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The Cost to Sites of Remote Monitoring

By Michael Kassin and Norman M. Goldfarb

Risk-based monitoring focuses 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 documents from a location remote from the site. Documents can be inspected anywhere, provided they are the same documents (which might not be the case for "certified" copies of electronic medical records). 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."

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. 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.

The primary driver behind remote monitoring appears to be cost reduction — in-person site monitors is an extravagantly expensive proposition. However, the cost savings to the study sponsor 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 Survey

In March through June 2016, we collected survey data from 237 site personnel in an exploratory survey comparing clinical study coordinator (CRC) time and costs related to site monitoring between studies with traditional, in-person monitoring and studies with remote monitoring.

Analysis of the data revealed great diversity in the numbers, as well as in how people think about monitoring-related costs. As a result, the findings below are preliminary and do not reflect the experience of any particular site with any particular study. Nor do they reflect costs for other personnel, e.g., investigators, or other activities, e.g., serious adverse event (SAE) reporting.

Nevertheless, the data does appear to confirm reports by many sites that remote monitoring increases site costs. Sponsors and sites can use the models below to assess the costs for their own remote-monitoring studies.

Survey Findings

Figures 1 and 2 present our findings based on data from the survey and discussions with experienced site managers.

Figure 1. Study Coordinator Costs for a Typical Study with Traditional Monitoring Visits

CRC visit preparation (minutes)	60
Site visit duration	360
CRC visit support (minutes)	60
CRC site visit follow up (minutes)	75
CRC time/study visit (minutes)	195
CRC fully-burdened cost/hour	$50
CRC cost per site visit	$163
Site visits/study	10
CRC cost for all site visits ($)	$1,625
Revenue for study ($)	$50,000
Monitoring costs as % of revenue	3.3%

Figure 2. Study Coordinator Costs for a Typical Study with Remote Monitoring Visits

CRC time/site visit preparation (minutes)	90
Site visit duration	360
CRC time/site visit support (minutes)	120
CRC time/site visit follow up and additional document requests (minutes)	75
CRC time/study visit (minutes)	285
CRC fully-burdened cost/hour	$50
CRC cost/study visit	$238
In-person site visits/study	3.5
CRC cost per site visit	$831
Remote Visits:	
CRC time/preparation for a remote visit (minutes)	90
CRC time/support for a remote visit (minutes)	60
CRC time/site visit follow up (minutes)	60
CRC time/site visit additional document requests	120
CRC time/study visit (minutes)	239
CRC fully-burdened cost/hour	$50
CRC cost/remote visit	$199
Remote site visits/study	6.5
CRC cost per remote visit	$1,295
CRC cost for all visits	$2,126
CRC time for additional document requests/week (minutes)	60
Study weeks	72
CRC total time for additional document requests/week (minutes)	4,320
CRC total cost for additional document requests	$3,600
CRC cost for all time related to monitoring	$5,726
Revenue for study	$50,000
Monitoring costs as % of revenue	11.5%

Reducing the Burden on Sites

There appear to be four primary ways to reduce the burden of remote monitoring on sites:

- Employ online systems to create study documents of interest to site monitors, or at least maintain electronic versions of such documents.
- Provide site monitors with secure, online access to the site's regulatory and source documents, including electronic medical records (EMR) at sites that have EMR systems, limited to the patients in the study (easier said than done with most current EMR systems).
- Manage site personnel interactions with remote monitors to minimize interruptions.
- Minimize repeat requests for documents by storing requested documents in a secure, online location for site monitor access.

Conclusions

It appears that remote monitoring increases the study coordinator cost for a "typical" study from $1,625 to $5,726, increasing the share of revenue of these activities from 3.3% to 11.5%. However, as noted above, these numbers are only preliminary.

Sites and sponsors can take steps to reduce the burden of remote monitoring on sites, although most sites cannot provide secure, online access to EMR systems that is limited to the patients in the study.

We plan to conduct a second survey to refine the model and numbers. Comments and suggestions are welcome.

Although the survey focused on cost metrics, a number of sites expressed reservations about the effectiveness of remote monitoring vs. in-person monitoring. One would like to believe that study sponsors have validated their remote monitoring methodologies through auditing and other techniques and can share their findings to assure sites — and the FDA — that remote monitoring is, in fact, effective.

Authors

Michael Kassin, MD, is Clinical Director at Florence Healthcare, provider of the Florence eBinder Suite electronic investigator site file product. Contact him at 1.770.712.6913 or mike.kassin@florencehc.com.

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.