**Table 1. Number of submission cycles and days to post results for Johns Hopkins University clinical trial results, 2017-2018**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2017** | | **2018** | |
|  | **pACT** | **non-ACT** | **pACTa** | **non-ACT**b |
| **Number of records with submitted results** | 73 | 15 | 24 | 9 |
| **Number of records with posted results** | 73 | 11c | 24 | 7c |
| **Total days in review (mean, SD)**  JHU  NIH  Total | 17.00 (24.26)  62.15 (27.35)  79.15 (42.16) | 59.00 (66.61)  145.73 (105.86)  204.73 (149.21) | 16.33 (17.19)  51.00 (19.95)  67.33 (29.14) | 19.71 (26.47)  75.14 (72.61)  94.86 (98.49) |
| **Number of submission cycles**  mean (SD)  median (IQR) | 2.27 (0.89)  2 (1) | 2.27 (0.65)  2 (0) | 2.21 (0.51)  2 (0.5) | 2.14 (0.90)  2 (2) |
| **Posted after first cycle** | 11/73 (15%) | 0/11 (0%) | 1/24 (4%) | 2/7 (29%) |
| Total days in review (mean, SD)  JHU  NIH | Not applicable  31.27 (10.47) | Not applicable  60.78 (26.25) | Not applicable  27 (Not applicable) | Not applicable  30 (1.41) |
| **Posted after second cycle** | 40/73 (55%) | 9/11 (82%) | 17/24 (71%) | 2/7 (29%) |
| Total days in review (mean, SD)  JHU  NIH | 18.85 (24.70)  56.15 (15.31) | 65 (72.27)  152.56 (116.17) | 14.35 (16.81)  46 (13.23) | 49 (38.18)  144 (131.52) |
| **Posted after third cycle** | 14/73 (19%) | 1/11 (9%) | 6/24 (25%) | 3/7 (43%) |
| Total days in review (mean, SD)  JHU  NIH | 12.79 (13.34)  75.14 (18.29) | 52 (Not applicable)  85 (Not applicable) | 24.67 (17.47)  69.17 (25.98) | 13.33 (8.14)  59.33 (3.51) |
| **Posted after fourth cycle** | 7/73 (10%) | 1/11 (9%) | 0/24 (0%)d | 0/7 (0%)d |
| Total days in review (mean, SD)  JHU  NIH | 28.43 (23.56)  106 (23.32) | 12 (not applicable)  145 (not applicable) | Not applicable | Not applicable |
| **Posted after fifth cycle** | 1/73 (1%) | 0/11 (0%)d | 0/24 (0%)d | 0/7 (0%)d |
| Total days in review (mean, SD)  JHU  NIH | 109 (not applicable)  153 (not applicable) | Not applicable | Not applicable | Not applicable |

Abbreviations: IQR, interquartile range; JHU, Johns Hopkins University; NIH, National Institutes of Health; non-ACTs, non-Applicable Clinical Trials; pACTs, probable Applicable Clinical Trials; SD, standard deviation

Legend: We included records in the “JohnsHopkinsU” account, which include studies conducted by the Johns Hopkins School of Medicine and the Johns Hopkins School of Nursing. Other parts of Johns Hopkins University, including Bloomberg School of Public Health and Sidney Kimmel Comprehensive Cancer Center, have separate accounts.

aThe Food and Drugs Administration Amendments Act of 2007 (FDAAA) requires results reporting for Applicable Clinical Trials (ACTs). Only one JHU record, submitted in 2018, was identified as an Applicable Clinical Trial (ACT); ClinicalTrials.gov identifies trials that likely meet this definition as “probable” Applicable Clinical Trials (pACTs). We combined the ACT with the pACTs in our analysis.

bnon-ACTs do not require results reporting under FDAAA, but non-ACTs may require results reporting according to a complementary policy if funded in full or in part by NIH. JHU investigators voluntarily submitted results for most non-ACTs.

cAs of January 7, 2019 4/15 (27%) non-ACTs submitted in 2017 had been returned by NIH to JHU with comments at least once. These records had been in JHU and NIH review for 211.00 (234.82) and 271.50 (173.13) days, respectively. As of January 7, 2019 2/7 (29%) non-ACTs submitted in 2018 had not been returned by NIH after their first submission; these records had been in NIH review for 132 and 153 days.

dAll records were posted before this review cycle.