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Driving ROI:
The Case for Investing in Global Site Payment Services

Biopharmaceutical and medical device companies rely on investigative sites to complete their clinical trials. Building strong relationships with high-quality sites is critical to addressing a number of key challenges, from the growing number of trials to mounting pressures that minimize cycle times. Yet investigative sites consistently express their dissatisfaction with the grant payment process and highlight this as one of their biggest pain points in participating in clinical trials — potentially keeping new sites from entering the industry and tempting existing sites to drop out of clinical trials due to slow payments. Many sponsors and CROs continue to use standalone spreadsheets and databases to manage grant calculations, increasing financial risk and the probability of error. Clinical trial sponsors are also facing stringent financial compliance regulations that mandate detailed descriptions of every payment made to every investigator throughout the course of a clinical trial. Gathering and accurately reporting detailed grant payment information is difficult. Yet failing to comply could lead to significant penalties and trial delays.

The goal of this study and white paper is to highlight examples of the operational and business benefits that can be realized when outsourcing global payment services to a standalone service provider. The impact of investing in global payment services is not only strategic but also measurable. Research consisting of six in-depth interviews with DrugDev customers found that DrugDev addressed customer challenges and delivered measurable results and a compelling return on investment (ROI).

Global Site Payment Challenges

Reducing the time spent by study teams on site payments, while increasing the frequency and accuracy with which payments are made was a key goal for many customers. The effort to ensure payments were being made in a timely way in local currencies, while understanding local tax implications and risks, and providing the needed level of detail to the sites about each payment, was still significant when handled with largely manual processes and procedures.

Another key pain point often noted was the challenge to maintain strong site relationships when payment processes were inefficient and long periods of time would elapse between payments. In addition, site and clinical research associate time would be taken up trying to determine or confirm the details of each payment. These issues could lead to frustration on the sites' part and could also result in having to provide sites with higher start-up costs to give them some financial stability, not to mention increased costs to sponsors by utilizing valuable CRA time to focus on payments. Given the number of sites often needed per study, as well as sites often being used for multiple studies, ensuring site satisfaction and strong site relationships was a key focus area for customers.

Beyond the operational challenges with their prior approaches, customers also noted that effective budget management for each study could be difficult. Challenges included not being able to accurately forecast payments that would be required over any given time period, CROs requiring large upfront cash floats to cover future payment needs — placing an unnecessary drain on sponsor working capital and potentially exposing the sponsor to increased currency exchange rate risk and lack of planning in the management of taxes (VAT/GST, withholding, and R&D tax credits). This results in significantly increased trial costs or unnecessary cash flow delays due to local VAT recovery processes.

Finally, compliance was a key concern for customers. Ensuring that all required aggregate spend reporting could be quickly and accurately pulled together could be difficult

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to do when manual processes were being used or payments were being managed across a number of groups or organizations such as CROs. At a minimum, this could result in errors in the reporting, and added time being spent to correct these, but it could also result in financial penalties.

Customers identified benefits of a global site payment solution from DrugDev in four key areas: increased operational efficiencies, enhanced investigator relationships, improved budget management, and strengthened compliance.

Increased Operational Efficiencies

Eliminate time spent on site payments. When site payments are managed manually/via spreadsheets they can take up as much as 10-15% of a study team's time, which could otherwise be spent against the core tasks associated with clinical trials. DrugDev's Payment InSite™ is a highly controlled, fully integrated payment-processing environment allowing for the management of grant payments and pass-through expenses for investigative sites around the world. Payments are delivered through electronic funds transfer (EFT) and detailed reports are provided to payees in their local language and currency.

Able to free up study team's time that used to be spent on payments, about 10% of their time previously. —Project Manager

Reduce time needed for financial reporting and reconciliations. When site payments are managed by a large number of CROs, or multiple groups within an organization, it can make the task of pulling together all of the data needed for audits or financial reporting very time consuming and prone to errors and omissions. DrugDev allows for an increase in the effectiveness of regulatory/financial compliance efforts and transparency through: comprehensive auditing capabilities and deep reporting; improved finance/treasury reporting, cash flow management and analytics; and by providing accurate and timely accruals.

Reconciliations used to take 10% of 2 FTE's time for an average of 30-60 days at the end of a study, time that has now been essentially eliminated. —VP, Clinical Services

Enhanced Investigator Relationships

Reduce site start-up costs. When sites are frustrated with slow payments, it's possible they become less engaged with the study and spend more time than needed collecting the required data, costing the sponsor more, as on-going site support would need to be extended. In addition, sites may request more in start-up costs to account for the long intervals between payments. With DrugDev, investigative sites are paid as often as monthly, based on the data they submit, and can trust that these payments will be made, an approach that results in them requiring less funding up front in the form of start-up costs.

Reduced start-up costs by an average of 50-65% across all sites. —VP, Clinical Services

Increase site satisfaction. When sites receive and have to manage their payments manually, it can create a lot of administrative work for them, as it can be difficult to determine what the payments being received are for, creating frustration at the site level. DrugDev provides fast, accurate payments, removing the site's administrative burden and letting them focus on enrolling patients, while 24/7 access lets them view all of their grant payment information in one place, at the level of detail needed to understand the specifics of each payment.

With DrugDev Payments, we could move from paying quarterly to monthly, making sites happier and willing to work harder to enroll patients. —Head of R&D Procurement

Improved Budget Management

Reduce cash float advances. When site payments are managed by CROs, it can be difficult to accurately predict exact site spend requirements, resulting in greater than needed cash advances to the CROs — dollars which place a significant drain on a sponsors working capital. DrugDev's innovative software and rigorous processes allow for the precise calculation of monthly spend. With that insight, a sponsor can make just-in-time payments and better manage their trial budget and cash flows. Accurate, real-time accruals and reporting enhance business intelligence, while electronic billing transactions and straight-through processing enable superior financial control.

Used to have an average float of $1.0M out with CROs at any given time, which has now been eliminated. — Head of R&D Procurement

Reduce foreign exchange rate exposure. Sponsors pay large cash advances to the CROs, based on the best estimates of site payments needed for the next quarter. If the study has international sites and the exchange rate fluctuates over the quarter then they may need to provide CROs with more funds to cover this. DrugDev minimizes this risk through their "just-in-time" funding capabilities and through their strategic partnership with Wells Fargo, which has flexibility to make payments globally in foreign or local currency; and foreign exchange capabilities.

With DrugDev Payments, we no longer have to worry about trying to project/forecast for foreign exchange impacts, or to protect against these. —Director, Clinical Business Operations

Reduce site overpayments. Without an automated, centralized way to track all site payments, the chance that a site gets paid twice or gets paid in error increases substantially. DrugDev's innovative software and rigorous processes allow for the precise calculation of payments owed to each site each month and tracks all payments made to ensure they are accurate, and that they are paid to the sites quickly and correctly.

Strengthened Compliance

Reduce time needed to generate aggregate spend reports. When multiple CROs are involved in managing multiple studies, there is no single source for clinical trial payment data. So when compliance teams need payment data it can take days or weeks to gather all of the information required, as they need to collect the information from multiple sources and then compile it into a single report. DrugDev's Payment InSite™ generates reports quickly and easily, capturing all spending across all sites in a centralized database from which reports can then be generated as needed to meet federal and growing global regulatory requests for this data.

Time to complete aggregate spend reports down by 60% for studies in North America, and by 80-85% for studies which include global sites. —VP, Clinical Services

Reduce fines/penalties for non-compliance. Gathering and accurately reporting on detailed grant payment information across a large number of CROs can be very difficult, yet failing to comply can lead to penalties and trial delays. DrugDev's Payment InSite™ generates reports around both investigative sites and individual investigators, improving compliance with federal (Sunshine Act), state and growing global aggregate spend reporting requirements, as payments can be seen at any level of detail required.

Avoidance of fines is key as a first offence could be $1.0M and the next could be a percentage of total study costs. —Head of R&D Procurement

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KEY ROI FINDINGS

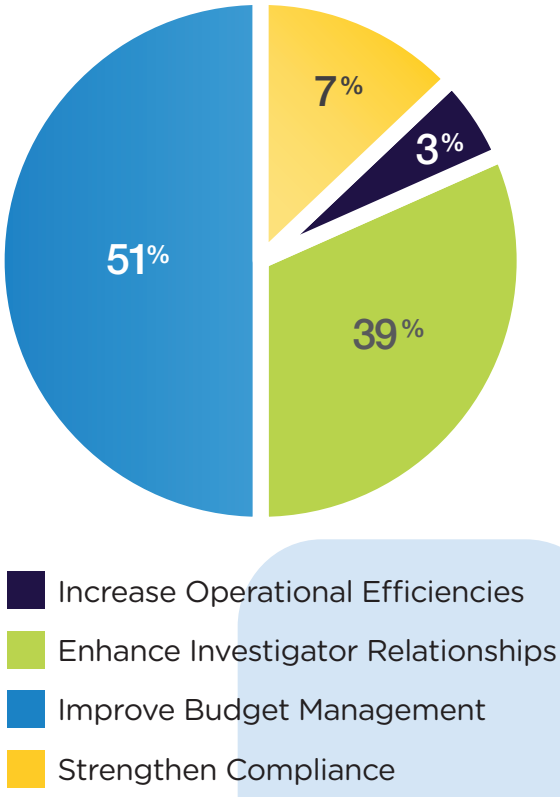
The value of a global site payment solution is immediate and demonstrable. A sample sponsor with 5 studies a year over 5 years, an average of 140 sites per study, study length of 33 months, average cost per patient of $10K, start-up costs of $20K per site, 30% of sites outside of the U.S., and who is currently outsourcing payments to a CRO, can experience $4.7M in savings a year from improved budget management alone. With increased operational efficiencies, enhanced investigator relationships and strengthened compliance, annual benefits can be as much as $8.7M.

For the sample organization, the three year investment totaling $4.5M begins generating a positive return in 2.2 months. The three year net present value (NPV) and return on investment (ROI) are strong at $13.3M and 358%, respectively. The key financial metrics for the sample organization were calculated by standard methods and are shown opposite. The NPV calculation assumes a 10% cost of capital.

Figure 1: Key Financial Metrics

FINANCIAL METRIC	3-YEAR VALUE
Payback (months)	2.2 months
NPV	$13,280,203
ROI	358%

Figure 2: Benefits by Value Driver



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About DrugDev

DrugDev is an innovative technology company which provides cloud-based solutions to help sponsors, CROs and investigators do more clinical trials together. Built around the largest global network of active opted-in investigators, DrugDev's unified solutions suite optimizes site selection and startup, investigator payments and clinical operations. DrugDev also serves as the trusted third-party host of the revolutionary Investigator Databank collaboration and powers the TransCelerate Investigator Registry.

Learn why 9 of the top 10 sponsors and 4 of the top 5 CROs rely on DrugDev technology to do more trials at drugdev.com.

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