Designing Clinical Trials to Improve Diversity, Equity and Inclusion (DEI): A Machine Learning Approach to Evaluate Clinical Trial Criteria

Alexander Chang, Aditya Singh, Katelin Lauren Avenir, Anirudh Venkatasubramanian, Yuwei Guo, Shiqi Liang, Rabira Tusi, Rema Padman, Ph.D.

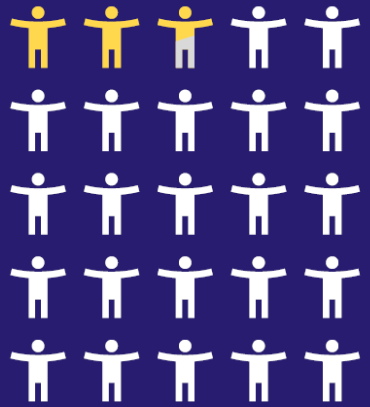
MSK Researchers Target Side Effects More Common in Black Women with Breast Cancer | Memorial Sloan Kettering Cancer Center. (n.d.).

Entry points

Lack of Diversity in Clinical Trials of Breast Cancer Treatment

Less than 10%

of population in clinical trials
over the last 25 years were **people of color**



AIquitas

Source: Ma et al,. 2021

Entry points

Lack of Diversity in Clinical Trials of Breast Cancer Treatment

Less than 20%

of FDA approved drugs have clinical trial data regarding treatment benefits or side effects for **Black patients**

AIquitas

Source: Ma et al,. 2021

Entry points

Lack of Diversity in Clinical Trials of Breast Cancer Treatment

38%

increase in breast cancer mortality amongst **Black women** from 2000 to 2010.

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Source: Ma et al,. 2021

Entry points

Lack of Diversity in Clinical Trials of Breast Cancer Treatment

$1.2 Trillion

in costs saved in healthcare if racial and health disparities gap had been closed during the 2003 to 2006 period.

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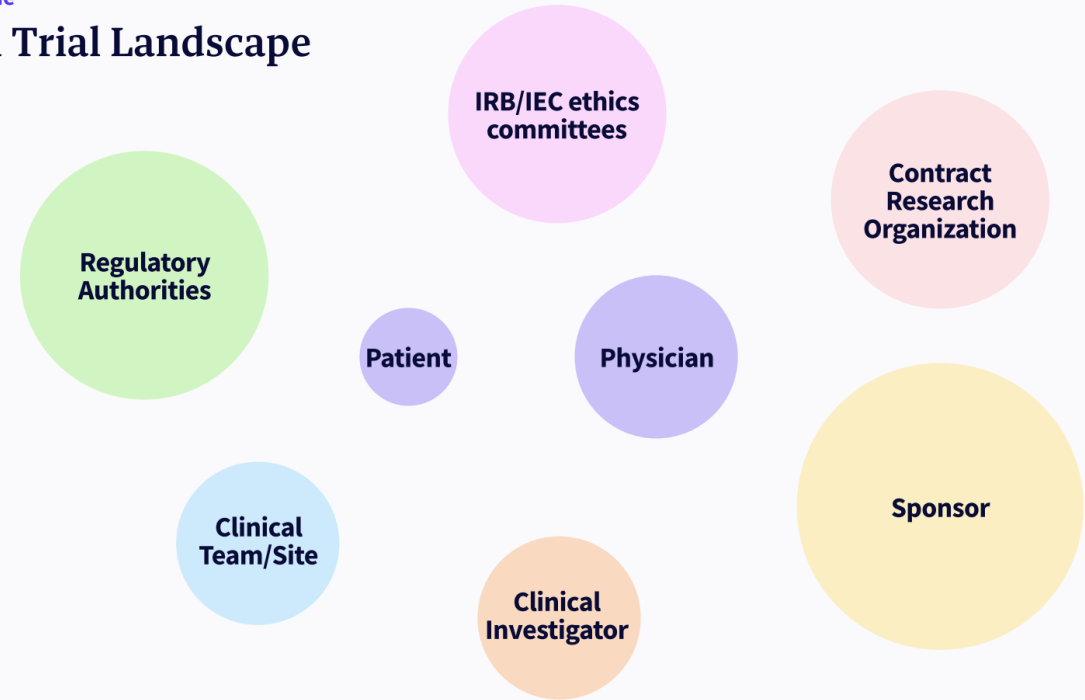
Source: Ma et al,. 2021

Problem Frame

Clinical Trial Landscape



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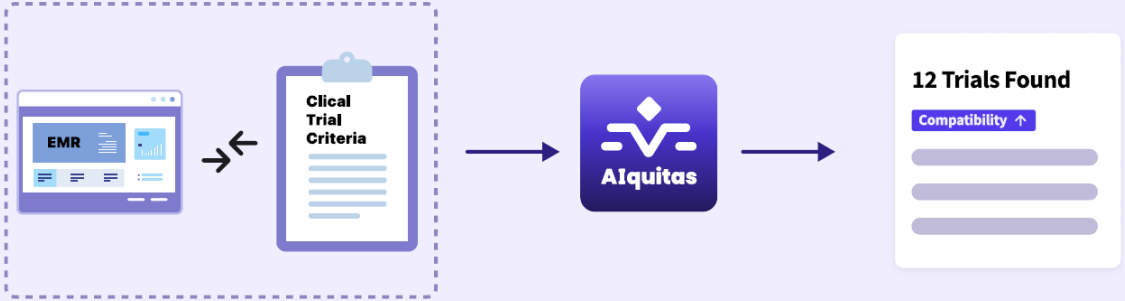
Solution

AIquitas Technology



AIquitas uses machine learning algorithms that intelligently compares patient records with clinical trial language and calculates compatibility scores.

How AIquitas Works

Data processed

8206 Patients

6401 Trials

All of Us Research Hub

NIH U.S. National Library of Medicine
ClinicalTrials.gov

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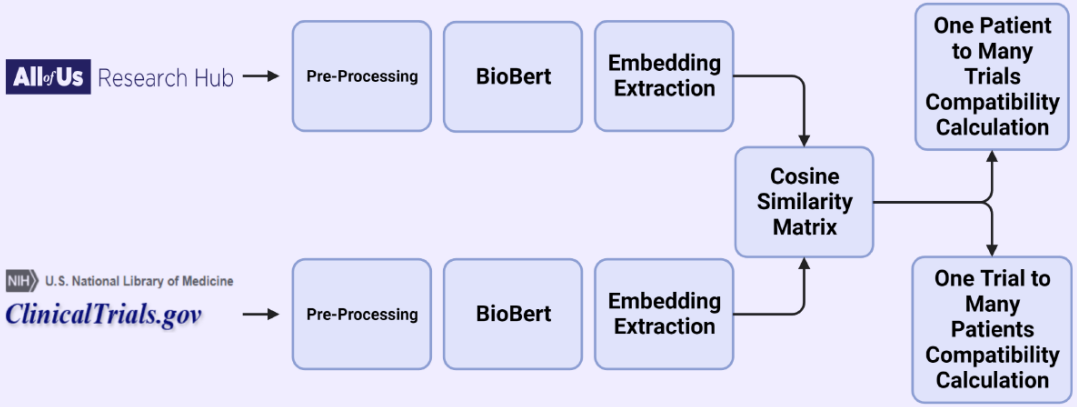
How AIquitas Works

AIquitas Pipeline



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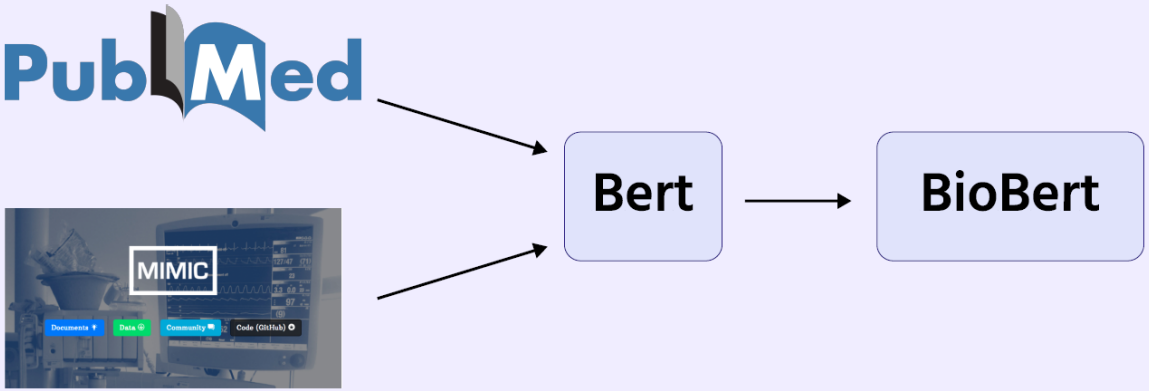
How AIquitas Works

Clinical BioBert



How AIquitas Works

Cosine similarity Matrix

Matching Clinical Trial Language to Patient Information

Patient Record	Clinical Trial Criteria 1: Histologically or cytologically confirmed breast cancer that is metastatic or unresectable	Documented germline mutation in BRCA1 or BRCA2	Patients with estrogen and /or progesterone receptor-positive disease must have received and progressed on at least one endocrine therapy (adjuvant or metastatic),	...
Primary malignant neoplasm of the breast	**0.95**	0.23	0.41	
Pelvic fracture	0.11	0.09	**0.21**	
Secondary neoplasm of the bone	**0.67**	0.32	0.54	
⋮				

How AIquitas Works

Cosine similarity Matrix

Matching Clinical Trial Language to Patient Information

Patient Record	Clinical Trial 2 Criteria			
	Measurable disease at baseline as assessed by the Investigator per RECIST V1.1	ECOG Performance Status ≤ 1	Acceptable bone marrow function: Absolute neutrophil count (ANC)≥ 1.5x109/L, platelet count ≥ 80x 109/L, and hemoglobin ≥ 90g/L	...
Primary malignant neoplasm of the breast	**0.32**	0.23	0.12	
Pelvic fracture	0.06	**0.09**	0.07	
Secondary neoplasm of the bone	**0.82**	0.64	0.18	
⋮				

Breast Cancer vs Diabetes

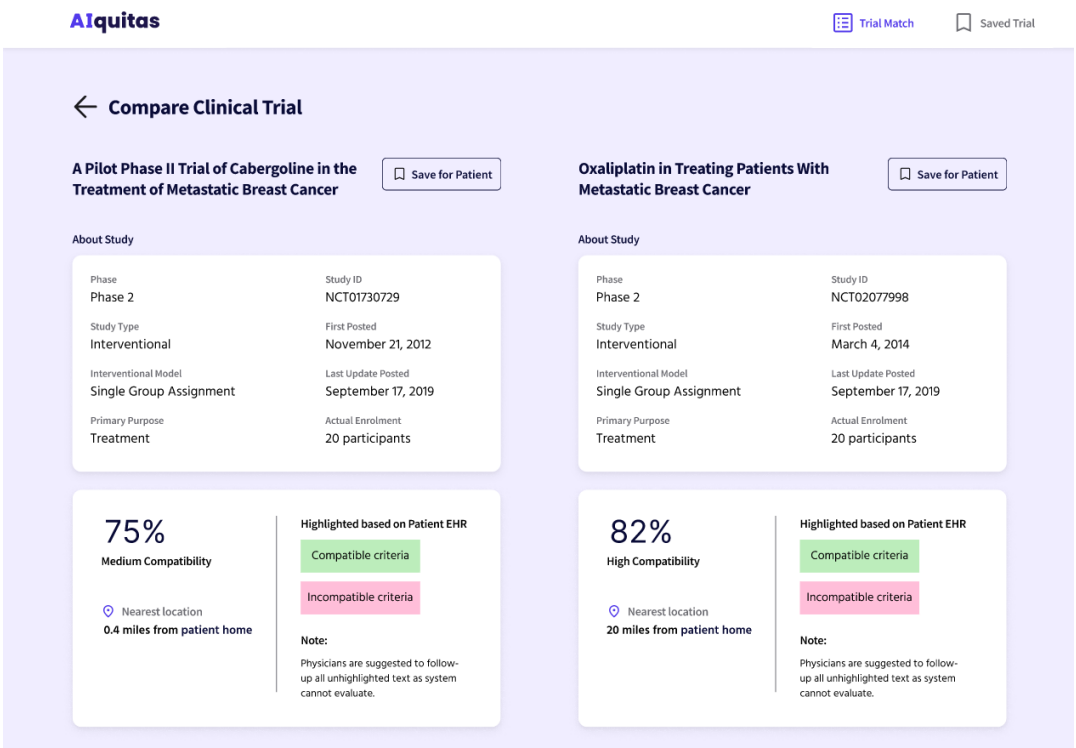
95% Accuracy

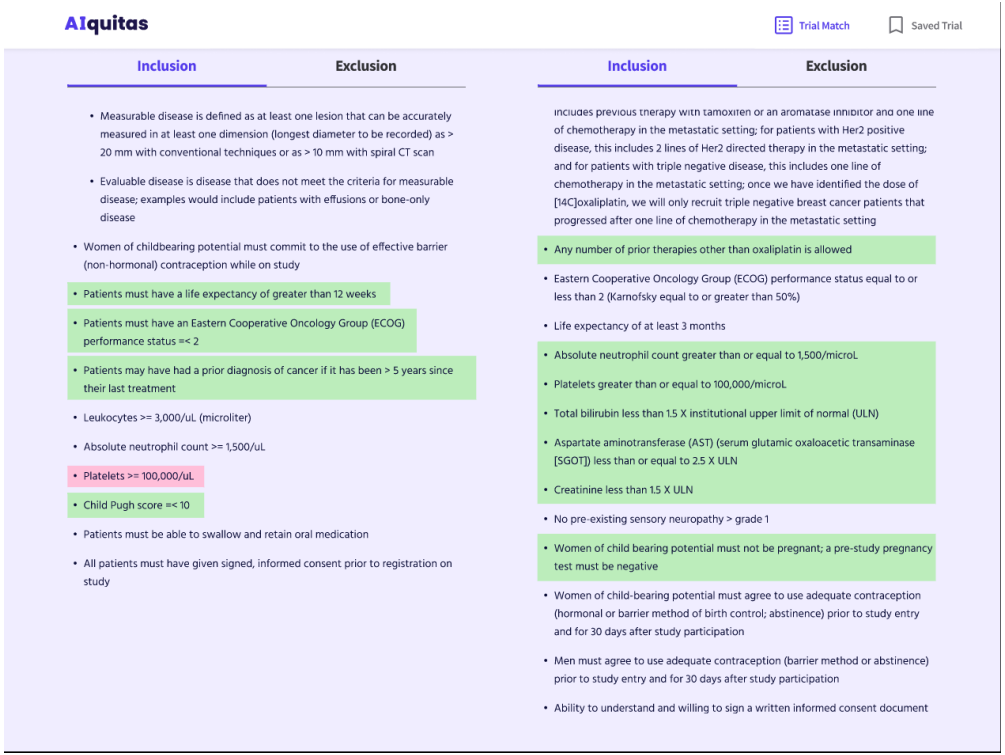
Breast Cancer vs Lung Cancer

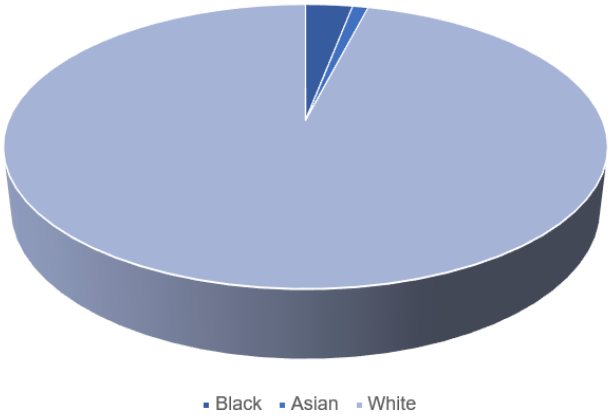
83% Accuracy

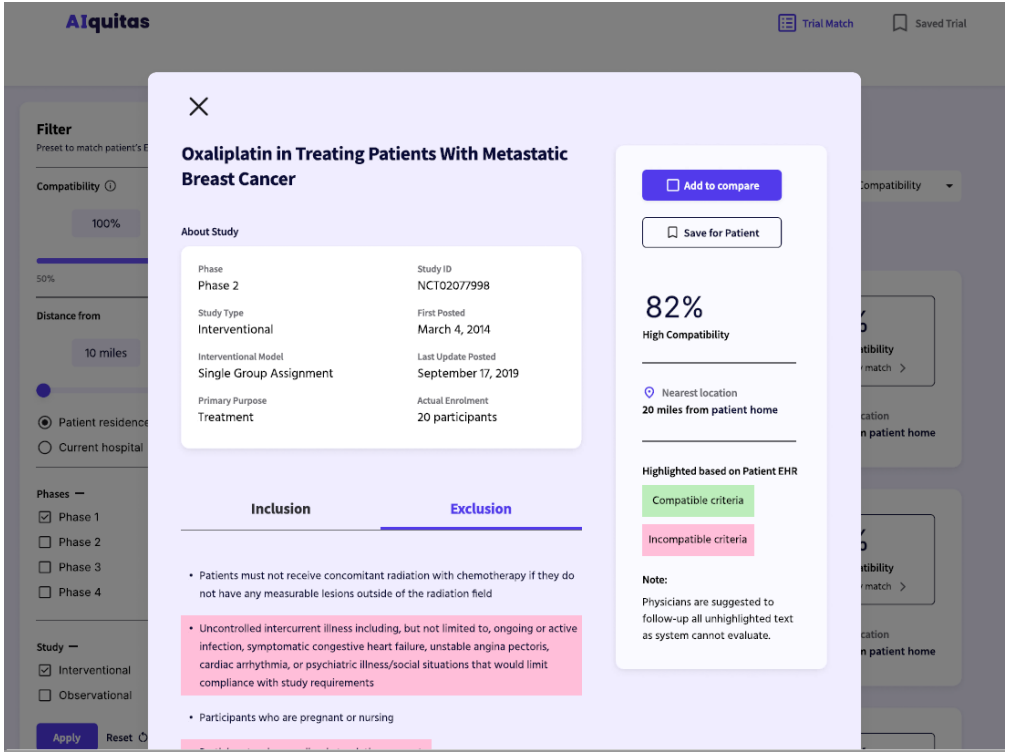
Manual Comparison of the top 10 trials for a Breast Cancer Patient

nDCG is 0.84


AIquitas
Trial Match
Saved Trial
Compare Clinical Trial
A Pilot Phase II Trial of Cabergoline in the Treatment of Metastatic Breast Cancer
Save for Patient
About Study
Phase
Phase 2
Study ID
NCT01730729
Study Type
Interventional
First Posted
November 21, 2012
Interventional Model
Single Group Assignment
Last Update Posted
September 17, 2019
Primary Purpose
Treatment
Actual Enrolment
20 participants
75%
Medium Compatibility
Nearest location
0.4 miles from patient home
Highlighted based on Patient EHR
Compatible criteria
Incompatible criteria
Note:
Physicians are suggested to follow-up all unhighlighted text as system cannot evaluate.
Oxaliplatin in Treating Patients With Metastatic Breast Cancer
Save for Patient
About Study
Phase
Phase 2
Study ID
NCT02077998
Study Type
Interventional
First Posted
March 4, 2014
Interventional Model
Single Group Assignment
Last Update Posted
September 17, 2019
Primary Purpose
Treatment
Actual Enrolment
20 participants
82%
High Compatibility
Nearest location
20 miles from patient home
Highlighted based on Patient EHR
Compatible criteria
Incompatible criteria
Note:
Physicians are suggested to follow-up all unhighlighted text as system cannot evaluate.


AIquitas
Trial Match
Saved Trial
Inclusion
Exclusion
• Measurable disease is defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded) as > 20 mm with conventional techniques or as > 10 mm with spiral CT scan
• Evaluable disease is disease that does not meet the criteria for measurable disease; examples would include patients with effusions or bone-only disease
• Women of childbearing potential must commit to the use of effective barrier (non-hormonal) contraception while on study
• Patients must have a life expectancy of greater than 12 weeks
• Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status =< 2
• Patients may have had a prior diagnosis of cancer if it has been > 5 years since their last treatment
• Leukocytes >= 3,000/uL (microliter)
• Absolute neutrophil count >= 1,500/uL
• Platelets >= 100,000/uL
• Child Pugh score =< 10
• Patients must be able to swallow and retain oral medication
• All patients must have given signed, informed consent prior to registration on study
Inclusion
Exclusion
includes previous therapy with tamoxifen or an aromatase inhibitor and one line of chemotherapy in the metastatic setting; for patients with Her2 positive disease, this includes 2 lines of Her2 directed therapy in the metastatic setting; and for patients with triple negative disease, this includes one line of chemotherapy in the metastatic setting; once we have identified the dose of [14C]oxaliplatin, we will only recruit triple negative breast cancer patients that progressed after one line of chemotherapy in the metastatic setting
• Any number of prior therapies other than oxaliplatin is allowed
• Eastern Cooperative Oncology Group (ECOG) performance status equal to or less than 2 (Karnofsky equal to or greater than 50%)
• Life expectancy of at least 3 months
• Absolute neutrophil count greater than or equal to 1,500/microL
• Platelets greater than or equal to 100,000/microL
• Total bilirubin less than 1.5 X institutional upper limit of normal (ULN)
• Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase [SGOT]) less than or equal to 2.5 X ULN
• Creatinine less than 1.5 X ULN
• No pre-existing sensory neuropathy > grade 1
• Women of child bearing potential must not be pregnant; a pre-study pregnancy test must be negative
• Women of child-bearing potential must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for 30 days after study participation
• Men must agree to use adequate contraception (barrier method or abstinence) prior to study entry and for 30 days after study participation
• Ability to understand and willing to sign a written informed consent document


Black
Asian
White


AIquitas
Trial Match
Saved Trial
Filter
Compatibility
100%
50%
Distance from
10 miles
Patient residence
Current hospital
Phases
Phase 1
Phase 2
Phase 3
Phase 4
Study
Interventional
Observational
Apply
Reset
Oxaliplatin in Treating Patients With Metastatic Breast Cancer
About Study
Phase
Phase 2
Study ID
NCT02077998
Study Type
Interventional
First Posted
March 4, 2014
Interventional Model
Single Group Assignment
Last Update Posted
September 17, 2019
Primary Purpose
Treatment
Actual Enrolment
20 participants
Inclusion
Exclusion
• Patients must not receive concomitant radiation with chemotherapy if they do not have any measurable lesions outside of the radiation field
• Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements
• Participants who are pregnant or nursing
Add to compare
Save for Patient
82%
High Compatibility
Nearest location
20 miles from patient home
Highlighted based on Patient EHR
Compatible criteria
Incompatible criteria
Note:
Physicians are suggested to follow-up all unhighlighted text as system cannot evaluate.

Impact

How does AIquitas improve inclusivity and diversity in clinical trials?

- Every patient gets a clinical trial regardless of their social-economic status and race
- Increased transparency and participation from a patient-centred perspective
- Improved communication between the healthcare ecosystem and diverse communities

Acknowledgements

Dr. Rema Padman PhD, CMU

Alexandra Lutz, CMU

Felicia Savage Friedman, Community Perspective

Judd Englert M.D. Ph.D., Amgen

Christine Lee-Flemming, Ph.D., PharmD, FDA

Judd Englert MD Ph.D.

Dr. Richard Steinman, M.D. Ph.D., UPMC

Dr Julia Foldi M.D. Ph.D., UPMC

Dr. Stevan Evans, M.D., UPMC

Digital Medicine Society