CASE STUDY SUMMARY

Medidata

Rave EDC, Coder, eCOA, Detect, Safety Gateway, Trial Assurance, Medidata Clinical Cloud

Moderna

DASSAULT SYSTEMES

Moderna, Inc is an American pharmaceutical and biotechnology company based in Cambridge, Massachusetts. It focuses on vaccine technologies based on messenger RNA. Moderna's vaccine platform inserts synthetic nucleoside-modified messenger RNA into human cells using a coating of lipid nanoparticles.

OVERVIEW

TA: mRNA Therapeutic Vaccine
Stage: Phase 3, 30,000 participants
Products: Medidata Clinical Cloud, Rave EDC, eCOA, Coder, Detect, Safety Gateway, Trial Assurance
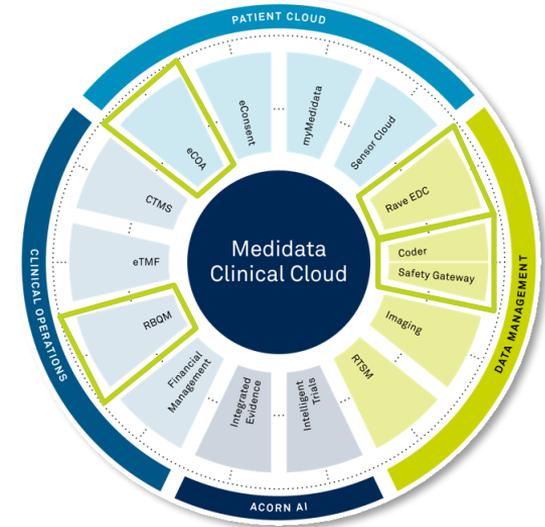
OBJECTIVE

Data capture with the decreased need for office visits.

Accelerate clinical development to bring a vaccine to the public.

Ensure recruitment and safety follow-ups are executed in real-time and ensure data integrity.

SOLUTION

eCOA: Pre-built instruments, once validated, were reused and effort minimized, and automatically ingested into EDC.

Rave EDC: Direct patient data capture, including electronic patient-reported outcomes (ePRO).

Coder: Powered by a machine learning algorithm, ensure consolidated data, queries, and reconciliation to reduce cycle times.

Detect: Monitors data on a real-time basis. The sponsor clinical ops and data management teams uncovered unanticipated data anomalies and triggered corrective action.

Safety Gateway: Automate AE & SAE data collection, tracking, and transmission into the sponsor safety system. Combined with Coder, eliminate multiple data entry and SAE reconciliation, reduce errors, improve patient safety, and save time.

Trial Assurance: All collected data consolidated into an Analysis report. Insights from the report enable the Sponsor to take preventative and corrective action for missed AE, data anomalies, procedural deviations, and other issues.

OUTCOMES

1200% faster delivery of the highly effective and safe vaccine to the public.

Virtualization allowed participants to use their own devices if they chose to.

Centralized Statistical Monitoring.