

Init3SD1_Formal representation of policies and regulations

Pre Interview:

Item	Information/Response
Date:	01/13/2010
Requirement # unique id <SemCon Ops Initiative>.<analysts initials><requirement number> e.g. Init1dbw1 (eventually linked to Use Cases)	Init3SD1
Originator/Customer's Name:	Hannes Neidner
Originator/Customer's Company:	San Diego Supercomputer Center
Summary of requirement pre-interview, by Reviewer:	<p>Due to the plethora of legal, regulatory, policy,proprietary, and contractual barriers to data exchange in caBIG, the set of guidelines that define compliance to caBIG should reflect the regulatory framework under which the data exchange would happen so that it creates a synergy amongst all regulatory and compliance obligations.</p> <p>Primary actor is clinical researcher who wants to make sure that while he doing research and collaborating with others still complies to all regulatory requirement.</p> <p>The business goal is to make regulatory compliance simple and computable.</p> <p>1) There needs to be a computable representation of all regulatory requirement (legal, regulatory, policy,proprietary, and contractual) that can be plugged into the application design process and consumed by caBIG applications/services.</p> <p>2) caBIG should make it a priority to unify and simplify the regulatory and legal context of clinical research</p>
Recommended Next Step Enter one: Follow-up interview, Observe, Use Case Template (text), Use Case Model (formalized /UML diagram), Group Discussion, Prototype, Waiting Room	Interview