



NRG Oncology General Session

July 23, 2021
12:30-1:45pm



@NRGOnc



NRG Oncology





NRG Group Chairs/Principal Investigators

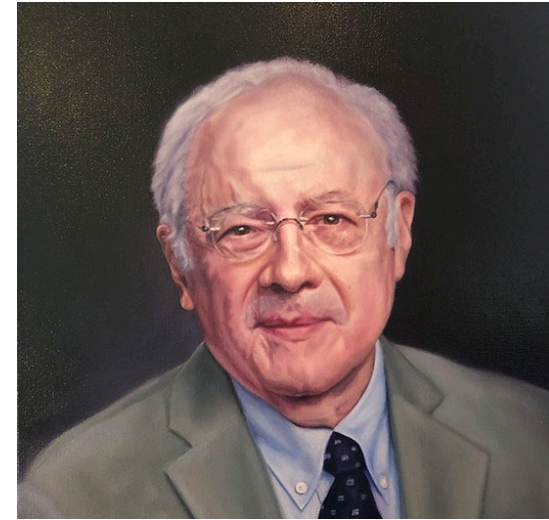


**Philip J. DiSaia, MD
(1937-2018)**



**Walter J.
Curran, MD
Dec 2020**

Global CMO GenesisCare



**Norman
Wolmark, MD**



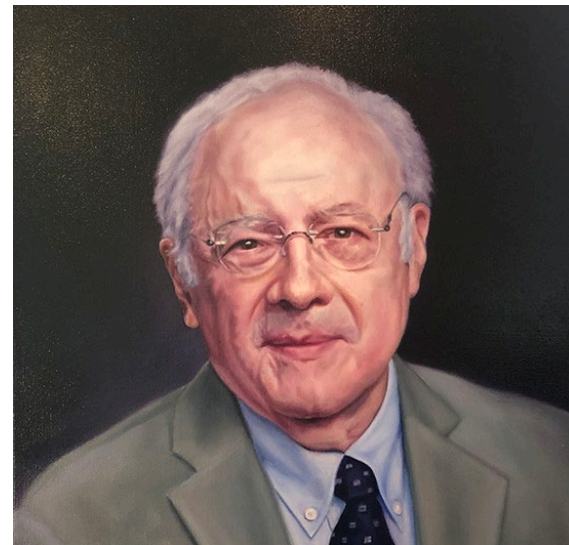
NRG Group Chairs/Principal Investigators



**Robert Mannel, MD
(2017)**



**Mitchell
Machtay, MD
interim**



**Norman
Wolmark, MD**

July 1, Chair/PI NRG and RTOG Fnd

**Chair of the NRG Head and Neck
Committee 2014**

BS, Biol and Chem, Caltech, 1989

MD, UCSF, 1993

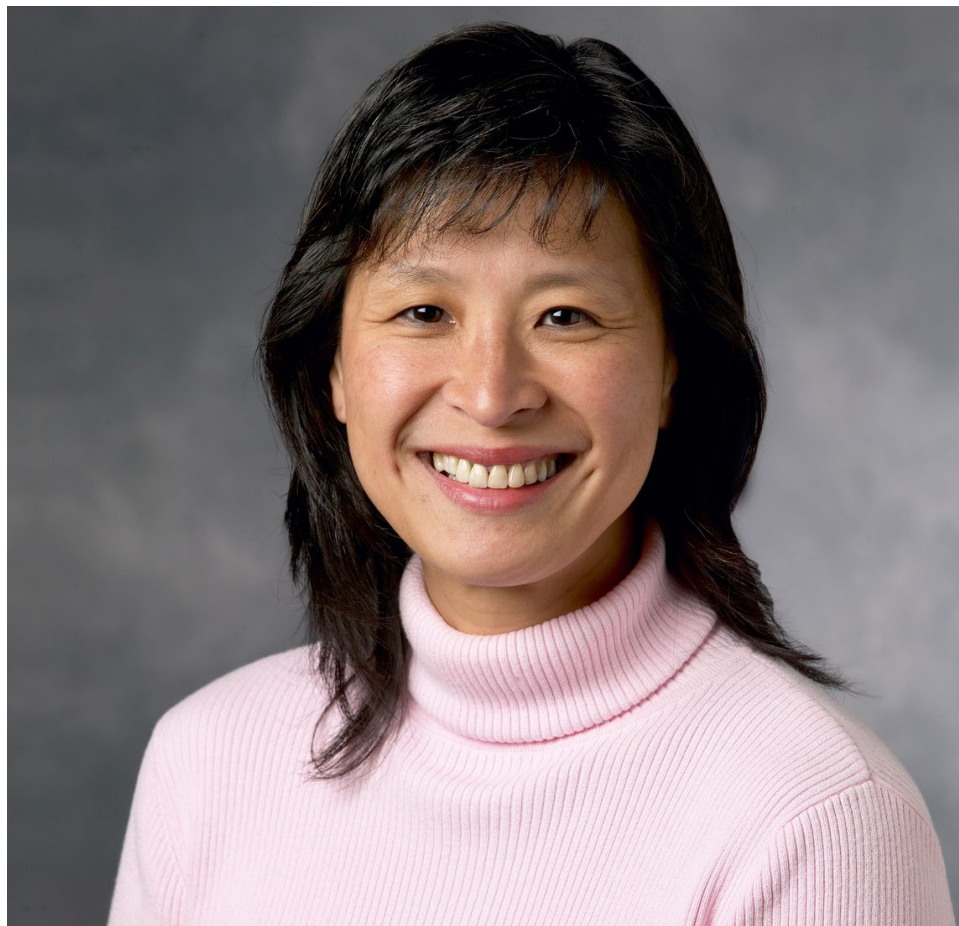
Residency, UCSF, 1997

**Co-Director, Radiation Biology Program,
Stanford Cancer Institute 2004**

McCormick Memorial Professor, Stanford

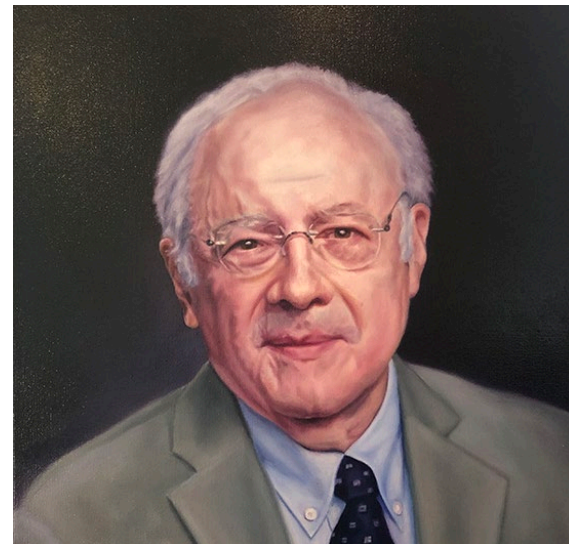
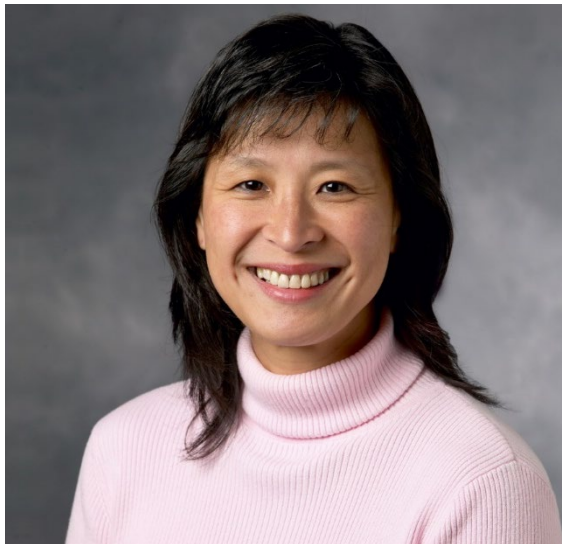
**Chair, Dept of Radiation Oncology,
Stanford 2011**

NRG
ONCOLOGY™



Quynh-Thu Le, MD

NRG Group Chairs/Principal Investigators





NRG Oncology General Session

July 23, 2021
12:30-1:45pm



@NRGOnc

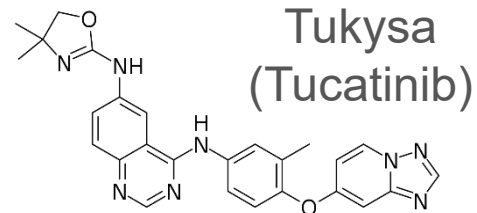


NRG Oncology





Platinum Sponsor





#NRG2021

- 50 Sessions
- 10 Days
- >2000 attendees





#NRG2022 Winter Meeting
February 10-12, 2022
Phoenix, AZ



NRG Strategic Initiatives

- Optimize NRG meetings
- Support our New Investigators

Optimize our Meetings

- **Return to in-person meetings (when safe to do so)**
- **Increase participation through virtual offerings**
- **Primary meeting will remain in-person**
- **Potential to off-load some “overlap” through virtual meetings pre/post in – person**



NRG Strategic Goals

Attract, recruit, develop, mentor, and retain members and future leaders – especially PI

1. Provide adequate guidance for clear and consistent committee membership

Posted under Policies
www.nrgoncology.org

I. INTRODUCTION. NRG Oncology is organized into Scientific Committees (disease – specific and disease agnostic), Scientific Core Committees, Administrative Committees, and Executive/Oversight Committees. Having a homogeneous committee structure and standards for rotating members across the committees assists in the overall efficient functioning of NRG Oncology and ensures opportunities are regularly made available for interested investigators to get involved, infusing different ideas and ensuring diversity across our organization.

II. SCOPE. This guidance applies to NRG Oncology Scientific Committees and Scientific Core Committees. Administrative Committees may have a different structure defined by Bylaws as appropriate to the function of the committee, but generally should comply with the intent herein where feasible.

III. NRG ONCOLOGY GUIDANCE. Each committee is expected to have a governance structure and defined processes which allow for the transparent and open management of committee business and supports opportunities for rotating new members in on a routine basis.

- **Core and General Committees.** For committees that are particularly large, such as the scientific committees, it may be appropriate to establish a Core Committee, generally of 30-40 individuals including committee liaisons and chairs, as the voting membership. Where a core committee structure is utilized, a non-voting general

NRG Strategic Goals

Attract, recruit, develop, mentor, and retain members and future leaders – especially PI

1. Provide adequate guidance for clean and consistent committee membership
2. Develop a robust, comprehensive New Investigators Program within NRG

New (Early Career) Investigators Committee

- **Charged with helping us execute our strategic goal**
- **Designed and implementing Mentoring Program**
- **Assigned liaisons with each therapeutic committee**

ECNI Committee

53 mentee applicants





| Specialty | |
|----------------|----|
| Gyn Onc | 12 |
| Med Onc | 17 |
| Rad Onc | 21 |
| HN Surgery | 2 |
| Breast Surgery | 1 |

| Interest | |
|----------|----|
| Breast | 6 |
| CNS | 5 |
| GI | 14 |
| GU | 7 |
| GYN | 16 |
| HN | 9 |
| Lung | 9 |
| Sarcoma | 2 |

ECNI Committee

https://www.nrgoncology.org/Committees-Programs/Disease-Specific-Scientific-Committees/Gastrointestinal-Cancer

Gastrointestinal Cancer Committee

| Colorectal Cancer | Non-colorectal Cancer |
|---|---|
| Chair  Thomas George, MD | Chair  Theodore Hong, MD |
| Vice Chair Scott Koepsz, MD, PhD, FACP | Vice Chair David Ilson, MD, PhD |
| New Investigator Liaisons  Evan Wutbrick, MD |  Heloisa Soares |

- **Match ECNI with liaisons in area of interest**
 - Small group meetings
 - liaison to get to know ECNI
 - Introduce ECNI to others with complimentary interest

ECNI Committee

- **Liaison “job”**
 - Introduce ECNI to committees
 - Pair ECNI with mentors
 - Assist with developing ideas
 - ancillary projects
 - study concepts, etc
 - Identify appropriate ECNIs for positions on studies or other NRG opportunities

Committee Liaisons

- Identified on each NRG Oncology disease team web page
- Listed on the New Investigator committee page
- The go to for all investigators new to NRG or old with new interest

Committee Activities

- **ECNI Webinar July 13, 2021**
 - See On Demand Video
 - Available on the NRG Oncology NIC web page
 - Future educational sessions are planned



Thank you!

Co-Chairs

Elizabeth Gore

Priya Rastogi

Angeles Secord



Support a Health Equity New Investigator



<https://www.nrgoncology.org/Health-Equity>

Donate



NRG Oncology
Health Equity New Investigator
Mentorship Program

A healthcare professional with blonde hair, wearing a blue scrub top, is operating a large white medical device. A Black woman with curly hair, wearing a pink patterned hospital gown, stands next to her, smiling and looking at the device. The scene is set in a clinical environment.

OUR MISSION:
Improving the lives of cancer patients

2021 NCTN Activations

| Study # | Title |
|-----------|---|
| NRG-GY023 | A Randomized Phase II Trial of Triplet Therapy (A PD-L1 Inhibitor Durvalumab (MEDI4736) in Combination with Olaparib and Cediranib) Compared to Olaparib and Cediranib or Durvalumab (MEDI4736) and Cediranib or Standard of Care Chemotherapy in Women with Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer Who Have Received Prior Bevacizumab |
| NRG-BR007 | Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage 1, Hormone Sensitive HER2-Negative, Oncotype Recurrence Score < 18 Breast Cancer (DEBRA) De-Escalation of Breast Radiation |
| NRG-BN010 | A safety run-in and phase II study evaluating the safety, efficacy and impact on the tumor immune microenvironment of the combination of tocilizumab (anti-IL6R), atezolizumab (anti-PD-L1), and stereotactic radiosurgery in recurrent glioblastoma |

2021 NCORP Activations

| Study # | Title |
|-----------|--|
| NRG-CC009 | Randomized Phase II Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for Brain Metastases from Small Cell Lung Cancer |
| NRG-CC005 | FORTE (Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps) |

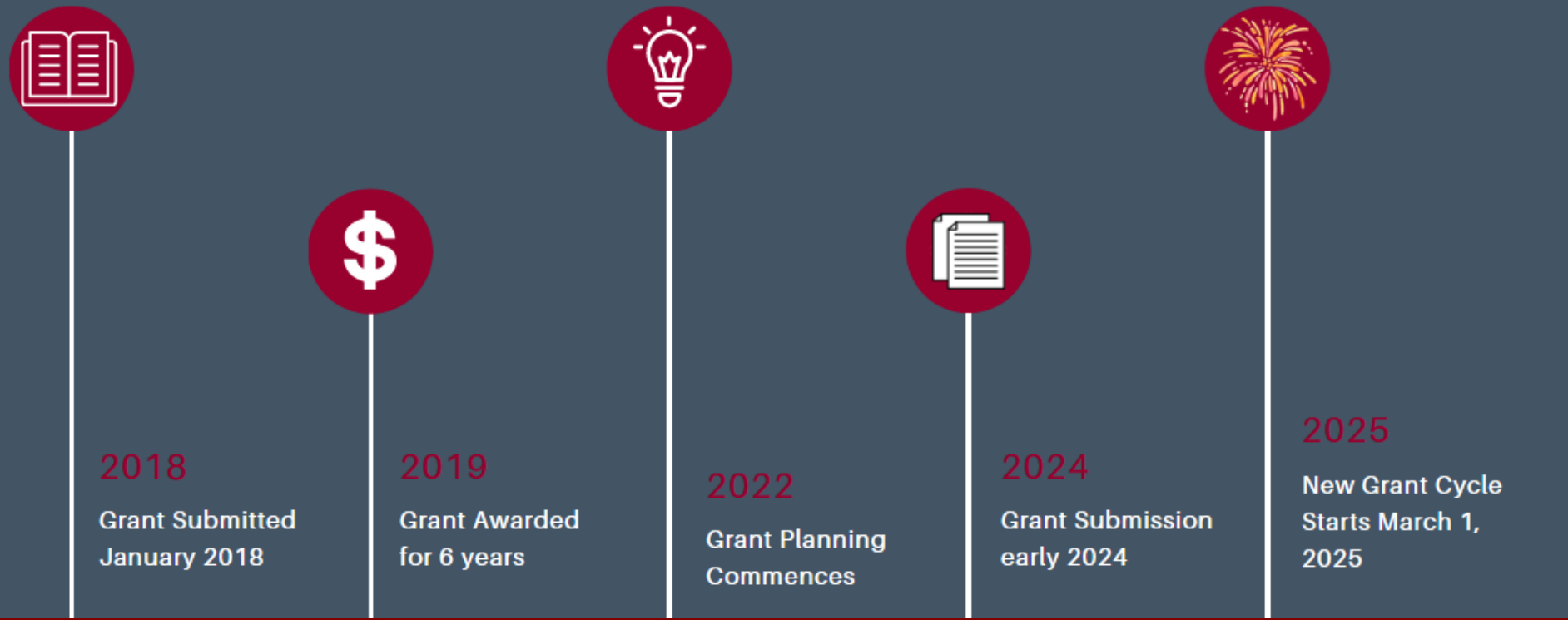
Overall Metrics

March 1, 2019 to July 28, 2021

Total 34 trials have been activated/open to enrollment;

| # Trials Activated | 2019 | 2020 | 2021 | Total |
|----------------------|------|------|------|-------|
| CTEP | 12 | 11 | 3 | 26 |
| CTEP - Joint studies | 1 | 2 | | 3 |
| NCORP | 2 | 1 | 2 | 5 |
| Total | 15 | 14 | 5 | 34 |

NCTN Grant Cycle





Dr. Jeff Michalski voted President-elect of the American Society for Radiation Oncology (ASTRO)

ARLINGTON, Va., July 21, 2021

The members of the American Society for Radiation Oncology (ASTRO) elected three new officers to ASTRO's Board of Directors, including Jeff M. Michalski, MD, MBA, FASTRO, as President-elect, Catheryn Yashar, MD, FASTRO, as Health Policy Council Vice Chair and John Buatti, MD, FASTRO, as Science Council Vice Chair. The officers will begin their terms in October during [ASTRO's 63rd Annual Meeting](#) in Chicago.



In his tenure as President-elect and eventual Chair of ASTRO, Dr. Michalski plans to focus on the Society's priority issues including safeguarding equitable patient access to life-saving cancer treatment; building a pipeline of diverse radiation oncology clinicians and researchers; and developing programs and policies that will prepare the future workforce to meet the evolving cancer care landscape.

"Radiation oncologists have led many essential and innovative clinical research advances that enhance patient outcomes and extend survival. We face ever-growing challenges, however, and as the world emerges from a transformative pandemic, we are reminded that collaboration, inclusion and equity are indispensable for progress, whether within our specialty, with our partners in multidisciplinary oncology or with our patients," said Dr. Michalski. "I will work to ensure that ASTRO's membership and leadership more closely represent the diverse populations we care for and



Welcome New NRG Oncology Board Member



Tashanna Myers, MD, FACOG, FACS

Associate Professor of Obstetrics and Gynecology

University of Massachusetts School of Medicine

Baystate Department of OB/GYN

Division of Gynecologic Oncology Division Chief



Staff Retirements



Mimi Passarello
Director,
NRG Audit/Operations



Denise Mackey
Team Director,
NRG Meeting Services



NRG Oncology Scientific Highlights

General Session
July 23, 2021



2021 ASCO[®]
ANNUAL MEETING



SABCS
SAN ANTONIO BREAST CANCER SYMPOSIUM

December 8-11, 2020
Virtual Symposium
San Antonio, TX U.S.A.

17 NRG Abstracts Presented
38 Manuscripts Published

GLOBAL ONCOLOGY:
RADIATION THERAPY IN A CHANGING WORLD

ASTRO

ANNUAL  MEETING

NRG
ONCOLOGY™

IASLC   | 2020 World Conference
on Lung Cancer Singapore

JANUARY 28-31, 2021 | WORLDWIDE VIRTUAL EVENT

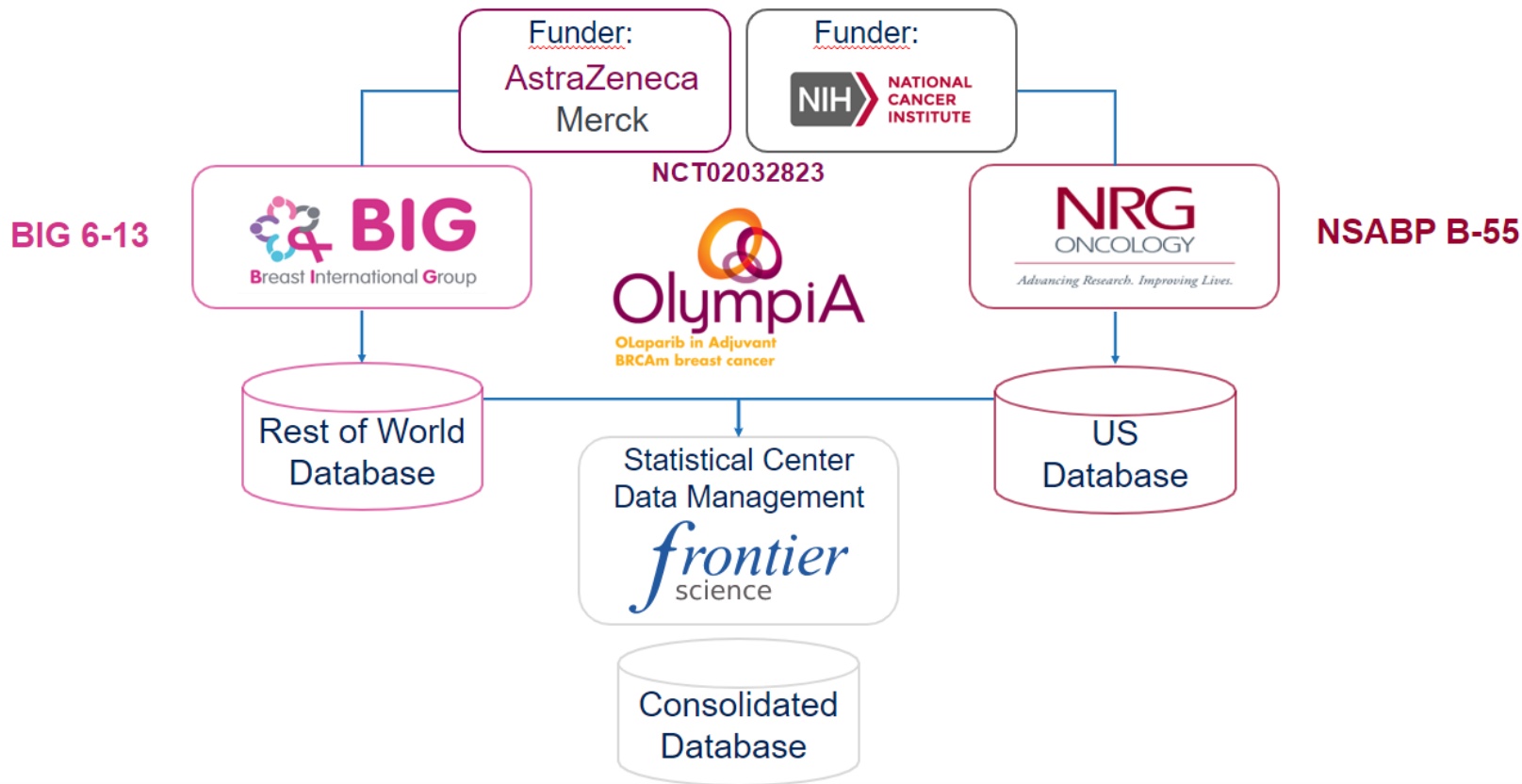




Tutt ANJ, Garber JE, Kaufman B, Viale G, Fumagalli D, Rastogi P, Gelber RD, de Azambuja E, Fielding A, Balmaña J, Domchek SM, Gelmon KA, Hollingsworth SJ, Korde LA, Linderholm B, Bandos H, Senkus E, Suga JM, Shao Z, Pippas AW, Nowecki Z, Huzarski T, Ganz PA, Lucas PC, Baker N, Loibl S, McConnell R, Piccart M, Schmutzler R, Steger GG, Costantino JP, Arahmani A, Wolmark N, McFadden E, Karantza V, Lakhani SR, Yothers G, Campbell C, Geyer CE Jr; OlympiA Clinical Trial Steering Committee and Investigators. **Adjuvant Olaparib for Patients with *BRCA1*- or *BRCA2*-Mutated Breast Cancer.** N Engl J Med. 2021 Jun 24;384(25):2394-2405. doi: 10.1056/NEJMoa2105215. Epub 2021 Jun 3. PMID: 34081848.

ASCO 2021 Plenary presented by Andrew Tutt MB ChB PhD FMedSci
The Institute of Cancer Research and Kings College London

OlympiA: Academia-industry partnership trial model



OlympiA is the first trial to examine the efficacy and safety of a PARP inhibitor in patients with germline BRCA-mutated, HER2-negative early breast cancer

Who was included?

- Adults with a **germline BRCA mutation** with **HER2-negative** breast cancer,
- who had been treated for **early breast cancer (stage II–III)**,
- and **completed surgery and chemotherapy** (with/without radiotherapy),
- but have a **high risk of cancer returning**

Randomization
1:1
N = 1836

Olaparib 300 mg
(n=921)



Placebo
(n=915)

What endpoints did we analyze?

Primary endpoint:

- Invasive disease-free survival

Secondary endpoints:

- Distant disease-free survival
- Overall survival
- Health related quality of life

Safety

Stringent criteria were met for OlympiA's Independent Data Monitoring Committee to recommend early full primary analysis and reporting of results despite relatively short median of follow-up of only 2.5 years

Screening

Trial treatment

1 year

Follow up

Trial will continue up to 10 years

HER2, human epidermal growth factor receptor 2

Invasive disease-free survival was longer with olaparib than with placebo

Compared with placebo, patients receiving **olaparib** had a **42% reduction in the risk of:**

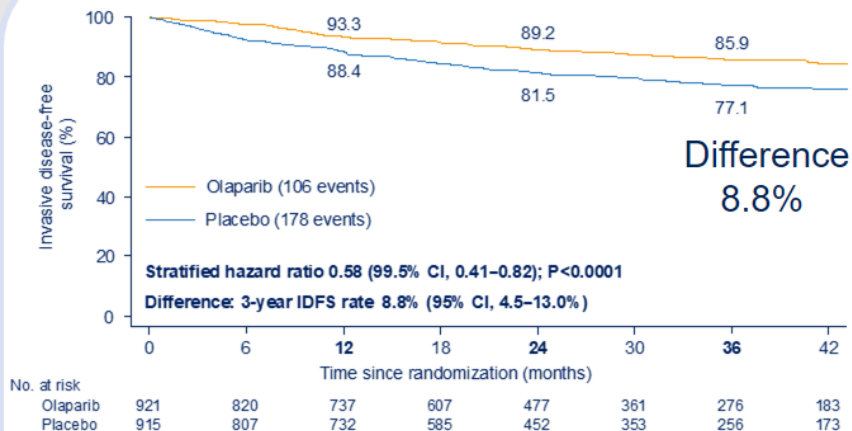
- local recurrence of breast cancer
- metastatic recurrence of breast cancer
- other new cancers
- death due to any cause

This is called invasive disease-free survival

**Invasive disease-free survival hazard ratio:
0.58 (99.5% CI: 0.41–0.82; P < 0.0001)**

Median follow-up: 2.5 years

At 3 years, more patients receiving olaparib were alive and free from invasive disease than with placebo



CI, confidence interval



Yom SS, Torres-Saavedra P, Caudell JJ, Waldron JN, Gillison ML, Xia P, Truong MT, Kong C, Jordan R, Subramaniam RM, Yao M, Chung CH, Geiger JL, Chan JW, O'Sullivan B, Blakaj DM, Mell LK, Thorstad WL, Jones CU, Banerjee RN, Lominska C, Le QT. **Reduced-Dose Radiation Therapy for HPV-Associated Oropharyngeal Carcinoma (NRG Oncology HN002).** J Clin Oncol. 2021 Mar 20;39(9):956-965. doi: 10.1200/JCO.20.03128. Epub 2021 Jan 28. PMID: 33507809; PMCID: PMC8078254.

NRG-HN002

Eligibility

- OP SCCA
- ≤10 pack-year
- T1-T2 N1-N2b
- T3 N0-N2b

R
E
G
I
S
T
E
R

Central
review

p16+
IHC*

S
T
R
A
T
I
F
Y

Declare
Intent

Unilat
vs
Bilat
Neck
XRT

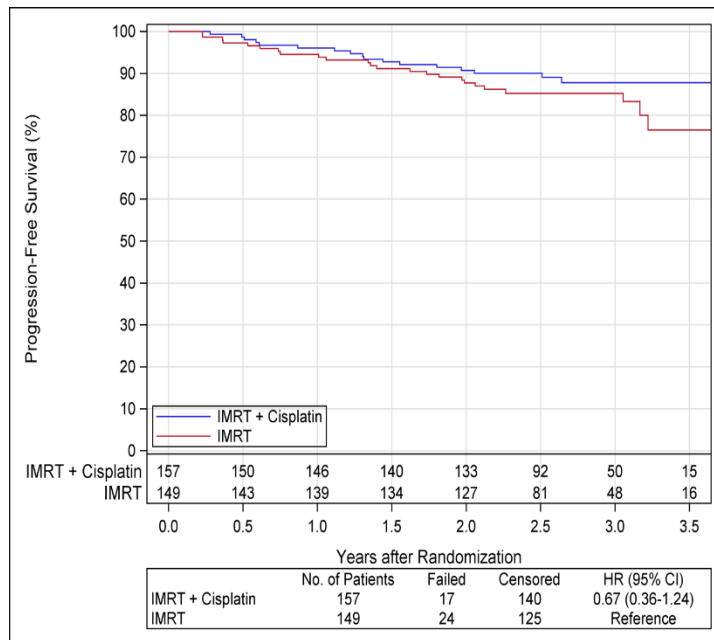
R
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Arm 1: 60 Gy XRT
(2Gy/fx) in 6 weeks
+ cisplatin 40
mg/m² weekly x 6
cycles

Arm 2: 60 Gy XRT (2
Gy/fx) at 6
fractions/week for 5
weeks

*confirmed by the NRG
Oncology Biospecimen
Bank

Results: PFS co-Primary Endpoint



- **2-year PFS estimate for IMRT + C is 90.5%**
- **2-year PFS estimate for IMRT is 87.6%**

PET/CT NPV analyses – ASCO 2020

¹⁸F FDG PET/CT Prediction of Treatment Outcomes in Patients with p16-Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer (LA-OPC) Receiving Deintensified Therapy: Results from NRG-HN002

Subramaniam RM¹, DeMora L², Yao M³, Yom SS⁴, Gillison M⁵, Caudell JJ⁶, Waldron J⁷, Xia P⁸, Chung C⁹, Truong MT¹⁰, Harrison L¹¹, Chan JW¹², Geiger JL¹³, Mell L¹⁴, Seaward SA¹⁵, Thorstad W¹⁶, Beitler JJ¹⁷, Sultanem K¹⁸, Blakaj D¹⁹, Le Q²⁰.

| | IMRT + Cisplatin | IMRT | Total |
|--------------------------------|--------------------|--------------------|--------------------|
| NPV of 2-yr PFS (95% exact CI) | 93.0% (83.0-98.1%) | 91.1% (80.4-97.0%) | 92.0% (85.4-96.3%) |
| NPV of 2-yr LRC (95% exact CI) | 94.6% (85.1-98.9%) | 94.4% (84.6-98.8%) | 94.5% (88.5-98.0%) |

Within the context of deintensification with reduced-dose radiation, the NPV of a 12-14 week post-therapy FDG PET/CT for 2-year LRC is statistically > 90%.

However, in this study, there was not enough evidence to conclude that the NPV of a 12-14 week post-therapy PET/CT for 2-year PFS is > 90%.



NRG
ONCOLOGY

Advancing Research. Improving Lives.™



International Journal of Radiation
Oncology*Biography*Physics

Volume 109, Issue 1, 1 January 2021, Pages 174-185



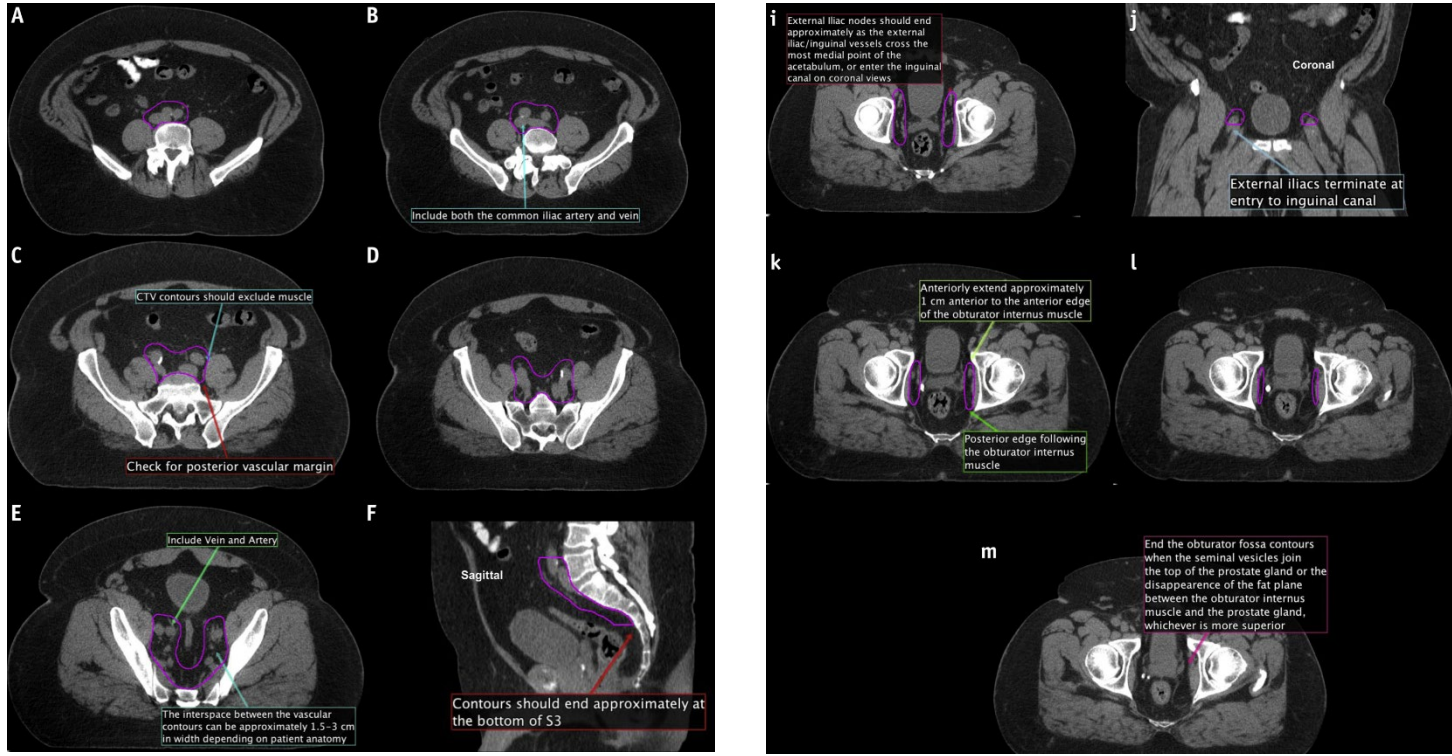
Clinical Investigation

NRG Oncology Updated International Consensus Atlas on Pelvic Lymph Node Volumes for Intact and Postoperative Prostate Cancer

William A. Hall MD *[✉], Eric Paulson PhD *, Brian J. Davis MD, PhD [†], Daniel E. Spratt MD [‡], Todd M. Morgan MD [§], David Dearnaley FRCR, MD ^{||}, Alison C. Tree FRCR, MD ^{||}, Jason A. Efstathiou MD, DPhil, FACRO, FASTRO [¶], Mukesh Harisinghani MD [#], Ashesh B. Jani MD, MSEE, FASTRO **, Mark K. Buyyounouski MD, MS ^{††}, Thomas M. Pisansky MD [‡], Phuoc T. Tran MD, PhD ^{‡‡}, R. Jeffrey Karnes MD ^{§§}, Ronald C. Chen MD, MPH, FASCO, FASTRO ^{|||}, Fabio L. Cury MD ^{¶¶}, Jeff M. Michalski MD, MBA, FASTRO ^{###}, Seth A. Rosenthal MD, FACR, FASTRO ^{***}, Bridget F. Koontz MD ^{†††}, Anthony C. Wong MD, PhD ^{‡‡‡}, Paul L. Nguyen MD ^{§§§}, Thomas A. Hope MD ^{||||}, Felix Feng MD ^{‡‡‡}, Howard M. Sandler MD, FASCO, FASTRO ^{####}, Colleen A.F. Lawton MD, FACR, FASTRO *

NRG ONCOLOGY

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All Sessions
On Demand

Qualitative Metrics: Count Map Analysis Example

00:10:51

Atlas Presentation

Voluntary FDG PET/CT substudy Analysis per Hopkins Criteria

- Score 1: Focal FDG uptake less than blood pool (BP) – Complete metabolic response
- Score 2: Focal FDG uptake greater than blood pool but less than liver
- Score 3: Diffuse FDG uptake greater than blood pool or liver
- Score 4: Focal FDG uptake greater than liver
- Score 5: Focal and intense FDG uptake greater than liver – Resected tumor

NEGATIVE – Scores 1 or 2; Indeterminate – Score 3; POSITIVE – Score 4 or 5

00:09:17

Head and Neck Cancer Committee

Communications for Patient Advocacy

Many advocates could reach patients through their organizations and an

00:08:25

NCORP Retreat PAC

Unsolicited LOIs and CRDLs
https://ctep.cancer.gov/initiatives/Programs/project_teams.htm

- CRDL
 - The Career Development LOI is intended to increase the success rate for LOIs submitted by junior PIs.
 - Must have a senior faculty mentor and letter of commitment from institution
 - Requirements
 - Unsubstantiated interest in developing career in clinical research
 - Within 7 years of completion of fellowship and be a faculty member (see below term)
- If you are submitting an LOI as a CRDL you MUST schedule a preliminary conference with the IOB medical officer(s) for the assets you are proposing

01:02:25

New Investigators

OlympiA is the first trial to examine the efficacy and safety of a PARP inhibitor in patients with germline BRCA mutations, HER2-negative early breast cancer

00:08:10

OlympiA Presentation

SYMPOSIUM: "CANCER IMMUNOTHERAPY: SUCCESSES, CHALLENGES AND NEW FRONTIERS"
JULY 21, 2021

Welcome to the Summer Virtual Symposium!

04:23:18

Summer Symposium "Cancer Immunotherapy: Successes, Challenges and New Frontiers"

[Visit Event Website](#) | [Privacy Policy](#)

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NRG Oncology COVID-19 Updates – Updated Feb. 23rd

Our [COVID Vaccine Statement](#) and other related resources for patients and our researchers and research staff are available on the [COVID-19 Updates webpage](#).

Publication Search

Reset all column filters

Search

Reset

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|----------------------------------|-------------------------|--|
| Key Phrase/Word - Title: | <input type="text"/> | |
| Key Phrase/Word - Abstract Text: | Not Currently Available | |
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Research Center Update

Mitch Machtay, M.D., Deputy Chair for Research
Professor, Associate Cancer Center Director and Associate Dean
for Clinical Oncology Research, Penn State University

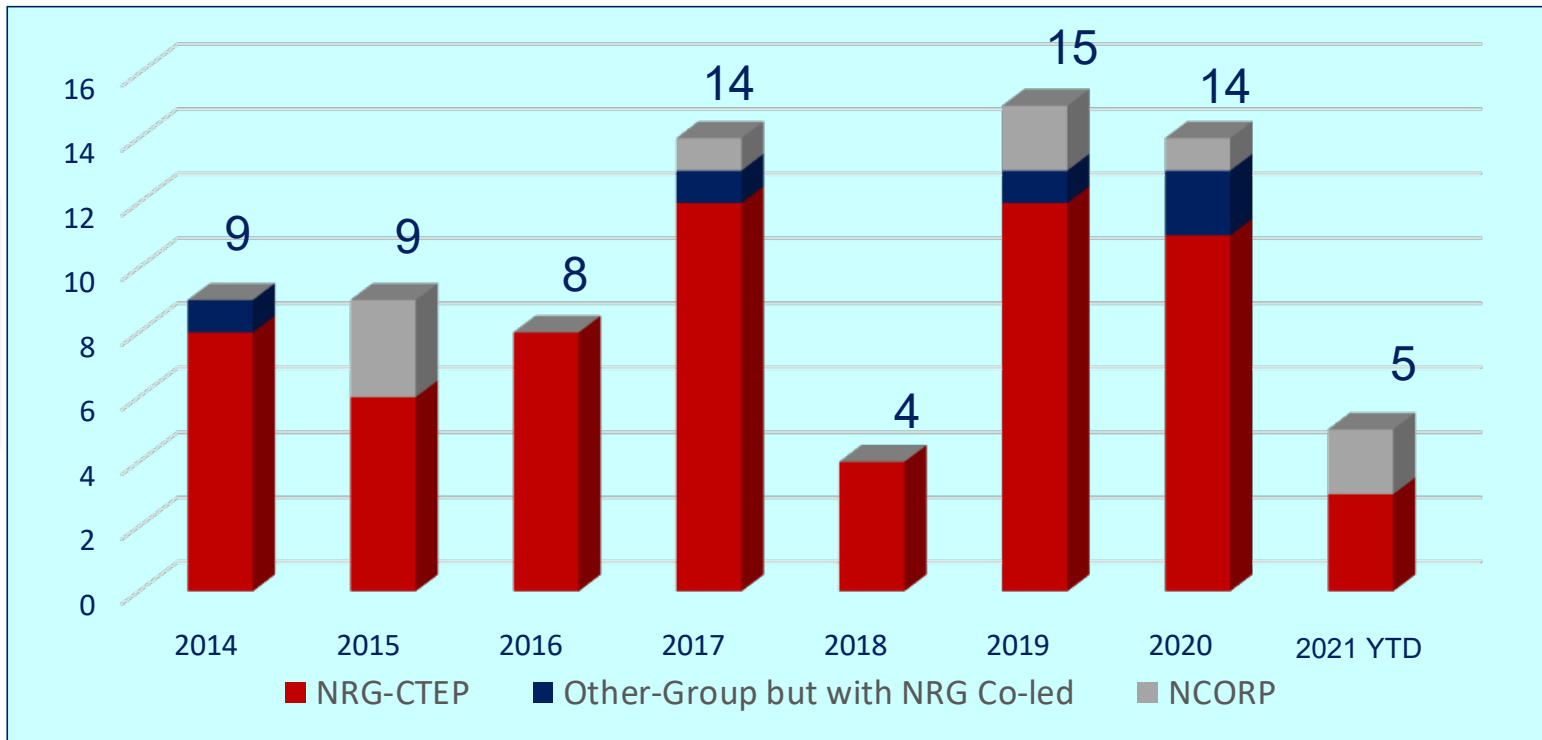
Research Highlights – Important Presentations

| Disease Site & Study # | Presentation |
|---|---|
| Breast: NRG Oncology/ NSABP B-55 (Plenary) (Andrew Tutt, MD) | OlympiA: A phase 3, multicenter, randomized, placebo-controlled trial of adjuvant olaparib after (neo)adjuvant chemotherapy in patients with germline BRCA mutations and high risk breast CA. |
| GYN: ANZGOG 0902/ RTOG 1174/GOG 0274 (Plenary) (Linda R. Mileskin, MD) | Adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: The randomized phase III OUTBACK Trial |
| Breast: NRG Oncology/ NSABP B-42 (Eleftherios P. Mamounas, MD) | Breast Cancer Index (BCI) and prediction of benefit from extended aromatase inhibitor therapy in HR+ breast cancer |
| Breast: NRG Oncology/ NSABP B-42 (Priya Rastogi, MD) | Utility of the 70-gene MammaPrint assay for prediction of benefit from extended letrozole therapy (ELT) |
| Lung/ NRG Oncology RTOG 1106/ ACRIN 6697 (Feng Ming 'Spring' Kong) | A phase IIR trial of standard versus adaptive (mid-treatment PET-based) chemoradiotherapy for stage III NSCLC |
| Lung: Alliance CALGB 30610/NRG- RTOG 0538 (Jeff Bogart MD) | Phase III comparison of high dose QD thoracic RT vs. BID RT in limited stage small cell lung CA |

NRG Protocol Development Highlights

- Since birth of NRG (3/1/2014): 65 CTEP; 9 NCORP; plus 5 'Intergroup' (Grand Total = 79)

2021 YTD:
5 studies
activated



NRG New Trials Opened 2021



| | Study Theme | Gender | M0 Curative | Novel Biomarker | Novel RT/Surg | QOL/ PRO |
|-------|--|--------|-------------|-----------------|---------------|----------|
| BN010 | Recurrent GBM: SRS +/- Immunotherapy | | ✓ | ✓ | ✓ | |
| BR007 | Breast (early stage): De-escalation of Breast Radiation | ✓ | ✓ | ✓ | | ✓ |
| GY023 | Ovarian (Platinum resistant): Triplet Therapy (Durva, Olaparib, Cedirinib) | ✓ | ✓ | ✓ | | ✓ |
| CC009 | SCLC with Brain Mets: SRS vs. HA-WBRT | | ✓ | | ✓ | ✓ |
| CC005 | Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps (FORTE) | | | | | ✓ |

Activated: NRG-BR007: *DE*-escalation of Breast RAdiation

(DEBRA)

pT1N0M0,
HER2-Negative,
ER and/or PgR
Positive
Breast Cancer

and

**Oncotype-DX*
Recurrence Score
≤ 18**



Step 1 Pre-entry registration

*Pts with T1a
disease that don't
already have an
Oncotype score will
have tissue sample
sent to Genomic
Health centralized
laboratory



Stratify:

Age (< 60; ≥ 60)

RS (≤11, > 11)

Tumor size
(≤ 1 cm; 1.1–2 cm)



R



Breast
RT
+
Endocrine
Therapy



Endocrine
Therapy

(No Breast
Radiation
Therapy)

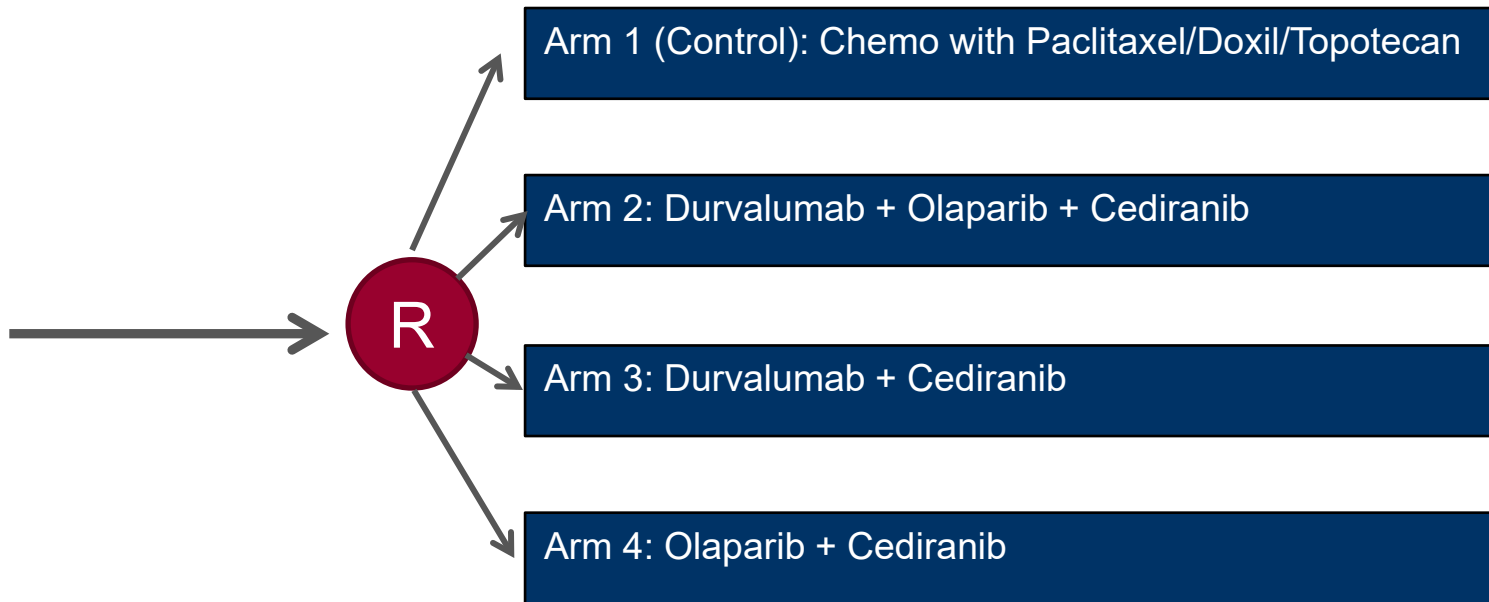
**1° Endpoint = 5-yr IBTR
Sample Size: 1,670**

Activated: NRG-GY023: *Recurrent Pt-Resistant Ovarian CA*

Platinum
resistant Ovarian
(or Fallopian
Tube/Peritoneal)
CA

and

2 to 5 prior lines
of therapy
including prior
Bevacizumab



1^o Endpoint = PFS
Sample Size: 164

Re-Activated/Amended: LU005 Limited Stage Small Cell CA

Amended to change from phase IIR/III (with pause)
to straight Phase III design (no pause).

Limited Stage
Small Cell Lung
Carcinoma
suitable for
curative intent
chemo-RT



Stratify:

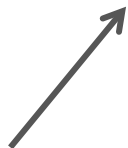
Radiation Schedule
(QD vs. BID)

Chemo (Cisplatin
vs. Carboplatin)

Performance
Status (0/1 vs 2)



R



Chemoradiation (45 Gy bid or 66 Gy
qd) including 4 cycles of
platinum/etoposide. PCI encouraged

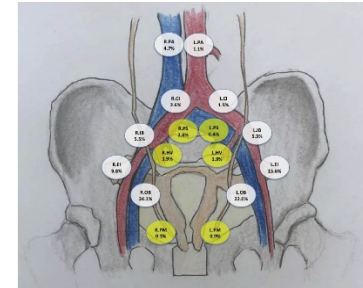
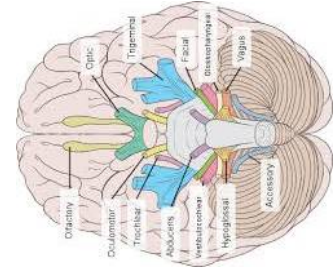
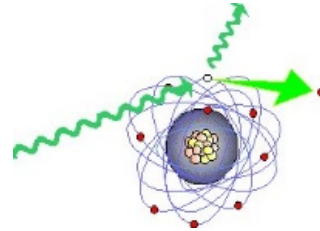


Chemoradiation as above plus
Atezolizumab q3weeks x 1 year
starting with Cycle #2 of chemo

1^o Endpoint = Survival
Sample Size: 506 pts

NRG Developing Trials – Currently N=35

- Brain: 3 studies (1 approved by NCI)
- Breast 4 studies (1)
- GI: 3 studies (1)
- GU: 5 studies (2)
- H&N : 2 studies (1)
- Lung: 3 studies (0)
- GYN: 7 studies (5)
- DT GYN 3 studies(1)
- DT ComboMatch 4 studies (3)
- NCORP: 1 studies (0)



Upcoming: NRG-HN009 –RT + High/Low Dose Cisplatin

For patients with oropharynx or unk. Primary: Local p16 determination is required

Sample Size:
1,250

STRATIFY

Zubrod (ECOG) performance status: 0 vs. 1
Smoking status: ≤ 10 pack-year vs. > 10 pack-year history
T stage: T0-3 vs. T4
Age: ≤ 50 vs. > 50 years
Randomization is 1:1 in each cohort

Non-OPC/p16-negative OPC Cohort

Arm 1: IMRT/IMPT + High-dose cisplatin Q 3 wks
Arm 2: IMRT/IMPT + Low-dose cisplatin weekly

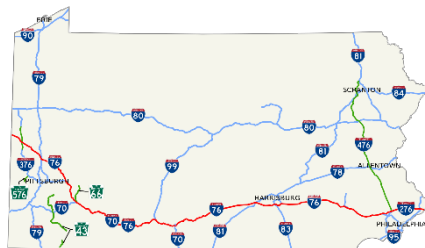
p16-positive OPC/CUP Cohort

Arm 3: IMRT/IMPT + High-dose cisplatin Q 3 wks
Arm 4: IMRT/IMPT + Low-dose cisplatin weekly

Thank you for Joining our NRG Virtual Meeting!

For Questions related to the NRG Research Center including requests for PI's to join RSC meeting (as a non-voting observer) or questions about Ancillary/Secondary Projects:

- Mitchell Machtay: mmachtay@pennstatehealth.psu.edu
- Ronnie Alvarez: Ronald.Alvarez@vumc.org
- Jame Abraham: abrahaj5@ccf.org
- Nancy Soto: SotoN@nrgoncology.org



Please help us to thank all of the incredible Staff at NRG's 3 Research Centers in Philadelphia and Pittsburgh!

- Nancy Soto
- Kia Neff
- Francy Fonzi



NRG Membership & Quality

David Scott Miller, M.D., F.A.C.O.G., F.A.C.S.

Deputy Group Chair for Membership and Research Integrity

July 23, 2021



@NRGOn
C



NRG Oncology



NRG Network Requirements

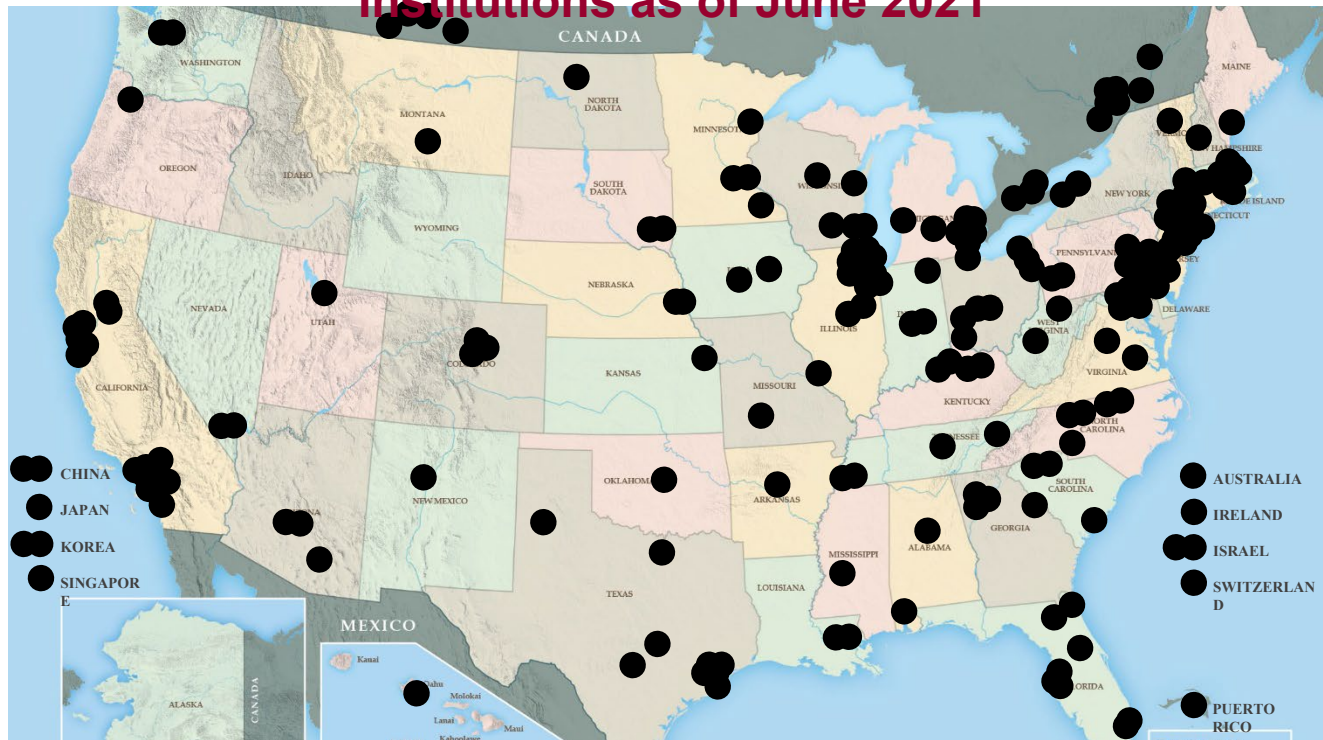
- Required to credit 15 patient cases per year to NRG
- Maintain satisfactory data quality and audit performance
- 15 cases from the entire NRG portfolio
- Affiliate accrual will count toward the 15 case requirement
- NCTN accrual credited to NRG will also count

New Networks

- FL003 – Baptist MD Anderson Cancer Center
- NE007 – Nebraska Methodist Hospital
- PA042 – Penn State Health Milton S. Hershey Medical Center
- USONC – The US Oncology Network



NRG Oncology Main Members, LAPS, and NCORP Institutions as of June 2021



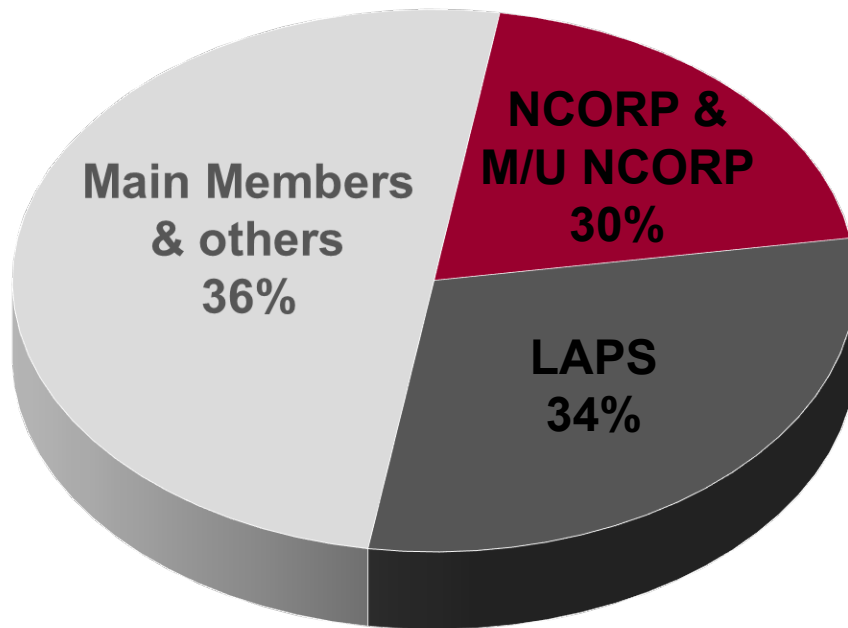
NRG Networks

| | |
|---|------------|
| • Lead Academic Performance Sites (LAPS) | 32 |
| • National Community Oncology Research (NCORP) Sites | 29 |
| • Minority/Underserved NCORP Sites | 11 |
| • Other Centers | <u>128</u> |
| Total | 200 |

NRG Oncology

Accrual by Network Category

January 1 – June 30, 2021



Top Accruing Main Members

NRG Oncology Trials

January 1 – June 30, 2021

- | |
|---|
| 1. Women and Infants Hospital |
| 2. Miami Cancer Institute |
| 3. Sun Yat-sen University Cancer Center |
| University of Cincinnati/Barrett Cancer Center |
| Women's Cancer Center of Nevada |
| 4. University Health Network-Princess Margaret Hospital |
| University of Arkansas for Medical Sciences |
| Stanford Cancer Institute Palo Alto |
| Moffitt Cancer Center |
| 5. GenesisCare USA - Farmington Hills |
| Banner University Medical Center - Tucson |

Top Accruing Lead Academic Participating Sites (LAPS) NRG Oncology Trials January 1 – June 30, 2021

1. CWRU Case Comprehensive Cancer Center LAPS
2. Memorial Sloan-Kettering Cancer Center LAPS
3. Washington University - Siteman Cancer Center LAPS
4. Ohio State University Comprehensive Cancer Center LAPS
5. University of Oklahoma Health Sciences Center LAPS
6. University of Texas MD Anderson Cancer Center LAPS
7. University of Rochester LAPS
8. Roswell Park Cancer Institute LAPS
9. Mayo Clinic LAPS
- Emory University - Winship Cancer Institute LAPS

Top Accruing NCI Community Oncology Research Program (NCORP)

NRG Oncology Trials

January 1 – June 30, 2021

1. Southeast Clinical Oncology Research Consortium NCORP
2. Upstate Carolina Consortium Community Oncology Research Program
3. Heartland Cancer Research NCORP
4. Kaiser Permanente NCI Community Oncology Research Program
5. Delaware/Christiana Care NCI Community Oncology Research Program
- University of Kansas Cancer Center - MCA Rural MU NCORP
6. New Mexico Minority Underserved NCORP
7. Metro Minnesota Community Oncology Research Consortium
- Cancer Research for the Ozarks NCORP
8. Cancer Research of Wisconsin and Northern Michigan Consortium

Top Accruing Non-US Sites

NRG Oncology Trials

January 1 – June 30, 2021

- | |
|--|
| 1. Sun Yat-sen University Cancer Center |
| 2. University Health Network-Princess Margaret Hospital |
| 3. Ottawa Hospital and Cancer Center-General Campus |
| 4. BCCA-Vancouver Cancer Centre |
| National Cancer Centre Singapore |
| 5. Kantonsspital Aarau |
| Allan Blair Cancer Centre |
| 6. Tom Baker Cancer Centre |
| 7. National Cancer Center Hospital |
| 8. Saitama Medical University International Medical Center |
| Korea Cancer Center Hospital |
| London Regional Cancer Program |
| Saskatoon Cancer Centre |
| Cross Cancer Institute |
| Juravinski Cancer Centre at Hamilton Health Sciences |
| Horizon Health Network-Saint John Regional Hospital |
| Niagara Health System-Saint Catharines General |

Audit Program Updates

- NRG Oncology did not suspend audits, although many were delayed due to COVID-19 pandemic.
- We adapted, offering to employ remote access to site EMRs, electronic files or submission of chart copies to NRG.
- NCI/CTSU now offers a “space” for uploading chart copies on the CTSU website.
- Can audit pharmacy by video chat mechanism.

Audit Program Updates cont.

- In 2021, conducted 1 on-site audit out of 60 audits conducted.
- At least 3 on-site audits planned for second half of 2021.
- We will continue with both options (on-site and remote) going forward.

NRG Networks with Commendable Audits:

- **MA125**, Berkshire Medical Center - Cancer Center



NRG Publications

Virtual General Session

July 23, 2021

Krishnansu S. Tewari, MD, FACOG, FACS, FRSM
Professor with Tenure & Division Director
The Philip J DiSaia, MD Endowed Chair in Gynecologic Oncology
University of California, Irvine



NRG
ONCOLOGY

Advancing Research. Improving Lives.™

Publications Committee

Chair: Krishnansu Tewari, MD

Vice-Chairs: Elizabeth Gore, MD, Tom Julian, MD

Members

Michael J Birrer, MD, PhD
Paul D Brown, MD
James J Dignam, PhD
Laurel A Habel, PhD
Himu Lukka, MD
Terry Mamounas, MD
Benjamin Movsas, MD

Members

Gilbert D Padula, MD
Stephanie Pugh, PhD
Priya Rastogi, MD
Rachel Rabinovitch, MD
Aaron H Wolfson, MD
Ying Xiao, PhD
Sue S Yom, MD, PhD

NRG Publications Volume Report

March 1, 2014-June 30, 2021

Abstracts and Manuscripts

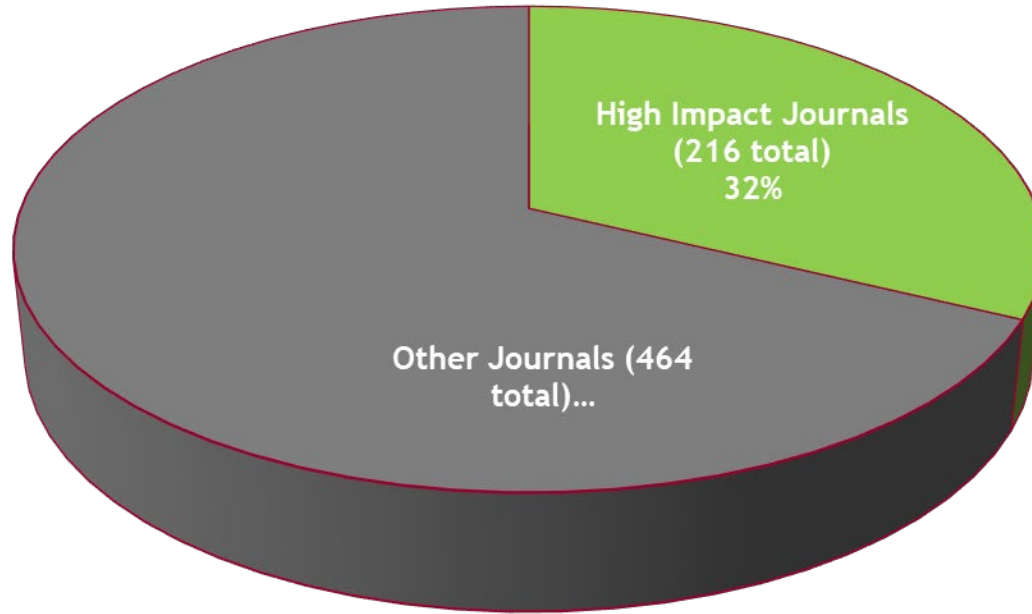
| Published/Presented | 4/1/14-6/30/21 |
|--|----------------|
| Abstracts | 649 |
| Manuscripts-Miscellaneous Publications | 680 |
| Total Publications | 1329 |

Publications in High impact journals 2014-2021

| Journal Published and e-Pub | Impact Factor | Mar 1, 2014-June 30, 2021 |
|-----------------------------|---------------|---------------------------|
| NEJM | 74.699 | 17 |
| Lancet | 59.102 | 12 |
| JAMA | 56.272 | 2 |
| Lancet Oncology | 41.316 | 12 |
| JCO | 32.956 | 38 |
| JAMA Oncology | 24.799 | 87 |
| European Urology | 18.728 | 4 |
| Annals of Oncology | 18.274 | 5 |
| JNCI | 13.506 | 39 |
| Total | | 216 |

Publications in High impact journals

March 1, 2014-June 20, 2021



Publications Issues

- Lack of familiarity with Guidelines

<https://www.nrgoncology.org/Clinical-Trials/Publications>

- Authorship inclusion/order
 - Author responsibilities
- Timely draft of publications
- Timely review by co-authors
- Timely signing of COI
- Minimum TWO step process for NIHMS submission
- Requests to submit to predatory journals

Clinical-Trials Tab → Publications Tab

NRG Oncology Publications Policy and Guidelines

- Pubs Policy v.02/18/2020

NIH Manuscript Submission Requirements

- What Corresponding Authors Need to Know

Data Sharing Policy

- Data Sharing Policy v2 10-2-15

Presentation Templates

- PowerPoint Presentation
- Poster Oblong
- Poster Square



NRG Staff Resources

- Central manuscript submission
- Help with NIHMS



NRG
ONCOLOGY

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Publications Committee Staff

| Pittsburgh | Philadelphia | Buffalo |
|--|--|---|
| Barbara Good Chris Rudock Wendy Rea | Sharon Hartson Eileen Quenzer Faith Wilkins Suzanne Baldwin | Sally Bialy Ann Reardon Kim Blaser |

Questions/Concerns

Is there something that we can do better,
please let us know.

Contact Information

NRG-Publications@NRGOncology.org



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NRG Communications
Summer Virtual General Session
July 2021
T. Julian, MD
Chair, NRG Communications Committee

Communications Committee

Staff

Angela Pier

Michelle Shepard

Cathy Galoppo

Josh Killion

Martha Duncan

Sally Bialy

Communications Committee

Chair: Thomas B. Julian, MD

Members

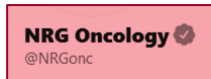
Noelle Cloven, MD
Michael Cowher, MD
Ginger Gardner, MD
Thomas George, MD
Kristin Higgins, MD
Matthew Hudson, PhD

Members

Whitney Jacobson
Jon Kiddy
Miriam Knoll, MD
Debbie Miller, PhD
Becca Previs, MD

Social Media Analytics for 2021

- **Twitter Followers – 5,617** (+559 since Jan meeting)
 - Verified as of July 1st
- **Facebook Followers – 453** (+125 since Jan meeting)
- **LinkedIn Followers – 547** (+156 since Jan meeting)
- **Instagram Followers – 837** (+270 since Jan meeting)



#NRG2021

Social Media Ambassadors



C. Jillian Tsai, MD, PhD
Memorial Sloan Kettering Cancer Center
@CJTsaioMDPhD



Pashtoon Kasi, MD, MS
University of Iowa
@pashtoonkasi



Gloria S. Huang, MD
Yale School of Medicine
@GloriaHuangMD



Kathryn Hitchcock, MD, PhD
University of Florida
@hitchcock_kate

Thank you to our #ASCO21 Social Media Ambassadors

Shoutout!





Social Media Workshops hosted by the Communications Committee



NRG Oncology Social Media Workshop

Extended Meeting Schedule
Wednesday, February 3, 2021
1:00 pm – 2:00 pm EST



NRG ONCOLOGY WINTER 2021
VIRTUAL MEETING
Jan. 28-30, 2021
#NRG2021

| | | | |
|---|--|---|---|
|  Miriam (Mimi) Knoll, MD Twitter: @MKNoil_MD Instagram: @Dr.Mimi.K Program Chair |  Narjust Duma, MD Twitter: @NarjustDumaMD "Let Me Tell You a Story: Recruitment Using Social Media" |  Ishwaria M. Subbiah, MD, MS Twitter: @IshwariaMD "Developing a Framework for Professional Engagement on Social Media Platforms" |  Yaakov Richard Lawrence, MA, MBBS, MRCP Twitter: @LawrenceYaakov "Running an Independent Clinical Trial in the Digital Age" |
|---|--|---|---|

Coming Soon!

NRG Oncology Social Media Workshop
Monday, July 26, 2021
11am-12pm EDT

NRG ONCOLOGY™ VIRTUAL SUMMER MEETING
JULY 19 - 28, 2021
#NRG2021

| | | | |
|---|---|---|--|
|  Miriam (Mimi) Knoll, MD Twitter: @MKNoil_MD Instagram: @Dr.Mimi.K Program Chair |  Jane Lowe Meisel, MD Twitter: @jane_meisel |  Stephanie Graff, MD Twitter: @DrSGraff |  Estelamari Rodriguez, MD Twitter: @Latinamd |
|---|---|---|--|

Communications Team Activities

- **Monthly Newsletters**
 - Disease site awareness months
 - Advocate, nurse interviews
 - New trials
 - Member & site news
 - Outreach to committee chairs
 - ~ 11,000 contacts
- **Weekly E-mail Broadcasts**
 - Closures
 - Activations
 - Other priority news
- **Daily Updates on Webpage**
 - Audits
 - Ops changes
 - Biospecimen collection
 - COVID updates

Website Analytics



Contact Us News Member Login Search...

For Patients ▾ Clinical Trials ▾ Scientific Program ▾ About Us ▾ Resources ▾ Support NRG

- 375,108 Page views Jan 1-July 5, 2021
- 276,626 Unique page views
- Ongoing efforts to improve navigation and sections
- Feedback welcome and can be sent to: nrg-broadcasts@nrgoncology.org

Search for clinical trials.

Search Publications ↻

Search Protocols ↻

Patient Engagement Working Group

- Patient Landing Webpages:
 - NRG-GI004 & NRG-LU005 – NOW OPEN!
 - FORTE pages coming soon!
- Social Media calendar with targeted messaging
- Plan rollouts for other trials as they are developed
- Helping with PI toolkits and creation of promotional materials and patient brochures for trials

Thank you



NRG Biobanking

July 23, 2021

Richard Jordan, DDS, Ph.D.

mPI, NRG Biobanking



NRG Oncology Statistics and Data Management Center

**General Session
James Dignam, Ph.D.
NRG Group Statistician
July 23, 2021**

NRG Statistics and Data Management Center (SDMC) Update

NRG Oncology Data Monitoring Committees

- **Met Thursday, July 22, reviewed 50 studies (phase IIR, III trials)**
 - Progress updates on accruing studies
 - Review of studies closed to accrual
 - Review of interim analyses and NRG recommendations
- **Favorable feedback on study progress**

SDMC Function Post- Pandemic

- **Transition back to Office/Home environment**
 - Well-positioned now for future adaptations as needed
- **Changes in trial conduct – Discussion have begun regarding ‘winding-down’ or retaining/modifying pandemic emergency measures, including:**
 - Remote consent
 - Reporting requirements for COVID related deviations
 - Remote audits
 - Other – drug delivery, labs, visits, etc.

Don't change anything yet (unless you have heard from us), more info to come



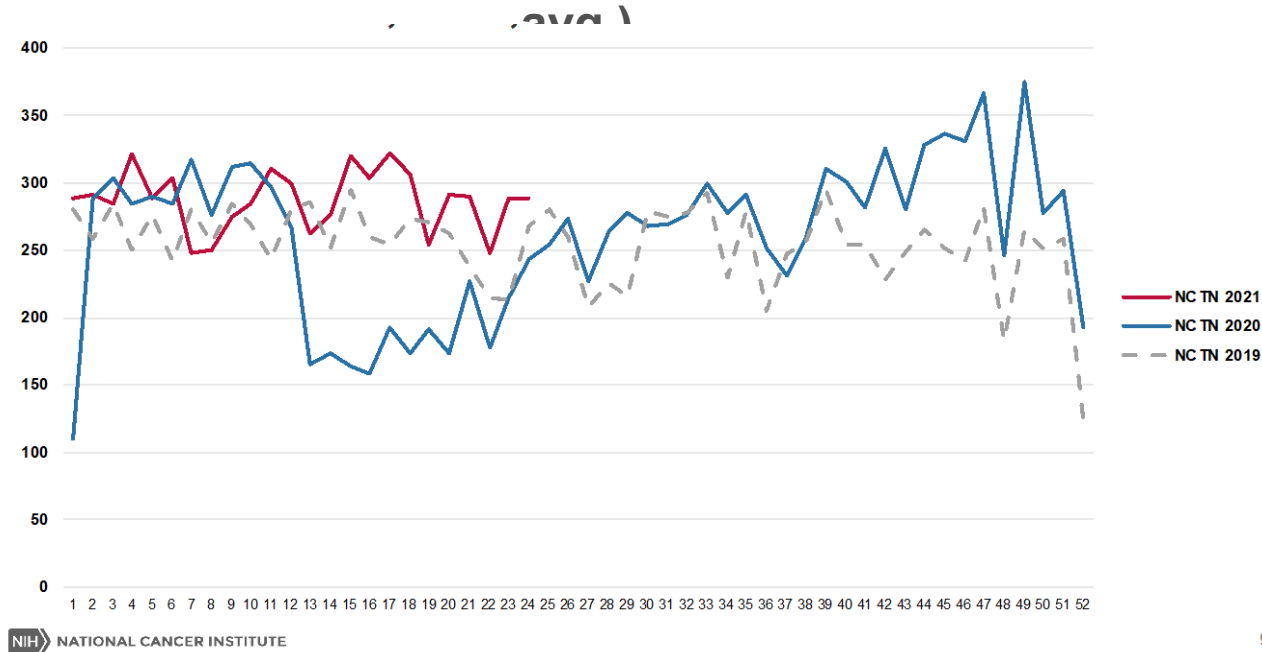
Accrual

NRG Oncology and NCTN Accrual Feb 2020 to June 2021 (CTEP screening/enrollments, weekly avg.):

| | Feb '20 | Mar '20 | Apr '20 | May '20 | Jun '20 | Jul '20 | Aug '20 | Sep '20 | Oct '20 | Nov '20 | Dec '20 | Jan '21 | Feb '21 | Mar '21 | Apr '21 | May '21 | Jun '21 | % Chnge 6/21 vs. 2/20 |
|----------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|-----------------------|
| NRG | 59 | 49 | 32 | 33 | 37 | 38 | 51 | 48 | 49 | 61 | 52 | 52 | 52 | 71 | 73 | 68 | 63 | +7% |
| All NCTN | 381 | 332 | 222 | 243 | 313 | 337 | 375 | 339 | 388 | 389 | 334 | 385 | 357 | 379 | 385 | 379 | 362 | -5% |

Source: NRG
and NCI

NCTN Accrual Contrasting 2019, 2020, and through June 2021 (CTEP screening/enrollments, weekly)



9

Source: NCI

Trial Accrual, Conduct, & Development

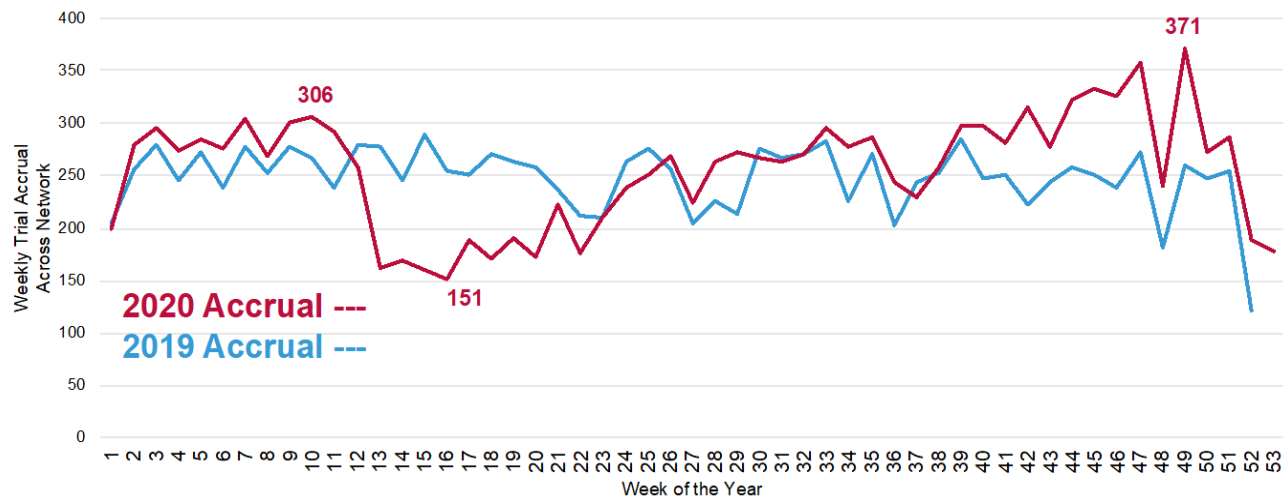
- Accrual recovered from the April-Jul 2020 lows, sustained through 2020: Grant Year Totals (intervention):
 - **2019-20: 2,799**
 - **2020-21: 2,227**
 - **2021(Mar-Jun): 1,063 – on target for ~3,000**
- Minor pandemic related protocol deviations are unlikely to affect trial outcomes. Impact of this and accrual slowing, etc., will be assessed, most studies not materially affected
- New trial development:
 - **5 activations in 2021, 5-6 more anticipated**
 - **33 studies in development, 15 NCI-approved and on development clock**

Thank you for your attention!

**General Session
NRG Oncolog Semi-Annual Meeting
July 23, 2021**



Pandemic Impact: All NCTN Trial Accrual by Week: Calendar Year 2020 Compared to 2019





NRG Oncology NCORP Research Base

General Session
Deborah Watkins – Bruner, RN, Ph.D.
mPI, NRG NCORP RB
July 23, 2021