

CCSS Coordinating Center Update

2015 CCSS Investigator Meeting

Todd Gibson, Ph.D.
CCSS Project Director

- Coordinating Center overview
- Major activity updates
 - Recruitment and survey data collection
 - Coordination of biologic sample collection
 - Coordination of SMN activities
 - Updated NDI search
 - Ancillary studies
- Challenges/opportunities

- **Dedicated team located at SJCRH**

Project Coordinator: Aaron McDonald, Ph.D.

Call Center Coordinator: Dayton Rinehart

Databases and Systems: Chris Vukadinovich

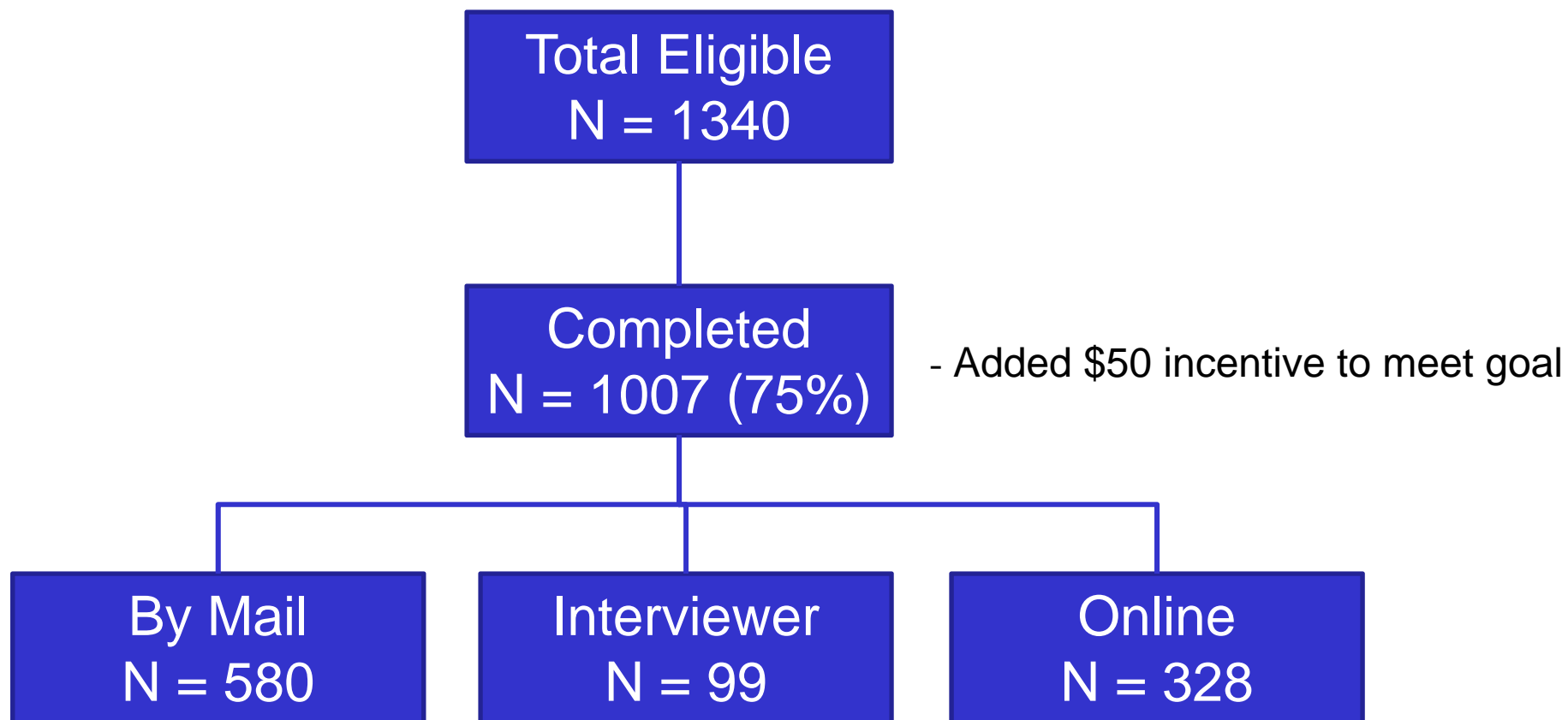


- Statistics from the past year:
 - 54,223 CCSS-related packets mailed
 - 77,536 newsletters mailed
 - 21,608 follow-up emails to non-responders
 - 57,004 outgoing phone calls



- Expanded cohort sibling recruitment
 - Closest age full sibling, alive 5 years after diagnosis
 - Two-step process
 - Survivor permission
 - Sibling consent
 - Goal: 1000 siblings

Flow diagram on page 19 of the meeting book:



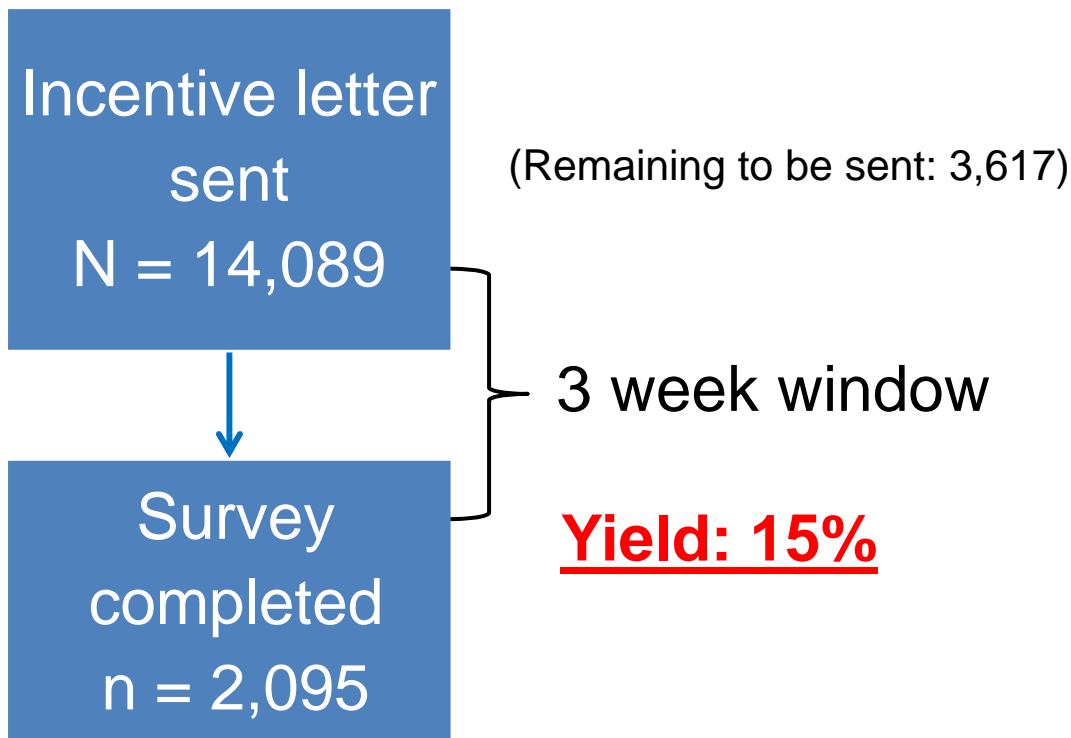
Follow-Up 5

- Purpose: To provide...
 - 5th follow-up of the Original cohort
 - 1st follow-up of the Expanded cohort
 - Harmonization of the cohorts going forward

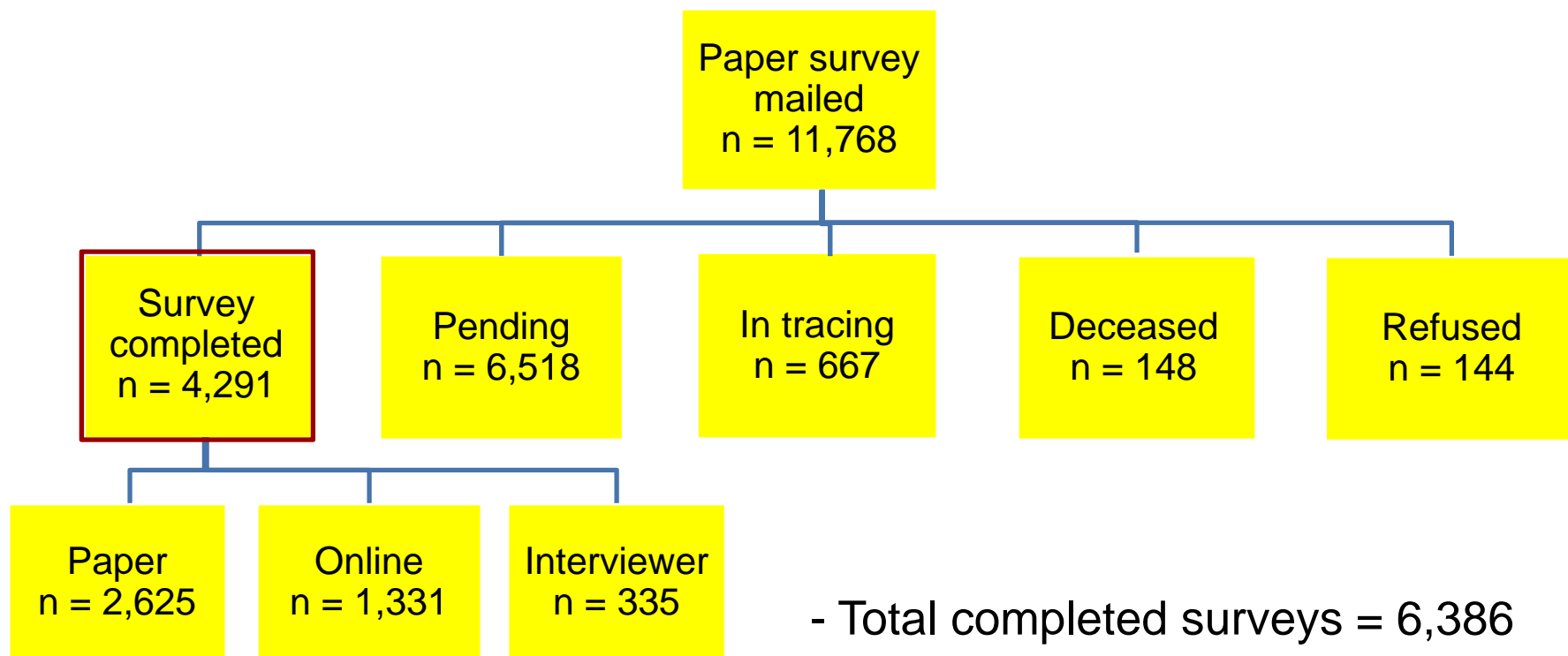
- FU5 survey:
 - Paper questionnaire (36 pages)
 - On-line questionnaire (DatStat)
 - Phone interview (DatStat)

Incentive:

- iPad drawings to promote use of electronic survey



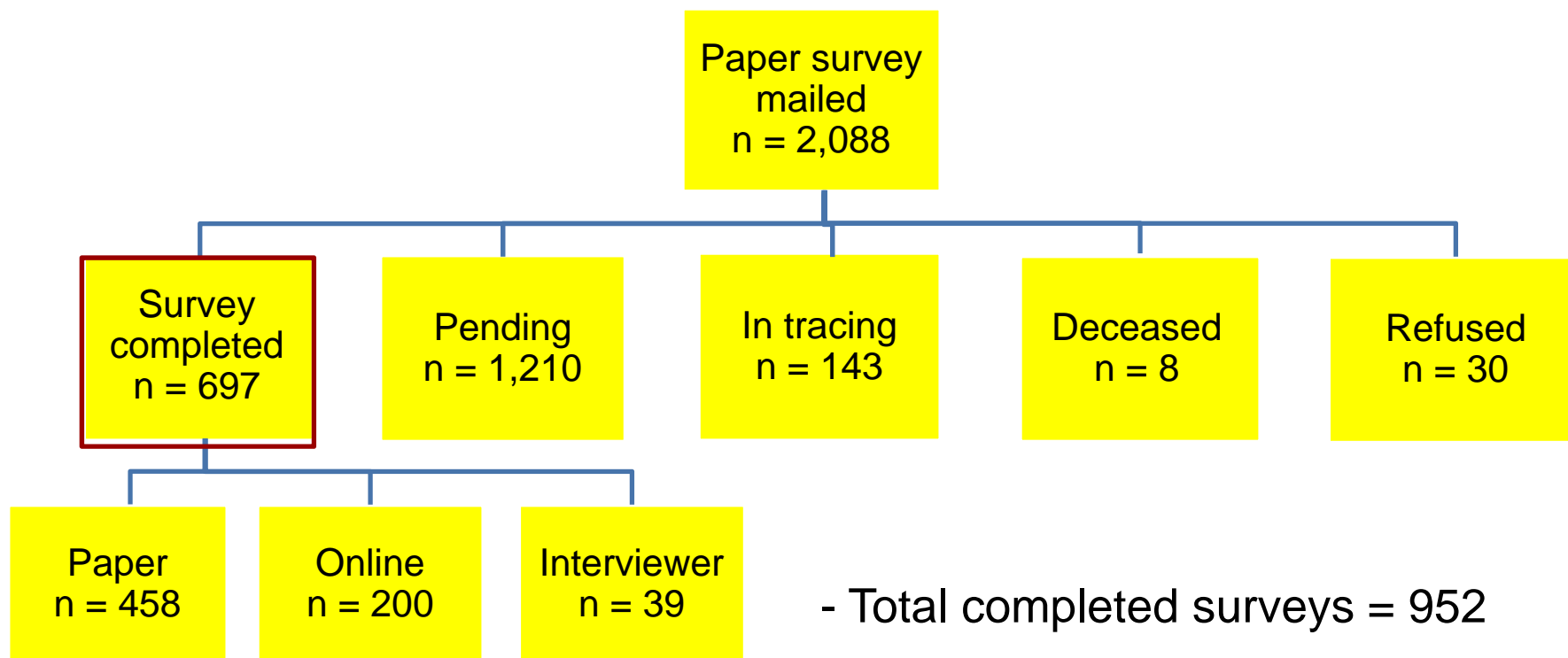
- After 3 weeks, the paper questionnaire is mailed to non-responders



- Total completed surveys = 6,386

- Response rate to date = 46%

- 2,359 incentive letters sent to siblings: 3 week yield = 11%



- Total completed surveys = 952

- Response rate to date = 41%

Follow-Up 5: Future Plans

- Remaining participants eligible for FU5 mailing:
 - 3,617 survivors
 - 2,059 siblings
- Target: All surveys in the field by end of summer
- Follow-up to maximize participation rate
 - Mass re-sends
 - Email reminders
 - Phone calls

- 8,646 DNA samples
- Blood, buccal swab, Oragene mouthwash kits
- Completed kits go to CCSS Biorepository for processing and storage



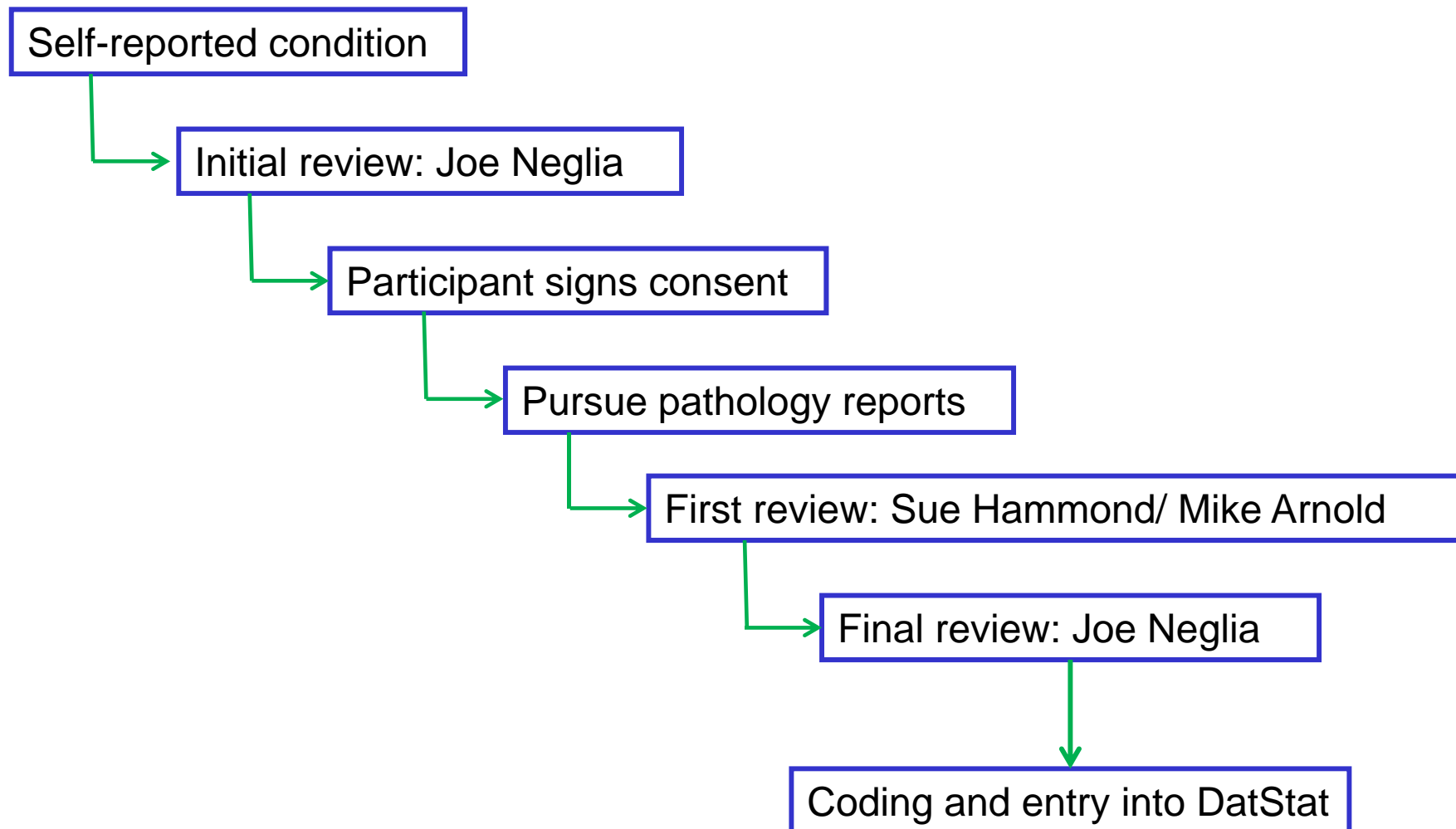
Kits Sent	Original Cohort Cases (n = 8,447)		Original Cohort Siblings (n = 2,710)	
	<i>n</i>	<i>% of Sent</i>	<i>n</i>	<i>% of Sent</i>
Returned	4,550	54%	1,014	37%
Refused	776	9%	173	6%
Pending	2,179	26%	1,061	39%
In Tracing	789	9%	454	17%
Deceased	153	2%	8	0.3%

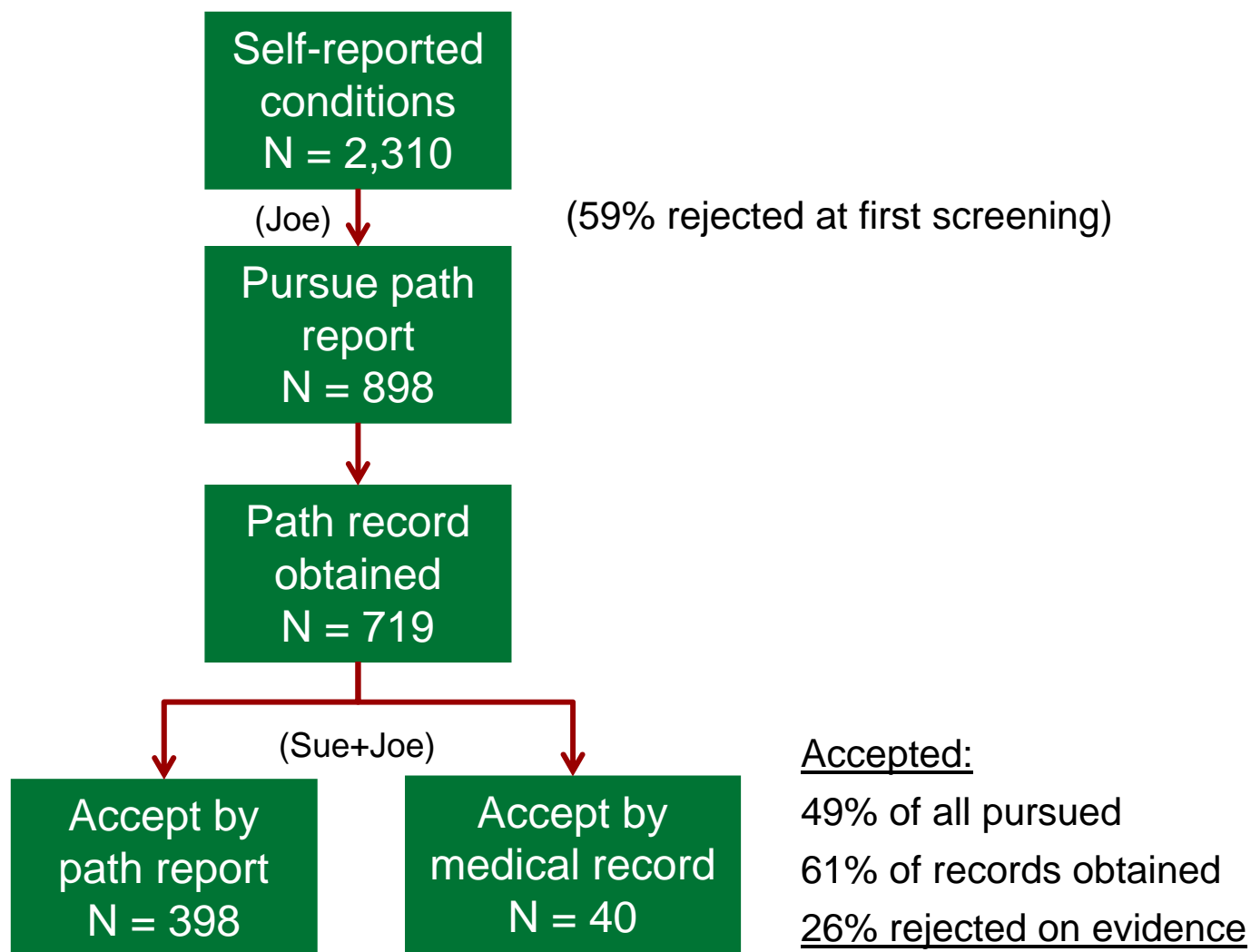
- Oragene collection for the Expanded cohort is ongoing...
 - \$25 front-end incentive

Kits Sent	Expanded Cohort Cases To Date (n = 1,998)	
	<i>n</i>	<i>% of Sent</i>
Returned	1,363	68%
Refused	91	5%
Pending	439	22%
In Tracing	101	5%
Deceased	4	0.2%

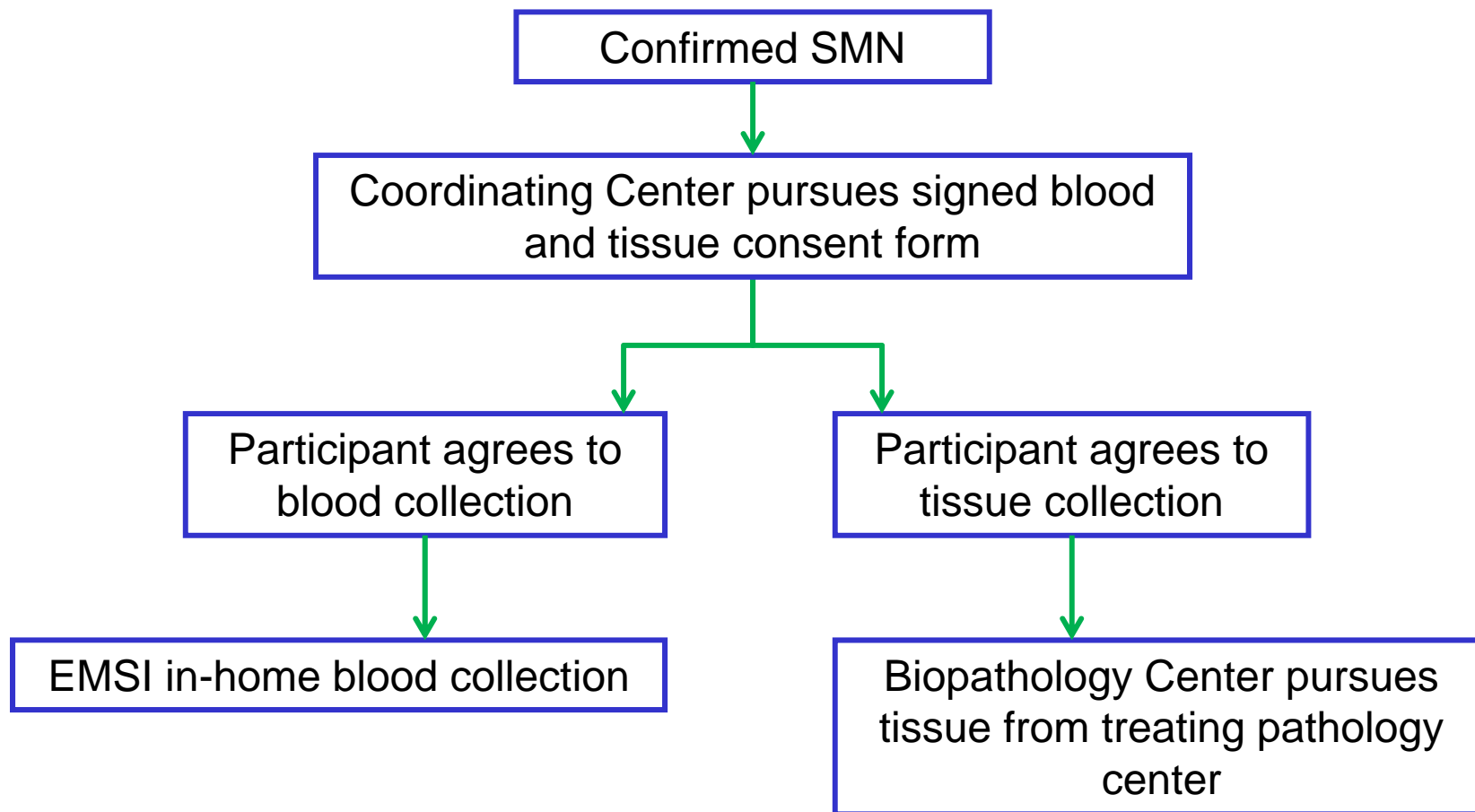
- CCSS outcomes identified by self-report
- Second malignant neoplasms are the leading cause of late mortality
- This warrants additional efforts to:
 - Confirm and accurately identify SMNs
 - Collect SMN tissue samples

SMN Confirmation Process

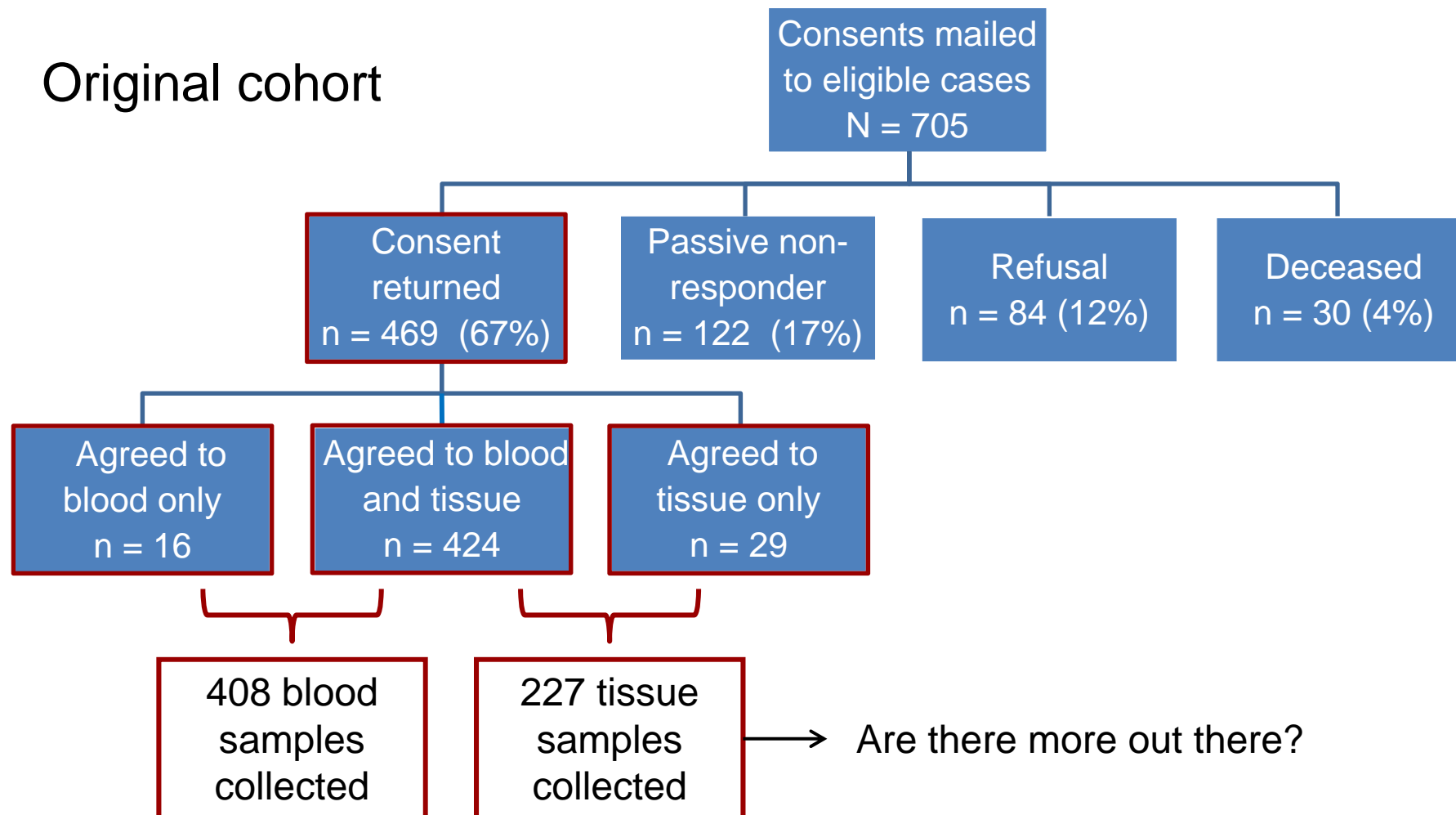




SMN Blood and Tissue Collection Process



Original cohort



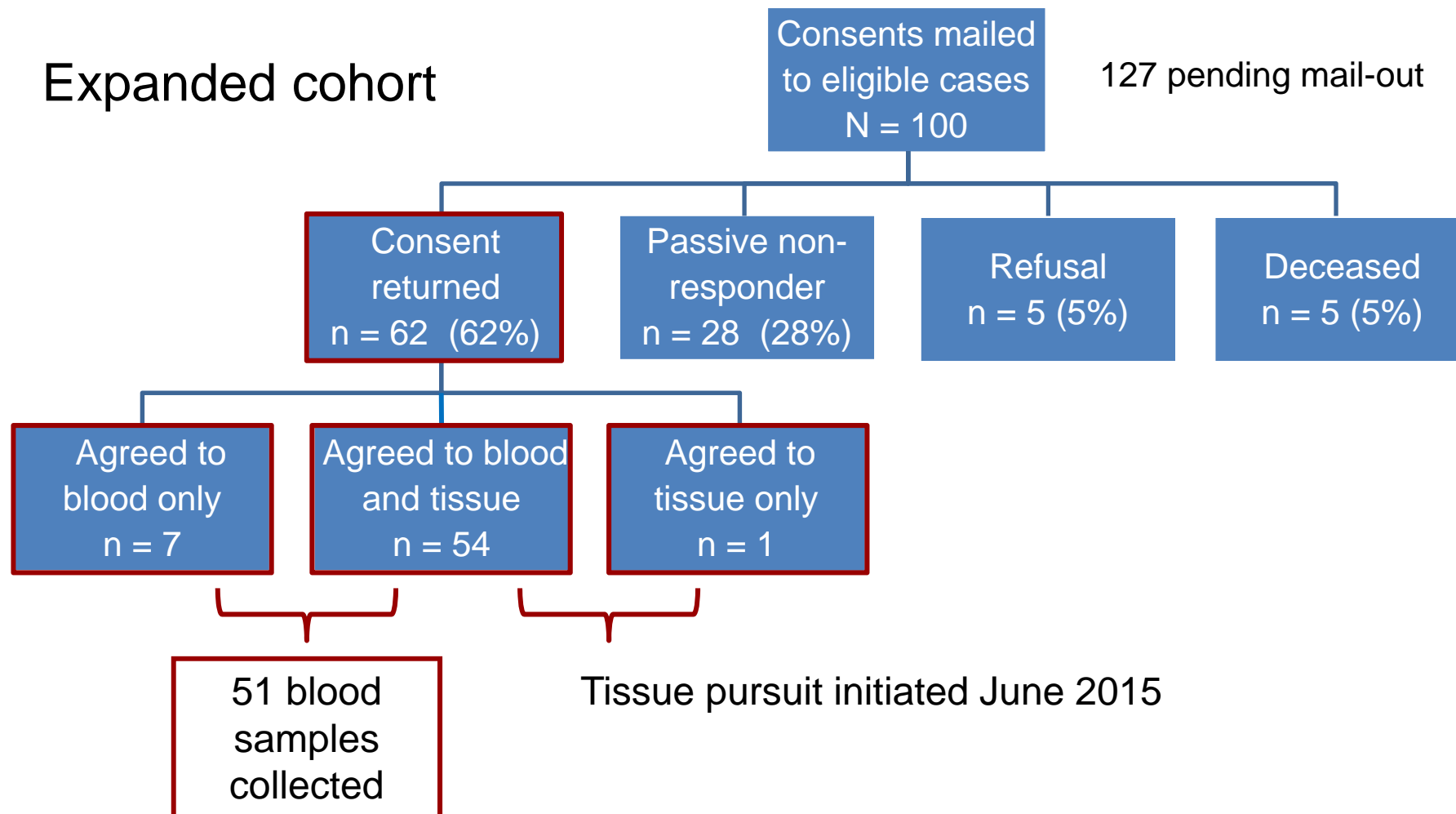
- Tissue enrichment pilot study
 - Maximize collection before facilities discard samples
 - “Full court press” by the Coordinating Center
 - Developed new materials to contact facilities, added phone follow-up
 - Selected 64 breast or thyroid SMNs with consent in-hand
 - Previously pursued unsuccessfully years ago



39 tissue specimens obtained (61%)

(39 unique, 42 total)

Expanded cohort



- Cook Children's Hospital
 - 526 eligible; recruitment by CCH
 - 67% returned HIPAA
 - 48% completed baseline to date
- University of Chicago
 - 353 eligible; recruitment packets mailed May 2015
- Lurie Children's Hospital
 - 792 eligible; recruitment packets mailed May/June 2015
- Children's Hospital of Orange County
 - 593 eligible; plan to initiate recruitment this summer

- Update application submitted June 2015
- Previous search provided deaths through 2007
- N = 31,624 (includes all eligible with unknown vital status)

- Provide support for extramurally-funded ancillary studies

Current studies:

- EMPOWER: Encourage Mammography and Prevention Opportunities for Women Exposed to Radiation (PI: Kevin Oeffinger)
- ASK (PI Alan Geller)
- EQUAL (PI Emily Tonorezos)

Challenges

Participant burden

Need for incentives

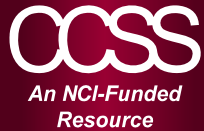
Competitive renewal application

Resource management

Opportunities

Increased efficiency

- Electronic data collection and participant contact
- Updated data management and connected systems
- Cloning



Childhood Cancer Survivor Study

The Childhood Cancer Survivor Study is a NCI-funded resource (U24 CA55727) to promote and facilitate research among long-term survivors of cancer diagnosed during childhood and adolescence.

Investigators interested in potential uses of this resource are encouraged to visit:

<http://ccss.stjude.org>

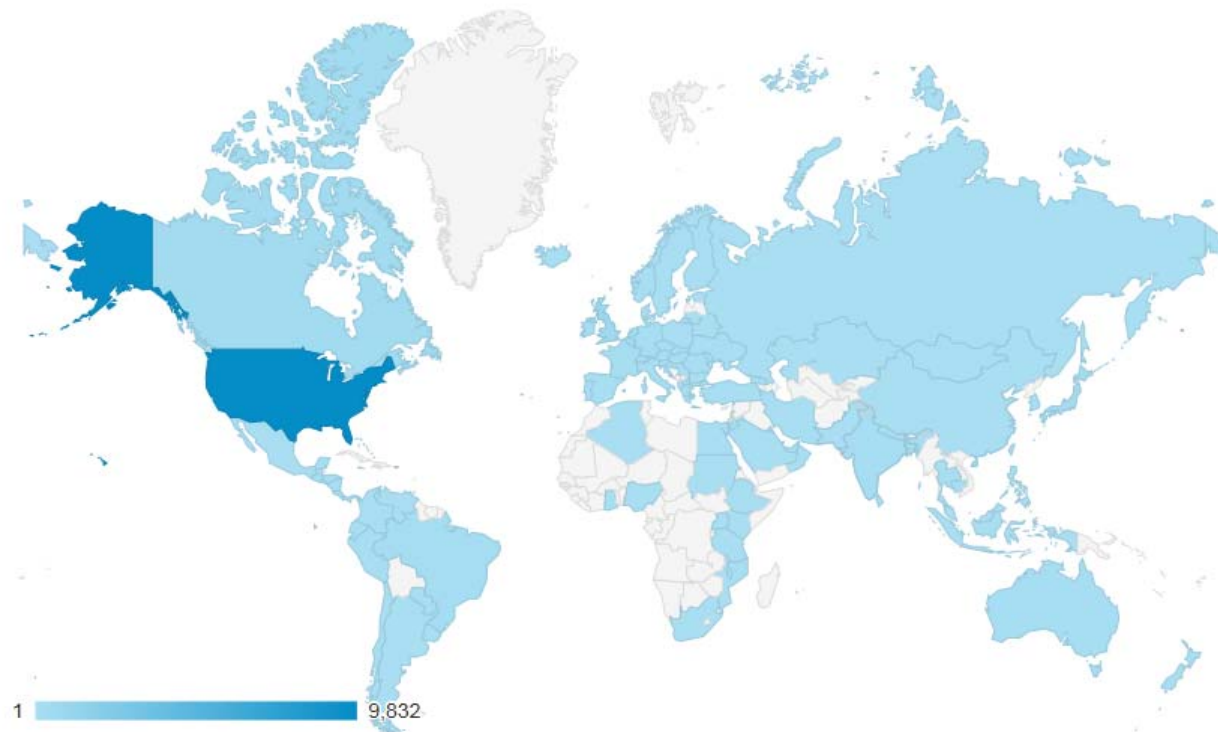
Website in 2014:

Average pages: 3.37

Average time: 03:14

% new visits: 58%

Total views: 44,044



13,062 visits came from 107 countries/territories (Jan 1 – Dec 31, 2014)



Acknowledgements

The Coordinating Center Team

Aaron McDonald

James Ford

Lynn Harrison

Janna Lipford

Olivia McGregor

Lauren Williams

Sheila Crutcher

Komal Kochar

Twanna Smith

Talarescia Gillenwaters

Linda Barnes

Carol Lee

Teresa Hardin

Tishana Sharp

Dayton Rinehart

Renee Massey

Ana Oyuela

Amy Stock

Andrew Cobble

Barbara Lewis

Cynthia Cantu-Voyles

Danixa Semorile

Donna Davis

Kathy Rothammer

Lisa McKinney

Patti Davis

Robbin Daniels



Encourage Mammography and Prevention Opportunities for Women Exposed to Radiation



Principal Investigator: Kevin Oeffinger, M.D. (MSKCC)

Dates of Funding: 09/09 – 07/14

Study Aims: Determine the efficacy of a stepwise two-component intervention on mammography rates; explore moderating/mediating factors.

Data Collection: Recruited 204 eligible females (ages 25-49) who had chest radiation; 12-month follow-up completed by 167 to date

Project Timeline: 12 scheduled 12-month visits still outstanding; imminent completion of Coordinating Center activities

Advancing Survivors' Knowledge About Skin Cancer



Principal Investigator: Alan Geller, R.N., M.P.H. (Harvard)

Dates of Funding: 6/1/13 – 5/31/18

Primary Aim: Improve rates of thorough skin self-examination and receipt of provider full-body skin cancer examination measured at 12 and 18 months

Population: N=800 exposed to radiation, no previous skin cancer, smart phone

Intervention: Teledermatology, physician education



Eligible for
Baseline Survey (Among FU5 responses)
n = 1,219

Survey mailed
n = 200

Survey returned
n = 107 (54%)

Pending
n = 65 (33%)

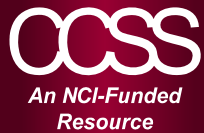
Deceased
n = 1

Refused
n = 8 (4%)

Ineligible
n = 19 (10%)

(In 2 months)

17 without
teledermatology
capable device



The Exercise and Quality of Life After Leukemia Study

EQ^UAL

Principal Investigator: Emily Tonorezos, M.D., M.P.H. (MSKCC)

Primary Aim: Determine the effectiveness of a 24 month remotely delivered diet and physical activity intervention, compared to self-directed weight loss, among obese adult survivors of childhood ALL.

Population: N=400, randomized to intervention (n=200) vs. control (n=200)

Intervention: *Healthways at Hopkins*, phone and web-based counseling

Outcomes: weight, lipids/insulin, diet history at baseline, 12 and 24 months

The Exercise and Quality of Life After Leukemia Study

