

Addressing Pain Points  
of Investigator Payments  
for Clinical Trials  
**am INC Research**

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# **Addressing Pain Points of Investigator Payments for Clinical Trials**

**The terms and processes by which investigative sites are paid to conduct clinical trials have long been a thorny issue. These issues have impacted clinical research sites' ability to focus on conducting quality research and meet enrollment goals — as well as continue their role as the bridge from promise to reality for new therapeutic treatments.**

**Factors such as limited cash flow, intense resource demand, patient recruitment challenges and increasing staff payroll also have contributed to significant sustainability challenges for research sites. According to those in the trenches, these concerns have largely gone unheard.**

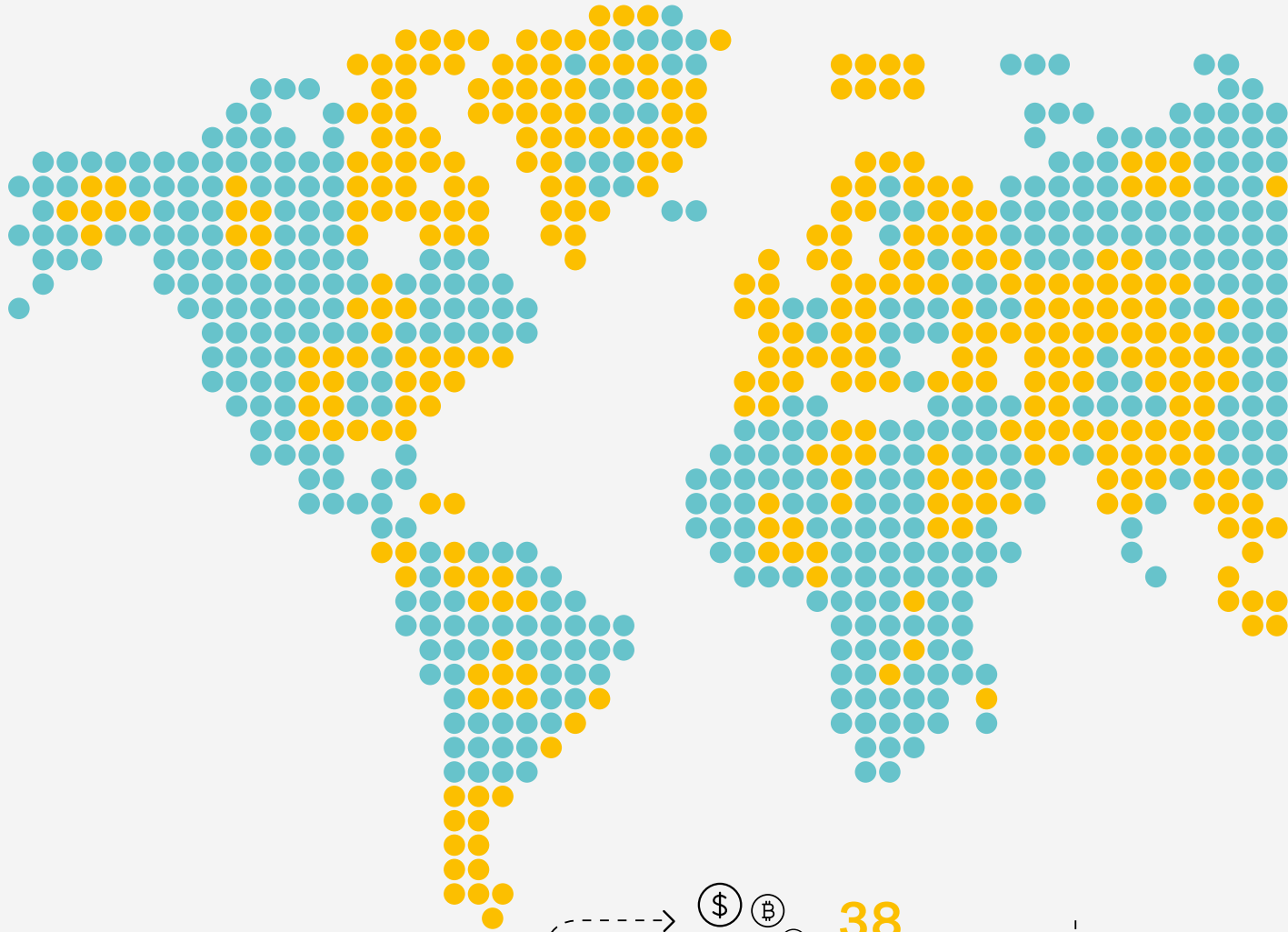
**This paper addresses the challenges surrounding site payments, highlights key insights from the INC Research Site Advocacy Group (SAG) that was established to address this issue and outlines initiatives that are already improving the process.**

The need to enlighten key stakeholders in the clinical research enterprise to the tangible payment-related challenges that principal investigators (PIs) and their staff experience is critical. A predominant sentiment from sites is that they are forced to devote excessive attention to financial matters and many worry whether payments will be made for activities completed. The result is that time and resources are spent chasing down payments — time that otherwise could be spent on patient care and enrollment — adversely affecting overall site performance.

Mindful of these new dynamics, the life sciences industry has made notable progress in better responding to the needs of sites. One example

is the formation of site advocacy groups (SAGs) — an initiative established in 2014 by the Society for Clinical Research Sites (SCRS).

INC Research, a leading global CRO, launched with SCRS the first U.S.-based SAG focused solely on streamlining and improving the payment process for clinical trial sites — otherwise known as the Investigator Payment (IP) SAG.<sup>1</sup> Through this forum, open and direct feedback from sites on their key “pain points” was solicited, identifying key components governing the management and execution of payments that can be modified or, if necessary, overhauled all together.



**78**  
COUNTRIES



**38**  
CURRENCIES



**12,800**  
PAYEES



**550**  
PROJECTS



**4,000**  
PAYMENTS  
PER MONTH



MORE THAN  
**\$31.7 MILLION**  
ON AVERAGE PER MONTH

These values are based on monthly data from July 2015 to June 2016

## Site payment picture

While many aspects of clinical trial management stand to benefit from SAG support, the payment process is particularly fertile ground. The ecosystem for payments has many moving parts. Consider in particular, a single large-scale randomized controlled trial for a pivotal Phase III study can generate in excess of 1,800 payments in nearly 20 currencies.

INC Research currently makes payments to sites in 78 countries in 38 different currencies. The Company has more than 12,800 active payees for investigator payments on 550 projects, and processes more than 4,000 payments per month, totaling more than \$31.7 million monthly on average.

Numbers such as these point to the complexity and obvious administrative burden for the industry and sites. But they also spotlight a key area of frustration where sponsors and CROs can aid their site partners. In many cases, sites get bogged down in the bureaucracy of sending an invoice for services rendered, and then waiting through long cycle times for the invoice to process. The average industry accounts receivable delay for payments is reportedly 140 days<sup>2</sup>, with differing circumstances and scenarios attributable.

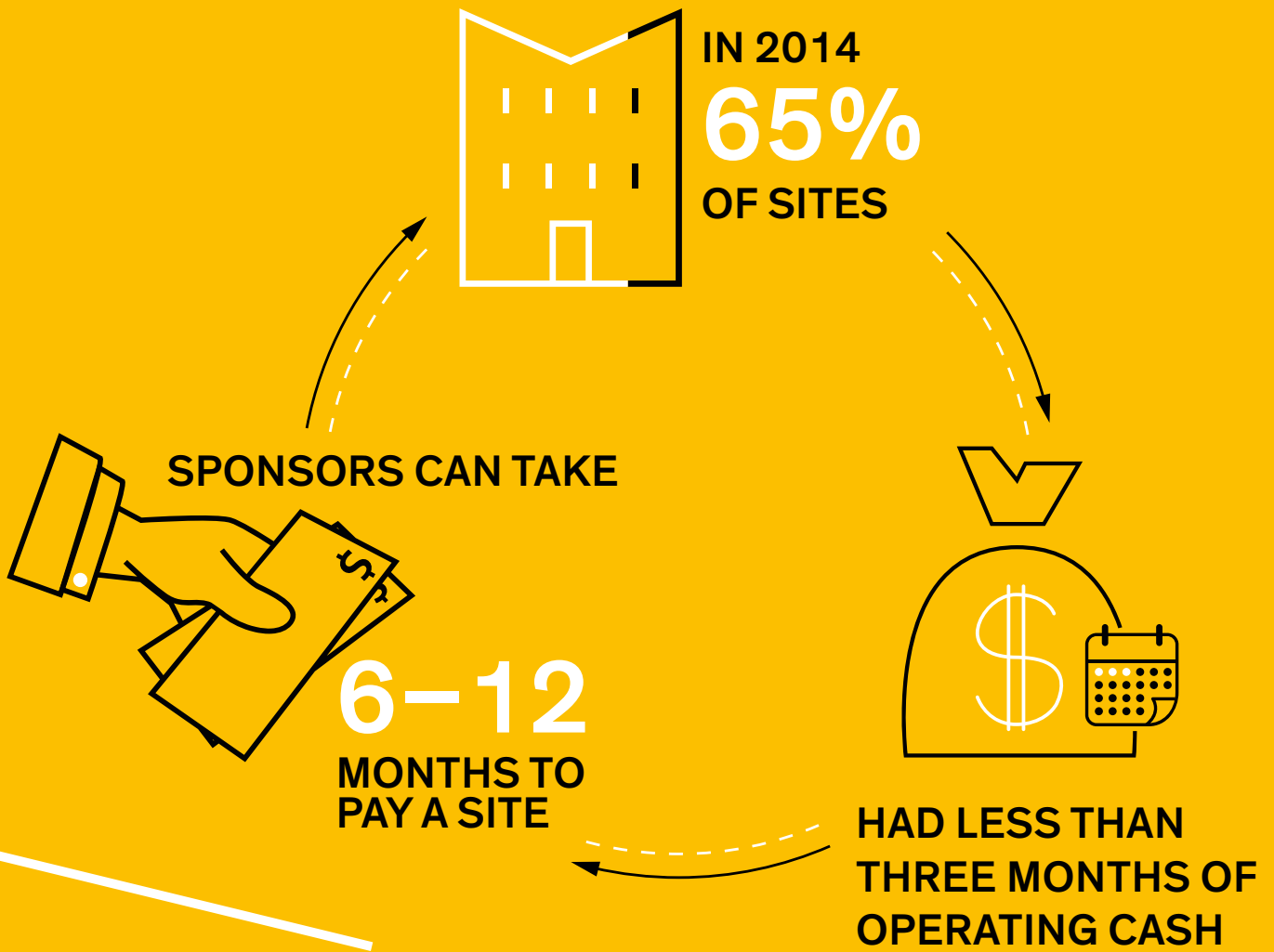
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From a broader perspective, it is important to remember the reality of today's site operating structure. Many sites function as independent, private businesses, and exist solely to perform clinical research. They frequently have only three to four months of operating cash. For example, in 2014, SCRS found that 65 percent of sites had less than three months of operating cash.<sup>3</sup> However, in many cases, it can take up to six or even 12 months for many sponsors and CROs to pay a site for a trial activity.

In these cases, sites are left with a balancing act of meeting day-to-day operational costs while making the necessary investments to complete patient visits and deliver data on schedule. Many are not able to survive and end up withdrawing from the industry, reducing an already shrinking pool of qualified sites for patients to access.

According to the Clinical Trials Transformation Initiative (CTTI), lengthy delays in payment result in high turnover rates among clinical research sites, with 40 percent of sites dropping out of FDA-regulated clinical trials.<sup>4</sup>





## Insights directly from sites

As part of the IP SAG activities, INC Research conducted its Investigator Payments Survey in 2015, which contains feedback from a sample of SCRS' 2,600 members, most of which are dedicated research facilities. In addition, INC collected information during one-on-one interviews and interactive group sessions with SAG members. The key learnings from both efforts centered on the major IP-related pain points revealed by sites.

### Top three pain points of site payments

#### 1. Communication

Sites expressed particular frustration around the line of communication with sponsors/CROs on financial matters. The participants felt strongly that this should not be handled through the Clinical Research Associate (CRA) noting that a CRA's main focus is on protocol compliance and site adherence to ICH-GCP regulations. Instead, sites would prefer that all financial queries be channeled through a separate and dedicated single point-of-contact with the CRO or sponsor, who manages all payments across multiple studies.

#### How can we improve communication?

- Understand the desire by sites to be paid within 30 days of entering patient visit data
- Have a clear contact process/workflow for each study to support payment-related queries
- Communicate a payment escalation process for sites at the beginning of a study, which involves accessible and informed staff
- Do not rely on CRA availability and knowledge of complex financial reconciliation requirements

#### 2. Information

Sites' second pain point was the lack of timely information to accompany the payments they receive. They expressed their desire for a minimum line-level remittance advice (i.e., "necessary" data points) to enable speedier and more efficient reconciliation. Sites want to be able to clearly identify which payments they have received and which are still pending. SAG members support adopting this expectation uniformly across all sites, and point to the benefits of achieving this through standard use of an electronic remittance advice.

#### How can we improve information?

- Provide line-level detail remittance advice at the same time as the payment
- Clearly indicate payments received and payments pending
- Use electronic remittance advice for speed and convenience



### 3. Payment terms and contractual issues

The number one concern from sites is the long duration between work completed and payment. Sites are struggling to bridge this gap on behalf of sponsors and feel that payment within 30 days of data entry should be the industry best practice. Specific concerns from sites regarding payment contractual terms include the large number of invoices often required, particularly during study start-up, and the use of “holdbacks” — a practice that sites believe is obsolete.

Holdbacks refer to sponsors or CROs withholding up to 10 percent or more of the total site fee until the end of the study. Sites feel strongly that this is an outdated approach based on the days of paper-based data query systems. They point to evidence where less than 4 percent of patient data is amended after entry into electronic data capture (EDC) systems, and do not understand why the PI and research staff must wait until the very end of the study to receive full compensation.

Other issues raised includes addressing the use of insolvency language or the “paid when paid” clause often used by CROs, which stipulates that sites will be paid only once the sponsor has paid the CRO. Many sites see this as an excuse for late payment of patient costs and indicate it causes significant challenges for them.

#### How can we improve payment terms?

- Reduce the number of invoices required particularly for patient stipends and expenses
- Remove the use of “holdback” clauses as these are no longer applicable to current electronic practices
- Remove the “paid when paid” clause or restrict to insolvency protection only

## Applied knowledge

Now that the fact-finding and improvement planning phases of the IP SAG is complete, the next crucial step is transforming those learnings into measurable process advancements. For the pacesetters of this movement, that means expanding on existing technology, automation and reporting capabilities – and further championing the principle of “site payments as a science.”

The ability of sponsors and CROs to think outside the box, and show a willingness to respond to the basic and long-held payment frustrations of sites, will dictate much of the progress in this area. This may simply involve CROs working more closely with sponsors to reduce the need for backup invoices, explaining the rationale to sponsors on removing holdbacks as a standard clause, or acknowledging the effects of insolvency language on sites and exploring ways to limit the impact of inefficient cash flow management.

The result of these changes will be a sustainable clinical research industry with a strong population of financially-stable clinical research sites able to support the development of new medicines for patients.

INC Research, for instance, which already has a revamped payment-support system in place, has made additional changes to its payment structure, process and systems where necessary. In addition, INC Research recognizes the importance of measuring performance when it comes to the payment process.

Importantly these findings and the output of INC Research’s IP SAG have been transferred to the SCRS Industry Working group tasked with developing a broader industry solution to the site payment challenge.

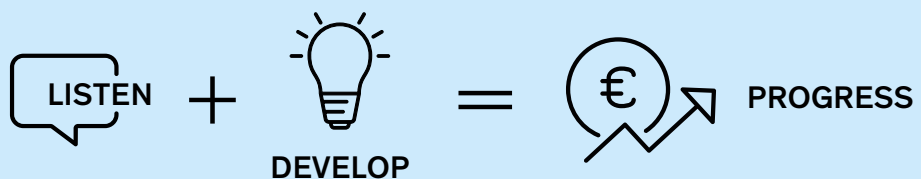
## A formula for the future

Much like other key aspects of clinical trial management, improving the investigator and site payment process is critical to strengthening the overall relationship among research sites, biopharma companies and their CRO partners.

Through efforts such as the Investigator Payment Site Advocacy Group, sponsors and CROs recognize the importance of reducing the financial and administrative burdens that have long weighed on sites when conducting clinical studies.

Listening more effectively to sites and using their ideas and perspectives on payments helps to foster strategic change at the system level and rise above the challenges of cash-flow management and other financial barriers. By providing the infrastructure and process support they sorely need, sites are better able to focus on the patient’s safety and care –first and foremost – which is the priority focus in any clinical study.

However, sustaining these dynamics, and the open and transparent dialogue needed to guide future process refinements, will not be easy. The industry must continue to shed many of the traditional concepts governing site relationships that have been ingrained in their beliefs for years—and embrace change. Though still early days, it is clear the industry is making progress in the right direction.



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Want to know more about  
INC Research's commitment  
to supporting sites?

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