



TO INVESTIGATORS SUBMITTING PROPOSALS TO HSR&D OR QUERI Guidance on Addressing EHRM in Applications (April 2024)

As VA continues its Electronic Health Record Modernization (EHRM) through implementation of the new Oracle Health-based EHR in VHA facilities, researchers will have to adapt their study designs to accommodate new EHR workflows and changes in data utility and comparability.

Additional considerations may include the impact on sampling, site selection, and comparability implications across sites for multisite studies. This memo is designed to provide guidance on how to address the EHR Modernization in applications to HSR&D or QUERI effective immediately insofar as the proposed research relies on the use of the VA EHR or data from it. We anticipate that this guidance will be updated ahead of each submission cycle as the Federal EHR rollout progresses and as new information about the resulting data and tools becomes available.

1. EHRM Implementation Status

As of April 2, 2024, six VA facilities are using VA's new Oracle Health-based EHR, known as the Federal EHR, for clinical care.

NEW: The newest facility to use the Federal EHR is the Captain James A. Lovell Federal Health Care Center (FHCC), which incorporates facilities, services, and resources from the North Chicago VA Medical Center and the Naval Health Clinic Great Lakes. At the time of go-live, four research studies at Lovell FHCC were using the Federal EHR for ordering medications, labs, or procedures. These studies are the first across the six VA facilities to use the full research capabilities of the Federal EHR.

Federal Facility	Location	Deployment Date
Mann-Grandstaff VAMC	Spokane, WA	October 24, 2020
Jonathan M. Wainwright Memorial VAMC	Walla Walla, WA	March26, 2022
VA Central Ohio Healthcare System	Columbus, OH	April 30, 2022
Roseburg VA Health System	Roseburg, OR	June 11, 2022
VA Southern Oregon Rehabilitation Center and Clinics	White City, OR	June 11, 2022
Captain James A. Lovell Federal Health Care Center	North Chicago, IL	March 9, 2024

In April 2023, the VA Under Secretary for Health announced an enterprise-wide reset of the EHRM program, stopping all new deployments. During the reset, work is focused on addressing challenges with the system and ensuring optimal functioning for Veterans and for VA personnel.

NOTE: There is currently <u>no schedule</u> for further VA deployments, but researchers can check the <u>EHRM Integration Office</u> website for updates to the schedule, when available. At this time, we do not have confirmation that additional VA sites will be deployed in 2024 or 2025, but the deployment schedule may change without notice.





2. Data Availability and Use

Data generated from current deployments of the new EHR are being sent to the Corporate Data Warehouse (CDW) daily, where they are available in CDWWork2 (format similar to the native Oracle Health EHR data model) and CDWWork3 (partially merged with VistA CDW). These data remain available for request by approved research projects and can be provisioned to research workspaces. However, researchers cannot assume that the same variables collected within CPRS will be available within the new EHR data, or that those variables will have the same properties and meaning. As a result, researchers choosing to use data generated at EHR-transitioned sites should be prepared for the additional investment required to learn and vet the new data for their use.

NOTE: Additional support for using the new data from both enclaves is available via <u>vinci@va.gov</u> or <u>ResearchEHRMHelp@va.gov</u>.

3. Customized Data Capture in the EHR

Some VA research relies on CPRS-based data collection through customized data capture during clinical encounters (e.g., templates). We anticipate that studies relying on such data collection may continue at VA Medical Centers that have not yet made the EHR transition (i.e., are still on VistA). A process for implementing an analogous mechanism within the new EHR remains under development. Researchers with studies using customized data capture or other customizations within CPRS can contact ResearchEHRMHelp@va.gov for assistance or guidance.

4. New EHR Capabilities and PowerTrials

The new EHR may offer opportunities to support research not previously possible (e.g., sexual orientation and gender identity data, additional discrete or structured variables, new machine-generated data, etc.). In addition, the new EHR includes a research-specific solution from Oracle Health—PowerTrials—that manages research billing, facilitates research orders, and integrates clinical trials into the EHR. Proposed studies involving a clinical intervention or trial should consider the EHRM deployment schedule (when available) to account for potential differences in fielding at transitioned sites and may want to exclude those sites until PowerTrials has been further evaluated. The first studies using these capabilities are now active in the new EHR, and the VA is closely monitoring these studies to gain additional information about conducting clinical research in the Federal EHR. The VA is currently assessing the capacity of PowerTrials to accommodate all VA research requiring research orders, and whether any additional or alternative approaches will be needed.

The processes for supporting clinical trials involving oncology treatment, investigational drugs, or other research orders in the new EHR are new and can be time consuming to implement. Investigators planning new studies of these types may wish to exclude transitioning sites until further information is available or to develop and describe detailed contingency plans in grant submissions in case a study is delayed at these sites. If you are planning a clinical trial with these needs at one of the sites currently using the Federal EHR, or have questions about how your study might be affected by future implementations, please reach out to ResearchEHRMHelp@va.gov as early as possible in the planning process.





5. Guidance for Application Preparation

In addition to the specific contingency plans mentioned above, we recommend that studies that may be affected by VA's transition to the new EHR provide a general contingency plan in their application, including (as applicable):

- Study design shifts
- Site modification
- Statistical analyses to account for missing or discrepant data

Studies may also consider incorporating some version of the following template language into their applications.

If funded, we recognize that our project may occur during the VA transition to the new Oracle Health-based EHR. Depending on how the rollout schedule evolves, the use of the new EHR and the implications of the resulting data may affect our site selection, research design, or analytical approach. This may result in excluding sites with upcoming deployments or modifying data use and analysis plans to account for system differences. We will work closely with the VA Coordinating Hub to Promote Research Optimizing Veteran-centric EHR networks (PROVEN) and the VA Information Resource Center (VIReC) to address issues related to data availability and use to maximize study progress.

6. For Additional Guidance

If you have specific questions, please reach out to PROVEN, HSR&D's coordinating hub for EHRM research, at PROVENHub@va.gov or OSIRES, ORD's strategic team for supporting research transition needs, at ResearchEHRMHelp@va.gov.

Additional Resources for Understanding the EHRM and its Impact on Research

General Resources

- The ORD Strategic Initiative for Research & EHR Synergy (OSIRES) maintains general EHRM information and resources for research on the *EHRM & Research* SharePoint site.
- The Promoting Research Optimizing Veteran Centric EHR Networks (PROVEN) coordinating hub provides guidance and support for researchers *studying* the EHRM.
- The <u>Research and EHR Synergy</u> cyberseminars highlight topics including conducting research using the new EHR, accessing and using Millennium-generated and CDW-converged data, and VA investigations into EHRM implementation and impact. The presentation, "<u>An Update on the EHR Modernization for Research</u>" (December 2023), provides an overview of the EHRM's anticipated impact for research and quality improvement investigations.

More about data

- VIReC's intranet site includes <u>EHRM & Implications for Data Users</u>, <u>VA Millennium EHR Data Documentation & Resources</u>, and VIReC Research User Guides.
- The EHRM IO Data Migration and Management Team provides information and education on data migration, syndication, and mapping. These are housed on the <u>DMM Knowledge Share</u> SharePoint and Microsoft Teams sites.



