Innovative Precision Medicine Trial, Lung-MAP, Expands Across Nation

More than 700 sites activated
210 patients enrolled

May 19, 2015 – Friends Creates Momentum for Enhancing Patient Input and Regulatory Innovation
Leaders from advocacy, industry, science, academia and government discuss pressing issues with FDA leadership and develop framework for patient input

Friends Plays Key Role in House 21st Century Cures Act

February 23, 2015 – Friends holds congressional briefing on 21st Century Cures Act
May 21, 2015 – House Energy & Commerce Committee unanimously passes bill
July 10, 2015 – Bill passes House

June 10, 2015 – Friends Convenes Multi-stakeholder Forum Exploring Rate-limiting Steps in Manufacturing Readiness for Breakthrough Drug Development

September 9, 2015 – Friends Charts Blueprint for Personalized Medicine
Friends partners with Alexandria Real Estate Equities to host forum addressing how genetic databases alter research
Breakthrough Continues to Revolutionize Drug Development

*Friends* was pivotal in creating the designation, moving it from an idea to reality in just 13 months. Since the program began there have been:

- 384 breakthrough therapy designation requests
- 118 designations granted
- 39 FDA approvals
- 30 approvals for novel indications

Within the last year there were:

- 34 cancer drugs that received the designation
- 21 breakthrough cancer drugs approved

**Breakthrough Designations by Therapeutic Categories**

- Cancer: 49.1%
- Infectious Disease: 14.2%
- Cardiovascular: 2.8%
- Rare Inherited Disorders: 13.2%
- Other: 20.8%

**Key Dates**

**October 22, 2015 – *Friends* Celebrates Incredible Leaders, Accomplishments**

*Friends* honors Marlene Malek, Rep. Diana DeGette (D-CO) and Rep. Fred Upton (R-MI) at 19th Annual Cancer Leadership Awards Reception; NIH Dir. Francis Collins surprises attendees through song “If Not Now, Tell Me When”

**November 12, 2015 – *Friends* Partners with Prevision Policy to Launch Biopharma Congress**

Keynotes delivered by CMS Acting Administrator Andy Slavitt and FDA CDER Dir. Janet Woodcock; Former FDA Commissioners Margaret Hamburg and Mark McClellan discuss future of FDA with Ellen Sigal

**November 17, 2015 – 8th *Friends*-Brookings Annual Meeting**

Califf makes first appearance post-Senate confirmation hearing; meeting sought recommendations to:
- Integrate new measures of tumor response into drug development programs
- Develop a framework to improve use of expansion cohorts to support drug approvals
- Facilitate incorporation of patient reported outcomes into drug development and support improved collaboration between government and sponsors
About Friends

Friends of Cancer Research (Friends) drives collaboration among partners from every healthcare sector to power advances in science, policy and regulation that speed life-saving treatments to patients.

During the past 20 years, 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 to date due to our ability to convene the right people at the right time and put forth revolutionary, yet realistic ideas.

As we embark on this milestone year, we look forward to continuing this critical work with our trusted partners and continue to lead the way in evolving cancer research and treatment.

2015 Publications

The articles below were created either entirely by or with input from Friends of Cancer Research and published in 2015.

- The role of nonrandomized trials in the evaluation of oncology drugs. Clinical Pharmacology and Therapeutics, May 2015.
- Improving evidence developed from population-level experience with targeted agents. Clinical Pharmacology and Therapeutics, May 2015.
- Capturing Symptomatic Adverse Events From the Patients’ Perspective: The Potential Role of the National Cancer Institute's PRO-CTCAE Measurement System. 2015 Conference on Clinical Cancer Research.
- The Blurring of Phase 1, 2 and 3 Trials in Oncology: Expansion Cohorts in Phase 1 Trials. 2015 Conference on Clinical Cancer Research.
- Regulatory decision-making meets the real world. Science Translational Medicine, November 2015.

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Thank you to all of the Friends staff and collaborators who contribute to our work.

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A note from the Executive Director

On behalf of Friends of Cancer Research, I would like to thank all of our supporters and collaborators for your steadfast commitment to our mission. We’ve made great strides in developing new models to enhance science and innovation.

As we embark on our 20th year, we look forward to continuing partnerships built on cutting-edge science to create solutions that will change the cancer landscape.

Your support is vital to ensuring this work can continue.

With great appreciation,

Jeff Allen, Ph.D., Executive Director, Friends of Cancer Research
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