

Aggiornamenti ASCO 2018 neoplasie toraciche

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di Cuneo, Mondovì e Savigliano



Aggiornamenti:

Lung cancer prevention
Surgery in Lung cancer
“Other “



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Lung cancer prevention

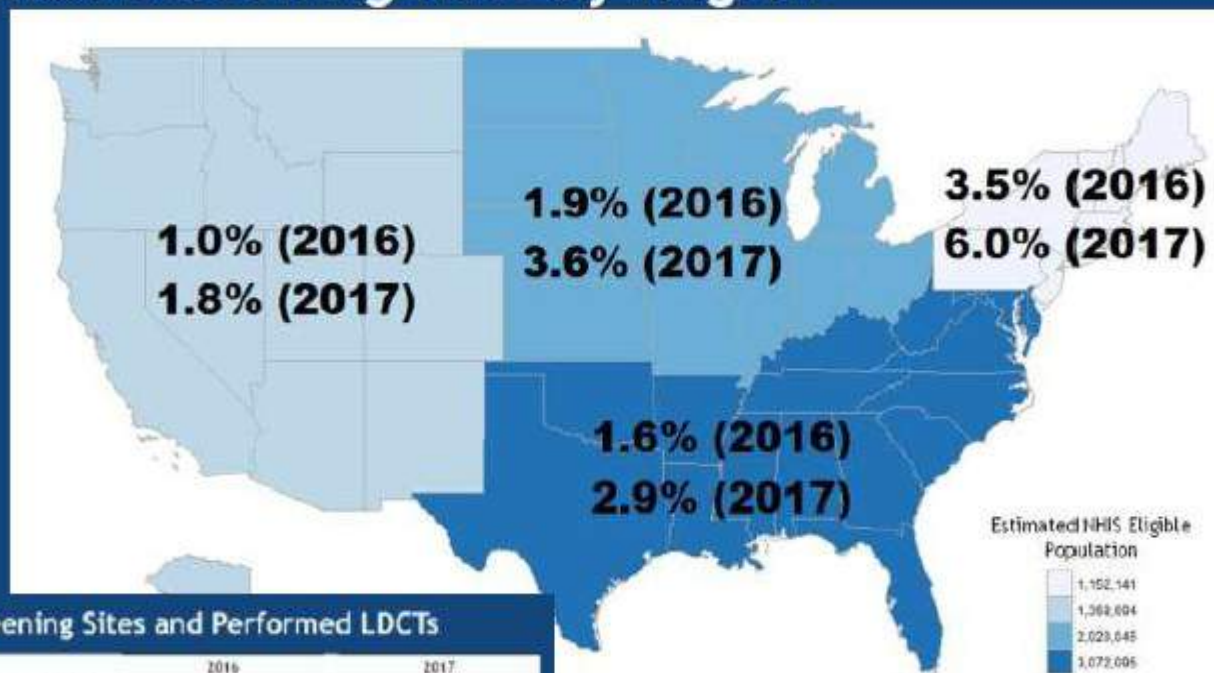
Abstract 6504 (Oral Session)

Lung cancer screening rates: Data from the lung cancer screening registry.

Author(s): Danh
Center, Universi
University of Lo
University of Lo
Brown Graham

Lung Cancer Screening

Results: Screening Rate by Region

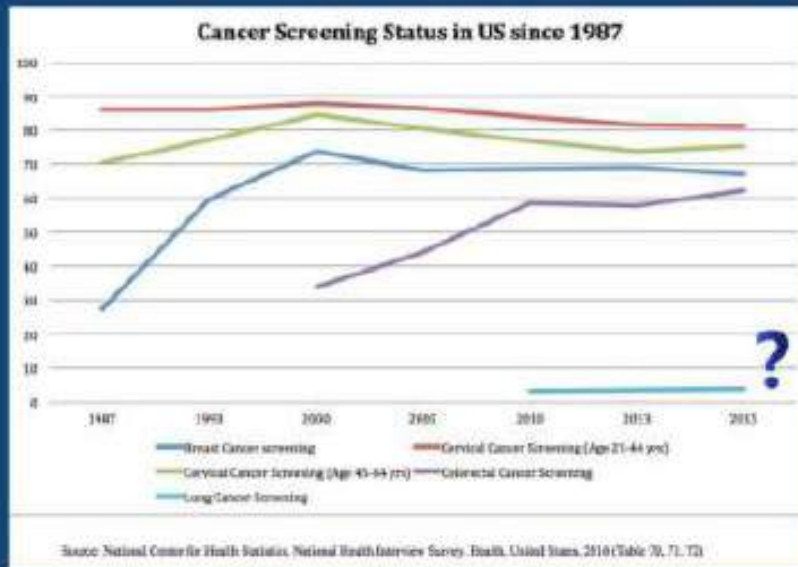


Results: Screening Sites and Performed LDCTs

U.S. Census Region	Estimated Eligible Smokers	2016			2017		
		Facilities	LDCTs	Rate	Facilities	LDCTs	Rate
Northeast	1,152,141	404	40,105	3.5	487	68,792	6.0
Midwest	2,020,045	497	38,931	1.9	672	73,490	3.6
South	3,072,095	663	47,966	1.6	905	88,649	2.9
West	1,368,694	232	14,080	1.0	293	24,912	1.8
Total	7,612,975	1796	141,260	1.9	2357	256,088	3.4

Lung Cancer Screening

Discussion: Comparison of USPSTF cancer screenings



Summary/Conclusions

- Annual LDCT screening (1.9% → 3.5%) remains inadequate across the United States following USPSTF recommendations, especially when compared to the other known cancer screenings.
- Effective screening can prevent 12,000 premature lung cancer deaths per year

Tobacco Dependence Predicts Higher Lung Cancer and Mortality Rates and Lower Rates of Smoking Cessation in the National Lung Screening Trial

Alana M. Rojewski, PhD; Nichole T. Tanner, MD; Lin Dai, PhD; James G. Ravenel, MD; Mulugeta Gebregziabher, PhD; Gerard A. Silvestri, MD; and Benjamin A. Toll, PhD

TABLE 2] Likelihood of Quitting Smoking by Level of Dependence According to FTND and HSI

Variable	FTND		HSI	
	OR	95% CI	OR	95% CI
Low dependence	0.94	0.76-1.16	0.95	0.80-1.14
Medium dependence	0.67	0.54-0.84	0.75	0.63-0.89
High dependence	0.71	0.58-0.87	0.72	0.60-0.85
Very high dependence	0.59	0.48-0.73	0.59	0.49-0.72

Chest 2018, article in press

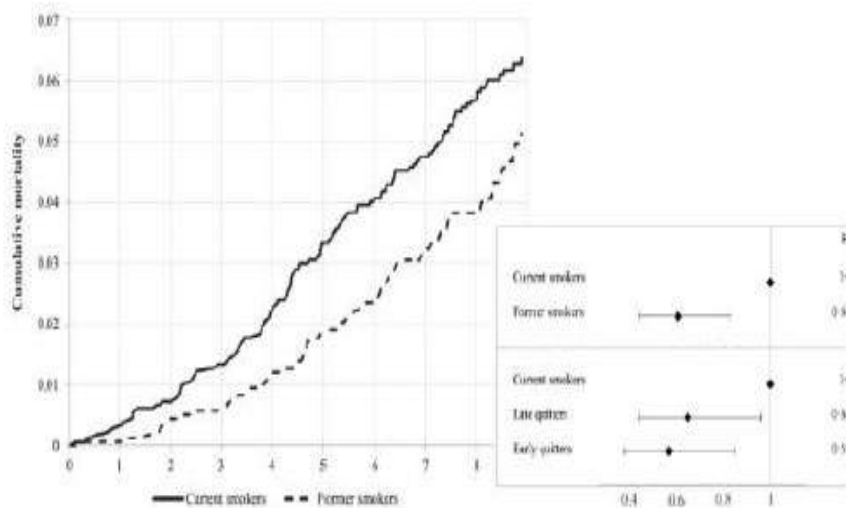
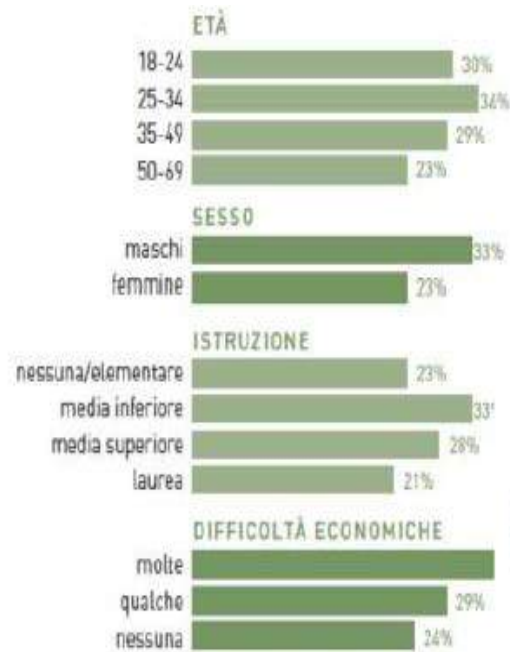


Figure 2. Kaplan-Meier overall mortality experienced by current and former smokers. Patients who still smoked and those who had stopped smoking during the last screening visit were regarded as current and former smokers, respectively.

Smoking status ^h	n	HR	95% CI	p-value
Current smokers	151 (17,846)	8.46	(7.11-9.81)	0.2235
Former smokers	109 (15,012)	7.26	(5.89-8.62)	



TJ
 ISSN 0300-8916
 Tumori 2017; 103(6): 543-550
 DOI: 10.5301/TJ.5000684
 ORIGINAL RESEARCH ARTICLE

Trends in lung cancer and smoking behavior in Italy: an alarm bell for women

Annalisa Trama¹, Roberto Boffi², Paolo Contiero³, Carlotta Buzzoni⁴, Roberta Pacifici⁵, Lucia Mangone⁶; AIRTUM Working Group*

A point of concern is that in just 1 year (from 2016 to 2017) the number of smoking women increased from 4.6 million to 5.7 million whereas the number of smoking men decreased from 6.9 to 6 million.



European position statement on lung cancer screening

Matthijs Oudkerk, Anand Devaraj, Rozemarijn Vliegenthart, Thomas Henzler, Helmut Prosch, Claus P Heussel, Gorka Bastarrika, Nicola Sverzellati, Mario Mascialchi, Stefan Delorme, David R Baldwin, Matthew E Callister, Nikolaus Becker, Marjolein A Heuvelmans, Witold Rzyman, Maurizio V Infante, Ugo Pastorino, Jesper H Pedersen, Eugenio Paci, Stephen W Duffy, Harry de Koning, John K Field

- 3 All future screenees entering into early detection programmes for lung cancer should be provided with carefully constructed participant information on the potential benefits and harms of screening to enable them to make an informed decision as to whether they wish to participate or not. Smoking cessation advice should be offered to all active smokers.

Current Lung Cancer Screening Paradigm is Not Widely Adopted

Early Detection of Lung Cancer is a High Unmet Medical Need



- Low-dose computed tomography (LDCT) improves lung cancer mortality in high-risk individuals
- Rate of clinical adoption remains low (1.9%)^{2,3}
- Criticisms of LDCT include risk of false positives and logistical challenges⁴

cfDNA-Based Tests Represent an Untapped Opportunity for Cancer Detection

- **Cancer genotyping** using plasma cfDNA
 - Adopted for detection of specific actionable mutations
 - Only validated for advanced cancer
 - Uses smaller targeted gene panels
- **Cancer detection** using plasma cfDNA
 - Aims to identify a broader cancer “signature” rather than specific individual mutations
 - Genome-wide approaches offer additional information that allow early detection
 - Could address the unmet medical need

¹National Lung Screening Trial Research Team. *N Engl J Med* 2011; 365:395-409. ²Pham D et al. *J Clin Oncol* 36, 2018 (suppl; abstr 6504). ³Jemal A, Fedewa SA. *JAMA Oncol* 2017;3:1278-1281. ⁴McCunnet RJ et al. *Chest Journal* 2014;145(3):618-24.

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PRESENTED BY: Geoffrey R. Oxnard, MD

3



Vital status & cancer
status



Participants without cancer: Data on cancer diagnosis + treatment, recurrence, mortality, or remain cancer-free

FPI: 08/2016; 11,648 enrolled; Target: Complete Enrollment of all 15,000 Participants in 2018

CCGA is a Prospective Longitudinal Cohort Study Designed for Early Cancer Detection: First Training and Test Set Analyses

12,292 of 15,000 participants enrolled
70% cancer:30% non-cancer

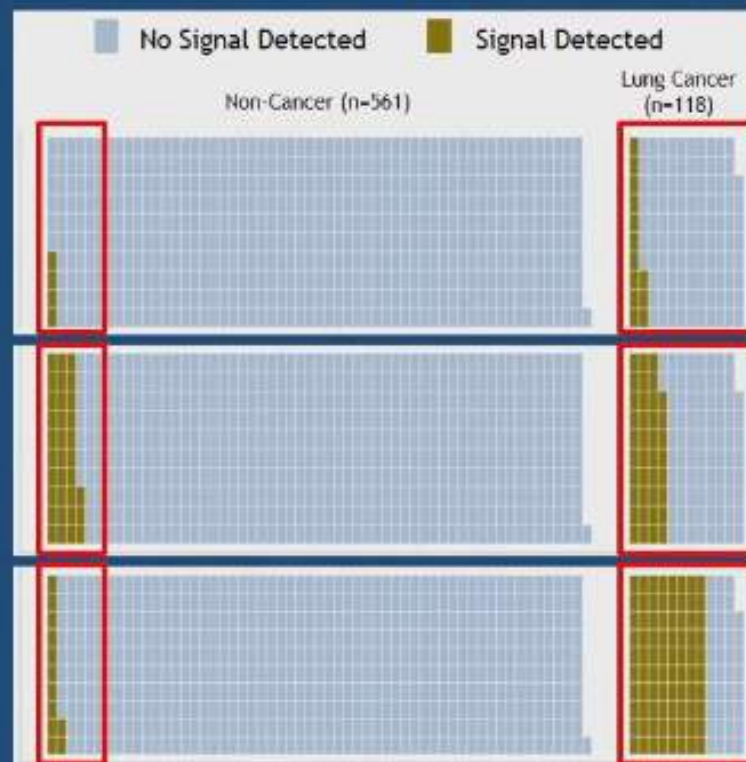
142 active sites
24 U.S. states,
one site in Canada
FPI: 08/2016

12,200 reserved for future validation studies

2,800 participants:
Pre-specified case-control
substudy

Simulating Existing Assays: Not Optimized for Screening

- 561 non-cancer and 118 pts with lung cancer from CCGA analyzed
- Testing a single location (emulating ddPCR) **without WBC filtering**
 - KRAS:p.G12X
 - Excellent specificity
 - Small number of cancer cases detected
- NGS panel reporting 813 clinically actionable variants (OncoKB levels 1-4)* **without WBC filtering**
 - Many cancer cases with variants
 - Many non-cancer cases with variants
- CCGA Targeted Assay with **WBC filtering**
 - Increased detection
 - Reduced false-positives (set at 98% here)
 - Continuous statistical score allows for tradeoffs in sensitivity/specificity



Conclusions

- This first interim analysis of the CCGA study (2,800 participants, 174 with lung cancer) shows:
 - Comprehensive sequencing of plasma cfDNA generates high-quality data across the spectrum of genomic features that permits non-invasive cancer detection
 - These assays detect lung cancer across stages, histologies, and populations, and results replicate in an independent test set
 - WBC-derived mutations and copy number variations are a major source of potential false positives that must be accounted for to achieve high specificity
- Together, these early results support the promise of using cfDNA-based sequencing to develop an early cancer detection test with high specificity
 - Further assay and clinical development in large-scale clinical studies is ongoing
 - CCGA (NCT02889978): remaining participants for further training and clinical validation
 - STRIVE (NCT03085888): clinical validation in an intended use population

About liquid biopsies...

Key points

- Biopsies are a fundamental part of lung cancer care, and will never be eliminated
- A good liquid biopsy can replace some inconvenient tumor biopsies
- But... don't let a bad liquid biopsy supplant an inconvenient tumor biopsy
- Liquid biopsies may create new opportunities impossible with tumor biopsies

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Meeting Home

Potential role of serial liquid biopsies to guide treatment decisions in NSCLC.

Sub-category:
Metastatic Non-Small Cell Lung Cancer

Citation:

J Clin Oncol 36, 2018 (suppl; abstr e21079)

Author(s): Todd Cory Knepper, Theresa A. Boyle, Jhanelle Elaine Gray, James Kevin Hicks; H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL; Department of Pathology, Moffitt Cancer Center, Tampa, FL; Moffitt Cancer Center, Tampa, FL

Results: 17 pts with NSCLC had serial liquid biopsies (35 total tests) performed. GAs were detected in 14 pts (82.4%) (median = 4 GAs per test; range = 0-13). **Of the 14 pts with GAs detected, none of the intra-patient reports were identical.** New GAs were detected in 13 (92.9%) pts and GAs were lost in 4 (28.6%). [...]

Conclusions: The **results of serial liquid biopsies performed on pts with NSCLC are not static with none having identical results between tests.** Serial liquid biopsies revealed clinically important results with known resistance alterations detected on the subsequent test in 27.3% of cases treated with EGFR inhibitors and previously undetected potentially targetable alterations detected in 42.9% of cases.



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Surgery in Lung Cancer



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Lymph Node Collection Kit

Non-small Cell Lung Cancer: Low Tech to High Tech*



David Harpole, M.D.
Professor of Surgery
Associate Professor of Pathology
Director of the Duke Thoracic Oncology Laboratory
Duke University Medical Center
Dutham, NC USA

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Wicked Heterogeneity Across NCDB Institutions

	Community	Comprehensive Community	Academic/Research	NCI-designated Comprehensive
Quality of lymph node examination				
pNX rate*	9	7	6	5

Patients: Kit v Non-Kit Resections

Prospective study: 1,171 resections*, 32 surgeons; 650 (56%) kit cases by 20 surgeons

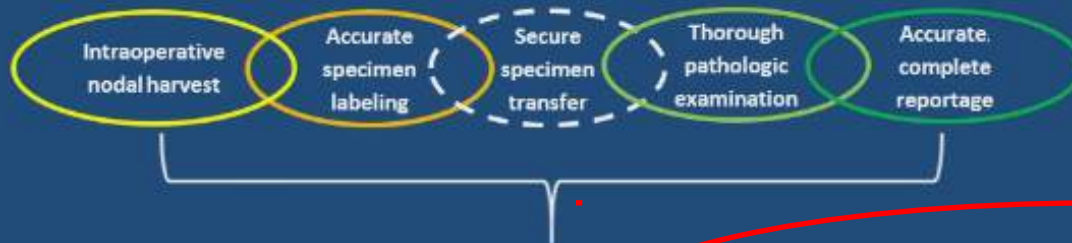
	Kit [†]	Non [†]	P
Mean age, years	68	67	0.03
Female sex	53	48	0.09
Race			0.12
White/black	80/18	76/23	
Insurance			0.52
Medicare	43	43	
Commercial	18	17	
Medicaid	36	37	
Histology			<.0001
Adeno	46	51	
Squamous	28	31	
Other	25	18	
Extent of resection			<.0001
Pneumonectomy	3	6	
Lobe/bilobectomy	91	76	
Sublobar	6	18	

*Primary surgical resections, excluding neoadjuvantly treated patients;

[†]percentage unless otherwise indicated

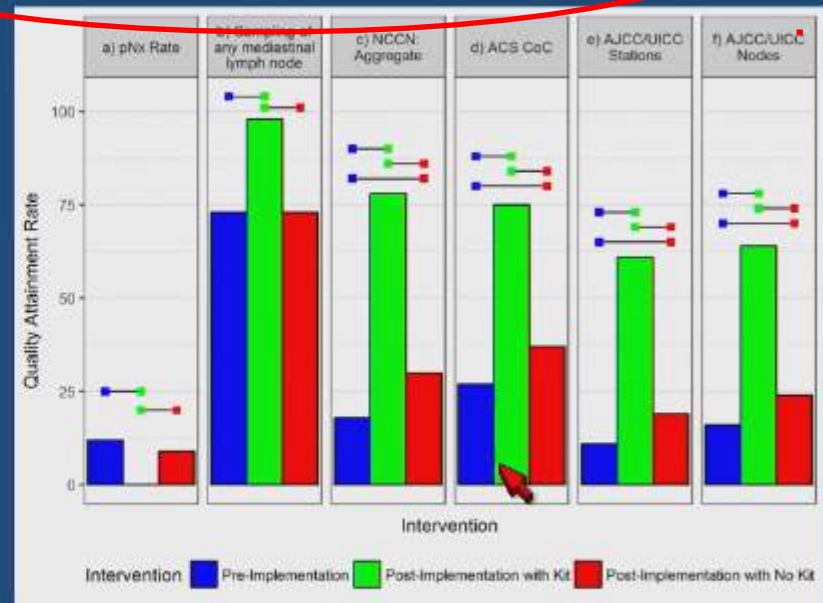
	Kit [†]	Non [†]	P
Clinical Stage			0.18
I	72	68	
II	16	15	
III	8	10	
IV	4	0	
Technique of resection			<.0001
Open	42	52	
Robotically-assisted	44	28	
Video-assisted	14	20	
Pathologic stage			0.23
IA1	5	4	
IA2	20	26	
IA3	14	15	
IB	22	21	
IIA	4	2	
IIB	17	18	
IIIA	13	12	
IIIB	3	2	
IV	1	0	

Conceptual Model: The Chain of Responsibility



It is the Kit, Not Heightened Awareness

- Post-Implementation with the kit has better quality than pre-implementation levels
- Post-Implementation cases without the kit have quality closer to pre-implementation



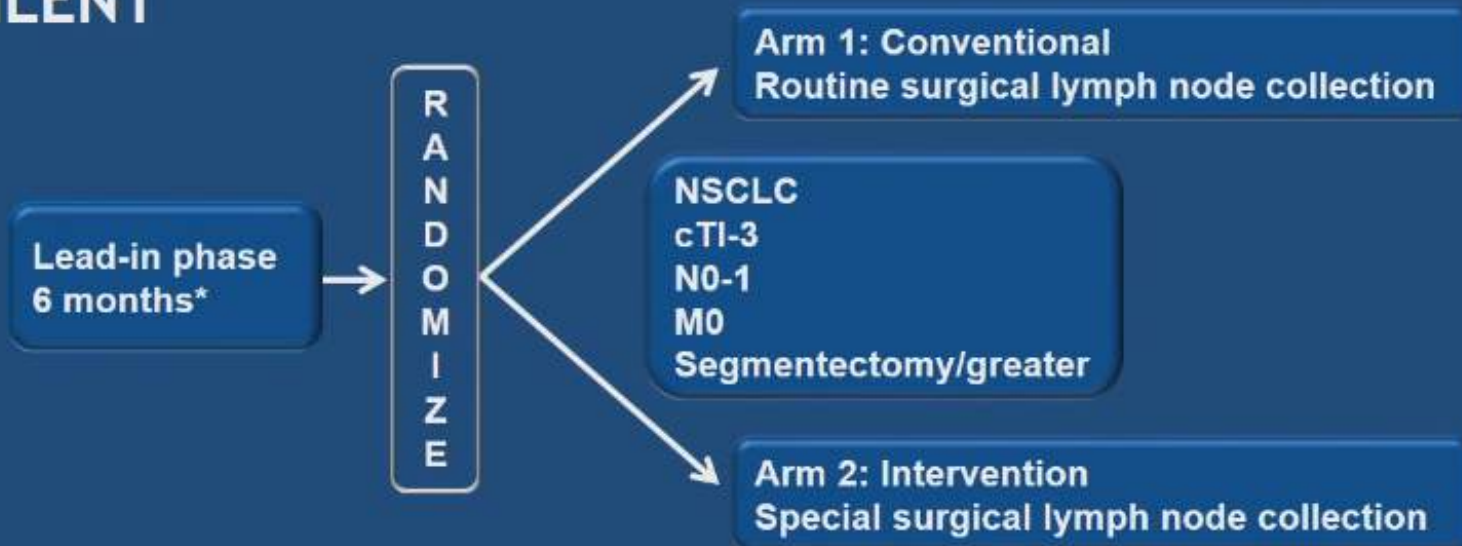
Indicates 'mandatory'
Pre-labelled with anatomic name

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Prospective randomized trial

SILENT



Primary Endpoint: 3 Year RFS rate

Waiting for results.....



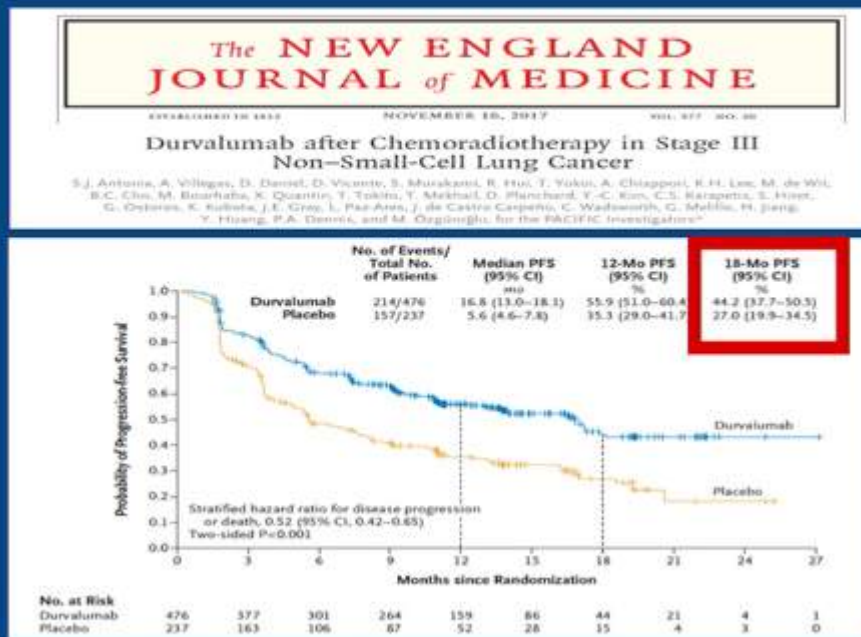
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Systemic treatments



Bending the disease free and progression free survival curves in lung cancers

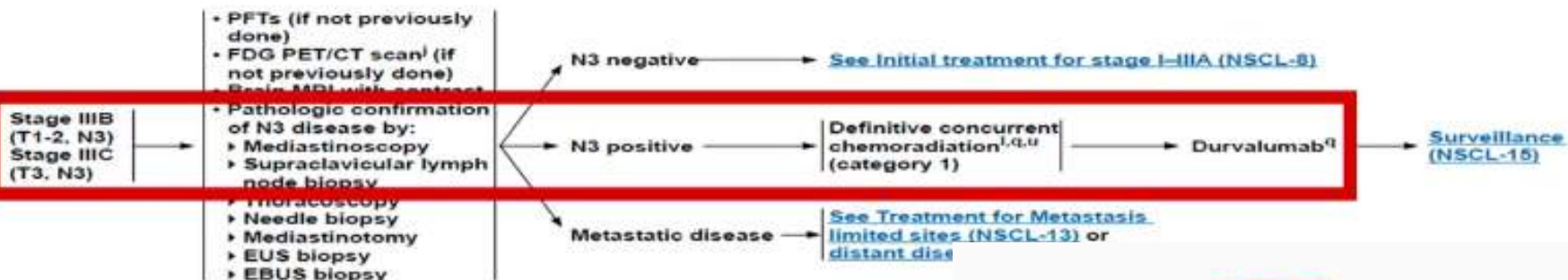
Stage III Inoperable and Unresectable Lung Cancers: Durvalumab vs Placebo after Concurrent Chemotherapy & Radiation



	Pneumonitis Any Grade	Pneumonitis Grade 3 or 4
Durvalumab	34%	3%
Placebo	25%	3%

CLINICAL ASSESSMENT PRETREATMENT EVALUATION

INITIAL TREATMENT



¹PET/CT performed skull base to knees or whole body. Positive PET/CT scan findings for distant disease scan positive in the mediastinum, lymph node status needs pathologic confirmation.

⁴See Principles of Radiation Therapy (NSCL-C).

¹¹See Chemotherapy Regimens Used with Radiation Therapy (NSCL-E).

¹¹If full-dose chemotherapy is not given concurrently with RT as initial treatment, give additional 2 cycles.

Note: All recommendations are category 2A unless otherwise indicated.

Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation

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How does radiation modulate tumor/immune system?

INCREASE OF ANTIGEN
VISIBILITY

MICROENVIRONMENT
MODIFICATION

TRIGGERING OF IMMUNE
RESPONSE

Blocking PD-1/PD-L1 axis improves response in anti-CTLA-4 + RT treated tumors while adding them to RT and anti-CTLA-4 induces tumor control.

BUT...

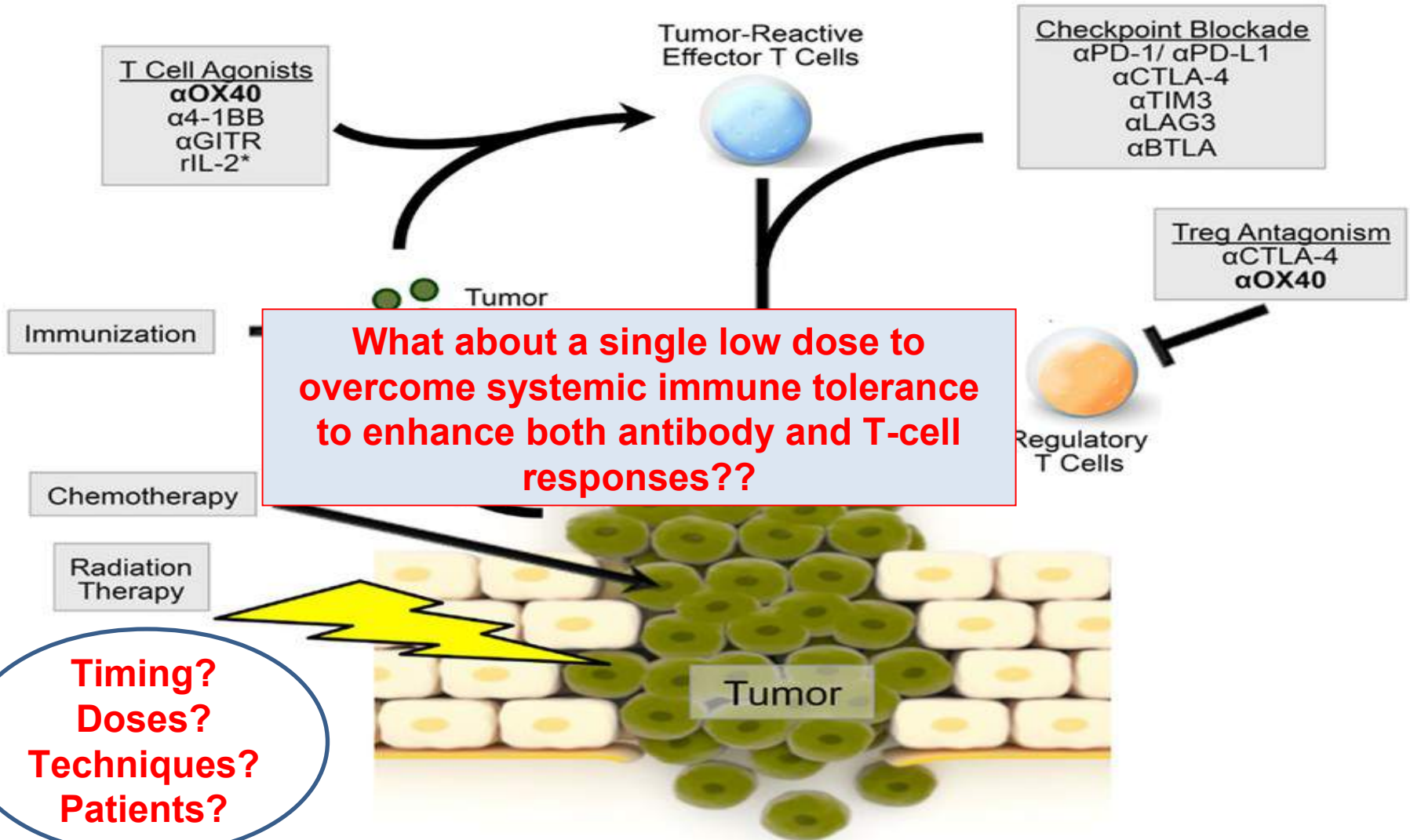
*Preclinical data **suggest both stimulating and suppressive functions**

°Signals of immunogenic cell death (ICD).

ang Y, Front Pharmacol 2018; Demaria S, JAMA Oncol



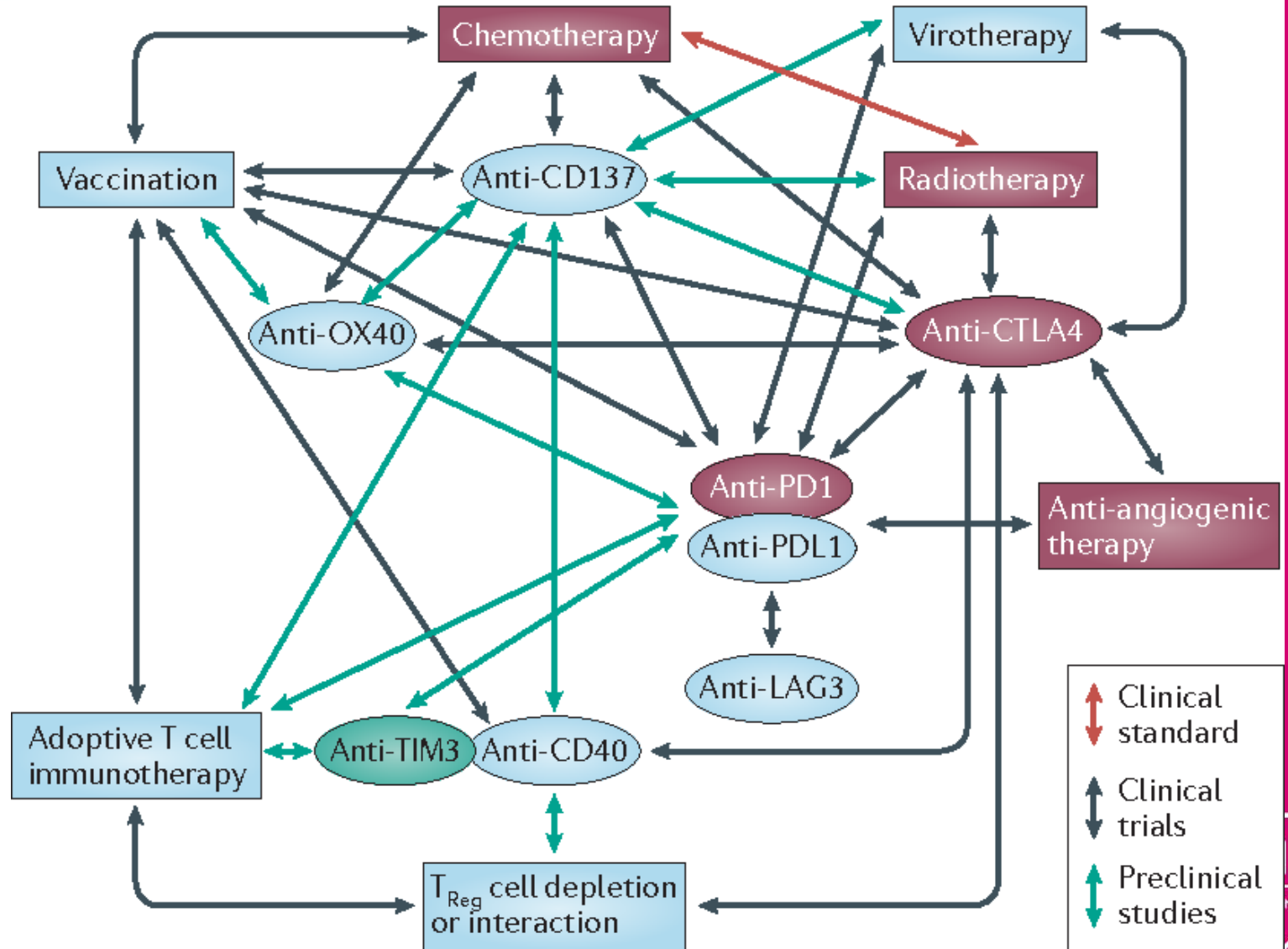
OPEN QUESTIONS





How many combinations?

Current status (2015)



ANTI-PD/PD-L1 AS BACKBONE TO COMBINATION TX?

Nivolumab	Pembrolizumab	Atezolizumab	Durvalumab
<ul style="list-style-type: none"> - Chemotherapy - Radiation/ablation - EGFR/ALK TKI - Anti-VEGF/VEGFR inhibitor - Vasc disrupt agent - Hypomethylating agent - HDAC inhibitor - SPK inhibitor - C-Met inhibitor - Glutaminase inhibitor - Dasatinib - Vaccine - Gene therapy - IL15 agonist - PEG IL10 - TGFβR1 inhibitor - Anti-CD27 - Anti-CXCR4 - Anti-CSF-1R - IDO-1 inhibitor - Anti-CTLA4 - Anti-LAG - Anti-TIM-3 - Anti-KIR 	<ul style="list-style-type: none"> - Chemotherapy - Radiation - EGFR/ALK TKI - Anti-VEGF/VEGFR inhibitor - Hypomethylating agent - HDAC inhibitor - CDK inhibitor - BTK inhibitor - PI3K inhibitor - KIT/CSF1R/FLT3 inh - FGFR inhibitor - JAK1 inhibitor - CRM1 inhibitor - FAK inhibitor - Anti-EGFR - Anti-CEACAM1 - PEG hyaluronidase - Vaccine - Oncolytic - PEG IL10 - Anti-CSF-1 - IDO1 inhibitor - Anti-CTLA4 - Anti-B7-H3 	<ul style="list-style-type: none"> - Chemotherapy - Radiation - EGFR/ALK TKI - Anti-VEGF/Ang-2 - MEK inhibitor - Vaccine - Adoptive cell therapy - Anti-CEA/CD3 - Anti-CEA/IL-2 - Anti-OX40 - Anti-CD40 - Anti-CD27 - Anti-CSF-1 - Adenosine A2A inhibitor - IDO-1 inhibitor - Anti-CTLA4 - Anti-TIGIT 	<ul style="list-style-type: none"> - Chemotherapy - Radiation - EGFR/ALK TKI - VEGFR inhibitor - BTK inhibitor - MEK inhibitor - HDAC inhibitor - PARP inhibitor - WEE1 inhibitor - ATR inhibitor - Anti-OX40 - CXCR4 inhibitor - CSF - Anti-CD73 - Anti-CCR4 - Anti-CSF1R - Anti-NKG2A - Adenosine A2a inhibitor - IDO1 inhibitor - Anti-CTLA4 - Anti-PD-1
		<p>Avelumab: ALK inhibitor (crizotinib and lorlatinib), anti-41BB, anti-OX40</p>	



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Combinations in advanced disease



Immunotherapy plus chemotherapy



Immunotherapy plus immunotherapy



Immunotherapy plus radiotherapy

Early stage

Abstract #8510

Phase III Neoadjuvant Trials of Immune Checkpoint Inhibitors

	IMPower030	Checkmate 816	KEYNOTE 671
Agent	Atezolizumab	Nivolumab	Pembrolizumab
Patients Planned	302	642	786
Stages	II-IIIb	IB-IIIa	IIb-IIIa
Endpoints (1 st /2nd)	MPR/EFS-PCR	EFS-PCR/MPR	EFS-OS/MPR-PCR
Arms	Atezo-Chemo Chemo	Ipi-Nivo Nivo-Chemo Chemo	Pembro-Chemo Chemo

Phase III Adjuvant Trials of Immune Checkpoint Inhibitors

	ANVIL	BR.31	IMPower010	EORTC 1416
Agent	Nivolumab	Durvalumab	Atezolizumab	Pembrolizumab
Patients Planned	714	1360	1127	1380
Endpoints	DFS	DFS	DFS	DFS
Duration of ICI	1 year	1 year	1 year	1 year



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Biomarkers

Biomarkers

Abstract 12000

8:00 AM - 8:12 AM

Association of high tissue TMB and atezolizumab efficacy across multiple tumor types.

Fatema A. Legrand, PhD - First Author • **Disclosure**
Roche/Genentech

Abstract 12001

8:12 AM - 8:24 AM

Prospective clinical evaluation of blood-based tumor mutational burden (bTMB) as a predictive biomarker for atezolizumab (atezo) in 1L non-small cell lung cancer (NSCLC): Interim B-F1RST results.

Vamsidhar Velcheti, MD - First Author • **Disclosure**
Taussig Cancer Institute, Cleveland Clinic

Tumor biology oral session Tuesday, June 5, 8-11AM,

Circulating Biomarkers

Poster Board: #239 • **Abstract 3025**

Serum interleukin 8 (IL-8) may serve as a biomarker of response to immuno-oncology (I-O) therapy.

Michael Carleton, PhD - First Author
Bristol-Myers Squibb

2,000

Poster Board: #305 • **Abstract 3091**

Phase I trial of BMS-986253, an anti-IL-8 monoclonal antibody, in patients with metastatic or unresectable solid tumors.

Julie Marie Collins, MD, MPH - First Author
National Cancer Institute

Monother

Poster Board: #319a • **Abstract TP53109**

Phase 1b/2 study of nivolumab in combination with an anti-IL-8 monoclonal antibody, BMS-986253, in a biomarker-enriched population of patients with advanced cancer.

Ignacio Melero Bermejo, MD, PhD - First Author
Clinica Universidad de Navarra

Combinati

Overall Survival by PD-L1 TPS

TPS <1%

TPS 1-49%

TPS ≥50%

Events	HR (95% CI)	<i>P</i> ^a
38.6%	0.59 (0.38-0.92)	0.0095

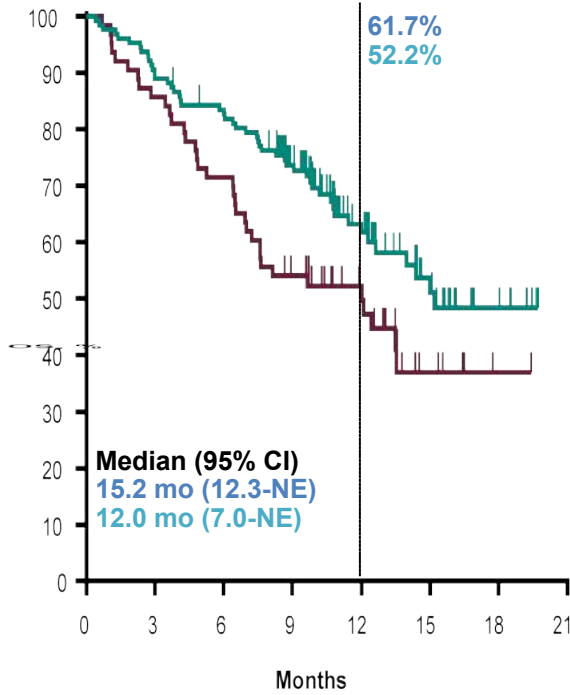
Events	HR (95% CI)	<i>P</i> ^a
28.9%	0.55 (0.34-0.90)	0.0081

Events	HR (95% CI)	<i>P</i> ^a
25.8%	0.42 (0.26-0.68)	0.0001

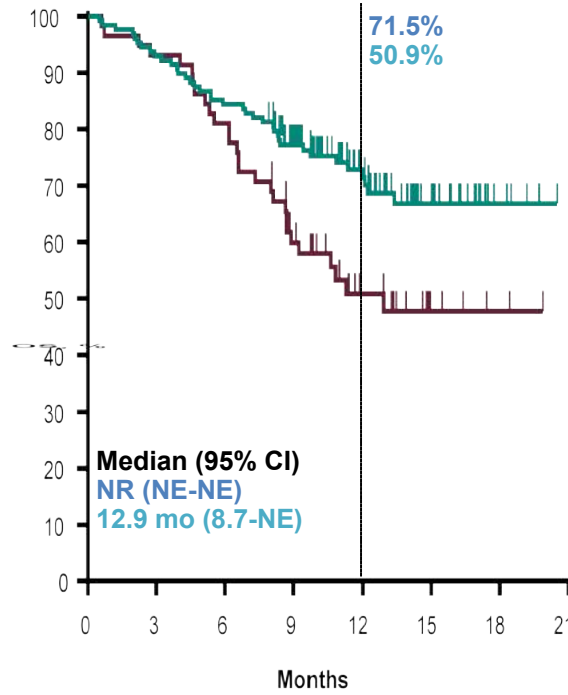
Pembro/Pem/PI at

Placebo/Pem/PI at

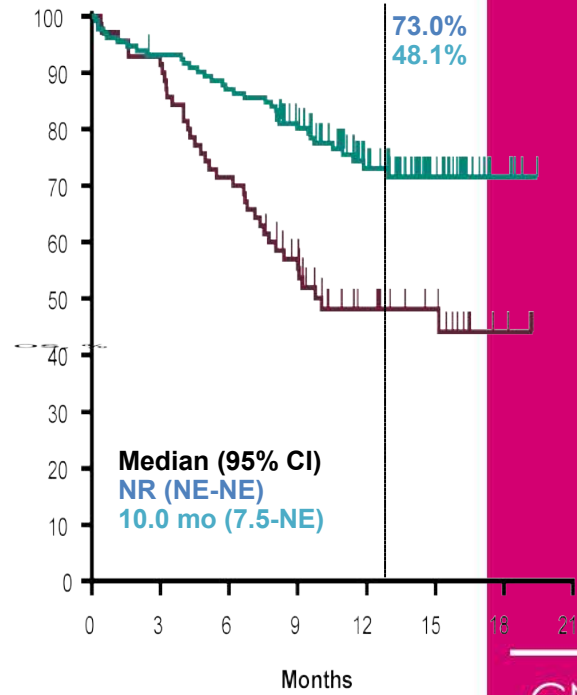
55.6%



No. at Risk							
0	3	6	9	12	15	18	21
127	113	104	79	42	20	6	0
63	54	45	32	21	6	1	0



No. at Risk							
0	3	6	9	12	15	18	21
128	119	108	84	52	21	5	0
58	54	47	32	17	5	2	0



No. at Risk						
0	3	6	9	12	15	18
132	122	114	96	56	25	6
70	64	50	35	19	13	4

^aNominal and one-sided. Data cutoff date: Nov 8, 2017.



Selection of TMB ≥ 10 mut/Mb Cutoff for Nivolumab + Ipilimumab Using FoundationOne CDx™

- Retrospective testing from CheckMate 026, 012, and 568 informed selection of the TMB cutoff (≥ 10 mut/Mb)¹⁻³
- ORR increased in patients with higher TMB, and plateaued at TMB ≥ 10 mut/Mb

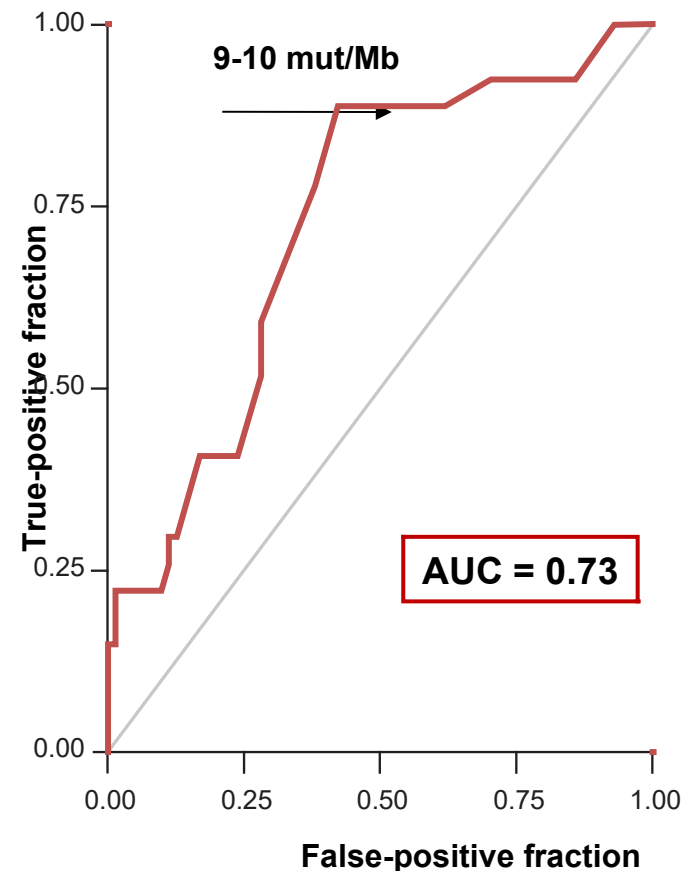
CheckMate 568:

Phase 2 study of nivolumab + ipilimumab in 1L NSCLC Tumor Mutational Burden (TMB) as a Biomarker for Clinical Benefit From Dual Immune Checkpoint Blockade With Nivolumab + Ipilimumab in First-line Non-Small Cell Lung Cancer: Identification of TMB Cutoff From CheckMate 568

Ramalingam S, et al.

Date: April 16, 2018 Time: 12:05 – 12:25pm

CheckMate 568: ROC for TMB by ORR irrespective of tumor PD-L1 expression (n = 98)

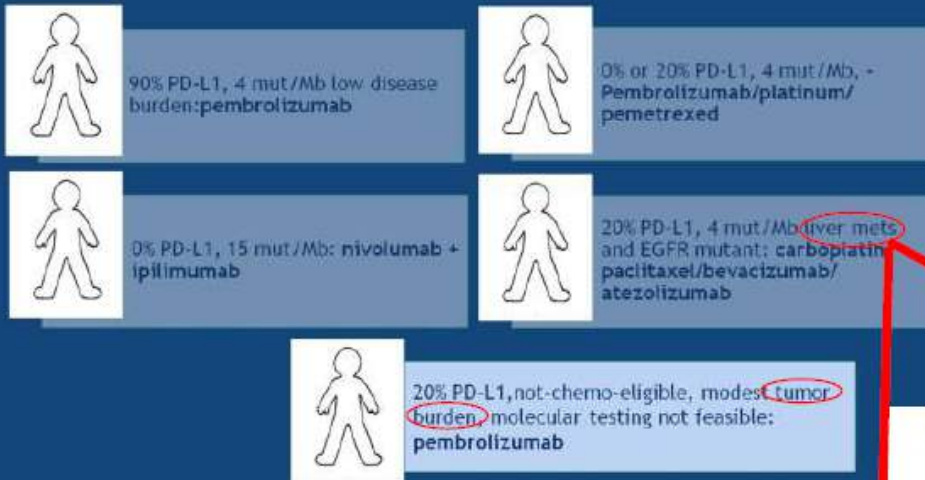


1. Carbone DP, et al. *N Engl J Med* 2017;376:2415–2426; 2. Hellmann MD, et al. *Cancer Cell* 2018. doi: <https://doi.org/10.1016/j.ccell.2018.03.018>. Epub; 3. Ramalingam S, et al. Presented at AACR Annual Meeting; April 14–18, 2018; Chicago, IL, USA. CT078.

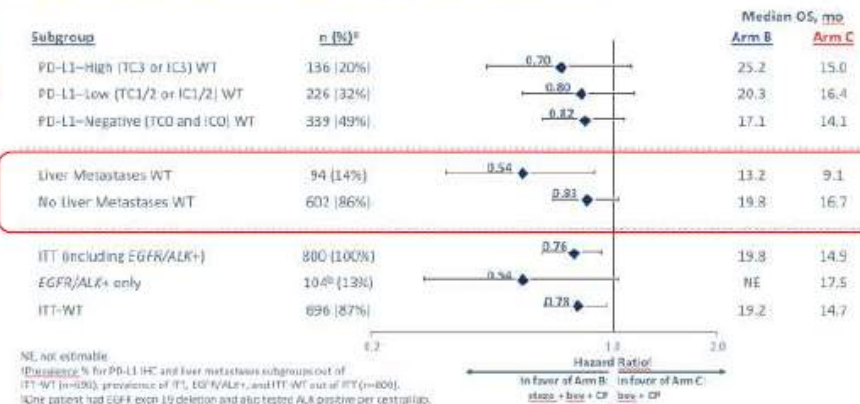


New options?

Theoretical treatment scenarios



IMpower150: OS in key subgroups (Arm B vs Arm C)

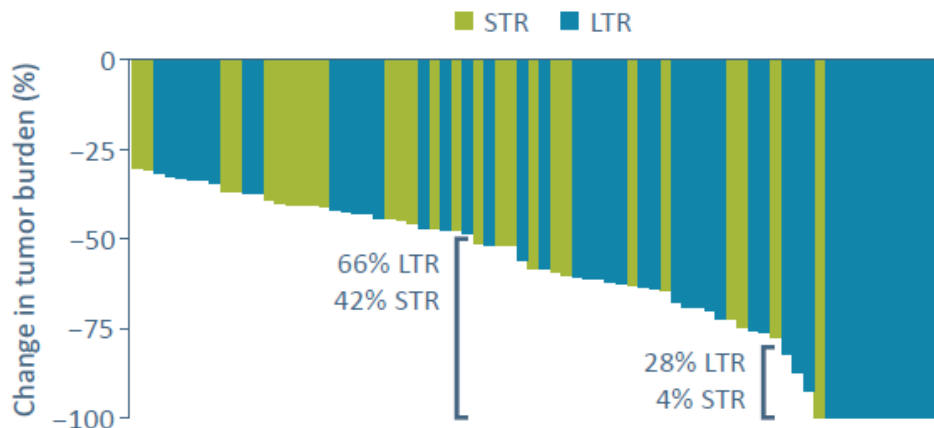


Gandhi L, Discussant Plenary ASCO 2018

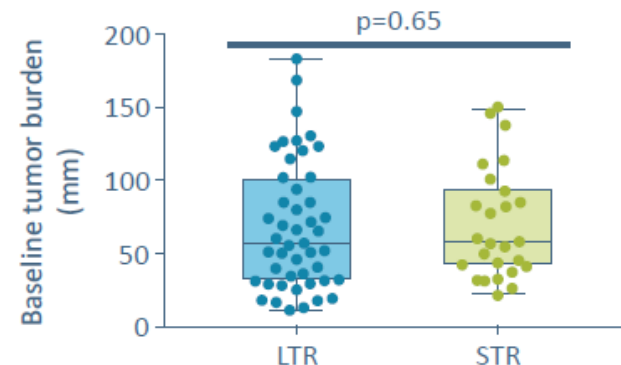
Focus on initial response or on durable one?

Clinical and molecular features predicting long-term response (LTR) to anti-PD-(L)1 based therapy in patients with NSCLC

- Responders with LTR vs STR: Depth of response, but not tumor burden, correlated with LTR
 - Greater proportion of patients with BOR <-50% and <-80% in LTR



- Baseline tumor burden in patients with LTR is similar to those with STR



Smoking status, PD-L1 expression, and TMB correlate with long-term response in NSCLC patients treated with anti-PD-(L)1 based therapy. **TMB, but not PD-L1 expression, is distinctly increased in those with LTR compared to those with transient response.** The features predicting initial response compared to durable response may be distinct.



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Infine....



Patient & Oncologist Discordance in Goals of Care in EOL Decision Making

Funded by NINR: NRO14856

Sara L. Douglas, PhD, RN¹, Barbara J. Daly, PhD, RN¹,
Neal J. Meropol, MD², Amy R. Lipson, PhD³

¹ Case Western Reserve University, School of Nursing & Case Comprehensive Cancer Center, Cleveland, OH

² Flatiron Health, New York, NY; Case Comprehensive Cancer Center; Case Western Reserve University.

³ Case Western Reserve University, School of Nursing

Measuring Goals of Care

- Patient screen:
- Oncologist version: (2 questions)
“Regarding the care of this patient, what is most important to YOU right now?”




Discord b/w patients & oncologists goals in end of life care #10007 Sara Douglas, Case CCC

Question	Concordance between goals of patients and their oncologists		
Strategy	168 patients with advanced cancer and their 8 oncologists questioned every 3 months: quality of life vs length of life		
Methods	Discordance: 40 point diff, scale from 0 (QOL) – 100 (length)		
Findings	Pts goal	vs	onc goal, r = .13
	Pts goal	vs	onc view of pts goal, r = .29
	Oncs goal	vs	onc view of pts goal, r = .71
	Discordance in 30%, persisted from enrol't to death in 77%		
Conclusions	Substantial discordance persisted from enrolment to death Oncologists thought patients' goals were similar to their own		

ASCO Meeting Library

A feasibility study to examine the role of a mindfulness-based wellness curriculum for early clinical trainees.

 Presented Monday, June 4, 2018

Authors:

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45%-80% of practicing oncologists worldwide reporting symptoms of burnout (Hlubocky et al. ASCO 2017)

A total of **six monthly 30 minute sessions**. Participants will complete questionnaires pre- and post-intervention.

Primary aim is feasibility determined through recruitment, participation, completion and compliance rates.

Secondary aim is acceptability, assessed using post-intervention questions addressing usefulness of the program. 27 of 28 eligible participants have enrolled and completed pre-session questionnaires.

Mindfulness is a strategy that can be used to recognize and cope with stress and burnout and foster resiliency. **The goal is not to focus on relaxation, but rather on self-awareness, thus extending into a form of “reflective practice”**

Opportunities to Cure More Patients with Localized Lung Cancers

Take Home Messages: Re-imagine Care

- The goal of care is cure. The risk-benefit analysis here is different than when caring for patients with extra-thoracic metastases
- All members of the multimodality team need to promote and support the overall regimen and not just individual components
- With more modalities, more agents, and less lifestyle disruption by all our modalities, re-imagine both care and research for all individuals with localized lung cancers
- Choosing “the best” for each component matters
- Achieving optimal results requires even closer attention to the sequence, timing, and benefits of concomitant use



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Grazie

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