NRG Oncology General Session

July 23, 2021
12:30-1:45pm
Quynh-Thu Le, 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™
NRG Oncology General Session

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

Seagen®

Tukysa
(Tucatinib)
#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
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

<table>
<thead>
<tr>
<th>Specialty</th>
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</thead>
<tbody>
<tr>
<td>Gyn Onc</td>
<td>12</td>
</tr>
<tr>
<td>Med Onc</td>
<td>17</td>
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<tr>
<td>Rad Onc</td>
<td>21</td>
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<tr>
<td>HN Surgery</td>
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<tr>
<td>Breast Surgery</td>
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<table>
<thead>
<tr>
<th>Interest</th>
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<tbody>
<tr>
<td>Breast</td>
<td>6</td>
</tr>
<tr>
<td>CNS</td>
<td>5</td>
</tr>
<tr>
<td>GI</td>
<td>14</td>
</tr>
<tr>
<td>GU</td>
<td>7</td>
</tr>
<tr>
<td>GYN</td>
<td>16</td>
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<tr>
<td>HN</td>
<td>9</td>
</tr>
<tr>
<td>Lung</td>
<td>9</td>
</tr>
<tr>
<td>Sarcoma</td>
<td>2</td>
</tr>
</tbody>
</table>
**ECNI Committee**

- 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

NRG Oncology
Health Equity New Investigator Mentorship Program
OUR MISSION:
Improving the lives of cancer patients
<table>
<thead>
<tr>
<th>Study #</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRG-GY023</td>
<td>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</td>
</tr>
<tr>
<td>NRG-BR007</td>
<td>Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage 1, Hormone Sensitive HER2-Negative, Oncotype Recurrence Score &lt; 18 Breast Cancer (DEBRA) De-Escalation of Breast Radiation</td>
</tr>
<tr>
<td>NRG-BN010</td>
<td>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</td>
</tr>
</tbody>
</table>
# 2021 NCORP Activations

<table>
<thead>
<tr>
<th>Study #</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRG-CC009</td>
<td>Randomized Phase II Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for Brain Metastases from Small Cell Lung Cancer</td>
</tr>
<tr>
<td>NRG-CC005</td>
<td>FORTE (Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps)</td>
</tr>
</tbody>
</table>
## Overall Metrics

March 1, 2019 to July 28, 2021
Total 34 trials have been activated/open to enrollment;

<table>
<thead>
<tr>
<th># Trials Activated</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>Total</th>
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<tbody>
<tr>
<td>CTEP</td>
<td>12</td>
<td>11</td>
<td>3</td>
<td>26</td>
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<tr>
<td>CTEP - Joint studies</td>
<td>1</td>
<td>2</td>
<td></td>
<td>3</td>
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<tr>
<td>NCORP</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>5</td>
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<tr>
<td>Total</td>
<td>15</td>
<td>14</td>
<td>5</td>
<td>34</td>
</tr>
</tbody>
</table>
NCTN Grant Cycle

2018
Grant Submitted
January 2018

2019
Grant Awarded
for 6 years

2022
Grant Planning
Commences

2024
Grant Submission
early 2024

2025
New Grant Cycle
Starts March 1,
2025
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 Yoshar, 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
17 NRG Abstracts Presented
38 Manuscripts Published
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)
- Oral tablets twice daily
- For 1 year

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.

Difference 8.8%
NRG-HN002

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

*confirmed by the NRG Oncology Biospecimen Bank

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

*confirmed by the NRG Oncology Biospecimen Bank

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

*confirmed by the NRG Oncology Biospecimen Bank

Central review p16+ IHC*  
Declare Intent  
Unilat vs Bilat Neck XRT

Register  
Stratify  
Randomize

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

Arm 2: 60 Gy XRT (2Gy/fx) at 6 fractions/week for 5 weeks
Results: PFS co-Primary Endpoint

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

Yom et al., ASTRO 2019
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 Updated International Consensus Atlas on Pelvic Lymph Node Volumes for Intact and Postoperative Prostate Cancer

William A. Hall MD *, R, Eric Paulson PhD *, Brian J. Davis MD, PhD †, Daniel E. Spratt MD ‡, Todd M. Morgan MD §, David Dearnaley FRCP, MD §, Alison C. Tree FRCP, MD §, Jason A. Efstatiiou 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. Curry 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 *
On Demand Videos

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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
<table>
<thead>
<tr>
<th>Disease Site &amp; Study #</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast: NRG Oncology/ NSABP B-55 (Plenary) (Andrew Tutt, MD)</td>
<td>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.</td>
</tr>
<tr>
<td>GYN: ANZGOG 0902/ RTOG 1174/GOG 0274 (Plenary) (Linda R. Mileshkin, MD)</td>
<td>Adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: The randomized phase III OUTBACK Trial</td>
</tr>
<tr>
<td>Breast: NRG Oncology/ NSABP B-42 (Eleftherios P. Mamounas, MD)</td>
<td>Breast Cancer Index (BCI) and prediction of benefit from extended aromatase inhibitor therapy in HR+ breast cancer</td>
</tr>
<tr>
<td>Breast: NRG Oncology/ NSABP B-42 (Priya Rastogi, MD)</td>
<td>Utility of the 70-gene MammaPrint assay for prediction of benefit from extended letrozole therapy (ELT)</td>
</tr>
<tr>
<td>Lung/ NRG Oncology RTOG 1106/ ACRIN 6697 (Feng Ming ‘Spring’ Kong)</td>
<td>A phase IIR trial of standard versus adaptive (mid-treatment PET-based) chemoradiotherapy for stage III NSCLC</td>
</tr>
<tr>
<td>Lung: Alliance CALGB 30610/NRG-RTOG 0538 (Jeff Bogart MD)</td>
<td>Phase III comparison of high dose QD thoracic RT vs. BID RT in limited stage small cell lung CA</td>
</tr>
</tbody>
</table>
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**

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

- **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)

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

- **Breast RT + Endocrine Therapy**
- **Endocrine Therapy** (No Breast Radiation Therapy)

*Julia White, MD (PI) and Eleanor E. Harris, MD (co-PI)*
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

Arm 1 (Control): Chemo with Paclitaxel/Doxil/Topotecan
Arm 2: Durvalumab + Olaparib + Cediranib
Arm 3: Durvalumab + Cediranib
Arm 4: Olaparib + Cediranib

1º Endpoint = PFS
Sample Size: 164

PI: Jung Min Lee, MD
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)

- **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

- **1⁰ Endpoint = Survival**

- **Sample Size: 506 pts**

**PI:** Kristin Higgins, M.D.
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 study (0)
Upcoming: NRG-HN009 –RT + High/Low Dose Cisplatin

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

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

Sample Size: 1,250

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

Paul Harari, MD, (PI); Christine Chung; Matt Witek; Jed Katzel, Quynh Le
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
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 128

Total 200
NRG Oncology
Accrual by Network Category
January 1 – June 30, 2021

- Main Members & others: 36%
- NCORP & M/U NCORP: 30%
- LAPS: 34%
## Top Accruing Main Members
### NRG Oncology Trials
**January 1 – June 30, 2021**

<table>
<thead>
<tr>
<th>Rank</th>
<th>Institution</th>
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<tbody>
<tr>
<td>1.</td>
<td>Women and Infants Hospital</td>
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<tr>
<td>2.</td>
<td>Miami Cancer Institute</td>
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<tr>
<td>3.</td>
<td>Sun Yat-sen University Cancer Center</td>
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<tr>
<td></td>
<td>University of Cincinnati/Barrett Cancer Center</td>
</tr>
<tr>
<td></td>
<td>Women's Cancer Center of Nevada</td>
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<tr>
<td>4.</td>
<td>University Health Network-Princess Margaret Hospital</td>
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<td></td>
<td>University of Arkansas for Medical Sciences</td>
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<tr>
<td></td>
<td>Stanford Cancer Institute Palo Alto</td>
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<td></td>
<td>Moffitt Cancer Center</td>
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<tr>
<td>5.</td>
<td>GenesisCare USA - Farmington Hills</td>
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<tr>
<td></td>
<td>Banner University Medical Center - Tucson</td>
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</tbody>
</table>
Top Accruing Lead Academic Participating Sites (LAPS)  
NRG Oncology Trials  
January 1 – June 30, 2021

<table>
<thead>
<tr>
<th></th>
<th>Top Accruing Lead Academic Participating Sites (LAPS)</th>
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<tbody>
<tr>
<td>1</td>
<td>CWRU Case Comprehensive Cancer Center LAPS</td>
</tr>
<tr>
<td>2</td>
<td>Memorial Sloan-Kettering Cancer Center LAPS</td>
</tr>
<tr>
<td>3</td>
<td>Washington University - Siteman Cancer Center LAPS</td>
</tr>
<tr>
<td>4</td>
<td>Ohio State University Comprehensive Cancer Center LAPS</td>
</tr>
<tr>
<td>5</td>
<td>University of Oklahoma Health Sciences Center LAPS</td>
</tr>
<tr>
<td>6</td>
<td>University of Texas MD Anderson Cancer Center LAPS</td>
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<tr>
<td>7</td>
<td>University of Rochester LAPS</td>
</tr>
<tr>
<td>8</td>
<td>Roswell Park Cancer Institute LAPS</td>
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<tr>
<td>9</td>
<td>Mayo Clinic LAPS</td>
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</tbody>
</table>

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
# Top Accruing Non-US Sites
## NRG Oncology Trials
### January 1 – June 30, 2021

<table>
<thead>
<tr>
<th>Rank</th>
<th>Site Name</th>
</tr>
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<tbody>
<tr>
<td>1.</td>
<td>Sun Yat-sen University Cancer Center</td>
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<tr>
<td>2.</td>
<td>University Health Network-Princess Margaret Hospital</td>
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<tr>
<td>3.</td>
<td>Ottawa Hospital and Cancer Center-General Campus</td>
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<tr>
<td>4.</td>
<td>BCCA-Vancouver Cancer Centre</td>
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<td></td>
<td>National Cancer Centre Singapore</td>
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<td>5.</td>
<td>Kantonsspital Aarau</td>
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<td></td>
<td>Allan Blair Cancer Centre</td>
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<td>6.</td>
<td>Tom Baker Cancer Centre</td>
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<td>7.</td>
<td>National Cancer Center Hospital</td>
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<td>8.</td>
<td>Saitama Medical University International Medical Center</td>
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<td>Korea Cancer Center Hospital</td>
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<td>London Regional Cancer Program</td>
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<td>Saskatoon Cancer Centre</td>
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<td>Cross Cancer Institute</td>
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<td></td>
<td>Juravinski Cancer Centre at Hamilton Health Sciences</td>
</tr>
<tr>
<td></td>
<td>Horizon Health Network-Saint John Regional Hospital</td>
</tr>
<tr>
<td></td>
<td>Niagara Health System-Saint Catharines General</td>
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</tbody>
</table>
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
# Publications Committee

**Chair:** Krishnansu Tewari, MD  
**Vice-Chairs:** Elizabeth Gore, MD, Tom Julian, MD

## Members

<table>
<thead>
<tr>
<th>Members</th>
<th>Members</th>
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</thead>
</table>
| 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 | 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

<table>
<thead>
<tr>
<th>Published/Presented</th>
<th>4/1/14-6/30/21</th>
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<tbody>
<tr>
<td>Abstracts</td>
<td>649</td>
</tr>
<tr>
<td>Manuscripts-Miscellaneous Publications</td>
<td>680</td>
</tr>
<tr>
<td>Total Publications</td>
<td>1329</td>
</tr>
<tr>
<td>Journal Published and e-Pub</td>
<td>Impact Factor</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>NEJM</td>
<td>74.699</td>
</tr>
<tr>
<td>Lancet</td>
<td>59.102</td>
</tr>
<tr>
<td>JAMA</td>
<td>56.272</td>
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<tr>
<td>Lancet Oncology</td>
<td>41.316</td>
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<tr>
<td>JCO</td>
<td>32.956</td>
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<tr>
<td>JAMA Oncology</td>
<td>24.799</td>
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<tr>
<td>European Urology</td>
<td>18.728</td>
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<tr>
<td>Annals of Oncology</td>
<td>18.274</td>
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<tr>
<td>JNCI</td>
<td>13.506</td>
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<td><strong>Total</strong></td>
<td><strong>216</strong></td>
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Publications in **High impact journals**

**March 1, 2014-June 20, 2021**

High Impact Journals (216 total) 32%

Other Journals (464 total)...
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
# Publications Committee Staff

<table>
<thead>
<tr>
<th>Pittsburgh</th>
<th>Philadelphia</th>
<th>Buffalo</th>
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</thead>
<tbody>
<tr>
<td>Barbara Good</td>
<td>Sharon Hartson</td>
<td>Sally Bialy</td>
</tr>
<tr>
<td>Chris Rudock</td>
<td>Eileen Quenzer</td>
<td>Ann Reardon</td>
</tr>
<tr>
<td>Wendy Rea</td>
<td>Faith Wilkins</td>
<td>Kim Blaser</td>
</tr>
<tr>
<td></td>
<td>Suzanne Baldwin</td>
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</tbody>
</table>
Questions/Concerns

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

Contact Information

NRG-Publications@NRGOncoology.org
NRG Communications
Summer Virtual General Session
July 2021
T. Julian, MD
Chair, NRG Communications Committee
## Communications Committee

<table>
<thead>
<tr>
<th>Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angela Pier</td>
</tr>
<tr>
<td>Michelle Shepard</td>
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<tr>
<td>Cathy Galoppo</td>
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<tr>
<td>Josh Killion</td>
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<tr>
<td>Martha Duncan</td>
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<tr>
<td>Sally Bialy</td>
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Communications Committee

Chair: Thomas B. Julian, MD

<table>
<thead>
<tr>
<th>Members</th>
<th>Members</th>
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<tbody>
<tr>
<td>Noelle Cloven, MD</td>
<td>Whitney Jacobson</td>
</tr>
<tr>
<td>Michael Cowher, MD</td>
<td>Jon Kiddy</td>
</tr>
<tr>
<td>Ginger Gardner, MD</td>
<td>Miriam Knoll, MD</td>
</tr>
<tr>
<td>Thomas George, MD</td>
<td>Debbie Miller, PhD</td>
</tr>
<tr>
<td>Kristin Higgins, MD</td>
<td>Becca Previs, MD</td>
</tr>
<tr>
<td>Matthew Hudson, PhD</td>
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</tbody>
</table>
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)
#NRC2021
Social Media Ambassadors

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

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

Follow our Social Media Ambassadors for NRG Oncology during #ASCO21

Vonetta M. Williams, MD, PhD
@VonettaMW
University of Washington

James Bates, MD
@JamesBatesMD
Emory University

David Miller, MD
@dsmgyo
UT Southwestern Medical Center

Pashtoon Kasi MD, MS
@pashtoonkasi
University of Iowa

Shoutout!
Social Media Workshops hosted by the Communications Committee
Communications Team Activities

• **Monthly Newsletters**
  o Disease site awareness months
  o Advocate, nurse interviews
  o New trials
  o Member & site news
  o Outreach to committee chairs
  o ~ 11,000 contacts

• **Weekly E-mail Broadcasts**
  o Closures
  o Activations
  o Other priority news

• **Daily Updates on Webpage**
  o Audits
  o Ops changes
  o Biospecimen collection
  o COVID updates
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
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 Statistics and Data Management Center (SDMC) Update

NRG Oncology Data Monitoring Committees

• Met Thursday, July 22, reviewed 50 studies (phase IIR, III trials)
  o Progress updates on accruing studies
  o Review of studies closed to accrual
  o 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.):

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

Source: NRG and NCI
NCTN Accrual Contrasting 2019, 2020, and through June 2021 (CTEP screening/enrollments, weekly average)

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

Plot provided courtesy of NCI
NRG Oncology
NCORP Research Base

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