Incorporating Patient Reported Outcomes into the Lung Cancer Registry

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DISCLOSURES

Commercial Interest	Relationship(s)
AstraZeneca, Foundation Medicine, Merck, Thermo Fisher,	Speaker Honoraria/Travel Expenses
GRAIL, Guardant,	Advisory Boards
	All paid to GO2 Foundation for Lung Cancer

Today's presentation

- Overview of the Lung Cancer Registry
- Immunotherapy Patient Reported Outcomes Study
- Understanding Quality of Life Longitudinally
- Opportunities for Patient-Directed Research: Sexual Health Assessment of Women in Lung Cancer
- Summary

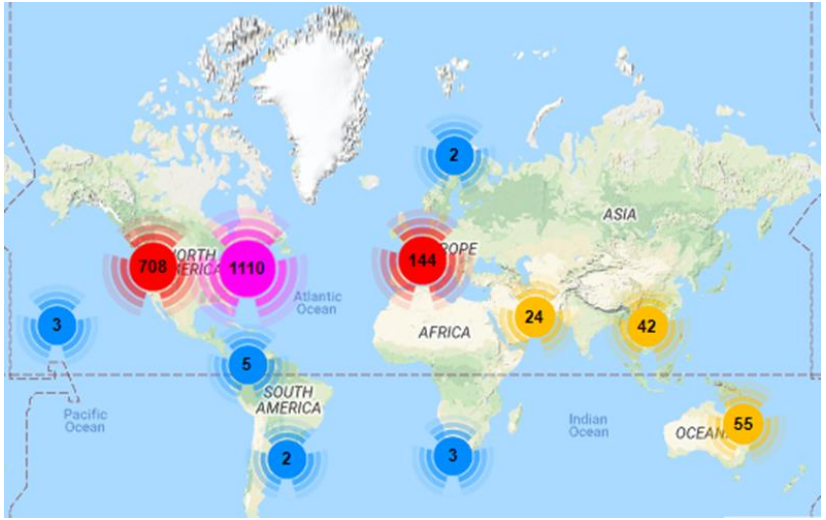
Together we are fueling the future of lung cancer research.

www.lungcancerregistry.org

Global Patient-Reported Registry

- 2200+ members and growing
  - Patients, survivors and caregivers
  - Ages: 18 to 85
  - 40 countries and 6 continents

- Registration – FREE
  - You join an international patient, caregiver, and research community
  - After completing surveys view other deidentified data to compare with your own
  - Medical record keeping - upload medical documents, images and test results
  - Find health care providers
  - Advance our understanding about lung cancer



Symptoms

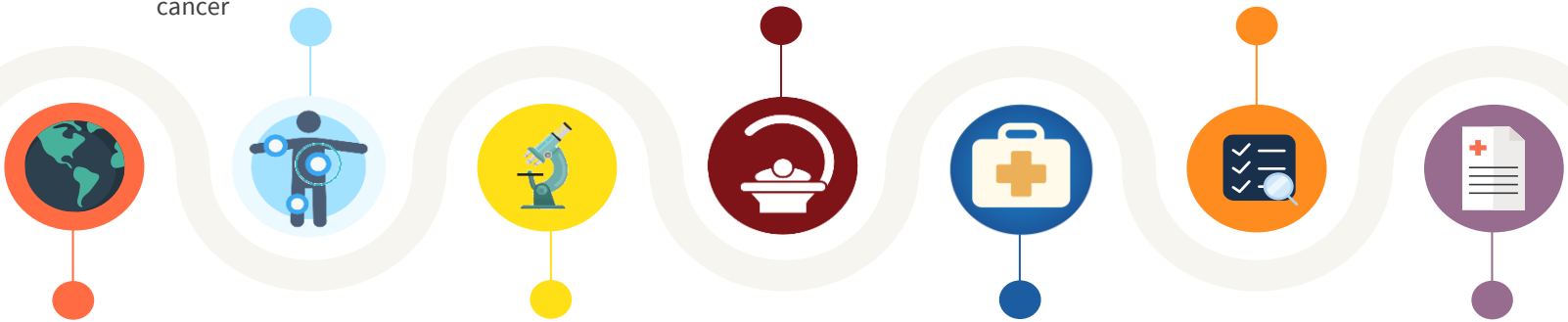
- Before Diagnosis
- Specialty of diagnosing MD
- Treatment for Symptoms
- Symptoms experienced after diagnosis
- Patient experiences due to cancer

Testing

- Diagnostic Tests
- Molecular / Biomarker / Genetic Testing

Prior Treatment

- Details on Surgery
- Details on Chemotherapy
- Details on Targeted Molecular Therapy
- Details on Radiation Therapy
- Details on Immunotherapy



Demographics

- Education
- Gender
- Ethnicity
- Marital Status
- Occupation
- Smoking Habits

Diagnosis

- Type of Cancer
- Type of Biopsy
- Stage of Cancer
- Location of Tumor
- Other Cancer History

Current Treatment

- Line of Therapy
- Details on Surgery
- Details on Chemotherapy
- Details on Targeted Molecular Therapy
- Details on Radiation Therapy
- Details on Immunotherapy

General Questions

- Supportive Services
- Insurance Coverage
- Quality of Life

Patient Reported Outcomes (PROs) of Immune Checkpoint Inhibitors (ICIs) for Lung Cancer

Goals of the study:

1) Evaluate the feasibility and acceptability of using patient registries to collect PRO data of novel anti-cancer agents

2) Evaluate ICI-specific patient-reported toxicities and overall quality of life in patients treated with ICIs in the real-world setting

Patient Reported Outcomes (PROs) of Immune Checkpoint Inhibitors (ICI) for Lung Cancer

Methods:

- English speaking adults over the age of 18 with a lung cancer diagnosis who had taken a PD-1/PD-L1 inhibitor
- Complete the survey instrument online in the Lung Cancer Registry portal
- Data collection: January 2018 – December 2019

Participant Demographics

	All (n=226)	Durvalumab (n=29)	Nivolumab (n=81)	Pembrolizumab (n=111)	Atezolizumab (n=13)	*p* value
Age: M (SD) years	61.16 (10.52)	61.48 (9.13)	61.24 (10.29)	61.02 (10.79)	56.69 (10.00)	0.37
Gender: n (%) female	170 (75%)	23 (79%)	61 (75%)	81 (73%)	11 (85%)	0.76
Race: n (%) white	200 (90%)	27 (93%)	75 (94%)	94 (86%)	12 (92%)	0.37
Comorbidities: M (SD)	2.86 (1.62)	2.79 (0.94)	3.00 (1.75)	2.78 (1.65)	2.85 (1.52)	0.82
Time on treatment: n (%)						<0.001
≤1 month	23 (10%)	3 (10%)	5 (6%)	14 (13%)	1 (8%)	
2-6 months	105 (47%)	18 (62%)	30 (37%)	54 (50%)	7 (58%)	
7-12 months	35 (16%)	7 (24%)	9 (11%)	21 (19%)	0 (0%)	
13-24 months	30 (14%)	1 (3%)	12 (15%)	17 (16%)	2 (17%)	
>24 months	29 (13%)	0 (0%)	25 (31%)	2 (2%)	2 (17%)	

Jim et al., Cancers, 2020 Dec 31;13(1):E103

Results

	All (n=226)
Treatment delay due to toxicity: n (%)	56 (25%)
ER visit due to toxicity: n (%)	26 (12%)
Hospitalization due to toxicity: n (%)	20 (9%)
FACT-G Total: M (SD)	74.08 (17.28)
Physical	21.37 (5.68)
Functional	16.74 (6.34)
Emotional	16.39 (4.96)
Social	19.54 (6.02)
PROMIS Depression 4a: M (SD)	7.11 (3.14)

Jim et al., Cancers, 2020 Dec 31;13(1):E103

Most Common Symptomatic Immune Related Adverse Events (irAEs)

Symptom	Any severity n (%)	Moderate-severe n (%)	Missing n	Responses n
Fatigue	190 (85%)	92 (41%)	10	224
Aching joints	137 (63%)	58 (27%)	16	218
Aching muscles	122 (57%)	43 (20%)	21	213
Insomnia	122 (56%)	38 (18%)	17	217
Shortness of breath	109 (51%)	27 (13%)	20	214
Itching	108 (50%)	40 (18%)	16	218
Skin dryness	108 (50%)	38 (18%)	20	214

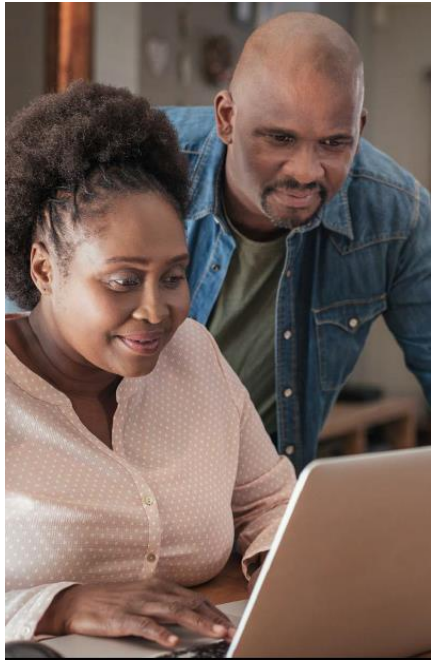
Jim et al., Cancers, 2020 Dec 31;13(1):E103

Summary: Immunotherapy PRO Study

- Feasible to track real-world PROs
- Health-related quality of life (HRQoL) data consistent with prior studies of people with lung cancer
- There are common symptomatic irAEs for patients taking ICIs that need to be considered and addressed: fatigue, aching muscles & joints, insomnia, dyspnea, skin conditions
- Reduced HRQoL, functional and emotional well-being compared to U.S. population and cancer norms warranting further evaluation

How Do We Track PROs Longitudinally?

- Symptoms vs Side Effects
- Instruments
- Timing
- Stakeholder Feedback
- Implementation & IRB Approval



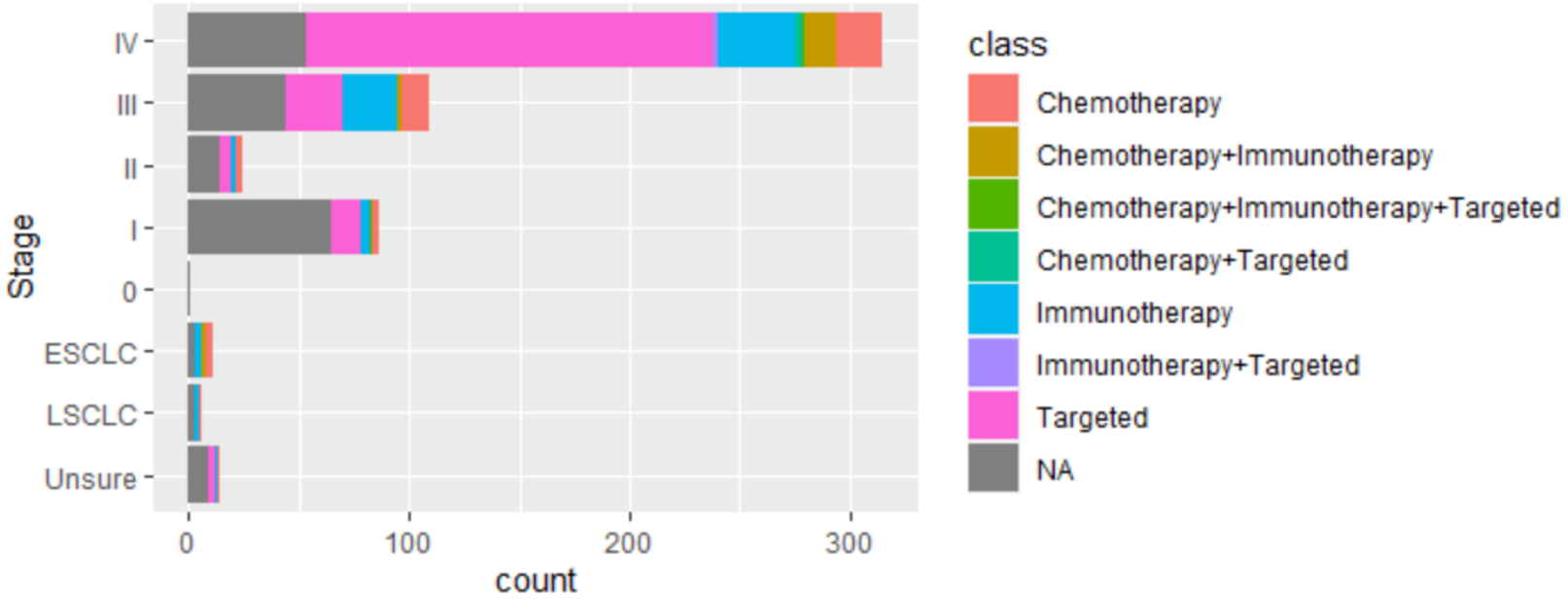
Data Collection To-Date

- Launched new Lung Cancer Registry general informed consent (Nov. 2019)
- Lung cancer patient baseline survey updated with EORTC QLQ-C30 and LC-29
- More granularity about timing of treatment initiation and discontinuation in each line of therapy
- Lung cancer patient quarterly surveys launched (Nov. 2019)

Participant Demographics: IC/Baseline Survey

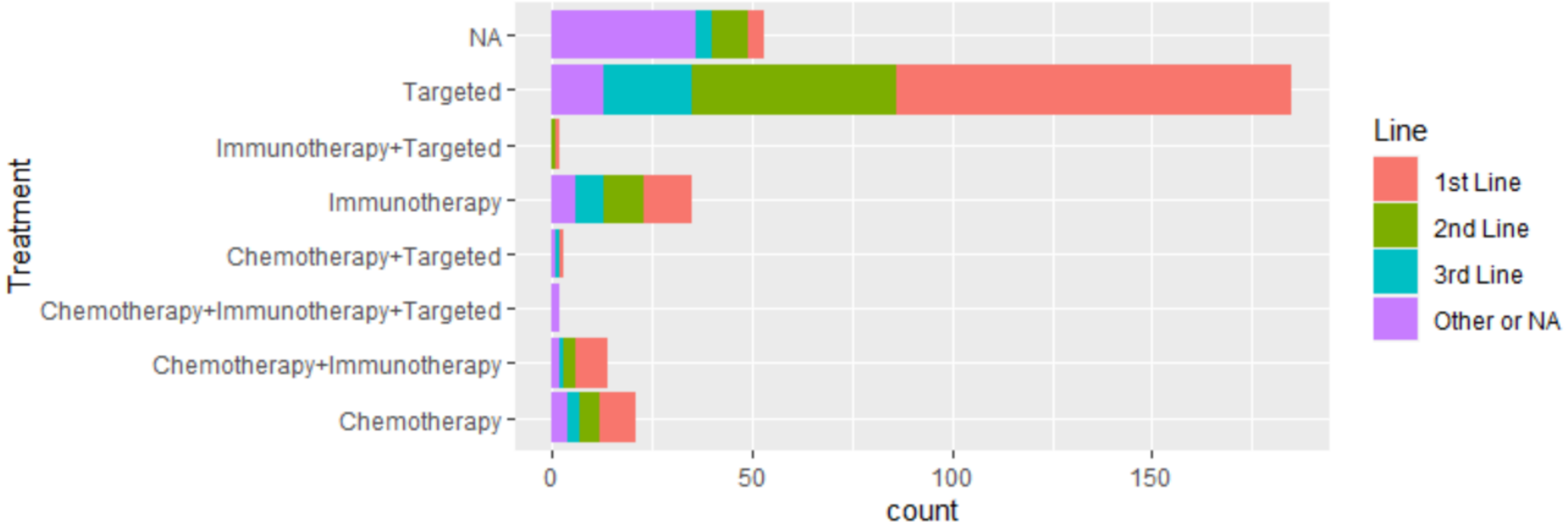
		N	%
Country			
	United States	489	86.50%
	Australia	20	3.50%
	United Kingdom	15	2.70%
	Canada	12	2.10%
	17 Other Countries	1 to 5	
Sex			
	Male	132	23.36%
	Female	433	76.64%
Race			
	White	488	86.37%
	Asian	30	5.31%
	Black or African American	8	1.42%
	Native Hawaiian or Other Pacific Islander	3	0.53%
	American Indian or Alaska Native	1	0.18%

Cancer Staging & Current Treatment



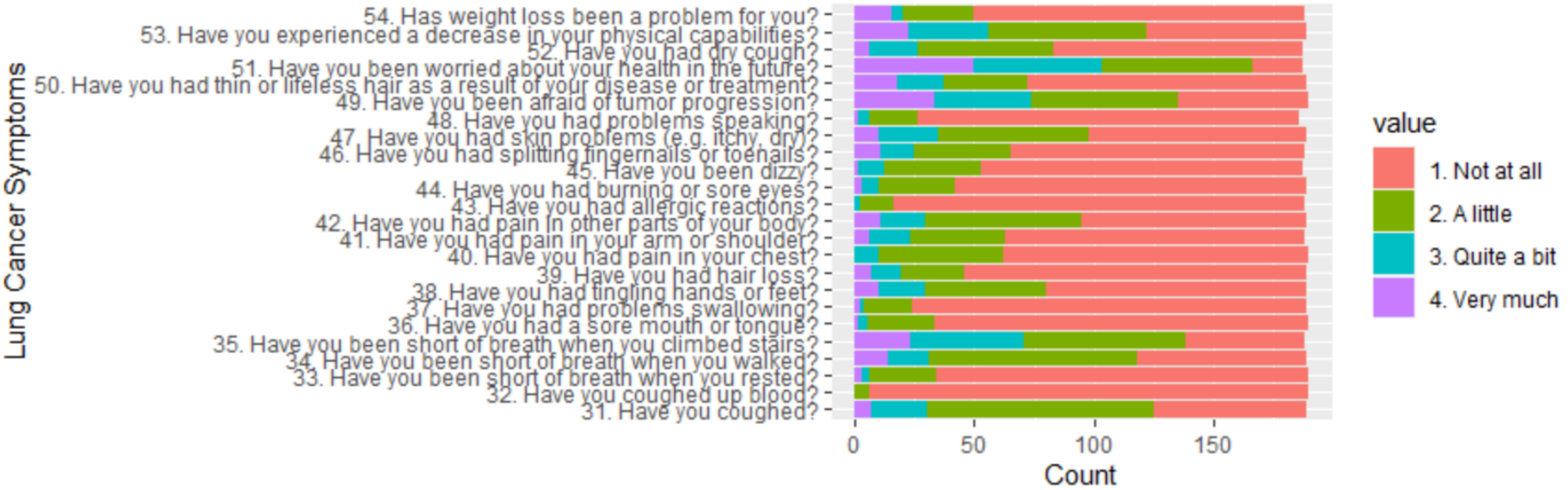
N = 566 unique participants who accepted informed consent (IC) and completed a baseline questionnaire.
NA = No self report of chemotherapy, immunotherapy, or targeted therapy

Stage IV: Current Line of Therapy



N = 315 Stage IV participants who accepted IC and completed a baseline questionnaire.
NA = No self report of chemotherapy, immunotherapy, or targeted therapy

EORTC-QLQ-C30 Symptoms/Side-Effects



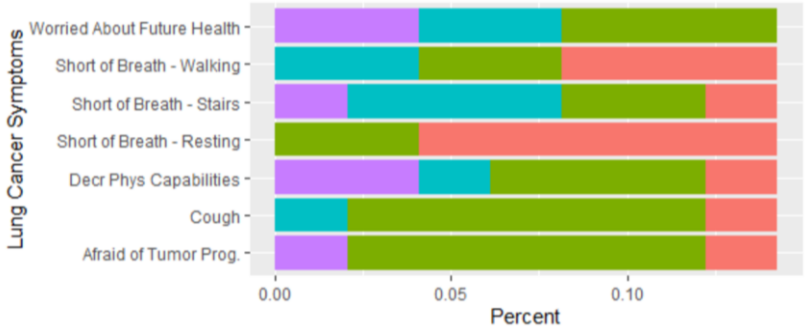
N = 189 who registered as new participants, accepted IC, and completed a baseline questionnaire.

Trend: Different patterns by treatment class

Chemotherapy (n= 10)

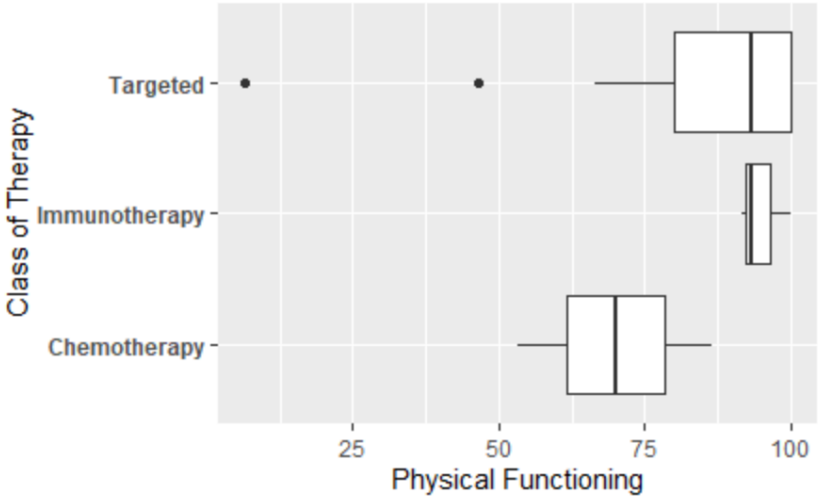
Targeted Therapy (n=50)

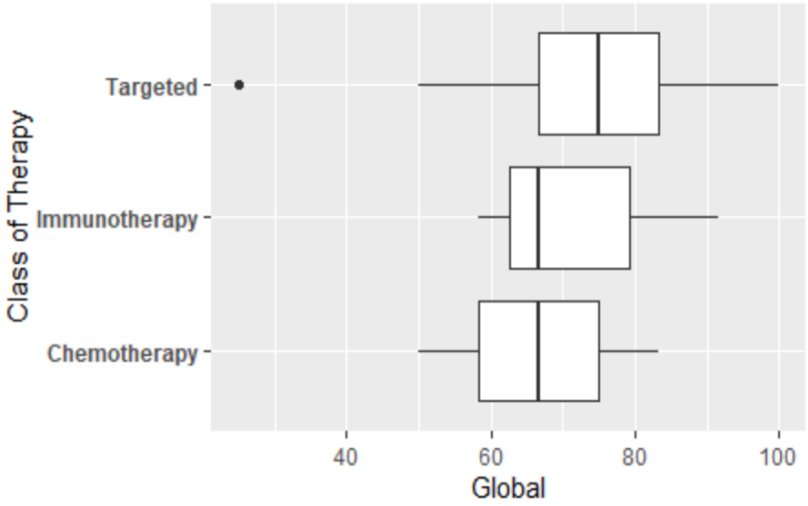
Immunotherapy (n=7)



Stage IV participants currently taking chemotherapy, immunotherapy, or targeted therapy, in first- or second-line.

Physical Functioning & Global Health Status

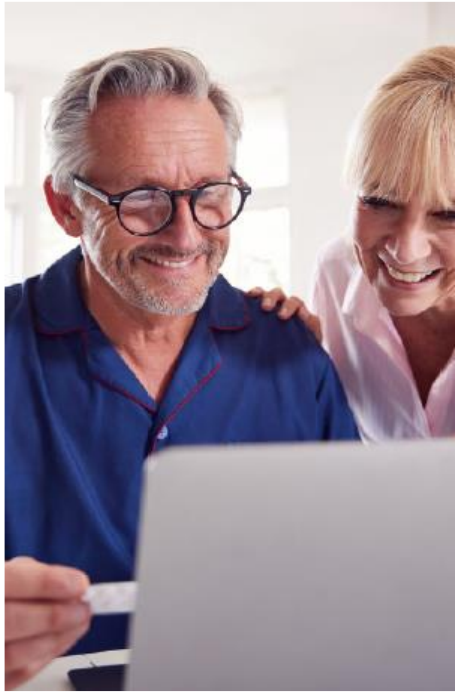




N = 60 Stage IV participants currently taking chemotherapy, immunotherapy, or targeted therapy, in first- or second-line.

Summary: Longitudinal HRQoL Data Collection

- Just beginning analyses of these data
- Registry participants are completing the validated EORTC instruments within the baseline survey
- Early insights: treatment groups show quality of life differences that appear to be attributable to class of treatment & specific symptoms
- Future: In-depth analysis of symptoms/side effects along with QoL over time, aiming to elucidate differences in specific treatments and treatment sequencing



Power Lung Cancer Research into Women's Sexual Health.

No one asks about your sexual health. But we do.

"We need to empower our patients to ask questions about what matters to them… I want all patients out there with lung cancer to feel empowered to ask their doctor because they don't have to suffer in silence."

– Dr. Narjust Duma,
Principal Investigator, SHAWL

Learn how the SHAWL survey is helping researchers and how ***you*** can make a difference.

LUNG CANCER REGISTRY

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GO2 FOUNDATION FOR LUNG CANCER
Empower Everyone. Ignore No One.

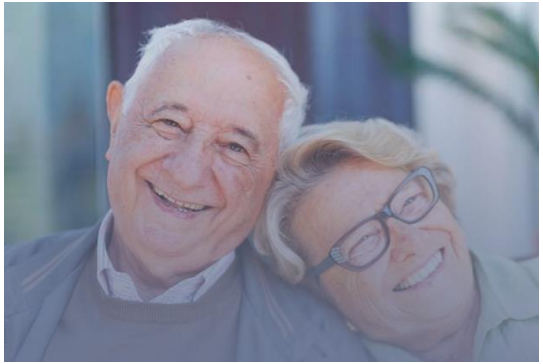
EGFR resisters
PATIENTS driving RESEARCH

Coming in 2021 to www.lungcancerregistry.org

- New easier-to-use, more engaging web interface with additional features
- Translations in 4 additional languages (Spanish, French, German, simplified Chinese)
- Efforts to diversity Registry population to be more reflective of entire lung cancer community
- Opportunities for research collaborations

LUNG CANCER REGISTRY

Take Homes



- Health-related quality of life can be measured in a real-world setting and provide important information about people who have been diagnosed with lung cancer
- More research is needed to elucidate quality of life issues in people diagnosed with the lung cancer, as many remain unrecognized
- This work is critical for developing and implementing clinical solutions as lung cancer survival rates improve

Thank you!

Most importantly, to all of the participants in the Lung Cancer Registry who are driving research and powering all of the insights presented today

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Narjust Duma, MD (U of Wisconsin) & SHAWL study team

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