

Coordinating Center Report

CCSS Investigator Meeting

June 14, 2021

CCSS

Childhood Cancer
Survivor Study



St. Jude Children's
Research Hospital

An NCI-funded Resource

- Provide a staffing overview
- Discuss the core activities of the CCSS Coordinating Center
- Introduce the myLTFU participant portal
- Review priorities for the next 5 years

Primary role: coordinate the daily activities of the study

3 main teams within the Coordinating Center:

- Project coordination, recruitment, survey administration, biologic specimen and medical record collection, coding
 - Led by James Ford, CCSS Project Coordinator
- Phone-based recruitment and data collection, participant tracing
 - Led by Dayton Rinehart, Call Center Coordinator
- Survey creation, database design, data cleaning, myLTFU portal development
 - Led by Chris Vukadinovich, Director of Data and Systems

Serve as the central liaison for all support facilities, committees, working groups, collaborating sites, and external investigators

Coordinate Follow-Up Surveys

- Administer questionnaires to 22,000+ active participants every 2 – 3 years
- Paper, online, and phone survey completion options
- Format, mail, process, code, transcribe, scan
- Reminders (lots of reminders!)
 - Email, text messages, phone calls, mailings
- Participant tracing

Follow-Up 7 Survey Status (Ongoing)

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Participants Invited

Survivors (N = 17,840)

Siblings (N = 3,750)

	n	% of Invited	% of Completed
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	n	% of Invited	% of Completed
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Total Completed

10,482 58.8%

2,009 53.6%

Completed Online

7,179 40.2% 68.5%

1,479 39.4% 73.6%

Completed by Mail/Paper

2,786 15.6% 26.6%

486 13.0% 24.2%

Completed by Phone

517 2.9% 4.9%

44 1.2% 2.2%

Pending

6,841 38.3%

1,667 44.5%

Refused Survey

85 0.5%

7 0.2%

Refused Further Contact

169 0.9%

53 1.4%

Deceased/Unavailable

263 1.5%

14 0.4%

Survey Period: 9/19 - Present

Survey Period: 1/20 - Present

External investigator-initiated studies (ancillary studies)

- Project coordination
- Recruitment
- Data collection
- Regulatory requirements

Subsequent neoplasm confirmation

- Obtain pathology reports/records to histologically confirm reported conditions

Biologic specimen collection

- Oragene (saliva) kits
- Blood sample for participants with a subsequent malignant neoplasm
- Somatic tumor tissue for subsequent malignant neoplasms

Collection of DNA: Oragene

- Completed kits go to CCSS Molecular Biology Support Center in Cincinnati
- Front-end \$25 Target gift card

Kits Sent	Overall Survivors (n = 19,199)		Overall Siblings (n = 4,002)	
	<i>N</i>	<i>% of Sent</i>	<i>N</i>	<i>% of Sent</i>
Returned	10,409	54%	1,643	41%
Refused	1,486	7%	325	8%
Pending	5,165	27%	1,408	35%
In Tracing	1,636	9%	581	14%
Deceased	503	3%	45	1%

Participant tracing

Data checks and quality control for survey data

Maintain participant and researcher websites

Participant communication and education in coordination with the CCSS Education Committee (M. Hudson, Chair)

- Newsletters 3 – 4 times per year
- Study results
- Respond to requests and questions
- Liaison with Participant Advisory Committee

Sample Participant Newsletter

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50 years of survivorship: “Living the best life I can, each and every day”

Nancy Getsi, LTFU Study participant, shares her story.

It's been 50 years since I was diagnosed with Ewing sarcoma. I was 10 years old and living in Tennessee. At first, my pediatrician said my pain was hypochondria.

After X-rays and a biopsy, my doctor had difficulty sharing the bad news with us. Fortunately, a pathologist put us in touch with the Mayo Clinic in Rochester, MN. I went there for surgery and radiation, then we returned home.

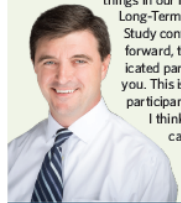
My chemotherapy drugs were shipped to my local pediatrician, who infused them straight into my veins (ports hadn't been developed yet). It made me very ill, and I continued to get chemo through all three years of junior high, but I was a typical teen in most regards. continued on page 3



"I'm a big believer in the LTFU Study," says Nancy Getsi. "I need to know I'm doing my part."

A NOTE FROM US

The coronavirus has changed many things in our lives, but the Long-Term Follow-Up Study continues to move forward, thanks to dedicated participants like you. This issue shares one participant's story, and I think her resilience can inspire all of us. On page 2, you'll find our thoughts



and advice on survivorship in the pandemic, including links to helpful resources.

SURVEY UPDATE

Paper surveys Participants who did not complete the current follow-up survey via their personal myLTFU portal have all been sent a paper version. COVID-19 paused our survey mailout in April, but we have returned to the St. Jude campus on a limited basis to print and mail them. **We need to hear from everyone**, so please call 1-800-775-2167 or email ltfu@stjude.org if you'd like us to send you another copy.

myLTFU portal The survey is also open in the study portal. One of the great things about completing it here (in addition to saving trees and research dollars) is that you can compare some of your responses to more than 7,000 other participants and get early access to lots of interesting data.

Our important work continues. We thank all of you for being our research partners, and we wish you good health.

Greg Armstrong, MD
Principal investigator

Survivorship in a pandemic

Survivors are experiencing a range of physical and emotional challenges related to COVID-19. Members of the LTFU Study Education Committee share their experiences, encouragement, and expert advice.



Linda Rivard, RN, LTFU Study Education Committee member, and her son Baly, a cancer survivor.

For many cancer survivors, the ways in which the COVID-19 pandemic changed their lives feels strangely familiar. "I'm hearing people say, 'It feels like when I was first diagnosed,'" says Melissa Hudson, MD, Director of the Cancer Survivorship Division at St. Jude Children's Research Hospital.

"It relates back to their original experience—losing control, not being able to be around their support system. Their lives have been turned upside down again," she explains.

New options emerge amid disrupted care

Many survivors have health issues related to their cancer or its treatment that have been linked to higher COVID-19 risk. Follow-up care is as important as ever, but many people are postponing clinical visits as they try to evaluate the risks of in-person appointments.

"One good thing to come out of this is telehealth," says Linda Rivard, RN, a survivorship nurse at Advocate Aurora Children's Hospital in Oak Lawn, IL.

Use of telemedicine efforts increased dramatically during the early days of COVID-19. Because of its

Resources

Resources on COVID-19 and survivorship are available by logging into your **myLTFU portal** and on our website ltfu.stjude.org

success, it may be here to stay—not to replace in-person care, but to offer an effective, efficient, and safe alternative to in-person care when a physical exam is not needed.

"Things are different now," Linda says. "If you have an immediate concern or are scheduled for a follow-up appointment, communicate with your team. Even if you don't see

them in person, you can stay on top of things with a phone call or a remote visit."

Meanwhile, outpatient health care settings are reopening with new safety precautions in place, and are working hard to educate and reassure the public. If you have concerns, call your health care facility and ask what systems are in place to ensure that you can safely receive the care you need.

Staying home doesn't mean staying still!

Even when restrictions are eased, many people are choosing to avoid gyms, crowded parks and trails, and other places where they could be active. "Physical activity is more important than ever," says Kathy Ruccione, PhD, RN, co-author of *Childhood Cancer Survivors: A Practical Guide to Your Future*.

"Don't sit on the couch or work at your kitchen table all day. Put on your mask, go outside, and walk around. Or do things inside your house. We all still have to move!"

Keeping calm during COVID-19

Anxiety, depression, and sleep issues often worsen when we're living with uncertainty and missing in-person contact with other people.

"Survivors may find it useful to explore some of the mindfulness websites and apps that are available. A good one to explore is HeadSpace (www.headspace.com). I also like Calm (www.calm.com)," Kathy says. "And if you're struggling, reach out for support, either from family, a friend, or a professional."



Kathy Ruccione, PhD, RN, is a member of the LTFU Study's Education Committee.

Childhood Cancer Survivor Study

An NCI-funded resource

Goals:

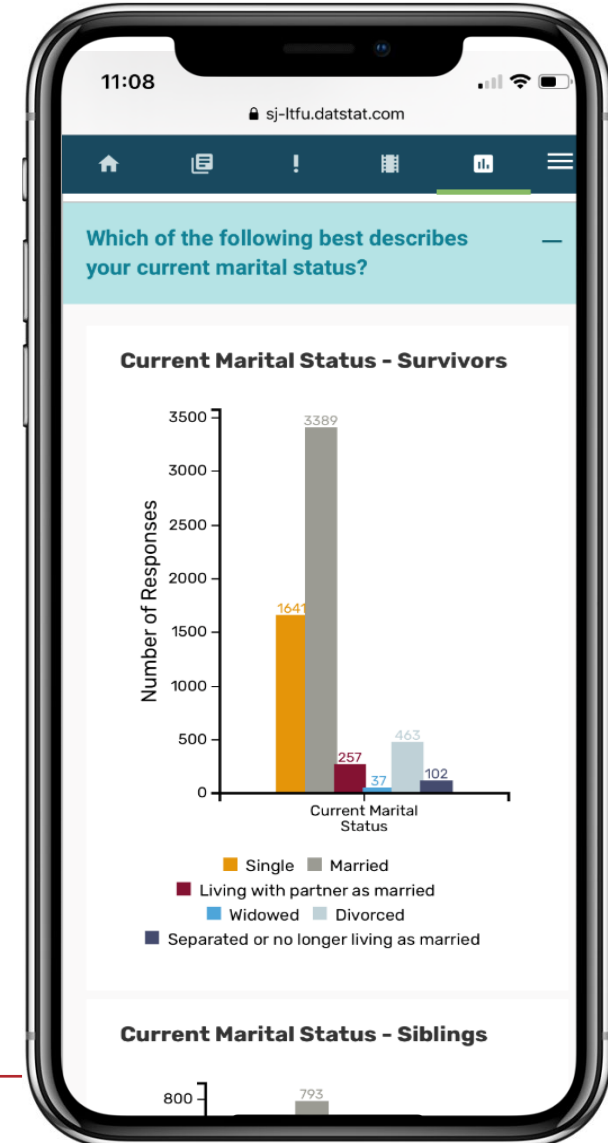
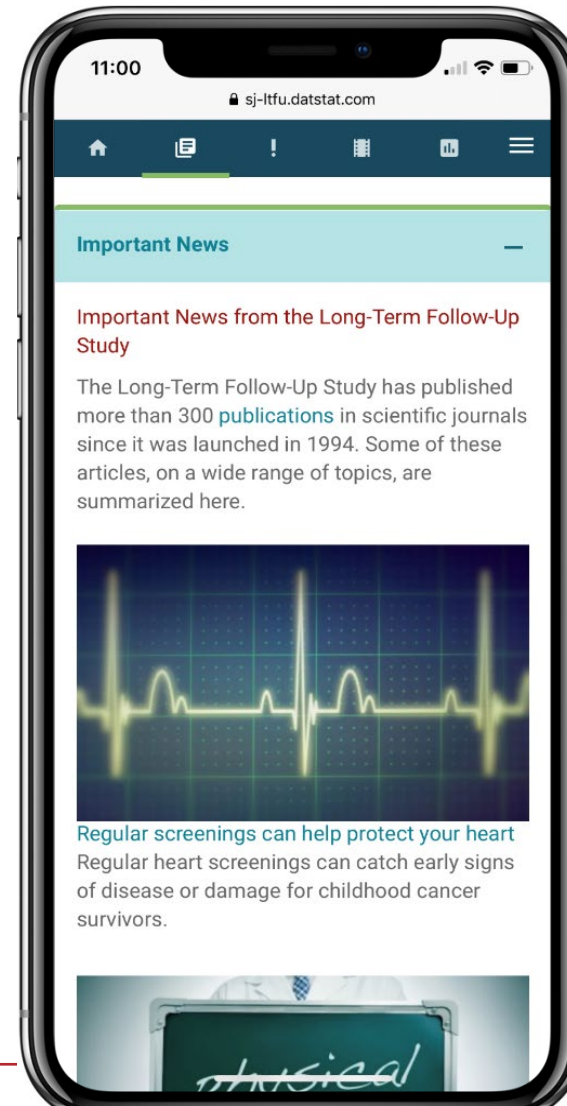
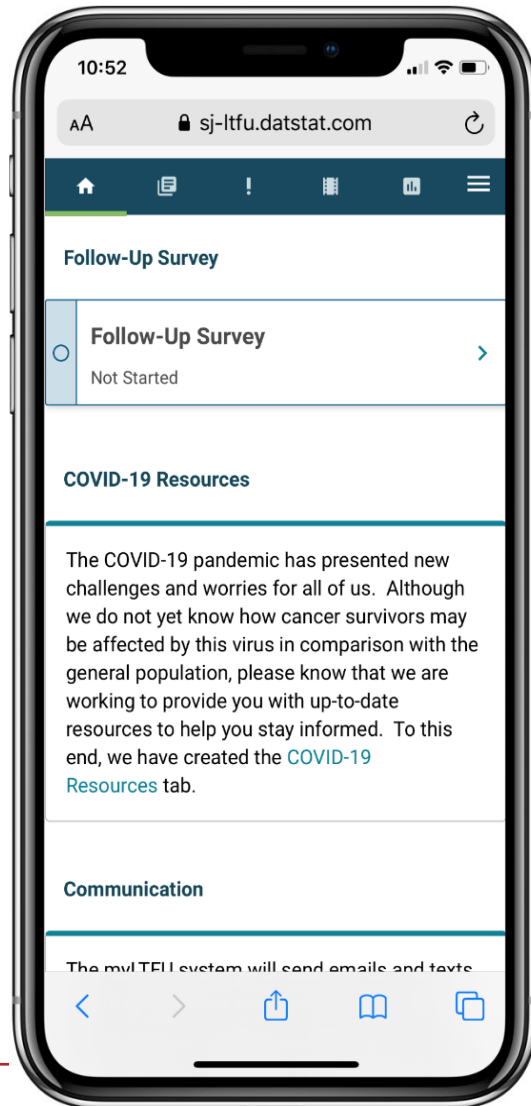
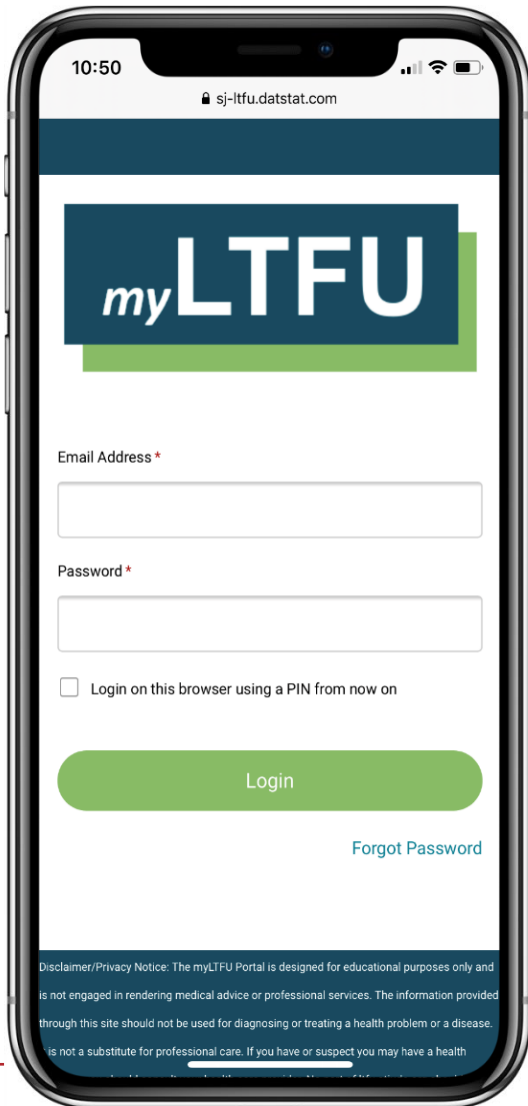
- Implement a flexible, mobile participant portal that can remotely collect self-report and sensor-based data
- Scalable and adaptable system architecture to reliably curate large quantities of data
- Automate study processes
- Dynamic coordinator interface/dashboard for the study team
- Foster participant engagement and communication
- Establish a pool of participants available for mHealth and intervention studies

Utilize the DatStat Connect platform to create a mobile-friendly web portal accessible by smartphone, tablet, or PC

- Participants can bookmark site and save shortcut/icon to mobile device
- Administer online consents, forms, and surveys
- Upload files to the study team
- Schedule messaging (emails and texts) and data collection activities
- Provide participant resources
 - Recommended websites; newsletters; brief study results/updates; live survey results
- Coordinator portal

myLTFU Sample Screenshots

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myLTFU Participant Portal

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Invited participants to the portal with the current follow-up survey

Over 12,000 participants have activated their account

Used myLTFU to rapidly collect data regarding experiences during COVID-19

Three randomized, controlled intervention trials now funded that utilize myLTFU as the primary mode for interaction with participants

Priorities – Next 5 Years

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Administer two follow-up surveys to the cohort

Conduct an in-home assessment of 1000 participants to examine frailty/aging

Administer online cognitive assessment to the cohort

Conduct National Death Index search

Continue subsequent neoplasm adjudication

Continue collecting blood and tumor tissue specimens

Coordinate recruitment and data collection for ancillary studies

Continue participant engagement efforts while minimizing burden