FACT SHEET

LifeSphere EDC™

KEY BENEFITS

- Optimizes clinical drug supply and recording patient outcomes by offering out-of-box (OOB) unification with RTSM and eCOA/ePRO modules.
- Supports DDE and hybrid paper/EDC studies
- Easily creates the most complex study designs
- Manages clinical trials seamlessly when integrated with ArisGlobal's CTMS (CTMS) and medical coding solution (Medical Dictionary Coding)
- Also allows integration with other third-party applications through Webservices
- Eliminates SAE reconciliation through seamless integration with Global Adverse Event Management
- Provides a centralized tool that anyone can easily access and fully supports all data management activities, including query resolution, recording, etc.
- Reduces IT infrastructure and support overhead costs by offering quick deployment of a hosted solution
- Comes with 30+ standard reports OOB
- Provides a complete annotated CRF

As the adoption of electronic data capture (EDC) has increased across all phases of clinical trials, it is now recognized as a commodity that is helping companies reduce costs while increasing efficiency and improving trial outcomes. On the surface, today's EDC applications are mostly comparable in functionality. The key differentiators are found in the level of service provided, study build times, time to study startup, flexibility to adapt during the trial and integration with other systems/departments, such as randomization and trial supply management (RTSM), supply, electronic patient reported outcomes (eCOA/ePRO) and clinical trial management system (CTMS).

Innovative LifeSphere EDC™

LifeSphere EDC is an innovative data capture system that is fully-unified with RTSM and eCOA/ePRO. Unification means that all these modules are built on the same set of data structures and architecture. This solution represents a seismic shift not offered by any other vendor, enabling organizations to finally realize the potential of clinical data management technologies.

It is also fully-integrated with CTMS, medical coding, and internal patient compliance modules, giving sponsors and CROs a cost-effective way to capture, manage and report clinical research data during Phase I-IV studies. LifeSphere EDC offers a comprehensive platform for study designers, investigators, contract research associates (CRAs) and data managers with access control based on study-dependent user privileges.

Built on a single database repository, LifeSphere EDC is 100% Web-based and requires no additional software or utilities to be installed. Its advanced feature set built on the same architecture significantly reduces study development times and easily supports the implementation of changes to live studies without disrupting study progress.

Flexible, Configurable Study Design

LifeSphere EDC offers the flexibility and configurability needed to help build visit schedules, case report form (CRF), edit check and workflow required. Advanced form designing capabilities provide users with a drag-and-drop design wizard that enables rapid study design – a typical study taking only eight to twelve weeks to complete – including all edit checks and visit scheduling with allowance for multiple review cycles. LifeSphere EDC also provides multi-lingual support for global studies, and has the capability to create forms into the native language of a site.

LifeSphere Clinical™ - eClinical Platform

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

The study design module allows users to quickly generate eCRFs by copying from a library of existing forms, CDISC-compatible templates or by creating new forms. Forms can be designed to change dynamically based on the responses recorded for a given patient. Configurable page layouts allow more data to be shown on the screen with less scrolling and faster data entry and cleaning. An integrated validation builder allows the user to create simple or complex edit checks without requiring sophisticated programming skills.

Data Entry

LifeSphere EDC's intuitive user interface is appreciated by site staff, investigators and CRAs located worldwide. Rich help and guidance is provided through the data collection process, with clear navigation and user messages assisting along the way. Images and documents are stored directly on the eCRF to allow easy review.

Dynamic views provide users with a single location from which to see important data points across multiple pages and visits. A dramatic configurable workflow allows sponsors to access and perform activities based on their internal processes and roles, ensuring users only view what they need to see in the system.

An electronic signature capability conforms to all regulatory guidelines and allows investigators to sign each eCRF including SAE forms. Through the course of the trial, the internal alerting (patient compliance) module will automatically send out alert notifications to the patient.

Double Data Entry (DDE)

LifeSphere EDC optimizes data capture by providing DDE functionality (blinded or non-blinded) for paper or hybrid paper/LifeSphere EDC studies. This handles most data delivered on paper, whether in a paper or hybrid study. It provides the flexibility required for sites to manage data collected by paper and EDC. Once the data has been entered and validated, the data will be available for cleaning and review.

Workflow support can be attached to forms as they flow through the DDE review process to aid with the reconciliation and cleansing effort. It has an automated query workflow which includes the printing of data clarification forms and any new questionnaires/forms required to be outputted to sites. LifeSphere EDC DDE function is supported by a full audit trail.

Query Management

As greater focus is being applied to risk-based monitoring, CRAs can use LifeSphere EDC to effectively manage all site data. CRAs can review data, manage site queries and perform full or partial source document verification (SDV) with ease. Investigators can easily search for and navigate to open queries, enabling them to clean the data efficiently.

As with all ArisGlobal® solutions, LifeSphere EDC 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.

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