Deloitte.

CognitiveSpark™ for Clinical

Data and AI-powered Clinical Trials

As drug development becomes more complex and specialized, it can take more than a decade to complete clinical trials and bring a new drug to market. Take a closer look at how ConvergeHEALTH CognitiveSpark for Clinical is designed to automate data management across the clinical trial lifecycle—to help reduce cycle time and deliver breakthrough therapies to patients at the speed of need.

Automating reuse of data components to speed trials

For a patient waiting a life-saving treatment, the current drug development timeline can feel like an eternity. As life sciences CIOs and R&D leaders well know, that's because the traditional flow of data across the clinical trial life cycle can be a complicated maze marked by manual effort, rework, and inefficiency. As one life sciences executive summed up, "We still use the same processes that we used over 20 years ago. It feels like it's 2003, not 2023."

How efficient is your clinical trial lifecycle?

Based on Deloitte's analysis and experience, we found:

- On average, 11+ systems are used during a typical clinical trial
- Trial stakeholders can experience 1-2-week lags before they get the data they need
- An average clinical protocol amendment costs $250-$450K
- The industry median for the study start-up phase is 150 days
- 3+ functions are involved in data management during the typical trial

Key data-related limitations of the traditional clinical trials process:

Fragmented data and disconnected systems

Inputs for trial artifacts are scattered across dozens of systems and formats.

Extensive manual effort

Artifact creation requires manual data transcription from documents and systems.

Rework and repetition

Although trials typically reuse data components, the same work is repeated across trials. In the words of one pharma executive, "We end up building the same database 400 times."

Challenges in enabling innovative trial models

Complexities and limitations related to integrating data from new sources create challenges with virtual trial designs.

These pain points add up, contributing to both trial time and cost. To help alleviate the pain, and open new opportunities, life sciences companies need an advanced solution that harnesses the power of AI to streamline the clinical trials life cycle.

CognitiveSpark for Clinical uses AI to power digital data flow

ConvergeHEALTH CognitiveSpark for Clinical is a modular, cloud-based, metadata-driven solution. It is designed to automate data management across the clinical trial lifecycle to digitally generate structured and standardized deliverables from a range of input documents and sources. These elements are then intelligently interpreted and transformed to set up downstream systems, auto-populate required reports and analyses, and generate content for key trial artifacts.

Our solution can complement your existing core transactional management systems by sitting on top and enabling the sharing of common pieces of data and metadata. It is designed to leverage existing systems to seamlessly integrate the data flow—providing a single, collaborative touchpoint for virtually all interactions during a clinical trial.

Efficiency
+
Speed
+
Savings
=
Value for you and your patients

The benefits

With ConvergeHEALTH CognitiveSpark for Clinical, you gain a machine learning-enabled and user-friendly interface that puts power in clinical researchers' hands that can empower you to deliver faster, more efficient, and significantly less expensive clinical trials. Potential benefits include:

Faster trial cycle times

- Downstream use of data elements, combined with automated suggestions based on past studies, eliminate repetitive data input, and reduce completion times
- Automated data quality checks provide prompt feedback and enable faster queries to sites
- User-driven Study Data Tabulation Model (SDTM) conversions reduce the need for developer involvement, reducing time-consuming back-and-forth between end users and developers
- Cloud-based design and application accelerators reduce implementation time

Greater trial efficiency and data quality

- Collaborative authoring platform allows for efficient workflows and approval submissions
- Metadata traceability to standards, and digital export to the Electronic Data Capture (EDC) system, eliminates manual configuration and preserves data quality
- Machine learning automates SDTM configuration and conversion
- Faster data availability for analytics improves site monitoring, enabling you to make well-informed decisions regarding study feasibility
- The system automates manual, time-intensive processes to free up resources for other value-add activities

Lower trial costs

- Standardized workflows and documentation reduce manual error and result in cost reduction
- Automation capabilities enable you to add studies at a lower cost by limiting resource needs

Scalability and customization

- ConvergeHEALTH CognitiveSpark for Clinical can be extended across therapeutic areas and trial types
- It can be embedded in your company's ecosystem and workflow through an end-to-end digital workflow
- The product is accompanied by Deloitte's organizational change management services to help you get up and running

ConvergeHEALTH CognitiveSpark for Clinical spans six areas to automate the entire clinical trials lifecycle:

Foundational Data and Metadata Backbone

Clinical Data Repository (CDR):

- Scalable data foundation (information exchange and integration) for automated quality profiling
- Unified storage for raw, enriched, and analytical data sets
- Business rule engine capability to support data driven alerts

Metadata Repository (MDR):

- Scalable platform foundation
- Enterprise integration with sponsor ecosystem
- Standards management with link to industry standards
- Seamless access to metadata for consumption by downstream systems

AI/ ML Algorithm Store:

- Shared analytical services through a set of standard APIs focused on insight generation

ConvergeHEALTH CognitiveSpark for Clinical can help significantly cut cycle times and reduce trial costs

Workflow Orchestration

Study Designer:

- Guided digital study builder
  - Creates a comprehensive digital study specification (objectives, endpoints, biomedical concepts, and eligibility criteria)
  - Disseminates digital study design for more efficient downstream usage in the clinical trial life cycle

Data Harmonization:

- Integrated mapping from source systems to SDTM and Analysis Dataset Model (ADaM), using metadata-based, reusable transformation rules aided by automation and machine learning
- Robust data quality checks support mapping accuracy and identify potential issues in source data

Tables, Listings, and Figures (TLF) Creation:

- Intuitive web-based interface automates creation of TLF shells using standards and templates

How the product works

Through API integrations with leading content authoring tools, the product exchanges digital information to generate a draft protocol and clinical study report that contain data elements—which are traced back to source concepts and individual writers.

With this information, life sciences leaders can address amendments, understand the impact of changes, and finalize the protocol. All at a faster pace and lower cost.

How the product continuously improves

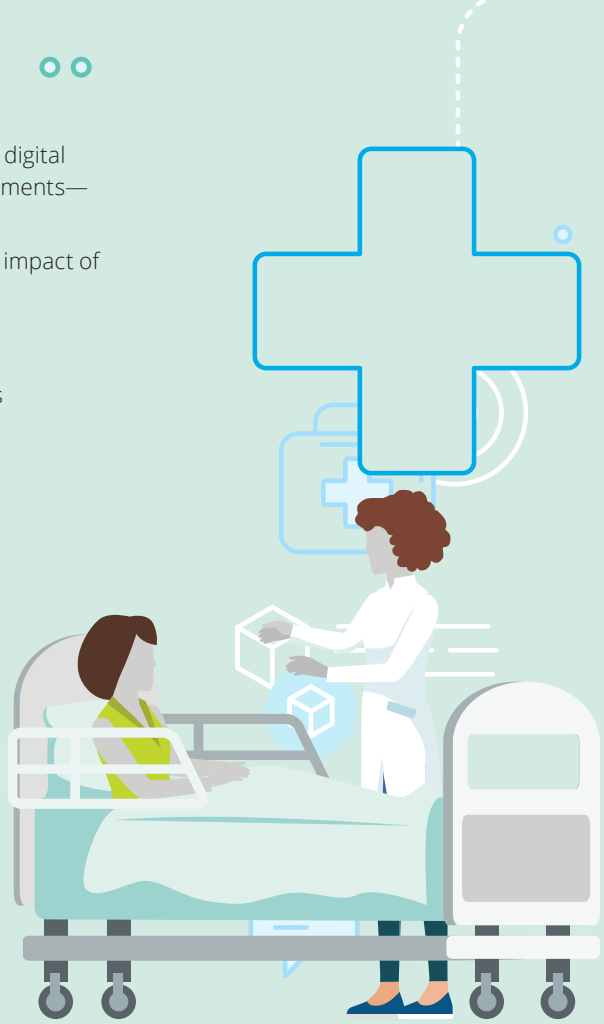
Continuous ingestion and analysis of data support the workflow of clinical researchers

Consumes: Clinical study artifacts and other data sources are ingested into Deloitte's secure platform

Analyze: AI technologies convert unstructured data to digitixed data elements, made available to end users

Streamlines: Clinicians, biostatisticians, and medical writers are armed with digital tools, data elements, & recmomendations to rapidly create new deliverables

Learns: The system learns from ongoing use to more efficiently and accurately process data and provide recommendations



So, what's the bottom line? Patients could get faster access to safe medications that can change—and potentially save—their lives.

AI solutions for life sciences leaders

AI will likely be most impactful when deployed strategically and scaled across the entire enterprise. That is why Deloitte is developing AI offerings that can span the life sciences value chain, from molecule to market.

Deloitte offers a robust, integrated suite of AI-driven capabilities, solutions, and products, built on a common platform, that can enable new transformative opportunities, drive operational efficiency, fuel business growth—and most importantly, can benefit patients.

Our key AI solutions can help biopharma:

- Automate data management for clinical trials
- Increase trial efficiency and data quality
- Reduce trial cycle times
- Reduce trial costs

Start the conversation.

For more information, please contact:

Siddharth Karia
Principal
Deloitte Consulting LLP
skaria@deloitte.com

Amy Cheung
Principal
Deloitte Consulting LLP
amyycheung@deloitte.com

Suman Kumar
VP, Product Management
Deloitte Consulting LLP
sumankumar8@deloitte.com

Designed by CoRe Creative Services. RITM1275968