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The State of Remote Monitoring and Quality Processes in Clinical Trials

Remote Monitoring Is Now, and Will Continue to Be Critical for Clinical Trial Management

The processes for conducting oversight and quality assurance of clinical trials have traditionally centered on site visits. However, the idea of performing these processes remotely, without visits to clinical study sites, has been widely discussed in the industry in recent years. With the Covid-19 pandemic's arrival, this developing interest in remote monitoring and remote quality processes has become a critical requirement.

In the summer of 2020, Agatha surveyed sponsors, CROs, and clinical sites to understand where they stand today in their use of remote processes technologies and their plans going forward.

We found that many organizations are implementing or planning to implement remote monitoring to ensure their clinical trials' continuity. Obstacles remain, including regulatory concerns and what some indicate as the lack of available technology.

The good news is that the FDA does support remote monitoring, although it has not provided in-depth guidance on the best path forward.

Finally, there are a number of key requirements for a remote monitoring solution, including secure uploading of documents, the collaboration between monitors and sites, and secure access to patient data.

We cover all these points and more in the following report, providing insights and additional information where appropriate.

Quick Note:
This was a non-scientific poll, and the survey pool was not balanced to represent the entire industry. The responses and analysis we provide and any interpretations should be treated as impressions rather than conclusions.

As part of Agatha's response to the pandemic, we invested time and resources to understand what sponsors, CROs, and sites need to embark on remote monitoring from a technology perspective. When we use the phrase "remote monitoring," it includes remote monitoring and remote quality management processes. You can find a summary of our analysis of the technologies available and required in the whitepaper: Implementing Remote Monitoring and Quality Management: A Technology Guide.

Agatha also developed Agatha Remote ISF, a new SaaS application for Clinical Sites (ISF stands for 'Investigator Site File,' also known as the Site Binder). It is a subset of the Trial Master File standard reference model. Agatha Remote ISF is used in conjunction with Agatha Clinical, our TMF solution for sponsors and CROs. Agatha currently has a number of customers using Agatha Remote ISF.

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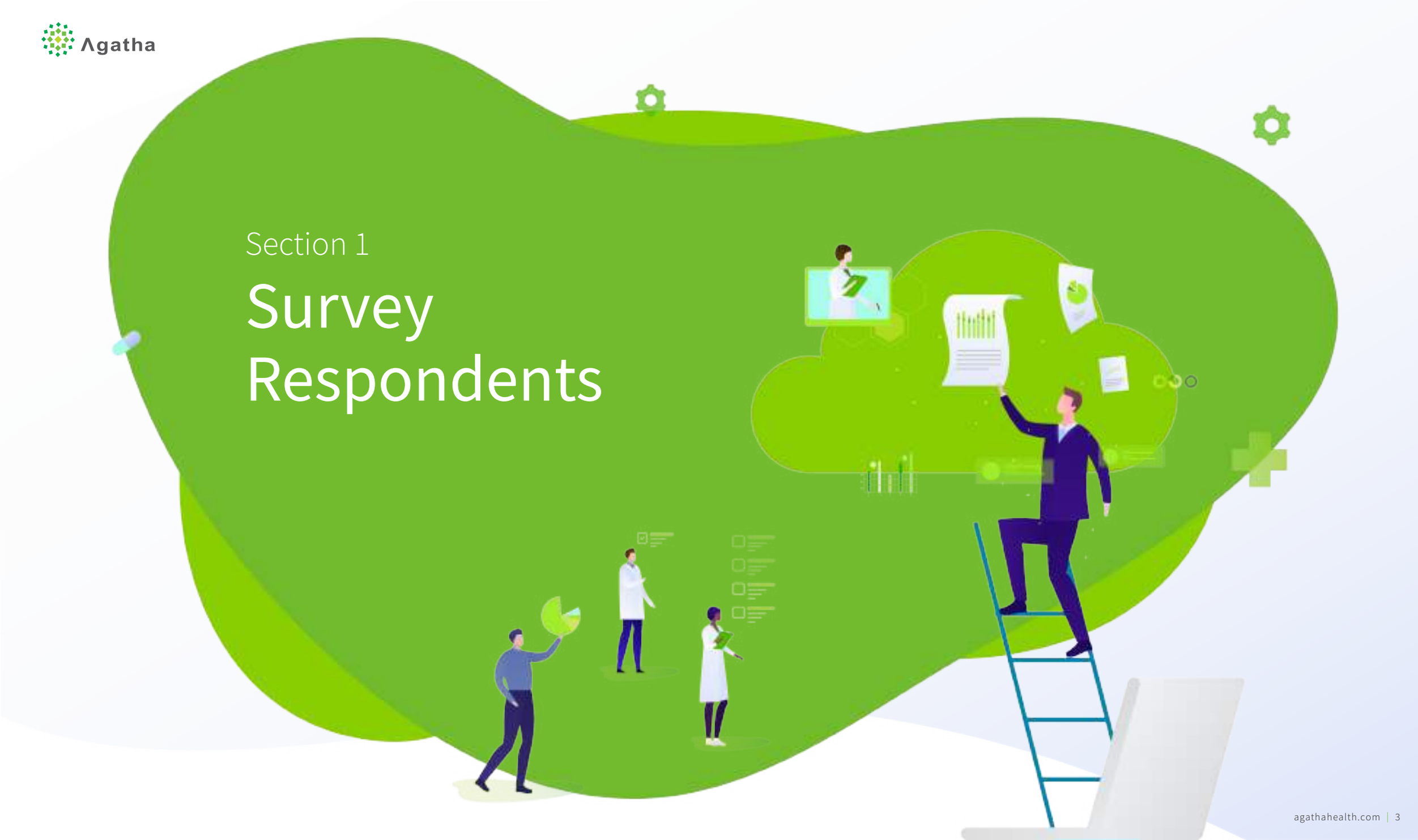
Section 1

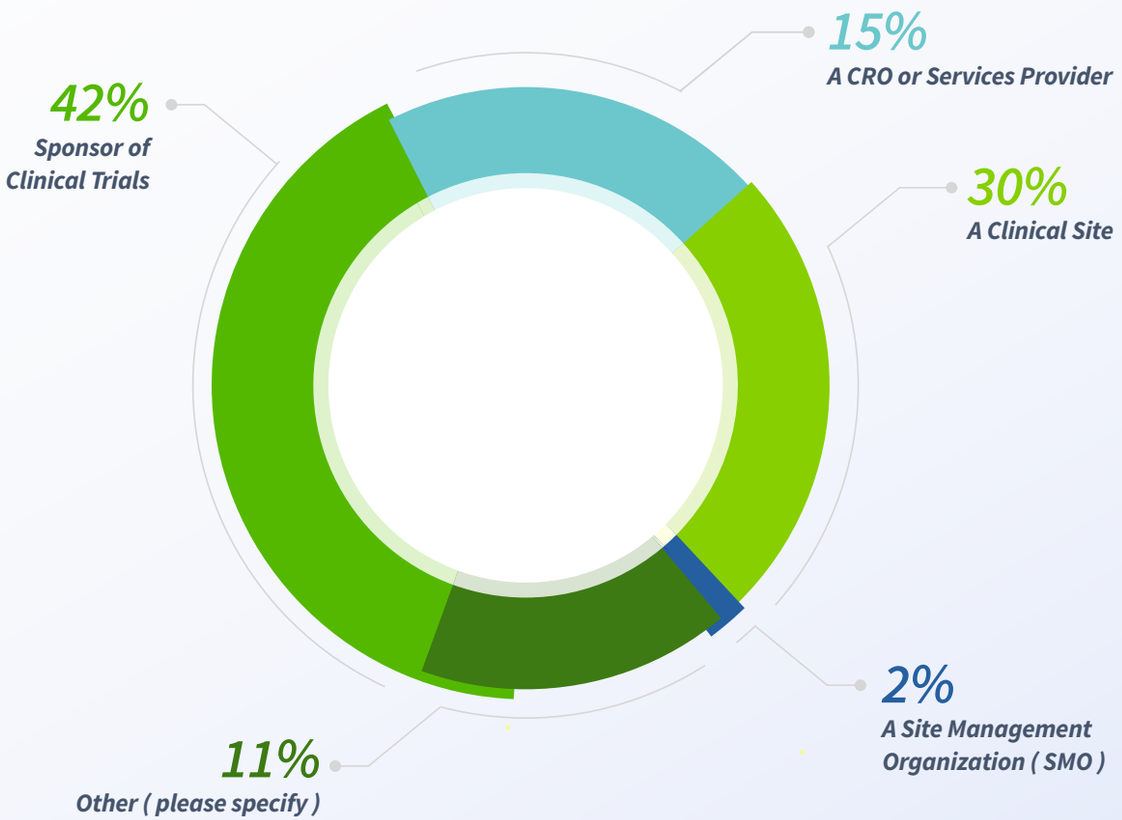
Survey Respondents

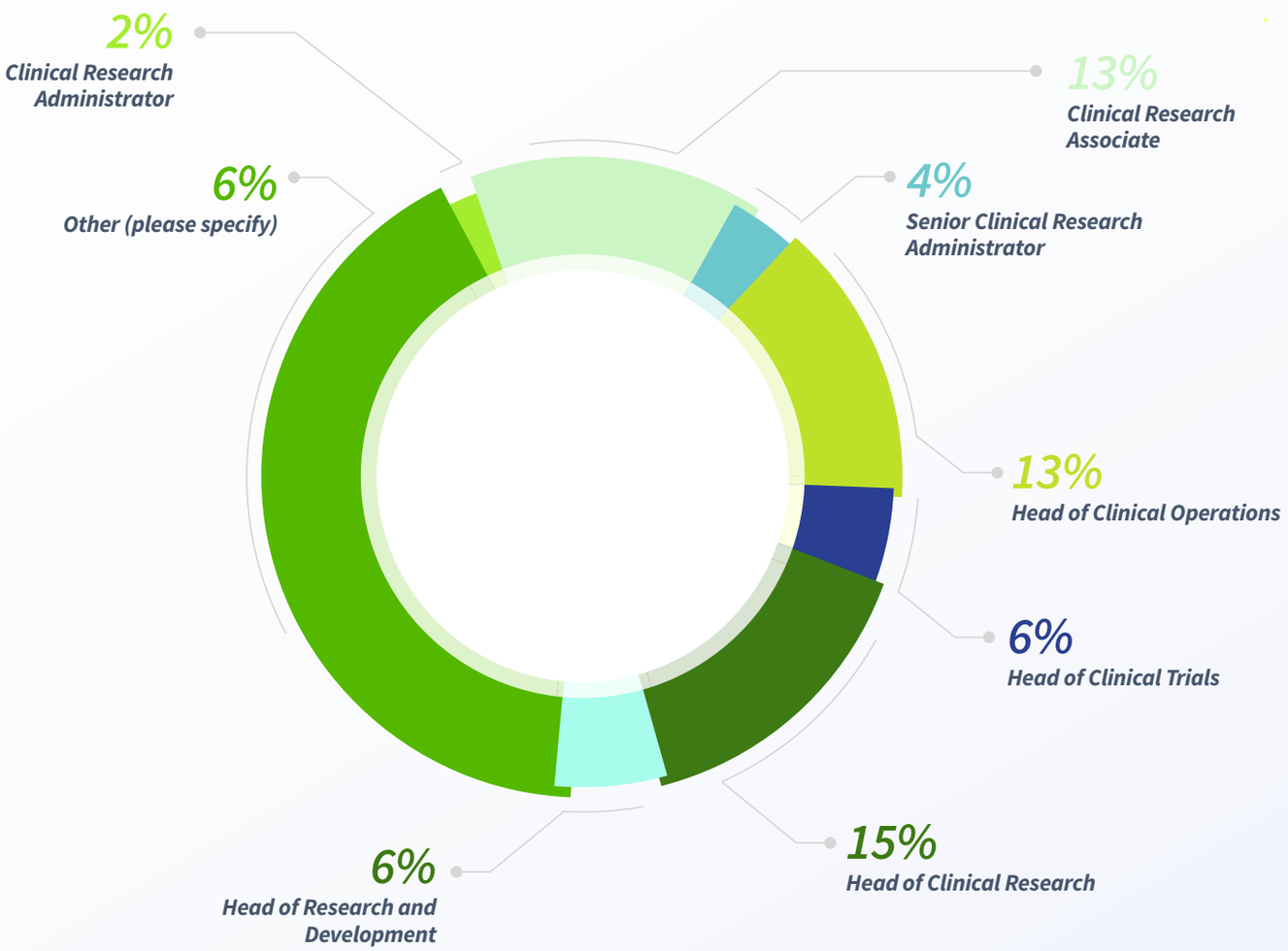


Who Completed the Survey?

Almost half the respondents -- 42% -- represent sponsors. 30% of the respondents represent clinical sites, while 15% work at CROs. The respondents make up a mixture of medical device, biopharma, biotech, or molecule-based pharma companies, and are from the US and Canada.

My organization is...





This breakdown of respondents gives us a representative group of individuals from a variety of types of organizations. The larger number of sponsor organizations slightly skew the results toward the capabilities and the thinking of larger organizations. In general, sponsors are larger organizations than clinical sites (with many exceptions, of course).

Survey respondents represented a broad spectrum of roles, including a balanced representation of management and non-management roles. “Other” was the most-selected response, and included titles such as Director, QA and Compliance, Head of Clinical Systems or Clinical QA, Clinical Research Coordinator, and others.

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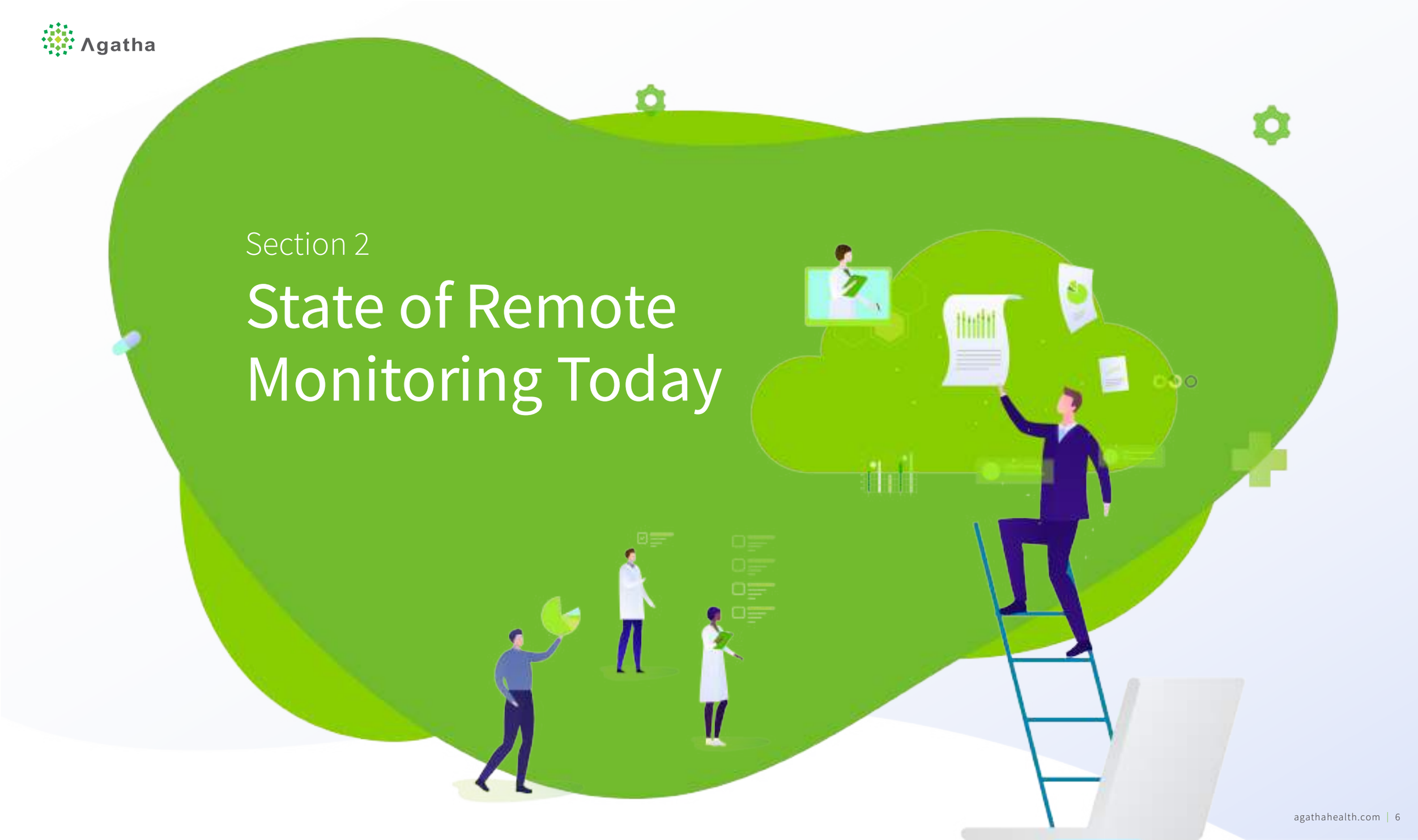
Section 2

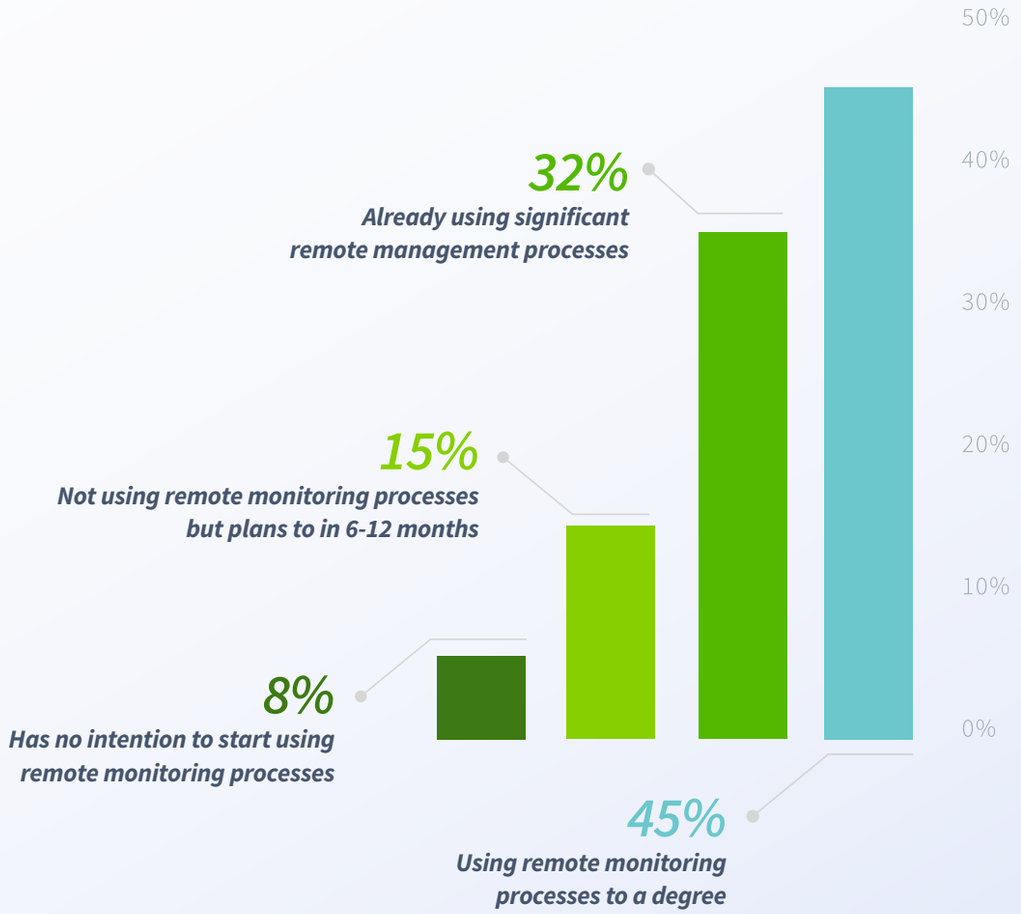
State of Remote Monitoring Today



The Degree of Remote Monitoring Happening Today

We asked respondents about the current use of remote monitoring processes in their organizations, and the answer was a lot more than we thought. **Seventy-seven percent of respondents said they are using remote monitoring to a degree.**

In terms of Remote Monitoring and Quality Management, at this time, my organization is:



We did not ask for examples of the tools and methods respondents are using to facilitate remote monitoring. It is possible that of the 45% of respondents who indicated they are using remote monitoring to a degree, some could have meant that they were doing something as simple as making phone calls.

In interviews, however, it seems people meant more than that. The 32% that said they use “significant” remote management processes indicates they have relatively comprehensive processes and systems in place for exchanging site files and documents between sponsors, CROs, and sites.

This was the single biggest surprise of the survey. It changed our perspective in that we no longer think of remote monitoring as a single change in process, but rather as a continuum of processes and systems adopted over time to go from “not doing remote monitoring” to “doing a lot of remote monitoring.” Interviews that accompanied the survey completely back up this interpretation.

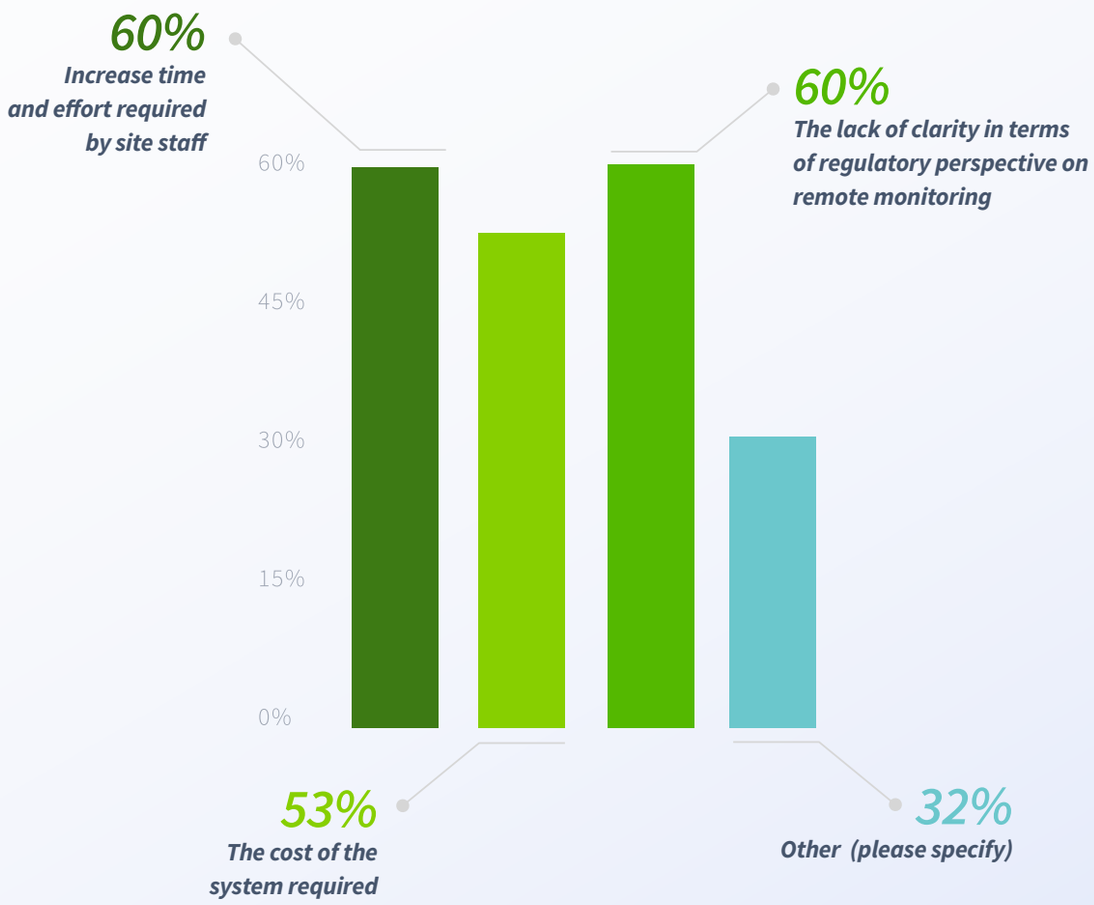
It turns out that the transition to remote monitoring is happening quickly and already well underway.

A follow-on survey would be essential to understand what each respondent means when they refer to remote monitoring and what tools and methods they are using. For example, we could ask if they are exchanging files, and if so, how. It would be good to know the percentage mailing files versus those sharing files across file-sharing tools like Box or Dropbox, and those who are using trial-specific systems like Veeva and Agatha to share files following regulatory requirements.

Obstacles to Remote Monitoring

The responses to questions about obstacles were some of the most interesting in the survey. The initial question asked respondents to indicate **all the obstacles** they felt were significant. 60% selected “increased time and effort,” and a “lack of regulatory clarity.”

Which of the following are significant obstacles to increasing the use of remote processing?



The regulatory response is interesting because of the respondents who selected this obstacle, 87% also felt the FDA supports remote monitoring practices. The key to understanding this dichotomy is the phrase “lack of clarity” concerning regulations. Perhaps many know the FDA is supportive but still are unclear when it comes to specifics.

The high score for “Increased time and effort” reflects the respondents’ clarity and maturity, indicating the ultimate obstacle to moving to new monitoring processes is the impact on site staff. Unlike sponsor and CRO personnel, site administrators are typically short on time, short on budget, short on staff...and their priority is patients walking in the door. Understanding site administrators’ reality and assisting them through a change process is clearly key to successfully transitioning to remote monitoring.

We also asked survey participants to choose the single largest obstacle to implementing remote monitoring practices.

“ Behavioral economics is a powerful lens to look through when managing change. Fundamentally, it insists that we answer the question “What’s in it for me?” when we look at implementing changes in the way people act – in this case, in their jobs. And when you think about site staff, that’s a tough question. What do they have to gain from shifting from paper to the electronic systems needed for remote monitoring and quality management? ”

- 5 Key for Successful Remote Monitoring & Quality Management

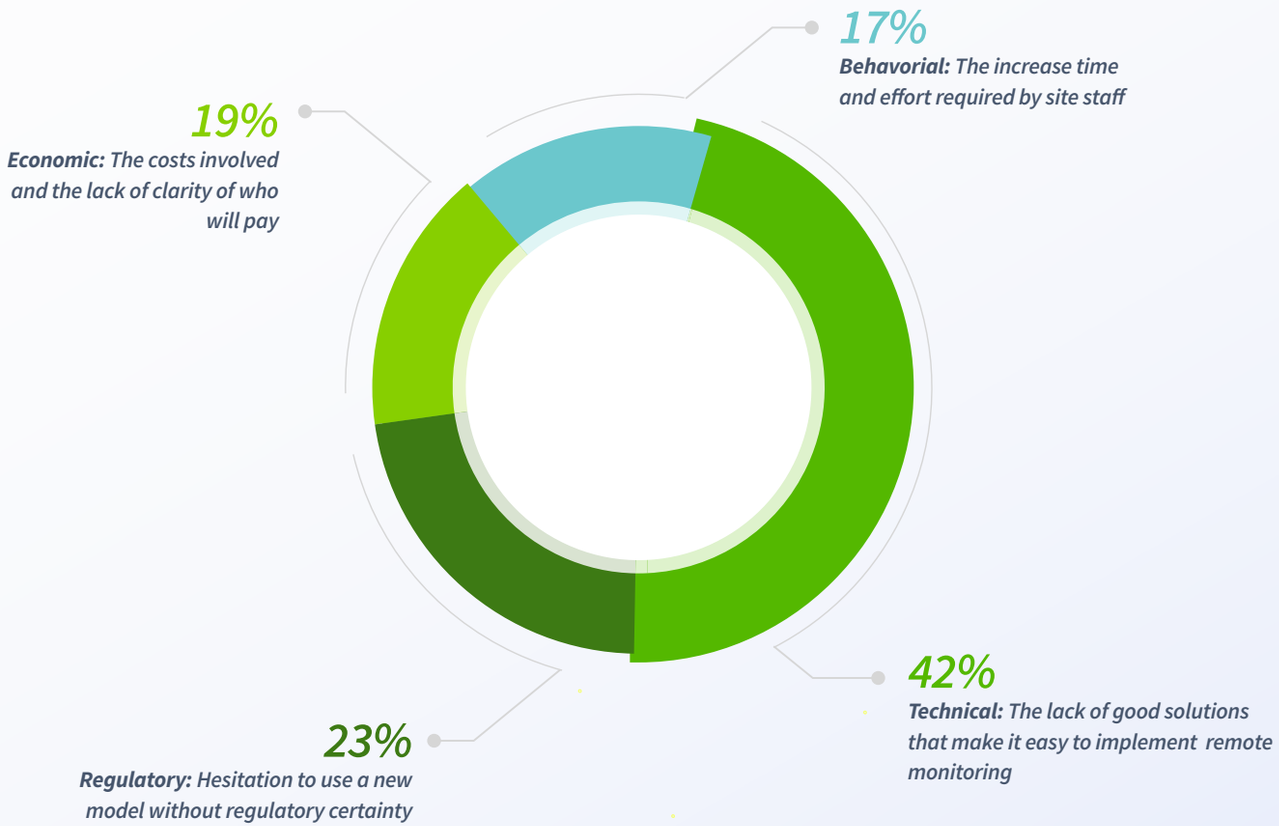
The answer here was fascinating to us since we work at a software company – 42% selected technology as the single biggest obstacle.

We discuss this more in the Conclusion, but for the moment, we will note that the actual technology required to do remote monitoring is entirely available, including the ability:

- To securely share binder files with a monitor
- For the monitor to comment on those files
- To assign and respond to tasks

Some organizations share files using basic file-sharing technology such as a network drive or file sync and share tools likes Box and Dropbox. The same is true for collaboration capabilities to share comments and tasks. While these technologies are available and proven, they are problematic from a regulatory perspective. Many of these tools do not provide the necessary document management capabilities such as tracking versions and auditing required by 21 CFR part 11.

Perhaps what is missing is the packaging of that technology that is easy to implement, and which organizations can be confident will stand up to regulatory scrutiny.



Which of the following is the SINGLE BIGGEST OBSTACLE to increasing the use of remote processing?

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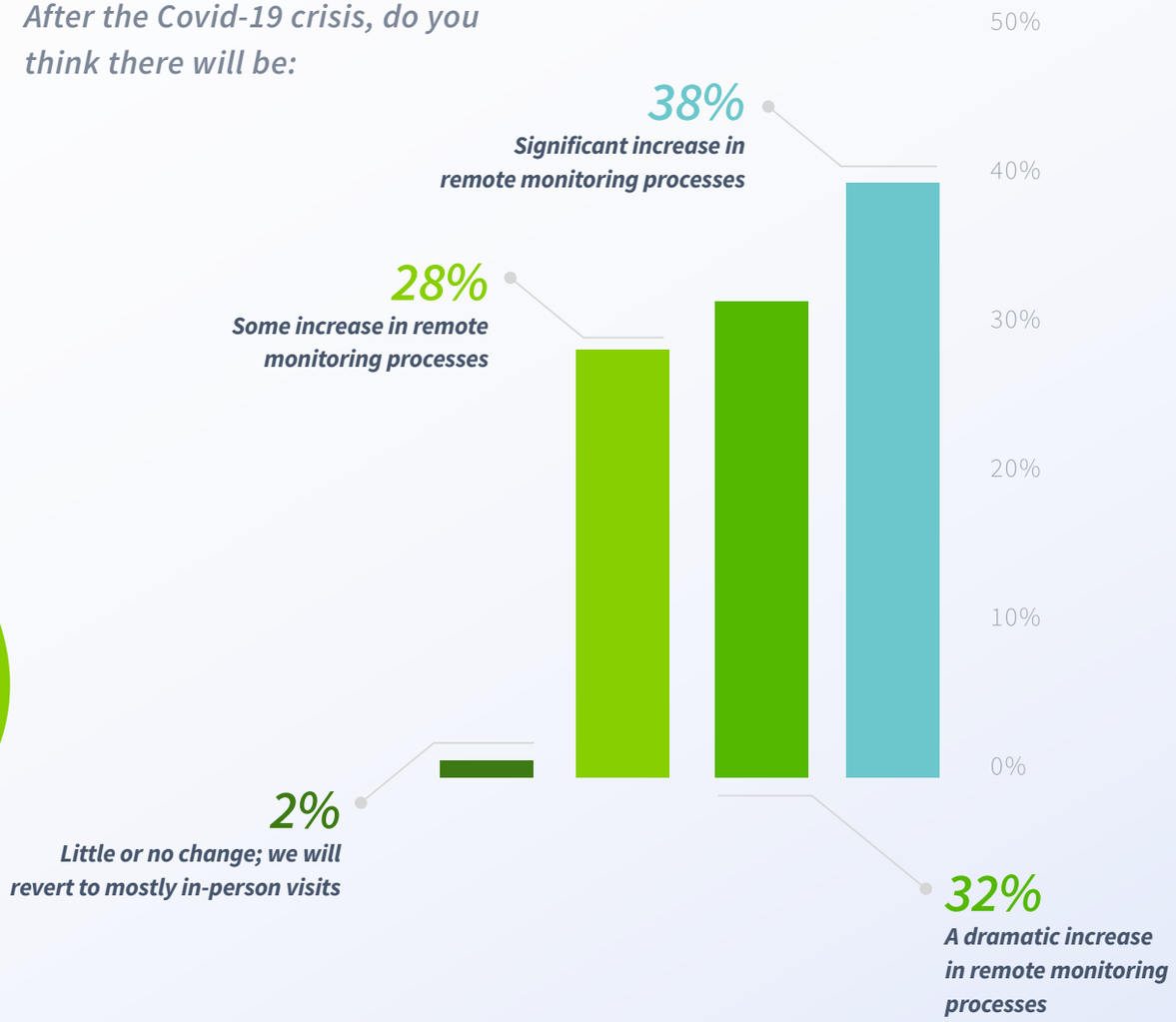
Section 3

The Future of Remote Monitoring

What are the expectations going forward for Remote Monitoring?

Survey respondents have a clear perspective on the future of remote monitoring: **It will be expanding significantly.** Seventy percent selected choices corresponding to a dramatic or significant increase in remote monitoring.

After the Covid-19 crisis, do you think there will be:



In interviews, we discussed this topic, delving into what the future looks like in terms of day-to-day remote monitoring practices. The consensus was that there would be a hybrid model combining on-site and remote monitoring processes.

This makes perfect sense because, with experience sharing binder files, exchanging comments, and completing assigned tasks, these processes will stay after the pandemic and grow in use with increasing familiarity. However, some activities are more natural and effective in an in-person setting, making in-person, on-site visits a valuable tool.

However, there will be fewer visits, if for no other reason than economics. The costs of on-site visits are extraordinary, with one study indicating that they comprise 25 to 30% of total study costs.

The use of remote monitoring delivers dramatic cost savings, and sponsors will adjust budgets appropriately, with travel reductions becoming permanent.

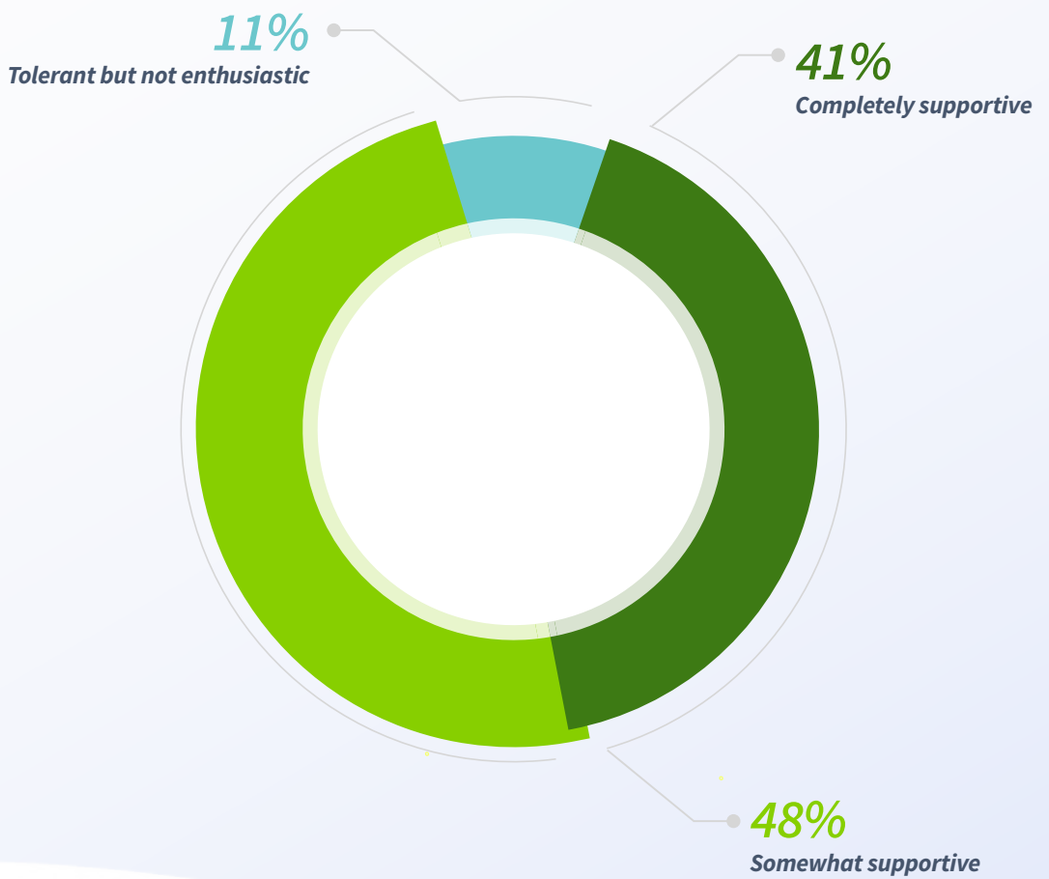
Monitoring is another very costly aspect of clinical trials, with on-site monitoring making up around 25 to 30 percent of the overall cost of clinical trials.[2] As a direct result of drastically reducing the number of investigator sites, traditional on-site monitoring and management costs are also reduced.

- Measuring The Financial Impact Of Remote (Digital) Clinical Trials, Débora S. Araujo. Clinical Leader, January 29, 2019.

What is the Perception of the FDA's posture?

The survey included a question about the FDA's posture regarding remote monitoring. This question's results were obvious: 90% of those surveyed said that they think the FDA is either completely or somewhat supportive of remote monitoring and remote quality processes.

From your understanding at the moment, is the FDA:



There is not a lot to say about this response, except that the respondents are right. The FDA has repeatedly expressed support for centralized and remote processes for clinical trials. Here is one example from FDA guidance that was issued after the onset of the travel restrictions in the Spring of 2020:

“ If planned on-site monitoring visits are no longer possible, sponsors should consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites. ”

Interestingly, while 90% of those surveyed said they think that the FDA is supportive, in an earlier question, 24% still said they feel that the single largest obstacle to implementing remote monitoring is regulatory.

Our interpretation of this discrepancy is that we are always a little uncertain regarding FDA regulatory guidance. We have an extremely conservative filter when it comes to the regulatory authorities, and no one wants to do anything that somehow might be challenged. The result is a kind of stasis to innovation in clinical trials.

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Section 4

Remote Monitoring Technology

What Does a Remote Monitoring Solution Look Like?

Since we work at a software company, our fundamental interest is in the market's needs for new applications and solutions. Therefore, a centerpiece of the survey focused on a remote monitoring solution's key capabilities to support sponsors, CROs, and site organizations.

The answers indicate that all of the features we offered are important. However, according to respondents, the ability to upload binder documents to a secure location was the most critical function, with 88% indicating that this is essential.

Which of the following do you think are essential capabilities for a remote monitoring solution?"

Respondents were able to select multiple answers.

ANSWER CHOICES	RESPONSES
A monitor can specify documents required	71.70%
A site can securely upload binder documents to a secure location	86.79%
A monitor can read BUT NOT download or print documents uploaded by the site	56.60%
A monitor can create notes for the site staff about documents and other matters that require action	69.81%
Site staff can easily upload patient source documents (medical records)that have been extracted from the patient record system	77.36%
A monitor can access patient source documents (medical records) directly in the patient record system	62.26%
A monitor can easily move documents from the ISF application to the TMF application	60.38%
Other (please specify)	9.43%

A Few Notes on Essential Capabilities

Secure Upload

We suspect the key term here is “securely upload.” This is consistent with interview findings, where concerns about the security of the clinical trial files and documents were consistently most important to all types of organizations, especially clinical sites.

Clinical sites are responsible for patient data and are under regulatory scrutiny for how they protect patient information. Subject to HIPAA (Health Insurance Portability and Accountability Act) and the focus on data privacy in general, including the General Data Protection Regulation (GDPR) act in the EU and similar regulations at the state level in the United States, organizations are very concerned and careful when it comes to handling data. In interviews with sites, the question we are sometimes asked when we talk about sharing Binder Files with sponsors or CROs is, “Are we allowed to do that?”

The answer is yes, absolutely (and they already are with paper files). There are requirements for how information is shared, protected, and how each document’s lifecycle is recorded in an audit trail that a remote monitoring solution must support.

Collaboration: Notes and Comments

A second capability important to respondents was the ability for a monitor to make notes and comments for site administrators. This requirement replicates the monitoring process in an on-site visit when a monitor leaves “sticky notes” on specific documents or files indicating observations or issues the site team must remedy.

Uploading & Sharing Patient Data

Also essential to survey respondents was a way to upload and share patient data. As a software company, this is the hardest function to implement in a software solution. It requires the monitoring solution to access the patient records system, which is possible (and relatively straightforward technically).

It is challenging from a business process perspective, however. Issues regarding access to the patient record system and access to a particular patient record can be difficult to overcome due to the processes preventing unauthorized access. Anyone who has arranged permission for a monitor to access a patient record system has experienced those challenges as they complete IT requests and wait for access to be granted.

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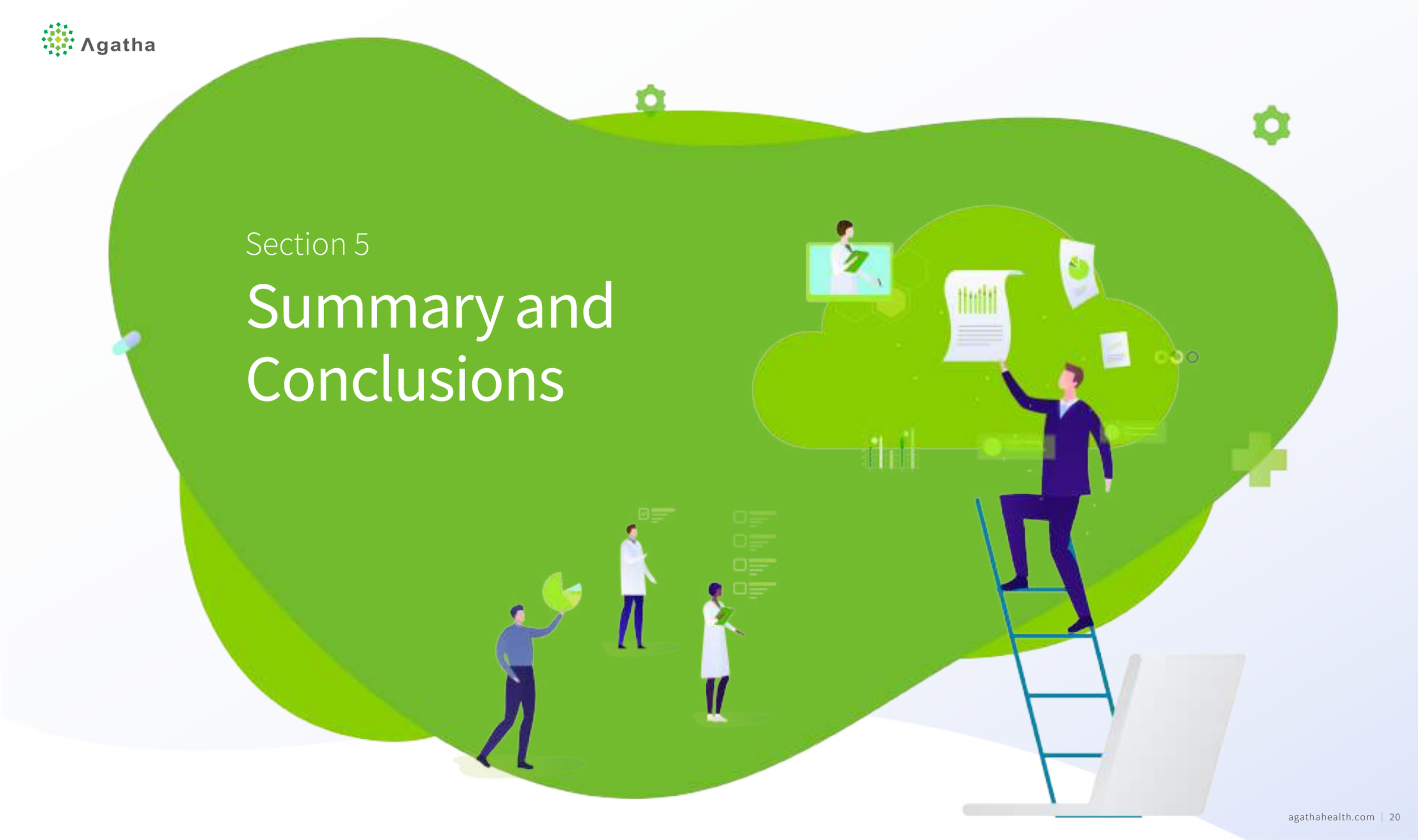
Section 5

Summary and Conclusions



As noted earlier, this was a brief, unscientific survey. It undoubtedly has a selection bias built-in based on who chose to respond and the mix of organizations included (sponsor versus CRO versus Site).

None-the-less, we think it is fair to use the results, combined with interviews we completed, to make some summary observations. For our purposes as a software company, this allows us to plan our products accordingly. For you, it may be useful in determining where you fit in relation to your peers and help guide your plans going forward.

The most significant takeaway from the survey is that the majority of survey respondents are already using remote monitoring processes. We expected this to be a minority, maybe even a small minority. Instead, 77% indicated they are well on their way using remote monitoring processes and practices.

On the other hand, it was interesting that there are very significant obstacles. And we (as technology people) were particularly surprised that the largest obstacle cited was technology. 42% cited technology barriers as the single biggest obstacle to implementing remote monitoring processes. That is remarkable to us because there are few technology obstacles. None of the functional requirements for a remote monitoring application is particularly challenging from a technology perspective.

A second capability important to respondents was the ability for a monitor to make notes and comments for site administrators. This requirement replicates the monitoring process in an on-site visit when a monitor leaves “sticky notes” on specific documents or files indicating observations or issues the site team must remedy.

Identifying technology as a barrier may have more to do with implementing technology, such as user adoption, management, and administration of a solution or other issues. Equally as likely, it seems that there is a lack of awareness that technology solutions are available.

The consensus is that remote monitoring is here to stay and will increase as a practice. As an industry, then, the key is to help organizations continue to make the transition successfully. Applications like Agatha Remote ISF for remote monitoring can address the functional requirements.

Now, we have to focus on how to implement these solutions effectively to ensure high user adoption and little disruption.

As described in the next and final section, this reflects Agatha’s priority. Through benchmarking studies with individual organizations and case studies with those who have made the transition, our goal is to identify and evangelize the proven practices that will illuminate the path forward for organizations as they continue to expand their use of remote monitoring.

The Next Step: Benchmarking your Organization

There are two primary audiences of survey data, such as that presented above. The first is for organizations trying to understand the current state of the market, the needs of organizations, and their future plans. For companies like Agatha, who build software applications, this type of information is critical.

The second audience is the companies that comprise the market because they can use the data to assess where they fall in comparison to their peers. Using this information for benchmarking your own organization is a valuable way to layout your plans in the area of remote monitoring.

Our next step in this area is intended to facilitate that process. We are conducting readiness assessments that will allow an organization to identify the opportunities and obstacles to implementing remote monitoring technologies within their organization.

The result is an individualized current state/future state analysis that summarizes insights into an organization and provides guidance for a transition into remote monitoring.

Unlike a survey, the readiness assessment is a one-on-one process that includes an interview with one or more individuals from the organization, developing a draft assessment, and a final report. It is a two-day process that includes about two hours of the organization's time.

Agatha is starting to schedule these interviews for Fall 2020 and is targeting twenty organizations to benchmark. The results are entirely confidential. If you are interested in a "Remote Monitoring Technology Benchmark Analysis" for your organization, contact us at the email below for more information.

About the Author

Ken Lownie is the head of North American Operations for Agatha Inc. He works with life sciences companies to implement technology solutions that automate and accelerate clinical operations processes and is a frequent writer and speaker on technology adoption in life sciences.

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About Agatha Remote Monitoring

Agatha Remote Monitoring is a complete, ready-to-use, pre-validated cloud-based application that allows clinical sites to securely upload source files to a 21 CFR Part 11 and HIPAA compliant application. It enables monitors and inspectors to review the source files, make notes, and complete their monitoring tasks. The application also allows for the creation and assignment of tasks for site administrators, including notifications and tracking.

Sign up for a trial:

www.agathahealth.com

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About Agatha

With offices in the US, Europe, and Japan, Agatha is dedicated to helping the world's Hospitals, biotechnology, pharmaceutical, contract research organizations, and medical device firms optimize the management of their Quality, Regulatory and Clinical documentation and processes. With lower costs and faster on-boarding, Agatha delivers the best ROI on business applications for life sciences that are ready to use and easy to adopt. Agatha, Inc. is a strategic software solutions provider to the healthcare and life sciences industry, providing SaaS-based business applications for managing SOP, regulatory documents, and clinical trial master file records.