



TO INVESTIGATORS SUBMITTING PROPOSALS TO HSR&D OR QUERI Guidance on Addressing EHRM in Applications (9/29/23)

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 new EHR rollout progresses and as new information about the resulting VA Millennium data and tools becomes available.

1. EHRM Implementation Status

As of September 29, 2023, five VA facilities are using VA's new Oracle Health-based EHR, aka Millennium, for clinical care:

VA 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

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 it is functioning optimally for Veterans and for VA health care personnel. The only site where deployment activity is continuing is the James A. Lovell Federal Health Care Center (FHCC), a joint VA-DoD facility which is scheduled to transition to the new EHR in March 2024. While there is currently no schedule for resuming VA deployments, researchers can monitor the EHRM Integration Office website for up-to-date information on the schedule.

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 (Millennium format) and CDWWork3 (partially integrated into VistA CDW). These data are now 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 EHR data generated at Cerner-transitioned sites should be prepared for the additional investment required to learn and vet the new data for their use. Additional support for using the new data from both enclaves is available via winci@va.gov or ResearchEHRMHelp@va.gov.





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 VAs that are later in the rollout schedule (i.e., still on VistA). At this point in time, a process for implementing an analogous mechanism within the new EHR is still under development and should not be assumed at sites coming up on the deployment schedule.

Researchers with studies utilizing 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/structured variables, new machine-generated data, etc.) In addition, the new EHR includes a research-specific solution from Oracle Health, PowerTrials, that will be used for research drug ordering and integration of clinical trials into the EHR. Proposed studies involving a clinical intervention or trial should consider the EHRM deployment schedule to account for potential differences in fielding at transitioned sites and may want to exclude those sites until PowerTrials has been deployed and further evaluated. Questions remain about the process and timeline for supporting clinical trials involving oncology treatment and/or investigational drugs – investigators planning new studies of these types may wish to exclude transitioning sites until further information is available and/or develop and describe detailed contingency plans in case the study is delayed at these sites.

- **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 will 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 for 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 and/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 <u>EHRM & Research SharePoint site</u>.
- 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 ranging from conducting research using the Millennium EHR to accessing and using Millennium-generated and CDW-converged data to VA research studying EHRM implementation and impact. The presentation <u>A Ground-Level View of EHR Modernization and Research</u> (September 2022) provides an overview of the EHRM's anticipated impact for research and quality improvement investigations.

Data Specific

- VIReC's intranet site includes <u>EHRM & Implications for Data Users</u>, <u>VA Millennium EHR Data</u> Documentation & Resources, 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> <u>SharePoint</u> and <u>Microsoft Teams sites</u>.

