

Digital Data Flow (DDF) Accelerator

Start Studies Weeks Sooner

Flyer



A protocol may be approved, but its information is still repeatedly interpreted and re-entered across EDC, CTMS, IWRS, data management, and monitoring teams. Hexaware's Digital Data Flow Accelerator converts the protocol into governed, reusable study data, allowing downstream activities to start earlier while keeping every team aligned.

Why This Matters Now

The shift from document-centric protocols to structured study definitions is already underway.

Hexaware's Digital Data Flow initiative is advancing protocol digitalization, CDISC USDM provides a standardized model for exchanging study definitions, and ICH M11 establishes a harmonized protocol structure. Organizations that act now can accelerate study start-up while preparing for the industry's next operating model.

By acting now, organizations can:



Reduce weeks of repeated interpretation, transcription, and reconciliation.



Maintain consistent study definitions as they move across teams and systems.



Reuse approved protocol information across systems, documents, and study workflows.



Adopt structured protocols incrementally without replacing their existing clinical technology landscape.

One Approved Study Definition. Multiple Downstream Uses.

1. Structure

Convert the Protocol into Governed USDM Data

- Convert protocol PDF or DOCX documents into structured CDISC USDM 4.0 study definitions, enriched with terminology mapping, confidence scores, validation rules, and expert review.
- Capture core study design elements, including objectives, endpoints, eligibility criteria, study arms, cohorts, interventions, epochs, visits, activities, and the schedule of activities.
- Preserve end-to-end source traceability, enabling reviewers to verify every extracted element against the corresponding protocol page or section.

2. Approve

Review and Approve Before Reuse

Apply validation and human approval before publishing the study definition downstream. Automation supports extraction and review, while the approved USDM record remains controlled and authoritative.

Reviewers can ask traceable protocol questions such as:

- What are the inclusion and exclusion criteria?
- When is the first pharmacokinetic assessment?
- Which visits require ECG collection?

Answers are grounded in the protocol and linked to the supporting source, helping reviewers confirm meaning rather than trust an opaque AI response.

3. Connect

Deliver Approved Study Definitions Across the Clinical Landscape

Publish the approved USDM study definition to the SDR Hub, creating a governed distribution layer for existing clinical systems and document workflows without requiring a wholesale platform replacement.

- Protocol → USDM 4.0 → SDR Hub → EDC | CTMS | IWRS | DMP | CMP | downstream study assets.
- Use APIs and governed exports to make approved study information available for system configuration, document drafting, portfolio analysis, and study-design reuse.
- Extend the same approach to historical protocols, turning archived documents into structured and searchable study assets.

Key Benefits

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Reduce repeated setup and reconciliation so downstream teams can begin with approved study information earlier.

Reuse Approved Study Information

Publish the governed USDM study definition through the SDR Hub for controlled use across multiple downstream consumers.

Reduce Manual Risk

Limit transcription errors, inconsistent interpretation, and version drift across functions.

Prepare for the Industry Shift

Build on CDISC USDM 4.0 and align with the movement toward structured protocol content reflected in DDF and ICH M11.

Make Traceability Visible

Connect extracted fields, review answers, and generated content to their supporting protocol evidence.

Work with the Existing Landscape

Deploy in the client's cloud and integrate through APIs or governed exports rather than forcing platform replacement.

4. Generate

Accelerate Downstream Setup and Drafting

Use the approved USDM record to provide consistent structured inputs and accelerate the creation of downstream drafts.

Illustrative downstream outputs include:

- Data Management Plan (DMP)
- Central Monitoring Plan (CMP), risk profile, protocol deviation list, and structured system-configuration inputs

Maintain traceability from generated content to the approved study definition and, where applicable, back to the original protocol source.

What You Gain

A protocol becomes an approved, traceable USDM study definition that can be governed in the SDR Hub and reused across downstream workflows.

- Earlier downstream execution with less repeated protocol interpretation
- Greater consistency across teams, systems, and study documents
- A traceable foundation for EDC, CTMS, IWRS, DMP, CMP, and other study assets
- A practical, incremental path to structured protocols without replacing the existing technology landscape

See It with Your Own Protocol

Bring one representative protocol and see how it is transformed into a structured, traceable CDISC USDM 4.0 study definition.

You'll see:

- Extracted study elements linked directly to the supporting protocol evidence.
- An approved USDM record published through the SDR Hub and exposed through APIs.
- Initial downstream DMP and CMP drafts generated from approved study information.

Bring Us One Protocol

We'll demonstrate the complete journey—from protocol to approved USDM, governed distribution through the SDR Hub, and reusable downstream study assets. **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.