MRO. ART
INNOVATIVE TREATMENTS AND PATIENTS COMPLIANCE
31° RESIDENTIAL COURSE

PHARMACOLOGICAL INNOVATIONS AND INTEGRATION WITH RADIOTHERAPY IN THIRD STAGE NSCLC

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UNIVERSITÀ CAMPUS BIO-MEDICO DI ROMA

Conflict of interest

Name of Ineligible Companies	Nature of the Relationship(s) with Ineligible Companies	If "Other" relationship, please describe.
Astra Zeneca	Other	Advisory Board, Speakers Bureau, Research Funding
Roche	Other	Speakers Bureau, Research Funding
Amgen	Other	Speakers Bureau, Research Funding
Merck (MSD)	Speakers Bureau	
Genetec	Speakers Bureau	
Gentili	Speakers Bureau	

2021 ASCO ANNUAL MEETING

2021 ASCO ANNUAL MEETING #ASCO21

Abstract number: 8511

5-YEAR SURVIVAL OUTCOMES WITH DURVALUMAB AFTER CHEMORADIOTHERAPY IN UNRESECTABLE STAGE III NSCLC – AN UPDATE FROM THE PACIFIC TRIAL

David R. Spigel,[1] Corinne Faivre-Finn,[2] Jhanelle E. Gray,[3] David Vicente,[4] David Planchard,[5] Luis Paz-Ares,[6] Johan F. Vansteenkiste,[7] Marina C. Garassino,[8,9] Rina Hui,[10] Xavier Quantin,[11] Andreas Rimner,[12] Yi-Long Wu,[13] Mustafa Özgüroğlu,[14] Ki H. Lee,[15] Terufumi Kato,[16] Maike de Wit,[17] Euan Macpherson,[18] Michael Newton,[19] Piruntha Thiyagarajah,[20] Scott J. Antonia[3]

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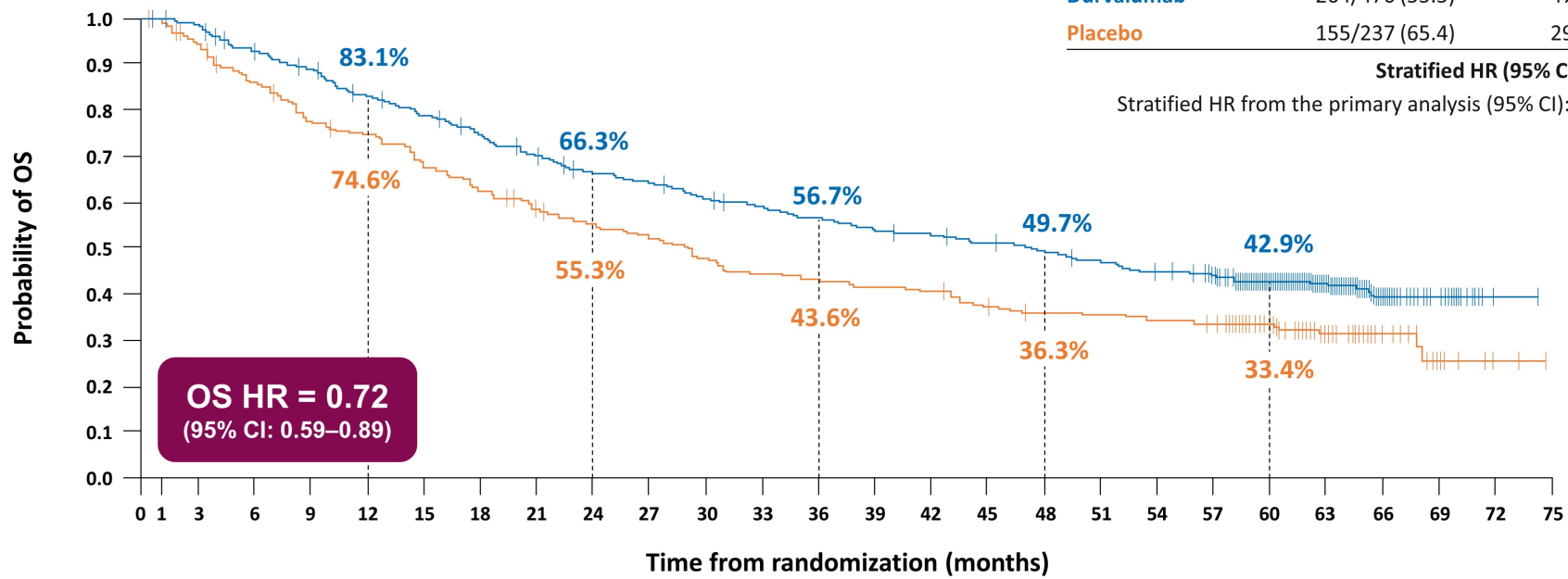
Updated OS (ITT)

	No. of events/ total no. of patients (%)	Median OS (95% CI), months
Durvalumab	264/476 (55.5)	47.5 (38.1–52.9)
Placebo	155/237 (65.4)	29.1 (22.1–35.1)

Stratified HR (95% CI): 0.72 (0.59–0.89)

Stratified HR from the primary analysis (95% CI):[1,2] 0.68 (0.53–0.87)



No. at risk

Durvalumab	476	464	431	414	385	364	343	319	298	289	273	264	252	241	236	227	218	207	196	183	134	91	40	18	2	0
Placebo	237	220	199	179	171	156	143	133	123	116	107	99	97	93	91	83	78	77	74	72	56	33	16	7	2	0

CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; OS, overall survival

Data cutoff: 11 January 2021 (median follow-up: all patients, 34.2 months [range, 0.2–74.7]; censored patients, 61.6 months [range, 0.4–74.7]).

1. Antonia SJ, et al. New Engl J Med 2018;379:2342–50; 2. European Medicines Agency. Durvalumab (Imfinzi). Summary of product characteristics 2020. Available from: https://www.ema.europa.eu/en/documents/product-information/imfinzi-epar-product-information_en.pdf 5. [Accessed April 2021]

RANDOMIZED TRIALS ON CHEMORADIATION IN LOCALLY-ADVANCED NSCLC

Endpoints	PACIFIC[1] Durvalumab	PACIFIC[1] (Placebo)	RTOG 0617 60Gy	PROCLAIM standard	PROCLAIM Pem/Plat	PET-Plan standard	PET-Plan IF
Median Follow-up	34.2 months	34.2 months	5.1 years	22.6	22.2	29m	29m
No	476	237	217	301	297	99	106
IMAGING	**TC mdc**		**PET 91% RM brain**	**PET 83%**		**PET 100%**	
Progression Free Survival							
Median	16.9 m	5.6 m	11.8	9.8	11.4	10.2	11
5 years	33.1%	19%	18.3%				
Overall Survival							
Median	47.5m	29.1m	28.7m	25m	26.8m	36m	30m
12-month	83.1%	75.3%	80.0%	77%	76%	80%	75%
3 years	56.7%	43.6%	45%	37%	40%	50%	40%
5 years	42.9%	33.4%	32.1%	-	-	33%	33%

ASTRO ANNUAL MEETING 2019

Patterns of Disease Progression with Durvalumab in Stage III NSCLC (PACIFIC)

Memorial Sloan Kettering Cancer Center

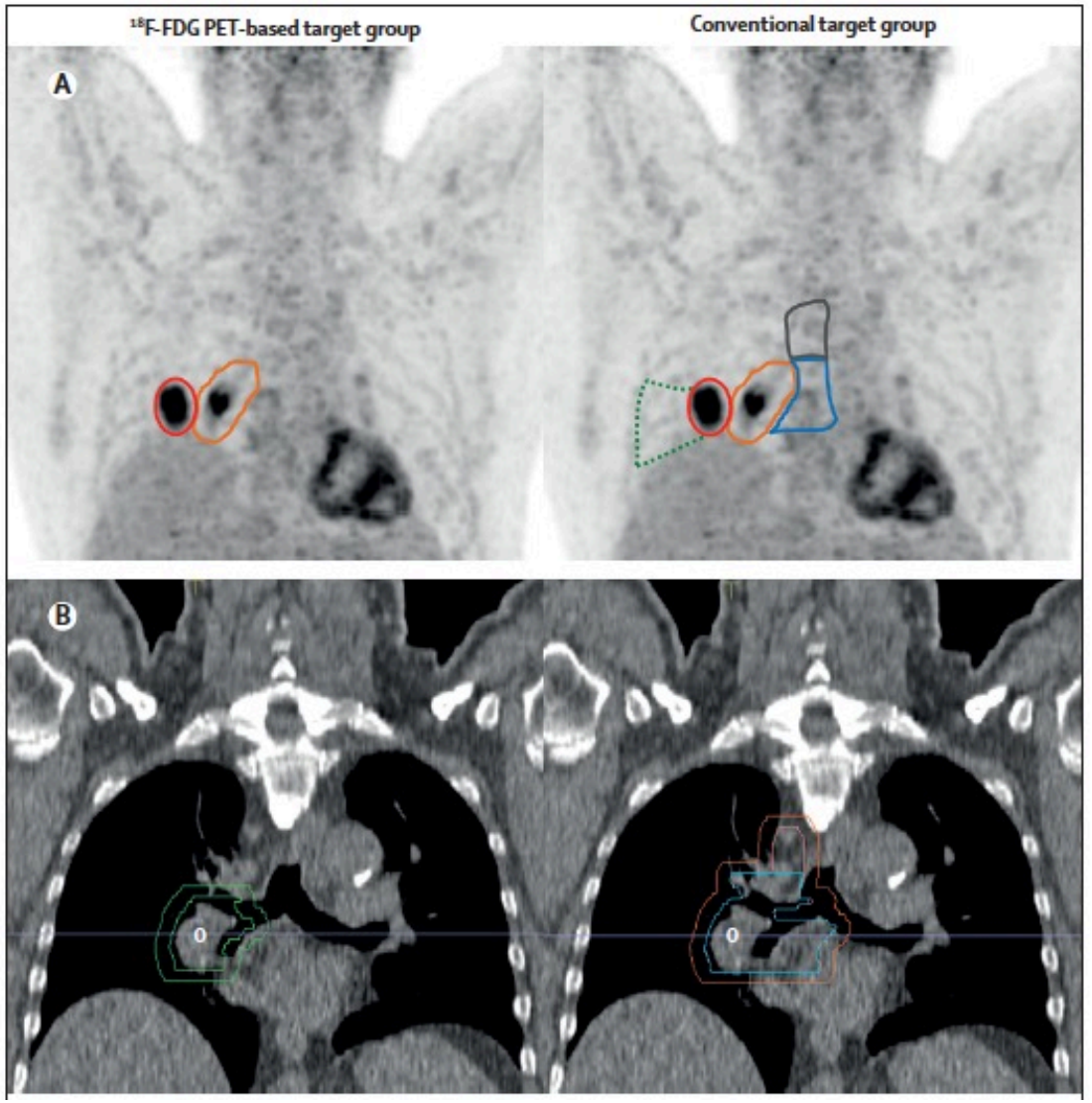
Prof Rimner

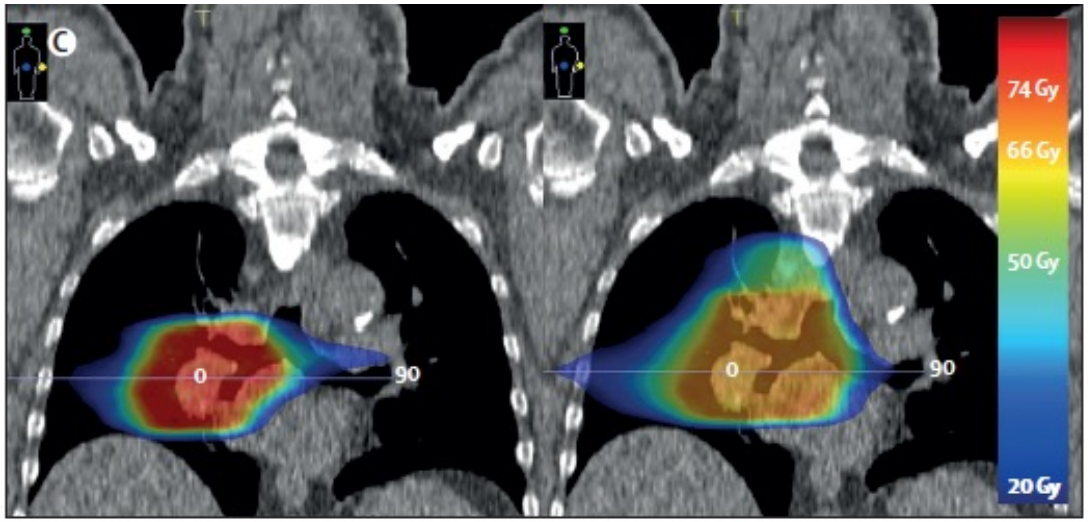
INTRATHORACIC PROGRESSION WAS THE MOST COMMON PROGRESSION (**80.6% VS 74.5**% OF PROGRESSORS, 36.6% vs 48.1 of ITT population)

Imaging-based target volume reduction in chemoradiotherapy for locally advanced non-small-cell lung cancer (PET-Plan): a multicentre, open-label, randomised, controlled trial

Ursula Nestle, Tanja Schimek-Jasch, Stephanie Kremp, Andrea Schaefer-Schuler, Michael Mix, Andreas Küsters, Marco Tosch, Thomas Hehr, Susanne Martina Eschmann, Yves-Pierre Bultel, Peter Hass, Jochen Fleckenstein, Alexander Thieme, Marcus Stockinger, Karin Dieckmann, Matthias Miederer, Gabriele Holl, H Christian Rischke, Eleni Gkika, Sonja Adebahr,

Lancet Oncol 2020; 21: 581–92





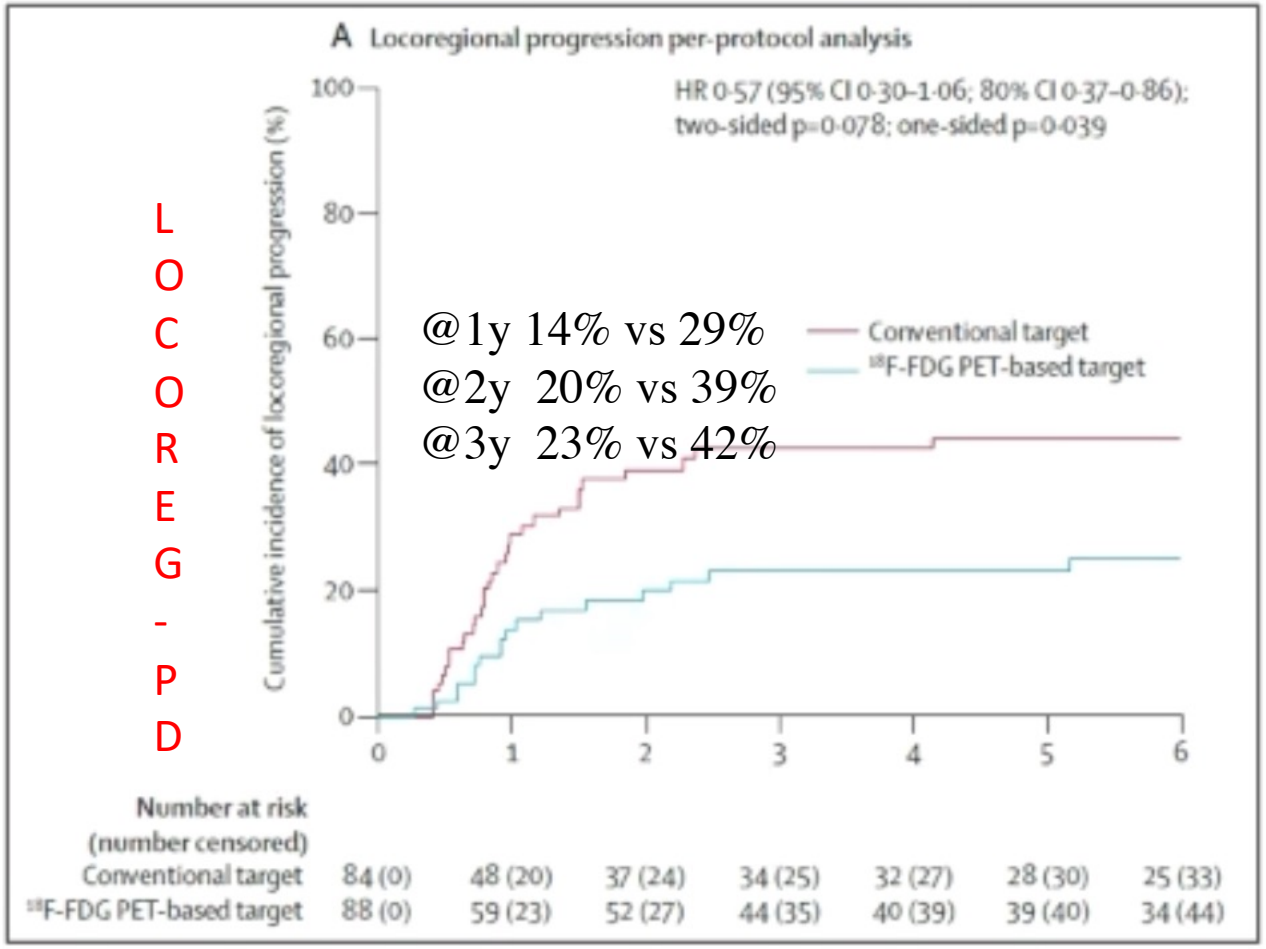
PET-Plan target volumes

All **PET-based CTV**
primary tumour (PET-GTV + 3 mm to CTV)
pathologically and/or FDG-positive LN-stations
(anatomical, Chapet)

Arm A **conventional target group**
expanded PET-CTV
+ atelectasis (3cm), + CT positive LNS)
-> isotoxic dose escalation 60- 74 Gy / 2 Gy

elective LN volumes (10%-risk involvement)
50 Gy / 2 Gy

Arm B **experimental purely PET-based target group**
PET-CTV
-> isotoxic dose escalation 60- 74 Gy / 2 Gy

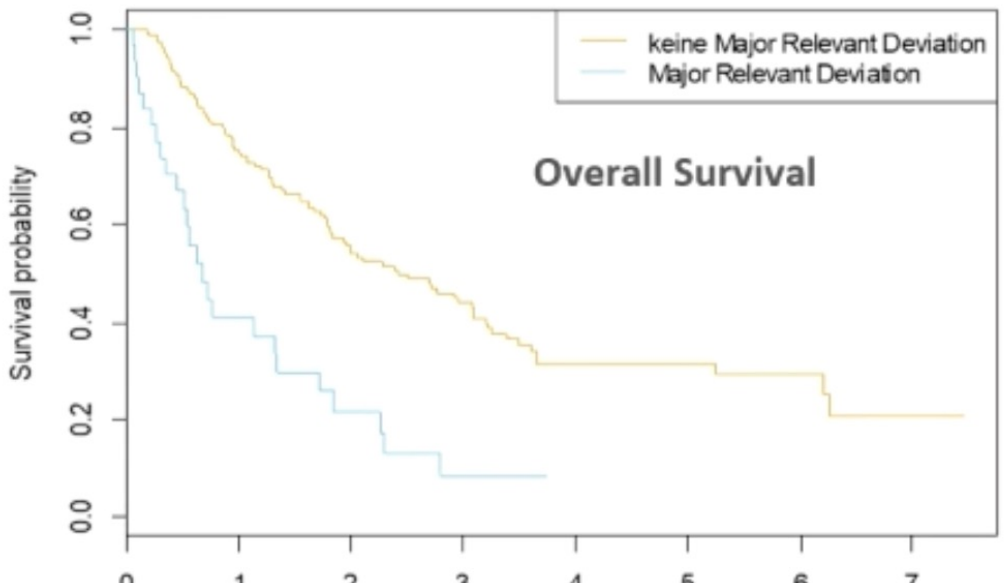


LOCOREG-PD

Lancet Oncol 2020; 21: 581–92

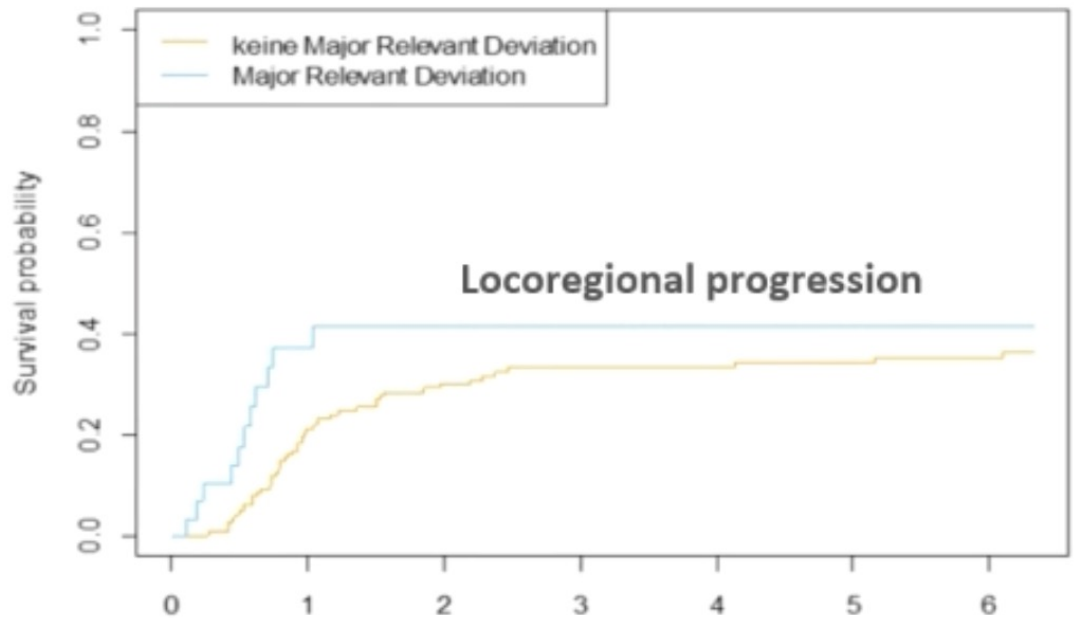
RT Plan data RTQA: A24, B20 items

PP	MI	MA-	MA+
No deviation per protocol	Minor deviation	Major deviation non-relevant (treatment)	Major deviation relevant (treatment change)



Inferior OS

HR 2.9 [95% CI 1.8–4.4], p<.001



Higher risk of loco-regional progression

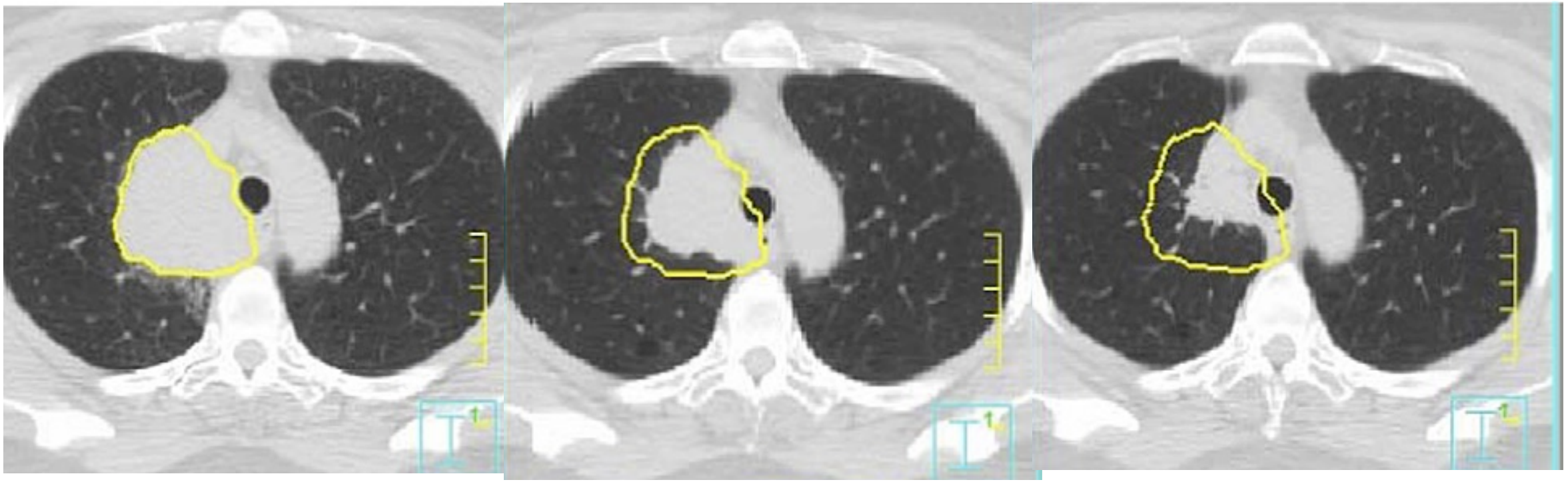
HR 5.7 [95% CI 2.7–11.1], p<.001

RANDOMIZED TRIALS ON CHEMORADIATION IN LOCALLY-ADVANCED NSCLC

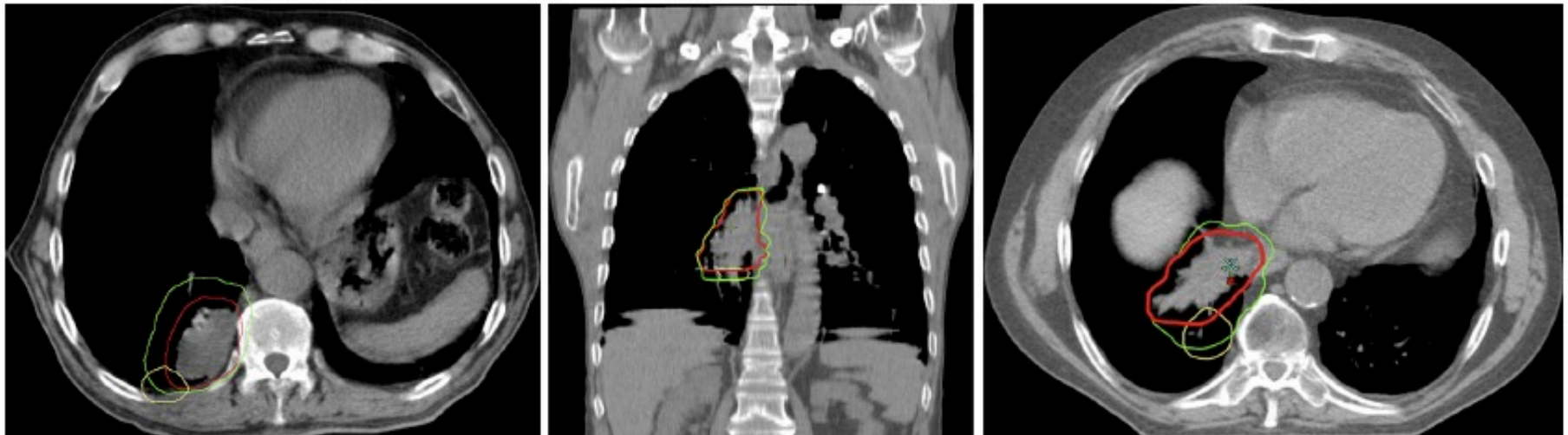
Endpoints	PACIFIC[1] Durvalumab	PACIFIC[1] (Placebo)	RTOG 0617 60Gy	PROCLAIM standard	PROCLAIM Pem/Plat	PET-Plan Stand	PET-Plan PET-based IF	PET boost Whole T	PET boost PET subvol	RTOG 1106 Stand	RTOG 1106 PET based Adaptation
Median Follow-up	34.2 m	34.2 m	5.1years	22.6m	22.2m	29m	29m	61m	61m	3.6years	3.6years
N°	476	237	217	301	297	99	106	54	53	43	84
IMAGING	**TC mdc**		**PET 91% RM brain**	**PET 83%**		**PET 100%**		**PET 100%**		**PET 100%**	
Progression Free Survival											
Median	16.9 m	5.6 m	11.8	9.8	11.4	10.2	11	-	-	-	-
5 years	33.1%	19%	18.3%								
Local Failure/ LRP Freedom	-	-	2y: 30.7%	37.3%	45.8%	2y: 39%	2y: 20%	FFLF 2y: 89%	FFLF 2y: 82%	LRPF 2y:59.5 %	LRPF 2y:54.6%
Overall Survival											
Median	47.5m	29.1m	28.7m	25m	26.8m	36m	30m	18m*	17m*		
3 years	56.7%	43.6%	45%	37%	40%	50%	40%	-	-	49.1%	47.5%
5 years	42.9%	33.4%	32.1%	-	-	33%	33%	30%	20%	-	-

Local Failure is low with PET-based reduced volume

ADAPTIVE RADIOTHERAPY



Fox J, IJROBP, 2009

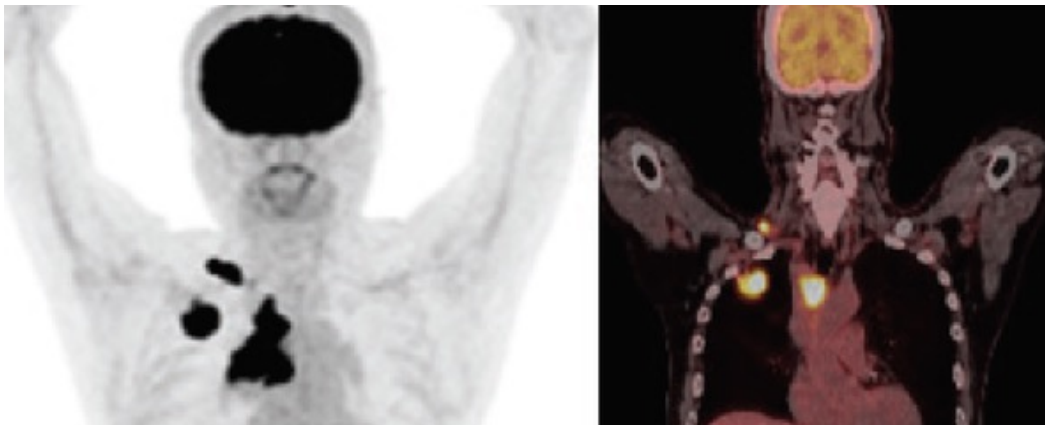


Ramella S et al ,
J Thoracic Oncology 2017

«ONE NEVER NOTICE WHAT HAS BEEN DONE; ONE CAN ONLY SEE WHAT REMAINS TO BE DONE»

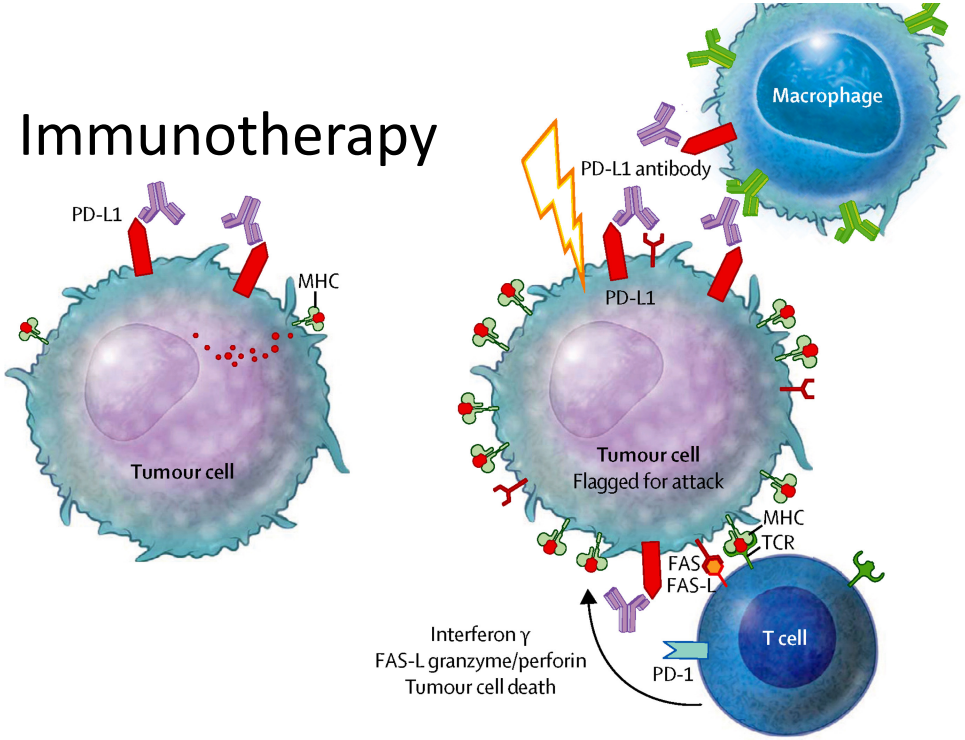
FUTURE TRIALS….

NEW Radiotherapy Volumes*



+

Immunotherapy



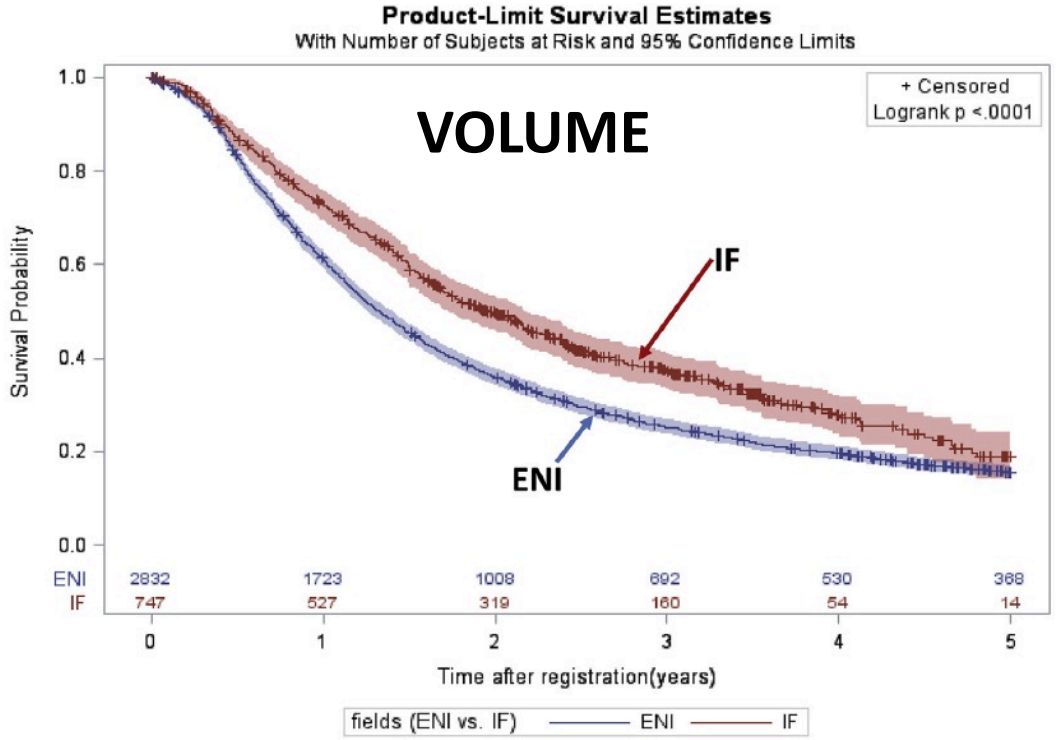
*not the same of PACIFIC trial

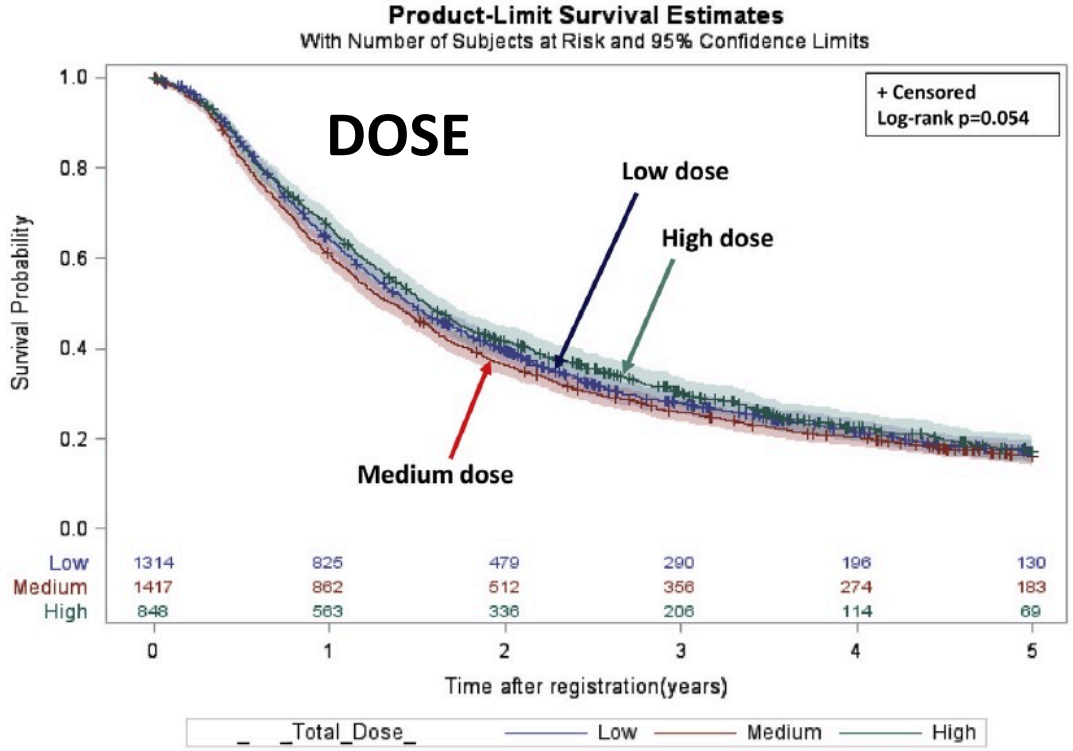
Nestle U et al, Trans Lung Cancer Res 2021; 10(4): 1999

Exploring Radiotherapy Targeting Strategy and Dose: A Pooled Analysis of Cooperative Group Trials of Combined Modality Therapy for Stage III NSCLC

3600 LA-NSCLC, 16 coop group trials of cCRT

Schild JTO 2018; 13(8): 1171-1189





«Schild e al showed IMPROVED LOCAL CONTROL in REDUCED TARGET VOLUMES not necessarly related to dose……One may speculate that a reduction of CTVs could contribute to optimum RT-induced immune stimulation by omitting the irradiation of draining lymph nodes»

Nestle U et al, Trans Lung Cancer Res 2021; 10(4): 1999-2010

Lymphocytes Rich Organs (LRO)

a) The organs or structure rich in *circulating* lymphocytes - sensitive to the dose rate (DR) of irradiation and Beam-On-Time (BOT)

b) The organs or structure rich in *non*-circulating lymphocytes or its precursor such as the nodes, the spleen and the bone marrow - less or not sensitive to DR or BOT

The new paradim

Tumour + OAR

Lymphocytes Sparing Radiotherapy: next step…

A Randomized phase II trial (e.g. in stage III NSCLC) comparing

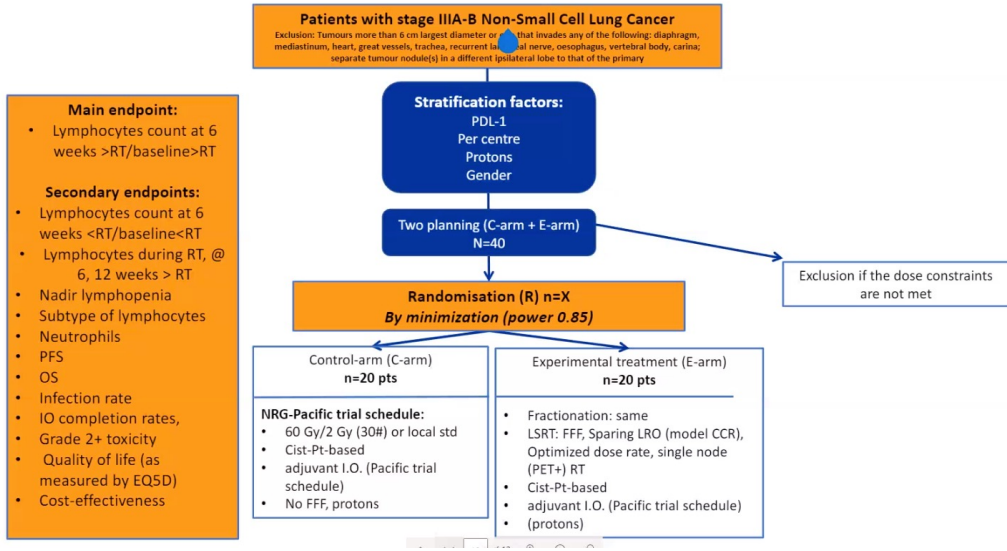
SOC (60 Gy/2 Gy + Chemo) followed by adjuvant I.O. (Pacific trial schedule)

vs

LSRT + chemo followed by adjuvant I.O. (SOC)

Main endpoint = Lymphopenia at baseline/ 6 weeks (= short trial & feasible, validated biomarker…)

Sec endpoints: acute & chronic Lymphopenia, PFS….



Lambin P, EORTC Lung Cancer Group 2021

the future is now

2021 ASCO ANNUAL MEETING

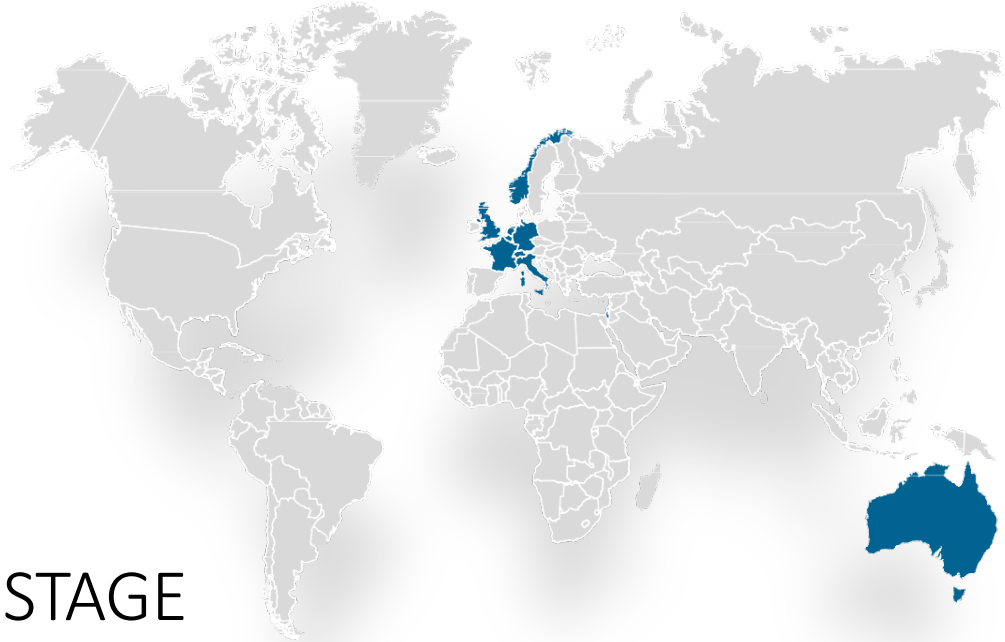
#ASCO21

ESTRO 2021

PARIS 2021 ESMO congress

elcc European Lung Cancer Virtual Congress *2021*

elcc European Lung Cancer Virtual Congress 2021



79MO - PACIFIC-R: REAL-WORLD CHARACTERISTICS OF UNRESECTABLE STAGE III NSCLC PATIENTS TREATED WITH DURVALUMAB AFTER CHEMORADIOTHERAPY

Fiona McDonald,[1] Francoise Mornex,[2] Marina Garassino,[3] Andrea Riccardo Filippi,[4] Daniel Christoph,[5] Vilde Drageset Haakensen,[6] Abed Agbarya,[7] Michel van den Heuvel,[8] Piet Vercauter,[9] Christos Chouaid,[10] Eric Pichon,[11] Shankar Siva,[12] Laurie Steinbusch,[8] Idit Peretz,[13] Ben Solomon,[12] Lore Decoster,[14] William Sawyer,[15] Allison Allen,[16] Muriel Licour,[17] Nicolas Girard[18]

1193 patients enrolled in **254 active sites** in **10 participating countries**

17:30 - 18:30 Mini oral session - Non-metastatic NSCLC and other thoracic malignancies

CHAIRS : ALFREDO ADDEO, LIZZA HENDRIKS, MICHAEL THOMAS

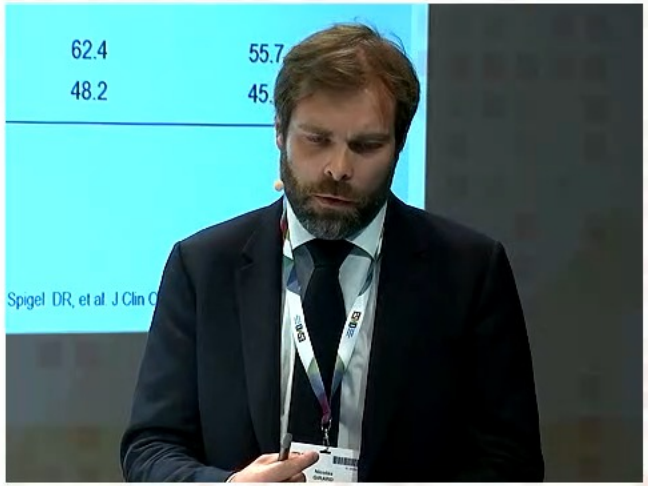
Real-world PFS (FAS) – Median Follow-up Duration = 23.0 Months*

- Median rwPFS in PACIFIC-R was higher than the median PFS reported for the durva. arm of the PACIFIC trial[1†]
- Challenges with collecting rwPFS data limit comparisons between PACIFIC-R and PACIFIC
- RwPFS is likely overestimated as:
  - Germany and UK sites did not collect deaths that occurred prior to study enrolment‡ (50 early deaths not counted)
  - RECIST criteria for tumour assessments is used heterogeneously across countries
  - Assessments for progression in the real world may not occur as frequently or consistently as in clinical trials; the COVID-19 pandemic may also have resulted in fewer hospital visits

	PACIFIC-R FAS	PACIFIC trial (durva. arm)[1]
PFS	N=1,399	N=476
Total events, N (%)	737 (52.7)	268 (56.3)†
Progression per RECIST	456 (32.6)	
Progression per physician assessment	170 (12.2)	
Progression, assessment unknown	30 (2.1)	
Deaths in absence of progression	81 (5.8)	
Median PFS, months	**21.7**	**16.9**
95% CI	19.2–24.5	13.0–23.9
PFS rate, %		
12 months	62.4	55.7
24 months	48.2	45.0

*Range for median follow-up duration = 0–35.6 months; †In the PACIFIC trial, PFS was assessed by blinded independent central review per RECIST v1.1; ‡Per local regulations
CI, confidence interval; FAS, full analysis set; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; rw, real-world; UK, United Kingdom

1. Spigel DR, et al. J Clin Oncol 2021;39(15_suppl):8511



Nicolas Girard

PACIFIC-R Real-World Study: Treatment Duration and Interim Analysis of Progression-Free Survival in Unresectable Stage III NSCLC Patients Treated with Durvalumab After Chemoradiotherapy

17:30 - 18:30 Mini oral session - Non-metastatic NSCLC and other thoracic malignancies

CHAIRS : ALFREDO ADDEO, LIZZA HENDRIKS, MICHAEL THOMAS

Durvalumab Treatment Discontinuation

FAS (N=1,399)	Discontinuation reason, n (%)*	Median time from durva. start to discontinuation
Patient decision	20 (1.4)	6.1 months
AE	233 (16.7)	2.8 months
Completed treatment†	659 (47.1)	12.0 months
Disease progression	377 (26.9)	5.1 months
Death	21 (1.5)	1.9 months

- **Pneumonitis/interstitial lung disease (ILD)** was the most common AE leading to (% of FAS):
  - **Permanent** discontinuation: 133 (**9.5%**)‡
  - **Temporary** interruption: 73 (**5.2%**)‡

Pneumonitis/ILD

	FAS (N=1,399)
Patients with any pneumonitis/ILD, n (%)§	250 (17.9)
Mild event¶	56 (4.0)
Moderate event¶	118 (8.4)
Severe event¶	41 (2.9)
Life-threatening or fatal event¶	5 (0.4)

- Median **time to onset** of pneumonitis/ILD from durvalumab initiation: **2.5 months**
- **Corticosteroid** administration was required in **71.3%** of events#

Nicolas Girard

PACIFIC-R Real-World Study: Treatment Duration and Interim Analysis of Progression-Free Survival in Unresectable Stage III NSCLC Patients Treated with Durvalumab After Chemoradiotherapy

*Other discontinuation reason: missing (n=2), 'other' reasons (n=68), lost to follow-up (n=3), and ongoing durvalumab at time of data extraction (n=16); †Investigator's decision per country protocol and, where applicable, was after >12 months' treatment; ‡Categories are not mutually exclusive (i.e. a single patient could both interrupt and permanently discontinue durvalumab due to pneumonitis/ILD); §37/1,399 patients (2.6%) had pneumonitis/ILD events of unknown severity; ¶Categories are not mutually exclusive – patients experiencing ≥2 events of different severity can be counted under both categories. #A total of 279 pneumonitis/ILD events were reported among the 250 patients who experienced pneumonitis/ILD
AE, adverse event; FAS, full analysis set; ILD, interstitial lung disease

PACIFIC: is it real enough? ***(5y OS: 42.9%)***

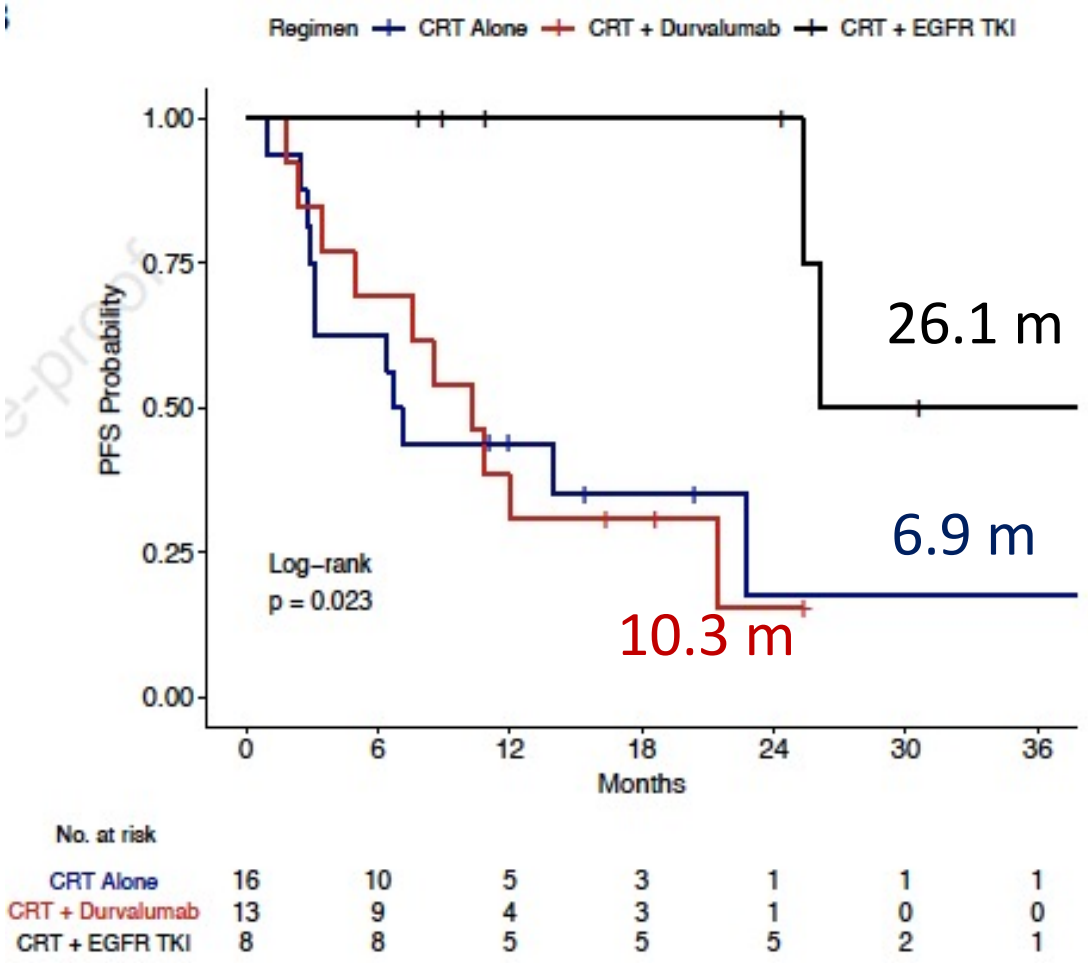
1. Impact of EGFR mutations on efficacy of consolidation IO
2. Role of consolidation durvalumab in patients not receiving cCRT
3. Role of concurrent durvalumab in patients receiving cCRT
4. Identification of new bio-markers for selection

Modified by R. Soo

Durvalumab for Stage III EGFR-Mutated NSCLC After Definitive Chemoradiotherapy

Aredo JTO 2021

EGFR+= N=37,
RT alone=43%durva= 35%, EGFR TKI 22%
PFS: 6.9m v 10.3m v 26.1m



ONGOING TRIAL in unresectable LA NSCLC EGFR-mutated

LOGIK0902/OLCSG0905	phase II	8-week gefitinib followed by docetaxel-cisplatin concurrent radiotherapy (60 Gy/30 F)
RTOG 1306 (NCT01822496)	phase II randomized	erlotinib induction for 3 months followed by CCRT or CCRT only
LAURA trial (NCT03521154)	phase III	CCRT followed by osimertinib consolidation vs placebo
NCT04304638 trial	observational	3 treatment strategies (CRT, radiation plus EGFR-TKI, and EGFR-TKI only) based on the real-world data.

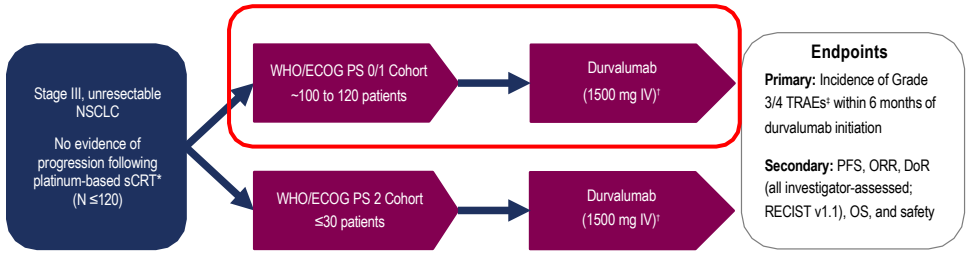
PACIFIC: is it real enough? ***(5y OS: 42.9%)***

1. Impact of EGFR mutations on efficacy of consolidation IO
2. Role of consolidation durvalumab in patients not receiving cCRT
3. Role of concurrent durvalumab in patients receiving cCRT
4. Identification of new bio-markers for selection

Modified by R. Soo

78MO Early safety assessment of durvalumab after sCRT in patients with Stage III, unresectable NSCLC (PACIFIC-6): Early safety assessment in WHO/ ECOG PS 0-1

PACIFIC-6: Phase 2, Open-label, Multicentre, International Trial



- A pre-specified early safety assessment was planned after ≥50 patients in the PS 0/1 cohort had the opportunity to receive durvalumab for ≥6 months
  - We summarised AEs overall and by causality, severity, and seriousness (CTCAE version 4.03)

AE, adverse event; CRT, chemoradiotherapy; CT, chemotherapy; CTCAE, Common Terminology Criteria for Adverse Events; DoR, duration of response; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PREA, AE possibly related to study treatment; PS, performance status; Q4W, every 4 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; sCRT, sequential chemoradiotherapy; TRAE, treatment-related AE; WHO/ECOG, World Health Organization/Eastern Cooperative Oncology Group

*Defined as ≥2 cycles of platinum-based CT before RT with ≤6 weeks interval between the last dose of CT and the start of RT. Patients who received no more than 1 cycle of overlapping platinum-based CT and RT were also eligible. †Q4W for 24 cycles or until disease progression, alternative anticancer therapy, unacceptable toxicity, withdrawal of consent, or another discontinuation criterion is met. ‡As reported by the investigator and alternatively referred to as PRAEs in the case report form.

- Median age 64 years, 64% male, 64% adenocarcinoma, ECOG PS 0= 46%
- Most common doublets
  - Carboplatin/ VNR 36%
  - Carboplatin/ pemetrexed 18%
  - Cisplatin/pemetrexed 16%
  - Carboplatin/paclitaxel 14%
- Time from RT to durvalumab <14d: 100%
- Any grade pneumonitis: 32%
- Discontinuation due to pneumonitis: 18% (PACIFIC 6%)

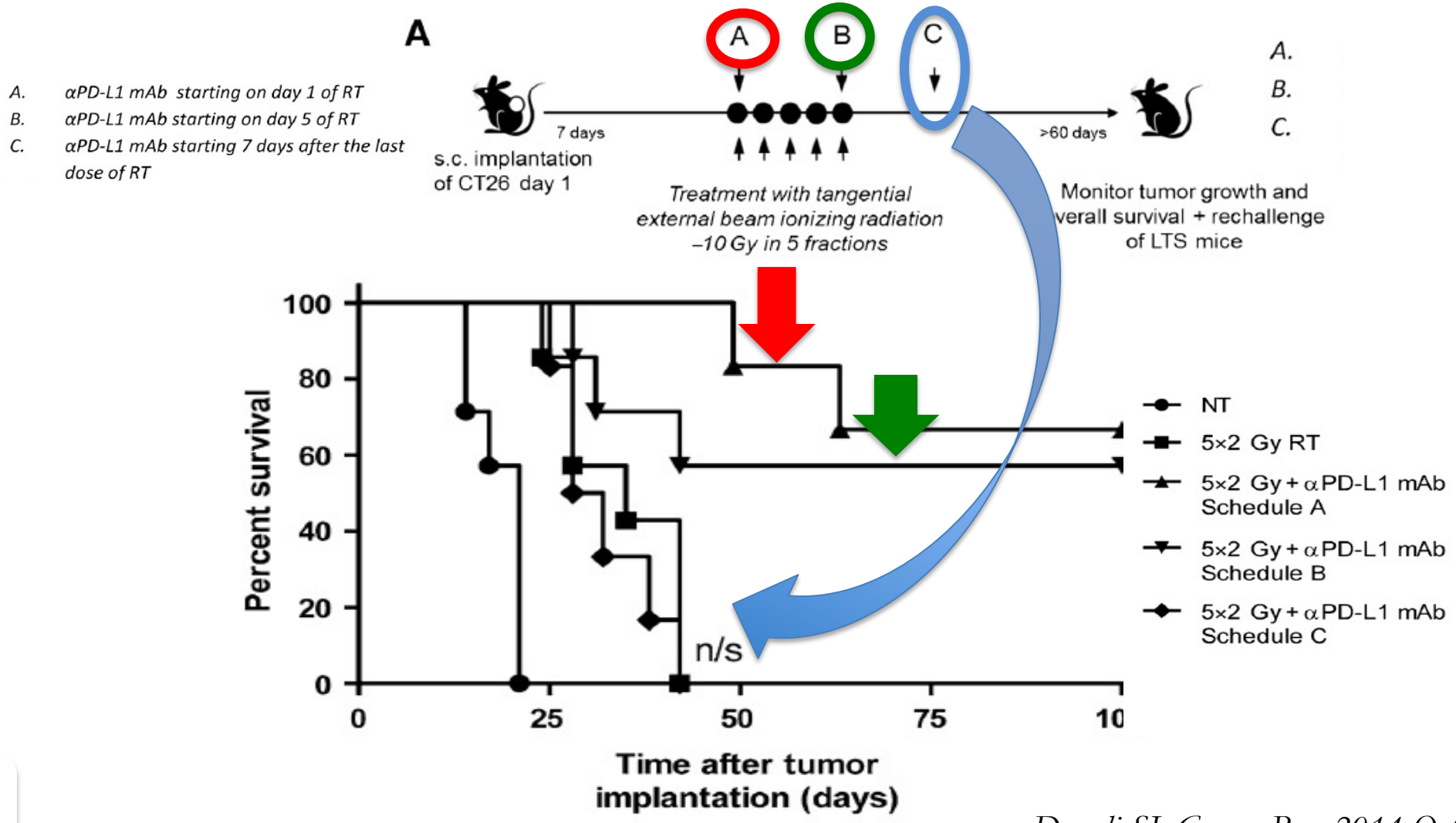
elcc

PACIFIC: is it real enough? ***(5y OS: 42.9%)***

1. Impact of EGFR mutations on efficacy of consolidation IO
2. Role of consolidation durvalumab in patients not receiving cCRT
3. Role of concurrent durvalumab in patients receiving cCRT
4. Identification of new bio-markers for selection

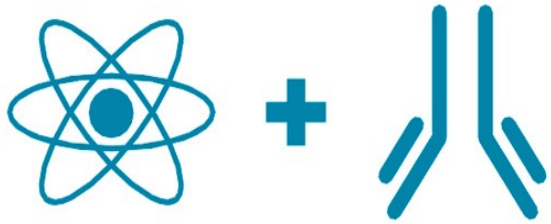
Modified by R. Soo

Preclinical evidence shows SEQUENCING of radiation was critical for anti-tumor response to anti-PD-L1



Dovedi SJ, Cancer Res. 2014 Oct 1;74(19):5458-68.

RT+CT+IO



Endpoints	KEYNOTE 799 Pembro + Carbo Taxol RT	KEYNOTE 799 Pembro + Cisp Pem RT	NICOLAS TRIAL Nivo + CT+ RT	DETERRED Trial Atezo + Carbo Taxol + RT
Median Follow-up			32.6	
No	112	101	79	30
Progression Free Survival				
Median	NR	NR	12.7 months	NR
12-month	67.7%	65.2%	53.7%	66%
Overall Survival				
Median	NR	NR	38.8 months	NR
12-month	81.2%	88%	75.5%	77%
24-month			63.7%	
Pneumonitis ≧G3	8%	7.9%	11.7%	20%

PACIFIC: is it real enough? ***(5y OS: 42.9%)***

1. Impact of EGFR mutations on efficacy of consolidation IO

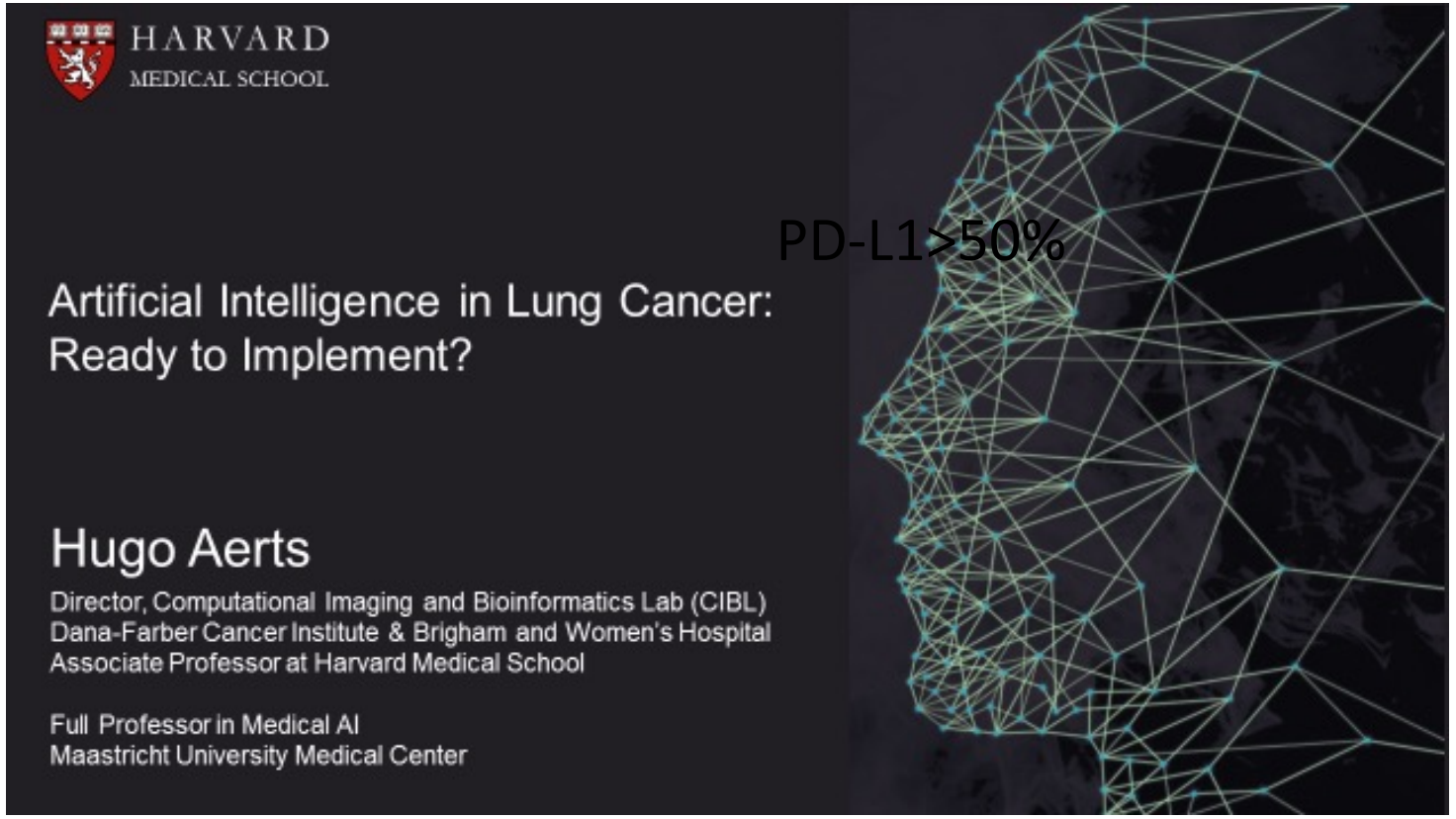
2. Role of consolidation durvalumab in patients not receiving cCRT

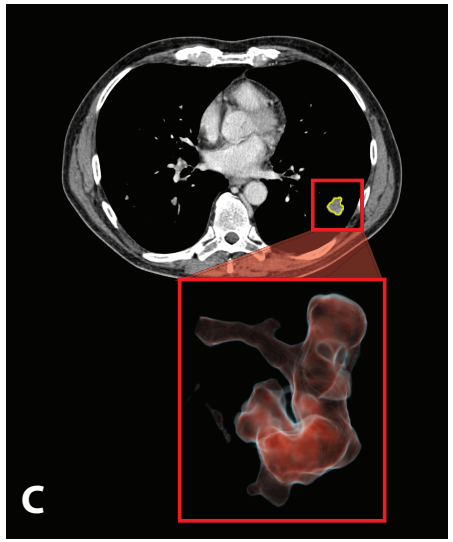
3. Role of concurrent durvalumab in patients receiving cCRT

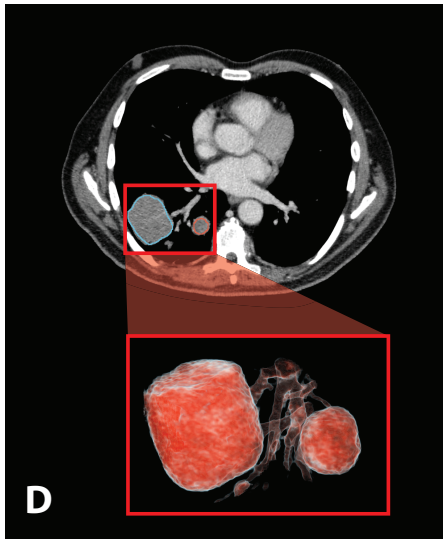
4. Identification of new bio-markers for selection

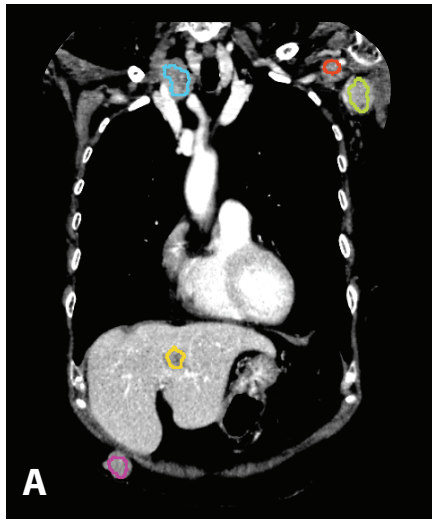
Modified by R. Soo

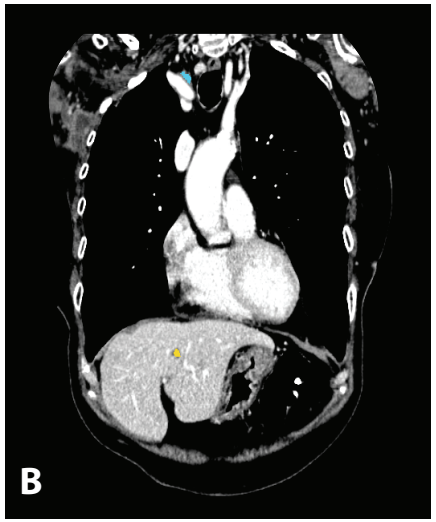
Imaging-AI Biomarkers for Immunotherapy Response







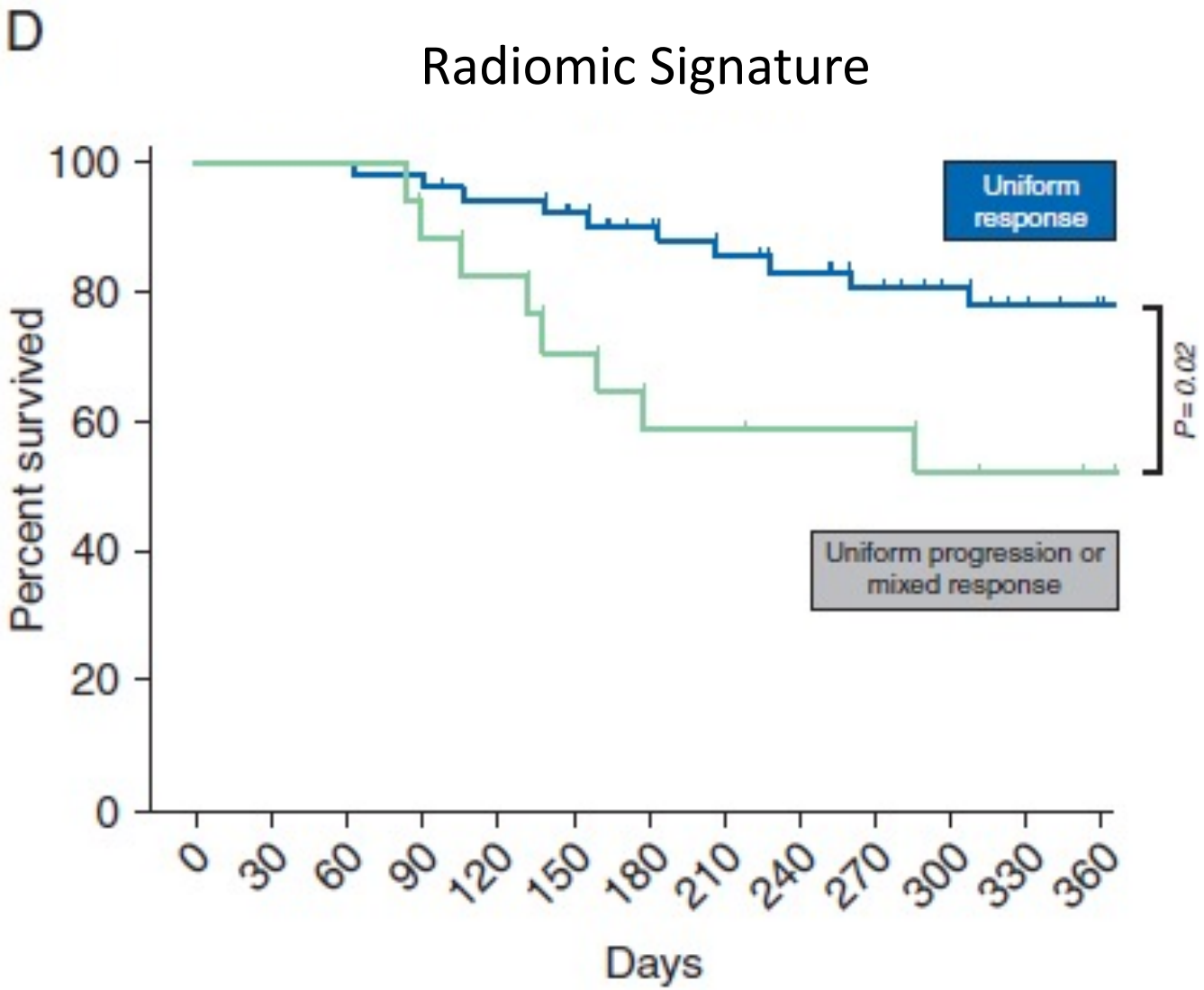


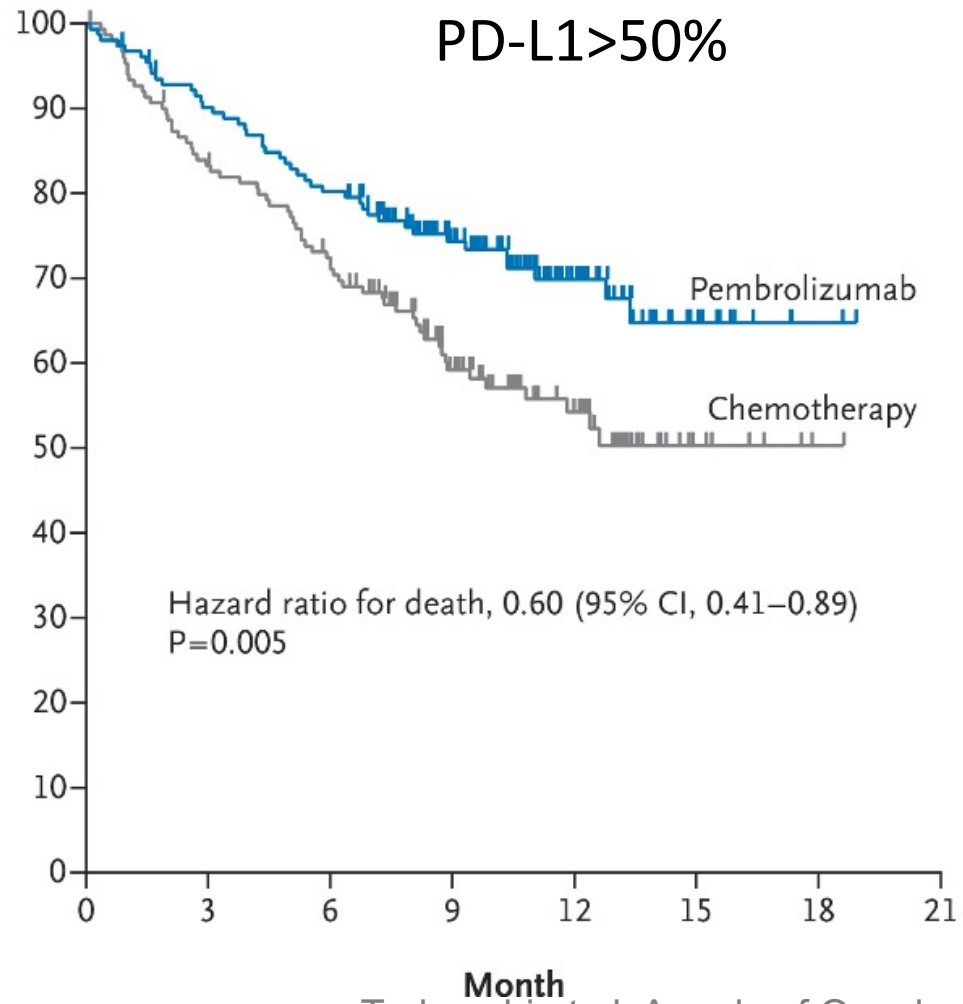


Trebeschi et al, Annals of Oncology, 2019

Imaging-AI Biomarkers for Immunotherapy Response

CAN RADIOMICS PERSONALISE IMMUNOTHERAPY?





Trebeschi et al, Annals of Oncology 2019

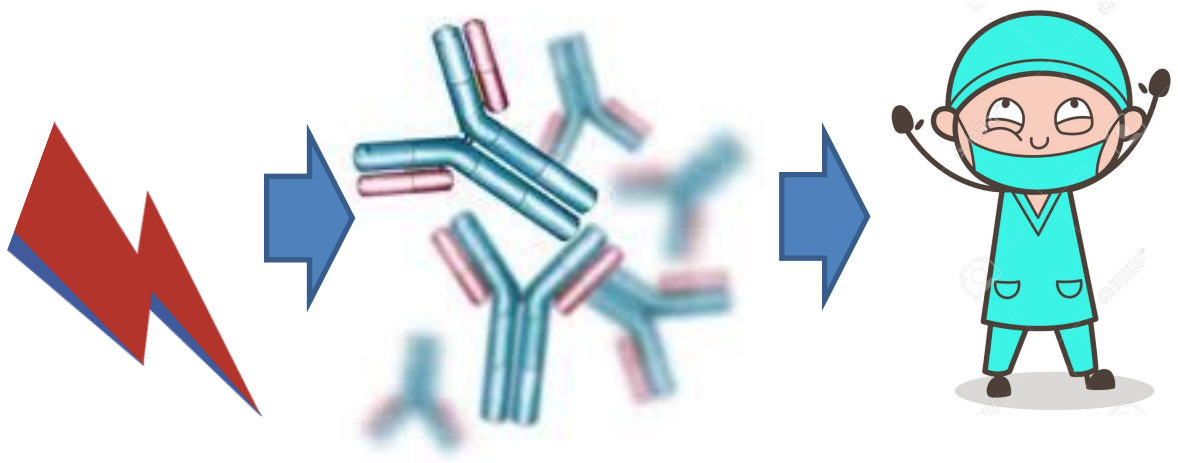
MRO . ART
INNOVATIVE TREATMENTS AND PATIENTS COMPLIANCE
31° RESIDENTIAL COURSE

PHARMACOLOGICAL INNOVATIONS AND INTEGRATION WITH RADIOTHERAPY IN THIRD STAGE NSCLC

1. Inoperable patients
    - *Target Volume definition*
    - *Lymphocytes Sparing Radiotherapy*
    - *Oncogene addicted, consolidation and concurrent ICI*
    - *New Biomarkers*

2. Neoadiuvant strategies

Neoadjuvant durvalumab with or without stereotactic body radiotherapy in patients with early-stage non-small-cell lung cancer: a single-centre, randomised phase 2 trial



Methods

We did a single-centre, open-label, randomised, controlled, phase 2 trial, comparing in c-stages I–IIIA

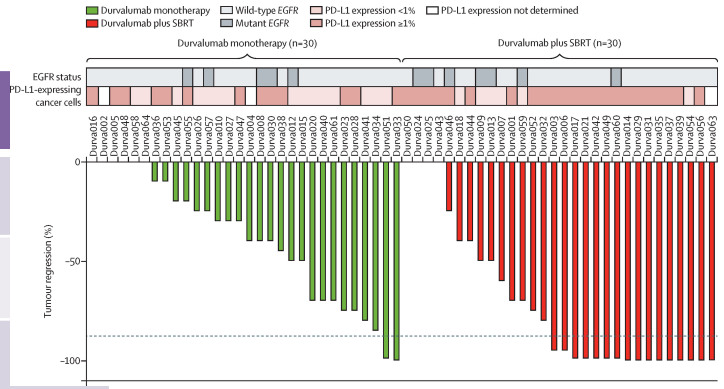
1. **neoadjuvant durvalumab alone**
2. **neoadjuvant durvalumab plus stereotactic radiotherapy (8 Gy × 3 fractions)**

This trial is registered with ClinicalTrial.gov, NCT02904954, and is ongoing but closed to accrual.

ALTORKI NK,...FORMENTI, LANCET ONCOLOGY, 22, 6, P824-835, JUNE 01, 2021

Neoadjuvant durvalumab with or without stereotactic body radiotherapy in patients with early-stage non-small-cell lung cancer: a single-centre, randomised phase 2 trial

Findings	DURVA	SBRT+DURVA
Pts	30	30
Surgery	87%	87%
Major pathological response	**6.7%** [95% CI 0·8–22·1]	**53.3%** [34·3–71·7] **(59% complete response)**
	crude odds ratio 16·0 [95% CI 3·2–79·6]; p<0·0001	
Grade 3-4	10% hyponatraemia	10% hyperlipasaemia
SAE	6.7%	6.7%



Neoadjuvant durvalumab combined with stereotactic body radiotherapy is well tolerated, safe, and associated with a high major pathological response rate. This neoadjuvant strategy should be validated in a larger trial.

Nasser K Altorki, LANCET ONCOLOGY, 22, 6, P824-835, JUNE 01, 2021

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2. Neoadiuvant strategies

«Oggi ci resta la bellezza della vita fatta accanto a lei, per il Maestro che è sempre stato e che continuerà ad essere»

UNIVERSITÀ CAMPUS BIO-MEDICO DI ROMA

thank you