

CCSS

Childhood Cancer Survivor Study

2007 Investigators' Meeting

St. Jude Children's Research Hospital

August 24-25, 2007

CCSS

CHILDHOOD CANCER SURVIVOR STUDY

Agenda

Friday

- AM Epi/Biostat and Therapy Working Groups
Plenary Session – Reports and Presentation
- PM Working Group Breakout Sessions
Reception

Saturday

- AM Publications Committee
Working Group Reports
- PM Steering and Advisory Meeting

Organizational – Leadership Changes

Working Groups

Epidemiology & Biostatistics

Mertens, Leisenring

Therapy (Temp.)

Neglia

Chronic Disease

Sklar, Diller

Genetics

Strong

Neuropsychologic

Zeltzer

Neurologic (Probationary)

Packer, Armstrong

Second Malignancies

Meadows, Neglia

Prevention and Control

Hudson, Oeffinger

Reproductive

Green

Organizational – Leadership Changes

Pathology Center:

Steve Qualman

Steering Committee:

Lisa Diller, Barry Anderson, Roy Wu

Publications Committee:

Chuck Sklar (Chair, Jan. 2008)

New Institutional Principal Investigators

- University of California Los Angeles
Jackie Casallis replaces Lonnie Zeltzer
- UT Southwestern - Dallas
Dan Browers replaces Gail Tomlinson
- University of Alabama - Birmingham
Kimberly Whelan replaces Jane Sande

Funding

Current Award: 12/1/05 – 11/30/10

Year 12 - Awarded at 54% of recommended
Removed funding to expand cohort
Funds provided to maintain current cohort
St. Jude support used to allow institutional
funding of CRA support to begin IRB process
and identification of eligibles for expanded
cohort

Funding

Year 13 -

Awarded at 47% of recommended

Removed funding to expand cohort

Funds provided to maintain current cohort

Initiated plan to begin a scale-down approach to expand the cohort. Through St. Jude support and removing reallocating funds (e.g. investigator support, decreased sample size, no sibling cohort, etc.) developed strategy to move forward.

In June 2007 received exception funding to allow CCSS to expand the cohort as proposed.

Funding – Percent of Recommended

Year	(%)
12	54%
13	82%
14	85%
15	87%
16	89%

Funding Plans

Year 13

Revising subcontracts to provide additional support:

Institutional PI – 5%

Steering Committee – 5%

CRA – up to 100% for (8/1/07 – 11/30/07)

Increased support for Radiation Dosimetry

Statistical support in Alberta

Public access – Gurney

Funding Plans

Year 14

- Continue investigator support

- Maximize CRA support to complete all medical record abstraction before the end of Year 14

- Biological sample collection

- Sibling cohort

Years 15-16

- Decrease institutional PI support (2%)

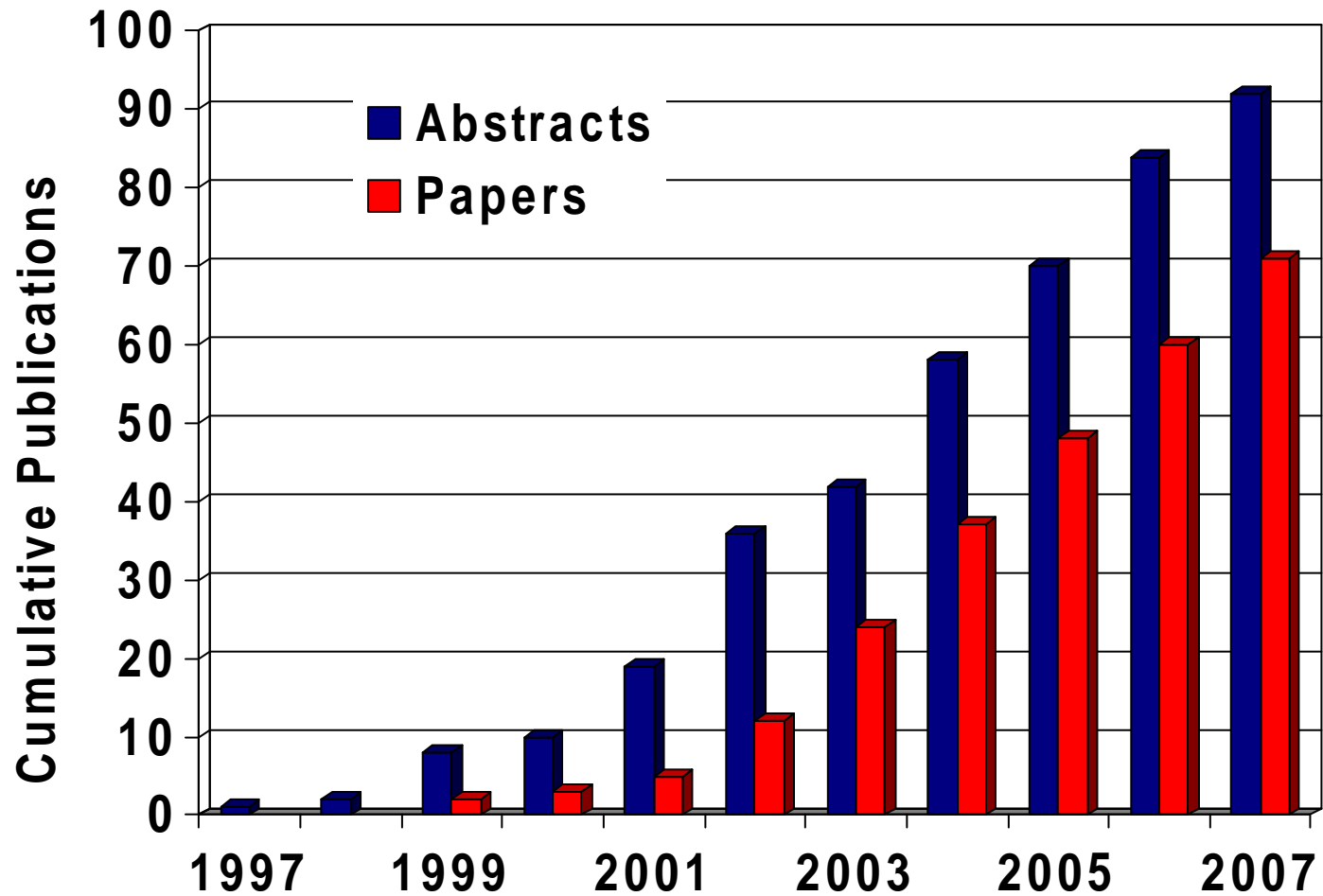
- Begin follow-up 1 surveys

Publications Committee

Anna T. Meadows, Chair
Charles Sklar, (Chair – Jan. 2008)

Barry Anderson
Richard Aplenc
Greg Armstrong
Lisa Diller
Sarah Donaldson
Dan Green
Wendy Leisenring
Ann Mertens
Marilyn Stovall
Les Robison, ex officio
Yutaka Yasui, ex officio

Publications



Publications

two or more in each of the following:

- 16 J Clin Oncol
- 8 Cancer
- 8 Pediatr Blood Cancer
- 6 J Clin Endocrinol Metab
- 5 JNCI
- 3 Psychol Oncol
- 2 J Clin Epidemiol
- 2 JAMA
- 2 Cancer Epidemiol Biomarkers Prev
- 2 Ann Intern Med

1 paper in each of the following:

- Lancet
- NEJM
- J Pediatr
- Pediatr
- Am J Gynecol
- Epidemiology
- Am J Epidemiol
- Ann Fam Med
- J Pub Health Dent
- Int J Radiat Oncol Biol Phys
- Br J Cancer
- Prev
- Psychol Assess
- Radiat Res
- Sleep
- Arch Phys Med

Ancillary Studies (2006-7)

Grants Funded:

- R21 Ken Onel (Univ. of Chicago) – Prognostic Genetic Biomarkers for Cancer
- LAF Lillian Meacham (Emory) – Testicular and Sexual Function

Grants Submitted:

- R21 Richard Sposto (USC) – Statistical models for risk/benefit
- K-07 Anne Lown (SF State) – Alcohol consumption
- LAF Andrea Patenaude (Dana Farber) – Genetic guide for survivors
- R01 Kim Robien (Univ. of MN) – Body weight: diet, exercise, genetics
- R01 Doug Ris (Cincinnati) – Neurobehavioral outcomes in low grade BT
- R21 Whitney Witt (Univ. of Wisc) – Stress and aging among caregivers of BT
- R01 Melissa Hudson (St. Jude) – Promoting health monitoring
- ACS Elyse Park (Mass. General) – Health Insurance

Utilization of the CCSS Resource

Objective:

Further increase access of the CCSS resource through

- Advertising availability of CCSS through publications and national meetings
- Development of a strategy for establishing a platform for public access to CCSS data.

Utilization of the CCSS Resource

Task Force for Public Access: James Gurney (Chair), John Whitton, Wendy Leisenring, Greg Armstrong, June Ni, Janet Donohue, Kiri Ness, Nina Kadan-Lottick, Les Robison

Phase-in plan for (1) static reports, (2) interactive reports, (3) data sets, and (4) on-line analyses.

Proposal to make data available in the public access forum 24 months after the data freeze. That is, CCSS investigators have 2 years to analyze and publish the data before it is put into the public domain.

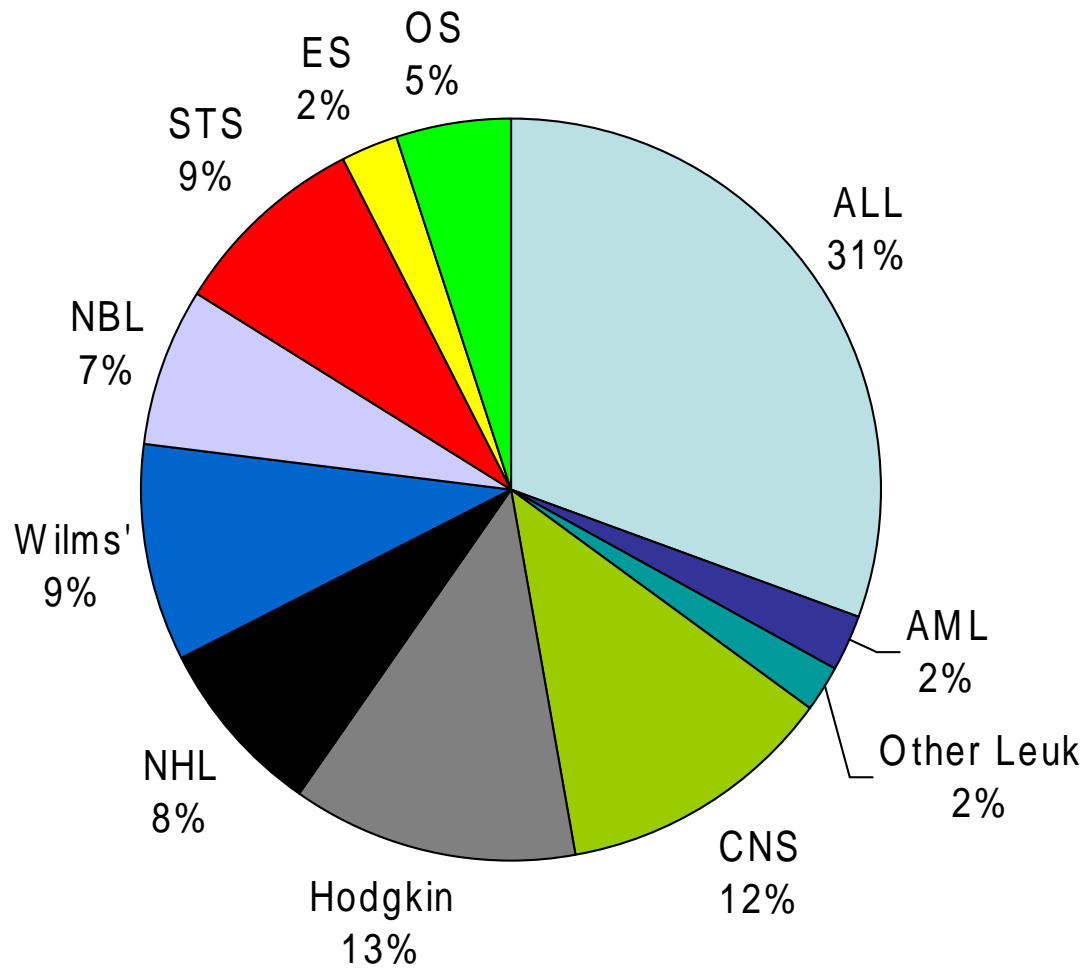
Current Cohort

		Survivors n= 10,254	Siblings n= 3165
Current age:	Mean	35.0	35.5
	Median	35.0	35.0
	Range	20 – 57	12 - 61

Drop-out rate of survivors approx. 1% per year

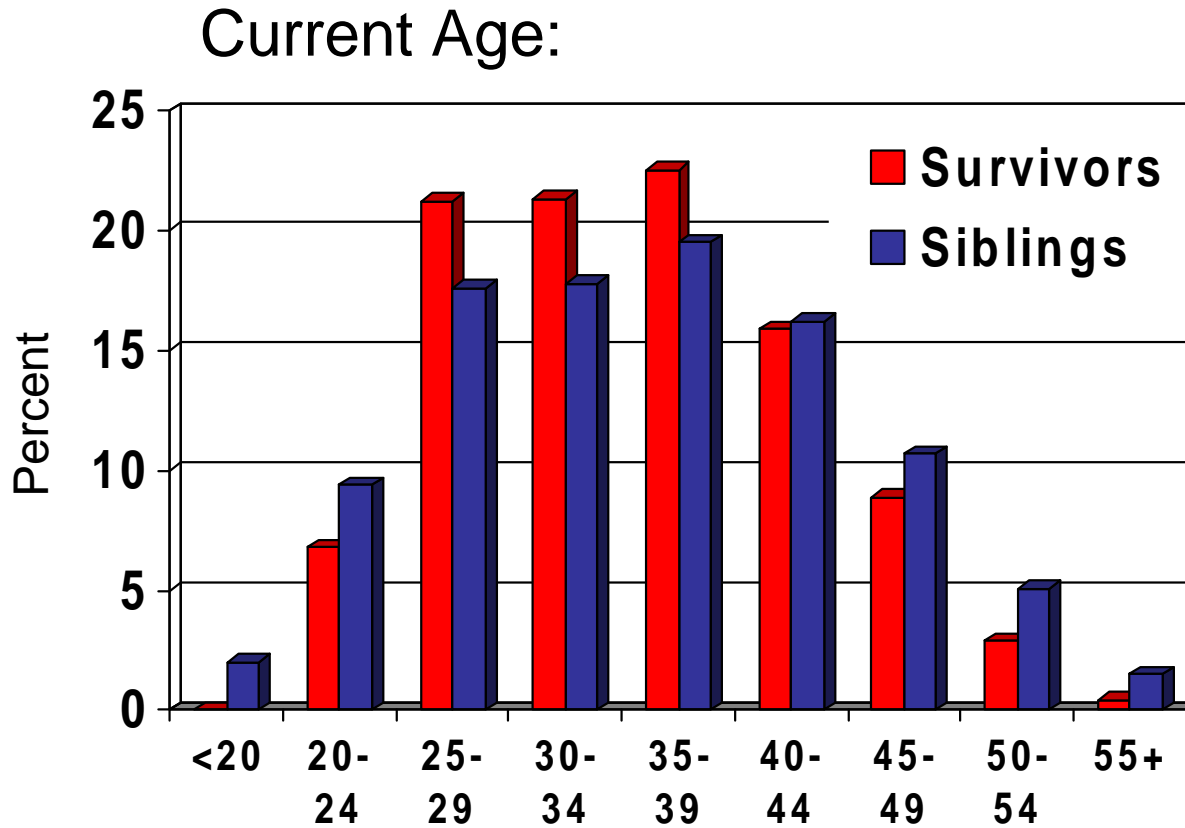
Current Cohort

Under Active Follow-up (n=10,254)



Current Cohort

Survivors Under Active Follow-up (n=10,254)



Sex:

Survivors

Females (48%)

Males (52%)

Siblings

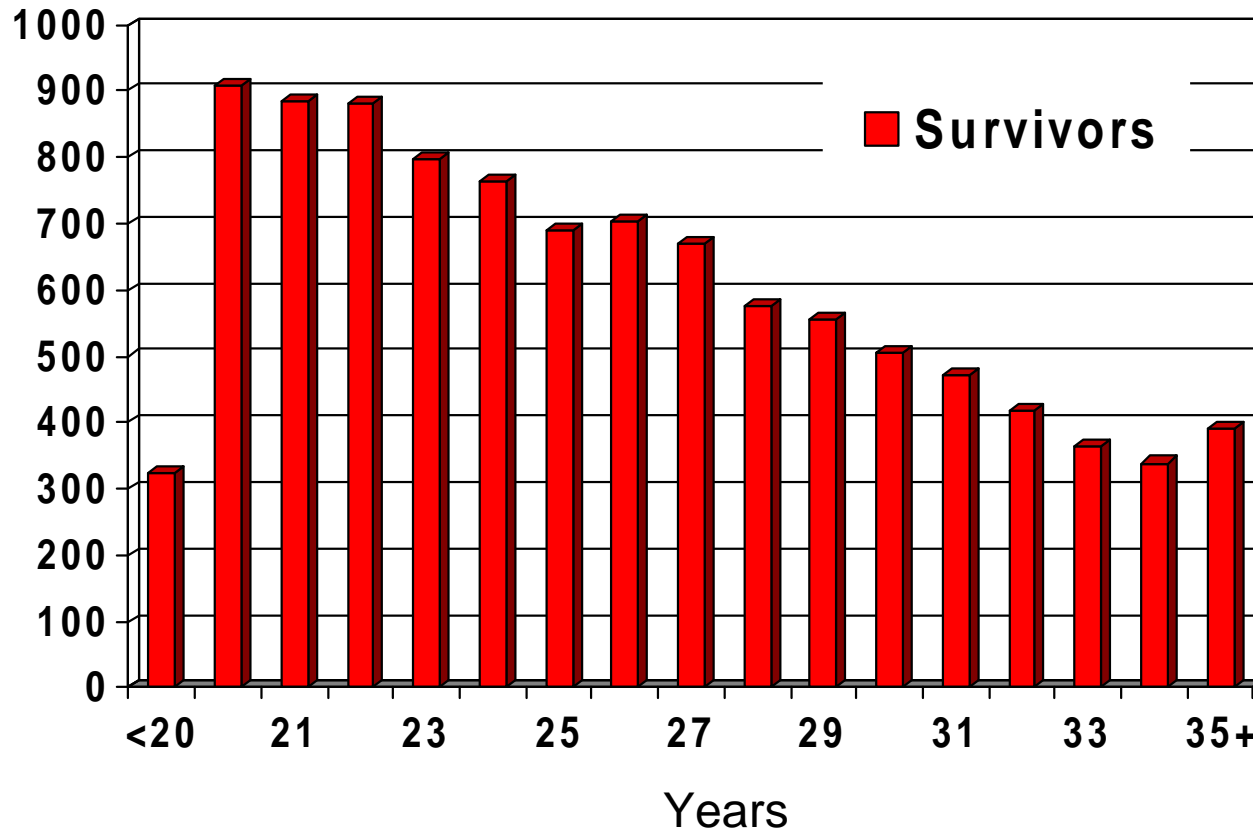
Females (52%)

Males (48%)

Current Cohort

Survivors Under Active Follow-up (n=10,254)

Time Since Diagnosis:



Race:

White, NH	88%
Hispanic	4%
Black, NH	4%
Native Am.	<1%
Asian/PI	1%
Other	3%

Cohort Expansion

Specific Aim 2 - Enhance the resource by recruiting individuals diagnosed between 1987-99.

- Recruit and follow an additional 14,800 five-year survivors
- Enrich the recruited cohort with respect to ethnic/racial minorities and disease/treatment groups of greatest interest
- Collect selected baseline and follow-up outcomes information to ensure comparability to the initial cohort
- Enroll 4000 siblings of survivors
- Collect biologic samples for molecular genetic studies

CCSS Expanded Cohort

Selection Factors

Diagnosis	Selection Factors	Weighting Ratio	Total Target # Participants
Acute Lymphoid	Age Dx <1, >10 (intensive Rx)	3:1	2000
Acute Myeloid	None		650
CNS	Race/Ethnicity	2:1	3000
Hodgkin Disease	None		1500
Non-Hodgkin	Race/Ethnicity	2:1	2000
Neuroblastoma	Race/Ethnicity	2:1	1000
Wilms'	Dx 1986-94 (> Doxorubicin)	2:1	1000
Rhabdomyosarcoma	Race/Ethnicity	2:1	1000
Osteosarcoma	Race/Ethnicity	2:1	1000
Ewing Sarcoma	None		650

Race/Ethnicity is ratio of non-white : white

Cohort Expansion

CCSS Follow-up Center at USC

Institutional Rosters (n= 26,093)

Changes in eligibility (retinoblastoma)

Selection of eligible cohort (n= 20,729)

Pilot of St. Jude cases

Tracing and contact

Cohort Expansion

Characterization of the eligible cohort

Demographic characteristics

Cancer-related characteristics

Abstraction of treatment data for non-participants

Characterize participants and non-participants to determine potential selection.

Ability to characterize without disclosure of any personal identifying information (CCSS Follow-up Center).

Cohort Expansion

20,729 Eligible cases selected

Participation rate = 70% → Expanded cohort = **14,500**

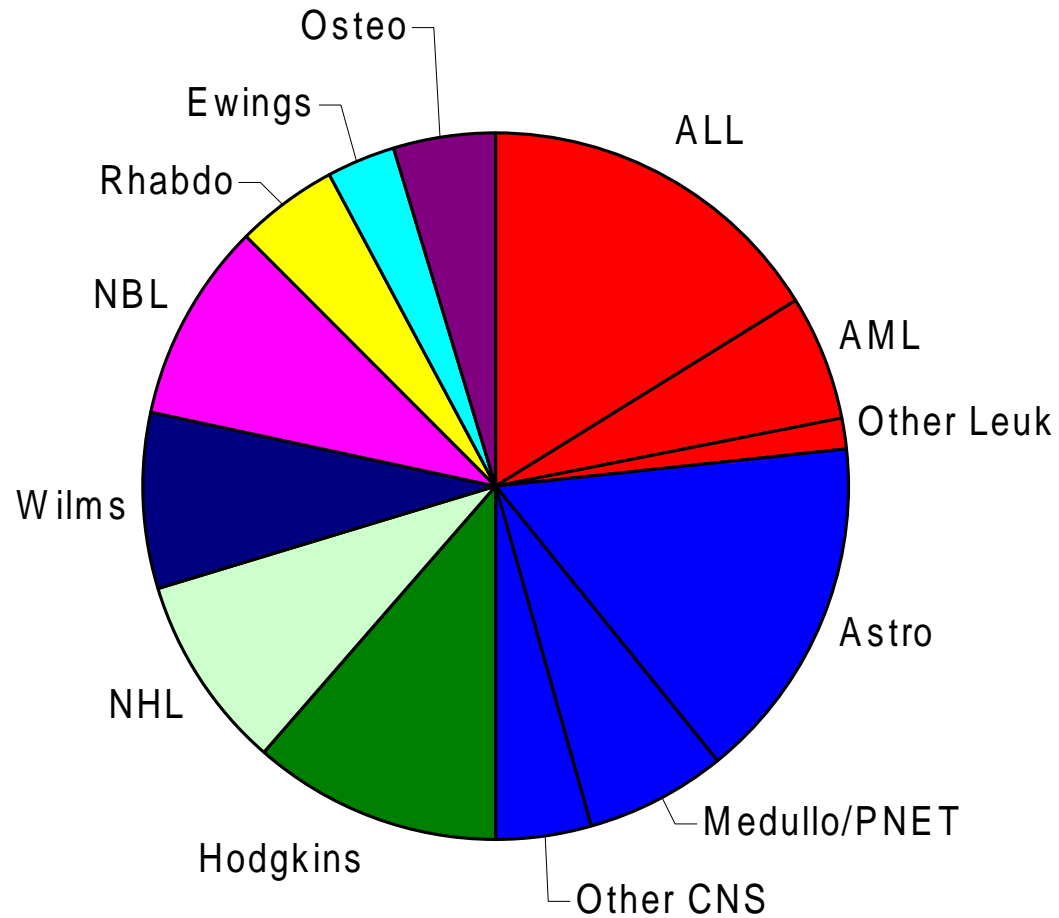


Participation rate = 80% → Expanded cohort = **16,500**

Cohort Expansion

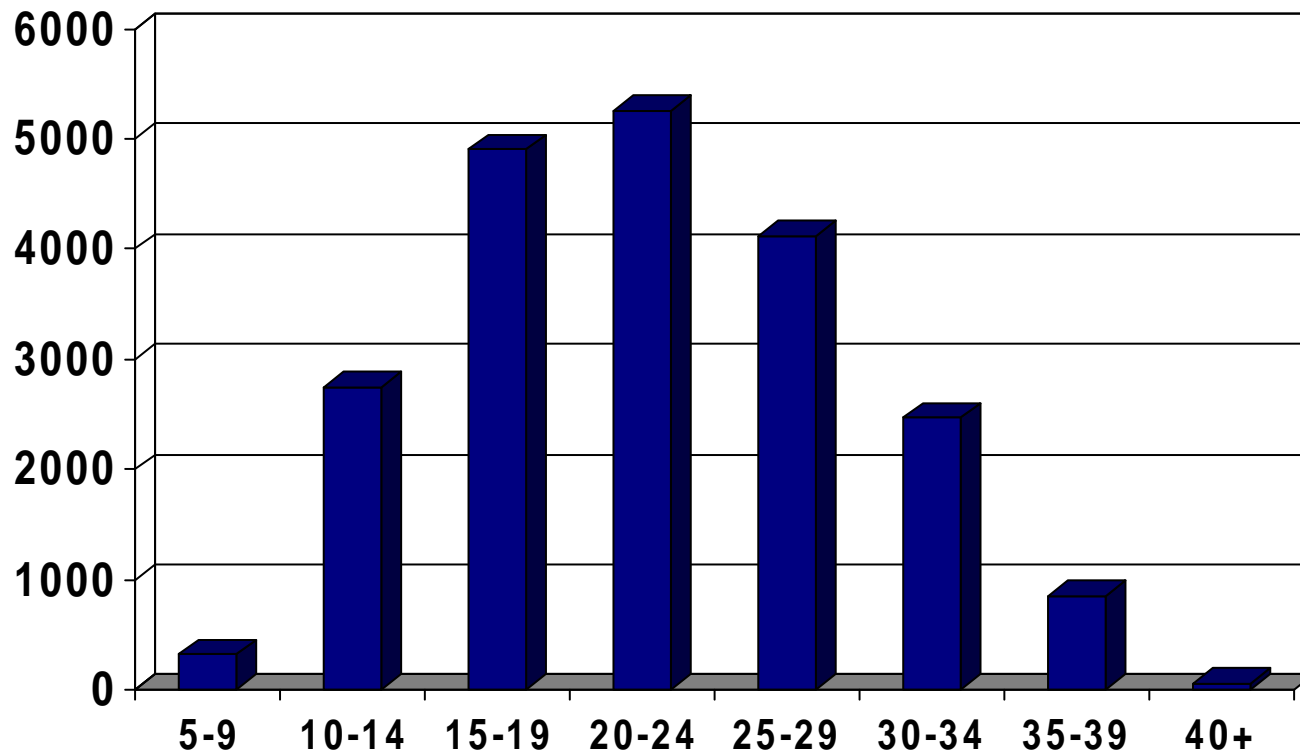
Institution	Submitted	Eligible	Selected
University of Minnesota	492	447	356
Denver Children's Hospital	816	797	625
Pittsburgh Children's	1070	1049	875
Stanford	677	670	479
Dana Farber	1939	1904	1595
Emory	1240	1198	938
Washington DC	576	557	443
MD Anderson	762	750	654
Memorial Sloan Kettering	1626	1548	1409
UC San Francisco	796	666	663
Children's Seattle	1161	1122	854
Toronto	2153	2153	1724
St. Jude	2387	2303	2303
Columbus Children's	687	666	506
Roswell Park	317	317	284
Minneapolis Children's	761	750	593
Children s Hospital of Philadelphia	1505	1352	1128
St. Louis Children's	618	589	473
Children's Los Angeles	1184	1071	762
UCLA	133	133	95
Riley University of Indiana	1253	1234	972
University of Alabama	572	567	422
Mott University of Michigan	932	890	736
UT Southwestern Medical Center	977	955	750
Texas Children's	1174	1122	863
City of Hope	285	285	227
Total	26,093	25,095	20,729

Cohort Expansion (n= 20,729)



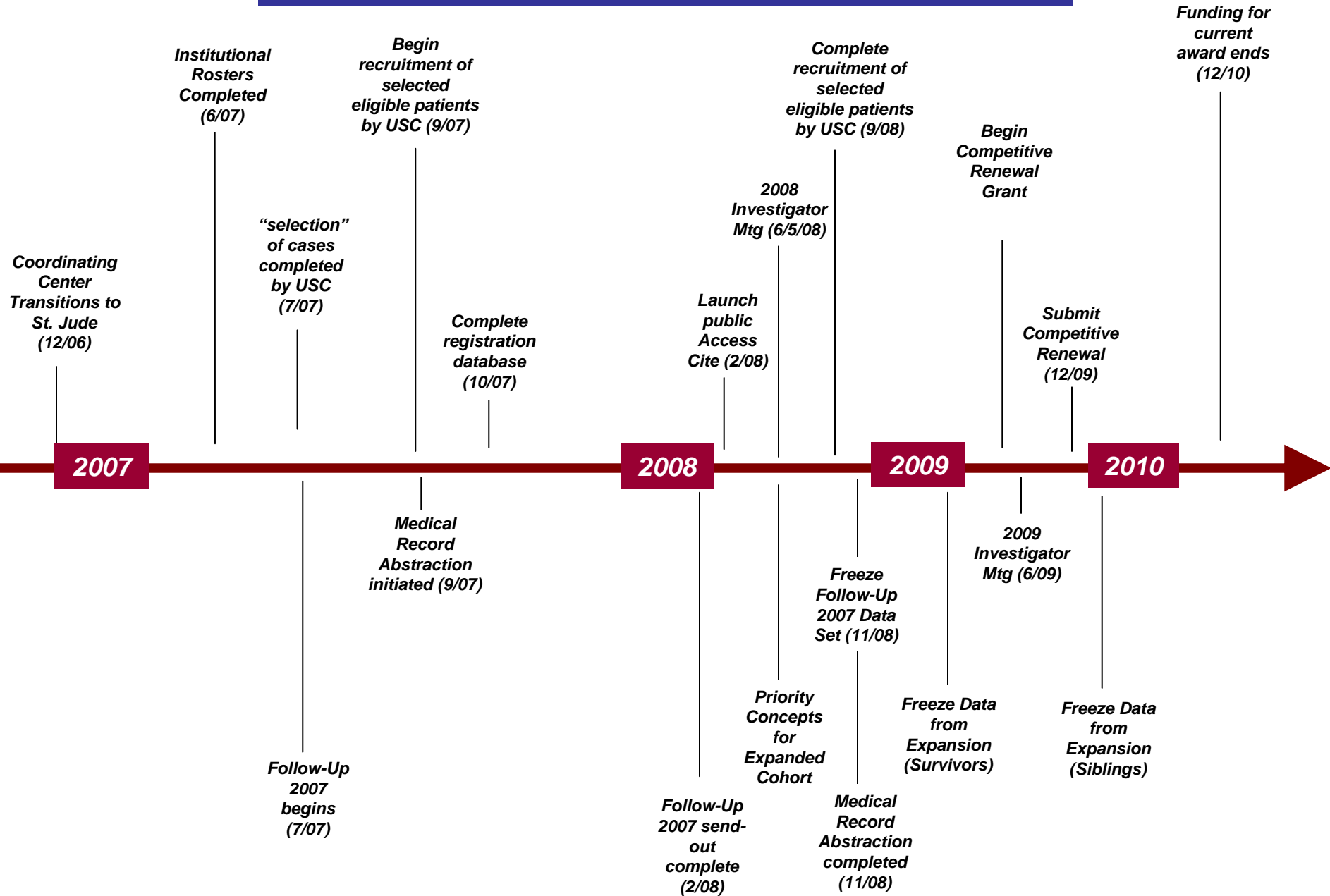
Cohort Expansion (n= 20,729)

Current Age



Age in 2007

CCSS Working Timeline



Future Meetings - Communications

Investigator Meetings: Spring 2008, 2009, 2010 (Niagara-on-the-lake in 2008 and 2010)

Steering Committee Meetings: Winter 2008, 2009, 2010 (venue based on cost), day and half in length

Conference calls for Steering Committee: Every other month, set date/time, 90 minutes

Investigator Update: Every other month

Future Development of CCSS

- Increased innovation
- Translation of results into interventions
- Measures of productivity and impact
- Involvement and mentoring of new investigators
- Review of ancillary proposals
- Oversight of biological samples
- Involvement of other centers
- International collaborations
- Others?

Charge to Working Groups

ACTIVITY UPDATE

- Inventory and Status of Current Concept Proposals
Identify priorities and problems
- Summary of Future Concept Proposals
Identify those to be submitted to PC in next 6 mos.
- Status of Ancillary Study Proposals
- Priorities for analyses from the 2007 survey
- Priorities for Future Surveys (initial cohort)

EXPANDED COHORT

- Identification of priority analyses for the expanded cohort.
- Plans for development of the top two from each working group

PUBLIC USE DATA BASE

- List of data elements that would be considered