

LifeSphere Trial Disclosure™

KEY BENEFITS

- Ensures compliance with global clinical trial regulations
- Maintains consistent data across multiple registries
- Allows reuse of data across multiple registries
- Provides built-in flexibility for fast implementation of new regulatory requirements and new registries
- Improves planning and tracking of registrations
- Delivers built-in support for data requirements of all key registries, with the ability to easily configure others
- Automatically updates with the newest versions of the registries

Greater transparency requirements have increased the workload for biopharmaceutical companies. Sponsors find it difficult to manage clinical trial registrations worldwide. Limitations in staff and budget, labor-intensive manual processes, frequent changes in the regulatory environment and new emerging registries all make it difficult to comply with current regulations. As each registry requires differing data sets with unique business rules, the entire disclosure process has become increasingly complex.

LifeSphere Trial Disclosure™

LifeSphere Trial Disclosure enables life science organizations to efficiently manage the registration of clinical trials to the global registries such as clinicaltrials.gov and EudraCT. It supports the complete process – from gathering required data, reviews by stakeholders, conducting checks against registry-specific validation rules, to generating XML files for upload and submission. LifeSphere Trial Disclosure helps companies to ensure compliance and consistency of data published in registries worldwide.

Plan, Prepare and Submit All Registrations

Through LifeSphere Trial Disclosure, sponsors can easily plan, prepare and manage submissions to multiple registries. Users can effortlessly generate and review datasets, run validation checks, and create submission-ready XML files for upload. For many registries, LifeSphere Trial Disclosure contains out-of-the-box validation rules. A flexible database structure and business rules adapt to future regulatory requirements with new fields being added without coding efforts.

Data can be imported from any CTMS. All data is then approved via the configurable, integrated workflow process, which automatically manages and tracks multiple reviews from multiple reviewers. Once data is approved, the applicable submission sets can be created with appropriate registry-specific validations applied to ensure the integrity of the submission process. Necessary trial updates can also be submitted to the respective registries.

As well as being able to create multiple versions of a protocol or results data, users also have the ability to directly import adverse events into the results section using Excel files.

LifeSphere Clinical™ - eClinical Platform

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.

Single Platform

LifeSphere Trial Disclosure allows companies to manage all registrations from a single platform. As organizations often need to enter data numerous times in multiple registries, automating this process enables companies to reuse one entry multiple times. This speeds global registration while ensuring the consistency of data published around the globe.

Reports, real-time metrics and dashboards give users insight into the worldwide status of all their registrations while the system's planning functionality ensures that none are missed.

Ensure Global Compliance

Companies stay up to date with the latest requirements from the registries through LifeSphere Trial Disclosure's subscription-based Software-as-a-Service (SaaS) deployment model. Any changes needed to align with the newest versions of registries will be automatically delivered by ArisGlobal® as an easy-to-upload package, requiring no upgrades of the software or any coding or customization efforts. The subscription model allows you to stay current with latest validation rules required, ensuring all future submissions are fully compliant. New country-specific registries can be easily set up, and an advanced rule builder adds and manages validation and mapping rules to ensure data quality – all without the need for programming skills.

Hosted Offering

ArisGlobal® understands that not all companies have the time, resources, budget or staff expertise to handle the effort involved in implementing, managing and supporting all the software solutions they require. Delivered as a hosted Software-as-a-Service (SaaS) solution through ArisGlobal®'s agOnDemand platform, LifeSphere Trial Disclosure eliminates the investment in new hardware, software and application, as well as infrastructure support staff. Organizations benefit from quick deployment and return on investment.