Site Budget Development and Payment Systems: A Call for Transparency from Clinical Research Sites

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Society for Clinical Research Sites

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As Stephen Covey said, "When the trust account is high, communication is easy, instant, and effective."[1] In clinical research, trust and communication are essential to the efficient functioning of the many layers around budget negotiations and payments to sites. Payment is a multifaceted process that starts with the development of the budget and continues through to the actual method by which payments are made and received by the site. This entire process must work for all parties.

SCRS has long advocated for monthly site payments, and in 2015-2016 convened a multi-stakeholder site payment working group of 31 industry partners and site representatives to take a deep dive into this critical and complicated issue. At the conclusion of the first year of their work, the group produced a white paper, *Site Payment,* outlining best practices. These best practices address not just payment frequency, but additional issues necessary to supporting a healthy and transparent financial exchange between sponsors, CROs, and sites. At the heart of SCRS' advocacy is building a stronger relationship between sponsors, CROs, and sites in order to support site sustainability. This benefits all industry stakeholders and allows us to get new medicines to patients faster.

As the working group was developing that white paper, and over recent years, technological solutions have continued to advance. These solutions facilitate the payment process by tracking and sharing information around site payments and providing more transparency than ever before.

At the beginning of 2017, SCRS launched the *Budget and Payment Technology Survey* and conducted follow-up interviews to determine how technology could aid in building more streamlined and transparent budget and payment systems. The *Budget and Payment Technology Survey* was open globally to all sites and was advertised through a mass email to the SCRS database and via social media. Two hundred eighteen site representatives responded representing a variety of research site types, with 78% representing sites within the United Sites and the remaining from outside the United States. 81% of United States sites and 65% of sites outside of the United States reported being in clinical research for more than 10 years. (Fig. 1)

Respondent Demographics

TYPE OF SITE

Part of a clinical practice	**44%**
Freestanding site	**24%**
Hospital-based site	**23%**
Academic site	**9%**

SITES OUTSIDE US — 22% — 35% — 65%

US SITES — 19% — 81% — 78%

- Sites outside US
- US sites
- US sites with >10 years experience
- US sites with ≤10 years experience
- Sites outside US with >10 years experience
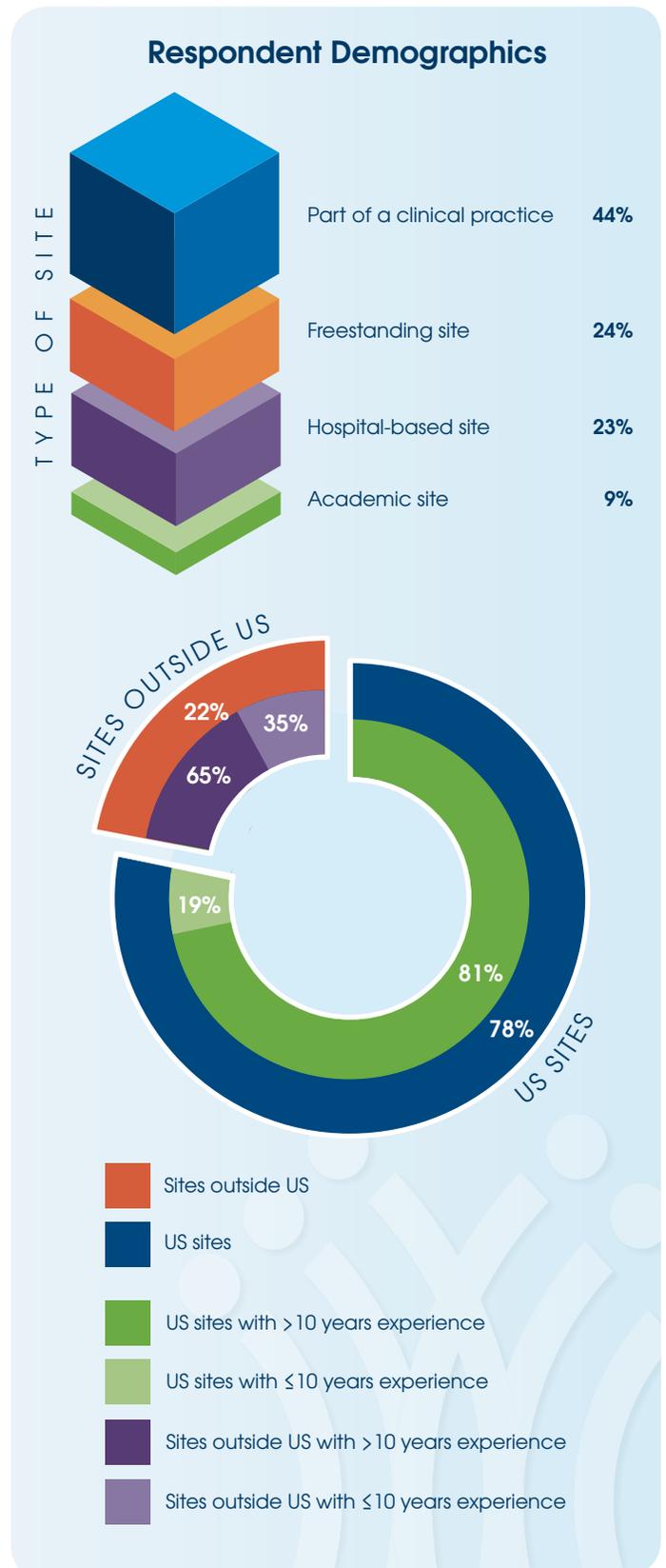- Sites outside US with ≤10 years experience

Figure 1

The *Budget and Payment Technology Survey* expands upon previous research conducted by SCRS by asking specific questions about the value of features an electronic system could provide in five areas: payment terms, access to financial information, invoicing, budget negotiation and ease of use of such a system. Interviews following the survey expanded on the sites' perspective related to these areas.

Survey results demonstrated that any element of technology utilized for greater transparency is desirable. All electronic system features included in this survey were selected by greater than 60% of respondents as "extremely important" or "very important". (Fig. 2)
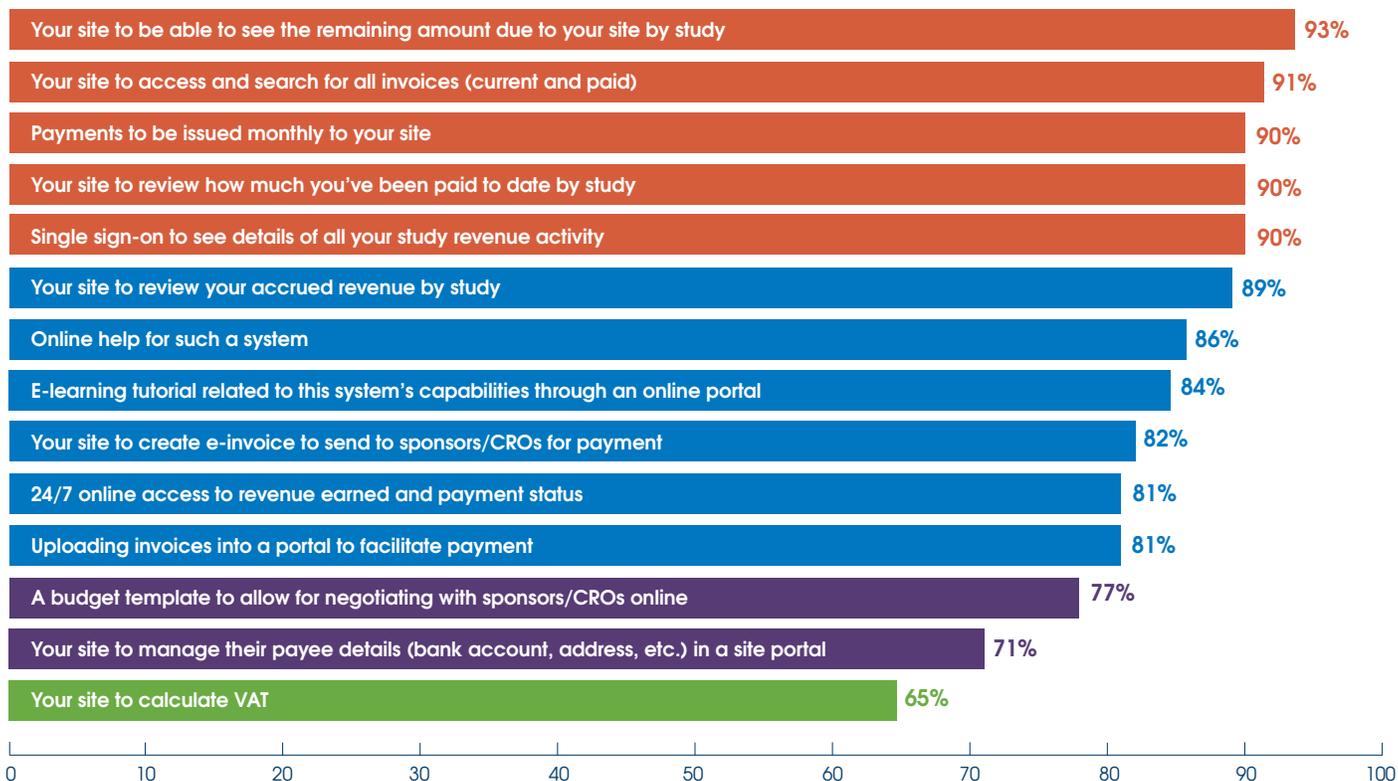
It is interesting to note that sites with less than 10 years of experience had a greater desire for certain functionality than the more experienced sites. (Fig. 3)

Today's research sites continue to operate on a narrow profit margin, averaging 13%.[2] Many sites are attempting to navigate that margin with very little experience. A 2016 report found that half of all investigators started research after 2012.[3] Site sustainability is made more difficult due to the complex and demanding nature of the work, the pool of inexperienced sites, and cash flow concerns with 66% of sites reporting having less than three months operating cash on hand.[2]

The mission of SCRS is to support site sustainability through advocacy, education, connection, and mentoring. SCRS continually collects input through initiatives such as the *Budget and Payment Technology Survey* to advance best practices, and this information is shared with industry and through SCRS' education

66%
of sites have less than three months operating cash on hand

How Valuable Would a System be if Provided to Your Site, at No Cost, and Allowed for:

Feature	Percent
Your site to be able to see the remaining amount due to your site by study	93%
Your site to access and search for all invoices (current and paid)	91%
Payments to be issued monthly to your site	90%
Your site to review how much you've been paid to date by study	90%
Single sign-on to see details of all your study revenue activity	90%
Your site to review your accrued revenue by study	89%
Online help for such a system	86%
E-learning tutorial related to this system's capabilities through an online portal	84%
Your site to create e-invoice to send to sponsors/CROs for payment	82%
24/7 online access to revenue earned and payment status	81%
Uploading invoices into a portal to facilitate payment	81%
A budget template to allow for negotiating with sponsors/CROs online	77%
Your site to manage their payee details (bank account, address, etc.) in a site portal	71%
Your site to calculate VAT	65%

Percent of respondents who replied extremely or very important

Figure 2

How Valuable Would a System be if Provided to Your Site, at No Cost, and Allowed for:
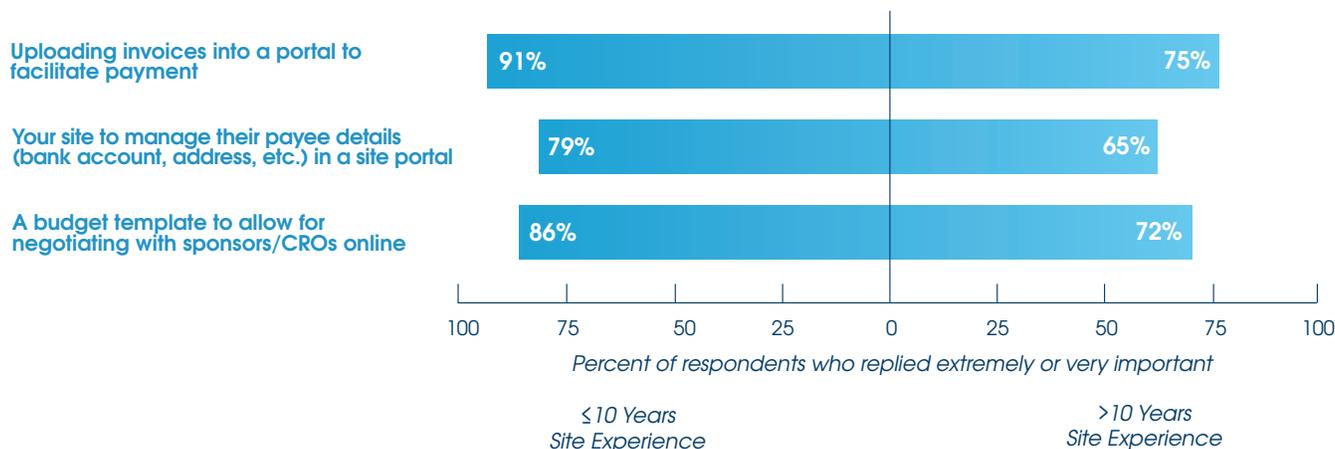
Uploading invoices into a portal to facilitate payment — 91% | 75%

Your site to manage their payee details (bank account, address, etc.) in a site portal — 79% | 65%

A budget template to allow for negotiating with sponsors/CROs online — 86% | 72%

Percent of respondents who replied extremely or very important

≤10 Years
Site Experience

>10 Years
Site Experience

Figure 3

and mentoring programs. SCRS helps sites understand the importance of knowing their financial information, and encourages industry to provide that information to the sites. As sites learn both the importance and availability of such financial information, sites will continue to ask for transparent access to that data.

Ultimately, meeting sites' expressed need for financial information is in the industry's best interest as sites continue to attempt to thrive and grow, and remain involved in research. Bob Vanourek, author of *Triple Crown Leadership*, said, "Trust is built when someone is vulnerable and not taken advantage of."[1] Payment systems with poor transparency to the sites can create mistrust, even in situations where sponsors and CROs have the best of intentions.

The findings of the *Budget and Payment Technology Survey* are not new. In 2012 SCRS published a white paper, *Better Payment Terms for Sites: An Industry Imperative,* which was followed by the creation of the Site Payment Working Group. The working group found that the landscape had remained essentially unchanged since the 2012 report. As the working group looked forward to solutions in the 2016 Site Payment white paper, two of the top five burdens identified were recognized as having technological solutions: payment within 30 days and back-up information accompanying payments.[4]

PAYMENT TERMS

Ninety percent of all site respondents indicated monthly payments are "extremely important" or "very important," with sites inside the United States selecting that response at a rate 21% higher than sites outside of the United States. (Fig. 4) After years of similar research findings, monthly payments for research sites is

How Valuable Would a System be if Provided to Your Site, at No Cost, and Allowed for Monthly Payments:

95% US Sites

76% Sites Outside the US

Percent of respondents who replied extremely or very important

Figure 4

recognized as critical for site sustainability and remains a fundamental principal to SCRS in representing sites. The SCRS' Site Payment Working Group was clear in their 2016 recommendation: Sites should be paid within 30 days of data entry.[4]

In interviews for this white paper, site representatives reinforced the SCRS' Site Payment Working Group's recommendation that back up data accompanying each payment was equally important as payment frequency.

Each payment should be accompanied by a report to include the protocol name and number, investigator name, and details of each payment line item including subject identifier, visit number, visit date and procedures outlined if the payment is for items outside the visit payment (i.e. storage fee, pharmacy start-up, etc.) or if any items invoiced were denied or delayed for payment.[4]

While adjusting the frequency of payment terms has been recognized as a major hurdle for sites, industry has used legacy logic and stating lack of systems to address this issue. As technology has aided in many aspects of life, the solutions for site payment frequency and accompanying payment data should also have advanced. These advances should be realized through either third-party providers or the modification of industry's own internal processes and systems advancing. Additionally, with the adoption of Risk Based Monitoring one of the fundamental principles is the need for data to be entered in real time related to the patient visit. SCRS supports this expectation placed on sites, and it is included as one of SCRS' Best Site Practices.[5] In exchange, it is reasonable to expect industry to also accommodate the site's needs to pay in a timely manner for these services provided.

ACCESS TO FINANCIAL INFORMATION

In recent research conducted by SCRS it was identified that approximately one third of sites use a Clinical Trial Management System (CTMS), and of those sites 77% had been conducting clinical research for greater than 10 years. (Fig. 5) The reality is that almost 60% of all sites use less sophisticated and more resource-intense systems to manage their accounts receivable and payments, such as paper or spreadsheets. Most alarming is the finding that over 4% of all sites report using no financial tracking system at all.[6]

The lack of adequate financial tracking contributes to a hidden cost for all. Only 52% of sites report having dedicated accounting staff.[7] Accounting in the remaining sites is managed by staff

Type of Accounting System Used by Sites

- None — 4%
- Spreadsheet — 44%
- Paper — 15%
- CTMS — 37%
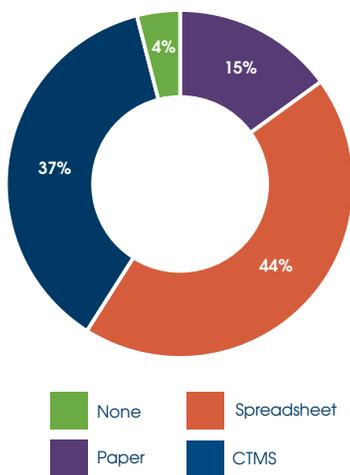
Years of Site Experience Among CTMS Users

- ≤10 years site experience — 23%
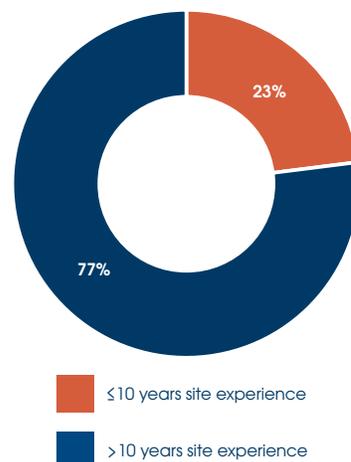- >10 years site experience — 77%

Figure 5

that are also responsible for seeing study patients. Accounting for these sites is therefore time taken away from study patient engagement. When physicians report why they do not do, or stopped doing research, administrative burden is frequently cited.[3] Keeping sites in research and patient-focused could be improved by leveraging information already contained in sponsor and CRO's electronic system to reduce the administrative burden on sites.

While it is not traditional business practice for the payor to provide a platform for the payee to have access to their earned financial information, this survey found such access would be highly valued by all sites, regardless of their years of experience, type of site or country of practice. (Fig. 6) Sites' accrued revenue, amount paid to date and balance due, by study, were identified as highly desirable by the site respondents. It is recognized that new programming may need to occur to allow sites such access, however, with the advances in technology this would appear to be implementable without a significant burden to the sponsor or CRO, and it would yield tremendous benefit to the sites, and thereby to all those involved in the clinical research industry.

INVOICING

While it is not an industry-wide practice to ask sites to produce invoices for all payments, there are some countries and contracts where this is required. In previous research, SCRS found that 78% of United States sites generate invoices for pass-through costs and 77% of sites outside of the United States create invoices for all study-related activity.[7] That same research found that almost half of all sites generate invoices by hand, and an additional 12% use a spreadsheet program such as Microsoft® Excel® rather than accounting software or a CTMS.[6]

Building on the importance of transparency through advancements in industry-sponsored technology solutions, sites would value a system which could aid in the practice of invoicing. Over 80% of all sites would value a system that could assist in creating and sending invoices, searching for invoices and uploading invoices into a portal to facilitate payment. Inexperienced sites found greater value than experienced sites in the ability to create and send invoices, and to upload them into a portal to facilitate payment. (Fig. 7)

How Valuable Would a System be if Provided to Your Site, at No Cost, and Allowed for:

Your site to review your accrued revenue by study

EXPERIENCE	
≤10 years site experience	91%
>10 years site experience	88%
REGION	
US sites	89%
Sites outside the US	91%
TYPE OF SITE	
Academic	88%
Hospital	93%
Clinical Practice	90%
Freestanding	85%

Percent of respondents who replied extremely or very important

Your site to review how much you've been paid to date by study

EXPERIENCE	
≤10 years site experience	91%
>10 years site experience	87%
REGION	
US sites	90%
Sites outside the US	93%
TYPE OF SITE	
Academic	94%
Hospital	93%
Clinical Practice	91%
Freestanding	85%

Percent of respondents who replied extremely or very important

Your site to be able to see the remaining amount due to your site by study

EXPERIENCE	
≤10 years site experience	91%
>10 years site experience	91%
REGION	
US sites	93%
Sites outside the US	93%
TYPE OF SITE	
Academic	94%
Hospital	91%
Clinical Practice	93%
Freestanding	96%

Percent of respondents who replied extremely or very important

Figure 6

How Valuable Would a System be if Provided to Your Site, at No Cost, and Allowed for:

Your site to create e-invoice to send to sponsors/CROs for payment
84%   78%

Uploading invoices into a portal to facilitate payment
91%   75%

100 75 50 25 0 25 50 75 100
Percent of respondents who replied extremely or very important

≤10 Years
Site Experience

>10 Years
Site Experience
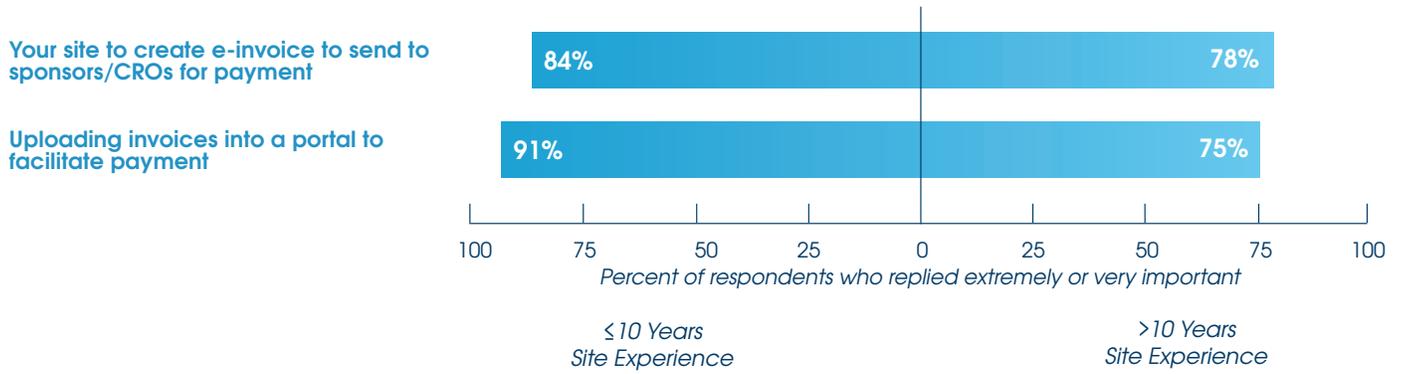
Figure 7

Although payment frequency is usually the main aspect of financial management considered by sponsors and CROs when looking to enhance the relationship with the site, it is clear that the issue is much broader. In reducing the burden to sites by providing such a platform, it is recognized that time and resources expended by sites could be redirected towards study patient-related activities.

BUDGET NEGOTIATION

Budget templates are typically created in one of two ways; line-item or per visit. Line-item budgets make up 58% of budgets in North America and have been steadily growing in other regions of the world. (Fig. 8)[8] For sites to ensure they are adequately compensated for study-related activities, they must build their study budget via a line item template, regardless of the manner in which the site receives the budget template. One site expressed concern that it is typical for a site to receive a per-visit budget but be paid on a line-item basis. She further shared "When I get a per-visit budget I wonder what is being hidden, I often unlock the spreadsheet provided to me to see how the per-visit budget was created or have to

Percent of Study Budgets that Are Line Item, by Region Between 2006 and 2014

2006-2008: 9%, 18%, 21%, 22%, 42%, 54%

2012-2014: 34%, 39%, 37%, 22%, 47%, 58%

Per Procedure

Legend:
- Eastern Europe
- Asia/Pacific
- Western Europe
- South/Central America
- Middle East/Africa
- North America
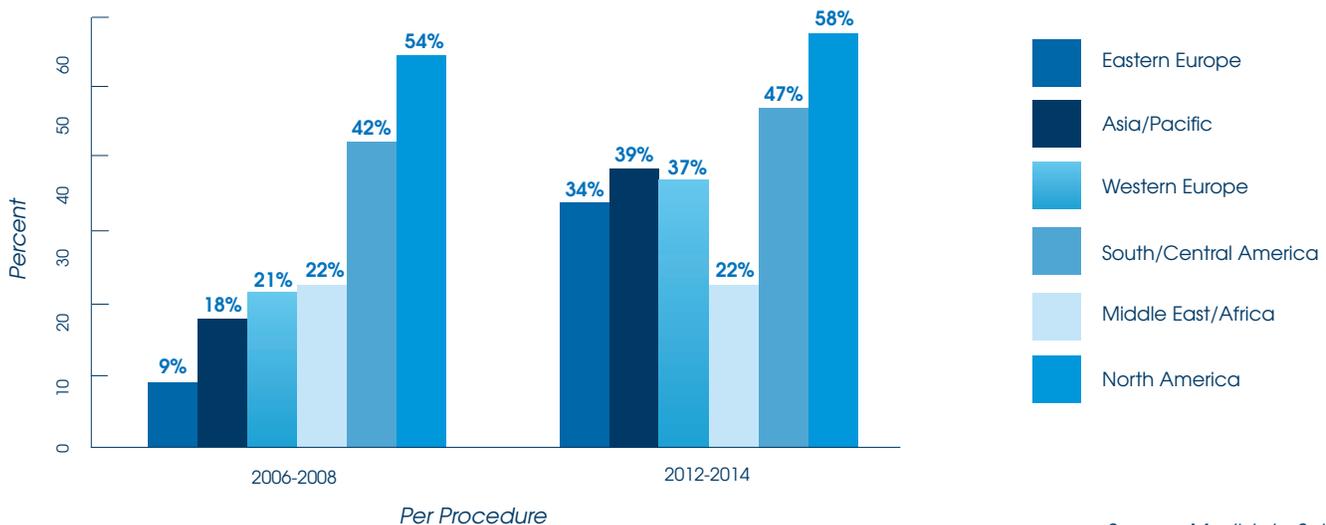
Source: Medidate Solutions

Figure 8

> ## "It is typical for a site to receive a per-visit budget but be paid on a line-item basis."

create a line-item budget from scratch." Another site professional noted that "even when a line-item budget is provided, it often fails to capture all of the elements required by the site to fulfil compliance with the protocol". Such practices create the opportunity for distrust and inefficiencies in the budding relationship between the sponsor/CRO and site.

The sharing of the budget template usually occurs through email correspondence. An online platform to allow budget negotiations is desired by 77% of all sites, with no difference between sites within or outside the United States. Not surprisingly, sites with less than 10 years of experience see greater value in such a platform when compared to sites with more experience. Similarly, sites within a clinical practice saw the most value in having a transparent platform for budget negotiations compared to other types of sites. (Fig. 9)

On average, over 10 weeks are spent negotiating every clinical trial budget and contract.[9] Providing access to an online platform where the budget template could be shared and negotiated with greater transparency could greatly reduce time required to finalize the budget, and build a more trusting and valued relationship.

How Valuable Would a System be if Provided to Your Site, at No Cost, and Allowed for:

A budget template to allow for negotiating with sponsors/CROs online

EXPERIENCE
- ≤10 years site experience — 86%
- >10 years site experience — 72%

TYPE OF SITE
- Academic — 69%
- Hospital — 70%
- Clinical Practice — 88%
- Freestanding — 69%

Percent of respondents who replied extremely or very important
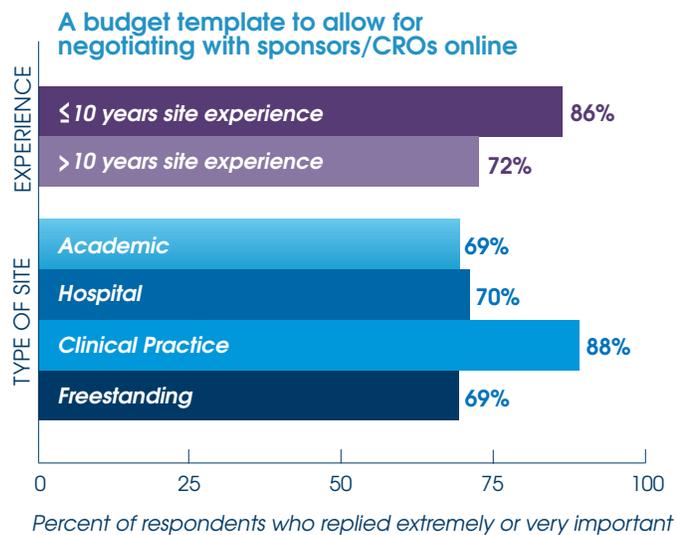
Figure 9

EASE OF USE OF THE SYSTEM

The proliferation of computer systems and multiple log-ins associated with clinical studies is cumbersome and often disconnected between systems. Sites clearly value computer systems; however, they expect them to have a single sign-on to access all study related activity, 24/7 access to financial information, an online help system, and have e-learning available as needed. (Fig. 10) There is no significant difference in these expectations based on years of research experience, geography, or

Sites Value

Computer systems with single sign-on	**90%**
Online help system	**86%**
E-learning available as needed	**84%**
24/7 access to financial information	**81%**

Percent of respondents who replied that such a feature would be extremely or very important

Figure 10

site type. Sites have a vision for the use of technology that goes far beyond simply being able to use the same password.

This paper has discussed a number of areas where technology could greatly benefit all. Such solutions provide no value unless they are actually adopted and used by the interested parties, in this case the sites. For such systems to achieve maximum impact it must be one that the sites would actually use. We encourage developers of such solutions to ensure the sites' voice and perspective is included during the development phase.

CONCLUSION

The voice of the sites has been clear and concise with regard to the need for technology and the value it adds in addressing many areas that cause inefficiencies and ultimately delay study completion. As sites call for greater transparency and efficiencies, SCRS strongly encourages industry to adopt and implement these recommendations. As technology continues to allow for new solutions to solve long-identified problems, industry would be wise to incorporate these solutions into practice. SCRS looks forward to collaborating with all stakeholders to make these recommendations a reality. While such solutions may not be easy to adopt and may require new platforms to be in place, the return on investment will yield exponential returns for all and increase site satisfaction. As Mr. Covey said, all that a declining cycle of trust does is decrease efficiency.[1]

In collaboration with Medidata

[1] Daskal L. 30 quotes on trust that will make you think. Inc. February 5, 2015. Accessed June 2017 from: https://www.inc.com/lolly-daskal/trust-me-these-30-quotes-about-trust-could-make-a-huge-difference.html

[2] SCRS *Site Landscape Survey*, 2016

[3] Tufts Center for the Study of Drug Development survey reference in: Myshko D. Principal investigator turnover. PharmaVoice. September 2016. Accessed June 2017 from: http://www.pharmavoice.com/article/2016-09-principal-investigator/

[4] SCRS *Site Payments* white paper, 2016

[5] SCRS *The Quest for Site Quality and Sustainability: Perceptions, Principles, and Best Practices* white paper, 2014

[6] SCRS *Site Payments and Patient Reimbursement Survey*, 2017

[7] SCRS *Site Payments and Patient Reimbursements: A Global Perspective* white paper, 2017

[8] Medidata PICAS Database, 2015

[9] KMR Group, 2016

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