Semantic Infrastructure Concept of Operations Stakeholders

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Stakeholders Overview

The caBIG® Semantic Infrastructure will operate within a broad stakeholder community consisting of representatives of all of the professions and services involved in medical research and clinical care.

Primary stakeholders of the caBIG® Semantic Infrastructure include caBIG® and BIG Health, federal and international semantic content development partners (notably FDA and CDISC), developers and users of the caEMR, and software vendors that rely on the ECCF artifacts to develop offerings compatible with caBIG® specifications. It is anticipated that many of these stakeholders will not leverage our implementations, but rather will provide independently developed implementation that will interoperate with caBIG® or caGrid.

Some stakeholders are direct or indirect end users of the terminologies (EVS) and the registered metadata (MDRs).

Direct Users

Direct end users of the semantic infrastructure are those who would leverage the terminology or metadata programmatically to build metadata driven software, for designing data services or for electronic data collection applications from the registered metadata. Others might use the user interfaces to look up the meaning of terminology when writing research papers, annotating instance data, or annotating metamodels for registration to be used in future software development, discovery and data/information mining services, data items found on forms, in applications or data repositories developed by the community.

Indirect Users

Indirect users are those using the software applications that have been developed on top of the semantic infrastructure such as an application to discover related data or analytic services, an online data collection application in which the reference documentation registered alongside the metadata item and made available by the application as on-line "Help" such as instructions or standard documentation. Other indirect users may use software written to leverage the semantic infrastructure to discover new or hidden relationships in the data.

Primary Users

The primary direct and indirect end users include:

- Software and Application designers and architects
- Software and Application engineers and developers
- Scientific and medical researchers
- Medical research protocol designers
- Clinical and scientific research data managers
- Clinicians
- Patients

- Medical research study participants

Broader Stakeholders

The broader stakeholders who will benefit from structured metadata driven software engineering and controlled terminology include:

- The caBIG® community
- NHIN, EMR and caEMR projects and related commercial COTS vendors
- Clinical care providers
- Patients and patient care advocates
- Insurance and payer communities
- Health care innovators
- Health care related companies and their investors
- Information technology communities
- Standards Development Organizations
    - CDISC, ISO, HL7
- Personal health organizations and proponents
- Health care and biomedical research related industry, such as pharmaceutical and medical equipment manufacturers
- Government and regulatory bodies
    - FDA, CDC, ONC
- International bodies
    - NCRI, CancerGrid

Stakeholders in New Semantic Infrastructure

The key to success for the next generation infrastructure is defining the critical, unmet usage scenarios of parties interested in leveraging this infrastructure. Interested parties are encouraged to become involved over the next few months as we attempt to characterize in more detail the requirements to achieve the interoperability vision.

Stakeholder	Contact	Analyst	Area of Interest	Usage/Primary Interaction Scenarios
Clinical Governance Group	John Speakman CTMS Storyboards and Semantic Profiles for services interoperabilty	Patrick McConnell (21090)	ScenPro Analyst and 5AM, ISO Datatype Documentation of ISO use for COPPA (all projects have to use the datatypes) Implementation of guidelines must be complete in June	'Operationalized' ISO 21090 Datatypes-Discover and share /reuse models -Rules engine and repository: Scenario #8: Management of Routine Non-Laboratory-Based Adverse Events (caAERS and CDMS) - Protocol Metadata and Rules Engine -C3PR FR-230 The system must integrate with the Cancer Data Standards Repository (caDSR) and Enterprise Vocabulary Services (EVS) (e.g. for eligibility criteria)
MediData	Dianne Reeves	---	Data Elements on Forms: Metadata registry information and semantic metadata, specifically data elements (CDEs) to record and share centrally defined forms variables that can be used to customize new protocols for clinical trials.	Share Forms including form structure, behavior and variables - similar to the way C3D uses caDSR but may have additional metadata that needs to be stored/shared
Genzyme	Sue Dubman Julie Smiley Director, Data ManagementGenzyme Oncology	---	MDR metadata exchange -->Implement global data standards to collect, process, analyze and report clinical research data throughout the entire product lifecycle (see GetSmart attachement)	Share data standards and variables (CDEs)-Get Smart Goal #2 Data Collection and Processing: Technology enabled standard Case Report Forms and edit checks. -Get Smart Goal #5 Core Infrastructure: Data Elements Dictionary, Validation Tools, Systems Interoperability Guidelines and Architecture, Metadata Repository, Mapping and Conversion Tools and Structured Authoring Tool
Medical and Scientific Researchers	Yolanda Gill	---	Workflow: Metadata and rule support	Metadata to support workflow
MD Anderson	Mike Riben	---	Alignment/Interoperability between NCI and MD Anderson's metadata and vocabulary solutions; Possible UAT (See MD Anderson Attachment).	Metadata Registry Interoperability
Emory	Stuart Turner, Eliot Seigel and Joel Saltz	---	Semantic interoperation requirement stemming from the TCGA Radiology and In Silico projects. See attached use case with 4 semantic requirements identified.	---
Novartis	Mehta Saurin	---	MDR toolsie. 1. Alternate names for permissible values i.e. currently you can register 'M', 'MALE' but we would like to register additional name such as 'm', '1', 'Male' etc. 2. Additional attributes for a data element - although there is a reference field available we would want (for operational purposes) additional attributes to define items such as 'SAS format', display format etc. 3. if the list of permissible values is Extensible flag 4. A way to relate data elements to each other 5. Distributed repository	Enhanced/standardized Metadata attributes- Metadata Registry Interoperability
CDISC and SHARE	Margaret Haber	---	Pilot of Semantic Media Wiki for harmonizing and updating data elements; Input on tooling and metadata extensions	---
Mayo Clinic	Robert Freimuth	---	New metadata repository and CTS2	Federated Terminologies
LS Governance and ICR	Juli Klemm, Baris Suzek	---	caB2B IRWG requirements, caBIG Gene Pattern and Analytical Services interoperability.Seamless interoperability, discover services and data that can be combined; construct new workflows	Integrated system of tools (see IRWG Requirements)- Support workflow authoring tools (such as Taverna and caB2B)

Terminologists	Margaret Haber and Sheri De Coronado	---	Formal requirements for the new terminology and metadata services and for assessing equivalence between pre- and post-coordinated terminology	See [[SI_Conop_Initiatives_Requirements_Master_List#Initiative_5_-_HL7_CTS_II. 2F_OMG_MIF_compliant_federated_terminology_services. |Master List Initiative 5][
caBIG Community	Various	---	Vocabulary Knowledge Center Semantic Requirements Wiki Forum - Spring and Wiki Forum - Winter	See Semantic Infrastructure Concept of Operations Initiatives - Requirements Master List organized by Semantic Infrastructure initiatives
Software Architects and Designers	Anand BasuCharlie Mead	Patrick McConnell	Discover and integrate services, on the fly, to perform scientific research	1. Build new services that can interact with other existing services using workflow authoring tools such as Taverna 2. Support for "Conformance Profiles" --> Profiles are a mechanism used to constrain broader service capabilities to meet specific functional needs identified within a domain or locality (See Conformance Profiles attachment)
Metadata Curators	Dianne Reeves	---	Creating new content in caDSR	1. Customizable metadata download 2. Clinician friendly browsing: improve search and browsing functions, leveraging existing semantics and metadata 3. Improve ability to organize and reuse content (Classifications) with batch upload/editing
FDA	Margaret Haber	---	Metadata and Terminologies	TBD
caEHR	---		---	---
NHIN	---	---	---	---

Graphical Depiction of Stakeholders