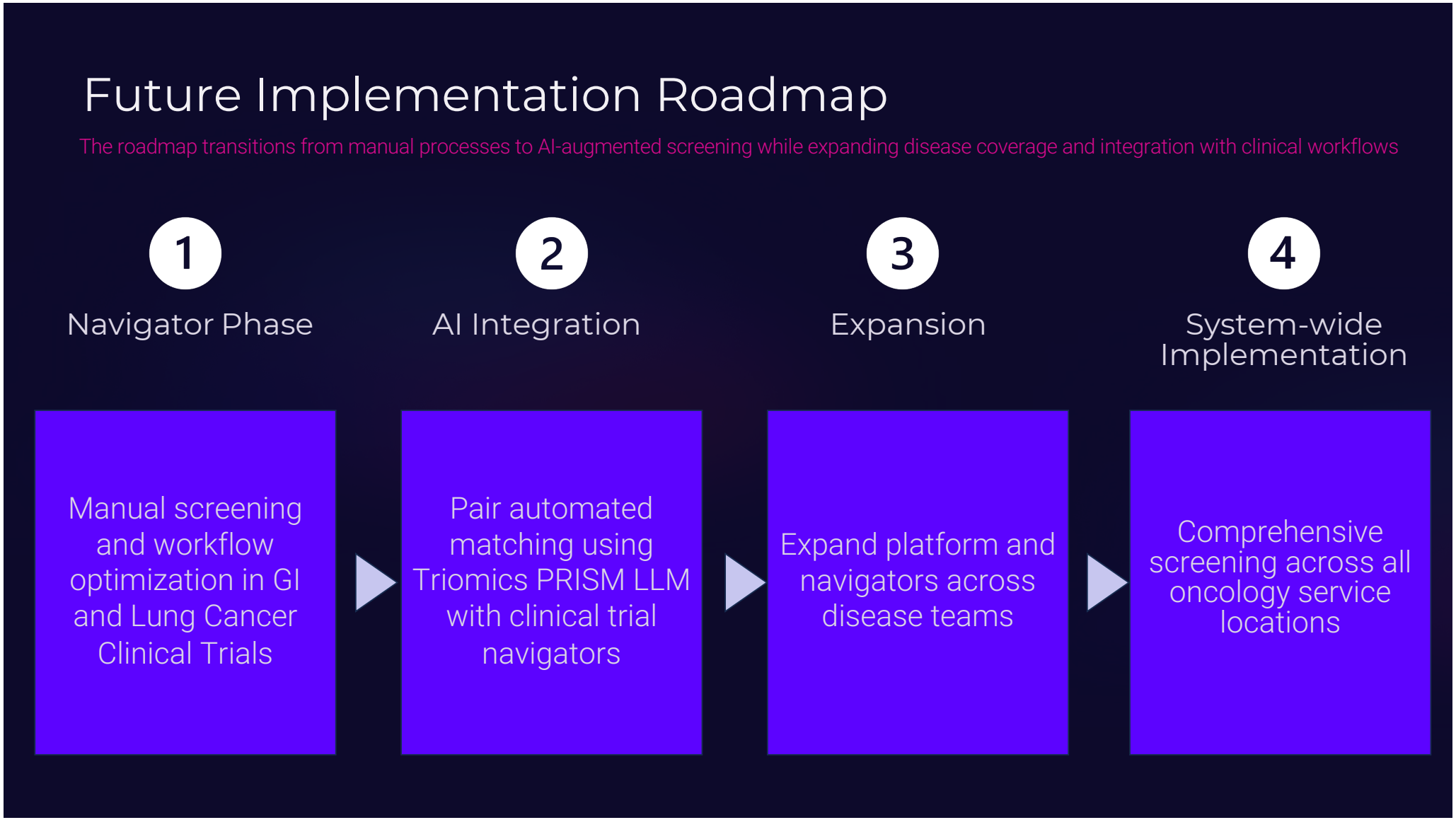
Targeted Screening

Small percentage of patients have suitable trial matches

The navigator approach demonstrates particular value for new trials, with early accruals establishing enrollment momentum. The watchlist concept holds promise for future enrollments.

Future Implementation Roadmap

The roadmap transitions from manual processes to AI-augmented screening while expanding disease coverage and integration with clinical workflows



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Jose Morillo, BA
William Liu, MPH

Not Pictured:
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Stephanie Chang
Julia Miller

Integration of AI/LLM to semi-automate trial recruitment

Erin E. Lynch, MS, CCRP

Administrative Director
Clinical Trials Office
MCW Cancer Center

Society of Clinical Trials 2025 Annual Meeting

Shaping the Future: The Right Questions, Robust Answers

Integration of AI/LLM to semi-automate trial recruitment

MEDICAL COLLEGE OF WISCONSIN

Introduction to MCW Cancer Center

- Premier academic cancer center located in Milwaukee, WI
- Largest treatment trial program in the state of Wisconsin
- Longstanding member of AACI
- Deeply focused on obtaining NCI designation

Introduction to MCW Cancer Center CTO

- Centralized Clinical Trials Office, clinical support of approx. 120 coordinators organized into Disease Oriented Teams (DOTs)
- 16 DOTs supported by 14 Disease Team Managers
- Centralized Support Services (Reg, Ed, QA, Finance, etc.)
- Robust IT infrastructure (EMR, CTMS, Part 11 Reg System)

Introduction to MCW Cancer Center CTO

Goals of CTO and CC Administration

Institutional Priorities

- Potential to optimize the trial portfolio (feasibility, target population, etc.).
    - Data-driven support for opening trials based on fit to population.
- Improve human resource utilization by introducing efficiencies.
- CCSG initial submission deadline and data lock approaching.
    - Aim to demonstrate accrual above the 10% minimum threshold for NCI-designated centers.

Goals of CTO and CC Administration

Staffing

- Dynamic staffing in the CTO necessitates agility in processes.
  - Increasing demands on coordinator time in midst of staffing shortages.
- Simplify the complex I/E criteria review process to improve efficiency.
  - Non-medical CTO staff with fewer years of experience can facilitate.
- Reduce time needed to pre-screen and confirm eligibility.
  - Track CTO effort effectively.

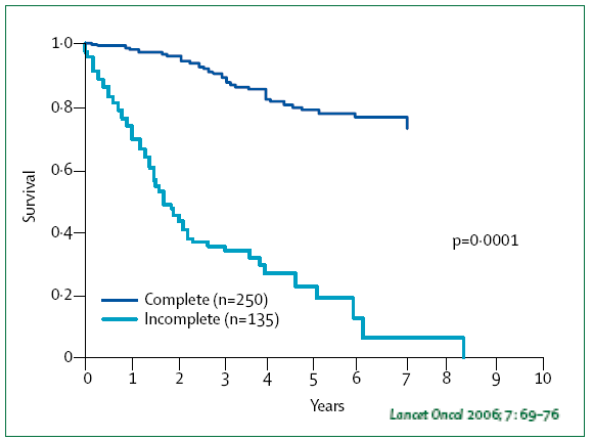
Goals of CTO and CC Administration

Accrual

- Potential to facilitate sustainability and growth in therapeutic clinical trial accruals.
  - Reduce need for manual pre-screening
  - Trial eligibility now largely driven by biomarkers in many priority cancers.
- Improve equitable access to clinical trials.
  - Process of identifying potential participants more objective and data-driven.

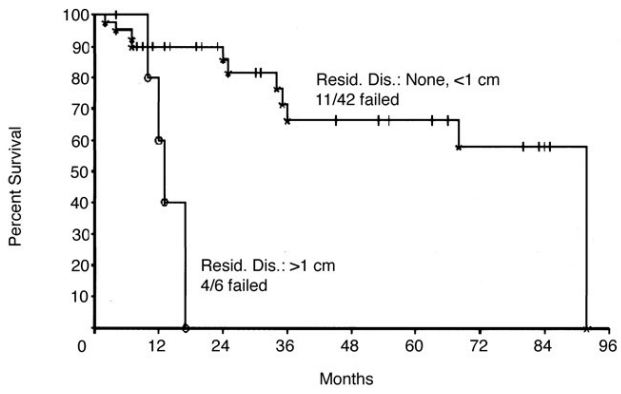
CLINICAL TRIALS MATTER

Observational clinical trial: Cytoreduction + HIPEC



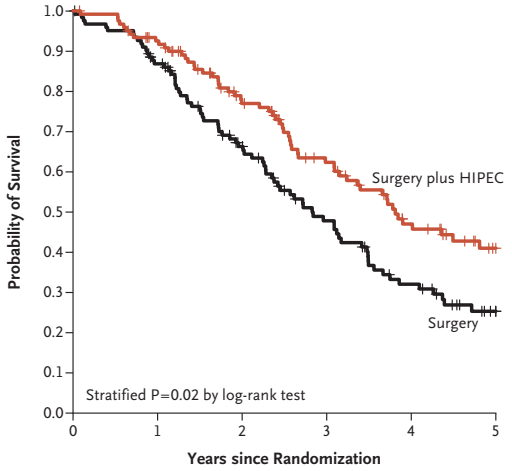
356 patients

Phase 2 Clinical Trial: CRS+HIPEC



49 patients

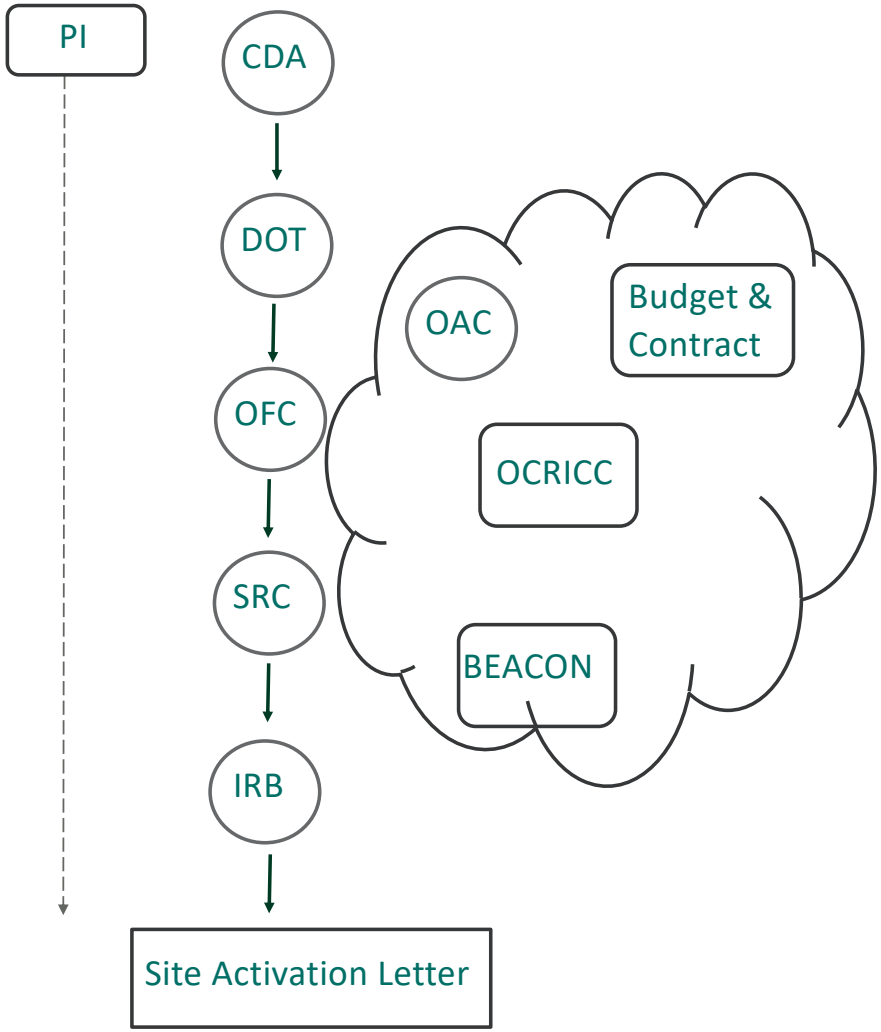
Large RCT: Cytoreduction + HIPEC



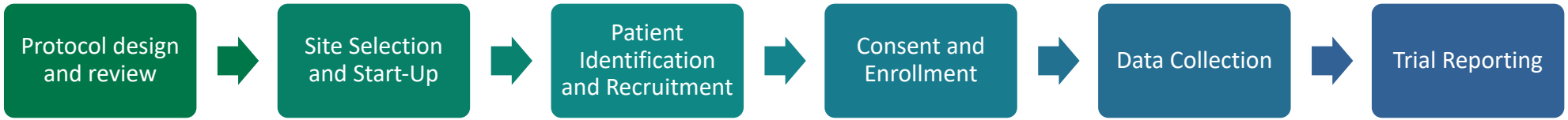
245 patients

Clinical Trial Processes Need Help

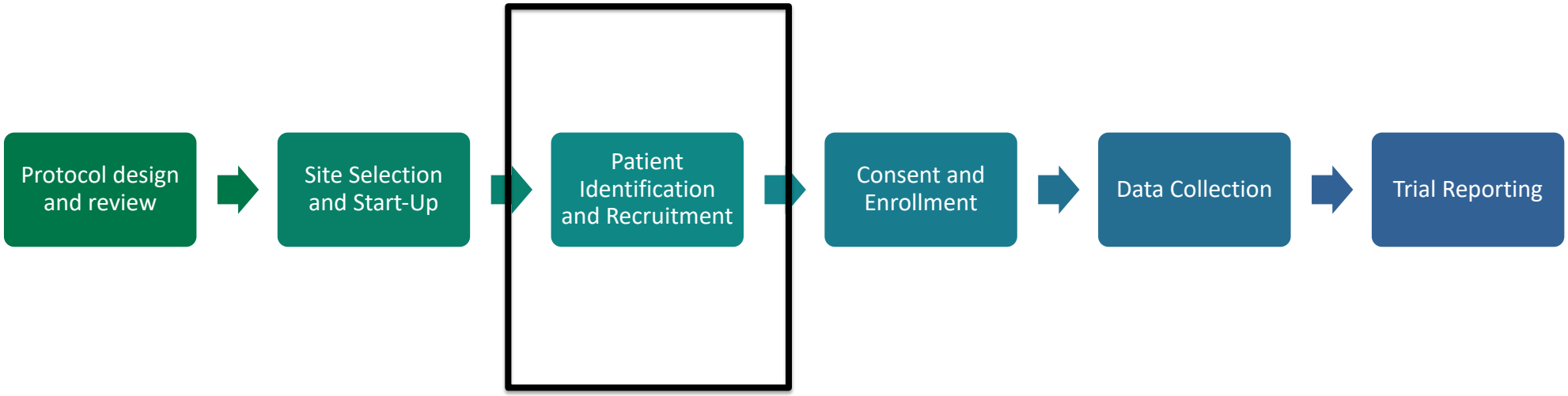
1) Time-intensive
2) Manual and labor-intensive
3) Slow and tedious
4) Multiple systems



35,000 Foot View: Trial Processes



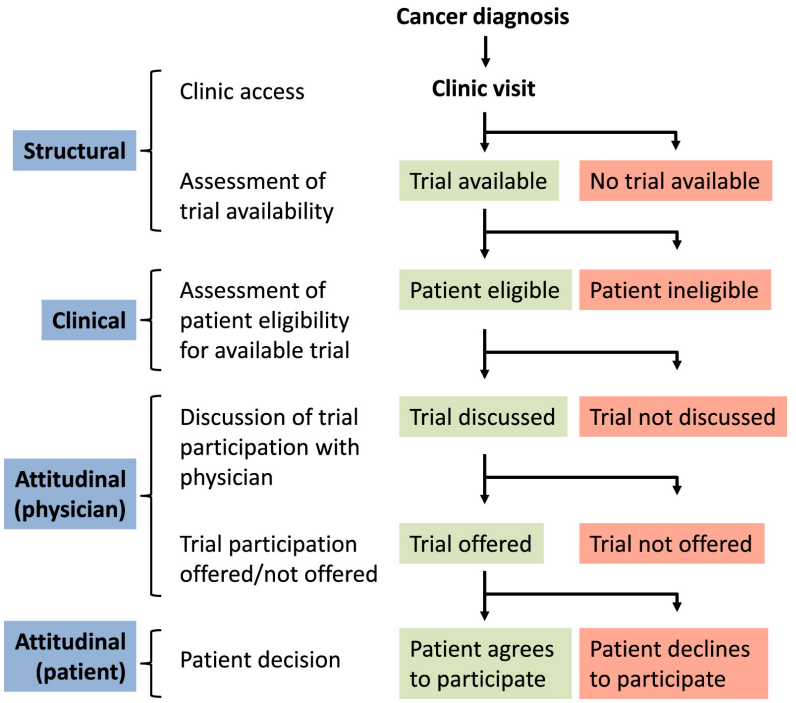
35,000 Foot View: Trial Processes



WHY CLINICAL TRIAL MATCHING?

80% interested in participating

~7% enrolled



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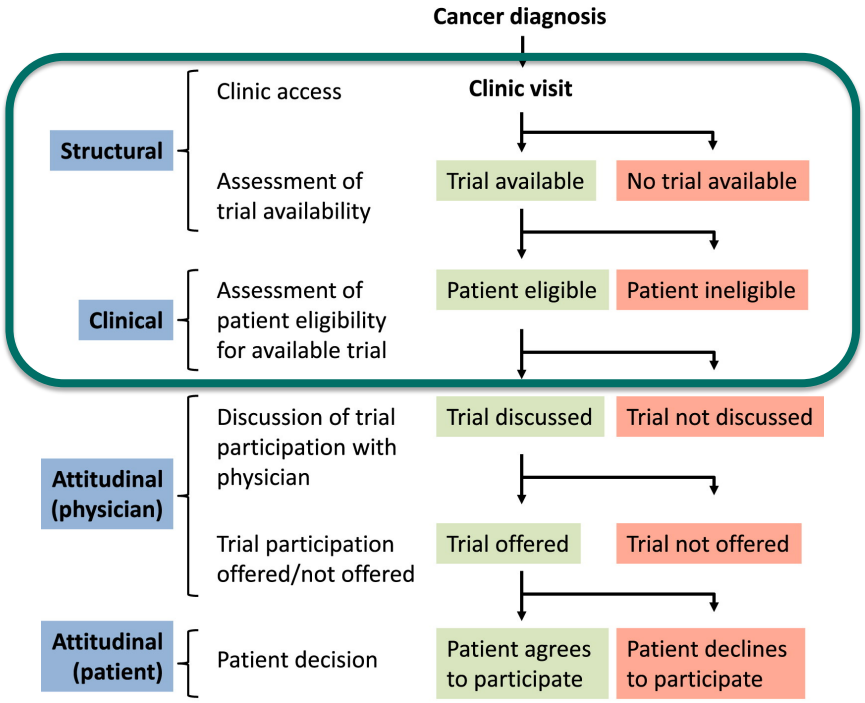
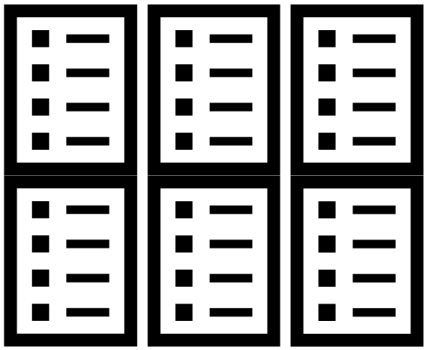
~7% enrolled



TRADITIONAL PROCESS

Patient health data

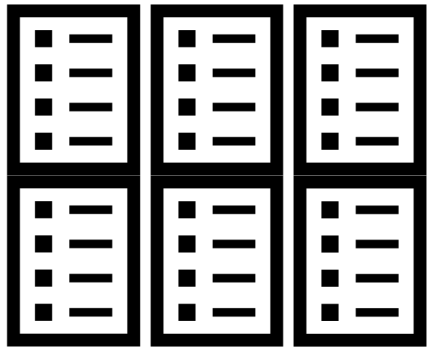


Clinical Trial documents

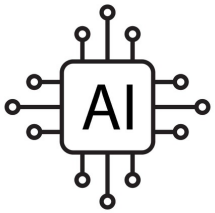
Best approximation of trial eligibility

LLM-BASED SOLUTION

Patient health data



Clinical Trial documents



OncoLLM

Top Clinical Trial Matches - Personalized

OPERATIONALIZATION OF PRISM: “BEFORE”

16 iDOTs at MCW Cancer Center
220+ active cancer trials in portfolio

MCW CC CTO Baseline Processes

- OnCore CTMS used by some DOTs to track patients who are screened for clinical trials
- Inconsistency in documentation of pre-screening efforts
- Interest in improving access to clinical trials through comprehensive pre-screening of patients with upcoming clinic visits
- Recognized need to improve pre-screening for biomarkers without manual tracking

OPERATIONALIZATION OF PRISM

- All coordinators with direct access to Triomics PRISM Platform
- Half day training for new users
- Able to review trial matches in platform, including at criteria-level
- **Finalize recommendation**

OPERATIONALIZATION OF PRISM

- All physicians with direct access to Triomics PRISM Platform
- Able to review trial matches in platform, including at criteria-level
- Review recommendation report

KEY PLATFORM WORKFLOWS

- **Screening of patients**
  - Deep-screening using their MRN when prompted by physicians
  - Pre-screening patients with upcoming appointments against the trial portfolio
- **Watchlisting and Tracking**
- **Trial specific lookups of eligible patients**
- **Feasibility analysis of upcoming trials**
  - High-level feasibility
  - Precise feasibility

MCW & Triomics Initial Timeline

- Agreement Signing: May 15th, 2024
- Integrations and Configurations: May 15th-June 15th
- Trial Setup: June 15th-22nd
- Dummy Run: June 23rd-30th
- Go-Live: July 1st with 1 DOT each week
    - GI, GU, Breast, Lung

Results

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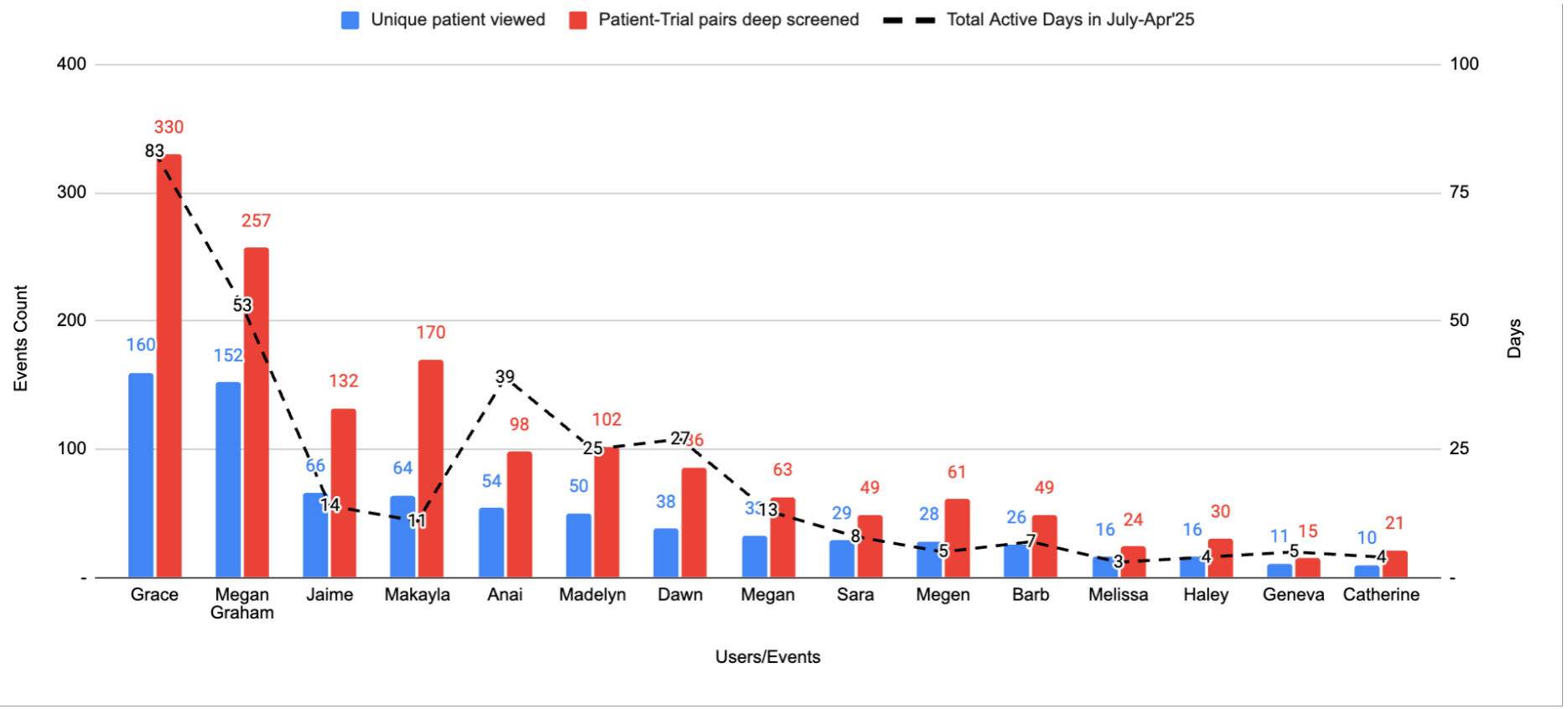
PRISM ADOPTION



Impact

- >5,000 patient visits automatically screened every month
- Reduction in chart review time from 20-25 minutes to 3-12 minutes (depending on complexity of the trial or eligible vs ineligible)
- 72% of all patients enrolled in Q3 & Q4 were found by the coordinators using the platform *before* their respective visits
- 39% and 27% increases in enrollment in Q3 & Q4 2024 over the same periods in 2023
  - Investments in clinical research infrastructure
  - Investments in technologies like Triomics

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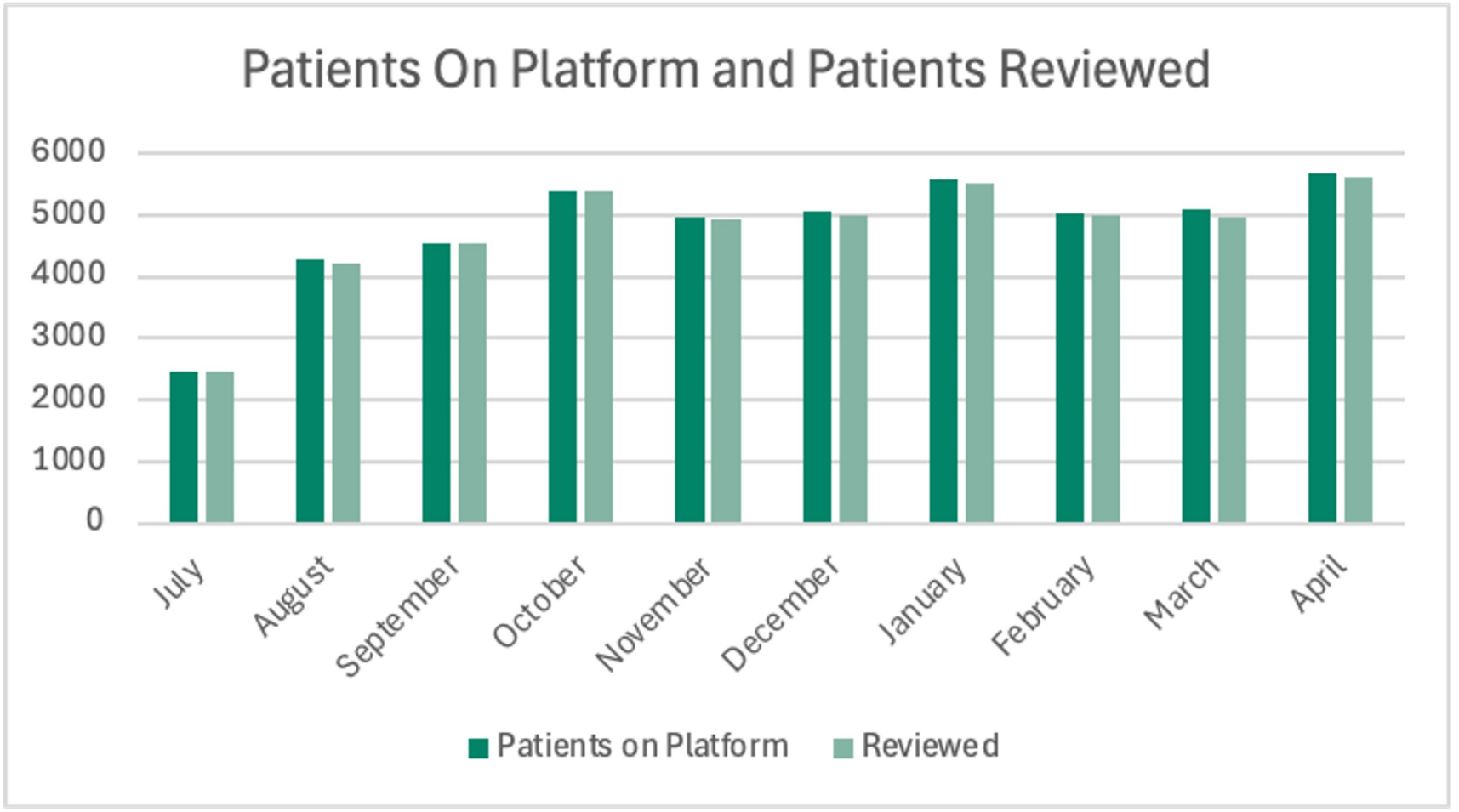
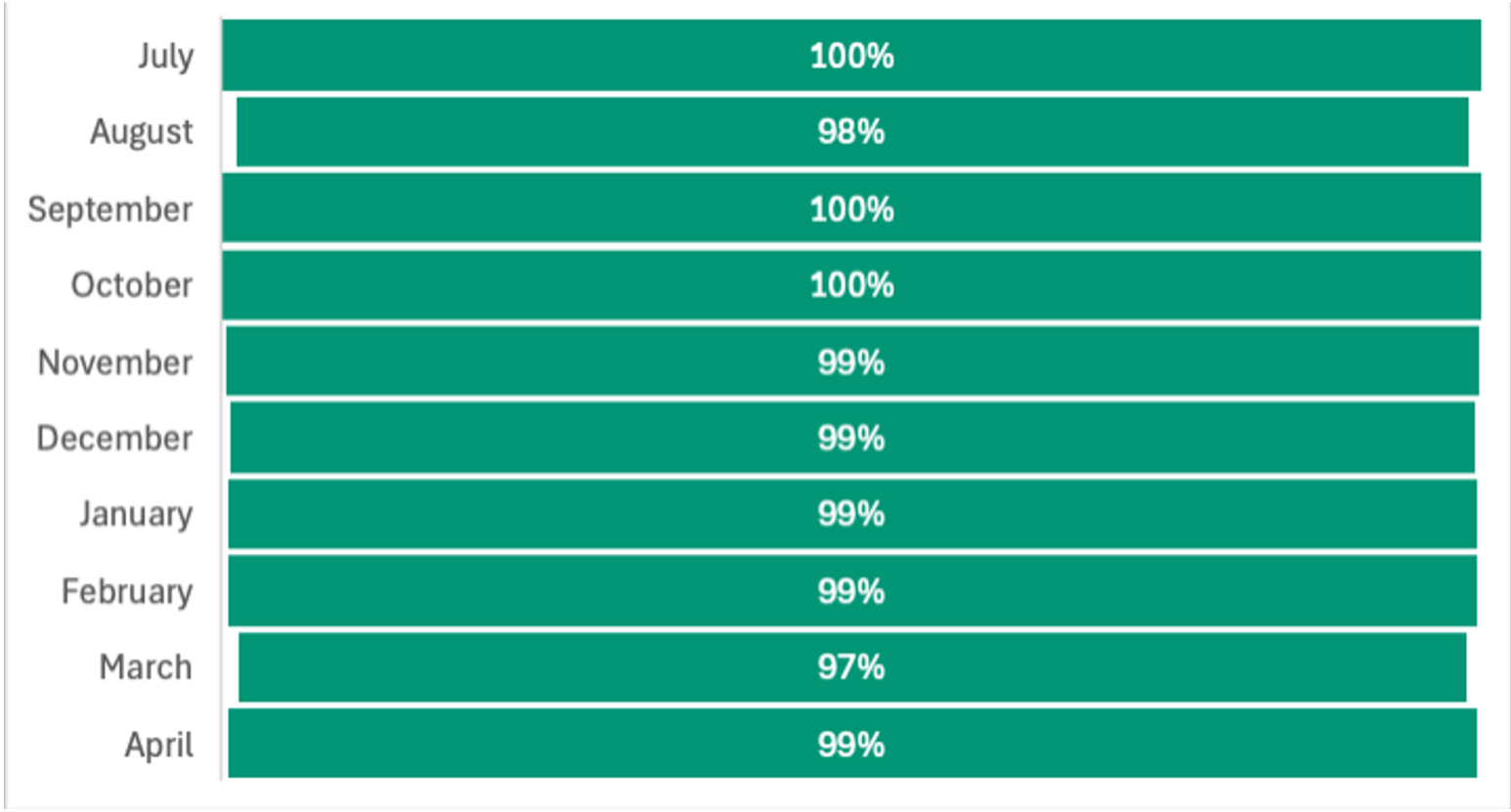
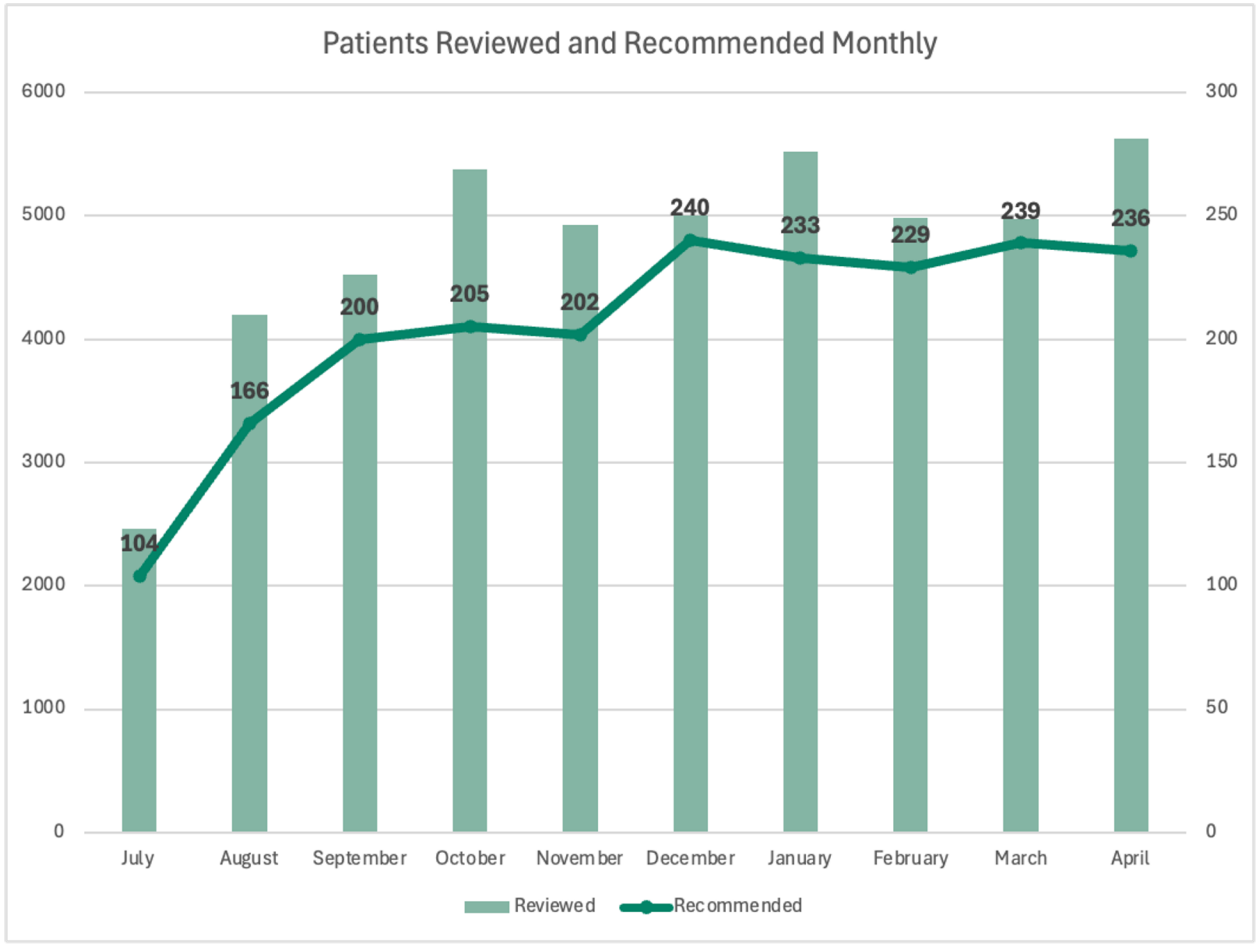

Patients On Platform and Patients Reviewed
6000
5000
4000
3000
2000
1000
0
July
August
September
October
November
December
January
February
March
April
Patients on Platform
Reviewed

Percentage of Patients Reviewed Monthly




Patients Reviewed and Recommended Monthly
6000
5000
4000
3000
2000
1000
0
300
250
200
150
100
50
0
104
166
200
205
202
240
233
229
239
236
July
August
September
October
November
December
January
February
March
April
Reviewed
Recommended

PRISM SCREENING (JULY – DECEMBER)

Top	Breast	GI	GU	Thoracic	Total
1	81%	70%	83%	100%	78%
2	88%	80%	92%	100%	86%
3	94%	95%	100%	100%	96%

Q3: 39% increase in clinical trial accruals for two live DOTs, GI and GU, with 25 treatment trial accruals (versus 18)

Q4: 27% increase in clinical trial accruals for GI, GU, Breast, and Thoracic, with 33 treatment trial accruals (versus 26)

Publication (Nature Digital Medicine)

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nature > npj digital medicine > articles > article

Article | Open access | Published: 28 October 2024

PRISM: Patient Records Interpretation for Semantic clinical trial Matching system using large language models

Shashi Gupta, Aditya Basu, Mauro Nievas, Jerrin Thomas, Nathan Wolfrath, Adhitya Ramamurthi, Bradley Taylor, Anai N. Kothari, Regina Schwind, Therica M. Miller, Sorena Nadaf-Rahrov, Yanshan Wang & Hrituraj Singh

npj Digital Medicine **7**, Article number: 305 (2024) | Cite this article

1886 Accesses | **1** Altmetric | Metrics

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Sections | Figures | References

In publication with MCW and Mount Sinai, demonstrated that the AI model could automatically read a longitudinal medical record, including free-text (notes or PDFs), and identify the matching trial(s) from a portfolio of hundreds of ongoing cancer trials with *95% accuracy (Top-3)*.

Additional Publications: Journal of the American Medical Informatics Association (paywalled) arXiv (full PDF)

Publication (Nature Digital Medicine)

Trial Criteria	Model's Explanation	Assessment
Example 1		
INC Participants must have received only 1 or 2 lines of prior systemic treatment for LA/mUC, including 1 line of platinum-containing chemotherapy" Tier 1	-	Criteria Met
↳ Has the participant received only 1 or 2 line of previous systemic treatment for LA/mUC?	The patient has received at least two lines of systemic treatment for metastatic urothelial carcinoma. The first line of treatment was Carboplatin and Gemcitabine, as indicated in the progress notes dated July 5, 2023 (1). The second line of treatment is Avelumab, as mentioned in the progress notes dated May 22, 2024 (2). There is no indication of a third line of treatment in the provided data.	Yes
Example 2		
EXC Has received more than two months of FOLFIRINOX or mFOLFIRINOX chemotherapy as first-line therapy. Tier 1	-	Criteria Met
↳ Has the patient received more than two months of FOLFIRINOX or mFOLFIRINOX chemotherapy as first-line therapy?	The patient started neoadjuvant FOLFIRINOX chemotherapy on April 27, 2023, and completed 4 cycles by June 30, 2023. This duration is slightly over two months. The treatment was modified by dose reduction and omission of irinotecan starting from the third cycle due to significant toxicity. The treatment period from April 27, 2023, to June 30, 2023, is approximately 2 months and 3 days, which is more than two months. 1 2 3 4 5	Yes

91% (Accuracy) *Explanations*

93% (Accuracy) *Citations to the clinical documents*

Matches the expert-level accuracy

Prospective Deployment - Triomics & MCW

1. Likely first full-scale production use of an LLM at an AMC for a use case outside of ambient scribing / patient engagement messaging
2. 19,312/19,651 patients screened (98.3% of upcoming patient visits) since going live in July
3. 627 patients recommended for at least 1 clinical trial
4. 30 research coordinators, 5 research managers and 20 physicians onboarded on the platform
5. Current Scope: GI, GU, Breast, Thoracic and GYN Onc
6. ~100 trials being screened against (1 week setup & go live timeframe for all trials)

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Future Outlook and Directions

- Expanding across all DOTs such as Hematology
- Current scope is at mothership -> community clinics
- Driving further physician engagement
- Collecting AEs/Toxicities using OncoLLM
- Expanding OncoLLM's use cases to include automated tumor registry curation, pre-charting and chart abstraction for quality improvement

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Platform Workflows

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Key Platform Workflows

- **Screening of patients**
  - Deep-screening using their MRN when prompted by physicians
  - Pre-screening patients with upcoming appointments against the trial portfolio
- **Watchlisting and Tracking**
- **Trial specific lookups of eligible patients**
- **Feasibility analysis of upcoming trials**
  - High-level feasibility
  - Precise feasibility

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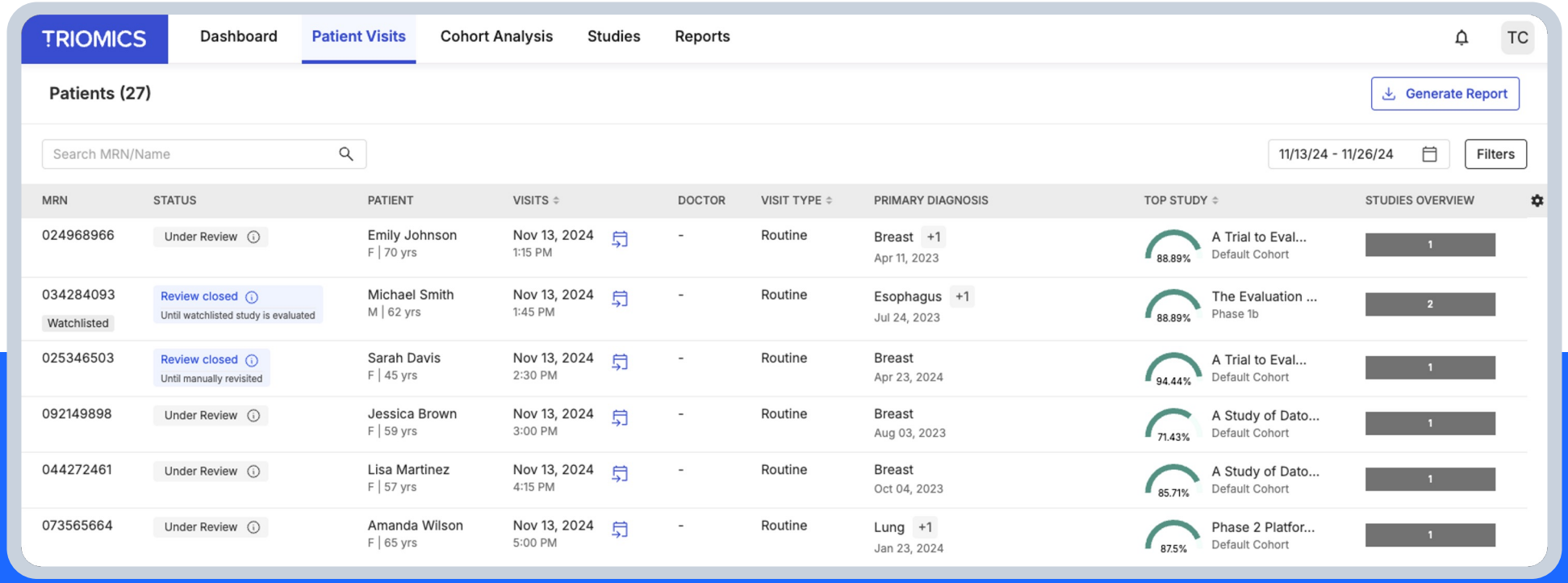
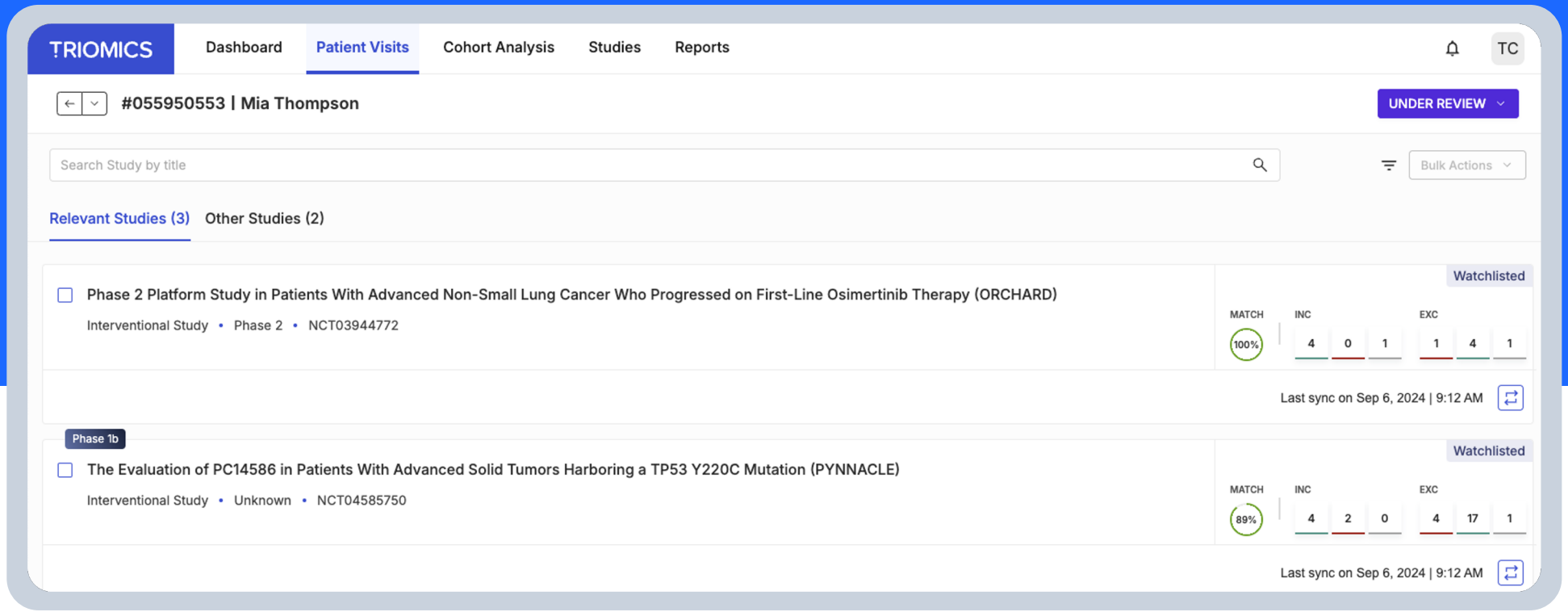


View for Physicians & Research Staff:

1. List of patients with upcoming appointments, including the number of potential studies available for each patient and the percentage match for the top study.

2. This list can be filtered by new patients, patients with recent imaging results, physicians, and sub-indications



For each patient, the system searches the portfolio of recruiting trials and identifies matching trials with varying degrees of percentage match.

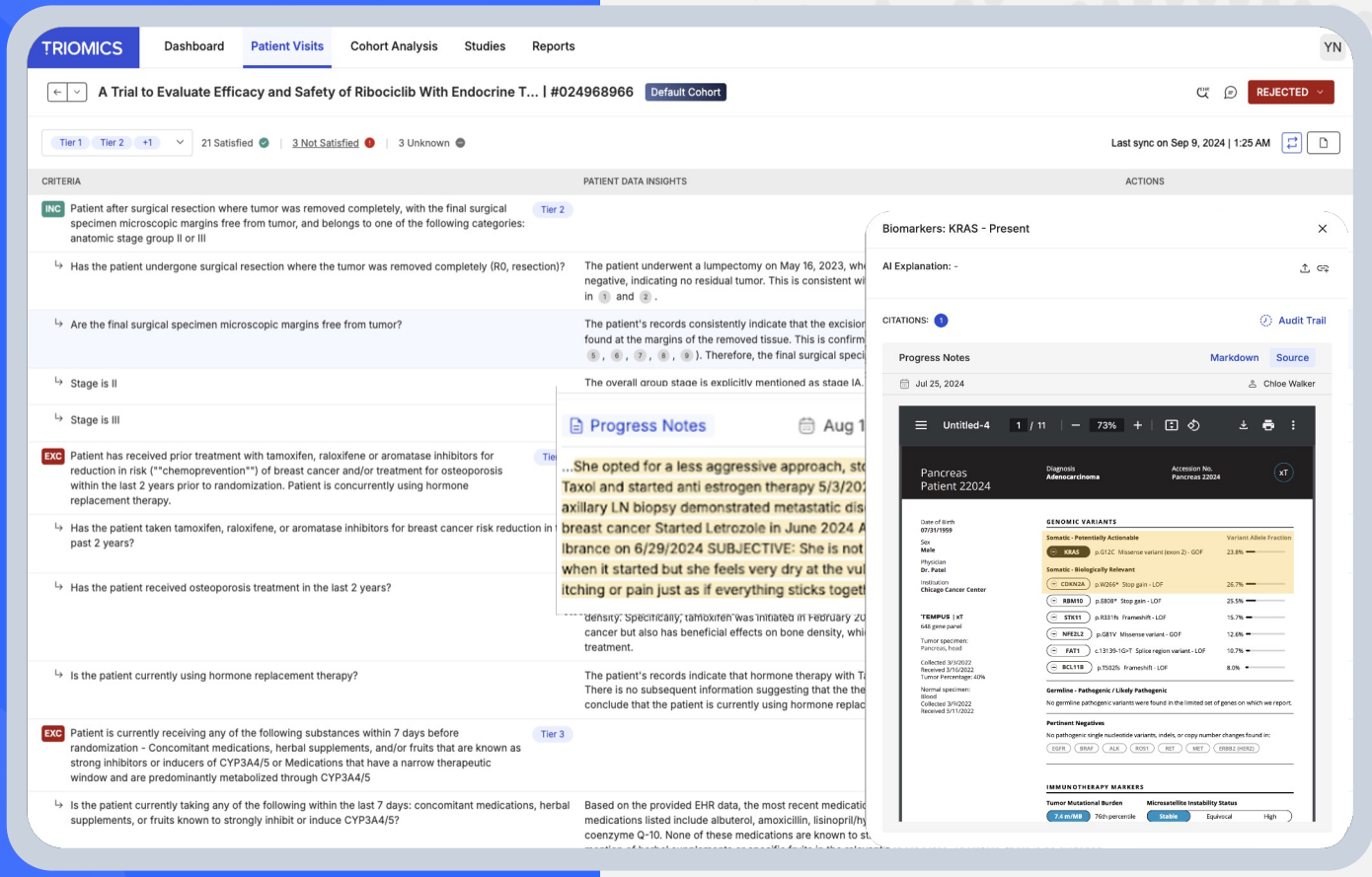
The numbers on the left indicate criteria that are met, not met, or unknown. This information is embedded alongside the individual patient files with the provider.

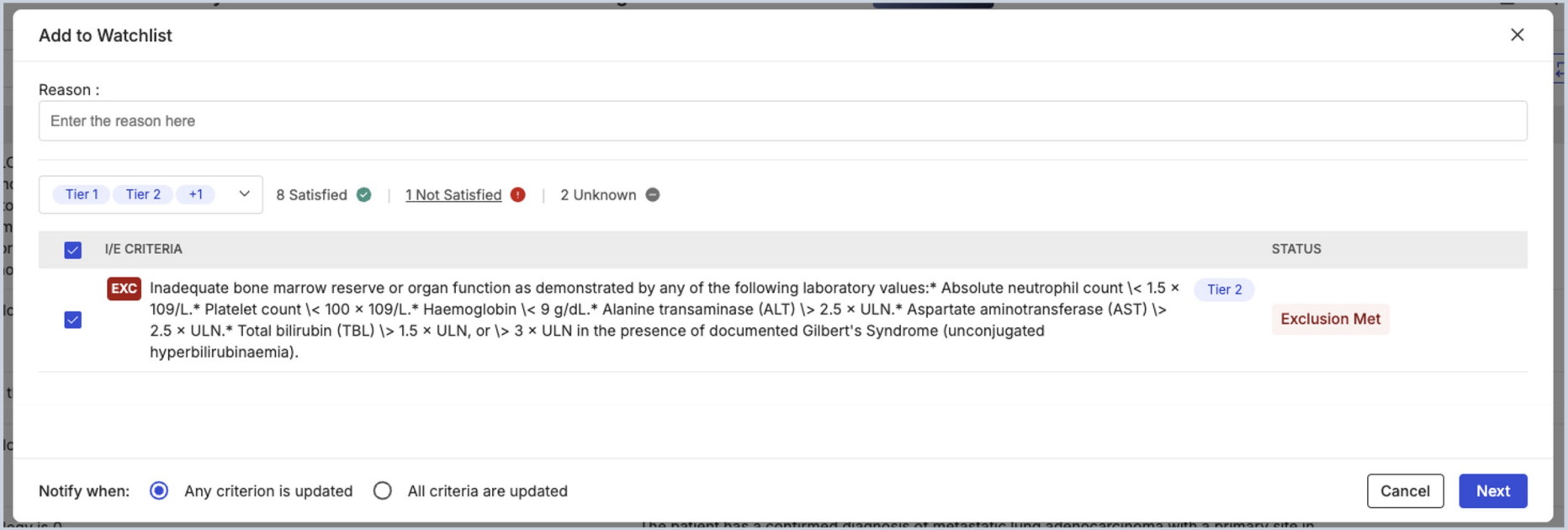
Explanations are provided for each individual criterion for the shortlisted trials.

This view is available within the platform and also exported in the PDFs shared with the providers.

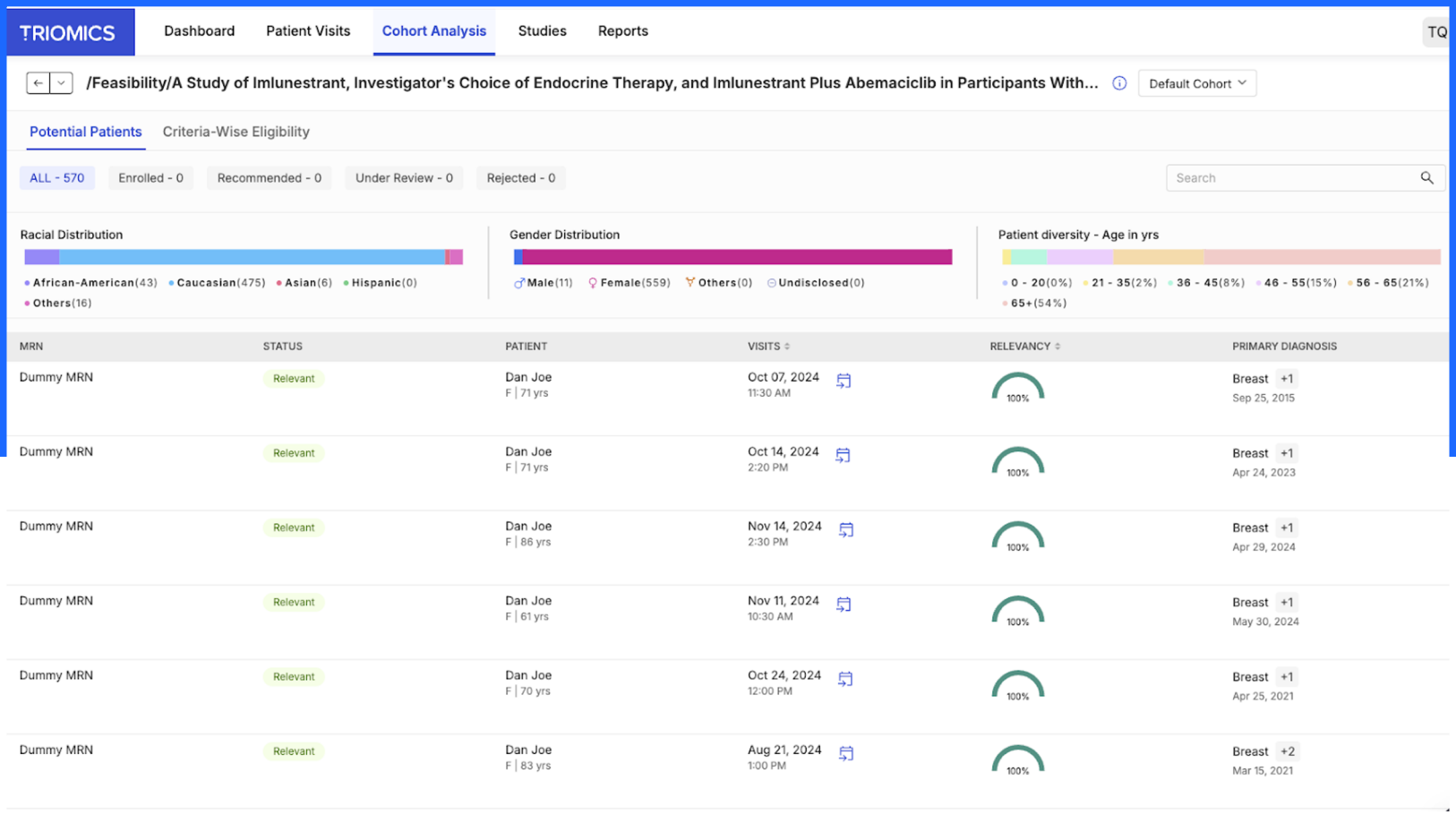
Note: The numbers within the bubbles indicate citations in the patient chart. Clicking on each number opens the corresponding clinical document or PDF.

Ruling out a patient for a trial takes less than a few minutes.

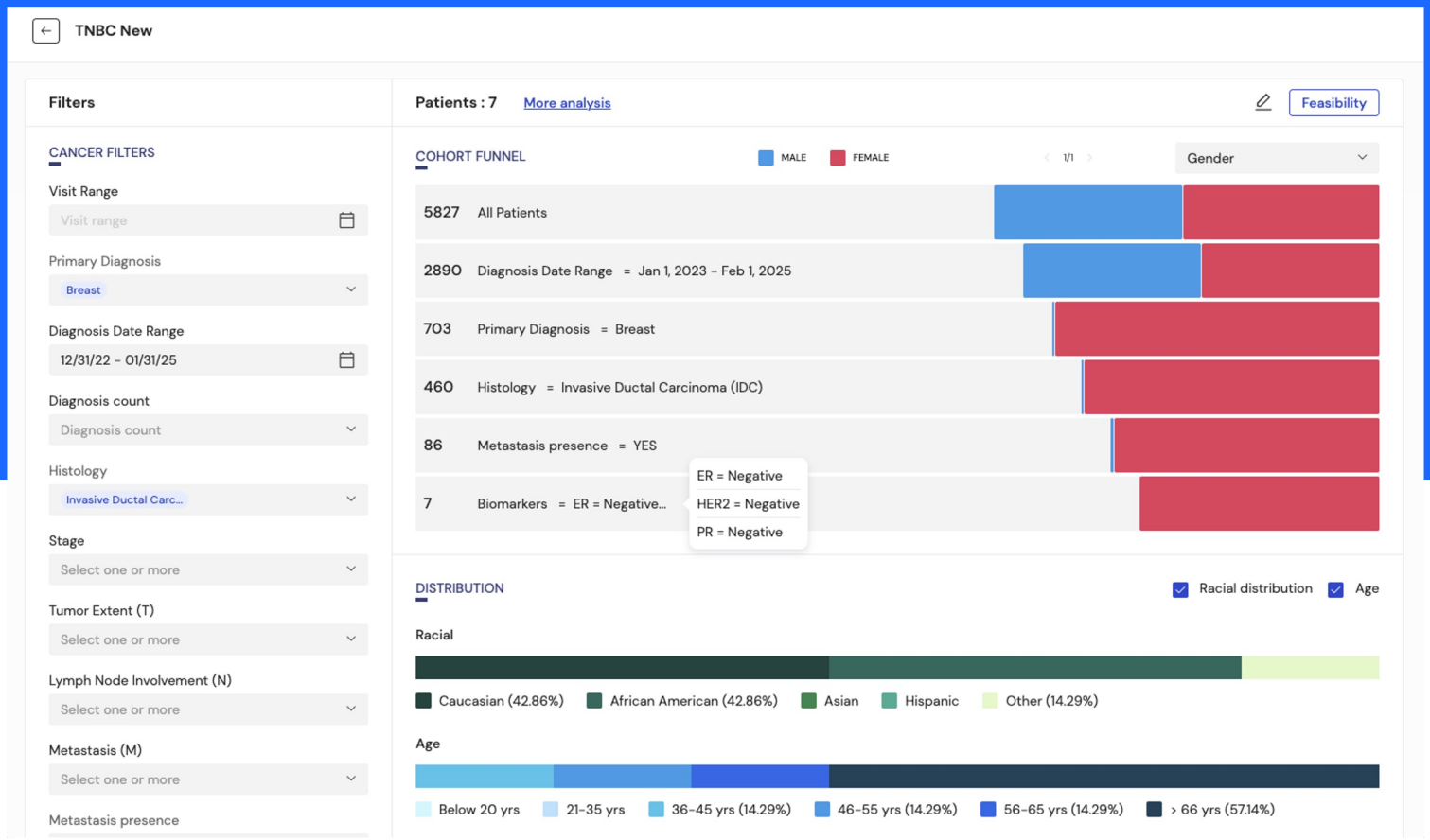




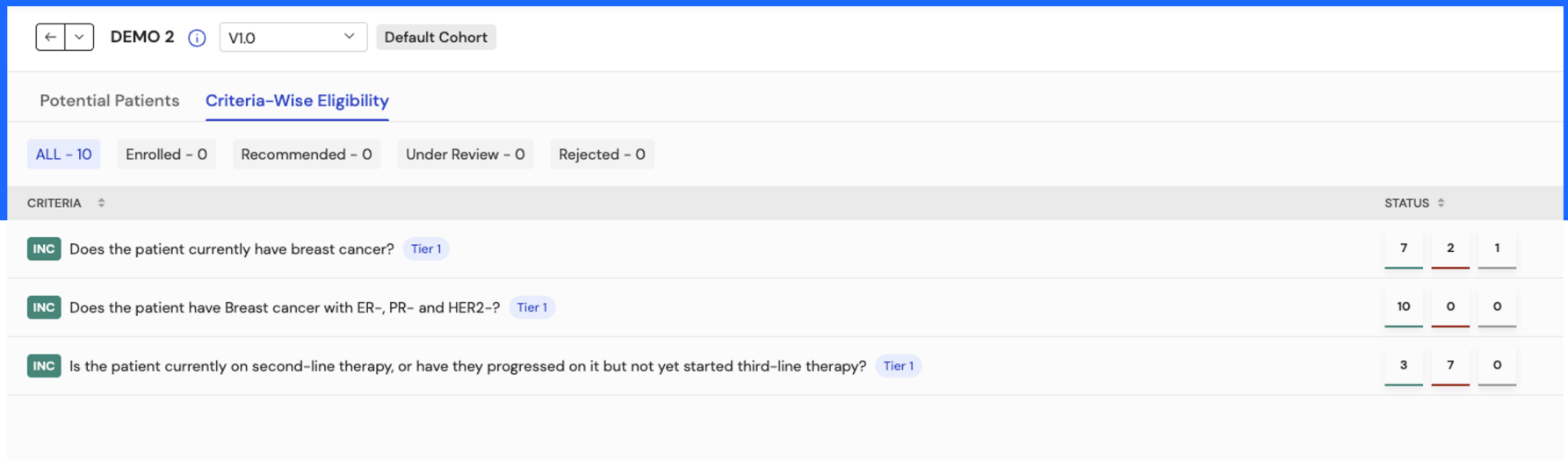
Physicians can place certain patients on a watchlist (e.g., second-line patients for a third-line trial), where the system continuously tracks changes in the patient record based on selected criteria. Once the criteria are met, the study team is notified via the platform, in-basket notifications in the EMR, and email.



Study-Specific View: PIs can view a list of patients who meet all or most of the inclusion and exclusion criteria for a particular study. By clicking on any patient, they can see a detailed, itemized review of their eligibility.



CTO can query the patient population in real time using filters available in a drop-down format. For example, the above query shows that there are 7 active patients with TNBC and IDC with metastasis who were diagnosed since the beginning of 2022.



Furthermore, if you want to run additional complex queries on the cohort—for example, identifying how many TNBC patients are currently on second-line therapy or have progressed on it but have not yet started third-line treatment—you can do so easily. As shown in the above example, there are 10 TNBC patients, but only 7 have active disease, of which 3 are currently on second-line therapy.