LUNGEVITY
Find it. Treat it. Live.

TAKE AIM INITIATIVE

Increasing Timely Access to Biomarker Testing in Non-Small Cell Lung Cancer: Education and Awareness

Summary Report of **April 4, 2017** Stakeholder meeting

Acknowledgments

LUNGevity is deeply indebted to the lung cancer patient/survivor community for taking the time to share their perspectives for the *Take Aim* initiative

Authors

Andrea Ferris
Kayla Haskins
Meriam Driss
Upal Basu Roy

LUNGevity Foundation

CHICAGO OFFICE
228 S. Wabash Avenue, Suite 700
Chicago, IL 60604
Phone: 312.407.6100
Fax: 312.464.0737
info@LUNGevity.org

BETHESDA OFFICE
6917 Arlington Road, Suite 352
Bethesda, MD 20814
Phone: 240-454-3100
Fax: 240-497-0034

List of abbreviations

AACR : American Association for Cancer Research
ACCC: Association of Community Cancer Centers
ACLA: American Clinical Laboratory Association
AMP: Association for Molecular Pathology
ASCO: American Society for Clinical Oncology
ATS: American Thoracic Society
CAP: College of American Pathologists
CMS: Center for Medicare and Medicaid Services
ESMO: European Society for Medical Oncology
HCP: Healthcare Provider
IASLC: International Association for the Study of Lung Cancer
IHC: Immunohistochemistry
NCCN: National Comprehensive Cancer Network
NGS: Next generation sequencing
OMB: Office of Management and Budget
PAG: Patient Advocacy Group
QOPI: Quality Oncology Practice Initiative
SIR: Society of Interventional Radiology

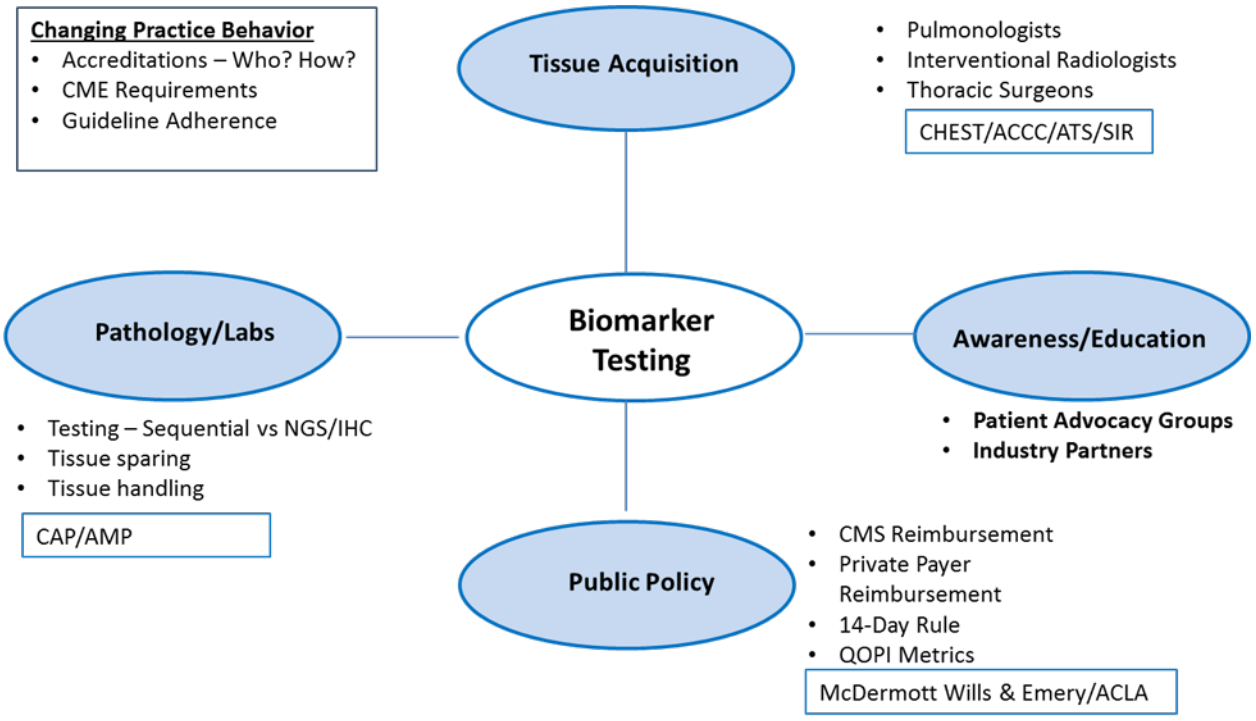
LUNGEVITY
Find it. Treat it. Live.

The *Take Aim* initiative: Overview

LUNGevity's Take Aim Initiative is aimed at increasing biomarker testing and ensuring that patients have access to testing to help guide their treatment decisions in a timely way.

The goal of LUNGevity's *Take Aim* initiative is to ensure that all lung cancer patients have access to precision medicine (including immunotherapy)—that patients are tested ***at diagnosis*** for the profile of their tumors, that they are given access to therapies or clinical trials targeted at their cancer's mutations, and that they have the information they need to participate in their healthcare decision making.

Take Aim is a multi-stakeholder, multi-year initiative to break down barriers to biomarker testing—a key component of precision medicine. LUNGevity works with multiple partners including professional societies, clinicians, industry partners, payers, and patients to address the following issues:



Multi-stakeholder marketing/education messaging meeting

On April 4, 2017, LUNGevity convened a multi-stakeholder roundtable during the AACR Annual Meeting, as part of the Take Aim Education/Awareness work stream. This roundtable included representatives from pharmaceutical companies, diagnostic testing companies, patient advocacy groups, and professional societies.

The purpose of the meeting was two-part:

1. To share with relevant stakeholders' updates on the initiative's progress since the October 3 meeting
2. To discuss results of our audit surveying the current landscape of patient and HCP-facing education and awareness materials with a particular focus on the messaging or "ask"

As a prelude to the roundtable, LUNGevity conducted an audit of marketing and education materials with a focus on key message points, the results of which were presented at this meeting. The goal of the meeting was to have an open dialogue about the results of this audit and discuss the possibility of creating and implementing consistent messaging across the various vehicles. Our ultimate hope was to identity three key elements for education and awareness materials that could be consistently used in both patient and HCP-facing materials created by **all** stakeholders. The resulting discussion included dialogue on this possibility among other proposed next steps to move forward with this work stream.

This report includes:

- Data from the audit
- Summary of the discussion at the April 4th meeting
- Suggested next steps for this work stream
- Appendices (Meeting agenda – Appendix A, List of Attendees – Appendix B, and List of Organizations – Appendix C)

Education and Awareness Material Audit

Background and methodology: The Material Audit included work from 25 PAGs, pharmaceutical and testing companies (industry), and professional society organizations (list of organizations included – Appendix C).

As part of the audit, LUNGevity identified six questions that would be relevant for patient education about biomarker testing and evaluated each of the materials to identify how/if they were answered. These questions are:

- ***What*** *is biomarker testing?*
- ***Why*** *biomarker testing is important? How is the information used to decide treatment plans?*
- ***Who*** *(which patients) should get tested?*
- ***When*** *(at what point in the treatment journey) should a patient get tested?*
- ***How*** *is testing done?*
- ***Where*** *is testing done?*

Materials were collected through organization/company ("organizations") websites, social media, and other educational resource websites. Partners and other stakeholders also provided proprietary and embargoed materials. The materials were both branded and unbranded.

The materials were then compiled by organization and reviewed as a whole to determine if each question was answered in at least one of the organization's materials. Materials were reviewed dichotomously rather than a quality-based rating scale; if the question was answered in some form in one material, this was determined to be a "yes." The answers were noted for qualitative insights during analysis, but were not included in the quantitative metrics of this audit.

The materials included were

- materials used by PAGs to talk to patients;
- materials used by industry to talk to patients;
- and materials used by industry to talk to HCPs.

This initial audit **excluded** any pulmonologist, radiologist, or pathologist-facing materials.

Findings:

PATIENT ADVOCACY GROUP – PATIENT-FACING MATERIALS

We first looked at patient-facing materials created by PAGs. Of the seven groups audited, all of them described ***why*** *biomarker testing* is essential for lung cancer patients (Figure 2). Furthermore, most of PAGs materials described ***who*** *should get tested* and ***what*** *is biomarker testing*.

The primary gap noted was that the majority of the PAGs materials did not identify ***when*** *should a patient get tested.* This was noted as an area that needed improvement in these materials.

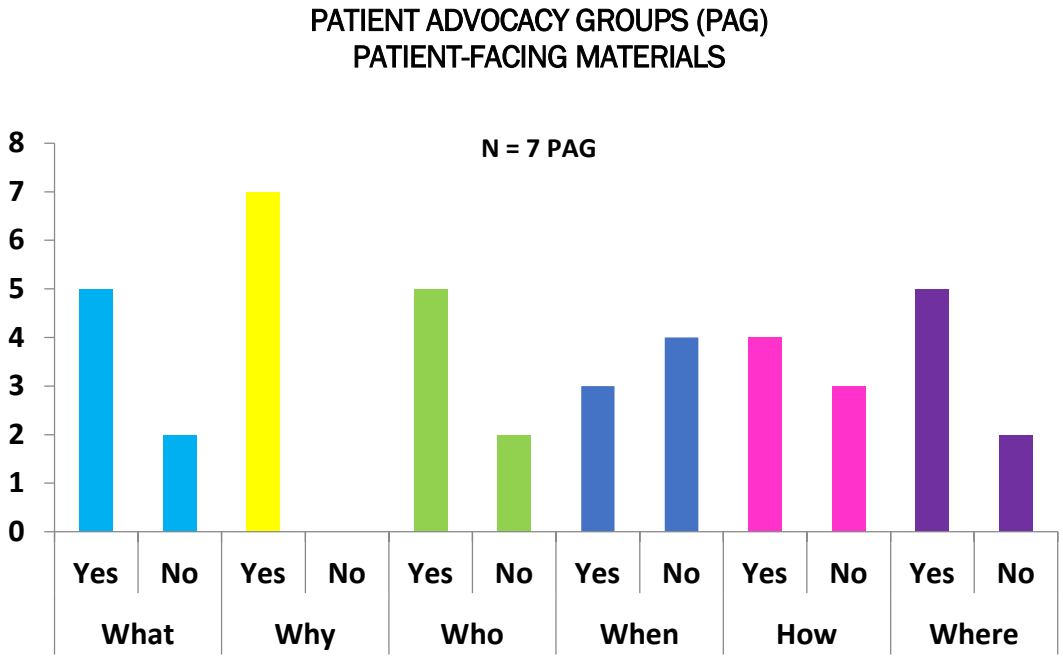


Figure 2

Some representative examples of the types of statements included in PAG materials in response to various questions are:

> ***Why*** *is biomarker testing important*? - "Comprehensive tumor testing helps identify the best treatment for your unique lung cancer."
>
> ***Who*** *should get testing done*? - "This is especially important for people with advanced stage (Stage IV) non-small cell lung cancer."
>
> ***When*** *should a patient get tested?* - "The best time to talk to your doctor about tumor testing is before a biopsy is done."

INDUSTRY – PATIENT-FACING MATERIALS

We then compared the materials created by industry for a patient audience.

As in the materials created by PAGs, ***why*** *is biomarker testing important* was most often included (Figure 3). Unlike in the materials created by PAGs, ***how*** *is testing done* was also frequently included in materials created by industry partners. Interestingly, when analyzing patient-facing materials, we found that most did not describe ***what*** *biomarker testing* was.

Finally, while more of the industry materials answered ***when*** *should a patient get tested* than PAG materials, there was still not a huge percentage of materials that provided the response to this question.

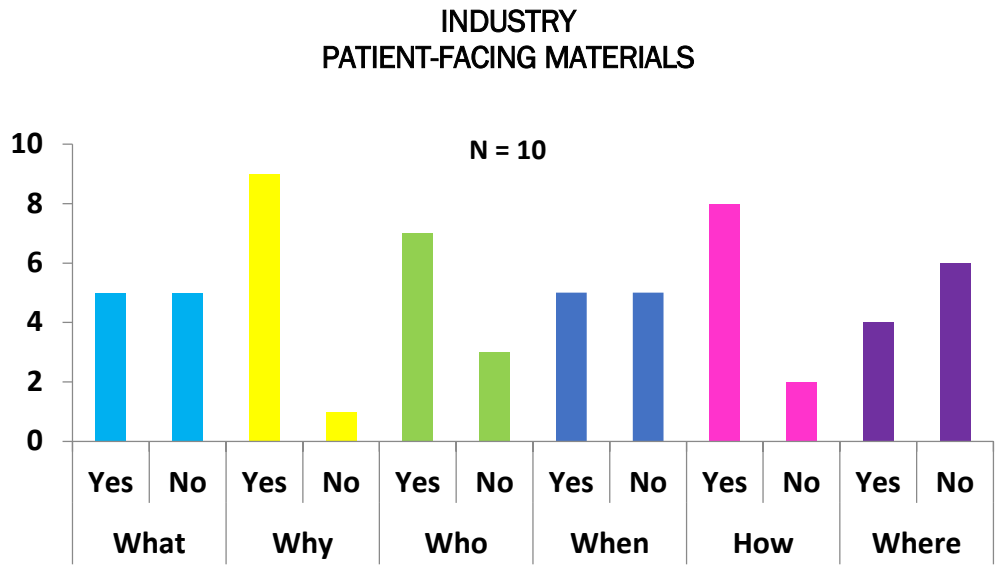


Figure 3

ANALYSIS

When comparing patient-facing materials from these groups, we found that both industry and PAGs created patient-facing education and awareness materials.

- PAGs' materials answered more of the proposed questions and did so more thoroughly than industry materials. PAGs' strengths were in their responses to ***who*** *should be tested* and ***why*** *biomarker testing is important* and —with each PAG including a response to ***why*** *biomarker testing is important.*

- Industry's strengths were in their responses to ***why*** *biomarker testing is important,* ***how*** *is biomarker testing done,* and ***when*** *should a patient be tested* (Figure 3).

While there is an opportunity for more information on ***how*** *is testing done* and ***where*** *testing is done*, the largest gap identified in this audit was the ***when*** *should a patient be tested.* The response to this question is essential when advocating for biomarker testing, which is why this was determined to be an area that needed most improvement.

Below is a graph comparing the contents of PAG materials and the industry materials.

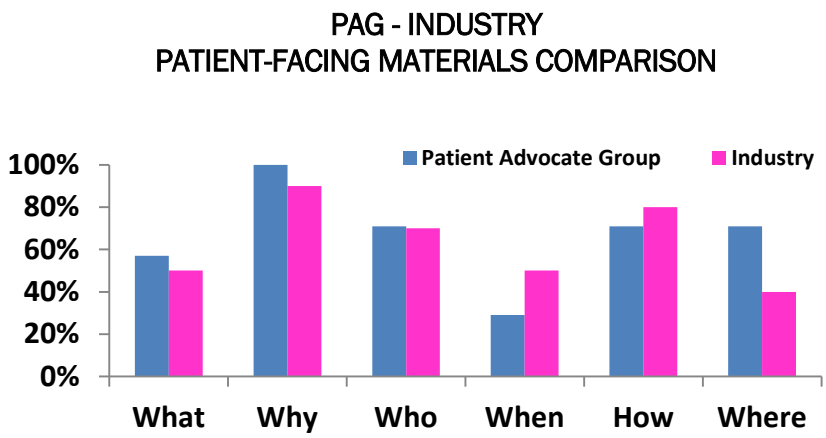


Figure 4

The audit was conducted using quantitative metrics, but qualitative trends were noted throughout the process. For the qualitative analysis, LUNGevity looked at the way questions were answered. There was very little consistency in the language used within the patient advocacy community. There was also very little consistency among the industry materials and an even greater divergence when comparing the PAG materials with industry materials. The lack of consistency could result in mixed messaging for the materials' audience. The PAGs' materials tended to provide more inclusive information that ultimately encouraged all patients to talk to their doctors about testing in general, while the industry materials tended to be mutation-specific based on the company's approved therapy.

For example, when we looked at how different groups described ***who*** *needs biomarker testing*, PAGs were broader in their ask than what was described by industry material.

PAG
"If you have NSCLC, the pathologist can usually tell the subtype of your tumor based on histology. Adenocarcinoma and squamous cell carcinoma are the most common subtypes of NSCLC. Even if your tumor does not have known characteristics that can be matched to a targeted treatment that is available commercially or through a clinical trial, molecular testing can still help you and your doctor decide on the right treatment option for you. In these cases, the very best care will still be given to you."

Industry
"If you've been diagnosed with non-small cell lung cancer (NSCLC) that has spread to other parts of your body (referred to as metastatic), your doctor may order a special test to see if your tumors have a specific kind of epidermal growth factor receptor (EGFR) mutation (EGFR M+)."

The inconsistency causes confusion for patients who may believe that different or additional tests are needed to ensure access to the right therapies. This could result in additional stress and misunderstandings in the patients' treatment journey.

HCP FACING MATERIALS

Currently, PAGs do not have any HCP-facing materials. Industry's materials (Figure 5) are far more varied in the information provided in response to each question. As with the other materials, their strength was their responses to ***why*** *patients should be tested* and their gap was their responses to ***when*** *patients should be tested.* A qualitative trend noted during the audit was that most HCP-facing materials did not focus on the benefit to a patient that testing provides; this was most apparent in addressing ***why*** to test, which focused more on cost-efficiency of personalized medicine or the potential for innovation with testing.

There were no consistent or specific calls to action across the HCP-facing materials as demonstrated in Figure 5.

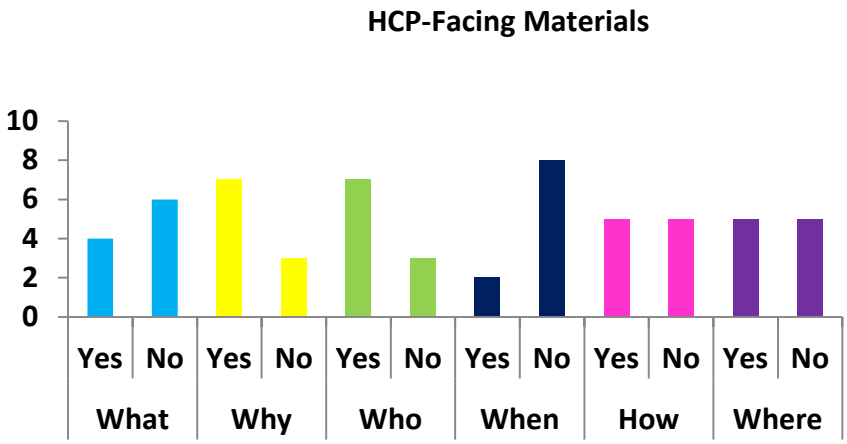


Figure 5

CAMPAIGNS

Further mixed messaging was caused by multiple awareness campaigns created by industry and pushed out by PAGs throughout the year and especially during Lung Cancer Awareness Month. These campaigns include:

- Test. Plan. Treat.
- Get tested. Chart your path.
- Test. Talk. Take Action.
- Let's test.
- Don't guess. Test.

While the campaigns are all very similar, when they are run during the same time periods, it can be confusing to patients and the message is weakened. For example, should a person just test; test and talk to their doctor; or test and chart their own path? Furthermore, these campaigns' asks are much more forceful than the patient education materials and HCP materials. Whereas the education materials advocated for patients to speak with their doctors, the campaigns directed the patients to take action.

An important point to note here is that findings from testing companies listed in the audit have not been included with industry findings. This is because of the five diagnostic companies included, only one answered the three main questions:

- ***What*** *is biomarker testing?*
- ***Why*** *biomarker testing is important? How is the information used to decide treatment plans?*
- ***Who*** *(which patients) should get tested?*

Discussion

The dialogue following the presentation of the audit findings focused on three key discussion topics:

- Education needs, including gaps and barriers, for both patients and HCPs
- Potential of a unified education/awareness campaign among all stakeholders
- Barriers preventing industry from using consistent messaging and the possible solutions to these barriers

1. Education needs: This discussion focused on patients who had not had their tumor tested for biomarkers (there are different messaging and reimbursement issues for patients who are being re-biopsied and tested at recurrence).

   The stakeholders agreed that patient education materials should include information on ***why*** *biomarker testing is important,* ***who*** *(which patients) should get tested, and* ***when*** *(at what point in the treatment journey) should a patient get tested.* It was proposed that PAGs convene to agree on messaging for these three pieces.

   A patient education gap identified during the discussion was lack of education on the importance of core tissue biopsies. Some participants felt that patients are not aware of the value of their sample. Additionally, some suggested HCPs may pull a more complete sample if patients asked specifically for it. Finally, it was suggested that it perhaps be important to patients to know that tissue sample may need to be pulled from several tumor sites (both primary and metastatic) in order to get a complete test result.

   Another education gap identified was that patient and HCPs may be receiving different information. This inconsistency could result in less meaningful conversations when the doctor and patient meet. Further, it could result in an HCP—who may treat more than lung cancer patients (such as pulmonologists)—feeling unprepared to have this conversation with their patients if the patient is more informed.

   Several solutions to this issue were suggested, such as PAGs working with professional societies to create a piece that was both patient and HCP-facing. Similarly, it was suggested there be an HCP-facing material created that answered the list of questions that patients are provided to ask their doctor. Another suggestion was to create a piece for patients to give to their HCPs in order for the HCP to see the same information the patient had. If patients would be too intimidated to hand their doctor materials, it was also suggested these materials could be distributed through the labs, which would provide an opportunity to stress the importance of testing to patients and how best to talk to your patient.

   For HCP-facing materials, it was determined that answering ***how*** *is testing done* would be essential. This is because care teams are now multidisciplinary, and who does what is less clear than it used to be. Additionally, it seemed beneficial for care teams to be educated on a broad testing spectrum as this might be more beneficial to those who treat more than just one tumor site type.

   Once again, education on the importance of pulling core tissue was a gap in HCP-facing materials. This is essential for HCP education materials to ensure that the HCP is pulling enough tissue to do complete testing. There also needs to be more discussion on the importance of pulling from the primary tumor site vs. the metastatic site.

2. Potential of a unified education/awareness campaign: LUNGevity proposed the idea of a unified awareness campaign during Lung Cancer Awareness Month (November) and possibly Hope Month (May) that would include all stakeholders in order for the messaging to be more consistent and productive.

   Some participants explained this would be difficult due to the fact that some of these campaigns have been running for years, and a lot of work and money have been put into them. Others suggested it was a possibility, but not sooner than 2018. Some industry partners suggested that partnering may be difficult, but support was certainly a possibility.

   Other participants—especially those who do not have their own campaigns yet—were interested in a unified campaign. If the messaging were kept simple and direct, it was seen as a possibility that they could move forward with this.

   Yet another participant suggested the possibility of creating a large campaign with a unified theme; the pieces would all look similar with similar messaging, and industry would support different pieces that were applicable to their company. This brought up the question of coordinating the content (even if the specific language used varied) as a good starting point.

   Industry participants were unable to commit to the possibility of this campaign and were tasked to return to their companies to determine the possibility of this.

3. Barriers: Several participants of the meeting identified roadblocks that might prevent message consistency. For industry, a large barrier was internal processes, such as the regulatory and compliance. This is because these groups may interpret certain messaging a specific way. For example, some may interpret certain messaging to be off-label promotion, which would prevent the company from using or promoting the messaging.

   A proposed solution suggested was for LUNGevity and the PAGs to develop messaging that was anchored in the various guidelines such as NCCN. Industry often uses terminology and recommendations from these guidelines and could then have an evidence-supported source to anchor their education materials to. While this would not result in a unified education material, this would at least ensure that the messaging was consistent.

   Another solution was to use the recommendations provided in the guidelines for *who* and *when*—more tangible recommendations—and each industry stakeholder could provide their own *why*—a more abstract recommendation—on their materials.

Next Steps

- ☐ Obtain buy-in from the major lung cancer patient advocacy groups regarding the top three messaging points to be included in all of our education materials.
- ☐ Develop a guide that includes responses to the key questions in biomarker testing (*what, why, who, when, how, where*) with key audiences (patients and healthcare providers) in mind.
- ☐ Discuss updates to guidelines (NCCN, ASCO, CAP/IASLC/AMP) with the developers to include important information on biomarker testing.
- ☐ Create an education and awareness campaign on the importance of pulling core tissue for both patients and HCPs. Determine the possibility of incorporating core tissue messaging into the biomarker testing appeal for patients.
- ☐ Develop further education for HCPs about the importance of core tissue from the primary tissue site and metastatic site and how both are essential to testing.

Moving forward

Over the course of 2017, LUNGevity will work alongside meeting participants to drive forward the activities identified as priority areas for educating patients and healthcare providers.

LUNGevity is committed to continuing to provide forums like this meeting to enable diverse stakeholders to gather and share updates on their programs, and help identify areas for partnership and collaboration where appropriate.

Appendix A

LUNGevity *Take Aim*

Meeting Agenda
April 4, 2017; 12 PM – 2 PM
Salon A, Washington Marriot Metro Center
775 12th Street NW

I.	11:30 PM	Registration/Lunch
II.	12:15 PM	Introductions
III.	12:30 PM	Presentation of findings from Messaging Audit
IV.	12:50 PM	BREAK
V.	1 PM	Open Discussion
VI.	2 PM	Conclusion

For attendees who are dialing in:
Toll Dial-in number: (641) 715-3580 (United States)
Access Code: 156-791#

LUNGEVITY
Find it. Treat it. Live.

Appendix B

Biomarker Testing Education and Awareness
Attendee List
Tuesday, April 4, 2017

Name	Organization
Liz Hanpeter	AbbVie
Marianne Gandee	ACCC
Sara Green	AstraZeneca
Meg Amplement	Boehringer Ingelheim Pharmaceuticals Inc.
Lara Crissey	Boehringer Ingelheim Pharmaceuticals Inc.
David LeDuc	Bonnie J. Addario Lung Cancer Foundation
Justin Balint	Bristol-Myers Squibb
Shawn Keogan	Bristol-Myers Squibb
Lee Krug	Bristol-Myers Squibb Company
Virginia A Burns	Bristol-Myers Squibb Company
Robb Rabito	CHEST
Rudy Anderson	CHEST
Kristen Eisterhold	Eli Lilly
David Marshak	Foundation Medicine
Elissa Quinn	Genentech
Nikki Martin	Genentech
Ide Miles	Ide Mills Strategic Consulting
Devon McGoldrick	Lilly
Meriam Driss	LUNGevity Foundation
Upal Basu Roy	LUNGevity Foundation
Andrea Ferris	LUNGevity Foundation
Kayla Haskins	LUNGevity Foundation
Sandra Shaw	Merck
Erin Darling	Merck
Jane Vesotsky	Novartis
Alexey Salamakha	Novartis
Bob Donovan	Pfizer Oncology
Andrea Miyahira	Prostate Cancer Foundation

LUNGEVITY
Find it. Treat it. Live.

Appendix C

List of organizations included in audit