

Colorado All Payer Claims Database Data Release Application

Thank you for your interest in obtaining data from the CO APCD. As you fill out this application, please let us know if you have any questions or concerns by reaching out to ColoradoAPCD@civhc.org. We are here to help!

Also, please be aware that if you are requesting Protected Health Information (PHI), your request requires a recommendation for approval by the Data Release Review Committee (DRRC). Data elements that are considered PHI under HIPAA are indicated below. If PHI is requested, a CIVHC Account Executive will help you successfully complete an application and navigate the DRRC process.

Please use this application to submit information regarding your request for data from the Colorado All Payer Claims Database (CO APCD). This information will help the Center for Improving Value in Health Care (CIVHC), the Administrator of the CO APCD, answer any questions you have regarding your data request and assist us in helping you complete the data application form.

Note: Please reference the CO APCD Data Elements Request Form found at <http://www.civhc.org/get-data/data-release/> when completing this form.

Introduction: Section 10 CCR 2505-5-1.200.5 describes how the CO APCD Administrator addresses Requests for Data and Reports:

1.200.5.A. A state agency or private entity engaged in efforts to improve health care or public health outcomes for Colorado residents may request a specialized report from the CO APCD by submitting to the administrator a written request detailing the purpose of the project, the methodology, the qualifications of the research entity, and by executing a Data Use Agreement (DUA), to comply with the requirements of HIPAA.

1.200.5. B. A data release review committee shall review the request and advise the administrator on whether release of the data is consistent with the statutory purpose of the CO APCD, will contribute to efforts to improve health care for Colorado residents, and complies with the requirements of HIPAA. The administrator shall include a representative of a physician organization, hospital organization, non-physician provider organization and a payer organization on the data release review committee.

This Data Release Application serves as the written request for information noted in section 1.200.5.A.

PART ONE

Project Information	
Project Title:	22.34 Freenome Cancer Risk Research
Date:	8/16
Organization Requesting Data:	Freenome
Contact Person:	Victoria Reid
Title:	Senior Director of Market Development
E-mail:	victoria.reid@freenome.com
Phone Number:	650.245.9545
Person Responsible for the Project (if different than above):	Alyssa Goodson
Title:	Director of RWD Informatics
E-mail:	Alyssa.Goodson@freenome.com
Phone Number:	N/A

Project Purpose:

Project questions to be discussed with client representative:

Freenome is committed to broad patient access and to multiomics blood tests for the early detection of cancer. Freenome's multiomics platform detects key biological signals from a routine blood draw. The platform integrates assays for cell-free DNA, methylation, and proteins with advanced computational biology and machine learning techniques to understand additive signatures for early cancer detection. This strategy incorporates a multidimensional view of both tumor- and non-tumor-derived (e.g. immune) signatures that enable the early detection of cancer, instead of relying only on tumor-derived markers, which may miss the early signs of cancer. By decoding cell-free biomarker patterns of once unthinkable complexity, Freenome's blood tests are powered by our multiomics platform and designed to detect cancer at its earliest stages to help clinicians optimize treatments and the next generation of precision therapies.

Although risk factors often influence the development of cancer, most do not directly cause cancer. Some people with several risk factors never develop cancer, while others with no known risk factors do. Knowing your risk factors and talking about them with your doctor may help you make more informed lifestyle and health care choices.

The purpose of this application is to request CO APCD Data for this research project to reinvent disease management through early detection and precision intervention and to equip all individuals and families with the tools they need to detect and treat cancer at its earliest and most manageable stages.

- Please describe your project and project goals/objectives.

The project is to better understand risk factors that drive cancer and why it is happening in early stages. This research is being conducted to better understand predetermined risks around procedures within the cancer patient population above 40 years of age

- What specific research question(s) are you trying to answer or problem(s) are you trying to solve with this data request? (Please list and number the individual questions.)

1. What are the risk factors that drive cancer?
2. Why is cancer occurring in younger age group 40+?

- How will this project benefit Colorado or Colorado residents? (this is a statutory requirement for all non-public releases of CO APCD data)

- If applicable, how will your project support be lowering health care costs?
- Our research is intended to understand patients who are not up to date with their cancer screening. This will enable to payers/ providers to work with these patients to get them into the screening paradigm.
- As new modalities of screening emerge, the model we build through the claims data provided by Colorado Claims data can serve as a tool to potentially help providers determine the best screening modality for the patient based on their risks.
- Through the development of the risk model, we seeking to commercially drive adherence to screening and hopefully reduce the cost through early detection and prevention and ultimately improve patient outcomes.
- If applicable, how will you project help improve the health of Coloradans?

Freenome intends to conduct research and analyze CO APCD Data in hopes of building a risk model that can provide Colorado residents and cancer patients a better understanding of their risks so that they may get into a screening paradigm. By using the CO APCD and claims data, Freenome will build risk models for cancer to better optimize clinical trials.

- If applicable, how will your project improve the quality of care or patient experience?

If our research and model development is successful, we will be able provide significant insights for the Colorado Department of Health on potential ways to drive adherence with cancer screening, help patient get into the screening paradigm and improve patient outcomes and ultimately, cost of care associated with potential development of cancer.

- Do you need a claims data set or would you like a custom report generated by CIVHC that addresses the specific questions/problems your project seeks to address?

All applicable and available Claims Dataset for those over the age of 40.

- Do you need Protected Health Information (PHI)? [No \(Limited Dataset\)](#)
 - Do you need patient-specific dates (e.g., dates of service or age) or 5 digit zip code. If so, this is a request for a Limited Data Set. [Yes - dates of service](#)
 - Do you need direct patient identifiers such as name, address, or city? If so, this is a request for an Identifiable Data Set (requires IRB approval). [No](#)
 - If you do not require any PHI, please only complete PART ONE of the application.

Please note: your CIVHC representative will work with you to complete **Addendum I – Analyst Supplement** to address data warehouse specific questions.

If you are requesting a Custom Report with analytics to be provided by CIVHC; [please stop here](#) and submit the information above to your CIVHC representative.

PART TWO

I. **Type of CO APCD Analytic Data Set Requested**

Please select the type of data set that you are requesting by checking one of the boxes below (**select only ONE option**). Details on each type of CO APCD data set can be found in *The CO APCD Companion Instruction Guide* (available from your CIVHC representative):

Types of Analytic Data Sets (Please select ONE below)

For users interested in a wide range of data to analyze on their own.

- ☐ De-Identified Data Set
- ☒ Limited Data Set*
- ☐ Identified Data Set *

*These types of data requests include Protected Health Information (PHI). Under HIPAA, PHI may only be released in limited circumstances for public health, health care operations, and research purposes under the terms of a HIPAA compliant data use agreement (DUA).

2. **Requested Data Elements – Limited and Fully Identifiable Data Sets**

The CO APCD is committed to protecting the privacy and security of Colorado's health care claims data. The CO APCD will limit the use of the data to purposes permitted under applicable laws, including APCD Statute/Rule and HIPAA/HITECH, to information reasonably necessary to accomplish the project purpose as described in this Application.

Data Element Selection and Justification

If you have not already done so, please use the Data Element Dictionary (DED) to identify the specific data elements that are required for this project. In keeping with the minimum necessary standard established under HIPAA, CO APCD policy is to release only those data elements that are required to complete your project.

Type of Data	Justification for Elements on the DED
Names	N/A – not requesting

Street Address	N/A – not requesting
City	N/A – not requesting
Zip Code	N/A – not requesting
Health Plan Beneficiary Numbers	N/A – not requesting
Dates (including Day and Month detail.) Specify which date fields are needed and why.	Dates of Service to accurately analyze the data and assist with developing methods for research
Provider Identifying Information	Need to know associated specialty and Zip 3 so that we can understand care was provided vs. where the patient resided to assist with our research.

A. Counts, Totals and other Summary Statistics

The CO APCD seeks to provide aggregated summary data whenever possible. Applicants are encouraged to request counts, totals, rates and other summary values whenever such information can reasonably accomplish the purpose of the project (add rows to the table below if necessary). The CO APCD supports the federal CMS minimum cell size suppression policy that requires any cell in any report or data table, printed or electronic, with less than eleven records or observations to be replaced by “Less than eleven” or similar text. You must also apply complementary cell suppression techniques to ensure that cells with fewer than eleven records cannot be identified by manipulating data in adjacent rows and columns.

Field Number and Name	Requested Count or Sum
	<i>[add rows as needed]</i>

B. Linkages to Other Data Sets

The CO APCD seeks to ensure that data cannot be re-identified if it is linked to or combined with information obtained from other sources. If this project requires claims line level detail or includes linkages to other databases, or if CO APCD data will be combined with other information, provide a justification for each proposed linkage. Be sure to describe how this will contribute to achieving the project purpose, including whether the project can be completed without this linkage, and the steps you will take to prevent the identification of individual patients:

Will you link the CO APCD data to another data source?

☒ No.

☐ Yes. If yes, please answer the following questions.

- Which CO APCD identifying data elements will be used to perform the linkage?
- Once the linkage is made, what non-CO APCD data elements will appear in the new linked file?

- Have all necessary approvals been obtained to receive and link with the other data files (e.g., IRB or Privacy Board approval)?
 - ☐ Yes, if so please provide copy
 - ☐ In progress, anticipated approval date: _____
 - ☒ No or N/A, reason: Limited Dataset_

C. Distribution of the Report or Product:
Prior Review by the CO APCD Administrator

If you are producing a report for publication in any medium (print, electronic, lecture, slides, etc.) the CO APCD Administrator must review the report prior to public release. The CO APCD Administrator will review the report for compliance with CMS cell suppression rules; risk of inferential identification; and consistency with the purpose and methodology described in this Application.

- Please describe your audience and how to you will make your project publicly available?
- If the report is not to be made publicly available, then briefly describe how the information derived from this data will be used and by whom:

Other Organizations: Do you intend to engage third parties who will have access to the data requested as part of this project? If so, list the organizations below, describe their role(s); and explain why they will be granted access to the requested data.

Organization/Company Name:	Potential to publish the work in a peer-review journal to be determined based upon the work
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Role or responsibility in this project	<i>[add rows as needed]</i>

Project Schedule:

Proposed Project Start Date:	November 1 st , 2021
Project End Date:	November 1 st , 2022
Proposed Publication or Release Date:	December 1 st , 2022
End of Date Retention Period:	January 1 st , 2023

D. Frequency

Data in the CO APCD Warehouse is refreshed every other month and data products can be provided on a one time basis or under a subscription model (e.g., quarterly, bi-annually or annually). Please select frequency below.

☐ One Time

OR

Subscription (Please select subscription model below)

☐ Quarterly

☐ Bi-annually

☒ Annually beginning 1 Nov 2021

E. Project Reporting

CIVHC highlights projects and data analysis on the public website: www.civhc.org/change-agents. This display of CO APCD projects provides future data requesters with ideas of how they can structure their analysis, and allows CIVHC's stakeholders to see how CO APCD data recipients are working to accomplish the Triple Aim for Colorado. Data recipients have the option of choosing whether to be identified or to not be identified.

☒ Yes, it is okay for CIVHC to identify my organization

We intend to build a risk model for CRC using the claims data set. If the data is successful we intend to publish this work and help the Colorado Dept. achieve its triple aims with improving patient health and improving outcomes in CRC.

☐ No, I do NOT wish for CIVHC to identify my organization

PART THREE

DATA MANAGEMENT PLAN (Not applicable for Custom Report Requests)

I. Organizational Capacity

As an Attachment, please provide copies of the Data Privacy and Security Policies and Procedures for the Requesting Organization as well as those of any third parties that will have access to the requested CO APCD data.

- Has the Requesting Organization or any member of the project team ever been involved with a project that experienced a data security incident? If so, describe the incident, the response procedures that were followed and any subsequent changes in procedures, processes or protocols to mitigate the risk of further events.

To the extent that the Data Privacy and Security Policies and Procedures, provided as an Attachment, do not already do so, please answer or attach answers for the following:

- **Physical Possession and Storage of CO APCD Data Files:**
 - Describe how you will maintain an inventory of CO APCD data files and manage physical access to them for the duration of the project:
 - Describe your personnel/staffing safeguards, including:
 - Confidentiality agreements in place with individuals identified as being assigned to this study. Include, for example, agreements between the Principal Investigator or Data Custodian and others, including research team members, and information technology and administrative staff:
 - Staff training programs you have in place to ensure data protections and stewardship responsibilities are communicated to the research team:
 - Procedures to track the active status and roles of each member of the research team throughout the project and a process for notifying the CO APCD of any changes to the team:
 - Describe your technical and physical safeguards. Examples include:
 - Actions taken to physically secure data files, such as site and office access controls, secured file cabinets and locked offices.
 - Safeguards to limit access to CO APCD data and analytical extracts among the research team (Note: if the distribution of analytical data extracts among the researcher team is part of your data management plan, the extracts remain subject to the terms of your Data Use Agreement).
 - Provide a brief description of your policies and procedures for ensuring that CO APCD data are protected when stored on a server.
 - Describe how your organization prevents the copying or transfer of data to local workstations and other hard media devices (CDs, DVDs, hard drives, etc.). Note that Applicants are required to encrypt CO APCD data both in motion and at rest:
 - Data Reporting and Publication
 - Your organization must ensure that all analytic extracts, analyses, findings, presentations, reports, and publications based on CO APCD

data files adhere to specific requirements of the Data Use Agreement (DUA: refer to sections 6, 7 and 8 in the Data Use Agreement). **Briefly describe your plan for demonstrating that data reporting and publication processes will be consistent with the DUA, including adhering to CO APCD cell suppression policies:**

2. Completion of Research Tasks and Data Destruction

Your organization must ensure that it has policies and procedures in place to destroy the CO APCD data files upon completion of the project and that you have safeguards to ensure the data are protected when researchers terminate their participation in the research project. Describe your plan for demonstrating that your organization has policies and procedures in place to reliably destroy the data files upon completion of the research:

3. Request for Privacy Board Approval *(Only Applicable to Identifiable Data Requests)*

Projects that request Identifiable information for a research purpose may require approval from the DRRC acting as a Privacy Board if an IRB is not available.

- The DRRC, acting as a Privacy Board, may approve a waiver of the individual authorization normally required to release PHI under CFR § 164.508 if:
- It would be impracticable for researchers to obtain written authorization from patients that are the subject of the research; and
- The research could not practicably be conducted without access to and use of the PHI.
- The DRRC, acting as a Privacy Board, is required to evaluate certain criteria in considering whether to approve an authorization waiver. If you are requesting Identifiable Information for a research purpose, explain why your proposed use of PHI involves no more than a minimal risk to the privacy of patients that are the subject of the research. Evidence of minimal risk to the privacy of patients that should be addressed in your explanation includes:
 - An adequate plan to protect PHI identifiers from improper use and disclosure;
 - An adequate plan to destroy PHI identifiers at the earliest opportunity; and
 - Adequate written assurances that PHI will not be reused or disclosed.

Appendix I

Certification of Project Completion and Destruction or Retention of Data

(Please Save)

Name:	Alyssa Goodson
Title:	Director of RWD Informatics
Organization:	Freenome Holdings Inc.
Address:	279 E Grand Ave. 5th Floor, South San Francisco, CA 94080
Tel Number:	650-446-6630
Fax Number:	
E-mail Address;	Alyssa.Goodson@freenome.com
Project Title:	CRC Risk Stratification
Data Sets:	All Requested
Years:	All Requested
<input type="checkbox"/> Certification of Data Destruction	Date the Data was Destroyed:
<input type="checkbox"/> Request to Retain Data	Date Until Data Will Be Retained:

Instructions: Data must be destroyed so that it cannot be recovered from electronic storage media in accordance with the methods established by the "Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals," as established by the U.S. Department of Health and Human Services (HHS).

I hereby certify that the project described in the Application is complete as of this date
_____, ___, 20__.

Complete the appropriate section, below:

☐ I/we certify that we have destroyed all Data received from the CO APCD Administrator in connection with this project, in all media that were used during the research project. This includes, but is not limited to data maintained on hard drive(s), diskettes, CDs, etc.

☐ I/we certify that we are retaining the data received in connection with the aforementioned project, pursuant to the following health or research justification (provide detail, use as much additional space as necessary and state how long the data will be retained).

☐ I/we hereby certify that we are retaining the Data received from the APCD Administrator in connection with the aforementioned project, as required by the following law. [Reference the appropriate law and indicate the timeframe].

By signing this Agreement, the Receiving Organization agrees to abide by all provisions set out in this Agreement.

SIGNATURES:

For the CO APCD: CIVHC	For Receiving Organization: Freenome
Signature:	Signature:
Name: Pete Sheehan	Name:
Title: VP of Client Solutions & State Initiatives	Title: