

CCSS Investigator Meeting

Principal Investigator Report

June 10, 2015

Arlington, VA

Wednesday, June 10

- Update reports: support facilities and standing committees
- Research presentations

Thursday, June 11

- Ancillary intervention studies
- Career Development Award (CDA) recipients
- Working group reports
- Working group break out sessions

Transition of Leadership

Position	Current Individual(s)	Tenure
Principal Investigator	Greg Armstrong	April 2014
Co-Principal Investigator	Melissa Hudson	2012-Present
Project Director		2014
Cancer Control Working Group	Paul Nathan	2013-Present
Chronic Disease Working Group	Kevin Oeffinger	2013-Present
Epidemiology/Biostatistics Working Group (co-chairs)	Ann Mertens Wendy Leisenring	1994-Present 2004-Present
Genetics Working Group	Smita Bhatia	2009-Present
Psychology Working Group	Kevin Krull	2008-Present
Second Malignancy Working Group	Joe Neglia	2008-Present

Transition of Leadership

Position	Current Individual(s)	Tenure
Principal Investigator	Greg Armstrong	Mid - 2014
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Todd Gibson, PhD



BS Nutrition - Cornell
MS Molecular Biology - Lehigh
PhD Epidemiology – Yale

Post-doctoral Fellow
Radiation Epi Branch, NCI

February 2014
Assistant Member
Epidemiology and Cancer Control
SJCRH

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Transition of Leadership

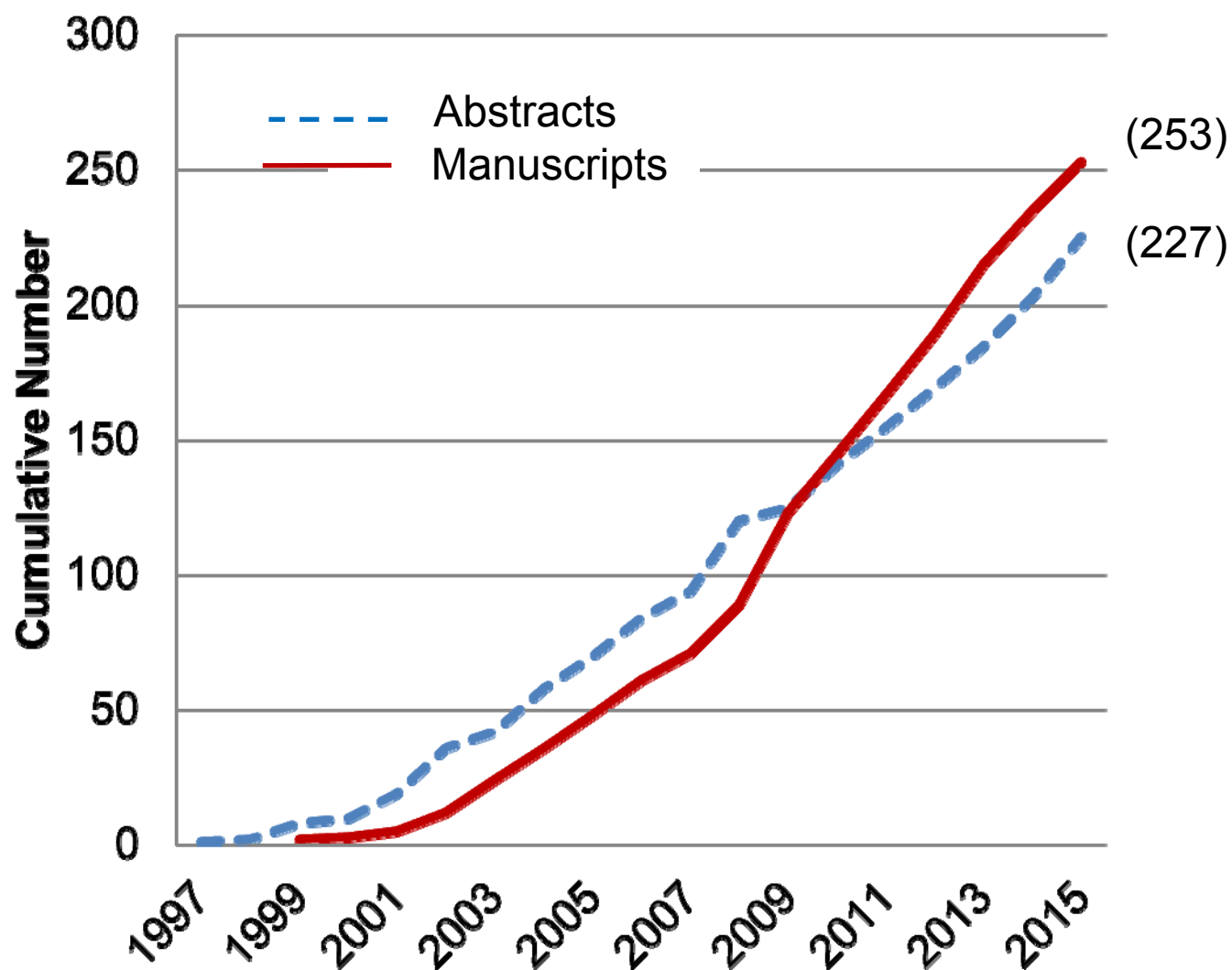
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Cancer Control Working Group	Paul Nathan	2013-Present
Chronic Disease Working Group	Kevin Oeffinger	2013-Present
Epi/Biostatistics Working Group	Yutaka Yasui	2014-Present
Genetics Working Group	Smita Bhatia	2009-Present
Psychology Working Group	Kevin Krull	2008-Present
Second Malignancy Working Group	Joe Neglia	2008-Present

Transition of Leadership: Support Facilities

- CCSS Biopathology Center, Columbus OH
 - Steve Qualman 1994-2008
 - Sue Hammond MD 2008-2015
 - Mike Arnold, MD, PhD 2016
 - MD, PhD UT Southwestern
 - Eric Olsen lab
 - Fellow, NIH
 - Assistant Professor
 - Nationwide Children's Hospital
 - The Ohio State University



CCSS Publications



Impact Factor >10

Ann Intern Med
Lancet Oncology
J Clin Oncol (12)
JNCI
Nat Commun

Impact Factor 5-10

Clin Cancer Res
J Clin Endocrinol Metab
Neurology
Neuro Oncol

Impact Factor <5

Am J Epidemiology
Am J Obstet Gynecol
Arch Phys Med Rehab
Biometrics
Biostatistics
Cancer (5)
CEBP (2)
Health Psychol (2)
Health Services Research
J Cancer Surv (2)
Neuropsychology
Nicotine Tobacco Research
PLOS One
Progress in Pediatric Cardiology
Psychooncology
Pediatr Blood Cancer (5)
Trials

- ASCO (11):
 - 3 oral presentations
 - 1 poster discussion
 - 7 poster presentations
- 14th International Conference (16)
 - 9 oral presentations
 - 7 poster presentations

- COG guidelines for long-term follow-up
 - 82 total references to CCSS manuscripts
 - 50% (36 of 72) guidelines for follow-up after chemotherapy or RT exposure are informed by CCSS publications
- Ancillary Studies
 - 41 studies including 15 RO1, 4 R21, 2 K07, 1 SPORE
 - Awards total \$36.7 million

12 new ancillary studies:

2 randomized intervention trials

ASK about skin cancer (Geller, Harvard RO1)

EQUAL (Tonorezos, MSKCC RO1)

3 utilize biospecimens

Neurofibromin and genotoxins (Nakamura, St. Baldricks)

NF-1 and SMNs (Bhatia, SPORE)

Telomere biology and SMNs (Gramatages, RO1 Provocative Questions)

2 Young Investigators

Bone deficits and adiposity (Mostoufi-Moab, K07)

Health status in Astrocytoma (Effinger, ASCO YI)

5 utilize existing data

= \$12 Million



Cohort Expansion

- Diagnosed and treated 1987-99
 - Baseline survey based on original cohort baseline
- Recruitment: two step process
 - HIPAA ascertainment
 - Baseline survey completion & consent
- Over time and over budget

Overall Cohort

	Original	Expansion	Overall
Eligible	20,690	15,233	35,923
Participant	14,364 (69%)	10,004 (67%)	24,368 (68%)
Active Refusal	3,203 (15%)	1,373 (9%)	4,576 (13%)
Passive Refusal/ Lost to Follow-up	3,123 (15%)	3,587 (24%)	6,710 (19%)

Diagnosis	Expansion Cohort	Overall Cohort	%
Acute Lymphoblastic Leukemia	1819	6148	25.2
Acute Myeloid Leukemia	512	868	3.6
Hodgkin Lymphoma	1069	2996	12.3
Non-Hodgkin Lymphoma	907	1989	8.2
Astrocytoma	1412	2594	10.6
Medulloblastoma	617	997	4.1
Wilms	903	2161	8.9
Neuroblastoma	898	1853	7.6
Soft Tissue Sarcoma	460	1706	7.0
Bone	828	2018	8.4

Expansion Data Freeze

- Highlights:
 - 43% received RT, compared to 68% (original cohort)
 - 28% with leukemia received RT, compared to 69% (original cohort)
 - Increased use of Cisplatin (656 original + 1,401 expansion = 2,057 overall)
 - Increased use of Ifosfamide (97 original + 1,107 expansion = 1,204 overall)
 - Overall:
 - >10,000 received Cyclophosphamide
 - Almost 12,000 received Doxorubicin/Daunorubicin
 - >9,000 received Methotrexate
 - 15,289 received Vincristine

Expansion Data Freeze

- Does not include:
 - CTCAE grading (complete this summer)
 - Siblings (available Fall 2015)
- Ongoing recruitment: 4 minority-enriched institutions

Institution / PI	Survivor Pool	Minority Population	Status
University of Chicago T. Henderson	353	Black: Hispanic (4:1)	Recruitment Ongoing
Cook Children's Hospital P. Bowman	351	Hispanic: Black (3:1)	Recruitment Ongoing
Lurie Children's Hospital J. Reichel	792	Hispanic: Black (2.3: 1)	Recruitment Ongoing
Children's Hospital of Orange County L. Sender	593	Hispanic: Asian: Black (25:5:1)	To begin this Summer

Expanded Cohort Priorities

Charge to Working Group chairs.....

- Develop one or two high priority, maximum impact, analyses that best utilize the data available from the initial dataset from the expanded cohort.
- GOAL: To have at least one analysis from each Working Group approved, completed and “in press” by submission of the competitive renewal (Feb 2016)

12 AOs resulting in 9 currently approved studies:

- Fertility following Contemporary Chemotherapy in Childhood Cancer Survivors (Chow)
- Late mortality by treatment era (Armstrong)
- Health status among adult survivors of childhood cancer by treatment era (Ness)
- Exploring latent clusters using the BSI-18 (D'Agostino/Krull)
- Changing patterns of subsequent neoplasms (Turcotte/ Neglia)
- Changes in long-term outcomes of Hodgkin survivors with contemporary, risk adapted therapy (Oeffinger)
- Impact of chronic disease on health care utilization (Nathan)
- Associations between key therapeutic exposures and outcomes: Gaps in knowledge (Bhatia)

Career Development Award

- Purpose: to create an opportunity for early career investigators and trainees with an aptitude and interest in survivorship research to develop and complete an initial research study within the CCSS.



Career Development Award

Category	Awardee	Project Title
2013		
Junior Faculty	Sogol Mostoufi-Moab, MD, MSCE Children's Hospital of Philadelphia	Overall risk of Chronic Endocrine Disorders in Adult Survivors of Childhood Cancer
2014		
Junior Faculty	Philip Lupo, PhD Baylor College of Medicine	Epigenomic profiling of metabolic outcomes in childhood leukemia survivors
Junior Faculty	Rebecca Howell, PhD UT MD Anderson Cancer Center	Radiation dose reconstruction methods for intensity modulated radiation therapy
Trainee	Giselle Perez, PhD Massachusetts General Hospital	Mental healthcare service availability and utilization among childhood cancer survivors
Trainee	Melissa Schapiro, MD St. Louis Children's Hospital	Cognitive and academic difficulties in survivors of head/neck rhabdomyosarcoma

Career Development Award

Category	Awardee	Project Title
2015		
Junior Faculty	Danielle Friedman, MD Memorial Sloan Kettering	Impact of radiation dose to the pancreas on subsequent risk of diabetes mellitus
Junior Faculty	Adam Esbenshade, MD Vanderbilt University	Using the Cumulative Illness Rating Scale to characterize the burden of chronic conditions
Trainee	Douglas Fair, MD University of Utah	Health care financial burden and missed opportunities for care
Trainee	Aurelie Weinstein Georgia State University	Predictors and outcomes of personal strengths in young adult cancer survivors
International Trainee	Miranda Fidler University of Birmingham, UK	Comparison of risks for mortality and subsequent cancers in the CCSS and the BCCSS

Announcement: Career Development Award 2016

- Two Categories
 - Junior Faculty: single award of \$30,000, salary support
 - Trainee Awards: travel support
 - International trainee- \$10,000
 - US or Canadian-based trainee: \$3000
- Applications due: October 1st
- Start of funding: November 1st
- Required application materials can be found on the CCSS website: <https://ccss.stjude.org/>

Significant and Lasting Influence on the Field Over the Next Five Years

- **Exploitation of expanded cohort data (1970-99)**
 - Identify how risk stratification of therapy has changed patterns of late effects
 - Low risk patients: reduced therapeutic expose, fewer late effects?
 - ALL with no cranial RT, reduced chest RT and anthracyclines for HL
 - High risk patients: intensified therapy, changing pattern of late effects?
 - High risk neuroblastoma, multi-modal therapy for CNS tumors
 - Key changes in therapeutic exposure:
 - 43% received RT 1987-99, compared to 68% in the original cohort (1970-86)
 - 28% with leukemia received cranial RT 1987-99, compared to 69% in the original cohort
 - Increased use of Cisplatin (656 original cohort + 1,401 in expansion = 2,057 overall)
 - Increased use of Ifosfamide (97 original cohort + 1,107 in expansion = 1,204 overall)
 - Almost 12,000 survivors exposed to anthracyclines overall
 - Over 10,000 exposed to cyclophosphamide overall

Significant and Lasting Influence on the Field Over the Next Five Years

- Resource for genetic investigation (n=5,739)
 - GWAS Collaboration with Division of Cancer Epidemiology and Genetics
 - Identify genetic variants that modify the effect of RT and chemotherapy on risk of subsequent neoplasms, and of risk independent of treatment exposure
 - Whole exome analysis to begin in late 2015
 - Request For Proposals (RFP):
 - unparalleled resource for investigation of associations between genetic variants and risk of other chronic health conditions
 - To be issued in 2015
 - GWAS data available on dbGaP
 - Full annotation with exposure and outcome data pending completion and approval through the application process
- Ongoing resource for intervention studies

Competitive Renewal of CA-55727

- Funding Opportunity Announcement: expected this summer
- Deadline for submission: early 2016
- CCSS Executive Committee
 - February 2014 Strategic Planning Retreat (San Diego)
 - September 2014 Executive Committee Meeting (Memphis)
- Unanimously determined that cohort expansion at this time NOT recommended
- Unanimously agreed that CCSS should, for the next five years, invest in opportunities to improve outcome validity through Direct Assessment of Key Outcomes
- Pilot two strategies for direct assessment:
 - CCSS Home Sample
 - mHealth technology to develop a “connected cohort”

Direct Physiologic Assessment: Home Sampling for Key Outcomes

Self Report vs. Direct Assessment

Key Outcomes that could be ascertained by Direct Assessment	
Primary Outcomes	Direct Measure
Obesity	Height, Weight, BMI
Hypertension	Blood Pressure
Adiposity	Waist circumference
Diabetes	Insulin, Hgb A1c, Fasting Blood Glucose
Dyslipidemia	LDL, HDL, Triglycerides, Cholesterol
Renal Function/Failure	Creatinine, serum electrolytes, GFR
Hepatic Function/Failure	Liver function test panel
Future genetic and/or biomarker studies	Bank whole blood

Expected Yield from Home Sample

	Self report*	Additional Yield from Direct Assessment*
Hypertension	15.2%	6.4%
Fasting lipid panel	18.6%	29.1%
Obesity	16.1%	20.4%
Diabetes mellitus	4.1%	1.3%
Pre-diabetes	1.3%	32.7%
Hepatopathy	3.3%	7.4%
Renal dysfunction	2.1%	2.2%

* Hudson MM, Ness KK et al, JAMA 2013

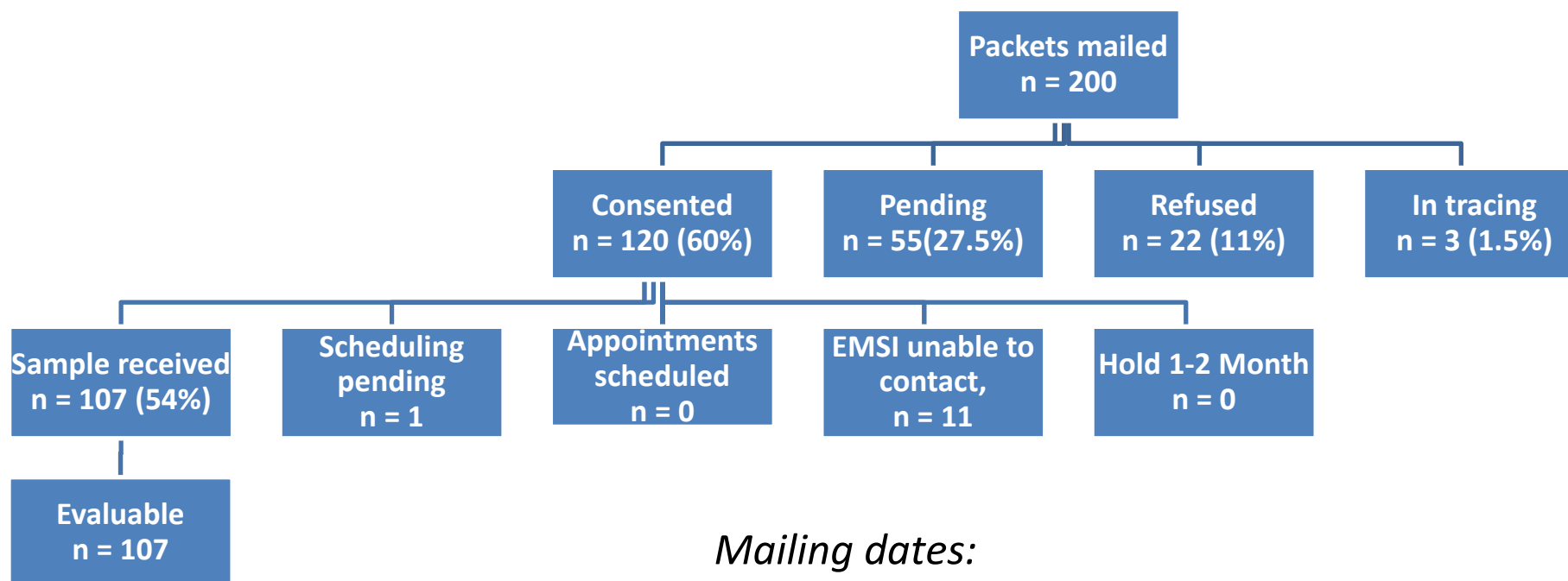
Approach

- Use of a small validation set to correct the bias of estimates obtained within a larger study while maintaining efficiency
- Would allow “correction” across the entire cohort
- EMSI (Examination Mgt Services, Inc) to provide in home assessment
-\$50 gift card upon study completion

Home Sampling Pilot Project

- Determine the feasibility of sampling various measures in-person using a home-based approach
- Develop procedures and preliminary data in advance of next competitive renewal

Pilot Results



Mailing dates:

09/22/14 –Initial mail out

11/19/14 –Mass Resend

12/09/14 – Email sent to “Pending” pts

03/30/15 –Mass Resend

Summary of Proposal

To determine the feasibility of direct assessment of survivors by:

- Recruitment of 5,000 CCSS participants for home sample, direct assessment by EMSI including a \$50 incentive.
- Use of home sample results to correct bias in results across the entire cohort for key outcomes.

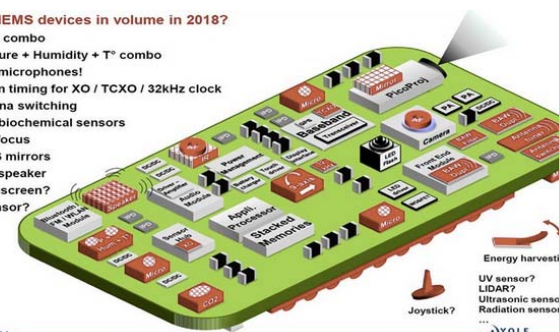
Direct Physiologic Assessment: Mobile Health Technology

Direct Physiologic Assessment: Mobile Health Technology



New MEMS devices in volume in 2018?

- 9-axis combo
- Pressure + Humidity + T° combo
- More microphones!
- Silicon timing for XO / TCXO / 32kHz clock
- Antenna switching
- Gas / biochemical sensors
- Auto-focus
- MEMS mirrors
- Microspeaker
- Touchscreen?
- IR sensor?



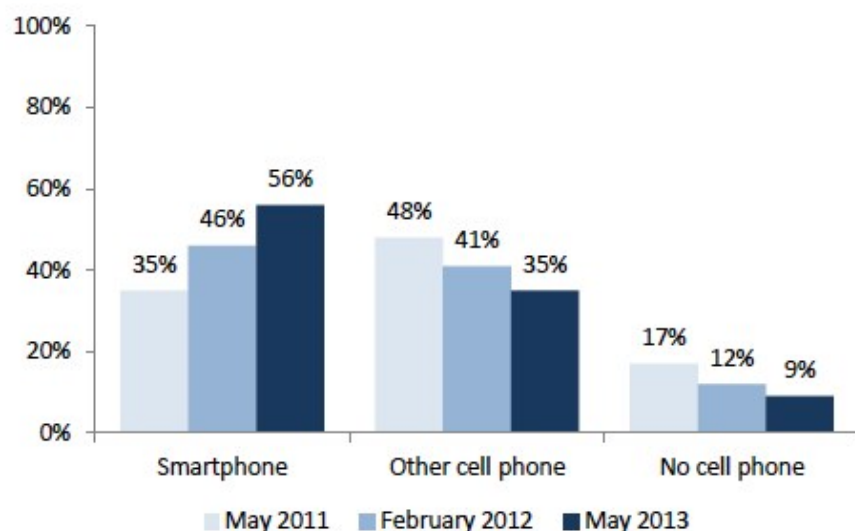
© 2013 - 11

The price has decreased 80% to 90% in the last 5 years

91% of smartphone owners keep their smartphones within **3 feet**, **24 hours** a day.

Changes in smartphone ownership, 2011–2013

% of all U.S. adults who own...



Source: Pew Research Center's Internet & American Life Project April 26-May 22, 2011, January 20-February 19, 2012, and April 17-May 19, 2013 tracking surveys. For 2013 data, n=2,252 adults and survey includes 1,127 cell phone interviews. All surveys include Spanish-language interviews.

Smartphone Ownership Highest Among Young Adults, Those With High Income/Education Levels

% of U.S. adults in each group who own
a smartphone

All adults	64%
Male	66
Female	63
18-29	85
30-49	79
50-64	54
65+	27
White, non-Hispanic	61
Black, non-Hispanic	70
Hispanic	71
HS grad or less	52
Some college	69

CCSS Participants: FU5 Early Responders (N=6,729)

Online survey completion: 3,482

Paper completion: 2,768

Phone completion: 479

1. Smart phone? 74%
2. How do you access the internet?
 - PC 86%
 - Smartphone 70%
 - Tablet 47%
3. Willing to receive study-related text messages? 53%
4. Participate in electronic health monitoring studies?
 - Very likely 42%
 - Possibly 35%
 - Unlikely 23%

- Survey completion
 - Paper (US mail, teleforms)
 - Telephone interview
 - Web-based completion (Datstat)
- Potential: Mobile/tablet-based communication
- Potential: Direct assessment, sensor-based

The Fourth Dimension

Vision for Mobile-based Communication

1. Push

- Resource for Survivors: Newsletters and Health-related information/updates
- Reminders to complete surveys
- Invite to participate in additional studies
- Resource for **treatment information**

2. Pull

- Updates on key health outcomes (second cancers, heart disease)
- Complete full surveys (tablet)

3. Monitor and Intervene

A Completely Connected Survivor Sub-Cohort

How to Achieve the Vision? Collaboration

1. Push



2. Pull

3. Monitor and Intervene



The Health *e*Heart Study™

Using big data to reduce heart disease

Who is Salesforce?

#1 in Enterprise Cloud Computing & Customer Relationship Management

#1

Forbes

The
Economist

World's Most
Innovative Company
2011, 2012, 2013, 2014

#1

IDC

Enterprise Cloud
Computing
Market Share

FORTUNE
WORLD'S MOST
ADMIRED
COMPANIES
2013
#1 COMPUTER SOFTWARE

#1

2013
MARKET LEADER

Market Leader:
Enterprise, MidMarket,
SMB & Sales Force
Automation

FORTUNE
100
BEST
COMPANIES
TO WORK FOR
2014
7 YEARS ON THE LIST!

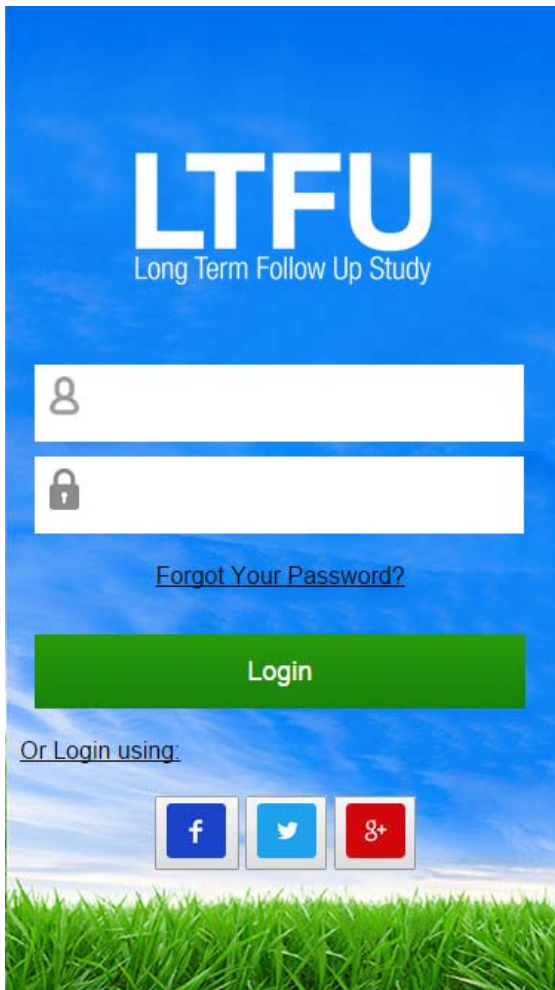


The Unveiling...



- Salesforce + Cloud Sherpas
- Development: Jan 2015
- Deployment: late Summer 2015
- Features:
 - Push newsletter and weekly message
 - Link to other resources for survivors
 - Provide resource for treatment information
 - Push reminders
 - Pull SMN and Cardiac outcomes
- Build a community of mobile-enabled survivors

LTFU Participant App






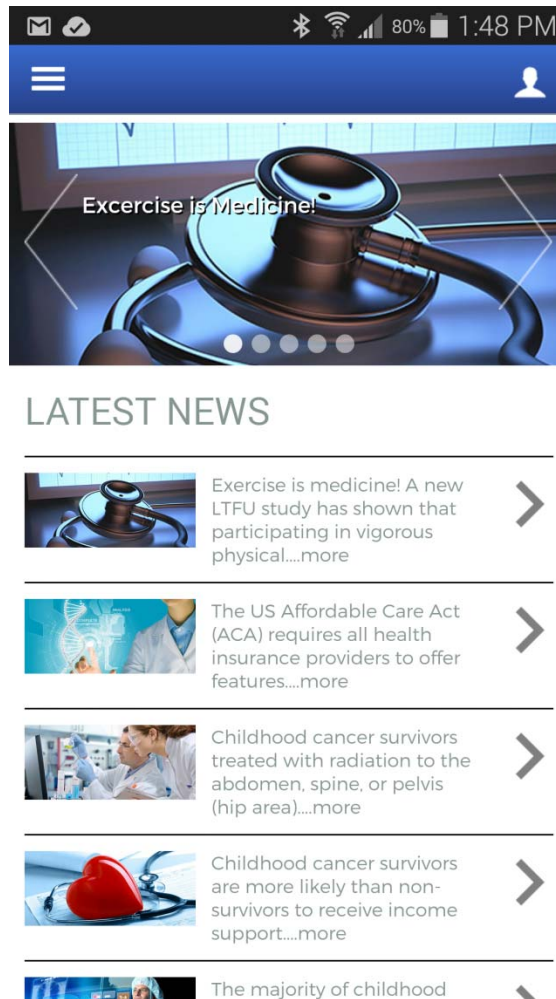
LTFU
Long Term Follow Up Study

[Forgot Your Password?](#)

Login






Or Login using:

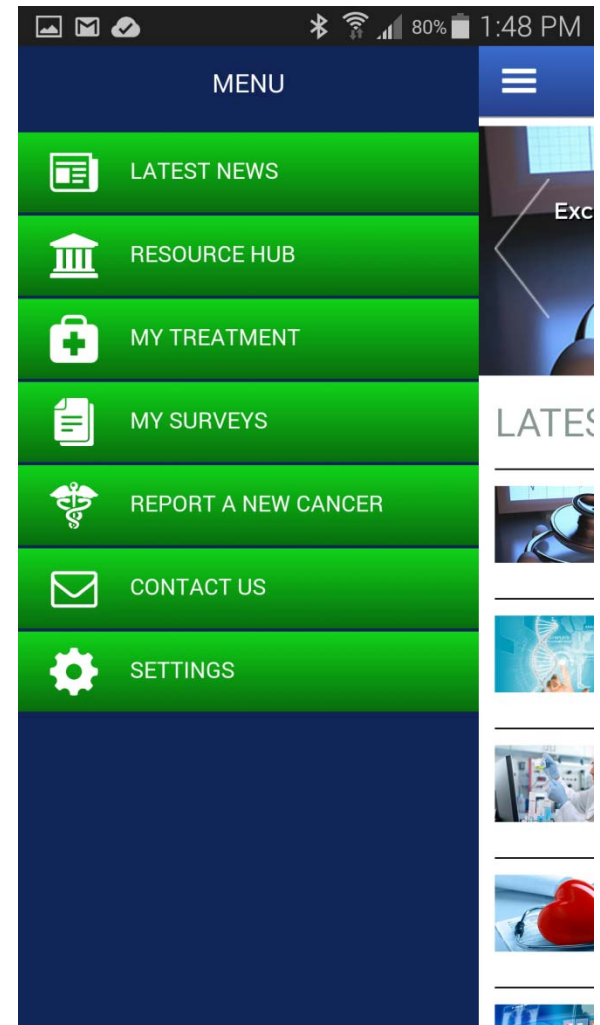
  










Exercise is Medicine!

LATEST NEWS

-  Exercise is medicine! A new LTFU study has shown that participating in vigorous physical....more
-  The US Affordable Care Act (ACA) requires all health insurance providers to offer features....more
-  Childhood cancer survivors treated with radiation to the abdomen, spine, or pelvis (hip area)....more
-  Childhood cancer survivors are more likely than non-survivors to receive income support....more
-  The majority of childhood



MENU

-  **LATEST NEWS**
-  **RESOURCE HUB**
-  **MY TREATMENT**
-  **MY SURVEYS**
-  **REPORT A NEW CANCER**
-  **CONTACT US**
-  **SETTINGS**

How to Achieve the Vision? Collaboration

1. Push

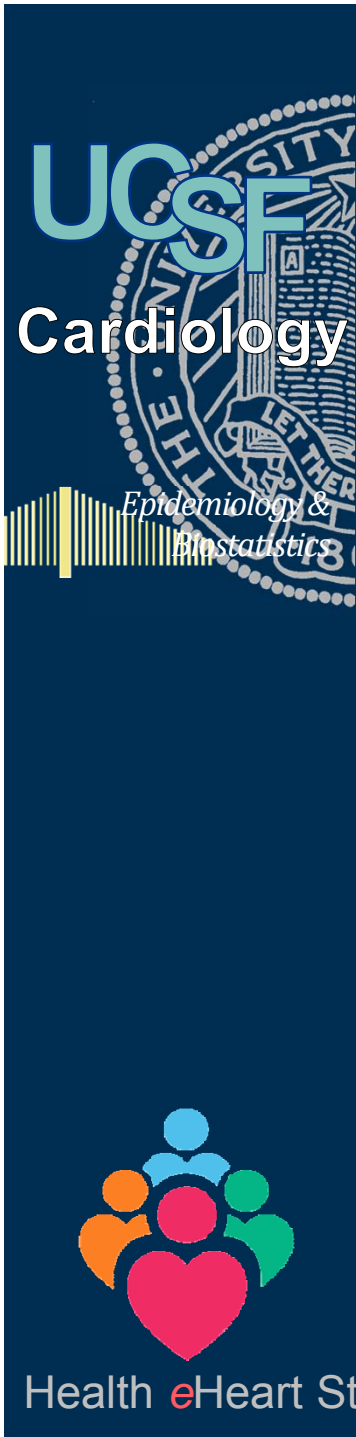


2. Pull

3. Monitor and Intervene



The Health *e*Heart Study™
Using big data to reduce heart disease



What is the Health eHeart Study?

A CV-focused “eCohort” study that leverages internet & mobile technology to collect real-time, real-life measures and outcomes via surveys, apps, sensors, electronic health information and biospecimens.

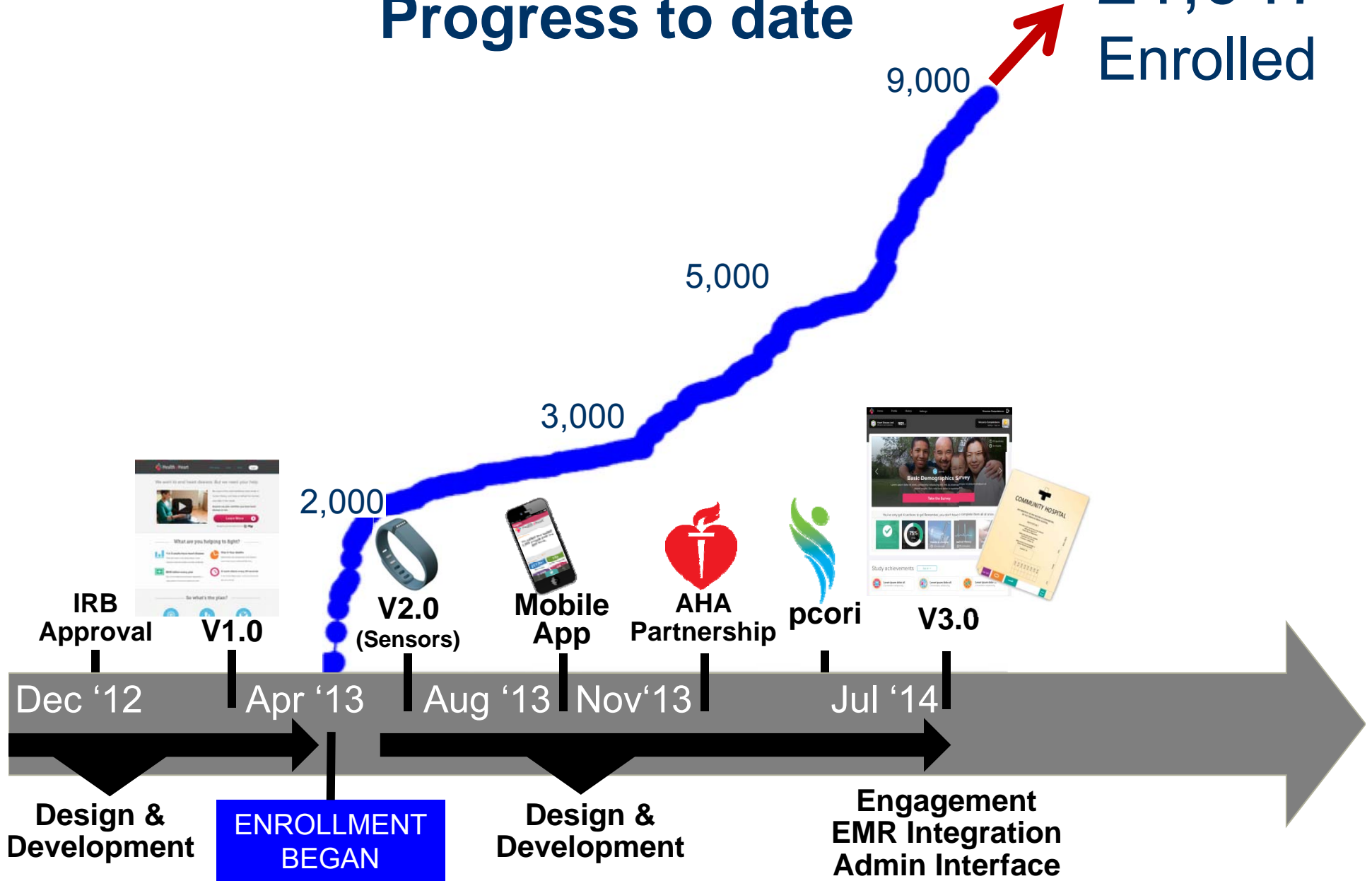
Collecting “big data” to predict, prevent and treat heart disease.

ELIGIBLE PARTICIPANTS:

Any adult ≥ 18 years of age

Progress to date

21,047
Enrolled





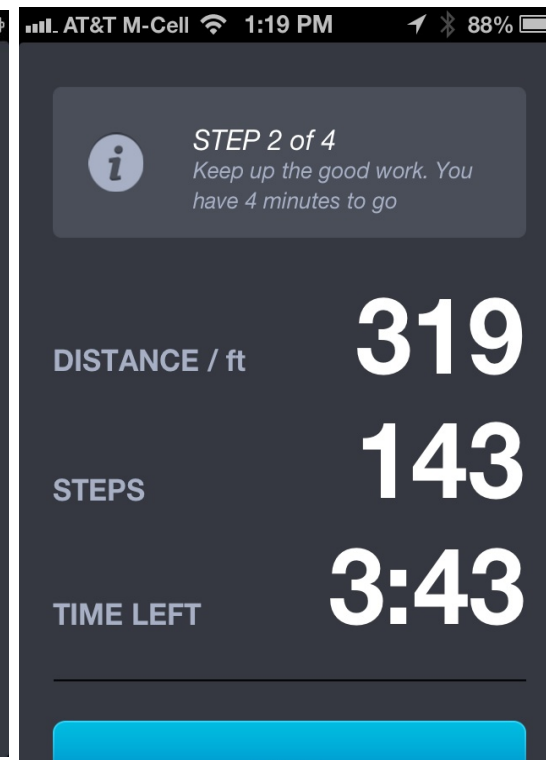
Apps: 6 MWT



AT&T M-Cell 4:01 PM 81%

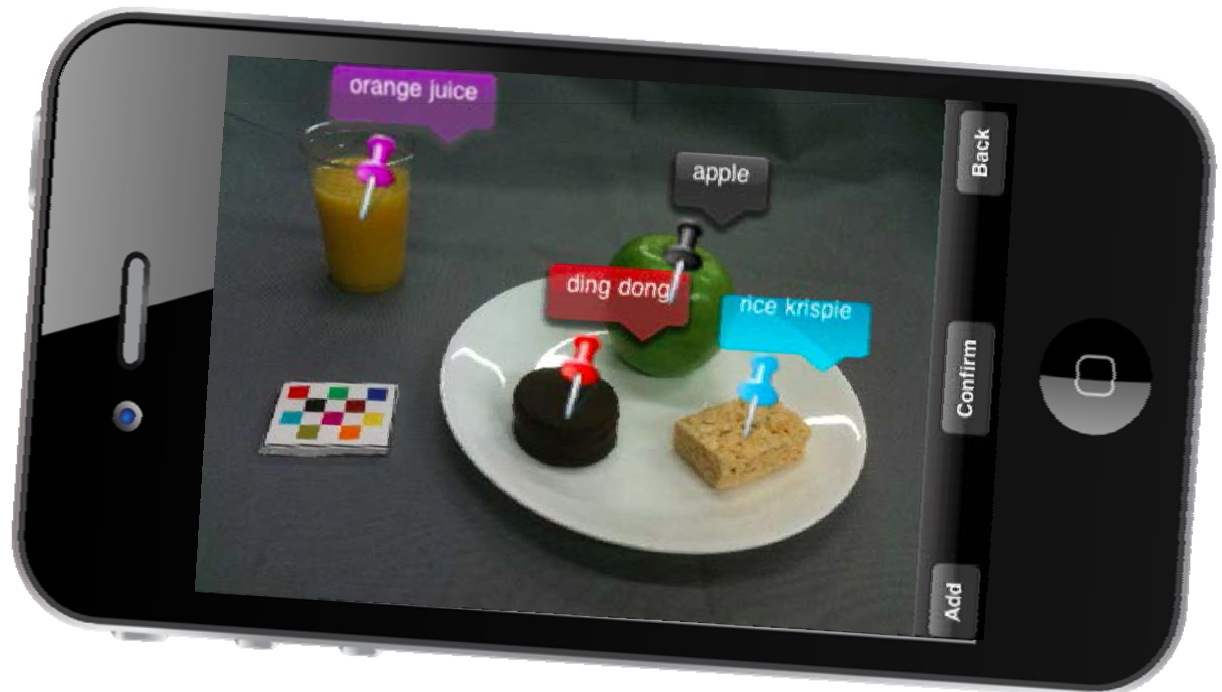
Please rate your current level of breathing difficulty:

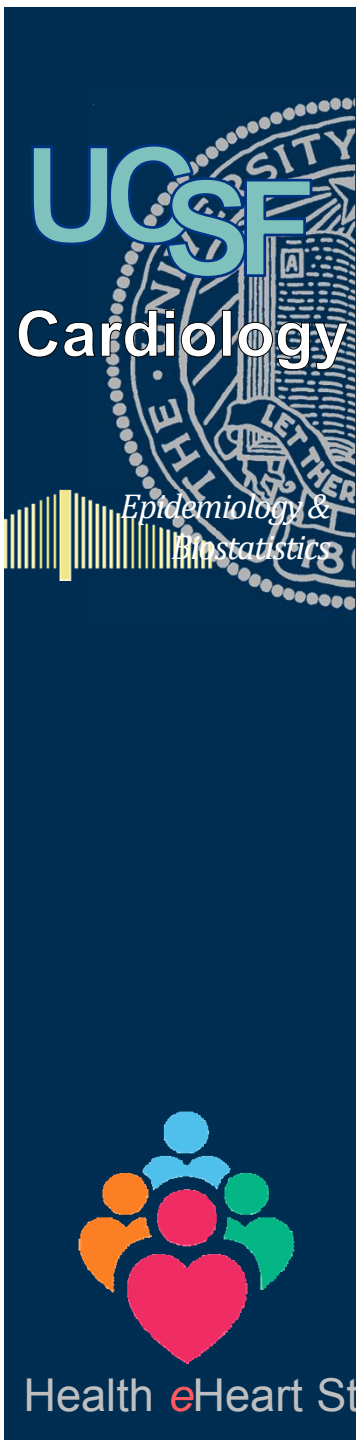
- 0: Nothing at all
- 0.5: Very, very slight (just noticeable)
- 1: Very slight
- 2: Slight (light)
- 3: Moderate
- 4: Somewhat severe
- 5: Severe (heavy)
- 6:
- 7: very Severe





Apps: Diet Capture—Food Diary





Hospitalization Detection App

●●●○ AT&T LTE 7:40 AM ↗ 95% 🔋

< Task

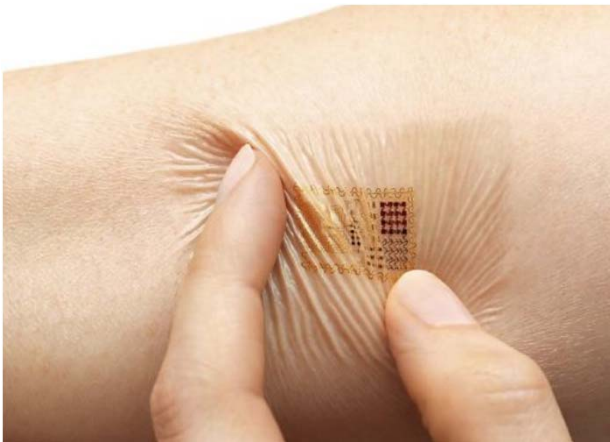
Were you at UCSF Medical Center for medical treatment on 1/22/2014?

Yes, for medical treatment

Yes, another reason

No, I was not there

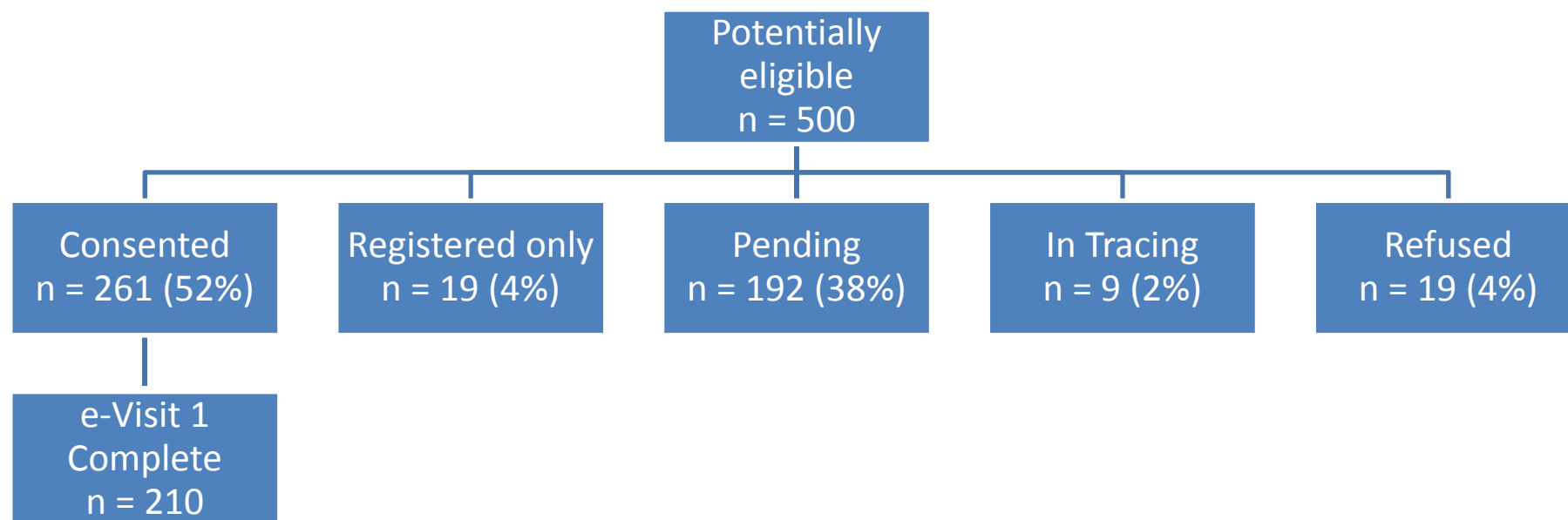
External Sensors



Potential for Collaboration

- Co-recruitment of CCSS participants into Health eHeart
 - Create a sub cohort for subsequent monitoring-based interventions
- Pilot (Feb 2015): Targeted 500 survivors for co-recruitment

Pilot Results to Date



Mailing and Follow-up

Batch 1 (n = 500)

- Mailed: 1/21/15
- Non-Responder Email (sent to people who have not registered): 2/19/15
- Follow-Up Phone Call Start Date: 2/26/15

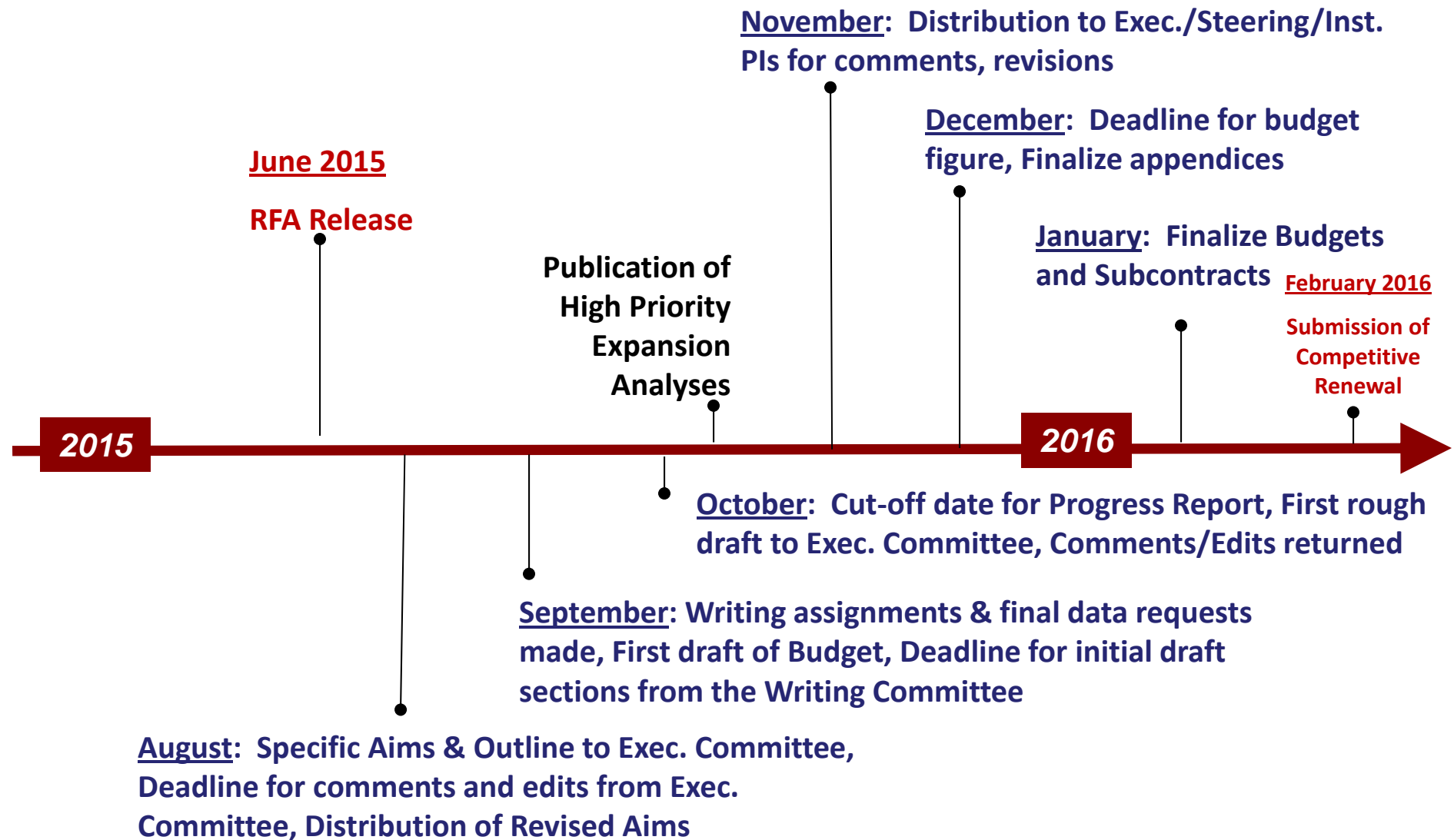
Mass Resend

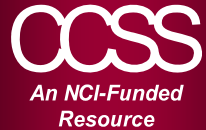
- Mailed 3/19

Summary of Proposal

- UCSF (Health eHeart Study) as a new Support Facility for CCSS for all mHealth monitoring and intervention-based research
- Recruitment of a 10,000 survivor “connected” cohort to provide a large pool for mHealth- based intervention studies where outcomes are directly assessed.
- Distant future: completely connected cohort providing direct measures in real time

Timeline for Submission of Competitive Renewal





CCSS Founders Reception

You are formally invited to attend the
CCSS Founders Reception

7pm-8pm

Crystal Ballroom

Initial Institutional Principal Investigators

Arthur Ablin
Roger Berkow
George Buchanan
Zoann Dreyer
Daniel Green
Mark Greenberg
Holcombe Grier
Melissa Hudson
Raymond Hutchinson
Michael Link
Anna Meadows
Joseph Neglia
Lorie Odom

Maura O'Leary
Thomas Pendergrass
Gregory Reaman
Kim Ritchey
Kathy Ruccione
Frederick Ruymann
Charles Sklar
Anthony Smithson
Louise Strong
Robert Weetman
Teresa Vietti
Lonnie Zeltzer

Steering Committee – Initial Members

Leslie L. Robison

John D. Boice

Norman E. Breslow

Sarah S. Donaldson

Daniel M. Green

Frederic P. Li

Anna T. Meadows

Ann C. Mertens

John J. Mulvihill

Joseph P. Neglia

Mark E. Nesbit

Roger J. Packer

John D. Potter

Charles A. Sklar

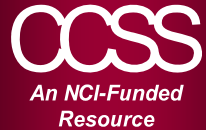
Malcolm A. Smith

Marilyn Stovall

Louise C. Strong

Yutaka Yasui

Lonnie K. Zeltzer



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Marilyn Stovall

Louise C. Strong

Yutaka Yasui

Lonnie K. Zeltzer

Miscellaneous Points

- Web Sites: CCSS and LTFU
- Public Access Data
- Newsletters
- Trainees – Career Development
- Children's Oncology Group – Liason Committee

New Centers - Expanded Cohort

- Desire to enrich the cohort for racial/minority populations
- Request for Proposals
- Available study population, institutional support
- Four Centers Selected – Probationary Status

Institution / PI	Survivor Pool	% Minority	Minority Population
University of Chicago T. Henderson	826	41%	Black: Hispanic (4:1)
Cook Children's Hospital P. Bowman	724	29%	Hispanic: Black (3:1)
Northwestern University K. Dilley	1039	27%	Hispanic: Black (2.3: 1)
Children's Hospital of Orange County L. Sender	695	46%	Hispanic: Asian: Black (25:5:1)

Funding Year 21: Total Cost

- December 2014 to November 2015
 - Budget: \$4,180,297
- Notice of Award 11/14: \$3,762,268 (10% cut)
- Increase 2/15: \$ 374,519
- Total Year 21: \$4,136,787 (1% cut)