Overview of the Innovator Research Program

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Technical Advisor
About ResDAC

- Centers for Medicare and Medicaid (CMS) contractor
- Offers assistance to researchers interested in requesting and using Medicare and Medicaid data for research
- Staffed by a team of public health and health services research specialists
- Provides services related to CMS data
Overview

- Description of the Innovator Research Program
- Data Available
- Description of Virtual Research Data Center (VRDC)
- Cost
- Request Process & Timeline
- Overview of the Request Materials
- Tips for Getting Started
- Common Questions
Innovator Research Program

A new policy that, for the first time, allows innovators and entrepreneurs access to identifiable CMS data for the purpose of creating a tool or product to sell or to conduct research to create analyses related to business needs.
Innovator Research Program

Requirements

- Projects submitted under the Innovator program must:
  - Be for research
  - Disseminate findings broadly and contribute to generalizable knowledge
  - Access data through the Virtual Research Data Center (VRDC)
  - Request only minimum data necessary
  - Include a CMS Privacy Board review and Data Governance Board review
Data Available

- RIF data available for Innovator Research

<table>
<thead>
<tr>
<th>Privacy Level</th>
<th>Requirements of Use</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Use File</td>
<td>No restrictions, downloadable, summarized or provider level data</td>
<td>Provider of Services</td>
</tr>
<tr>
<td>Limited Data Set</td>
<td>Requires Data Use Agreement</td>
<td>Denominator LDS, Medicare Standard Analytical Files</td>
</tr>
<tr>
<td>Research Identifiable</td>
<td>Requires Data Use Agreement and CMS Review</td>
<td>Medicare claims, Part D, Medicaid claims, Assessments</td>
</tr>
</tbody>
</table>
# Data Available for Innovator Research

## Research Identifiable Files

<table>
<thead>
<tr>
<th>Data Files</th>
<th>Years Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>chronic conditions*, cost &amp; utilization, NDI</td>
<td>NDI 1999-2007</td>
</tr>
<tr>
<td>Nursing Facility, Carrier, DME</td>
<td></td>
</tr>
<tr>
<td>Part D event and characteristics files (drug, plan, prescriber, pharmacy,</td>
<td>2006-2013; Formulary file 2010-2013</td>
</tr>
<tr>
<td>formulary)</td>
<td></td>
</tr>
<tr>
<td>Shared Savings Program ACO file: Provider and Beneficiary level</td>
<td>2013</td>
</tr>
<tr>
<td>Assessments: MDS, OASIS, IRF-PAI, Swing Beds</td>
<td>1999-2013</td>
</tr>
<tr>
<td>Medicaid: MAX &amp; MMLEADS</td>
<td>1999-2012 (MAX) 2006-2010 (MMLEADS)</td>
</tr>
</tbody>
</table>
Description of the VRDC

The CMS VRDC is a virtual research environment, within CMS’s Chronic Condition Data Warehouse (CCW), that provides access to identifiable Medicare and Medicaid program data in a more efficient manner.
Features of the VRDC

- Access to data is granted through a ‘seat’
- Seat holder would pay a flat price/year to access the data approved for the study
- VRDC seat holder would obtain 500 GB of storage for files and for analytical space
- SAS or Stata are available to manipulate the data
VRDC ‘Seat’

- A seat is defined as an individual with direct access into the VRDC environment
  - Only the ‘seat’ holder can access the VRDC
  - The user ids are person specific
  - Multiple researchers can’t share the same seat or split time on one seat

- One ‘seat’ holder and multiple projects
  - Within the VRDC, one ‘seat’ holder can access multiple approved projects.
  - Additional fee to add another project and receive an additional 500 GB of space
VRDC Uploading Data

- User held data can be uploaded to the environment
  - Uploaded files are reviewed to ensure they are virus free
  - User responsible for assuring any non-public data being uploaded into the VRDC environment are not proprietary/restricted by a license agreement.
    » If proprietary, user must obtain approval and include approval with data request package
VRDC Downloading Aggregate Data

- Users can download aggregate/statistical data files from the environment
  - Downloaded data will be reviewed to ensure no individual level data are removed from the VRDC
  - Aggregate data follows cell suppression policy of no cell sizes less than 11 will be released
  - Output review will take up to 48 hours

- Innovators will receive 3 output reviews per week
  - Maximum file size of 100MB per output review for a total of 300MB per week
  - Multiple files may be downloaded but each file must be within the specified size limit (100MB)
Data Storage After VRDC Access Ends

- After VRDC access has ended, project data will be stored for 3 years.
- Project data may be accessed for one month free of charge in order to conduct additional analysis, such as questions resulting from journal publication process.
- DUA for the project must remain open and active during this time.
Innovator Cost

- $35,000 per user/per year for each seat
- $25,000 project fee

Example: 1 user, 2yr project, no changes to cohort during the 2 yr project
  - Year 1 cost = $35,000 + $25,000 = $60,000
  - Year 2 cost = $35,000

Specifics on pricing are found in the CMS Price List for Research Files found on the Innovator Research Page, Request Resources.
## Innovator Request Process

<table>
<thead>
<tr>
<th>Researcher</th>
<th>ResDAC</th>
<th>CMS</th>
<th>CCW (GDIT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Packet</td>
<td>Review</td>
<td>Privacy Board</td>
<td>Onboarding</td>
</tr>
<tr>
<td>Packet Revisions</td>
<td>Final Packet</td>
<td>DGB</td>
<td></td>
</tr>
<tr>
<td>Payment</td>
<td></td>
<td>Decision Notification</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Confirmation</td>
<td></td>
</tr>
</tbody>
</table>

Work performed under CMS Contract #HHSM-500-2013-00166C
## Estimated Request Timeline

<table>
<thead>
<tr>
<th>Stage of the Process</th>
<th>Estimated Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>ResDAC review of draft materials</td>
<td>4 weeks *Dependent on how many revisions are needed.</td>
</tr>
<tr>
<td>CMS Privacy Board review</td>
<td>Minimum 4 weeks</td>
</tr>
<tr>
<td>CMS Data Governance Board (DGB) Review</td>
<td>Minimum 8 weeks DGB review initiated after CMS Privacy Board reviews</td>
</tr>
<tr>
<td>VRDC Onboarding</td>
<td>Minimum 4 weeks after CMS notifies GDIT of payment confirmation. Includes required user training and file access.</td>
</tr>
</tbody>
</table>
Request Materials

- Start at the ResDAC home page » CMS Data » Innovator

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# Request Materials List

<table>
<thead>
<tr>
<th>Request Document</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Request Letter</td>
<td>ResDAC has created a template. ‘VRDC Request Letter Template’</td>
</tr>
<tr>
<td>2. VRDC Executive Summary</td>
<td>The Executive Summary is the main document reviewed by the CMS Privacy Board.</td>
</tr>
<tr>
<td>3. Study Protocol</td>
<td>ResDAC has created a protocol template. This describes the research project in more detail.</td>
</tr>
<tr>
<td>4. Data Use Agreement</td>
<td>The 6-page DUA defines the terms of use and privacy requirements. Outlines agreement for a specific project.</td>
</tr>
<tr>
<td>4a. Signature Addendum to DUA</td>
<td>This is needed if the VRDC seat holder did not sign #16 (User) or #17 (Custodian) of the DUA.</td>
</tr>
<tr>
<td>4b. RIF DUA - Attachment B</td>
<td>Acknowledgement that requestor is allowed to identify physicians or suppliers.</td>
</tr>
</tbody>
</table>
## Request Materials List, continued

<table>
<thead>
<tr>
<th>Request Document</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Evidence of Funding</td>
<td>ResDAC has templates available if project is internally funded.</td>
</tr>
<tr>
<td>6. Specifications Worksheet</td>
<td>This document outlines the data files for the request.</td>
</tr>
<tr>
<td>7. Cost Invoice</td>
<td>Complete specifications worksheet to obtain a cost invoice. The cost invoice will outline the number of seats, the files, years, and size of the cohort.</td>
</tr>
<tr>
<td>8. IRB Documentation</td>
<td>Institutional review board review is necessary for all research requests. Document should include HIPAA waiver of authorization and Common Rule documentation.</td>
</tr>
<tr>
<td>9. Innovator Research Letter Template</td>
<td>Letter outlines the tool, product or analysis; the audience it will be marketed to; and the number of anticipated output reviews needed per week.</td>
</tr>
<tr>
<td>Other file specific materials</td>
<td>Examples include: Variable justifications for Part D and Assessment data</td>
</tr>
</tbody>
</table>
Getting Started & Tips

- Suggested Steps
  - Determine what data you need
    » Review the RIF Data Availability table
    » Contact ResDAC with any questions about the data
  - Submit a request for a Cost Invoice to resdac@umn.edu
  - Prepare your Study Protocol and Executive Summary
    » Visit ResDAC website for templates and tips
  - Obtain external IRB approval
  - Submit draft materials (no signatures) to resdac@umn.edu to begin the process
Common Questions

- What is the Data Use Agreement?

The CMS DUA outlines the data security and use requirements. The DUA is for a specific project and the data under the DUA can’t be used for any other purpose without CMS permission.
Common Questions

- **What is “Research”?**
  - This relates to the “research” provisions of release outlined in the HIPAA Privacy Rule.
  - “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”
    » [45 CFR 164.501](#)
  - Identifiable data can be disclosed for “...a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.”
    » Taken from Chronic Conditions Data Repository System of Records [09-70-0573](#)
Common Questions

- Does CMS approval grant me permission to 100% of all CMS data?
  - No
    - CMS approval allows the requesting organization permission to conduct the specific project that was described in the Executive summary and Study protocol under a specific DUA.
    - CMS is required under the HIPAA Privacy Rule to release only the minimum data necessary. Therefore, research must provide a sound justification for why the specific files, years, and cohort are the minimum data necessary. *(See 45 CFR 164.502(b))*
Common Questions

- Can data in the VRDC be linked together?
- Yes
  - CMS uses an encrypted beneficiary identifier called the BENE_ID to allow linkage across files and years in the VRDC.
Common Questions

- What is an Institutional Review Board (IRB)?
  - An IRB is a committee that performs ethical review of proposed research.
  - NIH’s Institutional Review Boards and the HIPAA Privacy Rule website provides a description of the IRB.
  - 45 CFR 46 provides description of IRB.

- What does the IRB approval need to include?
  - Waiver approval under Common Rule 45 CFR part 46
  - Waiver authorization under the HIPAA Privacy Rule 45 CFR 164.512
Resources for Help

- **ResDAC Assistance Desk**
  - Assistance with request process and file contents
  - Email: resdac@umn.edu
  - Phone: 1-888-973-7322
  - Web: [http://www.resdac.org](http://www.resdac.org)

- **VRDC Help Desk**
  - Assistance with VRDC technical questions, accessing and working in the environment
  - Email: ccwhelp@gdit.com
  - Phone: 1-866-766-1915
  - Web: [http://www.ccwdata.org](http://www.ccwdata.org)