2017

State of the Clinical Research Industry Report
About Forte

Forte Research Systems, Inc. has been developing specialized solutions for clinical research since 2000. Forte solutions include OnCore Enterprise Research, Allegro CTMS, Forte EDC, Forte Research Evaluation System (EVAL), and Forte eRegulatory Management System (eReg).

In 2015, Forte launched a wholly-owned subsidiary, Nimblify Inc., to solve chronic problems and change the industry by connecting key stakeholders such as sponsors, CROs and research sites. Nimblify solutions include: Participant Payments, clinical operations analytics such as Site Benchmarks and Research Insights and the Nimblify Marketplace, which offers business operations solutions to help relieve administrative tasks so they expedite study activation, and focus on the research and patients. Nimblify Marketplace services include Protocol Calendars, eCRF Builds and Coverage Analysis Certification.

Forte & Nimblify provide complimentary blog articles, eBooks, webinars and more to support continuous learning on industry topics. With a strong belief in community, collaboration and standards-based development, Forte also facilitates the Onsemble Community, which brings clinical research professionals together twice a year at the Onsemble Conference.
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Introduction

New challenges in an evolving industry

Over the years, the clinical research landscape has seen an evolution in the way research is conducted. New technology, regulations and scientific developments have significantly impacted clinical trials and the ways in which we get drugs, devices, therapies and preventions to market. In recent years, the industry has seen a rise in targeted therapies, patient-centric trial design, rare disease research, and much more. With these trends come new challenges and a greater need for industry solutions capable of addressing these evolving research practices.

In an effort to better understand the new and recurring challenges of today’s clinical research industry, Forte Research Systems conducted a survey exploring industry pain points, the influence of technology on trial operations, the outlook of current trends in research and more. Through this survey, we hoped to identify our respondents’ key operational challenges and learn how their organizations are currently addressing these roadblocks.

During our analysis, some survey results surprised us, while others reinforced our current beliefs. All of our results made it clear that the need to find solutions for inefficiencies in research operations has never been more pertinent.
Chapter 1

Survey Demographics Overview
Over the course of three weeks, we received 902 responses from individuals across the country that work for a variety of organizations, including research sites, AMCs, Cancer Centers, health systems, sponsors, CROs and more. Responses showed a fairly even distribution between participants working in the academic setting and those working at research sites. This healthy distribution of individuals from a variety of backgrounds allowed us to identify demographic trends and variations in regional distribution, role type, number of studies conducted annually and more. In this chapter, you’ll learn more about the demographic factors that guided our survey analysis.
On average, how many studies does your organization conduct annually?

Results show a relatively equal distribution of participants that conduct under 50 studies per year and those that conduct over 50 studies per year. These results could indicate our survey participants represent organizations of differing sizes and capacities.
On average, how many studies are conducted annually by each state?

This graphic shows the concentration of studies our survey participants conduct on an annual basis.

Participants by Region

It’s likely there is a connection between the regional distribution of survey respondents and the number of studies conducted annually in each state. The majority of our survey participants are from the regional South, so it makes sense to see Texas and Florida conduct a large number of studies per year.
ROLES

What is your role at your organization?

- Administration/Leadership
- Research Coordinator
- Monitoring
- Finance
- Patient Recruitment
- Regulatory
- Research Compliance
- Data Coordinator
- Other

Most frequent combinations of role and institution

This graphic shows five of the most commonly reported combinations of role and institution.

- Research Coordinators at a Research Site: 106
- Research Coordinators at an AMC: 86
- Administrator or Leadership at an AMC: 63
- Administrator or Leadership at a Research Site: 55
- Administrator or Leadership at a Health System: 41
Chapter 2
Pain Points
Our survey results reveal there are many individuals who share common challenges in the clinical research space. Be it administrative burdens, stalled research operations, or financial inaccuracy, the first step towards building greater efficiencies in the research industry is to identify and address pain points in everyday practices. To gain a greater understanding of the prevalence and severity of these challenges, we asked our survey participants to rate their level of pain for day-to-day research activities as minor, moderate or major.

We provided a list of 25 common research tasks, split into five categorical buckets. Participants were able to indicate their level of pain or if a task was not applicable to their position. In this chapter, we present their responses in hopes of identifying trends and insights.
We provided participants a list of 25 common research tasks, split into five categorical buckets. We then asked them to rate the pain they feel for each task by indicating if that task is a minor pain point, moderate pain point, or major pain point. Participants were also able to indicate if that task was not applicable to their position.
Top 15 tasks across all categories ranked by number of respondents, reporting major pain

Across all categories, financial management tasks showed the greatest amount of reported major pain.

<table>
<thead>
<tr>
<th>Task</th>
<th>Bar Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensuring billing compliance</td>
<td>Green</td>
</tr>
<tr>
<td>Invoicing to and tracking payment from sponsors</td>
<td>Green</td>
</tr>
<tr>
<td>Recruiting potential participants</td>
<td>Black</td>
</tr>
<tr>
<td>Maintaining positive cash flow</td>
<td>Green</td>
</tr>
<tr>
<td>Resource allocation and utilizing staff time efficiently</td>
<td>Blue</td>
</tr>
<tr>
<td>Preparing for FDA investigations</td>
<td>Purple</td>
</tr>
<tr>
<td>Duplicate data entry into systems</td>
<td>Orange</td>
</tr>
<tr>
<td>Staff turnover</td>
<td>Blue</td>
</tr>
<tr>
<td>Negotiating study budgets</td>
<td>Green</td>
</tr>
<tr>
<td>Managing the study activation process for regulatory operations</td>
<td>Purple</td>
</tr>
<tr>
<td>Accurately predicting target enrollment</td>
<td>Blue</td>
</tr>
<tr>
<td>Document management (Reg Binder, TMF, etc)</td>
<td>Purple</td>
</tr>
<tr>
<td>Managing the study activation process for clinical trial operations</td>
<td>Green</td>
</tr>
<tr>
<td>Determining trial feasibility</td>
<td>Blue</td>
</tr>
<tr>
<td>Tracking clinical trial performance data</td>
<td>Orange</td>
</tr>
</tbody>
</table>
Comparing top pain points by role

This table identifies tasks with the highest amount of reported major pain per category as determined by each individual role. Some of these tasks seem unique to an individual’s position at an organization. However, when evaluated by category, this table reveals notable similarities in the pain points across roles.

<table>
<thead>
<tr>
<th>Financial</th>
<th>Research Coordinator</th>
<th>Monitoring</th>
<th>Finance</th>
<th>Patient Recruitment</th>
<th>Regulatory</th>
<th>Research Compliance</th>
<th>Data Coordinator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintaining Cash Flow</td>
<td>Invoicing payment</td>
<td>Ensuring</td>
<td>Negotiating</td>
<td>Insignificant</td>
<td>Negotiating</td>
<td>Ensuring</td>
<td>Insignificant</td>
</tr>
<tr>
<td></td>
<td>from sponsors</td>
<td>Billing</td>
<td>Study</td>
<td>Data</td>
<td>Study</td>
<td>Billing</td>
<td>Data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Compliance</td>
<td>Budgets</td>
<td></td>
<td></td>
<td>Compliance</td>
<td></td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory</td>
<td>Preparing for FDA</td>
<td>Insignificant</td>
<td>Preparing for FDA</td>
<td>Managing Study</td>
<td>Preparing for FDA</td>
<td>Managing Study</td>
<td>Preparing for FDA</td>
</tr>
<tr>
<td>investigations</td>
<td>investigations</td>
<td>Data</td>
<td>investigations</td>
<td>Activation</td>
<td>investigations</td>
<td>Activation</td>
<td>investigations</td>
</tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Management</td>
<td>Tracking Clinical</td>
<td>Duplicate Data</td>
<td>Insignificant</td>
<td>Duplicate Data</td>
<td>Insignificant</td>
<td>Tracking Clinical</td>
<td></td>
</tr>
<tr>
<td>Performance Data</td>
<td>Entry</td>
<td>Entry</td>
<td>Data</td>
<td>Entry</td>
<td>Data</td>
<td>Performance Data</td>
<td></td>
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<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coordination</td>
<td>Recruiting Potential</td>
<td>Recruiting Potential</td>
<td>Managing</td>
<td>Recruiting Potential</td>
<td>Recruiting</td>
<td>Recruiting Potential</td>
<td>Recruiting Potential</td>
</tr>
<tr>
<td>Participants</td>
<td>Participants</td>
<td>Payments</td>
<td>Potential Participants</td>
<td>Potential Participants</td>
<td>Potential Participants</td>
<td>Potential Participants</td>
<td>Potential Participants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>to Participants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operations</td>
<td>Resource Allocation</td>
<td>Predicting Target Enrollment</td>
<td>Staff</td>
<td>Managing Staff Documents</td>
<td>Predicting Target Enrollment</td>
<td>Staff Turnover</td>
<td>User Adoption for Research Systems</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enrollment</td>
<td>Turnover</td>
<td>Documents</td>
<td>Enrollment</td>
<td>Turnover</td>
<td>Systems</td>
</tr>
</tbody>
</table>
It’s important to note, during our analysis of results for this section, we found patterns that revealed potential influences on some individuals’ responses. One such pattern was the connection between an individual’s role and the amount of reported pain for role-specific tasks.

Based on results, we believe it’s possible a person’s role at an organization and/or the amount of time a participant may spend thinking about a particular task could impact the amount of pain they report for that task. For example, an individual working in financial management might consider “negotiating study budgets” a significant pain point because that person spends a significant amount of time considering the financial aspects of a study. This task is top-of-mind and a substantial part of their job, therefore they could be more likely to find that task frustrating or challenging.

While such influences could impact some outcomes, there are similarities in the reported major pain across roles in particular categories. For example, in the Coordination category, it’s clear “recruiting potential participants” is a task that the majority of roles listed as a significant pain point. Such pain points seem to be universally felt throughout many participating organizations.

“Often we discover small issues with study requirements of which we were not aware during study acceptance and preparation. This brings study activation to a screeching halt.”

– Survey participant
Chapter 3

Systems
Common pain points found in the previous chapter confirmed our belief that there's a great need for improvement in multiple areas of clinical research operations. For many organizations, efforts to improve begin by finding the right tools to facilitate greater efficiency. With our survey participants’ significant pain points in mind, we examined the various ways they attempt to address these challenges with technology and services.

“Lack of centralization is a challenge at my organization. We currently have many systems that aren’t able to integrate with each other. Therefore, it is difficult to execute system wide communication, document storage and project updates.”

- Survey participant
Survey participants were given a list of 11 clinical research technologies and services and asked to select all options currently used at their organization.

**Most common tech combinations**

Many participants selected more than one of the listed options when asked to identify the technology and services used at their organization. Electronic Data Capture (EDC) was selected most often and was included in all of the most frequently reported combinations of systems.

### 2 Systems Only

- **EDC**
- **CTMS**

### 3 Systems Only

- **EDC**
- **CTMS**
- **Recruitment**

### 4 Systems Only

- **EDC**
- **CTMS**
- **Payment**
- **Homegrown**

### Systems Only

- **Electronic Data Capture** 77.93%
- **Clinical Trial Management System** 62.91%
- **Participant Payment System** 37.24%
- **Homegrown Systems** 31.83%
- **Patient Recruitment Services** 25.38%
- **Electronic Regulatory Binder** 24.62%
- **Protocol Calendar Building Services** 20.57%
- **Business Management Services** 12.61%
- **Operational Analytics Tool** 11.71%
- **Other** 6.01%
- **No systems used** 4.05%
How can systems influence pain reported by specific roles?
Some systems showed a statistically significant impact on the amount of reported pain for these particular roles.

**Research Coordinator Roles**

19% **Decrease in Major Pain**
An average of 13% of Calendar Building service users in Research Coordinator roles reported major pain preparing FDA Investigations compared to an average of 32% of non-Calendar Building service users who reported major pain completing this task.

19% **Decrease in Major Pain**
An average of 15% of CTMS/EDC/Additional System users in Research Coordinator roles reported major pain recruiting patients compared to an average of 34% of non-package users who reported major pain completing this task.

**Administration/Leadership Roles**

23% **Increase in Major Pain**
An average of 44% of CTMS users in Administrative Roles reported major pain managing resource allocation compared to an average of 21% non-CTMS users in Administrative roles who reported major pain completing this task.

23% **Increase in Minor Pain**
An average of 51% of CTMS users in Administrative Roles reported minor pain preparing FDA Investigations compared to an average of 28% of non-CTMS users who reported major pain completing this task.

Based on results, we believe it’s possible a person’s role at an organization or the amount of time a participant may spend thinking about a particular task and its complimentary vendor solution, could impact the amount of pain they report for that task.
How can systems influence amount of pain reported for specific tasks?

Results show some relationship between the amount of reported pain and the use of technology and services at an organization.

<table>
<thead>
<tr>
<th>Maintaining Positive Cash Flow</th>
<th>Preparing for FDA Investigations</th>
<th>Duplicate Data Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10% Decrease in Major Pain</strong></td>
<td><strong>10% Decrease in Minor Pain</strong></td>
<td><strong>10% Increase in Major Pain</strong></td>
</tr>
<tr>
<td>34% of EDC users reported major pain vs. 44% of non-EDC users.</td>
<td>35% of EDC users reported minor pain vs. 47% of non-EDC users.</td>
<td>33% of Calendar service users reported major pain vs. 23% of non-Calendar service users.</td>
</tr>
<tr>
<td><strong>10% Decrease in Minor Pain</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25% of CTMS users reported minor pain vs. 35% of non-CTMS users.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ensuring Billing Compliance</th>
<th>Resource Allocation</th>
<th><strong>16% Decrease in Minor Pain</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11% Increase in Major Pain</strong></td>
<td><strong>7% Increase in Major Pain</strong></td>
<td></td>
</tr>
<tr>
<td>43% of participant payment system users reported major pain vs. 32% of non-participant payment system users.</td>
<td>27% of CTMS users reported major pain vs. 20% of non-CTMS service users.</td>
<td></td>
</tr>
</tbody>
</table>
As shown on the previous pages, there seems to be a connection between technology use and the amount of pain our participants reported. This connection is particularly interesting to us because, as a solutions provider, we attempt to help organizations build efficient processes by providing the necessary tools. What we found throughout the course of this survey is there are a number of factors that could influence the connection between technology and services and the amount of reported pain for particular tasks.

Consider an individual’s role, for example. Depending on a person’s job responsibilities, implementing technology could have a greater or lesser impact on their day-to-day actions. A research coordinator will likely spend more time using a CTMS, and is more impacted by the technology, than an administrator or site leadership. As mentioned in the pain point chapter, the amount of time an individual spends thinking about a task, the more likely they are to report it as challenging—because it’s top-of-mind. Results show the same could apply to technology and services.

Seeing as these challenging tasks are top-of-mind, it’s possible an individual or organization would purchase technology or services to address this challenge. A participant may report system use and report major pain for related tasks because they wish to implement a system to address this pain and improve processes for that task.

The amount of time a system has been in place at an organization and the level of system optimization are also influential factors that were not addressed in our survey. Effective implementation and user adoption of a system can take time and, in the early stages of system use, some individuals may be reluctant to use the technology. This is particularly true if the technology is not implemented correctly. Poor system implementation can lead to larger challenges and thus could have influenced the amount of reported pain for some individuals. Further research needs to be conducted to gain a better understanding of how time and optimization of technology or services impacts the amount of reported pain for particular tasks, and how solution vendors can better approach user adoption.
Chapter 4

Metrics
In the previous chapter, we found new challenges and advantages associated with clinical research technology and services. One such advantage is the ability to effectively track clinical trial performance metrics throughout the study lifecycle. To better understand the influence of performance metrics on clinical research operations, we explored if and how organizations track this information and whether or not they use it to positively influence operational decisions.

“Our problems are based more with individuals, not technology. We have the tools at our disposal but the administration is not big on using them or disseminating information about them. We are a huge medical center spread out over five hospitals, so there is an ongoing challenge with communication.”

- Survey participant
Does your organization use clinical research technology to collect performance metrics data?

- Yes, consistently
- Somewhat
- Not at all
- My organization does not collect metrics

Read our Beginner’s Guide to Clinical Trial Performance Metrics for tips on how to start measuring and improving your organization’s operational performance.

For which of these performance metrics does your organization collect data?

- Contract fully executed to open to accrual: 340
- Draft budget received to finalized: 313
- IRB submission to approval: 375
- Milestone Dollar Value: 183
- Effort Tracking: 335
- Subject Population: 393
- Accrual by Protocol: 459
- Number of Active Protocols: 559
- Number of New Subject Accruals: 460
- Number of Enrolled Subjects: 574

Read our Beginner’s Guide to Clinical Trial Performance Metrics for tips on how to start measuring and improving your organization’s operational performance.
Is data used to influence research operations?

65.73% of participants indicated they use performance metrics to inform decisions about operational improvements, somewhat or consistently.

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somewhat</td>
<td>52.0%</td>
</tr>
<tr>
<td>Yes, consistently</td>
<td>26.4%</td>
</tr>
<tr>
<td>Not at all</td>
<td>13.9%</td>
</tr>
<tr>
<td>Doesn’t collect performance metrics</td>
<td>7.7%</td>
</tr>
</tbody>
</table>
Does using metrics to inform decisions about operations influence pain felt when conducting tasks?

Responses indicate a correlation between the use of performance metrics to inform operational decisions and the amount of pain indicated for particular tasks. In general, those who consistently use metrics show a reduced amount of pain for these tasks.
Chapter 5
What’s Next for Clinical Research?
Throughout our survey, we focused most of our attention on the state of research today to find how current practices influence clinical trial operations. However, we also realize it’s important to think forward and assess where the industry is headed in coming years. To encourage this forward thinking, we asked our participants to look to the future and consider the industry’s prospective potential.
A significant number of participants showed enthusiasm for the future of technology in clinical research. Many were optimistic about the ways technology can enhance connections with patients, advance care and treatment options, and help industry stakeholders collaborate to increase efficiencies in clinical trials.

What are you optimistic about in clinical research?

Survey participant responses

“The industry has become more streamlined due to technological advances.”

“I think we’re entering a phase with personalized medicine where we can predict, with greater certainty, the likely effect of a drug on a specific population--increasing positive experiences & outcomes.”

“Collaboration between institutions has been a positive force in research to create meaningful data from clinical trials.”
Conclusion

So, after digging through the survey results, what did we learn?

There’s more to be done.

In the pain points section of the survey, we learned there’s significant room for improvement in clinical trial operations. Many professionals struggle with tasks they encounter on a daily basis; tasks that are critical to the success of a clinical trial. Pain and frustration in the listed categories could reduce productivity, increase time spent performing tasks and lead to inaccurate results.

It’s possible this pain reported by our survey participants is caused by disparities in the way the industry is currently addressing common challenges. While many organizations are now using technology to improve research practices and increase operational efficiency, it’s clear the way organizations use that technology is significant to the amount of reported pain.

A key part of improvement lies in understanding the problem. Technologies, such as clinical trial management systems, have the potential to inform organizations about operational pain points, allowing them to focus on areas in need of attention. Respondents who indicated they consistently use these performance metrics to influence operational decisions reported less major pain for certain tasks.

These results reveal opportunities for solutions providers to build efficiencies for better research practices. Greater transparency and insight into challenges across multiple organizations is an essential step in identifying and solving some of the research industry’s most pressing issues.

Though the industry has made great strides in advancing clinical research and consistently evolving clinical trial practices, it’s important to remain aware of challenges that need to be addressed. Find out more about our philosophy and strategy for addressing common clinical research challenges on our website, ForteResearch.com. You can also find more resources like this eBook on the following page.
**Additional Resources**

- **Ebook**
  **How to Conduct Valuable Effort Tracking at Your Site**
  Watch the free, on-demand recording of this popular webinar to learn the five metrics your clinical research site should track to promote operational success.
  
  Get my copy

- **Webinar**
  **5 Reports Your Clinical Research Site Should be Running**
  Watch the free, on-demand recording of this popular webinar to learn the five metrics your clinical research site should track to promote operational success.
  
  Watch the recording

- **Ebook**
  **Improving Site Sponsor Relationships: Proactive Strategies for Transparent Clinical Trials**
  Download your copy of our top performing eBook to explore methods for improving relationships between sites and sponsors with practical changes and increased communication.
  
  Get my copy