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| Use Case DetailsCommon Use CasesVersion 1.0 ● Proposed |
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# Common Use Cases

Use Case diagram in package 'Common Use Cases'



1. Common Use Cases

## 1.0 Source Data Collection

**Source data collection** is the process of assembling the data required for submission to the registry.

Data may be collected from multiple sources using a variety of modalities. Typically sources and modalities include:

* abstraction from paper medical records;
* data extraction/export from electronic medical record systems; and
* manual collection using data collection forms
* patient generated data
* device generated data

When data are collected from multiple sources identity resolution may be necessary to ensure that all sources reflect data about the same individual.

##

## 1.1 Identity resolution

**Identity resolution** is the process of comparing person identifying data from multiple sources with the objective of determining to what extent consistency in identifying data elements suggests that the data sources pertain to the same individual.

Identity resolution includes calculation of a match confidence percentage based upon comparison of weighted identifying data elements. A confidence interval is established for Certain, Probable, and Unlikely matches.

* **Certain** matches are typically assigned automatically.
* **Probable** matches are subjected to human review for resolution.
* **Unlikely** matches are treated as separate individuals.

A periodic audit of matching outcomes is performed so that the assigned weights and confidence intervals can be adjusted as needed. Manual processes may be required to match or split person identity based upon audit findings regarding appropriateness of the assigned confidence percentage.

## 2.0 Registry Data Submission Preparation

**Registry Data Submission Preparation** is the process of preparing collected registry data for submission to the registry.

The cohort of submission eligible patients for whom registry required data has been collected is identified and set aside for further processing.

Further processing may include:

* anonymizing the collected data,
* translating coded values into normalized values,
* deriving additional data values, and
* producing a submission dataset in accordance with formats acceptable to the registry operator.

The resulting dataset is typically assessed for quality with regard to content and form.

## 2.1 Quality Assurance

**Quality Assurance** is the process of evaluating a submission dataset against pre-determined quality criteria assessing the content and format of the dataset.

Quality criteria typically includes:

* inspection for missing or non-permitted data element values,
* minimum and maximum data cardinality,
* appropriateness of coded values, and
* cross-field data value consistency.

Individual records or datasets that fail to meet quality criteria are set aside for correction.

## 3.0 Registry Data Submission

**Registry Data Submission** is the process of presenting the collected and prepared dataset of registry data to the target registry.

Data may be submitted using:

* direct data entry,
* file FTP or upload to the registry operator,  or
* transmission of the dataset through secured interface channels.

Once the submitted dataset successfully passes quality assurance, the dataset content is added to the registry.

## 4.0 Registry Data Use

**Registry Data Use** is the process of direct access to the registry data repository by authenticated and authorized personnel and organization for one or more of the intended data use scenarios.

Data use scenarios typically include:

* Retrospective clinical studies,
* Benchmarking and comparison of participant outcomes,
* Discovery of evidence-based best practices,
* Monitoring adherence to practice protocols, and
* Cost/benefit analysis of alternative treatment protocols, medications, and equipment used.

## 5.0 Registry Data Sharing

**Registry Data Sharing** is the processes of presenting registry data content for use outside the registry proper.

This typically includes exporting a defined subset of the registry content and provisioning that subset to authorized and authenticated indirect users of registry data.

Indirect users of registry data typically include other registries, academic or research groups, government entities, and industry groups/advocates.

Sharing of registry data will often include sharing the outcome of discoveries made during direct use of the registry. These outcomes are used to establish policy, inform guideline development, or establish performance, quality, or financial measures.

## 6.0 Define operating rules

**Define Operating Rules** is the process of establishing the operating parameters of the registry. Operating rules include identification of the goals and objectives of the registry, participation criteria, data use guidelines and agreements, and workflow and data quality processes.

## 7.0 Define Registry Data Content

**Define Registry Data Content** is the process of determining and defining the data to be collected. The data to be collected are determined based upon the goals, objectives, and intended use of the registry. Consideration is given to the cost and feasibility of data collection, consistency and harmonization with other data collection efforts, and use of existing informatic data standards.