



STRATEGIES FOR PATIENT-CLINICIAN COMMUNICATION IN CLINICAL TRIALS

A PLAYBOOK BY ERIC K. SINGHI, MD



Assistant Professor
Thoracic Medical Oncologist
University of Texas MD Anderson Cancer Center
[@lungoncdoc](#)





GAME PLAN FOR TODAY'S TALK

O Landscape of Lung Cancer

X Importance of Research

O Challenges in Lung Cancer Research

X Strategies to Enhance Research Experience

O The Future of Lung Cancer Research

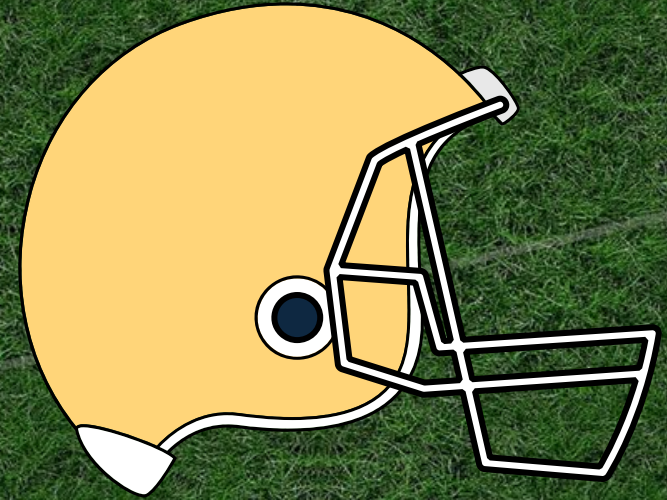
LUNG CANCER LANDSCAPE: THE CURRENT MATCHUP

In 2024:

- >230,000 new cases of lung cancer
- >125,000 deaths from lung cancer

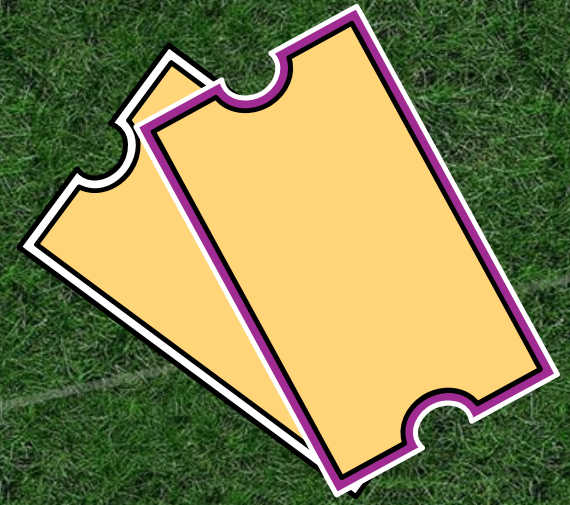
1 in 5 of all cancer deaths:

- Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined



LUNG CANCER LANDSCAPE: THE CURRENT MATCHUP

But, there is HOPE!!



Decreasing Incidence:

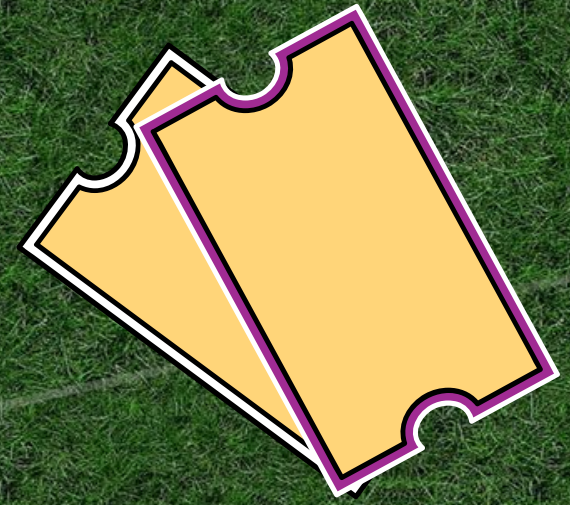
- New lung cancer cases are declining, thanks in part to more people quitting smoking or never starting.

Declining Mortality:

1. Fewer people smoking
2. Advances in treatment
3. Improvements in early detection

LUNG CANCER LANDSCAPE: THE CURRENT MATCHUP

But, there is HOPE!!



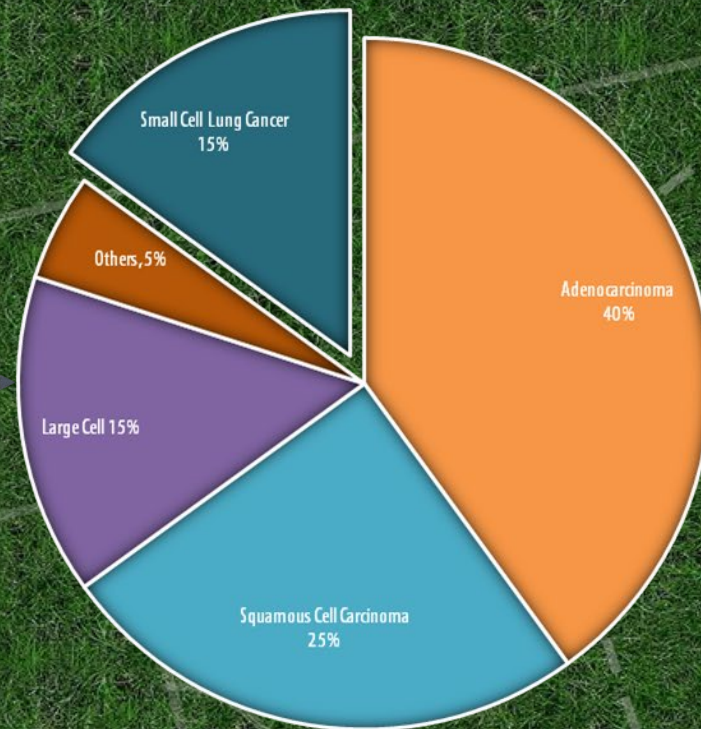
Advancements in treatment and early detection
are because of ***research!***

LUNG CANCER LANDSCAPE: THE CURRENT MATCHUP

*Lung
Cancer as
one
disease*

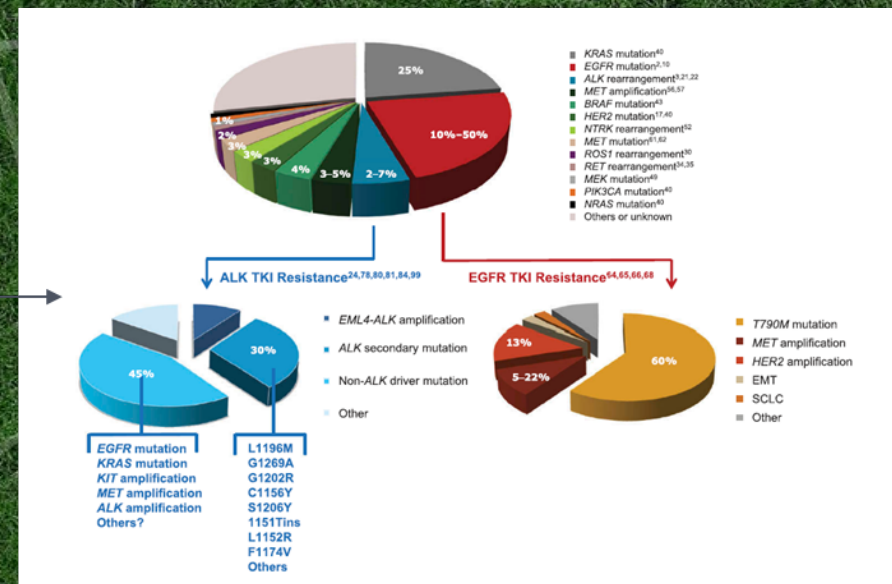
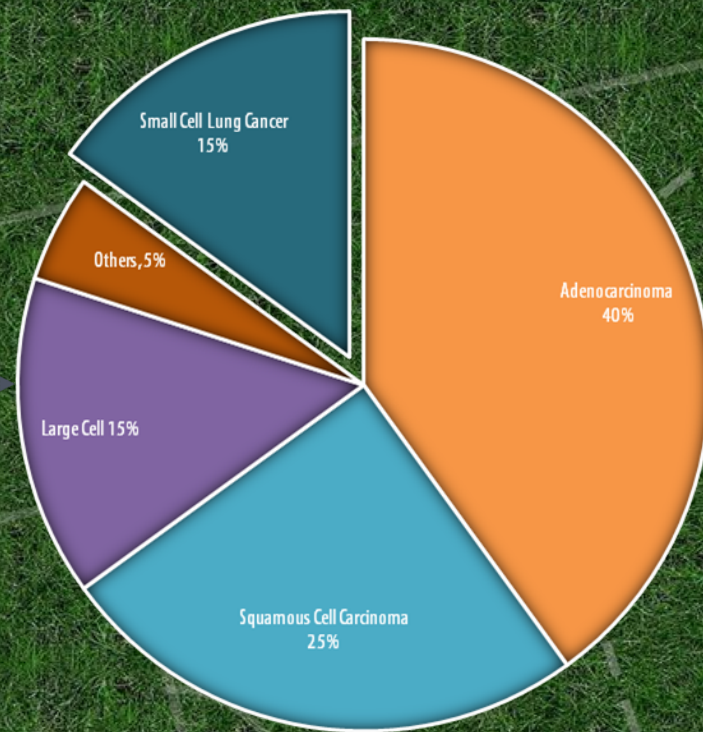
LUNG CANCER LANDSCAPE: THE CURRENT MATCHUP

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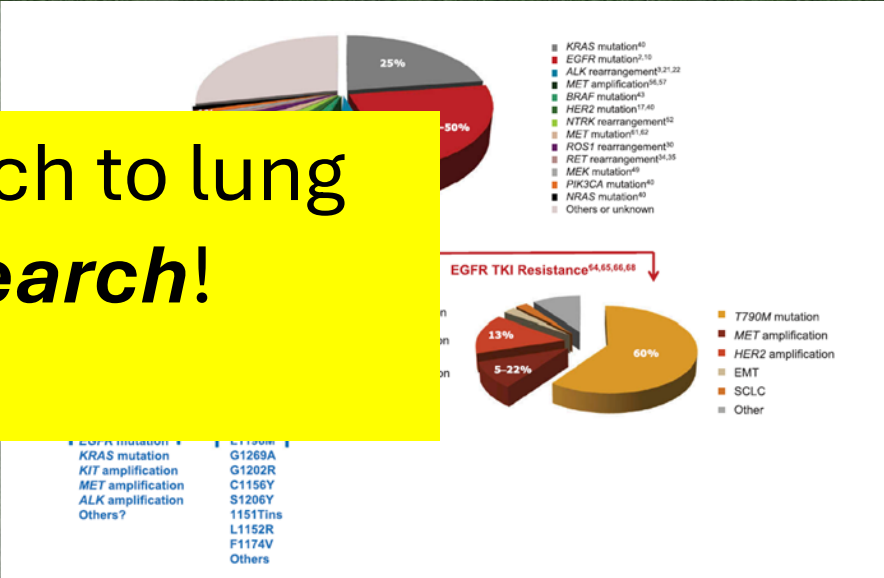


Infographics by Dr. Ravi Salgia

LUNG CANCER LANDSCAPE: THE CURRENT MATCHUP

Lung Cancer as one disease

This frameshift in our approach to lung cancer is because of **research!**



THE JOURNEY TO DRUG APPROVAL: A GAME CHANGER

By show of hands, who knows about...

THE JOURNEY TO DRUG APPROVAL: A GAME CHANGER

By show of hands, who knows about...

AZD9291

NCT02296125 Trial

THE JOURNEY TO DRUG APPROVAL: A GAME CHANGER

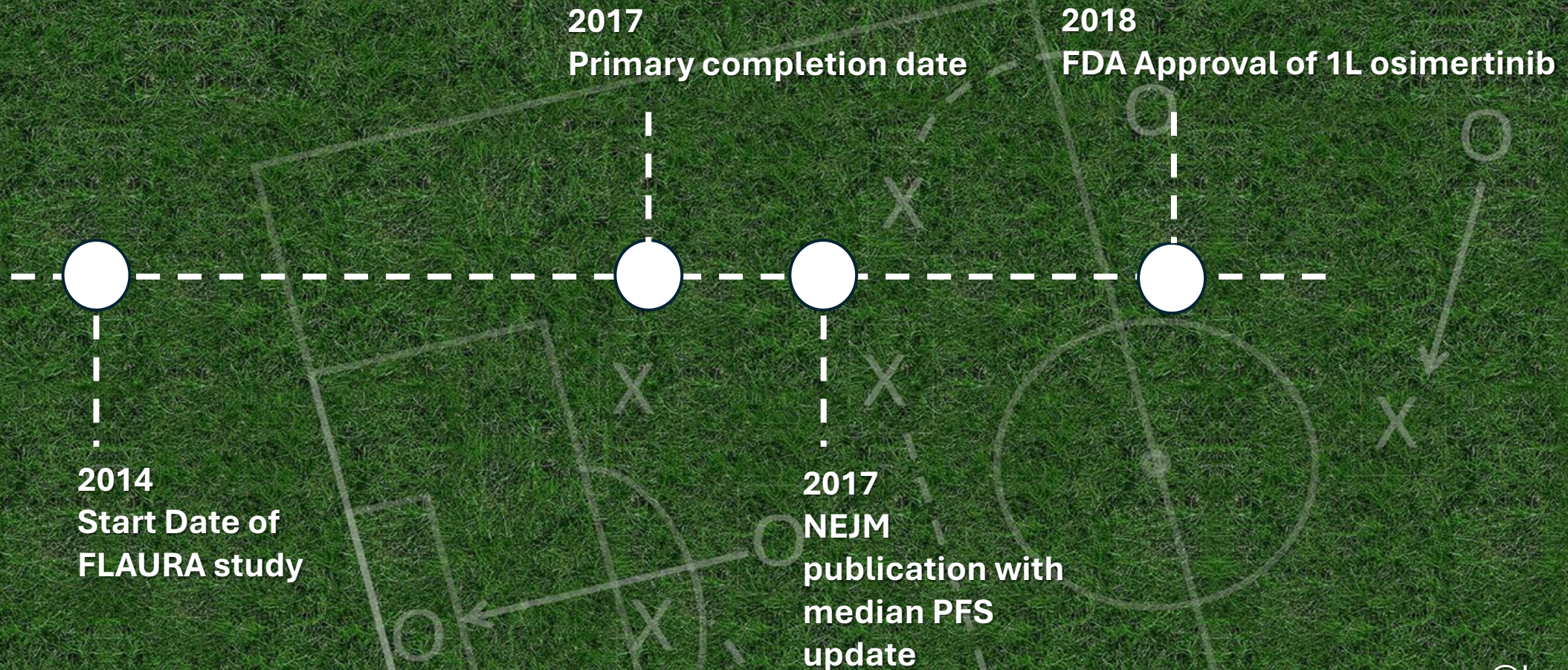
- AZD9291 = Osimertinib
- NCT02296125 Trial = Phase 3 FLAURA study

PROTOCOL SYNOPSIS

A Phase III, Double-Blind, Randomised Study to Assess the Efficacy and Safety of AZD9291 versus a Standard of Care Epidermal Growth Factor Receptor-Tyrosine Kinase Inhibitor as First-Line Treatment in Patients with Epidermal Growth Factor Receptor Mutation Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer

THE JOURNEY TO DRUG APPROVAL: A GAME CHANGER

AZD9291 = Osimertinib



THE JOURNEY TO DRUG APPROVAL: A GAME CHANGER

Impact on the Lung Cancer Community?

- Practice-Changing Clinical Trial: led to FDA approval of osimertinib as first-line treatment
- Overall Survival Benefit (i.e. extended the length of patient's life)
- Progression-Free Survival Benefit (i.e. improved duration without disease progression)
- Personalized Medicine: Reinforced the importance of biomarker testing and appropriate therapy

THE JOURNEY TO DRUG APPROVAL: A GAME CHANGER

Impact on Patients Who Enrolled on Study?

- Early Access to Treatment: Phase 3 trial started **FOUR YEARS** prior to FDA approval
- Validation of Treatment: Demonstrated safety and efficacy
- Community and Support: Contributed to significant advancements in cancer research

THE JOURNEY TO DRUG APPROVAL: A GAME CHANGER

Impact on Patients Who Enrolled on Study?

- Early Access prior to FDA approval
- Validation of efficacy and safety
- Community advancements in cancer research

This is the potential impact of ***research!***

FOUR YEARS

and efficacy

ant

WHY RESEARCH IS THE MVP?



**Working on slides for
an upcoming talk and
need your help!**



What's one word that
comes to mind when you
hear "clinical trial?"

Type something...

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Experimental Reply >	Confusing Reply >
Hope Reply >	Last resort Reply >
Desperation Reply >	

Responses

Placebo (which is terrifying) Reply >	Not proven Reply >
Hope! Reply >	Hope Reply >
Hope Reply >	Is it safe? Reply >
Experimental Reply >	Lifeline Reply >

Responses

H ^o PE Reply >	Testing Reply >
Placebo Reply >	A new drug and potential new treatment for patients Reply >
Expensive \$\$\$\$\$ Reply >	Guinea pig Reply >
Nothing. No one told me about one. Reply >	Scary Reply >

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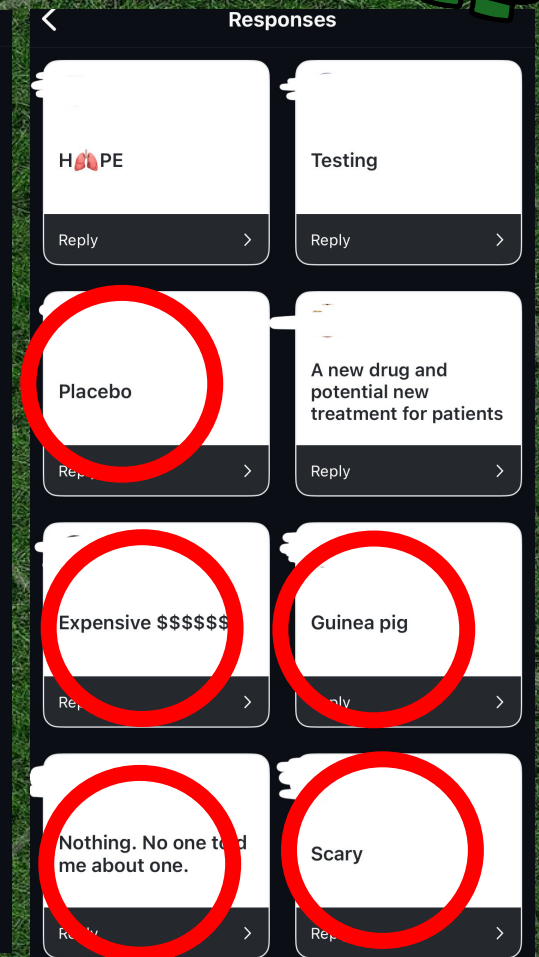
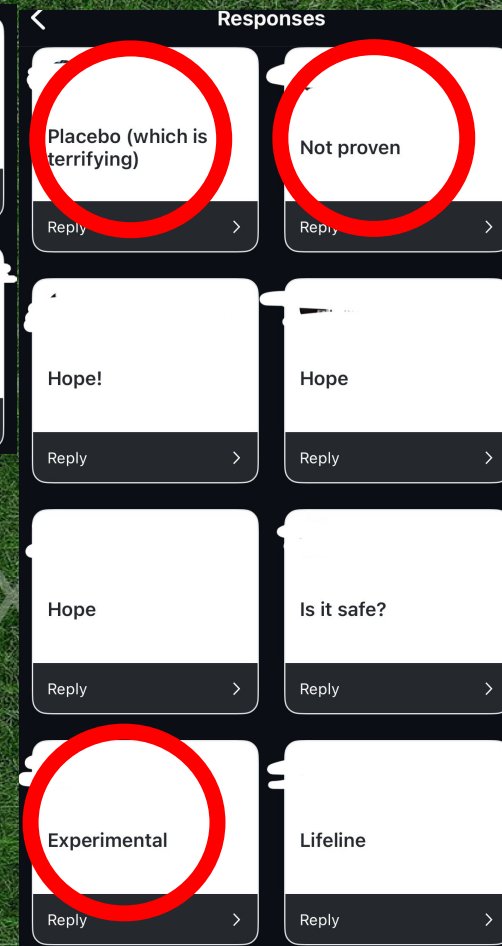
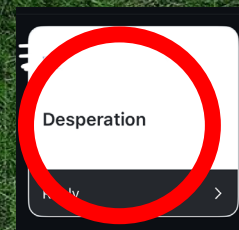
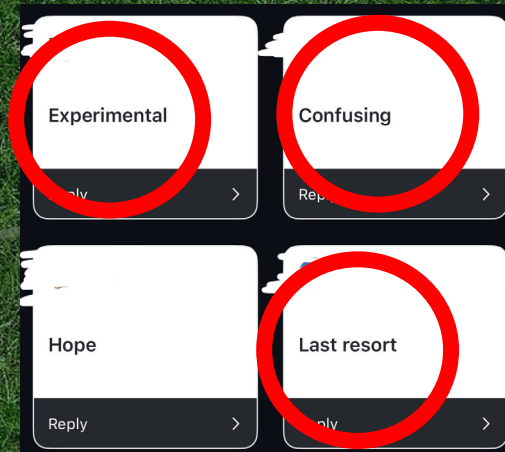
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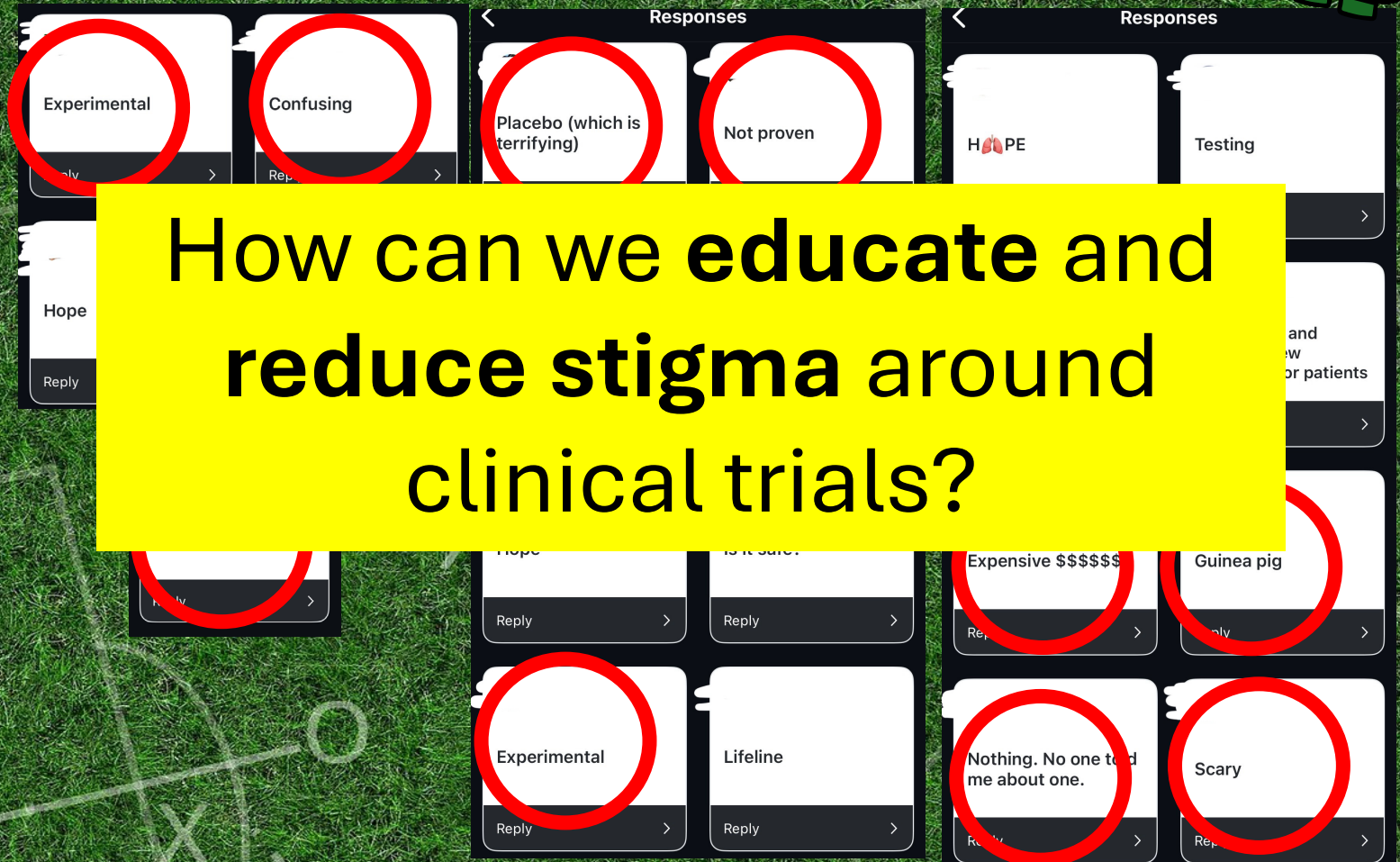


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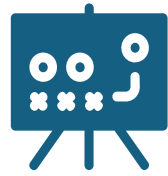
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Type something...



How can we educate and reduce stigma around clinical trials?

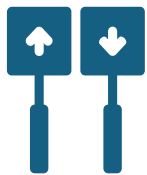
OBSTACLES ON THE FIELD FOR THE LUNG CANCER RESEARCHER



01 Funding Limitations



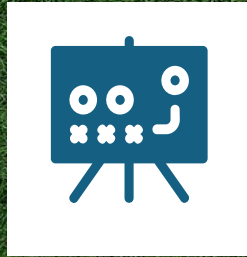
02 Regulatory Challenges



**03 Patient Recruitment
& Enrollment**

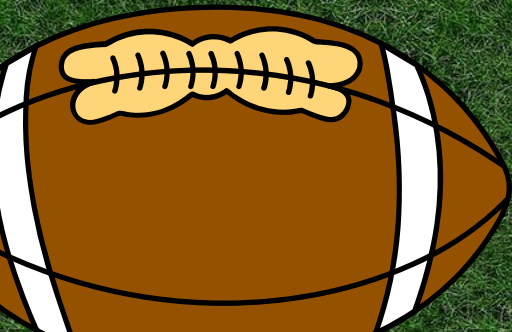


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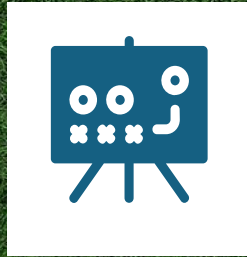


01 Funding Limitations

-Limited Funding: Less than 10% of federal cancer research dollars are allocated to lung cancer.

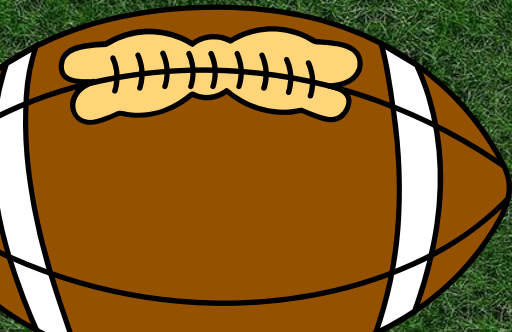


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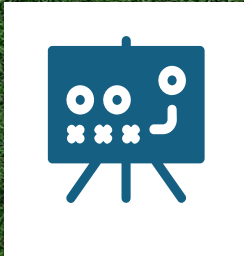


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- Funding Disparity: Lung cancer receives about \$600 million from NIH, compared to \$1.2 billion for breast cancer.

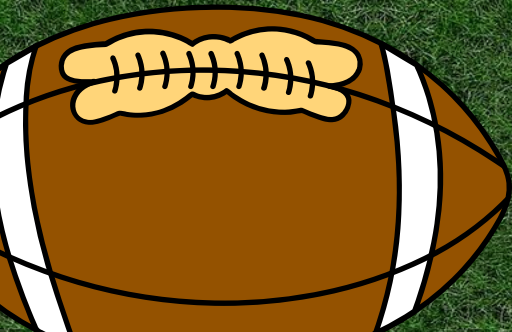


OBSTACLES ON THE FIELD FOR THE LUNG CANCER RESEARCHER



01 Funding Limitations

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- Competitive Grants: Success rate for NCI cancer research grants is only 11-14%.



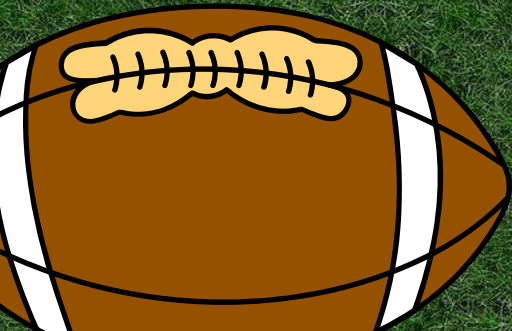
OBSTACLES ON THE FIELD: CHALLENGES FOR THE LUNG CANCER RESEARCHER



02 Regulatory Challenges

Complex Approval Process

- Protocol Development: Detailed study protocols outlining objectives, methods, and safety measures, which can be time-consuming to meet regulatory standards. Comprehensive statistical plan is also needed.



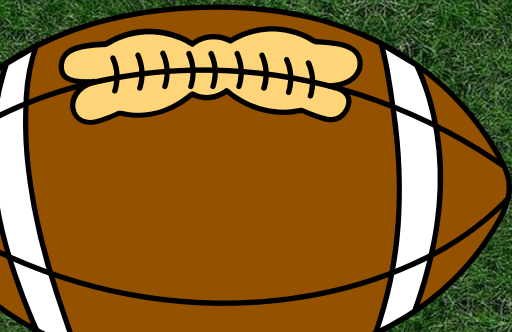
OBSTACLES ON THE FIELD: CHALLENGES FOR THE LUNG CANCER RESEARCHER



02 Regulatory Challenges

This supplement contains the following items with personal information redacted:

1. Original FLAURA clinical study protocol (edition 1.0) pages 1–171
2. Revised FLAURA clinical study protocol (edition 3.0): 172–289
3. Summary of amendments made to FLAURA clinical study protocol (amendment 1.0): 290–360
4. Summary of amendments made to FLAURA clinical study protocol (amendment 2.0): 361–403
5. Original FLAURA statistical analysis plan (edition 1.0): 404–419
6. Revised FLAURA statistical analysis plan (edition 3.0): 420–503
5. Revised FLAURA statistical analysis plan (companion diagnostic; edition 3.0): 504–522



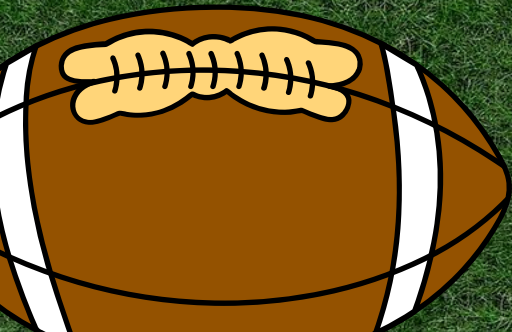
OBSTACLES ON THE FIELD: CHALLENGES FOR THE LUNG CANCER RESEARCHER



02 Regulatory Challenges

Complex Approval Process

-Ethics Review: Each study requires approval from an Institutional Review Board (IRB) to ensure ethical standards, adding time and complexity.



OBSTACLES ON THE FIELD: CHALLENGES FOR THE LUNG CANCER RESEARCHER



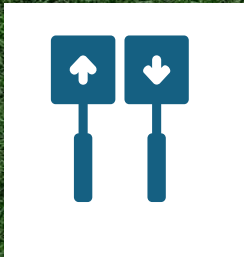
02 Regulatory Challenges *Complex Approval Process*

-Regulatory Changes: Must stay updated on evolving guidelines from regulatory agencies, which can delay study initiation.

-Regulatory Overlap: Varying requirements from different agencies (e.g., FDA, EMA) complicate multi-national studies, increasing administrative burdens.



OBSTACLES ON THE FIELD: CHALLENGES FOR THE LUNG CANCER RESEARCHER



03 Patient Recruitment & Enrollment

- **Low Participation Rates:** Only 5-10% of adult cancer patients participate in clinical trials.
- **Logistical Barriers:** Challenges like transportation and eligibility criteria hinder enrollment.
- **Strict Criteria:** Inclusion and exclusion criteria can limit eligible patient pool, making it difficult to recruit sufficient participants for impactful study results.



BARRIERS FROM THE PATIENT SIDELINE

Awareness and Understanding:

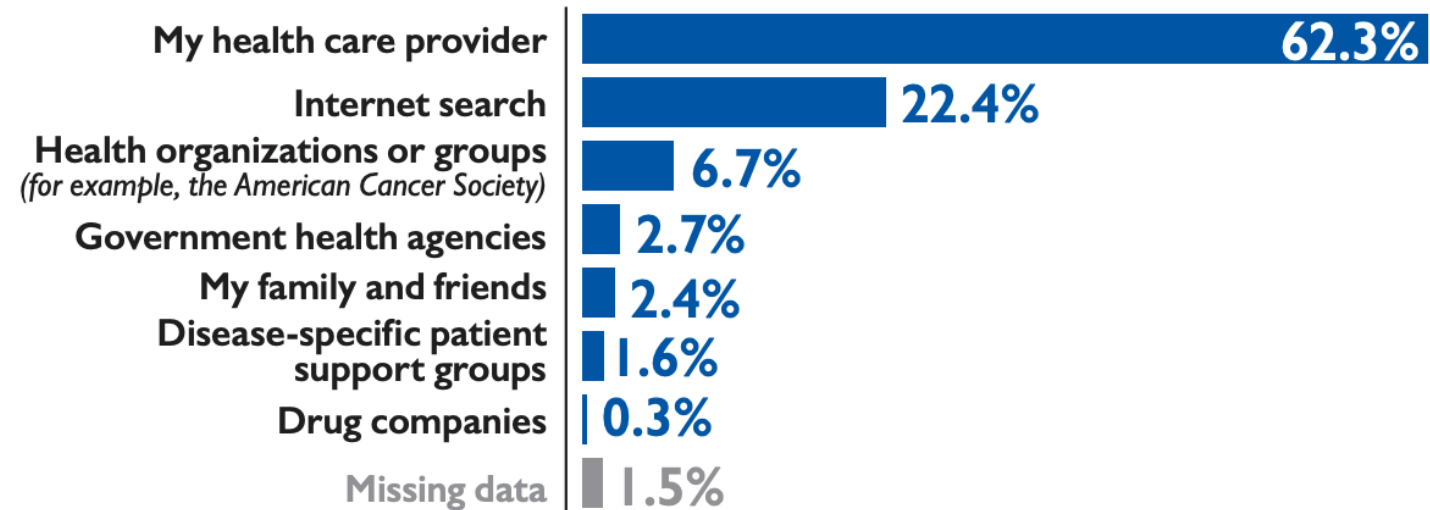
2020 NCI Survey

- 41% of Americans reported not knowing anything about clinical trials
- 87% reported never being invited to participate in a clinical trial

NCI - Hints Health Information National Trends Survey (HINTS). Briefs. Number 48. June 2022.

BARRIERS FROM THE PATIENT SIDELINE

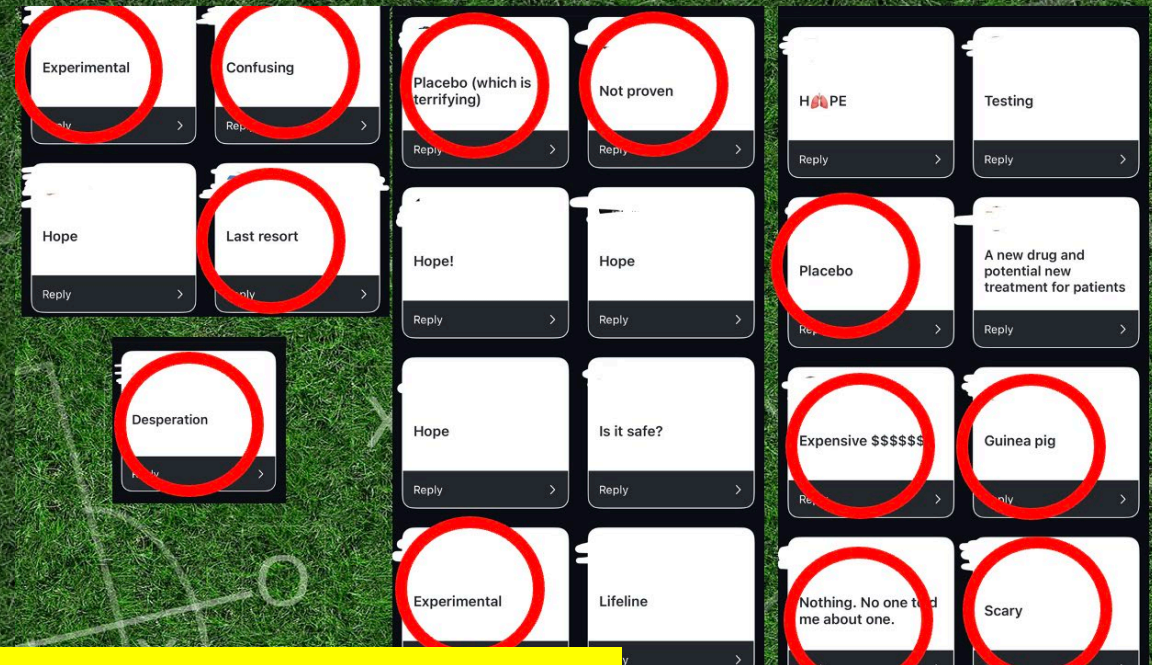
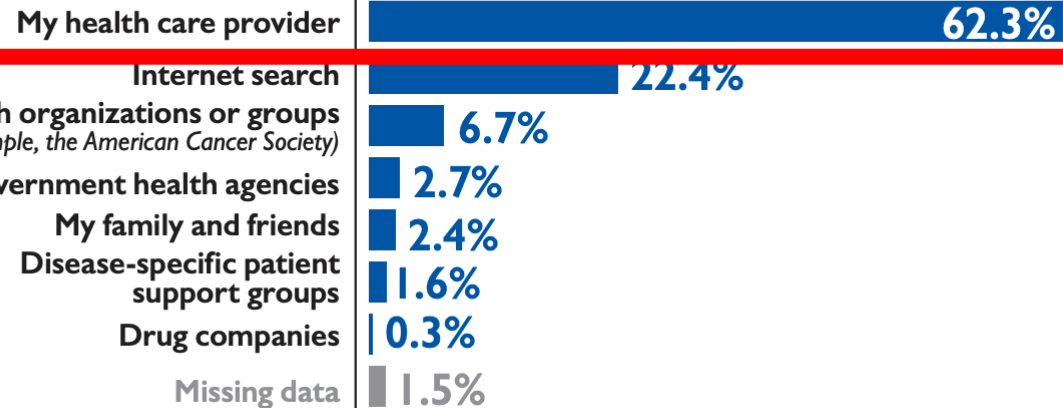
Imagine you had a need to get information about clinical trials. Which of the following would you go to first?*



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BARRIERS FROM THE PATIENT SIDELINE

Imagine you had a need to get information about clinical trials. Which of the following would you go to first?*



An urgent unmet need to improve patient-clinician communication about clinical trials

PLAYBOOK TO ENHANCE RESEARCH EXPERIENCE

What Strategies Can We Use to Improve Patient-Clinician Communication?



PLAYBOOK TO ENHANCE RESEARCH EXPERIENCE

Improving Patient-Clinician Communication:

1. Engage Patients Actively

- Initiate Conversations: Encourage clinicians to **START** discussions about clinical trials **EARLY** in the treatment process.
- Use Open-Ended Questions

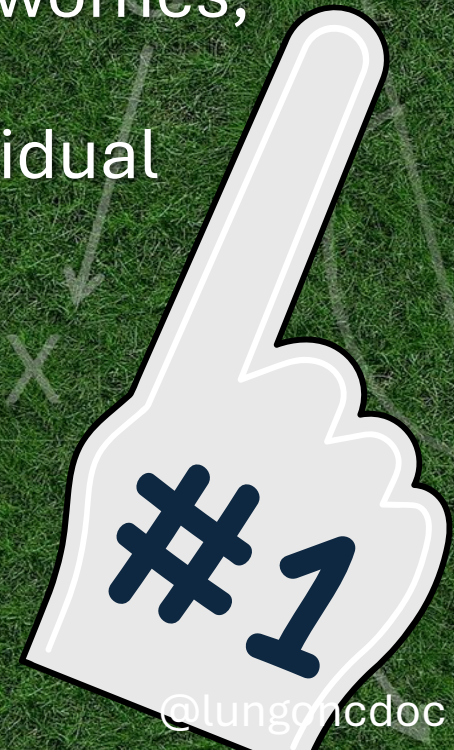


PLAYBOOK TO ENHANCE RESEARCH EXPERIENCE

Improving Patient-Clinician Communication:

2. Assess Patient Preferences

- Discuss Concerns: Ask patients about their preferences, worries, and motivations for considering participation.
- Tailor Information: Customize information based on individual patient needs and understanding.



PLAYBOOK TO ENHANCE RESEARCH EXPERIENCE

Improving Patient-Clinician Communication:

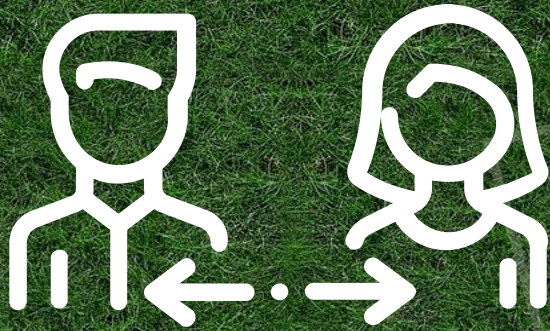
3. Utilize Clear Communication Tools

- Visual Aids: Incorporate diagrams, charts, and infographics to **SIMPLIFY** complex information.
- Plain Language: **AVOID** medical jargon; use clear and accessible language to explain trial concepts.



Assessing Availability and Demand for Patient-Friendly Resources in Lung Cancer Care: *The Patient Perspective*

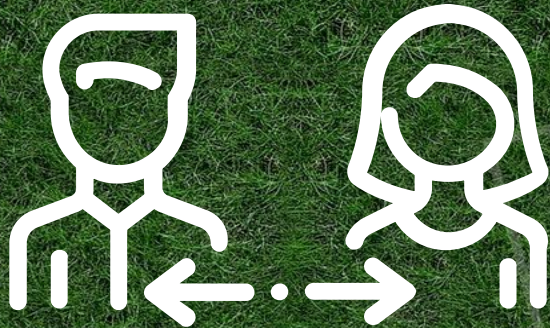
Singhi et al. Presented at WCLC 2023



- **Participants: 58 patients w/ non-small cell lung cancer (NSCLC)**
- **Findings:**
 - ***Most patients with lung cancer reported a lack of patient-friendly written resources***
 - ***Preference for oncology providers to personally deliver and use patient-friendly resources to explain diagnosis, staging, and treatment plan***

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- Participants: 58 patients w/ non-small cell lung cancer (NSCLC)
- Findings:

- Most patients with lung cancer reported a lack of patient-friendly written resources*

Can we develop a patient-friendly resource?

- Preference for oncology providers to personally deliver and use patient-friendly resources to explain diagnosis, staging, and treatment plan*

Can we develop a resource that oncology providers will use in clinic?

Patient-Friendly Guide

- One-page patient-friendly guide for the initial medical oncology visit
- Developed in collaboration with multiple medical oncologists & patient advocates across different tumor types

A PATIENT GUIDE TO THE INITIAL MEDICAL ONCOLOGY VISIT

1. CONTACT INFORMATION:
 -How to reach my healthcare team
 -How my healthcare team will contact me

2. WHAT:
 -I have a diagnosis of _____

3. WHERE:
 -My cancer is located _____
 -This is known as Stage _____

4. TREATMENT GOAL:
 -The goal of my treatment(s) is _____
 -Curative treatment aims to "cure the cancer," meaning it is intended to eliminate all cancerous cells, resulting in what doctors can sometimes call a "cure."
 -If the cancer can't be cured, palliative treatment is often given to patients with advanced cancer in hopes of making patients more comfortable with the goal of controlling the cancer for a period of time. It is sometimes given in combination with other cancer treatments.

5. PATIENT GOALS:
 Use this space to think about what you want your treatment to achieve for you (e.g. to improve physical activity, to better manage cancer symptoms, to not have the cancer come back etc.)

6. NEXT STEPS:

NEXT STEPS IN TREATMENT PLAN

Use this space to discuss potential treatment options (and potential side effects) and to better understand how/where you will spend your time receiving cancer care. This would be a good time to discuss barriers to care (such as insurance coverage) and to think about what additional tests might be needed before starting treatment.

7. SUPPORT SYSTEM:

SUPPORT/RESOURCES

Use this space to think about a network of people that can support you during your diagnosis. Think about how to discuss your diagnosis with family and friends. Consider asking for help and continuing to reach out for support. Consider connecting with fellow patients and other caregivers. Consider connecting with other support services such as Cancer Support Community, Cancer Care, American Cancer Society etc.

PATIENT TIPS:

- Develop an organization system (example: purchasing a folder or binder) to keep physical copies of test results, handouts, and all printed information that relate to your cancer, treatments and healthcare team
- Have health insurance information ready to discuss with your care team
- Keep an updated copy of all medications that you are taking (names and doses) to share with your care team.
- Ask your care team permission to record audio from your appointment to revisit at a later point in time

NOTES:

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TREATMENT INTENT

5. PATIENT GOALS:
-What do I want to achieve from my treatment?
-What are my priorities?
-What is most important to me?
PATIENT GOALS

Use this space to think about your goals and what is most important and meaningful to you? (e.g. to improve physical activity, to better manage cancer symptoms, to not have the cancer come back etc.)

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NEXT STEPS IN TREATMENT PLAN
Use this space to discuss potential treatment options (and potential side effects) and to better understand how/where you will spend your time receiving cancer care. This would be a good time to discuss barriers to care needed before starting.

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NOTES:

January 25, 2024

Clinical Trials for Patients With Cancer

Fawzi Abu Rous, MD¹; Aakash Desai, MD, MPH²; Eric K. Singhi, MD³

» [Author Affiliations](#) | [Article Information](#)

JAMA Oncol. 2024;10(3):416. doi:10.1001/jamaoncol.2023.5778

One page publication with plain-language & an infographic

Key Content:

- What Is a Clinical Trial?
- Definitions and Eligibility for a Clinical Trial
- Informed Consent
- Benefits and Barriers to Enrolling in a Clinical Trial
- Questions Patients Can Ask the Team Regarding Enrollment

Clinical trials for patients with cancer

Clinical trials are research studies that investigate if new treatments and tests to screen for diseases are safe and effective. Patients with cancer may benefit from participating in a clinical trial by having access to potentially more effective and/or safer treatments and more direct involvement in health care decisions.

There are 4 testing phases in clinical trials, and each has unique features and important differences

	Patients enrolled	Main questions being studied	Study design	Potential barriers to participation
PHASE 1	10-30	What is the optimal dose of the treatment being studied? What are the side effects?	Single-arm study No randomization	Fear of receiving a treatment with unclear side effects
PHASE 2	50-100	How effective is the treatment? How common are the side effects?	Single-arm study (usually) No randomization (usually)	Fear of receiving a treatment with unclear effectiveness
PHASE 3	100s	Is the treatment more effective and/or safer than the current standard of care?	Study with ≥2 arms Randomized between the standard of care (or placebo) and the new treatment	Fear of randomization and receiving placebo treatment
PHASE 4	1000s	How safe and effective is this treatment in the general population?	No randomization Population-based study usually conducted after treatment approval	Lack of direct benefit to participate when the treatment is already approved and available

Other common barriers to enrolling in clinical trials include lack of health care clinician awareness about ongoing trials, strict eligibility criteria, patient time and travel commitments, and language/cultural challenges.

@lungoncdoc

FINAL WHISTLE: KEY TAKEAWAYS

1. Lung Cancer Research is the MVP

Advancements in early detection and treatment are reducing mortality rates

2. Facing Obstacles on the Field

Researchers and patients face significant challenges in navigating clinical trials

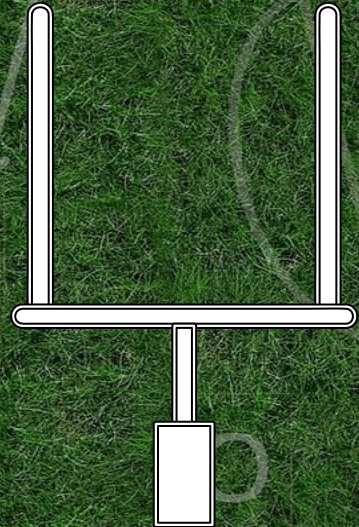
3. Engage the Team

Patients want their physicians to be “trusted coaches” in the clinical trial process

4. Strengthening the Game

Improving communication between patients & physicians is key to success

This is how we SCORE BIG for our patients with lung cancer!



THE MVPS OF MY JOURNEY

