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FDA & Flatiron Health expand Data Cancer Research collaboration

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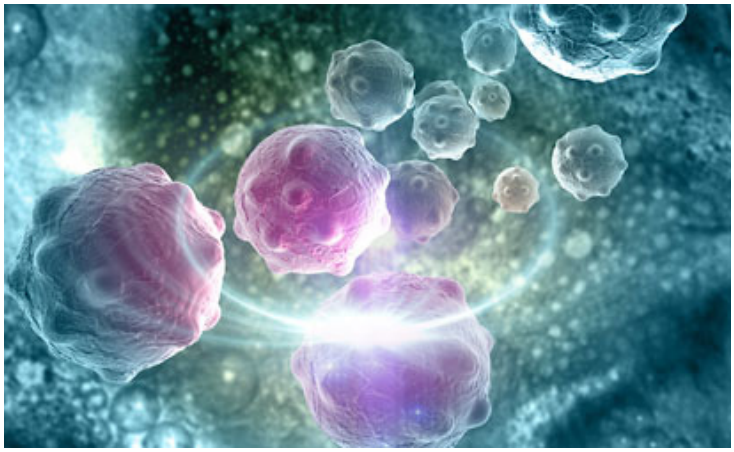

Flatiron Health and the Information Exchange and Data Transformation (INFORMED) Program at the U.S. Food and Drug Administration (FDA) announced a two-year renewal and expansion of their research collaboration agreement.

The collaboration, which began in 2016, has enabled the FDA to better understand how real-world evidence (RWE), derived from de-identified patient datasets curated from electronic health records, can support regulatory decision-making.

Over the past two years, the FDA and Flatiron have explored the use of RWE to generate insights into cancer treatment trends and clinical outcomes in the United States. The expanded collaboration will continue to focus on critical topics related to the use of RWE in regulatory decision-making, including characterization of data quality, validation of reliable real-world clinical endpoints, collaboration on new analytic methodologies, and exploration of innovative applications such as real-world control arms.

Flatiron and the FDA will also evaluate real-world cancer populations that are typically underrepresented in clinical trials. Complementing these direct collaboration efforts, Flatiron will also engage with the FDA through its life sciences partners, as they increasingly incorporate RWE into regulatory filings for postmarketing studies, label expansions and other supportive use cases.

In the first phase of the partnership, Flatiron provided the FDA with de-identified datasets to provide insights on cancer patients with advanced non-small cell lung cancer being treated with immunotherapy.

Richard Pazdur, MD, Director of FDA's Oncology Center of Excellence said, "The FDA recognizes the tremendous importance of analyzing treatment data from the real world. Traditional clinical trials have long provided the high-quality evidence the FDA needs to determine whether a product is safe and effective for its intended use, but traditional trials do not always represent the real world, lack clinical context, and may not provide sufficient follow-up to truly understand the impact of a new therapy on real-world patients. We believe that regulatory-grade real-world data can help inform our decision-making so that we can provide cancer patients with better care."

Zach Weinberg, Flatiron Health Co-Founder and President said, "In order for the entire industry to benefit from RWE, we must ensure that our datasets are comprehensive and of the highest-quality. Working with the FDA enables Flatiron to both learn from their leadership and continue to contribute to standards development. At the end of the day, this is how we're closing the evidence gap in oncology: real-world patient experiences inform research, which ultimately leads to better cancer treatments and outcomes."

INFORMED is an incubator for collaborative regulatory science research focused on supporting innovations that enhance FDA's mission of promotion and protection of public health. The research portfolio of INFORMED is focused on data science and health technology applications such as the use of real world data for clinical evidence generation, the utility of biosensors and the internet of things to quantify intrinsic and extrinsic factors influencing the patient's experience, and opportunities for machine learning and artificial intelligence to augment existing practices.