Yes, You Can (Digitalise That):

Streamlining Study Design through Protocol Digitalisation

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Disclaimer

The views expressed in this presentation are my own and do not necessarily reflect the views of ***novo*** *or the conference organizers.*

The Protocol as **Data**, Not a **Document**

Write it once. Reuse it everywhere.

One structured protocol feeding study design, start-up, analysis and submission

Built on open industry standards, CDISC SDTM & USDM and ICH M11, not a proprietary platform

In production at Novo since 2023, and growing across the industry

CDISC USDM

ICH M11

Agenda

- The Value of Protocol Digitization
- The Novo DDF Journey
- People and Process
- Where the Industry Goes Next
- 5 min Q&A

Value of Protocol Digitization

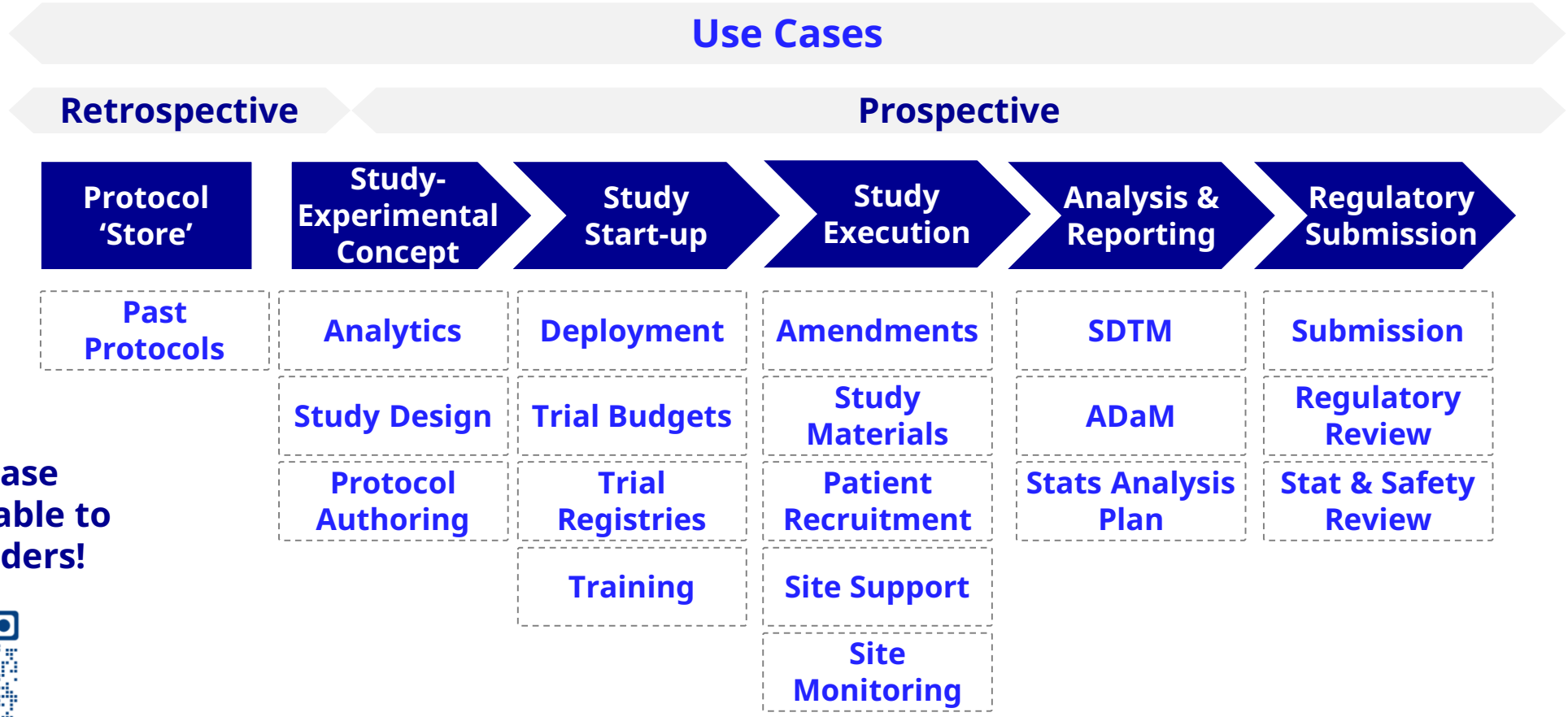
Reported value stories across the ecosystem

Study Design & Review Time Reduction	**75% decrease in average review,** through parallel stakeholder review, automated compliance checking, and predictive risk prioritization
Create Study Budget	**85% reduction in cycle time,** recognition and assignment of standard CPT codes and associated median costs
Develop Specimen Management Plan	**1 day reduction in creation time,** derived from a Digital Schedule of Activities
Manage Study Startup	**30% reduction in overall startup time,** EDC build, eCOA setup, IRT setup, CTMS setup, Data Transfer spec creation

Representative value stories; actual results will vary by organization

Protocol Digitization Use Cases

Across the study lifecycle



DDF Use Case Library Available to all stakeholders!

Above highlights example/potential use cases

Potential Implementation Pathways

Examples of ways to get started based on readiness and priorities, organizations can pursue different pathways or approaches

Pathway Reuse:

- Digitize completed study protocols to CDISC's USDM to enable analytics and reuse, without changing how protocols are authored today

Pathway Convert:

- Maintain document-based authoring and convert protocols to USDM to enable automation and reuse of both structured and narrative content downstream

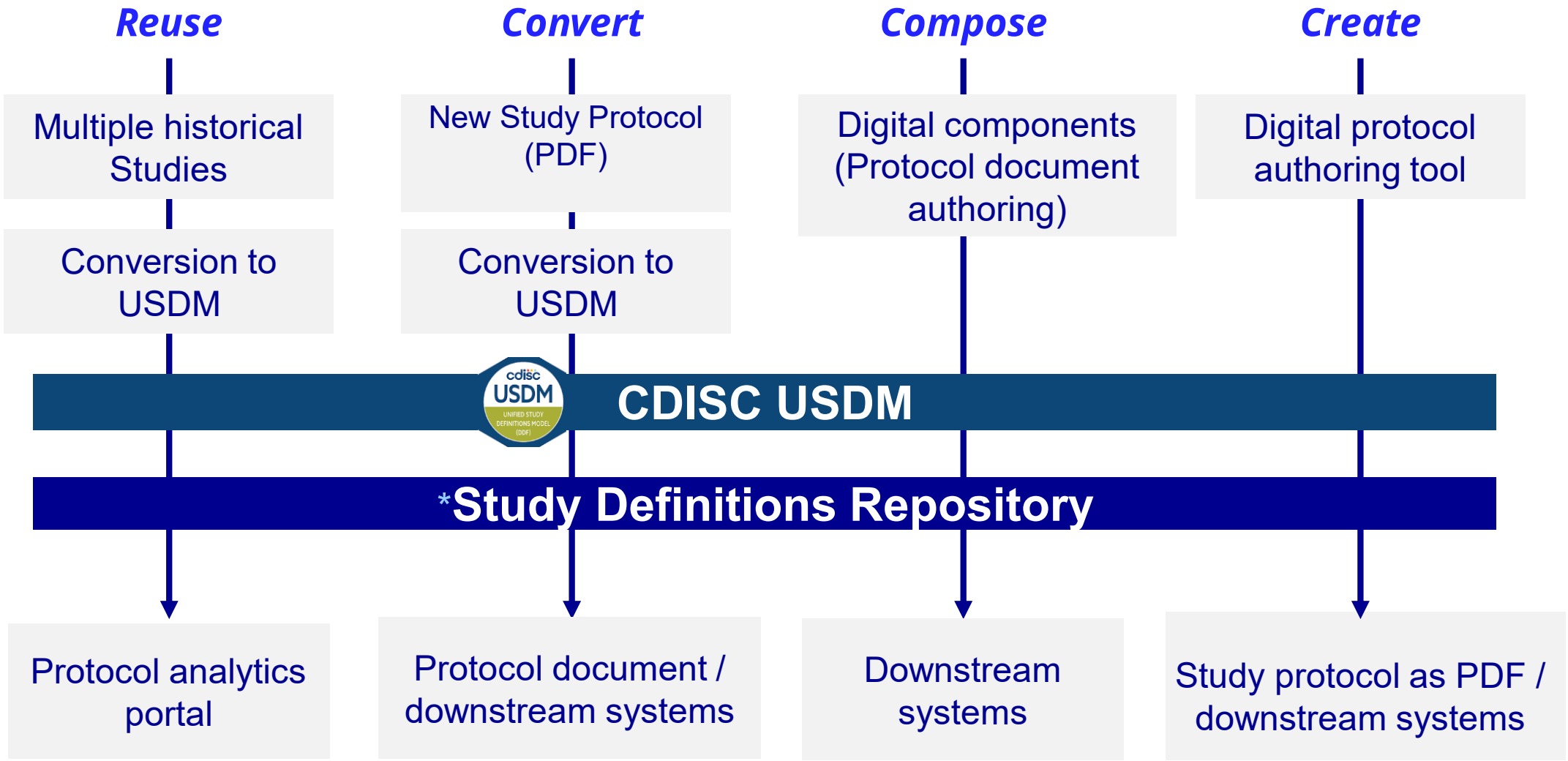
Pathway Compose:

- Digitize high-value structured components (e.g., SoA) to unlock targeted use cases while maintaining document-based authoring

Pathway Create:

- Author protocols digitally from the outset, establishing USDM as the source of truth for end-to-end reuse and integration

Multiple Routes, One Destination: Protocol Digitization



* Or protocol library, middleware or similar

We built our own DDF tool



CHALLENGE

- ***Why DDF:*** *Skill areas working in silos, inconsistencies due to interpretations and* ***no*** *one source of truth*
- ***The trigger***: 20-year-old metadata and study definitions repository (MDR/SDR) was reaching end-of-life



SOLUTION

- ***The search***: Scanned the market, **no** off-the-shelf solution fit the needs at that time
- ***The Need***: standards management, reusability, interoperability, one source of through!



IMPACT

- ***The decision***: build our own, keeping what worked, fixing what didn't
- ***The foundation***: open-source, industry standards (CDISC, emerging ICH M11) & the DDF vision

*2023: The Novo DDF tool – **OpenStudyBuilder (OSB)** - went live, supporting protocol authoring with a digitally connected Schedule of Assessments (SoA)*

What is DDF @Novo?

INPUT

Capture study concepts digitally, once

- **Regulatory data standards requirements**
- Study design, outcomes and criteria
- **Schedule of Activities**
- Data transfer and collection specifications
- Data quality elements

STANDARDIZE

One harmonized language across studies at Novo

- **OpenStudyBuilder (OSB) (MDR/SDR)**
- Single source of truth for study definitions
- Compliance with CDISC, USDM, and ICH M11 standards
- Inconsistencies resolved once, not per study

MAKE ACCESSIBLE

Reuse metadata automatically downstream

- **Protocol authoring**
- Study planning and data collection
- SDTM and ADaM generation, TFL
- Clinical study reporting, disclosure and submission

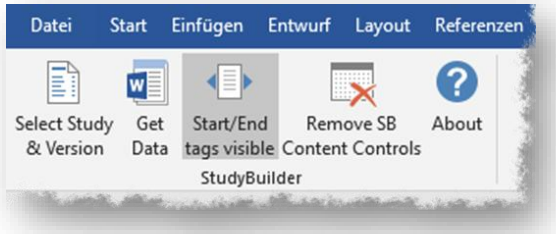
OPEN STUDY BUILDER

One place to specify and manage key clinical study concepts and standards

novo

From Structured Data to an ICH M11 Protocol

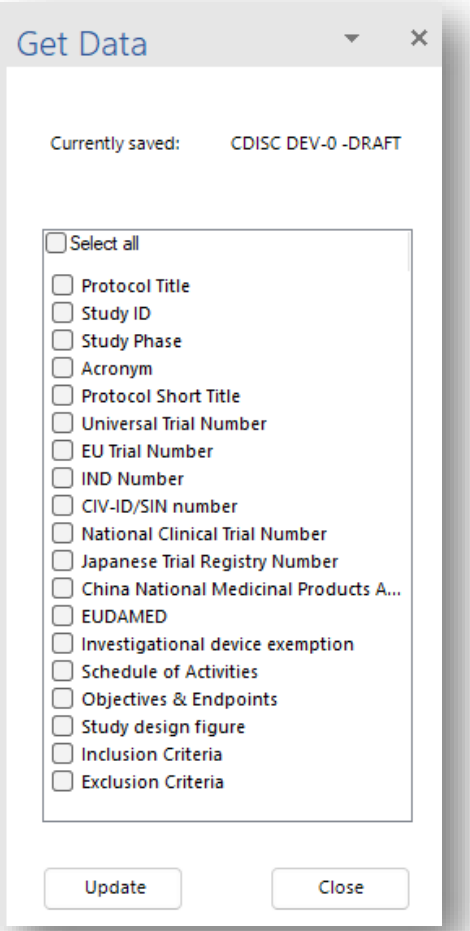


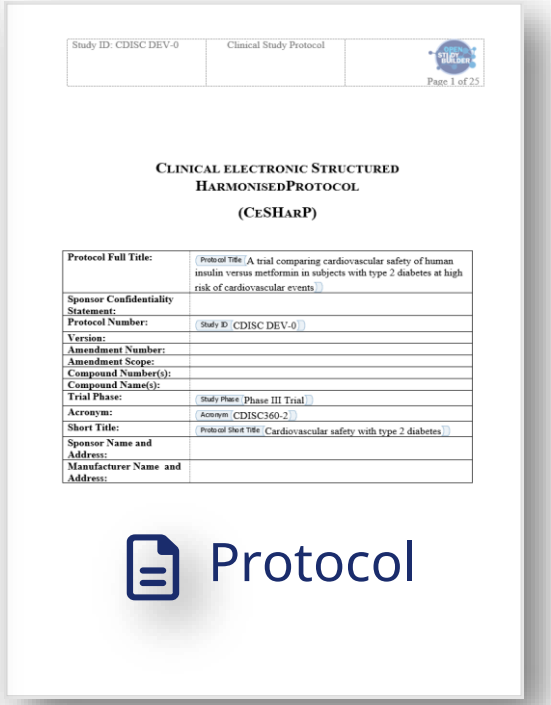


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One-way connection

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Protocol

Adoption Learnings: People and Process Win

People

- Engage end users early, technology enables, people adopt
- Fund the business change across all impacted business areas

Process

- Sharing metadata is high value but challenging across business areas
- Cross-functional products need central ownership and value-chain involvement
- Define clear, measurable outcomes, short and long term

Technology

- Documents to data is a behavior change, not a system swap, it needs training, support and visible leadership sponsorship
- Speed and ease of use are the adoption strategy, if it’s slow, people go back to Word

OpenStudyBuilder Collaboration Established



Collaboration Agreement signed 2026

Protocol Digitization: Inflection Point

ESTABLISH

Protocol digitization is an **industry-wide** shift, sponsors, providers, sites and regulators moving in one direction

MATURE

The foundation is **real, not theoretical,** a common data model, terminology and ICH M11 alignment are in place

ACCELERATE

From standards on paper to **protocols in production**, saving time, money and resources, and letting teams move faster

DDF is no longer a concept, implementation is happening now!

Stay in Touch!

OSB website

OSB YouTube

OSB LinkedIn

DDF Use Cases

DDF Adoption Stories

Check out the SCOPE Challenge



Automated Configuration of Data Acquisition: Use Cases of Interest

- The autoconfiguration of one or more applications that collect clinical trial data e.g. eCOA, ePRO, IRT/IWRS/IVRS/Randomization, LIMS, eSource, EHR, Imaging Systems, various digital health technologies, etc.
- For data types (e.g. central lab data) that are typically transferred to sponsors via file transfer or system-to-system connections challenge submissions can include the automation of data transfer specifications and/or the configuration of the file transfer process.
- Connections to additional metadata sources to achieve higher degrees of automation. For example, functionality that matches required protocol assessments and data to a standard forms library maintained by a sponsor.
- Features such as leveraging AI models and USDM input to auto-generate eCRF forms.
- Functionality to maintain and visualize the lineage between the requirements in a version of the protocol and forms, objects and fields in the data acquisition application.
- Procedures for quality control checking to confirm the correct configuration of data collection applications such as review of data required by timepoints and generation of test data and automated testing scenarios.
- Amendment impact analysis detailing the impact of a given amendment on the configuration of data acquisition applications