



Fact Sheet

Enhanced Datamart



EDM Enhanced Datamart

EDMs are Flatiron's foundational datasets that reflect cancer patients' journeys from diagnosis to treatment and include real-world outcomes.

- **250k+** patient records available
- **20+** tumor-specific data models and datasets
- Associated training, analytic & visualization support:
 - **Flatiron Knowledge Center:** Repository FAQs, analytic resources, trainings, and technical webinar series
 - **Flatiron Render™:** Interactive data visualizations to efficiently explore EDM data
 - **Flatiron R Package Universe:** Suite of R packages for statistical analysis and visualization

 Monthly delivery, up to 30 day recency



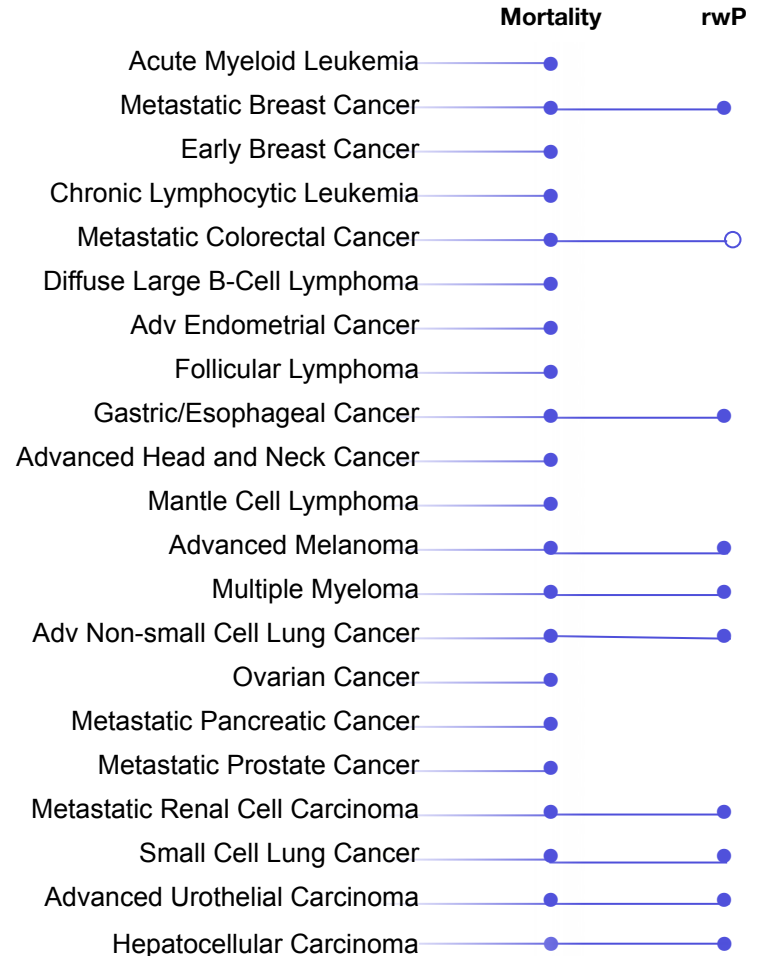
EDM Enhanced Datamart

Over 20 tumor types, each with a tumor-specific data model and real-world outcome variables.

● At Scale

○ In Development

rwP = real-world progression



Published research using EDMs

AM J HEMATOL. 2020

[Daratumumab-lenalidomide-dexamethasone vs standard-of-care regimens: Efficacy in transplant-ineligible untreated myeloma.](#)

FUTUR ONCOL. 2020

[Real-world outcomes associated with liposomal irinotecan dose reductions in metastatic pancreatic ductal adenocarcinoma.](#)

JCO CLIN CANCER INFORMATICS 2021

[Overall survival with second-line pembrolizumab in patients with non-small-cell lung cancer: randomized phase III clinical trial versus propensity-adjusted real-world data.](#)

FUTUR ONCOL. 2020

[First-line immunotherapy versus targeted therapy in patients with BRAF-mutant advanced melanoma: a real-world analysis.](#)

CLIN LUNG CANCER. 2021

[Real-world characterization of advanced non-small cell lung cancer in never smokers by actionable mutation status.](#)



Contact us to learn more



Fact Sheet

Clinico-Genomic Database



CGDB Clinico-Genomic Database

These growing datasets link Foundation Medicine's comprehensive genomic profiling data with Flatiron's EHR-derived clinical and outcomes data for tumor-specific and tumor-agnostic analyses.

- **67k+** linked clinico-genomic patient records across tumor types
 - **Genomic data of 300+ genes** from FDA-approved tissue and liquid biopsy-based comprehensive genomic profiling
 - Associated training and analytic support:
 - **Flatiron Knowledge Center:** Repository FAQs, analytic resources, trainings, and technical webinar series
- 🕒 Quarterly or biannual delivery, 3 month recency



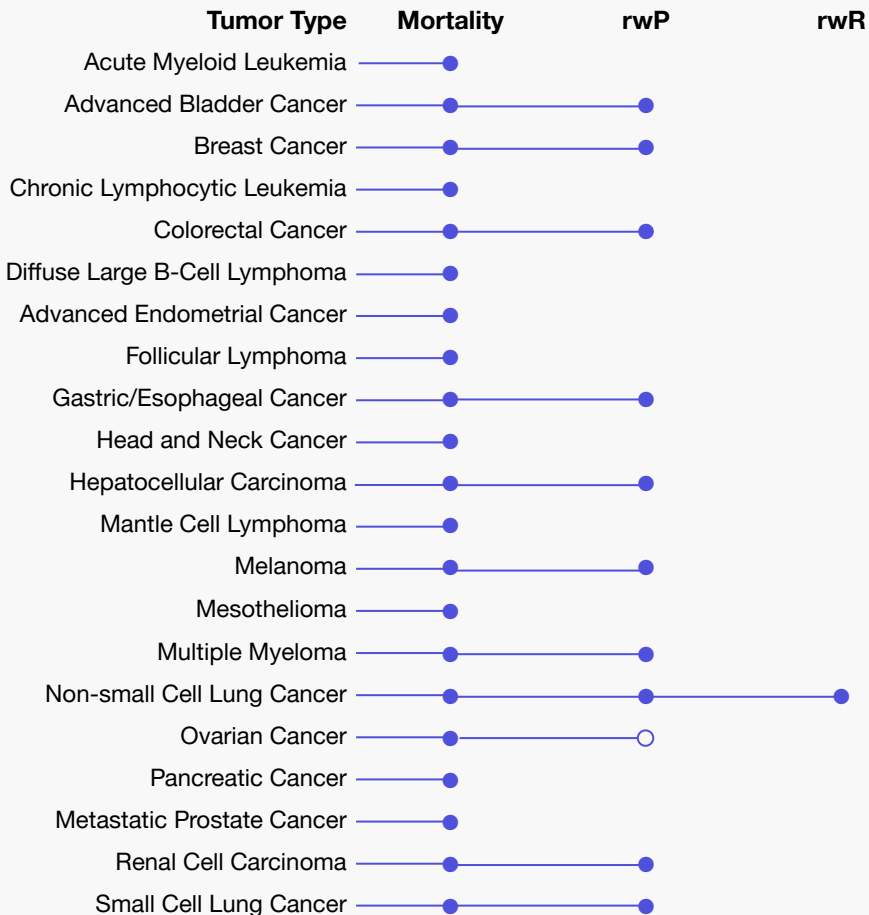
CGDB Clinico-Genomic Database

20+ tumor types with
tumor-specific data models
and real-world outcome
variables.

- At Scale
- In Development

rwP = real-world progression

rwR = real-world response



Clinico-Genomic Database (CGDB) data models enable users to conduct tumor-specific and tumor-agnostic analyses.

CLINICO-GENOMIC DATABASE

Tumor-type Specific Data Models

Full disease model tailored to each specific tumor type is available

Acute Myeloid Leukemia

Breast Cancer

Chronic Lymphocytic Leukemia

Colorectal Cancer

Diffuse Large B-Cell Lymphoma

Advanced Endometrial Cancer

Follicular Lymphoma

Gastric/Esophageal Cancer

Head and Neck Cancer

Hepatocellular Carcinoma

Mantle Cell Lymphoma

Melanoma

Mesothelioma

Multiple Myeloma

Non-small Cell Lung Cancer

Ovarian Cancer

Pancreatic Cancer

Metastatic Prostate Cancer

Renal Cell Carcinoma

Small Cell Lung Cancer

Advanced Bladder Cancer

Core Data Model

Lightweight clinical data model for all other histologies

EXAMPLES

Cholangiocarcinoma

Glioblastoma Multiforme (GBM)

Papillary/Follicular Thyroid

Published research using the CGDB

TUMOR SPECIFIC

CANCER RES. 2020

[Identification of genomic alterations related to treatment progression in RWD.](#)

ONCOLOGIST. 2021

[RAS amplification as a negative predictor of benefit from anti-EGFR containing therapy regimens in metastatic colorectal cancer.](#)

TUMOR AGNOSTIC

JAMA NETW OPEN. 2020

[Prevalence of high tumor mutational burden and association with survival in patients with less common solid tumors.](#)

AACR 2020

[Pan-cancer profiling of the effect of biopsied site on tumor mutational burden measurements in a real-world data cohort.](#)

[Browse more publications using the CGDB](#)



Contact us to learn more



Fact Sheet

Spotlight



Spotlight

Customized projects that include one-time data delivery, expert analytic, regulatory and HTA support tailored to answer a specific research question.

CUSTOM DATA WITH EXPERT SUPPORT

- Custom, licensed clinical and/or genomic data
- Tailored to specific research questions that require unique datasets, endpoints, variables, or precise patient cohort selection

CUSTOMIZED SUPPORT & SERVICES

- **Analytic Service:** In-house Quantitative Sciences team to help derive insights from our datasets for specific research questions
- **Regulatory expertise:** End-to-end regulatory support from pre-specification to submission and post-submission information requests



One time or custom delivery schedule, 3–4 month average recency



Spotlight

Flatiron has delivered over 100 customized Spotlight projects for which we have developed over 50 novel, derived variables.

Sample customized variables to add on top of EDM or CGDB data models:

Outcomes/Events

- Real-world progression*
- Real-world response*
- Real-world adverse effects
- Sites of metastases*

Treatment

- Starts, stops, and holds of oral drugs
- Dosing and dosing schedule
- Reasons for discontinuation
- Reasons for drug ineligibility
- Adjuvant therapy confirmation

Disease/Patient Characteristics

- Comorbidities
- Cardiac dysfunction
- Additional malignancies
- Menopausal status
- Side of colon

Procedures

- Treatment for CNS metastases
- Cardiac assessments
- Local treatment interventions
- Radiation/surgery data

**Available at scale in some disease-specific subscription datasets*



Spotlight

How to work with us on a
Spotlight project

● **Planning & Scoping**

~ 6 – 11 weeks

- Align on scope, cohort and project timelines
- Evaluation of study design and data fitness for use

● **Execution**

~ 6 – 16 weeks *dependent on nature of project and complexity*

- Cohort selection, feasibility for novel variables, data abstraction, patient-level and cohort-level QA
- Deliverables include a data dictionary, analytic guides and the data file, with options for analytic or regulatory deliverables

● **Post-Delivery**

- Training on data model, analytic guidance
- Flatiron review of publications or creation of regulatory collateral

Published research using Spotlight

ASCO-SITC. 2018

[Real world treatment patterns of first-line combination therapies among BRAF+ metastatic melanoma patients stratified by tumor burden](#)

AACR. 2019

[Real-world outcomes of first-line pembrolizumab monotherapy for PD-L1-positive \(TPS \$\geq\$ 50%\) metastatic non-small cell lung cancer \(NSCLC\)](#)

ISPOR EU 2020

[Deriving International Metastatic Renal Cell Carcinoma Database Consortium \(IMDC\) risk categories using oncology electronic health records \(EHRS\)](#)

ESMO 2020

[Real-world patterns of genomic testing in patients with metastatic castration-resistant prostate cancer \(mCRPC\)](#)

PLOS ONE 2020

[Concordance of real-world versus conventional progression-free survival from a phase 3 trial of endocrine therapy as first-line treatment for metastatic breast cancer](#)



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Fact Sheet

Real-World Outcome Variables

Real-world outcome variables

Flatiron's real-world outcome variables, used to derive real-world endpoints, account for the inherent complexities of patient outcomes specific to each cancer type.

Real-world mortality:

- Derived from information in the EHR, Social Security Death Index (SSDI) data, and obituary data
- Learn more: [Health Services Research](#) (2018), [AACR poster](#) (2020)

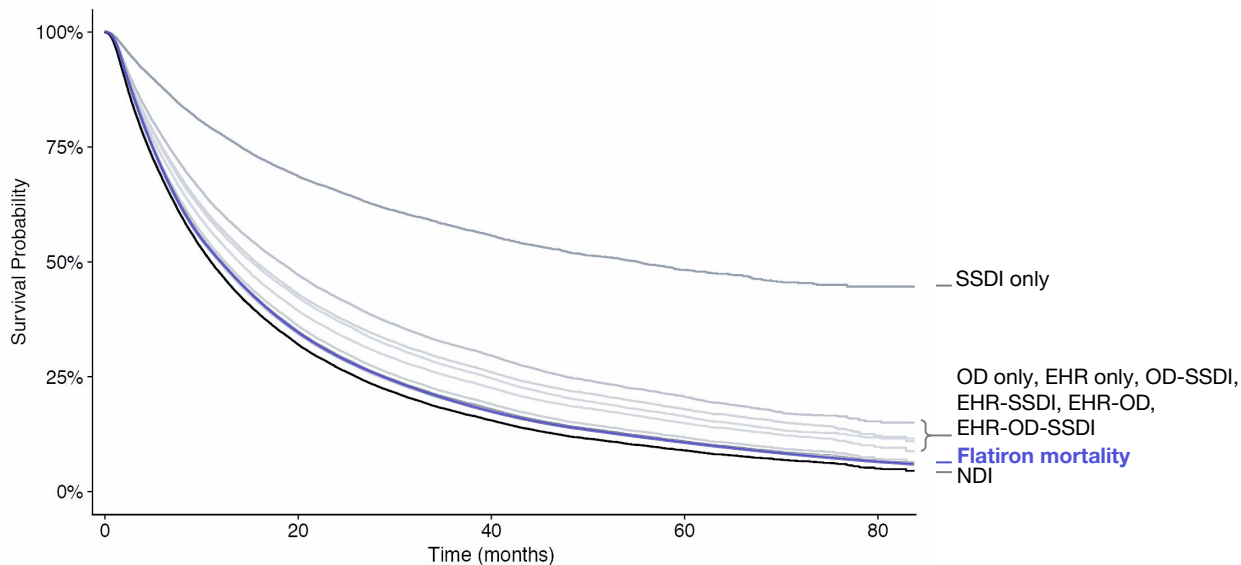
Real-world progression:

- Based on clinician documentation of disease burden from unstructured physician visit notes
- Learn more: [Advances in Therapy](#) (2019)

Real-world response:

- Based on clinician assessments documented in EHRs following radiographic evaluations
- Learn more: [Advances in Therapy](#) (2021)

We benchmarked our real-world mortality variable to the National Death Index to assess for performance and accuracy



Among real-world mortality as captured by SSDI, obituary and EHR data, the median OS estimate using **the composite variable is closest to that of National Death Index**

ADDITIONAL RESOURCES

Poster

[2020 Validation \(AACR\)](#) [↗](#)

Webinar

[RWD vs the Gold Standard](#) [↗](#)

Article

[RWD and the case of the missing deaths](#) [↗](#)

We engage in proof-of-concept projects with regulators to apply these real-world endpoints

**We have co-authored with the FDA on our real-world endpoints:
4 publications using real-world overall survival (rwOS) and 3 publications using real-world progression-free survival (rwPFS)**

	MANUSCRIPT TITLE	JOURNAL	YEAR
Flatiron rwOS used	Characteristics of Real-World Metastatic Non-Small Cell Lung Cancer Patients Treated with Nivolumab and Pembrolizumab During the Year Following Approval	The Oncologist	2018
	Real-World Evidence In Support Of Precision Medicine: Clinico-Genomic Cancer Data As A Case Study	Health Affairs	2018
	Real-World Outcomes of Patients with Metastatic Non-Small Cell Lung Cancer Treated with Programmed Cell Death Protein 1 Inhibitors in the Year Following US Regulatory Approval	The Oncologist	2019
	An Exploratory Analysis of Real-World End Points for Assessing Outcomes Among Immunotherapy-Treated Patients With Advanced Non-Small-Cell Lung Cancer	JCO Clinical Cancer Informatics	2019
Flatiron rwPFS used	Real-world Progression, Treatment, and Survival Outcomes During Rapid Adoption of Immunotherapy for Advanced Non-Small Cell Lung Cancer	Cancer	2019
	Generating Real-World Tumor Burden Endpoints from Electronic Health Record Data: Comparison of RECIST, Radiology-Anchored, and Clinician-Anchored Approaches for Abstracting Real-World Progression in Non-Small Cell Lung Cancer	Advances in Therapy	2019
	Characterizing the Feasibility and Performance of Real-World Tumor Progression End Points and Their Association With Overall Survival in a Large Advanced Non-Small-Cell Lung Cancer Data Set	JCO Clinical Cancer Informatics	2019



Contact us to learn more