

# Medidata Grants Manager<sup>®</sup> Optimizes Grants and Streamlines Budget Agreements

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Medidata Grants Manager provides clinical trial sponsors and contract research organizations (CROs) with a comprehensive, data-driven solution to quickly and accurately develop grant proposals and efficiently contract budgets for investigative sites. Grants Manager helps your organization:

- Develop accurate site budgets for clinical trials with few or many study arms.
- Ensure fair, consistent, data-driven investigator payments around the world to support multiple therapeutic areas, indications and geographies.
- Mitigate compliance risks in physician grants.
- Support financial reporting with transaction records readily available for analysis.
- Reduce elapsed time to site recruitment.
- Engage multiple sites simultaneously to review and edit proposed budgets and contracts.
- View progress of site budget acceptance across multiple studies in a dashboard display or at various study levels: region, country and site.

Delays in site contract and budget negotiations can cause unwanted delays in clinical study execution. Only Grants Manager provides industry-wide negotiated site cost information—which is critical to study start-up and clinical trial success—via an online, collaborative web platform with exclusive access to PICAS<sup>®</sup>.

## Accelerate a Key Process in Site Recruiting

Speeding site recruitment is a critical factor for success in clinical trials. Grants Manager helps meet key study start-up milestones by supporting the preparation of an optimum budget. It also helps improve cycle time and ease of operation in reaching budget and contract agreement with investigative sites. Cumbersome email and paper processes are replaced with web-based communication between sponsors or CROs and sites, enabling rapid review and exchange by both parties to approve and efficiently close the negotiation.

## Sharing Information to Foster Collaboration

With Grants Manager, clinical, project management, contracting and finance professionals worldwide can forecast project costs as well as develop detailed trial budgets that incorporate procedure and overhead costs, among others. Trial managers

## Grants Manager

Medidata Grants Manager is the site budgeting and contract negotiation suite that ensures appropriate payment and expedited site contract agreements. It's smart: Grants Manager provides only actual negotiated grants and industry benchmarks, allowing you to analyze your company's specific grant history so you can build more accurate budgets. It's unique: Grants Manager is the only product on the market that allows you to see protocol complexity, procedure frequency and site-specific costs so you can pay appropriate salaries and improve your negotiation strategy. And, it's actionable: Grants Manager facilitates payment setup and plugs into the Medidata Clinical Cloud<sup>™</sup> platform, providing access to upstream data for faster budget development and downstream data for better study execution.

## PICAS

The clinical benchmark and cost database of negotiated investigator grants with a store of more than 320,000 grants and contracts and 29,500 protocols in over 1,800 indications. Grants Manager accesses PICAS data to create budgets tailored to specific therapeutic areas, procedures, geographies and indications, while identifying the financial impacts of site selection and protocol changes.

and sponsor or CRO executives can collaborate on budget details using for example, visit, patient and country variables. The easy-to-view reports confirm key aspects of the grants process: for instance, they indicate whether the budget represents costing informed by industry negotiated benchmarks.

## Benchmark Internally

In addition to benchmarking your budgets and agreements against industry norms, Grants Manager documents and allows rapid analysis of a sponsor's or CRO's site agreements and contracts. Medidata extracts, assembles and stores the embedded data from the contracts and agreements between the sponsor or CRO and its sites. By providing an accessible, historical record of past grants, the analysis function assists in new site recruitment, reduces compliance risk and helps guide standardization across clinical programs. Documentation of past trials is instantly available, including protocols and amendments, as well as important profile information, such as site type, trial time, therapeutic area, payment trends and payment rationale. The analysis function also provides documentation of payment specifics for regulatory, audit and negotiation purposes.

## Identify and Analyze Complex Trials

Grants Manager provides a powerful tool for estimating the complexity of the trial design, namely, the complexity analyzer function. Sponsors and CROs can now refine payments to site investigators based on knowledge of the relative difficulty the site would have in executing the protocol. The complexity analyzer function calculates the site work effort that procedures, visits and the entire protocol require. Medidata and Tufts Center for the Study of Drug Development collaborated on the development of this insightful metric. The complexity analyzer function also contains benchmark industry complexity metrics helping trial planners understand the site work effort associated with a specific protocol relative to industry averages.

## Site Negotiations Made Easy

Grants Manager provides real-time information on the progress of site negotiation across all studies so that managers can assess progress and take corrective action if needed. This visibility for sponsors extends to CROs negotiating with sites on their behalf. Additionally, Grants Manager retains an audit trail of negotiation activity, which establishes the history of budget negotiations with sites and can help show compliance with fair market value regulations. Users can configure the fields and values displayed in the negotiation, increasing negotiation flexibility.

Used extensively by sponsors, Grants Manager's contracting function generates a new level of sponsor success as well as site satisfaction. The contracting function maximizes the capabilities of your budgeting and contracting operations by providing an efficient exchange of formatted communication and visibility of negotiation activities, which enables faster budget agreement and acceptance by sites.

## About Medidata

Medidata Solutions 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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### Medidata Clinical Cloud®

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics  
Reduced costs | Improved time to market | Faster decisions | Minimized risk