ACS Cancer Conference 2025

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Increasing Access to and Diversity in Clinical Trials

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ACS Cancer Programs

American College of Surgeons

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Outline

- Conceptual Framework
- Barriers to Enrollment
  - Implicit Bias
  - Access
  - Study Design
- Barriers to Recruitment
- Opportunities for Intervention
- Industry and New Technology

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Clinical Trial Access/Enrollment

- >75% of US cancer clinical trials do not representatively recruit their target population
- **Lack of representation = Lack of generalizability**

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An official website of the United States government

NIH NATIONAL CANCER INSTITUTE

About Cancer | Cancer Types | Research | Grants & Training | News & Events | About NCI

Home > Research > Participate in Cancer Research > Cancer Research Needs People from All Backgrounds

Participate in Cancer Research

- About Cancer Clinical Research
- **Research Needs People from All Backgrounds**
- Personal Stories
- How to Participate
- Plan Your Participation
- Clinical Trials Information
- Find a Clinical Trial

Cancer Research Needs People from All Backgrounds

The goal of cancer research is to advance treatments and care for everyone. While the number of people from different backgrounds who take part in cancer research has increased over time, we need your help to make more progress.

ON THIS PAGE

- Examples of diversity needed in cancer research
- How diversity improves cancer research
- Everyone can take part
- Ways to participate in cancer research

The goal of cancer research is to advance treatments and health care for everyone.

Examples of diversity needed in cancer

National Cancer Institute, National Institutes of Health (2025)

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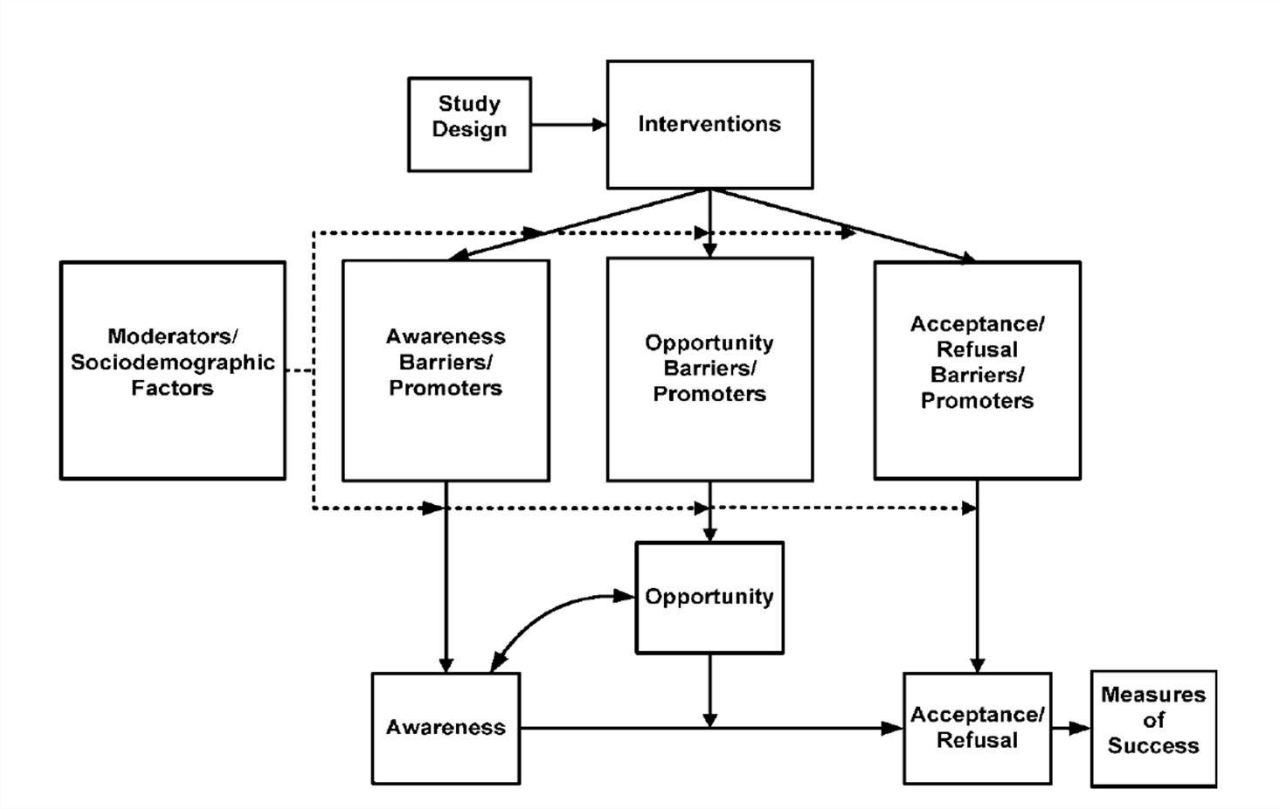
Conceptual Framework: Clinical Trial Disparities



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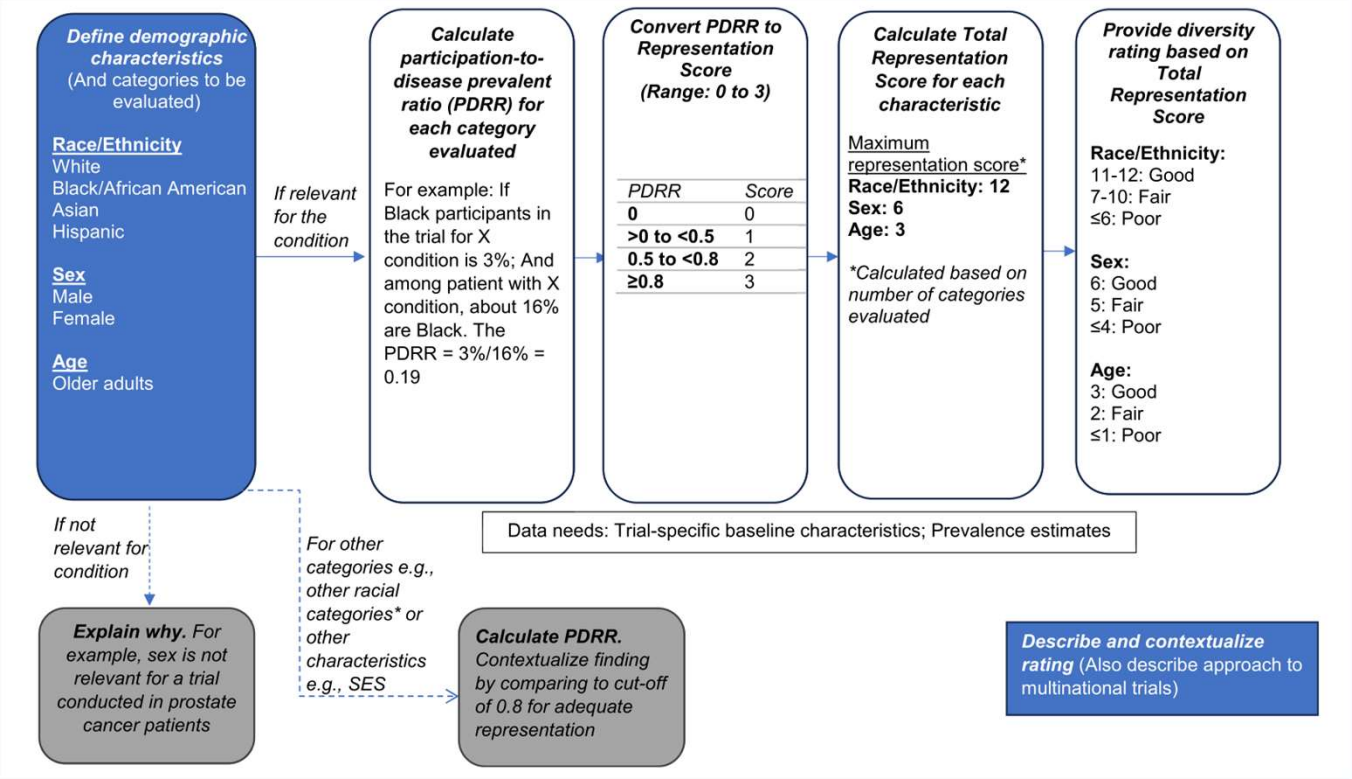
Conceptual Framework: Clinical Trial Disparities



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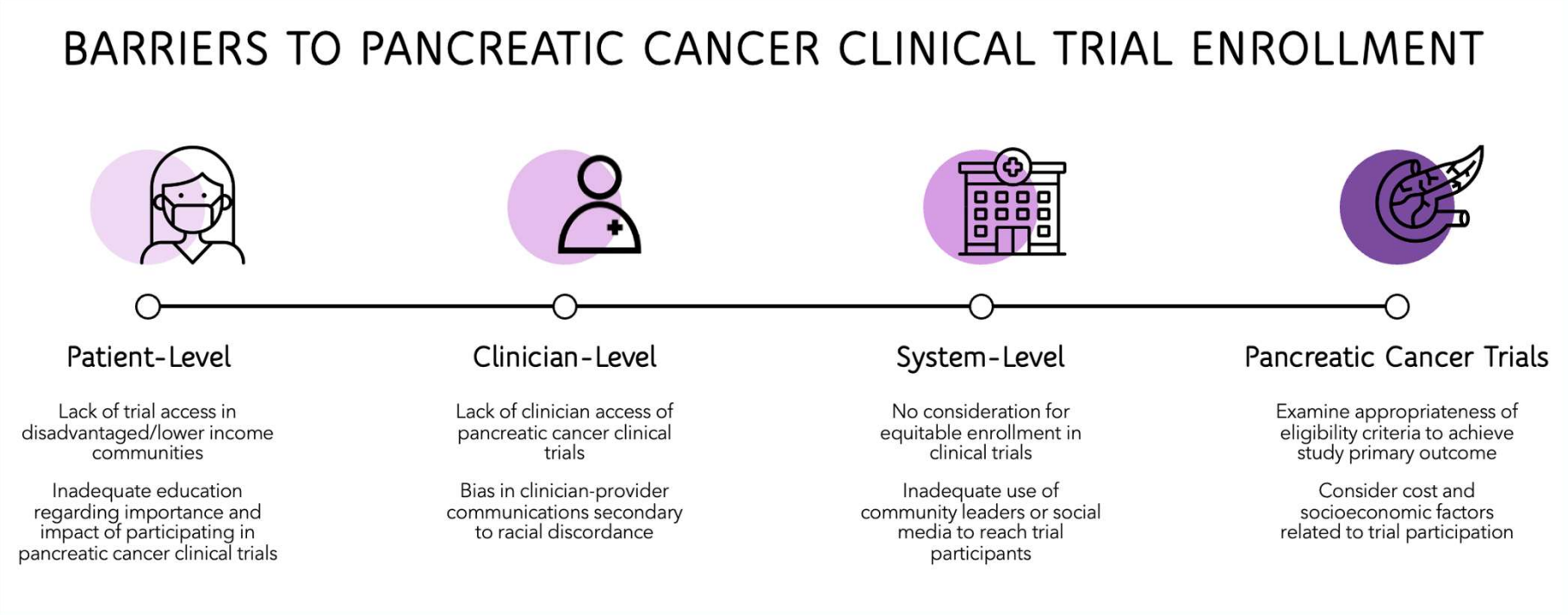
Conceptual Framework: Pancreas Cancer Trials



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Barriers to Clinical Trial Enrollment

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Implicit Bias

Both *conscious* and *unconscious* bias that may influence care delivered

- Individual-Level ("provider attitudes and beliefs")
  - Previously established care relationships
  - Supportive communication
  - Length of clinician-patient interaction
- System-Level ("institutional culture")
  - Likelihood of participation and/or anticipated non-compliance with study protocols
    - "Less ideal study candidates."
  - Communication with minority participants perceived to be difficult

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Example: Qualitative Approach

- Interactions With Potential Minority Participants Were Perceived to Be Challenging
  - "African Americans I think have less knowledge. We take a little bit more time to explain to [them]…they have a lot of questions." (Study PI)

- Potential Minority Participants Are Not Perceived to Be Ideal Study Candidates
  - "I think physicians think about whether or not the patient would comply with the study. Patient compliance I think is one of the things they think about… Well, he lives by himself. How are we going to make sure he does all this?" (Research Staff)

Niranjan SJ,, et al. *Cancer*. 2020;126(9):1958-1968.

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Access to Trials and Study Design Barriers

- Geographic proximity to trial sites
  - Area level measures of social vulnerability
  - Poverty rates
- Study design barriers
  - Disease-specific (e.g.
  - Patient-specific (e.g.
  - Comorbidity criteria
  - Study complexity (e.

Modernizing Clinical Trial Eligibility Criteria: Recommendations of the ASCO–Friends of Cancer Research Prior Therapies Work Group

Raymond U. Osarogiagbon[1], Diana Merino Vega[2], Lola Fashoyin-Aje[3], Suparna Wedam[3], Gwynn Ison[3], Sol Atienza[4], Peter De Porre[5], Tithi Biswas[6], Jamie N Holloway[7], David S Hong[8], Madison M Wempe[2], Richard L. Schilsky[9], Edward S. Kim[10], James L Wade III[11]

Adams-Campbell LL , et al.. Journal of Clinical Oncology. 2004;22(4):730-4.

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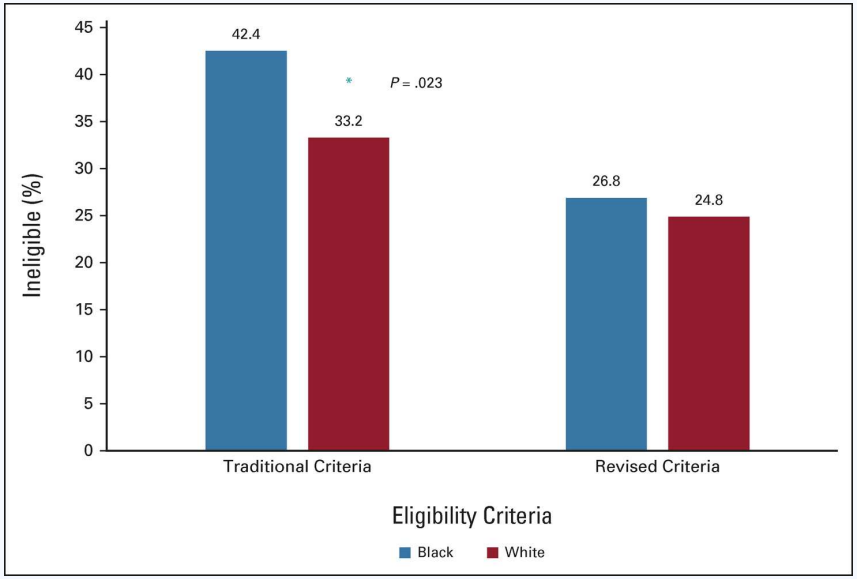
Example: Clinical Trials Eligibility Criteria

- PDAC clinical trial traditional eligibility criteria:
  - Creatinine <= 1.5 mg/dL or CrCl <30 mL/min
  - History of other malignancy within prior 3 years
  - Known HIV infection
  - Known HBC or HCV
  - Uncontrolled diabetes mellitus
  - Coronary stenting within prior 6 months
- Black patients were more likely to be ineligible for participation compared with White patients (42.4% v. 33.2%)



Riner, et al., J Clin Oncol. 2022 Mar 22;JCO2102492

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Barriers to Clinical Trial Recruitment

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Patient-Level and Clinician-Level Factors

- Patient-physician communication differences
  - Differences in communication and information needs
  - Patient-level cultural perspectives

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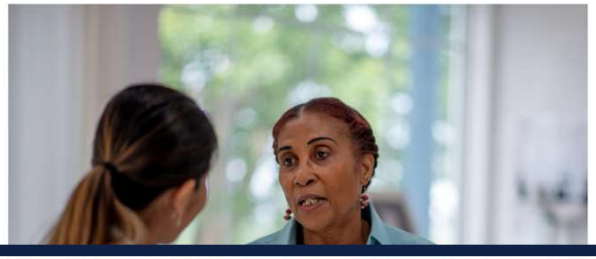
Patient-Level Cultural Perspectives

How Do Black People with Cancer View Clinical Research?

Subscribe

November 15, 2024, by Nadia Jaber

Findings from a small study suggest that more Black than White, Asian, or patients of other races distrust medical research and have spiritual beliefs about medical research. The study asked about 100 people being treated for cancer whether they agreed with certain statements about research.



The findings may help research staff talk with and recruit more Black patients for clinical trials, said the study's leader, Charlyn Gomez, a medical student at the University of Maryland School of Medici

Black people make up about 14% of the U.S. population but on of clinical trial participants. Clinical trial participation is importa it provides people with the opportunity to access emerging can treatments, tests, and approaches to improving cancer care.

More Black than non-Black participants of the new study agree statements like, "medical research is designed to harm minorit "God determines wellness, not research," Ms. Gomez reported at the American Society for Radiation Oncology (ASTRO) annual meeting in

Credit: iStock/FatCamera

More Black than non-Black participants of the new study agreed with statements like, "medical research is designed to harm minorities," and "God determines wellness, not research," Ms. Gomez reported October 1 at the American Society for Radiation Oncology (ASTRO) annual meeting in Washington, D.C.

National Cancer Institute, National Institutes of Health (2025)

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Patient-Level and Clinician-Level Factors

- Patient-physician communication differences
  - Differences in communication and information needs
  - Patient-level cultural perspectives
- Trial awareness (geography)
  - Clinician-Level
    - Inadequate information about trials (community MDs, 75% vs. oncologists 36%).
  - Patient-Level
    - Rural residents less likely to report discussion of clinical trials with their oncologists (compared to inner-city)
- Patient-level resources

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Interventions targeted at enrollment

Patients

- Culturally appropriate marketing materials for patients
  - Endorsements by trusted community leaders and survivors
  - Vary the marketing approach
- Targeted educational interventions
- Clinical navigation programs

Clinicians

- Targeted outreach to community physicians
  - Long-term community outreach partnerships

Pinto HA, et al. Ann Epidemiol. 2000;10(8 Suppl):S78-84.
Du W, Mood D, Gadgeel S, Simon MS.. Journal of Thoracic Oncology. 2008;3(1):23-9

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Opportunities for Intervention

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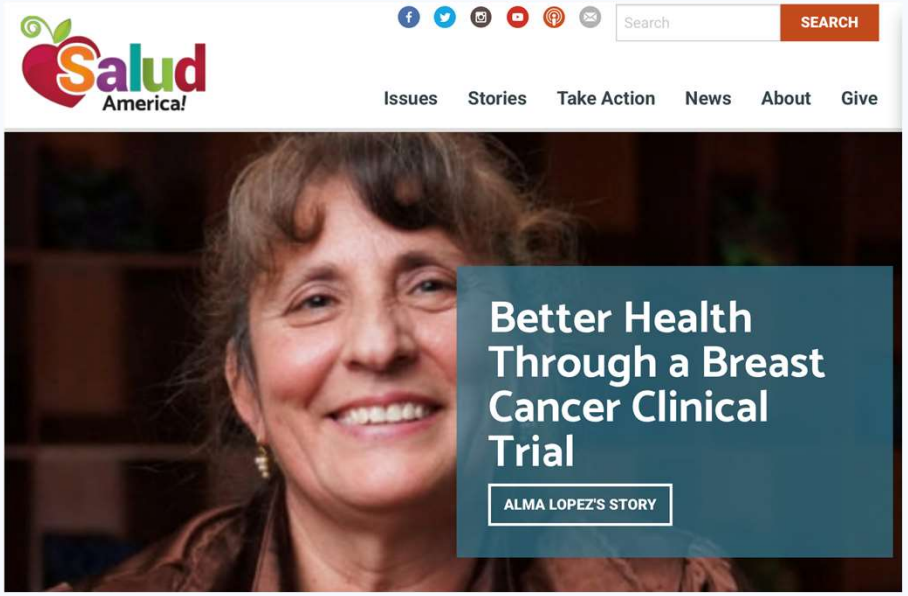
Example: Social Media Advertising

- Salud America!
  - Effort to improve clinical trial participation
  - Social media advertising
    - Facebook, Twitter, and Instagram
    - Directs to website with patient stories
- Get Randomized
  - Public awareness initiative
  - 9.2% increase in awareness/understanding of RCT
  - ~1% increase in enrollment



Ramirez AG, et al. Health Education & Behavior. 2011;38(3):251-60.
https://salud-america.org/trials/

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Most Common Types of Interventions Implemented

Older adults: 4
Racial/Ethnic minorities: 15
Sexual/Gender minorities: 1
Financial barriers: 2
Health literacy: 1
Access to clinical trial screening to community hospitals: 1

- **Recruitment in the community/in partnership with trusted community groups or online vs standard hospital recruitment**
- **Educational modalities (community session, pamphlets, videos)**
- **Assignment of trained patient navigators / patient screening employees**
- **Provider/ staff-centered training**





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SenthilKumar et al. In preparation

"no photos" icon by Muhammad Shabraiz from Noun Project.

Takeaways From Successful Interventions

1. Use culturally tailored materials that address key barriers/concerns reported by patients. These materials need to be simple, understandable across literacy levels, and delivered to patients by trusted sources
2. Involve community hospitals, groups, and partners in clinical trial screening, recruitment, and education strategies
3. Provide resources to decrease the burden of travel, lodging, and time associated with clinical trial participation
4. Assign dedicated, flexible, and culturally trained patient navigators who can provide personalized help on factors that most affect a given patient
5. Recruitment strategies (social media, community, versus clinical/referral) needs to be optimized based on population and center, and a multipronged approach is likely more beneficial
6. Institute operational practices within the institution to track, measure, and implement DEI efforts for trail recruitment and design

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Industry and New Technology

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Industry/Pharma

CITI PROGRAM 25th Anniversary

Solutions Catalog Organizations Individuals

Webinar Demo:

https://www.merckclinicaltrials.com/diversity-inclusion/

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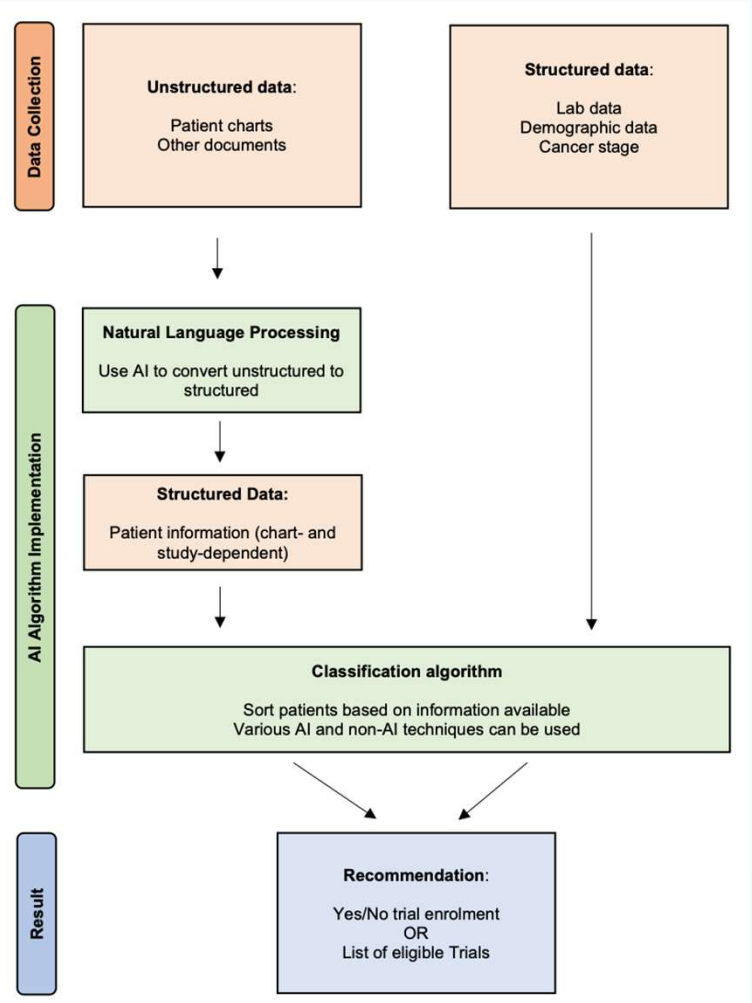
AI/Site Selection Tools

Artificial Intelligence

- Identify trial eligible patients
- Synthesize large sets of data
- “Bias-free” recommendations

Site Selection Tools

- Example: TriNetX
  - Cloud-based platform to query and analyze longitudinal, de-identified data



Chow R, et al. J Natl Cancer Inst. 2023 Apr 11;115(4):365-374.

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