

5.3 Clinical Data Forms Definition and Modeling

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Clinical Data Forms Definition and Modeling

Clinical Data Forms are the primary channel for capturing information in the healthcare and clinical domain. Forms also play a key role in information exchange and are critical to supporting interoperability in healthcare.

A form differs from a document, in that a document is used to capture information, while a form defines skip patterns, validation rules, and other aspects required to capture or render information for a document.

A document in this context is specifically a clinical document which represents information about a clinical activity. The document contains the specific information gained during that clinical activity and supports the broader definitions of a document. Documents can be transformed into human readable forms, and be transferred or transmitted electronically for use across different systems.

Clinical data forms definition and modeling help to accomplish the following:

Define data entry forms using robust data representation. Ultimately the data that is captured on a form is used in many ways, but that data must provide a high level of meaningful use to insure the consumer knows how the data was captured and what context it represents. In this way even a simple question on a form may result in a much more complex representation in the data. As an example, a Yes or No question on a form may result in a codified representation of an observation.

Reuse contextual representation. Since a given form may collect data for a context that might be common to many forms, being able to reuse these elements in a way that insures contextual consistency is a must. Forms created with the form definition tool must retrieve from well defined metadata sources that provide common contexts, default values, and coded representations including value set binding.

Reuse form elements. When defining a form element which is bound to a specific contextual representation, it should be easy to reuse that element with minimal reconfiguration.

Provide governance support. Forms and the supporting schemas need to be versioned as well as support the governance workflows. This insures that documentation follows a consistent and planned use.

5.3.1 Clinical Data Form Functions

The functions of clinical data forms include the ability to:

- Define model objects for reuse
- Define form templates
- Bind value set to data element
- Provide default form delivery
- Provide form data transformation

Based on the use cases the key forms requirements include:

- Tools and services for defining form templates
- Ability to leverage models and reusable segments for defining these forms
- Ability to bind terminology in the form of value sets to form controls
- User friendly tools that hide the complexity of the underlying semantics

The requirements listed above are derived from the following use cases:

- *Electronic Health Records*
- *ONC and Other external EHR adopters*
- *Clinical Trials*