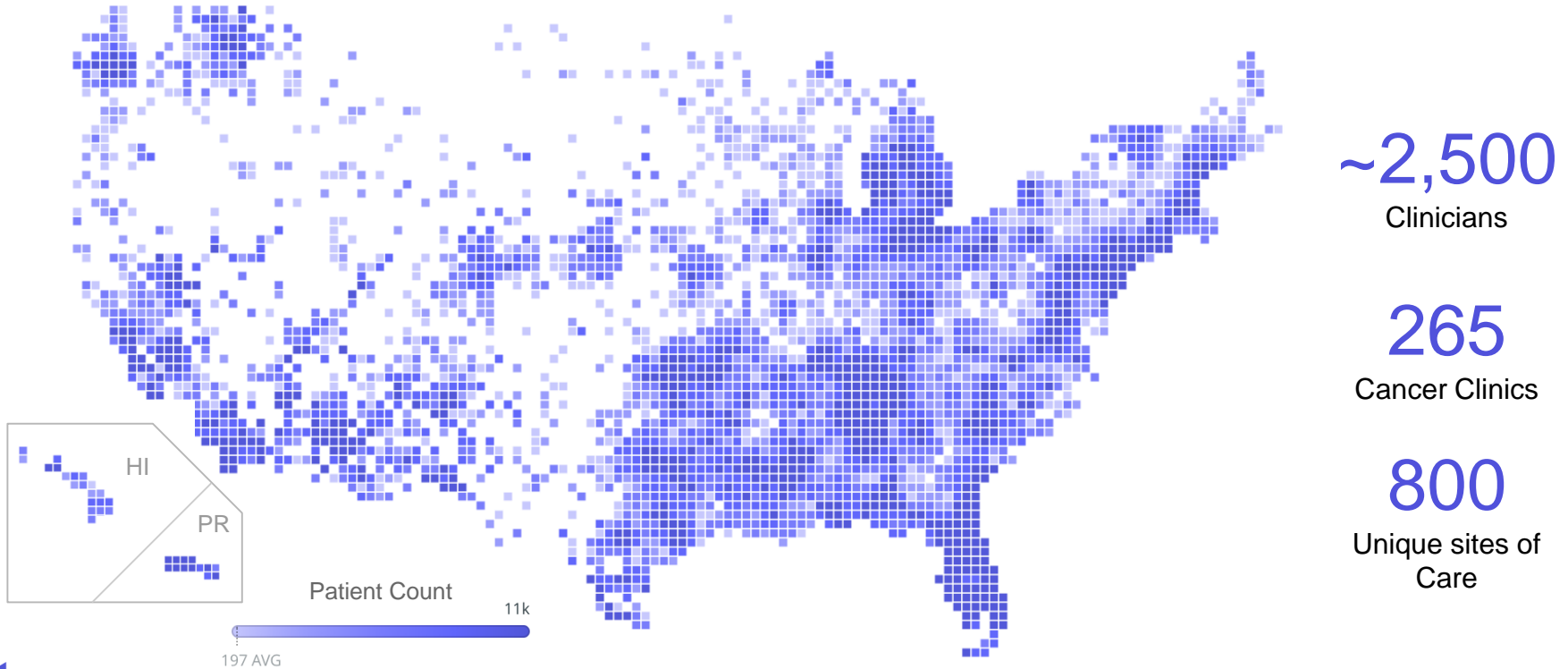


Use of RWD in Study Recruitment and Enrollment

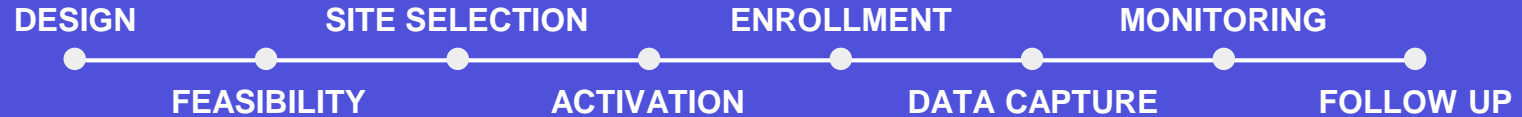
An EHR-enabled platform for efficient clinical trials

James Hamrick, MD
Senior Medical Director

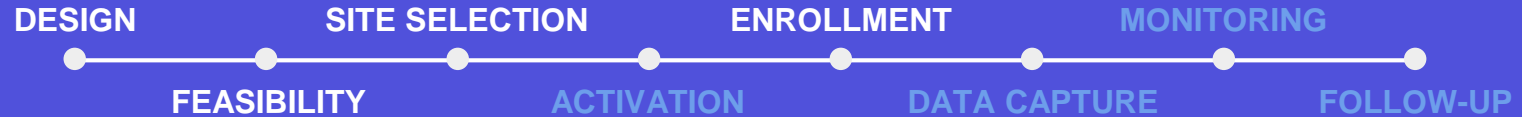
For over 2,000,000 active patients



Flatiron powers major aspects of a clinical trial, end to end.

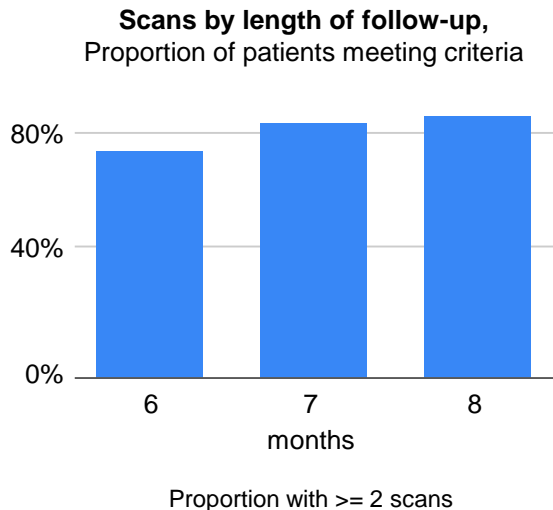


Flatiron powers major aspects of a clinical trial, end to end.

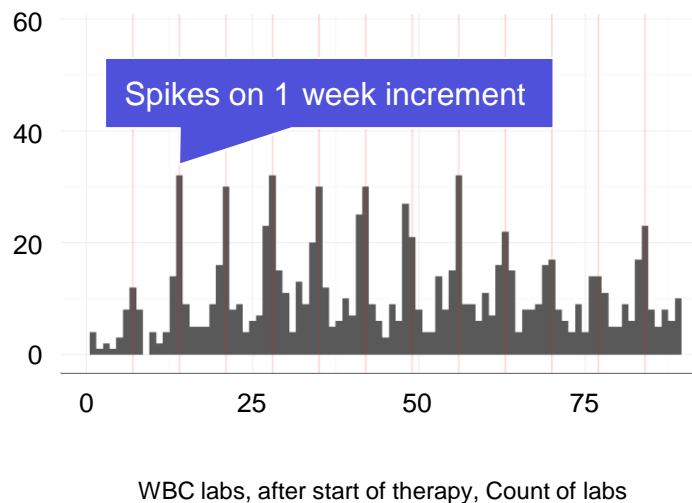


Case Example: Inform study protocols with real-world practice data

Follow-up consistent with timing of scans in routine practice.



Specify assessments consistent with standard practice.



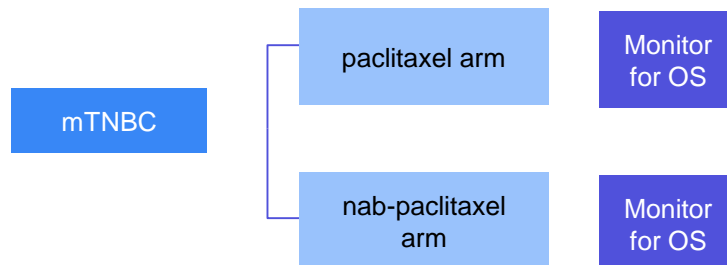
Case Example: Flatiron RWE used to demonstrate study comparator arm reflects standard of care in mTNBC

Challenge

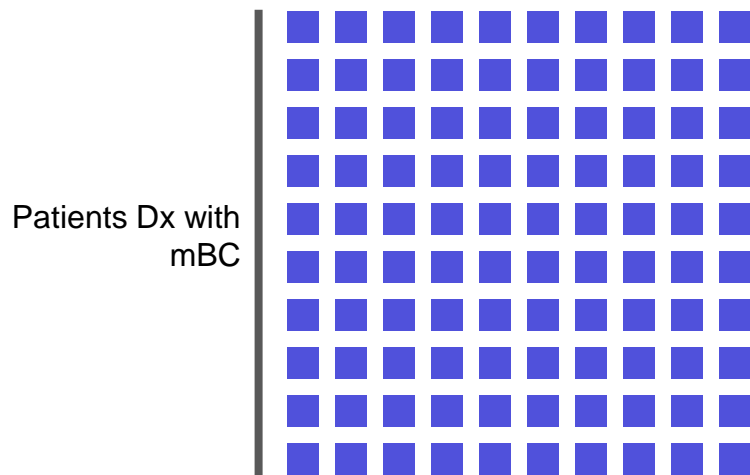
- Life sciences partner conducted a study in metastatic Triple-Negative Breast Cancer
- EU Health Authority pushed back on their choice of comparator arm (nab-paclitaxel)

Solution

- Partner conducted initial analysis with Flatiron data to demonstrate selected comparator arm reflected standard real-world treatment patterns
- Subsequent analysis with Flatiron data used to demonstrate selected comparator arm was non-inferior to Health Authority's preference



Case Example: Modeling the impact of inclusion / exclusion criteria with contemporary data



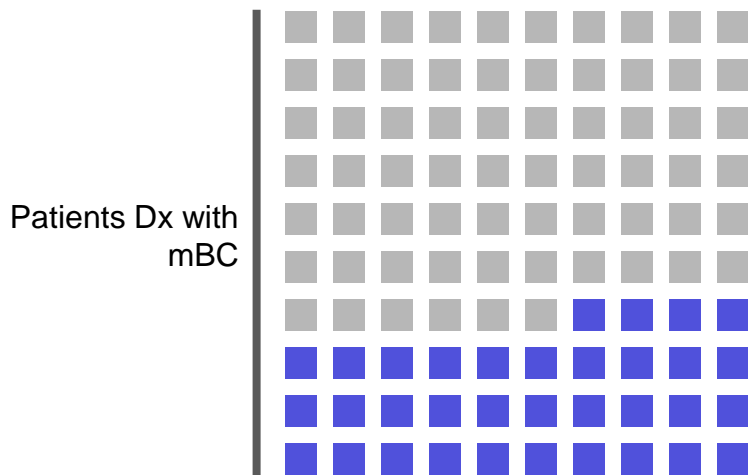
Initiated therapy between 4/1/16 and 3/31/17

Likely to start next line within 12 months

HR + / HER2 -

Have received drug X

Case Example: Modeling the impact of inclusion / exclusion criteria with contemporary data



34%

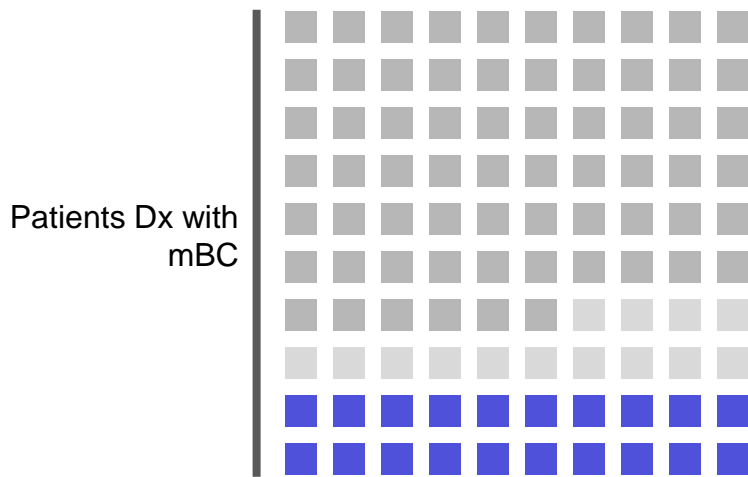
Initiated therapy between 4/1/16 and 3/31/17

Likely to start next line within 12 months

HR + / HER2 -

Have received drug X

Case Example: Modeling the impact of inclusion / exclusion criteria with contemporary data



19%

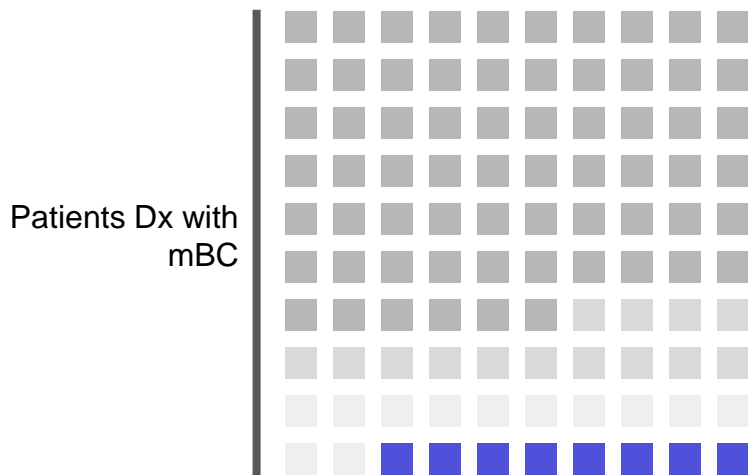
Initiated therapy between 4/1/16 and 3/31/17

Likely to start next line within 12 months

HR + / HER2 -

Have received drug X

Case Example: Modeling the impact of inclusion / exclusion criteria with contemporary data



7.5%

Initiated therapy between 4/1/16 and 3/31/17

Likely to start next line within 12 months

HR + / HER2 -

Have received drug X

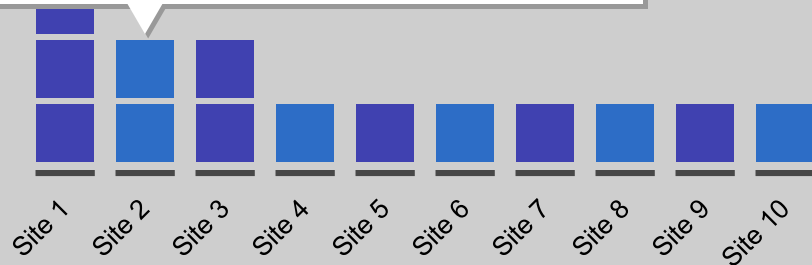
Case Example: Identifying sites with eligible patients for a

“ We had a similar trial open for 3 years and never found a patient.

We aren’t looking for another trial [for this biomarker], but **we will do this because you can help us find the patients”**

—Community site

Using Technology-Enabled Abstraction, Flatiron identified 15 candidate patients across 10 sites in the community setting

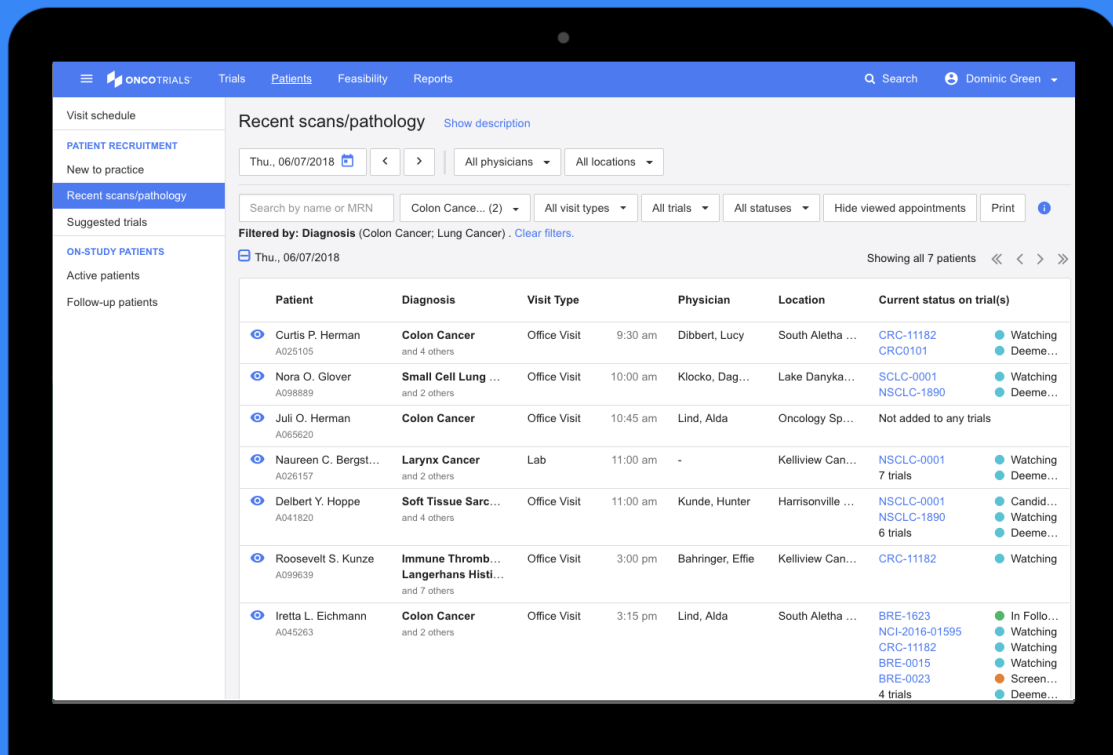


Candidate (potentially eligible) patients by site

¹ Includes patients with the study indication, at least one NGS result, and a recent office visit

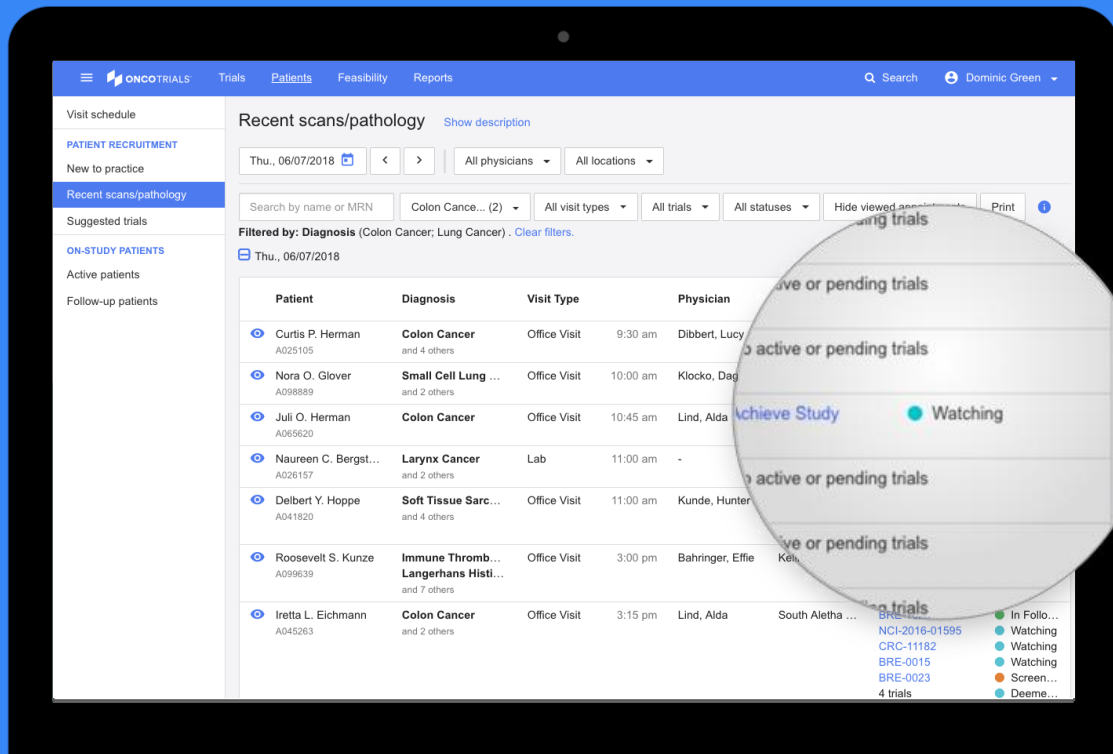
Practices use OncoTrials software to manage patients through the enrollment process.

OncoTrials integrates directly into the workflow of research staff at each site, enabling efficient research management and assisting with patient enrollment.



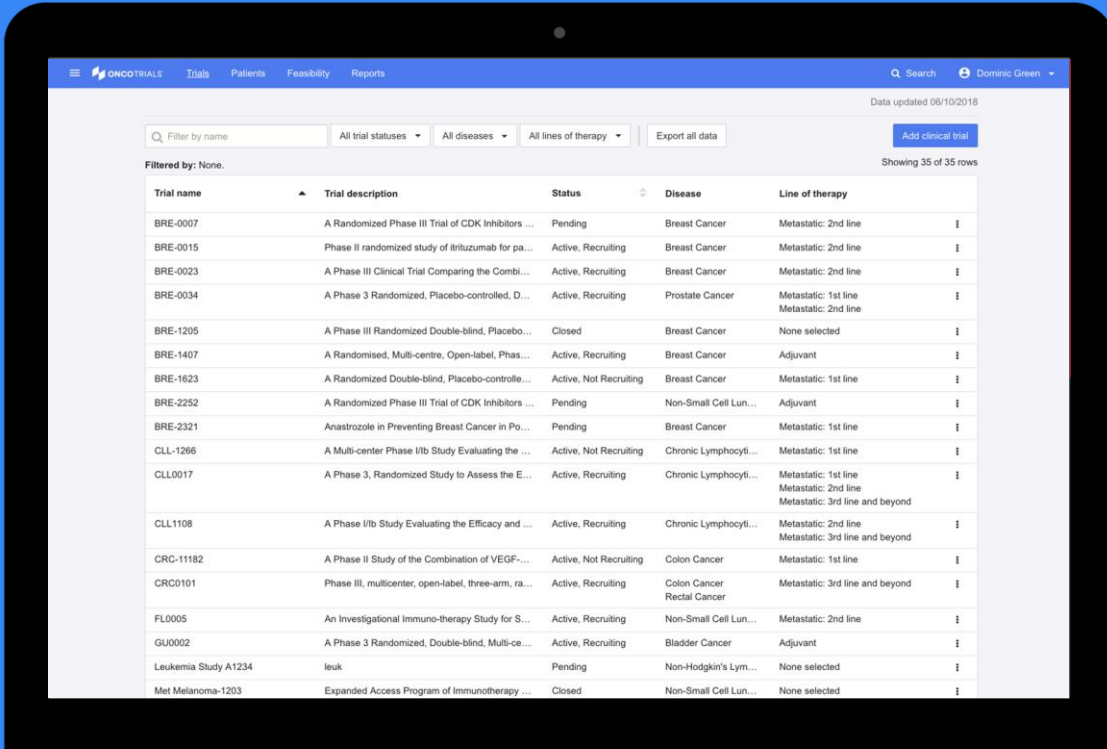
Practices use OncoTrials software to manage patients through the enrollment process.

OncoTrials integrates directly into the workflow of research staff at each site, enabling efficient research management and assisting with patient enrollment.



Trial management

Manage your practice's menu of recruiting and active clinical trials.



The screenshot displays the ONCO TRIALS web application interface. At the top, there is a navigation bar with 'ONCO TRIALS' and tabs for 'Trials', 'Patients', 'Feasibility', and 'Reports'. A search bar and user profile 'Dominic Green' are on the right. Below the navigation, there are filter options: 'Filter by name', 'All trial statuses', 'All diseases', 'All lines of therapy', and 'Export all data'. A blue button labeled 'Add clinical trial' is also present. The main content area shows a table of clinical trials with columns for 'Trial name', 'Trial description', 'Status', 'Disease', and 'Line of therapy'. The table is filtered to show 35 rows.

Trial name	Trial description	Status	Disease	Line of therapy
BRE-0007	A Randomized Phase III Trial of CDK Inhibitors ...	Pending	Breast Cancer	Metastatic: 2nd line
BRE-0015	Phase II randomized study of Irituzumab for pa...	Active, Recruiting	Breast Cancer	Metastatic: 2nd line
BRE-0023	A Phase III Clinical Trial Comparing the Combi...	Active, Recruiting	Breast Cancer	Metastatic: 2nd line
BRE-0034	A Phase 3 Randomized, Placebo-controlled, D...	Active, Recruiting	Prostate Cancer	Metastatic: 1st line Metastatic: 2nd line
BRE-1205	A Phase III Randomized Double-blind, Placebo...	Closed	Breast Cancer	None selected
BRE-1407	A Randomised, Multi-centre, Open-label, Phas...	Active, Recruiting	Breast Cancer	Adjuvant
BRE-1623	A Randomized Double-blind, Placebo-controlle...	Active, Not Recruiting	Breast Cancer	Metastatic: 1st line
BRE-2252	A Randomized Phase III Trial of CDK Inhibitors ...	Pending	Non-Small Cell Lun...	Adjuvant
BRE-2321	Anastrozole in Preventing Breast Cancer in Po...	Pending	Breast Cancer	Metastatic: 1st line
CLL-1266	A Multi-center Phase IIb Study Evaluating the ...	Active, Not Recruiting	Chronic Lymphocyt...	Metastatic: 1st line
CLL0017	A Phase 3, Randomized Study to Assess the E...	Active, Recruiting	Chronic Lymphocyt...	Metastatic: 1st line Metastatic: 2nd line Metastatic: 3rd line and beyond
CLL1108	A Phase IIb Study Evaluating the Efficacy and ...	Active, Recruiting	Chronic Lymphocyt...	Metastatic: 2nd line Metastatic: 3rd line and beyond
CRC-11182	A Phase II Study of the Combination of VEGF-...	Active, Not Recruiting	Colon Cancer	Metastatic: 1st line
CRC0101	Phase III, multicenter, open-label, three-arm, ra...	Active, Recruiting	Colon Cancer Rectal Cancer	Metastatic: 3rd line and beyond
FL0005	An Investigational Immuno-therapy Study for S...	Active, Recruiting	Non-Small Cell Lun...	Metastatic: 2nd line
GU0002	A Phase 3 Randomized, Double-blind, Multi-ce...	Active, Recruiting	Bladder Cancer	Adjuvant
Leukemia Study A1234	leuk	Pending	Non-Hodgkin's Lym...	None selected
Met Melanoma-1203	Expanded Access Program of Immunotherapy ...	Closed	Non-Small Cell Lun...	None selected

Research patient tracking

Track research patients from pre consent through enrollment and completion or discontinuation on a clinical trial

The screenshot displays the ONCOTRIALS web application interface. The top navigation bar includes 'ONCOTRIALS', 'Trials', 'Patients', 'Feasibility', and 'Reports'. The user is logged in as 'Dominic Green'. The main content area is titled 'BRE-0007' and 'Pre-consent patients (16)'. A search bar is available for finding patients by name or MRN. The interface is divided into two sections: 'Watching (14)' and 'Candidate (1)'. The 'Watching' section contains a table with 14 rows of patient data, including names, primary diagnoses, research physicians, next appointments, locations, and latest notes. The 'Candidate' section contains a single row of patient data.

Patient	Primary Diagnoses	Research Physician	Next Appointment	Location	Latest Note
Adrienne T. Abernathy A048803	Soft Tissue Sarcoma ...	Reichert, Isaac	07/15/2018 Office Visit	Harrisonville Oncology...	Waiting to see if patient fails current line of therapy 06/11/2018 by dgreen@flatiron.com
Bertie S. Abshire A078422	Breast Cancer	Reichert, Isaac	06/18/2018 Office Visit	Cancer Center of Jaed...	-
Claudette D. Abbott A095443	Breast Cancer	Funk, Norene	-	Oncology Specialists o...	-
Corlene R. Abshire A097911	Breast Cancer	Johnston, Curt	07/03/2018 Treatment	Kelliview Cancer Spec...	No progression - check back at next office visit 05/30/2018 by dgreen@flatiron.com
Darlene J. Abernathy A095530	Breast Cancer	Bahringer, Effie	07/13/2018 Office Visit	Cancer Center of Jaed...	-
Katherine Abbott A068835	Breast Cancer	Dibbert, Lucy	09/24/2018 Office Visit	Cancer Specialists of ...	-
Londa R. Abernathy A016121	Breast Cancer	Barrows, Aurelia	11/16/2018 Office Visit	Oncology Specialists o...	-
Lucille Abernathy A033932	Breast Cancer	Ernser, Alessia	09/18/2018 Office Visit	South Aetha Cancer ...	-
M Rosalie B. Adams A092163	Breast Cancer	King, Jerod	06/28/2018 Office Visit	Cancer Specialists of ...	-
Melanie Adams A017785	Breast Cancer	Ernser, Alessia	03/19/2019 Office Visit	Harrisonville Oncology...	-

Patient	Primary Diagnoses	Research Physician	Next Appointment	Location	Latest Note
Marianne Leuschke A042673	Breast Cancer	Dibbert, Lucy	06/12/2018 Office Visit	Oncology Specialists o...	Waiting to see scan results 05/09/2018 by dgreen@flatiron.com

Candidate identification

Review potential research candidates from the OncoTrials visit schedule. Click on patients to review their trial options and relevant clinical information side by side, with a direct link to the medical record

The screenshot displays the OncoTrials interface for a patient named Mary Jane Ryan. The interface is divided into several sections:

- Left Sidebar:** Contains navigation options such as "Visit schedule", "PATIENT RECRUITMENT", "Recent scans/pathology", "Suggested trials", "ON-STUDY PATIENTS", "Active patients", and "Follow-up patients".
- Top Header:** Shows the patient's name "Mary Jane Ryan", ID "A017528", and date of birth "DOB: 09/26/1984 (33 years old)".
- Recent scans/pathology:** A table listing recent medical scans and pathology results for the patient.
- Trials:** A section titled "Flatiron suggested trials (3)" showing a list of clinical trials with their status (e.g., "active, recruiting", "pending") and eligibility status (e.g., "Watching", "Deemed ineligible").
- Patient Note:** A section for adding notes to the patient's record.
- Patient Clinical Info:** A section displaying various clinical information, including "Diagnosis" (Secondary Malignant Neoplasm, Neutropenia, etc.), "Biomarkers" (ER, HER2, PR), and "Drug order history".

Feasibility

Use the Feasibility feature to determine cohort sizes and to identify and screen patients meeting specific trial criteria

The screenshot displays the 'Feasibility analysis' interface on the ONCO TRIALS platform. The top navigation bar includes 'ONCO TRIALS', 'Trials', 'Patients', 'Feasibility', and 'Reports'. The user is logged in as 'Dominic Green'. The main section is titled 'Feasibility analysis' and contains several filter categories:

- Locations:** Cancer Specialists of South Maci, Lake Darykaside Cancer Clinic
- Visits between:** 2018-01-01 and 2018-06-11
- Diagnoses:** Breast Cancer
- Stages:** All stages
- Biomarkers:** HER2 (Negative), ER (Negative), PR (Negative)
- Exclude deceased patients:**
- Included drugs:** All of, Palbociclb
- Excluded drugs:** All of

An 'Apply' button is located at the bottom of the filter section. Below the filters, the 'Patients (19)' section shows a list of 19 patients. The first three patients are visible in the table below:

Patient	Primary physician	Location	Current status on trial(s)
<input type="checkbox"/> Linda Auer A017656	Abbott, Nona	Cancer Specialists of South Maci	BRE-0015 BRE-0023 ● Watching ● Watching
<input type="checkbox"/> Alicia K. Berge A042057	Ermer, Alessia	Lake Darykaside Cancer Clinic	BRE-0015 BRE-0023 BRE-1623 NCI-2014-00746 ● Active ● Watching ● Active ● Deemed Ineligible
<input type="checkbox"/> Be V. Ferry A022113	Barrows, Aurelia	Cancer Specialists of South Maci	BRE-0015 BRE-0023 BRE-1407 BRE-1623 NCI-2014-00746 NCI-2016-01595 ● Active ● Watching ● Watching ● Deemed Ineligible ● Deemed Ineligible ● Screen Fail

Reports

Gain insight with practice wide research reporting, such as monthly and quarterly overviews of your clinical trial accrual and operational and screening metrics for your research department.

