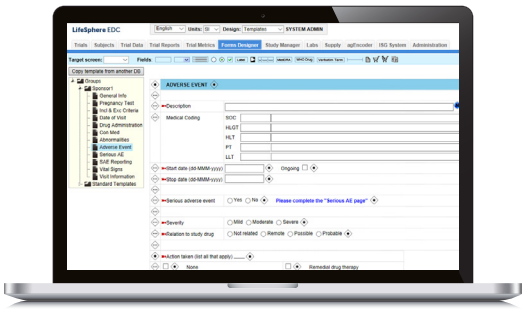
LifeSphere® EDC

Realizing Full Potential of Clinical Trial Management through Integration

The competitive pressures life sciences companies now face is forcing them to find better ways to reduce drug development times and increase productivity. Yet despite a growing number of solutions in the marketplace, clinical data management departments still struggle to achieve their goals of faster study builds, better data integration and access and reducing the time from protocol approval to go-live.

LifeSphere EDC is an innovative, unified data capture software solution that delivers sponsors and CROs a cost-effective way to capture, manage and report clinical research data regardless of trial phase and complexity. Seamless integration with other systems enables organizations to realize the potential of clinical data management technologies.



Enabling a Flexible, Configurable Study Design

While today's EDC solutions appear to be comparable on 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.

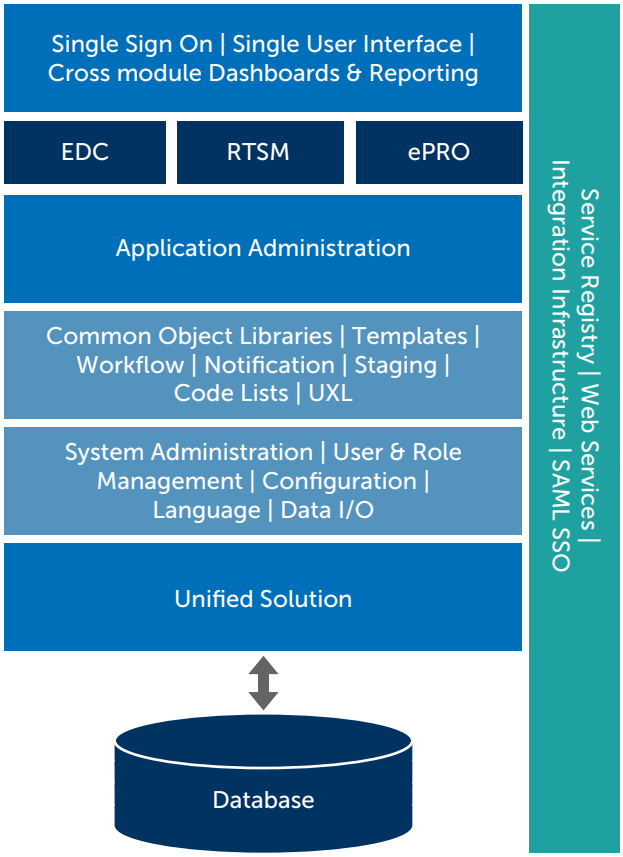
Built on a single database repository, LifeSphere EDC is 100% Web-based, requires no additional software to be installed and is fully integrated with randomization and trial supply management, clinical trial management systems, electronic patient reported outcomes and internal patient compliance modules. Its advanced feature set significantly reduces study development times and easily supports the implementation of changes to live studies without disrupting study progress.

Simplifying study processes

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 including all edit checks and visit scheduling with allowance for multiple review cycles. LifeSphere EDC also provides multi-lingual support for global studies.

LifeSphere EDC unifies randomization and trial supply management (RTSM), ePRO and EDC with medical dictionary coding, CTMS and internal patient compliance modules.

A Unified Clinical Data Management Platform



Intuitive User Interface

An intuitive user interface assists site staff globally. 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 give users a single location from which to see important data points across multiple pages and visits. A configurable workflow lets sponsors access and perform activities based on their internal processes and roles.

Enabling Double Data Entry

LifeSphere EDC optimizes data capture by providing DDE functionality (blinded or non-blinded) for paper or hybrid paper/LifeSphere EDC studies. This provides the flexibility required for sites to manage data collected by paper and EDC.

Aiding Regulatory Conformity

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.

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