Request for Information:

Research Data Request and Access Policy Changes

February 2024; updated March 1, 2024

Background:

The Centers for Medicare & Medicaid Services (CMS) currently offers researchers two options for accessing CMS Research Identifiable File (RIF) data: (1) researchers can request that physical data extracts are shipped to their institution; and (2) researchers can access the data they need in the Chronic Conditions Warehouse Virtual Research Data Center (CCW VRDC), a secure CMS research environment. However, due to growing data security concerns and an increase in data breaches across the healthcare ecosystem, CMS is taking steps to discontinue the delivery of physical data in support of external research projects. Instead, researchers will be required to use the CCW VRDC to conduct all research using CMS RIF data.

CMS will be implementing this policy change in two phases. This RFI seeks feedback from stakeholders to aid CMS in planning for the implementation of phase 1 (i.e., new research studies using the CCW VRDC and new fees for physical data) and preparing for phase 2 (i.e., the transition of ongoing research studies into the CCW VRDC beginning in 2025).

Please note, CMS will not be responding to individual comments on the RFI. Instead, CMS will be sending out additional guidance later this year and final guidance prior to requiring researchers to transition their ongoing research studies to the CCW VRDC. The implementation dates for phase 1 and phase 2 may be adjusted based on RFI feedback. CMS will include final implementation dates in future guidance. In addition, only federal and state agencies may request an exception to the policy requiring research to be conducted in the CCW VRDC. CMS will communicate directly with eligible agencies on the process for requesting a policy exception.

Directions:

To ensure that the feedback collected through this RFI is specific and actionable, please respond to the questions listed below. The questions cover a range of topics related to the CMS research data request and delivery process, and use of the CCW VRDC. CMS does not expect respondents to provide feedback on all questions; respondents should focus on questions that are most relevant to them.

Note: If you are not familiar with the CCW VRDC – how to access/connect, what analytic tools are available, options for seats/users, and what comes with each option, please review the *About the VRDC and Requesting Access* page identified in the announcement.

The RFI is open for comment until May 15, 2024.

Responses must be sent via email to VRDCRFI@cms.hhs.gov

1: CCW VRDC Processes/Access

1. How much lead time will you need to transition your research study into the CCW VRDC? Please include details about the steps you will take, and the anticipated timeframes associated with each step.
2. What hurdles or challenges do you anticipate you will have with working in the CCW VRDC?

3. Is there specific training or assistance you will need to be successful in the CCW VRDC? If possible, please indicate the level of training needed and on which tools.
4. Would you consider moving your research study to the CCW VRDC prior to the implementation of the new CMS policies? If so, why and when?
5. Are there research studies that you expect to complete in 2024 or 2025? If yes, please provide the Data Use Agreement (DUA) number and expected completion date.
6. How many seats/users do you anticipate having on your research study once transitioned into the CCW VRDC?
    a. Do you anticipate using the Statistical Analysis Software (SAS) only or the full VRDC option? For information on the CCW VRDC access options, please review the *About the VRDC and Requesting Access* page identified in the announcement.
    b. Will your research study require the purchase of additional space or Databricks credits?

2: CCW VRDC Tools

1. What analytic tools, program languages, or specific analytic packages and libraries are you using for your research study?
    a. Are you using any analytic tools that are not currently available in the CCW VRDC? For information on the analytic tools currently available in the CCW VRDC, please review the *About the VRDC and Requesting Access* page identified in the announcement.
2. If you are using analytic tools not currently available in the CCW VRDC, please describe the workstation used to perform research (Central Processing Unit (CPU), memory, Operating System (OS), number of workstations, etc.).

3: Data/Project

1. Do you have data files that will need to be uploaded into the CCW VRDC to complete your research? If so, please describe the data and provide details about the files (format, size, etc.).
2. Do you have project-specific code that will need to be loaded to your CCW VRDC workspace? If so, please describe and provide details about the code (format, size, volume, language, etc.).
3. Please estimate the amount of data storage growth per year for your DUA, including the total size of current data in your environment and amount of data imported and generated each month.
4. How long does your data need to be retained for your research?

4: Data Access Fees (new as of March 1, 2024)

1. How does your organization currently cover costs related to IT infrastructure, security, software licensing, etc. when physically receiving CMS data, and what are estimates of these costs? What is the scope of anticipated cost savings your organization could realize by not paying for IT infrastructure, security, software licensing, etc. related to maintaining a physical copy of CMS data?
2. How many people are currently associated with your research project that require access to record-level (i.e., non-aggregated) data? How do you anticipate the new policies would affect the number and team structure of researchers accessing record-level data for your project, and what would be the impact of any changes? Could some members of your project team contribute at the same level by reviewing aggregated output?

3. Could other types of lower-cost CCW VRDC access meet your needs (e.g., a viewer role that doesn't have access to any analytic tools or software)? If so, what types of roles would you need?
4. How do your anticipated CCW VRDC fees compare to the total data access fees and internal IT costs associated with your research project?
5. CMS is required to recoup the cost of making data available to researchers to allow the agency to continue offering this important service. Do you have suggestions for an alternative fee structure that would allow CMS to recoup fees associated with VRDC use?
6. How many student dissertation projects does your organization expect to conduct on an annual basis? Based on use, do you have suggestions for the fee structure for dissertation projects?
7. Would it be valuable for CMS to expand the dissemination of lower-cost limited data sets that would not require VRDC access to promote more training and research opportunities for students and other researchers?

5: Transition Timing (new as of March 1, 2024)

1. CMS announced plans to require all new RIF Data Use Agreement (DUA) requests to access RIF data within the CCW VRDC beginning on August 19, 2024. If 6 months of advance notice about this change is not sufficient, how much notice would allow you to prepare for this transition? In the interim, what additional security assessments and conditions would you prioritize to address growing security and privacy risks?
2. To cover growing costs associated with physical data delivery, CMS is updating fees for physical delivery of CMS data beginning on August 19, 2024. If 6 months of advance notice about this change is not sufficient, how much notice would allow you to prepare for the updated data fees?
3. What other factors not addressed above should CMS consider in determining transition timing for phase 1 or phase 2?