

Abstract 1565: Oncology Trial Enrollment Trends Following the First Wave of the COVID-19 Pandemic

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BACKGROUND

- The COVID-19 pandemic has disrupted healthcare delivery including clinical research & development
- Prior reports suggest the initial pandemic wave caused a 60% drop in new oncology trials & slowed patient enrollment in oncology trials by a similar magnitude^{1,2}
- Did the pandemic continue to hinder clinical research and development in oncology beyond its first wave?

METHODS

Global Data Sources:

- **Clinical Trial Enrollment Counts** - weekly incident counts of oncology drug or biologic agent trial enrollees in operational clinical trial data from a commercial clinical trial electronic data capture platform. Approximately 30% of the world's oncology clinical trials are hosted by the platform¹
- **COVID-19 Case Counts** - weekly incident counts of COVID-19 cases during 1/5/2020-1/2/2021 from the European Center for Disease Control³

Time Period Specification (i.e., "waves"):

- All years of trial enrollment data were partitioned according to 2020 COVID-19 weekly incidence case inflection points (i.e., post-peak nadirs) at weeks 18 and 34. This resulted in three consecutive time periods: period 1=weeks 1-18, period 2=weeks 19-34, and period 3=weeks 35-52

Statistical Approach:

- Negative binomial regression model of weekly oncology trial enrollment counts according to years 2018-2020. Data lacked PII and research was IRB exempt.

CONCLUSIONS

- COVID-19 pandemic had its maximal negative effect on 2020 global oncology trial enrollment in period 1 (i.e., first wave)
- A subsequent surge in trial enrollment in period 3 largely offset the effect with cumulative enrollment in 2020 similar to 2018 and 2019

FUTURE DIRECTIONS FOR RESEARCH

- Ongoing research is directed at identifying and quantifying the adaptive mechanisms which facilitated the stunning enrollment rebound

References:

1. Lamont EB, Diamond SS, Katriel RG, et al. Trends in oncology clinical trials launched before and during the COVID-19 pandemic. *JAMA Netw Open*. 2021;4(1):e2036353.
2. Tolane SM, Lydon CA, Li T, et al. The impact of COVID-19 on clinical trial execution at Dana-Farber Cancer Institute. *J Natl Cancer Inst*. 2020;113(11):djaa144.
3. European Centre for Disease Prevention and Control. Data provided subject to license available at: <https://www.ecdc.europa.eu/en/copyright>

Oncology trial enrollments surge after first COVID-19 shock, puts 2020 patient enrollment on par with 2018 and 2019



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RESULTS

Table 1: Distribution of Oncology Trial Patient Enrollment and COVID-19 Cases Across Time

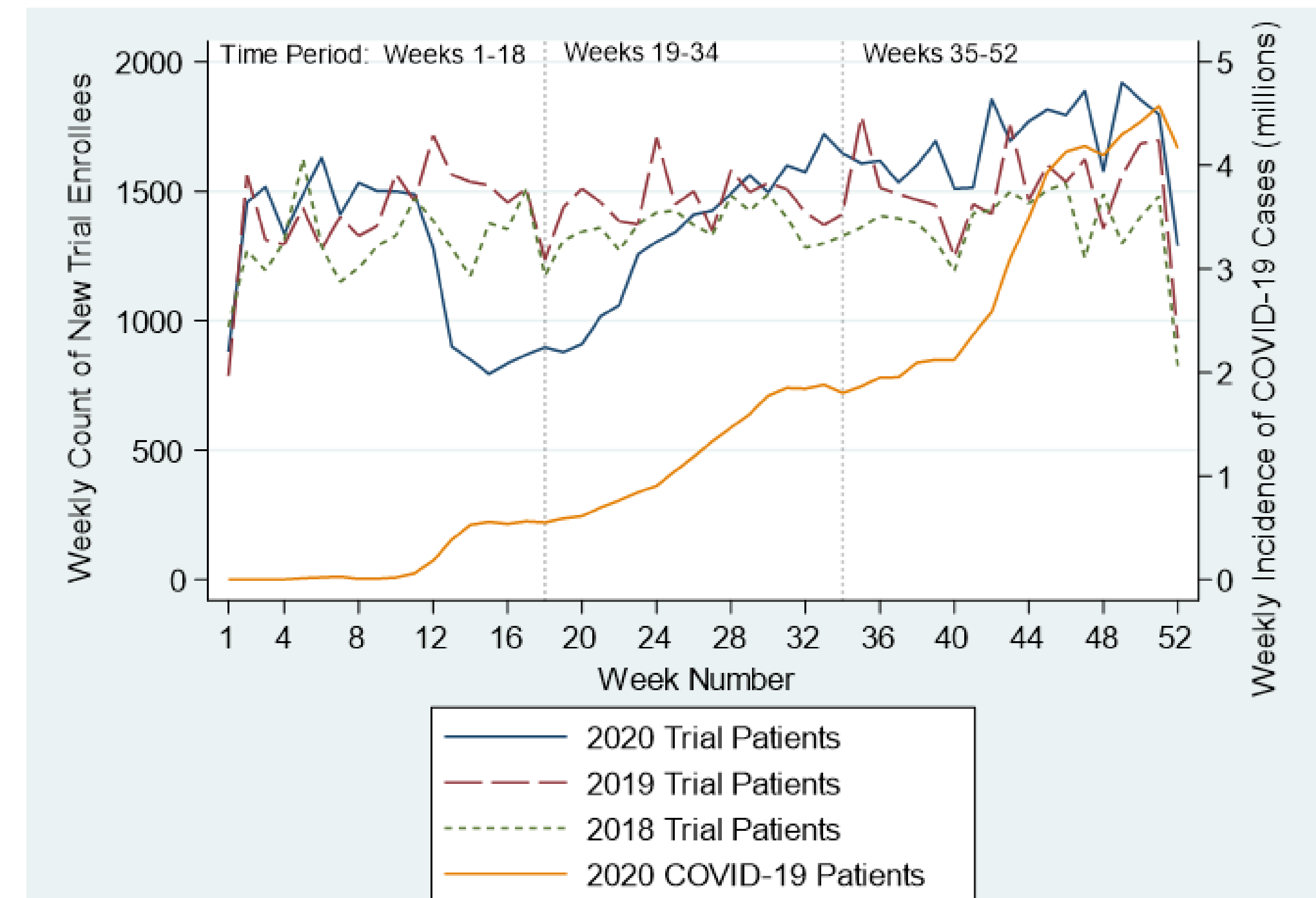
Period	Oncology Trial Enrollees			COVID-19 Cases
	2018	2019	2020	2020
1	23,355	25,335	22,164	3.5 x 10 ⁶
2	21,905	23,482	21,693	20.2 x 10 ⁶
3	24,598	27,016	30,328	57.5 x 10 ⁶
Total	69,858	75,833	74,185	81.1 x 10 ⁶

Table 2: Regression of Counts of Oncology Trial Enrollees 2018-2020, N = 219,876

Year	IRR	95% CI
2018	1.00	(referent)
2019	1.09	1.02-1.16
2020	1.06	1.00-1.13

IRR = incidence rate ratio; 95% CI = 95% confidence interval

Figure 1: Global Weekly COVID-19 Cases and Oncology Trial Patient Enrollment Over Time



Legend: Counts of weekly oncology clinical trial enrollees 2018-2020 according to three time periods defined by empiric study of globally aggregated COVID-19 case data for peaks and subsequent nadirs (weeks 18 and 34): period 1 (weeks 1-18), period 2 (weeks 19-34) and period 3 (weeks 35-52)