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Introduction

Last year, Informa Pharma Intelligence and Oracle surveyed the Life Sciences industry to understand the impact of the COVID-19 pandemic on clinical trial management and found the industry rapidly shifting to decentralized clinical trial methods, while balancing concern around data quality and regulatory compliance. Now, a year later, we tap the industry again to explore clinical trial management in a post-pandemic world.

To investigate this, Informa Pharma Intelligence and Oracle surveyed professionals involved in clinical trials at biopharmaceutical companies, medical device companies, and contract research organizations (CROs) based around the world to understand the adaptations that have been made to clinical trials, the effect of these adaptations, and the impact of these changes on the future of clinical trials.

The research results provide valuable insight into the lasting and positive impact of the adaptations made during the pandemic and reveal an industry embracing change.

Key Findings from the Research

Newly adopted methods embraced during the pandemic had a positive impact on clinical trials.

82% of respondents who implemented new clinical trial approaches during the pandemic report they have had a positive impact on clinical trials overall, including 26% reporting a “significantly” positive impact.

The industry is confident in the data generated from newly adopted clinical trial approaches.

92% of respondents who implemented new clinical trial methods during the pandemic are equally or more confident in the data collected from these methods, compared data collected via pre-pandemic methods.

Newly adopted clinical trial methods are here to stay.

97% of respondents who implemented new clinical trial methods during the pandemic indicated their organization will continue using at least one of these new methods.

Continue reading for deeper insight into these key findings.
Research Methodology

This research was conducted by Informa Engage, on behalf of Oracle. Data was collected from July 14 through September 16, 2021. The research methodology used conformed to accepted marketing research methods, practices, and procedures. The research was conducted through an online survey sent to Informa Pharma Intelligence subscribers around the world who work in organizations involved in clinical research. Only respondents who worked for biopharmaceuticals, CROs, and medical device companies qualified to participate.

The vast majority of respondents were from biopharmaceutical companies (76%), with the balance representing medical device companies and CROs.

Respondents were primarily located in North America and Europe, with some representation from Japan, Asia Pacific, and the rest of the world.
A variety of job functions were represented in the sample, most commonly R&D (21%), Clinical Operations (17%), and IT (15%), and just over half held Director level or higher positions (57%).

**Functional Area**

- **21%** R&D
- **17%** Clinical Operations
- **15%** Information Technology
- **12%** Quality
- **11%** Data Management
- **10%** Regulatory
- **2%** Digital Transformation
- **5%** Site Management
- **2%** Other
- **11%** Trial Lead
- **1%** Patient Empowerment

**Position**

- **40%** Manager
- **36%** Director
- **11%** EVP/SVP/VP/Head
- **10%** C-Suite
- **3%** Other

**Qualified Respondents**

The survey garnered 251 qualified respondents, representing a significant voice of the market. All results are based on responses from all 251 respondents unless otherwise noted.

**Questions**

The survey consisted of multiple-choice questions exploring the adaptations made to clinical trials during the COVID-19 pandemic, the effect of these adaptations, and the impact of these changes on the future of clinical trials.

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76%

In last year’s industry survey conducted by Informa Pharma Intelligence and Oracle, 76% of respondents indicated that the COVID-19 pandemic had accelerated their adoption of decentralized clinical trial methods.

**Source:** *The Accelerated Evolution of Clinical Trials in a Pandemic Environment Research Report (November 2020)*
Results

The Impact of Newly Adopted Methods in Clinical Trials

The COVID-19 pandemic radically changed the world in an instant and forced adaptation across the board. Some industries such as retail, hospitality, and transportation screeched to a halt, while others, such as healthcare, had to immediately adapt to support the overwhelming human crisis caused by COVID-19.

In the life sciences industry, those conducting clinical trials had to quickly adjust to support alternative ways of monitoring and caring for clinical trial participants in a world where physical access was not an option. Many data collection methods that have been available for years but not widely used were suddenly adopted at scale in clinical trials during the pandemic.

A decisive majority of respondents (84%) reported implementing new approaches in order to continue existing clinical trials and/or start new trials during the COVID-19 pandemic. Of the 16% who did not adopt new approaches, many said the reason was because they had already implemented pandemic-compatible approaches prior to the onset of COVID-19.

Did your organization implement any new clinical trial approaches during the pandemic?

- Yes: 84%
- No: 16%

Reasons for opting not to implement new approaches

- 49% Already adopted approaches that were compatible with pandemic requirements (e.g., remote working)
- 27% Conducted Trials without Interruption
- 12% Lack of Necessary Expertise
- 12% All Clinical Trial Activity was Paused
- 10% Lack of Necessary Technology
- 7% New Approaches are Incompatible with Our Pipeline

Base: Respondents not implementing new approaches (n = 41)
**New Clinical Trial Approaches Implemented During the Pandemic**

A wide variety of alternative approaches in clinical trials were implemented during the pandemic, with the most common being remote monitoring, video visits, phone visits, eConsent, and electronic health records (EHR). While many of these approaches have been around for several years, the COVID-19 pandemic served as a catalyst for adoption.

<table>
<thead>
<tr>
<th>Approach</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remote monitoring</td>
<td>45%</td>
</tr>
<tr>
<td>Video visits</td>
<td>37%</td>
</tr>
<tr>
<td>Phone visits</td>
<td>35%</td>
</tr>
<tr>
<td>eConsent</td>
<td>28%</td>
</tr>
<tr>
<td>Electronic health records (EHR)</td>
<td>26%</td>
</tr>
<tr>
<td>Patient apps</td>
<td>23%</td>
</tr>
<tr>
<td>Home healthcare</td>
<td>20%</td>
</tr>
<tr>
<td>Mobile health wearables</td>
<td>19%</td>
</tr>
<tr>
<td>Central labs</td>
<td>19%</td>
</tr>
<tr>
<td>Central monitoring</td>
<td>19%</td>
</tr>
<tr>
<td>Local labs</td>
<td>18%</td>
</tr>
<tr>
<td>eCOA (health professional)</td>
<td>18%</td>
</tr>
<tr>
<td>ePRO (patient)</td>
<td>18%</td>
</tr>
<tr>
<td>eSource</td>
<td>15%</td>
</tr>
<tr>
<td>Social media</td>
<td>14%</td>
</tr>
<tr>
<td>N/A</td>
<td>10%</td>
</tr>
</tbody>
</table>

**How has the implementation of these new approaches impacted your clinical trials overall?**

Digging into this a bit deeper, the survey revealed that **82% of respondents feel that the new clinical trial approaches they adopted during the pandemic have had a positive impact** on clinical trials overall, including 26% reporting a “significantly” positive impact.

<table>
<thead>
<tr>
<th>Impact</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somewhat Positive Impact</td>
<td>56%</td>
</tr>
<tr>
<td>Significantly Positive Impact</td>
<td>26%</td>
</tr>
<tr>
<td>No Meaningful Impact</td>
<td>16%</td>
</tr>
<tr>
<td>Negative Impact</td>
<td>3%</td>
</tr>
</tbody>
</table>

*Base: Respondents implementing new approaches during the pandemic; multiple answers permitted (n = 225)*
Positive Impacts of Newly Adopted Clinical Trial Approaches

When asked about the specific ways in which the newly adopted approaches had a positive impact on clinical trials, many outcomes were cited, with the most common being more timely data, improved flexibility for patients, and increased speed.

**BIGGEST POSITIVE IMPACTS**

- More Timely Data: 48%
- Improved Flexibility for Patients: 41%
- Increased Speed: 38%

**OTHER NOTED IMPACTS**

- Higher Quality Data: 30%
- More Frequent Data: 30%
- Increased Protocol Compliance: 29%
- Improved Retention: 25%
- More Robust Data: 23%
- Increased Visibility Into the Clinical Trial: 23%
- Improved Patient Engagement: 19%
- Improved Recruitment: 17%

*Base: Respondents reporting positive impact of newly adopted approaches; multiple answers permitted (n = 183)*
Data Collected from Newly Adopted Methods in Clinical Trials

With the introduction of new approaches and technology in clinical trials — especially those related to remote data collection from patients — comes an increase in data volume and variety. As such, it is not surprising that many of the positive impacts of clinical trial approaches newly implemented during the pandemic relate to data.

As shared on the previous page, respondents using new methods in clinical trials found their data to be more timely, higher quality, more frequent, and more robust.

But the big question is: Do study teams find all this additional data useful, and do they have confidence in it?

**Amount of Additional Data Respondents Were Able to Use**

87%

The great news is that the vast majority of survey respondents (87%) reported being able to use “most” or “all” of the additional data their newly implemented approaches have generated.

**Confidence in Quality of Additional Data Resulting from Newly Adopted Approaches**

81%

And, when asked about their confidence in the data, most (81%) have high confidence in this additional data, including 30% who report “complete” confidence.
**Confidence in Data Generated by Newly Adopted Approaches vs. Data Generated by Pre-Pandemic Methods**

Even more compelling, when asked about their confidence in the data generated by newly adopted approaches versus data generated by pre-pandemic methods, **92% of respondents who implemented new clinical trial methods during the pandemic are equally or more confident in the data collected from these methods, compared to data collected via pre-pandemic methods.**

**Increased Confidence Level**

- **37%** Equally confident
- **35%** Somewhat more confident in data resulting from new approaches
- **20%** Much more confident in data resulting from new approaches

**Decreased Confidence Level**

- **92%** of respondents are confident in the data collected
- **7%** Somewhat less confident in data resulting from new approaches
- **1%** Much less confident in data resulting from new approaches

*Base: Respondents implementing newly adopted approaches during the pandemic; multiple answers permitted (n = 225)*
The Future of Newly Adopted Methods in Clinical Trials

While the COVID-19 pandemic forced change in the way clinical trials were conducted and managed, the question is — will these changes remain? And what does this mean for the future of clinical trials?

Newly Adopted Approaches Planned for Continued Use Post-Pandemic

Based on the results of this research, these newly adopted clinical trial methods are here to stay. Of the respondents who implemented new clinical trial methods during the pandemic, 97% indicated their organization will continue using at least one of these new methods, with remote monitoring, video visits, EHR, and phone visits being the approaches most likely to continue.

Base: Respondents implementing new approaches; multiple answers permitted (n = 225)
Top Two Consequences of Continuing to Use Newly Implemented Approaches

When probed regarding the effects of continuing to use newly implemented approaches in clinical trials, more complex work for investigators and site staff (37%) and increased volume of data (36%) emerged as the most significant consequences.

<table>
<thead>
<tr>
<th>Consequence</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>More complex work for investigators and site staff</td>
<td>37%</td>
</tr>
<tr>
<td>Increase in quantity of data</td>
<td>36%</td>
</tr>
<tr>
<td>More complex protocol design considerations</td>
<td>24%</td>
</tr>
<tr>
<td>Increased vendor management</td>
<td>21%</td>
</tr>
<tr>
<td>Need for additional site/patient training</td>
<td>20%</td>
</tr>
<tr>
<td>Increased participation options for patients</td>
<td>13%</td>
</tr>
<tr>
<td>Need for additional institutional review board (IRB) approvals</td>
<td>12%</td>
</tr>
</tbody>
</table>

*Base: Respondents planning to keep at least one newly implemented approach; up to two responses permitted (n = 217)*

Expected Change in Use of Select Clinical Trial Models Post-Pandemic

The adoption of new clinical trial approaches reflects the movement on the continuum of clinical trial models from site-based to decentralized, which occurred during the pandemic — but what shifts are expected going forward?

Survey respondents who implemented new clinical trial methods during the pandemic expect their organizations to increase their use of hybrid (44%) and fit-for-purpose models (42%) after the pandemic. Of the four models considered — site-based, fit-for-purpose, hybrid, and decentralized — respondents expect the use of the site-based model to decrease the most (24%).

<table>
<thead>
<tr>
<th>Model</th>
<th>Increase</th>
<th>No Change</th>
<th>Decrease</th>
<th>Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site-based Model</td>
<td>26%</td>
<td>44%</td>
<td>24%</td>
<td>6%</td>
</tr>
<tr>
<td>Fit-for-purpose Model</td>
<td>42%</td>
<td>45%</td>
<td>8%</td>
<td>5%</td>
</tr>
<tr>
<td>Hybrid Model</td>
<td>44%</td>
<td>38%</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Decentralized Model</td>
<td>36%</td>
<td>47%</td>
<td>10%</td>
<td>7%</td>
</tr>
</tbody>
</table>

*Base: Respondents implementing new approaches (n = 225)*
Application of Fit-for-purpose, Hybrid, and/or Decentralized Clinical Trial Models

Of those survey respondents who expect an increase in fit-for-purpose, hybrid, and/or decentralized clinical trial models going forward, most expect these models will be used for both existing trial restarts (63%) and new trials (61%).

Base: Respondents expecting an increase in the use of fit-for-purpose, hybrid and decentralized trials, hybrid models; multiple responses permitted (n = 148)

Organizations Planning to Give Patients the Option to Choose How They Participate in Clinical Trials

As noted earlier, the top three positive outcomes resulting from the adoption of new clinical trial methods during the pandemic were more timely data, improved flexibility for patients, and increased speed. Interestingly, the importance of improving the patient experience emerged again when survey respondents were asked whether their organization planned to give patients the option to choose how they participate in clinical trials. A slight majority of respondents (58%) said that their organizations plan to give patients the option to choose how they participate in clinical trials.

Base: Respondents implementing new approaches (n = 225)
Impact of Patient Choice on Clinical Research

Most respondents believe allowing patient choice will have a positive impact on clinical research (61%).

- **40%** Somewhat Positive Impact
- **36%** No Meaningful Impact
- **21%** Significantly Positive Impact
- **3%** Negative Impact

**PATIENT CHOICE**

- **61%** Positive Impact
Last year, in the throes of the COVID-19 pandemic, we saw industries adapt and evolve in rapid fashion in response to an environment never experienced before. People, organizations, and industries came together, got creative, and left their comfort zones in order to survive.

For those involved in clinical trials, that meant quickly adjusting to support alternative ways of monitoring and caring for clinical trial participants in a world where traditional, in-person methods were no longer an option. The pandemic accelerated the adoption of new approaches, technology, and models — many of which were being cautiously explored and piloted before — at scale.

While this forced change was disruptive and surely worrisome, the impact of these changes, as we emerge from the pandemic, is overwhelmingly seen as positive. The results of this survey revealed:

• New clinical trial methods adopted during the pandemic had a positive impact on clinical trials,
• The industry is confident in the data generated from newly adopted clinical trial methods,
• And these newly adopted clinical trial methods will continue in the post-pandemic world.

Additionally, the forced adoption of fit-for-purpose, hybrid, and decentralized clinical trial models during the pandemic has helped the industry understand when and how to implement these approaches to improve clinical research. This is reflected in results of this survey, with respondents expecting the continued use of these models in the post-pandemic world and giving patients the option to choose how they participate in clinical trials.

Fortunately, the technology and software to support these changes in clinical research exists today, and are designed to carry the industry into the future of clinical trials. As approaches to clinical trials continue to evolve, study teams can rest assured that technology will not slow them down.

For More Information
Oracle’s Clinical One unified platform makes it easy for sponsors, sites, and patients to adopt new approaches for collecting clinical data and supports the use of any trial model — whether it’s site-based, fit-for-purpose, hybrid, or decentralized. With Clinical One, you can collect data sets from any source and easily harmonize them in a single place to draw valuable clinical insight to make decisions faster.

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