Key Benefits

- Optimizes clinical drug supply and recording patient outcomes by offering out-of-box (OOB) unification with RTSM and 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 (agClinical™) and medical coding solution (agEncoder™)
- Also allows integration with other third-party applications through Web-services
- Eliminates SAE reconciliation through seamless integration with ARISg™
- 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

UNIFIED EDC

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 (ePRO) and clinical trial management system (CTMS).

Innovative EDC

agCapture™ is an innovative EDC system that is fully-unified with agSupply™ (RTSM) and agOutcomes™ (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. agCapture™ 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, agCapture™ 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

agCapture™ 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. agCapture™ also provides multi-lingual support for global studies, and has the capability to create forms into the native language of a site.

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
agCapture™'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. Throughout the course of the trial, the internal alerting (patient compliance) module will automatically send out alert notifications to the patient.

Double Data Entry (DDE)
agCapture™ optimizes EDC by providing DDE functionality (blinded or non-blinded) for paper or hybrid paper/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. agCapture™ DDE function is supported by a full audit trail.

Query Management
As greater focus is being applied to risk-based monitoring, CRAs can use agCapture™ 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, agCapture™ is available as a hosted solution on the agOnDemand™ platform.

For more information, contact us at www.arisglobal.com / clinicalteam@arisglobal.com

About ArisGlobal®
ArisGlobal® is a leading provider of integrated software solutions for pharmacovigilance and safety, regulatory affairs, clinical research and medical information. Hundreds of life science companies rely on ArisGlobal®’s advanced solutions for maintaining regulatory compliance, workflow automation, improving operational efficiency and easily sharing information around the globe.