

Regulatory Cell

Purpose

To support the management of regulatory information pertaining to research studies and enabling the controlled exchange of patient and sample data between electronic systems.

Use Scenarios

The flexible design of the i2b2 platform permits a user to configure the system to meet their own specific operational. Listed below, are two such permutations as they relate to this project.

A Central Warehouse Of All Protocols

This scenario would permit an institution to collate IRB or IACUC protocol information across their enterprise within a central secure data warehouse. this would enable easy monitoring of subject participation across multiple protocols (Requires CRC). When used in conjunction with the Sample cell, sample utilization can also be tracked.

To offset potential security issues relating to intellectual property and patient privacy, by default, this configuration would restrict access to this data to a super user group and a special i2b2 project called crimson.

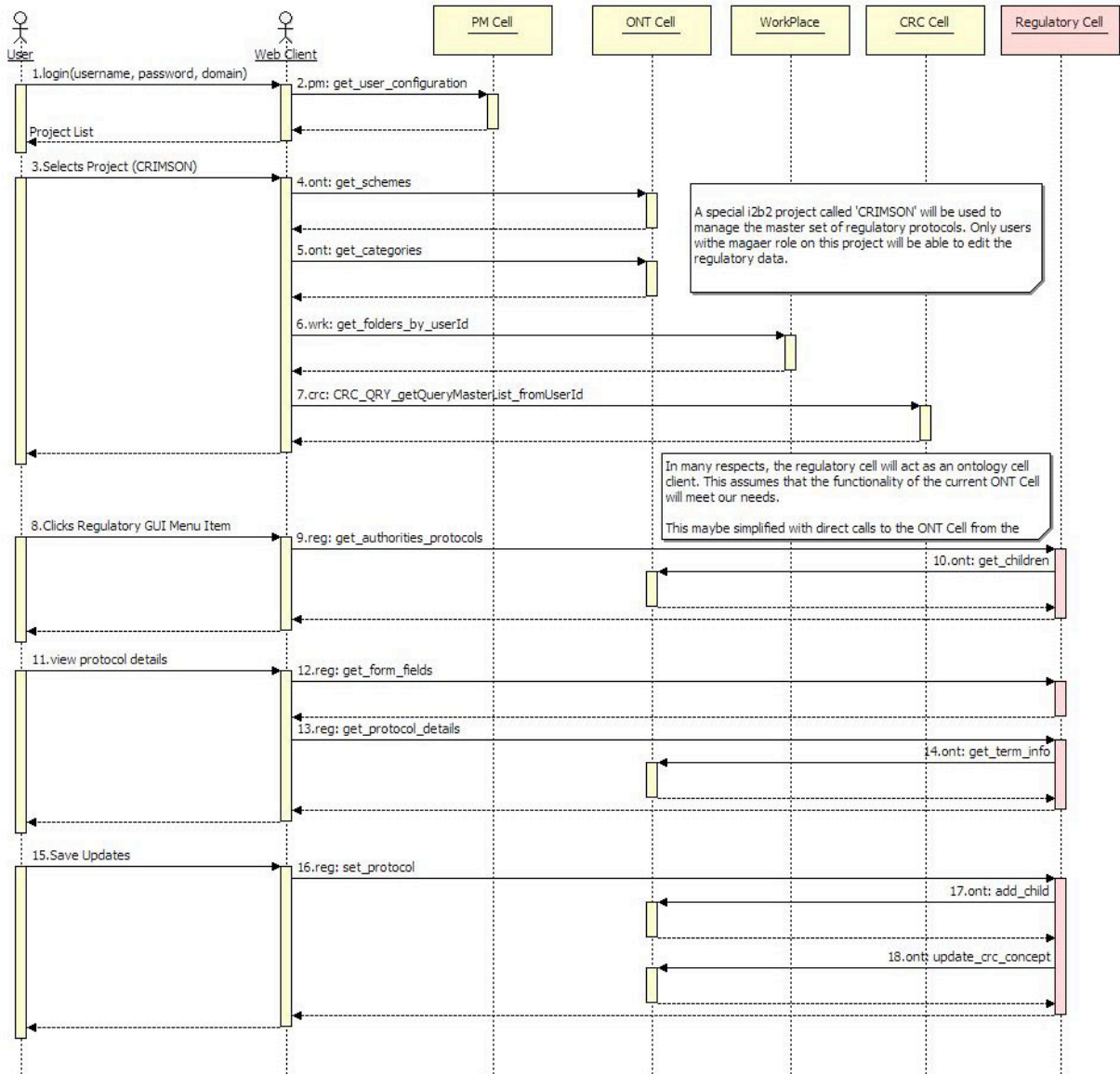
Project or Program Specific Protocol Management

Alternatively, a hive maybe configured to mange data for a single project or program e.g. a SPORE. In such a scenario, the user can restrict the protocols recorded within the cell to those related to the program.

Work Flow Example(s)

The following example UML sequence diagram provides a description of the sequence of events and messages that will be triggered when a user attempts to update a protocol entry. This document is a work in progress, additional UML sequence diagrams describing other facets of the Cells functionality will be added over time.

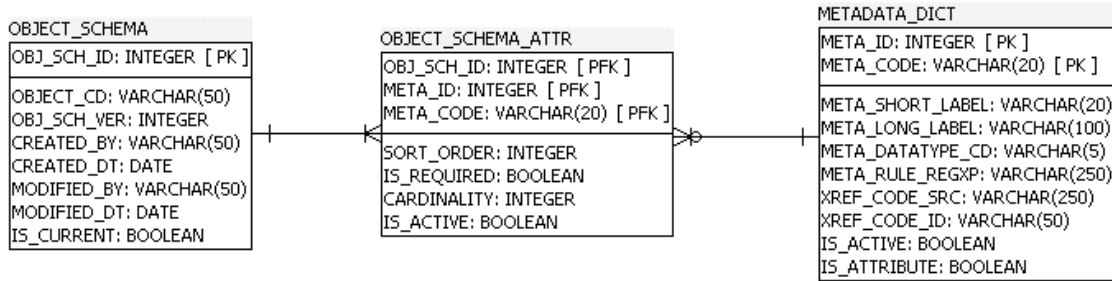
UML Sequence Diagram: Update An Existing Protocol



Database Physical Model

Metadata Definition

The Regulatory Cell will allow different institutions the ability to capture different metadata when describing their protocols. The following schema supports this functionality and is used to dynamically generate the GUI used to create and update protocol data within a hive.



(Note: the **METADATA_DICT** table will likely be replaced by traditional i2b2 Ontology Table)

Data Persistence

The Regulatory Cell exploits existing i2b2 infrastructure to persist regulatory data. By default, the regulatory cell creates a table, **REGULATORY** within the ontology cell for managing protocol and authority information. This table adheres to the i2b2 Ontology Cell structure and is registered within the **TABLE_ACCESS** table. Access to this ontology is restricted to a 'master' i2b2 project - crimson. This potentially allows this regulatory ontology to act as a central resource for tracking patient participation across multiple protocols.

As needed, the i2b2 system administrator can clone and/or create subsets of this ontology for use with specific i2b2 projects, following existing i2b2 working practices.

Q	Q	Q	Q	Q	Q	Q
Q	COLUMN_NAME	DATA_TYPE	NULLABLE	DATA_DEFAULT	COLUMN_ID	COMMENTS
	C_HLEVEL	NUMBER (22,0)	No	(null)	1 (null)	
	C_FULLNAME	VARCHAR2 (900 BYTE)	No	(null)	2 (null)	
	C_NAME	VARCHAR2 (2000 BYTE)	No	(null)	3 (null)	
	C_SYNONYM_CD	CHAR (1 BYTE)	No	(null)	4 (null)	
	C_VISUALATTRIBUTES	CHAR (3 BYTE)	No	(null)	5 (null)	
	C_TOTALNUM	NUMBER (22,0)	Yes	(null)	6 (null)	
	C_BASECODE	VARCHAR2 (450 BYTE)	Yes	(null)	7 (null)	
	C_METADATAXML	CLOB	Yes	(null)	8 (null)	
	C_FACTTABLECOLUMN	VARCHAR2 (50 BYTE)	No	(null)	9 (null)	
	C_TABLENAME	VARCHAR2 (50 BYTE)	No	(null)	10 (null)	
	C_COLUMNNAME	VARCHAR2 (50 BYTE)	No	(null)	11 (null)	
	C_COLUMNDATATYPE	VARCHAR2 (50 BYTE)	No	(null)	12 (null)	
	C_OPERATOR	VARCHAR2 (10 BYTE)	No	(null)	13 (null)	
	C_DIMCODE	VARCHAR2 (900 BYTE)	No	(null)	14 (null)	
	C_COMMENT	CLOB	Yes	(null)	15 (null)	
	C_TOOLTIP	VARCHAR2 (900 BYTE)	Yes	(null)	16 (null)	
	UPDATE_DATE	DATE	Yes	(null)	17 (null)	
	DOWNLOAD_DATE	DATE	Yes	(null)	18 (null)	
	IMPORT_DATE	DATE	Yes	(null)	19 (null)	
	SOURCESYSTEM_CD	VARCHAR2 (50 BYTE)	Yes	(null)	20 (null)	
	VALUETYPE_CD	VARCHAR2 (50 BYTE)	Yes	(null)	21 (null)	

Within this table the organization of the protocol data is controlled.

- C_HLEVEL = 1 : Protocol Type (IRB | IACUC)
- C_HLEVEL = 2 : Protocol Authorities/Organizations
- C_HLEVEL = 3 : Protocols
- C_HLEVEL = 4-5 : Associated i2b2 Projects
- C_HLEVEL = 4-5 : Protocol Events (Sample Collection | Informed Consent Recv'd | Informed Consent Withdrawn)
- C_HLEVEL = 6 : Under Sample Collection Events, associations defined as synonyms, are created to samples acquired under the related protocol/event. These samples are not displayed within the i2b2 Term Navigator, but are still retrievable by dragging the parent event or protocol concept into the query tool interface.

Additional metadata associated with the protocol and authority are persisted as an XML object within the **c_METADATAXML** field. See i2b2 Messages for more information on the format of this XML.

Honest Broker

The regulatory cell will provide the mechanism that protects the PHI data as its transferred from the hive to other systems. As an added safe guard the regulatory cell will only store one half of any project specific PHI encryption key. This avoids exposing PHI data from multiple projects to the system administrators or dba and allows user to execute PHI related requests without needing to know the whole encryption key, ensuring the integrity of any PHI information stored within the hive is maintained.

Access to the regulatory cell is further controlled by using i2b2 roles.

The regulatory cell GUI will persist the honest broker encryption key with the **PM_PROJECT_PARAMS** table (PM CELL)

Webservices & i2b2 Messages

Message Formats

One of the goals of the regulatory cell is to allow a user to customize some of the attributes that should be captured when describing any regulatory entity. Our initial XML schema for communicating this information within an i2b2 message and for encapsulating the resultant values is described here:[crimson.xsd](#)

However, we are also considering adopting the caBIG Common Data Element XML Message format ([cabig_dataelement_v4.0.xsd](#)) to perform part of this role in order to help facilitate closer integration of i2b2 and caBIG platforms, specifically caTissue.

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