

## **TO INVESTIGATORS SUBMITTING PROPOSALS TO HSR&D OR QUERI Guidance on Addressing EHRM in Applications (as of May 9, 2022)**

As VA makes progress on Electronic Health Record Modernization (EHRM) through implementation of the Cerner EHR in VHA facilities, researchers may have to adapt their study designs to accommodate changes in data availability, comparability, and methodological strategies over time. This memo is designed to provide guidance on how to address EHRM changes for applications to HSR&D or QUERI effective immediately insofar as the research proposed 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 EHRM rollout progresses and as new information about the resulting Cerner-generated data and tools becomes available.

1. **EHRM Implementation Status** As of May 9, 2022, three VA facilities are using VA's new Cerner EHR, Millennium, for clinical care. The Mann-Grandstaff (Spokane, WA) VAMC has been using the new EHR since October 24, 2020. In Spring of 2022, Jonathan M. Wainwright Memorial VAMC in Walla Walla, WA (March 26, 2022) and the VA Central Ohio Healthcare System in Columbus, OH (April 30, 2022) both began using the new EHR. Additional sites in VISNs 10 and 20 are planned to go live in FY22. A **tentative deployment schedule** is available on the VA EHRM intranet site, but the schedule may be modified.
2. **Data Availability and Use** Data generated from the Millennium EHR are being sent to the Corporate Data Warehouse (CDW), but they are not yet fully integrated with existing CDW VistA data and it is unclear when they will be integrated. This data **is now available** for researchers to request for provisioning to research workspaces. However, researchers cannot assume that the same variables collected within CPRS will be available within the Millennium 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.

The implications of VA Millennium data developments may differ depending on whether a proposed study includes transitioned sites. Applications focused on the conduct of regional or national analyses of VA data from FY21 onward may want to consider excluding Spokane, Walla Walla, and any other early rollout sites (e.g., VISN 10 and VISN 20 medical centers) if possible.

3. **Customized Data Capture** 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. At this point in time, a process has not been finalized for implementing an analogous mechanism within Millennium.
4. **New Functionalities and PowerTrials** Millennium may offer new functionalities that could support research not previously possible (e.g., Millennium will capture sexual orientation and gender identity data not currently available in CPRS, is likely to provide additional discrete variables, and more machine-generated data.)

In addition, the Millennium EHR introduces a new research solution, PowerTrials, that will be used for research drug ordering and integration of clinical trials into the EHR. Proposed

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studies involving a clinical intervention or trial should consider the EHRM implementation schedule to account for potential differences in fielding at Cerner-transitioned sites and may want to exclude transitioning sites until PowerTrials has been deployed and further evaluated. In particular, significant 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 the EHRM transition include a general contingency plan including (as applicable):
- study design shifts
  - site modification
  - statistical analyses to account for missing or discrepant data

to support feasibility. 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 Cerner Millennium Electronic Health Record implementation. Availability of data from VA sites that have transitioned to Cerner Millennium might be affected. This may result in excluding sites where data are not available or modifying our data collection and analysis plans. 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](mailto:PROVENHub@va.gov) and/or OSIRES, ORD's strategic team for supporting research transition needs, at [ResearchEHRMHelp@va.gov](mailto: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 [Research and EHR Synergy](#) 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.

#### Data Specific

- VIREC's intranet site includes [EHRM & Implications for Data Users](#), and [VA Millennium EHR Data Documentation & Resources](#).
- The EHRM IO Data Migration and Management Team provides information and education on data migration, syndication, and mapping. These are housed on the DMM Knowledge Share [Sharepoint](#) and [Microsoft Teams](#) sites.

