

Integrated Clinical Trial Matching for Cancer Patients and Providers “Blue-button” Pilot Project

Mark Fleury, PhD



Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer

A Landscape Report



www.fightcancer.org/clinicaltrialbarriers

Project Steering Committee Members

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LiveSTRONG Foundation

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American Cancer Society

Archie Tse, MD, PhD
Merck

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Chuck Westbrook
American Cancer Society

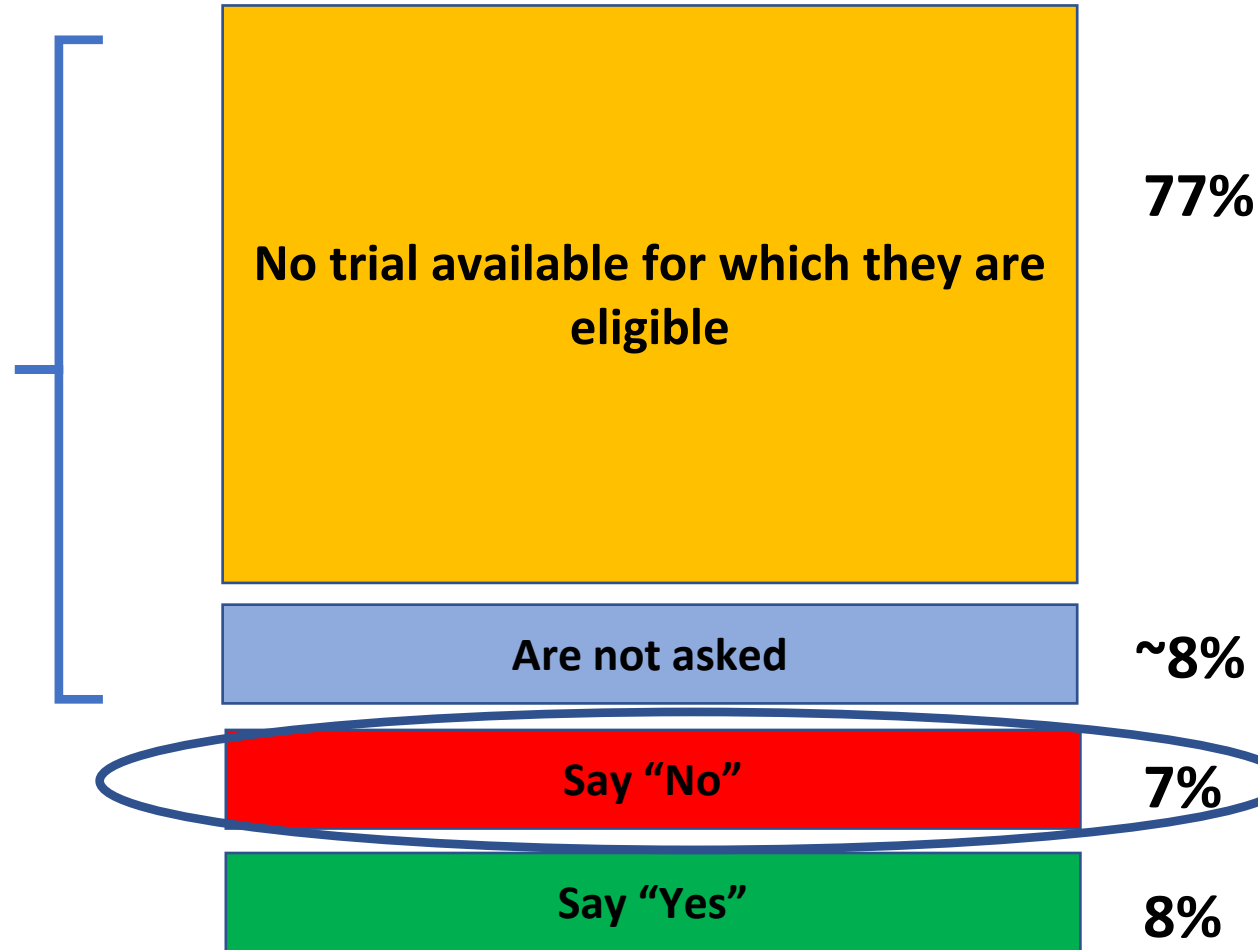
Dawn Wiatrek, PhD
American Cancer Society



Background

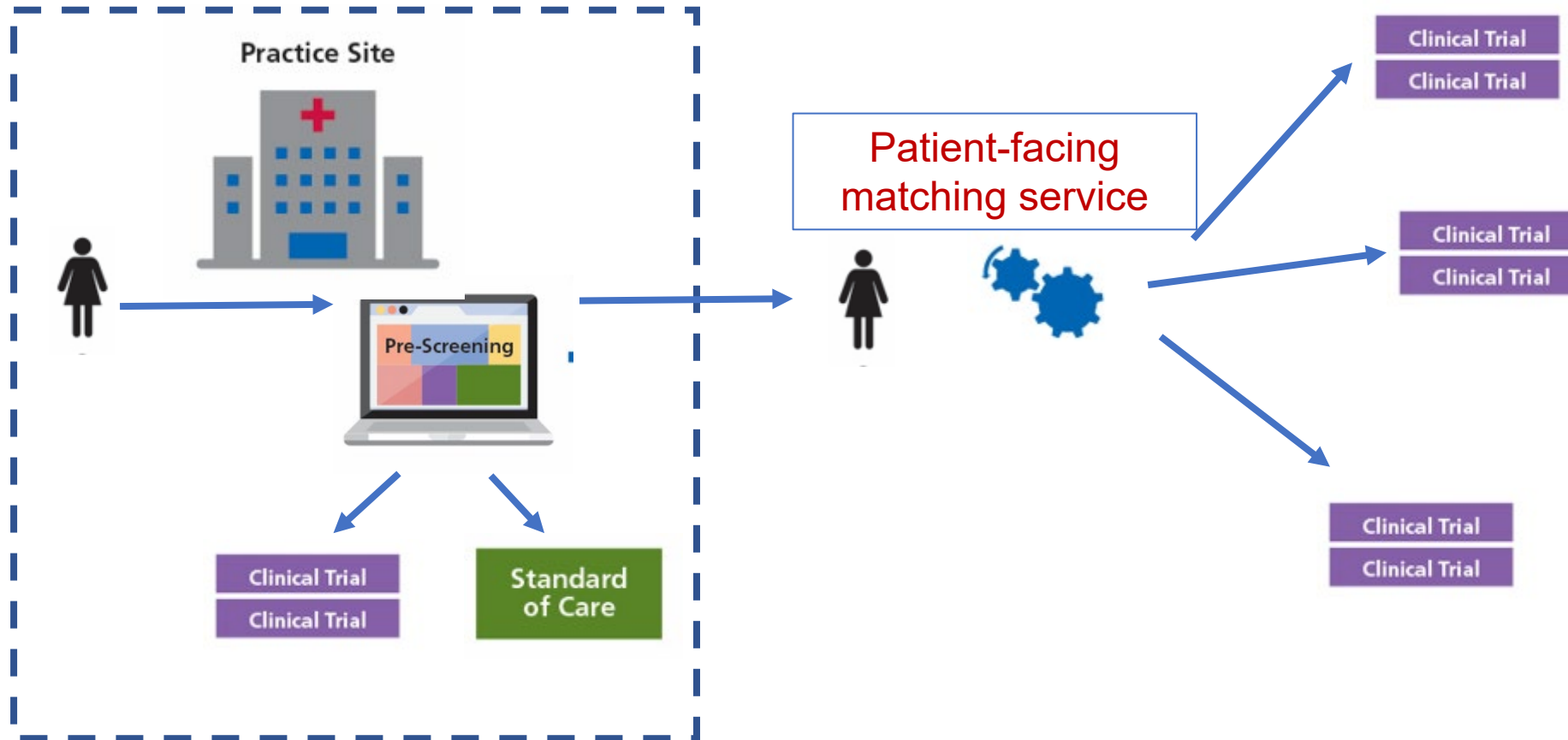
Why Patients Do Not Participate

85% of patients are prevented from participating by structural and clinical barriers outside their control



Where almost all effort is spent trying to increase trial participation

How Do Patients Find Trials?



Incoming Patients

23%

Patients on CTs

85%

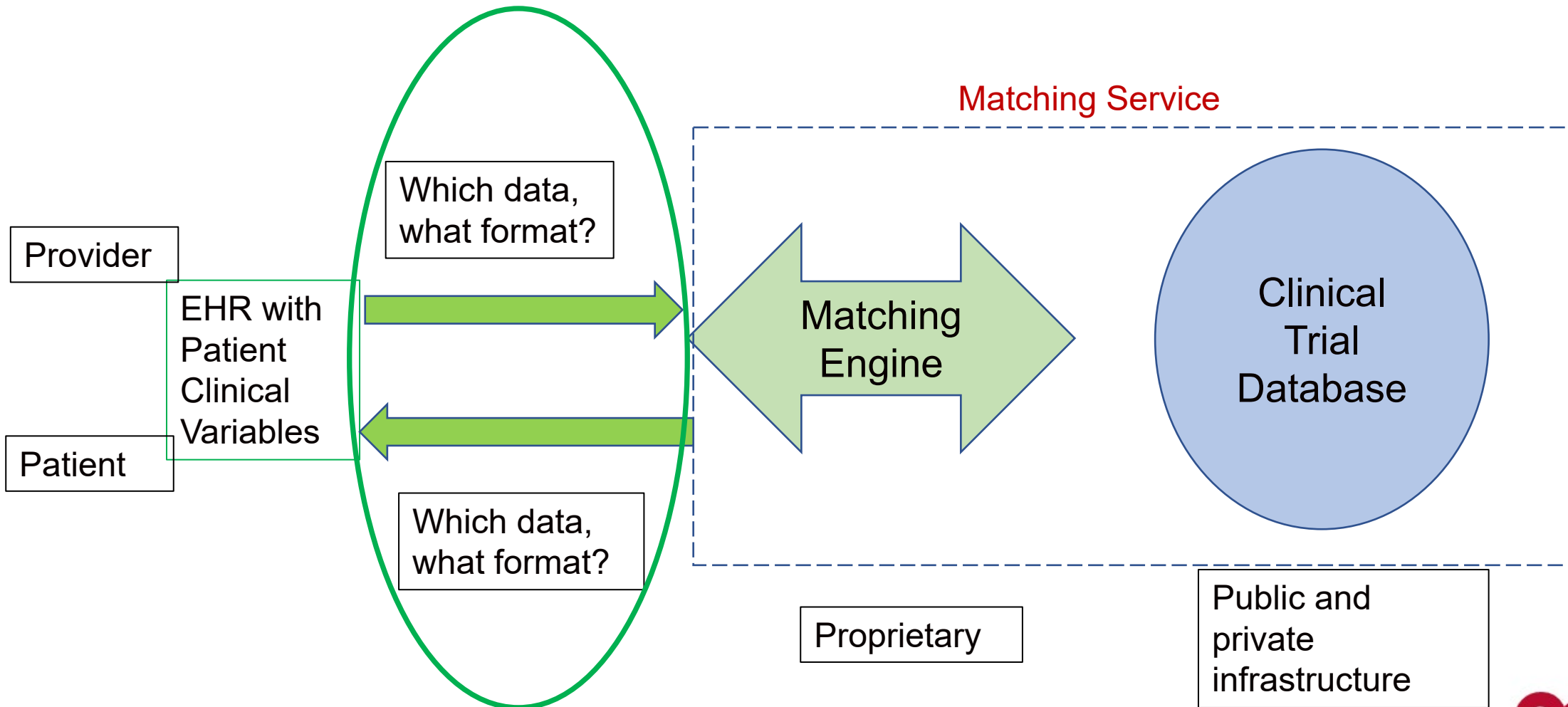
77%

15%

Georgia Case Example

- 20 synthetic breast cancer patients searched with Atlanta zip code 30303
 - 20 miles: 2 to 29 trials, median of 5 trials (9.35 average);
 - 100 miles: 2 to 34 trials, median of 6 trials (10.85 average).
- 38 unique trials returned for all the patients in the 20-mile radius.
 - Emory 24 (63%)
 - Northside 13 (34%)
 - Piedmont 9 (23%)
 - Dekalb 6 (16%)
 - Grady 5 (13%)
 - **Average 11.4 (30%)**

Blue-button Functionality



A New HL7 FHIR Accelerator

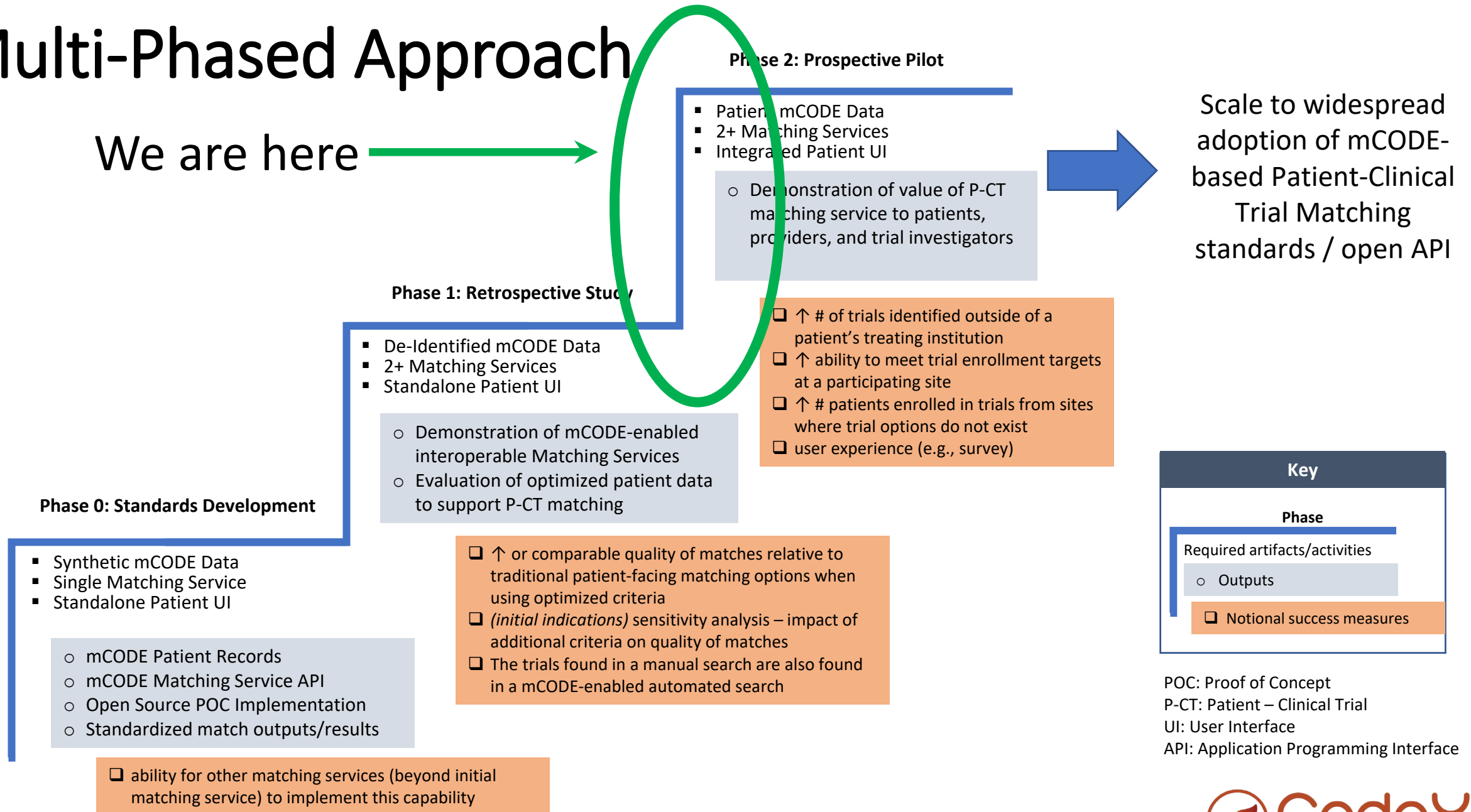


<http://hl7.org/CodeX>

A community and platform to accelerate interoperable data modeling and implementation around mCODE, leading to step-change improvements in cancer care and research

Multi-Phased Approach

We are here →



Filters to Support Minimal Eligibility Criteria

Eligibility Criteria

- Cancer Type
- Cancer Subtype
- Biomarker Status
- Stage
- Presence of Metastases
- Age
- Treatments
- Performance Status

Required Filters and mCODE Mapping

1. PrimaryOrUncertainBehaviorCancerDisorderVS
2. HistologyMorphologyBehaviorVS
3. HGNCVS
4. TumorMarkerTestVS
5. TNMStageGroupVS
6. SecondaryCancerDisorderVS
7. Age derived from birthdate in CancerPatient profile (filter already exists)
8. RadiationProcedureVS
9. Cancer Related Medication Statement
10. Cancer-RelatedSurgicalProcedureVS



 Alyssa971 Goodwin327
female 40 yrs



Let's find some clinical trials

Search with data populated from your record, or change to find matching trials

Matching Services

- BreastCancerTrials.org
- Trajectory
- Trialscope

Zip Code *
02215

Travel Distance (miles)
100

Age
40

Cancer Type *
Breast

Cancer Subtype

Metastasis
Lymph Node Lung

Stage
IV

ECOG Score
1

Karnofsky Score

Biomarkers

- ER Positive
- PR Positive
- HER2 Positive
- Add biomarker...

Radiation

- Radiation Therapy
- Add radiation...


Surgery

- Bilateral mastectomies
- Add surgery...

Medications

- Doxorubicin
- Cyclophosphamide
- Methotrexate
- Fluorouracil
- Anastrozole
- Fasiodex
- Ibrance
- Eribulin
- Add medication...

 SEARCH

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Cancer Subtype
invasive ductal carcinoma

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- ER Positive  PR Positive  HER2 Positive  Add biomarker...

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 SEARCH



Alyssa971 Goodwin327
female 40 yrs



EXPORT ALL



New Search



Filters



SORT BY ▲

Match Likelihood

Distance

FILTER BY ▲

RECRUITMENT STATUS ▲

Recruiting 19

Closed to Accrual 13

Completed 6

Terminated 2

TRIAL PHASE ▲

Phase 1 23

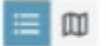
Phase 2 10

STUDY TYPE ▲

Interventional 39

Observational 1

We found 40 matching trials...



RECRUITING	Keytruda plus Abraxane Before Surgery for Stage II-III Hormone Positive, HER2 Negative Breast Cancer BREAST CANCER PHASE 1 INTERVENTIONAL	High-likelihood match 82.1 miles Feb 23, 2017 - Jan 2023	
CLOSED TO ACCRUAL	Ibrance Before Surgery for HR-Positive Stage I-III Breast Cancer BREAST CANCER PHASE 2 INTERVENTIONAL	High-likelihood match 1.3 miles May 24, 2016 - Apr 2031	
CLOSED TO ACCRUAL	Neratinib plus Faslodex for Women With Advanced HER2 Positive, Estrogen Receptor Positive Breast Cancer BREAST CANCER PHASE 2 INTERVENTIONAL	High-likelihood match 15.0 miles Oct 25, 2017 - Aug 31, 2025	
CLOSED TO ACCRUAL	Immunotherapy and Radiation Therapy for Women With Triple Negative Breast Cancer That Has Spread to the Brain BREAST CANCER PHASE 2 INTERVENTIONAL	High-likelihood match 15.0 miles May 1, 2018 - Sep 30, 2025	
RECRUITING	Olaparib & Sapacitabine for People with Advanced Breast Cancer & an Inherited BRCA1/2 Mutation BREAST CANCER PHASE 1 PHASE 2 INTERVENTIONAL	High-likelihood match 12.9 miles Oct 1, 2018 - Jun 22, 2025	
RECRUITING	Helping Researchers Learn Why Tumors Stop Responding to Treatment BREAST CANCER OBSERVATIONAL	High-likelihood match 87.8 miles Jul 9, 2007 - Jan, 2023	

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New Search

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- Trialscope

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Travel Distance (miles)
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Cancer Type *
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Cancer Subtype
invasive ductal carcinoma

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Lymph Node Lung

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IV

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Karnofsky Score

Biomarkers

- ER Positive
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- Doxorubicin
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- Fluorouracil
- Anastrozole
- Faslodex
- Ibrance





EXPORT ALL

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- | | | | |
|-------------------|--|--|--|
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Feb 23, 2017 - Jan 2023 | |
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12.9 miles
Oct 1, 2018 - Jun 22, 2025 | |
| RECRUITING | Helping Researchers Learn Why Tumors Stop Responding to Treatment
BREAST CANCER OBSERVATIONAL | High-likelihood match
87.8 miles
Jul 9, 2007 - Jan, 2023 | |
| RECRUITING | GDC-0084 with Trastuzumab for HER2 Positive Breast Cancer with Brain Metastases
BREAST CANCER PHASE 2 INTERVENTIONAL | High-likelihood match
32.4 miles
Feb 11, 2019 - Nov 30, 2025 | |
| RECRUITING | Abemaciclib in Advanced Triple Negative Breast Cancer That Tests Positive for Rb Protein
BREAST CANCER PHASE 2 INTERVENTIONAL | High-likelihood match
3.9 miles
May 26, 2017 - Nov 30, 2025 | |

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female 40 yrs

 New Search 

 Filters 

SORT BY 

Match Likelihood

Distance

FILTER BY 

RECRUITMENT STATUS 

Recruiting 19

Closed to Accrual 13

Completed 6

Terminated 2

TRIAL PHASE 

Phase 1 23

Phase 2 10

STUDY TYPE 

Interventional 39


























Observational 1



EXPORT ALL

We found 5 matching trials...



- | | | | |
|------------|---|--|---|
| RECRUITING | <p>Keytruda plus Abraxane Before Surgery for Stage II-III Hormone Positive, HER2 Negative Breast Cancer</p> <p>BREAST CANCER PHASE 1 INTERVENTIONAL</p> | <p> High-likelihood match</p> <p> 82.1 miles</p> <p> Feb 23, 2017 - Jan 2023</p> |   |
| RECRUITING | <p>Olaparib & Sapacitabine for People with Advanced Breast Cancer & an Inherited BRCA1/2 Mutation</p> <p>BREAST CANCER PHASE 1 PHASE 2 INTERVENTIONAL</p> | <p> High-likelihood match</p> <p> 12.9 miles</p> <p> Oct 1, 2018 - Jun 22, 2025</p> |   |
| RECRUITING | <p>Ipatasertib, Hormone Therapy and Ibrance for Metastatic Breast Cancer (TAKTIC)</p> <p>BREAST CANCER PHASE 1 INTERVENTIONAL</p> | <p> Possible match</p> <p> 49.2 miles</p> <p> May 30, 2019 - Jun 30, 2024</p> |   |
| RECRUITING | <p>Sacituzumab Govitecan and Talazoparib for Women With Metastatic Triple Negative Breast Cancer</p> <p>BREAST CANCER PHASE 1 PHASE 2 INTERVENTIONAL</p> | <p> Possible match</p> <p> 12.9 miles</p> <p> Oct 9, 2019 - Aug 31, 2024</p> |   |
| RECRUITING | <p>Neratinib and Xeloda for Metastatic HER2+ Breast Cancer</p> <p>BREAST CANCER PHASE 1 PHASE 2 INTERVENTIONAL</p> | <p> Possible match</p> <p> 32.5 miles</p> <p> Dec 13, 2017 - Dec 2022</p> |   |



EXPORT ALL

We found 5 matching trials...



RECRUITING

Keytruda plus Abraxane Before Surgery for Stage II-III Hormone Positive, HER2 Negative Breast Cancer

BREAST CANCER
PHASE 1
INTERVENTIONAL

✔ High-likelihood match

📍 82.1 miles

📅 Feb 23, 2017 - Jan 2023

CONDITIONS Breast Cancer

TRIAL ID NCT02999477

SOURCE Trialscope

SUMMARY This research study is exploring chemotherapy in combination with immunotherapy (a therapy that uses the body's own immune system to control cancer) as a possible treatment for hormone receptor positive breast cancer. The interventions involved in this study are: - Pembrolizumab (MK-3475; Keytruda™) - Nab-Paclitaxel (Abraxane)

DESCRIPTION This research study is a Pilot Study, which is the first time investigators are examining this study intervention.

In this research study, the investigators are looking at how the participants body and tumor respond to the combination of Nab-paclitaxel and Pembrolizumab. Also, the investigators will be examining the participants tumor tissue to learn more about the disease.

The FDA (the U.S. Food and Drug Administration) has not approved Pembrolizumab for this specific disease; but it has been approved in the United States for the treatment of other diseases.

The FDA has not approved Nab-paclitaxel as a treatment option for this type of breast cancer; but it has been approved in the United States for the treatment of metastatic breast cancer (breast cancer that has spread to other parts of the body).

Pembrolizumab is a medicine that may treat cancer by working with the participant's immune system. The immune system is the body's

[🔗 MORE INFO](#)

[💾 SAVE STUDY](#)

SPONSOR

Dana-Farber Cancer Institute

📞 617-632-2335

✉ cancer@dana-farber.org

FACILITIES

Dana-Farber Cancer Institute

📞 617-632-2335

✉ cancer@dana-farber.org

📍 82.1 miles

RECRUITING

Olaparib & Sapacitabine for People with Advanced Breast Cancer & an Inherited BRCA1/2 Mutation

BREAST CANCER
PHASE 1
PHASE 2
INTERVENTIONAL

✔ High-likelihood match

📍 12.9 miles

📅 Oct 1, 2018 - Jun 22, 2025

Technical Validation

- Positive predictive values (proportion of pre-screen trials returned from the tool that are true matches after manual review) ranging from 20% to 50% depending on cancer type
- In UTSW analysis, searching in a 20-mile radius resulted in an ~80% true match rate, increased many fold over onsite-only matches

Desired attributes of a site

- Capacity to conduct pilot and associated data collection
- Interest in optimizing CT participation (even if that means referrals)
- Most patients have prescreened trials within the geographic area, with not all trials available onsite
- Has multiple options of other nearby sites for referral (ideally center has relationships with other nearby sites that would make referral for offsite trials easier)
- Epic EHR system

Development of a Pilot Site Feasibility Tool

- Data from 12 patients with 2 each from the following cancer types
 - Multiple Myeloma
 - Colon
 - Lung
 - Prostate
 - Brain
 - Breast
- Searched for trials within a 20 miles radius of given zip code

Georgia Examples (20 miles)

Location	Range of Trials per patient	Average number of trials per patient	Number of sites	Patients with prescreen trials
Atlanta (30303)	1-7	3.4	>5	12/12
Macon (31201)	0-1	<1	2	3/12
Savannah (31405)	0-2	<1	4	6/12
Columbus (31904)	0-1	<1	1	3/12
Waycross (31501)	0	0	0	0/12

Next steps

- ❖ **Finalizing technical validation in additional cancer types**
 - ❖ Brain
 - ❖ Lung
 - ❖ Colon
 - ❖ Bladder
- ❖ **Clinical implementation partners (UTSW plus 1-3 more)**
- ❖ **Additional matching services (Multiple onboarding)**

Clinical Implementation Sites

- ❖ **UTSW—Ongoing conversations**
- ❖ **Call for additional sites (RFP)**

Blue-button collaborators



Blue-button Funders

AMGEN

 **Seagen**[®]

Genentech
A Member of the Roche Group

parexel[®]

Thank you!

Mark.fleury@cancer.org

www.fightcancer.org/clinicaltrialbarriers

