



**PRECISION MEDICINE AND BIOMARKER TESTING:
*TWO SIDES OF THE SAME COIN***

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**December 11, 2018
National Lung Cancer Roundtable**

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THE LUNG CANCER PATIENT ... *THEN...*



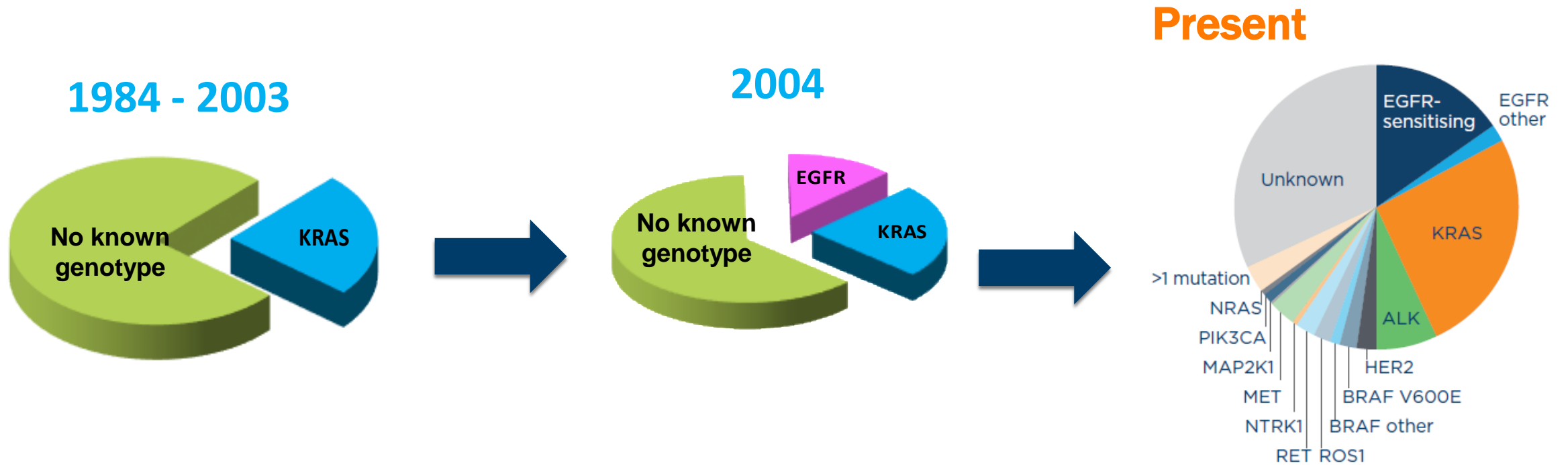
AND... NOW...



When the lung cancer patient climbs mountains.

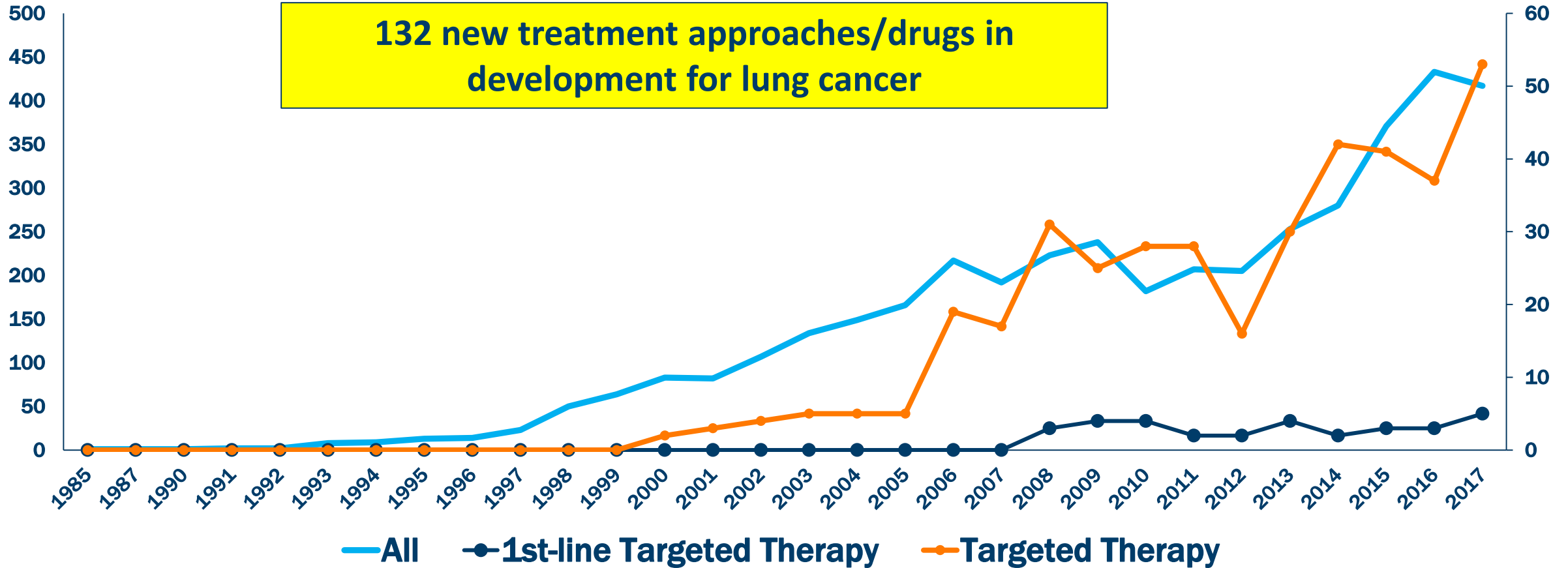
<https://www.nytimes.com/2018/01/04/well/live/when-the-lung-cancer-patient-climbs-mountains.html>

AS OUR UNDERSTANDING OF THE MOLECULAR HETEROGENEITY OF LUNG CANCER INCREASES....



Biomarkers identified in lung adenocarcinoma

SO IS CLINICAL RESEARCH...

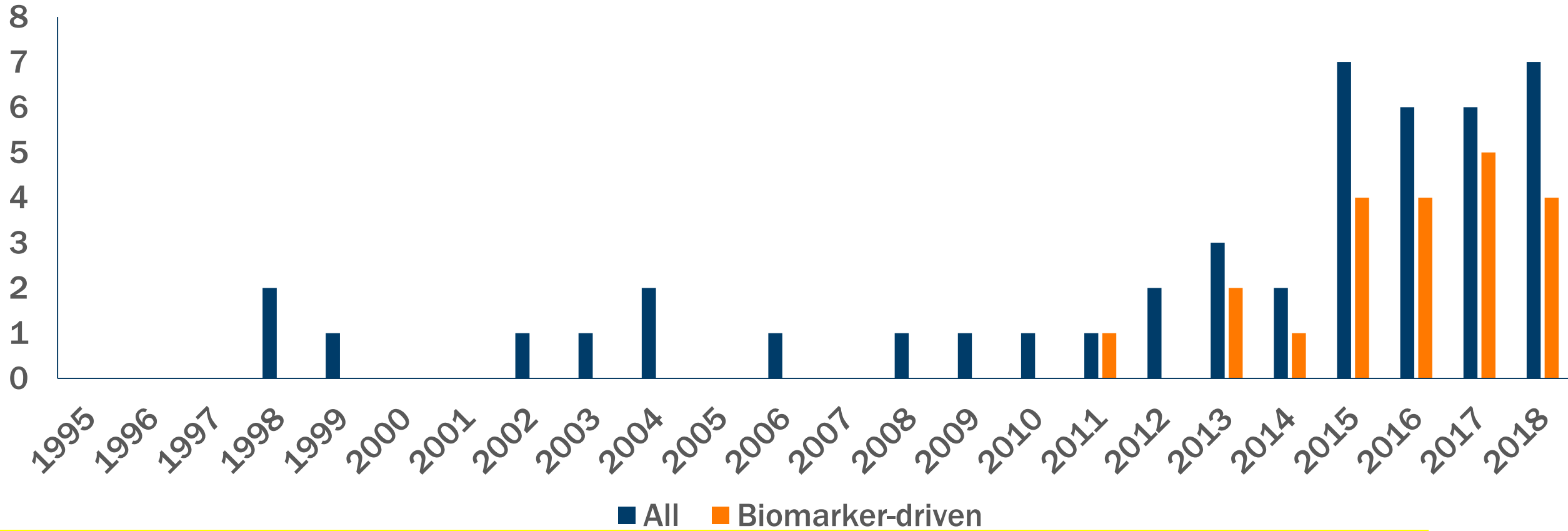


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From: Data downloaded from Clinicaltrials.gov and analyzed (data from April 2018), PhRMA report, 2018, Medicines in Development for Cancer 2018 report

...AND BIOMARKER-DRIVEN DRUG APPROVALS

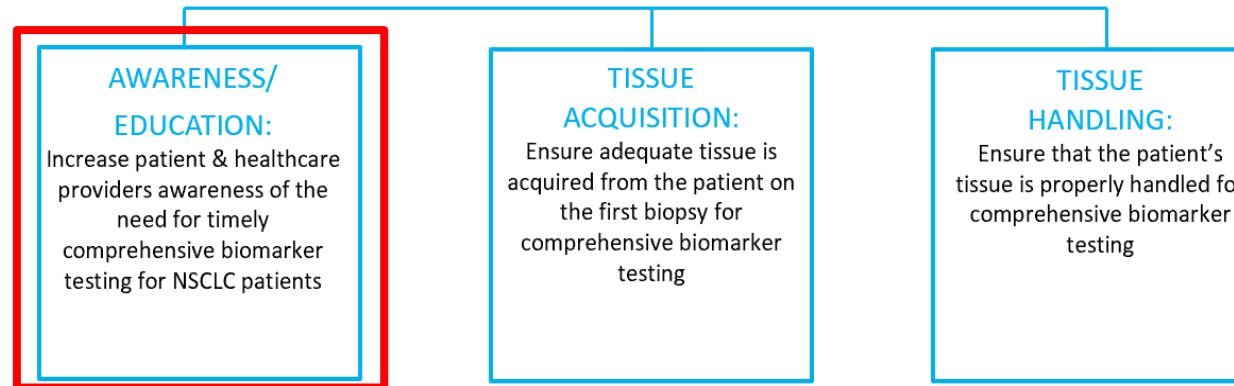
New treatment approaches approved by FDA



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STAKEHOLDERS IN THE TREATMENT JOURNEY

Take Aim is a multi-year, multi-stakeholder initiative to ensure that **all people diagnosed with advanced stage non-small cell lung cancer** have access to **high quality, comprehensive biomarker testing**— a key component of precision medicine



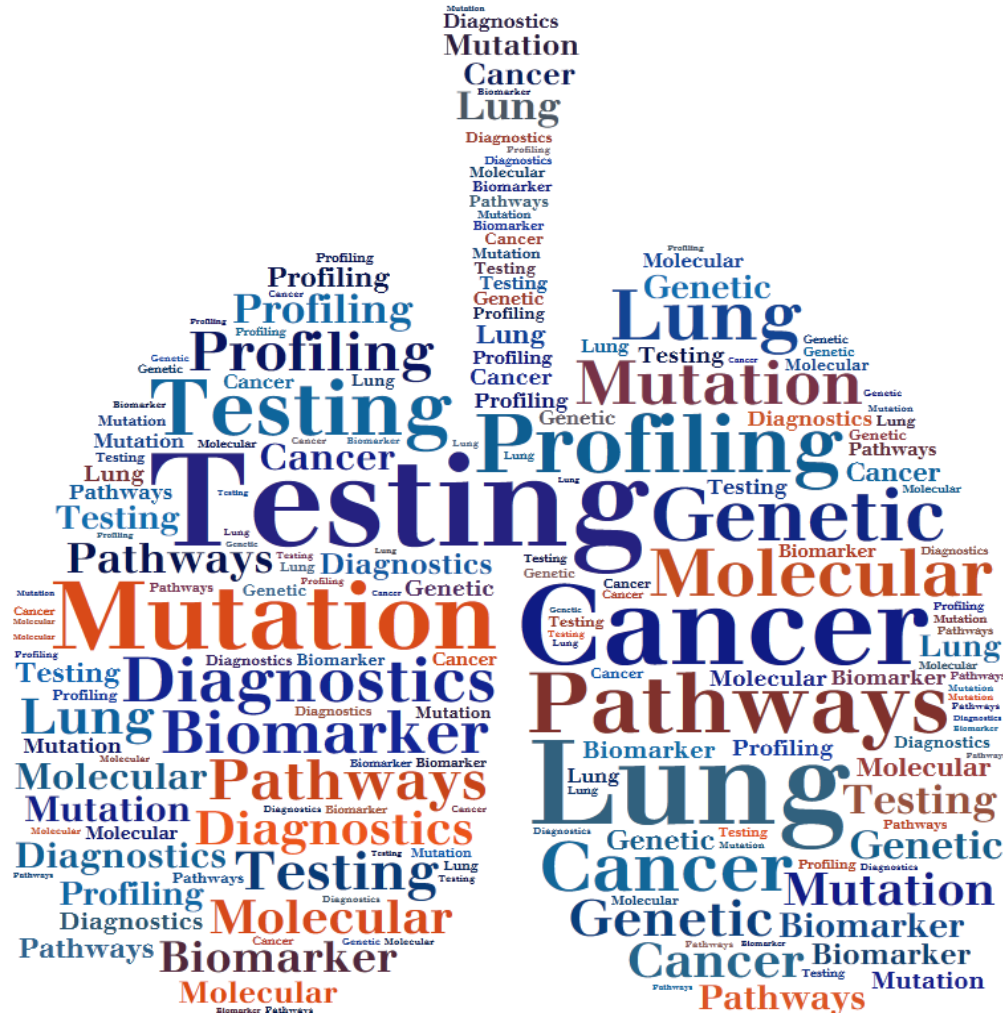
PUBLIC POLICY:
LUNGeivity's Public Policy agenda and initiatives complement and support Take Aims goals of ensuring that patients diagnosed with NSCLC have timely access to high quality, comprehensive biomarker testing

ARE WE BEING CONSISTENT IN OUR TERMINOLOGY?

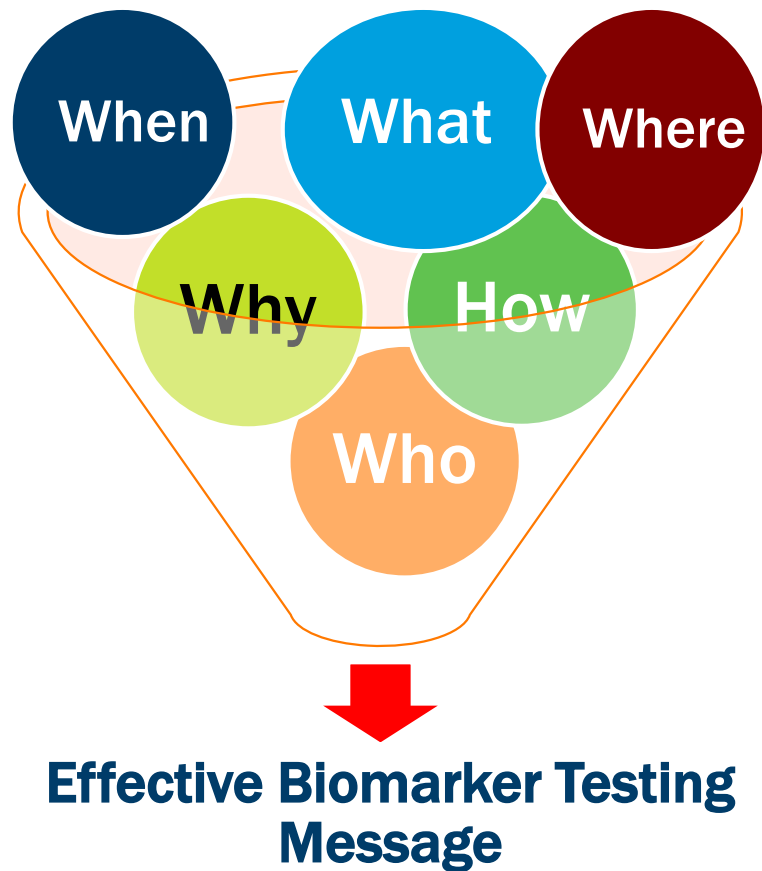
Analyzed terminology being used by 28 organizations (patient advocacy organizations, pharmaceutical and diagnostic companies, and government and health sites)

Major Findings/Recommendations:

1. Too many terms are used by organizations, leading to confusion on the patient's part
2. Participating organizations agreed to use **BIOMARKER TESTING** (because it encompasses both gene-based and IHC-based tests)



ARE WE BEING CONSISTENT IN OUR MESSAGE/CALL-TO-ACTION?



Analyzed messaging content from 24 organizations (patient advocacy organizations, pharmaceutical and diagnostic companies, and professional societies)

Major Findings/Recommendations:

1. Patients are receiving confusing messages **without a clear call to action**
2. Most organizations included in the audit are not answering all six questions
3. Results presented at CancerCare Roundtable → Working with CancerCare and LungCAN to operationalize findings

ARE NSCLC PATIENTS AWARE ABOUT BIOMARKER TESTING?

		REM (N=336)	LUNGevity (N=373)
Race	American Indian or Alaska Native	11 (3.3%)	2 (0.6%)
	Asian	15 (4.5%)	9 (2.5%)
	Black or African American	61 (18.2%)	14 (3.9%)
	Native Hawaiian or Other Pacific Islander	8 (2.4%)	1 (0.3%)
	Other	20 (6.0%)	14 (3.9%)
	White	221 (65.8%)	321 (88.9%)
Education	College or graduate/professional school	154 (45.8%)	245 (68.2%)
	Some college or technical school	116 (34.5%)	97 (27.0%)
	High School or GED	62 (18.5%)	17 (4.7%)
	No High School	4 (1.2%)	0 (0.0%)
Biomarker testing (Self-reported)	I have not been tested for a biomarker/I don't know	83 (51.5%)	51 (16.3%)

REM – Racial and Ethnic Minority

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REPORTS TO DATE

Testing Terminology Audit – LUNGEvity conducted an audit that looked at the terminology that various parties (diagnostic companies, pharma companies, NCI, non-profit organizations) use when discussing testing. The goal was to identify a common vernacular that we can all use – to reduce confusion in the patient population. We convened a roundtable to discuss results of the audits. Findings from the audit and roundtable are encapsulated in a whitepaper.

Guidelines Comparison and Literature Review – LUNGEvity compared seven guidelines that govern various bodies (ASCO, NCCN, ACCP, IASLC/CAP/AMP, ESMO). We identified areas of similarity, differences, and gaps. We also conducted a lit search to look for any existing studies that demonstrate the benefit (outcome/economic) of biomarker testing to guide treatment decisions.

Re-biopsy survey – LUNGEvity conducted a survey to understand patients' attitude toward repeat biopsy at various decision points. The purpose of the survey was to address HCP's inherent perception that patients do not want invasive procedures and therefore do not perform biopsies when they perhaps should. When asked, patients overwhelmingly stated that they would opt for a biopsy to aid decisions on better treatment options including clinical trials.

Testing Messaging Audit – LUNGEvity conducted an audit of marketing and education materials created by key stakeholders with a focus on key message points. The results of this study were presented at a meeting in April 2017. A discussion at this meeting included barriers to, and solutions for, consistent messaging between industry partners; the educational needs for both patients and HCPs; and potential unified education/awareness campaigns. LUNGEvity's short-term goal is to spearhead a unified biomarker campaign in patient advocacy. Long-term goals include more education about the importance of acquiring core tissue and including more information on testing in major guidelines.

Policy Meeting Summary – LUNGEvity conducted a meeting to discuss policy issues related to biomarker testing (Date of Service (DOS), NGS NCD, DAIA). The conversation and next steps are summarized in a whitepaper.

Comment Letters – As part of the Public Policy arm of the Take Aim Initiative, LUNGEvity submitted comment letters to various agencies re: Date of Service Rule (DOS) and the Next Generation Sequencing National Coverage Determination (NGS NCD).

MEETINGS TO DATE

July 11, 2018 – LUNGEvity multi-stakeholder Take Aim Planning Meeting with Take Aim Partners

February 23, 2018 – LUNGEvity/FOCR/ACS CAN – In-person DAIA Education & Engagement Meeting for patient advocates

November 30, 2017 – In-person meeting to update on progress and policy issues (DAIA, CMS, DoS) as well as discuss the Kraft Precision Medicine Accelerator

October 16, 2017 – Co-hosting Hill Briefing with AdvaMed Dx on the role of advanced diagnostics in the precision medicine paradigm

April 4, 2017 – In-person roundtable to disclose results of messaging audit and develop consensus around next steps to create consistency of an “ask”

October 3, 2016 – In-person multi-stakeholder meeting to discuss progress on Biomarker testing in the community setting, reimbursement and real-world examples

March 4, 2016 – Webinar to discuss results of guideline audit and lit search

September 7, 2015 – In-person roundtable to disclose results of language audit and develop consensus around terminology to be used

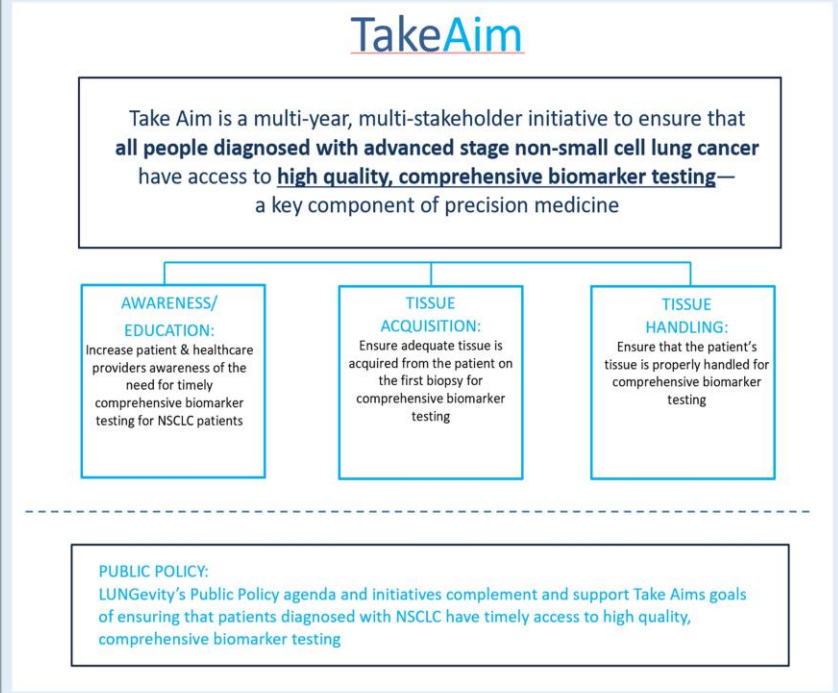
July 17, 2015 – In-person multi-stakeholder meeting to identify barriers to biomarker testing and develop action plan

OVERVIEW

LUNGEvity's Take Aim Initiative focuses on biomarker testing and ensuring that all people with advanced stage NSCLC have access to **timely, high quality comprehensive biomarker testing** – a key component of precision medicine – at both diagnosis and recurrence of their disease. Completing comprehensive biomarker testing at diagnosis and recurrence ensures that patients will be given access to therapies and clinical trials targeted at their cancer's mutation, and that they have the information needed to participate in their healthcare decision-making.

LUNGEvity created Take Aim in 2015 as a multi-stakeholder, multi-year initiative to break down barriers to comprehensive biomarker testing. Multiple partners including professional societies, clinicians, diagnostic companies, leaders in the pharma/biotech industry, payers, and patients work together to address the following issues:

- Increasing patient/provider awareness about biomarker testing
- Changing healthcare practice on inadequate tissue acquisition
- Changing healthcare practice on improper tissue handling



2019 ACTIVITY

MEETINGS

- LUNGEvity-ACS CAN Joint Meeting – Payor Coverage Report Briefing
- Nursing Roundtable
- Pan-Cancer Best Practices Roundtable
- Pre-Analytic Tissue Handling Summit

PROJECTS

- Collaborate with societies, laboratories, diagnostic test manufacturers, and the biotech/pharma community to better support patients' needs on reading, understanding and acting on information from biomarker testing pathology reports.
- Collaborate with the ACCC to lead "Empowering & Educating Patients" workstreams within ACCC's Integration of Pathology into Oncology Care Initiative.

CAMPAIGNS

- Right Track* Campaign with Harvard Business School Kraft Precision Medicine Accelerator
- Inhale For Life* – Biomarker Campaign



Emily Daniels
Colon, CA
Diagnosed with lung cancer at age 22 while 23 weeks pregnant

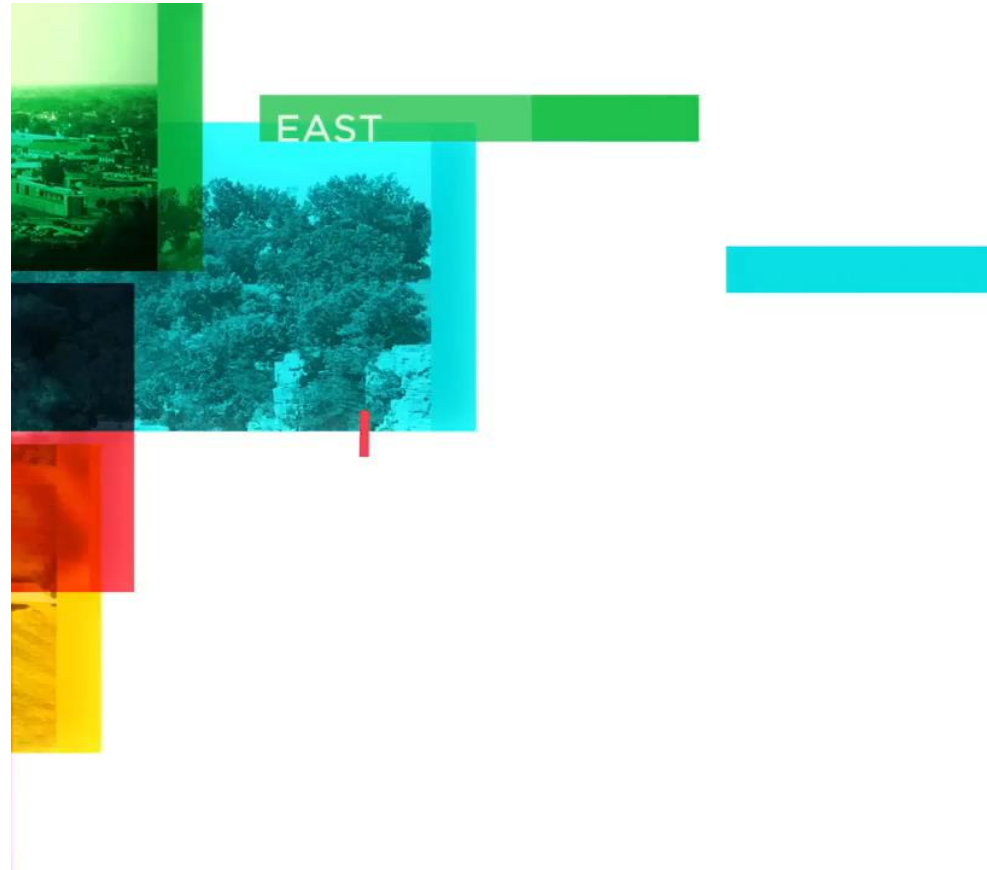
"I had biomarker testing that allowed for me to have very targeted treatment. I take one pill a day that targets those biomarkers and gives me a real chance."

PARTNERS

- | | |
|--|--|
| <p>PROFESSIONAL SOCIETIES</p> <ul style="list-style-type: none"> AdvaMedDX American Clinical Lab Association (ACLA) American College of Chest Physicians (CHEST) Association of Community Cancer Centers (ACCC) Association of Molecular Pathologists (AMP) College of American Pathologists (CAP) Oncology Nursing Society (ONS) <p>COLLABORATORS</p> <ul style="list-style-type: none"> Friends of Cancer Research Harvard Business School, Kraft Precision Medicine Accelerator McDermott, Wills & Emery Todd Strategy | <p>PHARMACEUTICAL COMPANIES</p> <ul style="list-style-type: none"> AbbVie AstraZeneca Boehringer Ingelheim Bristol-Myers Squibb Genentech Merck Novartis Pfizer <p>DIAGNOSTIC COMPANIES</p> <ul style="list-style-type: none"> Biodesix Foundation Medicine Guardant Health Myriad Veracyte |
|--|--|

NIKKI MARTIN
Director of Precision Medicine Initiative

BIOMARKER TESTING MAKES A DIFFERENCE



IF WE GET IT RIGHT...

Surviving lung cancer should be the *EXPECTATION*...



... *NOT* the exception