The Clinical Trials Transformation Initiative
CTTI Project: ClinicalTrials.gov

On-line Survey
FINAL: December 10, 2022

***The survey questions and response options were informed by previous CTTI qualitative research.**

Intro text

Thank you for your willingness to complete this survey.

Before you begin, here are answers to questions you might have about the survey.

What is the purpose of the survey?

- The U.S. Food and Drug Administration (FDA) is partnering with The Clinical Trials Transformation Initiative (CTTI) to conduct this survey.
- The FDA is interested in documenting diverse perspectives from different organizations about their experiences with registering and/or reporting clinical trial results information to ClinicalTrials.gov, including useful practices and challenges faced. Experiences with the usability of the ClinicalTrials.gov site interface or the ClinicalTrials.gov Modernization effort are not the focus of this survey.
- Data will be used to inform FDA's approach to further support and promote more complete reporting of clinical trial information.

Who is completing the survey?

We are asking individuals at organizations—such as academic institutions, medical product companies, government agencies, and non-government organizations—who provide oversight and/or register and/or report trial results to ClinicalTrials.gov to complete this survey.

How does the survey work?

You are asked to answer questions about your organization's administrative unit's engagement with ClinicalTrials.gov.

By "administrative unit", we mean the entity or individual(s) at your organization/institution/company that provides oversight and/or registers and/or reports results information in ClinicalTrials.gov. For example, this could be the Office of Research Compliance, a study team, or Principal Investigator, depending on your organization's approach to ClinicalTrials.gov compliance.

Survey questions focus on the policies and the approaches that your organization's administrative unit takes to comply with ClinicalTrials.gov regulatory requirements, including advantages and disadvantages of your approaches, challenges faced, and suggested strategies for addressing challenges. You do not need to include information about all trials at your organization—only those that your administrative unit or group is responsible for.

Must I complete the survey?

- No. Completing this survey is voluntary. You do not have to complete it if you do not want to. You can also choose not to answer questions if you prefer not to disclose the information.
- There are no consequences for not completing the survey.

Who will see my data?

- CTTI will view the individual responses that you provide.
- The FDA and NIH will not have access to your individual responses. Instead, CTTI will send FDA and NIH an aggregated summary of the survey findings.

- We will post a de-identified dataset on the CTTI website (https://www.ctti-clinicaltrials.org/) for others to analyze if they wish. We will not include any information that could identify you or your organization.

Who do I contact if I want to know more about the survey or have concerns?
If you have questions about this survey, please contact the CTTI Senior Project Manager, [name], by email at [email] or by telephone at [tel]. You may also contact the Duke University Health System Institutional Review Board Office at 919-668-5111, with any questions you may have (Study Protocol #Pro00108922).

We appreciate your time and interest in helping FDA learn about organization's experiences with ClinicalTrials.gov. Please complete the survey by January 9, 2023.

Survey questions

Your candid feedback can help support and promote more complete reporting of clinical trial information to ClinicalTrials.gov. Neither FDA nor NIH will have access to your individual responses and will both be provided an aggregated summary of survey findings instead.

The first set of questions focus on you and your organization.

#	Question	Response	Branching logic/additional questions

1.	a) What is the name of your organization?
	b) What is the name of the unit that you work in at your organization?
	c) What is the name of the sub-unit where you work?
	
	Examples:
	• **University/academic research center**
	  • Organization: Name of University
	  • Unit: Office of Clinical Research
	  • Sub-unit/Work group: Clinical Research Unit
	• **Medical product company**
	  • Organization: Name of medical product company
	  • Unit: Scientific Communication/Public Disclosures Group
	  • Sub-unit/work group: Registry and Transparency
	• **Government agency**
	  • Organization: Name of government agency
	  • Unit: Division/Center
	  • Sub-unit/work group: Branch
	
	Why do we ask this? We anticipate receiving responses from multiple people at the same organization. We want to be able to account for this during analysis. Your organizational information will not be shared with FDA or NIH, or lead to an enforcement action from the FDA. It will not be shared with other groups or linked publically to your responses. Answers will make your organizational information known to CTTI. We
		Please complete as applicable:
		
		a) Organization:
		b) Unit:
		c) Sub-unit/Work group	

#	Question	Response	Branching logic/additional questions
	take numerous steps to keep your data confidential; although as with all research, confidentiality cannot be 100% guaranteed. We do not believe any harm could result from a confidentiality breach as the survey questions below are not sensitive in nature.		
2.	Which of the following best describes your organization?	a) University/academic research center affiliated with a hospital/medical center b) University/academic research center not affiliated with a hospital/medical center c) Hospital/medical center not affiliated with a university/academic research center d) Pharmaceutical company e) Biotechnology company f) Medical device company g) Contract research organization (commercial/for profit) h) Government i) Another type of organization (please specify): _____ j) Choose not to disclose	
3.	Which of the following best describes your job title?	a) Principal Investigator b) Supervisory/leadership role for scientific/clinical operations but not the Principal Investigator (e.g., clinician, statistician) c) Supervisory role for regulatory affairs (e.g., Protocol Registration and Results System [PRS] administrator, compliance, project or database management) d) Staff/Specialist of scientific/clinical operations e) Staff/Specialist of regulatory affairs f) Scientific disclosure writer specific to transparency for ClinicalTrials.gov g) Another role (please specify: ___) h) Choose not to disclose	

#	Question	Response	Branching logic/additional questions
4.	How are you personally engaged in ClinicalTrials.gov compliance activities at your organization? I am involved in some way with— *Check all that apply*	a) Registering clinical trials in ClinicalTrials.gov b) Updating trial information in ClinicalTrials.gov (e.g., change in study status) c) Submitting results information in ClinicalTrials.gov d) Managing/providing oversight of organization compliance with registering and/or reporting results information in ClinicalTrials.gov e) Something else (please specify: ___) f) Choose not to disclose	
5.	How long have you been engaged in ClinicalTrials.gov compliance activities? This includes time in your current and any previous positions	|_____| years a) I do not know b) Choose not to disclose	
6.	At your organization, who is considered to be the ultimate responsible party? a) For registering trials in ClinicalTrials.gov? b) For reporting results information in ClinicalTrials.gov? The responsible party is the person or entity responsible for submitting and updating information about a clinical study to ClinicalTrials.gov.	For each question: a) Principal Investigator or Study Officer b) Organization or Sponsor c) Other (specify): d) I don't know e) Choose not to disclose	
7.	Which of the following best describes the overall management approach your administrative unit follows for complying with ClinicalTrials.gov regulatory requirements? By "administrative unit", we mean the entity or individual(s) at your organization/institution/company that provides oversight and/or registers and/or reports results information in ClinicalTrials.gov.	a) A **centralized/dedicated approach**—A *single office or group* vets and supports all submissions of clinical trial information to ClinicalTrials.gov and monitors compliance with requirements. b) A **decentralized/distributed approach**—*Each Principal Investigator* or another organization *employee* is solely responsible for meeting clinical trial information reporting requirements. c) A **hybrid approach**—Both centralized and decentralized components are used (please describe: __) d) We use **another approach** (please describe: _)	

#	Question	Response	Branching logic/additional questions
		e) I don’t know f) Choose not to disclose	

These questions focus on the applicable clinical trials your administrative unit registers and reports.

No.	Question	Response	Branching logic/additional questions
8.	[Ask if **centralized/dedicated, hybrid, other approach**—6a, c, d] About how many **applicable clinical trials** did YOUR administrative unit register and report results information in ClinicalTrials.gov in the past year? *This includes the number of* **applicable clinical trials** *that you and other people in your administrative unit registered or reported. This is the sub-unit level you mentioned at the beginning of the survey.* *It does NOT include* **applicable clinical trials** *registered or reported by other administrative units and centers at your organization.* The FDA defines applicable clinical trial as: • Controlled clinical investigations (other than phase 1 investigations) of any U.S. FDA-regulated drug or biological product for any disease or condition • Certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric postmarket surveillances of a device product [Ask if **decentralized/distributed approach**—6b] About how many **applicable**	**Register** a) 0 studies b) 1 study c) 2 to 5 studies d) 6 to 15 studies e) 16 to 40 studies f) More than 40 studies g) I don't know h) Choose not to disclose **Report results information** a) 0 studies b) 1 to 5 studies c) 6 to 15 studies d) 16 to 25 studies e) More than 25 studies f) I don't know g) Choose not to disclose	

	clinical trials did Principal Investigators or other organization employees register and report results in ClinicalTrials.gov in the past year? *This includes the number of **applicable clinical trials** that Principal Investigators or other organization employees registered or reported at your organization.* The FDA defines applicable clinical trial as: • Controlled clinical investigations (other than phase 1 investigations) of any U.S. FDA-regulated drug or biological product for any disease or condition • Certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric postmarket surveillances of a device product		
9.	What are the external funding sources of the applicable clinical trials that your administrative unit registers and/or reports results information in ClinicalTrials.gov? By "administrative unit", we mean the entity or individual(s) at your organization/institution/company that provides oversight and/or registers and/or reports results information in ClinicalTrials.gov. *Check all that apply*	a) Industry b) Government c) Foundation d) Other (please specify): _____ e) I don't know f) Not applicable g) Choose not to disclose	

These questions focus on your organization's ClinicalTrials.gov policies and procedures for registering and reporting in ClinicalTrials.gov

No.	Question	Response	Branching logic/additional questions
10.	Does your organization have written policies or standard operating procedures on registering trials and/or reporting results information in ClinicalTrials.gov?	**Register** a) Yes b) No c) I don't know d) Choose not to disclose **Report results information** a) Yes b) No c) I don't know d) Choose not to disclose	
11.	What types of research does your organization require or encourage to be registered in ClinicalTrials.gov? We are interested in learning about all types of clinical trials. *Check all that apply* *Check "encourage" if your organization encourages but does not require the research to be registered.* *"Interventional trial" means that participants are assigned to an intervention.*	**Required to register** a) Phase 1 clinical trials b) Phase 2 clinical trials without participant randomization c) Prospective interventional trials of a drug, biological product, or medical device intended for regulatory submission d) Prospective interventional trials of a drug, biological product, or medical device NOT intended for regulatory submission e) Prospective interventional trials not involving a drug, biological product or medical device f) Research that prospectively assigns people to an intervention without a comparison or control group g) Observational clinical research h) Feasibility clinical research (e.g., feasibility device trial) i) Other (please specify) j) I don't know k) Choose not to disclose .	➔ For each trial checked: For what reasons are you required to register this type of research in ClinicalTrials.gov? *Check all that apply* a) Regulatory requirement for current trial b) Anticipate future regulatory submission c) Organizational requirement d) Funder or sponsor requirement e) Journal requirement f) Other (please specify) g) Choose not to disclose For each trial checked: For what reasons are you encouraged to register this

No.	Question	Response	Branching logic/additional questions
		Encouraged to register a) Phase 1 clinical trials b) Phase 2 clinical trials without participant randomization c) Prospective interventional trials of a drug, biological product, or medical device intended for regulatory submission d) Prospective interventional trials of a drug, biological product, or medical device NOT intended for regulatory submission e) Prospective intervention trials not involving a drug, biological product or medical device f) Research that prospectively assigns people to an intervention without a comparison or control group g) Observational clinical research h) Feasibility clinical research (e.g., feasibility device trial) i) Other (please specify) j) I don't know k) Choose not to disclose	type of research in ClinicalTrials.gov? [_____]

No.	Question	Response	Branching logic/additional questions
12.	How does your administrative unit become aware that a clinical trial at your organization needs to be registered and/or report results information in ClinicalTrials.gov? By "administrative unit", we mean the entity or individual(s) at your organization/institution/company that provides oversight and/or registers and/or reports results information in ClinicalTrials.gov. *Check all that apply*	**Register** a) An Institutional Review Board informs the administrative unit that a trial must be registered b) An Institutional Review Board informs the administrative unit of an approved trial and the administrative unit determines if the trial must be registered c) The administrative unit receives an internal notification from within the organization to register a trial d) The Principal Investigator contacts the administrative unit requesting assistance with registering a trial e) The trial's coordinator/clinical operations manager notifies the administrative unit that they are registering a new trial f) The trial's coordinator/clinical operations manager notifies the administrative unit that a new trial must be registered g) The administrative unit tracks records in an internal Clinical Trials Management System (CTMS) h) The administrative unit reviews Protocol Registration and Results System (PRS) Reports i) Through a Notice of Award/Contract j) Other (please specify: _____) k) I don't know l) Not applicable m) Choose not to disclose	

No.	Question	Response	Branching logic/additional questions
		Report results information a) The Principal Investigator contacts the administrative unit requesting assistance with reporting trial results information b) The administrative unit tracks records in an internal Clinical Trials Management System (CTMS) c) The administrative unit is notified by an internal CTMS that trials need to be registered and/or results info reported d) The administrative unit reviews Protocol Registration and Results System (PRS) Reports e) An external third-party database identifies and notifies the administrative unit's internal database of trials needing results information reported f) The trial's coordinator/clinical operations manager notifies the administrative unit that results information must be reported g) Other (please specify: _____) h) I don't know i) Not applicable j) Choose not to disclose	

No.	Question	Response	Branching logic/additional questions
13.	Is there a process for notifying Principal investigators/study teams in advance of when results for an applicable clinical trial are due so that they can prepare results information?	a) Yes b) No c) I don't know d) Not applicable e) Choose not to disclose	➔ IF YES BRANCHING LOGIC How far in advance are Principal Investigators/study teams initially notified that results information is due? a) 1-3 months b) 4-6 months c) 7-9 months d) 10-12 months e) More than 1 year f) Other (please specify): g) Choose not to disclose
14.	Does your organization have a policy (formal or informal) detailing penalties and/or consequences for failing to register a clinical trial and/or report results information?	**Register** a) Yes b) No c) I don't know d) Choose not to disclose **Report results information** a) Yes b) No c) I don't know d) Choose not to disclose	IF YES BRANCHING LOGIC: Which of the following penalties or consequences are applied for not registering a clinical trial in ClinicalTrial.gov? *Check all that apply* [list below] Which of the following penalties or consequences are applied for not reporting results information in ClinicalTrial.gov? *Check all that apply*

No.	Question	Response	Branching logic/additional questions
			a) Escalation to compliance team and/or higher levels of leadership within organization b) Increased negative visibility of trials that are non-compliant c) The Principal Investigator may not begin any new research projects d) The Principal Investigator may not continue with enrollment on current study e) The Principal Investigator may be suspended from conducting any research f) The Principal Investigator may be assessed a monetary penalty g) The Principal Investigator's department may be assessed a monetary penalty h) The organization may decrease/limit bonuses and/or raises if compliance requirements are not met i) Other (please specify) j) I don't know k) Choose not to disclose
15.	Does your organization or administrative unit have a process in place to assess trials'	**Response options for both:** **Register**	→ IF YES BRANCHING LOGIC (for all questions)

No.	Question	Response	Branching logic/additional questions
	compliance with ClinicalTrials.gov regulatory requirements?	a) Yes b) No c) I don't know d) Choose not to disclose **Report results information** a) Yes b) No c) I don't know d) Choose not to disclose	Is the process in place to assess compliance with registering clinical trials in ClinicalTrials.gov required or optional? a) Required b) Optional Is the process in place to assess compliance with reporting results information in ClinicalTrials.gov required or optional? a) Required b) Optional
16.	Does your organization or administrative unit have a process in place to conduct pre-submission reviews to assess the quality of clinical trial information *before* it is reported in ClinicalTrials.gov?	**Response options for both:** **Register** a) Yes b) No c) I don't know d) Choose not to disclose **Report results information** a) Yes b) No c) I don't know Choose not to disclose	→ IF YES BRANCHING LOGIC (for all questions) Is this process for assessing quality before registering clinical trials in ClinicalTrials.gov required or optional? a) Required b) Optional Is this process for assessing quality before reporting results information in ClinicalTrials.gov required or optional? c) Required d) Optional

These questions focus on Principal Investigator engagement with implementing the ClinicalTrials.gov requirements. The questions focus on Principal Investigators at your organization.

*Branching logic: (1) Skip if "Principal Investigator" is checked for Q3 (option a) – or checked d, e, f in Q2 (*Pharmaceutical company, Biotechnology company, and Medical device company)

No.	Question	Response	Branching logic/additional questions
17.	In general, how aware are Principal Investigators of the ClinicalTrials.gov's regulatory requirements for:	• Registering clinical trials in ClinicalTrials.gov • Updating/maintaining records in ClinicalTrials.gov • Reporting trial results information in ClinicalTrials.gov ANSWER OPTIONS FOR EACH QUESTION: a) Very aware b) Somewhat aware c) Not at all aware d) It depends on the Principal Investigator—some are aware and others are not e) I don't know f) Not applicable g) Choose not to disclose	
18.	In general, how engaged/involved are Principal Investigators in activities related to registering clinical trials in ClinicalTrials.gov?	a) Very engaged b) Somewhat engaged c) Not engaged at all d) It depends on the Principal Investigator—some are engaged and others are not e) I don't know f) Not applicable g) Choose not to disclose	
19.	In general, how engaged/involved are Principal Investigators in activities related to updating/maintaining records in ClinicalTrials.gov?	a) Very engaged b) Somewhat engaged c) Not engaged at all d) It depends on the Principal Investigator—some are engaged and others are not e) I don't know f) Not applicable g) Choose not to disclose	

20.	In general, how engaged/involved are Principal Investigators in activities related to reporting results in ClinicalTrials.gov?	a) Very engaged b) Somewhat engaged c) Not engaged at all d) It depends on the Principal Investigator—some are engaged and others are not e) I don't know f) Not applicable g) Choose not to disclose	

Branching logic: Respondents who checked d, e, f in Q2 (Pharmaceutical company, Biotechnology company, and Medical device company) get this question:

No.	Question	Response	Branching logic/additional questions
21.	In general, how aware are study teams of the ClinicalTrials.gov's regulatory requirements for:	• Registering clinical trials in ClinicalTrials.gov • Updating/maintaining records in ClinicalTrials.gov • Reporting trial results information in ClinicalTrials.gov ANSWER OPTIONS FOR EACH QUESTION: a) Very aware b) Somewhat aware c) Not at all aware d) It depends on the study team—some are aware and others are not e) I don't know f) Not applicable g) Choose not to disclose	
22.	In general, how engaged/involved are study teams in activities related to registering clinical trials in ClinicalTrials.gov?	a) Very engaged b) Somewhat engaged c) Not engaged at all d) It depends on the study team—some are engaged and others are not e) I don't know f) Not applicable g) Choose not to disclose	
23.	In general, how engaged/involved are study teams in activities related to updating/maintaining records in ClinicalTrials.gov?	a) Very engaged b) Somewhat engaged c) Not engaged at all d) It depends on the study team—some are engaged and others are not e) I don't know	

		f) Not applicable g) Choose not to disclose	
24.	In general, how engaged/involved are study teams in activities related to reporting results in ClinicalTrials.gov?	a) Very engaged b) Somewhat engaged c) Not engaged at all d) It depends on the study team—some are engaged and others are not e) I don't know f) Not applicable g) Choose not to disclose	

These questions focus on resources and tools on ClinicalTrials.gov that your administrative unit uses

No.	Question	Response	Branching logic/additional questions
25.	Which of the following external resources and tools does your administrative unit reference for guidance on the ClinicalTrials.gov regulatory requirements? By "administrative unit", we mean the entity or individual(s) at your organization/institution/company that provides oversight and/or registers and/or reports results information in ClinicalTrials.gov. *Check all that apply*	a) ClinicalTrials.gov Protocol Registration and Results System (PRS) Resources (e.g., Quick Start Guide, PRS User's Guide, Guided Tutorials, Hot off PRS Updates, Data Element Definitions, ACT Checklist, Frequently Asked Questions) b) ClinicalTrials.gov Training Materials (e.g., Train the Trainer Workshop, Online Presentations) c) NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information d) NIH website on Basic Experimental Studies Involving Humans (BESH) Training e) FDA website on FDA's Role: ClinicalTrials.gov Information f) FDA Guidance on Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank g) CITI Program ClinicalTrials.gov Training h) Clinical Trials Registration and Results Reporting Taskforce i) Drug Information Association's (DIA) Clinical Trial Transparency Community j) Third-party solutions (please specify): k) Other (please specify): l) I don't know m) Choose not to disclose	
26.	How helpful, if at all, do you find the following FDA resources for providing guidance on complying with the ClinicalTrials.gov regulatory requirements?	a) FDA.gov page on FDA's role related to ClinicalTrials.gov b) FDA.gov page on ClinicalTrials.gov Notices of Noncompliance and Civil Money Penalty Actions c. FDA guidance Form FDA 3674 d. FDA guidance on Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank ANSWER OPTIONS FOR EACH ITEM: a) Extremely helpful b) Very helpful c) Helpful d) Somewhat helpful e) Not at all helpful f) Choose not to disclose g) Unfamiliar with resource	

No.	Question	Response	Branching logic/additional questions
27.	What additional resources from the FDA would be helpful for complying with ClinicalTrials.gov regulatory requirements? *Check all that apply*	a) Better communication around FDA guidances b) Better communications on notices of non-compliance c) Virtual events, conferences, and workshops d) In-person events, conferences, and workshops e) Pre-recorded informational sessions on ClinicalTrials.gov compliance f) Other (please specify): _____ g) I don't know h) Choose not to disclose	
28.	What additional resources are needed, if anything, to help you comply with ClinicalTrials.gov regulatory requirements? *Check all that apply*	a) Tutorials and tip sheets about changing regulations and adjustments in ClinicalTrials.gov as changes happen b) Training sessions with ClinicalTrial.gov reviewers to learn from their experiences c) Providing a list of common mistakes made during the PRS review process d) BESH training (Basic Experimental Studies Involving Humans) e) Practice environment in Protocol Registration and Results System (PRS) where people can practice entering registrations and results information f) Other (please specify): _____ g) I don't know h) Choose not to disclose	

These questions focus on the advantages and disadvantages of your administrative unit's management approach for complying with the ClinicalTrials.gov regulatory requirements

[Display logic based on what they reported in Q7]

No.	Question	Response	Branching logic/additional questions
29.	Earlier you selected that your administrative unit follows a **centralized/dedicated** approach. Based on your experience, what are the **advantages** of a **centralized/dedicated** approach, if any? *Check all that apply*	a) Streamlines/increases efficiency of compliance activities b) Improves ability to monitor/control study records c) Contributes to more timely submissions d) Fosters unified/consistent presentation of all records e) Improves quality of submissions f) Improves completeness of submissions g) Functions as a single resource of expertise and support for Principal Investigators/study teams h) Facilitates adherence to meeting compliance metrics i) Fosters improved compliance by proactively educating stakeholders about updates and changes in ClinicalTrials.gov requirements j) Other (please specify): k) No advantages l) Choose not to disclose	

No.	Question	Response	Branching logic/additional questions
	Based on your experience, what are the **disadvantages** of a **centralized/dedicated** approach, if any? *Check all that apply*	a) Lack of Principal Investigator/study team engagement/accountability for compliance with the ClinicalTrials.gov requirements b) Having to rely on the accuracy and completeness of information provided by Principal Investigators/study teams since limited or no access to data c) Working with other stakeholders who have limited knowledge of ClinicalTrials.gov requirements d) Having to keep up with the workload e) Needing more financing of staff and other resources to maintain a centralized/dedicated centralized administrative unit f) Other (please specify): g) No disadvantages h) Choose not to disclose	
30.	Earlier you selected that your administrative unit follows a **decentralized/distributed** approach. Based on your experience, what are the **advantages** of a **decentralized/distributed** approach, if any? *Check all that apply*	a) Streamlines/increases efficiency of compliance activities b) Improves ability to monitor/control study records c) Contributes to more timely submissions	

No.	Question	Response	Branching logic/additional questions
		d) Fosters unified/consistent presentation of all records e) Improves quality of submissions f) Improves completeness of submissions g) Facilitates adherence to meeting compliance metrics h) Principal Investigators are fully responsible and accountable for their research i) The administrative unit does not need to locate Principal Investigators/study teams to get information j) Fewer staff are required k) Other (please specify): l) No advantages m) Choose not to disclose	
	Based on your experience, what are the **disadvantages** of a **decentralized/distributed** approach, if any? *Check all that apply*	a) Lack of Principal Investigator/study team engagement/accountability for compliance with the ClinicalTrials.gov requirements b) Lower compliance rates c) Steep learning curve for Principal Investigators/study teams d) Other (please specify): e) No disadvantages f) Choose not to disclose	
31.	Earlier you selected that your administrative unit follows a **hybrid** approach.	a) Allows for evaluating adherence to requirements	

No.	Question	Response	Branching logic/additional questions
	Based on your experience, what are the **advantages** of a **hybrid** approach, if any? *Check all that apply*	b) Allows for reviewing quality of records before being released to ClinicalTrials.gov c) Allows for Principal Investigators to be responsible and accountable for their own studies d) The administrative unit does not need to locate Principal Investigators/study teams to get information e) Other (please specify): f) No advantages g) Choose not to disclose	
	Based on your experience, what are the **disadvantages** of a **hybrid** approach, if any? *Check all that apply*	a) Involves individuals' with varying experience with using ClinicalTrials.gov b) Requires Principal Investigators/study staff to be aware of deadlines c) Other (please specify): d) No disadvantages e) Choose not to disclose	
32.	Earlier you selected that your administrative unit follows **another** approach. Based on your experience, what are the **advantages** of this approach, if any?	[*Open field to describe advantages of other approach*]	
	Based on your experience, what are the **disadvantages** of this other approach, if any?	*[Open field to describe disadvantages of other approach]*	

These questions focus on the challenges you have faced with registering and report trial results information in Clinicaltrials.gov and strategies you have used to address challenges.

No.	Question	Response	Branching logic/additional questions
33.	Which of the following challenges has your administrative unit faced when registering clinical trials and/or reporting results information in ClinicalTrials.gov? By "administrative unit", we mean the entity or individual(s) at your organization/institution/company that provides oversight and/or registers and/or reports results information in ClinicalTrials.gov. *Check all that apply*	*Note: Experiences with the usability of the ClinicalTrials.gov site interface or the ClinicalTrials.gov Modernization effort are not the focus of this survey.* **Register** a) Lack of harmonization between ClinicalTrials.gov and other registries on registering clinical trials b) Lack of harmonization between ClinicalTrials.gov and other regulatory agency's requirements on registering clinical trials c) No or unclear organizational policies on registering clinical trials d) Unclear who is responsible for registering a new clinical trial *in general* e) Unclear who is responsible for registering a new clinical trial *when multiple entities are involved* f) Principal Investigator/study teams' lack of understanding of organizational policies on registering clinical trials g) Principal Investigator/study teams' lack of understanding of the types of trials that must be registered h) Principal Investigator/study teams' lack of understanding on when to register clinical trials i) Data owners' lack of knowledge of the specific content that needs to be included in the Clinical Studies Report (CSR) j) Absence of well-specified and measurable outcome measures in protocol that meet ClinicalTrials.gov requirements k) Non-responsive Principal Investigators/study teams l) Inconsistencies across Protocol Registration and Results System reviewers' comments m) Lack of concern regarding potential consequences of noncompliance n) No organizational policies/penalties for noncompliance o) Other (please specify): p) I don't know q) Choose not to disclose	➔ BRANCHING LOGIC: For each challenge identified] For each checked item: How burdensome, if at all, were any of the challenges that you selected? a) Extremely burdensome b) Very burdensome c) Burdensome d) Somewhat burdensome e) Not at all burdensome f) Choose not to disclose

No.	Question	Response	Branching logic/additional questions
		Report results information a) Lack of harmonization between FDA Final Rule and other registries on reporting clinical trial results information b) Lack of harmonization between ClinialTrials.gov and other regulatory agency's requirements on reporting clinical trial results information c) No or unclear organizational policies on reporting results information of clinical trials d) Unclear who is responsible for reporting trial results information *in general* e) Unclear who is responsible for reporting trial results information *when multiple entities are involved* f) Principal Investigator/study teams' lack of understanding of organizational policies on reporting results information of clinical trials g) Principal Investigator/study team's lack of understanding regarding which trial results information must be submitted to ClinicalTrials.gov h) Principal Investigator/study teams' lack of understanding of the regulatory timelines for submitting results information i) Principal Investigator/study teams' lack of understanding on when to report results information *for unsuccessful trials* j) Principal Investigator/study teams' concerns about disclosing competitive data k) Principal Investigator/study teams' concerns about ability to publish if results information is reported in ClinicalTrials.gov prior to publication l) Misunderstanding about why results information need to be submitted to ClinicalTrials.gov if they have already been published m) Concerns about needing to wait until all data are analyzed before reporting results information in ClinicalTrials.gov to prevent potential discrepancies between ClinicalTrials.gov records and published results	

No.	Question	Response	Branching logic/additional questions
		n) Lack of understanding/clear guidance on whether the information provided is considered accurate and/or complete o) Non-responsive Principal Investigator/study team p) Inconsistencies across Protocol Registration and Results System reviewers' comments q) Lack of concern regarding potential consequences of noncompliance r) No organizational policies/penalties for noncompliance s) Other (please specify): _____ t) I don't know u) Choose not to disclose	
34.	Which of the following **internal strategies** has your administrative unit used to address challenges related to registering trials and/or reporting results information in ClinicalTrials.gov? *Check all that apply*	a) Escalating to upper levels of leadership for Principal Investigators/study teams that are non-responsive to the administrative unit's communication about compliance b) Informing Principal Investigators/study teams about the possibility of fines for non-compliance with ClinicalTrials.gov regulatory requirements c) Informing Principal Investigators/study teams that submitting results information to ClinicalTrials.gov is separate from publishing results d) Informing Principal Investigators/study teams that per ICMJE, reporting results information to ClinicalTrials.gov does not preclude publishing results in journals e) Reviewing the purpose of ClinicalTrials.gov requirements during training f) Collaborating with internal group(s) to facilitate communication and compliance g) Using a dedicated/centralized approach to meeting ClinicalTrials.gov requirements h) Using a decentralized approach to meeting ClinicalTrials.gov requirements to put the onus for compliance on Principal Investigators/study teams i) Providing education, resources, guidance, and support about meeting ClinicalTrials.gov requirements to Principal Investigators/study teams and other research personnel j) Using internal database or other tracking system	

No.	Question	Response	Branching logic/additional questions
		k) Collaborating with Institutional Review Boards to determine if trials need to be registered l) Linking to Institutional Review Boards' systems to track trials throughout their lifecycle m) Taking a proactive, rather than reactive, approach to complying with ClinicalTrials.gov regulatory requirements n) Assigning Principal Investigators (rather than organization) as responsible party o) Other (please specify): _____ p) I don't know q) Choose not to disclose	

This is the last set of questions. They focus on the FDA's response to non-compliance to ClinicalTrials.gov requirements. This means the timely and accurate registration, submission of results information, and updating of trials information as needed.

No.	Question	Response	Branching logic/additional questions
	Thinking broadly across the clinical trial enterprise, how aware, if at all, do you feel responsible parties are that: *Definition: The responsible party is the person or entity responsible for submitting and updating information about a clinical study to ClinicalTrials.gov.*	35-37	
35.	FDA may issue **pre-notices of noncompliance** to the responsible parties of applicable clinical trials that do not appear to be in compliance with ClinicalTrials.gov regulatory requirements?	a) Extremely aware b) Very aware c) Aware d) Somewhat aware e) Not at all aware f) I don't know g) Choose not to disclose	
36.	FDA issues **notices of noncompliance** to responsible parties for applicable clinical trials that do not comply with ClinicalTrials.gov regulatory requirements?	a) Extremely aware b) Very aware c) Aware d) Somewhat aware e) Not at all aware f) I don't know g) Choose not to disclose	
37.	FDA may issue civil money penalties to the responsible parties for applicable clinical trials that do not comply with ClinicalTrials.gov regulatory requirements?	a) Extremely aware b) Very aware c) Aware d) Somewhat aware e) Not at all aware f) I don't know g) Choose not to disclose	

No.	Question	Response	Branching logic/additional questions
38.	How impactful, if at all, do you think FDA's notices of noncompliance have been on **responsible parties** for ensuring that the ClinicalTrials.gov regulatory requirements are met?	a) Extremely impactful b) Very impactful c) Impactful d) Somewhat impactful e) Not at all impactful f) Choose not to disclose	
39.	Did you complete the survey alone or with others in your administrative unit?	a) Alone b) With others c) Choose not to disclose	

Thank you very much for your time in completing this survey.