Suspension of Oncology Randomized Clinical Trials during the COVID-19 Pandemic: A Cross-Sectional Evaluation of COVID-Related Suspensions

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ABSTRACT
We conducted a cross-sectional analysis of ClinicalTrials.gov-registered oncology randomized controlled trials between September 2019 and December 2021 to identify predictors of trial suspensions. The dataset included 1,183 oncology trials, of which 384 (32.5%) were suspended. COVID-19 accounted for 47 (12.2%) suspensions. Trials that were single center- or US-based had higher odds of COVID-19 (ORs: 3.85 and 2.48, 95% CIs: 1.60–11.50 and 1.28–4.93, respectively) or any-reason suspensions (ORs: 2.33 and 2.04, 95% CIs: 1.46–3.45 and 1.40–2.76, respectively). Phase two (OR 1.27), three (OR 6.45) and four trials (OR 11.5) had increased odds of COVID-19 suspensions, compared to phase one trials.

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Introduction
While randomized controlled trials (RCTs) are critical to guiding the practice of oncology, multiple barriers to the conduct and completion of RCTs have long existed. Funding shortages, limited staff availability, high personnel turnover, excessive administrative requirements, short enrollment periods, lengthy/complex informed consents, overly centralized care, and significant patient dropout rates are notable examples of such barriers (1–3). The significance of these barriers has been further magnified by the coronavirus disease 2019 (COVID-19) pandemic. Resource reallocation, both with respect to clinical/research personnel availability and decreased research funding, along with research site shutdowns owing to state, local, sponsor, or institutional restriction have further handicapped the ability to conduct clinical research (4–8). This has manifested in a 60% decrease in the number of oncology clinical trial launches during the current pandemic compared to the pre-COVID-19 era, with available resources preferentially reallocated toward the infectious disease space (9). Furthermore, nearly one-fifth of cancer patients now report that they are less likely to enroll in an RCT during the pandemic secondary to fears of increased COVID-19 exposure or difficulty accessing care during the pandemic (10).

Given the increase in potential barriers to conduct of oncology-related RCTs during the COVID-19 pandemic, we sought to determine the study-level variables that predicted both COVID-19- and non-COVID-19-related RCT suspensions during the COVID-19 pandemic.

Materials and methods
Study design
ClinicalTrials.gov was systematically searched to identify all registered oncology RCTs between September 1st, 2019 and January 12th, 2022. Suspended RCTs were those with a ClinicalTrials.gov designated status of “suspended”, “terminated”, or “withdrawn”, whereas non-suspended trials were those with a “recruiting”,
“enrolling by invitation”, “active not recruiting”, or “completed” status. Suspensions were designated as COVID-19-related if clearly stated as such under the “Recruitment Status” heading on the ClinicalTrials.gov website. All suspended RCTs during this timeframe were included in the final dataset. A 2:1 control sample of non-suspended RCTs was included by randomly selecting every tenth non-suspended study on the ClinicalTrials.gov-generated list during this timeframe (11). This selection procedure was agreed upon a priori by the authors’ consensus due to the large amount of available non-suspended oncology RCTs during the study period (n = 10,433). Study start date of September 2019 was chosen to allow for a six month look-back window prior to the pandemic start of March 2020.

Study objectives
The primary objective was to identify the study-level variables predicting a COVID-19-related suspension during the COVID-19 pandemic, with a secondary objective of identifying predictors of any-reason suspension (i.e. either COVID-19 or non-COVID-19 related).

Study variables
The following study variables were included: tumor consistency (solid, hematologic, or both), study type (observational or interventional), study phase, funding source (industry, National Institute of Health [NIH], or other), patient sex and age, study location (United States or other), and study centricity (single or multiple).

Statistical analysis
Categorical variables were reported using frequency counts and percentages and continuous variables reported using medians and interquartile ranges. Chi-square and student t-tests were used to perform univariable comparisons. Univariable and multivariable logistic regression analyses were used to evaluate predictors of outcomes of interest. All study variables, operationalized as categorical variables, were included in both the univariable and multivariable models to minimize potential sources of confounding. Variable multicollinearity was evaluated using the variance inflation factor test, with a cut-off value of five used to exclude variables based on high degree of multicollinearity. Statistical significance was set at p < 0.05. Statistical analyses were performed using R version 4.0.3 (The R Foundation for Statistical Computing, Vienna, Austria).

Results
The study dataset included 1,183 RCTs, of which 384 (32.5%) were suspended during the COVID-19 pandemic (Figure 1). COVID-19 accounted for 47 (12.2%) suspensions. Nine hundred eighty-eight (83.5%) RCTs were interventional, 419 (35.4%) were phase two trials, 548 (46.3%) were funded by the NIH and/or industry, and 596 (50.4%) were US-based (Table 1).

Compared to RCTs suspended for non-COVID-19 reasons and those not suspended, COVID-19 suspended RCTs were significantly more observational (23.4% versus 8.9% and 19.3%), funded by non-NIH/non-industry sources (72.3% versus 40.1% and 58.3%), included female-only patients (21.3% versus 9.2% and 12.6%), and single center/single country-based (89.4% versus 57.0% and 55.1%) in nature, respectively (Table 1).

On multivariable regression analysis, RCTs with female only patients (Odds ratio [OR] 2.19, 95% confidence interval [CI]: 1.07–4.77), those that were US-based (OR 2.48, 95% CI: 1.28–4.93), and single center/country-based (versus multicenter/single country-based OR 3.85, 95% CI: 1.60–11.50) had significantly higher odds of a COVID-19-related suspension. Phase two (OR 1.27, 95% CI: 0.31–6.38), three (OR 6.45, 95% CI: 0.70–50.3), and four trials (OR 11.5, 95% CI: 1.02–151.4) had increased odds of a COVID-19-related suspension compared to phase one RCTs (Table 2, Supplementary Table 1).

Predictors of any-reason suspensions included hematologic malignancies (OR 1.89, 95% CI: 1.23–2.90), industry- (OR 1.88, 95% CI: 1.23–2.62) and NIH-funded (OR 2.50, 95% CI: 1.42–4.46) RCTs, single center/country-based trials (versus multicenter/single country-based OR 2.33, 95% CI:
1.46–3.45), and US-based trials (OR 2.04, 95% CI: 1.40–2.76, Table 3, Supplementary Table 2).

**Discussion**

In this analysis of 1,183 oncology-related RCTs registered in ClinicalTrials.gov between September 2019 and December 2021, we determined predictors of both COVID-19-related and any-reason suspension. RCTs that were single center- or US-based had significantly increased odds of being suspended for COVID-19 or any other reason. Phase two, three, and four trials and those with female-only study patients were at increased odds of COVID-19 suspensions only. Conversely, RCTs of hematologic malignancies and those industry- or NIH-funded were at significantly increased odds of any-reason suspension.

While the COVID-19 pandemic initially exacerbated pre-existing barriers to completion/conduct of RCTs, it has also created opportunities to optimize clinical trial implementation in oncology by highlighting existing deficiencies. Multiple nationwide collaborative groups have emerged to allow for the facile, efficient collection and dissemination of clinical data and conduction of clinical research, such as The UK Coronavirus Cancer Programme (12, 13) and The COVID-19 and Cancer Consortium (14). Furthermore, existing large, population-based datasets, such as those available via the U.S. Department of Veterans Affairs healthcare system, have been increasingly leveraged to allow for large scale reporting of relevant clinical outcomes (15). Efforts have been made to reduce existing administrative loads by minimizing redundant documentation and procedures, decreasing on-site and increasing remote visits for research staff, audits, and monitoring meetings, increasing the use of validated artificial intelligence tools, and developing shared resource databases.
The informed consent process has been simplified by increasing the utilization of remote electronic consents (eConsent) and developing concurrent eConsent guidelines and resources for both patients and research staff. Furthermore, there has been a concerted effort to promote the use of telemedicine and decentralize point of care. This has been facilitated by the provision of research, training and validated guidelines for telemedicine and remote procedures in RCTs, developing and using validated electronic patient reported outcomes and tools, allowing examinations to be performed close to patient homes, and delivery of oral medicines to patient homes, with pre-existing accountability, monitoring, compliance and follow up procedures in place.4

A recent cross-sectional analysis of 4,411 COVID-19 trials evaluated predictors of trial

| Tumor type, n (%) | COVID related suspensions (n = 47) | Non-COVID related suspensions (n = 337) | Non-suspended (n = 799) | p Value |
|-------------------|------------------------------------|----------------------------------------|-------------------------|--------|
| Solid             | 35 (74.5%)                         | 248 (73.6%)                            | 655 (82.0%)             | <0.001 |
| Hematologic       | 6 (12.8%)                          | 70 (20.8%)                             | 82 (10.3%)              |        |
| Both              | 6 (12.8%)                          | 20 (5.9%)                              | 62 (7.8%)               |        |
| Urologic related, n (%) | 5 (10.6%)                         | 36 (10.7%)                            | 82 (10.3%)              | 0.98 |
| Study Type, n (%) |                                    |                                       |                         | <0.001 |
| Interventional    | 36 (76.6%)                         | 307 (91.1%)                            | 645 (80.7%)             |        |
| Observational     | 11 (23.4%)                         | 30 (8.9%)                              | 154 (19.3%)             |        |
| Study phase, n (%)|                                    |                                       |                         | <0.001 |
| I                 | 3 (6.6%)                           | 80 (23.7%)                             | 123 (15.4%)             |        |
| II                | 6 (12.8%)                          | 151 (44.8%)                            | 262 (32.8%)             |        |
| III               | 2 (4.3%)                           | 25 (7.4%)                              | 59 (7.4%)               |        |
| IV                | 1 (2.1%)                           | 2 (0.6%)                               | 13 (1.6%)               |        |
| Not applicable    | 35 (74.5%)                         | 80 (23.7%)                             | 342 (42.8%)             |        |
| Funding source, n (%) |                                    |                                       |                         | <0.001 |
| Industry          | 7 (14.9%)                          | 144 (42.7%)                            | 263 (32.9%)             |        |
| NIH               | 5 (10.6%)                          | 51 (15.1%)                             | 62 (7.8%)               |        |
| NIH and Industry  | 1 (2.1%)                           | 8 (2.4%)                               | 8 (1.0%)                |        |
| Other (i.e. Non-NIH/ Non-Industry) | 34 (72.3%) | 135 (40.1%) | 466 (58.3%) |        |
| Participants enrolled, n (%) | 10 (0-57.5) | 0 (0-2) | 75 (36-200) | <0.001 |
| Participants enrolled, median (IQR) | 0 | 233 (69.1%) | 0 (0.0%) | <0.001 |
| 0                 | 14 (29.8%)                         | 233 (69.1%)                            | 0 (0.0%)                |        |
| 1–49              | 21 (44.7%)                         | 80 (23.7%)                             | 275 (34.4%)             |        |
| 50–99             | 2 (4.3%)                           | 10 (3.0%)                              | 177 (22.2%)             |        |
| 100–199           | 5 (10.6%)                          | 8 (2.4%)                               | 138 (17.3%)             |        |
| 200+              | 5 (10.6%)                          | 8 (2.4%)                               | 209 (26.2%)             |        |
| Gender, n (%)     |                                    |                                       |                         | 0.03  |
| Male only         | 3 (6.4%)                           | 15 (4.5%)                              | 59 (7.4%)               |        |
| Female            | 10 (21.3%)                         | 31 (9.2%)                              | 101 (12.6%)             |        |
| Both              | 34 (72.3%)                         | 291 (86.4%)                            | 639 (80.0%)             |        |
| Pediatric patients eligible, n (%) | 3 (6.4%) | 27 (8.0%) | 71 (8.9%) | 0.77 |
| Study start date, n (%) |                                    |                                       |                         | 0.008 |
| September 2019 or later | 47 (100.0%) | 337 (100.0%) | 799 (100.0%) |        |
| March 2020 or later | 14 (29.8%) | 208 (61.7%) | 582 (72.8%) |        |
| September 2020 or later | 9 (19.1%) | 124 (36.8%) | 373 (46.7%) |        |
| March 2021 or later | 5 (10.6%) | 38 (11.3%) | 126 (15.8%) |        |
| Multicentricity/ Multinationality, n (%) |                                    |                                       |                         | <0.001 |
| Single center, single country | 42 (89.4%) | 192 (57.0%) | 440 (55.1%) |        |
| Unknown number of centers, single country | 0 (00%) | 29 (8.6%) | 1 (0.1%) |        |
| Multiple centers, single country | 5 (10.6%) | 89 (26.4%) | 275 (34.4%) |        |
| Multiple centers, multiple countries | 0 (0.0%) | 28 (8.3%) | 83 (10.4%) |        |
| Country Location |                                    |                                       |                         | <0.001 |
| US-based          | 31 (66.0%)                         | 230 (68.2%)                            | 335 (41.9%)             |        |
| Non-US based      | 16 (34.0%)                         | 107 (31.8%)                            | 464 (58.1%)             |        |

COVID: coronavirus disease 2019; NIH: National Institute of Health; US: United States.
Bold values are statistically significant.
completion versus cessation. Consistent with our findings, cessation trials were significantly more industry sponsored (18.1% versus 9.7%) compared to completed trials (16). Industry-sponsored trials are often burdened by excessive administrative/recording procedures that require additional research staff, many of whom have been repositioned during the pandemic (4). This, combined with the re-routing of available research funding towards COVID-19 studies, (17) likely explains the increased odds of industry-sponsored RCT suspension during the study timeframe. This excess regulatory/administrative burden characteristic of industry-sponsored trials is similarly seen in NIH-sponsored studies, thus potentially explaining why industry- and NIH-sponsored trials were at increased risk of suspension during the COVID-19 pandemic. Elkin et al. also demonstrated that cessation trials were significantly more US-based (27.1% versus 11.2%), compared to completed trials (16). This likely reflects strict COVID-19 lockdown measures employed by specific population-dense

Table 2. Predictors of COVID-19-related suspension of oncology randomized controlled trials on multivariable logistic regression analysis.

| Variable                                      | Odds Ratio | 95% Confidence Interval | p Value |
|-----------------------------------------------|------------|-------------------------|---------|
| Tumor consistency (Reference: Solid tumor)    |            |                         |         |
| Hematologic                                   | 1.21       | 0.43 – 2.98             | 0.70    |
| Both                                          | 1.67       | 0.59 – 4.12             | 0.29    |
| Interventional study (Reference: Observational study) | 0.75 | 0.37 – 1.62 | 0.44 |
| Study phase (Reference: Phase I)              |            |                         |         |
| Phase II                                      | 1.27       | 0.31 – 6.38             | 0.74    |
| Phase III                                     | 6.45       | 0.70 – 50.3             | 0.07    |
| Phase IV                                      | 11.5       | 1.02 – 151.4            | 0.04    |
| Funding source (Reference: Non-NIH/Non-Industry source) | 0.54 | 0.21 – 1.25 | 0.17 |
| Industry                                      | 0.56       | 0.18 – 1.44             | 0.26    |
| NIH and Industry                              | 0.96       | 0.05 – 5.32             | 0.97    |
| Patient sex (Reference: Both males and females included) | 0.75 | 0.12 – 4.52 | 0.74 |
| Males only                                    | 0.75       | 0.12 – 4.52             | 0.74    |
| Females only                                  | 2.19       | 1.07 – 4.77             | 0.046   |
| Pediatric patients eligible (Reference: Adult patients only) | 0.60 | 0.14 – 1.75 | 0.41 |
| Multicentricity/Multinationality (Reference: Single center, single country) | 0.26 | 0.087 – 0.64 | 0.007 |
| Multiple centers, single country              | 0.10       | 0.02 – 0.49             | 0.98    |
| Multiple centers, multiple countries          | 0.26       | 0.087 – 0.64            | 0.007   |
| US-based trials (Reference: Non-US based)     | 2.48       | 1.28 – 4.93             | 0.008   |

COVID: coronavirus disease 2019;
NIH: National Institute of Health;
US: United States.

Bold values are statistically significant.

Table 3. Predictors of any-reason (i.e. both COVID-19 and non-COVID-19-related) suspension of oncology randomized controlled trials on multivariable logistic regression analysis.

| Variable                                      | Odds Ratio | 95% Confidence Interval | p Value |
|-----------------------------------------------|------------|-------------------------|---------|
| Tumor consistency (Reference: Solid tumor)    |            |                         |         |
| Hematologic                                   | 1.89       | 1.23 – 2.90             | 0.004   |
| Both                                          | 0.90       | 0.46 – 2.02             | 0.80    |
| Interventional study (Reference: Observational study) | 1.01 | 0.03 – 33.4 | 0.98 |
| Study phase (Reference: Phase I)              |            |                         |         |
| Phase II                                      | 1.05       | 0.72 – 1.53             | 0.82    |
| Phase III                                     | 0.97       | 0.51 – 1.79             | 0.91    |
| Phase IV                                      | 0.60       | 0.13 – 2.07             | 0.46    |
| Funding source (Reference: Non-NIH/Non-Industry source) | 1.88 | 1.23 – 2.62 | 0.004 |
| Industry                                      | 2.50       | 1.42 – 4.46             | 0.002   |
| NIH and Industry                              | 2.72       | 0.92 – 8.35             | 0.07    |
| Patient sex (Reference: Both males and females included) | 0.36 | 0.12 – 1.01 | 0.057 |
| Males only                                    | 0.36       | 0.12 – 1.01             | 0.057   |
| Females only                                  | 0.78       | 0.47 – 1.48             | 0.46    |
| Pediatric patients eligible (Reference: Adult patients only) | 0.78 | 0.47 – 1.48 | 0.46 |
| Multicentricity/Multinationality (Reference: Single center, single country) | 0.43 | 0.29 – 0.64 | <0.001 |
| Multiple centers, single country              | 0.38       | 0.24 – 0.66             | <0.001  |
| Multiple centers, multiple countries          | 0.38       | 0.24 – 0.66             | <0.001  |
| US-based trials (Reference: Non-US based)     | 2.04       | 1.40 – 2.76             | <0.001  |

COVID: coronavirus disease 2019; NIH: National Institute of Health; US: United States.

Bold values are statistically significant.
regions of the US with limited patient ability to complete in-person study visits and decreased likelihood of patient consent to study participation owing to increased distancing between investigators and patients/caregivers (4, 10). An analysis of SWOG trials between January and April 2020 demonstrated decreased patient enrollment during COVID-19 surges with sites from states with the highest number of COVID-19 cases per capita only half as likely to enroll patients during surges (OR 0.56, 95% CI: 0.41-0.76) (18).

These same factors also likely explain the clear “dose-response” relationship seen between progressively advanced study phase types and odds of COVID-19 suspensions (Table 2). Although only phase-IV studies had a statistically significant increased odds of COVID-19-related suspensions, we see a progressive increase in the magnitude of the odds ratio from 1.27 ($p=0.74$) for phase-II studies, to 6.45 ($p=0.07$) in phase III and 11.5 ($p=0.04$) in phase-IV studies (all compared to Phase-I studies). Although it may have been anticipated that smaller, earlier phase studies would be at increased risk of being suspended during the COVID-19 pandemic, more advanced RCT phase types require progressively larger study sample sizes, which are more difficult to attain given the aforementioned COVID-19-related restrictions, (4, 10) thus increasing their odds of suspension due to COVID-19. Similarly, recruitment for RCTs of hematologic malignancies is notoriously difficult compared to solid organ malignancy RCT secondary to the relatively low incidence of these malignancies (9% of new patients diagnosed annually). This likely explains why such trials were at increased risk of suspension during the COVID-19 pandemic (19).

This study is limited by its cross-sectional nature with suspended trials at time of data collection potentially being later resumed. This analysis is also likely limited by a length time bias, whereby trials at different stages of recruitment/follow up are at varying risks of suspension. For example, a phase three trial that had recruited only 10% of its target population may be at higher risk of suspension compared to a similar phase three trial that had completed 90% recruitment at the start of the pandemic. This inherent suspension bias for trials with a lower recruitment tally at the time of analysis could not be ascertained or accounted for in our analysis due to the absence of such quantitative data in ClinicalTrials.gov. Furthermore, a measurement bias secondary to either a lack of a timely study status update by the clinical trials team or inaccurate recording of reason for suspension under the “Recruitment Status” heading on the ClinicalTrials.gov website is plausible given the lack of known validation studies assessing its reporting accuracy. Although all COVID-19 suspended RCTs were included, the total sample size of such studies, and thus the resultant statistical power, remained limited ($n=47$). Although the control sample of non-suspended RCTs was selected at random in a 2:1 fashion, there remains a theoretical risk of sampling bias due to the omission of a significant number of non-suspended oncology RCTs.

**Disclosure statement**

No potential conflict of interest was reported by the author(s).

**Author contributions**

RKS: Conceptualization, data analysis and interpretation, manuscript drafting and approval, accountable for accuracy and integrity of work. AH: Study conception, data acquisition, manuscript critical revision and approval, accountable for accuracy and integrity of work. PW: Study conception, data acquisition, manuscript critical revision and approval, accountable for accuracy and integrity of work. MDO: Data interpretation, manuscript critical revision and approval, accountable for accuracy and integrity of work. MKT: Data interpretation, manuscript critical revision and approval, accountable for accuracy and integrity of work. JHL:Data interpretation, manuscript critical revision and approval, accountable for accuracy and integrity of work. CJDW: Study conception and design, data interpretation, manuscript critical revision and approval, accountable for accuracy and integrity of work. ZK: Study conception and design, data interpretation, manuscript critical revision and approval, accountable for accuracy and integrity of work.

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