FRIENDS of CANCER RESEARCH

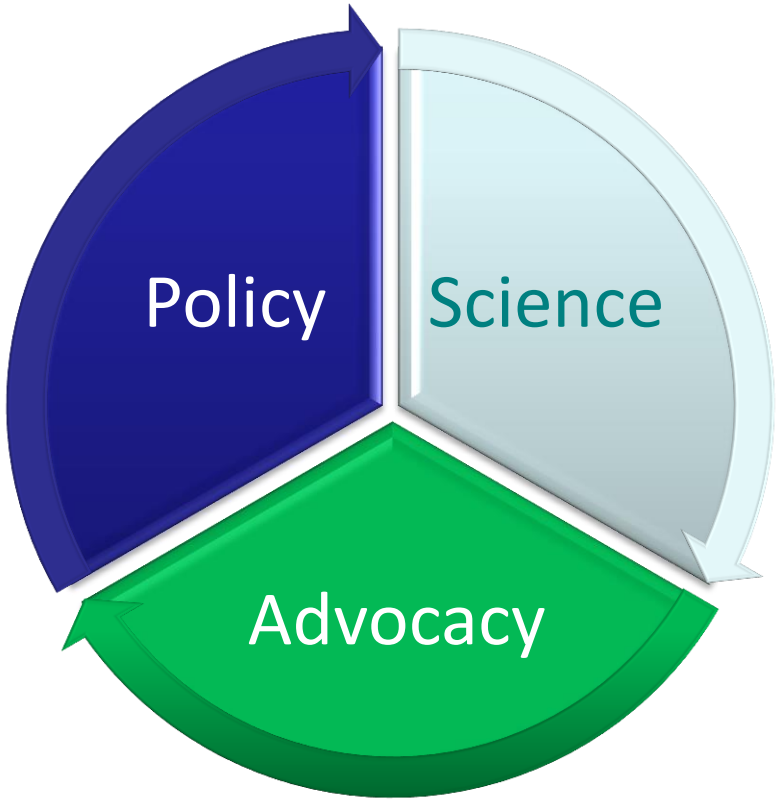
Accelerating the Pace of Innovation

Washington, DC-based Think Tank & Advocacy Organization

A unique model to create a path to better drug development and approval through **scientific**, **regulatory**, and **legislative solutions**.

Develops groundbreaking partnerships:

- Federal Agencies (FDA, NIH, NCI)
- Academic Research Centers
- Professional Societies
- Industry
- Advocacy Organizations



Ryan Hohman, JD, Managing Director, Policy & Public Affairs

Overcoming Delays in Drug Approvals:
Breakthrough Therapy

Problem: Progress in personalized medicine is producing drugs with unprecedented impact visible early in their development, but better regulatory tools were needed to keep pace.

Drugs showing obvious, outsized potential to help patients still were required to go through the standard review procedure.

Solution: 2011 *Friends*-Brookings Conference: Advocacy-initiated collaboration of experts from FDA, NIH, NCI, academia, and industry created Breakthrough Therapy pathway to expedite the drug development process for products that show remarkable clinical activity early.

✓**Patients get revolutionary drugs faster, industry gets their therapies to market sooner, FDA is more efficient— But didn't happen until advocacy got it started.**

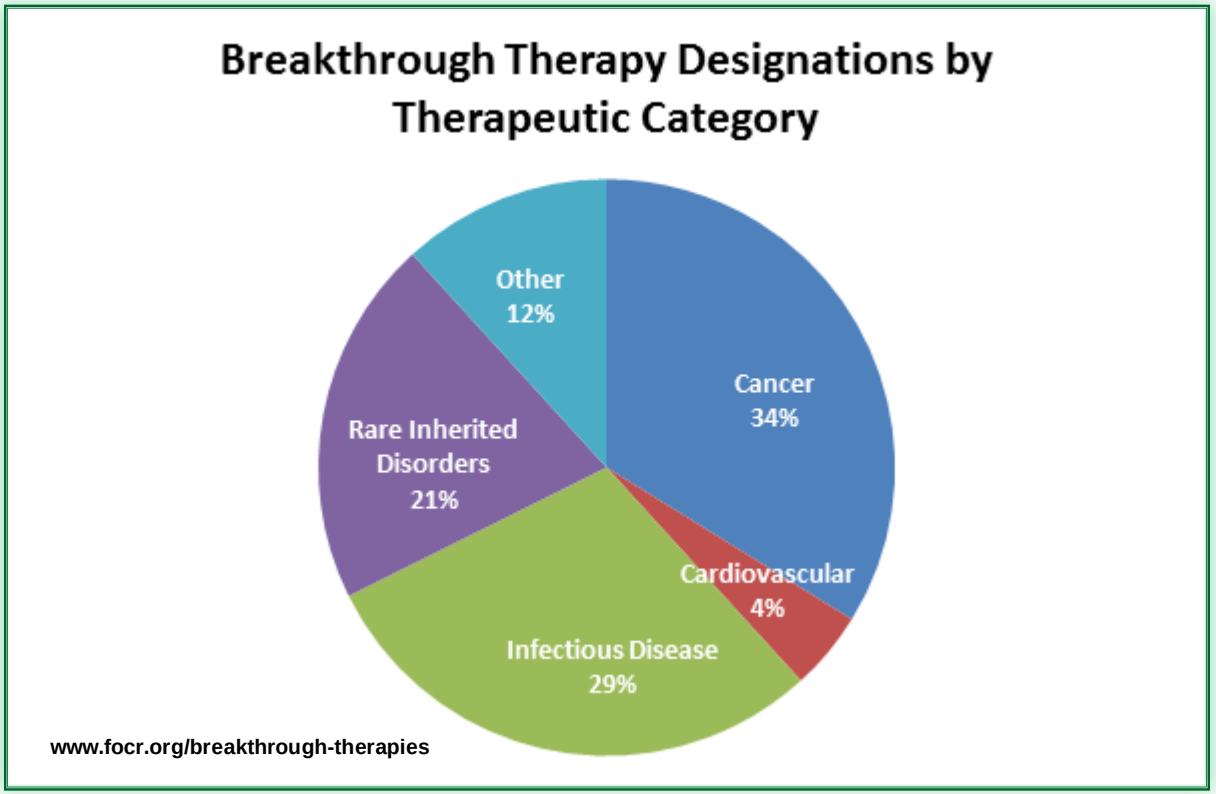
1 Year: Panel → Whitepaper → Bipartisan Legislation → New Pathway at FDA

1 Year: 100+ Applications → 38 Designations (13 in cancer) → 3 Full Approvals

Breakthrough in Action

As of October 7, 2014, FDA has given **11 approvals** to drugs designated as Breakthrough Therapies.

- FDA lists **228* total requests** for Breakthrough designation, **65 requests granted**, and **124 requests denied**.



*FDA does not disclose information regarding specific drugs or sponsors.

Overcoming Hurdles in Clinical Trials: LUNG-MAP

Problem: Clinical trials can be inefficient, expensive, time-consuming, and infrastructure-intensive, difficult to enroll patients and often times require expensive genetic testing.

Solution: Multi-drug, multi-arm, biomarker-driven clinical trial protocol.

✓**A more efficient and effective model:** Trial matches companies with the patients whose tumors are most genetically relevant to the therapies they are developing.

✓**Groundbreaking Public-Private Partnership:** Five major pharmaceutical companies, Foundation Medicine, NCI, SWOG, FDA, FNIH, and multiple advocacy organizations

✓**Better trials for patients, more efficient for industry, increased government collaboration.**

"Lung-MAP will, I think, set a standard for how we want to conduct this sort of precision medicine for cancer going forward."–Dr. Francis Collins, Director, National Institutes of Health (NIH)

Nov. 2012 *Leaders from industry, FDA, NCI, academic research, & advocacy developed the concept* → **Nov. 2013** *Final trial design and first experimental drugs announced* → **June 2014** *Lung-MAP launched at cancer centers nationwide* → **October 2014:** *Over 350 sites across the United States now participating*

LUNG-MAP

HOW IT WORKS.

GENOMIC PROFILE SCREENING

Patients are screened using a comprehensive genomic profiling platform (FoundationOne) that looks at over 200 cancer-related genes for genomic alterations. Instead of having to undergo multiple diagnostic tests to determine eligibility for many different studies, enrollees are tested just once

SUB-STUDY ASSIGNMENT

Based on the results of this screening, patients are assigned to whichever one of up to five sub-studies testing different investigational treatments best suits their genomic profile.

INNOVATIVE APPROACH

This innovative approach improves a patient's likelihood of receiving a drug that will work for them while allowing for new therapies in development to be added as the trial progresses.

Lung-MAP Trial Arms for Treatment