

QUESTIONS AND ANSWERS

What is ClinSpark?

ClinSpark is an eSource platform designed for Phase I automation, leveraging electronic source data to connect systems and devices (vital signs, ECG, diagnostic labs, etc.) and centralize all clinical trial data. ClinSpark provides remote access to data, and is expected to replace 95% of the paper source documents at Altasciences.

ClinSpark was developed by Foundry Health, which has clients – including CROs and large pharmaceutical organizations – based in the U.S. and Europe.

What are the benefits of ClinSpark for our clients?

Operational efficiencies: ClinSpark provides clients with rapid visibility of their data due to its direct electronic capture and full CRF integration, eliminating the need for retrospective data entry. It allows for remote monitoring of data for speed and convenience. ClinSpark also streamlines data reviews for safety monitoring and facilitates timeline reductions between dose escalations.

Error reduction: ClinSpark improves data quality by reducing human error and documentation and processing errors, decreasing the number of data queries, as a result. Barcodes assigned to tubes, the investigational product, and study participants reduce the risk of major human errors occurring in early phase trials. Equipment Integration reduces data entry errors and allows automated verification of protocol-specific or SOP ranges. Integration with the clinical laboratories, where possible, minimizes the potential for errors during sample ordering, reconciliation, data entry, and transfer. It also provides investigators with a central location to trend laboratory results, applying a consistent and holistic approach to subject safety.

Data management: The error reduction inherent in direct data capture and ClinSpark's integration with clinical laboratories and other systems such as Watson for PK/PD sample management can expedite database lock timelines. The system's design also allows for seamless generation of CDISC-compliant datasets.

When and where is ClinSpark being deployed?

ClinSpark has been deployed at our Kansas and Montreal clinical trial sites. We are currently planning for implementation at our Los Angeles site in early 2023.

Will we be implementing ClinSpark for external clinical sites?

No, at this time we do not expect to be deploying the system external to Altasciences.

Is ClinSpark validated?

Altasciences has performed a complete 21 CFR Part 11 validation that includes all peripheral equipment used as eSource for the platform (e.g., automated vital signs and R-Scribe ECG collection). As it is a cloud-based system, we leveraged our robust vendor qualification process to supplement our extensive User Acceptance Testing (UAT) as an integral part of the validation. Validation documents are available for electronic review upon client request.

How is the data collected in ClinSpark secured and stored?

ClinSpark is a cloud-based system residing on a top-tier Amazon AWS platform. This means that data is constantly replicated to a failover site, and backups are performed multiple times per day to ensure the availability, integrity, and durability of the system. Altasciences has two independent, fully redundant internet service providers (ISPs) at each clinical site.

Can the clinical laboratories be integrated?

ClinSpark can interface with each of our local laboratories (Dynacare and Quest) to route orders and receive results directly. Dynacare will temporarily provide a unidirectional interface (results received), while Quest interfaces bidirectionally (orders placed and results received).

Is ClinSpark replacing Medrio?

For trials where the majority of the data is collected in ClinSpark, Medrio will not be used. For trials where data is collected on paper or as a combination of paper and ClinSpark, Medrio remains an option. It will also continue to be used for all trials involving non-Altasciences clinics.

Does using ClinSpark affect study start-up timelines?

Start-up timelines will not change because of the ClinSpark deployment.

How are queries and deviations managed in ClinSpark?

Queries are managed directly in ClinSpark. Protocol and SOP deviations will still be tracked and reported in our deviation management system. Deviations related to the time of completion of scheduled procedures will be reported in ClinSpark.