



NRG Oncology
Statistics and Data Management Center
James Dignam, PhD

General Session
NRG Oncology Semi-Annual Meeting
July 21, 2023

NRG Oncology Data Monitoring Committees

NRG DMC Panels A, B, and C

- **Met Mon/Tues, July 10-11, reviewed 61 trial reports (phase IIR, II/III, III trials)**
 - **Progress updates on accruing studies**
 - **Review of accrued studies not yet reported**
 - **Review of protocol specified interim analyses**
- **Minutes will be posted on CTSU, PIs advised of recommendations shortly**

Trial Accrual & Development

- Grant Year Totals (intervention, accrual to NRG trials):
 - **2021-22:** 2,924
 - **2022-23:** 3,713
 - **2023:** 1,582 (March 1 – June 30)
(projection ~3,800)
- **New trial development:**
 - **5 activations so far in 2023**
 - **8 SC-approved trials with 2023 activation dates**
 - **11 activations in 2022**
 - **Combo-MATCH: 1st 2 trials (breast, ovarian/endometrial) – launched!**

NRG Ops/SDMC Initiatives 2023

- 1) **Clinical Trial Streamlining** –NCI Working Group meetings are proceeding – recommendations by 2024 – NCI will lead implementation
- 2) **NRG Quarterly Performance Report Card** – Updated to include a tab for data delinquency, outstanding queries, and case completeness by Protocol
- 3) **Summarization/tracking** of enrollment diversity in NRG trials

SDMC Initiatives 2023

Trial Enrollment Diversity

Population-representative sampling into NRG trials is critical for:

- **Relevance, generalizability of findings**
- **Evidence of trial accessibility, identification of barriers to enrollment**
- **Potential to identify differential benefits of interventions**

***Seeking and reporting on accrual diversity are a mandate of federal awards since 1993**

NRG Enrollment Demographics 2014-2023

Disease Committee	Race Group														All Pts	
	White		Black		Asian		Native AM/AK		Hawaiian /PI		Multi group		Unknown			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Brain	1040	82.3	58	4.6	73	5.8	4	0.3	.	.	4	0.3	85	6.7	1264	100.0
Breast	3816	76.0	653	13.0	296	5.9	31	0.6	17	0.3	18	0.4	191	3.8	5022	100.0
Gynecologic	6792	74.2	746	8.2	1154	12.6	91	1.0	25	0.3	17	0.2	323	3.5	9148	100.0
GI	1250	80.7	105	6.8	91	5.9	11	0.7	4	0.3	1	0.1	86	5.6	1548	100.0
GU	3824	77.8	792	16.1	99	2.0	10	0.2	9	0.2	6	0.1	176	3.6	4916	100.0
Head & Neck	1935	68.9	157	5.6	529	18.8	20	0.7	18	0.6	3	0.1	147	5.2	2809	100.0
Lung	1173	80.0	162	11.0	61	4.2	6	0.4	3	0.2	4	0.3	58	4.0	1467	100.0
NCORP	2145	74.4	216	7.5	52	1.8	12	0.4	3	0.1	11	0.4	445	15.4	2884	100.0
Dev Therap	30	76.9	6	15.4	1	2.6	2	5.1	39	100.0
All Trials	22005	75.6	2895	9.9	2356	8.1	185	0.6	79	0.3	64	0.2	1513	5.2	29097	100.0

Thank you for your attention!

**General Session
NRG Oncology Semi-Annual Meeting
July 21, 2023**