

# Init1bes9 - CDEs from Man. curation, UML models and CRFs

## Pre Interview:

Item	Information/Response
Date:	12/23/2009
Requirement # unique id <SemCon Ops Initiative>.<analysts initials><requirement number> e.g. Init1dbw1 (eventually linked to Use Cases)	Init1bes9
Originator/Customer's Name:	Tommie Curtis and Brian Davis
Originator/Customer's Company:	SAIC and BAH
Summary of requirement pre-interview, by Reviewer:	<p>Business goal: Ability to develop forms with persistence layers Actor: Metadata Specialist (Form Author) A metadata specialist will use a dynamic form development tool that allows the form designer to interact with the MDR /Models/Rules repository to create new forms that are compatible with existing content.</p> <p>This requirement includes the following 4 use cases: (1) collection of standardized data utilizing reusable data elements (2) defining the form structure (3) defining the form behavior (4) generating the data persistence models to support the form.</p> <p>The tool should interact with a repository (or multiple repositories) that stores:</p> <ul style="list-style-type: none"> <li>- Data Element-centric metadata including the abstract concept (CDE) with its associated value domain (e.g. in Knowledge Repository). Data elements should be able to be used regardless of their source (a form based CDE or model based CDE that became available through model load to Knowledge Repository).</li> <li>- Form metadata including the definition of the form structure including sections, order and their relationships. And also the form behavior including value set constraints, skip logic, repetition and optionality</li> <li>- Persistence metadata including the contextually defined and constrained instance of use of an abstract concept in a data persistence model, and the binding of form structural elements to persistence model elements in a given context of use</li> </ul>
Recommended Next Step Enter one: Follow-up interview, Observe, Use Case Template (text), Use Case Model (formalized/UML diagram), Group Discussion, Prototype, Waiting Room	Development of detailed use cases

## Post Interview - ongoing throughout development of use cases:

Item	Description	Information/Response
Stakeholder Community:	<p>Enter appropriate category of stakeholder from Primary Stakeholders:</p> <ul style="list-style-type: none"> <li>• Software and Application designers and architects</li> <li>• Software and Application engineers and developers</li> <li>• Scientific and medical researchers</li> <li>• Medical research protocol designers</li> <li>• Clinical and scientific research data and metadata managers</li> <li>• Clinicians</li> <li>• Patients</li> <li>• Medical research study participants</li> <li>• Broader Stakeholders: caBIG® Community WS NIH projects and related commercial COTS vendors (caEHR, SDO's (HL7, CDISC); International Collaborators (e.g NCRI, cancerGrid, China), Government and regulatory bodies (FDA, CDC, ONC) (<a href="#">link to view SemConOps Stakeholders description</a>).</li> </ul>	<p>Clinical and scientific research data and metadata managers <b>OR</b> <b>Metadata Specialist:</b> having a deep understanding of semantics and syntactic, assists Cancer Researchers and Information Technologists on modeling and managing metadata</p> <ul style="list-style-type: none"> <li>• <b>Forms Author:</b> constructs data collection forms based on a library of common data elements</li> <li>• <b>Metadata Curator:</b> works hands-on with Cancer Researchers and Information Technologists to model and manage their metadata</li> </ul>
Requirement Type (required)	<p>Analyst's assessment of the most appropriate category/type of requirement (<i>no need to ask interviewee</i>):</p> <ul style="list-style-type: none"> <li>• <b>Functional:</b> Fundamental or essential to the product - describes what the product has to do or what processing is needed</li> <li>• <b>Nonfunctional:</b> properties the functions must have such as performance, usability, training or documentation <ul style="list-style-type: none"> <li>◦ <b>Project constraint:</b> schedule or budget constraints</li> <li>◦ <b>Design constraint:</b> impose restrictions on how the product must be designed, such as conformant to ISO 11179, utilizes 21090 or is able to work on a particular type of device</li> <li>◦ <b>Project driver:</b> business-related forces such as descriptions of stakeholders or purpose of the product/project</li> <li>◦ <b>Project issue:</b> conditions that will contribute to the success or failure of the project</li> </ul> </li> </ul>	<b>Functional</b>

ConOp Initiative(s) <i>Requirements Analyst /Business Analyst</i>	<ul style="list-style-type: none"> <li>• Select most appropriate initiative: (click for descriptions)</li> <li>• <a href="#">Initiative 1 - Distributed, federated metadata repositories and model repositories and operations</a></li> <li>• <a href="#">Initiative 2 - Automated generation of metadata from line-of-business artifacts</a></li> <li>• <a href="#">Initiative 3 - Rules management and contracts support (behavioral semantics)</a></li> <li>• <a href="#">Initiative 4 - Semantics support for W3C service oriented architecture resources</a></li> <li>• <a href="#">Initiative 5 - HL7 CTS II/ OMG MIF compliant federated terminology services</a></li> <li>• <a href="#">Initiative 6 - Controlled biomedical terminology, ontology and metadata content</a></li> <li>• <a href="#">Initiative 7 - Assessment of semantic unification of compositional and derivational models</a></li> <li>• <a href="#">Initiative 8 - Other</a></li> </ul>	---
<b>High Level Use Case Summary)</b> <i>Requirements Analyst /Business Analyst</i>	Please write a short descriptive narrative use case; the steps or activities in this use case are usually the things the user wants to accomplish with the system (user/actor's goals).	---
<b>Use Case Linkage (required)</b> <i>Business Analyst</i>	Which use case(s) is this requirement linked to? (should follow Use Case numbering scheme <Sem Con Ops Initiative>.<analysts initials><requirement number>.<use case number>, for example Init1dbw1.1, Init1dbw1.2, Init2dbw2.1, 2.2, etc.	Use case Number(s):
<b>Conflicts / Dependencies (required)</b> <i>Requirements Analyst /Business Analyst</i>	Are there any conflicts with other requirements / use cases?	Yes OR No - If yes, what and why?
<b>Next Step (required)</b> <i>(Requirement Analyst / Business Analyst)</i>	After reviewing the results of the interview, the forum, and all other materials related to this requirement, the analyst should recommend the next step, then attach the Tiny Link (on the Info tab) for this page to the <a href="#">Master List</a> table.	Enter one: Follow-up interview, Observe, Use Case Template (text), Use Case Model (formalized/UML diagram), Group Discussion, Prototype, Waiting Room