

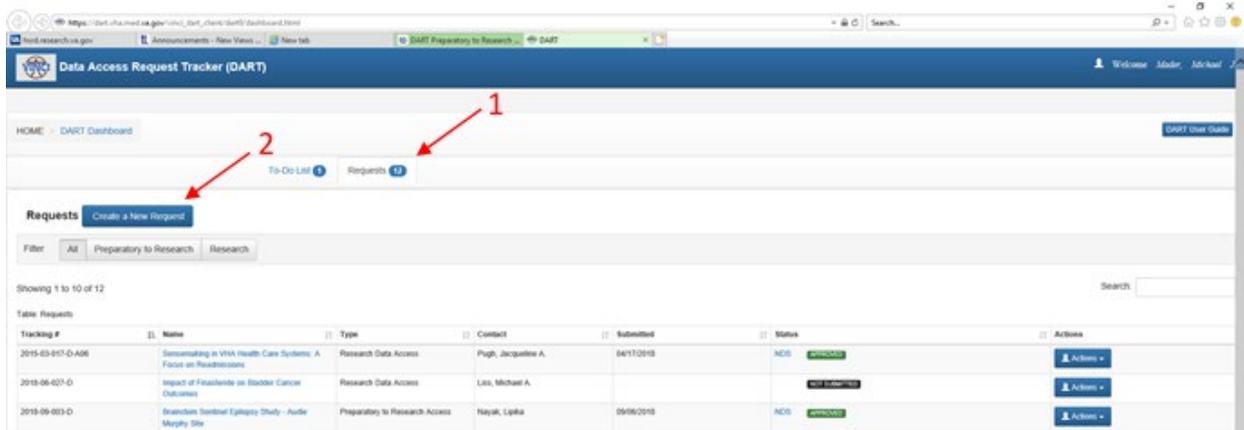
“Complete Guide” to Obtaining EHR Data for Research, at Audie L. Murphy VAMC IRB Approved Research Process.

If your study has been approved by an Institutional Review Board (IRB) and the Audie Murphy R&D Committee, and you need a list of names, SSNs, and addresses of patients that meet your criteria, or you are working on a retrospective study using VHA EHR data, then the IRB Research process can grant you access to the appropriate data.

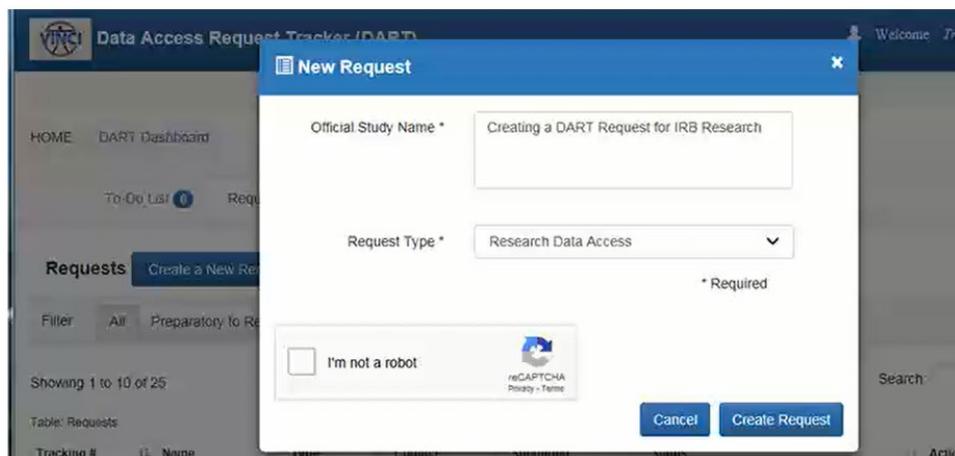
Processing time to expect: From the time you have IRB and R&D approval letters and are ready to start the data request process, until the CDW data is made available to your data analyst, you can expect about 10 to 15 business days (this depends on how many forms are required by the DART process, your ability to avoid mistakes in filling out the forms, and how busy the DART review staff are). For those wanting to generate a list of patients for recruitment purposes or to collect a modest list of medical record variables for a cohort defined by inclusion/exclusion criteria, expect the data analyst to need 2 to 10 business days to write code (this depends on how well laid out your inclusion/exclusion criteria are, and how complicated it is to translate them into SQL or SAS code). Altogether, you can expect a minimum of about two weeks and a maximum of 5 weeks under normal circumstances. [Note: for relatively simple inclusion/exclusion criteria, the VINCI concierge can develop a list for recruitment purposes in about 1 to 2 weeks. The VINCI concierge can be contacted by email for further information about this at vinciservices@va.gov .]

Steps in the process:

1. Define your query:
 - a. If you are wanting to generate a recruitment list or a modest set of medical variables for a cohort, fill out the local “Request for Data Query” form as completely as possible (see Appx 1). Plan to spend about an hour with the data analyst to discuss the details of the Inclusion and Exclusion criteria. To date, successful queries have included demographic information such as sex, age, or race; ICD-9 or ICD-10 diagnosis codes; CPT procedure codes; number of outpatient visits or inpatient stays within a given time frame; laboratory results; prescription fills using generic drug names; vital signs such as systolic and diastolic blood pressure or BMI; consults entered; and answers to mental health questions found in Health Factors.
 - b. If you are working on a retrospective study that doesn’t easily fall into an inclusion/exclusion criteria format, then skip the local form and spend time with the data analyst to develop the method for collecting data.
2. Gather together electronic copies of: the IRB Approval Letter, the R&D Committee Approval Letter, the approved protocol, the Sample Informed Consent form and HIPAA Authorization (if applicable), and the HIPAA waiver letter from the IRB (if applicable). The data analyst you’ve chosen to work with must be listed on the R&D Committee Approval letter.
3. Figure out who needs to look at/work with the data. They of course have to be listed on the R&D Committee Approval letter. If you are uncertain if someone will work with the data, the best practice is to include them in the DART request. After the DART request is turned in, if you decide later to add someone else for data access, you can do a DART amendment.
4. Ask the Research Statistician or data analyst to help you with filling out the DART request, if desired. You will start the online application at:
https://dart.vha.med.va.gov/vinci_dart_client/dart9/dashboard.html
 - a. Just below “HOME > DART Dashboard”, select the “Requests” button and then the “Create a New Request” button.



- b. On the next screen, type the exact name of the approved protocol into the Official Study Name box (or as much of the name as will fit), and then select “Research Data Access” in the drop-down box for Request Type. Then, check the “I’m not a robot” box and be persistent about following the instructions (such as identifying all photos with fire hydrants). Finally, click on the “Create Request” button.



- c. On the next screen, fill in a Short Name for the study: a nickname you create – have it include two or three key words about this study so you can quickly pick it out from other studies you may work on in the future. IRB Number and Expiration come from your IRB Approval letter. Start Date and End Date comes from the R&D Committee letter. Click on “Next”.
- d. Enter the names of individuals who you’ve decided need data access. Enter the Principal Investigator first. If there are individuals from more than one VHA healthcare system (such as South Texas and Puget Sound), you will need a PI for each site (you’ll specify them in the next step). For now, the best practice is to enter the PI you will be working directly with first. For each person you enter, start by clicking on the “Find People” tab. In the pop-up box, fill in the person’s last name, followed by a comma and at least part of the first name and click “Find Now”. Pick the correct username of the participant in the Search Results table, which will bring you back to the Participants screen. Next, click on “Select a Location”. Find South Texas

Data Access Request Tracker (DART)

HOME DART Dashboard Requests

Information Participants Data Documents Submit

2018-06-002-D Creating a DART Request for IRB Research

Activity Information

REQUEST INFORMATION

Short Name * Request for IRB Research

IRB Number * 1001

IRB Expiration * 06/18/2019

Start Date * 06/18/2018

End Date * 06/17/2021

HCS by typing in “(671)” (include the parentheses) and then click on the location. [If the individual is from a healthcare system other than STVHCS, the best way to find their location is to know their 3-digit station number, such as 663 for Puget Sound and type it in surrounded by parentheses. Otherwise, try searching by system name or the city or state where it is located.] Then, check boxes for what that person needs. The “Notifications” box will send an email for each step of the approval and provisioning process. The “Data Access” box will allow the person to see files behind the VINCI firewall and work in the CDW database. The “CAPRI/JLV Access” box will allow the person to see all EHR data for individual patients at any VHA location, such as doctor notes. The best practice is to select “Notifications” for only the research coordinator and data analyst and maybe the PI, to select “Data Access” for everyone (otherwise, why do you have them on the list?), and *not* select the “CAPRI/JLV Access” box for anyone, unless the project requires some of the participants to look at notes pages in the EHR for patients at sites other than Audie Murphy. (If someone needs to look at individual records

Data Access Request Tracker (DART)

HOME > DART Dashboard > Requests

Information Participants Data Documents Submit

2018-09-003-D Brainstem Sentinel Epilepsy Study - Audie Murphy Site

Participants

PARTICIPANTS & LOCATIONS

Table: Participants

Name	Location	Notifications	Data Access	CAPRI/ VistAWeb Access	Delete
Mader, Michael J.	(671) South Texas HCS (San Antonio TX)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Nayak, Lipika	(671) South Texas HCS (San Antonio TX)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Table: Locations

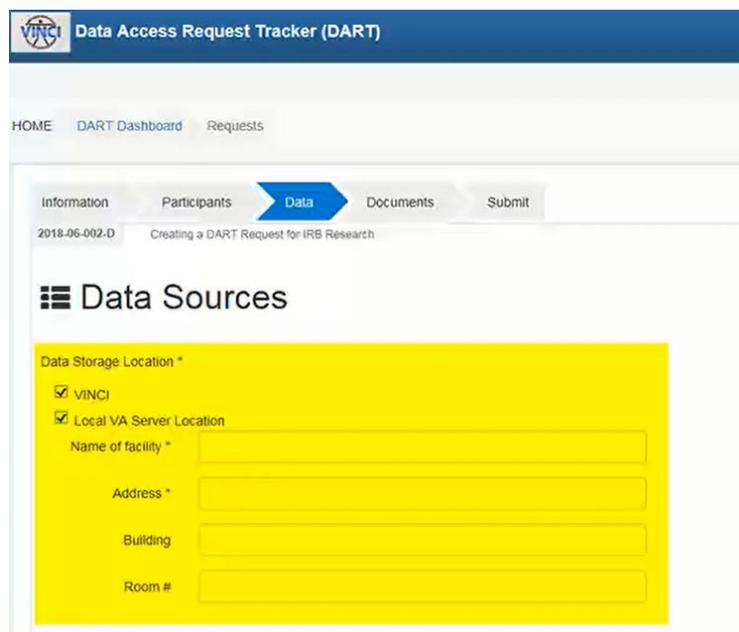
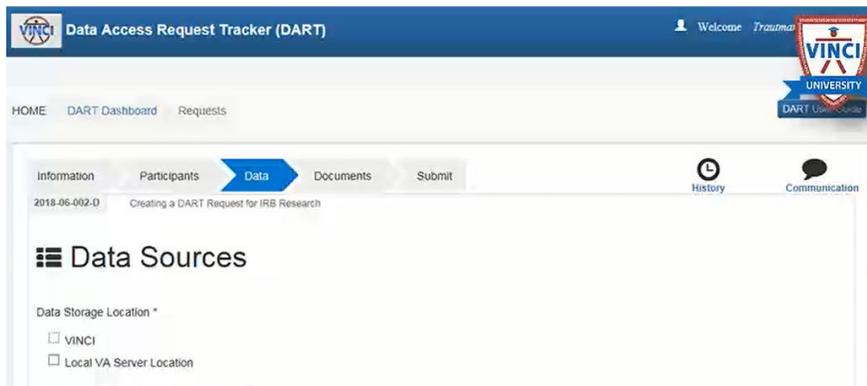
Primary	Location	Principal Investigator
*	(671) South Texas HCS (San Antonio TX)	Nayak, Lipika

Q Find People Q 508 Select a Location Add

← Previous Validate Save Draft Next →

from within Audie Murphy, access to CPRS is the equivalent of access to CAPRI/JLV.) When you've finished filling in the correct information for the first participant, click on the "Add" box and then do it again for each participant.

- e. When you've included everyone, make sure the PI you work with directly is listed in the Locations Table on the right of the screen with a solid black star under Primary. If there are participants from other VHA healthcare systems, the lead person from each site also needs to be in the Locations Table, with a hollow black star. Click Next.
- f. On the Data Sources screen, you have multiple options. A best practice is to discuss the choices with your data analyst and PI if you are uncertain about what option to select. The first choice to make is the Data Storage Location. For nearly all data requests, you will select "VINCI" at a minimum. If you intend to download patient level data from VINCI to store on a local VA server (such as to perform a mail-merge for recruitment letters), then you'll also select the "Local VA Server" box, even if the only data you plan to download from VINCI is deidentified. You will then need to enter information about the location of the local server, which the local ISO can provide. (If the only data you will download is aggregated at the clinic, hospital, or system level, then you are not required to select the "Local VA Server" box).



- g. If part of your study requires you to share VHA data outside of the VA, you'll select the "Yes (DUA is required)" button. Note that before submitting the DART request, you will need to establish a data user agreement (DUA) with the agency. This will require involvement from the Audie Murphy R&D Service and the local ISO. Contact vinciservices@va.gov for more information on this step.
- h. The next section on the Data Sources page asks you to select the type of patient identifier that will be used. Select "Real SSN" if you need patient names or SSNs or addresses. If you are working on a retrospective study that does not require you to know names or addresses, select "Identifiable data but no real or scrambled SSNs". Only rarely would "Scrambled SSN" be selected.
- i. In the next section of this page, you select the Requested Data Sources. "CDW Production Domains" is the most common choice, but there may be several others necessary for your project. See example below. Discuss the choices with your data analyst.

Scrambled SSN

Identifiable data but no real or scrambled SSNs

REQUESTED DATA SOURCES

Corporate Data Warehouse (CDW)

SQL Format

CDW Production Domains

CDW Raw Domains

CDW MCA (formerly DSS) NDE

MedSAS Files including VetsNet Files

TIU Text Notes (Requires Real SSN Approval)

Vital Status Files (includes BIRLS)

SAS Format (no longer available - same data available in SQL format above)

BIRLS

MCA (formerly DSS) NDE (legacy)

Vital Status Files with Scrambled SSN

Vital Status File Real SSN Crosswalk File

Mainframe - Access

BIRLS Real SSN (110JJ02)

MedSAS including VetsNet Files for National Level Real SSN (1100TT01)

MedSAS Files for VISN Level Real SSN (1100TT05)

Vital Status Files with Scrambled SSN (110NN06)

Vital Status File Real SSN Crosswalk File (110TT20)

Other Data

ADUSH Enrollment Files

Bereaved Family Survey

CAPRI/JLV (Individuals needing Capri/JLV access are selected on the participants page and require real SSN approval)

Care Assessment Need (CAN) Score (Requires Scrambled SSN Level Access)

GEC RAI/MDS

Health Economics Resource Center (HERC) Average Cost Data

Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

Homeless Registry

Legacy Data Warehouses (i.e. VISN 21)

MCA (formerly DSS) Web Reports

Million Veteran Program (MVP) - Available only to MVP approved studies

Million Veteran Program (MVP) plus Vital Status Files - Available only to MVP approved studies

OEF/OIF Roster File (DUA required for internal data distribution/use)

Patient Aligned Care Team (PACT) Implementation Index (Pi2)

Surgery Quality Data Users Group (SQDUG)

Traumatic Brain Injury Screening and Evaluation Data

Veterans Affairs Surgical Quality Improvement Program (VASQIP)

VSSC Web Reports

Data Access Systems

SAS Grid

- j. In the Data Access Systems section, select the "SAS Grid" box if the analyst will be using SAS rather than just SQL, which is likely for a complex set of inclusion/exclusion criteria.

- k. Finally, select the appropriate “Yes” or “No” buttons for questions about HIPAA Authorization and HIPAA Waiver, as agreed to by your IRB Approval letter. Click on “Next”.

The screenshot shows a web form with several checkboxes and two radio button questions. The questions are highlighted in yellow:

- Does your study require Informed Consent and HIPAA Authorization?
 - Yes
 - No
- Does your study require a HIPAA Waiver?
 - Yes
 - No

Other checkboxes include: Patient Aligned Care Team (PACT) Implementation Index (PI2), Surgery Quality Data Users Group (SQDUG), Veterans Affairs Surgical Quality Improvement Program (VASQIP), VSSC Web Reports, and SAS Grid. Navigation buttons at the bottom include "Previous", "Validate", "Save Draft", and "Next". A "* Required" label is present in the bottom right.

- l. The Documents screen will tell you which documents are required, and there is an upload button for each document. For IRB-approved protocols, there will be multiple documents listed. A common set of required documents is shown in the screen shot below. Some of the items will already exist, such as the approval letters and the research protocol. Others will need to be generated by you from forms created by VINCI, such as the “Research Request Memo”, the “CDW-Domain Checklist”, and the “Real SSN Access Request”. Some forms will require signatures, and others will not. All forms that require signatures can be signed electronically, if desired. To access the VINCI forms, there is a hyperlink named “DART Process and Forms” in the NOTICE below the large word “Documents” on the page. The hyperlink brings you to an Overview page for the DART Research Request Process. Click on the

The screenshot shows the "Data Access Request Tracker (DART)" interface. The breadcrumb trail is "HOME > DART Dashboard > Requests". The navigation tabs are "Information", "Participants", "Data", "Documents" (selected), and "Submit". The page title is "Documents".

NOTICE: Always check the Data Steward’s web site ([DART Process and Forms](#)) for the latest version of forms. Outdated forms will not be accepted. replace all the documents that are changing at one time.

Buttons: "Required Documents" and "Admin Documents".

REQUIRED DOCUMENTS

(671) South Texas HCS (San Antonio TX) (Primary Site)

- Research Request Memo**
Required for CDW Production Domains
- Research Study Institutional Review Board (IRB) Approval Letter**
Required for CDW Production Domains
- Sample Informed Consent and HIPAA Authorization**
Required for CDW Production Domains
- Research and Development (RD) Committee Approval Letter**
Required for CDW Production Domains
- IRB Approval of Waiver of HIPAA-Compliant Authorization**
Required for CDW Production Domains
- Research Protocol**
Required for CDW Production Domains
- CDW-Domain Checklist**
Required for CDW Production Domains
- Real SSN Access Request**
Required for CDW Production Domains

Documents & Forms tab on that page and then select the needed documents in the table on that page. (The link for the Documents & Forms page is: <http://vaww.vhdataportal.med.va.gov/DataAccess/PreptoResearchRequestProcess.aspx#DocumentsAndForms> .)

- m. When you select the Research Request Memo in the table, a fillable pdf will appear on your screen, like this:

Department of Veterans Affairs

Memorandum

Date: []

From: Principal Investigator [Insert Name of Principal Investigator]

Subj: Research Data Request Memo for: [Tracking Number - Name of Protocol]

To: Director, National Data Systems

The following information is required and all signatures must be obtained before any review of this request can take place:

Are all participants requesting access a VA employees or WOC employees? Yes No

Is this request for data use for a VA research study (includes pilot studies)? Yes No

Is this request for activities preparatory to research? Yes No

Select the type(s) of data needed: Real SSN Scrambled SSN PHI but No SSN

Is access to CAPRI / JLV being requested? Yes No

Is access to VSSC and/or MCA Web Reports being requested? Yes No

Will any requested data be transferred outside of the VA? Yes No

Will the data be stored in the VINCI Environment? Yes No Both

- n. Fill in the form with the same information you already entered into the online application. The middle block asks for information on 4 items, and you are expected to add the information directly into that block. Make use of the description that is already there and add in the requested information letter by letter. See the example below. For item A, give enough information about the tables within CDW that your analyst will use, without over-explaining. Ask the analyst to help with this. Finally, type in the signature blocks of the Principal Investigator and the Supervisor of the PI at the bottom of the form.

Department of Veterans Affairs

Memorandum

Date: Aug 14, 2019

From: Principal Investigator [Devjit Tripathy, MD, PhD]

Subj: Research Data Request Memo for: [2019-03-023-D, SELECT - Semaglutide effects on cardio]

To: Director, National Data Systems

The following information is required and all signatures must be obtained before any review of this request can take place:

Are all participants requesting access a VA employees or WOC employees? Yes No

Is this request for data use for a VA research study (includes pilot studies)? Yes No

Is this request for activities preparatory to research? Yes No

Select the type(s) of data needed: Real SSN Scrambled SSN PHI but No SSN

Is access to CAPRI / JLV being requested? Yes No

Is access to VSSC and/or MCA Web Reports being requested? Yes No

Will any requested data be transferred outside of the VA? Yes No

Will the data be stored in the VINCI Environment? Yes No Both

A. Data Requested: Access is requested for data from inpatient and outpatient records for all living veterans aged 45 to 80 who have been a patient within a VA facility associated with South Texas Veterans Health Care System (StA3n 671) within the previous 12 months (1 August 2018 through 15 August 2019). Data is requested from the Inpatient, Outpatient, Spatient, LabChem and VitalSigns domains, as listed in the CDW checklist.

B. How data will be used in the study: The data set will be searched by the data analyst for inclusion criteria and most of the exclusion criteria, looking back at least 15 years, to narrow down the list of persons to be recruited for the study. Real SSNs and names of patients will be collected and stored within the VINCI environment.

C. Real SSN is requested so the Research Coordinator can use local CPRS access to search the medical record for any remaining exclusion criteria that are difficult to observe by a database query, and also for contact information to recruit subjects.

D. Participants: Devjit Tripathy, MD, PhD (PI), VA Employee
Emina Case, BS (Coordinator), WOC
Michael J Mader, MS (Data Analyst), VA Employee

Estimated time the data will be needed for: [Dec 31, 2019]

- o. The Real SSN Access Request Form requires signatures from the PI, from the chair of the IRB (or a voting member), and the Associate Chief of Staff for Research (ACOS-R). If the IRB Approval letter specifically and clearly states that Real SSN access is required and approved, then the box can be checked and no signature is needed from the IRB chair.
 - p. Download and fill in any other required forms that you don't already have.
 - q. Upload documents that already exist such as the IRB approval letter and IRB protocol. To do this, click on the Upload button to the right of the document name and follow the prompts on the pop-up screen to Browse to the folder where the specified document is, highlight it, click Open, and then Upload File. This will bring you back to the Documents screen, and you can repeat the process for all remaining documents you have available. At this point, you can go no further in the DART application until you have required signatures on the new documents, so click on the "Save Draft" button at the bottom of the DART application and close it out.
5. Obtain signatures on the required DART documents. When you have all the forms ready, log back into the DART application and click on Next in the bottom right until you get to the Documents screen, and Upload the documents as described above. When all required documents are uploaded, click Next. This brings you to the Submit screen. If everything was filled in and attached correctly, you will get a positive message and can click on the "Submit Request" button, which will bring you back to the DART dashboard and you can relax a little, while NDS works on it. If something is missing however, you will be prompted to fix it.
6. Monitor your emails. Everyone with a checked Notifications box will receive emails. The sender address could be: dart@va.gov, VINCI@va.gov, ppt@va.gov, or Zzz_yyyymmaaD, where Zzz is the last name of the PI, yyyymm is the year and month of the request, and aaa is a 3-digit number that tracks the number of requests that month. If this is your first DART request, it's worthwhile to read all of the emails, but only the three with an asterisk below require action:
- a. Your DART application was initiated. (This will include your DART Tracking Number, which will be yyyy-mm-aaa-D as just described above.)
 - b. * Change requested. ***[If you get this email, click on the hyperlink in the email to go to the DART dashboard, find your DART request, click on the button corresponding to the change request, take the action requested, and re-submit the DART application.]***
 - c. Initial NDS review is completed and has been sent to another office for their review.
 - d. Request was approved by one of the offices and is being sent to the next one.
 - e. NDS has approved the request.
 - f. Welcome, you may begin to use the VINCI Standard Workspace.
 - g. You've been subscribed to a Sharepoint site for your study. (This one will have the name of the VINCI data manager in it.)
 - h. * The VINCI data manager is waiting for your input. ***[When you get this one, the data analyst needs to go to the study's Sharepoint site and give a detailed description of the data needed. It should include a description of the limits of the cohort for the VINCI data manager to establish, such as "only living veterans 40 years old or older who have been inpatients at Audie Murphy VAMC, station 671, between 1 Oct 2015 and 30 Sep 2018 with primary diagnosis icd10code of yyy". The data description also needs to include the names of domains and tables needed, as well as a date range for the fact tables (for instance, you***

might need to look at outpatient records for up to 10 years prior to the cohort date range). The data description needs to be compatible with what was in the DART request.]

- i. * The VINCI data manager has a new message for you *[This will either say the data has been provisioned (Hurray!), or that the data manager needs additional info to complete the request.]*

- 7. When the data is provisioned, if the query is simple the data analyst can now use SQL Server Management Studio and get you an answer within 2 or 3 business days. For more complex queries, the data analyst will probably use SAS. If that’s the case, the data analyst needs to email a request to VINCI SAS Admins to set up space on the SAS server (see example below). Setting up space on the SAS server usually takes up to one business day, and then the coding will take two to eight business days.

How to request space on the SAS server: The email from the VINCI data manager telling you the data has been provisioned has a table like the one below. Use that info, plus the Domains you listed in your request, in an email to the VINCI SAS Admins.

Database Connection Information:	
Database	ORD_Pugh_201903017D
VINCI Database Server	vhacdwrB03.vha.med.va.gov
Extracted Data Schema (read only)	Src
Study Read/Write Schema	Dflt

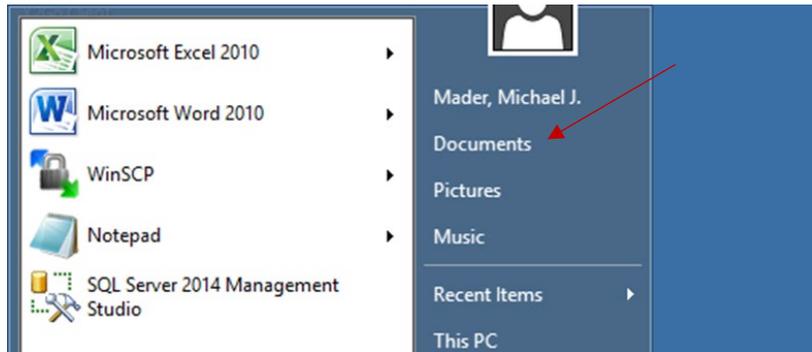
Example email to VINCISASAdmins@va.gov :

I have approval from NDS and VINCI for a prep-to-research study database. Can you please assign a DATASRC pointer?

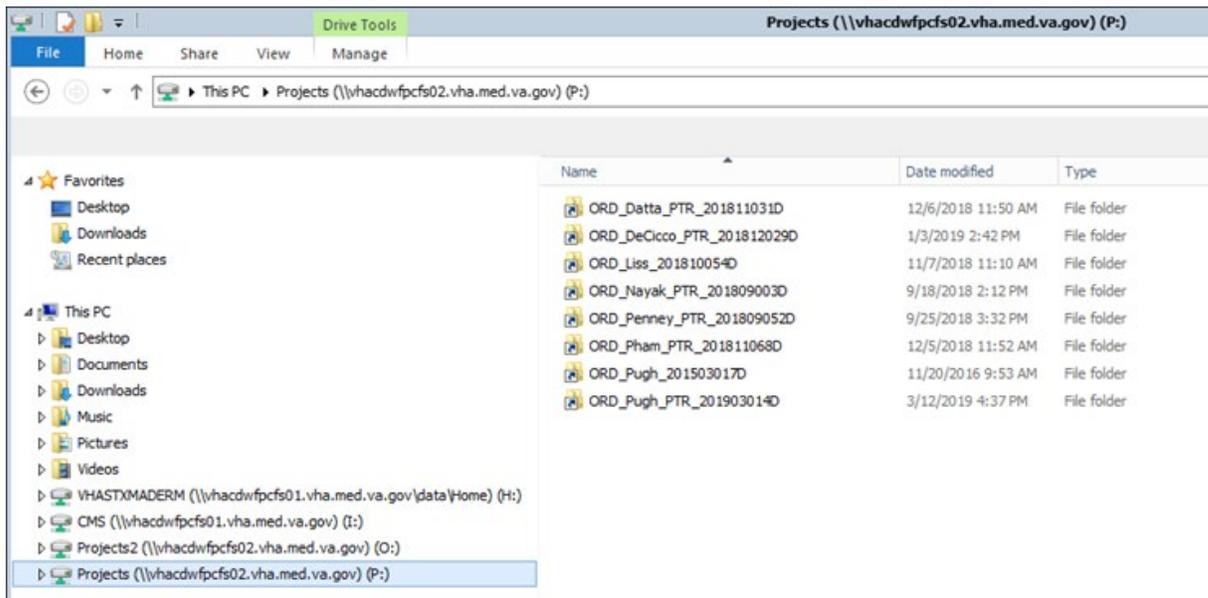
Server IP address: vhacdwrB03.vha.med.va.gov
Database created by VINCI: ORD_Pugh_201903017D
Schemas to query: Src, Dflt, Dim, Outpat, Inpat, Patient, HF

- 8. When the coding is completed and data is available, the analyst will most likely put data in an Excel spreadsheet in the project folder behind the VINCI firewall. To get to the data behind the firewall:
 - a. Go to <https://vaww.vinci.med.va.gov/VinciCentral/Home/Index>
 - b. Left click once on the Launch Workspace hyperlink in the upper left of the screen.
 - c. Left click once on Full Standard Workspace (1 Monitor) icon on the pop-up box.
 - d. Left click once on Open on the white dialog box at the bottom of the screen.
 - e. Enter your 6-digit PIV code and wait about 30 seconds. This takes you to a remote site.
 - f. When the Security Warning screen comes up, click OK and wait about 30 seconds. This will result in a blue desktop screen with a few icons and a Start button on the bottom left that looks like an aqua-colored shell.

- g. Left click once on the Start button, and left click once on Documents in the right column.



- h. When the list of folders comes up, left click once on Projects (P:) in the left column, which will then give you a list on the right of all the folders available to you. One of the folders will be named ORD_Zzz_yyyymmaaD, where Zzz is the PI's last name and yyyymmaaD is the DART tracking number for your study. Left click twice on the appropriate folder and you will find the file(s) that the data analyst left for you.



- i. There is a blue dialog box centered at the top of the remote screen, with a name in it, something like: VHACDWDWHRDBKR.VHA.MED.VA.GOV. If you need to take a break from the remote screen and get back to your local screen, left click once on the “minus sign” to the right of the name. When you want to go back to the remote screen, left click once on the icon of a blue screen you will find at the bottom of your local screen. When you are finished using the remote site, left click once on the “letter x” to the right of the name on the blue dialog box at the top of the remote screen and confirm that you want to disconnect.

9. You will receive an email from dart@va.gov on the data access expiration date. Data can no longer be pulled after the expiration date, unless you do an amendment to ask for an extension. You will also need to do an amendment if you need to grant data access to an additional participant.