Johns Hopkins University

ClinicalTrials.gov Satisfaction Survey

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EXECUTIVE SUMMARY

Most investigators are aware there are consequences for failure to keep their ClinicalTrials.gov record up to date, such as disapproval of their IRB continuing review, or denial of the ability publish with particular journals. To date, we have had only a few investigators experienced those results in addition to the withholding of grant funds. The Food and Drug Administration Amendments Act also includes civil monetary penalties for non-compliance.

The JHU CliicalTrials.gov Program assists study teams with registration, record maintenance, results entry, and also implements a proactive strategy of contacting study teams before a non-compliance issue arises. As part of our commitment to compliance and providing high quality customer service, the JHU ClinicalTrials.gov Program initiated its first satisfaction survey with JHU ClinicallTrials.gov users last year. Following is a summary of the background and results of the survey.

INTRODUCTION

The Johns Hopkins University ClinicalTrials.gov Program (Program) assists research teams with the registration and reporting requirements of clinical trials by ensuring transparency through accurate and timely registration of clinical trials, trial updates, and clinical trial results reporting. In 1997, the Food and Drug Administration Modernization Act (FDAMA[1]) passed the first law requiring a public information resource for clinical trial registration and as a result, the National Institutes of Health (NIH) released the ClinicalTrials.gov database which is hosted at the National Library of Medicine. Ten years later, Congress passed the Food and Drug Administration Amendments Act (FDAAA[2]) which expanded the types of trials that require registration; required the submission of summary results and adverse events; and imposed civil monetary penalties for non-compliance. This led to the addition of a results component to the ClinicalTrials.gov website in 2008.

Several entities require trial registration and results reporting, and impose penalties for non-compliance. The US Department of Health and Human Services (HHS), National Institutes of Health (NIH), and the National Cancer Institute (NCI), require registration within the first 21 days of participant enrollment, and The Veterans Administration requires registration prior to the release of funding. For results reporting, HHS, NIH, NCI and the Veterans Administration (VA), require reporting within 1 year of the primary completion date. Penalties for these agencies can include loss of funding, civil monetary penalties or criminal proceedings. Certain trials submitting claims to Medicaid are required to register their trials. If not registered, coverage can be denied, and investigations could be triggered. Trials funded by the Patient-Centered Outcomes Research Institute (PCORI), including observational trials, are required to register or they could lose their funding. Journals that fall under the International Committee of Medical Journal Editors (ICMJE) umbrella require registration prior to participant enrollment, or they will deny publication. The Department of Defense (DOD) requires registration prior to enrollment, and prior to the release of funding.

Johns Hopkins University (JHU) Administrators for the ClinicalTrials.gov Protocol Registration and Results System (PRS) assist study teams with compliance and have access to all records within the School of Medicine, School of Nursing, Sidney Kimmel Comprehensive Cancer Center, and All Children's Hospital's institutional accounts. The Administrators create and modify user accounts, run compliance reports, send emails in advance of due dates for record updates and results reporting, review records prior to release to NIH, provide local and national presentations about compliance and record maintenance, and assist users with all aspects of clinical trial reporting in ClinicalTrials.gov to avoid any non-compliance.

Penalties for non-compliance can include civil or criminal judicial actions. Civil monetary penalties have increased with inflation to $13,237 per day, per study[3].

As part of our commitment to compliance, and our dedication to providing customer service, the Johns Hopkins University ClinicalTrials.gov program implemented a survey to assess users' satisfaction with the Program.

METHODOLOGY

The survey was designed in Qualtrics by the JHU Program Administrators. Before email distribution, the survey was reviewed by peers at the School of Nursing, School of Medicine, and individuals on the ClincalTrials.gov Taskforce. Survey invitation links were distributed by email to 1,547 account holders at Johns Hopkins' School of Medicine, School of Nursing, and The Sidney Kimmel Comprehensive Cancer Center (SKCCC). Two reminders, at approximately one-week intervals, were distributed to encourage survey completion.

KEY FINDINGS

Of the 1,547 individuals who were sent a survey, we received 177 responses, resulting in an 11% response rate.

Sixty eight (41%) investigators had a trial registered in the JHU Protocol and Results Reporting System (PRS); five (3%) had a trial registered in the SKCCC PRS, and six (3.6%) had a trial registered in both the JHU and SKCCC PRS; sixty-six (39.8%) respondents were study team members on a trial registered in the JHU PRS; 7 (4.2%) were study team members on a trial registered in the SKCCC PRS; 14 (8.4%) were study team members on trials registered in both JHU and SKCCC PRS accounts. (Table 1). Of all respondents, 67% (111/166) received assistance from the Administrators (Table 2).

Account holders were asked which services they received assistance with. The majority of respondents (75%, 80/107) received assistance with updating a record (Table 3), with 80% (60/75) reporting being very satisfied with the Administrators' response time (Table 4).

We asked respondents about their level of satisfaction with the timing of the advance notice provided to them to keep their record free from errors. Sixty-nine percent (61/89) were very satisfied with the timing of the email notifications (Table 5). The respondents were also asked about their satisfaction with the instructions provided to assist them in maintaining their record. They were most satisfied with a summary of the procedure versus screenshots and step-by-step instructions (62%, 55/89) (Fig. 6). When asked what additional items would be helpful in maintaining records, 62% (52/84) of the respondents chose instructions as an email attachment (Table 6).

Seventy-one percent of respondents reported that they seek guidance for registering and reporting results by sending an email to the Program (Table 7).

Eighty-five percent of account holders reported being aware of the potential consequences for failure to update their records (Table 8). The consequences they were most aware of were disapproval of IRB continuing review (57%) and publication restrictions (53%). Of the consequences that could be imposed, 2% of Principal Investigators had their IRB continuing review disapproved; 2% experienced publication restrictions; and 1% had future grant funds withheld (Table 9).

CONCLUSIONS

The majority of the respondents indicated they were satisfied with the program. Program staff will use the data gathered from the survey to incorporate additional educational materials such as video tutorials and webinars. Program staff will also do more to educate faculty and staff members about the importance of ClinicalTrials.gov policies and to make them aware of consequences for non-compliance.

For future surveys we plan to advertise through various channels to increase the response rate for a more representative sample size. Comparision of surveys over time may help us to discover trends in the utilization of our serices and preferences in user needs.

While it is our intention to meet all Federal (e.g., Final Rule (42 CFR Part 11[4]), NIH Dissemination Policy[5]) statutes and avoid consequences for non-compliance, we are aware that some principal investigators/institutions do experience them. Highlighting these cases (de-identified) will serve to instruct others.

TABLES

Table 1. Are you the PI of at least 1 research study registered on ClinicalTrials.gov?	%	Count
Yes, I'm the PI for at least one trial registered with Johns Hopkins Univ.	41.0%	68
Yes, I'm the PI for at least one trial registered with Sidney Kimmel Cancer Ctr	3.0%	5
Yes, I'm the PI for at least one trial registered with both JHU and Sidney Kimmel Cancer Ctr	3.6%	6
No, I'm a study team member for at least one trial registered with Johns Hopkins Univ.	39.8%	66
No, I'm a study team member for at least one trial registered with Sidney Kimmel Cancer Ctr.	4.2%	7
No, I'm a study team member for at least one trial registered with both JHU and Sidney Kimmel Cancer Ctr.	8.4%	14
Total	**100%**	**166**

Table 2. Have you received assistance from the JHU ClinicalTrials.gov Program?	%	Count
No	33.0%	55
Yes	67.0%	111
Total	**100%**	**166**

Table 3. Which services have you received assistance for? (Select all that apply)	%	Count
Updating a record	74.8%	80
Registering a study on ClinicalTrials.gov	64.5%	69
Addressing errors in your record	54.2%	58
Requesting an account	47.7%	51
Reporting results	32.7%	35
Transferring a record to or from another institution	5.6%	6
Responding to NIH comments	5.6%	6
Total	**100%**	**107**

Table 4. Please rate your satisfaction with the process for updating a record

	Very dissatisfied		Moderately dissatisfied		Slightly dissatisfied		Slightly satisfied		Moderately satisfied		Very satisfied		Total
Response time for assistance from JHU Program	1.3%	1	1.3%	1	0.0%	0	4.0%	3	13.3%	10	80.0%	60	**75**
Knowledge of JHU Program	1.3%	1	0.0%	0	0.0%	0	5.3%	4	21.3%	16	72.0%	54	**75**
Time for NIH PRS reviewers to approve the record update	1.4%	1	1.4%	1	1.4%	1	8.2%	6	20.6%	15	67.1%	49	**73**

Respondents answered this question only if they selected that they received assistance updating a record, see Table 3.

Table 5. When your record is nearing time for an update or results reporting, we send email notifications prior to the due date to keep your record free from errors. Please indicate your satisfaction with the items below.													
	Very dissatisfied		Moderately dissatisfied		Slightly dissatisfied		Slightly satisfied		Moderately satisfied		Very satisfied		Total
Amount of time given to respond prior to due date	1.1%	1	2.3%	2	1.1%	1	9.0%	8	18.0%	16	68.5%	61	**89**
Summary of what to do	0.0%	0	2.3%	2	1.1%	1	15.7%	14	19.1%	17	61.8%	55	**89**
Screenshots of what to do	0.0%	0	2.7%	2	5.5%	4	16.4%	12	15.1%	11	60.3%	44	**73**
Step by step instructions	0.0%	0	2.5%	2	3.8%	3	17.5%	14	17.5%	14	58.8%	47	**80**

Table 6. What additional items would be helpful to you in registering, updating, and reporting results?	%	Count
Instructions as an email attachment	61.9%	52
On-demand PDF instructions on the JHU CTgov Program website	50.0%	42
On-demand videos housed on the JHU CTgov Program website	40.5%	34
Video instructions in the email body	32.1%	27
Other	15.5%	13
Webinars	10.7%	9
Total	**100%**	**84**

Table 7. Where do you seek guidance for registering and reporting results?	%	Count
I send an email to the Program (registerclinicaltrials@jhmi.edu)	70.5%	67
I look on the Program website for guidance	27.4%	26
I call the JHU Program staff	12.6%	12
I search the ClinicalTrials.gov PRS website	42.1%	40
I send an email to ClinicalTrials.gov PRS (register@clinicaltrials.gov)	11.6%	11
Other	8.4%	8
Total	**100%**	**95**

Table 8. Please select the potential consequences for failure to update ClinicalTrials.gov records of which you are aware.	%	Count
IRB disapproval of continuing review	57.3%	55
ICMJE publication restrictions	53.1%	51
Withholding of future grant funds	49.0%	47
Letter of potential non-compliance from FDA	46.9%	45
FDA monetary penalty	39.6%	38
Recovery of grant funds	26.0%	25
None of the above	14.6%	14
Potential criminal charges	10.4%	10
Total	**100%**	**96**

Table 9. Of the potential consequences, have you experienced any of the following?	%	Count
ICMJE publication restrictions	2.1%	2
Withholding of future grant funds	2.1%	2
IRB disapproval of continuing review	1.0%	1
Recovery of grant funds	0.0%	0
FDA monetary penalty	0.0%	0
Letter of potential non-compliance from FDA	0.0%	0
Potential criminal charges	0.0%	0
None of the above	96.9%	93
Total	**100%**	**96**

REFERENCES

1. Food and Drug Administration Modernization Act of 1997. Public Law 105-115, https://www.govinfo.gov/content/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf. (Accessed 14 March 2023).

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3. Civil Monetary Penalties Relating to the ClinicalTrials.gov Data Bank. August 2020. https://www.fda.gov/media/113361/download. (Accessed 14 March 2023)

4. Clinical Trials Registration and Results Information Submission. Final Rule. Federal Register. September 21, 2016. https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission. (Accessed 14 March 2023).

5. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm. (Accessed 14 March 2023).