Office of the Secretary Patient-Centered Outcome Research Trust Fund Project

Office of Enterprise Data and Analytics

Centers for Medicare and Medicaid Services

Human-Centered Design Study on Federal Data Access and Acquisition Processes of CMS Data

Final Report 2023

Overview and Objective

The goal of this project was to streamline the Centers for Medicare & Medicaid Services (CMS) data request process for federal agencies to facilitate more efficient and sustainable access to CMS data. CMS' Office of Enterprise Data and Analytics (OEDA) engaged the Lab at the Office of Personnel Management (OPM) to perform a human-centered design (HCD) study on CMS data access and acquisition processes that resulted in the identification of areas of opportunity/improvement in the federal data request process based on testing sessions. HCD is a creative and strategic approach to solving challenging problems that puts people at the center of the process, responding to their nuanced behaviors, mental models, and needs. This approach was used to identify and address the root causes of problems, rather than their symptoms. CMS utilized an HCD approach as the agency wants to enhance the user experience and ensure that the root causes of challenges are identified and corrected – thus, ensuring a more efficient and user-friendly approach to the federal agency data request process.

The objectives of this project were to: 1) conduct a HCD study to better understand the experience federal agencies have requesting CMS data and to understand the limitations; 2) develop a prototype of the future federal agency request process; and 3) test this prototype among federal requestors and provide recommendations to build on this prototype and for other avenues the process can be improved.

Background

CMS makes data that contains personally identifiable information (PII)/personal health information (PHI) available to certain stakeholders as allowed by federal laws and regulations and CMS policy. CMS established a standard process for researchers to request the data, including entering into a Data Use Agreement (DUA) with CMS. All researchers, including those at other federal agencies, follow the same request process. In addition, federal agencies often must complete supplemental agreements, such as an Information Exchange Agreement (IEA) and/or an Interagency Agreement (IAA). During the COVID pandemic, there was an increase in the number of federal agencies requesting special terms, and the standard data request process needs to be updated to account for the growing number and complexity of these requests. CMS also anticipates an increase in data requests from other federal agencies to facilitate data linkages and support patient-centered outcomes research. CMS, in collaboration with the Lab at the Office of Personnel Management (OPM), conducted a human-centered design (HCD) study to understand and identify the current gaps in the federal agency request process. The goal was to design a more streamlined and user-friendly process that meets federal agency partners' needs, while ensuring CMS compliance with relevant laws and CMS policies.

Data Request Process

CMS currently makes data containing PII/PHI available through a standard request process. Researchers work with the Research Data Assistance Contractor (ResDAC), a CMS contractor, to complete a research request packet. The materials in the request packet provide information on the research study that will be conducted, a list of and justification for the datafiles being requested to support the research study, information on how CMS data will be protected, and information on how research findings from the research study will be made publicly available. If the federal agency requests to access datafiles that are not available to standard researchers, in terms of datafiles or data timeliness, then the researcher must submit a letter to the CMS Chief Data Officer (CDO) that provides a justification for the special data request. After the request materials are finalized, they are sent to CMS for review by the CMS Privacy Board (PB). The CMS PB ensures that disclosures of CMS data for research purposes comply with the

HIPAA Privacy Rule, Privacy Act of 1974, and CMS data policies. A request for special data access will be sent to the CDO for approval. If the request is approved, the researcher enters into a DUA with CMS that provides the terms for how the data may be used and safeguarded. The researcher then submits payment for the data. Once payment is received, the data is sent for processing.

Additional Federal Agency Agreements

In addition to the research request process and materials (described in the previous section), federal agencies may also require an IEA and/or an IAA.

An IEA provides supplemental terms and conditions that support the initial research disclosure. For instance, it may lay out the terms and conditions under which the requesting federal agency can disclose linked datasets to extramural researchers. CMS works with a requesting federal agency to negotiate the terms, and the IEA is often reviewed by Privacy Offices and attorneys at both agencies.

An IAA is a payment vehicle to facilitate the transfer of funds for any applicable CMS data fees.
CMS has a current initiative in place to lessen the burden of the standard data request process and anticipates releasing new research request forms that reduce the number of forms required and the redundancy of the information collected in the research request forms.

This project identified updates and revisions to the federal agency data request process to strengthen and streamline the process, including for IEAs and IAAs associated with research requests.

CMS Data Access to support Patient-Centered Outcomes Research

Performing an HCD study, developing key opportunity areas and prototype to be used for testing and informing the guidance document for federal agencies in requesting CMS data, resulted in another step towards creating a more user-friendly data request process for federal agencies. More efficient access to CMS data is foundational for the Department of Health and Human Services and CMS initiatives to support patient-centered care research (PCOR). Many of the past and current projects in the Office of the Secretary Patient Centered Outcomes Trust Fund (OS-PCORTF) portfolio use CMS data to accomplish their research goals and project objectives. Facilitating more efficient data access to federal agencies engaged in OS-PCORTF projects reduces burden and ensures that research data are received in a timely manner to meet the timelines of PCOR projects.

Methods

The Lab at OPM applied HCD principles to conduct the study in three phases. The first phase involved collaborative strategizing and project framing. The second consisted of discovery research focused on 1) understanding the internal process and parties at CMS, and 2) the federal requestors. After synthesizing the research, the last phase saw the team engage in ideation and concepting around process improvements and potential prototypes.

Phase 1: Partnership Strategy and Framing

The Lab at OPM and the project team conducted activities to align on project goals, requirements, and roles of the staff who would be serving in different capacity on the project. CMS and The Lab at OPM

collaborated to identify and outline a detailed project plan, timeline, research goals, scoping, and discovery outline.

Phase 2: Discovery Research

During this phase, the Lab at OPM conducted discovery research to first understand the internal processes and then the federal requestor experience.

Phase 1 of research focused on internal learning conversations and was conducted with CMS staff and contractors who play various roles in processing federal research requests. The goals at this stage were to:

- Uncover and visualize the current processes that exist around non-standard federal agency research requests, including the people, tools, platforms, and requirement that are involved
- Identify challenges, misalignments, and/or redundancies within the current process.
- Outline the various paths special requests take and where they diverge from the standard process.

Learnings from this first phase of research informed the types of questions and topics important to discuss with federal requestors.

Phase 2 of research focused on the requestor experience. The team conducted semi-structured interviews with federal requestors from five different agencies that broadly covered the full data request experience. The research goals for these interviews were to:

- Better understand the variances in experiences and expectations across a range of federal requestors and request types.
- Understand how federal requestors navigate the request process.
- Explore common federal requestor challenges and sources of when and how confusion arise.

Phase 3: Ideation and Concepting

At this stage, the team gathered a wide range of ideas and opportunity areas from discovery interviews and workshops. The ideas ranged from immediate tactical suggestions to broader systemic changes at the organizational or policy level. Using the Scales of Intervention Framework, the team continued to map desired opportunity areas across various levels. The Scales of Intervention Analysis was a framework to help the team organize and interpret the range of near-future and long-term opportunities which was summarized into a refined set of opportunity areas (Appendix A).

Based on priorities highlighted in the internal stakeholder workshop, the opportunity area to "Improve Requestor Information Gaps" emerged as a high-need focus area for the project going forward. Various rationale supported this focus area, including:

- Building greater clarity on what's possible up front can cut down on the back and forth and confusion in defining the ask.
- Improving transparency and setting better expectations can help requestors act more strategically and efficiently.
- Setting requestors up well at the start will ensure they avoid unnecessary pitfalls and unexpected surprises as they move through the process.

While the team aligned on narrowing to this single opportunity area, there were still many possible interventions to explore, some big and some small. The project team did a quick assessment of the

existing ideas and possibilities using an importance-difficulty matrix. This provided guardrails for prioritizing how to move forward. By focusing on ideas that will have the highest impact with less difficulty to implement, the team developed some prototypes to learn more from requestors directly.

The project team aligned on prototyping a tool designed for federal requestors to help them orient their strategic decisions when getting started and develop realistic expectations for the process ahead. The focus was on narrowing requestor information gap, specifically for federal agencies requesting data for research purposes, ultimately developing:

1. **Federal Requestor Landing Page:** a single starting point that highlights key information specific to Federal requestors and directs them to relevant resources.
2. **Process Overview:** a visual diagram to clarify the process phases into 5 steps that are oriented to the requestor's experience (rather than internal OEDA processes).
3. **Assessment Form:** an interactive form that guides requestors through a series of questions to help them gather (and decide) on the key variables of their request.
4. **FAQ page:** an organized set of questions to guide requestors to key answers and resources.

The intention of the learning in this phase was testing assumptions that these types of tools would provide an immediate benefit to requestors, and identifying the key elements and information federal requestors need to feel confident navigating the request process. The rough prototypes were used as learning prompts to validate this approach and offer insight for how to develop more robust tools in the future. The team also gathered specific feedback on how to improve the prototypes.

The team tested these tools with two audiences: internal stakeholders (i.e., OEDA and ResDAC) and Federal requestors.

Lessons Learned

To ensure feedback from the testing sessions was actionable, the team crafted the following *Guiding Principles* to use when developing user-centered tools and interventions:

1. Use language that requestors understand :

In boththe discovery research and testing sessions, Federal requestors described the burden that confusion and misunderstandings around OEDA's terminology added to the overall process.

Principle 1 in practice

To ensure requestors at various levels of experience can comprehend critical information, prioritize utilizing easily comprehensible language by:

- Use plain language.
- Define CMS or OEDA-specific terminology.
- Always spell out acronyms at first use.
- Use consistent language and terms across all process materials.
- Investigate common language uses for different types of data sets so data catalog options align with common mental models.

2. Break down information to highlight at key moments

In the testing sessions, requestors responded positively to information being broken into sections on the landing page and process guidance materials. While the ResDAC website offers substantial information and guidance to requestors, many find it overwhelming and not specific enough to Federal requestor needs.

Principle 2 in practice
To reduce the burden on requestors, clearly call out the most important information by:

- Providing both a big picture overview and phase-specific guidance to help requestors zoom in and out during their process journey. (e.g., Process Overview prototypes)
- Highlighting key action items requestors need to take at each stage of the process.
- Standardizing information hierarchy across the process (For example, provide high level explanations with the option to learn more for every phase in the process)

3. Pave multiple moments for learning

While all requestors share the goal of acquiring data, how they come to the process in terms of their roles and expertise and how they make their way to information vary widely. Some requestors are data experts, others process managers, some go looking for information on their own, others are referred from their trusted contacted. This variation leads to different needs, questions, and starting points.

Principle 3 in practice
While an ideal experience is to have all federal requestors enter the process through the same front door, to ensure that any outlier requestors are still able to navigate the process with ease, the user experience must accommodate for a diversity of requestor circumstances and scenarios by:

- Offering multiple entry points and pathways for learning.
- Resurfacing key terms and information in multiple formats (i.e., defining a common term on the landing page does not negate the term being defined on materials given to requestors later in the process)
- Distinguishing between helpful process knowledge verse action-items that rely on the requestor to complete.

4. Be specific and provide rationale

It's easy for requestors to feel lost and overwhelmed by the multitude of requirements and steps involved in the data request process. Requestors question the validity and need of requirements that don't make sense to them, which can slow down the process. Vague instructions or questions also lead to confusion.

Principle 4 in practice
To reduce requestor frustration and resistance to requirements, make the who, what, when, where and why explicit by:

- Writing guidance that speaks to the requestor's perspective.
- Explaining the "why" behind requirements and protocols, like the CDO letter, additional processes (IEA, IAA)
- Communicating who must complete the action of the task and who is involved in supporting the action moves forward.
- Explaining when each task or phase happens (timeline estimates and order of operations).
- Alerting requestors about key considerations and possible progress barriers that may arise depending on their request.

5. Support strategic decision making.

At the beginning of getting started with a request, many federal requestors are unaware of the impact their data type will have on the distinct steps and layers of approval they may have to go through during the request process.

Principle 5 in practice
To ensure requestors understand their options and the implications of their decisions, ensure that decision-making factors are clearly highlighted by:

- Acknowledging early on that the process a requestor will have to go through is dependent on the type of data they want to request.
- Ensuring requestors can access both a catalog of data options and understand the special process that accompanies the type of data they want to request.
- Helping understand nature of non-standard requests (see Recommendation X for more detail).
- Articulating tradeoffs and dependencies embedded in different data choices to support requestors making informed decisions.
- Explaining costs and funding for data.
- Defining IAAs, IEAs, and the CDO letter and provide step-by-step guidance on the processes.

Additional Recommendations

The team also identified the following additional recommendations for future exploration:

1. **Conduct a User Experience (UX) Study of ResDAC website with Federal requestors.**
   Observe and analyze federal requestors current behaviors and mental models on the ResDAC website. Make recommendations for UX improvements to create a more user-friendly experience inclusive of federal requests.

2. **Standardize non-standard data sets.**
   Work to make protocol, timelines, and responsibilities for approving non-standard data requests consistent and established across stakeholders involved.

3. **Streamline process components so it's less complicated.**
   Consolidate divergent approvals and pieces of the process for requestors.

4. **Increase automation and tracking.**
   Reduce the amount of analog back and forth between requestors and approvers. Consider creating a streamlined communication platform and tracker.

5. **Increase information on different pathways.**
   Create a single landing point for federal agency requestors that provides information on various pathways beyond research, such as health oversight or requesting a CMA.

Conclusion

The goal of this project was to streamline the data access and acquisition process for federal agencies because data requests from federal agencies are more complex, can involve non-standard research files, and additional agreements, such as IEAs and IAAs. This project leveraged the HCD methodology, which

centers the user experience when problem solving, and is a unique approach critical for the purpose of this project. The objectives of this project were to 1) conduct a HCD study to better understand the experience federal agencies have requesting CMS data and to understand the limitations; 2) develop a prototype of the future federal agency request process; and 3) test this prototype among federal requestors and provide recommendations to build on this prototype and for other avenues the process can be improved. As a result, key opportunity areas for process improvements and a prototype of a new landing page were developed. The outcomes – summary process pain points, key opportunity areas, and the prototype – all serve as a foundation to build on as the data request process is streamlined in the future. Future projects that build on the outcomes of the HCD project will support a more efficient process of requesting CMS data and support the growth of patient-centered outcomes research.

Appendix A: Opportunity Areas to Improve the Federal Requestor Experience

Narrow Requestor Information Gaps

This area focuses on guidance to share process information and data possibilities with requestors early in their process.

Goal: Manage requestor expectations and provide communications that empower them to maximize efficiency on their end.

Primary audience: Newer federal requestors or newer requestor team members.

Limitations/challenges: To make an impactful change for the requestor experience, the guidance would include information in which OEDA defines several policies and principles for nonstandard data sharing that are not yet codified -- i.e., standardizing non-standard elements.

Examples: Federal requestor playbook; contact directory; data request templates; data use examples; visual and written tools that clarify the process.

Establish Communication Consistency and Transparency

This area focuses on consistent, clear, and timely communication channels and touch points throughout the approval process.

Goal: Proactively communicate request status, anticipated timelines, and decision-making rationale to instill requestor confidence and ability to plan.

Primary audience: All federal requestors.

Limitations/challenges: Without a streamlined backend end system to guide users through the process and designated points of contact in place, managing communication and increasing visibility is possible but may be limited and cumbersome.

Examples: Bi-weekly email status updates; Automated timeline communication; customer relationship management (CRM)/web-based tracking system accessible by both OEDA and requestors.

Refine Backend Tools

This area prioritizes new programs or processes that minimize manual inputs, maximize preservation of institutional knowledge, and promote efficiency.

Goal: Make existing operations easier by reducing opportunity for human error and promoting alignment across requests from year to year.

Primary audience: OEDA internally, federal requestors when filling out forms or renewals.

Limitations/challenges: May require new software. The impact on the federal requestor experience depends on the efficiency of implementation and won't necessarily be most apparent immediately.

Examples: Digitize wherever possible. This includes reducing copy-and-paste; more internal coordination to reference precedents; create shared system of documentation; and more automated intake forms.

Evolve and Streamline OEDA Processes

The focus of this area is structural changes to streamline existing operations.

Goal: Reduce approval times and promote transparency.

Primary audience: All federal requestors.

Limitations/challenges: May require significant leadership buy in for internal policy change.

Examples: Remove or standardize Chief Data Officer (CDO) letter requirement; single front door for federal requestors; standardize and/or streamline renewals; develop emergency protocols.

Standardize Non-Standard Elements

This area centers on identifying what is commonly true, or deciding what is possible to determine in advance, for all the subjective or individualized parts of the non-standard federal request process.

Goal: Minimize the need for individual consideration or discretion and streamline process so that actionable context can be shared with requestors and process may move more quickly.

Primary audience: Any federal requestor with a new request (novice or experienced).

Limitations/challenges: Will take significant effort to collate and develop, may force policy decisions that teams are not able or willing to dictate themselves. Potentially requires cooperation of business owners. Need to disseminate and share guidance after policies or protocols are developed.

Examples: Improve current data catalog, so there is a clear list of what is available and what is not; create principles of data sharing; define how to approach non-research or research adjacent asks; assign pre-approved data sets.

Expand Access to OEDA Data Across the Federal Government

This area centers on structural changes to make Chronic Conditions Warehouse (CCW) data available for more government and non-research projects that promote public health.

Goal: Maximize allowable data access under HIPAA and facilitate innovative projects, outreach, and programming.

Primary audience: Federal agencies broadly.

Limitations/challenges: May require buy-in and funding from CMS leadership; there would be need to disseminate and share guidance after policies or protocols are developed.

Examples: Develop umbrella Data Use Agreement (DUA) protocols; create alternative pathways; create authority to bypass restrictions in extreme circumstances