

**VistA Evolution's User Experience/Core
Work Effort Unique Identifying #20140101**

Business Requirements Document



February 2014

Revision History

Note: The revision history cycle begins once changes or enhancements are requested after the Business Requirements Document has been baselined.

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1. Purpose

The Business Requirements Document (BRD) is authored by the business community for the purpose of capturing and describing the business needs of the customer/business owner identified within the New Service Request (NSR) [#20140101 VistA Evolution's User Experience/Core](#).

The BRD provides insight into the AS-IS and TO-BE business area, identifying stakeholders and profiling primary and secondary user communities. It identifies what capabilities the stakeholders and the target users need and why these needs exist, providing a focused overview of the request requirements, constraints, and other considerations identified. This document does not state the development methodology. The intended audience for this document is the Office of Information and Technology (OIT).

2. Overview

The Veterans Health Administration's (VHA) Office of Informatics and Analytics (OIA) is requesting improvements to the user experience of the Veterans Health Information Systems and Technology Architecture (VistA) with the ultimate goal to provide enhanced clinical functionality, expanded interoperability, and a more flexible technical architecture, with planning and management under the VistA Evolution¹ Program.

The Department of Veterans Affairs (VA) uses VistA as its Electronic Health Record (EHR) system. The documentation that currently comprises the Veteran's longitudinal record consists of records that physically exist in both paper and electronic formats that are maintained in different places. There are 133 separate instances of VistA deployed enterprise-wide. The care is documented in the beneficiary's record in the instance used at that facility, resulting in a fragmented health record across the Department. To manage this fragmentation, VA has implemented solutions that allow clinicians to view a patient's data from multiple instances. For example, Remote Data View allows the users to see the data from any facility, but logically and physically the records are still separate, making it difficult to apply decision support on patient data across his or her lifecycle and across encounters at multiple facilities.

While users can get to the data from each VistA instance individually via Remote Data View, only a unified logical record will allow for longitudinal analysis of the data for activities (e.g., patient-specific decision support, provider panel management, automated clinical practice guidelines, and clinical workflows spanning multiple facilities). A longitudinal patient record that includes clinical data from encounters performed outside of VA facilities will enable transitions of care, better decision support, implementation of standards of care, and an ongoing ability to develop Evidence Based Care standards. When a patient transitions from inpatient, rehab, or outpatient care, the care team will be better equipped to fully monitor and manage the patient's outcomes and implement standards of care across clinical encounters.

The Computerized Patient Record System (CPRS), the user interface used by clinicians in VistA, is built upon a thick-client Delphi platform, a technology that is no longer in widespread use, making it difficult to leverage developer skills, costly to maintain, and challenging to modernize through input from the open source community. Furthermore, the thick-client architecture makes it difficult to perform upgrades, limits the accessibility to users outside VA facilities, and overall

¹ VistA Evolution refers to the overall VistA modernization project.

makes the task of modularizing and customizing views for different roles and workflows much more onerous. Finally, the specific Remote Procedure Call (RPC) brokers used by CPRS in order to access the data in VistA in a bidirectional manner are tightly coupled to specific CPRS calls and as such are not suitable for reuse by other platforms and applications, such as mobile. Using modern technologies will enable:

- Enterprise scalability
- Delivery of a single, common health record to be utilized throughout the continuum of care
- Improved data interoperability across the VA
- Improved care, increased visibility for providers, reduced unnecessary duplication of tests and other procedures, and healthcare cost containment
- Ability to address current and future requirements for EHR Certification and capabilities needed to support attestation for Meaningful Use (MU) in order to improve health care quality, efficiency, and patient safety

This request is focused on advancing the user's experience while easily integrating functionality to improve quality, safety, efficiency, and satisfaction in healthcare for Veterans.

In 2009, President Barack Obama charged the VA and Department of Defense (DoD) to work together to define and build a seamless system of integration of EHRs so that active and retired Service Members could easily access their health records. The Interagency Program Office (IPO), which oversees the Departments' integrated electronic health record project and other joint initiatives, is programmatically responsible for interoperability of the EHRs, and each Department is responsible for its own EHR system. DoD will undertake a competitive acquisition to replace its existing systems through the DoD Healthcare Management System Modernization (DHMSM) program. VA will use its existing VistA and incrementally deliver new functionality through the VistA Evolution Program. Both Departments' future EHR systems will endeavor to ensure seamless interoperability.

The User Experience (UX) is one of several projects undertaken by the VistA Evolution Program Executive Office (VEPEO) to develop an EHR. UX will be the focal point for a modern, flexible, powerful, and responsive software package and infrastructure used by providers at the point of care. The goal of the UX effort is to create a presentation structure and backend infrastructure for VA that will enable clinicians to view and edit VA patient data and images in a format that is seamless. The UX is not just an aesthetically pleasing graphical user interface (GUI)—what people refer to as the look-and-feel. To create a desirable UX, the GUI must help the user's thought-flows and workflows. There are other aspects of UX including clinical decision support (CDS), terminology and translation services, orders management, clinical workflow, knowledge management, activity management, and communication. The clinical application and GUI will facilitate integration into the workflow and simplify access to information that is reliable and securely available whenever and wherever needed by users. This effort will leverage and potentially reuse components of legacy applications and other VA services or components as identified.

Developing an approach to an EHR user interface (UI) will facilitate integration in the workflow and simplify access to information that is reliable and securely available whenever and wherever needed by users. UX will adopt multiple technical strategies for UIs which include touch-screens, traditional input/output devices, voice synthesis (text to speech) recognition products,

mobile devices, and fixed devices (e.g., desktop, laptop). Specifications for a consistent role-based look-and-feel will inform design. The UX must coordinate requirements and acquisition schedules with multiple capabilities defined within the VistA Evolution Program in order to integrate cross-functional capabilities into a single UI and improve provider and patient experience. Moreover, the functional design of the UI will drive certain technical decisions, such as data interoperability and clinical decision support.

With the increased number of Service Members transitioning to Veteran status, VA will need to migrate to a platform and GUI that allows for better extensibility and modularization to allow beneficiaries to receive improved patient-centered care and have access to a comprehensive medical profile that supports a seamless transition of care between VA facilities. Implementing a patient-centered team-based care model requires a new UX and the EHR infrastructure to support it. A new UX would allow VHA to

- Move beyond CPRS's chart-like interface to a knowledge-driven tool set.
- Evolve from long, static documents toward modular, interactive displays of smaller and more meaningful pieces of information.
- Incorporate advanced, evidence-based design principles proven to improve users' ability to find, understand, and use health information.
- Allow users to interact with and organize information in novel, intuitive ways.
- Support rapid, team-based development of user interface components.

3. Customer and Primary Stakeholders

Dr. Theresa A. Cullen, Director, Health Informatics (HI), and Chief Medical Information Officer, representing OIA, is the primary stakeholder and endorser for this request. Review [Appendix D](#) for the complete list of primary and secondary stakeholders.

4. Scope

This scope of work defines the services required by the VA to migrate to a clinical application and GUI that provides a Longitudinal Enterprise Integrated Patient Record (LEIPR), using VistA as the core.

VistA Core 1.0

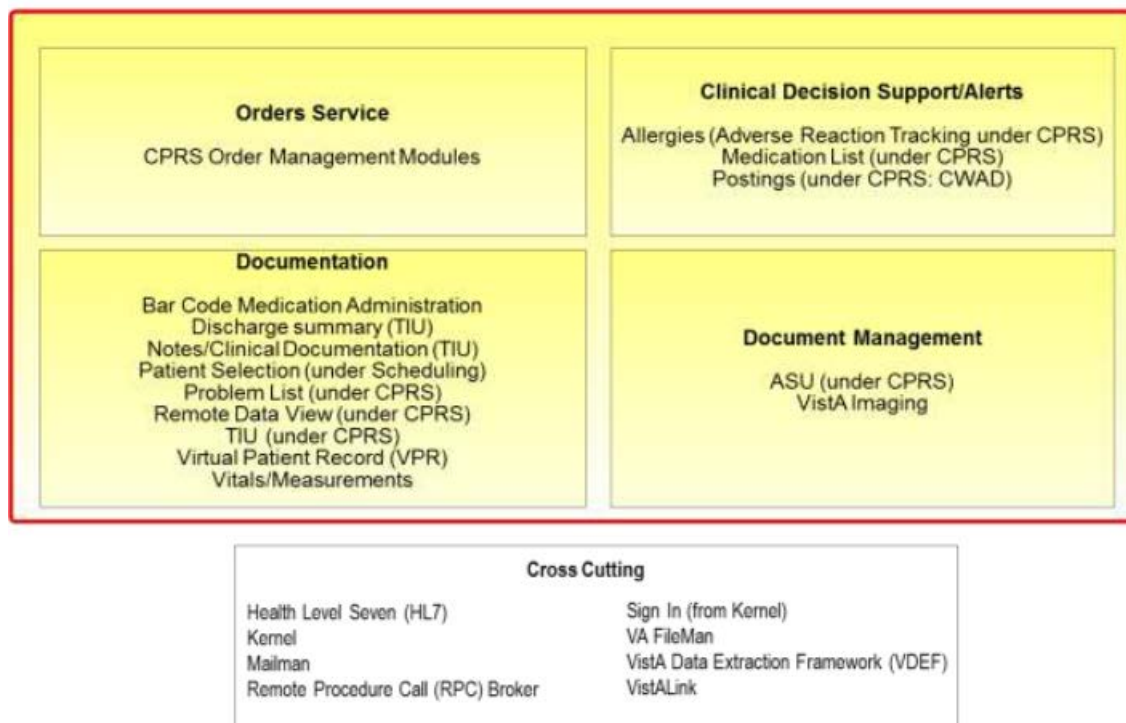


Figure 1 VistA Core

The Interagency Clinical Informatics Board (ICIB) identified a set of functional areas of the EHR that would become the core of the EHR. The top four boxes in Figure 1 are the identified functional areas of the clinical core, and the names within each box represent the VistA packages that provide each function at VA. The VistA packages listed under the “Cross-Cutting” heading are those needed to support the VistA packages in the four functional areas. They provide basic services like writing to the disk, user sign-on, messaging, and other underlying infrastructure.

Today, VA providers depend on CPRS for accessing and recording most of the patient information needed for clinical decision making. This information includes prescription and lab orders, problem lists, vital signs, progress notes, clinical reminders, lab results, and other information typically included in an electronic patient medical record. While CPRS has been an effective tool for over 17 years, VA would significantly advance care for Veterans by providing an improved point of care UX for clinicians.

The UX scope involves three layers: presentation, services, and data (see Figure 2). The presentation layer would allow end user interactions with a web-based clinical application that would provide viewing of normalized data and facilitate data entry and portability. The service layer would provide standard integration leveraging enterprise patterns. The data layer would be an enterprise caching of clinical data that uses a common terminology set and is normalized for Office of the National Coordinator (ONC) certification. Robust service and data layers are needed to support the development and deployment of the presentation layer.

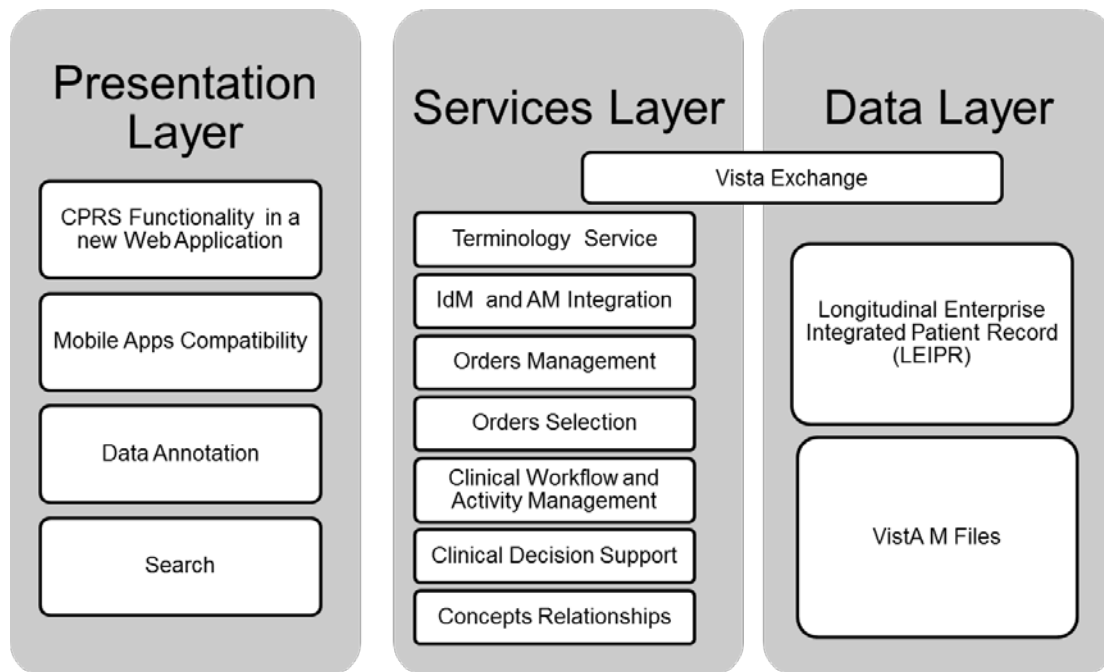


Figure 2 Layers of UX

The overall goal is to support the creation of a logical LEIPR that will ultimately enhance patient-specific decision support, provider panel management, automated clinical practice guidelines, and clinical workflows spanning multiple facilities.

The new UX will incorporate advanced, evidence-based design principles proven to improve users' ability to find, understand, and use health information. The UX will evolve the information environment from long, static documents (such as narrative progress notes) toward modular, interactive displays of smaller and more meaningful pieces of information. Users should be able to interact with and organize information in novel, intuitive ways. For example, a selection of lab results may be associated with a list of medication orders through simple, intuitive actions and gestures to trigger powerful data visualizations combining multiple sets of information.

CPRS provides very limited capability for accessing patient information that may have been recorded in many different locations both during and after a Veteran's military service. UX, when integrated with a shared VA/DoD interoperability platform, will provide access to a Veteran's complete LEIPR, comprised of data collected from every military and VA treatment facility in which the Veteran has received care. For many Veterans, health data from other government and non-government providers should be available as well. UX should also incorporate robust CDS and population health management features, leveraging the vast data repository VA has developed over nearly three decades.

Key requirements for the LEIPR service include providing and/or supporting the ability to: aggregate all of the clinical data for a patient from every source of VistA; physically centralize data located in multiple separate geographic locations; normalize the data; provide horizontal scalability; high availability; and role and attribute based access controls and integration with enterprise identity and access management services. Initially, the following patient record domains will be part of this service:

- Laboratory Results
- Inpatient and Outpatient Medications (dispensed and current directions for patient)
- Vitals
- Demographics / Basic Information
- Allergies
- Radiology Reports

Additional data domain standardization is on-going and will be added as they are completed in conjunction with the DoD through the IPO.

The clinical GUI will deliver tools to support searches within patient records, context-aware decision support functionality that link out to clinical monographs on the Web, and tools to facilitate medication reviews:

- Search functionality will enable users to find information in the patient record more quickly and accurately, similar to the familiar functions of a web search engine.
- Decision support options located next to data such as laboratory results, medications, problem list entries and diagnoses will allow quick access to additional information, from internal and external sources, specific to that data, with a simple click. Additional information may be simple attributes about the data, or a detailed set of relevant reference materials.
- Medication Review is a nursing practice subject to the MU core measure for medication lists, and has significant implications on patient safety. A medication review and reconciliation screen will retrieve all of the patient's medication history across disparate systems into one view, including order, administration, refill history, and renewal dates. InfoButtons may also display additional information about the medication orders, calculations, and links to further pharmaceutical references.

These tools will provide a springboard for future clinical enhancements and tools development.

5. Goals, Objectives and Outcome Measures

Goal/Objective and Desired Outcome	Impact/Benefit	Measurement
Longitudinal Patient Record and Supporting Enterprise Services	<ul style="list-style-type: none"> • Provides a flexible platform for enterprise access to the patient-centric aggregation of clinical data from all available EHR instances and other relevant sources. To provide greater interoperability and opportunities for data normalization and standards integration, the 	<ul style="list-style-type: none"> • Implementation of consolidated enterprise data services. • Improved data interoperability across the VA, DoD, private providers and other federal healthcare systems. • Ability to support the longitudinal patient data

	<p>Longitudinal Patient Record can be pre-populated based on anticipated clinical encounters or populated on demand. The enterprise services will support the creation of clinical systems with a secure and reliable longitudinal view of the patient record from VistA, DoD, or other new data sources.</p> <ul style="list-style-type: none"> • These services/systems will improve information continuity and will allow VA to implement agile practices to quickly adapt to future requirements, and support new clinical initiatives. 	<p>needs of existing products such as CPRS, VistAWeb, Health Management Platform and the Joint Legacy Viewer.</p> <ul style="list-style-type: none"> • Instantiation of a longitudinal patient record that is secure, reliable, current and complete.
Presentation of Patient Health Information	<ul style="list-style-type: none"> • Advance presentation of patient health information and integration of timely clinical services, such as decision support and orders management, to improve health status. • Achieve MU measures that are currently not implemented and ease of implementation of current and future MU standards that improve health care quality, efficiency and patient safety. • A consistent UX realized across multiple computer platforms including desktops/laptops and mobile devices 	<ul style="list-style-type: none"> • Propagate the usability features and end-user experience throughout all VistA enhancements. • Introduction of the Health Exchange platform to support the longitudinal view of the patient healthcare record. • Convergence of existing patient viewing capabilities into a single advanced GUI framework to support new clinical practices and workflows. • Provide the capabilities needed to support attestation for MU.
Advanced Clinical Support Tools and Processes	<ul style="list-style-type: none"> • The implementation of tools that improve the clinical UX and facilitate 	<ul style="list-style-type: none"> • The introduction of CDS against progress notes. • The introduction of activity

	<p>user adoption, productivity, and satisfaction. Allows for the incorporation of advanced capabilities such as CDS, Team-Based Panel Management, Enterprise Orders Management, and Activity-Based Workflows and Processes.</p> <ul style="list-style-type: none"> Facilitate the sharing of information with external providers of care to improve continuity across the continuum of care. 	<p>management capabilities.</p> <ul style="list-style-type: none"> The introduction of the next generation of the order entry framework.
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6. Enterprise Need/Justification

Although VistA serves VA and Veterans well, aspects of this aging technology make it difficult for VA to acquire or develop new functionality. Implementing a patient-centered team-based care model requires a new UX and the EHR infrastructure to support it. UX will support VistA's ability to improve quality, safety, efficiency, and satisfaction in healthcare for Veterans. UX will support the VA's vision to continue to be the benchmark of excellence and value in healthcare and benefits by providing tools for interactions that are patient centered and evidence based. It supports the triple goals of improving the experience of care, improving the health of populations, and reducing per capita costs of health care. It also supports VHA's Strategic Goals for Fiscal Years (FY) 2013-2018:

1. Provide Veterans personalized, proactive, patient-driven health care.
2. Achieve measurable improvements in health outcomes.
3. Align resources to deliver sustained value to Veterans.

Enabling a LEIPR will allow VA to improve VistA in order to achieve MU measures that are currently not implemented. For example, the MU criteria on electronic progress notes states that notes must be text-searchable. A LEIPR allows the indexing that is normally required for such a global text search to be created against the totality of the progress notes for the patient's record, instead of only searching within the notes for a single facility. The MU criteria on clinical decision support interventions related to clinical quality measures also become most relevant when those measures are established against the complete longitudinal record.

The technical enhancements will ultimately benefit the Veteran by allowing users to be more responsive to changes in practice, patient needs, system priorities, and advances in technology. The enhancements will benefit the organization by improving the provision of care and helping to meet EHR Certification and MU. UX will increase the satisfaction of VistA users, improve efficiency, improve patient outcomes, and ensure compliance with regulatory and statutory requirements.

7. Requirements

7.1. Epics

ReqPro Tag BN/OWNR Number	Business Need (BN)/Epic Owner (OWNR) Requirement/User Story	OWNR Priority*
NEED1555 BN 1	Adhere to the Enterprise Level requirements as specifically addressed in the RTM found in Appendix A of this document.	High
NEED2888/ ARCH527 BN 2	As a member of the care team, I want a User Experience that employs standardized data so that VHA can reduce costs while improving efficiency, safety, and quality.	High
NEED2889/ ARCH524 BN 3	As a member of the care team, I would like a User Experience with system interactions designed to save me time, increase the accuracy of my understanding, and the appropriateness of my decisions, so that I can help Veterans reach their health goals faster.	High
NEED3216/ ARCH561, ARCH564, ARCH557 BN 4	As a member of the care team, I want a system that will present DoD and VA patient information from enhanced ancillary services (e.g., Laboratory results, Inpatient and Outpatient Medications, Vitals, Demographics, Allergies, Notes, Immunizations, Problem List, and Radiology reports,) with robust CDS so that I can provide improved quality, safety, efficiency, and satisfaction in healthcare for Veterans.	High
NEED3217/ ARCH524 BN 5	As a member of the care team, I want a Longitudinal Enterprise Integrated Patient Record supported by an integrated user interface that is patient centric so that I can view and edit VA patient information in a format that is seamless and integrated into my clinical workflow.	Medium
NEED3221/ ARCH524 BN 6	As a member of the care team, I want a Documentation Text Search feature that will allow me to search across unstructured data such as progress notes as well as structured data, such as lab results, vitals, and medications, so that I can quickly reference the totality of my patients health information.	High
NEED3222/ ARCH540 BN 7	As a member of the care team, I want a new Clinical Workflow feature so that I can manage my activities.	Low
NEED3223/ ARCH528 BN 8	As a member of the care team, I want a Data Annotation feature so that I can mark text with a comment or explanation.	Low
NEED3224/ ARCH554, ARCH536 BN 9	As a member of the care team, I want to be able to view my Orders in the context of all other data, using decision support workflows, so that I can understand the relationships and provide appropriate care for that treatment scenario.	Medium
NEED3225/ ARCH540 BN 10	As a member of the care team, I want Clinical Decision Support features executing against the longitudinal patient record, that presents intelligently filtered knowledge and patient-specific health information at appropriate times so that healthcare delivery is enhanced.	Medium

ReqPro Tag BN/OWNER Number	Business Need (BN)/Epic Owner (OWNER) Requirement/User Story	OWNER Priority*
NEED3226 ARCH595, ARCH582 BN 11	As a member of the care team, I want to be able to access resources (e.g., files, directories, computers, networks) that I am authorized to for approved purposes so that the security and privacy of the health record is improved.	Low
NEED3227/ ARCH540 BN 12	As a member of the care team, I would like a Concept Relationship service so that I can relate basic concept categories.	Low
NEED3228/ ARCH593 BN 13	As a member of the care team, I want the ability to communicate electronically within the EHR with members of the healthcare team so that we can coordinate our patients' care.	High
NEED3229/ ARCH525 BN 14	As a member of the care team, I want to be able to access information from external systems so that interoperability is enabled and my patient's longitudinal record is complete.	High

*All listed requirements are needed by the business community. The Priority is merely a mechanism to suggest a sense of urgency and order to the technical community if the requirements are to be parsed into phases. The order of importance begins with those that are designated as High priority.

7.2. User Stories

The requirements (user stories) for this request are documented in the Requirements Traceability Matrix (RTM) which is a separate document referenced in [Appendix A](#).

7.3. Non-Functional Requirements

The non-functional requirements for this request are documented in the RTM which is a separate document referenced in [Appendix A](#).

7.3.1. User Access Levels

The table below defines the different levels of user access to the UX:

Name	Description	Provider-facing applications	Patient-facing applications
Primary Users	Healthcare Team	Enter/Edit	Read
Primary Users	Patients/Family	Read	Enter/Edit
Secondary Users	System Administrators	Full Control	Full Control

7.3.2. Performance, Capacity, and Availability Requirements

7.3.2.1. Performance

If this is a system modification, how many users does the current system support?
Population size is estimated to be 130,000 VA clinical and administrative users. Although peak usage would occur between 0800 and 1930 Eastern Standard Time, UX will be in use 24/7. In 2012, the MyHealtheVet (MHV) patient-facing web portal supported over 4,000 concurrent users.
How many users will the new system (or system modification) support?
UX will support all 130,000 users of the current system, but the system shall be scalable enough to support additional users as new end user functionality is introduced.
What is the predicted annual growth in the number of system users?
According to " Veteran Population Projections 2010-2040 ", the Veteran population is expected to decrease by approximately 1% per year between 2010 and 2040, and it might be inferred that the number of clinical users would decrease by a similar percentage over this time frame. However, Veterans may become more technologically savvy and wish to interact via patient facing systems such as MHV. Over 45,000 new users registered for an MHV account in April 2012, which represents a 47% increase over April of 2011; therefore, it is estimated that over 500,000 new users will access the MHV portal each year.

7.3.2.2. Capacity

What is the predicted size (average) of a typical business transaction?
A typical clinical note might be about 1 page, or 2 kilobytes.
What is the predicted number of transactions per hour (day, or other time period)?
<p>A typical patient visit occurring over the course of 30 minutes might include:</p> <ol style="list-style-type: none">1) Clerk checks patient in2) Nurse reviews the record3) Nurse resolves 5 clinical reminders4) Nurse writes a clinical note5) Physician reviews the record6) Physician orders a medication7) Physician orders 5 labs8) Physician writes a clinical note. <p>The physician and nurse would each only spend about 15 minutes with the patient and they would be working simultaneously with different patients. So, the number of transactions would be double the 16 transactions above, or about 32 per half hour time frame. Estimating from VHA Support Service Center (VSSC) data and a VHA Overview presentation by the Under Secretary for Health (USH), there would be approximately 20,000 outpatients + 70 surgical patients + 1,100 inpatients served in a half hour time slot or roughly 21,200 patients total * 32 transactions = 678,400 transactions VA wide in a half hour time period.</p>
Is the transaction profile expected to change (grow) over time?
As UX is deployed to all VA care settings and facilities, the number of transactions would be expected

to grow for the new system as care providers are trained to utilize the new functionality and legacy systems are phased out. But ultimately, after full implementation, the number of transactions would be expected to be similar to the current number.

What is the process for planning/adjusting capacity?

The VEPEO is a joint program between OIT and VHA that acquires and sustains VA's EHR and ancillary health IT systems, and facilitates their integration with clinical use. VEPEO will coordinate and collaborate with other OIT and VHA offices, DoD-VA IPO, Veterans Benefits Administration, Defense Health Agency, Indian Health Services (IHS), Department of Health and Human Services, and other health information technology and information management programs to minimize duplication of effort and maximize the effectiveness of, and interoperability with, technologies acquired by these programs. VEPEO will facilitate monitoring, planning, and adjustments to capacity, providing monthly and ad hoc reports detailing project status to the Executive Board and Executive Sponsors. The Initiative will use a variety of collaboration and communication tools to communicate changes in the plan or capacity with stakeholders and facilitate work among VEPEO staff and partners.

Does the update require a surge capacity that would be different from the base application?

No, the underlying application for the UX would be expected to manage the same surge capacity.

7.3.2.3. Availability

Describe when the envisioned system will need to be available (business hours only, weekends, holidays, etc) to support the business.

The UX shall be available 24 hours a day, seven days a week, with an uptime of 99.9%. All system updates and scheduled maintenance should occur between the hours of 1800 and 0600, when clinical usage would be lightest.

Browser-based control changes shall provide user feedback within 60 milliseconds. Component refreshes without new data loads shall occur within 2 seconds. Components shall update information within 15 seconds. On first load of a patient's data, data shall be displayed within 15 seconds 99% of the time and all non-image data shall load within 1 minute 99% of the time.

7.4. Known Interfaces

This is the business community's best understanding of known interfaces and may not be a comprehensive listing. All required interfaces will be stated as Business Needs in the RTM which is a separate document referenced in [Appendix A](#).

Internal Interface

The UX solution must support the ability to operate seamlessly with other systems, either internal or external, that adhere to recognized interchange standards. "Other systems" include other EHR Systems, applications within the EHR, or other authorized entities that interact with the EHR. Support interactions with entity directories to determine the address, profile and data exchange requirements of known and/or potential partners (e.g., specific public health systems).

External Interface

External interface requirements include persons, systems or organizations that require EHR data but do not interact with the UX solution on a regular basis. This may include State or Federal

registries, and/or Federal Agencies (e.g., Centers for Disease Control, the Food and Drug Administration [FDA], etc.).

Name of Application	Description of current application	Interface Type	Existing Functionality	Deliverables
VA Identity and Access Management (IAM)	N/A	Automated	No	Access and identity management
VA, DoD, and integrated EHR (iEHR) Systems and Services	N/A	Automated	No	Veterans' information will be viewable across systems
Specialized Access Control Authorization Service	N/A	Automated	No	This shall support the ability to control access to information at a coarse and fine-grained level to the UX.
Enterprise Automated Provisioning Service	N/A	Automated	No	To support user lifecycle management, which includes adding, updating, deleting, and modifying users, profiles, and identity and access control attributes
Enterprise User Session Management Solution	N/A	Automated	No	Will support users across a browser based and thick-client environment: <ul style="list-style-type: none"> a) VA Personal Identity Verification (PIV) and DoD Common Access Card (CAC) based authentication. Additional identity credentials may be added as necessary to support additional use cases. b) An authenticated user SSO to all integrated applications, portlets, and widgets. c) Global log off. d) SSO across distinct security domains by leveraging Security Assertion Markup Language (SAML) 2.0 federation technology.

Name of Application	Description of current application	Interface Type	Existing Functionality	Deliverables
Enterprise Compliance, Audit and Reporting Service	N/A	Automated	No	<p>To support:</p> <ul style="list-style-type: none"> a) Capturing and maintaining a chronological audit trail that reconstructs and examines the sequence of activities related to a specific session, operations conducted within the session, or a relevant security transaction. The chronological audit trail shall provide full reconstruction of an entire user session. b) Ability to define and store the audit data attributes in accordance with VA Directive 6500.

7.5. Related Projects or Work Efforts

NSR 20120103 iEHR User Experience FY14 Initial Operating Capability

Request is to gather requirements for the iEHR UX (Presentation Layer) solution to provide functional, non-functional requirements, and a product backlog of requirements that can be developed for the initial operating capability in 2014. The iEHR UX will be the user interface for the new iEHR.

NSR 20130905 VistA Evolution

The VistA-4 Project will be the first project in the VistA Evolution Program. VistA-4 will focus on syntactic, semantic, and process interoperability, care coordination, the integration of ancillary services, and MU. VistA-4 will rely upon infrastructure components, data models, and services that support an open, modular, extensible EHR platform allowing VA to provide high-quality solutions at increased speed and decreased cost. The resulting system will be flexible and agile, accommodating new technology advances and achieving optimal results more efficiently.

NSR 20110617 iEHR Presentation Layer

Request is to build out the iEHR (Integrated/Interagency Electronic Health Record) Presentation Layer GUI and associated functionality and technology to support the joint DoD-VA iEHR effort.

20120411 iEHR Access Control Capability

The Access Control capability safeguards and manages individuals' personal and health information and provides the ability to create and update sets of access control permissions granted to specific users. This information includes beneficiaries' medical history, test and laboratory results, insurance information, demographic information, and other data.

8. Other Considerations

8.1. Alternatives

Alternatives to the development of a UX product include the following:

- Build a new VistA system to meet the specific needs of the VA.
- Buy one or more components of an EHR Commercial-Off-The-Shelf (COTS) system.
- Combine creating and buying components of a system along with adopting any currently viable and interoperable system in place (adopt, buy, or create).

8.2. Assumptions

The assumptions for this request are

- The DoD and VA will continue efforts to share information about the Veteran, find common representations of Veteran information that can be understood, and make this information available on demand (under appropriate security controls).
- Sufficient funding is available and properly phased in the out-years.
- Staffing resources (testers, "super users" and workgroups, legacy developers, security specialists, system integration engineers, etc.) will be available as identified in project plans and schedules.
- Industry standard interfaces will be used.
- Implementation and training will be an activity incorporated into all deployment activities.

8.3. Dependencies

This request is dependent on the following:

- Supporting technology resources (toolsets, network resources, development/test hardware and platform software and environments) will be available on schedule in the development, test, and production environments.
- Supporting infrastructure resources (security, performance testing, architecture, software distribution mechanisms, etc.) will be available on schedule in the development, test, and production environments.
- Stakeholders are able to contribute at predefined involvement points as identified in project plans and schedules.

8.4. Constraints

The following constraints have been identified:

- Sufficient funding for the VEPEO to support development of the UX.
- UX must support and comply with the One VA Enterprise Architecture (EA).
- UX must comply with Section 508 Compliance criteria.
- UX must comply with iEHR interoperability requirements.
- UX must meet statutory and regulatory requirements such as MU.
- Development will follow the Program Management Accountability System (PMAS), tailored appropriately.
- The EHR core based on an evolved VistA will follow all VA standards, policies, procedures, and guidelines, as well as established VA and FDA guidelines for software development and project management.


8.5. Business Risks and Mitigation

At the project level, if a risk is identified, the project-level risk analysts, assigned risk owner, and the Project Manager (PM) will be responsible for providing a mitigation strategy. PMs will work with risk owners to mitigate risk and keep risk management information for their projects accurate and up-to-date, while the program manager will administer high-level risk mitigation activities and oversee the maintenance of the risk library.

Business Risks	Mitigation
1) Program-level funding is reduced.	The VistA Evolution Program Strategy will focus on accountability, transparency, and proper resource management.
2) Coordination across projects is slowed.	The PM will keep all stakeholders informed of high-level risks, along with their mitigation strategies, in the weekly report. These weekly reports will roll up into the monthly risk report. VA's Yellow Flags, Red Flags, and TechStats will also be used to monitor and escalate risk, as necessary.
3) Technical challenges impede progress.	Continual monitoring and monthly reviews of all open risks will ensure that all risks remain well-controlled. Once a risk has been successfully avoided or mitigated, it will be retired and documented in a risk library.
4) All business requirements may not have been identified at this time.	Ensure requirements are designed and developed via agile methodology and derived during high-level discovery meetings. Requirements elaboration is documented and mitigation plans are provided.

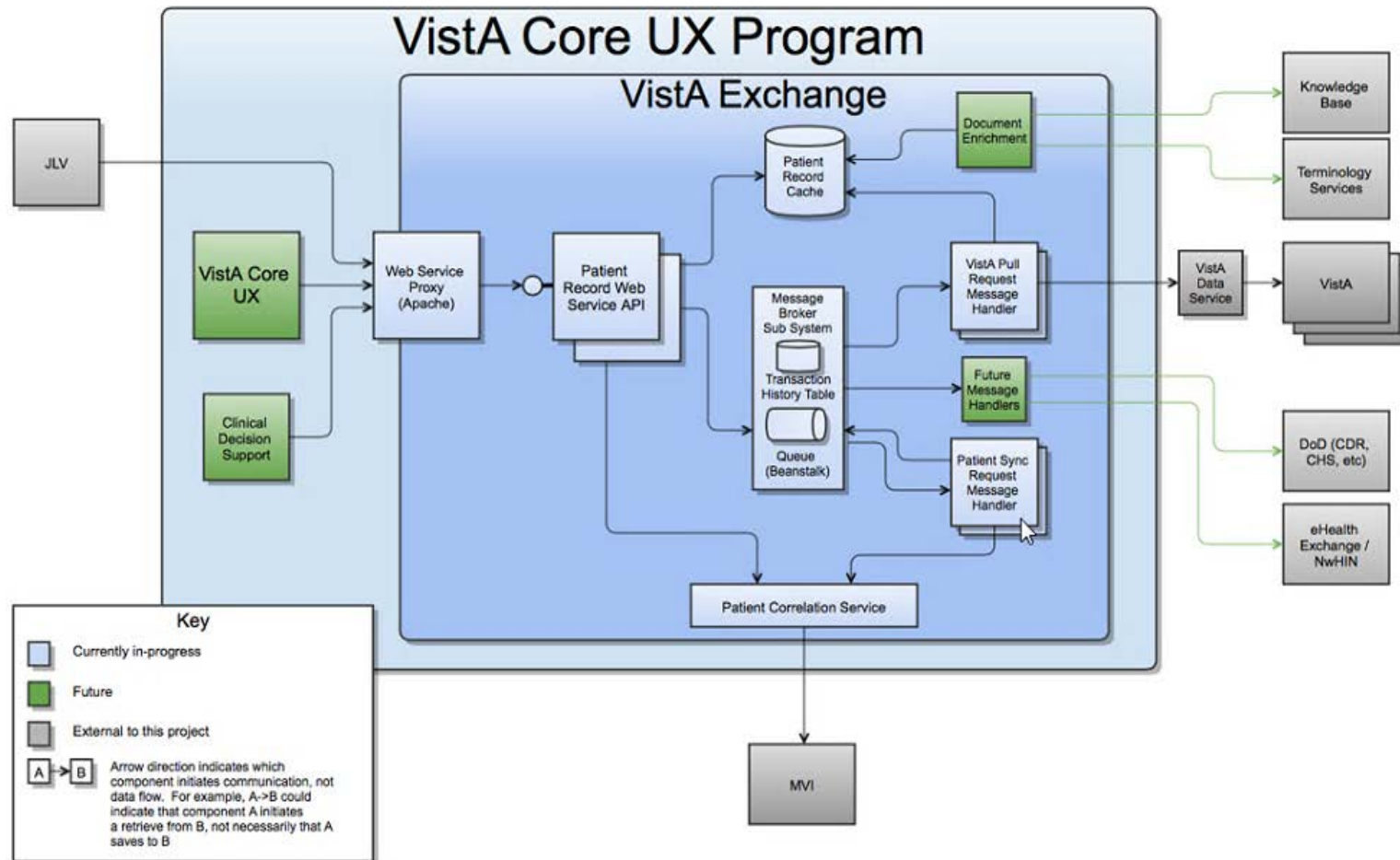
Business Risks	Mitigation
5) If concurrence from the stakeholders is not obtained, there could be negative impacts to schedule and scope.	Create and maintain a list of stakeholders and engage them as early as possible with considerations of time/schedules. Keep stakeholders informed of progress throughout the process.
6) If the UX does not maintain, at a minimum, the current functionality of VA systems, then end-users may be unable to complete tasks.	Monitor the AS-IS functionality and ensure TO-BE requirements fulfill end-user needs and current functionality is not lost.
7) Ability of the business and functional communities to meet their respective staffing and resource needs in order to fulfill the implementation effort.	Coordinate with the VEPEO to ensure staffing and resource needs are available.
8) Ability of the business, clinical, functional, and technical organizations to communicate and collaborate to ensure divergent interests do not impeded progress and delivery of UX.	Coordination and collaboration at executive level to foster cross-organization collaboration, identify and remove duplicative solutions, facility solutions re-use, and strike an appropriate balance between centralized and enterprise-based solutions and innovation.

Appendix A References

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- VA Handbook 6500 – Information Security Program
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- VHA Strategic Plan FY 2013-2018
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- VistA Evolution Program Charter
[REDACTED]
- VistA 4 Product Plan
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- VistA Evolution Stakeholders (Extended List):

VistA-4 Stakeholder
List JF.xlsx
- VistA Evolution User Experience/Core Requirements Traceability Matrix (RTM)
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Appendix B Model



Appendix C Stakeholders, Users, and Workgroups

Stakeholders

Type of Stakeholder	Description	Responsibilities
Requester	[REDACTED]	Submitted request. Submits business requirements. Monitors progress of request. Contributes to BRD development.
Endorser	[REDACTED]	Endorsed this request. Provides strategic direction to the program. Elicits executive support and funding. Monitors the progress and time lines.
Business Owner/Program Office	[REDACTED]	Provide final approval of BRD with sign-off authority. Provide strategic direction to the program. Elicits executive support and funding. Monitors the progress and time lines.
Business Subject Matter Experts (SMEs)	<ul style="list-style-type: none"> [REDACTED] [REDACTED] 	Provide background on current system and processes. Describe features of current systems, including known problems. Identify features of enhancement.
Technical SMEs	<ul style="list-style-type: none"> [REDACTED] [REDACTED] [REDACTED] [REDACTED] 	Provide technical background information about the current software and requested enhancements.
User SMEs	See Appendix A for an extended list of stakeholders	Ensure that the enhancements will account for current business processes and existing software capabilities.

Stakeholder Support Team (BRD Development)

Type of Stakeholder	Description	Responsibilities
Security Requirements SMEs	<ul style="list-style-type: none"> [REDACTED] [REDACTED] 	Responsible for determining the Assessment and Authorization (AA) and other security requirements for the request.

	Security Analyst, HCSR, HIG, OIA	
Service Coordination SME	[REDACTED]	Responsible for ensuring all aspects of non-functional requirements have been accurately recorded for this request.
Health Enterprise Systems Portfolio Management Staff	[REDACTED]	Serve as the liaison between the Program Office (Business Owner) and Product Development throughout the lifecycle.
Strategic Investment Management (SIM), Requirements Development and Management (RDM)	[REDACTED]	Responsible for working with all stakeholders to ensure the business requirements have been accurately recorded for this request.

Primary and Secondary Users

Type of User	Description	Responsibilities
Primary Users	Clinicians (e.g., nurses, physicians, pharmacists, radiologists, laboratory staff, technicians, dietitians, social workers, and other ancillary workers)	Responsible for the capture and documentation of patients' clinical information.
Primary Users	Administrative staff	Responsible for the capture and documentation of patients' administrative information.
Primary Users	Patients	Responsible for the provision of self/patient-entered information.
Secondary Users	System Administrators	Responsible for the technical support of the proposed system.

Appendix D Usability

UX encompasses the entire interaction between the user and the system. This includes direct interaction with the system as well as other interactions, understanding, awareness, perceptions, beliefs, feelings, and actions that result from that interaction. One key component of the UX is the usability of the system. Improving usability over the prior version is a key requirement for this application. The International Organization for Standardization (ISO) defines usability as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” (1998).

In order for this application to achieve a good UX for users who interact with it, the system must meet the requirements outlined in this section. These involve attributes of the application as well as the process that is required to achieve them.

In order to improve usability of VA-developed or purchased applications, the following actions are required:

- In accordance with the ONC for Health Information Technology’s (ONCHIT) MU Stage 2 final ruling, employ an industry recognized User Centered Design (UCD) process. The methods for UCD are well defined in documents and requirements such as ISO 9241–11, ISO 13407, ISO 16982, National Institute of Standards and Technology Interagency Report (NISTIR) 7741, ISO/International Electrotechnical Commission (IEC) 62366, and ISO 9241-210. Developers will choose their UCD approach; one or more specific UCD processes will not be prescribed.
- Adhere to an industry recognized UI Best Practices Guideline or Style Guide. For example, first follow UI guidelines for the development platform. In instances where platform guidelines are not available, adhere to VA’s Best Practices Guidelines/Style Guide.
- Inform requirements and designs with detailed human factors work products that have been/will be completed for the specific project. Examples of specific human factors activities might include heuristic evaluations, site visits, interviews, application-specific design guides, and usability testing on existing systems or prototypes.

A sound UCD and development process based on human factors should include the following activities:

- Understanding of the users, the users’ tasks, and the users’ environments
- Review of similar or competitive systems to inform requirements and design
- Heuristic evaluation of prior versions, prototypes, or baseline applications, if applicable
- Iterative design and formative usability testing (formative usability testing is used to discover usability problems during the design and development process)
- User risk analysis
- Summative validation usability testing (summative usability testing is used to quantify and validate usability of a product with measures of effectiveness, efficiency, user perceptions, etc.)

To demonstrate high usability, the application should be:

- Intuitive and easy to learn with minimal training

- Effective by allowing users to successfully complete tasks
- Efficient by allowing users to complete their work in a manner consistent with clinical practice and workflow
- Perceived to have high usability, as demonstrated by appropriate survey measures
- Designed to aid users in meeting task goals without being an additional burden

The system must be reliable and enable user trust by providing:

- Stable and reliable performance
- Accurate data
- Display of all data that is available in native or interfaced systems and intended to be available in the application
- Accessible information related to the source of data

The application should include a modern GUI that allows the user to view data from multiple sources and include:

- Integrated display of structured and unstructured data
- Rich data visualization and graphical display of data
- Ability to switch between tabular and graphical data views
- Ability to interact with displayed data to obtain additional details related to the data and source of the data
- User customizable components and settings

The application must provide for advanced and up-to-date searching, to include:

- Fast search functionality with auto-complete and real-time display of matched results during typing
- Search history

The application must provide for advanced filtering capabilities, to include:

- Filtering of data tables, lists, and grids
- Filtering of search results

The application design should be modified to:

- Address the specific findings from a human factors heuristic evaluation conducted on the prior version of the application
- Address the specific findings reported from field use of the prior version
- Address the specific findings reported from usability testing of the prior version or relevant prototypes

Usability requirements for this work effort are documented in the RTM in [Appendix A](#).

Appendix E Enterprise Requirements

The Enterprise-level Requirements in the RTM, found in [Appendix A](#), are of particular interest to the business community. These requirements **MUST** be addressed within each project resulting from this work effort. If OIT cannot address these Enterprise-level requirements, the Business Owners responsible for each area **MUST** be engaged in any waiver discussions prior to any decisions being made. This section is not meant to be a comprehensive list of all Enterprise-level requirements that may apply to this work effort and should not preclude the technical community from reviewing all Enterprise-level requirements and identifying others that should apply to this work effort as well.

Appendix F Acronyms and Abbreviations

OIT Master Glossary:

Term	Definition
AA	Assessment and Authorization
AM	Access Management
ANR	Automated Notification Reporting
API	Application Programming Interface
BN	Business Need
BRD	Business Requirements Document
CAC	Common Access Card
CCD	Continuity of Care Document
CDR	Clinical Data Repository
CDS	Clinical Decision Support
CHS	Common Hardware Systems
CM	Context Management
COTS	Commercial-Off-The-Shelf
CPRS	Computerized Patient Record System
DHMSM	DoD Healthcare Management System Modernization
DICOM	Digital Imaging and Communications in Medicine
DoD	Department of Defense
EDES	Emergency Department Encounter Summary
EHR	Electronic Health Record
EA	Enterprise Architecture
FDA	Food and Drug Administration
FIPS	Federal Information Processing Standard
FY	Fiscal Year
GUI	Graphical User Interface
HAIMS	Healthcare Artifact and Image Management Solution
HCSR	Health Care Security Requirements
HI	Health Informatics
HIG	Health Information Governance
HITECH	Health Information Technology for Economic and Clinical Health Act
HITSP	Health Information Technology Standards Panel

Term	Definition
HL7	Health Level Seven
HMP	Health Management Platform
IAM	Identity and Access Management
ICIB	Interagency Clinical Informatics Board
IEC	International Electrochemical Commission
iEHR	Integrated Electronic Health Record
IHE	Integrating the Healthcare Enterprise
IHS	Indian Health Services
IPO	Interagency Program Office
ISO	International Organization for Standardization
IT	Information Technology
JLV	Joint Legacy Viewer
KPC	Key Performance Criteria
LEIPR	Longitudinal Enterprise Integrated Patient Record
LOINC	Logical Observation Identifiers, Names, and Codes
MHV	My HealtheVet
MU	Meaningful Use
NIST	National Institute of Standards and Technology
NISTIR	National Institute of Standards and Technology Interagency Report
nonf	Non-Functional Requirement
NSR	New Service Request
NTRT	New Term Rapid Turnaround
NwHIN	Nationwide Health Information Network
OIA	Office of Informatics and Analytics
OIT	Office of Information and Technology
ONC	Office of the National Coordinator
ONCHIT	Office of the National Coordinator Health Information Technology
OWNR	Owner Requirement
PIV	Personal Identity Verification
PM	Project Manager
PMAS	Program Management Accountability System
QRDA	Quality Reporting Document Architecture
RDM	Requirements Development and Management

Term	Definition
RPC	Remote Procedure Call
RTM	Requirements Traceability Matrix
SAML	Security Assertion Markup Language
SDS	Standard Data Services
SIM	Strategic Investment Management
SLA	Service Level Agreement
SME	Subject Matter Expert
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SSO	Single Sign-On
STS	Standards and Terminology Services
USH	Under Secretary for Health
UCD	User Centered Design
UI	User Interface
UX	User Experience
VA	Department of Veterans Affairs
VEPEO	VistA Evolution Program Executive Office
VETS	VA Enterprise Terminology Services
VHA	Veterans Health Administration
VistA	Veterans Health Information Systems and Technology Architecture
VPR	Virtual Patient Record
VSSC	VHA Support Service Center
WAN	Wide Area Network

Appendix G Approval Signatures

The requirements defined in this document are the high level business requirements necessary to meet the strategic goals and operational plans of the Office of Informatics and Analytics. Further elaboration to these requirements will be done in more detailed artifacts.

Business Owner

Signifies that the customer approves the documented requirements, that they adequately represent the customers desired needs, and that the customer agrees with the defined scope.

[Redacted Signature] Date:2/5/2014
Core

Business Liaison

Signifies appropriate identification and engagement of necessary stakeholders and the confirmation and commitment to quality assurance and communication of business requirements to meet stakeholder expectations.

I [Redacted Signature] Date 2/5/2014
Wed 2/5/2014 10:41 AM

Office of Information and Technology

Indicates agreement that the requirements have been received, are clear, understandable, and are documented sufficiently to facilitate project planning when the project is approved and funded. It is understood that negotiations may need to occur with the business during project planning as a result of technical reviews and feasibility.

[Redacted Signature] Date 2/5/2014
Wed 2/5/2014 10:14 PM