Local Therapy for Advanced NSCLC: Ready for Primetime?

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NOSCM 2023

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Biology

We know that biology effectuates NSCLC outcomes:

EGFR mutant positive disease vs wild type

ALK mutant positive disease vs wild type

KRAS vs non-KRAS

Squamous vs Non-squamous

PD-L1 expressing vs non-expressing

Limited metastatic vs widely metastatic disease? Oligometastatic vs Oligoremnant?

Presence or absence of heightened inflammation – Cachexia, Host tissue contributions to therapy response?

Resistance mechanisms and patterns?

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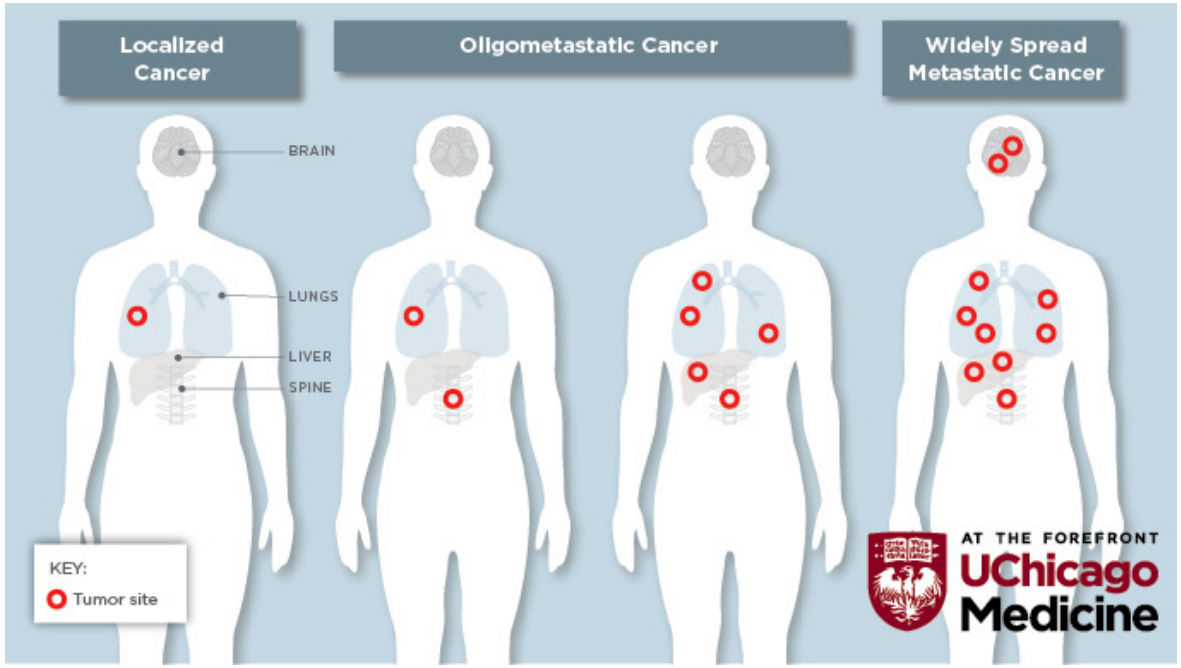

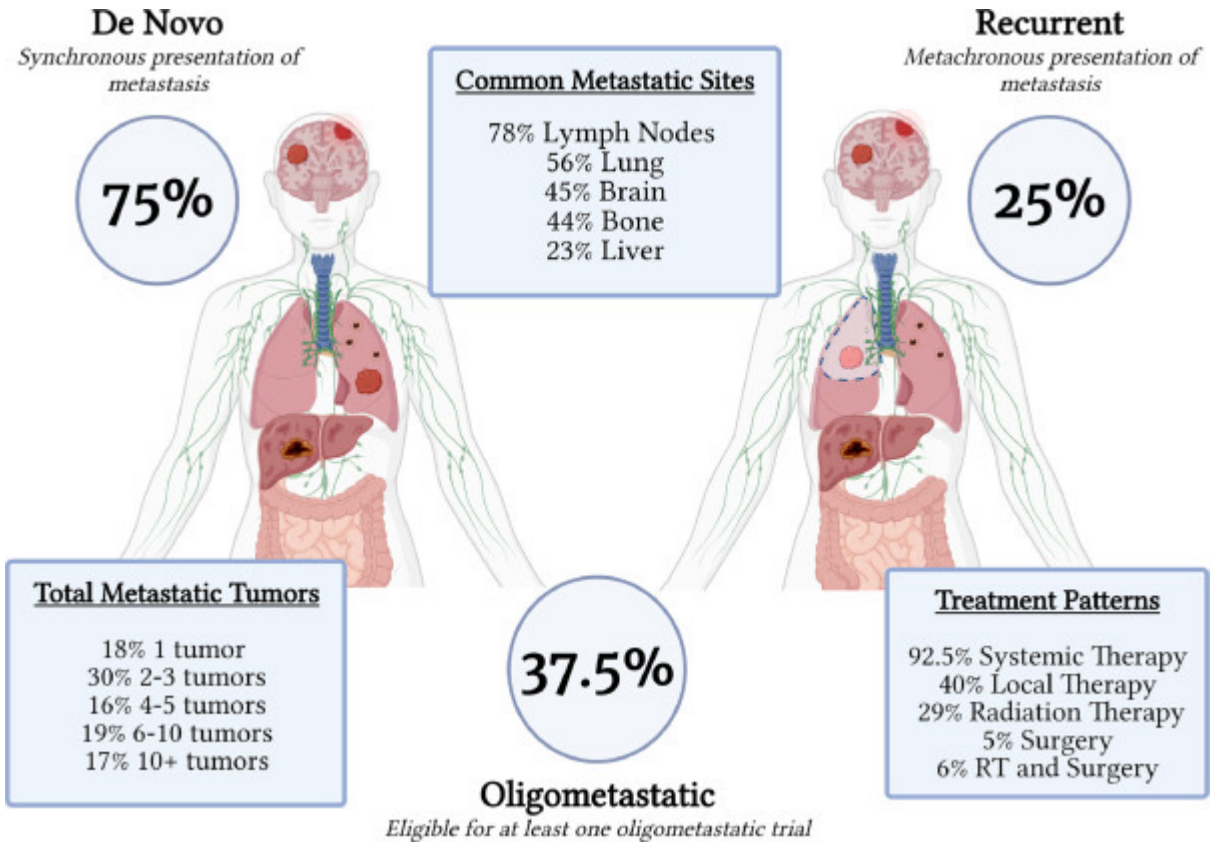

No et al, 2022

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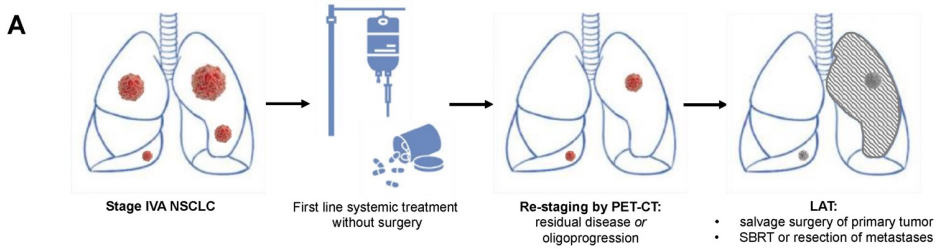
Indications for Local Therapy

1) Consolidation



2) Oligoprogression

3) Abscopal Effects

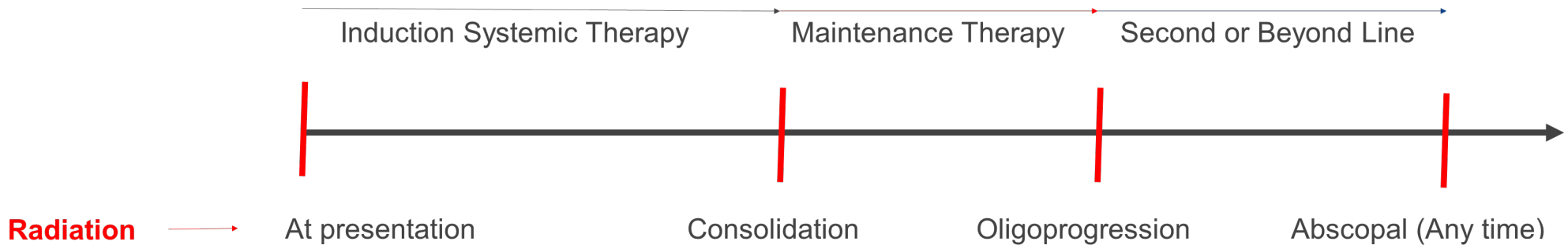


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Table 1 Completed studies

Study authors	Study design	Treatment setting	Patient eligibility	Study arm(s)	Results
De Ruysscher *et al.* (16,17)	Single arm phase II	Consolidation	Oligometastatic NSCLC (<5 sites), no response to systemic therapy required	Chemo with surgery or radiation for metastatic sites	Median PFS, OS 12.1 and 13.5 months, respectively
Gomez *et al.* (18,19)	Randomized phase II	Consolidation	Oligometastatic NSCLC (≤5 sites), EGFR mutations allowed (12% of patients)	Systemic therapy followed by local consolidative therapy (SABR, surgery, or chemoradiation) *vs.* maintenance treatment alone	Median PFS 14.2 *vs.* 4.4 months; OS 41.2 *vs.* 17 months
Iyengar *et al.* (20)	Randomized phase II	Consolidation	Oligometastatic NSCLC (≤6 sites including primary)	Chemo followed by SABR *vs.* maintenance treatment alone	Median PFS 9.7 *vs.* 3.5 months
Collen *et al.* (21)	Single arm phase II	Consolidation	Oligometastatic NSCLC (≤5 sites)	Chemo followed by SABR or SABR alone	Complete metabolic response (PET/CT) 30%; median OS 23.5 months
Petty *et al.* (22)	Single arm phase II	Consolidation	Oligometastatic NSCLC (≤5 sites)	Chemo followed by SABR if no evidence of progression	Median PFS, OS 11.2, 28.4 months, respectively
Arrieta *et al.* (23)	Single arm phase II	Consolidation	Oligometastatic NSCLC (≤5 sites), *EGFR/ALK* mutations allowed (43% of patients)	Systemic therapy followed by local consolidative therapy (conventional RT, SABR, surgery, chemoradiation, or RFA)	Median PFS 23.5 months, median OS NR; 51.4% of patients achieved CR by PET/CT, CR associate with significantly improved PFS (NR *vs.* 14.3 months) and OS (NR *vs.* 27.4 months)
Palma *et al.* (24)	Randomized phase II	Consolidation	Limited metastatic disease from any primary site (≤5 sites)	Standard of care plus SABR *vs.* standard of care alone	Median PFS 12 *vs.* 6 months; OS 41 *vs.* 28 months
Iyengar *et al.* (25)	Single arm phase II	Salvage	Limited metastatic NSCLC (≤5 sites), failed one line of systemic therapy	Erlotinib with SABR	Median PFS, OS 14.7, 20.4 months, respectively

Changes in Patterns of Failure

Delays in Failures

Synchronous/ Metachronous/ Surgery/Targetable Mutations

Synchronous/ Metachronous/ Radiation Only

No studies incorporated IO

Metachronous
All Histologies
Toxicity?
Signal/p value
Context BR002

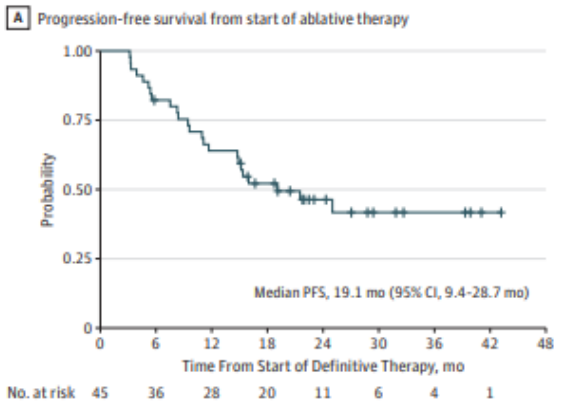
Transl Lung Cancer Res 2019;8(Suppl 2):S184-S191 | http://dx.doi.org/10.21037/tlcr.2019.07.09

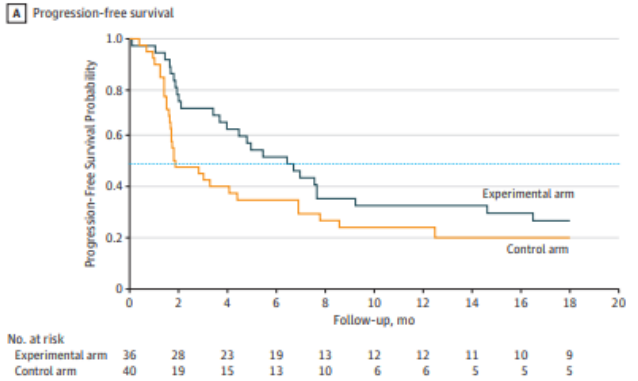
With better IO/systemic therapy outcomes, the benefits of local therapy may be diminished or enhanced
Radiation -/+ IO (Pacific) is different than IO -/+ Radiation?

2 Additional *JAMA Onc* Studies

1) IO after LCT single arm Phase II (Bauml et al, 2019)

2) IO -/+ Salvage Local Therapy RPh2 in 2nd line setting (Theelen et al, 2019)





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Durvalumab and Tremelimumab With or Without High or Low-Dose Radiation Therapy in Treating Patients With Metastatic Colorectal or Non-small Cell Lung Cancer

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT02888743

Recruitment Status : Active, not recruiting
First Posted : September 5, 2016
Last Update Posted : January 6, 2022

Advanced NSCLC pts who progressed through previous IO

No benefit with addition of local therapy – low dose or hypofractionation – with respect to ORR.

Why? IO was not beneficial, radiation was not optimally dosed or timed?

MIXED SIGNALS ABOUT LOCAL THERAPY AND IO

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Table 2 Currently accruing phase III trials

Trial	Initiation year	Study design	Patient eligibility	Study arms	Primary endpoint
NRG LU 002 NCT03137771	2018	Randomized phase II/III	Oligometastatic NSCLC (≤3 sites), received 1st line systemic therapy without progression, immunotherapy allowed	Maintenance therapy plus SABR *vs.* maintenance therapy alone	Phase II: PFS; phase III: OS
SARON NCT02417662	2016	Randomized phase III	Oligometastatic NSCLC (≤3 sites), eligible to receive chemotherapy	Chemotherapy plus SABR *vs.* chemotherapy alone	OS
SABR-COMET 10 NCT03721341	2019	Randomized phase III	Limited metastatic disease from any primary site (4–10 metastatic sites)	Maintenance therapy plus SABR *vs.* maintenance therapy alone	OS
HALT NCT03256981	2017	Randomized phase II/III	Advanced NSCLC with actionable mutation and confirmed response to TKI treatment with ≤3 sites of progression	Maintenance TKI plus SABR *vs.* maintenance TKI alone	PFS

NRG-LU 002

Maintenance Systemic Therapy Versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy For Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial

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Robert Timmerman MD *UT Southwestern* Hak Choy MD, *UT Southwestern* Clifford Robinson MD, *Washington University of St. Louis* Charles Simone MD, *Memorial Sloan Kettering Cancer Center (MSKCC)*	Co-Chairs
David Gerber MD, *UT Southwestern* Saiama Waqar MD, *Washington University of St. Louis*	Med Oncology
Jessica Donington MD, *University of Chicago* Stephen Swisher MD, *MD Anderson Cancer Center (MDACC)*	Surg Oncology
Michael Weldon MSc, DABR, *Ohio State University* Jackie Wu PhD, *Duke*	Physics
Ben Movsas MD, *Henry Ford Hospital*	Quality of Life
Kirk Jones MD, *University of California at San Francisco*	Pathology
Adam Dicker MD, PhD, *Jefferson* Max Diehn MD, PhD, *Stanford*	Translational
Chen Hu, PhD, *Johns Hopkins University/NRG Oncology*	Statistics

SWOG Champion – Daniel Gomez MD,
ECOG Champion – Sukhmani Padda MD,
ALLIANCE Champion – Pranshu Mohindra, MD
NRG – Wally Curran/Quynh-Thu Le/Mitch Machtay, Jeffrey Bradley, Fran Bradley, Jennifer Presley, Matt Novak, Jeffery Serianni

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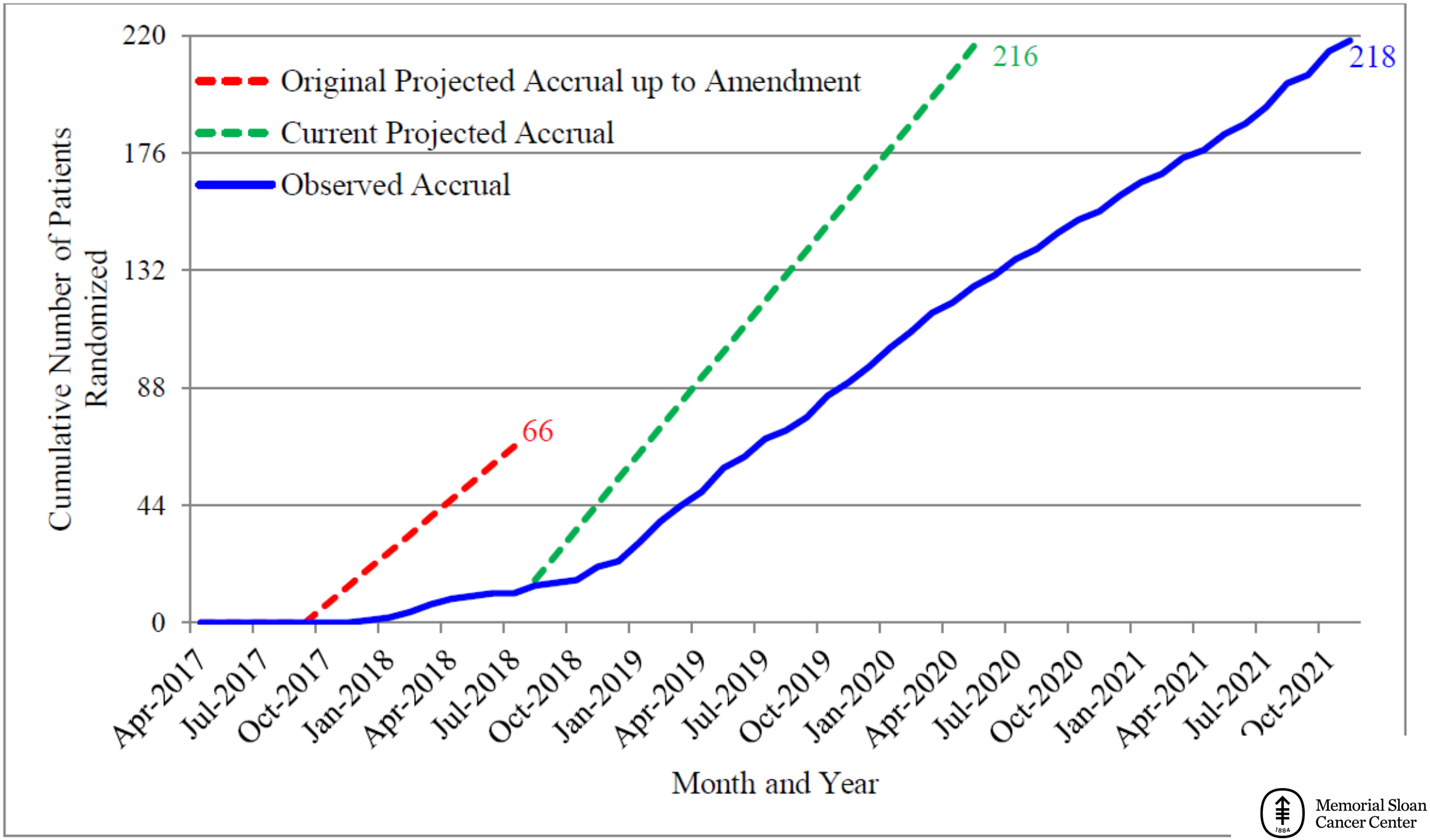

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NRG-LU 002
218/378

Nearly 70 sites have enrolled

Ph2 completed

The study is event-driven and plans to randomize up to **378** eligible patients with 2:1 ratio into the experimental and control arms. Guarding against ineligibility or lack-of-data rate of up to 5%, the targeted accrual of randomized patients for the entire phase II/III study is **400**.

Patients with metastatic NSCLC having completed at least 4 cycles or courses* of first-line/induction systemic therapy Restaging studies reveal no evidence of progression and limited metastatic disease (0-3 discrete extracranial sites), all of which must be amenable to SBRT/ radiation +/- Surgery A minimum of one disease site (metastasis or primary) needs to be present after first-line/induction systemic therapy and treatable with local consolidative therapy	**STRATIFY**	**Histology:** Squamous vs. Non-squamous **Systemic Therapy:** Immunotherapy-containing Induction Regimens vs. Cytotoxic Chemotherapy Only Induction Regimens**	**RANDOMIZE**	**Arm 1**: Maintenance systemic therapy alone** **Arm 2:** SBRT/radiation or SBRT/ radiation and Surgery to all sites of metastases (0-3 discrete sites) and/or irradiation (SBRT or hypofractionated RT) of the primary site followed by maintenance systemic therapy. All Arm 2 patients, even if treated with Surgery, must have one site of disease (metastasis or primary) treated with radiation*** If a metastatic site is best treated with hypofractionated radiation, this will be permitted if SBRT or surgery not indicated *** **As noted in Section 5**

QoL and Biomarker studies planned at same time points – after induction systemic therapy, after LCT, and at 1st recurrence

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The primary hypothesis of this study is that LCT and maintenance systematic therapy (Arm 2) will improve the progression-free survival (phase II) and overall survival (phase III), compared to the maintenance systematic therapy alone (Arm 1). We therefore project that, for the standard maintenance systemic therapy, the 6 month and 12 month rates of PFS are approximately 60% and 39%, and 12 month and 24 month rates of OS are 68% and 47%, respectively. **For the phase II portion, we consider an improvement in 6 month and 12 month rates of PFS from 60% and 39% to approximately 75% and 57%, respectively, to warrant a phase III study. This improvement is approximately equivalent to a hazard reduction of 40% in PFS (HR_{PFS} = 0.6).** For the entire study, we aim to demonstrate an improvement in 12 month and 24 month rates of OS from 68% and 47% to 77% and 61%. This improvement is approximately equivalent to a hazard reduction of 32% in OS (HR_{OS} = 0.68).

After 142 patients, we evaluated data:

1) 116 patients or 80% of patients had received IO-based systemic therapy.

2) 26 patients or 20% had received cytotoxic chemotherapy-only regimens.

This study has become an IO -/+ LCT trial due to changing SOC. Chemo still permitted.

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Patient and Tumor Characteristics for All Eligible Patients in NRG-LU002 - Data as of 10/31/2022

Patient or Tumor Characteristic	Maintenance Therapy (n=81)	LCT + Maintenance Therapy (n=134)	Total (n=215)
Age (years)			
Median	65	65	65
Min - Max	40 - 86	44 - 86	40 - 86
Q1 - Q3	60 - 72	60 - 72	60 - 72
≤ 49	4 (4.9%)	4 (3.0%)	8 (3.7%)
50 - 59	15 (18.5%)	29 (21.6%)	44 (20.5%)
60 - 69	31 (38.3%)	56 (41.8%)	87 (40.5%)
≥ 70	31 (38.3%)	45 (33.6%)	76 (35.3%)
Sex			
Male	40 (49.4%)	68 (50.7%)	108 (50.2%)
Female	41 (50.6%)	66 (49.3%)	107 (49.8%)
Race			
American Indian or Alaska Native	1 (1.2%)	1 (0.7%)	2 (0.9%)
Asian	2 (2.5%)	2 (1.5%)	4 (1.9%)
Black or African American	16 (19.8%)	19 (14.2%)	35 (16.3%)
White	59 (72.8%)	106 (79.1%)	165 (76.7%)
More than one race	1 (1.2%)	0 (0.0%)	1 (0.5%)
Unknown	2 (2.5%)	6 (4.5%)	8 (3.7%)

Histology*			
Non-Squamous cell carcinoma	64 (79.0%)	103 (76.9%)	167 (77.7%)
Squamous cell carcinoma	17 (21.0%)	31 (23.1%)	48 (22.3%)
Systemic Therapy Type*†	(n=75)	(n=129)	(n=204)
Cytotoxic Chemotherapy	8 (10.7%)	11 (8.5%)	19 (9.3%)
Immunotherapy	67 (89.3%)	118 (91.5%)	185 (90.7%)
Number of Lesions			
1	49 (60.5%)	77 (57.5%)	126 (58.6%)
2	20 (24.7%)	37 (27.6%)	57 (26.5%)
3	12 (14.8%)	18 (13.4%)	30 (14.0%)
4	0 (0.0%)	1 (0.7%)	1 (0.5%)
5	0 (0.0%)	1 (0.7%)	1 (0.5%)
Consented to tissue/blood collection			
No	13 (16.0%)	26 (19.4%)	39 (18.1%)
Yes	68 (84.0%)	108 (80.6%)	176 (81.9%)

Zubrod Performance Status			
0	35 (43.2%)	47 (35.1%)	82 (38.1%)

Table 3
Patient and Tumor Characteristics for All Eligible Patients in NRG-LU002 - Data as of 10/31/2022

Patient or Tumor Characteristic	Maintenance Therapy (n=81)	LCT + Maintenance Therapy (n=134)	Total (n=215)
1	44 (54.3%)	79 (59.0%)	123 (57.2%)
2	2 (2.5%)	8 (6.0%)	10 (4.7%)

- **Patient Accrual**

  Accrual was activated on April 7, 2017. Total accrual is 218, from a total of 68 sites (Table 1). The study is temporarily closed per the protocol design as results mature. As of October 31, 2022, the median time of follow-up for vital status is 16.7 months. The phase II analysis to determine whether the trial will proceed into phase III portion is projected to occur in Q1 2023. Institutional accrual is shown in Appendix 1.

- **Patient and Tumor Characteristics**

  Three patients are ineligible for analysis (1 patient on Maintenance Therapy and 2 patients on LCT + Maintenance Therapy, Table 2). The distribution by patient and tumor characteristics is shown in Table 3. Median (min-max) age is 65 years (40-86). Patient sex is evenly distributed, and most patients are white (76.7%), not Hispanic or Latino (91.2%), and had a Zubrod Performance Status of 1 (57.2%). As of October 31, 2022, 24 patients have withdrawn consent to follow-up, 13 on arm 1 and 11 on arm 2.

- **Adverse Events**

  Adverse events (AEs) were graded with CTCAE version 5. As of October 31, 2022, and regardless of attribution to treatment, there have been 10 patients (13.7%) with grade 4 AEs and 4 patients (5.5%) with grade 5 AEs reported on Maintenance Therapy, and 18 patients (13.7%) with grade 4 AEs and 11 patients (8.4%) with grade 5 AEs reported on LCT + Maintenance Therapy (Table 4). All adverse events, regardless of attribution to protocol treatment, for which at least one grade 4 or grade 5 event has been reported are shown in Table 5. There are no notable differences in grade 4-5 AEs by term. Since last report, th
  5 AE reported on LCT + Maintenance Therapy (respiratory failure, reported as unrelated t
  6).

NRG-LU002 - Functional Assessment of Cancer Therapy (FACT)

	Baseline[1]	Month 1[2]	Month 3[2]	Month 6[2]	Month 9[2]	Month 12[2]
Forms expected	148	136	119	95	74	51
% completed of forms expected	133 (89.9%)	97 (70.3%)	80 (67.2%)	56 (58.9%)	30 (40.5%)	20 (39.2%)
% with reason missing supplied by site	12 (8.1%)	37 (26.8%)	36 (30.3%)	29 (30.5%)	33 (44.6%)	24 (47.1%)
Assessment completed too early	--	3 (9.7%)	--	--	--	--
Assessment completed too late	6 (50.0%)	24 (77.4%)	17 (58.6%)	12 (50.0%)	14 (53.8%)	9 (47.4%)
Other reason	4 (33.3%)	4 (12.9%)	6 (20.7%)	11 (45.8%)	9 (34.6%)	6 (31.6%)
Patient refused due to illness	--	--	2 (6.9%)	--	--	1 (5.3%)
Patient unable to be contacted	--	--	4 (13.8%)	1 (4.2%)	3 (11.5%)	3 (15.8%)
Unknown	2 (16.7%)	--	--	--	--	--
% missing of forms expected	3 (2.0%)	4 (2.9%)	3 (2.5%)	10 (10.5%)	11 (14.9%)	7 (13.7%)

[1] On or before treatment start date
[2] +/- 14 days

NRG-LU002 - Euroqol EQ-5D-5L

	Baseline[1]	Month 3[2]	Month 6[2]	Month 12[2]
Forms expected	148	119	95	51
% completed of forms expected	131 (88.5%)	80 (67.2%)	56 (58.9%)	20 (39.2%)
% with reason missing supplied by site	14 (9.5%)	37 (31.1%)	29 (30.5%)	24 (47.1%)
Assessment completed too late	7 (50.0%)	17 (58.6%)	12 (48.0%)	9 (47.4%)
Other reason	5 (35.7%)	7 (24.1%)	12 (48.0%)	6 (31.6%)
Patient refused due to illness	--	2 (6.9%)	--	1 (5.3%)
Patient unable to be contacted	--	3 (10.3%)	1 (4.0%)	3 (15.8%)
Unknown	2 (14.3%)	--	--	--
% missing of forms expected	3 (2.0%)	2 (1.7%)	10 (10.5%)	7 (13.7%)

[1] On or before treatment start date
[2] +/- 14 days

NRG-LU002 - Cancer Patient Tobacco Use Questionnaire (C-TUQ)

	Baseline[1]	Month 3[2]	Month 6[2]	Month 12[2]
Forms expected	148	119	95	51
% completed of forms expected	131 (88.5%)	77 (64.7%)	53 (55.8%)	19 (37.3%)
% with reason missing supplied by site	14 (9.5%)	39 (32.8%)	32 (33.7%)	25 (49.0%)
Assessment completed too late	6 (42.9%)	16 (55.2%)	12 (48.0%)	9 (47.4%)
Other reason	5 (35.7%)	7 (24.1%)	11 (44.0%)	6 (31.6%)
Patient refused due to illness	--	2 (6.9%)	--	1 (5.3%)
Patient unable to be contacted	--	4 (13.8%)	1 (4.0%)	3 (15.8%)
Tool not available in patient's language	1 (7.1%)	--	1 (4.0%)	--
Unknown	2 (14.3%)	--	--	--
% missing of forms expected	3 (2.0%)	3 (2.5%)	10 (10.5%)	7 (13.7%)

[1] On or before treatment start date
[2] +/- 14 days

With hope that study opens again for enrollment, several reasons why it is crucial to get study done (as soon as possible):

1) Learn from BR 002 closure that a sure thing is not a sure thing.
2) SARON, UK equivalent study, went from Ph3 to Ph2 due to poor accrual.
3) We have to determine if LCT is helpful or not to OM NSCLC patients.

NRG LU 002, SARON, STOP, HALT, OMEGA, SABR-COMETS, CORE, and MANY MORE

What if not completed in timely fashion?

What if not accounting for newest systemic therapies?

What if NO OS benefit or small OS benefit, or ONLY PFS benefit – Good enough? How big does PFS benefit have to be?

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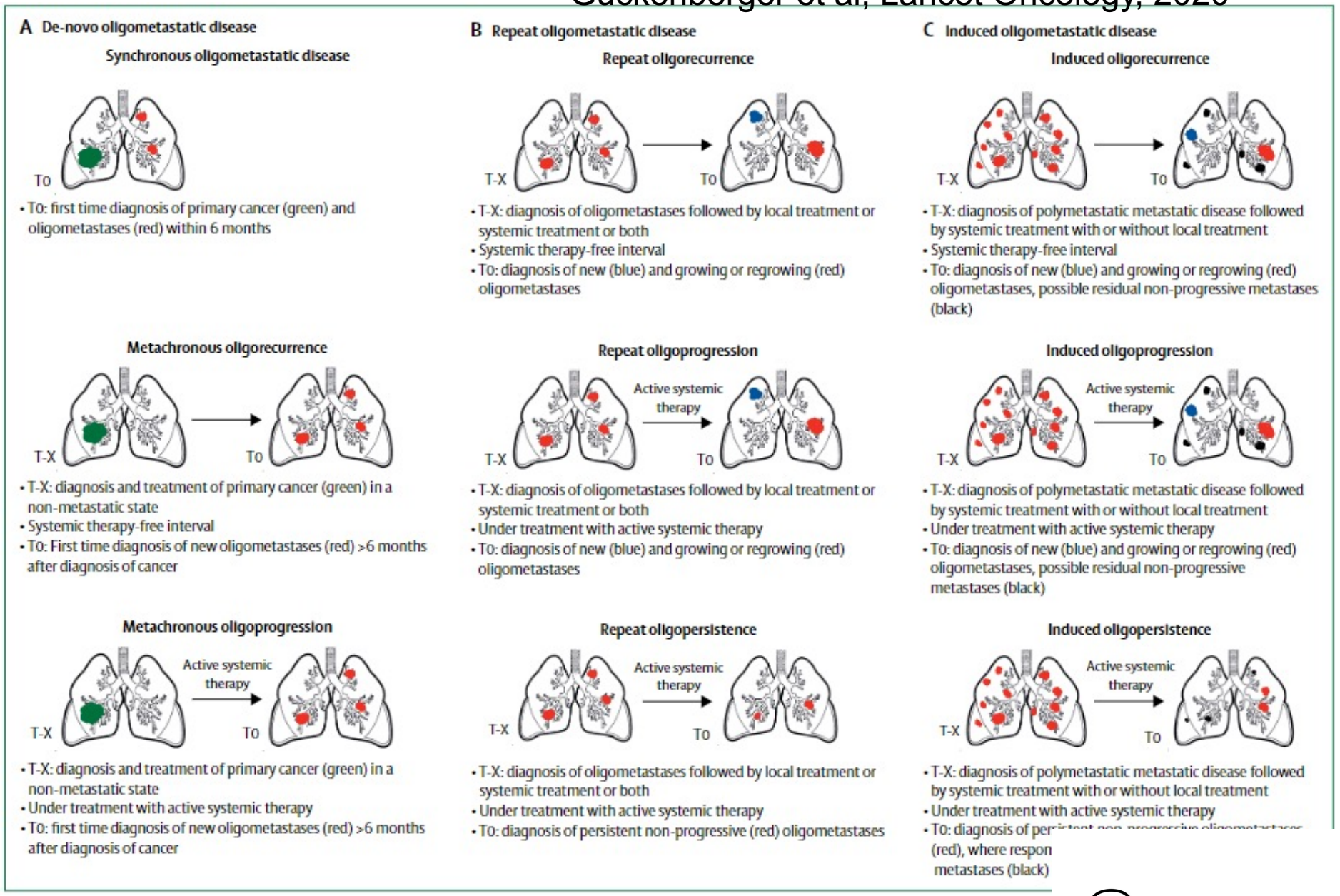
Not all OM disease created =

We have failed to personalize approach

We have failed to predict disease trajectories

Guckenberger et al, Lancet Oncology, 2020



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At time of **Consolidative Local Therapy**:

(Synchronous) Oligometastatic (or oligopersistent) disease – considered oligometastatic from diagnosis and remains that way through treatment

Oligoremnant (or oligoresidual) disease refers to an induced oligometastatic state where a former polymetastatic disease responded to initial treatments.

FYI – Gomez et al, Iyengar at al, NRG LU 002 all permitted/permit Oligometastatic/Oligoremnant Dx – an issue?

Personalized treatment for metastatic NSCLC:

What controls/predicts for Oligometastatic vs Oligoremnant vs Oligoprogression?

1) Tumor oncogenotype-driven

2) Host immunometabolic index-driven

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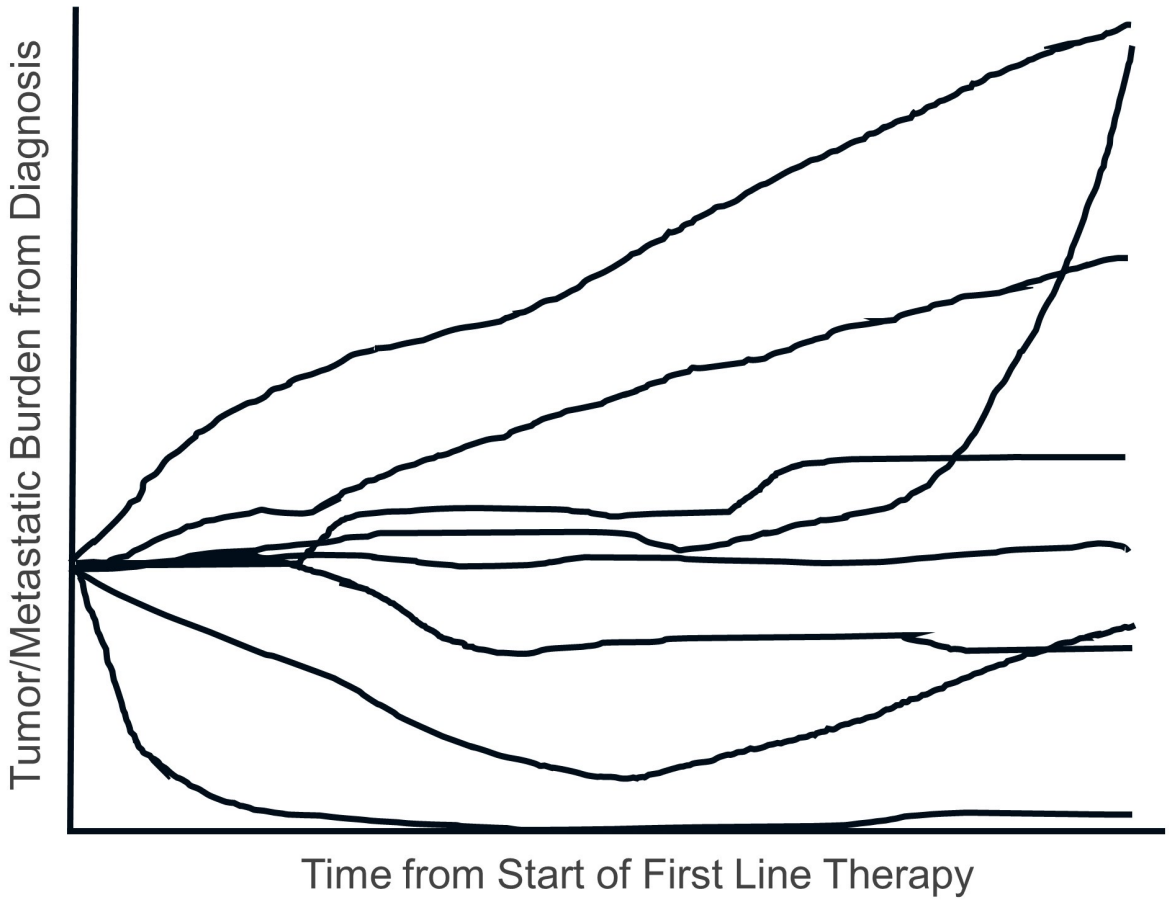
What have we learned from clinical trials in OMD:

1) Use of number of metastases to enroll patients at diagnosis, consolidation, or oligoprogression is an exceedingly poor criterion – it is unfortunately a snapshot in time.



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https://www.google.com/url?sa=i&url=https%3A%2F%2Fandonix.com%2Funcovering-the-iceberg-of-ignorance%2F&psig=AOvVaw147se1UUkbtOBXBWzjOm9I&ust=1675566073992000&source=images&cd=vfe&ved=0CAwQjRxqFwoTCICKqpvw-vwCFQAAAAAdAAAAABAI

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What have we learned from clinical trials in OMD, continued:

2) Being systemic therapy agnostic is **good** = all SOC treatments,
   BUT generalizing an outcome may **miss** unique synergies.

3) Use of **one** systemic therapy gives you one shot, but **easier** to interpret.

4) Induced OMD vs oligopersistent disease from diagnosis represent
   different biology, stratified or not in same trial.

5) Tumors with targetable mutations should have their own trials
   (multi-institutional for accrual) and different sequencing in light of patterns of
   failure.

What have we learned from clinical trials in OMD, continued:

6) **Metachronous** vs **synchronous** disease = different biology or different time-points in the evolution of the same disease.

7) **Radiation doses/fractionation** poorly understood within context of immune and host tissue responses – do trials need to permit use of high ablative doses, low ablative doses, or ablative doses at all?

8) Need to identify metastatic tumor or host tissue biomarkers predictive and prognostic of **a)** durable responders to systemic therapies and **b)** patients with true OMD who will maximally benefit from local therapies.

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Future Directions

A. Sequencing of Therapy and Trial Eligibility:

For non-targetable disease, is consolidation the best time to enroll patients and use local therapy?

Rather than number of lesions and strict time to start local therapy, we could follow ctDNA/MRD levels to determine disease burden that can potentiate the development of new sites of disease – if that level is low, we may want to treat all visible metastases no matter the number if safe and obvious. If the ctDNA level is high, the disease being seen is the tip of the iceberg and local therapy may be less relevant to disease outlook.

Tie in with genomics to anticipate worse actors.

B. Trial Design: Early phase, translational-heavy SMART or Umbrella/Basket Trials

C. Real World Data (RWD)

D. Predictive and Prognostic Biomarkers for OMD

E. Better Understanding of the Potential/Limits of Systemic Therapy and Its Synergy with Local Therapy

F. Personalization of Therapy

What predicts for Oligometastatic vs Oligoremnant vs Polymetastatic?

Match imaging patterns of disease/failure with:

MRD
ctDNA
Tumor Oncogenotype
Host Genotype
RNA-seq of Tumor and Host

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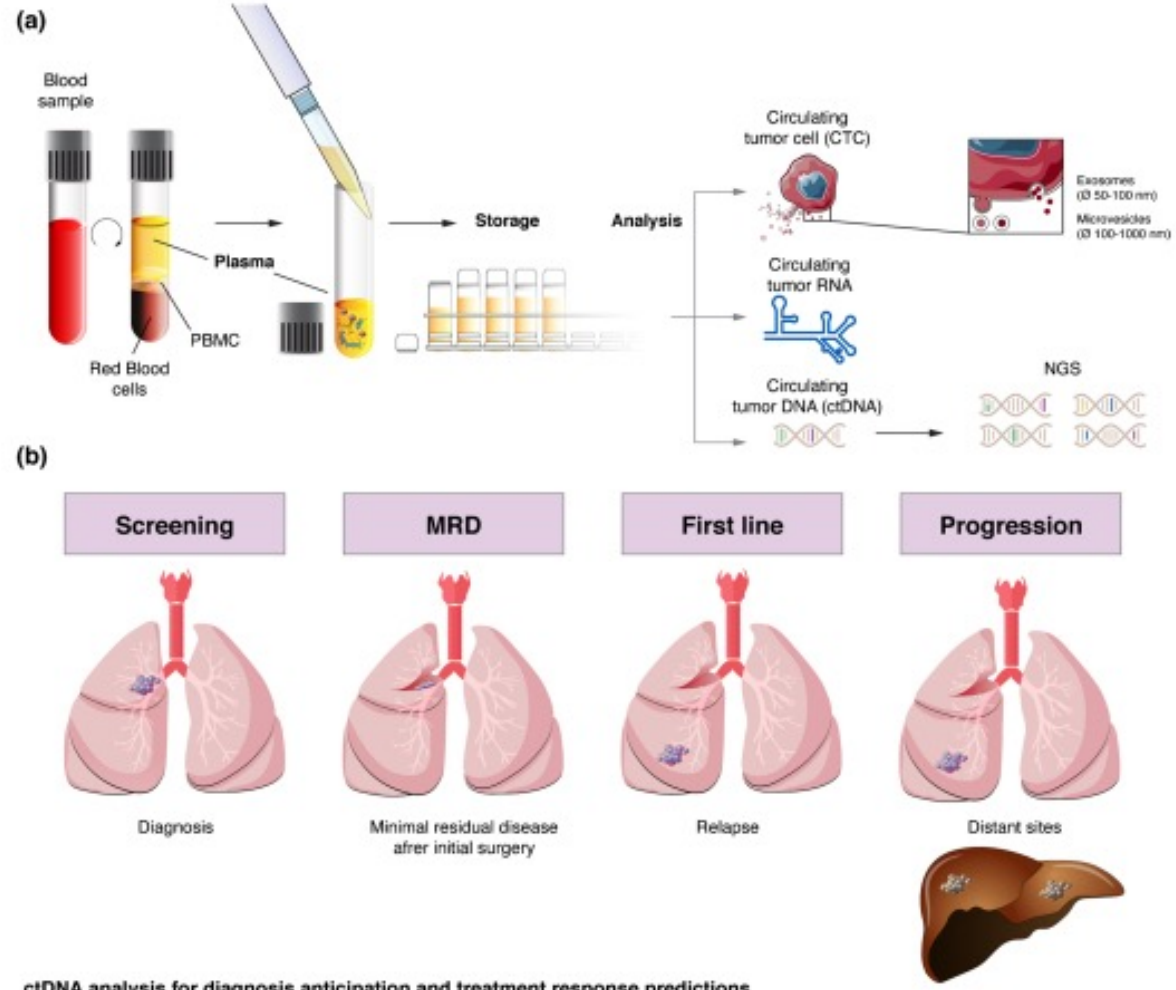
Current Oncology Reports (2021) 23: 136
https://doi.org/10.1007/s11912-021-01131-w

LUNG CANCER (H BORGHAEI, SECTION EDITOR)

The Role and Impact of Minimal Residual Disease in NSCLC

Daniele Frisone[1] · Alex Friedlaender[1,2] · Alfredo Addeo[1]



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Conclusions

1. Why think about metastatic disease that may benefit from local therapy as oligometastatic or oligoremnant?

2. More about extent of disease at time point and whether more is present or coming.

3. That will depend on oncogenotype, host genotype (immune, metabolism, local met site environments), and collective response to therapy.

4. We therefore need a lot of data on many patients with different oncogenotypes, all with different host responses, who respond differently to systemic therapy so we can predict the future and know when to use local therapy. ctDNA and MRD can help us get there.

5. Patients ask if we use genomics information to guide radiation therapy.
Normally no, unless unique aspects of DDR genetics.
Now we can say that oncogenotype can guide use of local therapy because it informs us regarding global disease control state when combined with information on previous slide.

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