

Immunization Functional Profile

**Based on ISO/HL7 10781 – Electronic Health Record System
Functional Model (EHR-S FM), Release 2.01**

Overview

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Table of Contents

| | |
|---|----------|
| PREFACE | 3 |
| NOTES TO READERS: INTRODUCTION..... | 3 |
| ACKNOWLEDGEMENTS | 4 |
| CHANGES FROM PREVIOUS RELEASE | 4 |
| BACKGROUND | 5 |
| PROJECT SCOPE STATEMENT | 5 |
| SPONSORS..... | 5 |
| <i>HL7 International and HL7 EHR Work Group</i> | 5 |
| WHAT IS A FUNCTIONAL PROFILE?..... | 5 |
| EHR-S DEFINITIONS AND STANDARDS | 6 |
| THE TERM “JURISDICTION” | 6 |
| SYSTEMS, COMPONENTS, AND APPLICATIONS..... | 6 |
| ORGANIZATION OF THE HL7 EHR-S FUNCTIONAL MODEL | 6 |
| SECTIONS OF THE FUNCTION LIST | 8 |
| CONFORMANCE CLAUSE | 10 |
| CONFORMANCE CRITERIA | 11 |
| FUNCTIONAL PROFILES | 11 |
| CONFORMANCE OF DERIVED FUNCTIONAL PROFILES..... | 11 |
| NORMATIVE LANGUAGE | 12 |

Preface

Note to Readers: Introduction

1. The Immunization Functional Profile Ballot Package includes the following documents:
 - a) Overview (this document, as .pdf) for reference.
 - b) Immunization Functional Profile (IFP) – a profile of ISO/HL7 10781 Electronic Health Record System Functional Model (EHR-S FM) Release 2.01 as the normative ballot. Functions and criteria are ordered according to EHR-S FM sections and subsections. File is in .pdf format.
 - c) Immunization Functional Profile Analysis Worksheet (as .xlsx) for reference.
 - d) Immunization Functional Profile/Enterprise Architect Model (as .eap) for reference.
2. The IFP Project Team spent several months in analysis of Immunization related user stories, use cases, work flows and scenarios from the following sources:
 - a) HL7 Immunization Domain Analysis Model (IDAM) Story Boards (first 4), May 2012. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=274
 - b) Immunization Integration Program (IIP) Work Flows (8 with 47 total Scenarios). IIP is a partnership of US Centers for Disease Control and Prevention (CDC), Chickasaw Nation Industries (CNI), HIMSS Innovation Center and ICSA Labs. Based on February 2017 update. <http://www.himssinnovationcenter.org/immunization-integration-program>
 - c) Work and Health User Stories (6). Submitted by CDC/NIOSH W&H Team. September 2017.
4. The Immunization Analysis Worksheet is keyed (and ordered row-wise) in the order specified in Item #3 above. In contrast, the HL7 EHR Immunization Functional Profile is keyed (and ordered) as per the Sections, Sub-Sections and Functions in the EHR-S FM, i.e.:

Overview (OV)
Care Provision (CP)
Care Provision Support (CPS)
Administrative Support (AS)
Population Health Support (POP)
Record Infrastructure (RI)
Trust Infrastructure (TI)
5. The Immunization Analysis Worksheet comprises three relevant TABs:
 - .1 IFP Scenarios, Events and Actions
 - .2 Actions to EHR-S Functions

- .3 EHR-S FM Release 2.01 – All Functions and Conformance Criteria (for reference)
6. GAPS from base EHR-S FM R2.01 are identified in Columns G of the Immunization Analysis Worksheet have been “filled” with conformance criteria as specified in Columns I&J. These are rendered as high order (numbered) criteria in the Immunization FP.

Column H is hidden and includes example actions/functions of an external system communicating with the EHR-S, such as a (US state) immunization information system. Actions/functions of the external system are not the subject of this EHR-S FM profile.

Column K has highlighted cells (green) on rows with revisions since the first (January 2018) ballot. Revisions represent corrections and/or are the result of ballot comment dispositions.

7. In development of the IFP, the Project Team decided not to include detailed immunization-related data requirements in conformance criteria but rather to reference:
- US Federal Health Information Model (FHIM) Immunization Domain – in transition to the HL7 Clinical Logical Information Model (CLIM):
http://www.fhims.org/content/420A62FD03B6_root.html
- Other points of reference for immunization-related data requirements:
- HL7 Immunization Domain Analysis Model
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=274
 - HL7 Fast Health Interoperability Resources (FHIR) – Immunization Resource
<http://hl7.org/fhir/immunization.html>
8. The Project Team established an HL7 Immunization Wiki page to capture project-related materials, references and links:
http://wiki.hl7.org/index.php?title=EHR_Immunization_Functional_Profile

Acknowledgements

This project was sponsored by the Health Level Seven International, Incorporated. A project team focused on this Immunization Functional Profile was formed under the HL7 Electronic Health Record Work Group (EHR WG). Many thanks to all who participated in Project Team meetings and contributed to the IFP analysis and development effort!

Changes from Previous Release

This is the first release of the EHR-S Immunization Functional Profile (IFP), now in its second ballot cycle. Changes from the previous ballot are shown in Column K of the IFP Analysis Worksheet in green highlighted rows.

BACKGROUND

Project Scope Statement

The scope of this project is to develop an EHR System Immunization Functional Profile, referred hereafter as IFP, by identifying functions and conformance criteria from HL7/ISO 10781, EHR System Functional Model Release 2.01, modifying and adding to those functions and conformance criteria where appropriate

The Project uses the Enterprise Architect-EA (© Sparx Systems) based HL7 EHR Functional Model/Profile Tooling Product to develop, ballot and publish the IFP.

Universal Profile

The Immunization Functional Profile is targeted to all realms, US and international.

Sponsors

HL7 International and HL7 EHR Work Group

Founded in 1987, Health Level Seven International (HL7, <http://www.HL7.org>) is a not-for-profit healthcare standards development organization (SDO) accredited by the American National Standards Institute (ANSI). While traditionally involved in the development of messaging standards used by healthcare systems to exchange data, HL7 has begun to develop structured document standards related to healthcare information systems. In 2002, a newly formed HL7 EHR Special Interest Group began development of a functional model for EHR systems. Shortly thereafter, a number of organizations approached HL7 to develop a consensus standard to define the necessary functions for an EHR system. The EHR Special Interest Group was promoted to a full EHR Technical Committee (EHR-TC) and subsequently renamed the EHR Work Group (EHR WG). In 2004 the EHR WG published the *EHR-S Functional Model (EHR-S FM)* as a Draft Standard for Trial Use (DSTU). The Functional Model underwent membership level ballot in September 2006 and January 2007, and was approved as a full Standard in February 2007. In 2009, EHR System Functional Model Release 1.1 was jointly balloted and published by ISO TC215 and CEN TC251.

In April 2014, EHR-S FM Release 2 completed HL7 balloting and was approved for publication. ISO also completed balloting and published the Standard in 2015.

Release 2.01 is an unballoted errata release, published by HL7 in 2017.

The HL7 EHR Work Group intends that unique functional profiles be developed by subject matter experts in various care settings to inform developers, purchasers, and other stakeholders of the functional requirements of systems developed for specific domains.

What is a Functional Profile?

The EHR-S FM is a list of all functions that COULD be present in EHR systems and criteria for achieving that function. Any given EHR-S will perform one or more functions (i.e., a subset) from the FM list (i.e., the superset), depending on the purpose of the system. The select subset of functions and the criteria for conforming to these functions characterize the EHR-S capabilities and are referred to as a “functional profile”. The functions and conformance criteria will vary across functional profiles, depending on the operational needs of the system, i.e., what the system is in place to accomplish.

EHR-S Definitions and Standards

ISO/HL7 10781 EHR-S FM references the International Organization for Standardization (ISO) *ISO/TR-20514 Health Informatics – Electronic health record – Definition, scope and context*¹ and states:

“The primary purpose of the EHR is to provide a documented record of care that supports present and future care by the same or other clinicians.... Any other purpose for which the health record is used may be considered secondary.”

“The Core EHR contains principally clinical information; it is therefore chiefly focused on the primary purpose. The Core EHR is a subset of the Extended EHR. The Extended EHR includes the whole health information landscape; its focus therefore is not only on the primary purpose, but also on all of the secondary purposes as well. The Extended EHR is a superset of the Core EHR.”

In this respect, the IFP may be regarded as a set of Extended (i.e., not Core) EHR functions.

The term “Jurisdiction”

For the purposes of this document, the term “jurisdiction” is used as follows:

A jurisdiction is an area, generally geo-political, in which a governmental agency or corporation has public health oversight and/or management responsibilities; a territorial range of authority or control. The jurisdiction could be a state, a metropolitan area (New York City, Chicago, etc.), a county within a state, or some other subdivision of a larger jurisdiction. A jurisdiction might encompass the entire country, as is the case with nationwide jurisdictions such as the jurisdictions of the Department of Veterans Affairs and the Federal Bureau of Investigation. A subordinate jurisdiction is a jurisdiction that is a subset of another jurisdiction.

Systems, Components, and Applications

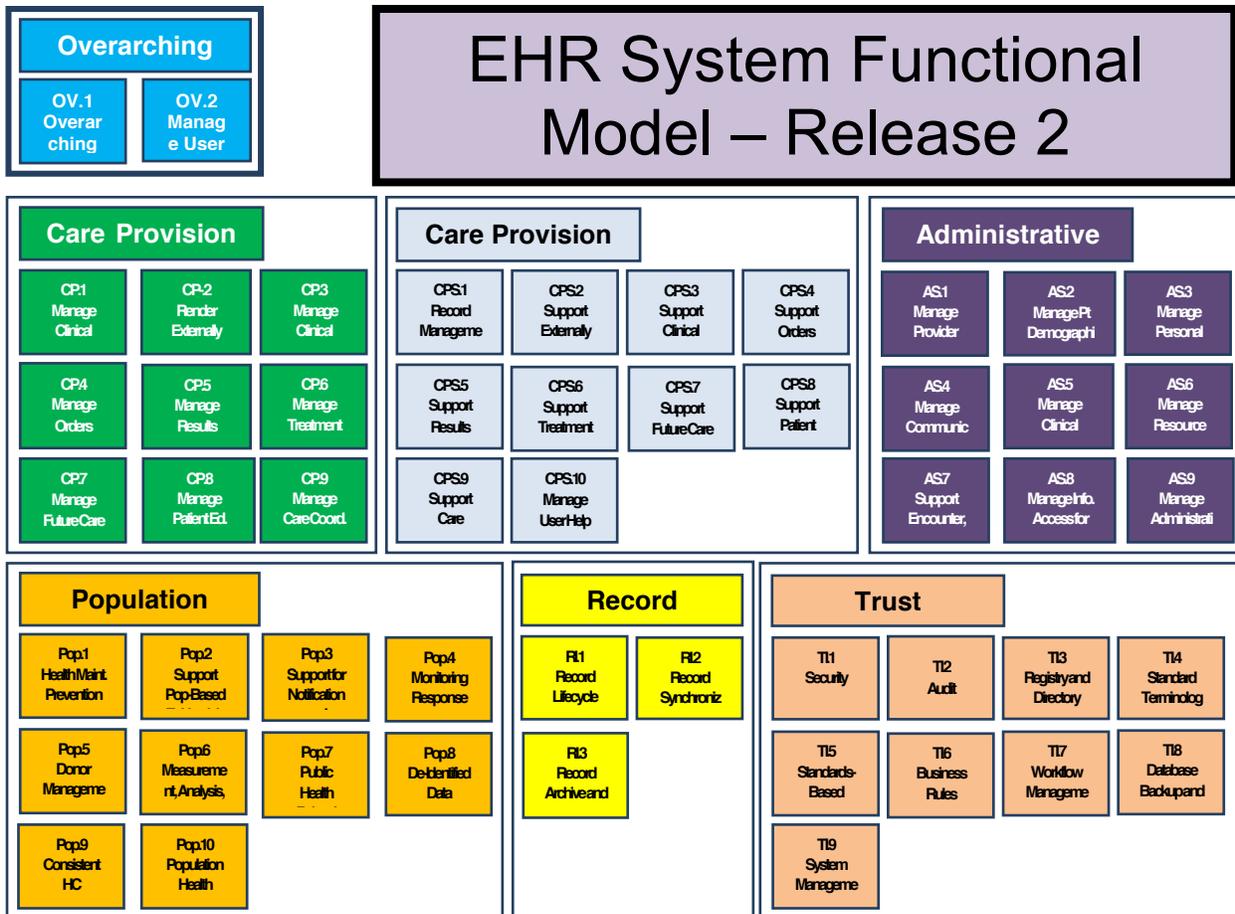
An EHR system consists of a collection of systems, applications, modules, or components, developed on different architectures. For example, a provider might pair one vendor's clinical documentation system with another's tracking, discharge, or prescribing system. An EHR system may be provided by a single vendor, multiple vendors, or by one or more development teams.

Organization of the HL7 EHR-S Functional Model

The EHR-S Functional Model is composed of a list of functions, known as the Function List, which is divided into seven sections: Overarching, Care Provision, Care Provision Support, Population Health Support, Administrative Support, Record Infrastructure and Trust Infrastructure.

Within the seven Sections of the Functional List the functions are grouped under header functions which each have one or more sub-functions in a hierarchical structure.

¹ ISO/TR 20514: Health informatics -- Electronic health record -- Definition, scope and context. 2005-10-17 (Available at: <http://www.iso.org>)



The seven sections of the function list reflect content from prior HL7 DSTUs (EHR Interoperability and Lifecycle Models), the Records Management/Evidentiary Support and other Functional Profiles (based on prior releases of the EHR System Functional Model).

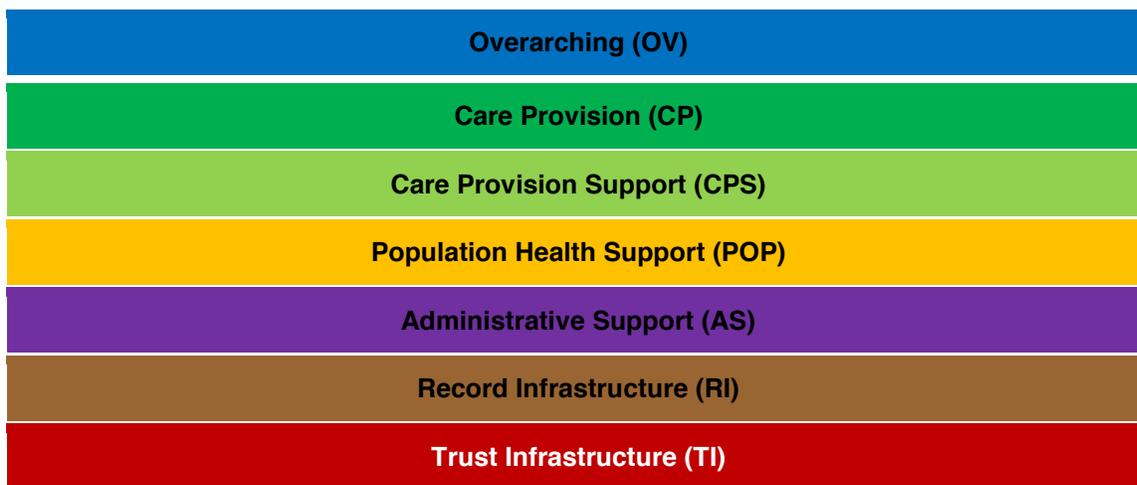


Table 1: Function List Sections

Sections of the Function List

The seven sections of the function list reflect content of the Interoperability Model, now integrated in the Functional Model, and input from several profiles of the earlier versions of the Functional Model. Below is a summary description of each of the seven sections:

- **Overarching:** The Overarching Section contains functions and conformance criteria that apply to complete EHR Systems and which are typically included in all EHR-S FM compliant profiles.
- **Care Provision:** The Care Provision Section contains those functions and conformance criteria that enable direct care to a specific patient and facilitate hands-on delivery of healthcare. The functions are general and are not limited to a specific care setting and may be applied as part of an Electronic Health Record supporting healthcare clinics, hospitals, services, specialties, acute, post-acute and long-term care settings.
- **Care Provision Support:** The Care Provision Support Section focuses on functions and conformance criteria supporting the provision of care. This section is organized generally in alignment with Care Provision Section. For example, CP.4 (Manage Orders) is supported directly by CPS.4 (Support Orders).
- **Population Health Support:** The Population Health Support Section focuses on functions and conformance criteria supporting the prevention and control of disease among a group of people (as opposed to the direct care of a single patient). This section includes functions to support input to systems that perform medical research, promote public health and improve the quality of care to a population.
- **Administrative Support:** The Administrative Support Section focuses on functions and conformance criteria enabling the management of clinical practice and facilitating administrative and financial operations. This includes management of resources, workflow and communication with patients and providers as well as the management of non-clinical administrative information on patients and providers.
- **Record Infrastructure:** The Record Infrastructure Section consists of functions and conformance criteria describing how an EHR system manages an EHR record, particularly those functions vital to managing the lifecycle of EHR record entries (such as origination/retention, attestation, amendment/update, access/use, translation/transformation, transmittal/disclosure, receipt, de-identification, archive...) and record entry lifespan (persistence, indelibility, continuity, audit, encryption). RI functions are core and foundational to all other functions of the EHR-S FM (CP, CPS, POP, AS).
- **Trust Infrastructure:** The Trust Infrastructure Section consists of functions and conformance criteria common to an EHR System infrastructure, particularly those functions foundational to system operations, security, efficiency and data integrity assurance, safeguards for privacy and confidentiality, and interoperability with other systems. TI functions are core and foundational to all other functions of the EHR-S FM (CP, CPS, POP, AS and RI).

Each function in the HL7 EHR-S Functional Model is identified and described using a set of elements or components as detailed below.

| ID | Type | Name | Statement | Description | Conformance Criteria |
|--------|------|-------------------------|--|--|---|
| CP.1 | F | Manage Clinical History | Manage the patient's clinical history lists used to present summary or detailed information on patient health history. | Patient Clinical History lists are used to present succinct "snapshots" of critical health information including patient history; allergy intolerance and adverse reactions; medications; problems; strengths; immunizations; medical equipment/devices; and patient and family preferences. | |
| CP.1.4 | F | Manage Problem List | Create and maintain patient-specific problem lists. | A problem list may include, but is not limited to chronic conditions, diagnoses, or symptoms, injury/poisoning (both intentional and unintentional), adverse effects of medical care (e.g., drugs, surgical), functional limitations, visit or stay-specific conditions, diagnoses, or symptoms... | |
| CP.1.4 | C | | | | 1. The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient. |
| CP.1.4 | C | | | | 2. The system SHALL capture and render a history of all problems associated with a patient. |
| CP.1.4 | C | | | | 3. The system SHALL provide the ability to manage relevant dates including the onset date and resolution date of problem. |

Table 2: Example of Functional Model Elements

Function ID

This is the unique identifier of a function in the Function List (e.g., CP.1.1) and should be used to identify uniquely the function when referencing functions. The Function ID also serves to identify the section within which the function exists (CP = Care Provision Section) and the hierarchy or relationship between functions (CP.1.1 is at the same

level as CP.1.2, CP.1.1 is also a parent of CP.1.1.1 and child of CP.1. In many cases the parent is fully expressed by the children.

Function Type

This is an indication of the line item as being a Header (H), Function (F) or Conformance Criteria (C). The Tag (T) is used to identify a new section in the spreadsheet and its related functions in the spreadsheet. A Tag has no directly associated Functions or Criteria.

Function Name

This is the name of the Function and while expected to be unique within the Function List; it is not recommended to be used to identify the Function without being accompanied by the Function ID.

Example: *CP.1.3, Manage Medication List*

Function Statement

This is a brief statement of the purpose of this function. While not restricted to the use of structured language that is used in the Conformance Criteria (see below); the Statement should clearly identify the purpose and scope of the function.

Example: *Create and maintain patient-specific medication lists*

Description

This is a more detailed description of the function, including examples if needed.

Example: *Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. All pertinent dates, including medication start, modification, and end dates are stored. The entire medication history for any medication, including alternative supplements and herbal medications, is viewable. Medication lists are not limited to medication orders recorded by providers, but may include, for example, pharmacy dispense/supply records, patient-reported medications and additional information such as age specific dosage.*

Conformance Criteria

Each function in the Function List includes one or more Conformance Criteria. A Conformance Criteria, which exists as normative language in this standard, defines the requirements for conforming to the function. The language used to express a conformance criterion is highly structured with standardized components with set meanings.

Example: *1. The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient.*

Conformance Clause

These profiles are based on the HL7 EHR-S Functional Model, Release 2, April 2014.

Key to the Functional Model and derived profiles is the concept of *conformance*, which is defined (by the EHR-S FM) as “*verification that an implementation meets the requirements of a standard or specification*”. In the Functional Model and in derived profiles, the general concept

of conformance may be expressed in a number of forms. For instance, a profile can be said to conform to the Functional Model if it adheres to the defined rules specified by the Functional Model specification. Similarly, an EHR system may claim conformance to one of these profiles if it meets all the requirements outlined in the profile.

Conformance Criteria

Each function defined in the Functional Model or profiles is associated with specific *conformance criteria*, which are statements used to determine if a particular function is met (i.e., “the system SHALL capture, display and report all hearing tests associated with a patient”). Conformance criteria have been developed in accordance with the standards set forth by the EHR Work Group. In order to ensure consistent, unambiguous understanding and application of the Functional Profile, a consistent set of keywords (normative verbs) has been employed to describe conformance requirements.

The key words SHALL, SHALL NOT, SHOULD, and MAY in this document are to be interpreted as described in HL7 EHR-S Functional Model, Release 2, April 2014 Conformance Clause:

| | |
|---------------|--|
| SHALL | Indicates a mandatory requirement to be followed (implemented) in order to conform. Synonymous with ‘is required to’ and ‘must’. |
| SHOULD | Indicates an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with ‘is permitted and recommended’. |
| MAY | Indicates an optional, permissible action. Synonymous with ‘is permitted’. |

Table 3: Optionality key words

Functional Profiles

A “Functional Profile” is a selected set of functions that are applicable for a particular purpose, user, care setting, domain, etc. Functional profiles help to manage the master list of functions. It is not anticipated that the full Functional Model will apply to any single EHR-S implementation. As such, an EHR system does not conform directly to the Functional Model; rather, it conforms to one or more Functional Profiles.

Functional profiles are the expression of usable subsets of, or modifications or additions to, functions and criteria of the EHR-S Functional Model.

The act of creating a Functional Profile is to support a business case for EHR-S use by selecting an applicable subset of functions from the EHR-S Functional Model list of functions, in effect constraining the model to meet specific requirements. For example, a Functional Profile may be created by a purchaser, to indicate requirements; by a vendor, to indicate the capability of specific products; or by any person/entity wishing to stipulate a desired subset of functions for a particular purpose, including a care setting within a specific realm.

Conformance of Derived Functional Profiles

Derived profiles may prove valuable for:

1. specifying certain subsets of EHR systems used to care for specific groups of population, e.g., children, adults, women, or geriatrics; and/or specific care settings, e.g., acute care, ambulatory care, specialty care, pharmacy, laboratory, or radiology.
2. supporting information exchanges between clinical care and public health information systems.

In order for a derived functional profile to claim conformance with one or more domain's listed in the IFP, the derived profile **SHALL** adhere to the principles and methods detailed in the Conformance Clause of the EHR-S FM.

Normative Language

Additional clarification is necessary to understand the standardized nomenclature used to describe the actions performed by a system. The following excerpt from the EHR-S FM R2 Glossary, illustrates the hierarchical nature of the nomenclature. For example, the term "Capture" is used to describe a function that includes both direct data entry ("Enter") and indirect data entry (e.g., "Import" from another system. Similarly, "Maintain" is used to describe a function that entails storing, updating, and/or removing data.

| Manage (Data) | | | | | | | | | | |
|---|---|---|-----------------|---------|---------|----------|---|-----------|--------|--|
| Capture | Maintain | | | Render | | | Exchange | Determine | | Manage-Data-Visibility |
| Auto-Populate Enter Import Receive | Store | Update | Remove | Extract | Present | Transmit | Export Import Receive Transmit | Analyze | Decide | De-Identify Hide Mask Re-Identify Unhide Unmask |
| | Archive Backup Decrypt Encrypt Recover Restore Save | Annotate Attest Edit Harmonize Integrate Link Tag | Delete Purge | | | | | | | |

Table 4: "Manage Data" Action-Verbs

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