

Converged Registries Solution Enhancements (CRSe)

Requirements Specification Document



November 2015

Version 2.0

Department of Veterans Affairs

Revision History

Date	Version	Description	Author
11/09/2015	2.0	Transferred to the latest ProPath template and made the mutually agreed changes discussed during the 11/4/15 Updated RSD Comments Review teleconference.	ManTech
10/28/2015	1.9	Updated following requirements elaboration sessions with Business Owner [REDACTED] including the following: BR-090, -170, -200, and -230 TD-020 and -040: PTL-070, -100, -110, -120, and -160 REP-010 and -030 DBE-020 DST-030 ETL-010 RW-030, -040, -080, -090, and -100 CRE-010 HMP-010 Section 1.6 Definitions	ManTech
7/16/2015	1.8	Updated Performance Section 2.7; updated requirements P-020 and P-030	[REDACTED]
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Date	Version	Description	Author
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Date	Version	Description	Author
		<p>Section 2.6.6 – DBS-050 Section 2.6.7 – DBE-040 Section 2.6.8.1 – DST-060 Section 2.6.8.2 – ETL-060, ETL-100 thru ETL-180 Section 2.6.10 Section 2.6.11 Section 2.7 – P-080 Appendix A – A.3.1 Appendix A – A.3.4 Appendix K</p> <p>Modified:</p> <p>Changed CRS to CRSe where applicable. Section 2, first paragraph to describe the type of requirements in each section. Section 2.1 - A-010 to add “documentation” Section 2.2 - BR-140 to use the BRCD language, old BR-190 – clarified and moved to ETL-110 Section 2.5- DOC-020 to include all users Section 2.6.1 – PTL-020, PTL-040, PTL-060, PTL-070, PTL-130, PTL-140, PTL-170, PTL-220 Section 2.6.2 – UDR-030 Section 2.6.3 – REP-040 thru REP-070 Section 2.6.4 – BM-030, old BM-040 modified and moved to BR-210, old BM-050 modified and moved to BR-220, old BM-060 modified and moved to DC-080 Section 2.6.6 – DBS-020, DBS-040 Section 2.6.8.1 – DST-040 Section 2.6.8.2 – ETL-020, ETL-070 Section 2.6.8.3 leading paragraph (clarification) Section 2.7- P-020, P-030, P-050 Section 2.8- REL-010, REL-020, REL-060 Section 3 – STD-040, STD-050, STD-060, STD-100 Section 4 – leading paragraph Section 5 – leading paragraph Appendix A – A.2 (added AD) Appendix A – A.3 (added AD) Appendix B - added several acronyms Appendix G – updated external interfaces Appendix I – updated diagram Appendix J – updated matrix</p> <p>Deleted:</p> <p>Section 2.6.1 –requirement for supporting mobile access</p>	

Date	Version	Description	Author
		<p>(old PTL-020)</p> <p>Section 2.6.3 – requirement for filtering reports (duplicate requirement – old REP-040), requirement for sharing reports (old REP-080), requirement for restricting report access/sensitive data (old REP-090)</p> <p>Section 2.6.5 – old ERR-020, and old ERR-030 (regarding setting logging levels)</p> <p>Section 2.6.6 – old DBS-050 regarding sensitivity levels, old DBS-060 regarding distinguishing non VA originated data</p> <p>Section 2.6.7 – old DBE-040 and DBE-050 (covered in reporting requirements)</p> <p>Section 2.6.8.2 – old ETL-050, old ETL-060 (duplicates)</p> <p>Section 4 - old INT-030 regarding distinguishing non VA originated data</p>	
11/26/14	1.0	Initial version	MITRE

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1. Introduction

This Requirements Specification Document (RSD) was developed for the Department of Veterans Affairs (VA) Converged Registries Solution Enhancements (CRSe) project, under the VA Transformation Twenty-One Total Technology acquisition program, known as T4.

The Department of Veterans Affairs (VA) Health Registries (HREG) program was established to facilitate and improve healthcare decision making for Veterans and their dependents. The registries that comprise the Health Registries program provide population-specific patient data required to ensure that quality health care services are delivered in a timely manner.

The Converged Registries Solution (CRS) is a centralized relational database framework and architectural platform for the registries in the Health Registries program. This relational database assists in effectively managing national registry data to support the goal of the Veterans Health Administration (VHA) to be a Veteran-centered, integrated organization that provides excellence in health care, research, and education. Comprised of standardized common patient data and registry-specific data elements, CRS provides the backend database architecture for each national health registry.

As VA moves forward with its registry solutions, it has identified opportunities for conceptual and technological improvement. VA is shifting from individual registry solutions to a more holistic technical and functional integration of data that allows Veteran information to be collected more efficiently. In this way, registry users can make more efficient use of the registry data and analytical products to better manage individual Veterans and the general health of the cohort. Registry functions and products will be available both in clinical and administrative contexts to facilitate action.

The current CRS design was analyzed through a review of CRS artifacts and interviews with subject matter experts. Based on this analysis, the CRS Enhancements (CRSe) effort will implement enhancements and improvements to the current architecture by employing a single CRSe Web portal with Web services. It will consolidate all registries into one Web portal system that accesses business logic and data to create reusable and common functionality.

1.1. Purpose

The purpose of this RSD is to outline the requirements needed to satisfy the areas of improvement identified in the CRS As-Is to To-Be Gap Analysis and CRS business requirements. These improvements are identified as Development / Modernization / Enhancement (DME) modifications, since they enhance the CRS database framework.

The intended audience for this RSD is a broad base of stakeholders who include, but are not limited to, CRS stakeholders, project management team, functional analysts, database developers, Web developers, software quality assurance (SQA) analysts, and documentation specialists.

1.2. Scope

The scope of this RSD includes requirements gathered from the CRS As-Is to To-Be Gap Analysis and the Business Requirements Change Document (BRCD). These artifacts are located in the CRSe project notebook in the Technical Service Project Repository (TSPR):

[REDACTED]

The scope includes improvements to the following:

- CRS project/program management structure
- Registry Uniform Resource Locators (URLs) and access
- Reporting
- Error handling and logging
- Data standardization
- Software and database design
- Extract, transform and load (ETL) processes
- Manual data uploads
- Security
- Folder tree and file naming conventions
- Source code best practices

These enhancements will modify the CRS framework so that it more effectively supports the needs of current and future national registry users.

1.3. References

- Business Requirements Change Document (BRCD) for the Converged Registries Solution (CRS), Supplemental to New Service Request # 20100406, version 1.1 (2014 proposed cuts), located in TSPR:
[REDACTED]
- CRSe RSD, Version 1.1, April 2014, located in TSPR:
[REDACTED]
- CRSe System Design Document (SDD), Version 1.7, May 2014, located in TSPR:
[REDACTED]
- CRS As-Is Design, Version 1.1, October 2014 (not published publicly)
- CRS As-Is to To-Be Gap Analysis, Version 1.0, October 2014 (not published publicly)
- Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. <http://www.effectivehealthcare.ahrq.gov/registries-guide-3.cfm>.
- Registry Development Requirements, located in TSPR:
[REDACTED]

2. Overall Description

The following sections describe the specifications for CRSe.

2.1. Accessibility Specifications

The CRSe implementation must adhere to Section 508 requirements.

Req. ID	Requirement
A-010	The system user interface component and documentation shall comply with Section 508 requirements as covered at http://www.section508.gov .

2.2. Business Rules Specifications

The following table defines the business rules applicable to CRSe.

Req. ID	Requirement
BR-010	CRSe will be managed as one system, encompassing all registries on the platform.
BR-020	All CRSe development (including registry development) will be managed as one system.
BR-030	All existing CRS functionality shall be preserved (unless stated otherwise in this document.)
BR-040	The system shall allow access from multiple VA facilities.
BR-050	Users shall access registries on the CRSe platform through a single CRSe user interface.
BR-060	User navigation and privileges shall be based on user role and individual registry.
BR-070	A common set of CRSe user roles and access privileges shall be identified and approved by the CRSe stakeholders, registry stakeholders, and VA subject matter experts.
BR-080	The CRSe project shall coordinate with the VA Customer Data Integration (CDI) initiative for data standardization.
BR-090	The system shall support a web browser portal interface and RESTful services.
BR-100	Each system release shall have a quality control plan that contains detailed test cases, pass/fail criteria, and metrics on number of test cases executed, passed, failed, open and closed bugs, and release acceptance criteria.
BR-110	Each release shall be accepted only when the release acceptance criteria specified in the quality control plan have been met.
BR-120	CRSe shall comply with all access requirements as specified by VA.
BR-130	The CRSe development team shall provide support when transitioning to sustainment.
BR-140	Unique data requirements, such as disease cohorts, will include all patient data regardless of age or gender.
BR-150	The CRSe patient table shall include any Veteran, Veteran beneficiary, Active Duty Servicemember, Active Duty Servicemember beneficiary, or other population determined by VHA without restrictions such as age, service status, or gender.
BR-160	The system shall only house in its patient table those individuals who are eligible for one or more of the registries hosted by CRSe.
BR-170	A technical training curriculum shall be developed and delivered to all levels of staff users.

Req. ID	Requirement
BR-180	The training curriculum developed by the Program Office shall state the expected task completion time for all user types.
BR-190	A referral shall have one or more work streams associated with it.
BR-200	A work stream shall have one or more activities associated with it.
BR-210	Referrals shall have a status such as new-waiting to be activated, new-manual-waiting on data, active, disqualified, canceled-criteria match no longer exists (see requirement ETL-120), subsequent-duplicate (see requirement ETL-130), and completed.
BR-220	Work streams, and activities shall have a state such as ready to start, in progress, paused, terminated, and completed.
BR-230	The system shall support cohorts and the integration of data with Enterprise Health Management Platform (eHMP) and VistA Exchange.

2.3. Design Constraints Specifications

The following represents mandated decisions that have been made regarding the design and development of CRSe

Req. ID	Requirement
DC-010	The system shall abide by VA enterprise services standards.
DC-020	The system shall follow VA coding practices guidelines.
DC-030	The system shall be compatible with the standards defined in the VA Technical Reference Model.
DC-040	The system shall use standards-based protocols, for example HTTP, HTTPS, and HL7 internet protocols.
DC-050	The system will leverage and maximize design patterns and create extensible solutions that promote code reuse.
DC-060	The system shall provide common capabilities that can be extended to create registry-specific capabilities.
DC-070	The CRSe framework shall provide the common user interface components, common extendable business managers, registry interface definitions, and common ETLs.
DC-080	The CRSe framework shall define standard application programming interfaces that each customized registry is required to implement, that allow the framework to be agnostic to the inner workings of registry-specific menu items and registry-specific data displays.

2.4. Disaster Recovery Specification

The CRSe implementation will use the existing CRS disaster recovery solution. The following are the requirements related to disaster recovery.

Req. ID	Requirement
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Req. ID	Requirement
DR-010	Existing disaster recovery solutions, locations, Recovery Time Objectives (RTO), and Recovery Point Objectives (RPO) shall be preserved.
DR-020	All backups shall provide the ability to be verified on demand, as well as on a regularly scheduled basis.
DR-030	All disaster recovery solutions shall be independent (not dependent on another disaster recovery solution.)
DR-040	The system shall comply with VA Enterprise Disaster Recovery Service Tiers and Technology Solutions Standards.
DR-050	The system shall be capable of supporting an RTO of 30 days in an event of a disaster.
DR-060	The system shall have the ability to recover data. The system shall meet the RPO of 24 hours. (The current system performs full system data backups weekly, and incremental backups daily.)

2.5. Documentation Specifications

2.5.1. Technical Documentation

The following are the requirements for CRSe technical documentation.

Req. ID	Requirement
TS-010	There shall be one set of CRSe documents that encompasses CRSe backend, and registry- specific information. For example, there shall be one CRSe SDD, one Master Test Plan, etc., instead of multiple SDDs and test plans for each registry.
TS-020	A Registry Developer's Implementation guide on how to integrate a registry with the framework shall be developed and made available.

2.5.2. Training Documentation

The following are the requirements for CRSe training documentation.

Req. ID	Requirement
TD-010	User manuals and training tools shall be developed for all users to include clinical staff, and enterprise operations staff. If they already exist, updates shall be made as necessary.
TD-020	User manuals and training tools shall be delivered to all levels of users.
TD-030	All training material shall be available to users online for their reference.
TD-040	All training classes shall be recorded and made available to users online for their reference.

2.6. Functional Specifications

2.6.1. User Defined Roles

This implementation of CRSe will provide role-driven access to registry data. The following are the CRSe user role requirements.

Req. ID	Requirement
UDR-010	The system shall provide the ability to configure a set of registries and roles for a user.
UDR-020	The system shall provide the ability to configure which registry or registries a user has access to.
UDR-030	The system shall allow the user to have unique user roles for each registry.
UDR-040	The system shall provide the ability to configure the user role for each registry.
UDR-050	The system shall provide the ability to configure access to each menu item/tab, based on defined user roles.
UDR-060	The system shall provide the ability to configure access to each menu item based on defined user roles.
UDR-070	User role configuration data shall be restricted to administrator user roles such as the registry administrator and system administrator user roles.
UDR-080	System configuration data shall be restricted to the system administrator user role.
UDR-090	The system shall track and log all configuration changes, including but not limited to the ID making the changes, time/date, and the configuration change details.

2.6.2. Business Managers

The following are the business manager requirements for CRSe.

Req. ID	Requirement
BM-010	The Core Business Managers shall encapsulate common or shared methods used by the Registries.
BM-020	Registry-specific Business Manager shall extend the existing capability provided by the Core Business Manager.
BM-030	A base implementation of the following areas shall be created such that they provide common functionality and can be extended to provide registry-specific functionality: <ul style="list-style-type: none"> • Users • Roles • Patient • Registry • Referral • Work Stream • Activity • Survey
BM-040	The system shall verify manually entered referral information on submission including verifying the patient and provider.
BM-050	The system shall save the survey question and the question response per survey such that the information is preserved and not affected by future updates to the framework survey questions and responses.
BM-060	Each survey taken shall be time stamped and saved.

2.6.3. Error Handling/Logging

The following are the error handling and logging requirements for CRSe.

Req. ID	Requirement
ERR-010	The system shall provide error handling and logging in all software components.
ERR-020	The system logger shall distinguish between errors logged and tracing events logged.

2.6.4. Data Standardization/Data Dictionary

The following requirements introduce formal data standardization techniques for the CRSe database.

Req. ID	Requirement
DBS-010	The database field names shall be the same as the data it contains, i.e. a patient last name field shall be named PATIENT_LASTNAME.
DBS-020	The system shall reference the VA Defined Standard (Standard Data Services (SDS)) as the authoritative source to access non-clinical reference terminology, such as ethnicity, race, country, gender, institution, marital status, service branch, and facility type.
DBS-030	The database shall contain a data dictionary database table that list the attributes stored in the database (in collaboration with CDI).
DBS-040	The data dictionary database table shall map the attributes to the data sources and the tables they are stored in.
DBS-050	The system shall provide a user interface to allow the user to view the information in the data dictionary database table.
DBS-060	All data shall conform to nationally accepted terminology and storage standards including but not limited to SNOMed, RxNORM, and LOINC.
DBS-070	The system shall conform to open source data models that are actively in use by healthcare communities of practice, such as the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), etc.
DBS-080	The system shall conform to standardized industry best practices regarding open source health care data models.

2.6.5. Database Enhancements

The following requirements will enhance the CRSe database and minimize duplication of data.

Req. ID	Requirement
DBE-010	The database shall contain a Registry table that contains information pertaining to each registry, including the registry name, acronym, description, owner, and support staff. See Appendix I – Logical Model.
DBE-020	The system will minimize the use of auto-generated row identifiers used as primary keys by utilizing composite primary keys when possible.
DBE-030	The database shall contain secondary indexes to support common non-primary key fields using queries.
DBE-040	The system shall provide a mapping of patient identifiers including but not limited to: <ul style="list-style-type: none">• SSN• Patient_ICN• Patient_IEN/Station Number combination• EDIPI

2.6.6. Extract Transform Load (ETL)

The following sections describe existing requirements as they relate to ETL processes, although the new CRSe architecture (outlined in the updated SDD) no longer utilizes ETLs.

2.6.6.1. Data-Staging Environment

Req. ID	Requirement
DST-010	The system shall establish a data-staging environment in a production environment.
DST-020	The system shall create and maintain a data dependency map that identifies data sources, data uploaded, and dependencies between data sets.
DST-030	The system shall upload all data to the data-staging environment, prior to loading in the production environment.
DST-040	The system shall only upload data from the data-staging environment to the CRSe production database server, once all data dependencies are met. For example, referral, provider, and patient data must all be met for a referral to be uploaded.
DST-050	The system production data-staging environment shall only be used for production data-staging activities.
DST-060	The system shall have the ability to execute individual ETLs for a specific patient. Note: This shall only be executed by a system administrator in response to ETL errors.

2.6.6.2. ETL Improvements

Req. ID	Requirement
ETL-010	The system will maximize the use of common ETLs and minimize the use of registry-specific ETLs.

Req. ID	Requirement
ETL-020	<p>The system shall consolidate existing ETL processes by data source, function, and destination. For example, consolidate existing ETL processes according to the following:</p> <ul style="list-style-type: none"> • Referrals • Patients • Providers • ER Encounters • Problems • Lab Results • Standard Codes • Standard References
ETL-030	The system shall provide error handling in all ETL components.
ETL-040	The system shall provide ETL logging, tracking and monitoring capabilities.
ETL-050	The system shall electronically notify the system administrator of the status and results of ETLs upon successful and failed completion.
ETL-060	The system shall have the ability to add users to a notification list, to electronically receive notifications on the status and results of ETLs upon successful and failed completion.
ETL-070	The system shall provide a dashboard for users to view the ETL status and results.
ETL-080	<p>The ETL status reporting information shall include, but is not limited to the following information:</p> <ul style="list-style-type: none"> • The name of the ETL script. • The execution log file name and location. • Machine name where the process runs. • Start/end date and time. • Source data and destination. • Event - step within the ETL process. • Event Status and description. • Final execution status. • Number of records created or updated.
ETL-090	The system shall obtain standard terminology services from CDW for daily updates of clinical and non-clinical standardized data.
ETL-100	The framework shall define a standard format for receiving referral data that identifies the fields included in the referral.
ETL-110	The system shall allow a patient to be referred to a registry multiple times.
ETL-120	The system shall provide an indicator flag for referrals currently in a registry that were not entered manually and that are no longer matched to referral criteria ("criteria match no longer exists"). That is, the referral no longer appear in the referral list generated by the ETL.
ETL-130	After the first referral is created, additional referrals shall be created and marked as a subsequent/duplicate referral and mapped to the original referral. A subsequent/duplicate referral is a referral where at least one criteria evaluation result is different than the original referral criteria evaluation result.

Req. ID	Requirement
ETL-140	Subsequent referrals shall not have work streams, activities, surveys, or registry data associated with it. (This is to ensure that only one patient record exists in the system.)
ETL-150	The system shall allow the user to configure ETL schedules for the registry, i.e. start times and frequency.
ETL-160	ETL schedules shall default to daily at midnight Central Standard Time.
ETL-170	ETLs shall retry up to a given number of attempts specified in a configuration setting.
ETL-180	ETLs shall retrieve patient and provider data for manually entered referrals based on the frequency defined in the registry's configuration.

2.6.7. Elimination of Manual Receipt and Upload of Data

The following are the requirements for receiving data from user uploads.

Req. ID	Requirement
MDU-010	The system shall not allow data to be manually sent by a user and uploaded into production by support staff, except as a one time work around needed in the event of a failure.
MDU-020	The system shall provide an automated mechanism for sending and uploading all data that is currently manually uploaded.
MDU-030	The system shall log the status and results of all data uploads.
MDU-040	The system shall notify the system administrator with the status and results of all data uploads.

2.6.8. System Configuration

The following are the system configuration requirements for the CRSe framework.

Req. ID	Requirement
SA-010	The system shall provide the ability to view and update system configuration settings.
SA-020	The system shall provide the ability to view and manage log files.
SA-030	The system shall provide the ability to configure the maximum size of log files, and how long log files are kept.
SA-040	The system logger shall provide the ability to turn logging on/off and set logging levels that control the amount of information logged.
SA-050	The system shall provide the ability to configure the default schedule for ETLs, the number of retry attempts, and the time between attempts.
SA-060	The system shall provide the ability to add/delete/update the framework provided common survey questions and predefined responses.
SA-070	The system shall log all system configuration changes.

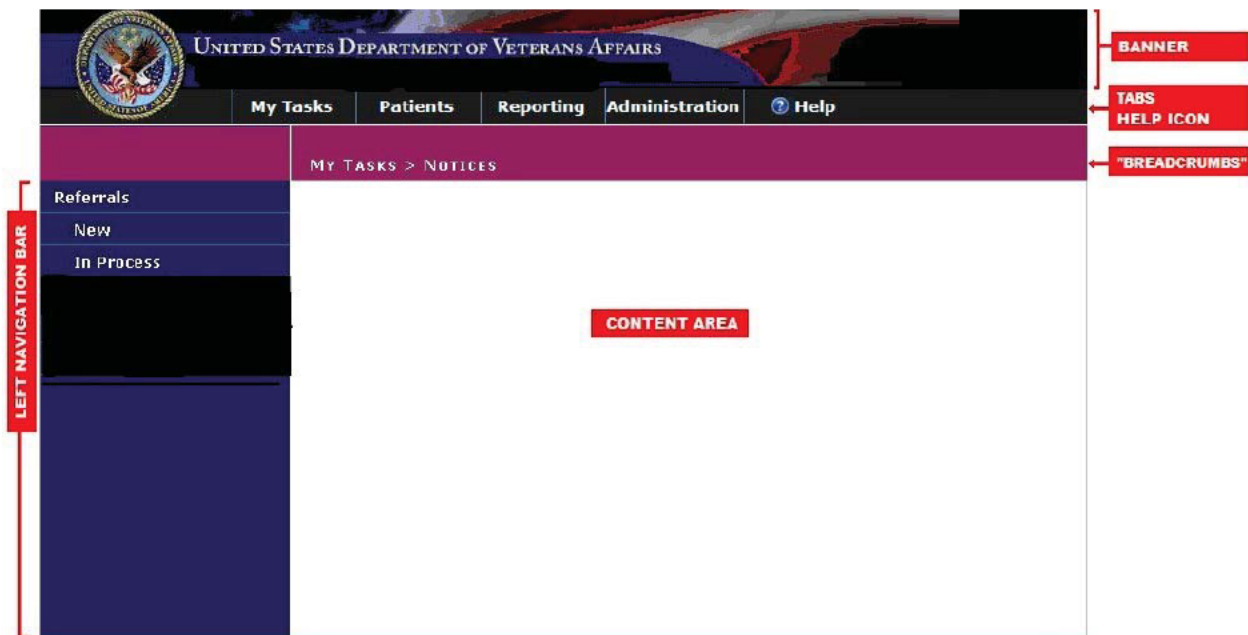
2.6.9. General Registry Specifications

Req. ID	Requirement
REG-010	Each registry shall implement all interfaces defined by the CRSe framework.

2.7. Graphical User Interface (GUI) Specifications

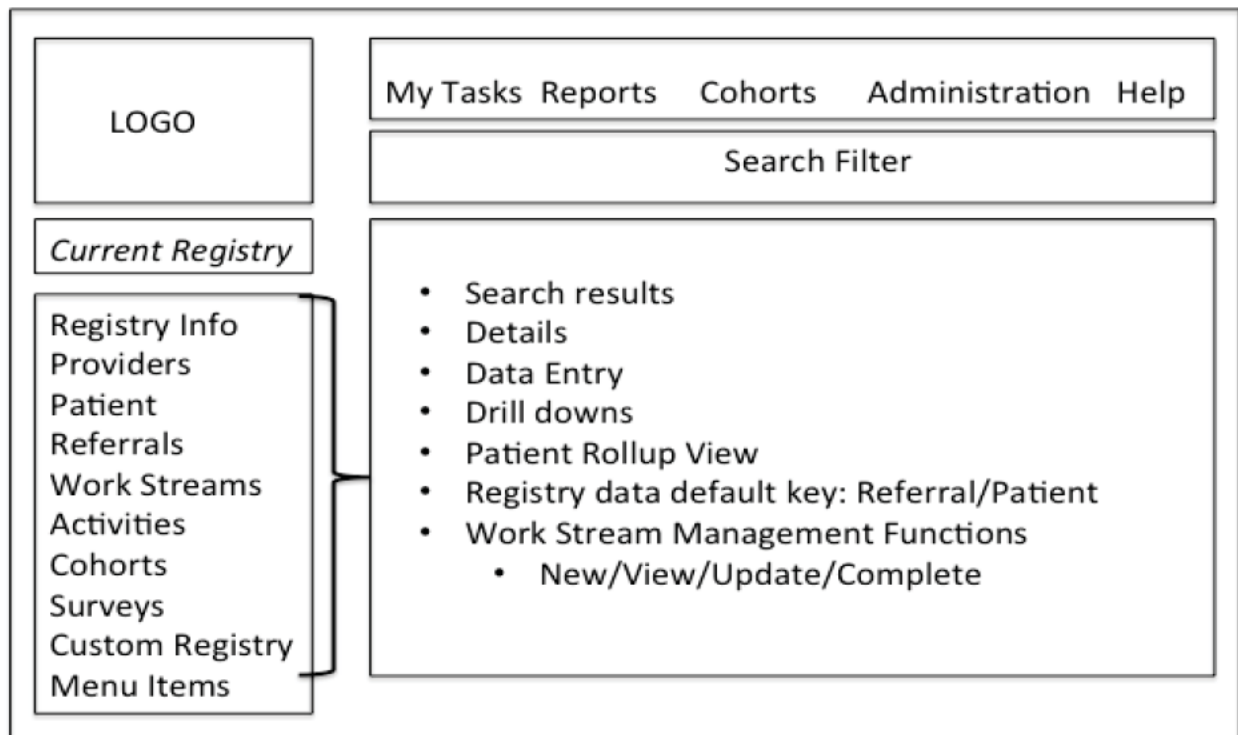
The following subsections describe the requirements for the user interface. The diagram below depicts the general layout for CRSe:

Figure 1: CRSe Layout



The diagram below depicts the conceptual design:

Figure 2: CRSe Conceptual Design



2.7.1. General Interface Specifications

CRS registries will maintain interfaces to internal and external systems when migrated to the new CRSe platform.

Req. ID	Requirement
INT-010	The system shall maintain the functionality of existing and any required interfaces to/from registries that are migrated to the new CRSe platform.
INT-020	The system shall support receiving, storing, and exchanging data with external business partners.
INT-030	The CRSe interface to VistA shall comply with the VistA access requirements as specified by VA.

2.7.2. Converged Registries Enhancements Portal

This implementation of CRSe will provide access to registries via a single user interface portal. Access to CRSe and registry data will be role driven. The following are the CRSe portal requirements. Note: References to “top” and “left” menu items are for description purposes only based on the current CRS system. The new layout will be restricted to the eHMP style guide.

Req. ID	Requirement
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Req. ID	Requirement
PTL-010	The system shall utilize one access point (website) for all registries.
PTL-020	The system shall provide a single user interface to access the system.
PTL-030	The system shall utilize VA approved mechanisms to authenticate users.
PTL-040	The system shall provide a set of common left menu items for each top menu item, as well as the ability to provide registry-specific menu items based on the user's role by extending the left menu. Note: Registry-specific menu items will require software development and a release deployment.
PTL-050	<p>The system shall dynamically create menus, menu items, and workspace content based on user roles and current registry chosen (general or a specific registry). The top menu contains general menu items such as:</p> <ul style="list-style-type: none"> • MyTasks • Reports • Cohorts • Administration • Help
PTL-060	The system shall dynamically create left menus based on the top menu item selected.
PTL-070	<p>The system shall provide the following default set of left menu items</p> <ul style="list-style-type: none"> • Registry Info: Provides the ability to view information such as the registry name, description, points of contact, status, and ETL dashboard • Patients: Provides the option to create a patient or search for a patient. The patient results will include attributes such as patient ID, referral ID, provider, etc. with the ability to drill down on any given attribute to see the detailed data. • Providers: Provides the option to create and search for providers, with the ability to drill down to detailed data • Referrals: Provides the option to create and search for referrals. • Work Stream: Provides the option to create and search for work streams. • Activities: Provides the option to create and search for activities • Surveys: Provides the option to create and search for surveys.
PTL-080	The system shall allow the user to specify a default registry.
PTL-090	The menus and pages shall be presented to the user based on user role and registry.
PTL-100	If a user has access to more than one registry, the system shall allow the user to switch from one registry to another without logging out.
PTL-110	The system shall allow the user to open multiple registry windows at a time by opening additional browser window(s).
PTL-120	The system shall have the ability to display multiple registry windows at a time by opening additional browser window(s).
PTL-130	The system framework shall support a default implementation of registry-specific clinical data that is uniquely identified by a combination of Referral ID, Patient ID, Facility ID, and Date/Time.
PTL-140	The system framework shall provide the ability to drill down to registry data and have the ability to add, display, and update registry data.
PTL-150	The system framework drill down shall provide a single referral view of patient data within a registry.

Req. ID	Requirement
PTL-160	The system framework shall provide a rollup view that provides all patient information for all referrals within a registry.
PTL-170	The system framework shall provide a search filter for Patients, Providers, Referrals, Work streams, Activities, and Surveys.
PTL-180	The system will utilize the eHMP style guide for page layout, color scheme, fonts, and navigation behavior. The current layout is depicted in Appendix D. A conceptual layout of the new CRSe is depicted in Appendix E. Note: This layout is based on the existing CRS system. The eHMP style guide should be used.
PTL-190	The system shall use design patterns that enable code reuse and minimize duplication of effort.
PTL-200	The system user interface shall use common displays to maximize reuse.
PTL-210	The system shall provide common displays for registry, patient, referral, work stream, activity, survey information, and registry data.
PTL-220	The system shall provide searchable online help.
PTL-230	The system shall provide the ability to create, view, and update patients, referrals, work streams, activities, and registry data, based on user role.
PTL-240	The system shall provide user interface and service capabilities for performing work flow management.
PTL-250	The system shall provide the ability for a user to manually enter a referral.
PTL-260	The system shall be able to identify referrals entered manually versus automated referrals such as those generated by ETLs.
PTL-270	The system shall provide a set of common survey questions with the ability to choose a pre-defined answer or enter a free text answer.
PTL-280	The survey questions shall have the ability to enter comments in a free text field.
PTL-290	The system shall allow the user to disqualify a referral along with specifying the reason for disqualification.
PTL-300	The system shall allow the user to cancel a referral due to "criteria match missing" (see requirement ETL-120).

2.7.3. Reporting

This implementation of CRSe will allow users to create, save, and share ad hoc reports. The following are the reporting requirements for CRSe which could occur at the program and/or registry level.

Req. ID	Requirement
REP-010	The system shall provide the ability for users to access the database and build ad hoc reports.
REP-020	The system shall provide the ability for users to create ad hoc reports built from existing user created reports.
REP-030	The system shall provide the ability for reports to span multiple registries based on user permissions.

Req. ID	Requirement
REP-040	The system shall provide the ability to create graphical reports, i.e., bar charts, line charts, pie charts, etc.
REP-050	The system shall provide the ability to export and save a report in Excel, Word, and PDF.
REP-060	The system shall have the ability to save a report (i.e., report logic) to the user's Reports menu.
REP-070	<p>The system shall provide the ability to generate common reports for reporting registry metrics and other general registry information. These reports include but are not limited to the following:</p> <ul style="list-style-type: none"> • Number of users by role • How often a registry is accessed (frequency) • Audit log report • Average time to complete a work stream • Average time to complete an activity • Listing of registries a patient is in • Listing of registries a provider is in • Number of patients in each registry • Patients without activity within user defined period
REP-080	The system shall have the ability to save a report to a "report store" accessible by other users.

2.7.4. Registry Configuration Wizard

The registry wizard is used to create a new registry in the production environment in order to stand up a quick reaction registry that does not require any software development or deployment. If a registry requires a custom solution, software development will be necessary and the registry wizard is not used. The custom solution is required to ensure that the registry deployment correctly configures the registry. The system administrator uses the registry wizard to specify the registry settings, and the data attributes and types that make up the registry-specific data. The registry wizard automatically creates the registry-specific data table based on the data attributes and types specified. The following are the registry wizard requirements for the CRSe framework.

Req. ID	Requirement
RW-010	The system shall provide the system administrator the ability to create a new registry in the production environment using a registry wizard.
RW-020	<p>The registry wizard shall provide the ability to specify general registry information, to include:</p> <ul style="list-style-type: none"> • Registry Full Name • Registry Short/Abbreviated Name – note this will be used to create the registry data table. • Registry Description • Registry Owner • Registry Support Contact • Registry Administrator

Req. ID	Requirement
RW-030	The registry wizard shall require the user to specify the referral work streams along with the ability to indicate if the work stream is automatically created when the referral is created.
RW-040	The registry wizard shall require the user to specify activities for each work stream along with the ability to indicate if the activity is automatically created when the work stream is created.
RW-050	The registry wizard shall allow the user to specify the framework provided data to be included in the registry i.e. Lab Results
RW-060	The registry wizard shall provide the ability to select the framework provided data to be included in the registry. For example, specifying the LOINC codes to filter lab results such that only the results matching the LOINC codes are returned.
RW-070	The registry wizard shall provide the ability to specify the referral criteria used to identify patients to be included in the registry. Referral criteria evaluation results include patient demographics, provider information, and patient health factors from CDW.
RW-080	The registry wizard shall permit the Registry Administrator to edit labels for up to 10 fields in each registry, to be associated with the patient record. These fields shall be available for inclusion in reports, and to be used in searches and report definition. Registry users shall be able to enter and modify data in these 10 fields if they have appropriate authorization. There shall be a separate web page accessible in the patient drill-down to view and edit these fields. The fields shall be specific to the patient AND the registry.
RW-090	The association of any item of data to a specific registry (or registries) will be determined by metadata linking the data item to that/those registries.
RW-100	The registry data table shall be made up of the data attributes and types as specified to the wizard (see requirement RW-080) along with a primary key consisting of Referral_ID, Patient_ID, Facility, Data/Time attributes.
RW-110	The registry wizard shall allow the user to specify the start time and frequency for which registry referrals are created and patient and provider data is retrieved.
RW-120	The registry wizard shall allow the user to specify the start time and frequency for which patient data and provider data are retrieved for manually entered referrals.
RW-130	The system shall allow the user to edit all registry configuration settings.

2.8. Multi-divisional Specifications

To the greatest extent possible, CRSe shall:

- Use interoperability standards recognized by the Secretary of Health and Human Services or the appropriate designated body at the time of the system update, acquisition, or implementation, in all relevant information technology systems.
- Acknowledge that interoperability and certification standards are constantly evolving.

CRSe will incorporate interoperability functionality as it evolves. Development shall be regularly reviewed, documented to ensure that new code complies with the Department of Health and Human Services (HHS) and the Nationwide Health Information Network (NHIN) interoperability standards in effect at the time of development.

When developing code for CRSe, the resulting enhancements will err in the direction of greater interoperability and flexibility to the extent permitted by security and privacy concerns.

2.9. Performance Specifications

The following requirements describe the performance specifications placed on the software and infrastructure.

Req. ID	Requirement
P-010	Specific performance metrics for the system shall be defined in the Service Level Agreement (SLA).
P-020	The system shall be able to process at least one hundred thousand (100,000) transactions per hour.
P-030	The system shall support at least ten thousand (10,000) concurrent users per registry.
P-040	The system software shall be scalable and not limit the number of registries to be added while maintaining required performance.
P-050	The system infrastructure shall be scalable to support additional registries.
P-060	The system shall be scalable to increase the number of transactions per hour, and number of concurrent users by 20% per registry and allow for additional ETLs without degrading performance.
P-070	The system user response time shall be in compliance with response times provided by VA. (Suggested response time for normal actions is 2 seconds or less. Long running actions should provide user feedback within 30 seconds.)
P-080	ETL execution time shall not exceed six hours for all registries.

2.10. Quality Attributes Specification

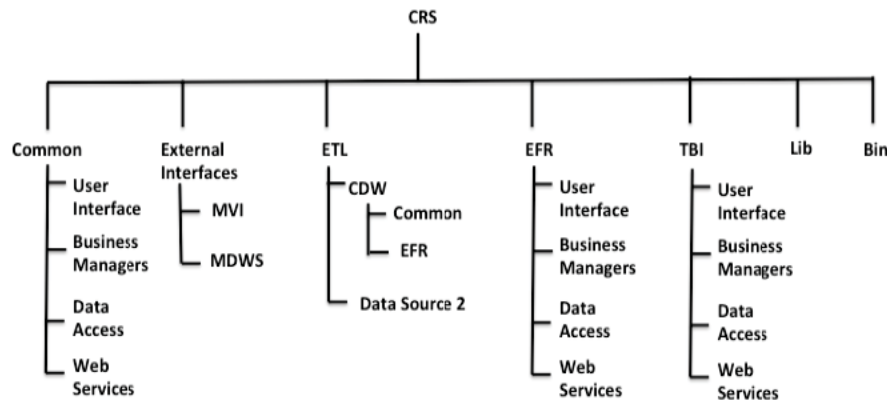
2.10.1. File Naming Conventions and Source Code Tree

The following are the file naming and source code tree requirements.

Req. ID	Requirement
FNM-010	The system source code shall utilize naming conventions for all file types.
FNM-020	The system source code naming convention shall include a prefix to aid in identifying the software commonality.
FNM-030	The naming convention for ETLs shall identify the purpose of the ETL, the data source, and data type. (For example, patient data from a Corporate Data Warehouse (CDW) extract ETL, that is a common core CRSe framework ETL, can be named <code>cre_cdw_patient_extract.dtxs</code>)
FNM-040	The CRSe source code tree structure shall utilize separate branches that clearly identify the type of code in the branch.

The diagram below depicts a sample source code tree structure:

Figure 3: CRSe Sample Source Code Tree Structure



2.11. Reliability Specifications

The following requirements describe the level of reliability required of the system.

Req. ID	Requirement
REL-010	The system shall be available at a minimum, 6am-10pm EST Monday through Friday and 8am through 8pm Saturday and Sunday.
REL-020	System maintenance shall be performed outside of hours identified in REL-010.
REL-030	Response time degradation and other events that degrade or halt system functionality and/or performance shall be disseminated to the user community within 30 minutes of the occurrence.
REL-040	The notification of degradation or halting of system functionality or performance shall include the information described in the current Automated Notification Report (ANR) template maintained by the VA Service Desk.
REL-050	The Automated Notification Report shall describe the specific business impact.
REL-060	Notification of scheduled maintenance periods that require the service to be offline or that may degrade system performance shall be disseminated to the business user community a minimum of 48 hours prior to the scheduled event (per the BRCD).
REL-070	All CRSe external interface components/services Mean Time Between Failures shall be in accordance with the Mean Time Between Failures identified in the Service Level Agreement.
REL-080	All CRSe external interface components/services Mean Time to Repair shall not exceed the Service Level Agreement.

2.12. Scope Integration

The following requirements describe CRSe as it relates to multiple clinical registries and other systems.

“Note: Specific requirements of CRSe integration with eHMP will be refined once the eHMP integration option is exercised and the RSD will be updated accordingly.”

Req. ID	Requirement
SCI-010	CRSe shall be one system that encompasses multiple registries.
SCI-020	Each registry in the system shall utilize the CRSe common framework and platform.
SCI-030	CRSe shall interface with other VA and non-VA systems, based on the interface specifications.
SCI-040	Services offered shall be compliant with the VA Enterprise Services standards.

2.12.1. eHMP Integration

The integration of eHMP and CRSe will require enhancements to both the CRSe framework and the eHMP system. The following sections describe the enhancements required for each system.

2.12.2. CRSe Integration Enhancements

The following are the CRSe enhancements are required to be implemented for eHMP integration.

Req. ID	Requirement
CRE-010	The system shall support the displaying of the CRSe user interface within eHMP.
CRE-020	The system shall provide authentication through Identify and Access Management (IAM) for exposing of the CRSe user interface within eHMP.
CRE-030	The system shall retrieve patient data for all patients active (within the last three years) in eHMP.
CRE-040	The system shall provide an active patient indicator that is used to identify active patients.
CRE-050	The system shall refresh patient and provider data daily regardless of the registry ETL schedule.
CRE-060	The system shall support the ability to create and manage cohorts.
CRE-070	The system shall provide a cohorts top menu.
CRE-080	The system shall provide cohorts sub-menus for creating, viewing, and managing cohorts.
CRE-090	The system shall support cohort attributes such as name, POC, purpose/description.
CRE-100	The system shall provide the ability to define and manage cohort rules used to classify a patient as a member of the cohort.
CRE-110	The system shall limit CRUD capabilities of users accessing CRSe through eHMP, based on the user's access privileges.
CRE-120	The system shall execute cohort searches on all eHMP active patients daily and on-demand.
CRE-130	The system cohort search shall be limited to the CRSe stored data.
CRE-140	The system shall execute cohort searches after the patient data has been loaded and ETLs have successfully completed.
CRE-150	The system shall provide the list of all patients identified as a member of the cohort.
CRE-160	The system shall provide the cohort results for a given patient for a given cohort.
CRE-170	The system shall provide the ability to generate a cohort report from a listing of patients in a registry, displaying all cohorts that the patient(s) is in.

Req. ID	Requirement
CRE-180	The system shall expose cohort and patient data through web services.
CRE-190	The system shall implement a web service that returns the list of defined cohorts
CRE-200	The system shall implement a web service that Returns the cohort criteria used to identify patients.
CRE-210	The system shall implement a web service that Returns the list of patients in a cohort
CRE-220	The system shall implement a web service that Returns the evaluation results of a patient
CRE-230	The system shall implement a web service that Returns all data for a patient.
CRE-240	The database shall contain a Cohort table that contains information pertaining to each cohort, including the cohort name, acronym, description, owner, and support staff. See Appendix I – Logical Model.
CRE-250	The system shall provide common displays for cohort data.
CRE-260	The system shall provide a patient view that includes all patient data and all data for all registries and cohorts that the patient is a member of, restricted by the user's access permissions.
CRE-270	The system shall electronically notify the Clinician of the status and results of the cohort population upon successful and failed completion.
CRE-280	The system shall include cohorts on the dashboard for users to view the status and results of the cohort processes.

2.12.3. eHMP Integration Enhancements

The following are the eHMP enhancements required to be implemented for integration with CRSe.

Req. ID	Requirement
HMP-010	eHMP shall provide a web service that returns the list of active patients and their associated providers.
HMP-020	eHMP user interface shall expose the CRSe user interface.
HMP-030	eHMP shall provide authentication through IAM for exposing of the CRSe user interface within eHMP.

2.13. Security Specifications

The following are the CRSe security requirements.

Req. ID	Requirement
SEC-010	The system security categorization shall be defined (e.g. low, moderate, or high).
SEC-020	The system Security Plan (SSP) shall be developed appropriately for the security categorization.
SEC-030	No anonymous access to VistA shall occur. Anonymous access to VistA shall be updated based on the findings of the VistA Enhancements project.

Req. ID	Requirement
SEC-040	The system shall use encrypted links whenever possible.
SEC-050	The system shall use data encryption in compliance with VA standards/mandates.
SEC-060	The system shall leverage the existing VA authentication and access control model for user access.
SEC-070	The system shall ensure only secured and authorized access according to exiting VA standards to any VA resources when plugged in to any external components or services.
SEC-080	The system shall be HIPAA information security compliant.

2.14. System Features

The system features for CRSe shall include the new features and enhancements specified in Section 2, which focus in the following capabilities: CRS project/program management structure; registry URLs and access; reporting; error handling and logging; data standardization; software and database design; security; folder tree and file naming conventions; and source code best practices.

2.15. Usability Specifications

Usability and performance requirements are outlined in throughout Section 2 of this RSD. Optimal workflow design will be considered and implemented using the fewest clicks and least additional navigation and time as possible.

IBM Common User Access (IBM CUA) conventions will be used where possible to achieve these enhancements. CRSe will also use available conventions for Web portal selection criteria.

Specifications for usability are outlined throughout this RSD, i.e, training (Section), performance (Section

3. Purchased Components

CRSe requires no purchased components, and as such, this section is not applicable.

4. Estimation

The estimation for CRSe is outlined in the CRSe Integrated Master Schedule, which is regularly reviewed with the CRSe stakeholders.

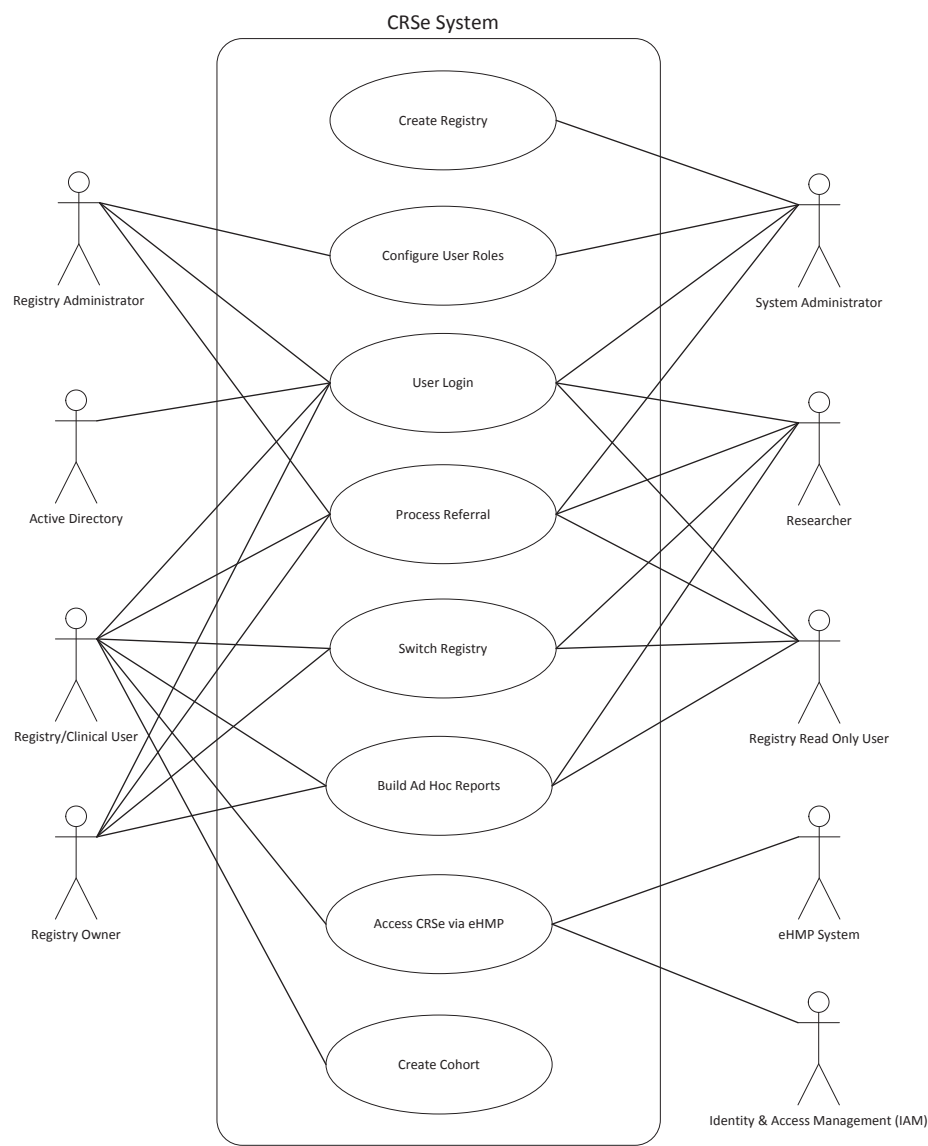
Appendix A: Use Case Specifications

This appendix contains Use Cases for CRSe and eHMP that introduce new functionality. These Use Cases do not contain requirements but are intended to provide a high-level description of the new scenarios required to be supported, from a user perspective. The actors described below are based on the set of example roles and privileges identified in the User Characteristics section.

A.1. Use Case Context Diagram

The following is the Use Case Context Diagram for the new scenarios to be implemented in this release of CRSe.

Figure 4: Use Case Context Diagram



A.2. Actors

The following are the actors involved with the use cases.

- **Registry Owner:** A management level registry stakeholder who has a need to view registry data and role configuration data for a registry.
- **Registry Administrator:** A person who is responsible for configuring, running, and managing access to a specific Registry in CRSe.
- **Registry/Clinical User:** - A person who is responsible for creating, managing, and viewing a registry or cohort.
- **Registry Read Only User:** A person who has a need to view registry information. This user can only view non-patient identifying data.
- **Researcher:** A person who has a need to view registry information. This user can view all registry data, including patient identifying data.
- **System Administrator:** A person who is responsible for configuring, running, and managing access to CRSe.
- **CRSe System:** The CRSe framework, platform, database, and user interface.
- **VA Authentication Services:** A set of processes and services used to authenticate a user.
- **eHMP System:** The eHMP platform, database, and user interface.
- **IAM:** Identity and Access Management (IAM) Services

A.3. Use Case: Create Registry

Use Case ID	UC-1	Use Case Name	Create Registry
Actors	System Administrator, CRSe System		
Description	This scenario is focused on the process of creating a registry using the Registry Configuration Wizard.		
Trigger	There is an urgent need for a registry to be implemented within 30 calendar days or less.		
Preconditions	<ol style="list-style-type: none">1. Registry SMEs have defined the necessary registry elements, outlined in the Registry Developer's Implementation Guide.2. The system administrator is logged in to CRSe.		
Normal Course	<ol style="list-style-type: none">1. The user accesses the Registry Configuration Wizard.2. The user enters the general registry information to include Registry Full Name, Registry Short/Abbreviated Name, Registry Description, Registry Owner, Registry Support Contact, and Registry Administrator3. The user specifies whether or not referrals will be entered manually or automatically retrieved via ETL.4. If the user specifies that referrals will be automatically retrieved		

Use Case ID	UC-1	Use Case Name	Create Registry
	<p>via ETL, the user then specifies the referral criteria used to identify patients to be included in the registry. The user specifies the start time and frequency for which registry referrals are created.</p> <ol style="list-style-type: none"> The user specifies the referral work streams. The user specifies whether or not the work streams are created automatically when the referral is created. The user specifies the work stream activities. The user specifies whether or not the activities are created automatically when the work stream is created. The user specifies the registry data attributes and types. The system creates the registry data table. The user promotes the registry to Production. 		
Alternate Course	N/A		
Post-conditions	<ol style="list-style-type: none"> The registry is implemented in Production. 		

A.4. Use Case: Configure User Roles

Use Case ID	UC-2	Use Case Name	Configure User Roles
Actors	Registry Administrator, System Administrator, CRSe System		
Description	This scenario is focused on the process of configuring user roles in CRSe.		
Trigger	A new CRSe user has been identified and needs a CRSe account, or an existing CRSe user's access/privileges need to be modified.		
Preconditions	<ol style="list-style-type: none"> The administrator is logged in to the system and the main menu is displayed. The user's access and rights have been approved. 		
Normal Course	<ol style="list-style-type: none"> The administrator accesses the Administration function from the main menu. The system displays the Administration page. The administrator creates a new user record or selects an existing user record to modify. The administrator defines the user's access by specifying the user role(s), the registries the user can access, and the menu items and functions the user can access. The administrator saves the user role configurations. The system logs all configuration changes, including but not limited to the user ID making the changes, time/date, and the configuration change details. 		

Use Case ID	UC-2	Use Case Name	Configure User Roles
Alternate Course	N/A		
Post-conditions	1. The user has a CRSe account with defined privileges and access based on user role.		

A.5. Use Case: User Login

Use Case ID	UC-3	Use Case Name	User Login
Actors	Registry Owner, Registry Administrator, Registry/ Clinical User, Registry Read Only User, Researcher, System Administrator, CRSe System, VA Authentication Services		
Description	This scenario is focused on the process of accessing CRSe. The user can only select a registry that he/she has permissions to.		
Trigger	The user has a need to access a registry in CRSe.		
Preconditions	<ol style="list-style-type: none"> 1. The user has VA intranet access. 2. The user has a CRSe account and has been granted access to the system. 		
Normal Course	<ol style="list-style-type: none"> 1. The user enters the URL for CRSe in a browser. 2. The system validates the user via VA Authentication Services. 3. The system displays the top menu, left menu, and content page based on the user's role and if a default registry has been assigned. The content frame can optionally contain a Welcome page and/or "message of the day". If a default registry has not been defined, the system displays the generic top menu, left menu, and content page. 		
Alternate Course	In step 2: Unauthorized user. The system displays an error.		
Post-conditions	1. The user has accessed the system.		

A.6. Use Case: Process Referral

Use Case ID	UC-4	Use Case Name	Process Referral
Actors	Registry Owner, Registry Administrator, Registry/Clinical User, Registry Read Only User, Researcher, System Administrator, CRSe System		

Use Case ID	UC-4	Use Case Name	Process Referral
Description	This scenario outlines the activities to be completed for the referral process.		
Trigger	Referral criteria is satisfied.		
Preconditions	1. A referral is received.		
Normal Course	<ol style="list-style-type: none"> 1. The system determines if the referral is qualified. 2. If the referral is qualified, a work stream is initiated. 3. Activities are initiated for the work stream. 4. The user performs the activity. 5. The user completes the activity. 6. The system determines if all activities have been completed in the work stream. 7. If all activities have been completed, the user closes the work stream. 8. The user determines if all work streams have been completed in the referral. 9. If all work streams have been completed for the referral, the system completes the referral. 		
Alternate Course	<p>In Step 1: if the referral is manual, the user determines if the referral is qualified.</p> <p>In Step 2: If the referral is not qualified, the system or user marks the referral “unqualified.”</p> <p>In Step 7: If all activities are not completed for the work stream, the user completes all activities in the work stream.</p> <p>In Step 9: If all work streams have not been completed for the referral, the user completes all work streams. The system completes the referral.</p>		
Post-conditions	1. The referral is completed.		

A.7. Use Case: Switch Registry

Use Case ID	UC-5	Use Case Name	Switch Registry
Actors	Registry Owner, Registry/Clinical User, Registry Read Only User, Researcher, CRSe System		
Description	This scenario is focused on the process of switching from one registry to another. The user can only select a registry that he/she has permissions to.		
Trigger	The user has a need to access a registry in CRSe.		
Preconditions	The user is logged in to the system and a registry's main menu is displayed.		

Use Case ID	UC-5	Use Case Name	Switch Registry
Normal Course	<ol style="list-style-type: none"> 1. The user accesses the Registry function from the main menu. 2. The system prompts the user to save the current registry information. 3. The user saves the current registry information. 4. The system displays a list of registries that the user has access to, based on user role access permissions. 5. The user selects the desired registry to switch to. 6. The system displays the top menu, left menu, and content page for the selected registry in the current window or a new window based on the user configuration. 		
Alternate Course	In step 3, the user opts not to save the information in the current registry.		
Post-conditions	<ol style="list-style-type: none"> 1. The user has switched from one registry to another. The new registry page is displayed. 		

A.8. Use Case: Create Ad Hoc Reports

Use Case ID	UC-6	Use Case Name	Build Ad Hoc Reports in CRSe
Actors	Registry Owner, Registry/Clinical User, Registry Read Only User, Researcher, CRSe System		
Description	This scenario is focused on the process of building ad hoc reports in CRSe.		
Trigger	The user has a need to create, save, and run a report.		
Preconditions	<ol style="list-style-type: none"> 1. The user is logged into the CRSe System, and the CRSe main menu is displayed. 		
Normal Course	<ol style="list-style-type: none"> 1. The user accesses the Report Builder function from the main menu. 2. The system displays a report builder page. 3. The user builds a report by specifying but not limited to, the data sources, attributes, filtering criteria, report title, and report format. 4. The user can optionally save the report, which will then appear in the Reports menu item. 		
Alternate Course	In Step 4, if the report contains sensitive data, the system will display an error stating that the data cannot be saved locally.		
Post-conditions	<ol style="list-style-type: none"> 1. If the report is saved, the report criteria is saved, associated with the user, and added to the user's report menu. 2. If the report is executed, the system displays the report with options for printing, and exporting to a file. 		

A.9. Use Case: Access CRSe via eHMP

Use Case ID	UC-7	Use Case Name	Access CRSe via eHMP
Actors	Registry/Clinical User, CRSe System, eHMP System, IAM		
Description	This scenario is focused on the process of accessing the CRSe user interface through eHMP.		
Trigger	1. A Clinician has a need to access a cohort or registry within CRSe.		
Preconditions	1. The user is logged in to eHMP.		
Normal Course	1. The user attempts to access CRSe. 2. The eHMP system grants access to the CRSe System via IAM authentication. 3. The CRSe user interface is exposed for the user, through eHMP.		
Alternate Course	1. In Step 2, IAM authentication fails and the use case ends.		
Post-conditions	1. The user has accessed the CRSe user interface through eHMP.		

A.10. Use Case: Create Cohort

Use Case ID	UC-8	Use Case Name	Create Cohort
Actors	Registry/Clinical User, CRSe System, eHMP System		
Description	This scenario is focused on the process of creating a cohort.		
Trigger	There is a need for a cohort to be created.		
Preconditions	1. A Registry/Clinical User has defined the necessary cohort criteria. 2. The Registry/Clinical User is logged in to eHMP and the CRSe user interface is displayed.		
Normal Course	1. The Registry/Clinical User accesses the menu item to create a cohort. 2. The Registry/Clinical User enters the general cohort information to include Cohort Name, Cohort POC, and Cohort Description 3. The Registry/Clinical User specifies the cohort rules to be used to classify a patient as a member of the cohort. 4. The Registry/Clinical User saves the cohort information. 5. The CRSe system creates the cohort. 6. The system executes the cohort rules to populate the cohort.		

Use Case ID	UC-8	Use Case Name	Create Cohort
	7. The system informs the Registry/Clinical User when the cohort is populated.		
Alternate Course	N/A		
Post-conditions	<ol style="list-style-type: none"> 1. The cohort is created and populated. 2. The Registry/Clinical User has received an alert that the cohort rules have been run and the cohort is populated. 		