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# **Minority and Underserved in Clinical Trials: NCI Programs to Enhance Accrual**

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National Cancer Institute  
National Institutes of Health  
HHS**



# 1993 NIH Revitalization Act

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Inclusion of:

- Women and minorities and their subpopulations in all **clinical** research
- Minorities in phase III trials so that **valid analysis** of differences in intervention effects can be performed
- Cost is not an acceptable reason for exclusion
- NIH initiate programs and support for outreach to recruit and retention



# Underrepresented Populations

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Elderly

Treatment: 70+ (5-7%)

Prevention: 70+ (9%)

Adolescents

Lower Socioeconomic status

Rural Areas

African Americans

Hispanics/Latinos

Asian Americans

American Indians



# Today's Presentation

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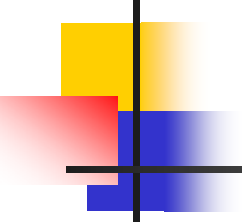
- Accrual in the Clinical Trials Network
- Beyond “Bean Counting”
  - Enhancing the Infrastructure
  - Generating Research Questions
- Trans NCI Initiatives



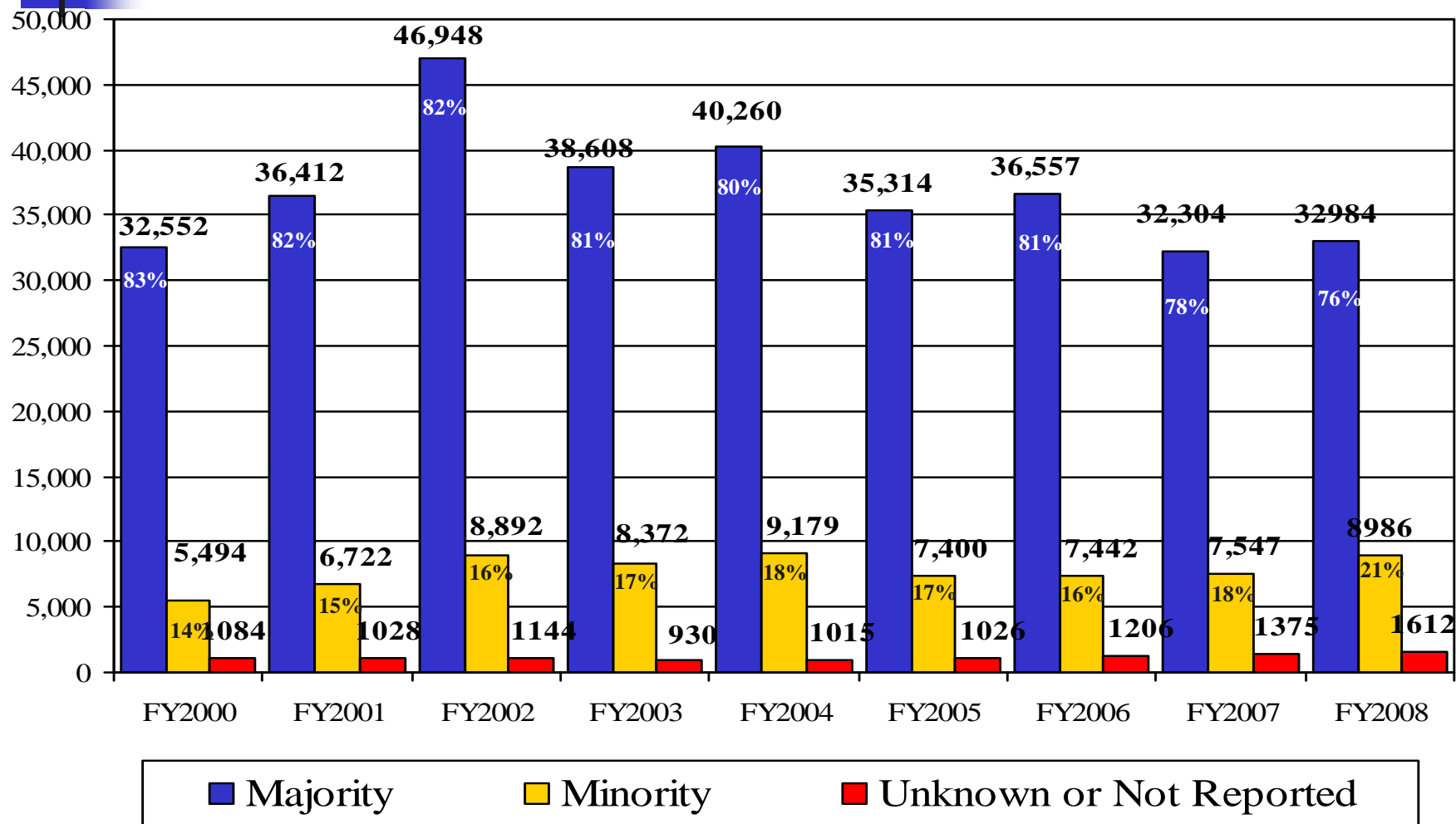
# NCI Clinical Trials Network

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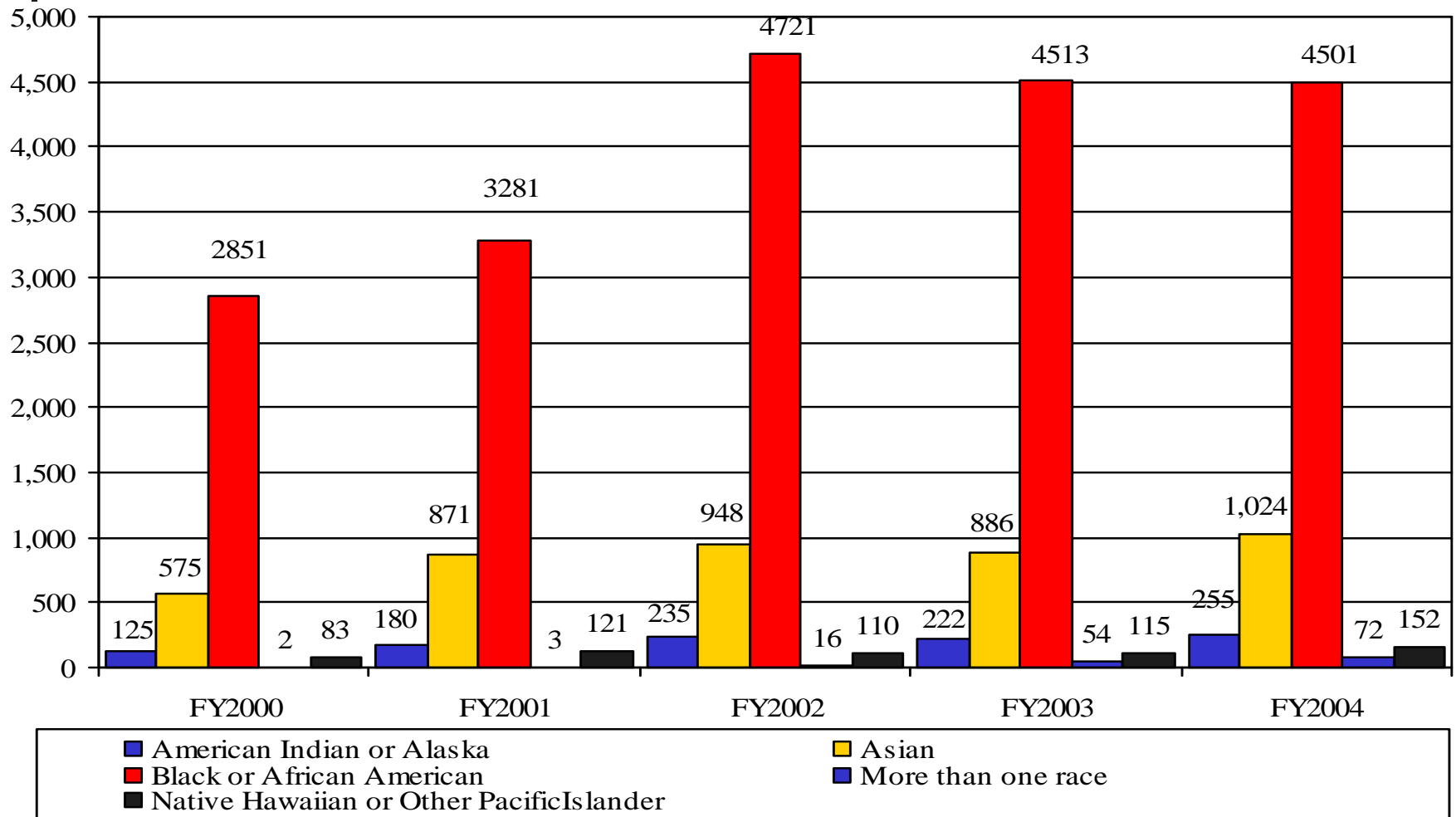
- NCI Cancer Centers (64), other academic centers
- Community Clinical Oncology Program (47)
- Minority-Based Clinical Oncology Program (13)
- Cancer Disparities Research Partnership Program (5)
- NCI Community Cancer Centers Program (16)

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- OMB Directive 15 issued in 1997:
    - Created racial and ethnic standards for Federal statistics and administrative reporting

# Minority Enrollment to NCI (CTEP, DCP, RRP) Clinical Trials

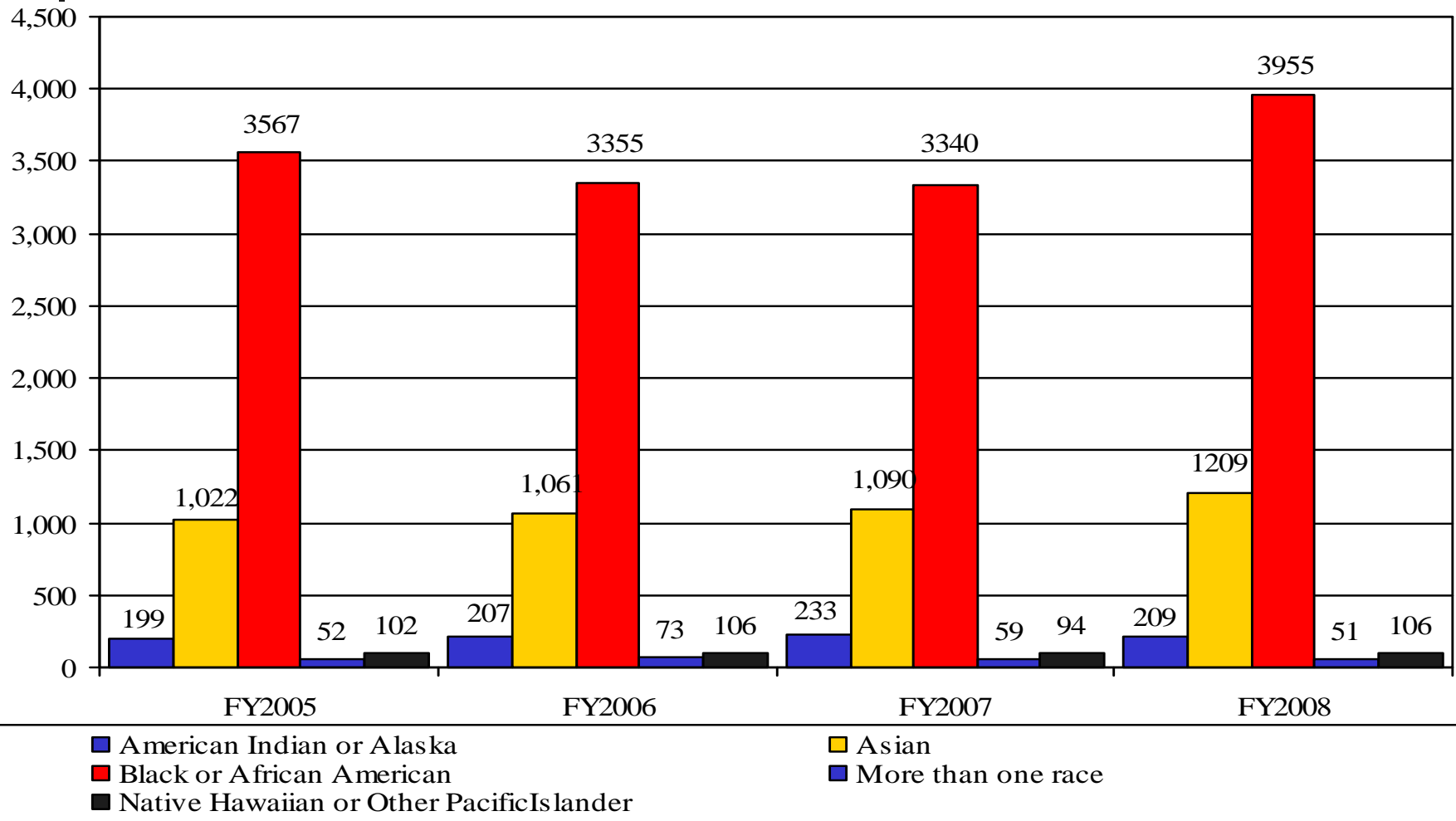


# Minority Enrollment on NCI (CTEP, DCP, RRP) Clinical Trials by Race

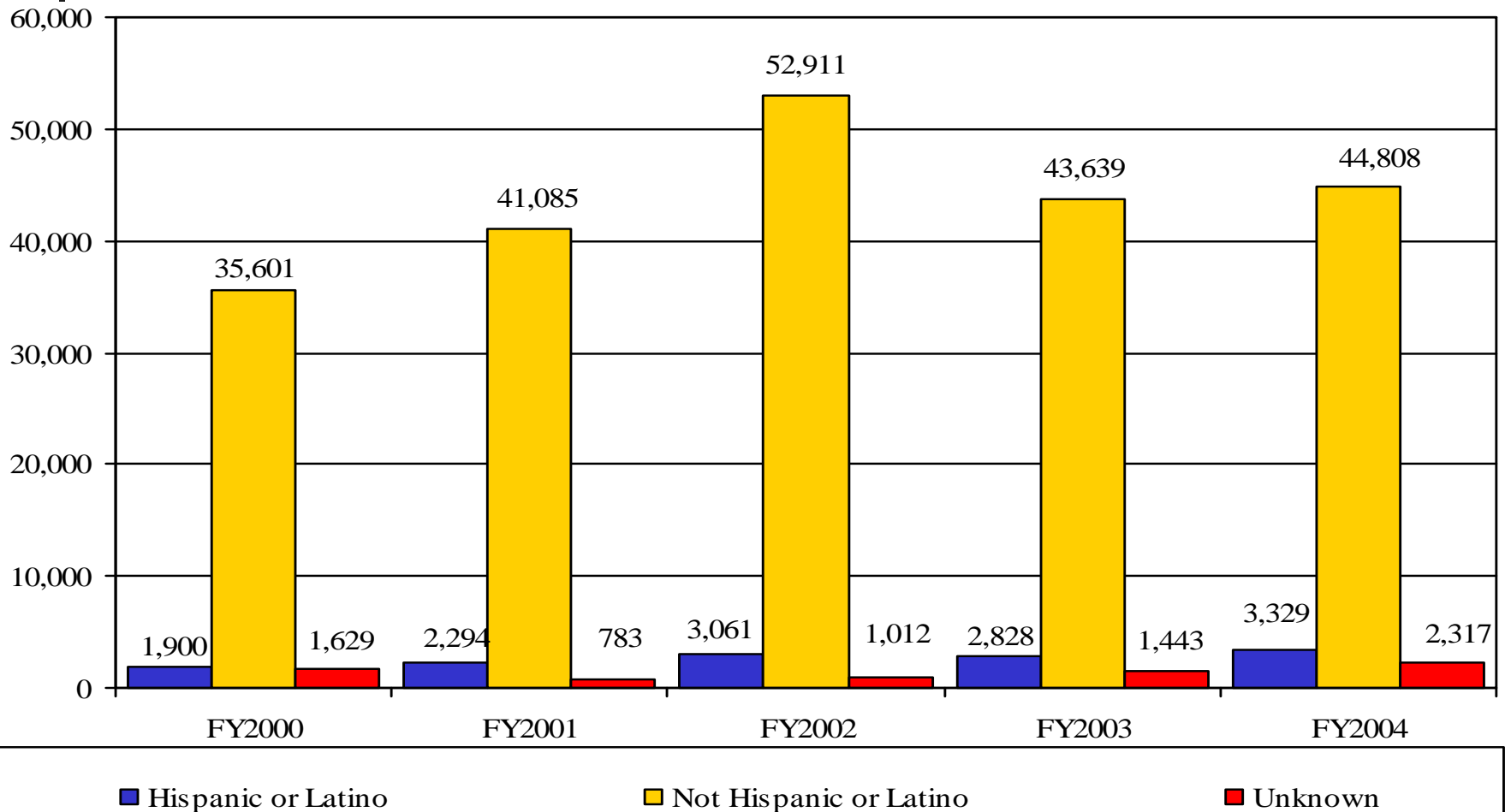




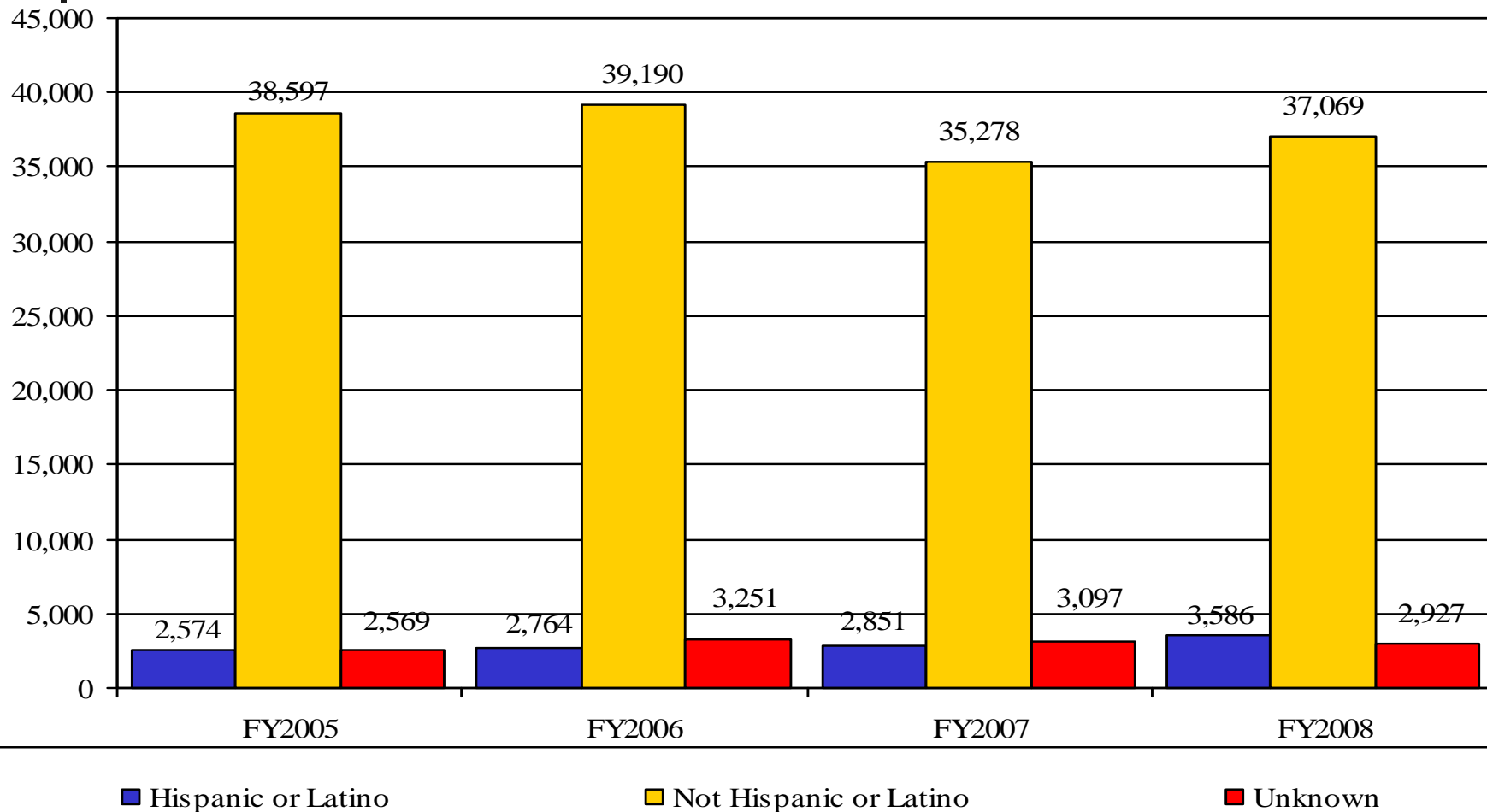
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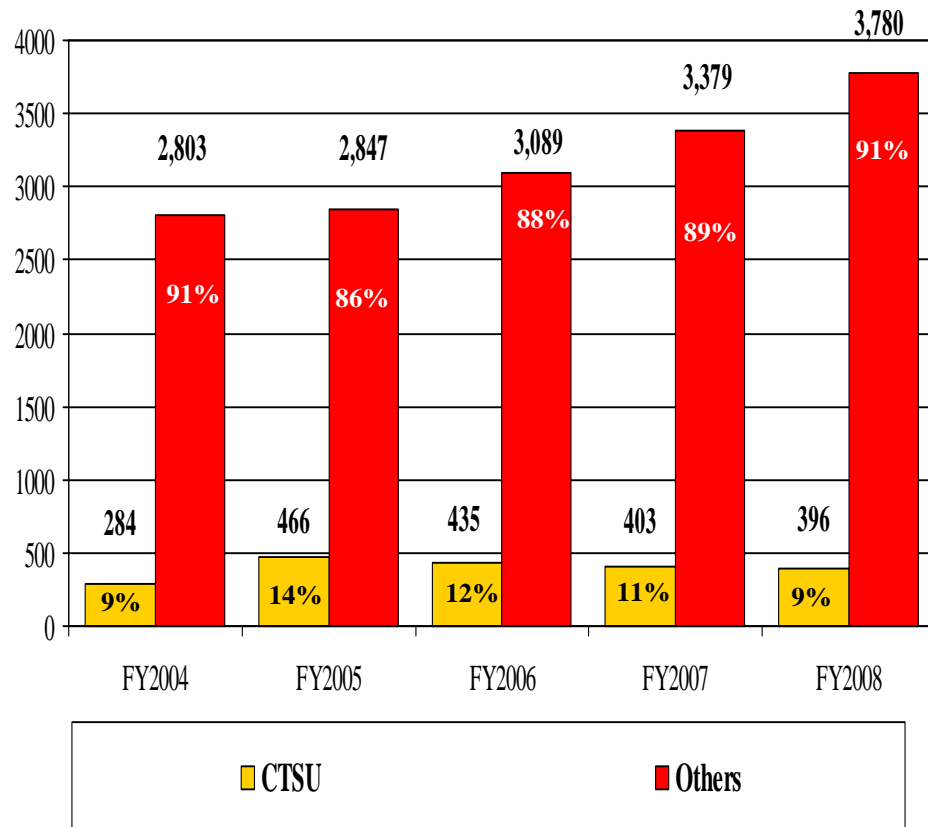
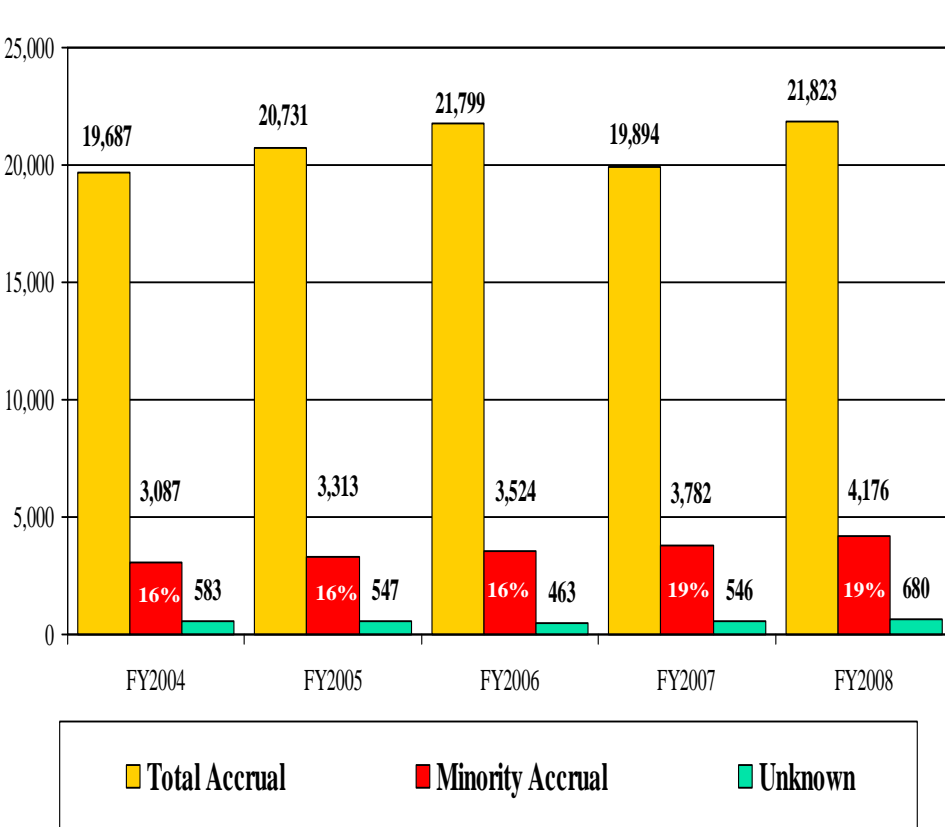
# Enrollment on NCI (CTEP, DCP, RRP) Clinical Trials by Ethnicity



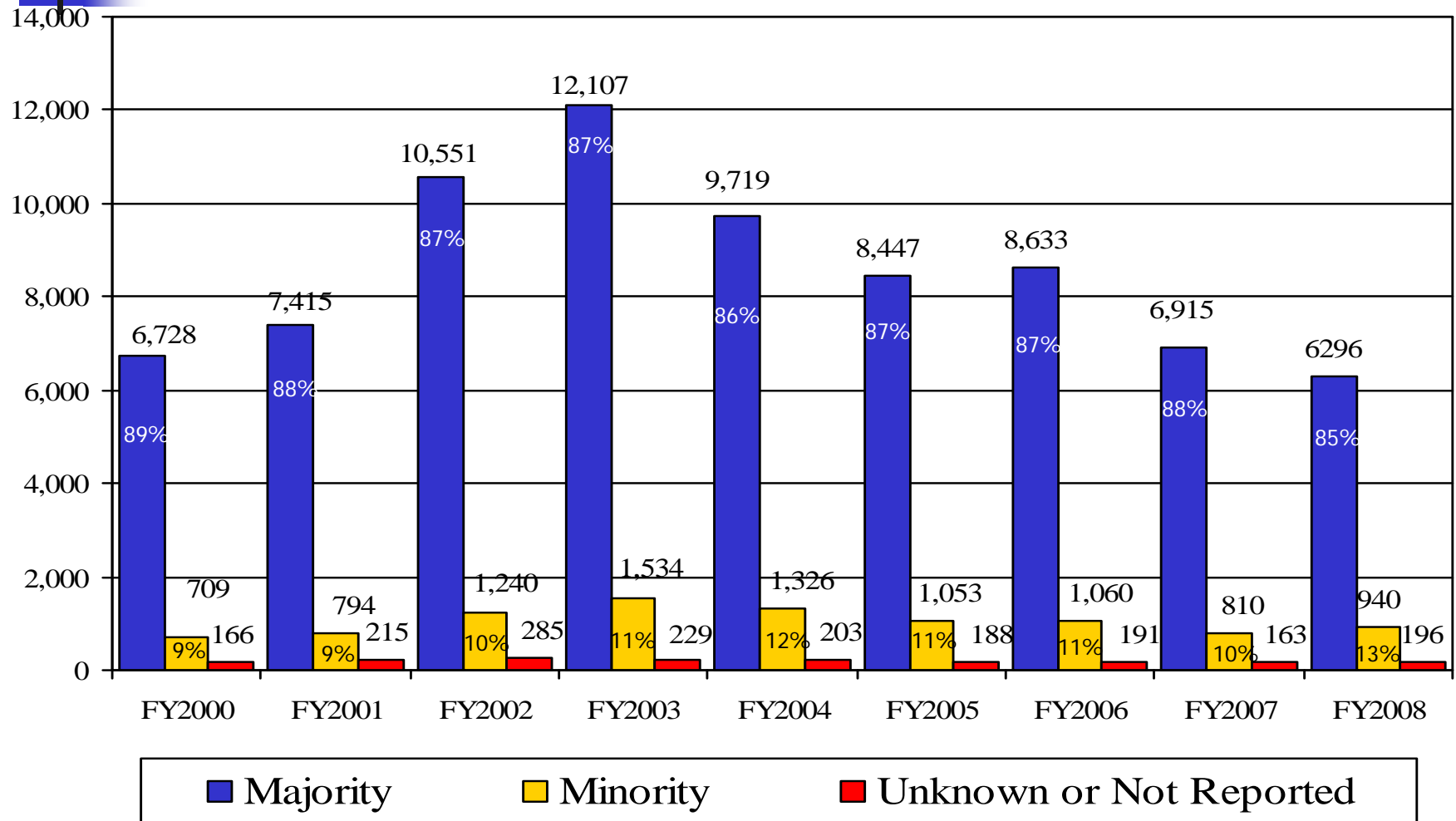
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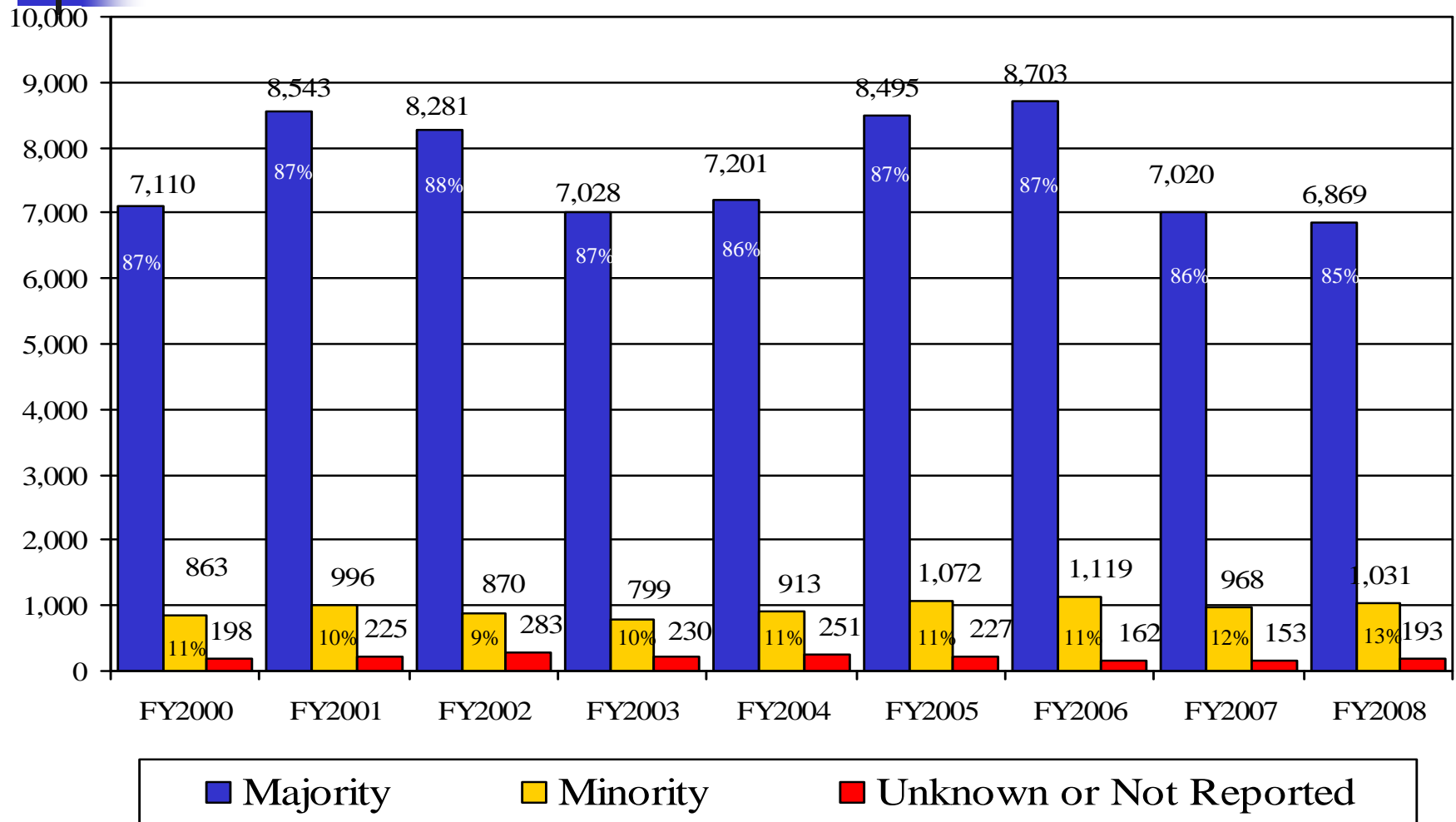
# Accrual to CTEP Treatment Phase III Clinical Trials CTSU vs. Others



# Minority Enrollment on NCI (CTEP, DCP, RRP) Clinical Trials For Patients 70 and Older



# Minority Enrollment on NCI (CTEP, DCP, RRP) Clinical Trials For Patients 65 and Older





## 13 Funded MBCCOPs

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- SUNY Downstate Medical Center, NY
- John Stroger Cook Co., IL
- Louisiana State University, LA
- Louisiana State University, LA
- Medical College of Georgia, GA
- Meharry Medical, TN
- Gulf Coast, AL
- South Texas Pediatrics, TX
- San Juan, PR
- University of Hawaii, HI
- University of Illinois, IL
- University of New Mexico, NM
- Va. Commonwealth U., VA

# Impact of MBCCOPS on Clinical Trials

Minority-Based CCOPS						
Grant/Fiscal Year	# of Funded MBCCOPS	Treatment Accrual	Prevention & Control Accrual	Overall Accrual	# of Minority Patients	% Minority Overall
2000	8	425	358	783	446	57 %
2001	10	642	541	1183	676	57 %
2002	11	567	682	1249	901	72 %
2003	11	521	930	1451	1088	75 %
2004	13	673	467	1140	674	59 %
2005	13	709	428	1137	579	51 %
2006	13	684	393	1077	602	56%
2007	14	805	776	1581	965	61%
<b>Total (2000 – 2007)</b>		<b>5,026</b>	<b>4,575</b>	<b>9,601</b>	<b>5,931</b>	
Community Clinical Oncology Program (CCOPS)						
2000	51	6241	4872	11,113	938	8 %
2001	50	6328	7936	14,264	991	7 %
2002	50	5257	6373	11,630	888	8 %
2003	50	5269	6963	12,232	1,038	8 %
2004	50	6729	4871	11,600	1,095	9 %
2005	50	7239	4783	12,022	846	7 %
2006	50	5718	4601	10,319	974	9 %
2007	49	5533	6020	11,553	1,115	10%
<b>Total (2000 – 2007)</b>		<b>48,314</b>	<b>46,419</b>	<b>94,733</b>	<b>7,885</b>	



# NCI Community Cancer Centers Program: Clinical Trials



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- Goals:
  - Increase Accrual to all trials
  - Accrual focus:
    - Minorities and Underserved
    - Multimodality and early phase trials

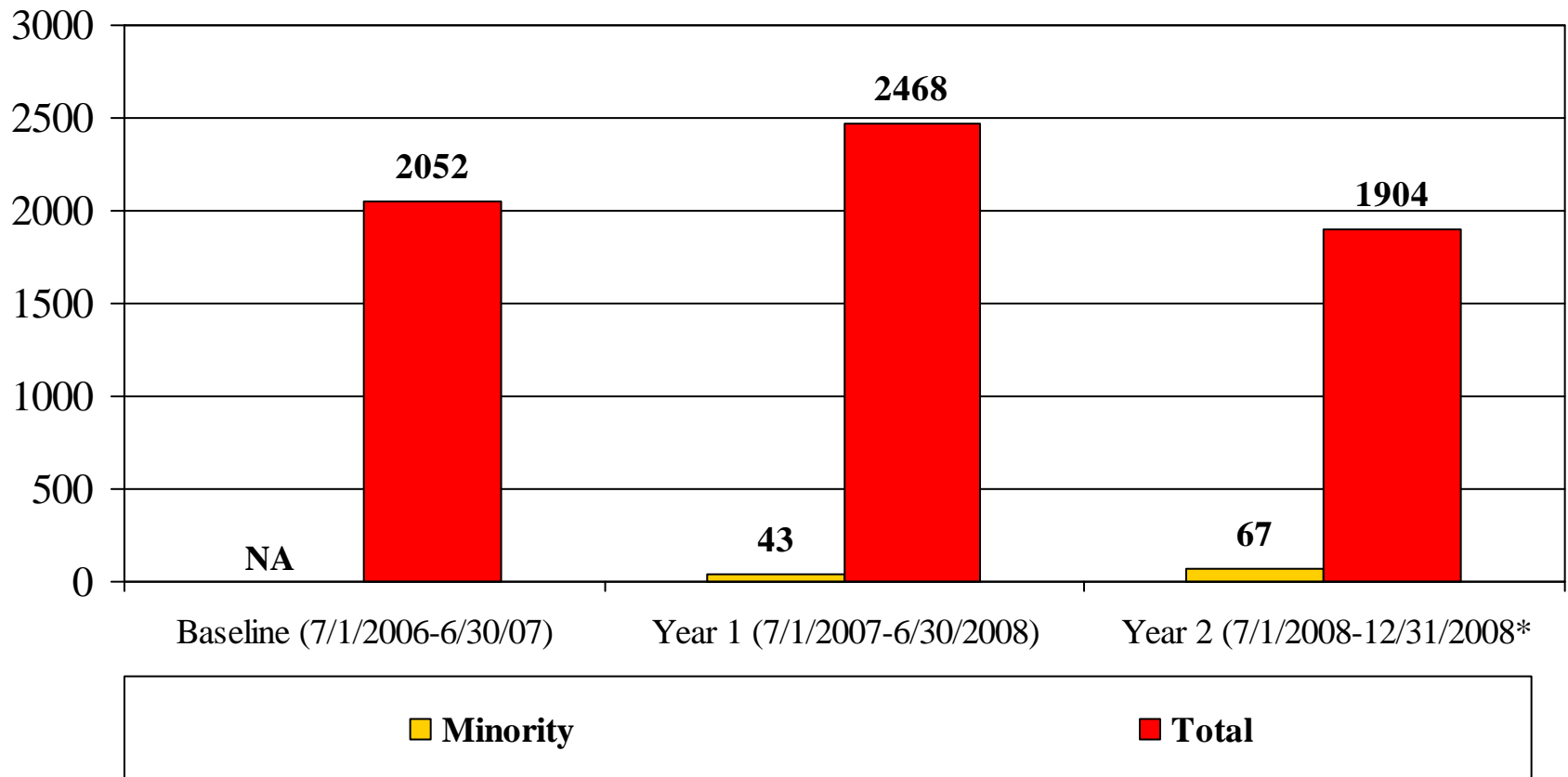


# 10 Organizations Selected

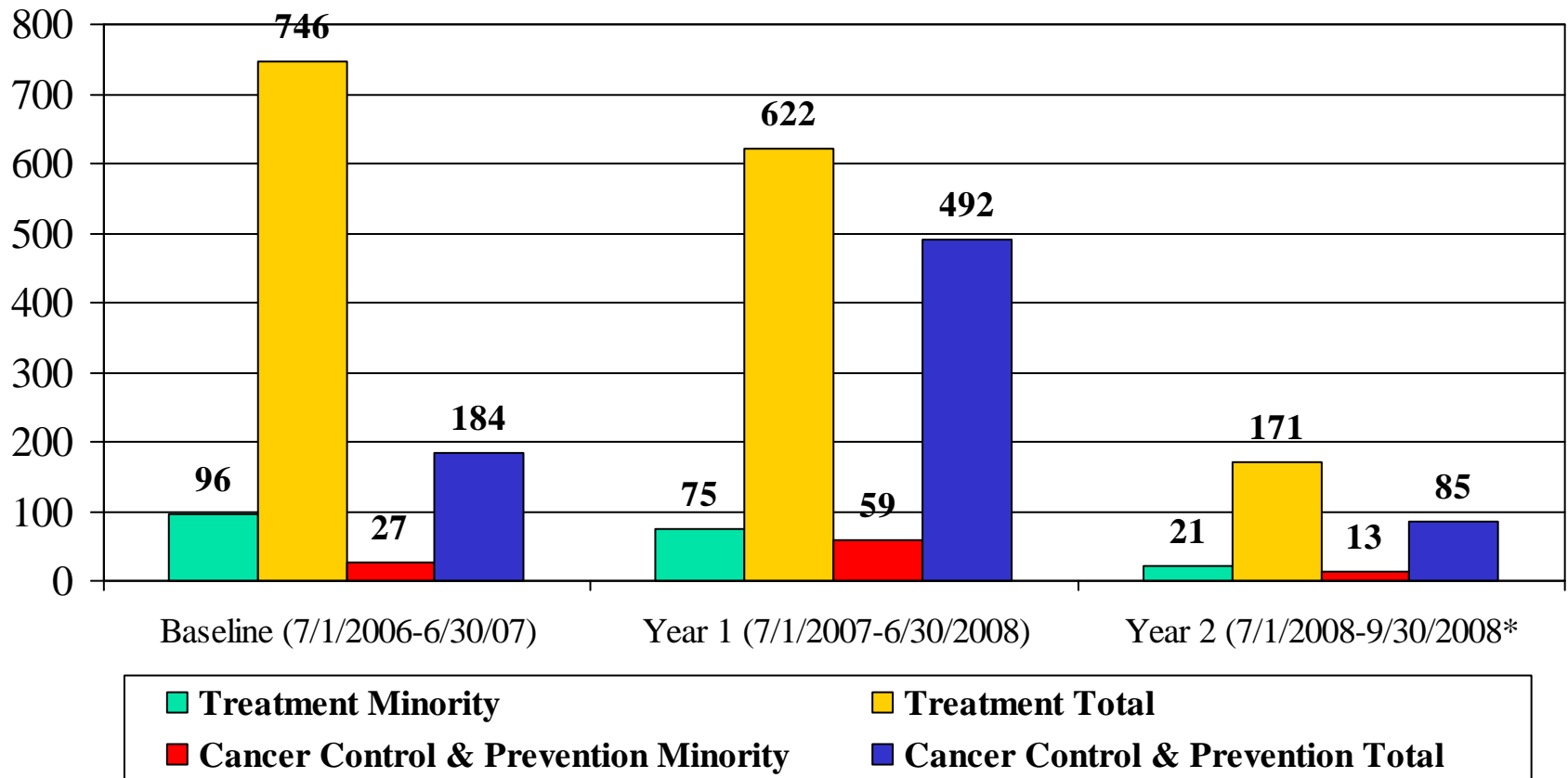
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- 6 Community Hospitals
  - Hartford Hospital, Connecticut
  - St. Joseph's/Candler, Georgia
  - Our Lady of the Lake Regional Medical Center, Louisiana\*
  - Spartanburg Regional Hospital, South Carolina\*
  - St. Joseph Hospital, Orange, California
  - Christiana Hospital, Delaware\*
- 2 Rural Hospitals – Native Americans
  - Billings Clinic, Montana\*
  - Sanford USD Medical Center, South Dakota\*
- 2 National Health Systems – Multistate with multiple program locations
  - Ascension Health: Indianapolis, Milwaukee and Austin
  - Catholic Health Initiatives: Towson, MD; Colorado Springs and 3 sites in Nebraska\*
  - \* CCOPMBCCOP or affiliation

# NCCCP All Clinical Trials Accrual



# NCCCP NCI Cooperative Group Trials





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# Beyond ‘Bean Counting’



# Addressing Comorbidity

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- Refining tools to assess comorbidity in older patients
- Expanding trials to include patients with comorbidity

# *K-ras Mutations and Colon Cancer Benefits from Cetuximab*

*Karapetis. NEJM 2008,  
Cutsem, ASCO 2008*

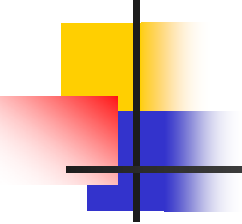
- Among minorities with colon ca: Higher incidence of regional & distant disease; higher mortality

- Ongoing Trials:

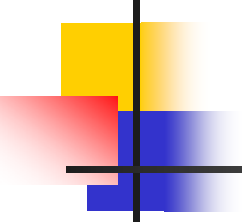
	MBCCOP	CCOP
C80405	90	448
N0147	130	854

Target: 2,289  
Accrual: 1,429  
% Min. accrual= 22

- Research Questions:
  - Prognosis vs. Prediction
  - Interaction with co-morbidity (adherence)
  - Sensitivity of assay; community/central concordance

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- What data should be collected to
    - Improve clinical outcomes?
    - Interpret clinical outcomes?



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- Data suggests SES influences clinical outcomes
    - IOM, Singh, Lantz, HHH PRG Health Disparities
  - Currently, we collect zip codes and insurance status: SES or surrogates are not routinely collected
  - Consideration for the future trials
    - Education
    - Census Tract information



# MBCCCOP Mentoring Case Report

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- Private Practitioner in San Juan , PR with staff to support practice
- Participating site in SELECT
- Accrued 1000 + men
- San Juan MBCCCOP Mentoring:
  - Data management
  - IRB access
  - Audit preparation

## SELECT

(Estudio del Selenio y la Vitamina E para Prevenir el Cáncer)  
Dr. Jaime Claudio-Investigador Afiliado 787-792-9028

Multivitámicos y suplementos del estudio gratis por 12 años



Pregunte hoy sobre como participar en el más grande estudio clínico de prevención del cáncer de próstata jamás realizado!



Se necesitan hombres sanos de 55 años y más para el estudio de prevención del cáncer de próstata más grande que se haya realizado hasta el momento y que lanzan hoy el Instituto Nacional del Cáncer (NIC) y el Dr. Jaime Claudio, investigador afiliado a la red de médicos en los EE. UU. y Canadá.

El estudio durará 12 años. Participación gratuita de selenio y vitamina E suplementos que están en suplementos nutricionales y vitaminas en un estudio solo por la inscripción con éxito. Cuando termine el estudio SELECT, los resultados se usarán para determinar si el selenio y la vitamina E ayudan a prevenir el cáncer de próstata.

**Dr. Jaime Claudio**

Profesor Ad-Honorem

Medicina de Familia-UPB-Ciencias Médicas

# Center for Health Disparities & Other Partners



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- Patient Navigator Program
  - Partnership (MBCCCOP, CCOPs, NCCCCP, Cancer Centers)
- Community Network Program
  - Education and collaboration with clinical trials network
    - Baquet, et al., Analysis of Maryland Cancer Patient Participation in National Cancer Institute–Supported Cancer Treatment Clinical Trials, JCO, 2008
- ENACCT (Ed. Network to Advance Ca Clinical Trials)

# Minorities in Chemoprevention Trials

	Total Enrollment/%	Minority Enrollment/%
<b>BCPT</b> <b>6/1992-9/1997</b>	<b>13,388</b>  <b>RAF: 98,018</b>	<b>3.7</b> <b>AA 220 (1.7)</b> <b>Other 319 (2.0)</b> <b>RAF: 5,530</b>
<b>PCPT</b> <b>1/1994-5/1997</b>	<b>18,882</b>	<b>8.0</b> <b>Black 723 (4)</b> <b>Other 767 (4)</b>
<b>STAR</b> <b>7/1999-11/2004</b>	<b>19,747</b>  <b>RAF: 184,461</b>	<b>6.5</b> <b>AA 474 (2.4)</b> <b>Hispanic 384 (2.0)</b> <b>RAF: 28,910</b>
<b>SELECT</b> <b>8/2001-6/2004</b>	<b>35,534</b>	<b>21.0</b> <b>Black 5,256 (15)</b> <b>Asian 474 (1)</b> <b>Hispanic (5)</b>



# Trans-NCI Clinical Trials Accrual Working Group (CTAWG) Goals

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- Foster collaboration and information sharing of clinical trials accrual initiatives among the NCI Centers, Offices, Divisions and Programs that review, support, and fund clinical trials.
- Develop initiatives that promote successful clinical trial accrual practices



## CTAWG Goals (cont.)

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- CTAWG is exploring holding an interactive workshop in 2010 on clinical trial accrual strategies
- CTAWG with OCE is investigating how sites might use an interactive web site of evidenced-based accrual strategies.

National Cancer Institute

We can all help in finding new cancer treatments.

Consider taking part in a clinical trial.



[www.cancer.gov](http://www.cancer.gov) 1-800-4-CANCER



National Cancer Institute

Today, we have better cancer treatments.

Why? Because people like you took part in a clinical trial.

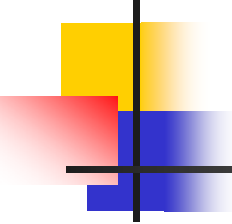
Ask if one is right for you.



[www.cancer.gov](http://www.cancer.gov) 1-800-4-CANCER

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
National Institutes of Health





# Impact of Programs Enrolling Minorities and Underserved in Cancer Clinical Trials

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- Serve as training ground for oncologists and related disciplines in oncology practices
- Laboratories for identifying preclinical, clinical and behavioral issues
- Collection of tissue for advanced technologies, (i.e., pharmacogenomics)
- Enrich literature on research, recruitment, retention and overall improvement in cancer clinical care in underserved populations.