Mapping the DEEP Stack to CDISC Standards: A Federated Library of Biomedical Concepts for Digital Measures

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1. Problem Statement

Digital measures are widely used in trials, but their metadata remains disconnected from Clinical Data Interchange Standards Consortium (CDISC) standards.

This creates inefficiencies:
- Manual translation into protocols
- Repeated Study Data Tabulation Model (SDTM) mapping
- Limited traceability for regulators

The CDISC DHT Portal introduces aligned DHT Concepts; a machine-actionable model linked to Biomedical Concepts and USDM could further improve consistency and reuse.

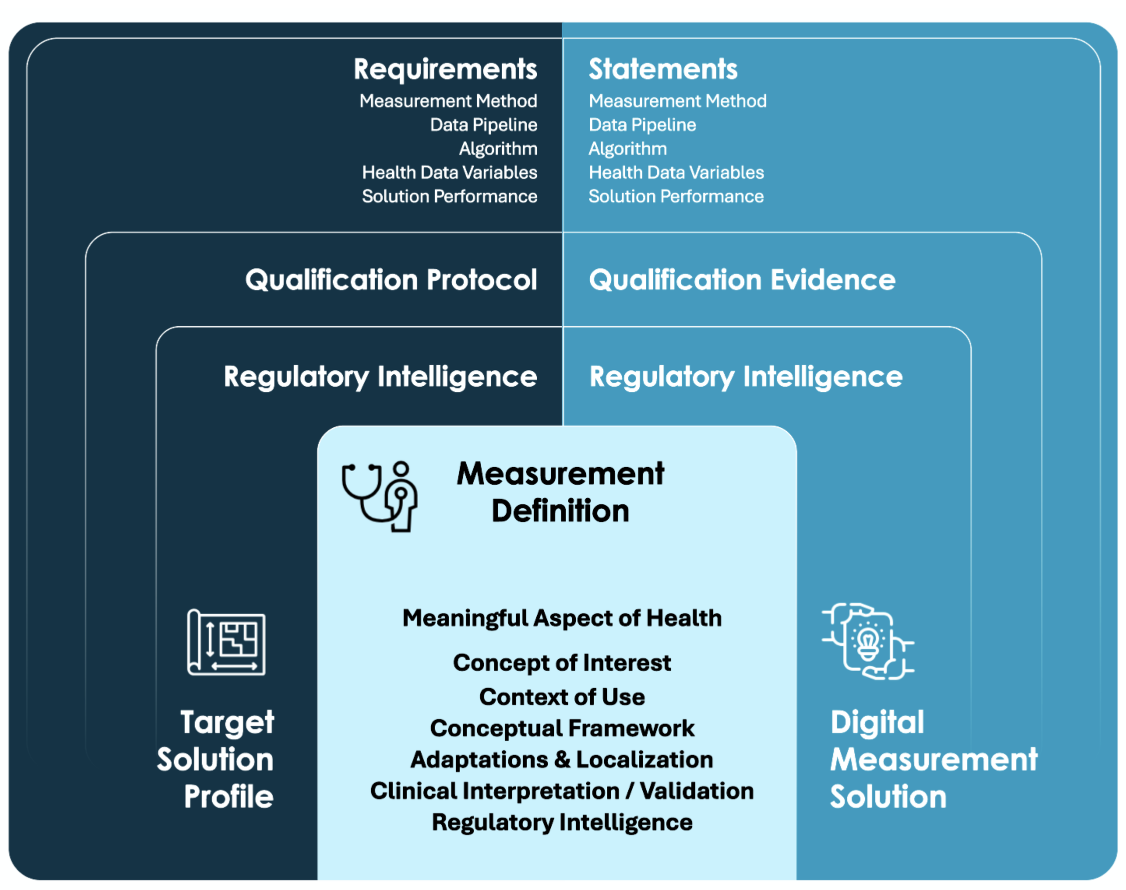
2. What is DEEP

DEEP Measures is a decentralized platform for curating, validating, and sharing digital measurement concepts. The DEEP Stack (Fig. 1) organizes knowledge into three layers:

- **Measurement Definition (MD):** what is measured (concept, context, population, regulatory context)
- **Target Solution Profile (TSP):** how it is measured (technical and performance requirements)
- **Digital Measurement Solution (DMS):** implementations with evidence-linked coverage

All layers are version-controlled and evidence-linked, enabling machine-actionable mapping to CDISC standards.

Figure 1: The DEEP Stack Model



3. Federated Library of Biomedical Concepts

The DEEP catalog is a federated library of digital measurement concepts with CDISC-aligned metadata, complementing the DHT Portal with structured, machine-actionable definitions.

Stride Velocity 95th Centile (SV95C) in Ambulant DMD

First wearable digital measure with EMA acceptance (primary endpoint 2023)

MEASUREMENT DEFINITION	TARGET SOLUTION PROFILE	DIGITAL MEASUREMENT SOLUTION
CONCEPT Max stride velocity (top 5%, real-world)	**SENSORS (essential)** accel · gyro · mag · barometer	**FORM FACTOR** 43×33×20 mm · 38 g · ankle-worn · Class I
HEALTH ASPECT Ambulation ability · ICD-11 8C70.1	**DEVICE** ≥100 Hz · ≥16 h battery · ≥7 d storage	**ALGORITHM** 130 Hz magneto-inertial · encrypted cloud
COU Primary endpoint · ambulant DMD · age 4+	**ALGORITHM** ≥97% stride detection · ICC ≥0.85	**PERFORMANCE** >99% normal · >97% atypical · ICC ≥0.90
VARIABLES velocity · length · duration · distance · count	**20 Requirements** ESSENTIAL / DESIRABLE	**Requirements** 20/20 matched
CDISC USDM Endpoint Definition; Biomedical concept; DHT Portal alignment	**CDISC** SDTM Device Metadata; Data collection specifications	**CDISC / FHIR** FHIR Device Definition; SDTM device char.

SDTM Mapping Validation

Interoperability Testing: Mapped SV95C against the CDISC DHT Portal's Step Count Example 1 (Ametris/CentrePoint) - the closest published SDTM pattern for a wearable digital measure.

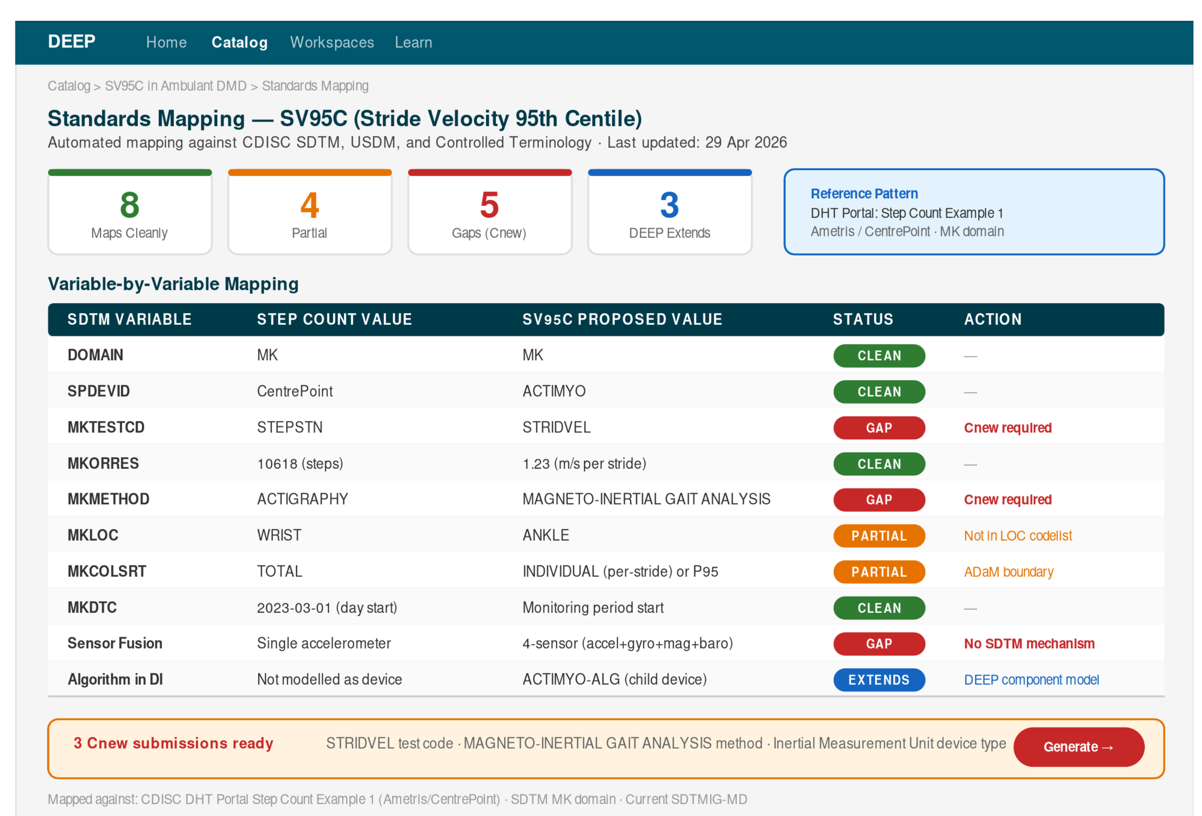
Results:
- ActiMyo device hierarchy aligns with DI/RELDEV parent–child structure
- MK variables, temporal fields, and result values transfer directly
- Gaps: no controlled terminology for stride-specific test codes or magneto-inertial gait methods; no SDTM mechanism for multi-sensor fusion metadata

Key finding: SV95C's 95th percentile derivation creates a clean SDTM–ADaM boundary: strides belong in MK, the percentile in ADaM (ADFA/ADQS). Step Count avoids this because total steps is a direct summary, not a derived statistic.

Mapping Scorecard

- **Maps Cleanly (8):** DI/RELDEV structure, MK domain, SPDEVID, MKREFID, result values, temporal variables, algorithm count
- **Partial (4):** Device Type terminology, MKLOC (ankle), stride vs step count semantics, algorithm transparency
- **Gaps (5):** Stride velocity test code, MKMETHOD terminology, sensor fusion, percentile derivation, TSP requirements
- **DEEP Extends (3):** Algorithm-as-device in DI, extended DI parameters, Measurement Definition layer

Figure 2: Mock-up of what a standards mapping view in the DEEP platform could look like.

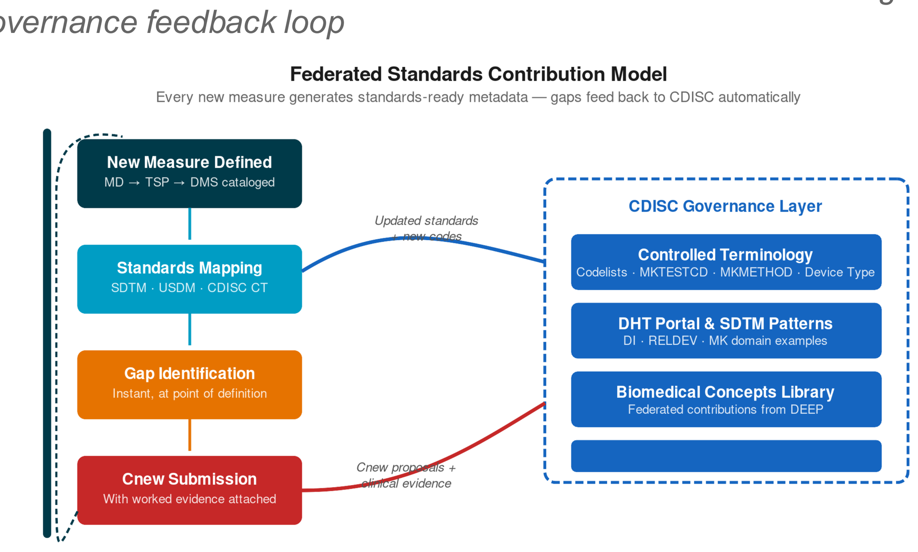


From Gaps to Standards

DEEP maps every measure to CDISC standards at the time of definition, so terminology gaps surface instantly - not months later during SDTM creation. Each gap generates a Cnew (New Controlled Terminology) ready submission package with evidence attached. As standards evolve, mappings refresh dynamically.

In a federated model, DEEP is a contributing node: consuming CDISC standards, surfacing gaps for digital measures, and feeding structured proposals back to governance. SV95C alone identified three Cnew candidates - stride velocity test codes, magneto-inertial gait method, IMU device type - each backed by an EMA-accepted use case (Ref. Qualification Opinion for Stride velocity 95th centile as primary endpoint in studies in ambulatory Duchenne Muscular Dystrophy studies - 2023)

Figure 4: Federated standards contribution model — DEEP catalog to CDISC governance feedback loop



4. Proposed Proof of Concept

We propose a focused pilot — analogous to CDISC 360i — to validate end-to-end standards mapping within a compressed timeline:

Phase 1: USDM / Protocol (Months 1–3)

Map DEEP Measurement Definitions to USDM Biomedical Concepts. Demonstrate automated protocol endpoint configuration using SV95C.

Deliverable: SV95C as USDM-conformant endpoint definition

Phase 2: SDTM Mapping (Months 3–5)

Map TSP variables and algorithm specifications to SDTM domains. Map DMS device metadata to DV domain, aligned with current SDTMIG-MD.

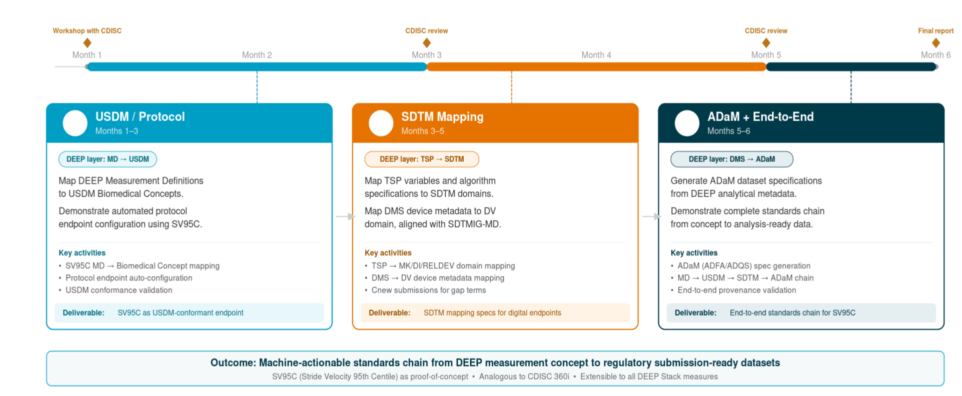
Deliverable: SDTM mapping specs for digital endpoints

Phase 3: ADaM + End-to-End Chain (Months 5–6)

Generate ADaM dataset specifications from DEEP analytical metadata. Demonstrate complete standards chain from measurement concept to analysis-ready structure.

Deliverable: End-to-end standards chain for SV95C

Figure 3: PoC timeline (indicative)

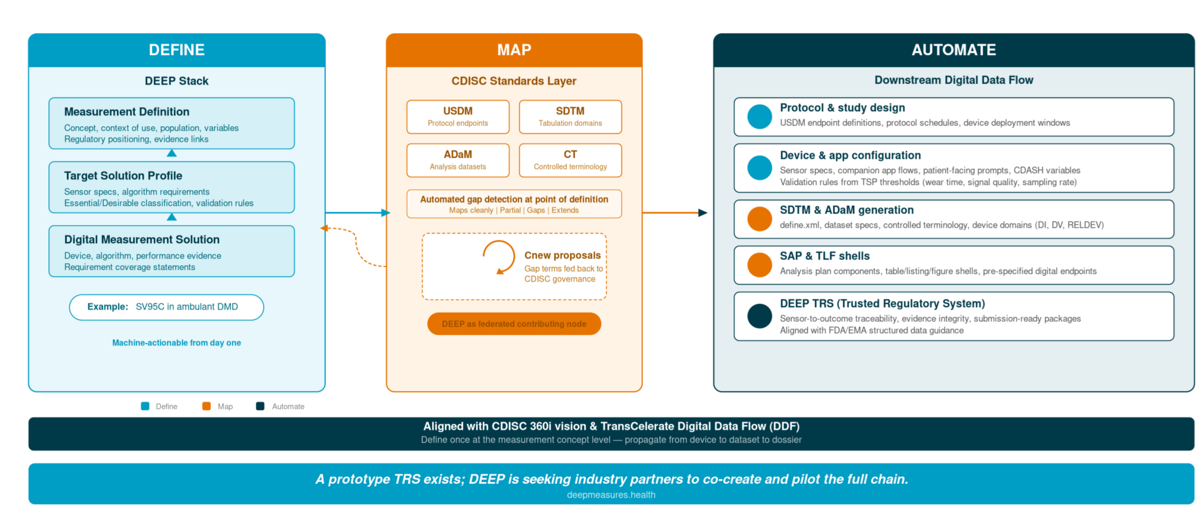


5. From Standards to Automation

When digital measurement concepts are machine-actionable and standards-mapped from the point of definition, the entire downstream chain becomes automatable — aligned with the CDISC 360i vision and TransCelerate Digital Data Flow (DDF).

Figure 5 illustrates this: DEEP Stack concepts flow through a CDISC standards mapping layer (surfacing gaps and generating Cnew proposals) then propagate to every downstream implementation step, from protocol design through regulatory submission. Define once at the measurement concept level, propagate everywhere, from device to dataset to dossier.

Figure 5: Define–Map–Automate — how machine-actionable DEEP Stack concepts flow through CDISC standards to enable downstream DDF automation.



6. Why It Matters to You

CDISC implementers & technology partners: Extend Biomedical Concepts to digital measurement endpoints: building on the DHT Portal's informative examples with machine-actionable metadata that drives automated EDC, device, and app configuration.

Sponsors & CROs: Compressed time-to-protocol for digital endpoints; machine-actionable metadata that eliminates manual SDTM mapping: automates data management plans, and generates submission-ready packages, reducing months of endpoint implementation to days.

Regulators: End-to-end traceability from sensor configuration to analytical plan: supporting regulatory acceptance, HTA submissions, and cross-study comparability of digital evidence.

Share your thoughts on regulatory submission, automation and standards with authors.

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