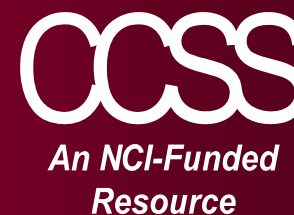


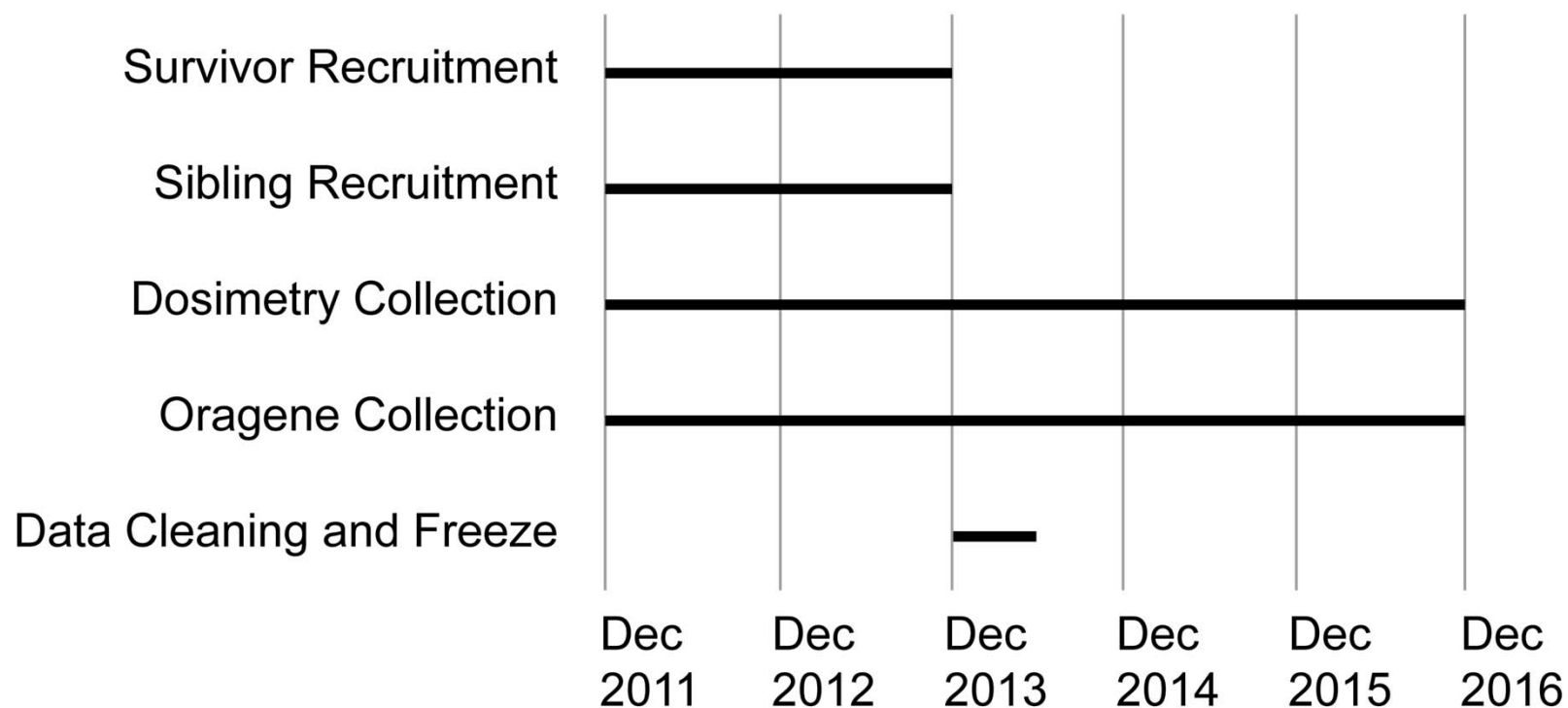
Childhood Cancer Survivor Study
Coordinating Center Update
Plenary Session
June 12, 2013

Greg Armstrong, M.D., M.S.C.E.
CCSS Project Director



Competitive Renewal Timeline (April 2011)

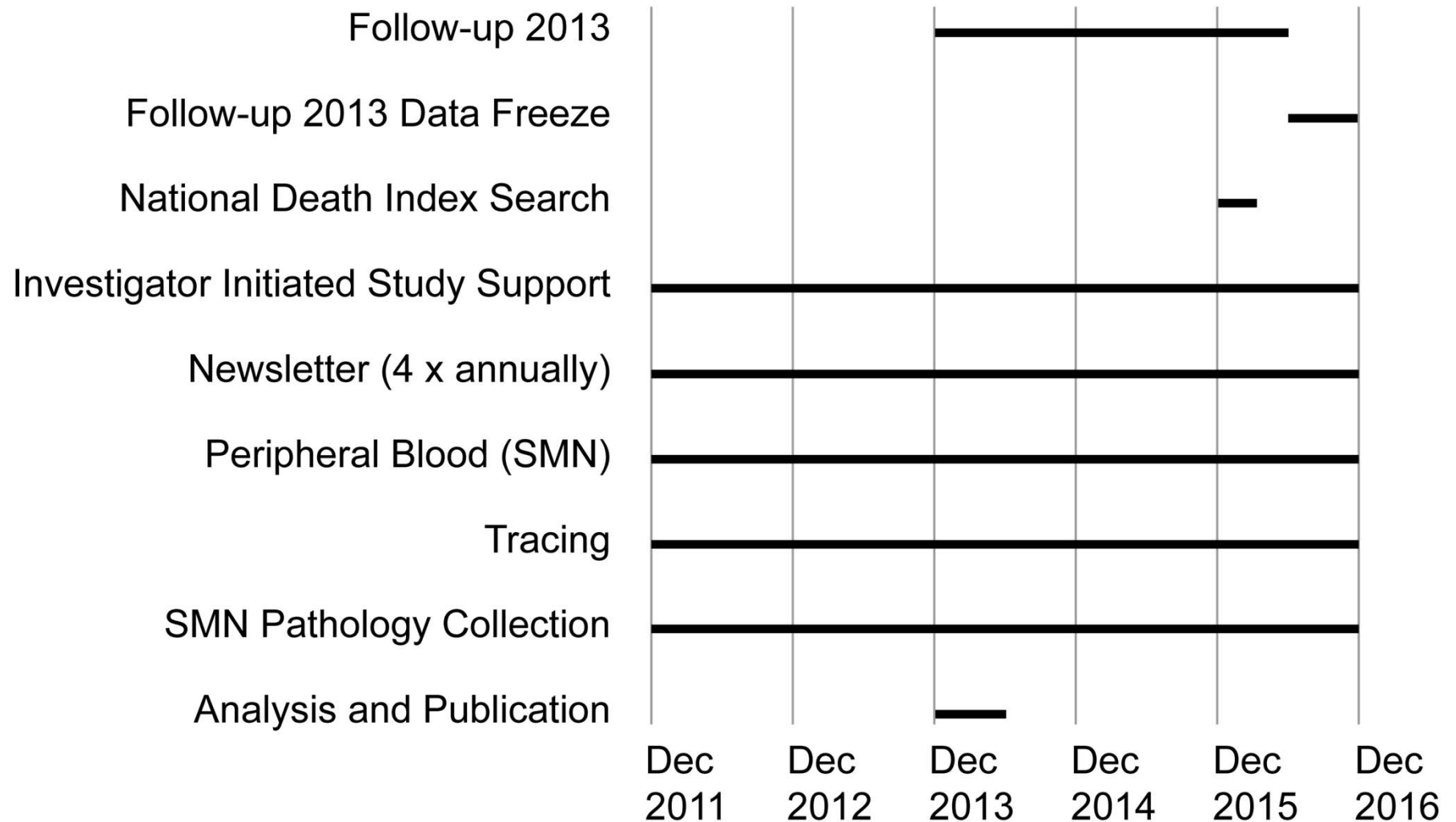
Expanded Cohort



Competitive Renewal Timeline

(April 2011)

All Participants

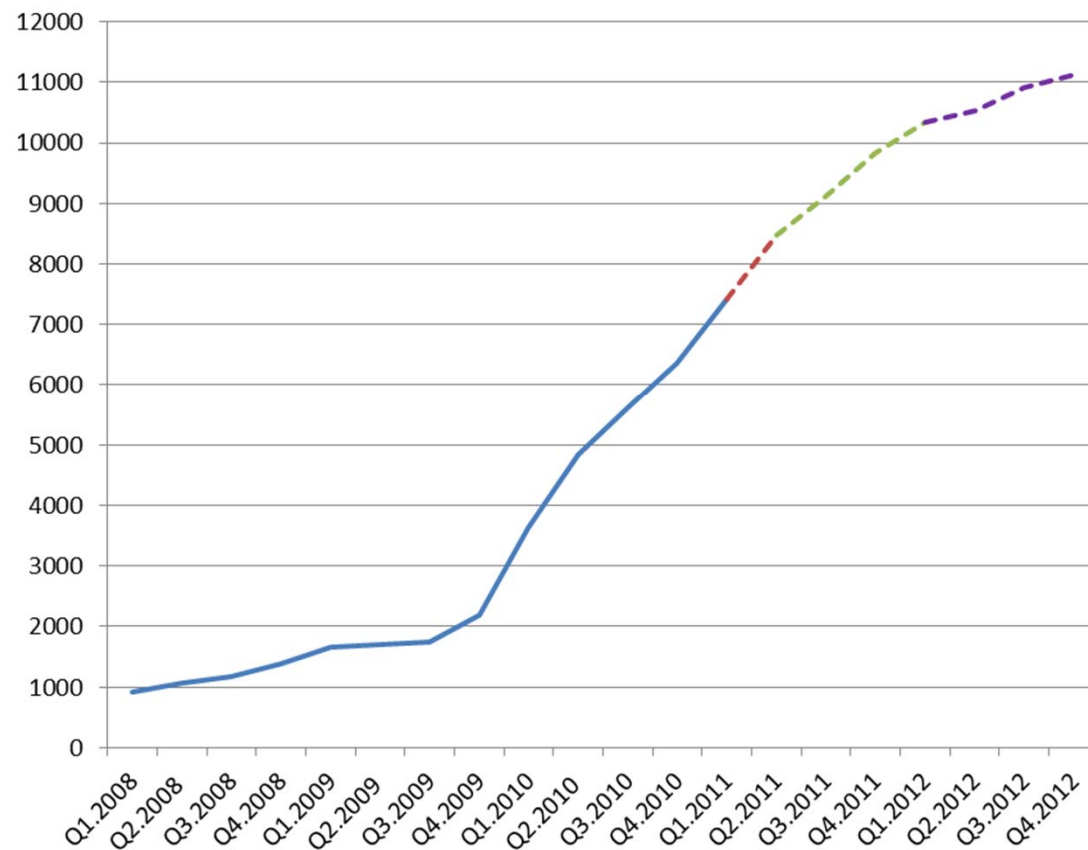


Cohort Expansion

Cohort Expansion

- Diagnosed and treated 1987-99
 - Baseline survey based on original cohort baseline
- Recruitment
 - Privacy laws (HIPAA), new methods needed
 - USC as business associate
 - Pilot testing: Sept. 2007- July 2009

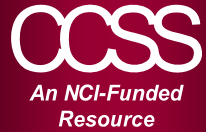
HIPAA Completion by Quarter



N=11,508

75% of
eligible
survivors

>4,000
verbal
HIPAA
completion



New Baseline Recruitment Packet: Incentive for Completion of the Baseline Survey



We Want Your Participation and You'll Want the Gift Card!

We need your help in this important research study!

A \$50 gift card is available for you now, if you complete your survey. Please call 1-800-775-2167 to complete a telephone survey. You may also mail in the print survey or complete the survey online.



Become Our Partner in Research

St. Jude Children's Research Hospital
LTFU
Long Term Follow-Up Study

Baseline Incentive

- \$50 gift card upon completion of survey
- Simplified, colorful presentation
- Mailed January 2013

Expansion Cohort Data Freeze

- Goal: Initial freeze of data for analysis and publication high priority/impact research
 - >60% completion of baseline survey
 - Simultaneous ongoing recruitment
 - Initial processes underway to clean and freeze
 - Medical record abstraction data
 - Expansion baseline data
 - Radiation dosimetry data (first pass)

Recruitment by Institution

as of May 2013

Name	Eligible	HIPAA Returned	% of Elig	Baseline Completed	% of Elig
St. Jude Children's Research Hospital	2,144	1,913	89.2%	1,728	80.6%
Children's Hospital Colorado	596	500	83.9%	414	69.5%
Minneapolis Children's Medical Center	582	468	80.4%	366	62.9%
St. Louis Children's Hospital	421	337	80.0%	274	65.1%
Riley Hospital for Children, Indiana Univ.	848	672	79.2%	509	60.0%
University of Minnesota	279	221	79.2%	167	59.9%
Children's Hospital at Stanford University	371	293	79.0%	232	62.5%
Univ of MI - Mott Children's Hospital	666	525	78.8%	434	65.2%
Emory University	717	564	78.7%	421	58.7%
Children's Hospital of Philadelphia	1,009	783	77.6%	634	62.8%
U.T.M.D. Anderson Cancer Center	607	469	77.3%	337	55.5%
Nationwide Children's Hospital	501	384	76.6%	320	63.9%
Children's Hospital of Pittsburgh	764	581	76.0%	461	60.3%
Children's Hospital of Los Angeles	744	551	74.1%	393	52.8%
Seattle Children's Hospital	829	601	72.5%	457	55.1%
Roswell Park Cancer Institute	241	171	71.0%	132	54.8%
University of California at San Francisco	399	280	70.2%	213	53.4%
Memorial Sloan-Kettering Cancer Center	651	450	69.1%	372	57.1%
Dana-Farber Cancer Institute	905	620	68.5%	428	47.3%
<i>Sub-Total for Initial Data Freeze</i>	<i>13,274</i>	<i>10,383</i>	<i>78.2%</i>	<i>8,292</i>	<i>62.5%</i>
UT Southwestern Medical Center	642	426	66.4%	279	43.5%
UAB/Children's Hospital of Alabama	365	241	66.0%	184	50.4%
City of Hope	132	86	65.2%	61	46.2%
UCLA Mattel Children's Hospital	67	42	62.7%	35	52.2%
Children's National Medical Center	311	117	37.6%	83	26.7%
Texas Children's Hospital	614	213	34.7%	168	27.4%
<i>Sub-Total for non-Data Freeze Sites</i>	<i>2,131</i>	<i>1,125</i>	<i>52.8%</i>	<i>810</i>	<i>38.0%</i>
Total	15,405	11,508	74.7%	9,102	58.4%

Proposed Initial Data Freeze

as of June 2013

Name	Eligible	HIPAA Returned	HIPAA Returned (% of Elig)	Baseline Completed	Baseline Completed (% of HIPAA)	Baseline Completed (% of Elig)
St. Jude Children's Research Hospital	2,144	1,914	89.27%	1,731	90.44%	80.74%
Children's Hospital Colorado	596	500	83.89%	414	82.80%	69.46%
Minneapolis Children's Medical Center	581	467	80.38%	366	78.37%	62.99%
St. Louis Children's Hospital	421	337	80.05%	274	81.31%	65.08%
Riley Hospital for Children, Indiana Univ.	848	674	79.48%	510	75.67%	60.14%
University of Minnesota	279	221	79.21%	167	75.57%	59.86%
Childrens Hospital at Stanford University	371	293	78.98%	233	79.52%	62.80%
Univ of Michigan - Mott Children's Hospital	666	525	78.83%	434	82.67%	65.17%
Emory University	717	564	78.66%	422	74.82%	58.86%
Childrens Hospital of Philadelphia	1,008	784	77.78%	635	80.99%	63.00%
U.T.M.D. Anderson Cancer Center	607	469	77.27%	341	72.71%	56.18%
Nationwide Childrens Hospital (Columbus)	501	385	76.85%	320	83.12%	63.87%
Children's Hospital of Pittsburgh	764	581	76.05%	462	79.52%	60.47%
Children's Hospital of Los Angeles	744	551	74.06%	395	71.69%	53.09%
Seattle Children's Hospital	829	602	72.62%	458	76.08%	55.25%
Roswell Park Cancer Institute	241	171	70.95%	132	77.19%	54.77%
University of California at San Francisco	399	280	70.18%	214	76.43%	53.63%
Memorial Sloan-Kettering Cancer Center	650	450	69.23%	372	82.67%	57.23%
Dana-Farber Cancer Institute	905	620	68.51%	430	69.35%	47.51%
UAB/The Childrens Hospital of Alabama	365	246	67.40%	192	78.05%	52.60%
UT Southwestern Medical Center (Dallas)	642	432	67.29%	285	65.97%	44.39%
City of Hope	131	87	66.41%	64	73.56%	48.85%
UCLA Mattel Children's Hospital	67	42	62.69%	35	83.33%	52.24%
<i>Sub-total Proposed Initial Data Freeze</i>	14,476	11,195	77.33%	8,886	79.37%	61.38%

**2013 Freeze: 23 institutions, 8,886 participants
(61% of eligible)**

MRAF Completion

Inst Code	Institution	Submitted Cases	Selected	Ineligible	Eligible	MRAFs* Completed	% of Eligible Completed
1	University of Minnesota	492	356	77	279	246	88%
2	Children's Hospital Colorado	816	625	29	596	594	99%
3	Children's Hospital of Pittsburgh	1,070	874	110	764	753	99%
4	Children's Hospital at Stanford University	677	479	108	371	358	96%
5	Dana-Farber Cancer Institute	932	932	27	905	905	100%
6	Emory University	1,240	938	221	717	703	98%
7	Children's National Medical Center	576	443	132	311	280	90%
8	U.T.M.D. Anderson Cancer Center	762	654	47	607	593	98%
9	Memorial Sloan-Kettering Cancer Center	1,626	748	97	651	650	99%
11	University of California at San Francisco	796	663	264	399	246	62%+
12	Seattle Children's Hospital	1,161	854	25	829	791	95%
13	Toronto Hospital for Sick Children	2,153	1,724	441	1,283	1,283	100%
15	St. Jude Children's Research Hospital	2,387	2,303	159	2,144	1,674	78%
16	Nationwide Children's Hospital	687	506	5	501	499	99%
17	Roswell Park Cancer Institute	317	284	43	241	240	99%
19	Minneapolis Children's Medical Center	761	592	10	582	582	100%
20	Children's Hospital of Philadelphia	1,505	1,128	119	1,009	992	98%
21	St. Louis Children's Hospital	618	473	52	421	421	100%
22	Children's Hospital of Los Angeles	1,184	762	18	744	731	98%
23	UCLA Medical Center	133	95	28	67	67	100%
24	Riley Hospital for Children, Indiana Univ.	1,253	972	124	848	722	85%
25	UAB/Children's Hospital of Alabama	572	422	57	365	349	96%
26	Univ. of MI/Mott Children's Hospital	932	736	70	666	641	96%
27	UT Southwestern Medical Center	977	750	108	642	642	100%
28	Texas Children's Hospital	1,174	863	249	614	608	99%
29	City of Hope National Medical Center	285	227	95	132	130	99%
Totals		25,086	19,403	2,715	16,688	15,700	

Over 4,000 documents missing: MRAFs, Radiation and Surgical Records

MRAF Completion Probationary Centers

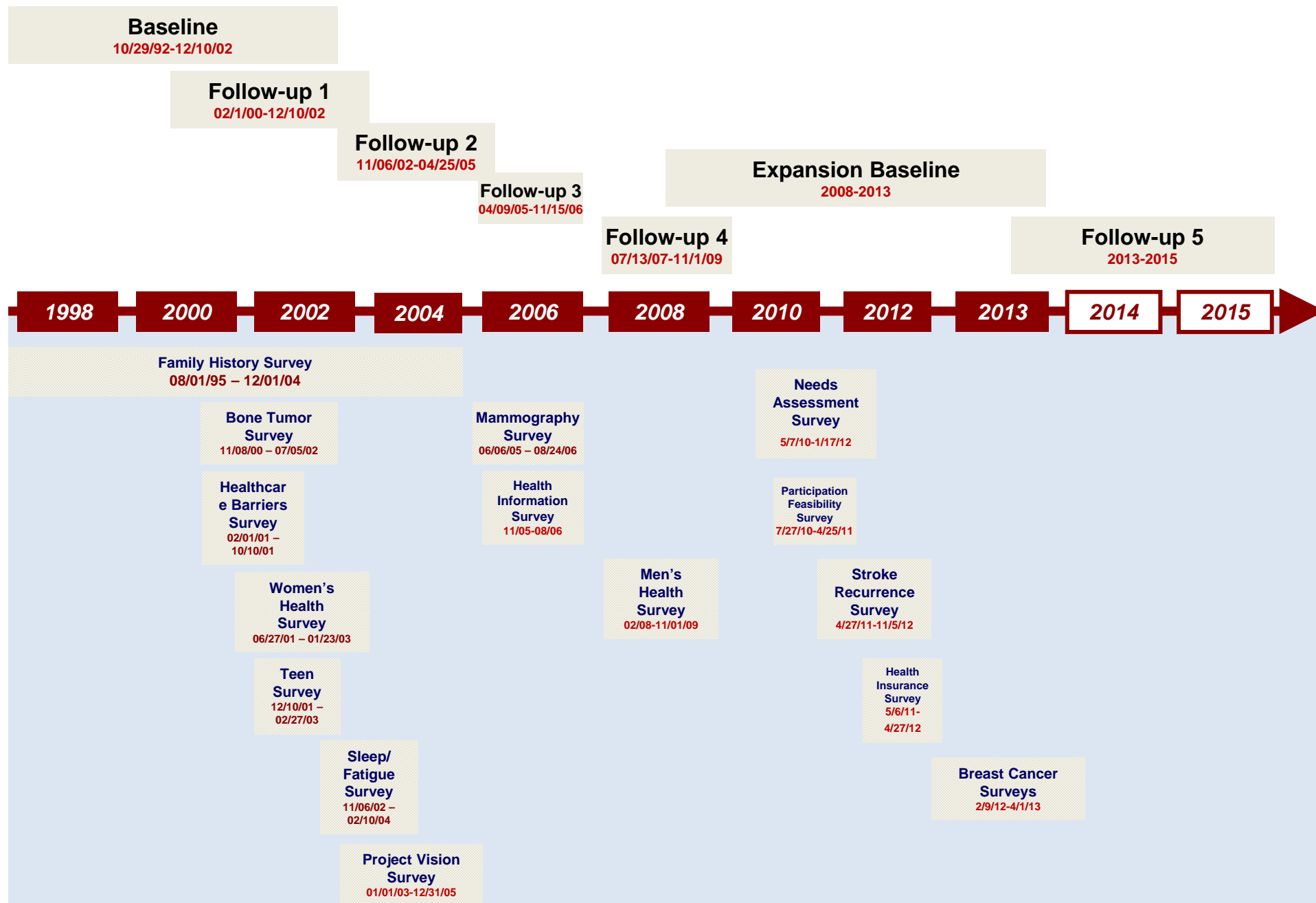
Institution	Submitted Cases	Selected	Ineligible	Eligible	MRAFs* Completed	% of Eligible Completed
<i>New Centers</i>						
Children's Hospital of Orange County	690	593	14	559	267	48%
University of Chicago	464	459	107	352	352	100%
Lurie Children's Hospital of Chicago	1,176	1,114	2	1,112	244	22%
Cook Children's Hospital	620	551	21	530	467	88%

*Medical Record Abstraction Forms submitted online

Sibling Cohort

- Eligibility
 - Full blood sibling of a participant
 - Survived at least five years
- Two-step recruitment
 - Contact participant to obtain “permission” and contact information
 - Contact sibling (or proxy)
- Recruiting 2000, to obtain 1000 siblings
- Mail out began March 2013

Follow-up 5



Follow-up 5

- Purpose: To provide...
 - 5th follow-up of the Original cohort
 - 1st follow-up of the Expanded cohort
 - Harmonization of the cohorts on key outcomes
- Timeline
 - Draft survey provided to Executive Committee
 - Mail out planned for Fall 2013
 - >20,000 eligible participants

Oragene, Blood & Tissue

Kits Sent	Cases (n = 8,334)		Siblings (n = 2,710)	
	<i>n</i>	<i>% of Sent</i>	<i>n</i>	<i>% of Sent</i>
Returned	4,305	51.7%	737	27.2%
Refused	786	9.4%	96	3.5%
Pending	2,617	31.4%	1,672	61.7%
In Tracing	486	5.8%	201	7.4%
Deceased	140	1.7%	4	0.1%

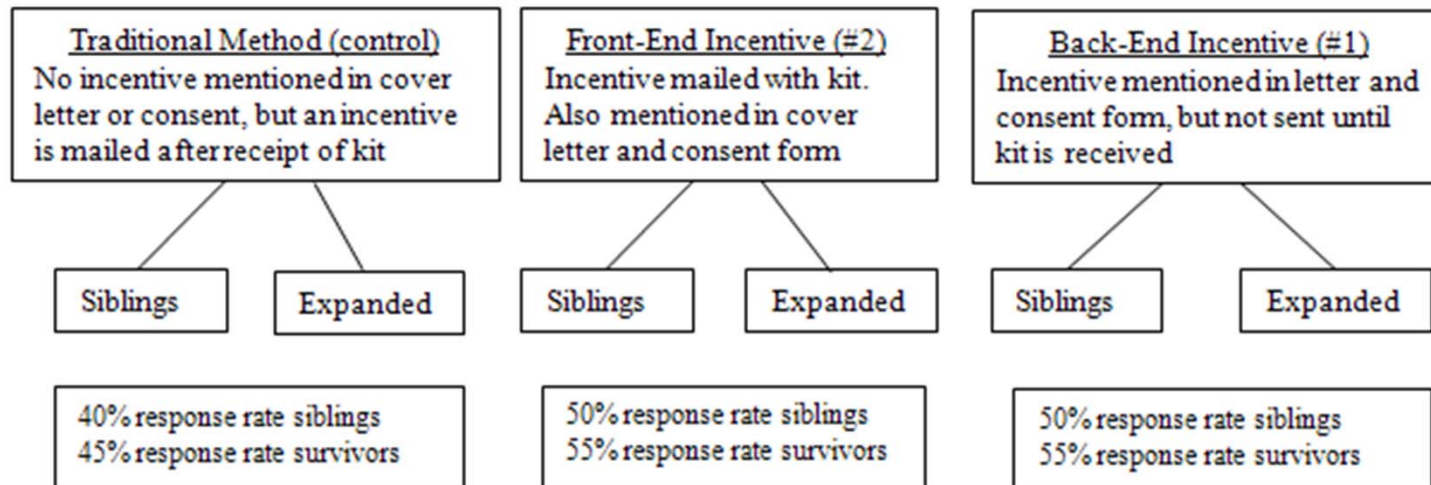
Methodology Summary

- **Send letter, consent form and kit to active participants.**
- Trace non-current addresses. Resend kit if new address found.
- Call non-responders 3-weeks after kit mailing date.
- Call until contact or until reminder message is left.
- Resend kit upon participant request.
- **Mass resend to all non-responders occurred in January 2010.**
- **Second Mass resend to cases (survivors) occurred in February 2012.**

Report Date 5/2013

Oragene Incentive Pilot: Original sibs, Expansion survivors

- Assess the effect of an incentive on the oragene kit return rate (\$25 gift card)
- Mailed October – November 2012



Oragene Incentive Pilot Return Rate at 6-month Follow-up

Expanded Cohort Survivors

Method	Sent	Mailing Date	Response Rate	P value
Front-End	392	10/19/2012	204 (52.0%)	<0.001
Back-End	392	11/9/2012	162 (41.3%)	0.11
Traditional (control)	392	11/30/2012	139 (35.4%)	---

Original Cohort Siblings (previous passive non-responders)

Method	Sent	Mailing Date	Response Rate	P value
Front-End	388	10/12/2012	111 (28.6%)	<0.001
Back-End	388	10/25/2012	65 (16.7%)	0.70
Traditional (control)	388	11/6/2012	60 (15.5%)	---

- SMN Audit 2012
 - Lucie Turcotte, Univ. of Minnesota
 - Comprehensive review of all SMNs
 - Focus on diagnosis, location
 - Datstat entry
 - Provides increased validity of SMN outcomes prior to GWAS analyses
 - SOP developed for uniform adjudication of these outcomes moving forward

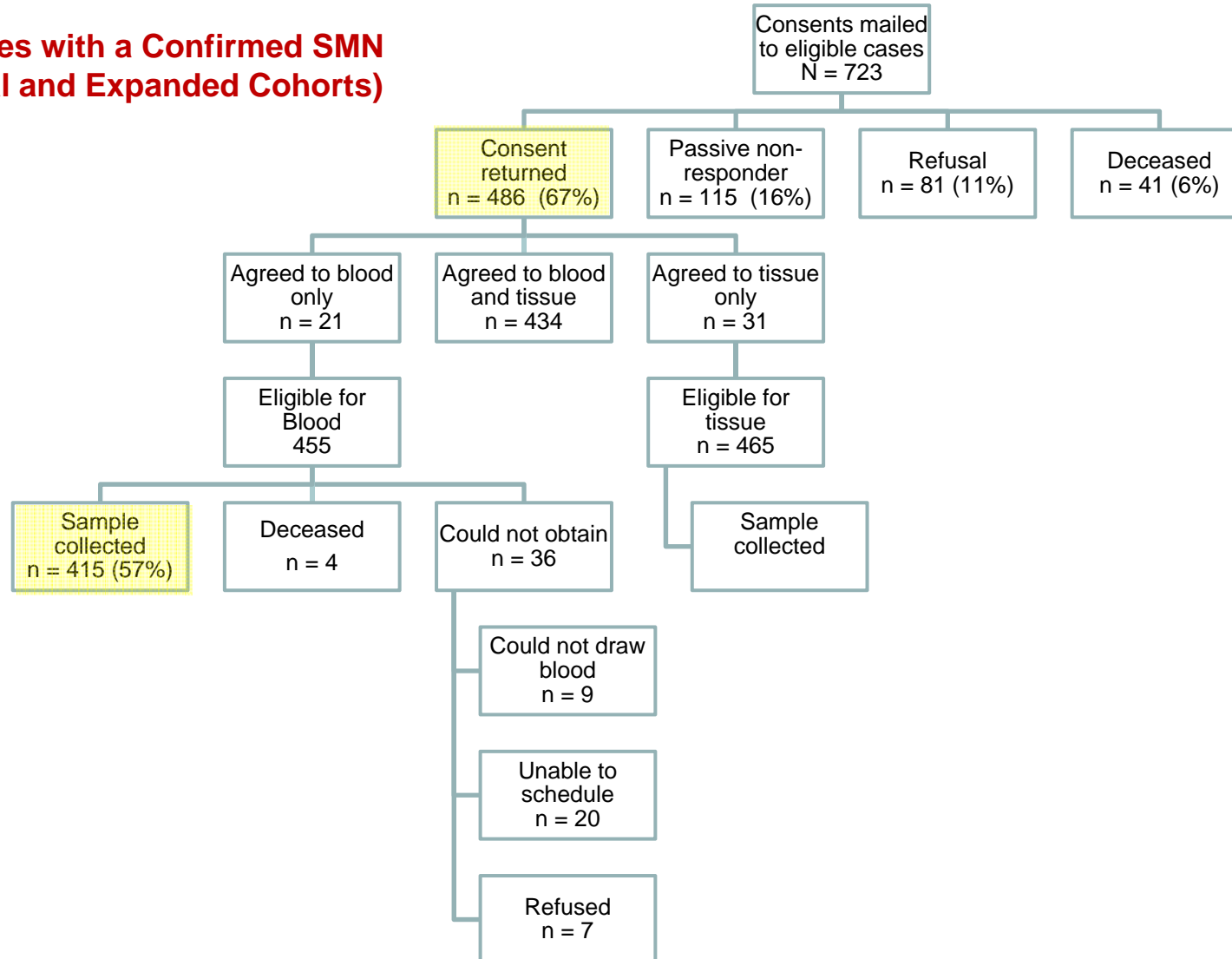
Subsequent Neoplasms by Primary Cancer Diagnosis

Primary Cancer Diagnosis									
Subsequent Neoplasm*	Leukemia	CNS	HD	NHL	Kidney	Neuro-blastoma	Soft tissue sarcoma	Bone cancer	Total
Breast	30	5	223	13	11	3	20	40	345
Meningioma	125	83	3	8	---	1	7	2	229
Other CNS	45	24	9	4	1	1	6	2	92
Thyroid	37	18	52	11	3	11	9	13	154
Soft tissue sarcoma	7	10	24	4	7	5	22	7	86
Leukemia	12	3	17	5	2	4	4	6	53
Bone	6	5	6	7	6	---	13	10	53
Melanoma	9	8	15	2	2	---	9	7	52
Lymphoma	10	4	20	4	---	2	5	1	46
Renal carcinoma	3	2	5	3	1	9	2	3	28
Other carcinoma	31	10	40	11	8	5	16	18	139
NMSC	582	209	876	124	45	9	55	47	1,947
All others	14	7	29	10	2	4	9	8	83
Total	911	388	1,319	206	88	54	177	164	3,307

*Includes in-situ breast cancer and non-invasive melanoma

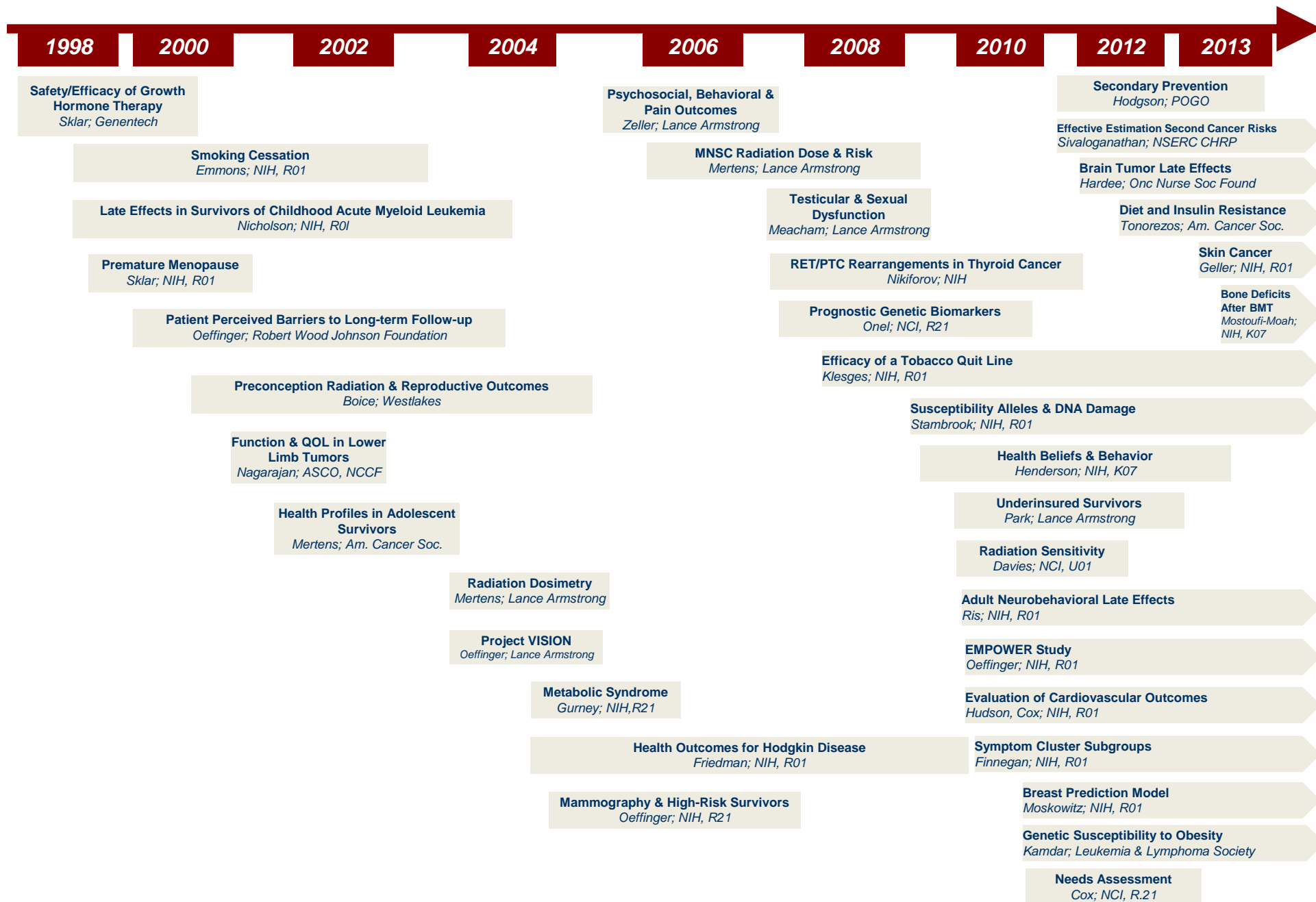
Blood and Tissue Collection

**For Cases with a Confirmed SMN
(Original and Expanded Cohorts)**



Ancillary Studies

CCSS Externally-Funded Ancillary Studies



Ancillary Studies

- Recently completed:
 - Are Adult Survivors of Childhood Cancer Underinsured?
 - Elyse Park, Massachusetts General
 - First and Recurrent Stroke in Survivors of Childhood Cancer
 - Heather Fullerton, UCSF
- New and Ongoing Intervention Studies (plenary session):
 - Screening for Skin Cancer (Geller)
 - ECHOS (Cox & Hudson)
 - EMPOWER (Oeffinger)

Ancillary Studies

- Active:
 - Adult Neurobehavioral Late Effects of Pediatric Low Grade Brain Tumors
 - Doug Ris, R01
 - Health Beliefs and Behavior: Cohort Studies in Pediatric Cancer Survivorship
 - Tara Henderson, K07
 - Prediction Model: Breast Cancer in Women Irradiated for Pediatric Malignancies
 - Chaya Moskowitz, R01

Newsletters

A BRIEF UPDATE

From the Long-Term Follow-Up Study January 2013

<http://ltfu.stjude.org>

Topic: EMPLOYMENT

Why we studied employment issues:
Supporting oneself and adjusting successfully to the work-place are milestones on the path to an independent life. Since treatment for childhood cancer can affect every area of a person's life, it may influence the ability to reach these milestones. We wanted to learn more about the challenges survivors face in relation to employment in the work world.

What we studied:
Employment is such a central concern that we looked at several different aspects of this topic. In separate studies we examined:

- Occupational Skill Level of Adult Childhood Cancer Survivors**
We looked at three occupational categories for survivors and siblings 25 years of age or older:
 - Managerial/professional occupations, for example, scientists, educators, healthcare providers
 - Non-physical service or blue-collar occupations
 - Physical service or blue-collar occupations
Examples of physical and non-physical service or blue-collar occupations include construction, maintenance, or repair, food service, office and administrative support, etc.
- Relationship between Physical/Mental Health and Employment**
We looked at how physical and mental health problems as well as problems with learning, memory, and information processing can affect employment.
- Unemployment among Adult Survivors**
We compared survivors with nearest-age members of the sibling group in two areas:
 - Being unemployed because of illness or disability
 - Being unemployed but able to work and looking for work

What we found:

- Survivors who worked were less often in higher-skilled occupations compared to siblings.
- Survivors' personal income was lower than siblings' incomes within each occupational skill level.
- Survivors in poor physical health were almost eight times more likely to be unemployed compared with adult survivors in good health.

Problems with memory, emotions, and similar mental health limitations were also linked to unemployment but the effects of these types of problems were not as great as the effect of poor physical health.

- Survivors were unemployed for health reasons more often than siblings. They were also more likely to report being unemployed but looking for work than siblings.
- Unemployed survivors had lower education and income and were more likely to rely on publicly funded health insurance.

The many benefits of work include . . .

- The financial means needed for independent living*
- Employer-provided health insurance*
- Opportunities for social interaction and friendships*
- Feelings of competence and self-esteem*

In summary:

- Adult survivors of childhood cancer are more likely to be unemployed and under-employed compared to siblings.
- Survivors may not know their employment rights. They may need help finding employment resources.
- Additional research is needed to identify survivors with health problems affecting their ability to work so they can receive the help they need to succeed in the workplace.



- 3 Brief Updates and 1 Newsletter per year

- Recent topics: Employment, Fertility, Heart Health


- Over 53,500 mailed during 2012


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What's New In CCSS

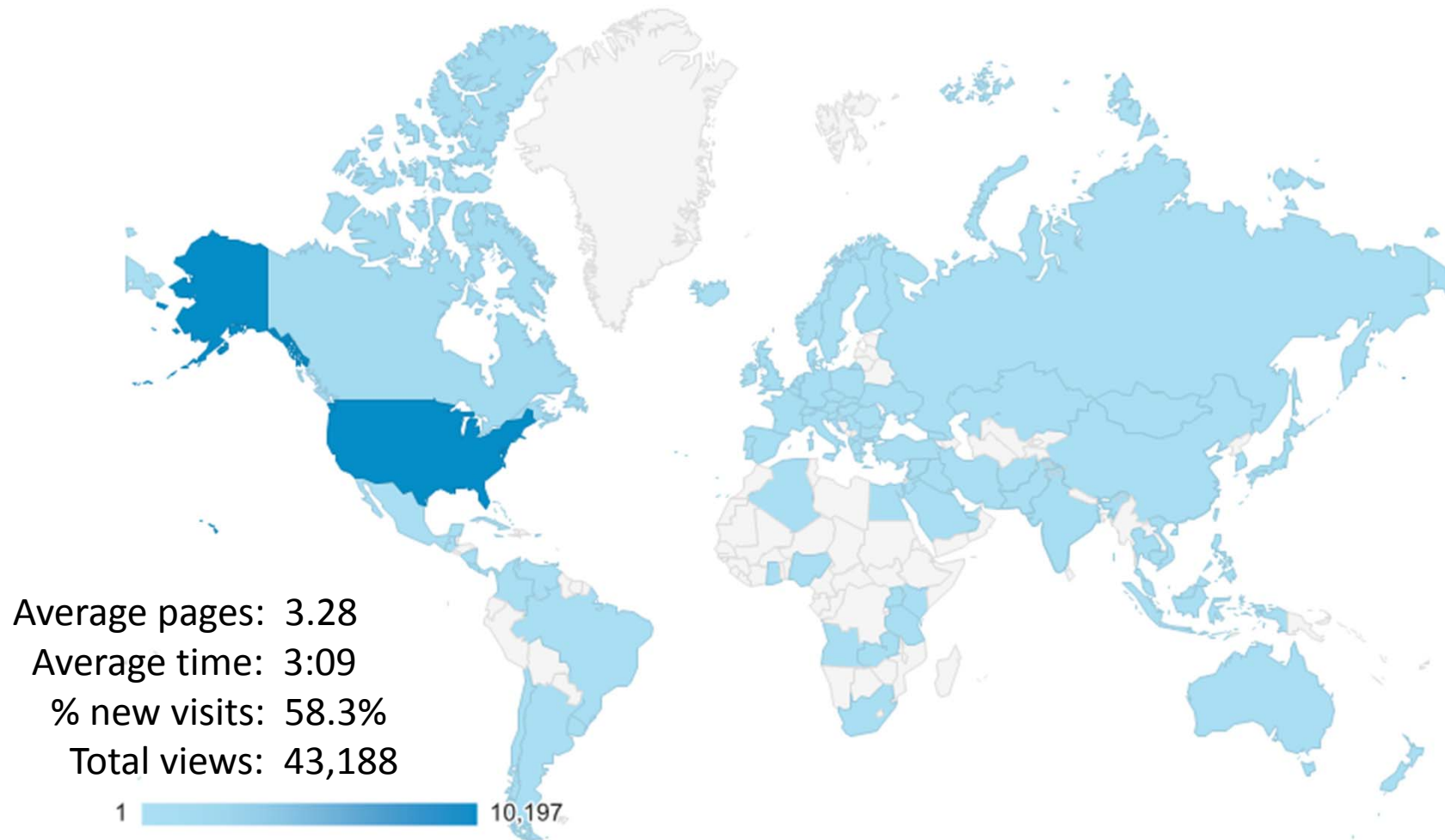
- [Request for proposals for the new CCSS Career Development Award](#)
- [LTFU Study Newsletter Summer/Fall 2012](#)

Publications Update

- [Risk Factors Associated with Secondary Sarcomas in Childhood Cancer Survivors: A Report from the Childhood Cancer Survivor Study.](#) Henderson TO, Int J Radiat Oncol Biol Phys, 2012
- [Psychoactive medication use and neurocognitive function in adult survivors of childhood cancer: A Report from the Childhood Cancer Survivor Study.](#) Brinkman TM, Pediatr Blood Cancer, 2012
- [Melanoma as a subsequent neoplasm in adult survivors of childhood cancer: A Report from the Childhood Cancer Survivor Study.](#) Pappo AS, Pediatr Blood Cancer, 2012
- [Survivor Typologies Predict Medical Surveillance Participation: The Childhood Cancer Survivor Study.](#) Cox CL, Psychooncology, 2012
- [Absolute risk prediction of second primary thyroid cancer among five-year survivors of childhood cancer.](#) Kovalchik SA, J Clin Oncol, 2012
- [Development of a comprehensive health-related needs assessment for adult survivors of childhood cancer.](#) Cox CL, J Cancer Surviv, 2012
- [Statistical analysis of mixed recurrent event data with application to cancer survivor study.](#) Zhu L, Stat Med, 2012

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Website



13,173 visits came from 99 countries/territories (6/1/2012 – 5/31/2013)

Priorities and Challenges

- Ongoing expansion recruitment → Goal: >70% participation
- Data freeze
- Sibling recruitment (n = 1000)
- Follow-up 5 (n>20,000) → Begins Fall 2013
- Oragene collection, expansion population
- Ancillary studies
- Newsletters & Website
- Home sample pilot → Begins Summer 2013



*An NCI-Funded
Resource*