
FRIENDS
of CANCER
RESEARCH
PARTNERSHIPS
SCIENCE
SOLUTIONS

ABOUT FRIENDS OF CANCER RESEARCH

For more than two decades, Friends of Cancer Research (*Friends*) has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. We've been successful due to our ability to convene the right people at the right time and put forth revolutionary, yet realistic ideas. Below are highlights of our collaborations and active initiatives.

A PATHWAY THAT REWARDS INNOVATION

When new drugs aiming to treat serious and life-threatening conditions show unprecedented effect in early clinical testing, patients shouldn't have to wait to receive treatment. To address this complex problem, *Friends* worked with partners across all sectors to take the Breakthrough Therapy Designation from an innovative concept, to scientific whitepaper, to federal law in just 13 months. This FDA development program has already led to the approval of more than 130 life-saving therapies.

THE FUTURE OF TREATING CANCER: TMB & IMMUNOTHERAPIES

Tumor mutational burden (TMB) measures the quantity of mutations found in a tumor. This type of biomarker is currently under study to evaluate whether it may help predict the likelihood a patient with cancer will benefit from immuno-oncology (IO) therapies. To address a significant lack of standardization for TMB calculation and reporting *Friends* is engaging stakeholders across all health sectors to set a new standard for the future of TMB.

MAKING CLINICAL TRIALS MORE OPEN & REPRESENTATIVE

Eligibility criteria are necessary in clinical trials to define the patient population, isolate the potential effect of an investigational drug, and ensure that the trial is conducted safely. However, excessive or overly rigid eligibility criteria may impair the rate of trial accrual, restrict patient access to investigational drugs, and limit the ability to generalize the results to the broader population of patients. The American Society of Clinical Oncology (ASCO) and *Friends* began a joint project to develop and advance specific strategies to change the exclusionary nature of eligibility criteria.

DESIGNING THE FUTURE OF CELL THERAPIES

Advancements in science have led to an improved understanding of cancer and the fruition of personalized therapies, such as immunotherapies. Research on T-cell receptor (TCR)-based therapies, including chimeric antigen receptor (CAR) T-cell therapy, have emerged as a new paradigm for treating cancers. To date, the use of CAR T-cell therapy is available at a limited number of FDA-approved treatment centers. *Friends* and the Parker Institute for Cancer Immunotherapy are partnering to optimize the regulatory process to adapt to the new frontier for patients.

ENHANCING INFORMATION ABOUT PRESCRIPTION DRUGS

Patients, caregivers, and their physicians and nurses need high quality sources of information about the prescription drugs they use. While many sources of information exist, none can deliver as strong assurances of reliability and scientific accuracy as FDA-approved product labels. *Friends* data shows that most cancer drug labels are currently out of date. To address this we have created a strategy for FDA to play a more active role in facilitating timely inclusion of new information on labels.

CREATING A BLUEPRINT FOR DRUG/DIAGNOSTIC CO-DEVELOPMENT

While cutting-edge drugs have access to special FDA pathways and approval mechanisms, the addition of companion diagnostics that enable their use can complicate the regulatory process. Through our annual "Blueprint" forum, with our partners at Alexandria Real Estate Equities, Inc., we develop innovative solutions and approaches to address the challenges of drug/diagnostic co-development.

ADVOCACY EDUCATION + ACTION

Advocates devote their time, energy, and resources to help patients. To make the greatest impact they need the knowledge and understanding of the laws and regulations affecting how new treatments get to patients and the institutions that are involved in the process. Through the *Friends* Advocacy Education program, advocates acquire the necessary tools to effectively communicate with developers and regulators enabling them to engage with all sectors who need to be better guided by patient input.

ENSURING SAFETY & EFFICACY THROUGH REAL-WORLD DATA

Real-world evidence (RWE) is the clinical evidence derived from data on the uses and potential benefits and/or risks of a medical product outside of a traditional clinical trial, which does not necessarily reflect the breadth of data that can be collected in a more diverse real-world setting. For the past year, *Friends* has convened stakeholders to create a standard dataset curation process and validated framework so data collection can be operationalized for RWE.

CIRCULATING TUMOR DNA (CTDNA)

The use of liquid biopsies and assessment of ctDNA is rapidly advancing with tests being promptly adopted within oncology clinical practice and drug development for cancer detection, prognosis determination, and molecular characterization of a patient's tumor. Leveraging the expertise of a multi-stakeholder group, *Friends* proposes to operationalize a pilot project to examine the role of ctDNA as a tool for monitoring a response to therapies.

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1800 M Street NW, Suite 1050 South
Washington, DC 20036

Tel: 202.944.6700 *Email:* info@focr.org

@CancerResrch
@FriendsofCancerResearch
www.focr.org