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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

From Protocol to SDTM: Implementing ICH M11 with the USDM Structure

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Speaker

Ron Fitzmartin
Decision Analytics

- Regulatory science and drug development leader with 25+ years of experience across FDA and industry, spanning regulatory policy, clinical data standards, submissions, informatics, and global harmonization.
- Former Senior Informatics Advisor at FDA CDER and CBER, with leadership roles in ICH M8 electronic submissions and ICH M11 clinical protocol modernization.
- Industry experience includes senior roles in biostatistics, clinical data management, and informatics supporting global drug development programs.
- Current work focuses on global data standards, regulatory workflow modernization, and practical evaluation of AI tools for regulatory use.

Agenda

1. The Current Workflow Problem
2. What ICH M11 / USDM Changes
3. Use Case Design and Governance
4. Validation and Structured Protocol Views
5. USDM-Driven SDE Configuration
6. AI/OCR/NLP Extraction and Review
7. Traceable SDTM Readiness
8. Use Case Results and Operational Impact
9. Conclusions

The problem

Current workflow model creates weeks of manual reconciliation between the patient visit and database lock.

Manual transcription and SDV create duplicate work, reconciliation burden, and delay.

~1/3 of total trial cost

Multiple duplicative manual steps

6–10 weeks added

Current workflow

Each step creates more manual handling, reconciliation, and delay.

6 –10 weeks added between last-patient-last-visit and database lock

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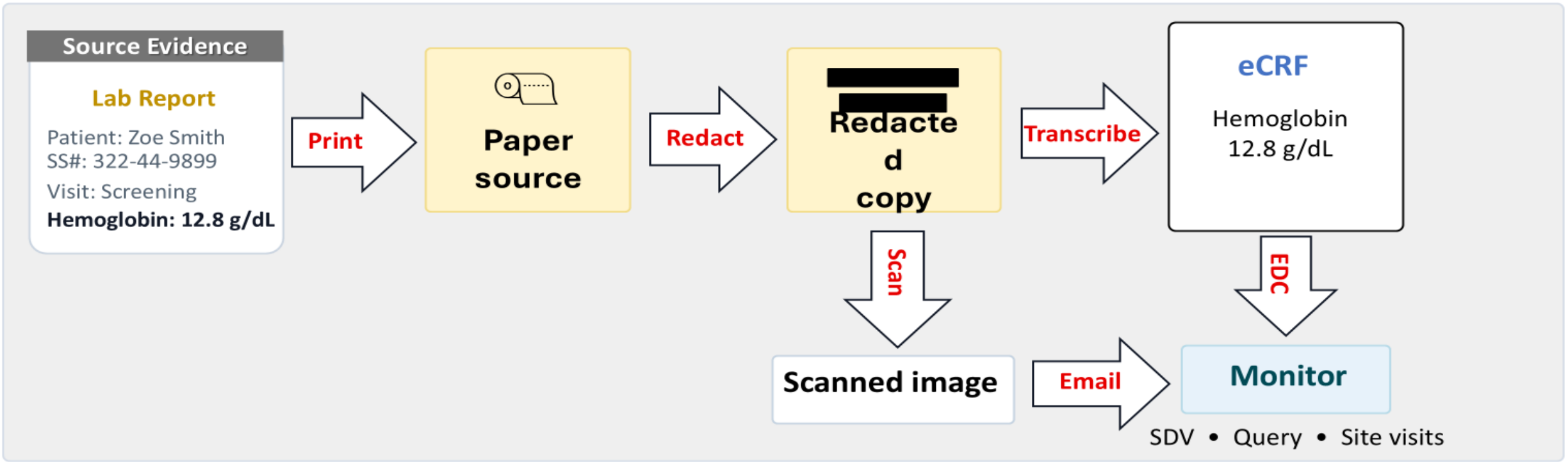
The common practice in monitoring workflow today



Operational issue	Copies multiply	Context fragments	Queries accumulate	Lock slows
	Print, scan, email, and archive create duplicate artifacts.	Source evidence, eCRF value, and review action separate.	Discrepancies are discovered downstream.	Manual reconciliation extends timelines.

Standards shift and use case setup

What ICH M11 changes

From narrative protocol to computable study content

Current State

- Narrative protocol
- Downstream reinterpretation
- Forms, checks, and datasets rebuilt downstream
- Traceability reconstructed after the fact

M11/USDM-enabled

- Structured, machine-readable content
- Protocol requirements become reusable trial metadata
- Standard definitions reduce rework & variation
- Traceable path to submission-ready data

1 source
Standard definitions

Less re-work
less re-interpretation

Faster
path to submission data

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How the pieces fit together

Each component answers a different readiness question in the digital trial workflow.

1 M11 Protocol

Defines the structured protocol as computable study content.

2 Trusted Regulatory Spaces

Governs validation, review, provenance, extraction, and final outputs in a cloud workspace layer

3 Unified Study Definitions Model (USDM)

Schema confirms structural fit & exchange readiness

4 CDISC CORE

Checks business & semantic conformance beyond schema validation.

5 Source Data Extraction (SDE)

Uses protocol USDM to configure forms, support source linkage, and enable exception-based SDV.

USDM structures the protocol; CORE checks conformance; SDE uses the structured content to support source-linked capture and SDTM dataset

Use case objectives

Test whether structured M11 / USDM content can drive downstream digital workflow

01 Validate M11 ingestion and visualization

Confirm that structured protocol content can be ingested, validated, and rendered into review views.

02 Demonstrate protocol-driven form set-up

Show that structured protocol elements can support study setup and AI-assisted form configuration.

03 Evaluate source-linked extraction, redaction, and provenance

Test extraction of synthetic source data with de-identification, redaction of identifiers, and auditable traceability.

04 Assess downstream operational and regulatory workflow impact

Evaluate exception-based SDV, SDTM dataset generation, efficiency gains, and traceable outputs.

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Use case sample & data collection plan

Experienced CRCs and monitors used synthetic records to compare SDE and conventional EDC workflows in a sandbox EHR environment.

1	24	12 / 12	6	80	1,920
sandbox EHR site	synthetic subjects	SDE group / EDC group	forms per subject	fields per subject	total study fields

Trial Volume

Forms and Visits:

6 Forms / Subject

Demographics, Labs, Vitals, ConMeds, AE, Endpoint

Visit Structure:

3 visits; Labs: 2 panels

Evaluation Sets

Redaction set

- 72 PDFs assessed for identifier masking

Extraction set

- 72 PDFs assessed for field-level extraction accuracy

QA Assessment

- **All source documents reviewed for:**
  - Redaction accuracy
  - Data extraction accuracy
  - Audit trail traceability

SDE Group workflow

Direct PDF upload → in-platform redaction → extraction → source-linked review

EDC Group workflow

Print → manual redaction → rescan → manual transcription → separate monitor review

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Use Case Inputs: Sponsor-Contributed Protocols

Two sponsor-contributed Phase 3 oncology protocols were used in the use cases*

- Reflected real protocol complexity, not a simplified demonstration model.
- Evaluated M11 validation, USDM representation, visualization, source-linked extraction, redaction, and SDTM readiness.
- Provided evidence across validation, schema, conformance, rendering, provenance.

* Results for only one sponsor presented here.

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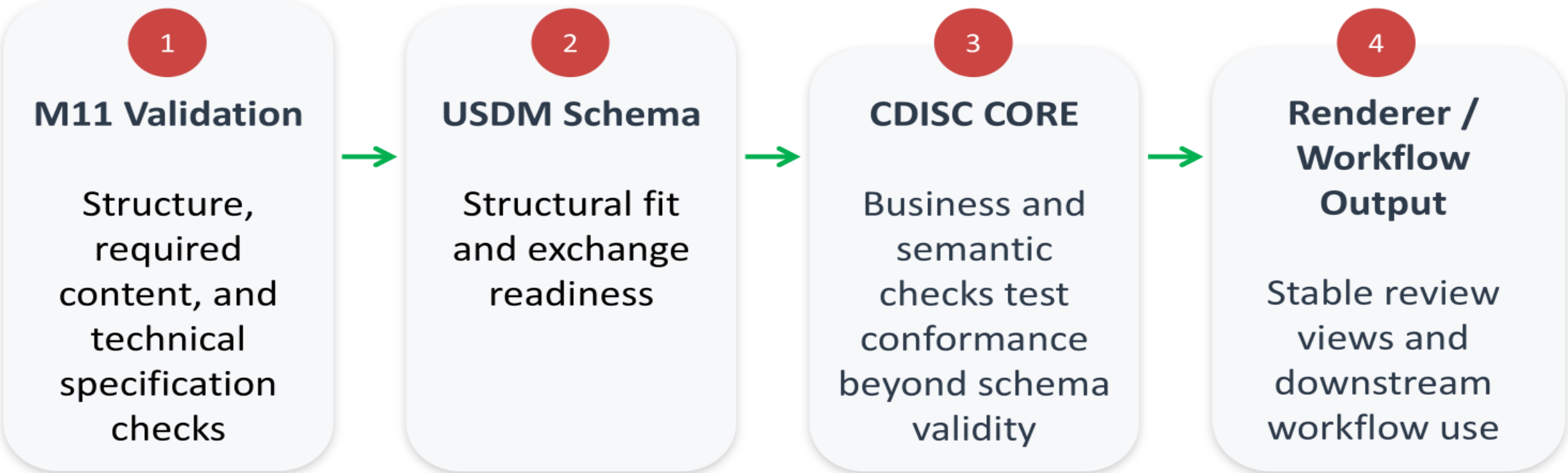
Standards readiness and visualization

Four gates to protocol visualization

Protocol content must pass layered checks before it is ready for downstream workflow use.



Validated M11 / USDM content supports visualization

Structured protocol content is routed into reviewer-facing views

Architecture

Fixed review shell

Consistent layout and formatting

Content mapped to views

Validated content is placed into defined view sections

Defined view sections

Stable sections support repeatable protocol views

Structured Views Table

Summary	Trial Design	SOA	Safety	Statistics
Phase, population, sponsor, version	Arms, eligibility criteria, randomization, objectives.	Visits, epochs visit windows, assessments.	Adverse events, analysis sets, safety assessments.	Analyses, populations, estimands, statistical models.

Validated USDM content can support consistent multi-discipline protocol views.

M11 Protocol Insight

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing [DRUG A] ([DRUG A CODE]), [DRUG B] and [DRUG C] ([REGIMEN A]) Versus [DRUG D], [DRUG B] and [DRUG C] ([REGIMEN B]) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM): Successor-1

Protocol Overview

Full Protocol Title	PHASE 3, TWO-STAGE, RANDOMIZED, MULTICENTER, OPEN-LABEL STUDY COMPARING [DRUG A] ([DRUG A CODE]), [DRUG B] AND [DRUG C] ([REGIMEN A]) VERSUS [DRUG D], [DRUG B] AND [DRUG C] ([REGIMEN B]) IN SUBJECTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA (RRMM): SUCCESSOR-1
Sponsor Protocol Identifier	[PROTOCOL NUMBER]
Original Protocol Indicator	No
Amendment Identifier	7
Amendment Scope	Global
Sponsor's Investigational Product Code	[DRUG A CODE]
Investigational Product Name	[DRUG A]
Trial Phase	Phase 3
Sponsor Name and Address	[SPONSOR NAME AND ADDRESS REDACTED]
Regulatory Agency Identifier Number(s)	[REGULATORY AGENCY IDENTIFIER NUMBER(S) REDACTED]
Sponsor Approval	February 11, 2026

Trial Schema

Study Period	Timing	Key Activities
Screening	Up to 28 days prior to randomization	Informed consent; eligibility determination; baseline assessments; screening procedures to confirm relapsed or refractory multiple myeloma and prior therapy history
Randomization / Start of Treatment	Day 1	Eligible subjects randomized using Interactive Response Technology (IRT); treatment assignment according to randomized treatment arm
Treatment Period	From randomization until confirmed progressive disease, unacceptable toxicity, withdrawal of consent, or death	Administration of study treatments in 21-day cycles; response assessments each cycle; safety monitoring including adverse events, laboratory tests, ECG, and physical examination; documentation of disease progression according to IMWG criteria
End of Treatment Visit	At discontinuation of study treatment	Final safety and efficacy assessments; documentation of treatment discontinuation; transition to follow-up period
28-Day Follow-up Visit	Approximately 28 days after last dose	Safety follow-up including adverse event assessment and clinical evaluation
PFS Follow-up Phase	For subjects who discontinue treatment without confirmed PD	Disease response assessments every 21 days until confirmed progressive disease; PFS Discontinuation Visit at progression
Long-term Follow-up Phase	Every 4 months for at least 5 years after the last subject is randomized	Survival status; EQ-5D-5L assessments; documentation of subsequent antimyeloma therapies and subsequent dates of progression; monitoring of second primary malignancies

Protocol Synopsis

M11 Protocol Insight

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing [DRUG A] ([DRUG A CODE]), [DRUG B] and [DRUG C] ([REGIMEN A]) Versus [DRUG D], [DRUG B] and [DRUG C] ([REGIMEN B]) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM): Successor-1

Description of Trial Design

Section 4.1 describes a two-stage, randomized, multicenter, open-label study in subjects with relapsed or refractory multiple myeloma. Eligible subjects in both stages are randomized using Interactive Response Technology and stratified by age, number of prior lines of therapy, and International Staging System stage at screening. In Stage 1, subjects are randomized across three [DRUG A] dose levels and the [REGIMEN B] control arm. After interim dose selection, one [DRUG A] dose continues into Stage 2 as Arm A versus [REGIMEN B] Arm B. Subjects continue treatment until confirmed progressive disease, unacceptable toxicity, or withdrawal of consent.

Overall Design

Section 1.1.2 identifies the study as a two-stage, Phase 3, randomized, multicenter, open-label study comparing the efficacy and safety of [REGIMEN A] versus [REGIMEN B] in subjects with relapsed or refractory multiple myeloma. The target population is subjects with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of antimyeloma therapy. Approximately 690 subjects are planned across Stage 1 and Stage 2 combined. Stage 1 initially randomizes subjects 1:1:1:1 to three [DRUG A] dose levels or [REGIMEN B], and Stage 2 randomizes approximately 620 additional subjects 1:1 between the selected [REGIMEN A] regimen and [REGIMEN B].

Trial Schema

Section 1.2 presents the trial schema across Screening, Randomization / Start of Treatment, the Treatment Period, End of Treatment Visit, 28-Day Follow-up Visit, PFS Follow-up Phase, and Long-term Follow-up Phase. The treatment period uses 21-day cycles with ongoing response and safety assessments, followed by protocol-defined follow-up phases after treatment discontinuation.

Overall Study Design

M11 Protocol Insight

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing [DRUG A] ([DRUG A CODE]), [DRUG B] and [DRUG C] ([REGIMEN A]) Versus [DRUG D], [DRUG B] and [DRUG C] ([REGIMEN B]) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM): Successor-1

Schedule of Activities

Screening

Procedure	Screening Day -28 to -1	Notes:
ELIGIBILITY ASSESSMENTS	ELIGIBILITY ASSESSMENTS	ELIGIBILITY ASSESSMENTS
Informed Consent	X	Must be obtained prior to performing any screening procedures.
Inclusion/Exclusion Criteria	X	-
Demographics and Medical History	X	All relevant medical conditions diagnosed/occurring prior to screening and history of toxicities related to prior treatments and allergies.
Prior Disease History and Therapies	X	-
IRT Assignment	X	-
SAFETY ASSESSMENTS	SAFETY ASSESSMENTS	SAFETY ASSESSMENTS
Prior/ Concomitant Medication and Procedure	X (-28 days from screening)	Continuous until 28 days after the last dose of study treatment.
AE Evaluation	X	Continuous, starting after informed consent signature, until 28 days after the last dose of study treatment.
Second Primary Malignancies (SPM) Surveillance	X	Continuous, starting after informed consent signature, until the end of study. All SPMs must be reported as Serious Adverse Events (SAEs); monitoring continues until end of study.
Physical Examination	X	A physical exam including general appearance, skin, lung, heart, abdomen, assessment for venous thromboembolic events, and neurological assessment should be conducted at screening.
Vital Signs	X	-
Weight	X	-

M11 Protocol Insight

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing [DRUG A] ([DRUG A CODE]), [DRUG B] and [DRUG C] ([REGIMEN A]) Versus [DRUG D], [DRUG B] and [DRUG C] ([REGIMEN B]) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM): Successor-1

Safety Assessments and Procedures

See Sections 8.4.1 through 8.4.6 and the Schedule of Activities. Safety assessments and procedures include physical examination, vital signs, electrocardiograms, clinical laboratory assessments, pregnancy testing, and suicidal ideation and behavior risk monitoring.

Adverse Events of Special Interest

Second primary malignancies will be monitored as events of interest and must be reported as SAEs regardless of the treatment arm the subject is in (Section 9.1.2). Events of second primary malignancy are to be reported using the SAE Report Form and must be considered “Important Medical Events” if no other serious criteria apply; these events must also be documented in the appropriate page(s) of the eCRF (ie, AE and SPM eCRFs) and subject’s source documents. Documentation on the diagnosis of the SPM must be provided at the time of reporting as an SAE (eg, any confirmatory histology or cytology results, X-rays or CT scans).

Disease Related Events or Outcomes

Events not considered to be SAEs are hospitalizations for:

- a standard procedure for protocol therapy administration. However, hospitalization or prolonged hospitalization for a complication of therapy administration will be reported as an SAE.
- routine treatment or monitoring of the studied indication not associated with any deterioration in condition.
- the administration of blood or platelet transfusion as routine treatment of studied indication. However, hospitalization or prolonged hospitalization for a complication of such transfusion remains a reportable SAE.
- a procedure for protocol/disease-related investigations (eg, surgery, scans, endoscopy, sampling for laboratory tests, bone marrow sampling). However, hospitalization or prolonged hospitalization for a complication of such procedures remains a reportable SAE.
- hospitalization or prolongation of hospitalization for technical, practical, or social reasons, in absence of an AE.
- a procedure that is planned (ie, planned prior to start of treatment on study); must be documented in the source document and the CRF. Hospitalization or prolonged hospitalization for a complication remains a reportable SAE.
- an elective treatment of or an elective procedure for a pre-existing condition, unrelated to the studied indication, that has not worsened from baseline.
- emergency outpatient treatment or observation that does not result in admission, unless fulfilling other seriousness criteria above.

M11 Protocol Insight

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing [DRUG A] ([DRUG A CODE]), [DRUG B] and [DRUG C] ([REGIMEN A]) Versus [DRUG D], [DRUG B] and [DRUG C] ([REGIMEN B]) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM): Successor-1

Analyses Associated with the Primary Objective(s)

- Section 10.4: analyses associated with the primary objective(s), including statistical analysis method and handling of data in relation to the primary estimand(s).
- Kaplan-Meier estimates will be used to estimate survival distribution functions.
- PFS will be compared between treatment arms using a stratified log-rank test.
- A stratified Cox proportional hazards model will estimate the hazard ratio and 95% confidence interval.

Analyses Associated with the Secondary Objective(s)

- Section 10.5: analyses associated with the secondary objective(s), including statistical analysis method, handling of data in relation to secondary estimand(s), sensitivity analyses, and supplementary analyses.
- Secondary analyses include OS, response endpoints, MRD negativity, safety, and Stage 2 HRQoL.

Analysis Sets

Analysis Set	Description
Intent-to-Treat (ITT) Population	The intention-to-treat (ITT) population: All randomized subjects. The primary efficacy analysis will be based on this population, and subjects will be analyzed according to the randomized treatment assignment.
Safety Population	Safety population: All randomized subjects who take at least one dose of study treatment. All safety analyses will be based on this population and subjects will be analyzed based on the actual treatment received.
Pharmacokinetic Population	Pharmacokinetic population: All subjects who received at least one dose of study treatment and have measurable plasma concentration data. All analysis of PK data will be based on the PK population.

Sample Size Determination

Approximately 690 subjects are planned to be enrolled in Stage 1 and Stage 2 combined and randomized equally (1:1 ratio) into 2 treatment arms (345 subjects each) for the primary analysis. In Stage 1, at least 140 subjects will be initially randomized 1:1:1:1 (at least 35 subjects in each arm) to three [DRUG A] dose levels or to the [REGIMEN B] comparator arm. In

USDM => SDE => SDTM

From M11 Protocol Authoring to Source-Linked SDTM

Structured protocol content moves through governed validation, review, extraction, and SDTM-ready output.

1 Structured protocol authoring

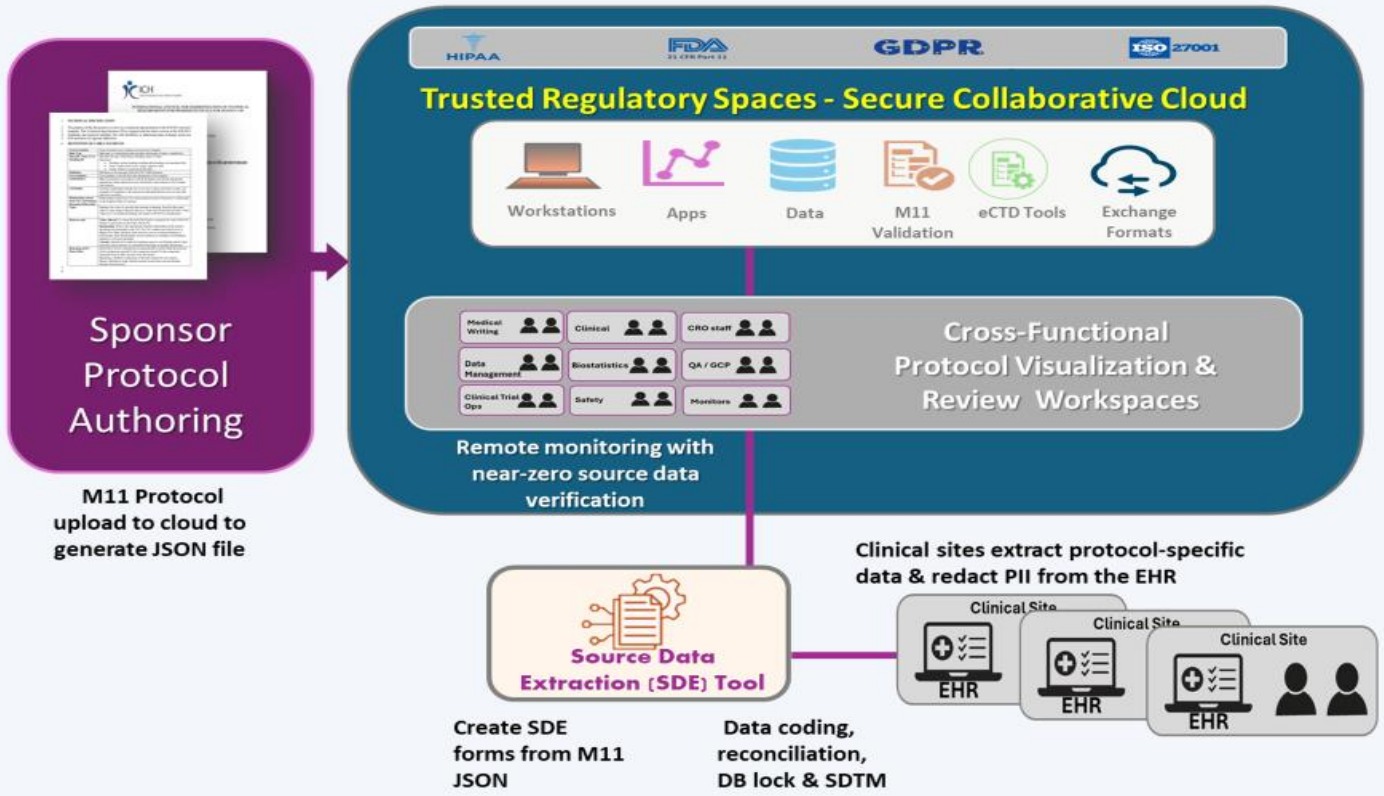
Machine-readable M11 JSON is created and uploaded.

2 Secure cloud workspace

Validation, governed collaboration, dashboards, and provenance controls.

3 Source-linked extraction

Structured protocol & SOA context support extraction form configuration, source-linked review, and SDTM-ready output.



M11/USDM & Standards Metadata Configure SDE Outputs

Protocol inputs

M11 / USDM JSON

machine-readable study content

Schedule of Activities

Visits
windows
assessments
procedures

where / when data are required

structure

requirements

SDE_Config

Study-specific SDE setup

combines protocol requirements with standards metadata

metadata

Standards Library

Capture templates
Terminology + units
Edit checks
SDTM targets

what / how each item is captured

SDE setup is configured from computable protocol structure and reusable CDISC-aligned metadata.

Configured data management outputs

Forms
Form and item requirements

Rules
Required fields + visit logic

Terminology
Controlled terms + units

SDTM targets
Pre-mapped dataset outputs

From USDM Metadata to Configured SDE Extraction Forms

M11 USDM JSON EXCERPTS

Objective -> Endpoint


```
{
  "id": "OBJ-PRI-001",
  "name": "Primary Objective 1",
  "text": "To compare the progression-
free survival (PFS) of [redacted]
to that of [redacted] in subjects
with relapsed or refractory
multiple myeloma (RRMM).",
  "level": {
    "id": "OBJ-PRI-001-LEVEL",
    "code": "PRIMARY",
    "codeSystem": "OBJECTIVE-LEVEL",
    "codeSystemVersion": "1.0",
    "decode": "Primary",
    "instanceType": "Code"
  },
  "endpoints": [
    {
      "id": "EP-PFS",
      "name": "PFS Endpoint",
      "purpose": "efficacy",
```


Activity -> Procedure -> Timeline


```
{
  "id": "Activity_20",
  "name": "HEMATOLOGY",
  "label": "Hematology",
  "description": "Hematology | Sections:
SAFETY LABORATORY TEST;
Safety Assessments",
  "previousId": "Activity_19",
  "nextId": "Activity_21",
  "childIds": [],
  "definedProcedures": [
    {
      "id": "Procedure_20",
      "name": "HEMATOLOGY",
      "label": "Hematology",
      "procedureType":
        "Protocol Schedule Activity",
```


USDM metadata

→

configured extraction forms

AI-assisted configuration with manual refinement

CONFIGURED EXTRACTION FORMS

PFS Endpoint Extraction Form

Protocol / Study ID	Site ID / Number	Subject ID / PTID	Visit Number / Name
Text (Auto)	Numeric	Alpha-numeric	Dropdown

Assessment

Date of Assessment	Method
Date	CT / MRI / Clinical

Survival Status

Subject Status	Date of Death
Alive / Deceased	Date

Progression Data

Target Lesion PD	New Lesions?	Non-Target PD	Overall Status
Yes / No	Yes / No	Yes / No	CR / PR / SD / PD

Hematology Extraction Form

Subject ID	Lab Test	Result	Reference Range	Status
001	HGB	12.8 g/dL	11.5-15.5	Accepted

Here is what that configuration looks like for two concrete extraction forms.

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Configured extraction forms guide AI / OCR / NLP

Once forms are configured, the form fields define what AI/OCR needs to recognize in source documents.

1. Configured extraction fields

PFS fields
assessment date
method
progression
overall status

Hematology fields
lab test
result
unit

2. OCR reads source documents

Converts scanned or PDF source content into machine-readable text.

3. NLP / AI identifies values

Finds the relevant clinical entities and values that match the configured fields.

4. Values populate review fields

Recognized values populate the configured fields. Reviewer confirms, corrects, or rejects.

Example: "Hemoglobin 12.8 g/dL" → Lab Test = HGB | Result = 12.8 | Unit = g/dL

Configured forms define the extraction targets; OCR / NLP identifies matching source values for review.

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Extracted outputs remain redacted, source-linked, and reviewable

The output remains reviewable and auditable; AI/OCR supports extraction but does not replace human confirmation.

1. Source recognition

OCR / NLP identifies relevant values and clinical entities in source documents.

2. Redaction + extraction

Sensitive source content can be masked as needed. Extracted values retain source linkage.

3. Human review

Reviewer confirms, corrects, rejects, or queries the extracted result.

4. Audit trail / downstream use

Decision history is retained, and outputs remain traceable and ready for downstream use.

EXAMPLE REVIEW OUTPUT

HGB = 12.8 g/dL | Overall Status = PD | Source link retained | Review status = Accepted

AI/OCR supports extraction and redaction; reviewer confirmation remains required.

Extracted values remain source-linked, redacted as needed, and reviewable through an audit trail.

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How Source Data Extraction (SDE) Works

Source Evidence

Lab Report

Patient: Zoe Smith
SS#: 322-44-9899
Visit: Screening
Hemoglobin: 12.8 g/dL

EHR export, PDF, image, or scanned source

Machine + Manual Redaction

Redacted Source

Lab Report

Patient [redacted]
SS# [redacted]
Visit: Screening
Hemoglobin: 12.8 g/dL

Source remains visible, but identifiers are masked

OCR + AI

Extracted value

Hemoglobin **12.8 g/dL**
Visit **Screening**

eCRF + Audit Trail

eCRF

SUBJID	LBTESTCD	LBORRES	LBORRESU
001	HGB	12.8	g/dL

Value + source link Audit trail

Monitor / sponsor review redacted source evidence from the audit trail.

What changes?

Source evidence to EDC without manual re-entry

No manual re-entry

Values are extracted from source evidence instead of manually transcribed into EDC.

Source agnostic

EHR extracts, PDFs, images, or scanned source; does not depend on FHIR.

Exception-Based SDV

Low-confidence or inconsistent fields are prioritized for human review.

Source-linked audit

Each accepted field retains a link to redacted source evidence and reviewer action.

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SDE redaction preserves reviewable source context

SDE PII Redaction

ORLANDO HEALTH
Cancer Institute

Dr. Sarah Mitchell, MD
Hematology/Oncology
1400 S Orange Ave
Orlando, FL 32806
Phone: Phone Number

Visit Date: 2026-04-17

PATIENT INFORMATION

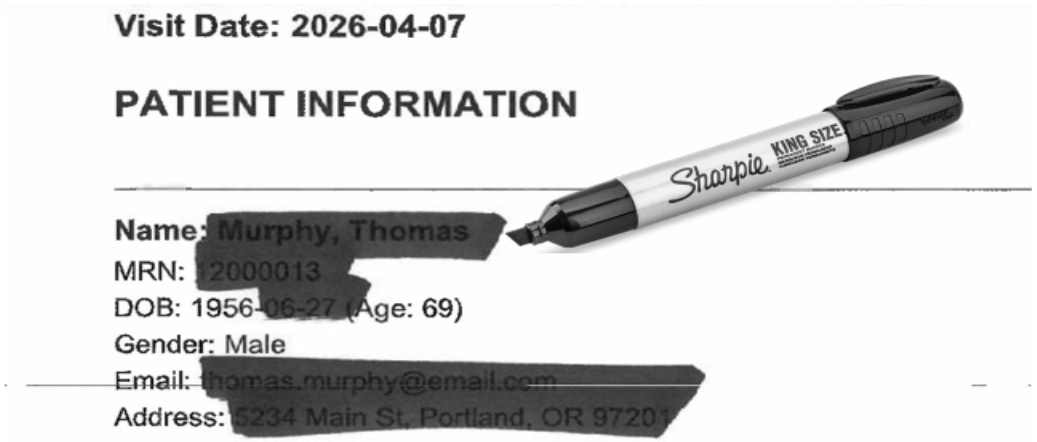
Name: NAME
MRN: MRN
DOB: 1954-12-20 (Age: 71)
Gender: Male
Email: Email
Address: Address

Identifiers masked

Clinical context retained

Audit-ready

EDC-Based Manual PII Redaction



Variable masking

Harder to audit

Potential leakage

Redaction must protect privacy while preserving the clinical context needed for review, traceability, and source-linked dataset creation.

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SDE supports traceable SDTM-ready outputs

Reviewed extracted value

Variable	Hemoglobin
Value	12.8
Unit	g/dL
Visit	Screening
Status	**Accepted**

source link retained

map

SDTM LB row

STUDYID	STUDY-A-001
USUBJID	SUBJ-001
LBTESTCD	**HGB**
LBORRES	**12.8**
LBORRESU	g/dL
LBDTC	2026-04-17

Provenance retained: source evidence + extraction run + reviewer action

validate

Validator feedback before database lock

What changes?

Pre-mapped output
Study setup carries SDTM targets forward.

Human-in-loop
Terminology and mapping are reviewable.

Validation earlier
Dataset checks occur before lock.

Provenance
Accepted values stay linked to source.

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Use case evidence / results

Protocol validation results: Sponsor A

Phase 3 oncology protocol with adaptive design complexity and downstream normalization needs.

Protocol Readiness	Structure: 76 pass / 0 fail Content: 51 pass / 0 fail / 1 skip	Document-level M11 structure and content checks performed strongly.
Tech Spec Field & USDM Schema	TS: 154 pass / 28 fail / 106 N/A USDM schema: pass	Field-level TS results identified triage items beyond document readiness.
CORE Conformance	CORE: 107 success / 98 skipped / 2 execution errors needing tech triage	Conformance and rendering remained distinct downstream gates.

Interpretation: document readiness, USDM schema validity, and CORE conformance are related but distinct readiness gates.

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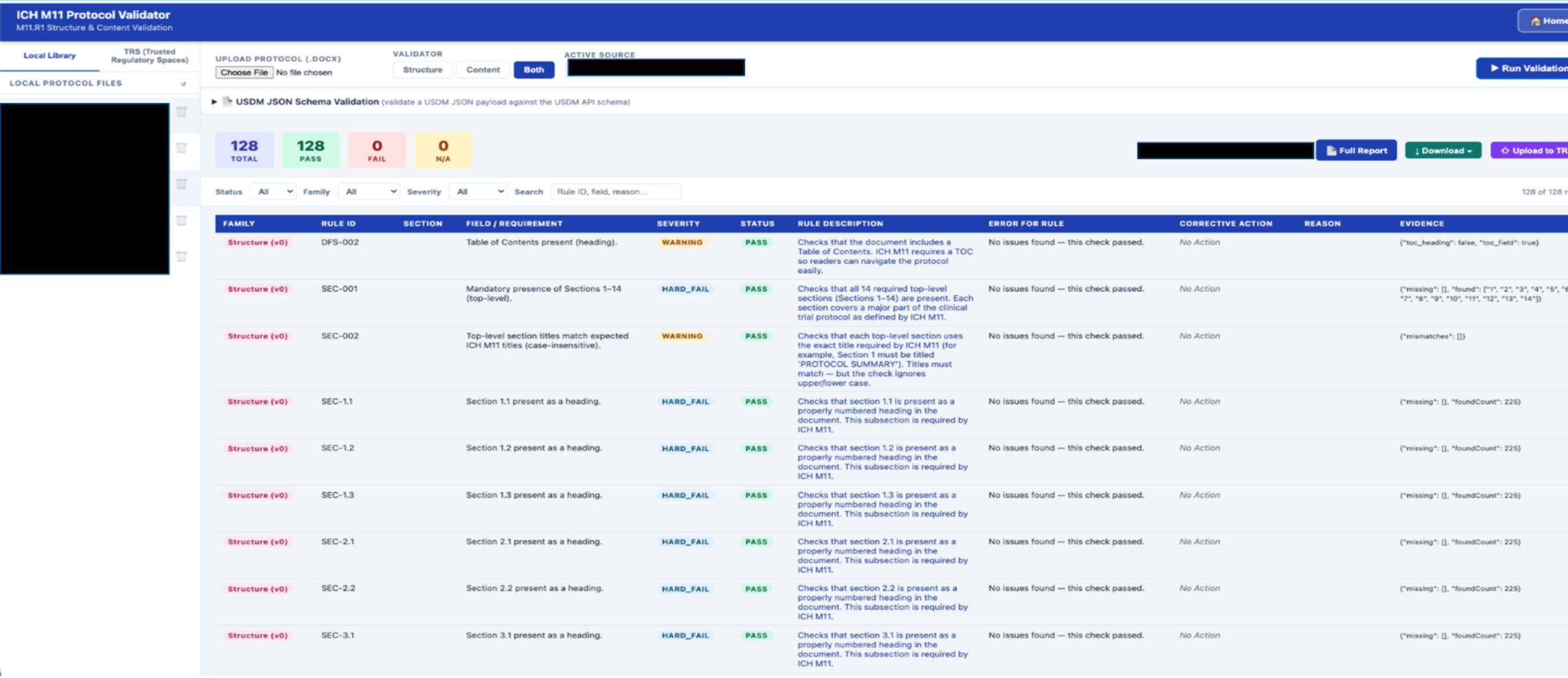
M11 protocol validation results output



FAMILY	RULE ID	SECTION	FIELD / REQUIREMENT	SEVERITY	STATUS	RULE DESCRIPTION	ERROR FOR RULE	CORRECTIVE ACTION	REASON	EVIDENCE
Structure (v0)	DFS-002		Table of Contents present (heading).	WARNING	PASS	Checks that the document includes a Table of Contents. ICH M11 requires a TOC so readers can navigate the protocol easily.	No issues found — this check passed.	*No Action*		{"toc_heading": false, "toc_field": true}
Structure (v0)	SEC-001		Mandatory presence of Sections 1–14 (top-level).	HARD_FAIL	PASS	Checks that all 14 required top-level sections (Sections 1–14) are present. Each section covers a major part of the clinical trial protocol as defined by ICH M11.	No issues found — this check passed.	*No Action*		{"missing": [], "found": ["1", "2", "3", "4", "5", "6", "7", "8", "9", "10", "11", "12", "13", "14"]}
Structure (v0)	SEC-002		Top-level section titles match expected ICH M11 titles (case-insensitive).	WARNING	PASS	Checks that each top-level section uses the exact title required by ICH M11 (for example, Section 1 must be titled 'PROTOCOL SUMMARY'). Titles must match — but the check ignores upper/lower case.	No issues found — this check passed.	*No Action*		{"mismatches": []}
Structure (v0)	SEC-1.1		Section 1.1 present as a heading.	HARD_FAIL	PASS	Checks that section 1.1 is present as a properly numbered heading in the document. This subsection is required by ICH M11.	No issues found — this check passed.	*No Action*		{"missing": [], "foundCount": 225}
Structure (v0)	SEC-1.2		Section 1.2 present as a heading.	HARD_FAIL	PASS	Checks that section 1.2 is present as a properly numbered heading in the document. This subsection is required by ICH M11.	No issues found — this check passed.	*No Action*		{"missing": [], "foundCount": 225}
Structure (v0)	SEC-1.3		Section 1.3 present as a heading.	HARD_FAIL	PASS	Checks that section 1.3 is present as a properly numbered heading in the document. This subsection is required by ICH M11.	No issues found — this check passed.	*No Action*		{"missing": [], "foundCount": 225}
Structure (v0)	SEC-2.1		Section 2.1 present as a heading.	HARD_FAIL	PASS	Checks that section 2.1 is present as a properly numbered heading in the document. This subsection is required by ICH M11.	No issues found — this check passed.	*No Action*		{"missing": [], "foundCount": 225}
Structure (v0)	SEC-2.2		Section 2.2 present as a heading.	HARD_FAIL	PASS	Checks that section 2.2 is present as a properly numbered heading in the document. This subsection is required by ICH M11.	No issues found — this check passed.	*No Action*		{"missing": [], "foundCount": 225}
Structure (v0)	SEC-3.1		Section 3.1 present as a heading.	HARD_FAIL	PASS	Checks that section 3.1 is present as a properly numbered heading in the document. This subsection is required by ICH M11.	No issues found — this check passed.	*No Action*		{"missing": [], "foundCount": 225}

How the use case performance was evaluated

Metrics were predefined to assess accuracy, privacy, traceability, and operational efficiency

Extraction Accuracy

% of
required data elements
correctly extracted

OCR / NLP Target Recognition Accuracy

% of target values and review flags
correctly identified

PII Redaction Accuracy

% of
PII correctly detected
& masked

Provenance Integrity

% of data values with
complete traceability back to
redacted source

Transcription Reduction

Reduction in manual data
entry compared to
current EDC workflow

Monitoring Effort

Reduction in CRC & monitoring
time compared to current EDC
review & SDV activities

All metrics were evaluated against predefined targets

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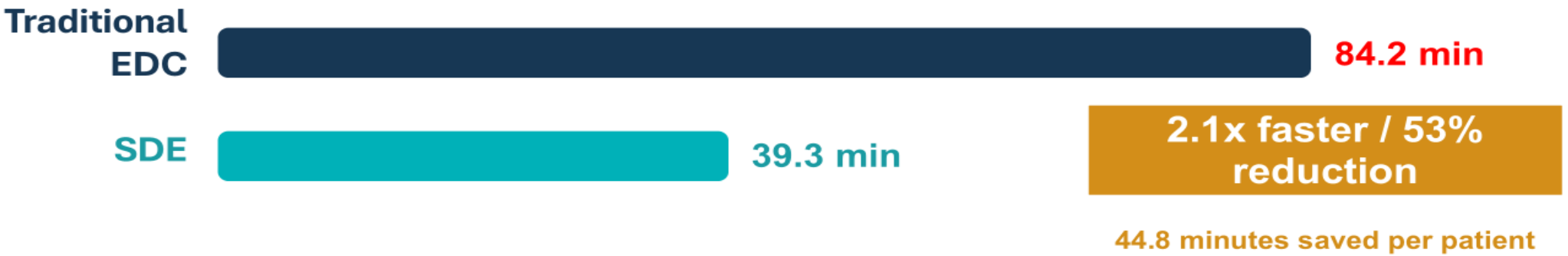
Sponsor A use case performance

Current use case performance against predefined targets

100%	100%	100%	100%	100%
Extraction accuracy	**OCR / NLP flag accuracy**	**PII redaction accuracy**	**Provenance integrity**	**Transcription reduction**
Target ≥95%	Target ≥90%	Target ≥99%	Target 100%	Target ≥80%

Measured CRC + Monitor Workflow Time per Patient*



*Includes measured CRC and monitor activities captured in both EDC and SDE use case workflows.

Estimated operational impact of SDE

The use case demonstrates a 53% reduction in measured workflow time—not elimination of the entire workflow-related operational costs

Phase III trial budget
$50M
Illustrative oncology trial

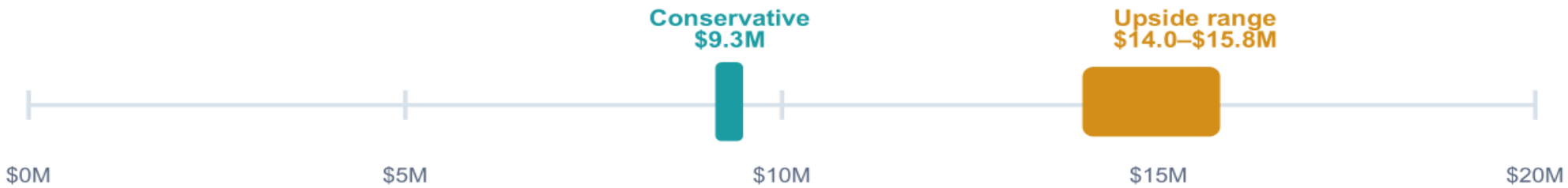
× 35%

Workflow Operational Costs
$17.5M
SDV / monitoring / duplicative entry

× 53%

Conservative estimate
$9.3M
Applies observed Sponsor A workflow reduction

Potential avoided effort per $50M Phase III trial



Conservative estimate applies observed 53% pilot workflow reduction. Upper range assumes 80–90% reduction of the broader transcription-dependent SDV, monitoring, and duplicative-entry costs.

Potential avoided effort per $50M Phase III trial: $9M–$16M

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Value at the portfolio level: reusable infrastructure

Across one trial

- Workflow efficiency improves
- Less manual transcription
- Earlier review
- Source-linked traceability

Across Many trials

- **Reusable**
  - Validation workflows
  - M11/USDM structures
  - Forms and mappings
  - TRS governance
  - SDE configurations

Portfolio-scale value comes from reuse, consistency, and governed workflow deployment — not simply multiplying per-trial savings estimates.

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From structured protocol to traceable SDTM output

A six-step flow turns a machine-readable protocol into traceable, SDTM-ready outputs.

01 M11 protocol ingested

Machine-readable protocol elements drive form requirements and reduced manual CRF setup.

02 Study-specific forms generated

USDM-aligned forms and domain mappings are pre-populated.

03 EHR content de-identified and redacted

PII/PHI is redacted before review.

04 Source-linked extraction with audit trail

Each field links back to its redacted source and low-confidence fields are flagged.

05 Automated checks and coding support

Reconciliation and discrepancy management occur before lock.

06 SDTM outputs delivered

Final datasets are transformed to CDISC SDTM and delivered with provenance.

Faster, traceable, standards-ready data — from protocol requirements to SDTM output with retained provenance

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Conclusions

M11 makes protocol content computable

USDM structures objectives, endpoints, activities, timelines, and study requirements as reusable metadata.

Validation is layered

M11 validation, USDM schema, CORE conformance, rendering, and SDTM validation address different readiness questions.

USDM drives SDE configuration

Structured objectives, endpoints, activities, and timelines support forms, rules, extraction targets, and SDTM-ready outputs.

Source-linked extraction strengthens traceability

Redaction and review decisions preserve traceability from source evidence to dataset output.

M11/USDM can provide the computable study structure needed to connect protocol requirements, source-linked extraction, validation, and SDTM-ready output.

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THANK YOU

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