



i2b2

Software Documentation

i2b2 Design Document

Identity Management (IM) Cell

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DOCUMENT MANAGEMENT

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ABOUT THIS GUIDE

The i2b2 design document describes the requirements, overview of the technical functionality, and the intended capabilities of the **Identity Management (IM) Cell**. This document is to be used as a guideline and continuing reference point as developers write the code and quality assurance writes the test plans.

1 IDENTITY MANAGEMENT CONCEPTS

1.1 Objectives of Identity Management Cell and Views

Information in the Identity Management cell is related to the setup, maintenance and security of patients from heterogeneous sources. This data may be encrypted and is restricted by project and user.

1.2 Identification of Users

1.2.1 Clinical Researcher

- Member of the research team who is setup with access to the project in i2b2.
- Their access role is **USER**.
- They can edit their user profile.

1.2.2 Manager of Clinical Researcher

- Manager of the research team.
- Their access role is **MANAGER**.
- They can create and edit users associated to their project.
- They can create and edit project related information.

1.2.3 Administrator

- They may or may not be part of the research team.
- They are responsible for the administrative tasks related to the i2b2.
- Their access role is **ADMIN** and the project id is @.
- They can create and edit users associated to any project.
- They can create and edit all projects.

- They can create and edit hive information.

2 REQUIREMENTS

2.1 Design Requirements

The following section outlines some of the basic design requirements and new views in the i2b2 Workbench to support the new Identity Management (IM) cell.

2.1.1 Patient Mapping View

A new plug-in called *edu.harvard.i2b2.eclipse.plugins.patientMapping* has been provided with the source code for the i2b2 Workbench. The view for this plug-in is called *Patient Mapping* and is available in the i2b2 Workbench.

The Patient Mapping view allows project managers and administrators to see all site IDs for a set of patients or a single patient.

These patient IDs can be dragged from the Patient Mapping view and dropped into other i2b2 views such as the Query Tool and Workplace views. All site IDs are able to be dragged; it is not limited to the HIVE number.

| HIVE | Hospital-1 | Hospital-2 | Hospital-3 | Hospital-4 | Hospital-5 | Hospital-6 | Hospital-7 | Hospital-8 |
|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| 1000000001 | 2000001961 | | | | 3000001821 | 4000002001 | S500003051 | U500004011 |
| 1000000017 | 2000001977 | | | | 3000001837 | | S500003067 | U500004027 |
| 1000000026 | 17028580 | 01954309 | 252304 | 00001003 | | 4000002026 | S500003076 | U500004036 |

Note

The patient IDs shown in the above screen print are from the i2b2 demo data and are strictly for demonstration purposes. It does NOT contain real patient information.

2.1.2 Admin Tool View

A new plug-in called *edu.harvard.i2b2.eclipse.plugins.adminTool* has been provided with the source code for the i2b2 Workbench. The view for this plug-in is called *Managers Tool* and is available in the i2b2 Workbench.

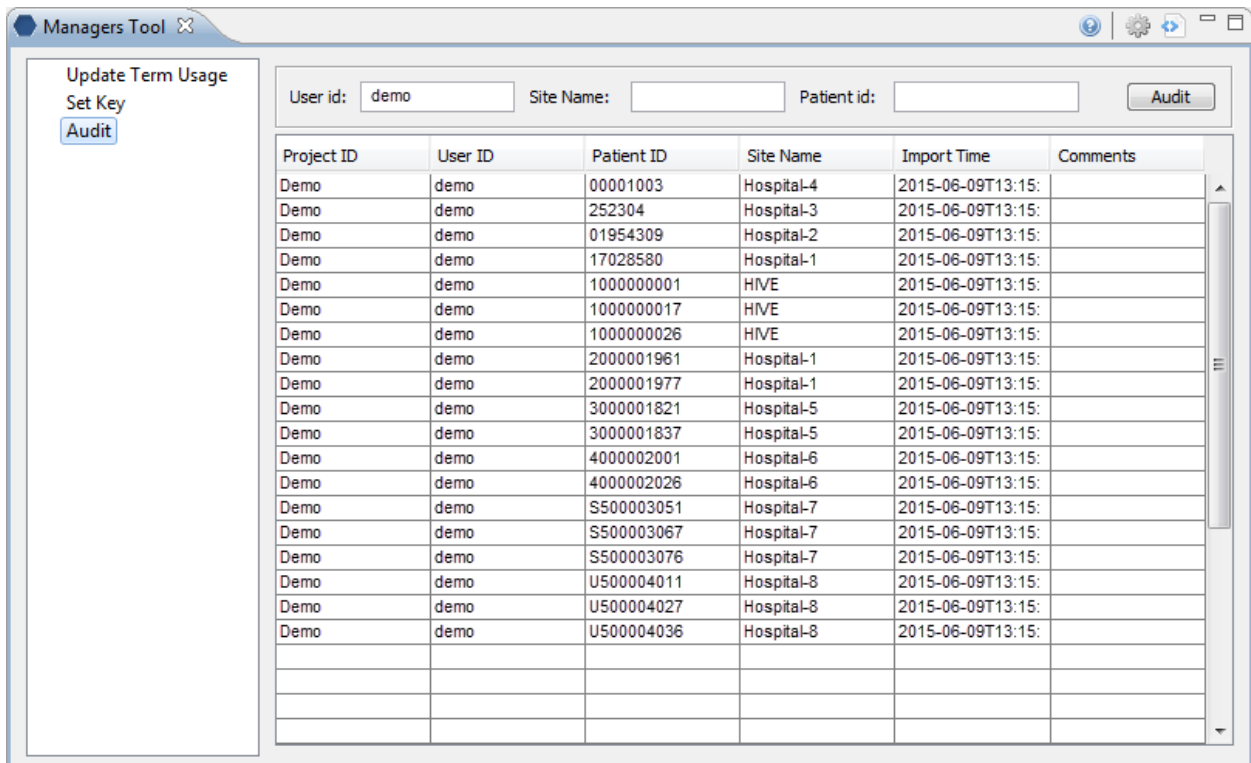
The Admin Tool view allows project managers and administrators to set or validate the AES encryption key for the IM cell. This same view also allows project managers and administrators to see the audit information stored in the **IM_AUDIT** table. This information can be viewed by user, by patient, or all audit records for the project.

2.1.2.1 View User Audit

A manager or administrator can view the audit trail for a particular user.

Example:

In the example shown below an audit report was run for the user “demo”. The IM cell returned all the patients that were accessed by the user “demo”.



The screenshot shows the 'Managers Tool' application window. On the left, there is a sidebar with buttons for 'Update Term Usage', 'Set Key', and 'Audit'. The main area contains a search form with fields for 'User id:' (filled with 'demo'), 'Site Name:', and 'Patient id:', along with an 'Audit' button. Below the search form is a table with the following columns: Project ID, User ID, Patient ID, Site Name, Import Time, and Comments. The table lists 20 rows of audit data for the user 'demo' across various hospitals and sites.

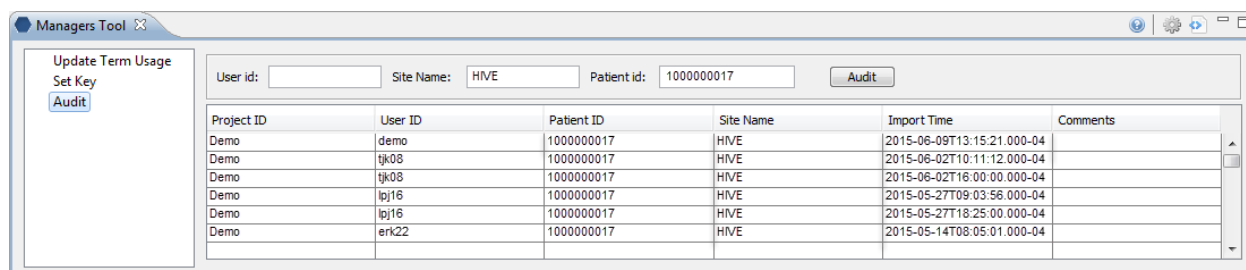
| Project ID | User ID | Patient ID | Site Name | Import Time | Comments |
|------------|---------|------------|------------|-------------------|----------|
| Demo | demo | 00001003 | Hospital-4 | 2015-06-09T13:15: | |
| Demo | demo | 252304 | Hospital-3 | 2015-06-09T13:15: | |
| Demo | demo | 01954309 | Hospital-2 | 2015-06-09T13:15: | |
| Demo | demo | 17028580 | Hospital-1 | 2015-06-09T13:15: | |
| Demo | demo | 1000000001 | HIVE | 2015-06-09T13:15: | |
| Demo | demo | 1000000017 | HIVE | 2015-06-09T13:15: | |
| Demo | demo | 1000000026 | HIVE | 2015-06-09T13:15: | |
| Demo | demo | 2000001961 | Hospital-1 | 2015-06-09T13:15: | |
| Demo | demo | 2000001977 | Hospital-1 | 2015-06-09T13:15: | |
| Demo | demo | 3000001821 | Hospital-5 | 2015-06-09T13:15: | |
| Demo | demo | 3000001837 | Hospital-5 | 2015-06-09T13:15: | |
| Demo | demo | 4000002001 | Hospital-6 | 2015-06-09T13:15: | |
| Demo | demo | 4000002026 | Hospital-6 | 2015-06-09T13:15: | |
| Demo | demo | S500003051 | Hospital-7 | 2015-06-09T13:15: | |
| Demo | demo | S500003067 | Hospital-7 | 2015-06-09T13:15: | |
| Demo | demo | S500003076 | Hospital-7 | 2015-06-09T13:15: | |
| Demo | demo | U500004011 | Hospital-8 | 2015-06-09T13:15: | |
| Demo | demo | U500004027 | Hospital-8 | 2015-06-09T13:15: | |
| Demo | demo | U500004036 | Hospital-8 | 2015-06-09T13:15: | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

2.1.2.2 View Patient Audit

A manager or administrator can view the audit trail for a particular patient.

Example:

In the example shown below an audit report was run for the patient whose ID is 1000000017. The data returned from the IM cell shows all the users who accessed this patient.



| Project ID | User ID | Patient ID | Site Name | Import Time | Comments |
|------------|---------|------------|-----------|----------------------------|----------|
| Demo | demo | 1000000017 | HIVE | 2015-06-09T13:15:21.000-04 | |
| Demo | tjk08 | 1000000017 | HIVE | 2015-06-02T10:11:12.000-04 | |
| Demo | tjk08 | 1000000017 | HIVE | 2015-06-02T16:00:00.000-04 | |
| Demo | lpj16 | 1000000017 | HIVE | 2015-05-27T09:03:56.000-04 | |
| Demo | lpj16 | 1000000017 | HIVE | 2015-05-27T18:25:00.000-04 | |
| Demo | erk22 | 1000000017 | HIVE | 2015-05-14T08:05:01.000-04 | |

2.1.2.3 View All Audit Records for the Project

A manager or administrator can view the audit trail for all users and patients in the project.

Example:

In the example shown below the data returned for the IM includes all the audit records for the entire project.

Managers Tool

Update Term Usage
Set Key
Audit

User id: Site Name: Patient id: Audit

| Project ID | User ID | Patient ID | Site Name | Import Time | Comments |
|------------|---------|------------|------------|-------------------|----------|
| Demo | demo | 00001003 | Hospital-4 | 2015-06-09T13:15: | |
| Demo | demo | 252304 | Hospital-3 | 2015-06-09T13:15: | |
| Demo | demo | 01954309 | Hospital-2 | 2015-06-09T13:15: | |
| Demo | demo | 17028580 | Hospital-1 | 2015-06-09T13:15: | |
| Demo | demo | 100000001 | HIVE | 2015-06-09T13:15: | |
| Demo | demo | 100000017 | HIVE | 2015-06-09T13:15: | |
| Demo | demo | 100000026 | HIVE | 2015-06-09T13:15: | |
| Demo | demo | 200001961 | Hospital-1 | 2015-06-09T13:15: | |
| Demo | demo | 200001977 | Hospital-1 | 2015-06-09T13:15: | |
| Demo | demo | 300001821 | Hospital-5 | 2015-06-09T13:15: | |
| Demo | demo | 300001837 | Hospital-5 | 2015-06-09T13:15: | |
| Demo | demo | 400002001 | Hospital-6 | 2015-06-09T13:15: | |
| Demo | demo | 400002026 | Hospital-6 | 2015-06-09T13:15: | |
| Demo | demo | S500003051 | Hospital-7 | 2015-06-09T13:15: | |
| Demo | demo | S500003067 | Hospital-7 | 2015-06-09T13:15: | |
| Demo | demo | S500003076 | Hospital-7 | 2015-06-09T13:15: | |
| Demo | demo | U500004011 | Hospital-8 | 2015-06-09T13:15: | |
| Demo | demo | U500004027 | Hospital-8 | 2015-06-09T13:15: | |
| Demo | demo | U500004036 | Hospital-8 | 2015-06-09T13:15: | |
| Demo | tjk08 | 100000017 | HIVE | 2015-06-02T10:11: | |
| Demo | tjk08 | 100000017 | HIVE | 2015-06-02T16:00: | |
| Demo | lpj16 | 100000017 | HIVE | 2015-05-27T09:03: | |
| Demo | lpj16 | 100000017 | HIVE | 2015-05-27T18:25: | |

2.2 Table Usage

There are several tables in the Identity Management (IM) Cell that have a unique role in the process of storing information about sites, projects and patients. This section outlines the various processes of accessing and using the IM tables.

Additional information about each table can be found in the *Identity Management Tables* section.

2.3 Security

The Identity Management (IM) Cell contains Protected Health Information (PHI), which can be used to identify patients. The HIPAA privacy rules state;

Audit Controls. A covered entity must implement hardware, software, and/or procedural mechanisms to record and examine access and other activity in information systems that contain or use e-PHI.¹

In order to comply with this regulation the IM Cell contains an Audit table that stores information about patient access. For more information about this table please see the section called *Audit Table* in the *Security Tables* section of this document.

3 IDENTITY MANAGEMENT TABLES

In the Identity Management (IM) cell there are several tables designed to store information from various sources. The information stored in these tables is listed below.

1. Projects associated with the different sites.
2. Patients who are included in a project.
3. Patient demographic information.
4. Mapping of the patient's site MRN and their i2b2 patient number.
5. Audit trail for patient access via the IM cell.

3.1 General Information

All the IM tables have the following five technically-oriented or administrative columns.

| Column Name | Datatype | Allow Nulls | Column Definition |
|-----------------|-------------|-------------|---|
| UPDATE_DATE | DATETIME | Y | Date the row was update by the source system The date is obtained from the source system |
| DOWNLOAD_DATE | DATETIME | Y | Date the data was downloaded from the source system |
| IMPORT_DATE | DATETIME | Y | Date the data was imported into the IM table |
| SOURCESYSTEM_CD | VARCHAR(50) | Y | A coded value for the data source system |
| UPLOAD_ID | INT | Y | A numeric id given to the upload |

3.2 Project Tables

3.2.1 Project Sites Table

The **IM_PROJECT_SITES** table contains information that links a project and local site.

3.2.1.1 Requirements for Project Sites Table

The IM_PROJECT_SITES table has two **REQUIRED** columns.

1. PROJECT_ID

- A unique id for the project.
- This column is part of the primary key.

2. LCL_SITE

- The local site that is associated to this project.
- This column is part of the primary key.

3.2.1.2 Column Definitions

| IM_PROJECT_SITES | | | | |
|------------------|----------------|-------------|-------------|---|
| Key | Column Name | Datatype | Allow Nulls | Column Definition |
| PK | PROJECT_ID | VARCHAR(50) | N | A unique ID for the project. This column is equivalent to the PROJECT_ID column in the <i>PM_PROJECT_DATA</i> table in the i2b2 pmdata. |
| PK | LCL_SITE | VARCHAR(50) | N | The local site (data source) that is included in the project defined at PROJECT_ID. Example: MGH, BWH This column is equivalent to the PATIENT_IDE_SOURCE column in the <i>PATIENT_MAPPING</i> and <i>ENCOUNTER_MAPPING</i> tables in the i2b2 datamart. |
| | PROJECT_STATUS | VARCHAR(50) | Y | The status of the project. A = Active I = Inactive |

| | | | | |
|--|-----------------|-------------|---|--|
| | UPDATE_DATE | DATETIME | Y | As defined in the above section (" <i>General Information</i> ") |
| | DOWNLOAD_DATE | DATETIME | Y | As defined in the above section (" <i>General Information</i> ") |
| | IMPORT_DATE | DATETIME | Y | As defined in the above section (" <i>General Information</i> ") |
| | SOURCESYSTEM_CD | VARCHAR(50) | Y | As defined in the above section (" <i>General Information</i> ") |
| | UPLOAD_ID | INT | Y | As defined in the above section (" <i>General Information</i> ") |

3.2.2 Project Patients Table

The **IM_PROJECT_PATIENTS** table stores the patients that are part of a project.

3.2.2.1 Requirements for Project Patients Table

The IM_PROJECT_PATIENTS table has two **REQUIRED** columns.

1. PROJECT_ID
 - A unique id for the project.
 - This column is part of the primary key.

2. GLOBAL_ID
 - An internal ID for the patient.
 - This column is part of the primary key.

3.2.2.2 Column Definitions

| IM_PROJECT_PATIENTS | | | | |
|---------------------|------------------------|--------------|-------------|---|
| Key | Column Name | Datatype | Allow Nulls | Column Definition |
| PK | PROJECT_ID | VARCHAR(50) | N | A unique ID for the project. This column is equivalent to the PROJECT_ID column in the <i>PM_PROJECT_DATA</i> table in the i2b2 pmdata. |
| PK | GLOBAL_ID | VARCHAR(200) | N | This is a unique identifier for the patient. It is equivalent to a Master Patient Index (MPI) id. Note: some sites may refer to it as the Enterprise Master Patient Index (EMPI). |
| | PATIENT_PROJECT_STATUS | VARCHAR(50) | Y | The status of the patient in this project. A = Active I = Inactive |
| | UPDATE_DATE | DATETIME | Y | As defined in the above section (" <i>General Information</i> ") |
| | DOWNLOAD_DATE | DATETIME | Y | As defined in the above section (" <i>General Information</i> ") |
| | IMPORT_DATE | DATETIME | Y | As defined in the above section (" <i>General Information</i> ") |
| | SOURCESYSTEM_CD | VARCHAR(50) | Y | As defined in the above section (" <i>General Information</i> ") |
| | UPLOAD_ID | INT | Y | As defined in the above section (" <i>General Information</i> ") |

3.3 Mapping Tables

3.3.1 Demographics Table

The **IM_MPI_DEMOGRAPHICS** table contains general demographic information for the patients.

3.3.1.1 Requirements for Demographics Table

The **IM_MPI_DEMOGRAPHICS** table has one **REQUIRED** column.

1. GLOBAL_ID

- An internal ID for the patient.
- This column is part of the primary key.

3.3.1.2 Column Definitions

| IM_MPI_DEMOGRAPHICS | | | | |
|---------------------|-----------------|--------------|-------------|---|
| Key | Column Name | Datatype | Allow Nulls | Column Definition |
| PK | GLOBAL_ID | VARCHAR(200) | N | This is a unique identifier for the patient. It is equivalent to a Master Patient Index (MPI) id. Note: some sites may refer to it as the Enterprise Master Patient Index (EMPI). |
| | GLOBAL_STATUS | VARCHAR(50) | Y | The status of the ID for this patient. A = Active I = Inactive M = Merged |
| | DEMOGRAPHICS | VARCHAR(400) | Y | This is an optional column. |
| | UPDATE_DATE | DATETIME | Y | As defined in the above section ("General Information") |
| | DOWNLOAD_DATE | DATETIME | Y | As defined in the above section ("General Information") |
| | IMPORT_DATE | DATETIME | Y | As defined in the above section ("General Information") |
| | SOURCESYSTEM_CD | VARCHAR(50) | Y | As defined in the above section ("General Information") |
| | UPLOAD_ID | INT | Y | As defined in the above section ("General Information") |

3.3.2 MPI Mapping Table

The **IM_MPI_MAPPING** table maps the patient's *i2b2 number* and their *local ID* from the source system.

3.3.2.1 Requirements for MPI Mapping Table

The IM_MPI_MAPPING table has three **REQUIRED** columns.

1. GLOBAL_ID
 - An internal ID for the patient.
 - This column is part of the primary key.
2. LCL_SITE
 - The local site.
 - This column is part of the primary key.
3. LCL_ID
 - The patient's local id (site MRN).
 - This column is part of the primary key.

3.3.2.2 Column Definitions

| IM_MPI_MAPPING | | | | |
|----------------|-------------|--------------|-------------|--|
| Key | Column Name | Datatype | Allow Nulls | Column Definition |
| PK | GLOBAL_ID | VARCHAR(200) | N | This is a unique identifier for the patient. It is equivalent to a Master Patient Index (MPI) |

| | | | | |
|-----------|-----------------|--------------|---|--|
| | | | | id. Note: some sites may refer to it as the Enterprise Master Patient Index (EMPI). |
| PK | LCL_SITE | VARCHAR(50) | N | The local site (data source). Example: MGH, BWH This column is equivalent to the PATIENT_IDE_SOURCE column in the <i>PATIENT_MAPPING</i> and <i>ENCOUNTER_MAPPING</i> tables in the i2b2 Datamart. |
| PK | LCL_ID | VARCHAR(200) | N | The local ID is the patient's MRN (Medical Record Number). The MRN is a unique identifier at a site (institution) that represents a patient. This column is equivalent to the PATIENT_IDE column in the <i>PATIENT_MAPPING</i> and <i>ENCOUNTER_MAPPING</i> tables in the i2b2 Datamart. |
| | LCL_STATUS | VARCHAR(50) | Y | The status of this local ID in the source system. A = Active I = Inactive |
| | UPDATE_DATE | DATETIME | Y | As defined in the above section ("General Information") |
| | DOWNLOAD_DATE | DATETIME | Y | As defined in the above section ("General Information") |
| | IMPORT_DATE | DATETIME | Y | As defined in the above section ("General Information") |
| | SOURCESYSTEM_CD | VARCHAR(50) | Y | As defined in the above section ("General Information") |
| | UPLOAD_ID | INT | Y | As defined in the above section ("General Information") |

3.4 Security Tables

3.4.1 Audit Table

As stated previously in the *Security* section of the *Requirements*, the IM cell contains PHI which can be used to identify patients. The audit table will store the following information when a patient is accessed via the IM cell.

1. The date the information was accessed.

2. The site that requested access to the patient.
3. The ID of the patient that was accessed.
4. The user who accessed the patient.
5. The project that the user was logged into when the patient was accessed.

3.4.1.1 Requirements for the Audit Table

All of the columns in the IM_AUDIT table are required. The only exception is the COMMENTS column.

3.4.1.2 Column Definitions

| IM_AUDIT | | | | |
|----------|-------------|--------------|-------------|--|
| Key | Column Name | Datatype | Allow Nulls | Column Definition |
| PK | QUERY_DATE | DATETIME | N | The date the request was received from the client and the response message was sent from the IM cell. |
| | LCL_SITE | VARCHAR(50) | N | The site that requested / accessed the information. |
| | LCL_ID | VARCHAR(200) | N | The local ID for the patient that was accessed. |
| | USER_ID | VARCHAR(50) | N | The unique ID for the user that accessed the patient. This ID is equivalent to the USER_ID in the <i>PM_USER_DATA</i> table in the PM Cell. |
| | PROJECT_ID | VARCHAR(50) | N | The project ID that the user was logged into when accessing the patient. This ID is equivalent to the PROJECT_ID in the <i>PM_PROJECT_DATA</i> table in the PM Cell. |
| | COMMENTS | TEXT | N | |

3.5 Joining Columns

All of the IM tables can be linked together using SQL joins to obtain more data. The IM tables can also be linked to the PATIENT_MAPPING table in the crcdata and the PM_PROJECT_DATA table in the pmdata.

The following are some examples of columns that can be used to join IM Tables and the i2b2 tables

IM_MPI_DEMOGRAPHICS

| | | |
|----------------------------------|------------------|---------------------------------|
| GLOBAL_ID in IM_MPI_DEMOGRAPHICS | can be joined to | GLOBAL_ID in IM_MPI_MAPPING |
| GLOBAL_ID in IM_MPI_DEMOGRAPHICS | can be joined to | GLOBAL_ID in IM_PROJECT_PATIENT |

IM_MPI_MAPPING

| | | |
|------------------------------|------------------|---------------------------------------|
| LCL_ID in IM_MPI_MAPPING | can be joined to | PATIENT_IDE in PATIENT_MAPPING |
| LCL_SITE in IM_MPI_MAPPING | can be joined to | PATIENT_IDE_SOURCE in PATIENT_MAPPING |
| LCL_STATUS in IM_MPI_MAPPING | can be joined to | PATIENT_IDE_STATUS in PATIENT_MAPPING |

IM_PROJECT_SITES

| | | |
|--------------------------------|------------------|-----------------------------------|
| PROJECT_ID in IM_PROJECT_SITES | can be joined to | PROJECT_ID in IM_PROJECT_PATIENTS |
| PROJECT_ID in IM_PROJECT_SITES | can be joined to | PROJECT_ID in PM_PROJECT_DATA |
| LCL_SITE in IM_PROJECT_SITES | Can be joined to | LCL_SITE in IM_MPI_MAPPING |

IM_PROJECT_PATIENTS

| | | |
|-----------------------------------|------------------|-------------------------------|
| PROJECT_ID in IM_PROJECT_PATIENTS | can be joined to | PROJECT_ID in PM_PROJECT_DATA |
|-----------------------------------|------------------|-------------------------------|

4 OBJECTS

4.1 Patient Data Object

The Patient Data Object (PDO) is the XML representation of patient data. This data corresponds to the values in the star schema tables in the i2b2 database.

The PDO object is maintained by the CRC cell. Additional information regarding the PDO can be found in the *CRC Design Document*.

4.2 IM Data Object

The IM Data Object (IMDO) holds patient and site information and performs auditing.

5 PATIENT MAPPING SCENARIOS

A patient may have more than one identifier in different source systems and will be given a single unique global identifier in the IM tables. All of these identifiers are grouped together in the **IM_MPI_MAPPING** table in the database.

The IM Mapping tables link the values used in the IM database to their counterparts in the source systems from which the identifiers came. The CRC PATIENT_MAPPING table links the ids in the IM_MPI_MAPPING table to their i2b2 PATIENT_NUM.

In the IM_MPI_MAPPING table the patient's local id is stored in the LCL_ID column. This number can be stored as either encrypted or unencrypted. Encrypted identifiers are indicated by appending '_e' to the name of the source system that is stored in the LCL_SITE column. For example, if the identifier is an encrypted number from Massachusetts General Hospital, the LCL_SITE will be 'MGH_e'.

Below is a generic <pid_set> from the XML Patient Data Object (PDO).

```
<pid_set>
  <pid>
    <patient_id source="source">value</patient_id>
    <patient_map_id source="source" status="A">value</patient_map_id>
    <patient_map_id source="source" status="A">value</patient_map_id >
    ...
  </pid>
</pid_set>
```

5.1 Self-Mapping

Self-mapping in the IM cell is similar to the self-mapping that occurs in the CRC. Each patient will have one record in which their id is mapped to itself.

6 GLOSSARY

6.1 General Terms

The following table contains terms that are used throughout this document.

| Term | Definition |
|-------------|---------------------------------|
| EMPI | Enterprise Master Patient Index |
| IM | Identity Management |
| MPI | Master Patient Index |
| MRN | Medical Record Number |

END NOTES

Audit Controls. A covered entity must implement hardware, software, and/or procedural mechanisms to record and examine access and other activity in information systems that contain or use e-PHI.²⁵

[25] 45 C.F.R. § 164.312(b).