Init1pm13 - Medidata

Pre Interview:

Item	Information/Response
Date:	12/17/2009
Requirement # unique id *<SemCon Ops Initiative>.<analysts initials><requirement number>* e.g. Init1dbw1 (eventually linked to Use Cases)	Init1pm13
Originator/Customer's Name:	Christo Andonyadis
Originator/Customer's Company:	NCI
Summary of requirement pre-interview, by Reviewer:	Medidata is the clinical trials database selected by NCI for use at trial sites. Medidata supports the import and creation of forms by Forms Authors based on common data elements. Associated with this are likely to be a number of use cases on the functionality that Medidata needs for querying and importing CDEs and forms. See attachments for additional information. • NCI Use Case Review_ Labs 20091211.ppt • NCI HLR Review All 20091209.ppt • medidata_notes_20081211.doc One of the requirements currently not met is the need to be able to specify that a CDE on a form can have multiple answers selected from the enumerated value list. Currently this is captured in the Question Instruction of the Form objects. Users would like to be able to specify this for the CDE. one approach is to create a Derived Data Element composed of the number of CDEs that are permitted in the response. this can be supported in the current 11179 Ed 2 metamodel. Furthermore, it appears that what is needed is a collection of metadata "things" - forms, CDEs, etc. that are named and have privileges. There are some in global scope (managed by a certain few people), a user can create any number of them, and that user can make his publicly available (say, give me John's public collections, then give me John's Breast Stdy 123 collection). There would be a service (API) with these types of functions.
Recommended Next Step Enter one: Follow-up interview, Observe, Use Case Template (text), Use Case Model (formalized/UML diagram), Group Discussion, Prototype, Waiting Room	Use Case Development (2/3/2010) Assigned to Mohamed