Cancer Disparities Research Partnership Program (CDRP)

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National Cancer Institute

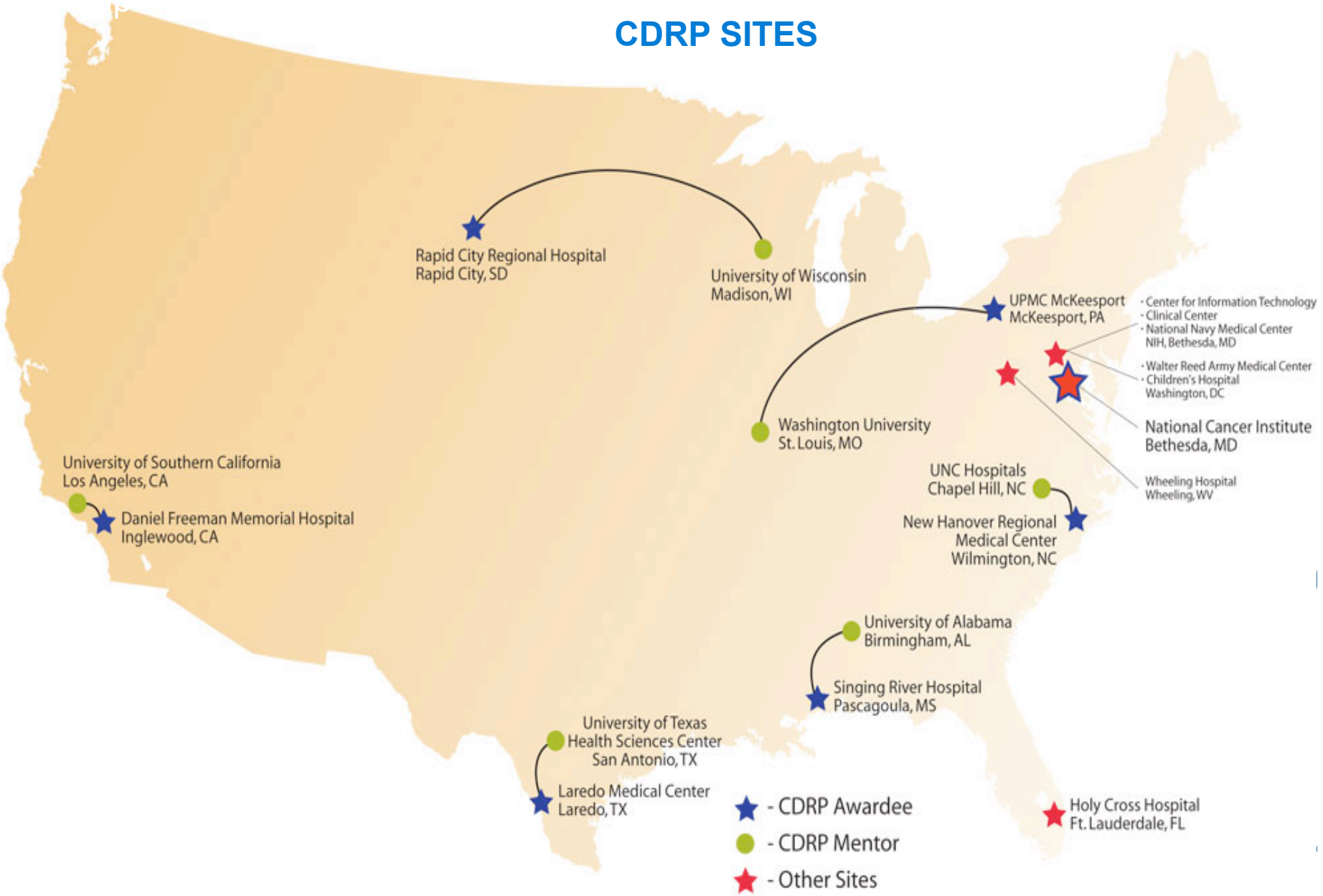
CDRP Program- background concepts

Unique pilot program for health disparities, community-based institutions to participate in **NCI clinical research**.

Research questions:

- Could the health disparities population be reached?
- Would there be an interest in such a program?
- What problems/issues would they face- as individual grantees and as a group?
- How would these problems be solved
- How would the partnership be established with the "reverse" flow of funds?

CDRP SITES


Rapid City Regional Hospital
Rapid City, SD
University of Wisconsin
Madison, WI
UPMC McKeesport
McKeesport, PA
Center for Information Technology
Clinical Center
National Navy Medical Center
NIH, Bethesda, MD
Walter Reed Army Medical Center
Children's Hospital
Washington, DC
National Cancer Institute
Bethesda, MD
Wheeling Hospital
Wheeling, WV
Washington University
St. Louis, MO
University of Southern California
Los Angeles, CA
Daniel Freeman Memorial Hospital
Inglewood, CA
UNC Hospitals
Chapel Hill, NC
New Hanover Regional
Medical Center
Wilmington, NC
University of Alabama
Birmingham, AL
Singing River Hospital
Pascagoula, MS
University of Texas
Health Sciences Center
San Antonio, TX
Laredo Medical Center
Laredo, TX
- CDRP Awardee
- CDRP Mentor
- Other Sites
Holy Cross Hospital
Ft. Lauderdale, FL

Community-Based CDRP Institutions and Mentors

Award Year	Grantee	Principal Investigator	Primary Mentor/Partner	Secondary Mentor/Partner	Service Area Population	Target Population
FY02	Rapid City Regional Hospital, Rapid City, SD	Daniel G. Petereit, MD	Univ. of Wisconsin, Madison, WI	Mayo Clinic, Rochester, MN	300,000	American Indian
FY02	Laredo Medical Center, Laredo, TX	Yadvindera S. Bains, MD[1]	UTHSC at San Antonio, San Antonio, TX	MD Anderson Cancer Center, Houston, TX	177,000	Hispanic/Latino
FY03	Centinela Freeman Regional Medical Center, Inglewood, CA	Michael L. Steinberg, MD	USC, Los Angeles, CA	RAND Corporation and UCSF	100,000	African American Hispanic/Latino
FY03	New Hanover Regional Medical Center, Wilmington, NC	Patrick D. Maguire, MD	UNC-CH, Chapel Hill, NC		616,000	African American Urban/Rural Poor
FY03	Singing River Hospital, Pascagoula, MS	W. Sam Dennis, MD	UAB, Birmingham, AL	Univ. of Mississippi, Jackson, MS	200,000	African American
FY03	UPMC McKeesport Hospital, McKeesport, PA	Dwight E. Heron, MD	Washington University, St. Louis, MO	Roswell Park Cancer Center, Buffalo, NY	935,000	African American Urban/Rural Poor

[1] Dr. Bains resigned on March 31, 2006; grant relinquished April 21, 2007.

Why Radiation Oncology?

- Involves the specialty in this important national (and international) effort.
- A major treatment alternative for those in advanced stages of disease.
- Internationally- many radiation oncologists are “clinical oncologists”
- IT nature makes the specialty more receptive to field training approaches and network arrangements.

Cancer Disparities Research Partnership Program

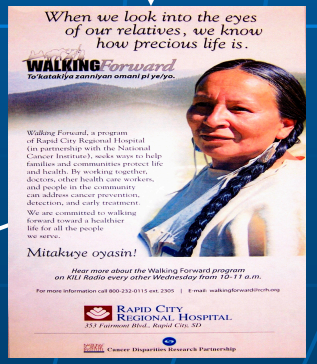
Clinical Trials
Investigator-Initiated
RTOG, Cooperative groups

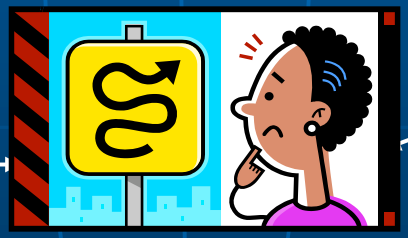
Mentor/Partner

Telesynergy®

CDRP Sites

Community Education





Patient Navigator

Community Outreach

Total Number of Patients Accrued or Navigated by Race/Ethnicity for All CDRP Sites*

Race/Ethnicity	Total # of Patients Accrued to CDRP Clinical Trials	Total # of Patients Navigated by CDRP Sites
American Indian/Alaska Native	87	311
Asian	1	21
Non-Hispanic Black or African American	66	682
Non-Hispanic White	748**	1,014**
Hispanic/Latino	325@	407@
Total	**1,217#**	**2,435$**

* Start of CDRP to September 2007; does not include behavioral/social science studies accrual.
** Includes underserved, elderly and disadvantaged white.
@ Includes STAR prevention & SABOR risk assessment trials accrual.
# 3 Centinela patients were enrolled in 2 different clinical trials, but were only counted once for ethnicity.
$ Includes 1 Native Hawaiian/Pacific Islander and 3 Unknown.

Yearly New Patient Accrual by All Sites to Different CDRP Clinical Research Trials#

CDRP Clinical Research	FY2003	FY2004	FY2005	FY2006	FY2007	Total Accrual
Investigator-Initiated Clinical Trials	0	2	43	87	72	204
RTOG Trials	10	8	22	28	31	99
Cooperative Group Trials (Total)	271@	348*	35	60	75	789*
• Rad/Comb. Treatment	*175*	*38*	*35*	*60*	*70*	*378*
• Cancer Control	*60*	*-*	*-*	*-*	*5*	*65*
• Prevention (STAR)	*36**	*9**	*-*	*-*	*-*	*45*
• Risk Assessment (SABOR)	*-*	*301**	*-*	*-*	*-*	*301*
Pharmaceutical/Industry Trials	0	0	5	1	8	14
Total	281@	358	105	176	186	1,217#

Data from start of CDRP in September 2002 thru September 2007; does not include patient navigation/social science study accrua
* Includes LMC/RCRH STAR prevention & LMC SABOR (EDRN) risk assessment trials in 2003-2004.
@ RCRH's RTOG, NCCTG and other coop. group accruals.
# 3 Centinela patients were enrolled in 2 different clinical protocols and therefore were counted twice for patient accrual.

Cumulative Patients Enrolled for All CDRP Sites*

Types of Research Activities	Total # of Patients Accrued
Surveys, Assessments	5,275
Behavioral Interventions, Patterns of Health Care Service Utilization	598
Patient Navigation	1,916
Clinical Trials - PI, RTOG, Other Coop. Grps, Pharm/Ind. (Radiation)	1,217**
Multimodality Trials - Surgical/Med Onc	63#
Other - Focus Groups	234
Total	9,303

* Start of CDRP program in September 2002 through September 2007
** Includes LMC's STAR & SABOR(EDRN) trials and RCRH's FY03 RTOG/coop. group trial accruals
# Accrual from 2006 CTOC supplement

New Hanover
PI: Patrick D. Maguire, MD
Accomplishments 9/2003 - 9/2009

Clinical Trials

- PI-initiated phase II H&N (ZCC 00204)
  - First of its kind in NC
  - 39 total pts enrolled (30 NHRO, 9 UNC)
  - 20% underserved
  - Manuscript written & submitted
- Highest accruing RTOG site in North Carolina 2008 & 2009
- Nominated for ASCO Clinical Trials Participation Award 2009

UPMC McKeesport
PI: Dwight E Heron, MD
Accomplishments 9/2003 - 9/2009

- Trial accruals – 1,091

Type of trial	Study Participants
Clinical therapeutic	110
Patient navigator study	846
Behavioral "white coat" study	135

2009 Update of the Phase II MammoSite® Brachytherapy Trial for DCIS

Last abstract presented at the 2007 San Antonio Breast Cancer Symposium, Abstract #4079 December 15, 2007 (The following slides do not represent the update for 2009)

Streeter, O., et al. Breast Cancer Research and Treatment, 106 (suppl 1.): S192, 2007.

Study Sites and Investigators

Principal Investigators:

Oscar Streeter, MD
Melvin Silverstein, MD
Susan Groshen, PhD (USC)

Additional Sites:

- Arizona Oncology, AZ — Coral Quiet, MD and Bob Kuske, MD
- St. Agnes Healthcare, MD — Richard Hudes, MD
- William Beaumont, MI — Pam Benitez, MD & Frank Vicini, MD
- Fox Chase, PA — Gary Freedman, MD
- MD Anderson, TX — Henry Kuerer,MD and Earl Strohm
- Mt. Sinai, FL — Martin Keisch, MD
- NY Pres Hospital, NY — Mary K. Hayes, MD
- Rhode Island Hospital, RI — Thomas DiPetrillo, MD
- Swedish, WA — Vivek Mehta, MD
- Virginia Commonwealth Univ, VA — Doug Arthur, MD
- Daniel Freeman Hospital, CA — David Khan, MD

D. Khan is supported by NCI U56 Disparity Grant #1056CA 1905389-01, B. Research Grant. S. Groshen is supported through the USC/Norris Comprehensive Cancer Center (Core) Grant #2 P30 CA 140898-26

Result of the Phase II DCIS MammoSite Trial

- The target goal of 100 treated patients was reached between May 2003 and January 2006.
- 133 patients were enrolled.
- 33 not treated due to: inadequate skin distance (n=13), poor cavity conformance of the balloon (n=10), microinvasion (n=3), MD decision (n=2), patient request (n=1), and other (n=1).

Streeter, O., Benitez P., Vicini, F., et al. Breast Cancer Research and Treatment, 106 (suppl 1.): S192, 2007.

Results (2007)

Median follow-up 2 years

No patients have been lost to follow-up

Cosmetic outcome is now excellent/good in 94 and fair in 6 patients.

No serious adverse events reported with an infection rate of 9% (7 breast infections; 2 with cellulitis)

Four recurrences