# Init1SD40-Requirements

## Initial Analysis:

| Item | Information/Response |
|---|---|
| **Date**: | 02/08/2010 |
| **Requirement # unique id** <*SemConOps Initiative>.<analysts initials><requirement number>*<br>e.g. Init1dbw1<br>(eventually linked to Use Cases) | Init1SD40 |
| **Originator/Customer's Name**: | Sue Dubman |
| **Originator/Customer's Company**: | Genzyme |
| **Summary of requirement initial analysis, by Reviewer:** (as unambiguously as possible, describe who (List of Actors) is interacting with the system, what the business goal is and how the system might support the actor's ability to acheive their goal) | The primary actors are the information Technologist and Biostatistician.<br><br>Unlike clinical data management systems designed for spotless clean accountability in all phases of the data entry and management functions, clinical biostatistics processes are largely ad hoc and tedious. Integrated systems are needed by industry to provide a programming environment for production of tables, figures, and listings, for storage of data in secure and compliant repositories, for easy data access to data and results in a collaborative environment, and electronic submission of results to regulatory authorities.<br><br>The business goal is to make whole data analytic process transparent, traceable and collaborative.<br>Requirements:<br>Their is a need for an ability to store and retrieve data objects and its associated semantics and metadata<br>Their is a need for standardized data exchange format clinical data generated over the entire period of clinical trial.<br>A standardized meta-framework needs to be defined for analytical services that is generic enough to represent a specific or a sequence of statistical methods.<br>A Security framework for access and analysis of data that will provide traceability. |
| **Recommended Next Step** Enter one: Follow-up interview, Observe, Use Case Template (text), Use Case Model (formalized/UML diagram), Group Discussion, Prototype, Waiting Room | Review from originators<br>follow-up interview |