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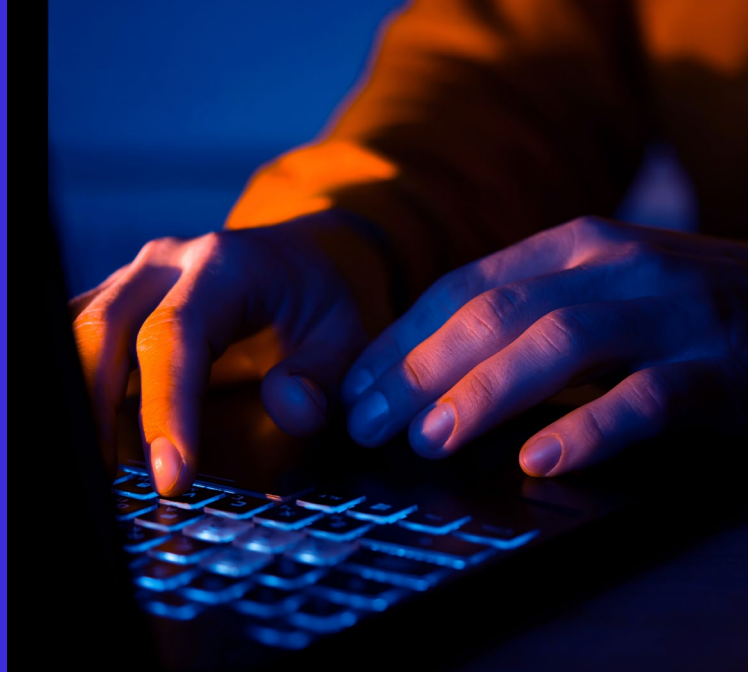
# Digital Data Flow Solution: From Protocol to Study Readiness

Create one structured study definition. Connect everything that follows

**Flyer**



## One Structured Study Definition. Connected Clinical Trial Execution.

Clinical study execution depends on how accurately study intent moves from the protocol into the systems, teams, documents, and data that bring a study to life.

Today, the same study information is repeatedly interpreted, re-keyed, and recreated across the clinical ecosystem—creating unnecessary handoffs, inconsistencies, and downstream rework.

Hexaware's digital data flow solution is a metadata-driven framework that transforms clinical protocols into a CDISC Unified Study Definitions Model (USDM) 4.0 study definition and connects it to downstream clinical systems, processes, and AI-assisted workflows.

The result is a structured foundation for more connected clinical trial automation.

## Digital Data Flow Capabilities Available Today

### Author Once

Transform protocol content into a structured, machine-readable USDM 4.0 study definition.

### Connect Everywhere

Share a common study-definition foundation across downstream clinical systems through governed integrations and APIs.

### Protocol Amendment Management

When study designs evolve, structured study definitions help synchronize downstream updates across connected processes, reducing repetitive manual effort while maintaining governance and review.

## Digital Data Flow Across the Study Lifecycle

Clinical Protocol

↓

CDISC USDM 4.0 Study Definition

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Study Design Metadata | Biomedical Concepts | Data Standards

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**Connected Clinical Systems**
EDC | CTMS | IWRS/IRT | eCOA | Labs | Data | Management | Monitoring

↓

Operational Study Assets & Downstream Reporting

↓

AI-assisted Clinical Trial Document Generation

**One structured study-definition foundation. Connected downstream execution.**

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## The Numbers That Matter

### 12–16 wk ➡ 4–6 wk

**Protocol final to database go-live**

Taking study build off the critical path entirely

### ~25 weeks

**Recovered on an illustrative Phase I study**

Roughly 3 to 6 months to first submission

### 45%

**Share of substantial protocol amendments**

That sponsors themselves deem avoidable

## Where Digital Data Flow Can Help

### Study Start-up

**26 wk ➡ 17 wk**

Protocol Final to First Patient In

### Study Build

**12–16 wk ➡ 4–6 w**

Protocol Final to Database Go-live

### Study Conduct

Reduce repeated interpretation by enabling connected systems to work from the same structured study definition.

### Study Closeout

4–8 Weeks ➡ 2–3 Weeks

Illustrative reduction in time from Last Patient Last Visit (LPLV) to Database Lock.

### Clinical Trial Data Lineage

Maintain continuity between protocol intent, study design metadata, downstream systems, and reporting through a structured study-definition foundation.

## Building on the USDM 4.0 Foundation

Once study information is structured in USDM 4.0, it can be combined with sponsor templates, SOPs, data standards, approved supporting documents, statistical and medical inputs, operational assumptions, and study-specific information to accelerate AI-assisted clinical trial document generation.

The objective is to help teams produce review-ready drafts faster—not replace expert judgment.

## Potential AI-assisted Deliverables

- Risk Assessment Draft
- Protocol Deviation Plan Draft
- Monitoring Plan Draft
- Data Management Plan Draft
- Full SAP Draft
- Protocol Amendment Draft

## Governed AI Generation

AI-generated drafts maintain traceability to the structured study definition and supporting source content.

Every deliverable is intended for human review, validation, and approval before use.

## Roadmap

### Target: Six Review-ready Drafts in Under One Day

The long-term vision is to combine Digital Data Flow with AI-assisted document generation to accelerate the creation of six core study documents.

## Illustrative Pilot Targets

### 6–8 Weeks → Under 1 Day

Target time to generate review-ready first drafts.

### 470 Specialist Hours → 88 Hours

Illustrative reduction in document preparation effort.

### 382 Hours Saved Per Study

Illustrative effort savings across six document deliverables.

Roadmap figures represent design targets and pilot objectives pending validation.

## Why It Matters

Digital data flow solution provides a structured foundation for:

- Clinical trial automation
- Clinical trial protocol automation
- Clinical trial data lineage
- Protocol amendment management
- AI-assisted clinical trial document generation

Together, these capabilities help reduce repetitive manual effort, improve consistency across downstream processes, and create a more connected approach to study execution.

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# Build the Study Once. Let the Ecosystem Move with It.

Digital Data Flow helps transform protocols into structured study definitions that connect clinical systems, support downstream execution, and establish the foundation for future AI-assisted workflows.

**Schedule a discovery session to explore how the digital data flow solution can support your clinical trial modernization journey.**

**Contact: marketing@hexaware.com**

## About Hexaware

Hexaware is a global technology and business process services company. Every day, Hexawarians wake up with a singular purpose: to create smiles through great people and technology. With this purpose gaining momentum, we are well on our way to realizing our vision of being the most loved digital transformation partner in the world. We also seek to protect the planet and build a better tomorrow for our customers, employees, partners, investors, and the communities in which we operate.

With offices across the world, we empower enterprises to realize digital transformation at scale and speed by partnering with them to build, transform, run, and optimize their technology and business processes.

Learn more about Hexaware at https://www.hexaware.com.