ETCTN

Team Driven. Cancer Therapy Focused.

Experimental Therapeutics Clinical Trials Network

National Cancer Institute at the National Institutes of Health

**Introduction**

The National Cancer Institute (NCI) would like to know about your experiences with the Experimental Therapeutics Clinical Trials Network (ETCTN) over the past grant year (April 2014 - March 2015).

Your input will help NCI assess and refine the ETCTN processes and identify areas for improvement.

The survey will ask questions about ETCTN processes and activities and trial portfolio. It should take approximately 15 minutes to complete.

Your responses are confidential and all results will be reported in the aggregate. Your participation and responses will have no bearing on your ETCTN grant, or any future interactions with NCI.

We thank you for your assistance!

**To continue and begin the survey, click the "Next" button below.**

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OMB# 0925-0046-09
Exp. Date: 05/31/2016

**Privacy Statement and Consent**

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Participation is voluntary and there are no penalties for not participating or withdrawing from the study at any time. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by User-Centered Design, Inc. via email to complete this instrument so that we can gain feedback from you on your experiences and recommendations regarding the implementation of the ETCTN program.

**Please click the "Next" button if you consent to taking this survey.**

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 208927974, ATTN: PRA (0925-0046-09). Do not return the completed form to this address.

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Opt-out of survey

5% Complete

## Role and Involvement with ETCTN

*The first set of questions asks about your role within the ETCTN and your overall experiences with the program during the first grant year (April 2014 - March 2015).*

1. Please review the following ETCTN staff roles and descriptions and select the primary role that best fits your day-to-day activities for the program. If other roles describe your activities to a lesser degree, please select these as Secondary Roles.

| | Primary role (select one) | Secondary role (select all that apply) |
|---|---|---|
| **Grant administrator:** Primary administrator for the program; makes roster changes in RSS; primary contact for program matters, including study announcements; disseminates ETCTN information from NCI to sites. | ○ | ☐ |
| **Site administrator:** Primary contact person at each LAO or P2C-participating site; makes roster updates for their sites via CTSU website; disseminates ETCTN information to site staff. | ○ | ☐ |
| **Study administrator:** Primary contact person at a LAO or P2C-participating site for a particular ETCTN study. | ○ | ☐ |
| **Rave CRA:** Accesses Medidata Rave to enter and manage patient data. | ○ | ☐ |
| **Registrar:** Accesses OPEN/IWRS to enroll patients and request slot reservations. | ○ | ☐ |
| **Other:** | ○ | ☐ |

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10% Complete

2. Thinking about your experiences with the ETCTN this past grant year (April 2014 - March 2015), how involved were you in the program?

- ○ Extremely involved
- ○ Very involved
- ○ Somewhat involved
- ○ Slightly involved
- ○ Not at all involved

3. Think about your experiences with the ETCTN this past grant year and indicate how much you agree with the statements below.

| | Strongly disagree | Disagree | Agree | Strongly agree |
|---|---|---|---|---|
| At the **beginning** of the ETCTN, I had a very clear understanding of how the program operated. | ○ | ○ | ○ | ○ |
| I **currently** have a very clear understanding of how the ETCTN operates. | ○ | ○ | ○ | ○ |
| I have a clear understanding of my role. | ○ | ○ | ○ | ○ |

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15% Complete

**Experience and Satisfaction with ETCTN Processes**

*The next set of questions asks about your experience with the process to develop and open ETCTN trials within the past grant year (April 2014 - March 2015).*

4. In the past grant year, were you involved in the process to submit a protocol to NCI for approval that was developed by investigators **at your site**?

- ○ Yes
- ○ No

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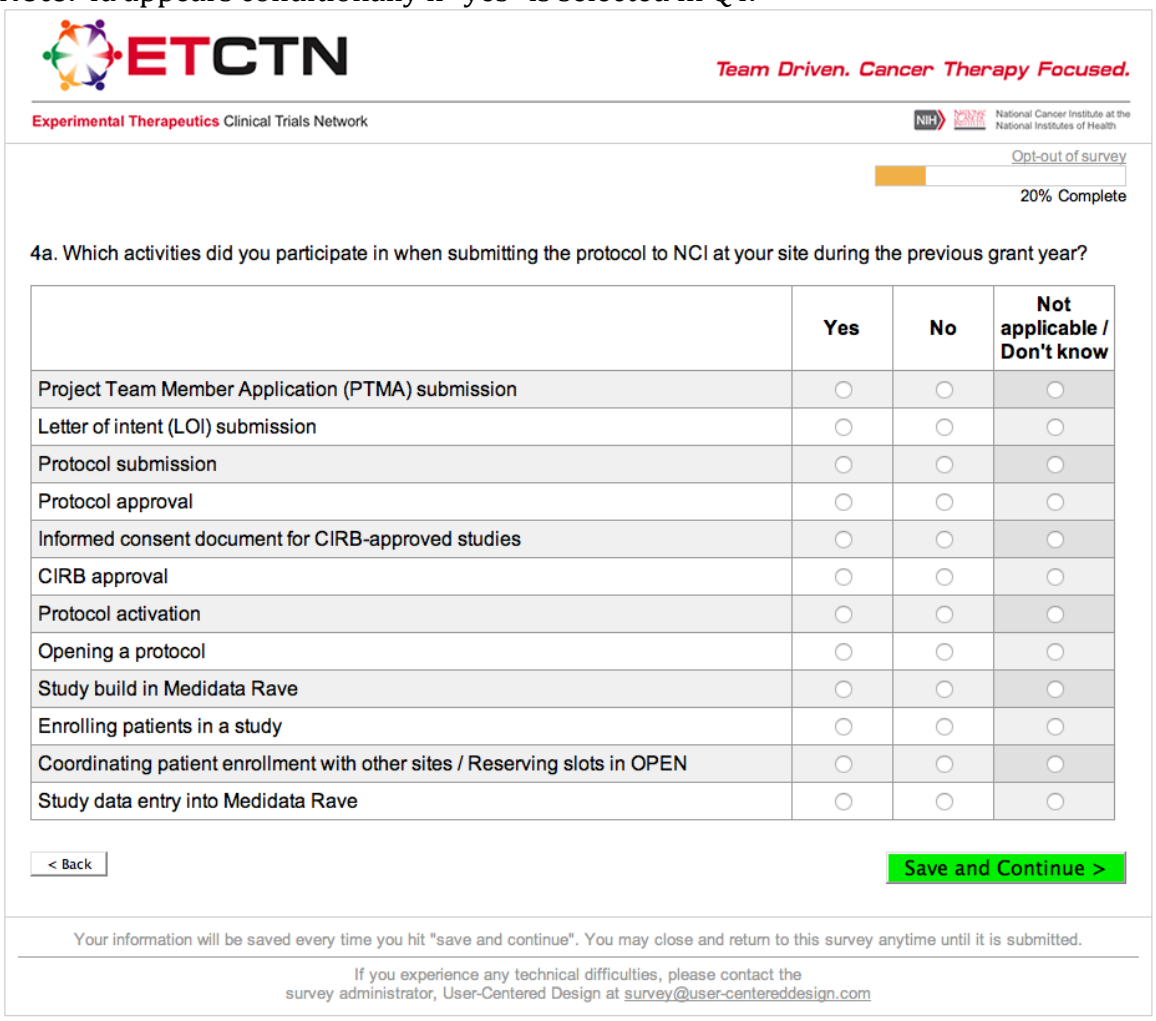
**Note**: 4a appears conditionally if "yes" is selected in Q4.



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Opt-out of survey

20% Complete

4a. Which activities did you participate in when submitting the protocol to NCI at your site during the previous grant year?

| | Yes | No | Not applicable / Don't know |
|---|---|---|---|
| Project Team Member Application (PTMA) submission | ○ | ○ | ○ |
| Letter of intent (LOI) submission | ○ | ○ | ○ |
| Protocol submission | ○ | ○ | ○ |
| Protocol approval | ○ | ○ | ○ |
| Informed consent document for CIRB-approved studies | ○ | ○ | ○ |
| CIRB approval | ○ | ○ | ○ |
| Protocol activation | ○ | ○ | ○ |
| Opening a protocol | ○ | ○ | ○ |
| Study build in Medidata Rave | ○ | ○ | ○ |
| Enrolling patients in a study | ○ | ○ | ○ |
| Coordinating patient enrollment with other sites / Reserving slots in OPEN | ○ | ○ | ○ |
| Study data entry into Medidata Rave | ○ | ○ | ○ |

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**Note**: 4b and 4c appear together conditionally if "yes" is selected for any activities in Q4a. 4b is populated with any activities identified as "yes" in Q4.

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Opt-out of survey

25% Complete

4b. What was your level of satisfaction with the activities in which you participated?

| | Not satisfied | | | | Very satisfied |
|---|---|---|---|---|---|
| Project Team Member Application (PTMA) submission | ○ | ○ | ○ | ○ | ○ |
| Letter of intent (LOI) submission | ○ | ○ | ○ | ○ | ○ |
| Protocol submission | ○ | ○ | ○ | ○ | ○ |
| Protocol approval | ○ | ○ | ○ | ○ | ○ |
| Informed consent document for CIRB-approved studies | ○ | ○ | ○ | ○ | ○ |
| CIRB approval | ○ | ○ | ○ | ○ | ○ |
| Protocol activation | ○ | ○ | ○ | ○ | ○ |
| Opening a protocol | ○ | ○ | ○ | ○ | ○ |
| Study build in Medidata Rave | ○ | ○ | ○ | ○ | ○ |
| Enrolling patients in a study | ○ | ○ | ○ | ○ | ○ |
| Coordinating patient enrollment with other sites OR reserving slots in OPEN | ○ | ○ | ○ | ○ | ○ |
| Study data entry into Medidata Rave | ○ | ○ | ○ | ○ | ○ |

4c. Overall, what challenges did you encounter during these activities in the table above? (Select all that apply)

- ☐ Did not experience challenges
- ☐ Insufficient training
- ☐ Lack of helpdesk support
- ☐ Limited communication from NCI
- ☐ Unaware of other sites that have opened trial
- ☐ Difficulty identifying who to contact at NCI
- ☐ Difficulty identifying who to contact at other sites
- ☐ Difficulty communicating with people at other sites
- ☐ Difficulty using centralized ETCTN resources (e.g., OPEN, Medidata Rave)
- ☐ Other (please describe):

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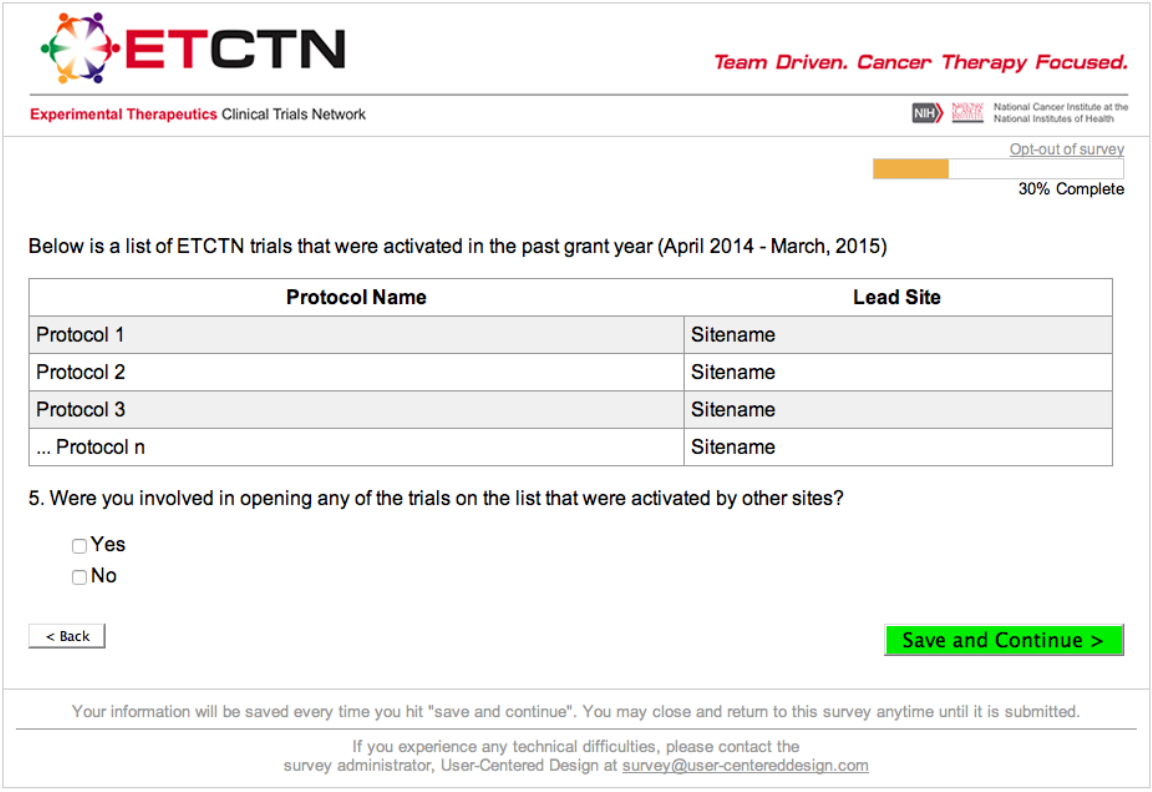

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Opt-out of survey

30% Complete

Below is a list of ETCTN trials that were activated in the past grant year (April 2014 - March, 2015)

| Protocol Name | Lead Site |
|---|---|
| Protocol 1 | Sitename |
| Protocol 2 | Sitename |
| Protocol 3 | Sitename |
| ... Protocol n | Sitename |

5. Were you involved in opening any of the trials on the list that were activated by other sites?

- ☐ Yes
- ☐ No

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**Note**: 5a and 5b appear together conditionally; they appear if "yes" is selected in Q5.

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Opt-out of survey

35% Complete

5a. What was your level of satisfaction with each of the processes listed below when opening an ETCTN trial at your site?

| | Not satisfied | | | | Very satisfied | Not applicable / Don't know |
|---|---|---|---|---|---|---|
| Communication received about trial while it was in the pipeline | ○ | ○ | ○ | ○ | ○ | ○ |
| Protocol activation notices | ○ | ○ | ○ | ○ | ○ | ○ |
| Communication received from NCI during the process to open a trial | ○ | ○ | ○ | ○ | ○ | ○ |
| Interactions with CTSU | ○ | ○ | ○ | ○ | ○ | ○ |
| Interactions with CIRB | ○ | ○ | ○ | ○ | ○ | ○ |
| Interactions with Theradex | ○ | ○ | ○ | ○ | ○ | ○ |
| Enrolling patients | ○ | ○ | ○ | ○ | ○ | ○ |
| Coordinating patient enrollment with other sites | ○ | ○ | ○ | ○ | ○ | ○ |
| Data entry in Medidata Rave | ○ | ○ | ○ | ○ | ○ | ○ |

5b. Please describe any changes NCI could make to increase your satisfaction with opening ETCTN trials at your site.

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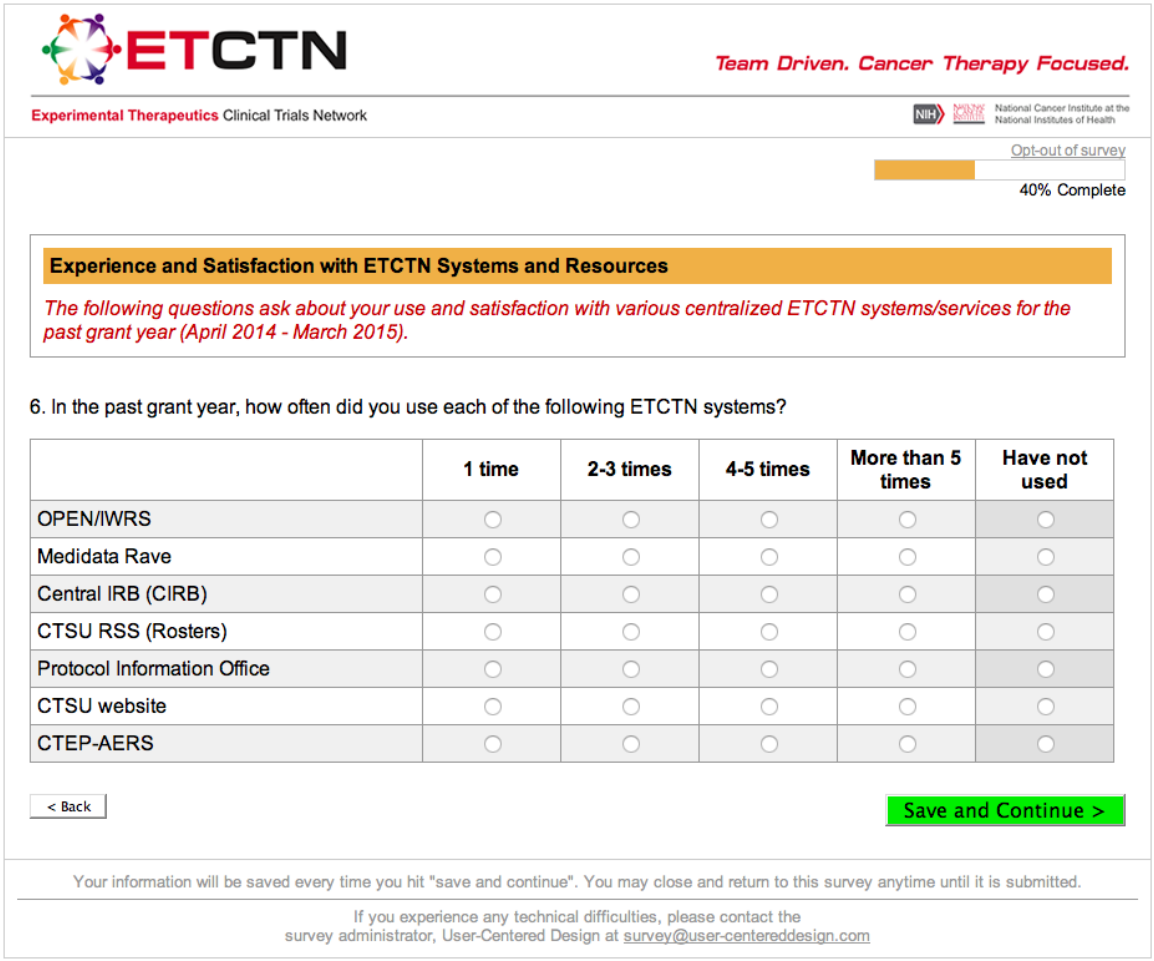

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Opt-out of survey

40% Complete

**Experience and Satisfaction with ETCTN Systems and Resources**

*The following questions ask about your use and satisfaction with various centralized ETCTN systems/services for the past grant year (April 2014 - March 2015).*

6. In the past grant year, how often did you use each of the following ETCTN systems?

| | 1 time | 2-3 times | 4-5 times | More than 5 times | Have not used |
|---|---|---|---|---|---|
| OPEN/IWRS | ○ | ○ | ○ | ○ | ○ |
| Medidata Rave | ○ | ○ | ○ | ○ | ○ |
| Central IRB (CIRB) | ○ | ○ | ○ | ○ | ○ |
| CTSU RSS (Rosters) | ○ | ○ | ○ | ○ | ○ |
| Protocol Information Office | ○ | ○ | ○ | ○ | ○ |
| CTSU website | ○ | ○ | ○ | ○ | ○ |
| CTEP-AERS | ○ | ○ | ○ | ○ | ○ |

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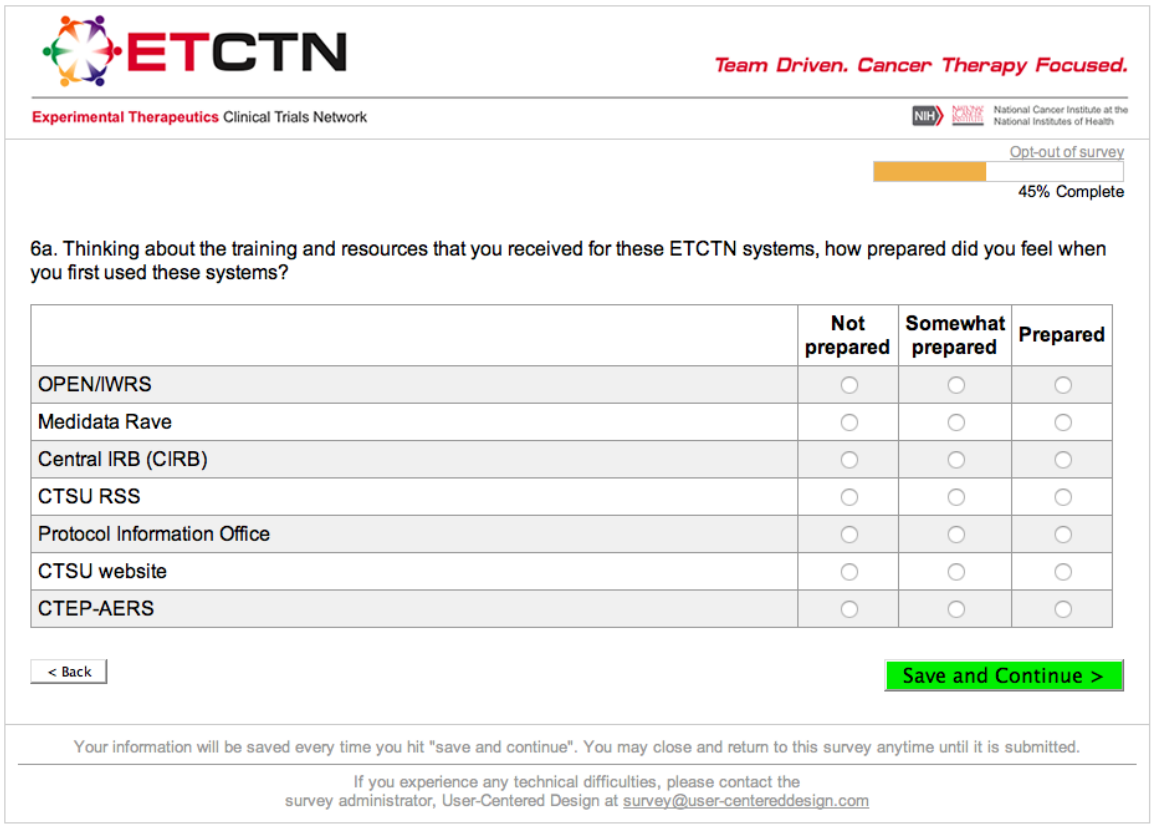
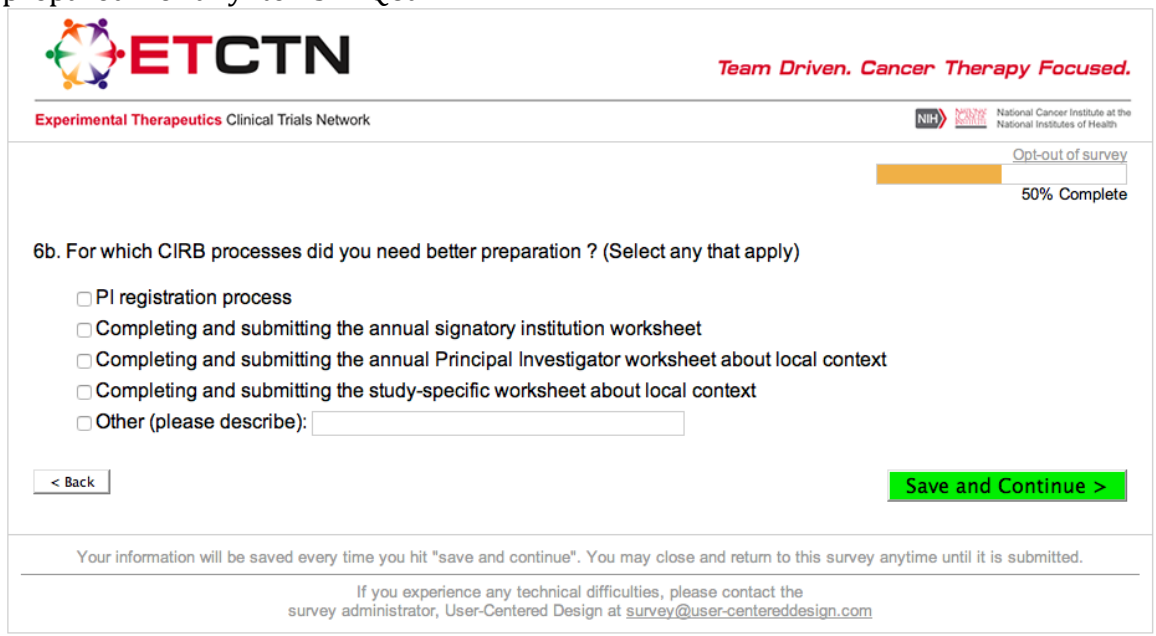
**Note**: 6a appears conditionally populated with any systems used 1 or more times in Q6.




Note: 6b appears conditionally, if the user has selected “not prepared” or “somewhat prepared” for any items in Q6a.




**Note**: 6c and 6d appear together conditionally; 6c appears populated with any systems used 1 or more times in Q6. 6d appears if 6c appears.

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Opt-out of survey

55% Complete

6c. Overall, how satisfied were you with using the following ETCTN systems during the past grant year?

| | Not satisfied | | | | Very satisfied |
|---|---|---|---|---|---|
| OPEN/IWRS | ○ | ○ | ○ | ○ | ○ |
| Medidata Rave | ○ | ○ | ○ | ○ | ○ |
| Central IRB (CIRB) | ○ | ○ | ○ | ○ | ○ |
| CTSU RSS | ○ | ○ | ○ | ○ | ○ |
| Protocol Information Office | ○ | ○ | ○ | ○ | ○ |
| CTSU website | ○ | ○ | ○ | ○ | ○ |

6d. Looking at the list below, what could have helped you better prepare to use the systems required to open ETCTN trials at your site? (check all that apply)

- ☐ Received training closer to utilizing ETCTN system
- ☐ Helpdesk support
- ☐ Increased communication from NCI
- ☐ Increased communication with other sites conducting trial
- ☐ Shared "best practices" with other sites
- ☐ ETCTN Q&A documents
- ☐ CTSU Q&A documents
- ☐ ETCTN FAQ documents
- ☐ ETCTN process flowchart to describe initial drug review to opening clinical trials
- ☐ Access to previously recorded ETCTN webinars
- ☐ Flowchart for CIRB process
- ☐ Other (please describe):

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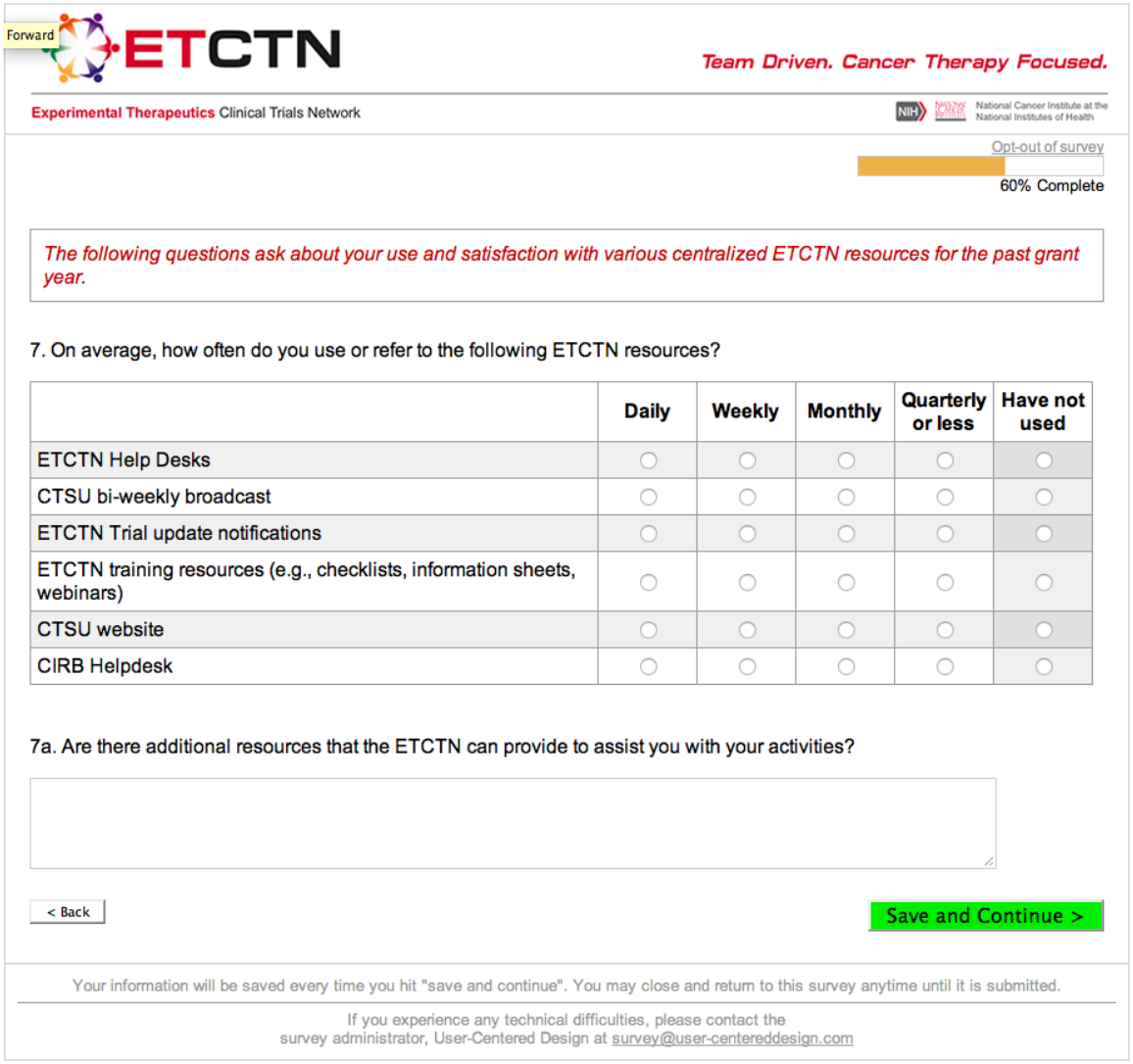
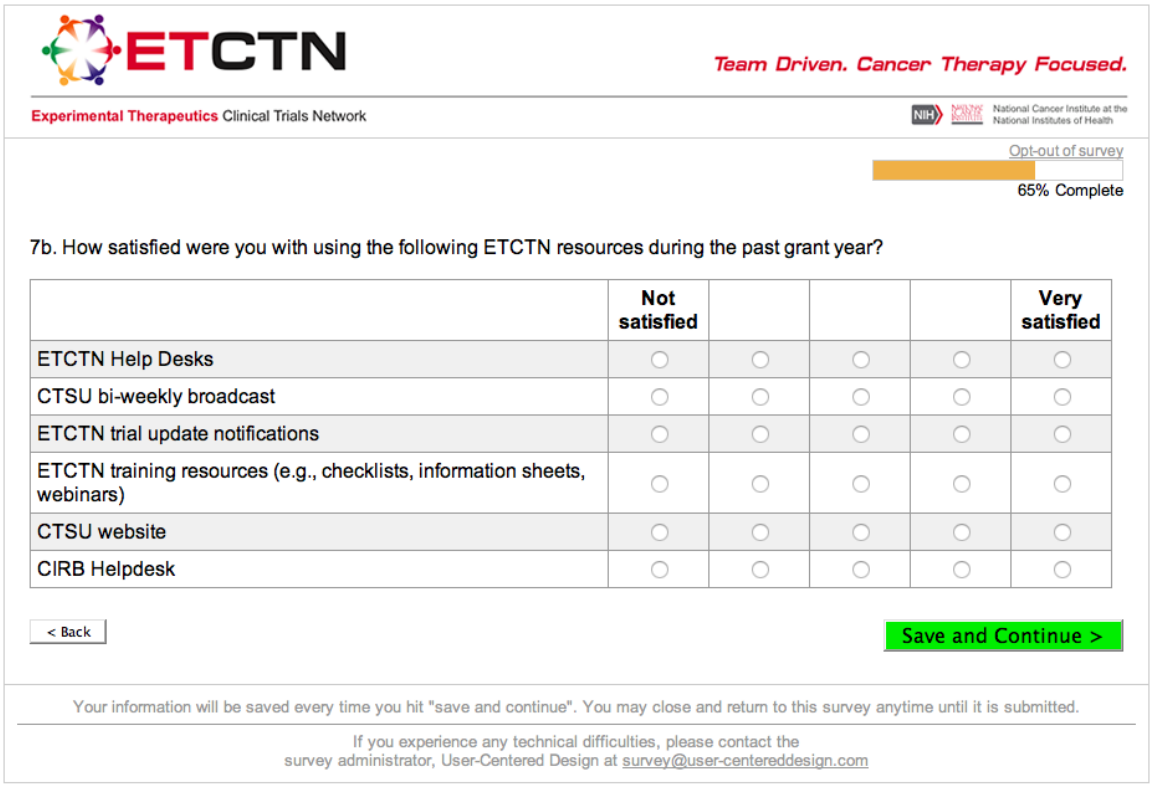
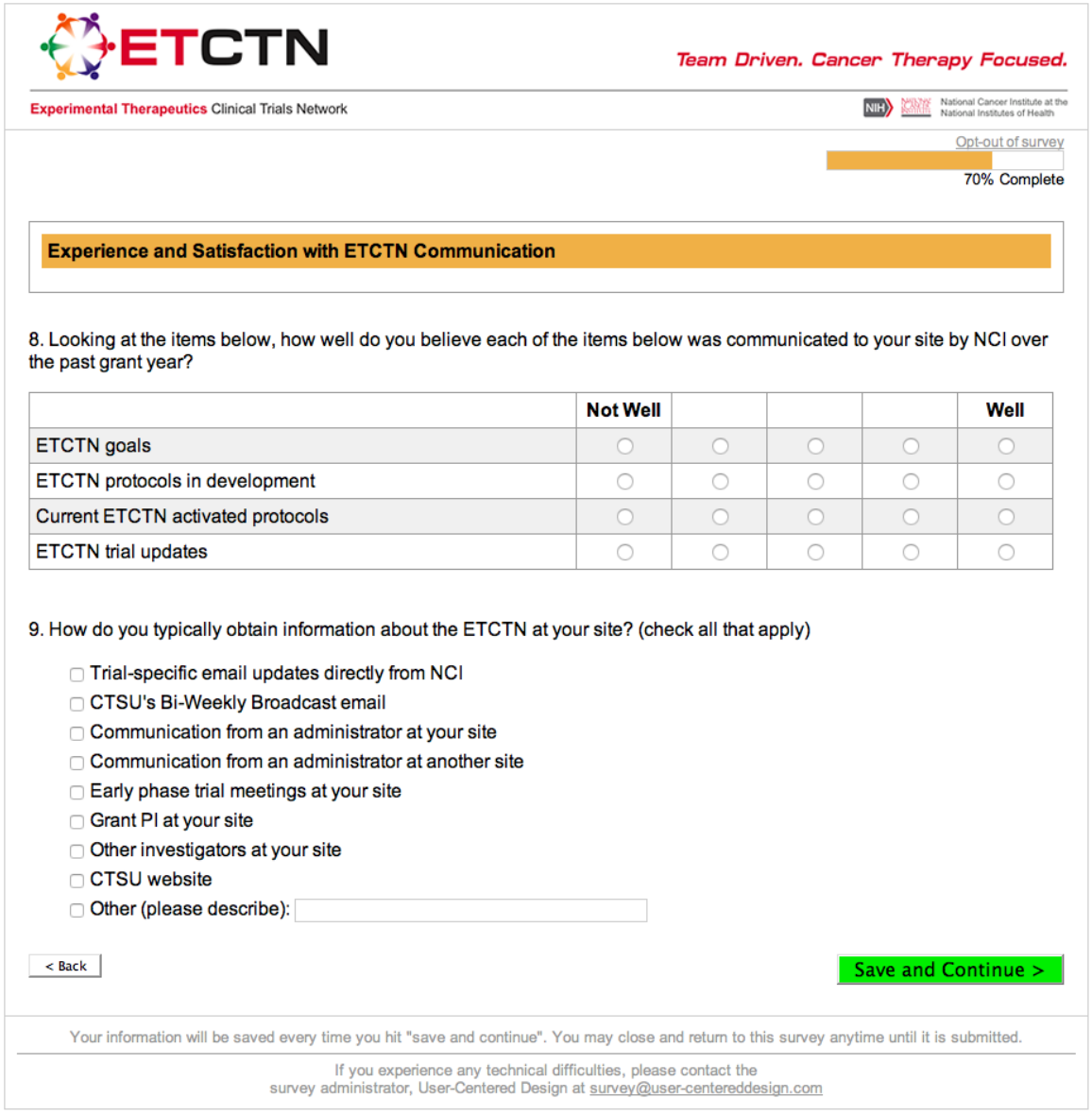



**Note**: Q7b appears conditionally, populated with any resources used quarterly or more frequently in Q7.

Attachment_C13_ETCTN_RS_survey



Attachment_C13_ETCTN_RS_survey



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Opt-out of survey

75% Complete

10. In this past grant year, how helpful has your communication with the people or organizations listed below been?

| | Not helpful | | | | Very helpful | Not applicable / Don't know |
|---|---|---|---|---|---|---|
| Staff at other sites who are opening an ETCTN trial led by my site | ○ | ○ | ○ | ○ | ○ | ○ |
| Staff at other sites who are helping me open an ETCTN trial led by their site | ○ | ○ | ○ | ○ | ○ | ○ |
| Staff at other sites who are coordinating with my site as part of the same ETCTN grant package | ○ | ○ | ○ | ○ | ○ | ○ |
| NCI CIRB | ○ | ○ | ○ | ○ | ○ | ○ |
| NCI CTSU | ○ | ○ | ○ | ○ | ○ | ○ |
| NCI PIO | ○ | ○ | ○ | ○ | ○ | ○ |
| NCI leadership | ○ | ○ | ○ | ○ | ○ | ○ |
| Third-party contractors (e.g., Westat, EMMES, Theradex) | ○ | ○ | ○ | ○ | ○ | ○ |

10a. Please describe what changes NCI could make to improve communications in the areas listed above..

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Opt-out of survey

80% Complete

## ETCTN Benefits

11. Below is a list of potential benefits to be achieved via the ETCTN network.

Please indicate if you think that each of the potential benefits is:

- More likely to occur with *ETCTN trials*,
- More likely to occur with *other investigator-initiated trials at your center*
  OR
- Equally likely to occur with *other investigator-initiated trials **and** with ETCTN trials*

| | More Likely to Occur With **ETCTN** Trials at my Center | More Likely to Occur With **Other** Investigator-Initiated Trials at my Center | Likely to Occur **Equally** With Other Investigator-Initiated Trials *AND* ETCTN Trials |
|---|---|---|---|
| Greater access to early phase trials. | ○ | ○ | ○ |
| Efficient unsolicited LOI process. | ○ | ○ | ○ |
| Obtain IRB approval quickly. | ○ | ○ | ○ |
| Activate trials quickly at my center. | ○ | ○ | ○ |
| Enroll patients to trials at the projected accrual rate. | ○ | ○ | ○ |
| Efficient patient registration. | ○ | ○ | ○ |
| Efficient data collection. | ○ | ○ | ○ |
| Efficient data management. | ○ | ○ | ○ |
| Easy data queries. | ○ | ○ | ○ |

12. What other benefits do you think will occur because of the ETCTN?

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85% Complete

**Social Network Collaborations**

*We would like to learn more about your work with other researchers that are involved in the ETCTN.*

13. Please look at the list of ETCTN organization members below and indicate a "yes" for those you had direct collaboration with over the past year (either developing protocols or opening trials).

| ETCTN Lead Academic Organizations and Affiliates | Yes | No |
|---|---|---|
| Translational Genomics Research Institute | ○ | ○ |
| City of Hope Comprehensive Cancer Center | ○ | ○ |
| UC Davis Comprehensive Cancer Center | ○ | ○ |
| USC Norris Comprehensive Cancer Center | ○ | ○ |
| University of Colorado Cancer Center - Anschutz Cancer Pavilion | ○ | ○ |
| Yale Cancer Center | ○ | ○ |
| H. Lee Moffitt Cancer Center and Research Institute | ○ | ○ |
| Emory University/Winship Cancer Institute | ○ | ○ |
| University of Chicago | ○ | ○ |
| Johns Hopkins University/Sidney Kimmel Comprehensive Cancer Center | ○ | ○ |
| National Cancer Institute Developmental Therapeutics Clinic | ○ | ○ |
| University of Maryland Greenbaum Cancer Center | ○ | ○ |
| Dana-Farber Cancer Center | ○ | ○ |
| Massachusetts General Hospital | ○ | ○ |
| Wayne State University/Karmanos Cancer Institute | ○ | ○ |
| Mayo Clinic Rochester | ○ | ○ |
| Washington University | ○ | ○ |
| Rutgers University - Cancer Institute of New Jersey | ○ | ○ |
| Roswell Park Cancer Institute | ○ | ○ |
| Duke University | ○ | ○ |
| UNC Chapel Hill | ○ | ○ |
| Case Western Reserve University | ○ | ○ |
| Cleveland Clinic Foundation | ○ | ○ |
| Ohio State University Comprehensive Cancer Center | ○ | ○ |
| Fox Chase Cancer Center | ○ | ○ |
| University of Pittsburgh Cancer Institute | ○ | ○ |
| Vanderbilt-Ingram Cancer Center | ○ | ○ |
| University of Texas MD Anderson Cancer Center | ○ | ○ |
| Virginia Commonwealth University | ○ | ○ |
| University Wisconsin Carbone Cancer Center | ○ | ○ |
| British Columbia Cancer Agency | ○ | ○ |
| Juravinski Cancer Center | ○ | ○ |
| University Health Network/Princess Margaret Cancer Center | ○ | ○ |

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90% Complete

**Demographics**

*The next set of questions asks about your background and experience with cancer research.*

14. Please indicate your sex:

- ○ Female
- ○ Male

15. Please indicate your ethnicity:

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino

16. Please indicate your race (mark one or more of the following):

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

17. What is the highest degree or level of education you have completed?

- ○ High school graduate
- ○ Completed some college
- ○ Associate degree
- ○ Bachelor's degree
- ○ Completed some postgraduate
- ○ Master's degree
- ○ Ph.D.
- ○ Medical degree
- ○ Other advanced degree beyond a Master's degree

18. How long have you been involved with ...

| | 1-5 years | 6-10 years | 11-15 years | 16-20 years | 20+ years |
|---|---|---|---|---|---|
| Early phase clinical trials | ○ | ○ | ○ | ○ | ○ |
| Cancer research | ○ | ○ | ○ | ○ | ○ |
| Your center | ○ | ○ | ○ | ○ | ○ |

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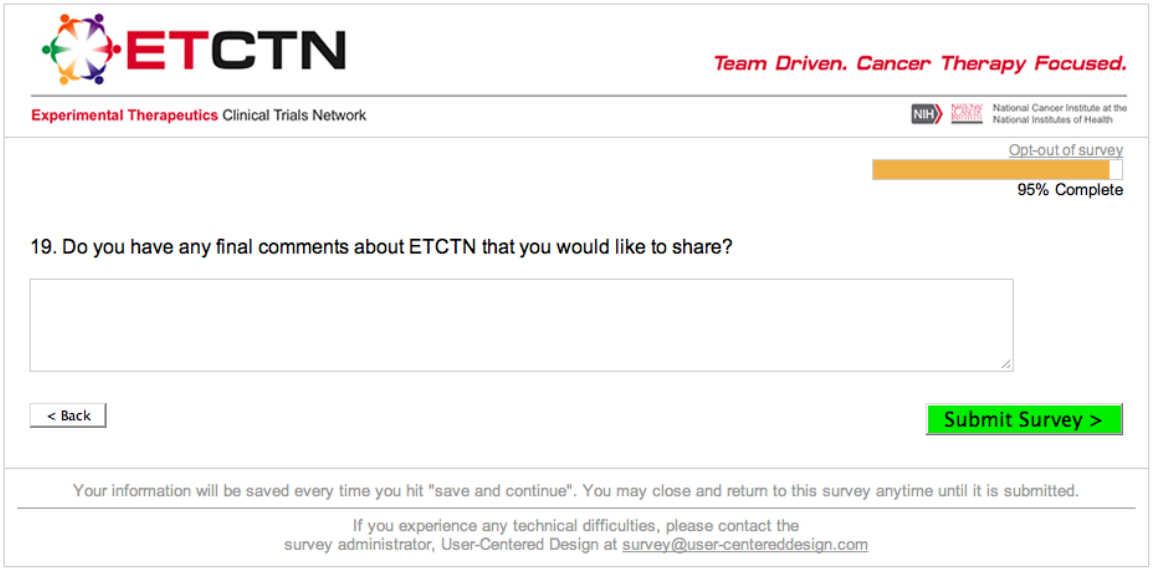
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95% Complete
19. Do you have any final comments about ETCTN that you would like to share?
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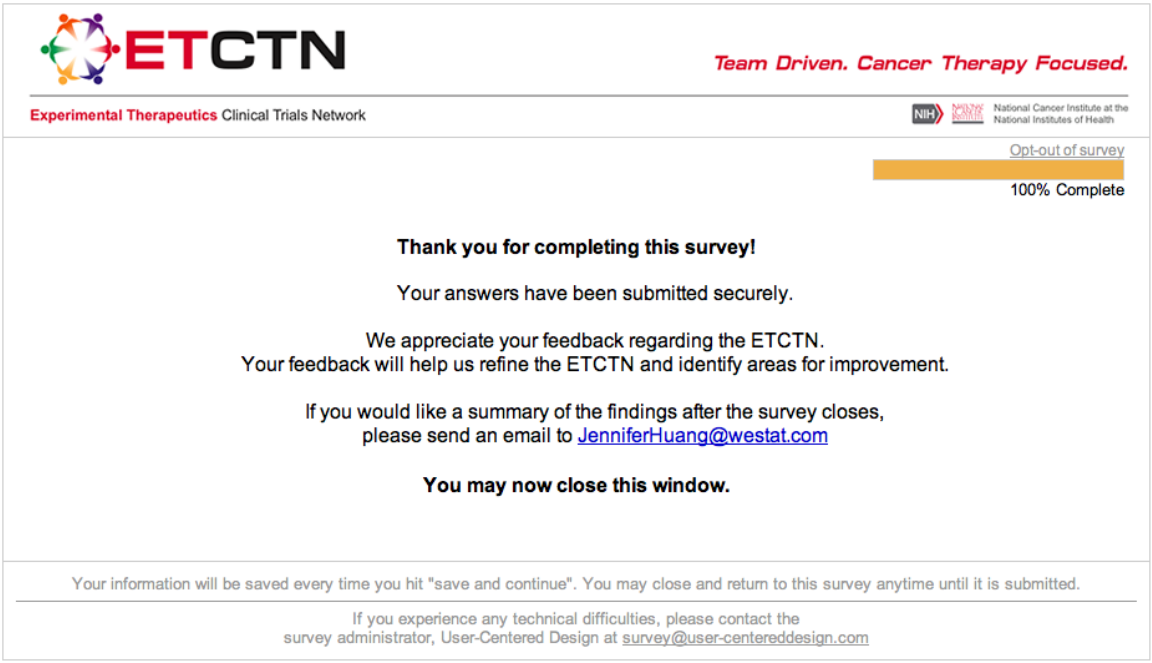
ETCTN
Team Driven. Cancer Therapy Focused.
Experimental Therapeutics Clinical Trials Network
National Cancer Institute at the National Institutes of Health
Opt-out of survey
100% Complete
Thank you for completing this survey!
Your answers have been submitted securely.
We appreciate your feedback regarding the ETCTN.
Your feedback will help us refine the ETCTN and identify areas for improvement.
If you would like a summary of the findings after the survey closes,
please send an email to JenniferHuang@westat.com
You may now close this window.
Your information will be saved every time you hit "save and continue". You may close and return to this survey anytime until it is submitted.
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