

At the Heart of Research: Patient Impact on Lung Cancer Research

Jill Feldman

Lung Cancer Patient and Advocate

Family Lost to Lung Cancer

Maternal Side



Mom

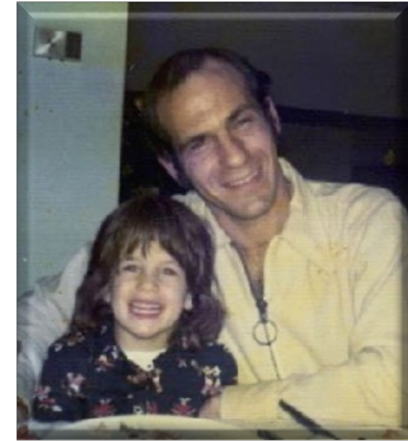


Aunt



Grandmother

Paternal Side



Dad



Grandfather

LUNGevity Founders

LUNGevity Foundation was founded in Chicago in 2001 by seven people diagnosed with lung cancer.



Kay
Barmore



Marge
Breit



Patti
Helfand



Gayle
Levy



Dick
Pemble



Dena
Winick



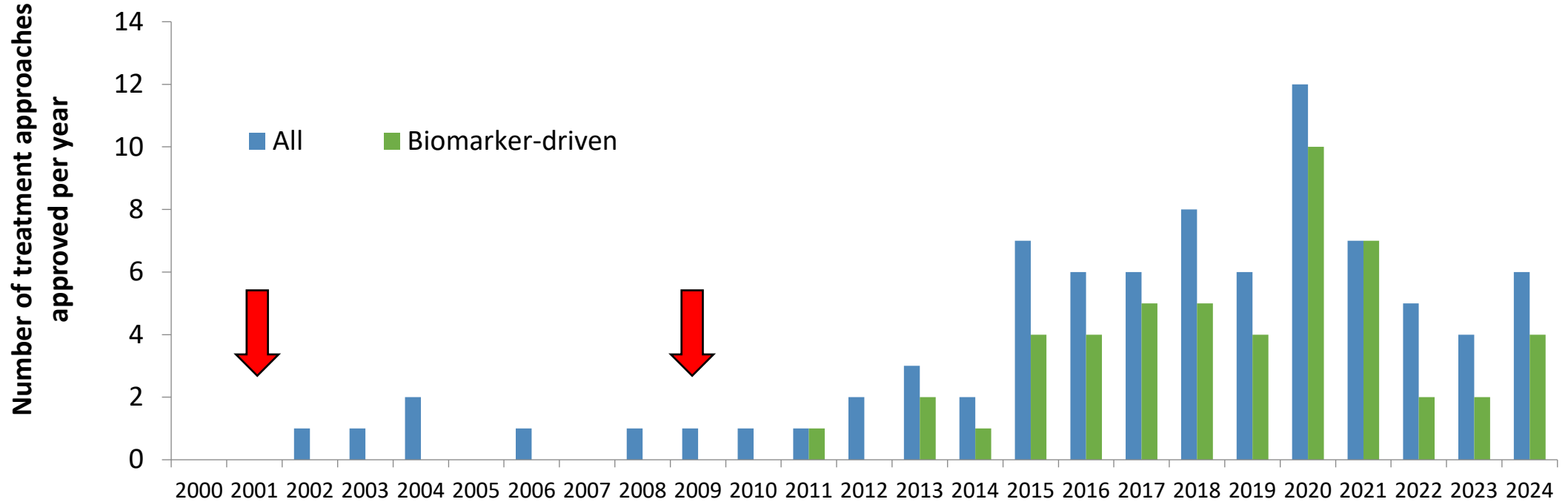
Melissa
Lumberg
Zagon

My Family



The Lung Cancer Treatment Landscape is Exciting...

Treatment approaches approved by FDA
for lung cancer treatment



From: LUNgevity Foundation (Data analyzed from individual FDA approval announcements)

Clinical Trials are Becoming More Complex and Complicated

Phase III clinical trial protocols have become increasingly complex

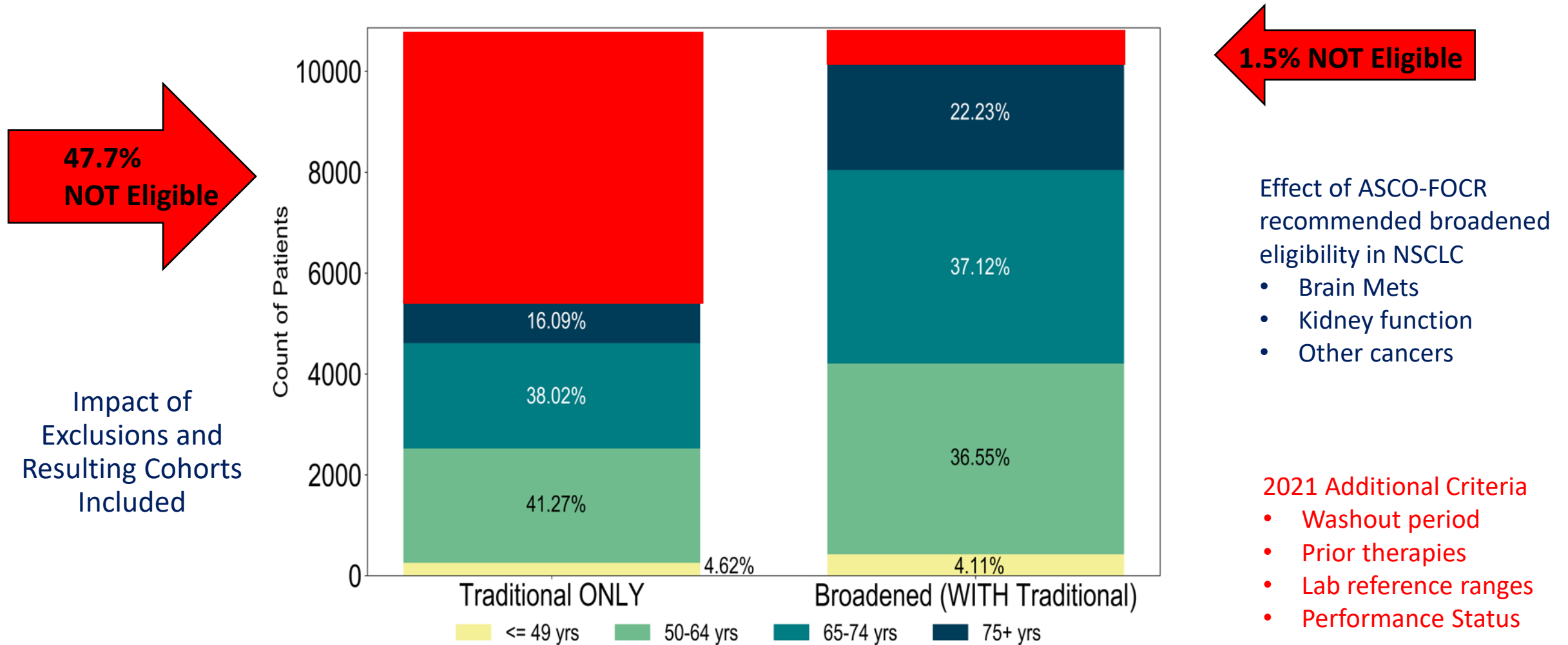
Phase III variable	2001-2005*	2011-2015*	Percentage increase
No of endpoints	7	13	86%
No of trial procedures	110	187	70%
No of eligibility criteria	31	50	61%
No of sites involved	40	65	63%
No of data points collected	494,236	929,203	88%
Cost per study volunteer/visit, \$	\$728	\$978	34%



European Alliance for Personalized Medicine

Sources: Getz and Campo, Ther Innov Regul Sci. 2018 Jan;52(1):22-28; PhRMA, 2019

Modernizing Eligibility Criteria Using the FOCR-ASCO Framework



From: Harvey RD et al., Impact of broadening clinical trial eligibility criteria for advanced non-small cell lung cancer patients: real-world analysis. J Clin Oncol 37, 2019 (suppl; abstr LBA108)

Overarching Health Disparities as “Restrictive Eligibility Criteria”



Engaged, Educated, Empowered, Savvy, Connected

Sick and/or older patients

Patients who are really sick and unable to participate in research. E.g. SCLC patients or PS2 and higher patients

Racial and Ethnic Minorities

African American, Asian American, Indian American, Native American, South Asian, Asian Pacific Islander, non-white Hispanic

Medically underserved

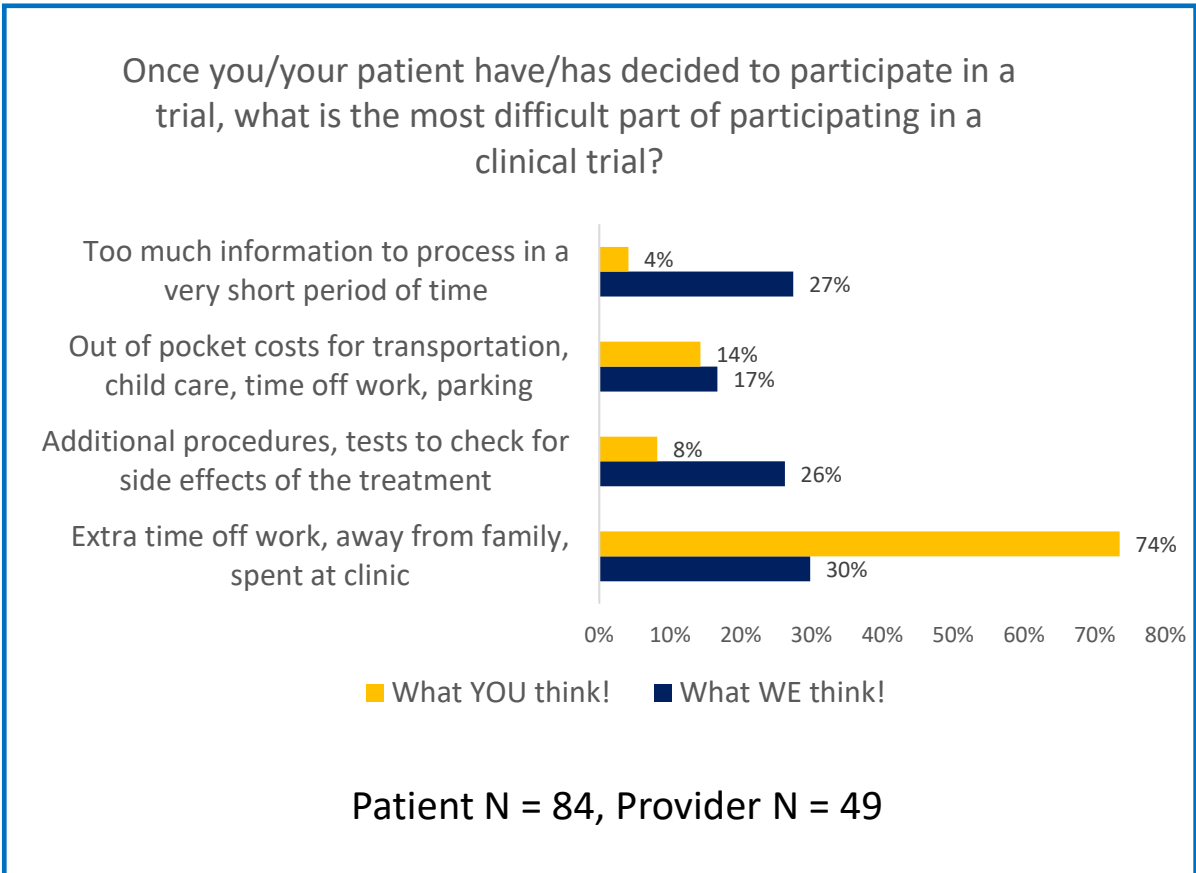
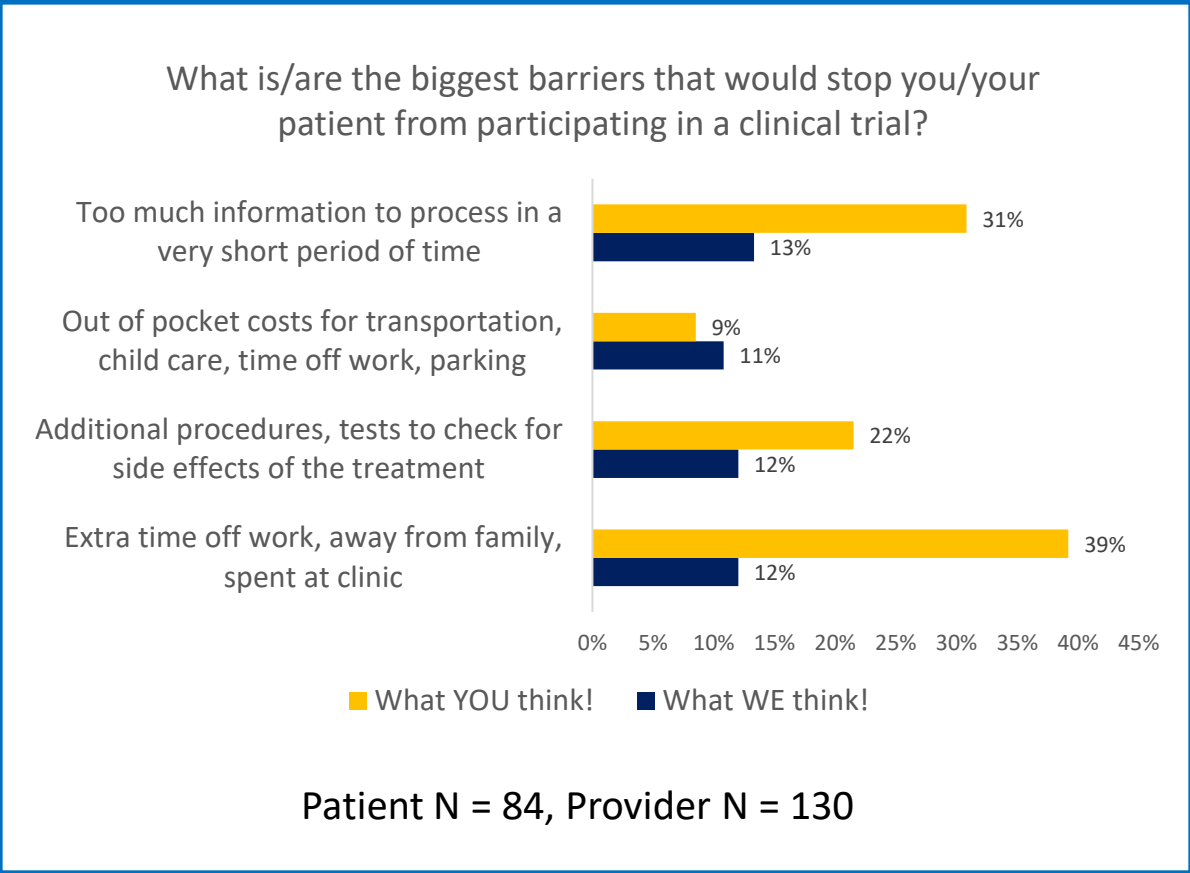
Elderly, Veterans, Linguistically isolated/ low health literacy, LGBTQIA, Rural/geographically isolated, **Financially underserved**

Hidden populations

Stigmatized members, trans community members, Victims of domestic violence, Homeless People

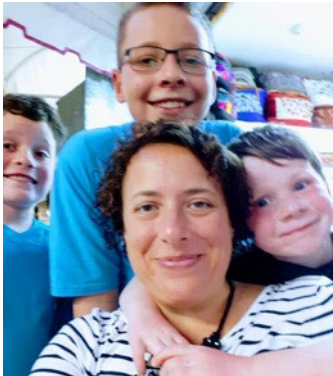
From: <https://www.iaslc.org/iaslc-news/ilcn/lung-cancer-health-care-delivery-community-building-and-research-are-they-truly>

What *Researchers* Feel vs What *Patients* Feel Are Barriers To Clinical Trials



In addition, 66% patients were concerned that trial drug won't work or will cause major side effects. *This was not asked of clinicians.*

The True P-Value of Research Behind the Data: People



Patient's Lives are Complicated!

Cancer Never Ends
 Journey continues for many
 Always Follow up
 Manage Care
 Very little support beyond medical
 Unique and long-term effects

Barrier to receiving treatment
Barrier to receiving support and survivorship
Barrier to receiving end of life care

Patient doesn't know they are eligible for screening

STIGMA in lung cancer

Lack of help navigating
 No support
 Getting Results

Multiple tests over many weeks and months

Anxiety, Confusion
 What do I do next?

Don't have transportation to treatment

Lack of support for caregivers

Disconnect in communication
 Who's the point person?

End-of-Life care

Don't want to burden my family
 Don't want to suffer

Never had advanced care planning conversation

Progression or recurrence



Screen detected

Fear of screening
 Fear of finding something

Is screening covered
 How much does it cost

Don't have GP
 Who do I schedule appointment with?
 Work schedule

Dismissed Multiple visits Treatment for other illness



Diagnostic Tests



Specialists



Diagnosis

Traumatic
 Am I going to die?
 How do I tell my family?



Treatment and Survivorship

Adverse events
 Complications
 Severe Fatigue
 Poor physical function

Support and resources not consistent

Symptomatic
 More testing

Hospice
 Other logistics



Incidental



Roadblocks

First clinical presentation



Symptomatic

First symptom

Time off work
 Childcare
 Out of pocket cost transportation

STIGMA in lung cancer



Diagnostic Tests

LONG wait for results difficult

Not part of treatment discussion

Not offered Supportive or Palliative care

More time off work
 Out of pocket cost

Fear
 Uncertainty
 What's next?

Pain Control
 Need assistance

**Team not culturally aware
 Food and housing security
 Lack appropriate education materials in lay terms**

Fragmented system
 Have to self advocate and navigate

Life Happens!

Caregiver for spouse
 Other morbidities
 Starting a family
 Patient lives alone
 Training for Marathon

Family Reunion
 Getting married
 Trip planned out of country
 Starting New Job
 Take care of House

Look after grandchildren
 Insurance coverage
 Coach children's sports
 Sick child
 Weekly social plans

Moving
 Pay Bills
 Child's wedding

No SDM if patient doesn't understand

Qualify for Clinical Trial – start

Treatment Decisions are Complicated

Is the Survival Benefit Worth the Risk of Side Effects?

Persistence	Type and Severity	Management	Functional Impact
Short and or long term	Physical	Possible dose reduction	On daily tasks and work
Cumulative	Emotional	Palliative care and/or assistance needed	On family relationships
Affect treatment	Cognitive	Co-existing conditions	On control over my own time

What if my insurance **doesn't** cover it?

How? When?

How much?

Can I still **enjoy my hobbies and activities?**

Will I be able to **think about anything other than cancer?**

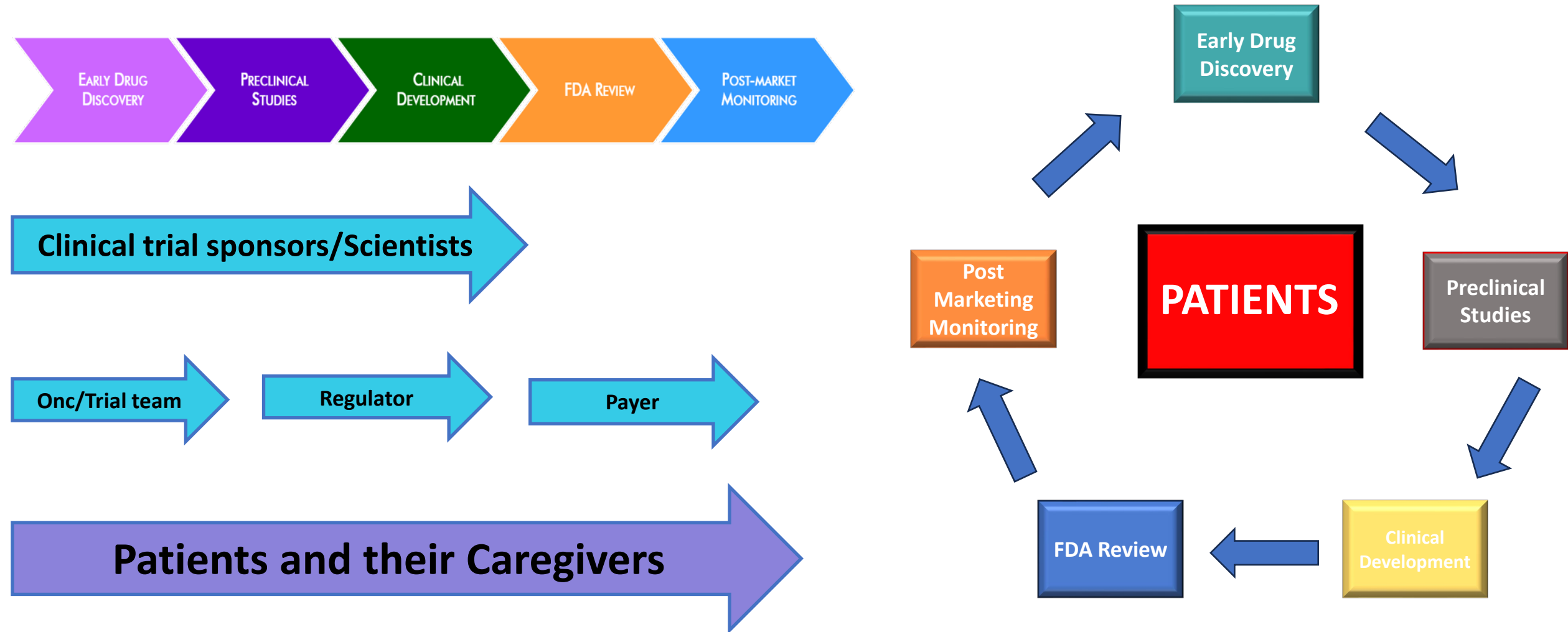
Will the treatment affect **how I Look?**

Will I be **able to work?**

Will I be able to maintain **my daily activities?**

Can I vacation with my family?

The Drug Development Lifecycle Has Multiple Stakeholders

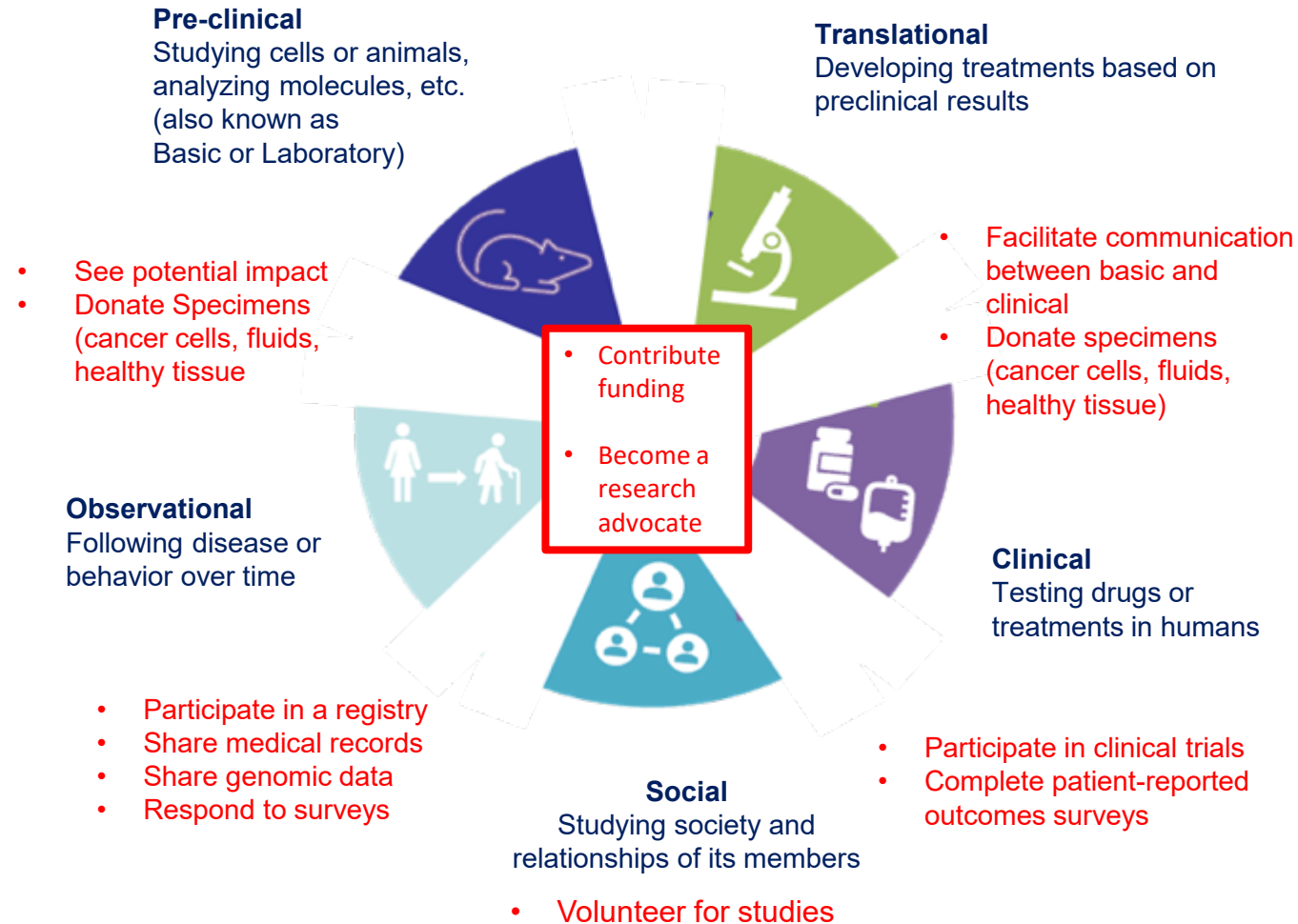


Biomarker Patient and Caregiver Groups

GROUP	FOCUS	CONTACT EMAIL	WEBSITE	TWITTER
 The ROS1ders	ROS1+ cancer	info@theros1ders.org	theros1ders.org	@ros1cancer
 ALK POSITIVE	ALK+ NSCLC	info@alkpositive.org	www.alkpositive.org	@ALKLungCancer
 Exon20 Group EGFR/HER2 EXON 20 MUTATION GROUP	EGFR & HER2 Exon 20 insertions	exon20@exon20group.org	exon20group.org	@Exon20Group
 EGFR Resisters	EGFR+ NSCLC plus resistance to EGFR TKIs	egfrresisters@gmail.com	www.egfrcancer.org	@EGFRResisters
 RET Renegades	RET+ NSCLC	retrenegades@gmail.com	N/A	@RetRenegades
 ALK Fusion	ALK+ NSCLC	info@alkfusion.org	www.alkfusion.org	@alk_fusion
 KRAS Kickers Lung Cancer	KRAS+ NSCLC	teri@kraskickers.org	kraskickers.org	@KRASKickers
 NTRKers	NTRK+ cancer	info@ntrkers.org	ntrkers.org	@NTRKers
 MET Crusaders	MET+ NSCLC	info@metcrusaders.org	metcrusaders.org	@metcrusaders
 BRAF Bombers	BRAF+ NSCLC	brafbombers@gmail.com	brafbombers.org	@BrafBombers
 RET positive	RET+ cancer	info@retpositive.org	retpositive.org	@RETpositive
 THE HAPPY LUNGS PROJECT	RET+ NSCLC	Info@happylungsproject.org	happylungsproject.org	--

Biomarker-focused patient-caregiver groups.

Forms of Cancer Research and Ways Patients Help Accelerate Research



Perception and Context Matter



Science CAN:

- Answer the “what?”
- Enable early detection
- Develop biomarker testing
- Provide treatment options
- Conduct clinical trials



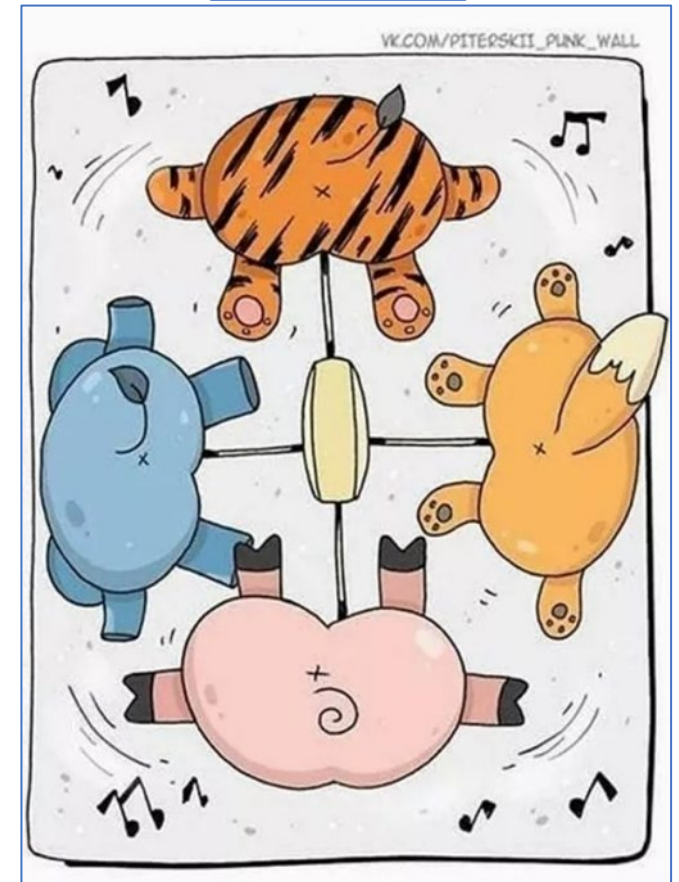
Science CANNOT:

- Answer the “why?” or “for whom?”
- Provide context
- Understand the whole person
- Comprehend fear and hope
- Replace human empathy

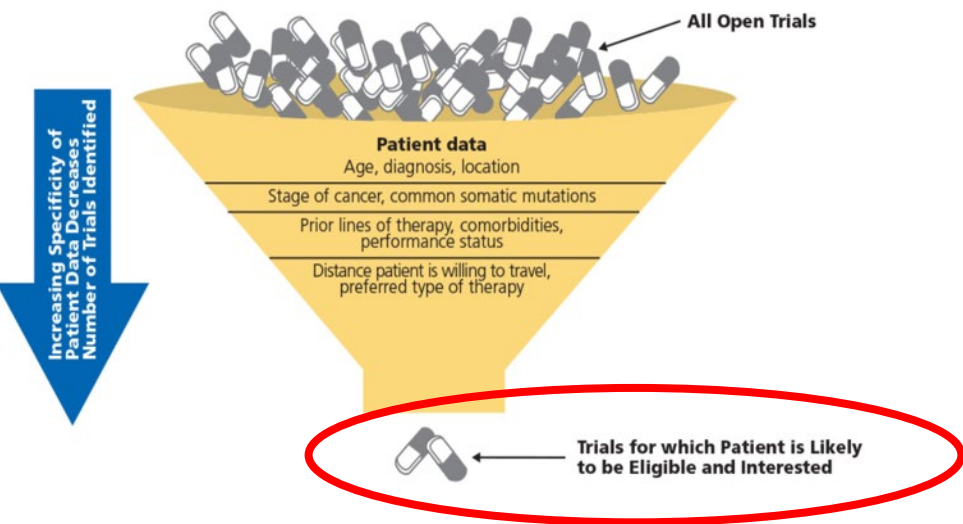
Doctors



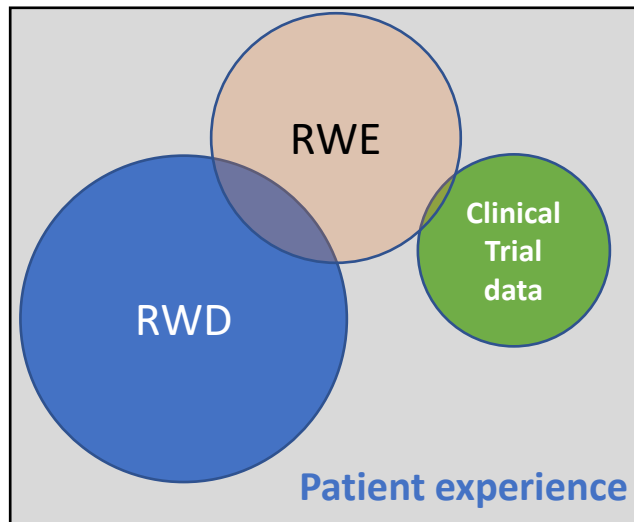
Patients



Potential of RWD to Improve Diversity and Generalizability in Clinical Trials



www.acscan.org/policy-resources/clinical-trial-barriers



GENERAL PRINCIPLES FOR USING RWD	RECOMMENDATIONS FOR USING RWD TO PLAN FEASIBLE ELIGIBILITY CRITERIA	RECOMMENDATIONS FOR USING RWD TO SUPPORT RECRUITMENT	RECOMMENDATIONS FOR ENHANCING RWD CAPABILITIES FOR THE RESEARCH ENTERPRISE
<ol style="list-style-type: none"> 1. Begin seeking insights from RWD as early as possible. 2. Use RWD to complement and support collaborative study design. 	<ol style="list-style-type: none"> 1. Evaluate available RWD sources against the particular needs of the study being planned. 2. Use RWD to identify and test important assumptions about the impact of potential eligibility criteria on trial feasibility. 3. Plan for iterative, targeted team discussions starting early in protocol design. 	<ol style="list-style-type: none"> 1. Start by designing realistic eligibility criteria. 2. Incorporate RWD-supported recruitment strategies whenever feasible. 3. Understand and address the needs of patients and sites with respect to RWD-supported recruitment. 	<ol style="list-style-type: none"> 1. Identify opportunities and risks of enhanced data linkage. 2. Support continued development of underlying technology. 3. Evaluate RWD-supported recruitment strategies and identify best practices. 4. Explore transparency of secondary data use to the patient community and opportunities to enhance patient agency with respect to usage of their data. 5. Enhance communication channels for RWD-supported recruitment. 6. Identify opportunities to increase diversity of study participants. 7. Identify and support approaches for creating global data sets.

From: https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_RWD_Recs.pdf

I Am Alive Because of Research



The Power of Patient Centered Language



Commonly used language	Patient-friendly reframing	Rationale
Lung cancer patient	Patient/person with lung cancer	Person-first language describes what the person has, not who the person is
Patient progressed	Cancer progressed	Eliminates blame language
Smoker	Patient/person with active tobacco use	Ends stigma; does not categorize a person by a behavior

IASLC Language Guide - <https://www.iaslc.org/IASLCLanguageGuide>



NCCN Language Guidance:
Sensitive, Respectful, and Inclusive
Language for NCCN Publications³

https://www.nccn.org/docs/default-source/about/nccn-guidance-on-inclusive-language.pdf?sfvrsn=53c8c78f_1

EDITORIAL | VOLUME 24, ISSUE 10, P1053, OCTOBER 2023

Patient first; person first

The Lancet Oncology

Treating patients with respect at every turn, including when referring to them and their disease in presentations, medical notes, the literature, and even in peer-to-peer conversation, will help to improve patient-clinician relationships, increase trust, and help to ensure that patients are confident they will receive the best medical advice possible when seeking help.

– *The Lancet Oncology*²

The Lancet Oncology. *Lancet Oncol.* 2023;24(10):1053..

Celebrate Progress, Push Forward with Urgency

- Honor Progress
- Engage, Educate and Empower Patients
- Balance Hope with Urgency
- Work Together to Transcend Limitations





Thank You!

*Imagine there's no lung cancer,
It's easy if you try,
No fear or scanxiety,
Just hope on the rise,
Imagine all the people,
Living life without disease...Ah!*

*Imagine there's a world without stigma,
It isn't hard to do,
Where research fuels compassion,
And empathy shines through,
Imagine all the treatments, advancing side
by side,
Bringing hope, with each breath, ooh-hoo.*

*You may say I'm a dreamer,
But I'm not the only one.
I hope someday you'll join us,
And the world will breathe as one.*

I am Grateful to...

