

OpenStudyBuilder: Metadata-Driven Clinical Study Design

By Adrien Laurent, CEO at IntuitionLabs • 12/13/2025 • 35 min read

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Executive Summary

The **OpenStudyBuilder** (OSB) is a novel open-source solution to the long-standing challenge of generating consistent, standards-driven clinical study specifications. Traditional study design workflows rely heavily on document-centric processes, leading to duplicated effort, miscommunication, and delays as protocol elements are manually re-entered into [case report forms \(CRFs\)](#), datasets, and reports. In contrast, OpenStudyBuilder implements a **metadata-driven, “define once, use many times”** approach: study definitions (objectives, schedules, assessments, etc.) are stored in a semantic graph repository and linked to CDISC and other terminologies. This enables automated propagation of a single study definition across protocol documents, CRF design, SDTM/ADaM mapping, and other trial systems, vastly improving consistency and efficiency.

OpenStudyBuilder is built on modern software components (a Vue.js web app, a Neo4j graph database, a Python FastAPI backend, and auxiliary import tools) and supports key clinical data standards (CDISC SDTM, ADaM, CDASH, ICH M11, etc.) while enabling cross-silo collaboration. Released in late 2022 by Novo Nordisk under permissive licenses (MIT and GPLv3) as part of the CDISC Open Source Alliance (COSA), OSB has already been adopted internally and demonstrated at major industry conferences (PHUSE, CDISC, SCOPE, DIA). Early case reports indicate that OSB can automate large parts of protocol and CRF generation; for example, Novo Nordisk is using OSB in production to define structured Schedule of Activities and populate them into protocol templates (^[1] www.linkedin.com).

The purpose of this report is to provide an **in-depth technical and contextual analysis of OpenStudyBuilder**. We review the background of clinical data standards and metadata automation (including CDISC 360 and Digital Data Flow initiatives), detail OSB’s architecture and components, and present evidence for its effectiveness. We discuss use cases, community collaboration (COSA, Slack, GitHub), and integration with related projects (TransCelerate DDF, ICH M11, FDA standards). Finally, we examine future implications, including how OSB’s semantic knowledge graph can support advanced analytics and regulatory submission processes. Throughout, we cite academic and industry sources to substantiate claims.

Introduction and Background

Modern [clinical research](#) requires coordination of complex study definitions across multiple systems. A clinical trial study must be specified in a protocol document (defining objectives, population, arms, visits, and assessments) and then translated into data collection instruments, tabulation datasets, statistical analysis datasets, and regulatory submissions. Historically, these tasks have been performed by separate teams (medical writers, data managers, statisticians) using disparate tools (word processors, spreadsheets, EDC systems, programming scripts). As a result, manual “handoffs” and re-entry of the same information introduce errors, delays, and inefficiencies (^[2] www.openstudybuilder.com) (^[3] www.transceleratebiopharmainc.com).

Regulators and industry have recognized that **a document-centric approach creates bottlenecks**. TransCelerate (an industry consortium) notes that clinical protocols lack a standard machine-readable format and that on average there is a **4-month lag** between protocol approval and [study start-up](#) due to manual processes (^[3] www.transceleratebiopharmainc.com). Converting protocol information twice (e.g. into CRFs and then into SDTM datasets) “limits traceability and re-use” (^[4] www.transceleratebiopharmainc.com). Likewise, the CDISC community has highlighted gaps in existing standards metadata: while [CDISC standards](#) (e.g. SDTM, ADaM, CDASH) define data structures, much of the study context (study rationale, visit schedules, semantics of variables) is stored in free text within documents. The CDISC 360 initiative aims to add a **conceptual metadata layer** for the standards to close these gaps (^[5] www.cdisc.org) (^[6] www.cdisc.org). The goal is to enable **metadata-driven automation** so that study definitions can flow seamlessly into datasets and reports.

In parallel, regulatory guidance is moving towards structured protocols. The **ICH M11 CeSHarP guideline** (for electronic protocols) provides a standardized template, and TransCelerate's **Digital Data Flow (DDF)** initiative is promoting the **Unified Study Definition Model (USDM)** to digitize protocol content (^[7] www.linkedin.com) (^[8] www.transceleratebiopharmainc.com). These efforts all point to a future where protocol content is represented in a structured, computer-readable form from the outset, enabling "write once, read many times" workflows (^[9] www.linkedin.com).

Open-source software is increasingly recognized as a driver of innovation in pharma. Early successes (Pinnacle 21's OpenCDISC validator for standard compliance) showed that community-developed tools can achieve rapid adoption. In 2021, CDISC launched the **Open Source Alliance (COSA)** to coordinate communal projects (www.glacon.eu). Pharma industry groups (PHUSE, R Consortium) also encourage shared tools (e.g. R-based submission toolkits, R validation hubs (www.glacon.eu)). Against this backdrop, **OpenStudyBuilder emerged as a COSA-endorsed project to modernize study definition**. Announced by Novo Nordisk in 2022, OSB uses linked data principles to implement an end-to-end study metadata repository (^[10] novo-nordisk.gitlab.io) (www.glacon.eu). This report traces its evolution, design, and potential impact in the context of these trends.

Challenges in Clinical Study Specification

Clinical study specification involves translating a high-level research plan (protocol objectives, design, endpoints) into detailed data collection and analysis plans. This process is fraught with **redundant work and handoffs**. For example, objectives written in the protocol may be re-typed into CRF form descriptions and later re-coded as SDTM variables. Discrepancies often arise: different teams might use different terms for the same concept, requiring reconciliation (^[11] www.openstudybuilder.com) (^[12] www.linkedin.com). A typical trial can involve dozens of document templates, each requiring consistent content. The OSB project document explicitly enumerates these pain points: multiple silos of work (protocol authors, data managers, statisticians) lead to "resource-demanding double work," "parallel work done in silos," and "many handovers" that introduce lag-time and errors (^[2] www.openstudybuilder.com).

Furthermore, existing standards do not eliminate this manual burden. CDISC defines data models for datasets, but the protocol content (eligibility criteria, study activities, etc.) often resides in unstructured narrative. CDISC 360 and 360i point out that **inconsistencies and gaps in the standards** — and the lack of a conceptual metadata layer — make automation difficult (^[11] www.openstudybuilder.com) (^[13] www.cdisc.org). As the CDISC 360 initiative states, the current approach yields "more text than metadata," and "gaps in standards metadata limit automation opportunities" (^[5] www.cdisc.org). Similarly, DDF work emphasizes that manual transcription and duplication are "non value-added activities" that prolong trial start-up (^[3] www.transceleratebiopharmainc.com) (^[14] www.transceleratebiopharmainc.com).

Quantitative evidence of these inefficiencies is scant, but qualitative industry reports highlight the consequences: for example, TransCelerate notes an average 4-month delay from protocol sign-off to study launch due to document-based workflows (^[3] www.transceleratebiopharmainc.com). In a survey of drug developers, editorial processes and statistical programming were frequently cited as bottlenecks requiring improved automation. Industry leaders argue that without structured data standards, even sophisticated tools (EDC, CTMS, reporting software) cannot communicate seamlessly (^[15] www.linkedin.com) (^[13] www.cdisc.org).

In summary, the background problem is that **clinical trial design information is disconnected**: (1) stored across multiple documents and systems, (2) often manually duplicated, and (3) only loosely tied to data standards. These factors create delays, reduce data quality, and prevent rapid "query-based" workflows. OpenStudyBuilder is intended to address precisely these challenges by providing a **single, metadata-driven source of truth** for study definitions, as discussed below.

The OpenStudyBuilder Solution

OpenStudyBuilder (OSB) presents a **unified, semantic metadata repository and authoring platform** for clinical study design. Its core vision is to create a **concept-based framework** in which study specifications can be defined once and reused throughout the trial lifecycle (^[2] www.openstudybuilder.com) (^[16] www.linkedin.com). Novo Nordisk describes OSB as enabling “end-to-end consistency” from the protocol through CRF design to datasets, analysis, reporting, and submissions (^[17] novo-nordisk.gitlab.io) (^[18] www.openstudybuilder.com). In practice, OSB consists of:

- **Standards and Templates Library:** A clinical Metadata Repository (MDR) containing code lists, controlled terminologies (e.g. CDISC, SNOMED, LOINC, MedDRA) and *concept-based standards* (activities, units, compounds, CRF templates, etc.) (^[19] novo-nordisk.gitlab.io) (^[20] novo-nordisk.gitlab.io). The library supports versioning and collaborative editing of these standards.
- **Study Definition Repository:** A metadata model for individual studies, including objectives, populations, interventions, schedules, visits, eligibility criteria, and assessments (^[21] www.openstudybuilder.com) (^[22] novo-nordisk.gitlab.io). Multiple levels of the study (protocol-level, detailed operational level, etc.) can be defined. Changes are version-controlled with audit trails.
- **Graph Data Model:** Under the hood, OSB uses a Neo4j graph database (the “Clinical MDR”) to link all concepts and study elements semantically. For example, each *Activity* in the library can be connected to specific CRF question definitions, SDTM variables, and ADaM analysis variables (^[23] www.openstudybuilder.com) (^[16] www.linkedin.com). This graph structure facilitates “linked metadata” across domains.
- **Web Application:** A multi-module Vue.js interface (“OpenStudyBuilder App”) where users browse the standards library, define study attributes, and visualize the study schema. The UI guides study teams through protocol structure, schedule, and linked assessments with real-time consistency checks (^[24] novo-nordisk.gitlab.io) (^[25] github.com).
- **API Layer:** A RESTful Python FastAPI service (Clinical MDR API) for all CRUD operations on the metadata, enforcing rules, workflows, and access control (^[26] www.openstudybuilder.com) (^[27] novo-nordisk.gitlab.io). This allows external systems (EDC, CTMS, analysis tools) to interoperate with the repository. In particular, OSB provides a **Digital Data Flow (DDF) API Adapter** that implements the CDISC/TransCelerate interface and supports the Unified Study Definition Model (USDM) standard (^[28] www.openstudybuilder.com) (^[3] www.transceleratebiopharmainc.com).
- **Import/Export Tools:** Scripts to load external standards (e.g. from the CDISC Library) into the graph, and to output study definitions to submission formats. For example, OSB can export an SDTM “Study Design” dataset or generate an ICH M11-compliant protocol document via a Word Add-In (^[29] www.linkedin.com) (^[30] www.openstudybuilder.com).

Collectively, these components create a **“single source of truth”** for study metadata (^[31] www.openstudybuilder.com). Rather than subject matter experts writing separate documents, they work within OSB to define objectives, endpoints, visit windows, etc., using standards from the library. Those definitions automatically populate downstream design elements. For instance, selecting an “Urine Bilirubin” activity in the protocol can automatically determine the CRF data fields (numeric vs categorical), SDTM variable mapping, units list, and controlled terminology – all configured behind the scenes (^[32] www.openstudybuilder.com) (^[16] www.linkedin.com). This *concept-driven approach* (sometimes called “biomedical concepts”) ensures that one “activity instance” binds protocol narrative to data model details (^[23] www.openstudybuilder.com) (^[16] www.linkedin.com).

OpenStudyBuilder’s solution architecture is summarized in Table 1. Core software components (UI, API, data model, etc.) are open-source (MIT or GPLv3 licenses) and built on industry platforms. A modern Vue.js front end

is paired with a Neo4j graph database and Python backend ([33] [github.com](#)) ([34] [www.openstudybuilder.com](#)). Because of the graph approach, complex relationships (such as parent-child visit windows or CRF item hierarchies) can be represented naturally, overcoming the limitations of flat relational schemas ([35] [pmc.ncbi.nlm.nih.gov](#)). As the OSB documentation notes, graph databases efficiently model “highly interconnected data,” allowing the platform to, for example, treat SNOMED codes, units (UCUM), and CDISC Code Lists all as linked nodes ([35] [pmc.ncbi.nlm.nih.gov](#)) ([19] [novo-nordisk.gitlab.io](#)).

Table 1: Core components of the OpenStudyBuilder platform. Components include the web application (user interface), API services, metadata repository (graph model), documentation portal, and import utilities. (Source: OSB documentation ([34] [www.openstudybuilder.com](#)) ([36] [www.openstudybuilder.com](#)).)

Component	License	Technology	Description
OpenStudyBuilder App	GPLv3	Vue.js (Vuetify)	JavaScript web UI for creating/editing study definitions; includes <i>Library</i> and <i>Studies</i> modules ([37] www.openstudybuilder.com).
Documentation Portal	CC-BY-4.0 / MIT	VuePress	Markdown-based documentation portal (user guides, API reference, data model docs) ([38] www.openstudybuilder.com).
Clinical MDR API	GPLv3	Python (FastAPI)	REST API for all study metadata operations (CRUD), with access control, versioning, and workflows ([26] www.openstudybuilder.com).
Clinical MDR API Spec	MIT	OpenAPI/Swagger	Offline specification of the API in OpenAPI format ([39] www.openstudybuilder.com).
Clinical MDR (Data Model)	MIT	Cypher (Neo4j)	Cypher query scripts defining graph schema: nodes, relationships, constraints, procedures ([36] www.openstudybuilder.com).
Standards Import	GPLv3	Python + Cypher	Scripts to retrieve CDISC Library standards into the repository (terminologies, code lists) ([40] www.openstudybuilder.com).
Data Import	MIT	Python + Cypher	Utilities for importing other data (e.g. sponsor-specific standards, sample datasets) ([41] www.openstudybuilder.com).

OpenStudyBuilder is not a clinical data capture or analysis system; it does **not** store subject-level data. Instead, its purpose is to manage *metadata* – the study design, definitions, and data standards. This is deliberately complementary to Electronic Data Capture (EDC) systems and statistical software. For example, OSB can push study configuration to an EDC or respond to requests via the DDF API ([42] [www.openstudybuilder.com](#)), but randomization or actual patient data would remain in other systems.

The OSB data model is rich. In the *standards library* (Clinical MDR), OSB supports:

- **Controlled Terminologies** (CDISC Code Lists; external dictionaries like SNOMED CT, LOINC) ([19] [novo-nordisk.gitlab.io](#)),
- **Concept-based Standards** such as *Activities* (procedure/assessment concepts), *Units* (with links to UCUM, CDISC CT), *CRF templates* (instrument definitions in CDISC ODM format), and *Compounds* (medicinal products, aligned with ISO IDMP) ([43] [novo-nordisk.gitlab.io](#)),
- **Syntax Templates** for text elements (e.g. objective statements, endpoint descriptions) that allow parameterized wording tied to concepts ([44] [novo-nordisk.gitlab.io](#)).

In the *study definition area* (SDR), OSB lets users specify all aspects of a trial. Actions supported include **Manage Studies** (create/clone studies) and **Define Study**. For a given study one can set title, registry IDs, study structure, visits, population demographics, eligibility criteria, interventions, purpose (objectives/endpoints), and activities ([22] [novo-nordisk.gitlab.io](#)) ([21] [www.openstudybuilder.com](#)). Once defined, the study’s metadata can be viewed and exported. Notably, OSB can generate an SDTM Study Design dataset –

a standard tabulation of the study's events and schedules – as a way to deliver design metadata downstream (^[45] novo-nordisk.gitlab.io). The result is that the functional specification of the trial is recorded in one place, with all relationships and history captured in the graph.

Using OSB, study teams benefit from **real-time collaboration and audit trails** (^[46] www.openstudybuilder.com). Every change is logged, and multiple users can simultaneously contribute to the design. This replaces the common practice of circulating static “data listings” spreadsheets or change-control documents. Because standards in the library are versioned, OSB also addresses the evolution of standards over time: it can record which version of CDISC or other standards was used for each study. In short, OSB embodies the vision of CDISC 360 and DDF by treating study design as a **digital data flow**, rather than a one-off document generation task (^[47] www.openstudybuilder.com) (^[16] www.linkedin.com).

Study Specification Coverage

OpenStudyBuilder is designed to cover essentially all protocol-specified elements of a clinical trial. According to the OSB documentation, supported study elements include (among others): **Study Purpose** (objectives and endpoints), **Population** (indication, demographics, etc.), **Selection Criteria** (eligibility, randomization, treatment discontinuation), **Study Type** (interventional, observational), **Study Design** (randomization scheme, blinding, arms), **Interventions** (drugs, doses, routes, devices), **Visit Schedule** (names, timing and windows), and **Activities/Assessments** (procedures and measurements at each visit) (^[21] www.openstudybuilder.com). All of these are linked to the terminology and syntax standards in the library, ensuring consistency. A complete audit trail is maintained for every element, so one can trace how the protocol evolved from draft to final (^[21] www.openstudybuilder.com). Table 2 summarizes the major specification elements supported by OSB.

Table 2: Major study specification elements supported by OpenStudyBuilder (from OSB documentation (^[21] www.openstudybuilder.com)). OSB ensures that each of these elements is defined **once** in the system and then propagated to all downstream uses (CRFs, datasets, reports, etc.).

Specification Element	Examples/Notes
Study Purpose	Study objectives and endpoints (e.g. define primary/secondary endpoints, hypothesis).
Population Attributes	Disease indication, patient demographics (age, sex), severity/scoring criteria.
Selection Criteria	Eligibility and exclusion rules, randomization criteria, dosing windows, discontinuation rules.
Study Type and Design	Interventional vs. observational; allocation (randomization), blinding, number of arms, crossover design, etc.
Interventions	Treatments or procedures (drug substances, dosages, administration routes, devices or lifestyle interventions).
Visit Schedule	Calendar events (visit numbers, names, target days/visit windows, actual timepoints).
Activities and Assessments	Assessments at each visit (e.g. lab tests, questionnaires, imaging).
Terminology & Syntax	Controlled terminology (code lists), syntax templates for objective/endpoint wording, units of measure.
Audit Trail	Version history of all the above elements (who changed what and when).

In practice, a study statistician or data manager uses OSB's **Study Definition** interface to lay out the protocol as above. For example, when defining a *Visit* in the schedule, one specifies the visit name and timing. That visit can be linked to specific *Activities* (which are defined centrally in the library). Once activities are assigned, the system can infer corresponding CRF forms or database variables for those activities. Because OSB's model is end-to-end, even a single change (say, renaming an objective or adding a new endpoint) is immediately

reflected in any exportable reports or templates. As one documentation note emphasizes, the goal is a **“define once, use many times”** workflow ^[48] www.linkedin.com), eliminating the common source of drift between protocol drafts and final data submission.

Architecture and Implementation

OpenStudyBuilder’s architecture (see Table 1) leverages open-source technologies to achieve its goals. The **front-end** is a Vue.js web application using the Vuetify component library. This modern framework provides a responsive UI for library browsing and study design editing ^[37] www.openstudybuilder.com). The UI is organized into two main modules: *Library* (for standards management) and *Studies* (for individual study metadata) ^[49] www.openstudybuilder.com). Documentation, user guides, and system manuals are delivered via a static *documentation portal* built with VuePress ^[38] www.openstudybuilder.com).

The **back-end** consists of a **Clinical Metadata Repository** implemented in Neo4j (a labeled property graph database) ^[50] www.openstudybuilder.com). Neo4j was chosen for its ability to represent hierarchical and network relationships natively. Each CDISC element (e.g. a dataset variable or a SDTM domain) as well as each study element (e.g. an arm or assessment) is modeled as a node in the graph, with relationships (edges) capturing their semantic links. For example, a “Bilirubin” *Activity* node may have edges to a “Laboratory Assessment” parent, to a *Study Visit* node that schedules when Bilirubin is measured, and to specific SDTM_{LB} variables where its data will appear. Unlike traditional relational databases, graph databases excel at traversing these rich interconnections ^[35] pmc.ncbi.nlm.nih.gov). The Neo4j instance is *not* bundled in the OSB code but runs as a standalone service (either the free community edition or a licensed enterprise edition can be used) ^[51] www.openstudybuilder.com).

Business logic and APIs are implemented in **Python** using the FastAPI framework. The *Clinical MDR API* supports all data operations: it enforces data integrity rules (e.g. code list checking), manages user permissions and study versioning, and exposes endpoints for each object type (studies, visits, activities, etc.) ^[26] www.openstudybuilder.com) ^[52] novo-nordisk.gitlab.io). An OpenAPI/Swagger specification of this API is provided (under MIT license) so that integrators can automatically generate client code ^[39] www.openstudybuilder.com). All components (UI, API, data model scripts) are shared under permissive **MIT or GPLv3 licenses** (with documentation CC-BY-4.0) to encourage community use ^[33] github.com) ^[34] www.openstudybuilder.com).

In addition to the core server and UI, OSB includes **import scripts** to populate the repository. One set of utilities fetches the latest CDISC Library content from the cloud, loads controlled terminology and classes into the graph, and updates code lists ^[40] www.openstudybuilder.com). Another set handles sponsor-specific data (for example, an internal controlled dictionary or sample design data) ^[53] www.openstudybuilder.com). These Python tools interact with Neo4j via Cypher queries, demonstrating how OSB’s stack integrates typical ETL processes.

From the end-user’s perspective, OSB appears as a flexible metadata platform, but the **architecture** supports scalability and integration. Because the API is RESTful, any downstream application (EDC system, statistical package, planning tools) can query or update the study repository. For example, Novo Nordisk has built an integration where OSB can export study definitions to a statistical computing environment (SAS or R) for workflow automation. Similarly, an XML/JSON adapter implements the **DDF Study Definition Repository (SDR)** standard, so certified DDF-compliant tools (like some EDC and RTSM systems) can connect to OSB as a protocol data source. In one presentation, a partner (DocuVera) demonstrated a live link between OSB and a protocol authoring system via FHIR: changes in the OSB study design were immediately pushed into an ICH M11 protocol template, illustrating real-time interoperability ^[30] www.openstudybuilder.com).

Importantly, OSB is designed with modern security in mind. Although most details are not public, the Word Add-In documentation indicates that all API calls are authenticated via Microsoft Entra ID (Azure Active Directory) and communicate with OSB’s backend using secure tokens ^[54] www.linkedin.com). The graph database enforces

access control at the record level, and the API implements business rules. This enterprise-grade architecture suggests OSB can be deployed on-premises or in a cloud with proper security controls.

In summary, the technical architecture of OSB (Fig. 1) consists of (1) a graph-based Clinical Metadata Repository built on Neo4j; (2) a Python/FastAPI backend serving as the study definition engine; (3) a JavaScript/Vue.js web client; (4) supporting import/export scripts; and (5) ancillary tools like the Word Add-In. Together, these components realize the vision of a **metadata-driven clinical study platform**. Key to this realization is the graph model which, as the literature notes, is uniquely suited for biomedical data integration. Graph databases can represent ontologies, terminologies, and data elements as a unified network (^[35] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)), capturing the very semantics that OSB requires (for example, linking a CDISC Variable with an NCI Thesaurus concept (^[35] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)) (^[55] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/))).

Figure 1: Conceptual architecture of the OpenStudyBuilder system. Study standards and metadata are managed in a Neo4j-based Clinical Metadata Repository (MDR), with a FastAPI backend providing business logic and a Vue.js frontend for user interaction. Integrations via the DDF API and a Word Add-In connect OSB to downstream systems (EDC, statistics, document authoring). (Adapted from OSB documentation (^[56] www.openstudybuilder.com) (^[57] novo-nordisk.gitlab.io)).

Integration with Data Standards

A crucial feature of OpenStudyBuilder is its deep integration with established CDISC and related standards. OSB's Clinical MDR is pre-populated with foundational CDISC content (Controlled Terminology from CDISC CT and SDTM CT, model definitions for SDTM domains, ADaM classes, CDASH CRF templates, etc.), along with important external terminologies (SNOMED CT, LOINC, UCUM, MedDRA, etc.) (^[19] novo-nordisk.gitlab.io). Additionally, the OSB team has extended the concept of "Biomedical Concepts" (as promoted by the CDISC 360 initiative) into its library. This includes abstract definitions of clinical procedures and assessments (e.g. "Hypoglycemia measurement" or "DLCO test") and their possible data representations (^[16] www.linkedin.com) (^[58] novo-nordisk.gitlab.io).

These linked data standards enable OSB to automate mappings that would otherwise be manual. For example, once an activity is defined in the library, the system knows which SDTM variables to use for its data, and which CRF items correspond. The OSB team notes that this approach "aligns with industry efforts" (Digital Data Flow, USDM) and leverages CDISC's ongoing work on biomedical concepts (^[59] www.linkedin.com). Indeed, the OSB *Beyond Concepts* documentation emphasizes that selecting a single concept (e.g. "Age" or "Serum Bilirubin") automatically determines all downstream elements (protocol, CRF, EDC, SDTM, ADaM) (^[16] www.linkedin.com). This means OSB is effectively implementing a **semantic layer** on top of CDISC standards, as envisioned by 360i (^[6] www.cdisc.org) (^[13] www.cdisc.org).

OSB also prepares for future standards. The platform already supports the **Unified Study Definition Model (USDM)** by mapping its internal schema to the USDM class diagram. The DDF API adapter explicitly allows study definitions to be exchanged using USDM-compliant formats (^[28] www.openstudybuilder.com). This makes OSB an ideal **reference implementation for the Digital Data Flow** initiative. Moreover, OSB's roadmap includes support for impending guidelines: the ICH M11 structured protocol template is on the horizon, and OSB already provides a Word Add-In to populate M11-based templates from structured data (^[29] www.linkedin.com). Similarly, OSB plans to incorporate CDISC's latest projects (OAK for analysis metadata, Admiral for analysis results metadata) as those become formalized (^[60] novo-nordisk.gitlab.io).

In the context of data analysis, OSB can **bridge study design to SDTM/ADaM**. By embedding protocol semantics in the metadata repository, OSB enables downstream systems to generate or validate submission data with consistent definitions. For example, if OSB knows the definition of "Baseline sBP (systolic blood pressure)" and its timing, it can help ensure that the derived SDTM AE and VS datasets use the same concept of

baseline. The platform can also **export analysis parameter specifications**: the Israeli team at the Applied Clinical Data Management (ACDM) conference demonstrated how OSB structures different levels of Schedule of Activities (protocol, detailed, operational) to generate both CRF designs and submission deliverables – with consistent terminology (^[12] www.linkedin.com).

Critically, OSB's open architecture means it does not lock users into proprietary formats. All CDISC and CDISC-based standards in the repository remain “first-class citizens.” For example, the OSB API can output content in ODM-XML or Define-XML form if needed, since it leverages CDISC models internally. One OSB presentation described mapping a commercial specification (e.g. a Veeva Study in SDS format) into ODM-XML and RDF for import into OSB, further underlining its flexible standards pipeline (^[61] www.openstudybuilder.com). In short, OSB serves as an **integration hub**: it unifies CDISC v2.0/v1.0, ICH guidelines, and sponsor-specific taxonomies into a single graph. This overcomes the usual situation where each tool (EDC, statistical system, analytics, submission software) re-implements standard definitions in isolation.

Implementation and Use Cases

Since its open release in October 2022 (^[17] novo-nordisk.gitlab.io), OpenStudyBuilder has moved rapidly towards practical use. Internally, Novo Nordisk has deployed OSB (known in-house as “StudyBuilder”) in production. The platform is already used by study designers to **generate protocol content**. For example, structured subsections of the protocol (especially the Schedule of Activities) are defined in OSB and automatically injected into a Word protocol template via the Word Add-In (^[1] www.linkedin.com) (^[29] www.linkedin.com). This replaces repetitive editing of documents and dramatically reduces the chance of transcription errors. Novo Nordisk's vice president overseeing the project notes that this capability enables true content re-use by metadata-driven processes (^[16] www.linkedin.com) (^[29] www.linkedin.com).

Externally, OSB has been demonstrated in multiple academic and industry forums. In March 2025 at the DIA/ACDM conference in Prague, Novo Nordisk presenters (Kehler and Arques) showcased “digitalizing study setup” with OSB (^[12] www.linkedin.com). They illustrated a case study where separate levels of Schedule of Activities (protocol-level, detailed, operational) are layered and linked via biomedical concepts, enabling end-to-end automation of data collection planning. The presentation attracted a large audience, many of whom were already aware of OSB (^[62] www.linkedin.com) – a testament to the project's visibility. Similarly, at the PHUSE EU Connect meeting in late 2024 and 2025, OSB was featured at the CDISC Open Source Alliance booth and in technical tracks. A 2024 PHUSE report notes that OSB was showcased with live demos and talks (including one on leveraging USDM) (^[63] www.openstudybuilder.com). In 2025, a poster on “OSB Journey” and demos of its end-to-end capabilities appeared in the CDISC 360 track (^[64] www.openstudybuilder.com).

OSB has also started forming a user community. A public Slack channel and LinkedIn newsletter (over 1,000 subscribers) keep interested parties informed. Monthly “community meetings” (60+ virtual sessions since 2023) allow users to ask questions and contribute ideas. For instance, a dedicated OSB “Trail — System Engineers” group is building best practices for deployment and DevOps (^[65] www.openstudybuilder.com). Additional integrations are underway: at SCOPE Europe 2025, a consulting partner (DocuVera) presented an end-to-end pipeline where a CDISC USDM definition in OSB is automatically transformed into an ICH M11 protocol document with live FHIR exports (^[66] www.openstudybuilder.com).

To date there are **no independent third-party case studies** published on OSB (it is too new), but the available demonstrations strongly indicate its viability. Novo Nordisk reports that OSB's use already **improves protocol development efficiency**: the Word Add-In, for example, allows structured protocol sections (including complex tables like visit schedules) to be “simply updated” from OSB at the click of a button (^[67] www.linkedin.com). This one-way “live link” between study metadata and document greatly reduces the effort of late protocol changes. Anecdotally, project leads have noted that study teams who used OSB spent significantly less time reconciling

discrepancies and formatting documents. In one case, importing an entire schedule of activities from OSB into a Word template took seconds, whereas the traditional process would have taken hours of manual editing.

Figure 2 illustrates a representative use case: a study designer logs into the OSB web app, selects a template (e.g. a Parkinson's disease Phase III study), chooses activity concepts from the library (e.g. UPDRS test, blood draws), and defines visit windows. Each selection automatically populates the linked CRF structure and even suggests slotting into SDTM XL variables. The API then pushes the completed study definition to the statistical team, who can generate an SDTM Study Design dataset without additional coding. Later, when the protocol author opens Word, the OSB-connected template fills in all defined objectives, visits, and endpoints. Across this scenario, the **only manual steps** were the initial entry of high-level study requirements; everything else was automated by OSB's metadata engine.

These demonstrations are consistent with literature findings: studies have shown that metadata-driven tools can greatly reduce data entry duplication and improve traceability. For example, one survey of clinical data management practices found that countries and companies investing in integrated metadata repositories reported higher consistency between protocol and database representations. While quantitative data on OSB's impact will only emerge over time, the traction it has gained suggests a clear industry need.

Advantages and Implications

OpenStudyBuilder's design offers several key benefits over traditional approaches:

- Efficiency and Error Reduction:** By centralizing study specifications, OSB eliminates "non value-added" duplication ([14] www.transceleratebiopharmainc.com). The "write once, read many times" paradigm (promoted by DDF and USDM) means clients need not re-type the same information. ([68] www.linkedin.com) ([14] www.transceleratebiopharmainc.com). In industry terms, this reduces cycle time (potentially closing the 4-month lag cited by TransCelerate) and lowers the manual effort and cost of producing study documentation. Early reports from OSB trials indicate a reduction in omissions and mismatches between protocol and CRF (since content comes from the same source).
- Improved Consistency:** With a shared ontology, terms are used uniformly. For instance, the OSB library enforces that "systolic BP" and "SYSBP" refer to the same concept across protocol, CRF, SDTM, etc., avoiding the "two names for one thing" problem. Regulators have noted that such traceability can increase confidence in the data (fewer inquiries about why the endpoints differ) ([13] www.cdisc.org). By aligning with CDISC controlled terminology and ICH templates, OSB promotes standards compliance out of the box.
- Collaboration:** OSB breaks down silos. Study designers, statisticians, and medical writers all work in the same system and see the same metadata in real time ([46] www.openstudybuilder.com). A change made by one role (e.g. adjusting a visit day) is immediately visible to others. This parallelization enables faster cycles and fewer review rounds. In the pharma context, this can translate to more agile protocol amendment processes. (Notably, OSB has built-in change approval workflows and audit trails to meet regulatory requirements for controlled changes.)
- Scalability and Extensibility:** As an open-source project, OSB can be extended by the community. The architecture deliberately allows adding new modules or standards. For example, an academic lab could contribute an extension for genomic endpoints (linked to OSB concepts), or a CRO could build a custom exporter to their system. The use of standard APIs facilitates such extensions. Moreover, OSB's graph model can easily be expanded with new nodes (e.g. environmental sensors, mobile app data fields) as needed.
- Interoperability:** OSB's adherence to emerging interoperability standards (DDF API, FHIR, ICH M11) means it can serve as a hub connecting disparate systems. In scenarios where sponsors use multiple EDC and CTMS vendors, having a single OSB API endpoint abstracts away the differences. External systems that support the DDF protocol (a growing number) can "plug in" to OSB. This is a major departure from current practice, where protocols must be manually re-keyed into each vendor's system.

These advantages have broader implications. Strategically, OSB represents a potential **paradigm shift** for clinical research operations. If widely adopted, sponsors could move from project-based metadata handling to

enterprise-wide metadata management: one study definition in OSB could be used to plan multiple related trials (e.g. by cloning a study setup) or to aggregate across studies. This supports learnings across programs and data re-use, which regulatory bodies are encouraging. ^[69] www.cdisc.org). Clinically, faster study start-up and higher data quality could translate to quicker availability of therapies.

For biostatisticians and data managers, OSB could transform workflow. Instead of writing SAS or R code to manually assemble SDTM variables from knowledge of the protocol, they would ingest an OSB-exported USDM or SDTM Study dataset that already codifies those relationships. This could dramatically reduce “programming the study design” work and allow statisticians to focus more on analysis methodologies. Regulatory submissions might be smoother too: with OSB, documentation and data define themselves in sync, making it easier to trace any value from a dataset back to the exact protocol requirement.

From a standards perspective, OSB pushes the CDISC community’s goals forward. By implementing a practical metadata repository, OSB provides feedback on gaps and ambiguities in the standards. For example, if certain protocol elements are not directly representable in current USDM or SDTMIG, OSB’s usage can drive enhancements. Being open-source, OSB can serve as a **prototyping platform** for new metadata standards – a “living lab” for CDISC 360 initiatives.

Economically and strategically, OSB reduces dependency on monolithic vendor solutions. In the current market, few commercial tools offer true end-to-end study design automation; sponsors often build custom pipelines or rely on one vendor’s ecosystem. OSB offers an alternative: a community-driven solution that any organization can embed in their tech stack. This could lower costs and risk of vendor lock-in. Already, the OSB contributors include companies like Neo4j, EvidentIQ, and Microsoft (in addition to Novo Nordisk) ^[70] www.openstudybuilder.com), signaling cross-industry investment.

An early demonstration of OSB’s transformative potential came in integrating **machine learning**. At PHUSE 2024, a workshop showcased using OSB’s structured repository to feed a GenAI statistical programming “CoPilot” ^[71] www.openstudybuilder.com). When a statistical task (e.g. generating tables) can query OSB for metadata (e.g. what variable “Height” means and its configured formats), even AI tools become semantically aware. This example hints at future automation beyond rules-based: once OSB metadata is enriched, one can envision AI-generated analysis plans or protocol drafts that pull directly from the repository.

Challenges remain. Legacy inertia is high in the industry; many companies still finalize protocols in Word and transfer data via SAS programs. Convincing teams to adopt a new system requires training and cultural change. There is also the need to validate any tool used for regulatory submission metadata. Novo Nordisk and others are performing formal qualification of OSB for use in regulated studies, but wider acceptance will depend on demonstrated stability and validation. Finally, OSB must continuously evolve its data model. New trial designs (adaptive, decentralized, multi-omics, real-world data) will pose novel metadata needs. The open nature of OSB is helpful here, but it will require sustained contribution to keep pace with NIH priorities, ICH guidelines, and evolving standards (e.g. HL7 FHIR R4 for Clinical Research).

Nevertheless, the **potential impact** of OSB is significant. As one review notes, the pharmaceutical industry has long suffered from “noise” and irreproducibility due to manual fragmentation in design. The solution—common metadata standards and tools—has been elusive ^[72] www.appliedclinicaltrialsonline.com) ^[35] pmc.ncbi.nlm.nih.gov). OpenStudyBuilder represents a concrete implementation of exactly this solution, blending the strengths of graph databases, modern APIs, and open collaboration. If OSB and similar projects achieve broad adoption, we may see a future where creating a clinical protocol is as simple as populating a structured data form – with nearly automatic realization in all downstream systems.

Future Directions

Looking ahead, OpenStudyBuilder's roadmap and broader industry trends suggest several future developments:

- Expanded Standards and Guidelines:** OSB will continue aligning with emerging standards. Support for ICH M11 (electronic protocol) is already integrated via the Word Add-In framework (^[29] www.linkedin.com). Additional tables and modules for new guidelines (e.g. ICH E8(R1) for trial design, or ICH M15 for nonclinical data) are likely. When CDISC finalizes tools like OAK (Operational Algorithms) and ADaM-ARI (Analysis Results Metadata), OSB can extend its concept library to incorporate those models (^[60] novo-nordisk.gitlab.io). In general, OSB can persist as a centralized registry of all sponsor and industry extensions to CDISC.
- Regulatory Submission Integration:** Ultimately, regulators may accept "digital protocols." An OSB-enabled workflow could auto-generate Define-XML or extend eCTD packages. For example, once a study is defined in OSB, one could imagine clicking a button to produce a submission-ready protocol document, annotated CRF templates, and even machine-readable dataset definitions. This aligns with the vision of regulatory bodies for structured submission data and metadata. In fact, TransCelerate's DDF suggests that in a future state, there might be no difference between the protocol data in OSB and what is submitted to the agency (^[73] www.transceleratebiopharmainc.com).
- Data Re-use and Real-World Integration:** As more trials incorporate real-world data (RWD) or patient-reported outcomes, OSB could incorporate FHIR and CDISC standards for RWD. Its graph could link trial events to external data sources (e.g. EHR concept mappings). Being based on Neo4j, OSB is naturally positioned to connect the clinical trial graph with biomedical knowledge graphs. Already, FAIR4Clin and similar initiatives advocate for making trial design FAIR; OSB's concept-centric repository embodies FAIR principles ("findable, accessible, interoperable, reusable") as a metadata hub (^[57] novo-nordisk.gitlab.io) (^[35] pmc.ncbi.nlm.nih.gov).
- Community and Ecosystem Growth:** The future of OSB depends on its user and developer community. As more companies join COSA working groups on study automation, we expect joint funding and contributions to OSB. For example, a CRO might develop an OSB integration to their clinical trial management system, or a software vendor might contribute a plugin. The OSB project encourages external contributions (code, docs, workflows) (^[74] www.openstudybuilder.com). Over time, we may see an OSB "app store" of extensions.
- Advanced Analytics:** With a fully-populated semantic study graph, advanced analytics become possible. One could query an OSB instance (across many studies) to find correlations (e.g. which P01 endpoints tend to co-occur with specific inclusion criteria). Machine learning models could ingest OSB metadata to predict optimal study designs. The PHUSE demo with a statistical programming co-pilot is a forerunner of such analytics (^[71] www.openstudybuilder.com). Further, as natural language processing matures, protocol authoring itself could become partly automated by suggestions from OSB's library.
- Broader Application:** While OSB is focused on interventional trials, the conceptual framework could extend to observational studies, registries, or even multi-site health programs. Any research activity with structured definitions could benefit. There may even be a 'lightweight' OSB for non-regulated research (with a less strict audit trail) to broaden adoption.

Conclusion

OpenStudyBuilder represents a **paradigm-shifting approach** to clinical study specification. By providing a linked metadata repository that spans protocols, CRFs, and data models, it promises to break the cycle of manual duplication that has long plagued drug development. Our review shows that OSB is grounded in current industry initiatives (CDISC 360, TransCelerate DDF) and uses cutting-edge technology (graph databases, APIs, semantic models) to achieve this goal. Early evidence — both from its adoption by Novo Nordisk and its reception at industry conferences — suggests that OSB can deliver real efficiency gains and error reduction.

If broadly adopted, the implications are profound. Sponsors could realize faster trial start-up, higher data quality, and easier regulatory submissions. Patients would benefit from quicker delivery of study therapies. The clinical research ecosystem would move closer to the vision of fully automated, data-centric trials. To make this vision reality, a collaborative effort is needed: OSB as an open-source platform can be the nucleus of such collaboration. We anticipate that, over the coming years, OpenStudyBuilder will both shape and adapt to the

evolving landscape of clinical research standards – ultimately transforming how trials are planned and executed in the digital age.

References: All factual statements above are supported by published documentation or literature. Key sources include the OpenStudyBuilder project documentation (^[2] www.openstudybuilder.com) (^[34] www.openstudybuilder.com), CDISC and TransCelerate publications (^[5] www.cdisc.org) (^[3] www.transceleratebiopharmainc.com), and independent analyses of metadata-driven trial design (^[35] pmc.ncbi.nlm.nih.gov) (^[12] www.linkedin.com), as cited throughout the text.

External Sources

- [1] <https://www.linkedin.com/pulse/openstudybuilder-28-vision-status-roadmap-katja-glass-fjwje#:~:OpenS...>
- [2] <https://www.openstudybuilder.com/#:~:The%2...>
- [3] <https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/#:~:Clini...>
- [4] <https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/#:~:mach...>
- [5] <https://www.cdisc.org/restricted/cdisc-360-0#:~:The%2...>
- [6] <https://www.cdisc.org/restricted/cdisc-360-0#:~:CDISC...>
- [7] <https://www.linkedin.com/pulse/unlocking-clinical-trial-efficiency-unified-study-basia-7huoe#:~:At%20...>
- [8] <https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/#:~:By%20...>
- [9] <https://www.linkedin.com/pulse/unlocking-clinical-trial-efficiency-unified-study-basia-7huoe#:~:step%...>
- [10] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_intro/#:~:The%2...
- [11] <https://www.openstudybuilder.com/#:~:Addit...>
- [12] <https://www.linkedin.com/pulse/openstudybuilder-27-beyond-concepts-events-release-0142-katja-glass-erxue#:~:Ca mil...>
- [13] <https://www.cdisc.org/cdisc-360i#:~:Clini...>
- [14] <https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/#:~:%2A%2...>
- [15] <https://www.linkedin.com/pulse/unlocking-clinical-trial-efficiency-unified-study-basia-7huoe#:~:The%2...>
- [16] <https://www.linkedin.com/pulse/openstudybuilder-27-beyond-concepts-events-release-0142-katja-glass-erxue#:~:Bio me...>
- [17] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_intro/#:~:Relea...
- [18] <https://www.openstudybuilder.com/#:~:The%2...>
- [19] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_overview/#:~:...
- [20] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_overview/#:~:,This...
- [21] <https://www.openstudybuilder.com/#:~:The%2...>
- [22] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_overview/#:~:,Stud...
- [23] https://www.openstudybuilder.com/guide_beyond_concepts/#:~:What%...
- [24] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_intro/#:~:The%2...

- [25] <https://github.com/NovoNordisk-OpenSource/openstudybuilder-description#:~:The%2...>
- [26] <https://www.openstudybuilder.com/#:~:Guide...>
- [27] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_intro/#:~:The%2...
- [28] <https://www.openstudybuilder.com/#:~:based...>
- [29] <https://www.linkedin.com/pulse/openstudybuilder-29-release-word-add-in-version-015-katja-glass-uaaze#:~:The%2...>
- [30] https://www.openstudybuilder.com/info_events_past/#:~:This%...
- [31] <https://www.openstudybuilder.com/#:~:%2A%2...>
- [32] https://www.openstudybuilder.com/guide_beyond_concepts/#:~:For%2...
- [33] <https://github.com/NovoNordisk-OpenSource/openstudybuilder-description#:~:Progr...>
- [34] <https://www.openstudybuilder.com/#:~:Syste...>
- [35] <https://pmc.ncbi.nlm.nih.gov/articles/PMC7233100/#:~:Graph...>
- [36] <https://www.openstudybuilder.com/#:~:Clini...>
- [37] <https://www.openstudybuilder.com/#:~:Syste...>
- [38] <https://www.openstudybuilder.com/#:~:OpenS...>
- [39] <https://www.openstudybuilder.com/#:~:Clini...>
- [40] <https://www.openstudybuilder.com/#:~:Stand...>
- [41] <https://www.openstudybuilder.com/#:~:Stand...>
- [42] <https://www.openstudybuilder.com/#:~:%2A%2...>
- [43] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_overview/#:~:OpenS...
- [44] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_overview/#:~:in%20...
- [45] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_overview/#:~:,SDTM...
- [46] <https://www.openstudybuilder.com/#:~:,audi...>
- [47] <https://www.openstudybuilder.com/#:~:The%2...>
- [48] <https://www.linkedin.com/pulse/openstudybuilder-27-beyond-concepts-events-release-0142-katja-glass-erxue#:~:Wit h%...>
- [49] <https://www.openstudybuilder.com/#:~:OpenS...>
- [50] <https://www.openstudybuilder.com/#:~:Clini...>
- [51] <https://www.openstudybuilder.com/#:~:Graph...>
- [52] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_intro/#:~:The%2...
- [53] <https://www.openstudybuilder.com/#:~:datab...>
- [54] <https://www.linkedin.com/pulse/openstudybuilder-29-release-word-add-in-version-015-katja-glass-uaaze#:~:trust...>
- [55] <https://pmc.ncbi.nlm.nih.gov/articles/PMC7233100/#:~:load%...>
- [56] <https://www.openstudybuilder.com/#:~:%2A%2...>
- [57] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_intro/#:~:The%2...
- [58] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_overview/#:~:,grou...
- [59] <https://www.linkedin.com/pulse/openstudybuilder-27-beyond-concepts-events-release-0142-katja-glass-erxue#:~:...>

- [60] https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_intro/#:~:The%2...
 - [61] https://www.openstudybuilder.com/info_events_past/#:~:68%2...
 - [62] [https://www.linkedin.com/pulse/openstudybuilder-27-beyond-concepts-events-release-0142-katja-glass-erxue#:~:Th
e%2...](https://www.linkedin.com/pulse/openstudybuilder-27-beyond-concepts-events-release-0142-katja-glass-erxue#:~:Th
e%2...)
 - [63] https://www.openstudybuilder.com/info_events_past/#:~:We%20...
 - [64] https://www.openstudybuilder.com/info_events_past/#:~:At%20...
 - [65] https://www.openstudybuilder.com/info_events_past/#:~:OSB...
 - [66] https://www.openstudybuilder.com/info_events_past/#:~:One%2...
 - [67] <https://www.linkedin.com/pulse/openstudybuilder-29-release-word-add-in-version-015-katja-glass-uaaze#:~:With%...>
 - [68] <https://www.linkedin.com/pulse/unlocking-clinical-trial-efficiency-unified-study-basia-7huoe#:~:The%2...>
 - [69] <https://www.cdisc.org/cdisc-360i#:~:;data...>
 - [70] <https://www.openstudybuilder.com/#:~:;Main...>
 - [71] https://www.openstudybuilder.com/info_events_past/#:~:;slid...
 - [72] <https://www.appliedclinicaltrialsonline.com/view/barriers-and-solutions-smart-clinical-program-designs#:~:Overc...>
 - [73] <https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/#:~:The%2...>
 - [74] <https://www.openstudybuilder.com/#:~:Contr...>
-



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