



SUCCESS STORY

Contract research organization

Industry

- Life sciences

Solutions

- OpenText™ Alloy™
- OpenText™ Lens™
- OpenText™ Managed Services

Results



Ensured data security and compliance, meeting the needs of pharmaceutical organizations



Improved onboarding of new sponsors



Sped delivery of EDC data via automated processing and upload to sponsor systems

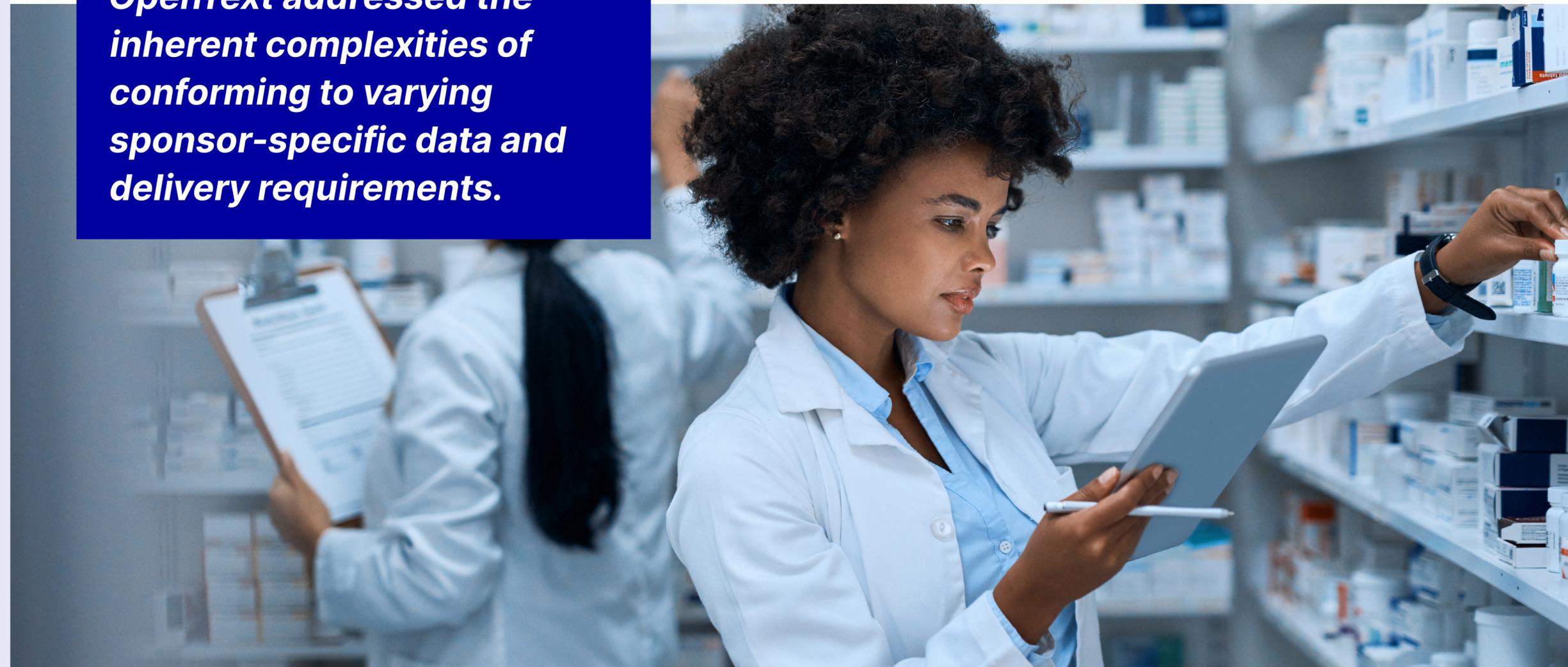


Reduced strain on IT resources by transferring data in native form

Contract research organization delivers timely, high-quality data with OpenText Alloy

CRO achieves realtime EDC uploads and fast sponsor onboarding

OpenText addressed the inherent complexities of conforming to varying sponsor-specific data and delivery requirements.



Contract research organizations (CROs) submit electronic data capture (EDC) data to many pharmaceutical sponsors. Each sponsor generally imposes differing data requirements, distracting CROs from their core business mission.

One CRO engaged OpenText to shield it from this distraction. As a result, OpenText implemented a fully managed solution on the OpenText™ Alloy™ platform to collect data in native form from the CRO, transform it into various sponsor-required formats and deliver the data via sponsor-preferred communications protocols, securely and in realtime. The solution allows the CRO client to meet the varying needs of its sponsors and provide them with timely, high-quality data in a compliant manner.

Prior to implementing OpenText, the CRO client maintained a custom in-house EDC solution to meet the requirements of its sponsors. Over time, and as new sponsor requirements were added, the implications for compliance, performance, operations, support and maintenance, coupled with a scarcity of resources, made it prohibitive for the CRO to continue with the solution.

Some of the key sponsor requirements included:

- Offer EDC data in CDISC LAB data model format
- Support for subsequent sponsor analysis, with data conforming to strict data quality requirements
- Uploading of incremental data feeds in realtime, through services exposed by various sponsor data ingest platforms, without manual intervention

OpenText addressed the inherent complexities of conforming to varying sponsor-specific data and delivery requirements by

developing a solution that allows the CRO to hand off its EDC data in native form. The native data is processed and validated between the CRO and OpenText through the implementation of a standard canonical map.

OpenText then takes the validated canonical data and transforms it into sponsor-specific formats. This approach enables reuse of the core data processing logic from one sponsor to another by implementing it on top of the canonical map. Additionally, OpenText™ Lens™ provides the CRO with end-to-end visibility across this data flow so that status and outcome can be verified. OpenText™ Managed Services, which consists of a combination of technology, processes and people, further met the needs of the CRO client by protecting highly skilled resources from the operational aspects of the solution.

In addition to meeting all sponsor requirements, the OpenText solution helped the CRO realize several additional key benefits. Cumulative EDC data feeds are converted to incremental feeds for sponsor systems, enabling accurate data lineage, a key requirement for regulatory submission. The EDC data is now available in sponsor systems within a matter of minutes through automated end-to-end processing and upload. In addition, the onboarding of new sponsors, and their data requirements, can be accomplished in a nimble timeframe of just two to three months. Highly skilled employees are now freed from the operational aspects of the former solution and can instead focus on core CRO competencies. Finally, end-to-end data flow is now transparent, making it easier to coordinate errors and data issues across multi-enterprise teams.

The CRO is thrilled with the implementation and plans to leverage more OpenText products in the future.



OpenText Alloy reduces overall time spent by key IT resources within the CRO team.



About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit opentext.com.

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