# SDC Scope Guidelines

This document summarizes the boundaries that will be used in evaluating what functionality should be included in the implementation guides (IGs) created as part of the SDC project. It also identifies the boundaries used for determining what content included in the IGs must be “supported” by implementers and what content is considered to be optional.[[1]](#footnote-1)

There are three primary areas of scope: Form Design and Answer Capture; Auto-populate/ pre-populate; and Data Element.

### Form design and answer capture

The scope for form design will be driven by the requirements in the [SOAP/SAML schema](http://wiki.siframework.org/SOAP+SAML+IG+Schemas). Any new requirements not present in the [SOAP/SAML schema](http://wiki.siframework.org/SOAP+SAML+IG+Schemas) will be deferred to a subsequent release unless they are deemed “essential” to the adoption/success of first release of the implementation guide. Content present in the [SOAP/SAML schema](http://wiki.siframework.org/SOAP+SAML+IG+Schemas) may be excluded or changed[[2]](#footnote-2) in the [FHIR IG](http://hl7.org/implement/standards/FHIR-Develop/sdc.html) if:

* FHIR architecture drives a distinct approach in order to be consistent with other resources (e.g. the handling of identifiers using the “identifier” data type)
* The functionality in the [SOAP/SAML schema](http://wiki.siframework.org/SOAP+SAML+IG+Schemas) is “placeholder” content which is not tight enough to allow direct interoperability[[3]](#footnote-3). (e.g. “rules”)

All changes and exclusions identified by the project’s FHIR representative will be discussed with the work group. If consensus can’t be reached, issues may be escalated using HL7’s normal processes (Orders & Observations FHIR committer, Orders & Observations work group, FHIR Management Group, FHIR Governance Board, etc.). SOAP/SAML “placeholder” content will be deferred for consideration in subsequent releases of the SDC FHIR specification.

The determination of whether a given element in a form design should be “must support” or “optional” will be based on the number of institutions (e.g. NCI, FDA, NLM, CAP, etc.) that currently support that element within their own form designs. The work group will determine a cut-off (e.g. “at least 2” or “at least 3”). Any element not supported by at least that many institutions would be deemed “optional”.[[4]](#footnote-4)

### Auto-populate/pre-populate

Both auto-population and pre-population will be supported by the specification. The [FHIR IG](http://hl7.org/implement/standards/FHIR-Develop/sdc.html) will cover data elements that support **pre-population** based on the HL7 Consolidated Clinical Document Arc hitecture (CCDA) as well as any other XML-based source specification. It will not mandate support for any specific data elements. Language describing expectations for conformance-testing around pre-population will be proposed to and discussed with the SDC work group prior to inclusion in the specification..

### Data Element

Data Element will be handled by two separate implementation guides – the “original” guide that focuses on form creation and population and a new guide that focuses on data element curation and exchange.

The former will look similar to the existing profile with a possible reduction in one or two elements or changing of a few existing requirements to optional. It will focus solely on what data element characteristics are necessary to support form design and auto/pre-population of forms and where the search space for data elements is no more than 1,000[[5]](#footnote-5). It is likely that most of the data element properties identified as “Core Form DE Attribute” in the original SDC project phase will be included in this list. However, in keeping with FHIR principles, the final list of attributes will be based on “what would an implementer realistically need to support form design and population?”.

The new profile will draw its requirements from the complete set of “final” properties in the SDC Data Element Attributes spreadsheet. As for form design, exceptions will be made where the requirements are not sufficiently refined to be directly interoperable or are in conflict with FHIR architectural principles. All exclusions or alterations will be discussed with the SDC work group and can be escalated if necessary. Mappings to the equivalent FHIR property will also be reflected in the SDC data element spreadsheet.

Like form design requirements, optionality (whether implementers must support a particular data element property) will also be driven by the number of institutional registry implementations that support the property. The cut-off point will be decided by the work group.

The “curation” implementation guide will include basic expectations for a data element registry in terms of supported RESTful FHIR operations (create, update, search, subscribe, etc.) but will not attempt to standardize business rules around curation (who can curate, workflow for the curation process, etc.)

1. Conditionality and cardinality are separate things – an element might be 0..1, while still requiring elements to support it. As well, a 1..1 element might be optional from a conformance perspective – an implementer could satisfy the 1..1 by always sending a fixed value or could ignore data received. [↑](#footnote-ref-1)
2. While particular elements might be excluded or modified, the underlying business requirement must be supported by FHIR in some manner, even if using a different architectural approach. For example, in FHIR, business identifiers and versions are conveyed using separate elements and the business identifier is conveyed with a complex structure separating namespace and ‘id’. This still meets the underlying business need for identification and versioning. [↑](#footnote-ref-2)
3. “Direct interoperability” means that two systems would be able to independently (no site-to-site negotiation/discussion) construct instances using the specification, share them and successfully process those instances in a manner where content is understood sufficiently to meet SDC use-cases. I.e. form display, population, etc. [↑](#footnote-ref-3)
4. The specification could define how systems handle different optional elements that are not supported – e.g. “ignore element” or “refuse to process form” [↑](#footnote-ref-4)
5. The number of data elements influences the complexity of metadata necessary to allow form designers to find and select the appropriate data element from among the list of possibilities. [↑](#footnote-ref-5)