

NCI Community Oncology Research Program Accrual Analysis August 2014-July 2018

**Clinical Trials and Translational Research Advisory Committee
November 7, 2018**

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A program of the National Cancer Institute
of the National Institutes of Health

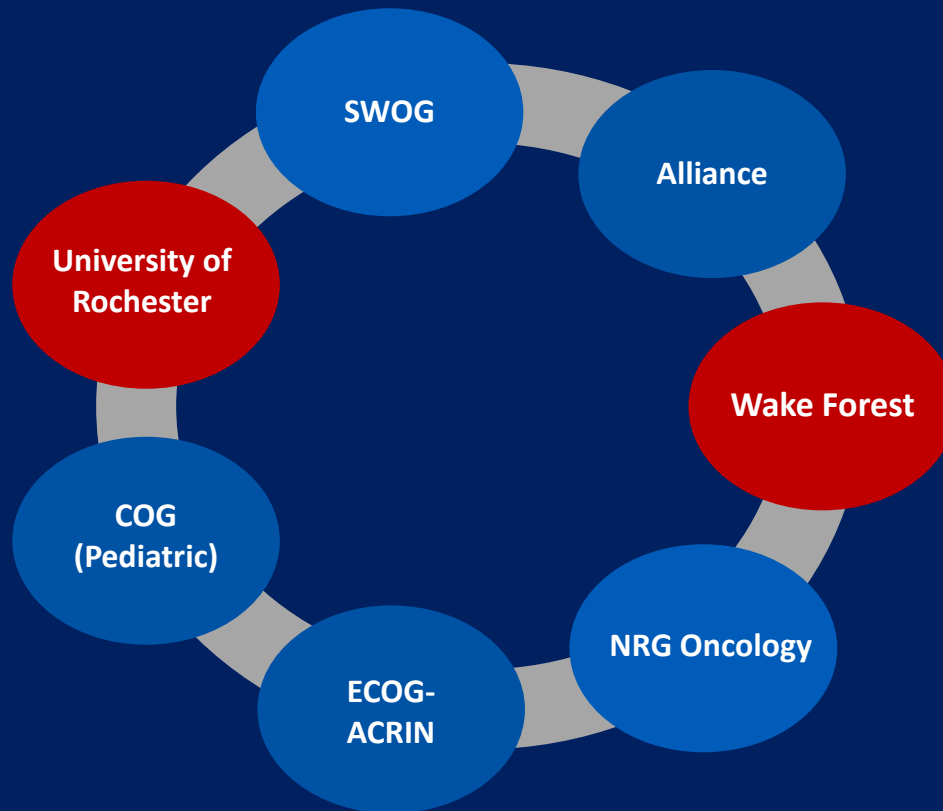
NCORP Accrual Analysis

- **NCORP Structure to Support Accrual**
- **Accrual by Research Type**
- **Characteristics of NCORP Patients/Participants**
- **Concept/Protocol Timelines**

NCORP Research Portfolio

- **Cancer Control, Prevention, Screening, Post-Treatment Surveillance**
- **Quality of Life Embedded in Treatment Trials**
- **Cancer Care Delivery**
- **Advanced Imaging and Treatment Trials**

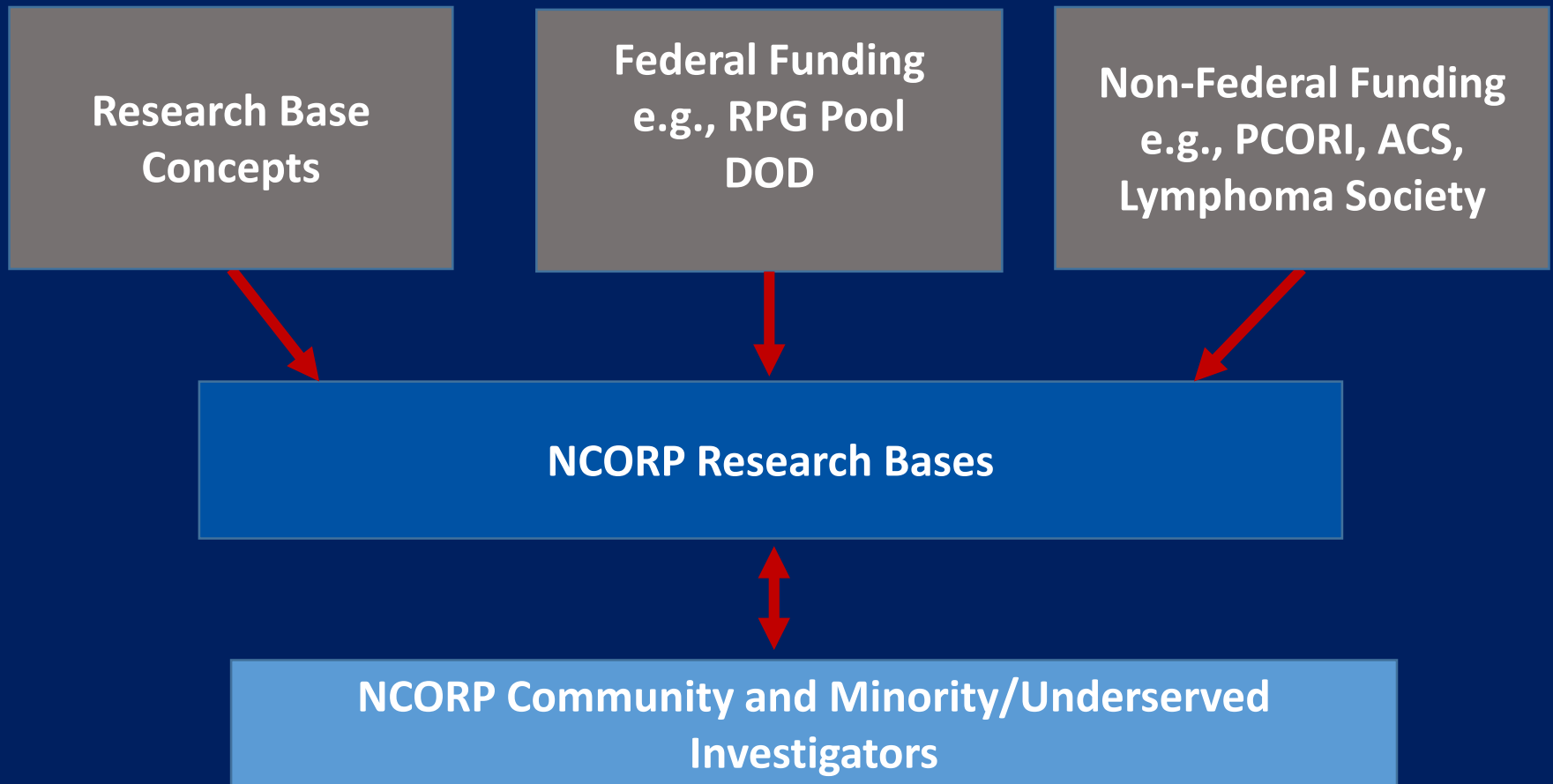
Sources of NCORP Trials/Studies: Research Bases



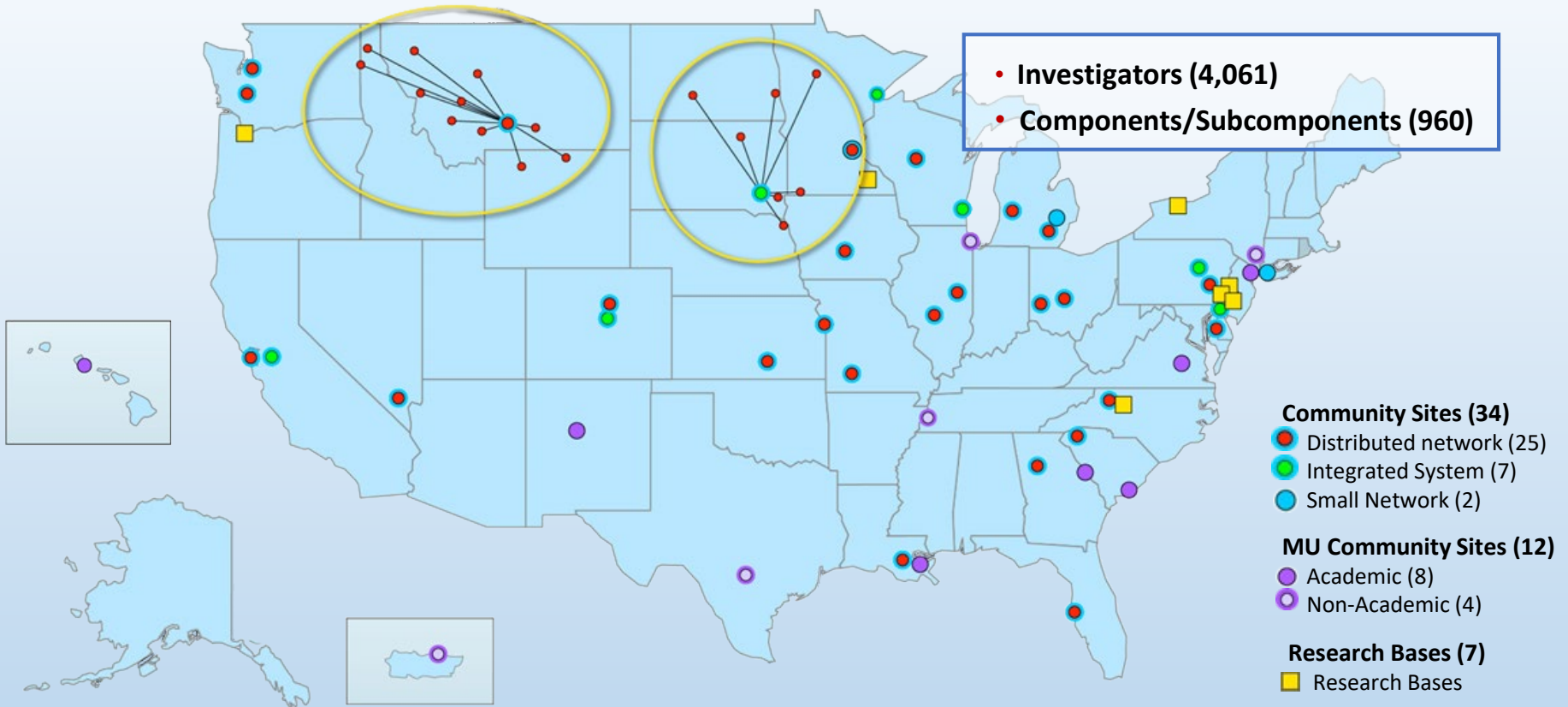
National Clinical Trials
Network (NCTN) Group
& NCORP Research Base

NCORP Academic
Research Bases

Sources of NCORP Academic/ Community Partnership



NCORP Community Site, M/U Community Site and Research Bases Geographic and Organizational Diversity



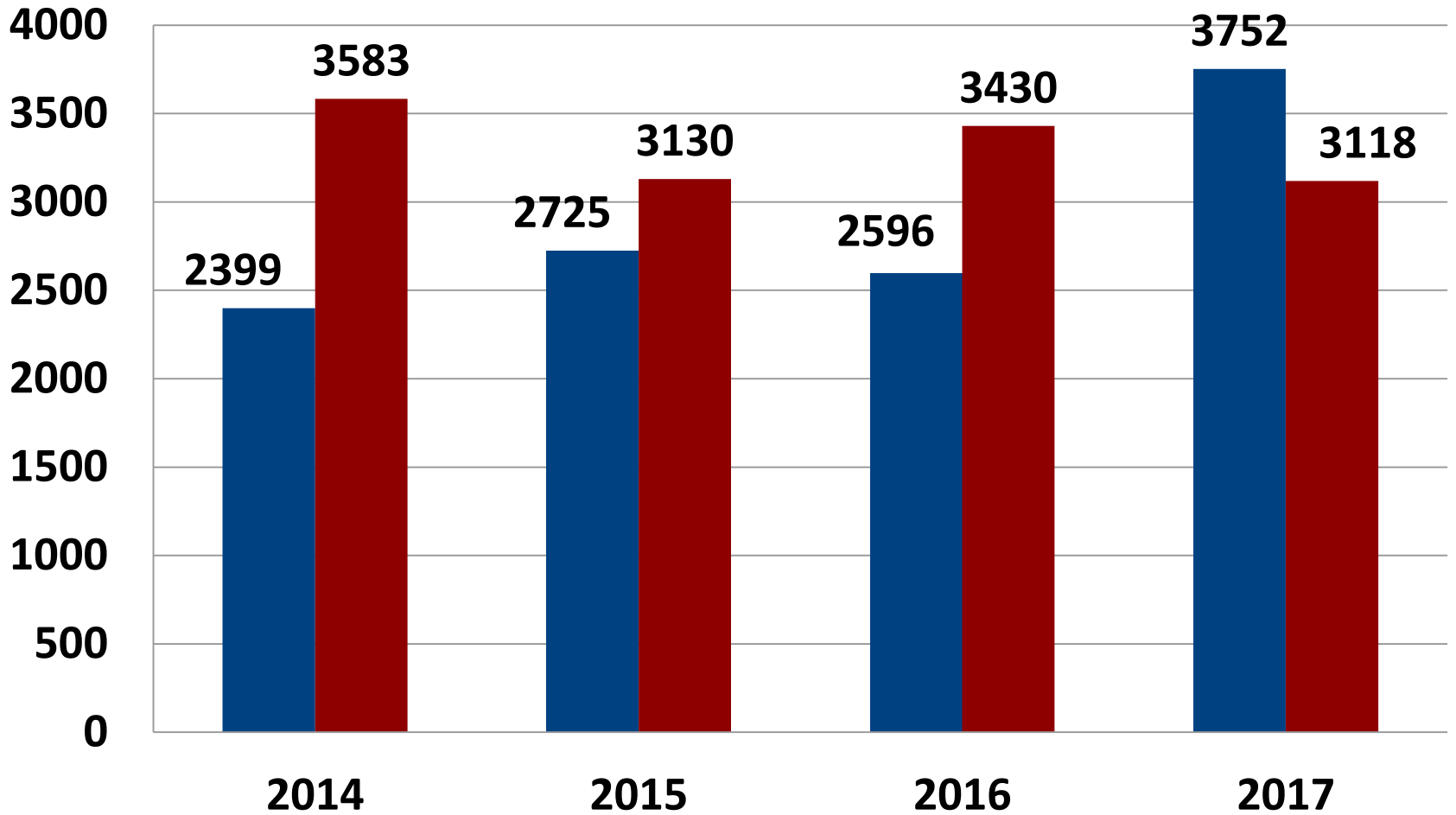
Updated: September 2018

Average Number of Trials Available per Year

2014	46
2015	43
2016	44
2017	46
2018	48

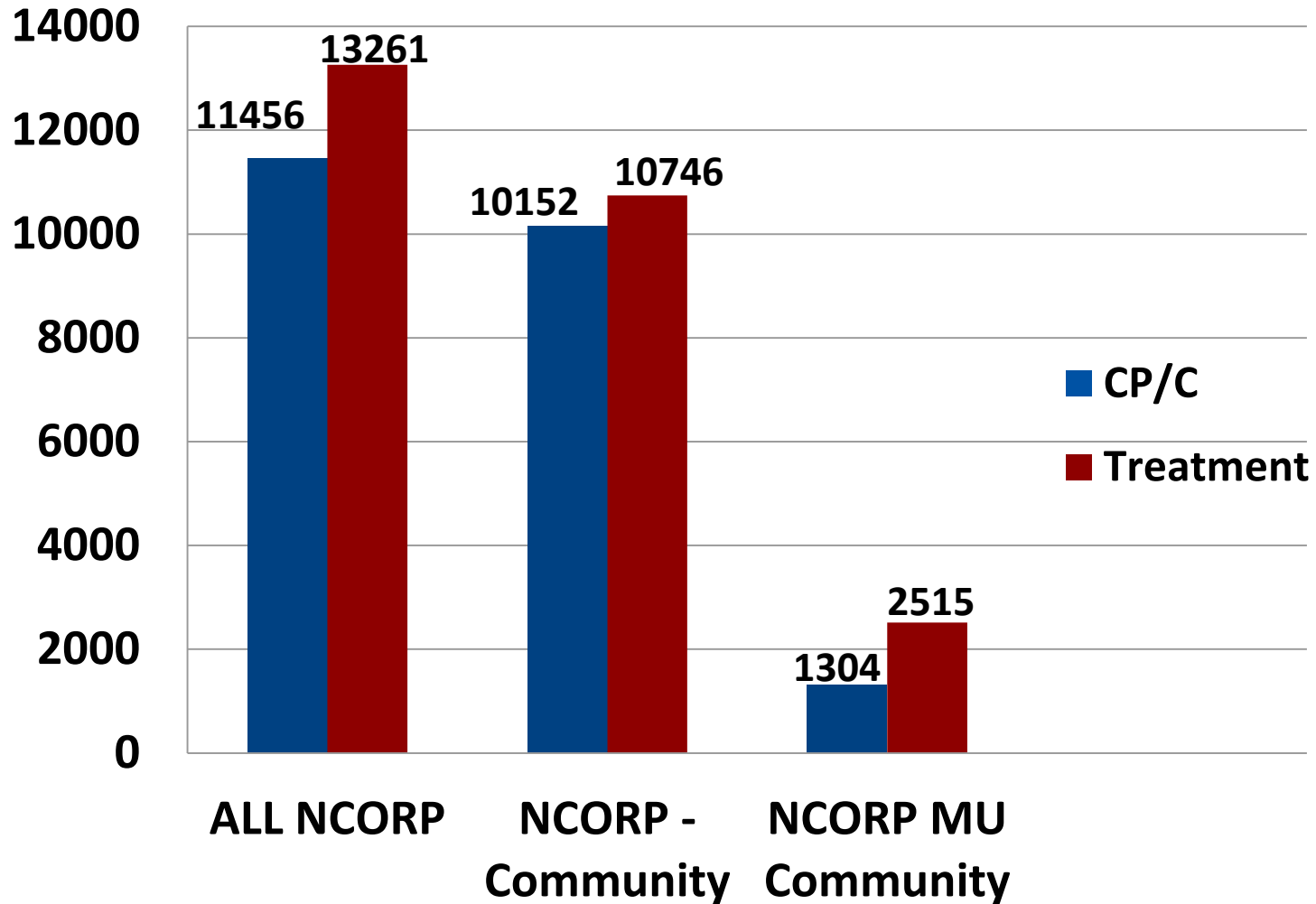
NCORP Cancer Control/Prevention Accrual by Year: 8/1/14 – 7/31/18

■ CP/C
■ TREATMENT



Total: 24,733

NCORP Cancer Control/Prevention Accrual 2014 - 2017

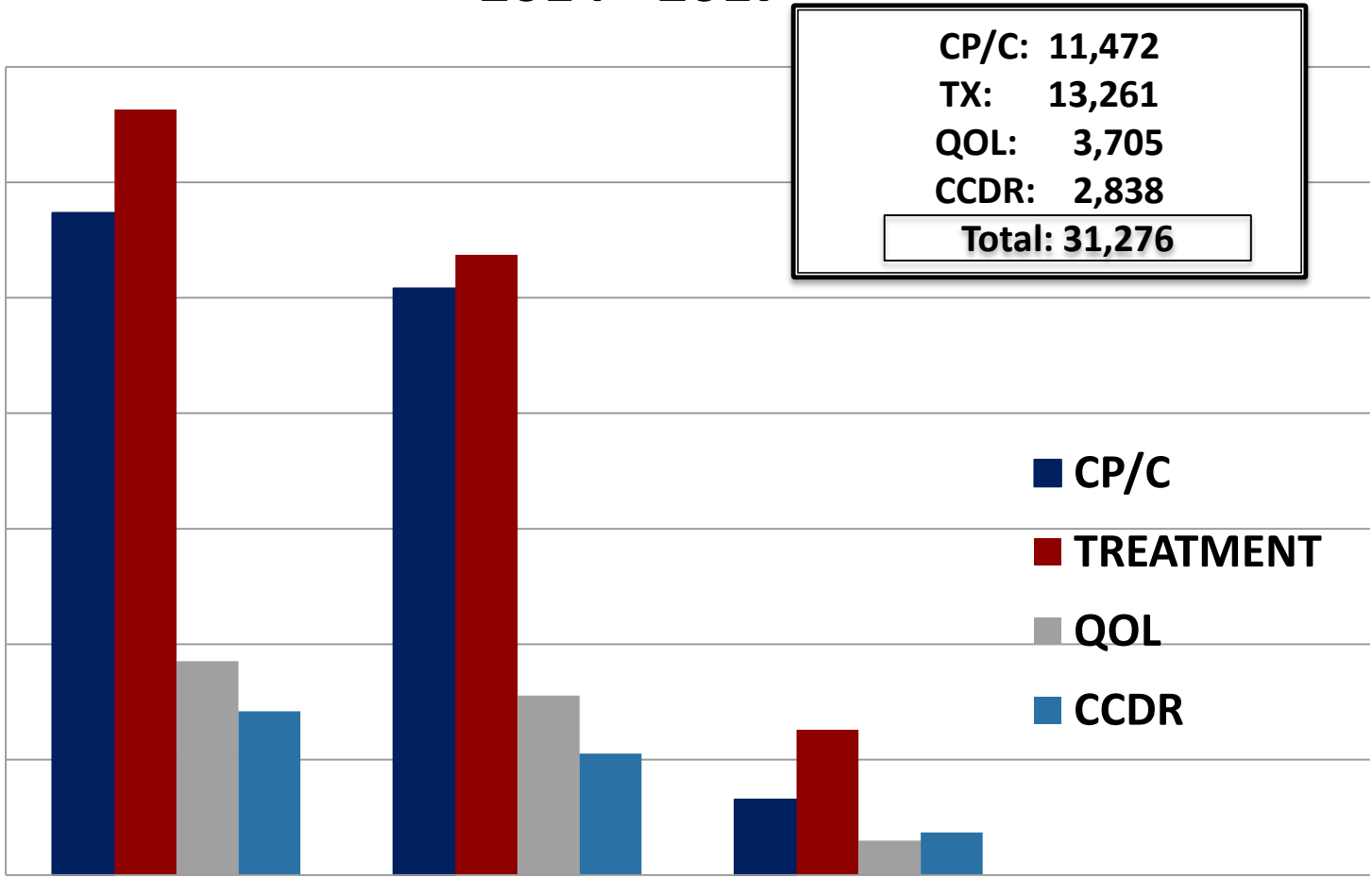


NCORP Cancer Care Delivery Research Studies

- **Cancer Care Delivery Research is a multidisciplinary science that seeks to improve clinical outcomes and patients well-being by intervening on patient, clinician, and organizational factors that influence care delivery**
- **CCDR Studies may include:**
 - **Patients**
 - **Caregivers**
 - **Non-patient participants (clinicians, physicians, pharmacists)**
 - **Practices/Organizations**

NCORP ACCRUAL 2014 - 2017

14000
12000
10000
8000
6000
4000
2000
0



CP/C: 11,472
TX: 13,261
QOL: 3,705
CCDR: 2,838
Total: 31,276

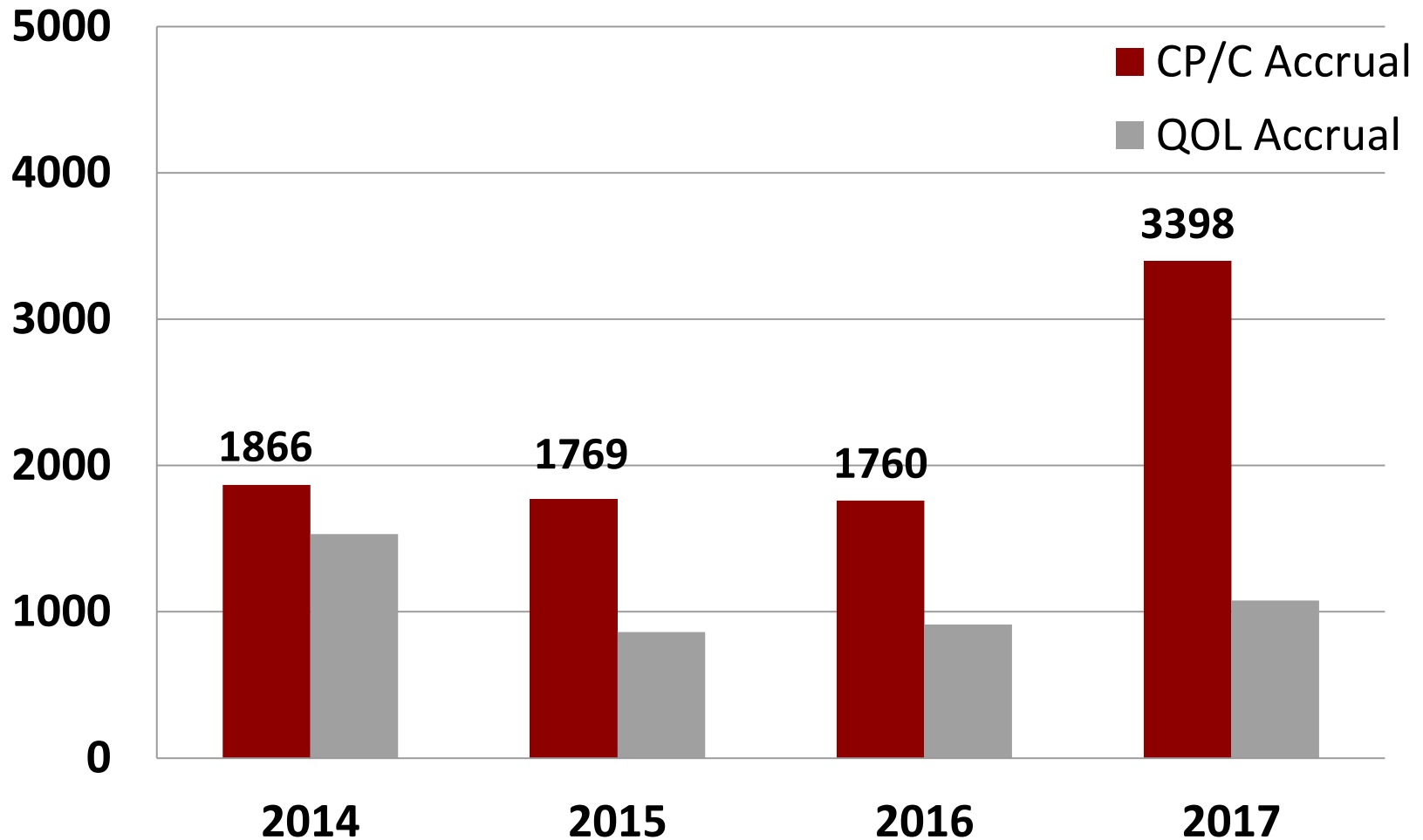
ALL NCORP

NCORP -
COMMUNITY

NCORP MU
COMMUNITY

■ CP/C
■ TREATMENT
■ QOL
■ CCDR

NON-NCORP* ACCRUAL TO CP/C & QOL TRIALS 2014 - 2017



*Non-NCORP: LAPs, Affiliates,
Rostered

NCI Tissue Procurement Studies

Patient Derived Model

100 Blood specimens

Columbia NCORP

Delaware/Christiana NCORP

Heartland NCORP

Michigan NCORP

Nevada NCORP

Northwest NCORP

Ozark NCORP

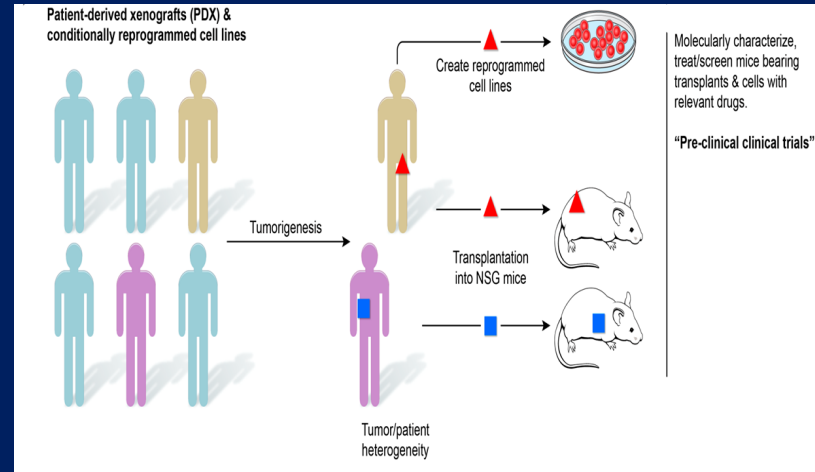
Stroger NCORP

West Michigan NCORP

Blood and Tissue Pairs (1st supplement)

Heartland NCORP (29)

Ozarks NCORP (28 + 8 blood only)



Blood and Tissue Pairs (2nd supplement)

Ozark NCORP (36 + 3 blood only)

Michigan NCORP (30)

West Michigan NCORP (30)

Wichita NCORP (30)

Early Onset Malignancy Initiative

To sequence early age malignancies in 6 cancers among 4 racial/ethnic groups, M/U Sites: 82

NCORP Accrual to Precision Medicine Trials

ALCHEMIST Accruals by Organization

Swim Lane	A151216	% of A151216 pts	A081105	% of A081105 pts	E4512	% of E4512 pts	EA5142	% of EA5142 pts
NCORP	1329	35.34%	75	32.33%	26	36.11%	211	40.34%

LungMap Accruals by Organization

	Study	% of S1400 pts	sub-study	% of sub-study pts
NCORP	640	35.52%	230	35.11%

NCI Community Oncology Research Program Molecular Analysis for Therapy Choice (MATCH)

44 Percent (2788/6408) of Patients Registered for Screening in the NCI MATCH Trial are from NCORP Community and Minority Community Sites



NCORP Accrual - 2014-2017

An Academic/Community Partnership

Cancer control, prevention, screening

11,456 patients

NCTN) treatment and imaging trials

13,261 patients

Quality of Life

3,705 patients

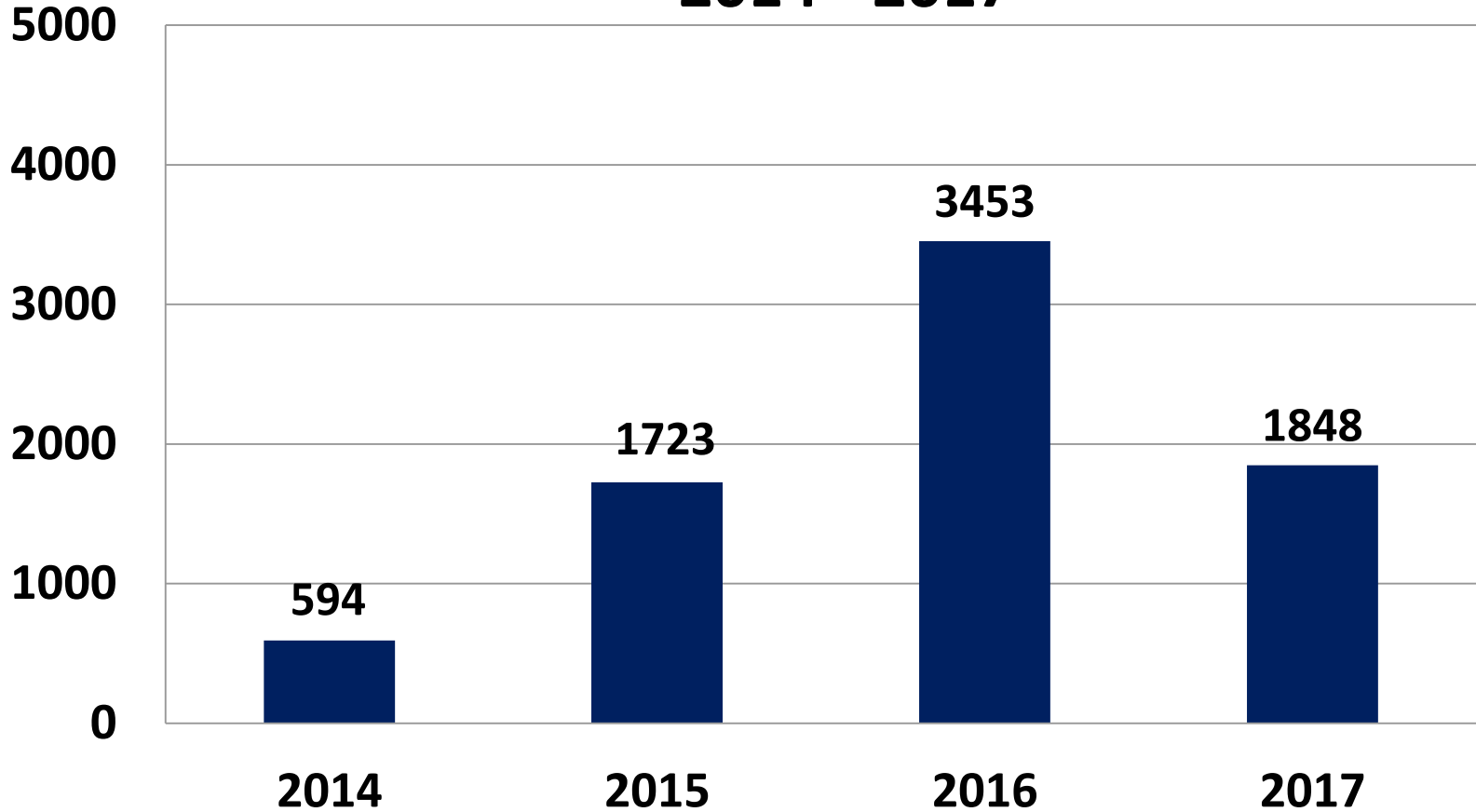
Cancer Care Delivery Research

2838 patients and clinicians

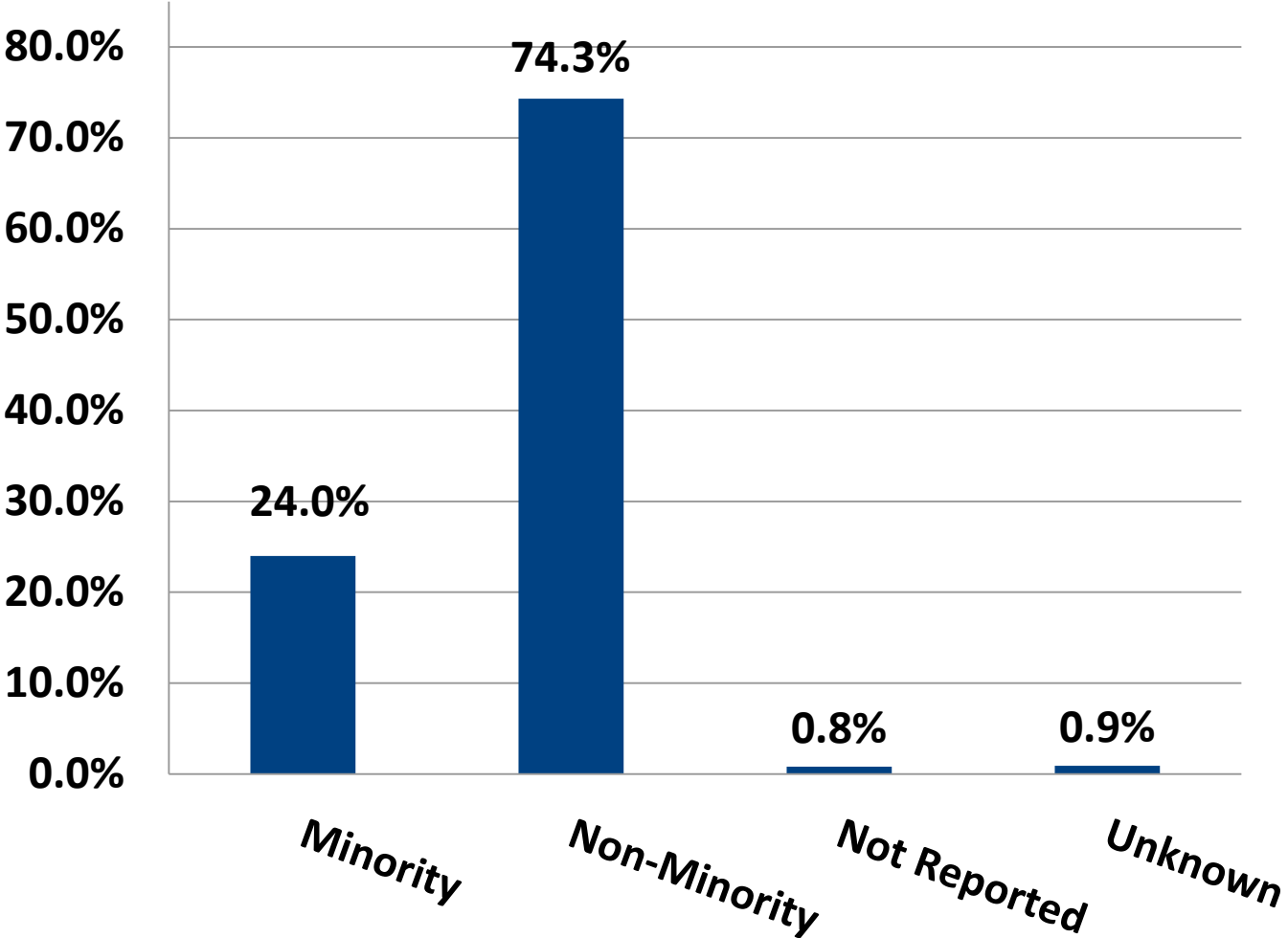
Tissue Acquisition Studies

276 patients

NCORP SCREENING ACCRUAL 2014 - 2017

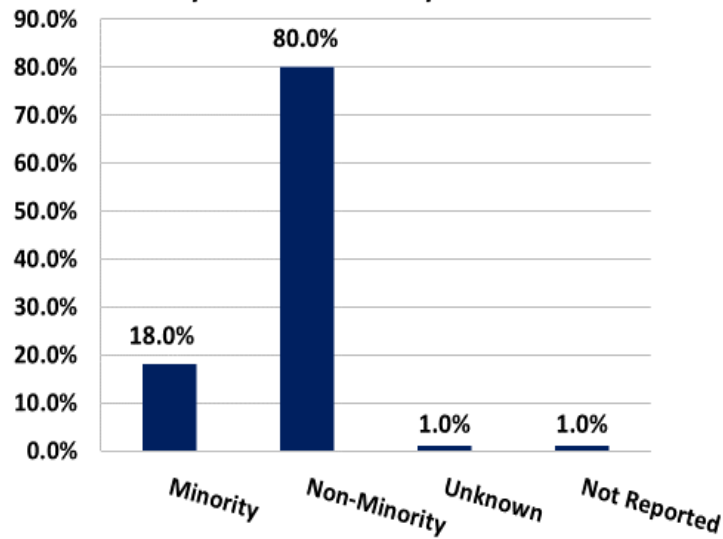


NCORP Overall Minority Enrollment 2017

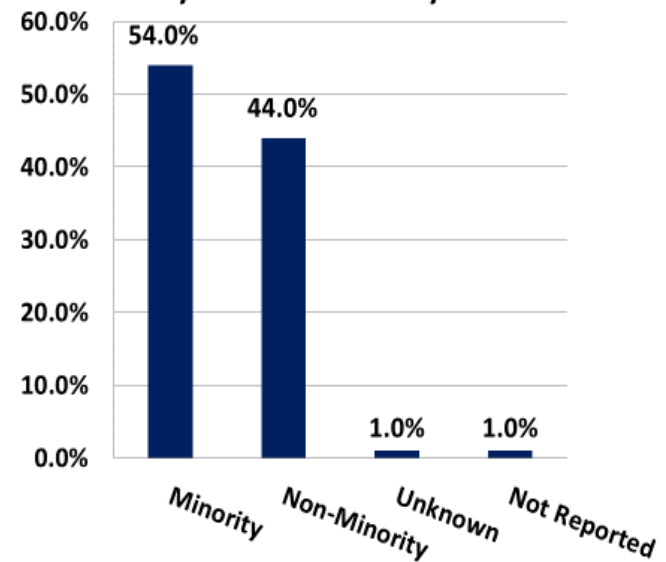


Minority Enrollment by Community Type

**Community Site NCORPS
Minority and Non-Minority Enrollment**



**Minority/Underserved NCORPS
Minority and Non-Minority Enrollment**



NCORP TREATMENT AND PREVENTION/CONTROL ACCRUALS

ETHNICITY AND RACE

2014 - 2017

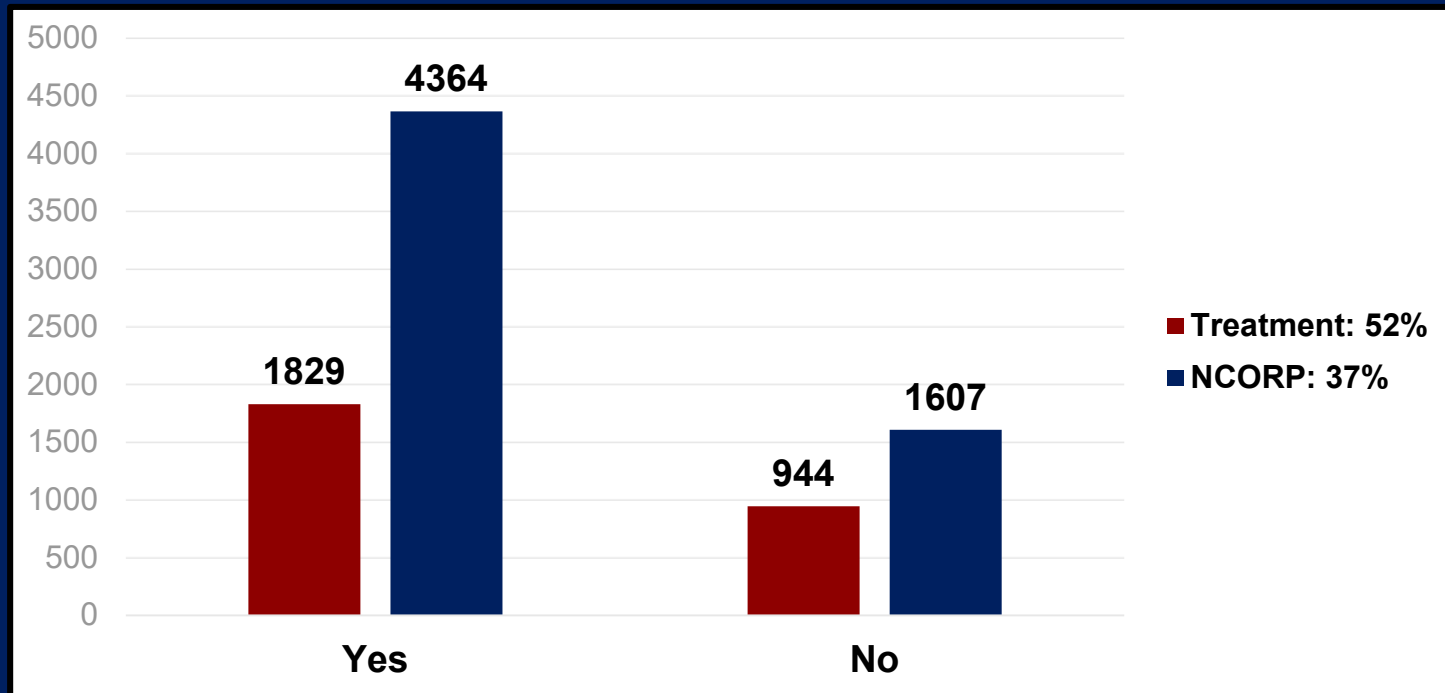
Racial Categories	Ethnic Categories				% of All Reported Racial Categories
	Not Hispanic or Latino	Hispanic or Latino	Unknown/Not Reported Ethnicity	TOTAL	
American Indian/Alaska Native	135	18	8	161	0.7%
Asian	681	16	13	710	3.0%
Native Hawaiian or Other Pacific Islander	96	6	1	103	0.4%
Black or African American	2,325	51	119	2,495	10.4%
White	17,787	1,273	863	19,923	83.3%
More than One Race	94	20	405	519	2.2%
TOTAL (All Reported Racial Categories)	21,118	1,384	1,407	23,911	100%
Unknown or Not Reported	200	371	251	822	3.4% of All Pts Enrolled with Unknown/Not Reported Race
TOTAL	21,318	1,755	1,658	24,733	

11/5/2018

DCP-001: Screening Tool

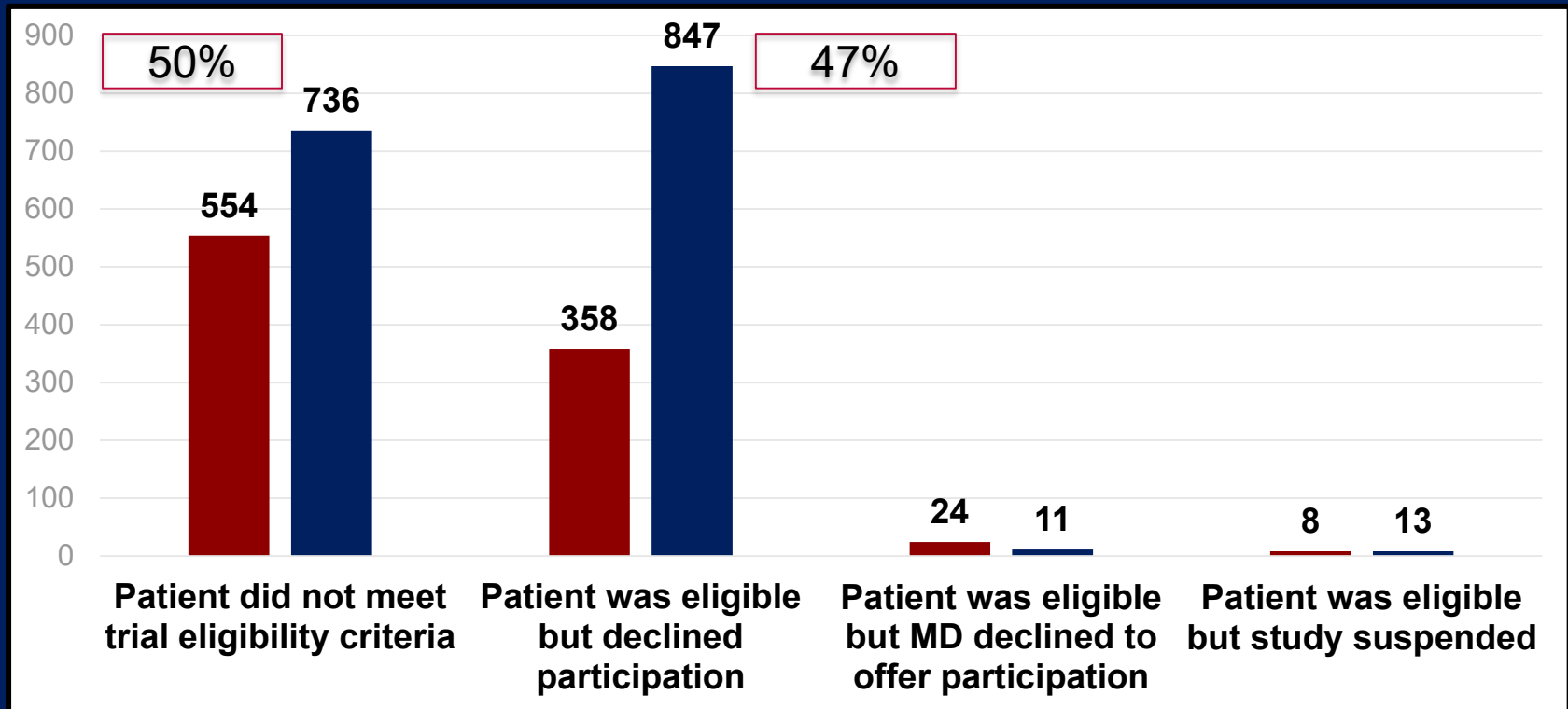
10,772 Entries, 8,744 consented to DCP-001

Enrolled on a Clinical Trial: 6193/8744 (71%)

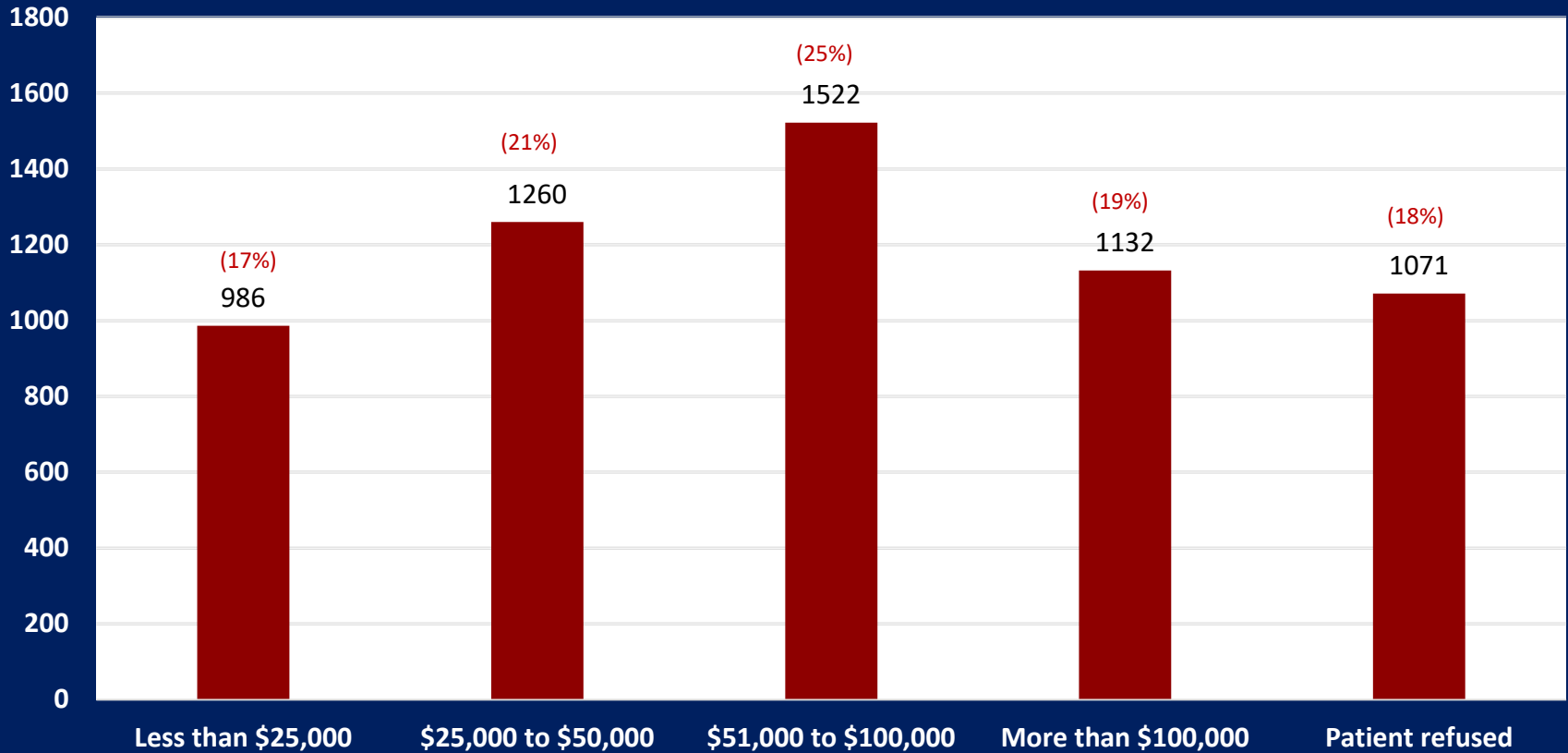


Reasons for Not Enrolling on a Clinical Trial

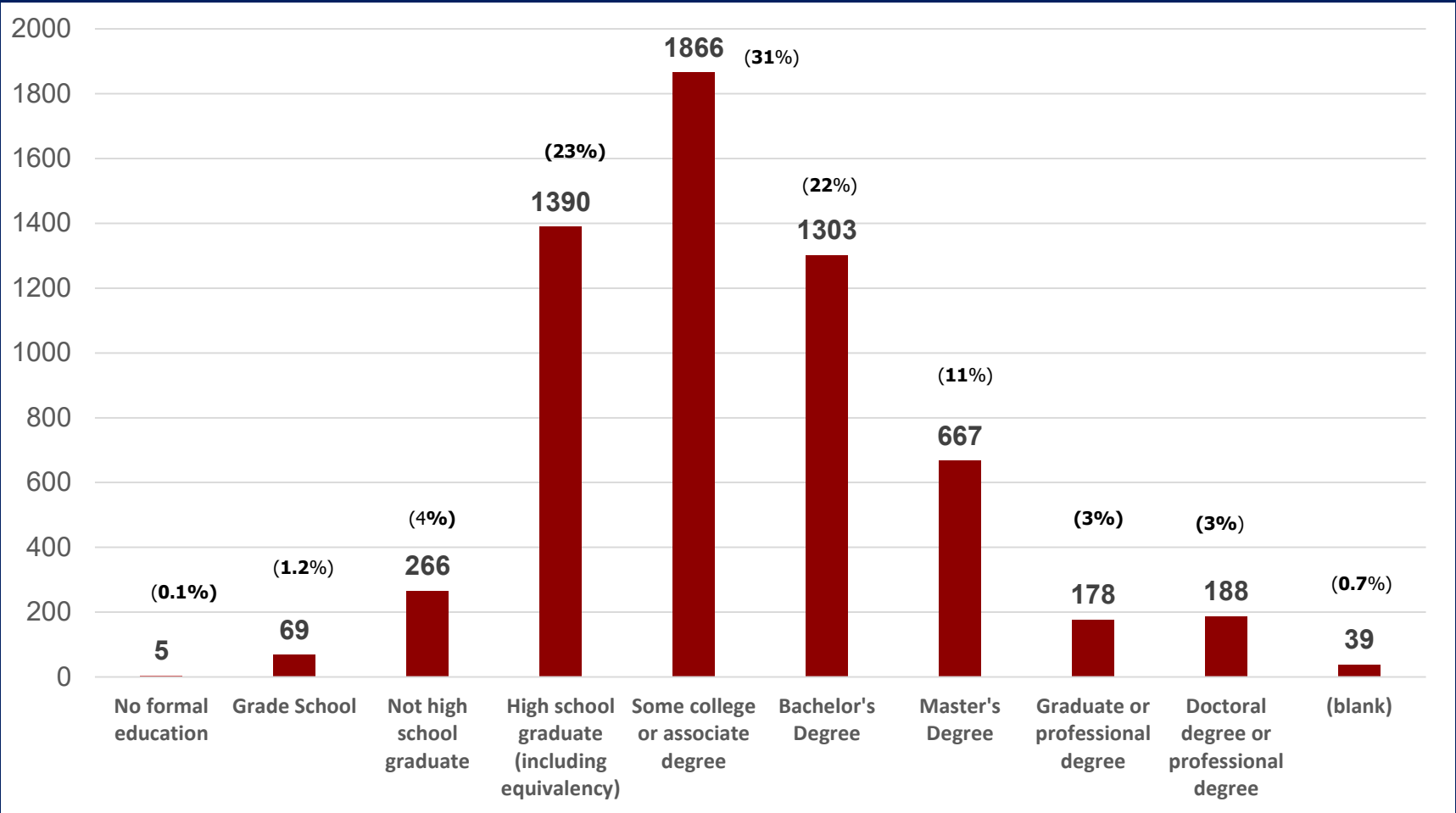
2,551/8744



Patient Income



Patient Education



Changes to NCORP Concept & Protocol Target Timeline Goals (Effective 8/1/2018)

Target Timeline Goals:

1. Concept Receipt to Approval	120 days
2. Protocol Authoring	90 days
3. Protocol Review & Approval	175 days
4. <u>Protocol Approval to Activation</u>	<u>90 days</u>
Total Target Timeline Goal	475

NCORP Target and Absolute Goals

Concept Receipt to Protocol Activation

Target	Absolute*
475 days	525 days

Protocol Receipt to Protocol Activation (Studies without Concepts)

Target	Absolute*
265 days	315 days

*Absolute Goal = includes one additional revision cycle 50 days
(Consensus Review Letter to Revision Receipt 30 days + Revision
Receipt to Approval On-hold 20 days)

Trials Activated & Completed During NCORP through 7/30/2018

Protocol Number	Title	Activation date	Accrual Cut Off Date	Planned Accrual	Actual Accrual
A221301	Olanzapine for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) in Patients Receiving Highly Emetogenic Chemotherapy (HEC): A Randomized, Double-Blind, Placebo-Controlled Trial	8/5/2014	4/5/2015	372	401
A221303	Randomized Study of Early Palliative Care Integrated with Standard Oncology Care Versus Standard Oncology Care Alone in Patients with Incurable Lung or Non-Colorectal Gastrointestinal Malignancies	5/15/2015	4/10/2017	400	405
A221304	A Phase III Placebo-Controlled, Randomized Three-Arm Study of Doxepin and a Topical Rinse in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Radiotherapy With or Without Chemotherapy	11/1/2014	3/29/2017	270	275
EA1141	Comparison of Abbreviated Breast MRI and Digital Breast Tomosynthesis in Breast Cancer Screening in Women with Dense Breasts	9/2/2016	11/7/2017	1450	1516
E4112	Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma In Situ (DCIS)	2/17/2015	4/28/2016	350	368
NRG-CC001	A Randomized Phase III Trial of Memantine and Whole-Brain Radiotherapy With or Without Hippocampal Avoidance in Patients With Brain Metastases	7/13/2015	3/12/2018	510	513
NRG-CC002	Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women with Gynecologic Cancers	2/10/2015	11/2/2015	228	190
URCC-13070	Improving Communication for Cancer Treatment: Addressing Concerns of Older Cancer Patients and Caregivers	10/29/2014	4/30/2017	1056	973
URCC-13091	Feasibility of Omega-3 Supplementation for Cancer-Related Fatigue	2/26/2015	3/31/2016	75	108
URCC-14079	Effectiveness of Prophylactic Topical Agents for Radiation Dermatitis	10/13/2015	6/30/2016	180	192

Thank you!