COVID-19 Impact: Clinical Trials

Impact & Expected Recovery
August 7, 2020

Globally, nearly 20 percent of clinical trial disruptions — and 15 percent of trials sponsored by top industry players — have been attributed to COVID-19 since December 2019. Continued delays will impact product launch timelines and revenues for non-COVID-19-related products, leaving patients with significant unmet needs. Although facing challenges related to developing a COVID-19 vaccine and viable treatments, the pharmaceutical industry should seize the opportunity to modernize its historical approach to clinical trials.

Since December, 5 to 6 percent of clinical trials have been paused...

Share of clinical trials stopped after Dec 2019 (Phases I-IV)

<table>
<thead>
<tr>
<th>Country</th>
<th>Stopped after Dec '19</th>
<th>Open trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>19,906</td>
<td>95%</td>
</tr>
<tr>
<td>Stopped due to COVID-19</td>
<td>1,029</td>
<td>81%</td>
</tr>
<tr>
<td>Stopped due to other reasons</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Share of clinical trials stopped after Dec 2019 - sponsored by top 25 pharma (Phases I-IV)

<table>
<thead>
<tr>
<th>Country</th>
<th>Stopped after Dec '19</th>
<th>Open trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>3,443</td>
<td>95%</td>
</tr>
<tr>
<td>Stopped due to COVID-19</td>
<td>200</td>
<td>85%</td>
</tr>
<tr>
<td>Stopped due to other reasons</td>
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</tbody>
</table>

...and recruitment for new clinical trials was postponed.

New patient enrollment in Mar and April 2020 vs. 2019

<table>
<thead>
<tr>
<th>Country</th>
<th>March 2020</th>
<th>April 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>-65%</td>
<td>-75%</td>
</tr>
<tr>
<td>France</td>
<td>-68%</td>
<td>-80%</td>
</tr>
<tr>
<td>China</td>
<td>-68%</td>
<td>-39%</td>
</tr>
<tr>
<td>India</td>
<td>-84%</td>
<td>-96%</td>
</tr>
<tr>
<td>UK</td>
<td>-80%</td>
<td>-98%</td>
</tr>
<tr>
<td>United States</td>
<td>-66%</td>
<td>-80%</td>
</tr>
</tbody>
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Companies report four main impacts of COVID-19 on clinical trials

**Shift in focus**
- By necessity, R&D has focused on COVID-19 vaccines and therapies
- Clinical trials, even for some vital medications, were suspended

**Patient & staff avoidance**
- Patients drop out due to mobility restrictions and safety concerns
- Staff needed for trials are furloughed or leery of entering testing sites

**Technological challenges**
- Digital capabilities for trials are not yet at scale (e.g., virtual access, remote monitoring)
- Trials involving diagnostic imaging & other in-person assessments are most impacted

**Supply chain interruptions**
- Inbound and outbound shipments of required clinical products and patient samples are slowed
- Healthcare workers lack PPE kits for use in trials

### Delays will have an impact on both life science companies and patients

**Revenue/margin hit**
Delays...may result in shorter periods of patent exclusivity and lower revenue forecasts while giving competitors more time to get to market. Smaller biotechs...will be particularly at risk for potential cash flow issues and may have limited options in financing.

- *The Pharma Letter, May 7, 2020*

**Unmet patient needs**
What happens with the lack of clinical trials is, treatment options lag behind...medical needs of patients remain unmet.

- *Medical Oncologist, Seattle Cancer Care Alliance*

**Delayed drug development**
Without data from pivotal clinical trials, new drug filings will be delayed, meaning some important new medicines will take longer to reach the market... The downstream impact for the drug industry could be substantial.

- *Stat News, Mar 23, 2020*
China’s clinical trial recovery cycle was 6-8 weeks due to successful utilization of technology & other methods\(^2,3,4\)

Recovery timeline for China

- **Jan 2020**: Disruption to clinical trials began
- **Mid-Mar 2020**: Resumption of some trials
- **Apr 2020**: New patient enrollment increased by 240% vs. March

**Steps taken by China**
- **Minimized** on-site visits by changing mode or location of visits
- **Improved protection** for clinical research coordinators
- **Shifted to virtualization** and other digital technologies
- **Mailed** oral medications to patients with detailed instructions

Some experts believe that the US has followed the same recovery pattern as China and is bouncing back after a 6-8 week slow down\(^5,6\)

**Chief Strategy Officer, Paraxel Informatics**

“Once that quarantine was lifted in China, the data...shows their return to a fairly normal volume of study visits.”

**Clinical Leader**

“Disruption to clinical trials in China began in early January 2020, so a resumption in some clinical trials there in mid-March suggests we may expect a similar timeframe here in the U.S. — approximately two months before study subjects can be seen freely for hospital visits.”

**CRO Executive**

“The slow down mostly occurred in new trial starts or with non-essential drug trials. Areas like oncology mostly remained healthy. And we’re now seeing a lot of pressure to accelerate the launch of new studies that had been put on hold between April and May.”

Sources:

- \(^2\) Coronavirus waylays China trials, may delay regulatory approvals too, BioWorld, February 18, 2020
- \(^3\) COVID-19 outbreak begins to disrupt booming China drug trials, Channel News Asia, February 13, 2020
- \(^4\) As coronavirus disrupts MNC operations in China, companies look to digital solutions, Biocentury, March 26, 2020
- \(^5\) A Closer Look at the COVID-19 Impact to Drug Development and Clinical Trials, JP Morgan, April 2020
- \(^6\) Clinical Study Conduct During The COVID-19 Pandemic: Challenges & Solutions, Clinical Leader, April 2020
Life sciences companies should focus on these short-term and long-term actions

**Short-term**
- Deploy alternative monitoring methods in patients’ homes
- Adopt direct to/from patient services to ensure safety along with real-time updates to patients
- Shift the site mix to lower-impacted countries & regions
- Eliminate patient touchpoints when possible

**Long-term**
- Partner to accelerate adoption of virtual trials – remote consent, data capture and reporting
- Acquire telemedicine and remote monitoring solutions for required technology capabilities
- Leverage CROs with advanced technology capabilities
- Employ eCOAs, eConsent, telehealth, centralized data management, etc.

“How virtual engagement is where we are going and it will be a positive development for the industry... This pandemic is really showing us a picture of what the future is going to look like” – CEO, IACT Health

**How can we help?**

- Identify partnership opportunities
- Perform deal diligence procedures (commercial and operational diligence)
- Support deal strategy
- Support integration through divestiture
- Assess working capital and improve systems impacting cash flow
- Help plan and execute enterprise-wide transformation

- Develop R&D/technology strategy
- Enable business and market strategy
- Implement digital/mobility programs
- Assess business and operating models for performance improvement opportunities

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