

Accrual of Minorities into NCTN and NCORP Clinical Trials: A Twenty Year View

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Background

- Clinical trials are the most important and reliable means available to **provide scientific evidence** for effective care and management of patients with cancer and individuals at risk for cancer.
- Clinical trials should provide evidence that is both **valid** and **generalizable** to all populations.
- Individuals of diverse populations need **access** to embark upon a journey into clinical trials for improved outcomes for themselves and others.
- Diverse enrollment is a major aim of **national research policies**

Today's Discussion

- Minority Accrual 1999-2019 as reported using OMB categories
- Minority Accrual in Newer Generation of Trials

Methods

- CTEP Enterprise System
- Cooperative Groups/NCTN and Community Clinical Oncology Programs (CCOPs) & Minority-Based CCOPs /NCORP
- 3-Year intervals for accrual numbers and percentages of minorities/total and by age intervals as subsets of minorities for Blacks/African Americans and Hispanics

Accrual to NCI's NCTN and NCORP Clinical Trials: All Phases

Minority Accrual (Numbers)

	1999 - 2001	2002-2004	2005-2007	2008-2010	2011-2013	2014-2016	2017-2019	Total 1999-2019
Majority	85,424	104,766	77,936	74,616	63,570	49,968	58,707	514,987
Minority	13,784	20,947	16,020	18,610	17,098	15,235	21,125	122,819
Black or African American*	7,614	11,612	7,700	8,603	7,106	5,555	8,877	57,067
Unknown/ Not Reported	2,044	2,247	2,276	2,887	1,912	2,878	3,110	17,354
Total	101,252	127,960	96,232	96,113	82,580	68,081	82,942	655,160

Minority Accrual (Percentages)

	1999 - 2001	2002-2004	2005-2007	2008-2010	2011-2013	2014-2016	2017-2019	Total 1999-2019
Majority	84%	82%	81%	78%	77%	73%	71%	78%
Minority	14%	16%	17%	19%	21%	22%	25%	19%
Black or African American	8%	9%	8%	9%	9%	8%	11%	9%
Unknown/ Not Reported	2%	2%	2%	3%	2%	5%	4%	3%

* Subset of Minority Accrual

Accrual to NCI's NCTN and NCORP Clinical Trials: All Phases

Minority Accrual by Age (Percent)

Age	1999 - 2001	2002-2004	2005-2007	2008-2010	2011-2013	2014-2016	2017-2019	Total 1999-2019
0-14	2,707 (20%)	2,322 (11%)	2,900 (18%)	3,766 (20%)	3,855 (23%)	3,771 (25%)	2,394 (11%)	21,715 (18%)
15-39	1,502 (11%)	1,308 (6%)	1,927 (12%)	2,144 (12%)	1,856 (11%)	1,975 (13%)	2,377(11%)	13,089 (11%)
40-64	6,646 (48%)	11,843 (57%)	7,765 (48%)	9,112 (49%)	8,020 (47%)	6,402 (42%)	11,940 (57%)	61,728 (50%)
65-69	1,253 (9%)	2,576 (12%)	1,486 (9%)	1,666 (9%)	1,559 (9%)	1,443 (9%)	2,316 (11%)	12,299 (10%)
70+	1,676 (12%)	2,898 (14%)	1,942 (12%)	1,922 (11%)	1,808 (11%)	1,644 (11%)	2,098 (10%)	13,988 (11%)

Black or African American Accrual By Age (Percentages)

Age	1999 - 2001	2002-2004	2005-2007	2008-2010	2011-2013	2014-2016	2017-2019	Total 1999-2019
0-14	940 (12%)	685 (6%)	798 (10%)	1,154 (13%)	1,059 (15%)	794 (14%)	541 (6%)	5,971 (10%)
15-39	734 (10%)	569 (5%)	744 (9%)	824 (10%)	617 (9%)	531 (10%)	684 (8%)	4,703 (9%)
40-64	4,038 (53%)	7,445 (64%)	4,223 (55%)	4,572 (53%)	3,685 (52%)	2,618 (47%)	5,416 (61%)	31,997 (56%)
65-69	775 (10%)	1,404 (12%)	826 (11%)	946 (11%)	819 (11%)	743 (13%)	1,223 (14%)	6,736 (12%)
70+	1,127 (15%)	1,509 (13%)	1,109 (14%)	1,107 (13%)	926 (13%)	869 (16%)	1,013 (11%)	7,660 (13%)

Accrual to NCI's NCTN and NCORP Clinical Trials: **All Phases**

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Majority	85,424	104,766	77,936	74,616	63,570	49,968	58,707	514,987
Minority	13,784	20,947	16,020	18,610	17,098	15,235	21,125	122,819
Hispanic or Latino*	4,099	6,650	5,475	6,687	6,485	6,051	8,235	43,682
Unknown/ Not Reported	2,044	2,247	2,276	2,887	1,912	2,878	3,110	17,354
Total	101,252	127,960	96,232	96,113	82,580	68,081	82,942	655,160

Minority Accrual (Percentages)								
	1999 - 2001	2002-2004	2005-2007	2008-2010	2011-2013	2014-2016	2017-2019	Total 1999-2019
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Minority	14%	16%	17%	19%	21%	22%	25%	19%
Hispanic or Latino*	4%	5%	6%	7%	8%	9%	10%	7%
Unknown/ Not Reported	2%	2%	2%	3%	2%	5%	4%	3%

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Accrual to NCI's NCTN and NCORP Clinical Trials: All Phases

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70+	1,676 (12%)	2,898 (14%)	1,942 (12%)	1,922 (11%)	1,808 (11%)	1,644 (11%)	2,098 (10%)	13,988 (11%)

Hispanic or Latino Accrual By Age (Percentages)

Age	1999 - 2001	2002-2004	2005-2007	2008-2010	2011-2013	2014-2016	2017-2019	Total 1999-2019
0-14	1,444 (35%)	1,310 (20%)	1,654 (30%)	2,024 (30%)	2,248 (35%)	2,318 (38%)	1,411 (17%)	12,409 (28%)
15-39	548 (13%)	504 (8%)	837 (15%)	982 (15%)	863 (13%)	998 (17%)	1,184 (14%)	5,916 (14%)
40-64	1,515 (37%)	2,912 (43%)	2,122 (38%)	2,760 (41%)	2,505 (39%)	1,961 (32%)	4,350 (53%)	18,125 (42%)
65-69	269 (7%)	848 (13%)	384 (7%)	421 (6%)	413 (6%)	369 (6%)	658 (8%)	3,362 (8%)
70+	323 (8%)	1,076 (16%)	478 (9%)	500 (8%)	456 (7%)	405 (7%)	632(8%)	3,870 (8%)

Accrual to NCI's NCTN and NCORP: Phase III Clinical Trials

Minority Accrual (Numbers)								
	1999 - 2001	2002-2004	2005-2007	2008-2010	2011-2013	2014-2016	2017-2019	Total 1999-2019
Majority	72,249	86,974	56,435	58,191	45,295	32,516	40,001	391,661
Minority	11,514	18,204	11,458	15,197	13,098	11,596	15,552	96,619
Unknown/ Not Reported	1,804	1,966	1,674	2,042	1,540	2,364	2,234	13,624
Total	85,567	107,144	69,567	75,430	59,933	46,476	57,787	501,904

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Accrual to NCI's NCTN and NCORP Clinical Trials: **All Phases**

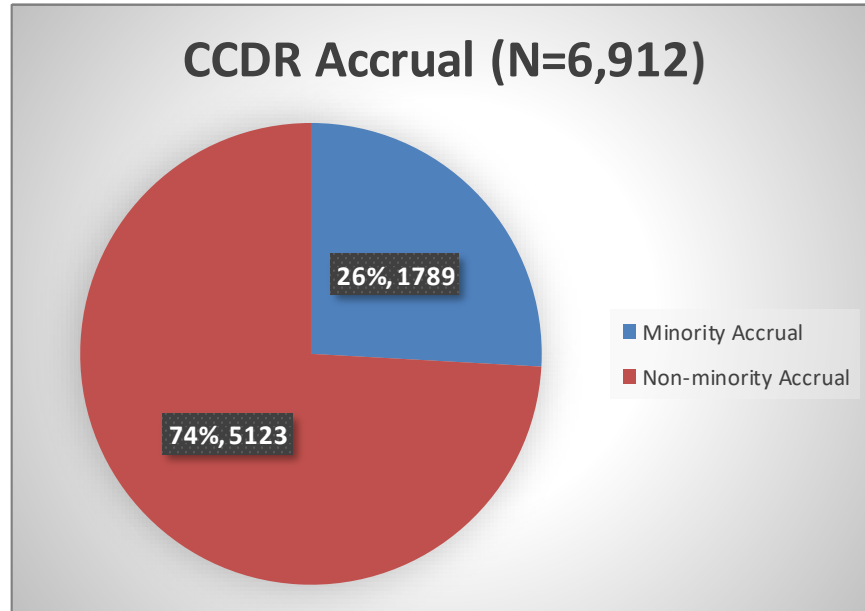
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Black or African American	8%	9%	8%	9%	9%	8%	11%	9%
Hispanic*	4%	5%	6%	7%	8%	9%	10%	7%
Asian	2%	2%	2%	3%	3%	5%	4%	3%
American Indian or Alaska Native	0.3%	0.4%	0.5%	0.4%	0.6%	0.6%	0.5%	0.5%
Native Hawaiian or Other Pacific Islander	0.2%	0.3%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%
More than one Race	0.01%	0.1%	0.2%	0.2%	0.2%	0.3%	0.6%	0.2%

NCORP Accrual to NCI's NCTN Clinical Trials

Minority Accrual (Numbers)			
	NCORP August 1, 2014 - 2019	Total Accrual to NCTN Clinical Trials August 1, 2014 - 2019	NCORP % of NCTN Clinical Trials Accrual
Majority	17,555	64,659	27%
Minority	5,664	21,341	27%
Unknown/ Not Reported	448	4,636	10%
Total	23,667	90,636	26%

**6,912 patients - Total Accrual
(Aug. 1, 2014 – Jan. 31, 2020)**

- **26% minority accrual**
- **M/U sites contribute 63%
of total minority accrual**





In Cancer Trials, Minorities Face Extra Hurdles

As immunotherapy research takes off, the patients getting the treatment have been overwhelmingly white. Researchers know this and say they are trying to correct it.

New York Times, Dec. 23, 2016

Minority Accrual to Immuno-oncology Trials

Minority Accrual, Actual and Percentages									
Protocol No.	Actual Accrual	Overall Minority %	Hispanic %	AI/AN %	Black/AA %	Native HI/PI %	Asian %	Not Reported %	White %
EA8143 Renal	366/766	20.6	9.6	0.3	7.1	0.3	3.3	3.8	81.1
S1418 TNBC	685/1000	28.3	9.6	0.7	14.2	0.4	3.4	5.5	75.6

Moving Forward

- Disaggregating Accrual within Race and Ethnicity
- Clinical Trial Log
- Inclusion of Accruals for Tissue Acquisition Studies
- Quality of Life Studies as Accruals
- Translation of Patient Reported Outcomes tools
- Across Research Bases and NCTN Groups Initiatives, e.g., working groups for elderly, adolescent and young adults, sexual gender minorities



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