FHIR Structured Data Capture (SDC): Enabling Smarter, Standards-Based Data Capture in Healthcare

Executive Summary

Healthcare depends on data, but much of it is still captured in unstructured or semi-structured formats—free text, scanned forms, or proprietary systems that resist interoperability. This lack of structured data undermines clinical decision-making, quality reporting, research, and public health surveillance.

FHIR Structured Data Capture (SDC) is designed to solve this problem. As an HL7 FHIR implementation guide, SDC provides a standardized way to design, distribute, and process electronic forms using FHIR's Questionnaire and QuestionnaireResponse resources. It ensures that data collected from patients, providers, and systems is structured, coded, and ready for integration into clinical workflows, registries, and reporting pipelines.

By enabling features such as **pre-population of forms from existing EHR data**, **real-time validation against clinical terminologies**, and **extraction of captured responses into interoperable FHIR resources**, SDC transforms forms from static documents into dynamic, machine-readable data sources.

The benefits are clear:

- For clinicians: reduced manual entry and improved accuracy.
- **For health systems**: streamlined reporting, better interoperability, and compliance with regulatory standards.
- **For public health and research**: standardized, high-quality data for population health and evidence generation.

As healthcare moves toward value-based care, real-world evidence, and patient-centered outcomes, FHIR SDC represents a critical enabler of interoperable, high-quality data capture.

Technical Architecture

FHIR SDC builds on core FHIR resources—primarily Questionnaire and QuestionnaireResponse—and extends them with profiles, extensions, and implementation guidance. The architecture is designed to support end-to-end workflows for structured data capture across clinical care, research, and public health.

Core Components

- Form Definition (FHIR Questionnaire): Defines the structure of the form, including items, value sets, conditional logic, UI hints, and rules for pre-population.
- **Data Capture (FHIR QuestionnaireResponse):** Represents the completed form, containing patient- or provider-supplied data.
- **Pre-Population:** Uses FHIR APIs to retrieve existing data (e.g., demographics, lab results, medications) to auto-fill portions of the form.
- Validation: Ensures captured data aligns with required code systems (SNOMED CT, LOINC, ICD, RxNorm).
- **Extraction:** Maps responses into other FHIR resources (e.g., Observations, Conditions) for downstream workflows.

Integration Patterns

- **EHR Systems:** Embed SDC forms directly into provider workflows; auto-fill demographics and clinical history.
- **Patient-Facing Apps:** Distribute structured questionnaires to patients through SMART-on-FHIR apps or patient portals.
- Registries/Public Health: Use SDC to standardize submissions for disease surveillance, vaccine monitoring, or adverse event reporting.
- Research Platforms: Deploy SDC-enabled eCRFs for clinical trials, ensuring harmonized data collection. Form Designer

Use Cases for FHIR SDC

1. Clinical Intake & Patient-Reported Outcomes (PROs)

Patients complete pre-populated intake forms before visits. Responses map into Observation and Condition resources, reducing clinician burden and supporting value-based care.

2. Public Health Reporting

Providers complete standardized forms for reportable diseases (e.g., COVID-19). Structured responses flow directly to public health agencies, improving timeliness and accuracy.

3. Clinical Trials & Research (eCRFs)

Research sites use SDC-enabled forms as electronic Case Report Forms (eCRFs). Captured data maps into standardized Observations, harmonizing data across trial sites.

4. Quality Reporting (CQMs)

Clinicians complete SDC-enabled forms that map directly to Clinical Quality Measures. This reduces manual chart abstraction and supports pay-for-performance programs.

5. Adaptive Questionnaires

Forms dynamically adjust based on responses (e.g., chest pain triggers cardiac follow-up questions). This improves efficiency and patient experience. Questionnaire (the structured form)

Questionnaire (the structured form

```
{ "resourceType": "Questionnaire",

"id": "sdc-example-1",

"status": "active",

"subjectType": ["Patient"],

"title": "Diabetes Risk Assessment",

"item": [ { "linkld": "q1",

"text": "Do you have a family history of diabetes?",

"type": "boolean" }, {

"linkld": "q2",

"text": "What is your age?",

"type": "integer" }, {

"linkld": "q3",
```

```
"text": "What is your BMI?",

"type": "decimal" } ]}
```

QuestionnaireResponse (the filled-out form)

```
{ "resourceType": "QuestionnaireResponse",
  "id": "sdc-example-response-1",
  "questionnaire": "Questionnaire/sdc-example-1",
  "status": "completed",
  "subject": { "reference": "Patient/example"
  }, "item": [ {
    "linkld": "q1",
    "answer": [
      { "valueBoolean": true }
    ] }, {
    "linkld": "q2",
    "answer": [ { "valueInteger": 52 } ] }, {
    "linkld": "q3",
    "answer": [
      { "valueDecimal": 27.5 } ] }]}
```

Challenges & Considerations

1. Implementation Complexity

SDC adds many extensions to base FHIR resources. Vendors need specialized rendering engines, and many EHRs don't fully support SDC yet.

2. Terminology Management

Reliable use of SNOMED CT, LOINC, ICD-10, and RxNorm is essential. Mapping local codes or free text remains difficult.

3. Interoperability Gaps

Pre-population and data extraction rely on consistent FHIR APIs, which vary across vendors.

4. Workflow Integration

Clinicians already face form fatigue. Without careful integration, SDC could add burden instead of reducing it.

5. Scalability

Large health systems may need to manage hundreds of forms, requiring governance, versioning, and lifecycle management.

6. Regulatory & Adoption Barriers

While SDC supports compliance, it is not yet mandated by regulators. Adoption is uneven across vendors and systems.

Future Outlook

FHIR SDC is still in early adoption, but several trends will drive its growth:

- 1. **Adaptive, Intelligent Questionnaires:** Al/ML-enabled forms will dynamically tailor questions based on responses.
- Integration with SMART-on-FHIR Apps: More patient- and provider-facing apps will embed SDC forms directly.

- 3. **Patient-Reported Data at Scale:** SDC will become a backbone for chronic disease management and outcomes tracking.
- 4. **Regulatory Alignment:** ONC, CMS, and FDA may incorporate SDC into compliance requirements for reporting.
- 5. **Real-World Evidence & Research:** SDC-enabled eCRFs will streamline trial submissions and evidence generation.

Conclusion

Healthcare has long struggled with inconsistent, unstructured, and siloed data capture. **FHIR Structured Data Capture (SDC)** offers a standards-based framework that turns forms into dynamic, interoperable sources of high-quality data.

By leveraging **pre-population**, **terminology binding**, **adaptive logic**, and **data extraction**, SDC ensures that captured data is complete, coded, and usable across clinical, research, and public health domains.

The challenges are real—complexity, workflow integration, and uneven vendor readiness. But the benefits are profound: less clinician burden, higher-quality data, streamlined reporting, and new opportunities for patient-centered research.

FHIR SDC is more than a technical specification; it is a bridge between human data entry and machine-readable healthcare intelligence. Organizations that adopt it now will be better prepared for value-based care, regulatory compliance, and data-driven innovation.

References

Standards & Technical Foundation

- The HL7 FHIR SDC Implementation Guide outlines how to standardize form structure, pre-population, and submission using Questionnaire and QuestionnaireResponse resources <u>HL7</u>.
- The IHE Structured Data Capture (SDC) Profile describes the underlying infrastructure for form retrieval, data capture, submission, and interoperability using XML-based forms wiki.ihe.net.
- The ASPE (HHS) project contextualizes SDC in enabling EHRs to provide and submit structured forms for case reporting, including examples like public health and adverse event reporting <u>ASPE</u>.

Use Cases & Domain Applications

- SDC's role in oncology demonstrates how structured data entry forms capture complex clinical information with maintained semantic integrity—vital in pathology, biomarkers, clinical trials, and aggregating research data <u>PubMedASCO Publications</u>.
- IHE's SDC on FHIR efforts aim to wrap traditional SDC forms into FHIR-compatible resources for transmission and interoperability <u>ASCO Publications</u>.

Real-World Implementations

 Aidbox Forms showcased at the HL7 FHIR Connectation 2025 demonstrates practical implementation of all SDC roles—from form design to data submission—within the FHIR ecosystem health-samurai.io.

Broader Interoperability Context

- HL7's FHIR standard is a spearhead for healthcare data exchange, evolving toward RESTful, resource-oriented interoperability <u>Wikipedia+1</u>.
- SDC bridges legacy IHE/FHIR, enabling structured form workflows essential for standards-based exchange in clinical, research, and public health domains wiki.ihe.netdeveloper.digitalhealth.gov.au.