Greenleaf Health Trio Health

REAL-WORLD EVIDENCE

Real-world evidence (RWE) – the concept of using real-world data (RWD) to improve clinical evidence – has the potential to transform the drug development landscape. The Food and Drug Administration (FDA) recognizes the opportunities presented by RWE and has taken steps to develop a new paradigm for its use in regulatory decision-making.

Companies prepared to employ the power of RWE will require more than just raw data – that's why Greenleaf has partnered with Trio Health to provide a cutting-edge combination of technology and regulatory insight.

Greenleaf's exclusive agreement with Trio Health, a leading provider of real-time data on real-world patients, gives clients the advantage of Trio's groundbreaking Multi-Disease Platform (MDX) technology integrated with Greenleaf's unrivaled regulatory knowledge. The result is a comprehensive resource for enhancing and contextualizing evidence derived from RWD.

MDX PLATFORM

The first-of-its-kind MDX platform tracks patients throughout the course of their treatment by combining disparate information from the physician, pharmacy, and payer 'trio.' MDX offers life science customers best-in-class speed, data certainty, and unparalleled visibility across the clinical and commercial lifecycle.

Trio's comprehensive and high-quality databases are on caliber with FDA-level rigor, giving pharmaceutical and biotechnology companies, specialty pharmacies, and physicians access to information and opportunities that can be leveraged to support pre- and postmarketing activities.

When integrated with Greenleaf's regulatory expertise, Trio's advanced analytics MDX platform delivers unrivaled insights to the industry. In particular, clients gain the ability to transform real-world data into actionable intelligence to innovate and make better decisions, with greater confidence, throughout the product lifecycle. Greenleaf's team of regulatory experts provides end-to-end guidance to companies utilizing MDX data on how to optimize and validate the information to drive effective regulatory strategies.

ABOUT GREENLEAF

Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and medical device companies researching, developing, and manufacturing innovative solutions to pressing global public health challenges.

Greenleaf is committed to serving our clients' needs with extensive expertise, unwavering integrity, and strategic insight in a manner that supports availability of safe, effective, and high-quality drugs, biologics, and devices.

ABOUT TRIO HEALTH

Trio Health's mission is to improve the quality of care in patient outcomes through coordinating the efforts of all patient care stakeholders. Their first-of-its-kind Multi-Disease Platform (MDX) tracks patients throughout the course of their treatment, giving pharmaceutical/biotechnology companies, specialty pharmacies, and physicians access to information and opportunities that simply doesn't exist anywhere else.

www.TrioHealth.com

LEADERSHIP

Greenleaf's team of regulatory experts provides unmatched insight and consultation on all aspects of the FDA's regulatory application of RWE.

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

With a 25-year career at the FDA, including 15 years in senior leadership positions within the Center for Drugs, Dr. Jenkins is an expert in the statutes and regulations that guide drug development.

BOB MEYER, M.D.

Principal, Drug & Biological Products

Dr. Meyer brings more than 25 years of regulatory, industry, and academic leadership to Greenleaf, including prominent roles at the FDA, Merck, and the University of Virginia.

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

An infectious disease physician by training, Dr. Midthun's 28-year career in public service includes her role as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

SEAN HILSCHER

Associate Vice President, Regulatory Affairs

Sean Hilscher has more than 10 years of experience as a consultant and product manager in the international and U.S. health care markets.

UNMATCHED EXPERTISE

Greenleaf is committed to serving our clients' needs with extensive expertise, unwavering integrity, and strategic insight in a manner that supports availability of safe, effective, and high-quality drugs, biologics, and devices.

Greenleaf is guided by experts with a combined total of more than 300 years of FDA experience. The firm's team of experts includes former leaders and regulatory professionals from the FDA, Capitol Hill, top global pharmaceutical and medical device companies, leading law firms, and the top U.S. biotechnology trade organization.

Greenleaf's team of advisors offers a rare blend of perspectives developed as leaders in both the public and private sectors. This wealth of experience informs Greenleaf's understanding of the broad life sciences industry and enables us to deliver valuable insight throughout the product lifecycle.

FULL-SERVICE SUPPORT

Greenleaf professionals work as teams specializing in product quality, manufacturing, and compliance; medical devices and combination products; and drug and biological products.

DRUGS & BIOLOGICAL PRODUCTS

Greenleaf serves as a trusted partner when maneuvering the sophisticated process of bringing new therapeutics to market. The Drug and Biological Products Team specializes in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements.

MEDICAL DEVICES & COMBINATION PRODUCTS

Greenleaf's Medical Device and Combination Products Team guides clients through the complete regulatory process, from the earliest stages of product development, through the FDA review process, to marketing authorization and compliance with postmarket requirements and quality systems.

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE

Greenleaf's Product Quality, Manufacturing, and Compliance Team identifies and promotes practices that will align a client's approach with the FDA's quality, safety, and compliance expectations.