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How Your Electronic Data Capture (EDC) System Can Streamline Clinical Site Payments

Today, EDC systems are widely adopted by life science companies and well established as a critical technology for conducting clinical research, especially for large multi-site trials. While EDC systems are primarily a source of clinical data, robust systems generate a significant amount of operational data too. And when integrated with other clinical technologies, an EDC system is capable of surfacing and feeding these operational data into analytics or operational technologies to automate workflows and auto-populate data. Integrations are what turn your traditional EDC system from a place to capture clinical data into a core component of data analytics and trial operations. The keys to unlocking this value and streamlining clinical site payments are, first, to understand what EDC data can be used to automate the site payment process and, second, what type of integration layer is needed.

Why EDC Is a Rich Source of Data for Site Payment Technology

For most clinical researchers, the first thing that comes to mind when they hear "electronic data capture (EDC) system" is electronic case report forms (eCRFs) used to collect clinical and laboratory data entered by physicians, nurses and study coordinators directly at the medical setting or pulled in from another system. However, EDC contains more than clinical data; it is a rich source of operational data too. Robust EDC systems can also surface that operational data and use it to automate workflows and pre-populate data fields when integrated with other clinical technology.

While the focus of this paper is to describe the applications for EDC's operational data to streamline the site payment process, let's not forget that there are other applications for this data across the clinical trial. Data analytics used in risk-based monitoring studies to pinpoint quality issues at clinical sites pull EDC operational data to measure quality. Metrics, like auto-query rates, subject visit to eCRF entry cycle times and screen failure rates, are all surfaced using algorithms that are fed with EDC data. Robust clinical trial management systems (CTMSs) that can be integrated with EDC systems are able to transfer data directly into site monitoring visit reports. Rather than entering source document verification (SDV) work twice—in CTMS and an EDC system—clinical research associates (CRAs) can enter it once and it is captured in both systems automatically.

What is often overlooked is that similar efficiencies are gained by using EDC data to feed site payment technology. Connecting an EDC system with site payment technology allows the systems to work together "behind the scenes" to trigger payments and assemble cost data, eliminating redundant data entry and transcription errors. It also streamlines the setup of payments for each study by delivering payee and cost center data directly into the payment technology. The data in EDC informs the payment technology of visit schedules and work completed by the site. For example, certain data determines if the entire visit is complete or incomplete; or if the procedure or visit has been monitored by the CRA or not yet monitored by the CRA. Robust EDC systems have a record of this information and more.

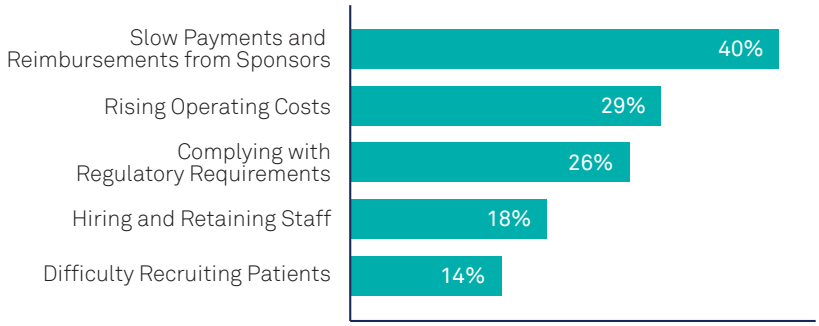
Delivering timely, accurate payments to your clinical sites keeps them happy and confident in your partnership.

- Timely payments give your sites the funds they need to continue enrolling patients, without the worry of when they will be reimbursed.
- Accurate payments save your sites time that might otherwise be wasted double-checking invoices and reimbursements.

Getting Site Payments Right Is an Advantage

Paying clinical sites is a critical part of any study. Sites need to be reimbursed for their work and costs incurred. The burdensome site payment process faced by many sponsors often results in slow payment terms and money withheld, which puts financial stress on clinical sites. On average, sites receive payment 120 days after the work is performed; yet, most sites need to pay their own bills within 45 days.[1] As a result, many sites cannot afford to participate in clinical trials. In fact, the top two concerns among investigative sites are slow payments and rising operating costs (Figure 1).

Figure 1: Top Investigative Site Operating Concerns[2]



An analysis conducted by Clinical Trials Transformation Initiative (CTTI) showed a high turnover rate among clinical investigators: "As many as 40% of investigators annually choose not to participate in another FDA-regulated trial."[3]

With clinical sites under increasing economic pressure, sponsors and CROs that consistently pay sites accurately and on time have an advantage. Streamlining the site payment process is critical to maintaining a strong reputation with qualified, experienced clinical sites. If sites are confident in their reimbursement terms and timelines, they can focus their attention on enrolling patients. Losing a relationship with an experienced site is costly. It means having to partner with a naive site, which requires more time spent on training and initiation. The risk, however, is that many naive sites never enroll a single patient, and making an investment mid-trial to rectify a situation with an underperforming site typically increases total trial costs. The average cost paid to a non-enrolling site—a site that fails to enroll even one patient in the study—is $40,000.[4] This cost combines payment to both the site and a CRO providing services. Site costs include study start-up costs, investigator meeting attendance, IRB fee, advertising, site close-out fees and pharmacy setup, maintenance and close-out fees. These costs are paid to the site upfront and are not refundable. CRO costs include pre-study site recruitment and prep, site initiation visit, two site monitoring visits, site close-out visit and CRA travel.

How EDC Automates Clinical Site Payments

Although seemingly simple on the surface, the payment process can be challenging for sponsor organizations to get right. There are a myriad of requirements and complexities which include invoicing, requests and approvals, prepayments, holdbacks, split payments, handling multiple currencies and more. While handling these complexities for a single study with a handful of sites might be manageable using spreadsheets, it becomes unmanageable by the same method when tens or hundreds of sites across multiple studies are involved, making it hard to ensure accuracy and timeliness of payments. To clinical operations professionals, providing and receiving grant payments is one of the most inefficient activities in study conduct and one of the most onerous tasks. For example, setting up payment schedules that reflect the contracted negotiated costs, and reconciling data between the calculated site payment and the contracted splits, advance payment, and activities actually performed are all done manually.

Applying financial discipline, rethinking core processes and adopting powerful technology presents a golden opportunity for sponsors and CROs to emerge as lean, best-in-class competitors. While automating the clinical site payment workflow is a core value of payment technologies, automation is not complete without a fully integrated EDC system, as there are several steps in the payment workflow that require EDC data. When data is pulled from an EDC system into the payment workflow it automates study setup and cost calculations.

Figure 2: EDC-Automated Site Payment Workflow

Figure 2 shows the process steps to completing the clinical payment workflow when using an EDC system and payment technology together. The first three steps in the workflow allow for automation of processes, which would otherwise be manual steps, producing a similar output. The value of an integration between these two systems is described below.

- **Shorten study setup time:** EDC stores the data you need about sites to set up payments. The subject visit schedule in EDC can be auto-populated into your payment technology, further reducing the effort needed to create payment triggers.
- **Automate payment calculation:** EDC data can tell your site payment technology that a site completed its work. It informs the payment technology on when and how much to reimburse. However, it is more advanced than that—there are a variety of triggers that can be used to determine if a site has "completed its work." Once the payment technology determines that EDC data has reached a preset threshold, the costs are routed through the payment workflow, including approvals by the clinical and financial teams.

  The first method by which EDC triggers a payment is by using subject visit events: for example, when a visit is completed, when SDV is completed, eCRF is verified. EDC can also trigger a payment by determining when an eCRF review completion date is entered into the eCRF billing review page—most commonly used in post-market surveillance studies. The second method, which only the latest payment technologies have the capability to do, trigger a payment at a more granular level of detail than a visit event. The technology is able to parse out work that was performed at each visit versus work that was not completed or procedures that are optional in the protocol. Arriving at that level of detail is critical for ensuring that sites are paid correctly, that spend on high-cost procedures is accounted for properly and that the payment is accurate, especially in today's era of payment transparency. EDC can be configured to identify what constitutes a complete procedure. As well, it can be set up to alert your payment technology by verifying data entered by the investigator.
- **Eliminate site-created invoices:** For procedures that are optional, EDC data can be used to eliminate the need for sites to create an invoice stating that they conducted and completed an optional procedure.
- **Automate mid-trial updates:** EDC data can be used to automatically update patient-site information. For example, in long-term studies, patients often relocate (particularly snowbirds in the United States) mid-trial, and this creates a need to transfer their association to a new site in your payment technology. Using EDC data eliminates the need to manually enter or reconcile site transfer data.

Medidata offers the industry's only out-of-the-box technology that can calculate payments using procedure costs from EDC, and can automatically remove the cost of incomplete procedures from the payment total.

Integrating EDC and Payment Technology

Before cloud technology became readily available to the life sciences, integrating an EDC system with payment technology was an arduous and time-consuming undertaking. Clinical operations teams were often faced with choosing between the lesser of two evils: building a custom integration or managing disparate systems. Today, they have options. Some vendors offer integrations that are completely pre-built, that is, ready out-of-the-box, and others require you to build a custom integration from scratch. No one will dispute the advantages of an out-of-the-box integration, the problem is: they are rarely available.

Pre-built integrations are the quickest to set up and they reduce validation time, making them less costly compared to partially-built or custom integrations. Vendors that create pre-built integrations often need to build them with configurability at the core, so they can meet the needs of any sponsor, team or study. These configurations are what make it possible for end-users to get set up without any coding or engineering expertise required.

While the time and cost associated with integration setup is a key consideration and front-of-mind during the technology selection process, the long-term maintenance costs of that integration are often overlooked. All integrations will eventually become outdated because processes change or system upgrades occur. Custom integrations require developers to recode all of the applications—EDC, payment technology and the integration layer—every time a change is made to either system, and the business team is often responsible for their upkeep. This can cause significant delays to trial progress. However, pre-built integrations often come with the expectation and assurance that changes made to either system will automatically flow downstream to the integration layer. As a result, the cost of maintaining pre-built integrations over the longer-term is low because every new release of your payment technology or your EDC system comes with the necessary enhancements to the integrating layer.

About Medidata

Medidata is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud® brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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