**Delayed posting of results on ClinicalTrials.gov**

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**Details of Contributors**

*Conception and design*: AK and DF conceived the idea for the study.

*Acquisition of data*: NA, AK, PN, AL and OT acquired data

*Analysis and interpretation of data*: AK, EMW and PN checked the data and developed a codebook. AK, EMW, and NA consulted with a statistician who conducted the statistical analysis. All authors contributed to interpreting the results.

*Drafting of manuscript*: AK and NA wrote the first draft of the manuscript. NA, AK, PN, AL, OT and EMW substantially revised the manuscript for critical content.

*Critical revision*: All authors reviewed, provided critical revisions, and approved the manuscript for publication.

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**Potential Conflicts of Interest**

AK is the Co-chair of the Clinical Trials Registration and results Reporting Taskforce, a national consortium of members of academic medical centers, universities, hospitals, and non-profit organizations focused on the implementation of domestic clinical trials registration and results reporting requirements in the ClinicalTrials.gov public repository.

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**Data access, Responsibility, and Analysis**

The data and statistical code used for generating results described in this paper are available from Dryad at LINK.

**Introduction**

The Food and Drug Administration Amendments Act of 2007 (FDAAA)1 requires that Applicable Clinical Trials (ACTs) submit results to ClinicalTrials.gov within one year of completion. A complementary National Institutes of Health (NIH) policy requires that non-Applicable Clinical Trials (non-ACTs) submit results if funded by grants submitted to NIH from January 18, 2017.2

After investigators submit results, NIH specialists at the National Library of Medicine perform quality reviews and may send comments to investigators. Investigators must resubmit records receiving comments within 25 calendar days. Whether or not NIH comments on records, NIH must post results on ClinicalTrials.gov within 30 calendar days of first submission.1,3 We evaluated the time between submitting and posting results for Johns Hopkins University (JHU) records.

**Methods**

We included JHU records that first submitted results to ClinicalTrials.gov in 2017 and 2018, including non-ACTs that were not required to submit results but submitted results voluntarily. We included data about eligible records up to January 7, 2019.

We used both publicly available information and information available only to JHU. Data and code used to conduct this analysis are available at [www.LINK.com](http://www.LINK.com).

For each record, we calculated the number of results “submission cycles” and the number days between first submission and public posting, including the number of days under review by NIH and under review by JHU (Table 1). The first "submission cycle” began the day investigators submitted results and concluded when results were either posted by NIH or the record was returned to JHU with comments.

We used Stata 15.1 to conduct the analysis.

**Results**

In 2017, JHU submitted 88 records, including 73/88 (83%) probable Applicable Clinical Trials (pACTs) and 15/88 (17%) non-ACTs (Table 1). By January 7, 2019, 84/88 (95%) had been posted. JHU submitted records between 1 and 5 times (mean=2.27, SD=0.86). Results for 11/73 (15%) pACTs were posted after first submission (i.e., without NIH comments); all non-ACTs received NIH comments that required resubmission (11/11, 100%). JHU responded to NIH’s first comments within 25 days for 47/62 (76%) pACTs. NIH posted 6/73 (8%) pACTs within 30 days of first submission. On average, pACTs were posted 79.15 (42.16) days after first submission; non-ACTs were posted after 204.73 (149.21) days (Figure 1).

In 2018, JHU submitted 33 records, including 24/33 (73%) pACTs and 9/33 (27%) non-ACTs. By January 7, 2019, 31/33 (94%) had been posted. JHU submitted records up to 3 times (mean=2.19, SD=0.60). Results for 1/24 (4%) pACTs and 2/9 (22%) non-ACTs were posted without NIH comments. Of the pACTs receiving comments, JHU responded to NIH’s first comments within 25 days for 19/23 (83%). The only pACT that NIH posted within 30 days was the pACT without comments (1/24, 4%). On average, pACTs were posted 67.33 (29.14) days and non-ACTs were posted after 94.86 (98.49) days (Figure 1).

**Discussion**

Multiple submission cycles and lengthy NIH review delayed posting of clinical trial results. NIH posted few results within 30 days. The duration of NIH review was unpredictable, and greatly exceeded the maximum time allowed to post results (Table 1).1,3

Our analysis underestimates the time to post non-ACT results because four records submitted in 2017 and two records submitted in 2018 had not been posted as of January 7, 2019.

If academic organizations learn to identify errors, deficiencies, and inconsistencies before submitting results,4 a higher proportion of results may be posted after first submission. Previous research suggests that academic organizations could better support trial registration and reporting.5 NIH could further support academic organizations by improving automatic error checking and by reducing the time it takes NIH to review submitted records.

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