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
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.

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

Proportion with >= 2 scans

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

Patients Dx with mBC

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

Initiated therapy between 4/1/16 and 3/31/17
Likely to start next line within 12 months
HR + / HER2 -
Have received drug X

34%
Case Example: Modeling the impact of inclusion / exclusion criteria with contemporary data

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Likely to start next line within 12 months

HR + / HER2 -

Have received drug X

Patients Dx with mBC

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

- Patients Dx with mBC
- Initiated therapy between 4/1/16 and 3/31/17
- Likely to start next line within 12 months
- HR + / HER2 -
- Have received drug X

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

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

“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

Candidate (potentially eligible) patients by site

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