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Investigative Sites Speak Out About Remote Monitoring

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Risk-based monitoring focuses resources on areas where the presence of errors is most likely and the consequence of errors is most significant. It makes sense that risk-based monitoring (managed by a central office remote from the sites) can increase quality and reduce costs.

Remote monitoring is not risk-based monitoring — it involves inspecting study data and documents from a location remote from the site.

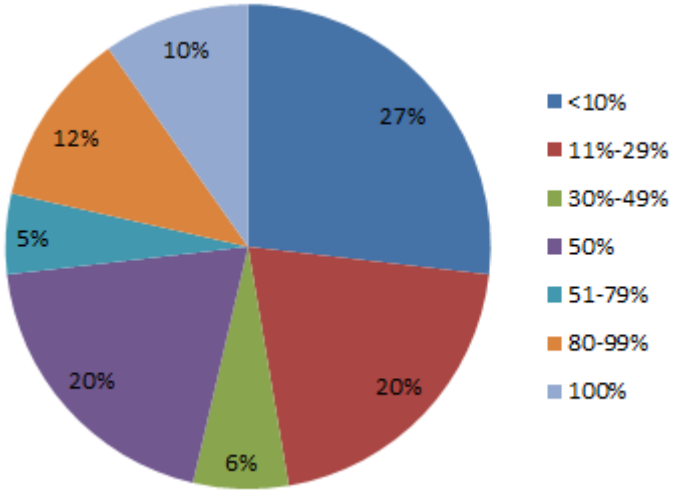
A previous article described the results of an exploratory survey on the cost of remote monitoring to sites. This article presents the results of a more accurate and comprehensive survey and provides recommendations for both sponsors and sites to address current shortcomings in the remote monitoring process.

In February and March 2017, 219 respondents from clinical sites participated in the survey. Eighty-nine percent of respondents were based in the U.S. or Canada. The survey asked respondents for data on "typical" Phase 3 studies with and without remote monitoring. The term "remote monitoring" described any study that had a "significant amount of remote, off-site access and/or monitoring."

Prevalence of Remote Monitoring

The median respondent was at a site with 30% of studies with remote monitoring. Fifty-three percent were at sites with less than 50% of studies with remote monitoring. Twenty-seven percent were at sites with 50% to 99% of studies with remote monitoring. Ten percent were at sites with 100% studies with remote monitoring. These percentages are probably higher than for non-respondent sites.

Figure 1. Respondent Percentage of Studies with Remote-Monitoring



Comparison of Site Labor Costs for Traditional On-Site vs. Remote Monitoring

An analysis of data from the survey shows that study coordinator time directly related to study visits in a typical Phase 3 study was only 5% more for remote vs. traditional monitoring (4,160 minutes vs. 3,970 minutes). However, studies with remote monitoring consumed 57% more time from other site personnel (e.g., data manager, regulatory specialist, pharmacy, research director) than studies with traditional monitoring (2,080 minutes vs. 1,323 minutes). In addition, studies with remote monitoring consumed 94% more time than studies with traditional monitoring for miscellaneous activities related to monitoring but not to specific monitoring visits (10,712 minutes vs. 5,508 minutes). Overall, studies with remote monitoring consumed 57% more time for monitoring-related activities than studies with traditional monitoring (16,952 minutes vs. 10,801 minutes).

Over the course of a typical Phase 3 study with a duration of 104 weeks from site activation to final close-out, studies with remote monitoring consumed 163 minutes per week vs. 105 minutes per week in studies with traditional monitoring. In other words, studies with remote monitoring consumed about one hour more per week than studies with traditional monitoring. It might seem like a small difference, but it adds up over the course of a two-year study.

Monitoring-related activities in remote-monitoring studies thus cost 57% more than monitoring-related activities in a traditional-monitoring study ($29,969 vs. $17,668). For the typical Phase 3 study with revenue of $60,000, monitoring activities consumed 50% of revenue with remote monitoring vs. 29% of revenue with traditional monitoring. Monitoring of any kind thus imposes a substantial cost burden on sites, as well as on sponsors.

Notes and Caveats on the Survey

The typical remote-monitoring study uses a hybrid model, with four on-site monitoring visits and six remote "visits."

Survey respondents were asked to imagine a "typical" Phase 3 study. Their responses were not based on actual data, i.e., time and motion studies. Respondents might not have been representative of the population of clinical sites as a whole. Some responses might have reflected a bias against remote monitoring. Some respondents might have misinterpreted some questions. Some respondents might have double-counted or not counted certain time spent on monitoring activities. The survey might have overestimated monitoring-related activities at the beginning and/or end of studies. Numerical results have been calculated based on median averages rather than mean averages to focus on the "typical" site experience and minimize the effect on the results of the wide variation in data.

Respondents reported that the median salary cost (including benefits and overhead) for a study coordinator was $50/hour and the median cost for an investigator was $200/hour. The median cost for other personnel was assumed to be $50/hour.

This analysis considers only the labor costs related to monitoring. Traditional on-site monitoring might require additional space, while remote monitoring might require additional equipment.

Figure 2. Site Labor Costs for Traditional On-Site vs. Remote Monitoring

	Traditional	Remote
Revenue from Phase 3 study at your site, US$*	$60,000	$60,000
Number of subjects enrolled in a study with remote monitoring*	10	10
Study duration from site activation to final close-out (months)*	24	24
In-person site monitoring visits	10	4
Remote monitoring visits	0	6
Study coordinator preparation time for an on-site visit (minutes)	60	75
Study coordinator preparation time for a remote visit (minutes)	0	60
Study coordinator time during an on-site visit (minutes)	120	120
Study coordinator time during a remote visit (minutes)	0	60
Study coordinator time for the follow-up letter from an on-site visit (minutes)	60	50
Study coordinator time for follow-up letter from a remote visit (minutes)	0	60
Study coordinator follow-up time for other matters after an on-site visit (minutes)	60	60
Study coordinator follow-up time for other matters after a remote visit (minutes)	0	60
Study coordinator time for other document requests related to site monitoring (minutes)	37	60
Study coordinator time for other matters related to site monitoring (minutes)	60	90
Total study coordinator time per on-site visit (minutes)	300	305
Total study coordinator time per remote visit (minutes)		240
Total study coordinator time for on-site visits (minutes)	3,000	1,220
Total study coordinator time for remote visits (minutes)		1,440
Total study coordinator time for other document requests and other matters (minutes)	970	1,500
Total study coordinator time directly related to monitoring visits (minutes)**	3,970	4,160
Other personnel time directly related to monitoring visits (as % of study coordinator time)	33%	50%
Other personnel time directly related to monitoring visits (minutes)	1,323	2,080
Additional time per week related to monitoring (minutes per week)	53	103
Study duration from site activation to final close-out (weeks)*	104	104
Total additional time (minutes)	5,508	10,712
Total time related to monitoring (minutes)	10,801	16,952
Weighted cost per hour**	$65	$65
Cost directly related to monitoring visits	$11,701	$18,365
Total additional costs	$5,967	$11,605
Total costs related to monitoring	$17,668	$29,969
Revenue for study*	$60,000	$60,000
Costs related to monitoring as % of revenue	29%	50%

* Applied number from remote monitoring for an apples-to-apples comparison

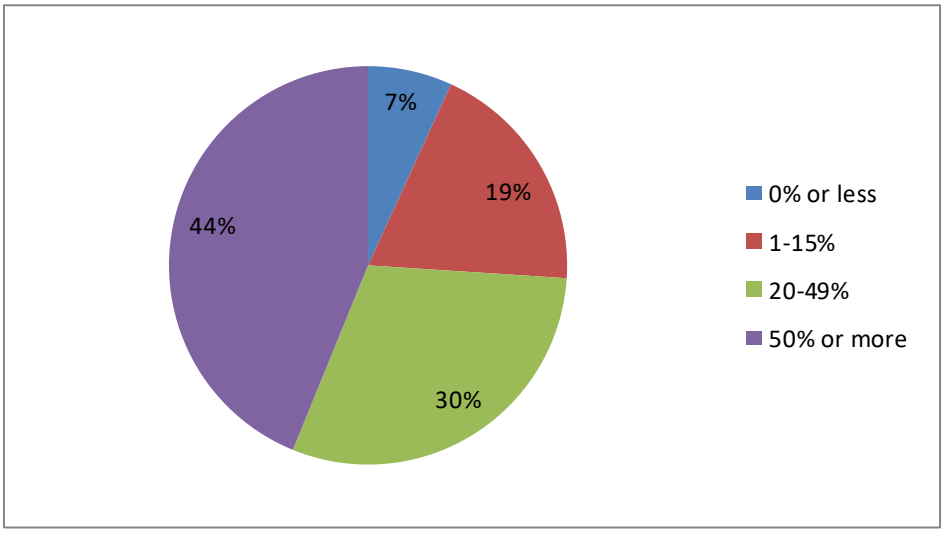
** Based on 10% of time being spent by investigator

Sites Want to Charge More for Studies with Remote Monitoring

The median respondent wants to charge 37% more for studies with remote monitoring. Eighty-three percent of respondents want to charge more for studies with remote monitoring, including 10% that want to increase charges by 50% or more. Ten percent would charge about the same. Seven percent would not charge more, including four respondents who would charge less. Unless these four respondents misunderstood the question, their sites have developed systems and processes that work well with remote monitoring.

These results appear to overstate the extra cost of remote monitoring to sites, which, according to the calculations in Figure 2, appears to be about 21% of revenue. However, they suggest that any errors in the calculations *understate* the extra cost of remote monitoring.

Figure 3. Extra Charge for Studies with Remote Monitoring

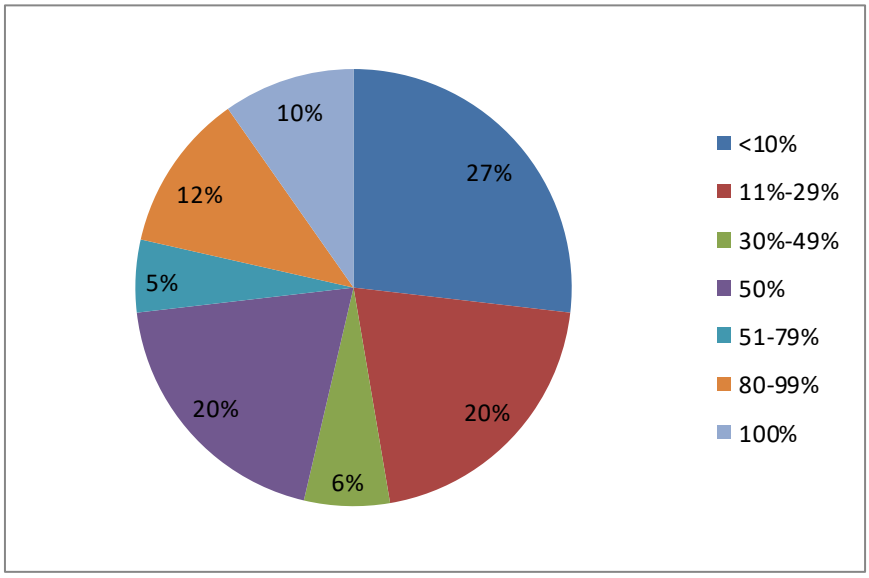


Remote vs. On-Site Monitoring for Assuring Quality

Sixteen percent of respondents believe remote monitoring is better than traditional on-site monitoring for assuring quality. Ten percent believe the two methods yield the same quality. Seventy-four percent believe traditional on-site monitoring is better for assuring quality.

Many sites are thus frustrated that they are spending more time to generate data of lower quality.

Figure 4. Remote Monitoring vs. On-site Monitoring for Assuring Quality



Site Criticisms of Remote Monitoring

Respondents had the following criticisms of remote monitoring, in rough order of frequency and importance:

Figure 5. Site Criticisms of Remote Monitoring

Increased burden on staff
Lack of relationship/engagement with monitor
Remote monitoring is not effective
Redundant queries and requests
Too much time required to copy, print, scan, redact and transmit documents
Queries and requests are unclear or nonsensical
Poor communications create confusion and misunderstandings
Sites do not understand the monitoring plan, activities and preferences; no feedback
No support for site issues; sites do not feel supported
Monitors do not see context in source documents
Technology issues
Requests are always urgent
Remote monitor lack knowledge of the protocol
Lack of attention to detail by remote monitors
Remote monitors lacks global/systemic perspective
Remote monitors unprepared or disorganized
With multiple monitors, point of contact is unclear
Additional staff training required

Constant requests
Less investigator engagement with the study and awareness of issues
Site monitors are not available for discussions and to answer questions
Remote monitors do not document what has been monitored and their findings
Cannot give remote monitor access to EMR
Absent or delayed communications with remote monitors
Document transmission and storage might not be secure
Hard to schedule phone calls across time zones
Issues take multiple communications to resolve
Lack of training for site by sponsor
More storage space required for returned drug bottles
In-person site monitors do not communicate with remote monitors
Remote monitors are poorly trained
Investigator has to be present for entire remote visit
Lack of consistency with multiple or changing remote monitors
Lack of confidence in resulting data quality
Remote monitor does not understand site's standards & processes
On-site monitoring has deteriorated
Remote monitors do not have time to cover remote visit agenda
Remote monitors do not communicate with each other

Site Perceptions of Remote Monitoring Benefits

Some respondents perceive the following benefits from remote monitoring, in rough order of frequency and importance:

Figure 6. Site Benefits from Remote Monitoring

More efficient/takes less coordinator time
Do not need a room and setup for monitor
More flexible/better time management
Easier to resolve issues with more frequent contacts
Do not need to schedule visits and appointments
Easier to reach monitors by telephone
More frequent payments
More focused monitoring
Investigator does not have to be on site during monitoring calls
Study coordinator is more accountable for quality
Study coordinator does not need to be present while monitor is on-site

Twenty-five respondents stated that remote monitoring is more efficient for study coordinators than on-site monitoring.

Site Activities to Support On-Site Monitoring

Respondents reported that they perform the following activities, in rough chronological order, to support on-site monitoring visits.

Figure 7. Other Activities with Traditional On-Site Monitoring

Scheduling visit dates with monitors
Arranging workspace, documents and Internet access for monitors
Preparing documents, drug accountability records, etc., prior to a visit
Providing documents for the monitor
Answering the monitor's questions
Addressing issues raised by the monitor
Escorting the monitor to visit ambient thermometers, storage areas, etc.
Scheduling and accompanying the monitor to meetings with the investigator, regulatory manager, pharmacy, etc.
Teaching the monitor how to use the site's systems
Setting up EHR access for the monitor (supervision, room, etc.)
Dealing with software and equipment malfunctions
Being available to the monitor
Performing the responsibilities of a host
Refiling/reshelving documents
Dealing with the monitor's issues, questions and document requests between visits
Training replacement monitor(s)

To various degrees, most of these activities are also required for remote monitoring.

Impact of Remote Monitoring on the Site's Internal Monitoring/Auditing Program

Respondents reported both positive and negative effects on their internal monitoring and auditing programs. (Many sites, probably including some of the respondents' sites, do not have comprehensive internal monitoring and auditing programs.)

Figure 8. Impact of Remote Monitoring on the Site's Internal Monitoring/Auditing Program

No impact
Increased QA because remote monitoring is less effective than on-site monitoring
Decreased QA because we limit it to participant records requested by sponsor
Decreased QA because time is spent supporting remote monitoring
Decreased QA because remote monitoring catches errors sooner, even in real-time
Streamlines our process, reducing workload

Advice for Sponsors

Respondents offered the following advice to study sponsors:

Figure 9. Advice for Sponsors

Use remote monitoring judiciously
Be aware that remote monitoring can affect site costs, so they need some understanding of the monitoring plan before the budget is finalized
Use a hybrid on-site/remote monitoring model
Employ remote monitors with experience at a site
Ensure remote monitors know the protocol and science, and form a good working relationship with the study coordinators
Designate a single primary remote monitor for each site
Designate a single contact person for a site for questions about the protocol, data queries, etc.
Minimize changes in remote monitoring personnel
Start a site with on-site monitoring and then phase in remote monitoring
Conduct in-person site monitoring at least three times per year
Have remote monitors visit sites at least once
Tell sites in advance what the monitoring plan will be for that site (including how it will/might adapt based on site performance), and when the plan changes
Specify in detail what documents will be required for remote monitoring and their properties, e.g., where initials/dates and subject IDs will be needed;, e.g., if EMR printouts are acceptable as source documents, the requirements for those documents and how they relate to visit worksheets
Use secure email and uploads instead of fax
Give sites technology, e.g., eSource, to make remote monitoring more efficient; allow sites to use their own technology
Be respectful of the study coordinator’s time and schedule
Schedule remote visits the same way on-site visits are scheduled; provide a detailed agenda so the site has adequate time to prepare
Use Skype or FaceTime for video conferencing
Make sure queries are clear
Minimize urgent questions
Broaden the scope of remote monitoring beyond EDC data points so monitors understand the context
Keep site management informed about site performance and metrics, since remote monitoring reduces their contact with sponsor personnel
Provide sites with resources to strengthen their internal quality systems

Advice for Sites

Respondents offered the following advice to sites:

Figure 10. Advice for Sites

Create a quality assurance program to ensure high-quality data and other documents
Use eSource, ISF, CTMS, EHR and other technology (with secure remote access, if possible)
Create a remote monitoring SOP, and share it with study sponsors
Factor indirect costs of remote monitoring into the budget, including a charge for resending documents
Find out how much experience the sponsor has with remote monitoring, since it will affect the efficiency of remote monitoring and how much information the sponsor can give you in advance
Before accepting a study, understand the sponsor's remote monitoring plans and how they will affect your site; learn more details during the study initiation phase
Require periodic on-site monitoring
Work with the sponsor as a partner to organize remote monitoring and make it work for both parties
Establish clear lines of communication
Create a checklist of documents the sponsor will want for remote monitoring
Negotiate the types of documents that will be monitored on site vs. remotely
Create an efficient and consistent system for transferring documents for sponsor
Get buy-in from the study coordinator for remote monitoring
Utilize low-cost personnel to process and transfer documents for remote monitoring
Keep records and data up to date
Prepare data, documents and questions ahead of time
Schedule live interactions with the remote monitor at mutually convenient times.
Schedule remote monitoring activities well in advance.
Fulfill requests on a consistent and timely basis
Record documents that have been sent, with the name of document, sender, method, date, fax number or email address (if applicable), recipient and confirmation information
Obtain confirmation of receipt for documents transferred to sponsors.
Minimize interruptions, especially for the investigator
Tell sponsors when their expectations are unreasonable

Other Comments

Respondents offered the following other comments:

Figure 11. Other Comments

Sponsors are rolling out remote monitoring without well thought out processes
Study sponsors all have different processes for remote monitoring
Remote monitoring is being implemented without site input or consideration of site issues
There is very little consistency in remote monitoring across sponsors and CROs, and even across studies with the same sponsor or CRO
Sponsors cannot assume that all sites can meet their remote monitoring requirements
The objective of remote monitoring seems to be to cut costs and transfer work to the sites, not improve or even maintain quality
Sponsors should use remote monitoring to motivate sites to improve their quality and reduce their monitoring burden
Most remote monitoring seems to be remote traditional monitoring, not risk-based
Remote monitoring requires sites to perform a lot of routine clerical work
Onsite monitoring prevents the same mistakes from happening again
If a site does not report an adverse event, on-site monitoring is more likely to catch it than remote monitoring
Remote monitoring focuses on EDC data, so it can miss a lot of important documentation that an on-site monitor would see
Remote monitoring focuses on the accuracy of specific eCRF data points, while on-site monitors look at the bigger picture, e.g., protocol compliance
It is easier to send all the source documents for a visit than to send just specific documents and then respond to multiple follow-up requests, which also creates opportunities for misfiling
It is more efficient to block out time for an on-site monitor than to deal with an incessant stream of urgent emails and document requests
It is harder to coordinate remote visits with investigators than when a monitor is on-site all day
It takes an organized coordinator to be successful with remote monitoring
Remote monitors interact with multiple site personnel, so the study coordinator no longer has the same broad perspective
During an on-site visit, the study coordinator and monitor work together efficiently to address issues and get the study records in order; remote monitoring trades that teamwork for flurries of confusing document requests and follow-up emails
Some queries are much harder to resolve with remote monitoring, sometimes because the answer is on a different source document
It is more difficult to resolve misunderstandings remotely

Remote monitors see only the documents they request, which gives them an incomplete picture and can require multiple requests for additional documents
Remote monitoring creates challenges for maintaining participant privacy
Study closeout takes a lot longer with remote monitoring

Discussion

While the financial calculations in Figure 2 might not be perfectly accurate — and they describe only the median site — they are accurate enough to demonstrate that remote monitoring — or any monitoring for that matter — imposes a significant cost burden on sites, in addition to the cost for sponsors. However, the fact that the median respondent wants to charge sponsors an extra 37% for remote-monitored studies suggests that the 21% extra share of revenue calculated in Figure 2 understates the true costs.

Some research sites equate quality with the study sponsor appearing to be satisfied with the data and records. Other sites care deeply about quality and are very concerned that remote monitoring is inadequate. Sponsors should better educate sites on the rationale behind remote monitoring (assuming there is one, other than shifting costs to the sites), how it is an integral element of risk-based monitoring (if it is so), and that the entire system yields equal or better quality than traditional on-site monitoring (if it does so).

Documents can be inspected anywhere, provided they are the same documents (which might not always be the case for even certified copies of electronic medical records). However, remote monitoring cannot substitute for the physical presence of a savvy monitor at the site, engaging with site personnel and seeing how the site actually operates. Most studies that employ remote monitoring therefore use a hybrid model that includes both in-person and remote "visits."

The primary driver behind remote monitoring appears to be cost reduction — in-person site monitoring visits are an extravagantly expensive proposition. However, the cost savings to study sponsors appear to be offset by increased costs for the sites. Sponsors and sites should consider these additional costs when negotiating budgets. Sponsors should design their remote monitoring programs to minimize such costs, and sites should develop systems and processes that minimize such costs. The calculations in Figure 2 suggest the sites' cost of remote monitoring could be reduced to the cost of traditional monitoring by saving only one hour per week.

To date, there does not appear to be any published evidence that demonstrates the merits of remote monitoring as a substitute for in-person monitoring. According to this survey, most sites are very skeptical of this proposition. A comparison should not be hard to perform — simply create two monitoring arms for a study and then send out the auditors and compare their findings.

Remote monitoring can have intangible deleterious effects. Many sites value their personal relationship with the site monitor, enhancing their commitment to a study. The mentoring/coaching role of the site monitor is also important for many sites.

Based on this survey, most sites are critical of remote monitoring. However, it appears that sponsors could address many site concerns with the following measures:

- Do not waste study coordinator time, e.g., by requesting multiple copies of the same documents and generating numerous, urgent, piecemeal queries.
- Collaborate with sites to improve remote-monitoring processes. Find out how sites that prefer remote monitoring make it work for them.

- Work with sites to deploy eSource, monitor-accessible EMR, and other technologies that give remote monitors secure, direct access into study records, with due respect for patient privacy.
- Publish evidence that remote monitoring actually works.
- Reward sites that generate high-quality data and thereby reduce the cost of monitoring those sites. Why not build quality in rather than work so hard to test errors out?

Reference

"The Cost to Sites of Remote Monitoring," Michael Kassin and Norman M. Goldfarb, Journal of Clinical Research Best Practices, October 2016.

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