REMOTE DATA REVIEW AND CLINICAL TRIALS MONITORING USING

COMMAND CENTER APPROACH

Customer

A top 10 pharmaceutical company.
Customer since 2018 – current

Business Owner

VP, Clinical Information Sciences
Senior Director, Clinical Information Management
Director, Clinical Information Management

Problem Statement

- Customer needed to adjust to the paradigm shift in clinical R&D on account of the sudden digital transformation in clinical trial conduct on account of the disruption to clinical trials caused by the COVID-19 pandemic with Effective remote-patient-monitoring, remote-trials-monitoring with effective integration of data from digital technologies.

- Customer traditionally outsources all study conduct to CROs, receives patient data from EDC, and manually transfers study conduct data received from the CROs to the internal CTMS system along with the enrolment progress data received from external IRT vendor systems as well as technologies which collect clinical data remotely.

- Customer has no access to a single-source-of-truth for their virtual/hybrid clinical operations data as multiple eClinical systems (e.g. IRTs, EDCs, Safety systems, Project Planning etc.), different patient-centric technologies (e.g. ePRO, eCOA, eConsent and other wearables) and multiple large CROs are being used across their portfolio of studies.

- Customer needed single-source-of-truth for all clinical operations data and integrations with all data sources, in real-time, with centralized access, monitoring, and control over the portfolio, not allowing errors or problems to grow out of control and affect the timelines and regulatory compliance status of the trials.

Business Drivers

The business had a clear set of goals. They wanted a platform which can offer them oversight across their clinical trial portfolio while remotely monitoring all their virtual/hybrid clinical trials to act as a command center for all integrated eClinical Systems and Virtual Patient Data sources via a secure, cloud-based offering. They needed to integrate data accessed from various patient-centric digital technologies into a single-source-of-truth for faster data review, data quality management and outcome assessment empowering clinical data management and data review teams to maintain the quality and integrity of clinical trials' patient data; and reduce cycle time of database lock.

This basically required us to integrate study conduct data taken from several CROs, multiple eClinical systems as well as patient-centric technologies and wearables. Using the CTOS, we automated all the processes, from data ingestion, validation, aggregation, and standardization. The platform ensures timely regulatory reporting and clinical operations monitoring via pre-built standard dashboards and metrics for effective decision making. It also offers the achievement of the following goals:

- Create a single validated, standardized, aggregated clinical operations data repository for all virtual/hybrid clinical trial operations data of current and legacy studies across the internal and external data sources.
- Integrate the multiple processes and data formats from various sources to the central data repository with a streamlined and automated source-agnostic data ingestion to validation to data loading processes and run at configurable schedules without any manual interventions.
- Easily detect errors and fix or restart process as needed with drag-n-drop data transformation and harmonization rules with easy-to-use data mapping wizard.
- Establish consistency of the data representation across the virtual/hybrid studies via clinical operations data standardization and enable governed access to clinical operations data for downstream analysis and reporting processes. Single-click export or porting of submission standard SDTM data for down-stream processing.

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- Keep track of myriad moving parts to gain insights at scale, as data is not in separate siloes but integrated into a cohesive whole and make data readily available for exploration and analysis by streamlining data access and integrating analytics and data review tools.

- Gain clear visibility into data to make in-time decisions for various risks mitigations, portfolio oversight, and produce regulatory reports on time. Stay on track to achieve targeted goal by fixing errors and problems in real-time.

- Respond faster to changing landscape and environment (e.g. ability to on-board new study/-data sources, types, and formats faster) to remotely track clinical trial data in a digitized environment across virtual, hybrid and traditional trials.

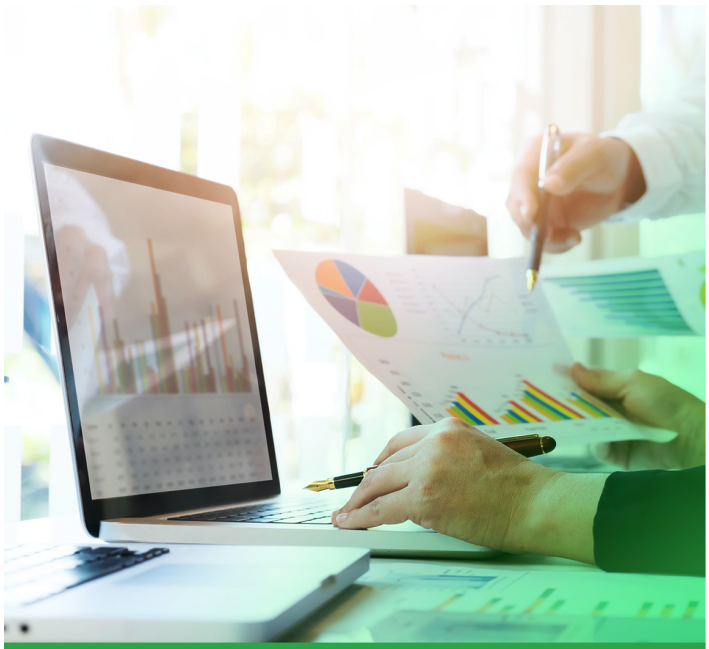
- Completely compliant with regulations, fully validated platform adhering to 21 CFR Part 11 compliance as well as GDPR compliance, with reportable built-in compliance; audit trail and traceability on each instance of data and its lineage – graphically depicted and exportable in desired reporting format for regulatory support.

Business Outcomes. Qualitative.

- Keep tabs on clinical trials getting executed at different locations around the world. Embrace digital transformation to collect data from remote app-based tools, streamline operations and manage the trials to shorten time-to-market, cut costs and enable better, more informed decisions.

- Integrated and automated data ingestion, validation, aggregation, and management; and reporting on clinical trial data through improved efficiency, consistency, and repeatability

- Improved and timely oversight on the portfolio of trials, in time decision making for the out-sourced clinical operations' risk management through built-in dashboards and governed



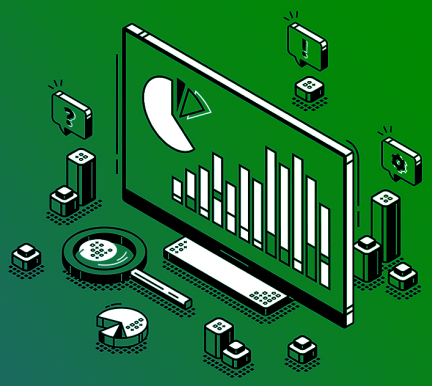
KPIs

- Agile implementation of overall solution in less than 4 months with on time deployment of qualified professional services team; Reduced effort to aggregate, review and clean data; Improved efficiency in managing clinical trial data quality across portfolio of studies; Reduced risk of inaccurate calculation through a single authoritative source; Improved response time to regulatory queries and clinical stakeholders' need for data review

Measure

- As a result of the new capabilities and process improvements across the benefits stated, it has been evaluated to have shown timely oversight, remote monitoring, data acquisition, and effective decision making in spite of the having social distancing norms forced on most, due to the pandemic. As the industry hurriedly turned to digitization and moved to a patient-centric approach with virtual/hybrid trials, MaxisIT®'s end-to-end solution enabled them to keep their trials on track with access to a single-source-of-truth data repository and offered millions of dollars in savings as a result of phasing out expensive and inefficient systems; and replacing it with an automated process, keeping trials on track with timelines and compliant with regulatory requirements.

The MaxisIT Approach



- MaxisIT®'s Clinical Trial Oversight System (CTOS) is conceptualized and designed as a command center par excellence to deliver similar control and assured results, to offer seamless interoperable and metadata-driven data.

- With source-agnostic data ingestion from diverse traditional/virtual/hybrid sources to enable compliance with metadata repository-based standards and a controlled statistical computing environment, the CTOS unifies trial data from disparate systems, to support study planning, clinical data quality, remote data review, clinical review, patient safety, clinical operations management, remote monitoring, CRO performance, portfolio management, risk mitigation, compliance, and submission.

- Offers data-driven digital transformation to acts as a single-source-of-truth data hub, and a complete AI-enabled analytics platform with self-service to conduct predictive and exploratory analytics.

- The platform's self-service data preparation and analytics products are regulatory compliant, validated and delivered through alternate models viz. Enterprise SaaS, On-premise deployment, or as a Hybrid software-enabled service.

- From study setup to data ingestion, the CTOS empowers clinical trial stakeholders to manage clinical development processes with insight into study conduct, take proactive actions to reduce costs, and mitigate risks and ensure compliance.

- Offers the ability to design and setup clinical studies and collaborate with CROs to exchange study setup and integrate data from multiple eClinical systems (e.g. IRTs, CDMS, CTMS, EDCs, Safety systems, IxRS, Labs, EMR Project Planning etc.), different patient-centric technologies (e.g. ePRO, eCOA, eConsent, Claims and other wearables) and multiple large CROs in real-time.

- This AI-powered technology is used to aggregate and report on clinical trials data under full governance to offer built-in oversight reports and supports risk-based quality assessment, qualitative study conduct, performance management, and patient safety.

- Delivers a scalable solution to manage thousands of clinical trials data including legacy and ongoing trials, for geographically distributed teams and remotely collected data from hybrid/virtual trials

- MaxisIT Platform Modules licensed – eXchange Data Management Platform, Clinical Data Repository, pre-configured self-service analytics & Dashboards, Metadata Repository

- MaxisIT Professional Services in use – Onsite and offshore team comprised of business analyst, data management professionals, databased programmers, statistical programmers, and project manager.

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