Use of RWD in Study Recruitment and Enrollment

An EHR-enabled platform for efficient clinical trials

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For over 2,000,000 active patients

~2,500 Clinicians

265 Cancer Clinics

800 Unique sites of Care

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

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**Scans by length of follow-up,**
Proportion of patients meeting criteria

- 6 months: 80%
- 7 months: 40%
- 8 months: 0%

Proportion with $\geq 2$ scans

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WBC labs, after start of therapy, Count of labs

Spikes on 1 week increment
Case Example: Flatiron RWE used to demonstrate study comparator arm reflects standard of care in mTNBC

- 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)

- 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

Patients Dx with mBC

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
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Patients Dx with mBC

19%
Case Example: Modeling the impact of inclusion / exclusion criteria with contemporary data

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Patients Dx with mBC

7.5%
Case Example: Identifying sites with eligible patients for a 11-armed basket trial

"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.

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Trial management

Manage your practice’s menu of recruiting and active clinical trials.
Research patient tracking

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

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