Medidata Edge Site Grants Optimizes Grants and Streamlines Budget Agreements

Medidata Edge Site Grants (formerly 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. Edge Site Grants helps your organization:

- Develop accurate site budgets for clinical trials with any number of study arms.
- Ensure fair, consistent, data-driven investigator payments around the world to globally 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 Edge Site Grants 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.

Accelerate a Key Process in Site Recruiting

Speeding site recruitment is a critical factor for success in clinical trials. Edge Site Grants helps meet key study start-up milestones by

- Supporting the preparation of optimum budgets
- Improving cycle time when reaching budget and contract agreement with investigative sites
- Replacing e-mail and paper processes with web based communication for efficient negotiations

Edge Site Grants

Medidata Edge Site Grants is the site budgeting and contract negotiation suite that ensures appropriate payment and expedited site contract agreements.

It's smart: Edge Site Grants provides only actual negotiated grants and industry benchmarks, allowing you to analyze your company's specific grant history.

It's unique: Edge Site Grants is the only product on the market that allows you to see protocol complexity, procedure frequency and site-specific costs so you can improve your negotiation strategy.

It's actionable: Edge Site Grants facilitates payment setup and plugs into the Medidata Clinical Cloud™ 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. Edge Site Grants 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.

Sharing Information to Foster Collaboration

With Edge Site Grants, clinical, project management, contracting and finance professionals worldwide can forecast project costs, as well as develop detailed trial budgets. Executives can also collaborate on budget details using multiple clinical 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

Edge Site Grants also documents and allows rapid analysis of a sponsor or CROs site agreements and previous contracts. 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.** This also provides documentation of payment specifics for regulatory, audit and negotiation purposes.

Identify and Analyze Complex Trials

Edge Site Grants includes a powerful tool called the complexity analyzer developed in collaboration with Tufts Center for the Study of Drug Development. The complexity analyzer function **calculates benchmarks with industry averages, along with a site's work effort** that procedures, visits and the entire protocol require. This helps sponsors and CROs determine site payments based on relative study complexity.

Site Negotiations Made Easy

Edge Site Grants provides real-time information on the progress of site negotiation so sponsors or their CROs can take proactive action. Additionally, an audit trail of negotiation activity is retained for reference and compliance with fair market value regulations. Users can configure the fields and values displayed in the negotiation, increasing negotiation flexibility.

Used extensively by sponsors, Edge Site Grants'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.

Edge Trial Planning and Management

Pioneering Analytics Accelerates Clinical Operations

Edge Trial Planning and Management is a product suite that increases patient enrollment, retention, and study execution. Medidata Edge Design Optimization, Site Feasibility, Site Grants, and Payment solutions use historical benchmarks and automation from MEDS to reduce patient burden and site feasibility as well as site grants and payments. This has been proven to increase patient recruitment and retention rates.

Medidata also solves many of the biggest challenges in trial management. Medidata Strategic Monitoring and CTMS holistically address regulatory requirements for RBM by combining anomaly detection with intelligent workflows to enable sponsors, CROs, and sites to confidently move away from 100% SDV. Medidata master data management means that up to 76% of an eTMF's artifacts can be pre-populated from other sources.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including over 950 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

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