FACT SHEET

LifeSphere CTMS™

KEY BENEFITS

- Provides centralized end-to-end management of all clinical trial and operational data
- Improves effectiveness of site monitoring activity
- Improves relationships with investigators
- Removes reliance on manual processes to ensure compliance with regulatory submission processes
- Facilitates better cost containment
- Increases control with real-time status tracking, metrics and KPIs
- Provides a central overview, distribution and tracking of all study documents
- Streamlines clinical operations including CRF, document and subject visit tracking
- Delivers improved efficiency with integrated workflow

The clinical trial process is one of the most expensive costs in drug development. Currently it is estimated that sponsors spend nearly $45 billion on clinical trial activity annually, of which $14 billion is spent on monitoring processes alone. Managing these costs is imperative in a climate with declining budgets, limited resources and increasing regulatory oversight.

LifeSphere CTMS™

LifeSphere CTMS is a comprehensive and versatile clinical trial management system (CTMS) that enables life sciences organizations to plan, track and control all tasks and activities related to the set-up, conduct and closeout of clinical trials. A core component of ArisGlobal®'s LifeSphere Clinical platform, LifeSphere CTMS facilitates study preparation activities such as set-up, site assessment and selection, document distribution, contract management and site visit monitoring from a centralized, unified platform. LifeSphere CTMS helps mitigate risk, supports adaptive trials and improves tracking and analysis while helping to control study costs.

Study Set-Up

LifeSphere CTMS facilitates study set-up by automating study preparatory activities such as study planning, site assessments, document distribution, enrollment, milestone and site visit planning. To expedite the study set-up process, LifeSphere CTMS provides numerous global and study-specific templates, ensuring new studies can be set up instantly and consistently regardless of type, complexity and scope of the study.

The comprehensive investigator database maintains investigator information, including previous study history/audit experience and areas of specialty to facilitate site and investigator selection. An integrated enrollment planner empowers clinical trial teams to produce adaptive enrollment plans by taking into account screen failure, dropout, enrollment rates and seasonal adjustments while the task planner supports task planning, tracking and resource allocation.

Study Conduct

LifeSphere CTMS provides users an impressive array of powerful functionality to facilitate study conduct. The site monitoring planner integrates event-based planning into configurable monitoring plans, which can also be linked with most EDC systems. The site monitoring function allows monitors to efficiently conduct and document monitoring visits with an automated report review and approval process governed by user-defined workflows.

LifeSphere Clinical™ - eClinical Platform
LifeSphere EDC™
LifeSphere CTMS™
LifeSphere Investigator™
LifeSphere Trial Disclosure™
LifeSphere Central Coding™
LifeSphere eTMF™
LifeSphere SUSAR Reporting™
LifeSphere eCOA™
LifeSphere RTMS™
agWorld™ - eClinical Portal

These features allow patient enrollment to be closely monitored while role-based user dashboards provide the necessary insight into the progress of the study to improve trial planning and decision making.

LifeSphere CTMS's powerful document module ensures all documents are tracked ready for the regulatory submission process. Supporting task, milestone and document tracking, LifeSphere CTMS allows the study team to effortlessly monitor the progress of all core activities. LifeSphere CTMS also allows protocol amendments to be made during the clinical trial and any issues relating to the site or study can be highlighted and easily reported to other users, eliminating unnecessary delays due to unexpected events.

Study Closeout

Using LifeSphere CTMS, study teams can track the completion of milestone activities and tasks, ensuring they are achieved before the study closes. Clinical trial teams can close site monitoring visits and update study statuses to reflect their progress. Trial Master Files (TMFs) provide efficient, secure document archiving and storing functionality. All issues can be tracked at all levels and closed with any trends identified for future trial activity.

LifeSphere CTMS is also equipped with an extensive reporting functionality, including an integrated, ad hoc reporting engine that generates a wide variety of operational and executive reports such as TMF return, visit status and payment reports. All reports can be exported into different file formats to aid in independent audits as well as the study closeout process.

Flexible Integration

For complete automation and to reduce redundant data entry, LifeSphere CTMS can be integrated with other corporate department systems including finance (e.g., SAP®), safety, trial disclosure and EDC systems (such as ArisGlobal®'s comprehensive EDC solution, LifeSphere EDC). When integrated with EDC, relevant data is automatically transmitted from the EDC system to trigger key activities such as investigator payments and monitoring visits. Study managers and monitors benefit from more timely and reliable operational data and more efficient management of study status.

Hosted Offering

As with all ArisGlobal® products, LifeSphere CTMS is available as a hosted solution on the agOnDemand platform.

ABOUT ARISGLOBAL®

ArisGlobal is a visionary technology company that's transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. The ArisGlobal LifeSphere™ cognitive technology platform integrates machine-learning capabilities to automate the core functions of the product lifecycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, our cognitive platform delivers actionable insights, boosts efficiency, ensures compliance, and lowers total cost of ownership through multi-tenancy.

Headquartered in the United States, ArisGlobal has regional offices in Europe, India and Japan. For more information, visit arisglobal.com or follow ArisGlobal on LinkedIn and Twitter.

For more information,
contact us at: www.arisglobal.com | info@arisglobal.com