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 magnitude1,2
- 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.

RESULTS

- 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

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

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

<table>
<thead>
<tr>
<th>Period</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2020 Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>23,355</td>
<td>23,355</td>
<td>25,355</td>
<td>4.9 x 10^6</td>
</tr>
<tr>
<td>2</td>
<td>21,905</td>
<td>21,905</td>
<td>23,482</td>
<td>4.8 x 10^6</td>
</tr>
<tr>
<td>3</td>
<td>24,598</td>
<td>27,016</td>
<td>30,328</td>
<td>4.0 x 10^7</td>
</tr>
<tr>
<td>Total</td>
<td>69,858</td>
<td>75,833</td>
<td>74,185</td>
<td>8.1 x 10^6</td>
</tr>
</tbody>
</table>

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Legend: Counts of weekly oncology clinical trial enrollees 2015-2020 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)