

Unlocking real-world evidence for regulatory decision making

Flatiron Health leads the industry in real-world evidence (RWE) regulatory experience.

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Supporting RWE Regulatory Success

Flatiron supports life sciences companies using RWE for regulatory use cases.

Flatiron has helped thoughtfully advance regulatory submissions to the FDA, EMA and PMDA with our biopharmaceutical partners. Informed by our deep experience interacting with health authorities on the use of RWE in oncology, Flatiron regularly:

Authors real-world data/evidence (RWD/E) portions of briefing packages to support our life science partner's health authority meetings on the use of Flatiron RWD/E for regulatory decision-making.

Participates in formal health authority meetings, to provide information on Flatiron's processes and data and support our client's regulatory positioning of RWD/E.

Provides clients with regulatory-facing documentation that supports Flatiron Health real-world data (RWD) as fit-for-purpose.

Flatiron's regulatory service offerings have resulted in Flatiron RWD being included in over 40 global regulatory submissions as of March 2025.

Supporting partners' regulatory submissions

In collaboration with life science partners, evidence from Flatiron RWD has been submitted to health authorities for advice and review for oncology indications in both the pre-approval and post-approval settings. We continue to learn from health authority feedback to advance the use of RWE in development programs and better inform our partners about inclusion of RWE in future submissions. Outside of written feedback on submissions involving Flatiron Health RWD, key learnings stem from engaging with regulators about potential regulatory projects on behalf of sponsors. We also work closely with our partners on their health authority meetings and regulatory submissions.

Flatiron's Regulatory Strategy services support includes regulatory Fit-for-Purpose Assessments, regulatory strategy-focused workshops and roadmap development, risk analysis, briefing book development, Information Request responses, and Health Authority meeting preparation and attendance.

Two recent examples of how Flatiron's RWD was successfully used to fill evidence gaps in the post-approval setting for regulatory decision-making.

Evidence from Flatiron's RWD played a supportive role in the FDA's accelerated approval of LUMAKRAS® for patients with aNSCLC with KRAS G12C mutation who had received at least one prior therapy. RWE from Flatiron's -CGDB was used to help establish unmet medical need for patients with aNSCLC with KRAS G12C mutation.

Pfizer's ELREXFIO® received EMA approval for treatment of adult patients with relapsed or refractory multiple myeloma, who received at least three prior therapies. Flatiron RWD was used as an external comparator arm to contextualize the Phase 2 single arm trial and was contributed as supportive evidence to the application.



Advancing regulatory science through thought leadership and external partnership

Flatiron collaborates on research to evaluate how RWD can answer key clinical questions and address evidence gaps in regulatory applications.

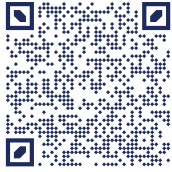
Partnership and Thought Leadership

Flatiron recently reached a milestone of over 1,500 research publications utilizing its electronic health record-derived RWD. This achievement reinforces Flatiron's position as a pioneer in the application of RWD and was made possible through its history of collaboration to support rigorous research projects across the oncology ecosystem, including the 20+ top global developers of oncology therapeutics, academic institutions, policy groups, and regulators around the world.

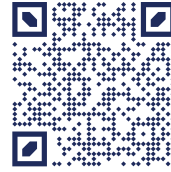
Flatiron has had the privilege to collaborate with policy-shaping organizations such as the Duke-Margolis Center for Health Policy, the U.S. Food and Drug Administration (FDA), and Friends of Cancer Research (FoCR). Since 2016, Flatiron has collaborated with FDA's Oncology Center of Excellence by jointly developing and evaluating innovative RWD study designs and methodologies in oncology to answer meaningful research questions on the care, treatment, and outcomes of patients with cancer. The evidence generated from these projects have advanced the RWE field in oncology.

Together, we are advancing the use of RWD/RWE to support regulatory decision-making.

Sample of recent Flatiron Health co-authored publications



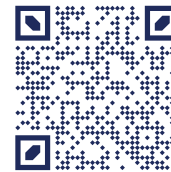
Pragmatism in
Postmarket Trials



Real-world Overall
Survival Using Oncology
Electronic Health Record
Data: Friends of Cancer
Research Pilot



Operational Tools and Best
Practices to Support Electronic
Health Record-Sourced Data
Quality, Relevance, and Reliability
at the Data Accrual Phase



Exploring Racial Disparities
in Treatment Patterns and
Outcomes for Patients with
Multiple Myeloma using
Real-World Data



The Friends of Cancer
Research Real-World Data
(RWD) Collaboration Pilot 2.0:
Methodological Recommendations
from Oncology Case Studies

Flatiron will continue to engage in the regulatory policy space through active collaborations, coalitions, trade associations, and with the FDA to advance the use of RWE.

To read more Flatiron Health authored-publications visit:

<https://flatiron.com/publications>



Regulatory intelligence and insights

Flatiron is a leader in the assessment of the global landscape of RWD/RWE use for regulatory decision-making

Flatiron Regulatory Strategy leverages AI technology to identify, evaluate, inform and predict regulatory success using RWE in oncology. Flatiron's regulatory intelligence tools:

- Monitor use and success of RWD in oncology regulatory applications
- Identify new and innovative potential uses of RWD for regulatory purposes across quickly-shifting treatment landscapes
- Synthesize regulatory feedback to perform rigorous risk analysis that predict success of RWD in regulatory submissions

“Beyond knowledge of our own data, Flatiron leverages industry intelligence gathered from regulatory decisions involving RWE in oncology—whether using Flatiron data or not—to continually refine our strategies. This industry intelligence, combined with direct commentary received from regulators on Flatiron's data, enables Flatiron to secure regulatory buy-in early, and ultimately, regulatory approval.”

Lockwood Taylor, PhD, MPH

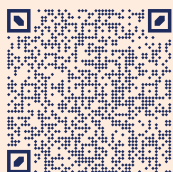
Senior Director, Head of Regulatory Strategy,
Flatiron Health

Unlock RWE for regulatory decision making

For more information:

Contact us to learn more about collaborating together:

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Visit our Resources Hub to learn more about real-world data and its application in oncology.

