

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

*Worta McCaskill Stevens, M.D., M.S.*

*Chief, Community Oncology and Prevention Trials Research Group*

*Division of Cancer Prevention*

# 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	<b>13,784</b>	<b>20,947</b>	<b>16,020</b>	<b>18,610</b>	<b>17,098</b>	<b>15,235</b>	<b>21,125</b>	<b>122,819</b>
<b>Black or African American*</b>	<b>7,614</b>	<b>11,612</b>	<b>7,700</b>	<b>8,603</b>	<b>7,106</b>	<b>5,555</b>	<b>8,877</b>	<b>57,067</b>
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%
<b>Black or African American</b>	<b>8%</b>	<b>9%</b>	<b>8%</b>	<b>9%</b>	<b>9%</b>	<b>8%</b>	<b>11%</b>	<b>9%</b>
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%)	<b>21,715 (18%)</b>
15-39	1,502 (11%)	1,308 (6%)	1,927 (12%)	2,144 (12%)	1,856 (11%)	1,975 (13%)	2,377(11%)	<b>13,089 (11%)</b>
40-64	6,646 (48%)	11,843 (57%)	7,765 (48%)	9,112 (49%)	8,020 (47%)	6,402 (42%)	11,940 (57%)	<b>61,728 (50%)</b>
65-69	1,253 (9%)	2,576 (12%)	1,486 (9%)	1,666 (9%)	1,559 (9%)	1,443 (9%)	2,316 (11%)	<b>12,299 (10%)</b>
70+	1,676 (12%)	2,898 (14%)	1,942 (12%)	1,922 (11%)	1,808 (11%)	1,644 (11%)	2,098 (10%)	<b>13,988 (11%)</b>

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%)	<b>5,971 (10%)</b>
15-39	734 (10%)	569 (5%)	744 (9%)	824 (10%)	617 (9%)	531 (10%)	684 (8%)	<b>4,703 (9%)</b>
40-64	4,038 (53%)	7,445 (64%)	4,223 (55%)	4,572 (53%)	3,685 (52%)	2,618 (47%)	5,416 (61%)	<b>31,997 (56%)</b>
65-69	775 (10%)	1,404 (12%)	826 (11%)	946 (11%)	819 (11%)	743 (13%)	1,223 (14%)	<b>6,736 (12%)</b>
70+	1,127 (15%)	1,509 (13%)	1,109 (14%)	1,107 (13%)	926 (13%)	869 (16%)	1,013 (11%)	<b>7,660 (13%)</b>

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<b>Minority</b>	<b>13,784</b>	<b>20,947</b>	<b>16,020</b>	<b>18,610</b>	<b>17,098</b>	<b>15,235</b>	<b>21,125</b>	<b>122,819</b>
<b>Hispanic or Latino*</b>	<b>4,099</b>	<b>6,650</b>	<b>5,475</b>	<b>6,687</b>	<b>6,485</b>	<b>6,051</b>	<b>8,235</b>	<b>43,682</b>
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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<b>Minority</b>	<b>14%</b>	<b>16%</b>	<b>17%</b>	<b>19%</b>	<b>21%</b>	<b>22%</b>	<b>25%</b>	<b>19%</b>
<b>Hispanic or Latino*</b>	<b>4%</b>	<b>5%</b>	<b>6%</b>	<b>7%</b>	<b>8%</b>	<b>9%</b>	<b>10%</b>	<b>7%</b>
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%)

## 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
<b>Minority</b>	<b>11,514</b>	<b>18,204</b>	<b>11,458</b>	<b>15,197</b>	<b>13,098</b>	<b>11,596</b>	<b>15,552</b>	<b>96,619</b>
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

## Minority Accrual (Percentages)

	1999 - 2001	2002-2004	2005-2007	2008-2010	2011-2013	2014-2016	2017-2019	Total 1999-2019
Majority	84%	81%	81%	77%	76%	70%	69%	78%
<b>Minority</b>	<b>14%</b>	<b>17%</b>	<b>17%</b>	<b>20%</b>	<b>22%</b>	<b>25%</b>	<b>27%</b>	<b>19%</b>
Unknown/ Not Reported	2%	2%	2%	3%	2%	5%	4%	3%

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

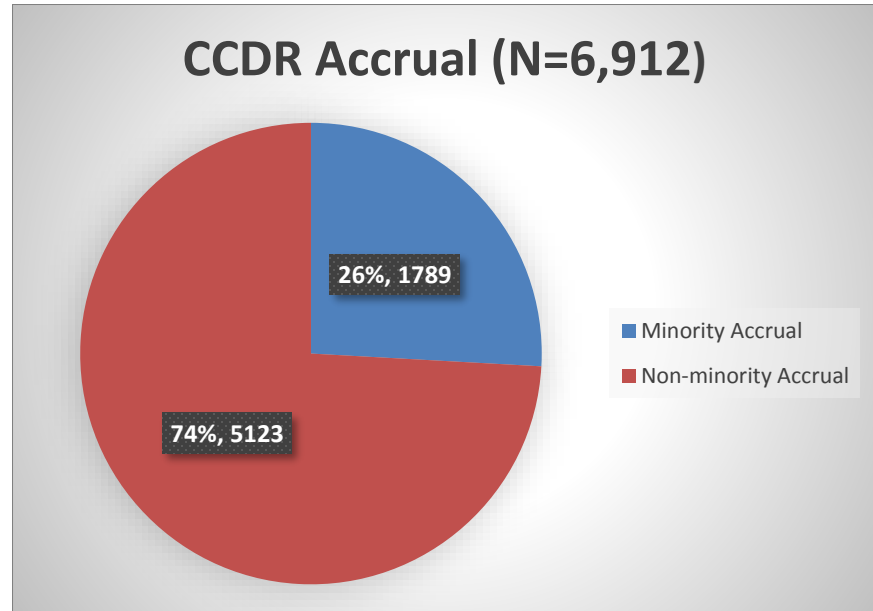
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Black or African American	8%	9%	8%	9%	9%	8%	11%	9%
Hispanic*	4%	5%	6%	7%	8%	9%	10%	7%
<b>Asian</b>	<b>2%</b>	<b>2%</b>	<b>2%</b>	<b>3%</b>	<b>3%</b>	<b>5%</b>	<b>4%</b>	<b>3%</b>
<b>American Indian or Alaska Native</b>	<b>0.3%</b>	<b>0.4%</b>	<b>0.5%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

# 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%
<b>Minority</b>	<b>5,664</b>	<b>21,341</b>	<b>27%</b>
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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