BMC CDW-R Data Delivery Resource

Investigator Responsibilities: Using, Sharing, and Securing CDW-R Data

Safeguarding data on OneDrive

BMC Clinical Data Warehouse for Research (CDW-R) analysts deliver all data sets using BMC's secure OneDrive system. CDW-R analysts grant access to the OneDrive folder to BMC investigators and their designees. Designees must be BMC or BUMC staff who are listed on the IRB protocol. Investigators agree to safeguard the data according to applicable agreements and policies. Investigators are responsible for monitoring data access and data security per applicable regulations and guidance. Investigators are expected to monitor data access upon receiving the data set from the CDW-R per the study's IRB protocol and any executed data sharing agreements. Investigators are responsible for managing IRB amendments and relevant data sharing agreements to manage study team members who access the data.

Sharing BMC data outside of BMC (including sending data to BU and BUMC)

If data are being transferred to any collaborator or third party outside of Boston Medical Center (including sending data to BU and/or BUMC study staff/collaborators), a data sharing agreement is required. BUMC is defined as investigators from Boston University School of Medicine, Boston University School of Public Health, and Boston University Goldman School of Dental Medicine. Before sharing any data, contact Asa Lopatin, Director Research Contracts and Industry Agreements, at Asa.Lopatin@bmc.org for steps to execute the appropriate data sharing agreement. The CDW-R does not manage data sharing agreements; Principal Investigators and study teams are responsible for taking the necessary steps to ensure the appropriate agreements are in place before any data are shared outside of BMC.

Acknowledge the CDW-R in your publications!

We suggest the following language to acknowledge the CDW-R in your publications: "The Boston Medical Center Clinical Data Warehouse for Research (CDW-R) supported the data strategy and provided data extracts for this research." Feel free to modify the language based on the services the CDW-R provided for your study so long as "Boston Medical Center Clinical Data Warehouse for Research" is listed fully.

Confirming data set completeness/accuracy

CDW-R analysts are available to respond to questions about your data set – or make routine modifications – within two weeks of supplying your data set. Questions and modification requests submitted within the two-week deadline will receive expedited priority. Requests or questions received after the two-week period will be added to the existing data request queue and may require the investigator to complete a new CDW-R data request form. Analyst time making routine modifications is subject to fees. In the event the investigator requests modifications that differ substantially from what was previously discussed during the initial request process, the analyst will provide an updated cost estimate. Examples of substantial modifications include new project components, additional variables, different dates, and complex changes to codes or variable definitions.

CDW-R billing and invoicing

The financial contact listed on your data request will receive an invoice for CDW-R services the month following data delivery. If you are paying from a BMC account, you do not need to do anything; you will receive an invoice for your records and the payment will be automatically journaled from your account via a cost transfer by Research Operations. If you are paying from a BU or other external account, directions for remitting payment will be included on the invoice. More information is on the CDW-R website.

Nondisclosure

Data recipients will not abstract, use, or further disclose the data except as permitted by the IRB protocol, data sharing agreement, and/or applicable regulations and policies.

CDW-R data recipient agreement

By accepting the data, the study investigator and data recipients acknowledge and agree to abide by the restrictions on the use and disclosure of these data as outlined above and in accordance with all applicable policies.

