**ArisGlobal**

# LifeSphere eCOA™

## KEY BENEFITS

- Ensures all reported data is captured in a timely and accurate manner

- Improves patient monitoring and safety through real-time reporting

- Eases and speeds patient acceptance of ePRO via the use of familiar handheld devices and an intuitive user interface

- Engages patients in their own care, ensuring better adherence to treatment protocols

- Enhances clinical trial efficiency through seamless integration with EDC and CTMS

- Improves protocol compliance and data quality through notifications

- Provides flexibility by operating on most smart phones, wireless PDAs, tablets and supporting standard Web browsers

- Provides automated alert notification to patients

**Clinical trials are increasingly dependent on the collection of quick and accurate patient self- reported data in quality-of-life assessments, medical compliance monitoring and symptom information. Electronic patient reported outcomes (ePRO) are now recognized as valid primary and key secondary endpoints in clinical trials. ePRO technology allows users to capture data securely and takes advantage of touch-screen devices for convenience and ease of use. Sponsors are increasingly aware that involving patients in their own care helps to improvetrial outcomes.**

## LifeSphere eCOA™

LifeSphere eCOA is an advanced ePRO system that runs fully integrated with a traditional EDC study. A core component of ArisGlobal®'s LifeSphere Clinical platform, LifeSphere eCOA facilitates data management activities such as capturing data directly from the patient, notifying them when intervention is required and providing status updates when posted. LifeSphere eCOA helps mitigate data risk by providing a central online system that is fully operable from most handheld mobile devices.

## Patient Friendly

LifeSphere eCOA provides accurate assessments of the effects of particular treatments in many therapeutic areas. As a patient's experience cannot be objectively measured (factors such as discomfort, breathing difficulties and the degree of pain experienced by the patient), the self-reporting mechanism provides an effective solution for recording the subjective response of the patient accurately and reliably. LifeSphere eCOA makes it simple for patients to respond to questionnaires. A simple and effective user interface ensures that data entry is made as easy as possible for the patient, increasing the accuracy and reliability of data sent to study managers.

## Real-Time Capabilities

Timely responses are essential when monitoring changes in a patient's health status. Using LifeSphere eCOA, the capture and delivery of real-time updates allow sponsors and contract research organizations (CROs) to feel confident with evaluating drug effects based on patient responses and enable them to quickly respond to serious adverse events, protocol violations and deviations. The reporting capabilities cover patient enrollment, compliance and eligibility, and help clinical sites and sponsors to monitor the study and subject progress.

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

**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.

## Device Agnostic

LifeSphere eCOA is fully Web-based and device agnostic, providing complete flexibility in the choice of smart device selected by the sponsor-including iPhone®, iPad® and Android. Staff can track the progress of patients throughout study sites from any device of their choice, and can provide users with a range of devices that suit their preferences and adapt to certain patient needs, such as devices that support the visually impaired.

## Supporting Services

ArisGlobal® ensures your successful use of LifeSphere eCOA and provides the necessary support and requirements for your ePRO studies. Our services team can provide consulting, project management, device logistics and training of the selected hardware devices. Our experts will provide advice on which device is best suited for your needs, ensuring LifeSphere eCOA is configured and installed to your requirements. We support customizable page layouts to fully utilize larger devices. A 24-hour, multilingual help desk supports any queries from study staff and site personnel that may arise throughout implementation.

## Effortless Integration

For complete automation and to mitigate redundant data entry LifeSphere eCOA is fully integrated with other clinical systems. It can be delivered as a unified platform when combined with our EDC solution (LifeSphere EDC) and supply management system (LifeSphere RTSM), and can be integrated with similar third-party solutions.

## Improved Compliance

LifeSphere eCOA increases protocol compliance and improves data quality by allowing subjects to respond seamlessly. The system generates notifications to patients and study teams, promoting quicker response times and more effective solutions. LifeSphere eCOA also automatically time stamps all data entries, and all collected data undergoes a vigorous validation process that is defined by range rules and front-end edit checks, and is protected against any data loss, alteration or unauthorized disclosure.

## Hosted Offering

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