Automating the Compliance of Health Research with Virtual Research Desktop (VRD)

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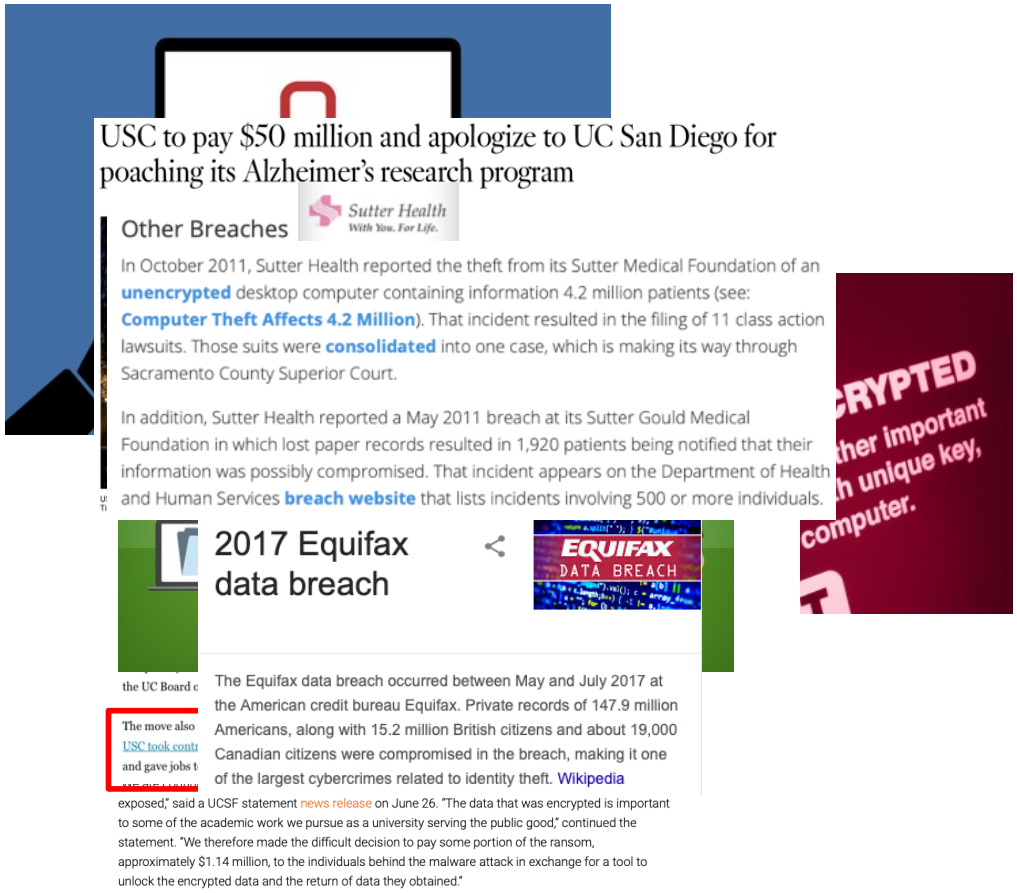
Why Is This Topic Important?

- Inappropriate removal of UC research data assets.
- Inappropriate third party data transfer requests ‘and the IRB approved it…”
  - Human research protections (IRB) vs policy and legal compliance (Data Use Agreement)
- A common risk for data breaches are loss of laptop/mobile devices.
  - Sutter hospital loss
- Ransomware
  - Unmanaged, unprotected, or misconfigured devices



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History and Compliance

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What's The History?

- In 2017 we identified about 800 UCSD Health associated AWS accounts
  - We had ZERO visibility or security controls in place to monitor account activity.
  - We did not know what types of data, work loads, or potential risks associated.
  - UC San Diego Health did not have an AWS environment for research.
- Dr. Hogarth's first week at UCSD
  - Data Extraction of 10 million narrative clinical notes.
- "Build it (right) and they will come"

  - In late 2017 we started working with AWS Professional Services and Xpertech to help build out the UCSD Health Secure Research Cloud (HSRC).
  - We partnered with IS Security, ACTRI, DBMI, and UCSD Health research groups.

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Quick Review of Federal and California Privacy Laws

- The Health Insurance Portability and Accountability Act (HIPAA), 1996
  - Electronic Protected Health Information (ePHI) and the 18 identifiable elements
  - HIPAA is a **policy**, not specific security controls. Only two specific technical controls are mentioned no generic logins and encryption required
  - **Covered entities** are defined in the **HIPAA** rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information.
- California's Confidentiality of Medical Information Act (CMIA) 2009
  - Provides stronger privacy protections for medical information.
  - CMIA's primary purpose is to protect an individual's medical information, in electronic or paper format, from unauthorized disclosure.
  - **Personal** and Administrative Fines and Civil Penalties (including jail time)

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Four Technical Safeguards Categories for PHI

1. **Access Control**
   - A covered entity must implement technical policies and procedures that **allow only authorized persons** to access electronic protected health information (e-PHI)
2. **Audit Controls**
   - A covered entity must implement hardware, software, and/or procedural mechanisms to record and examine access and other **activity in information systems** that contain or use e-PH
3. **Integrity Controls**
   - A covered entity must implement policies and procedures to ensure that e-PHI is **not improperly altered or destroyed**. Electronic measures must be put in place to confirm that e-PHI has not been improperly altered or destroyed
4. **Transmission Security**
   - A covered entity must implement technical security measures that **guard against unauthorized access** to e-PHI that is being transmitted over an electronic network.

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Framework(s) for Achieving Compliance

- National Institute of Standards and Technology (**NIST**)
  - Maps to security controls detailed in NIST SP 800-53 (FISMA moderate)
  - Both technical and organizational (access controls) security controls
    - https://www.nist.gov/healthcare/security/hipaa-security-rule

Moderate Impact Controls

Showing **159** controls:

No.	Control	Priority	Low	Moderate	High
AC-1	ACCESS CONTROL POLICY AND PROCEDURES	P1	AC-1	AC-1	AC-1
AC-2	ACCOUNT MANAGEMENT	P1	AC-2	AC-2 (1) (2) (3) (4)	AC-2 (1) (2) (3) (4) (5) (11) (12) (13)
AC-3	ACCESS ENFORCEMENT	P1	AC-3	AC-3	AC-3
AC-4	INFORMATION FLOW ENFORCEMENT	P1		AC-4	AC-4
AC-5	SEPARATION OF DUTIES	P1		AC-5	AC-5
AC-6	LEAST PRIVILEGE	P1		AC-6 (1) (2) (5) (9) (10)	AC-6 (1) (2) (3) (5) (9) (10)
AC-7	UNSUCCESSFUL LOGON ATTEMPTS	P2	AC-7	AC-7	AC-7
AC-8	SYSTEM USE NOTIFICATION	P1	AC-8	AC-8	AC-8
AC-11	SESSION LOCK	P3		AC-11 (1)	AC-11 (1)
AC-12	SESSION TERMINATION	P2		AC-12	AC-12

- Center for Internet Security **(CIS)**
  - CIS Level1 meets FISMA moderate and HIPAA requirements
  - CIS resources are developed to work well as stand-alone resources or as companions to additional frameworks
    - https://www.cisecurity.org/cybersecurity-tools/mapping-compliance/

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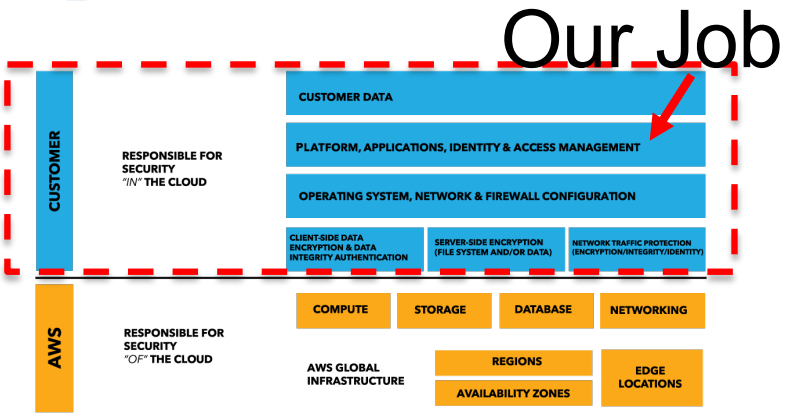
Compliance in AWS (PHI/HIPAA)

- Business Associate Agreement (BAA). Extension of the **covered entity** to vendor and contractors.
- Shared Responsibility Model
  - Hypervisor level and below is AWS responsibility
  - Above is customer responsibility
- HIPAA **eligible** ≠ compliant
  - Cloud providers offer 'HIPAA eligible services'
  - This still requires customer to apply all controls that fall in their section of the shared responsibility model
  - Non-HIPAA compliant services can be used in the architecture as long as no PHI/PII data passes through those services

HIPAA Business Associate Agreements

The HIPAA Regulations reflect the understanding that a covered entity, such as the University of California, often requires the services of third parties ("business associates") to conduct its operations. A business associate is a person or entity that creates, receives, maintains or transmits protected health information ("PHI") on behalf of the University. A business associate relationship exists when an individual or entity, acting on behalf of the University, assists in the performance of a function, activity or service involving the use or disclosure of PHI. These functions, activities and services, to or on behalf of the covered entity, include, but



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https://www.ucop.edu/ethics-compliance-audit-services/compliance/hipaa/hipaa-business-associate-agreements.html

Architecture:

UCSD Health Secure Research Cloud (HSRC)

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Andrew Greaves, Enterprise Cloud Architect, UC San Diego Health

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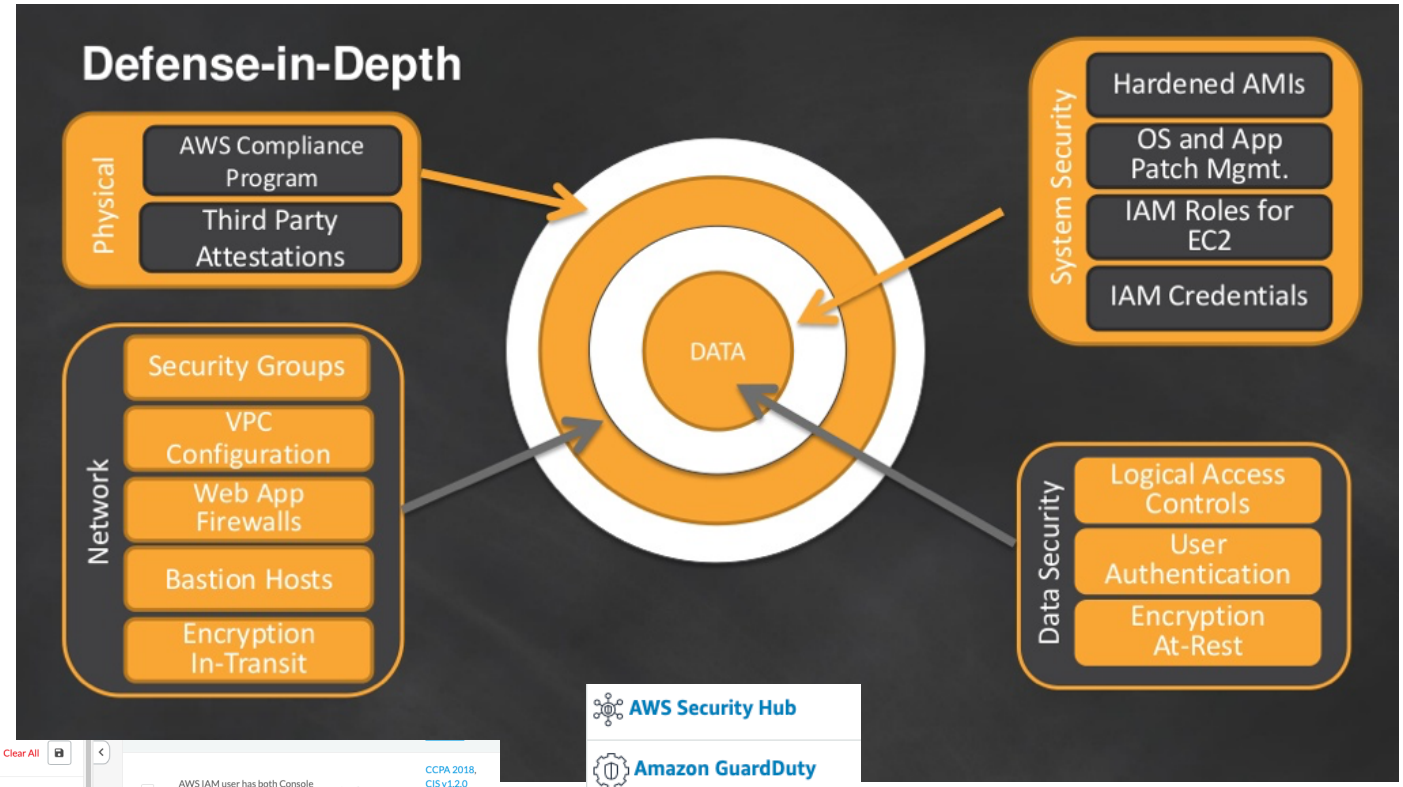
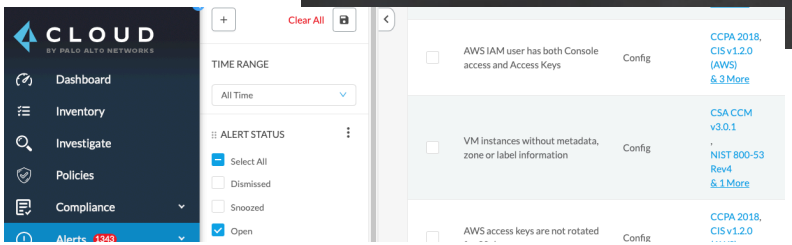
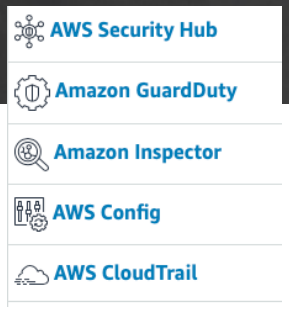
AWS HIPAA Environment

- Multi-layered Security Approach
- HIPAA Boundary
- Centralized Logging
  - VPC Flow Logs, CloudTrail, System logs
- Transit VPC and Palo Alto
- Ingress and Egress is only through the UCSDH PA's and their defined network rules rules
- VPC isolation
- CISO approval required







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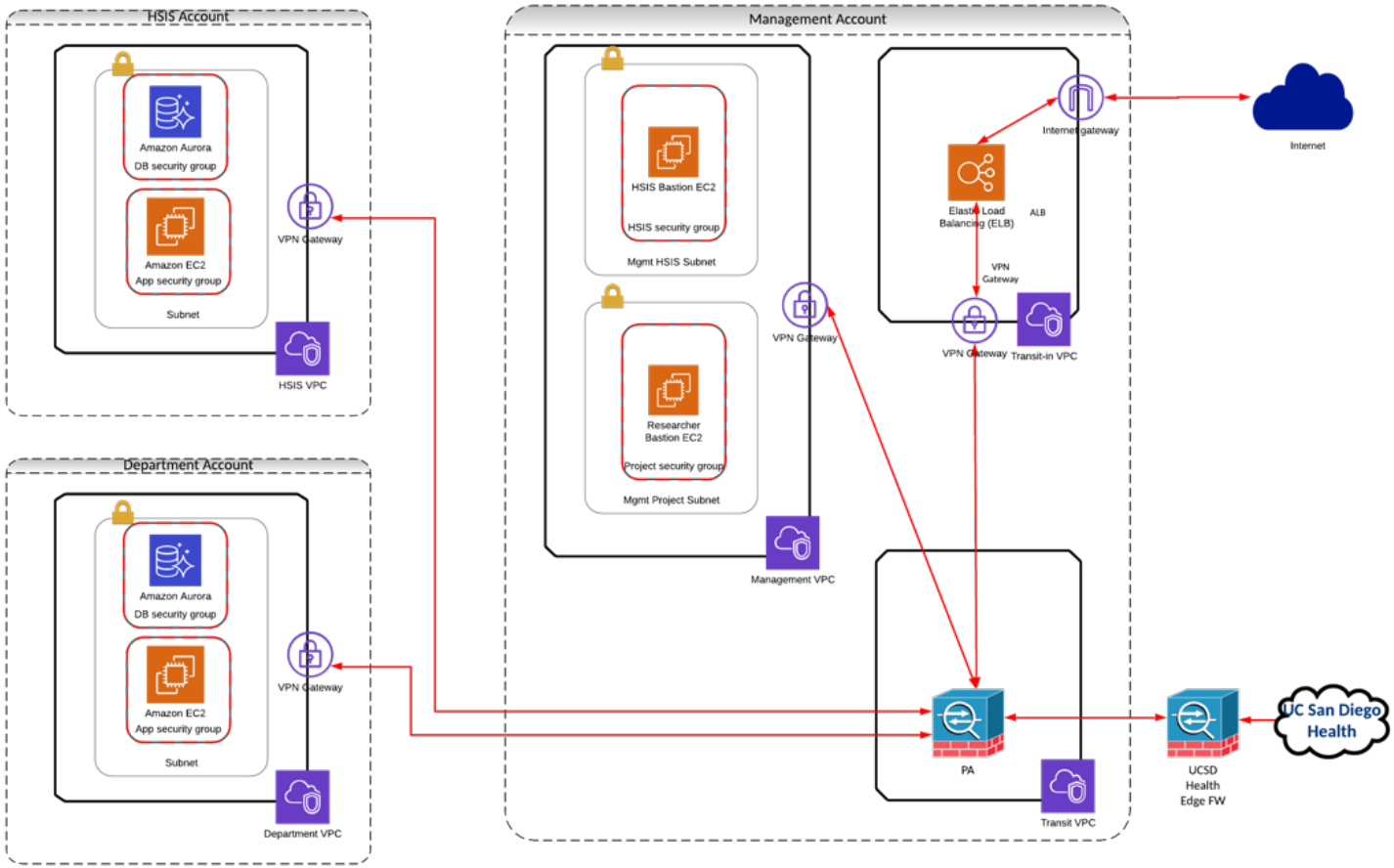
HIPAA Boundary Controls (simplified)



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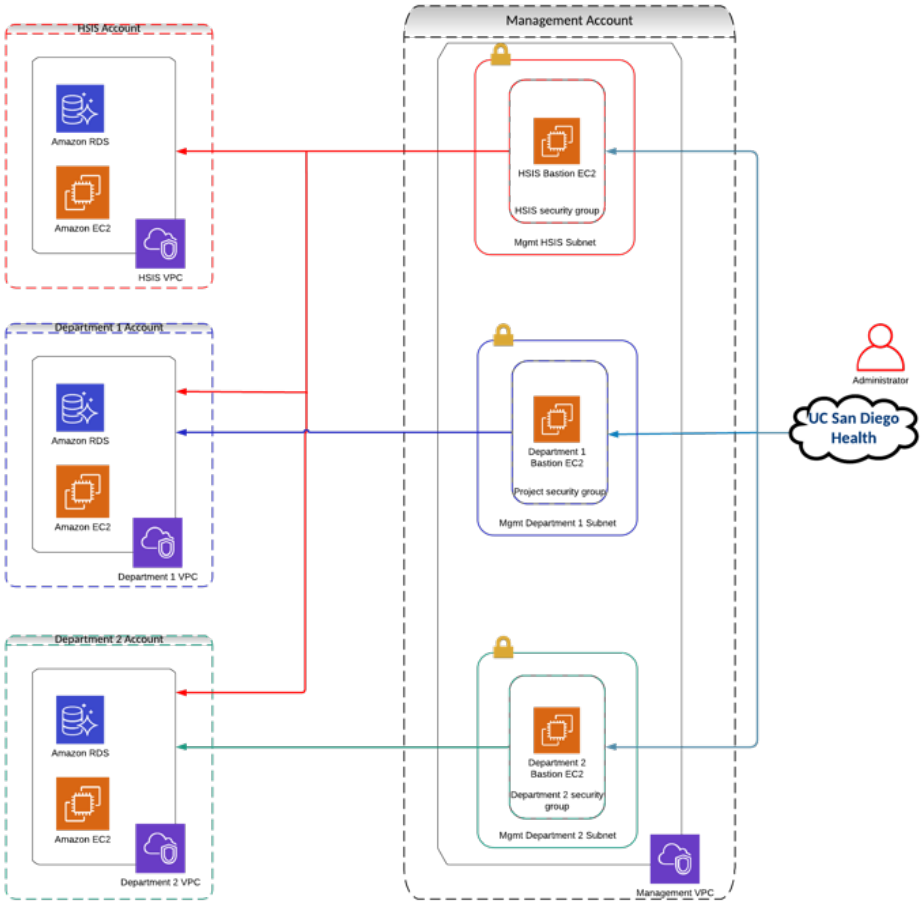
Multi-Researcher/Department Access Architecture



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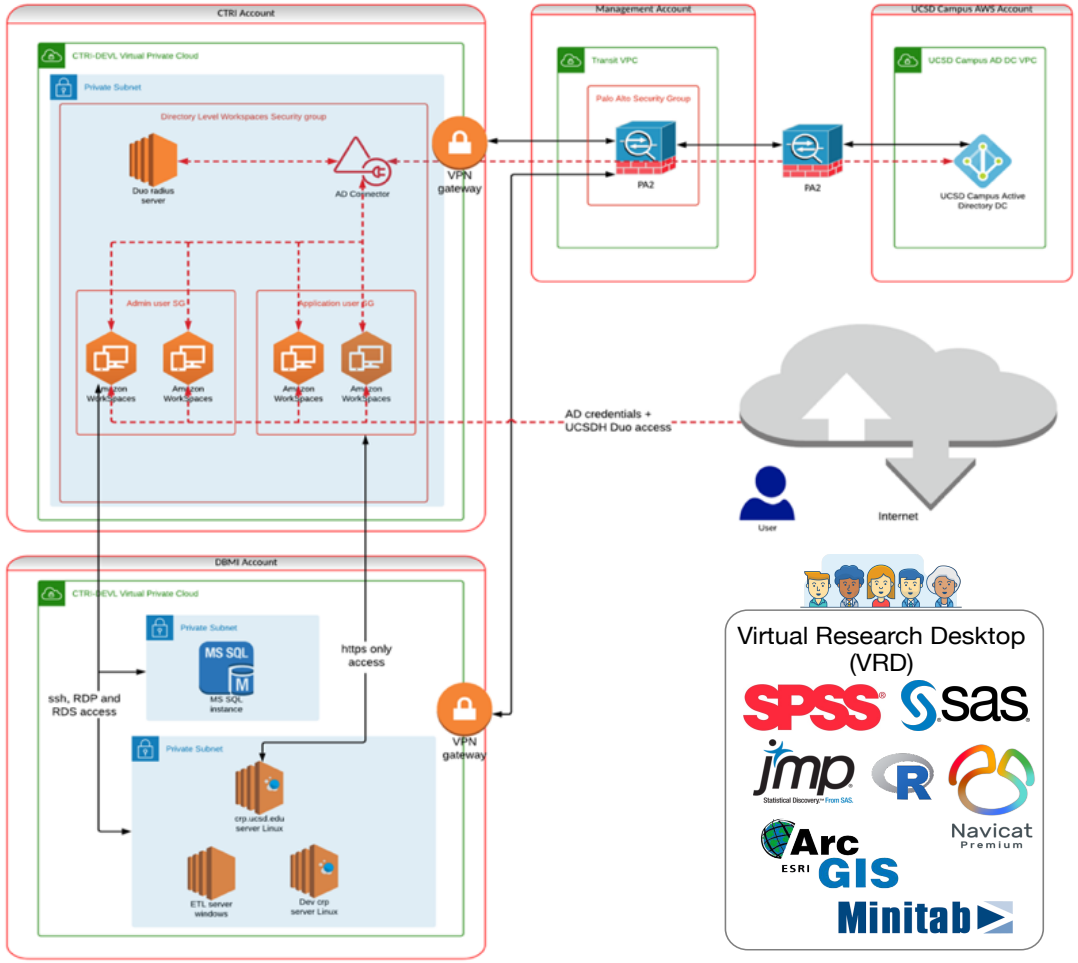
Secure AWS workspaces: Virtual Research Desktop (VRD)



ACTRI, the VRD and Use Cases

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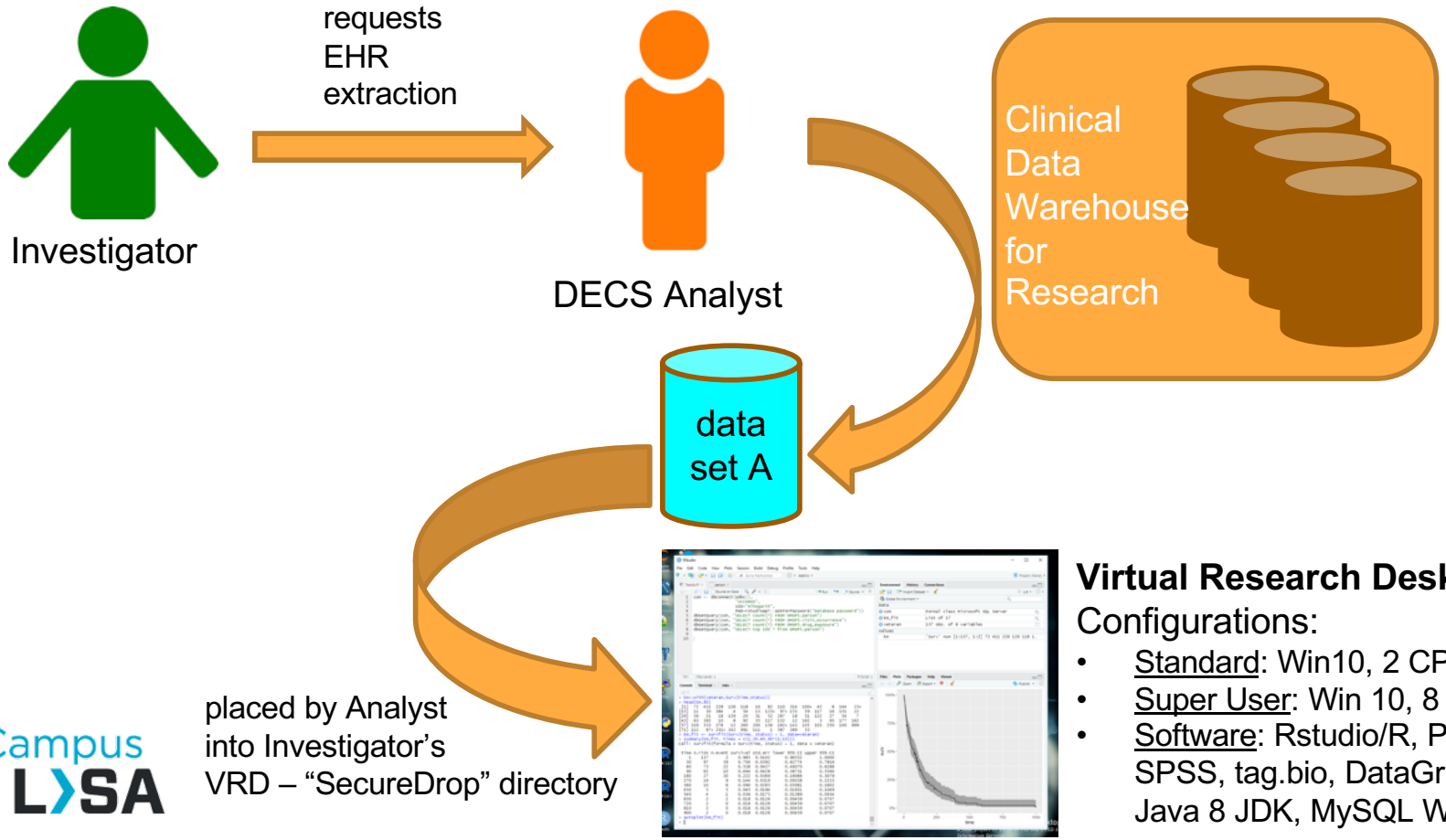
ACTRI –Data Extraction Concierge Service (DECS) and VRDs



Virtual Research Desktop (VRD)
Configurations:

- Standard: Win10, 2 CPU, 4Gb mem
- Super User: Win 10, 8 CPU, 32Gb mem
- Software: Rstudio/R, Python/PyCharm, SPSS, tag.bio, DataGrip SQL tool, MATLAB, Java 8 JDK, MySQL WB, PgAdmin

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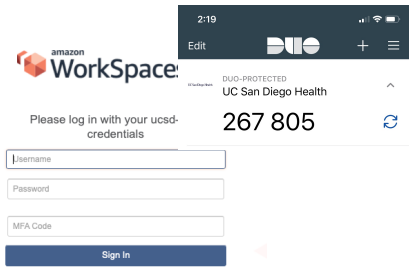
THE VIRTUAL RESEARCH DESKTOP (VRD)

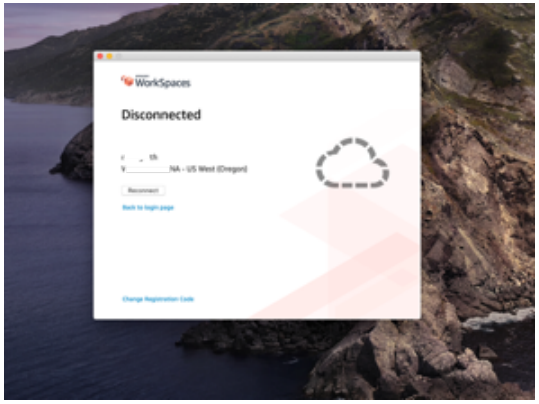
- It is a modified version of the Amazon Web Services (AWS) Windows 10 "Workspace" virtual machine
- Runs in the protected UCSDH Secure Cloud in AWS
  - in the AWS HIPAA environment
  - approved by UCSDH CSO for PHI
- Provisioned with:
  - SPSS
  - R/RStudio
  - Python/PyCharm
  - Java 8 JDK
  - Depending on approval, access to internal databases – ie, UC CORDS
  - tag.bio based access to available databases

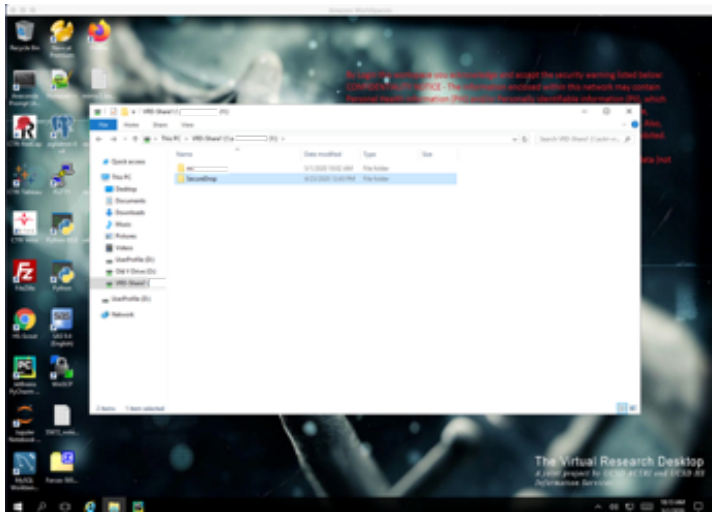
UCSD Health Virtual Research Desktop

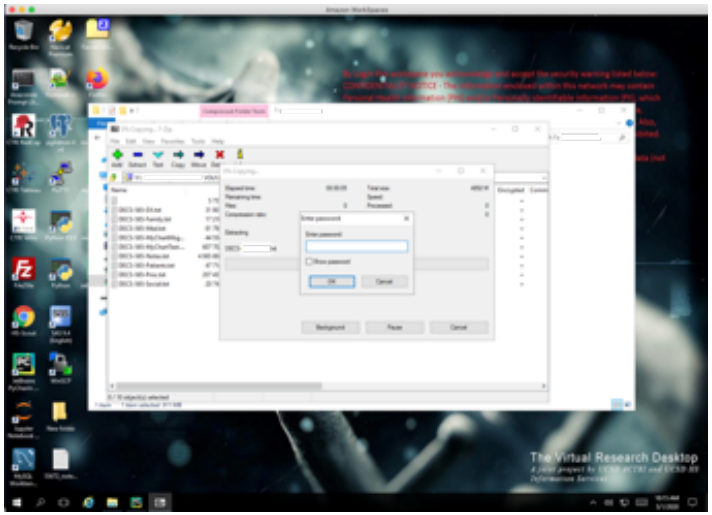
UC San Diego
ALTMAN CLINICAL AND TRANSLATIONAL RESEARCH INSTITUTE

Secure AWS workspaces: Virtual Research Desktop (VRD)









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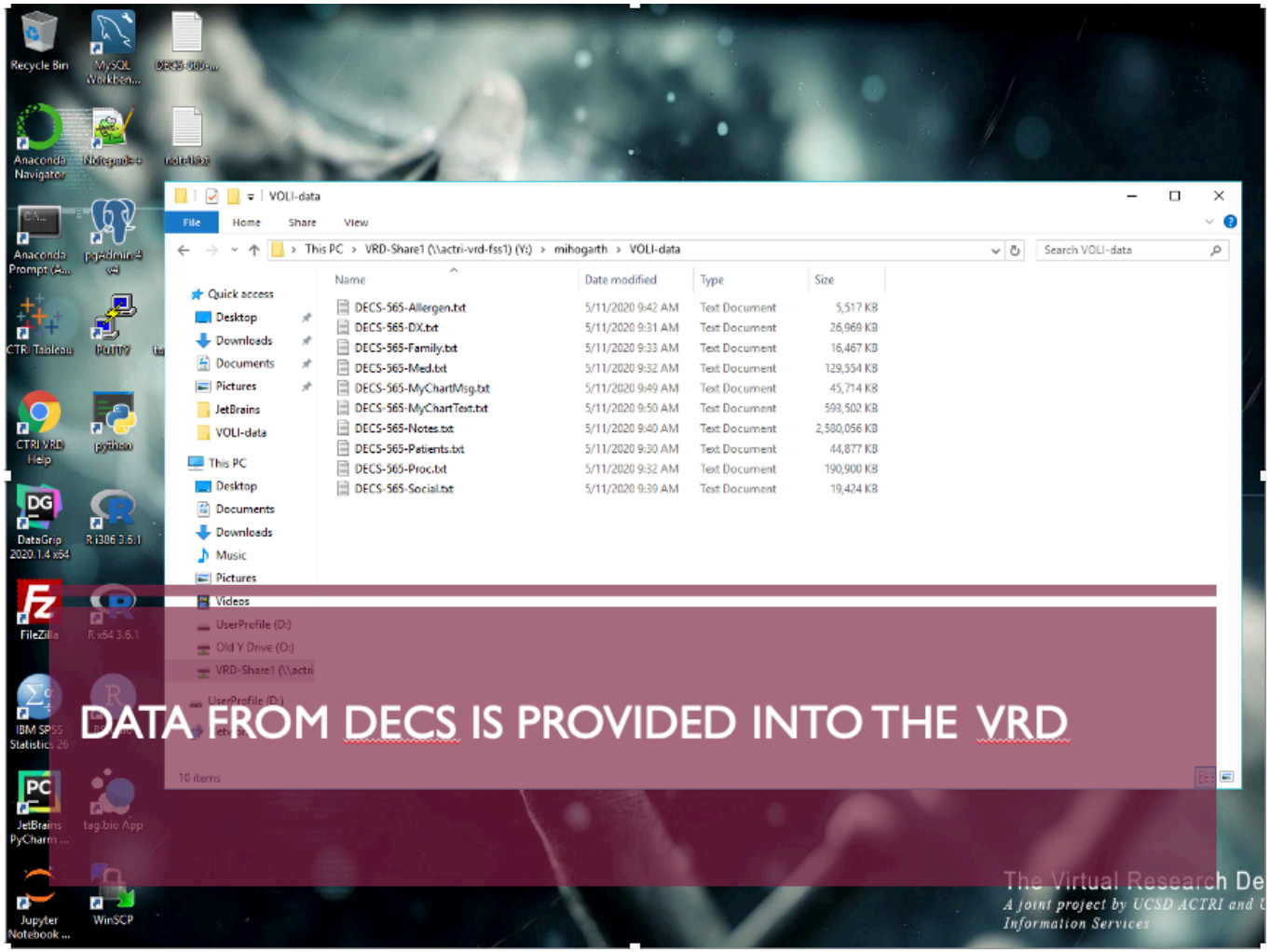

DATA FROM DECS IS PROVIDED INTO THE VRD

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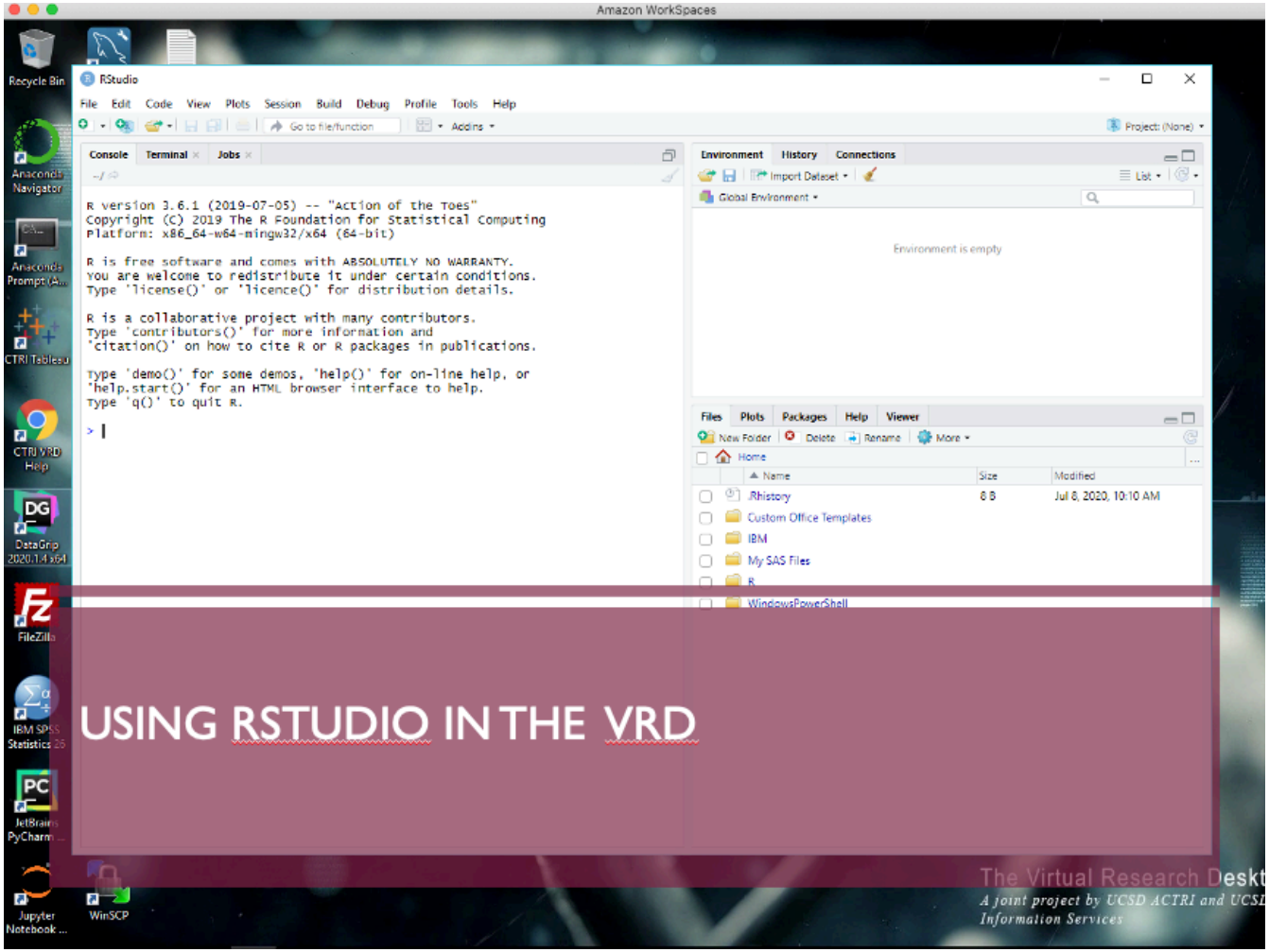

USING RSTUDIO IN THE VRD

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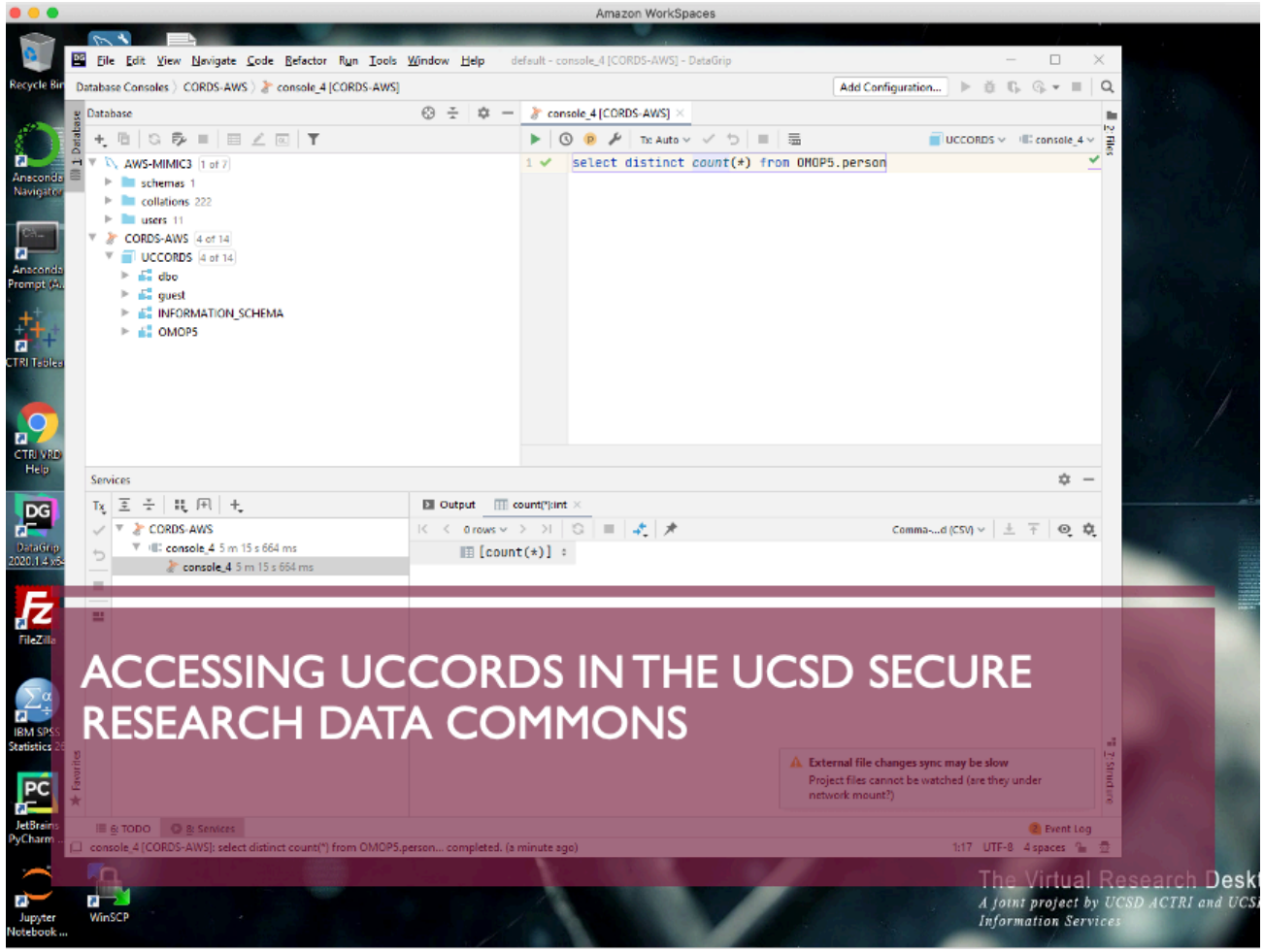
Amazon WorkSpaces
File Edit View Navigate Code Refactor Run Tools Window Help
default - console_4 [CORDS-AWS] - DataGrip
Database Consoles 〉 CORDS-AWS 〉 console_4 [CORDS-AWS]
Add Configuration...
Database
console_4 [CORDS-AWS]
AWS-MIMIC3 1 of 7
schemas 1
collations 222
users 11
CORDS-AWS 4 of 14
UCCORDS 4 of 14
dbo
guest
INFORMATION_SCHEMA
OMOP5
select distinct count(*) from OMOP5.person
Services
Output
count(*):int
[count(*)]
console_4 [CORDS-AWS]: select distinct count(*) from OMOP5.person... completed. (a minute ago)
ACCESSING UCCORDS IN THE UCSD SECURE RESEARCH DATA COMMONS
The Virtual Research Desk
A joint project by UCSD ACTRI and UCSD Information Services

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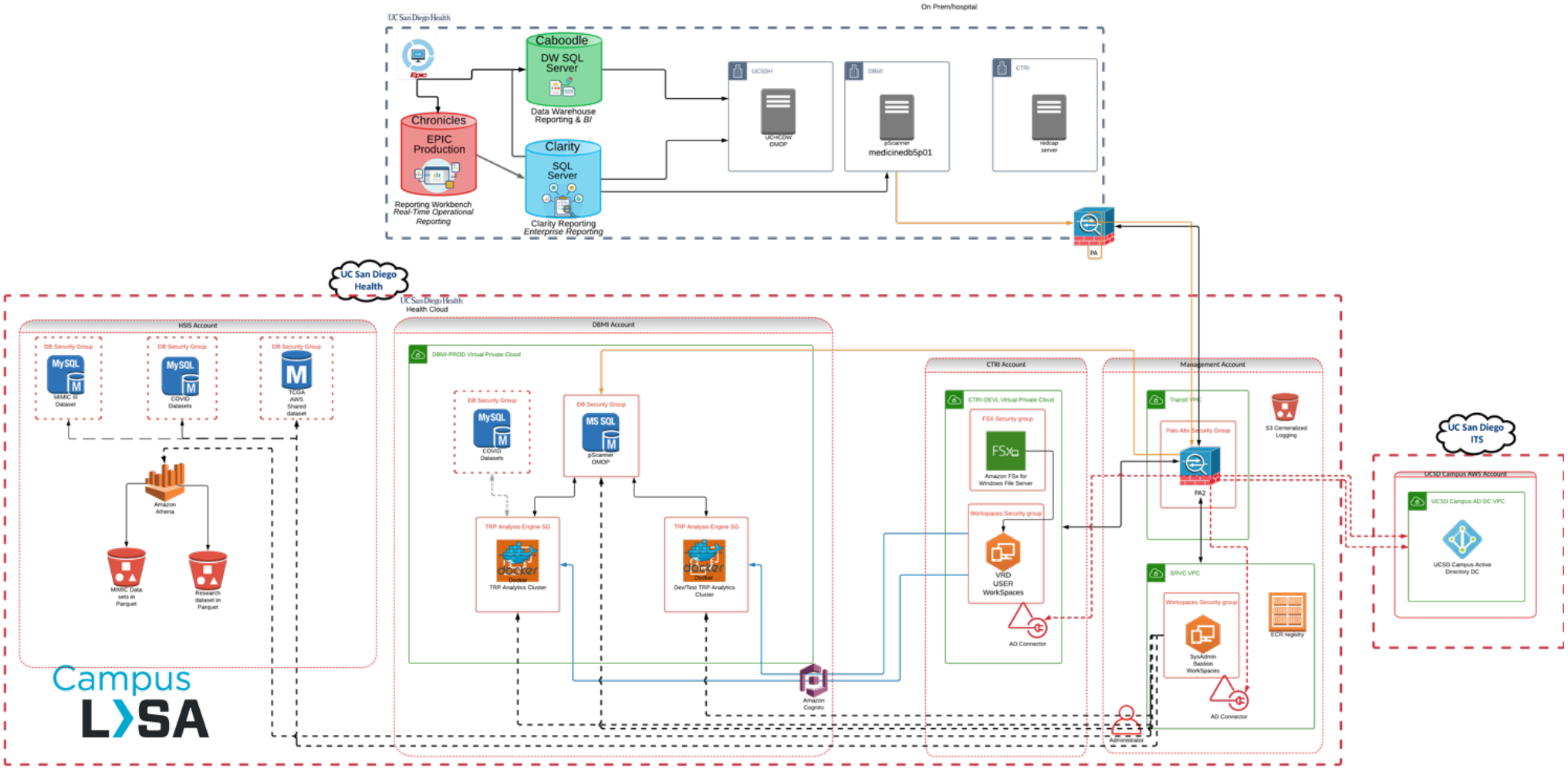
VRD and Multi-User Datasets

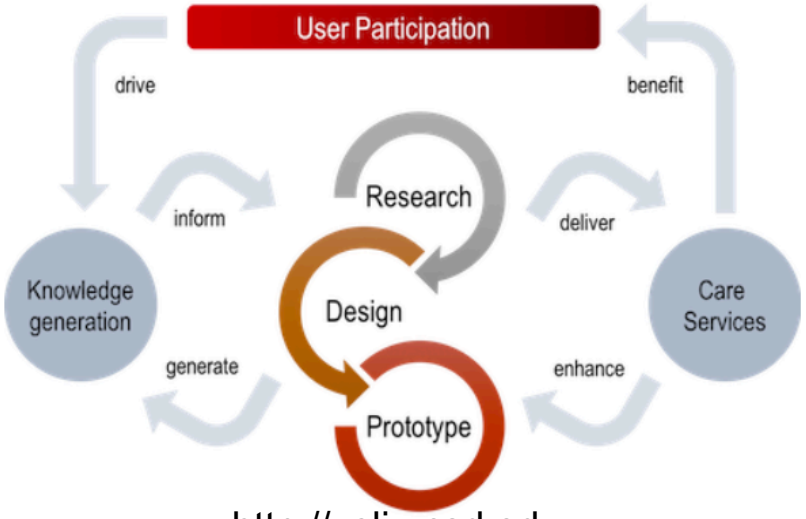


Use Case 1: VOLI Collaboration

Personalized and context-aware voice-based digital assistant to improve the quality of life and the healthcare of older adults, and consequently, to reduce caregiving burden and optimize the interactions with healthcare and service providers.

What Data is VOLI Requiring?

- Full text of all clinical notes for patients in the cohort
- All lab test data
- Patient demographics
- MyChart communications – messages between doctor and patient



http://voli.ucsd.edu

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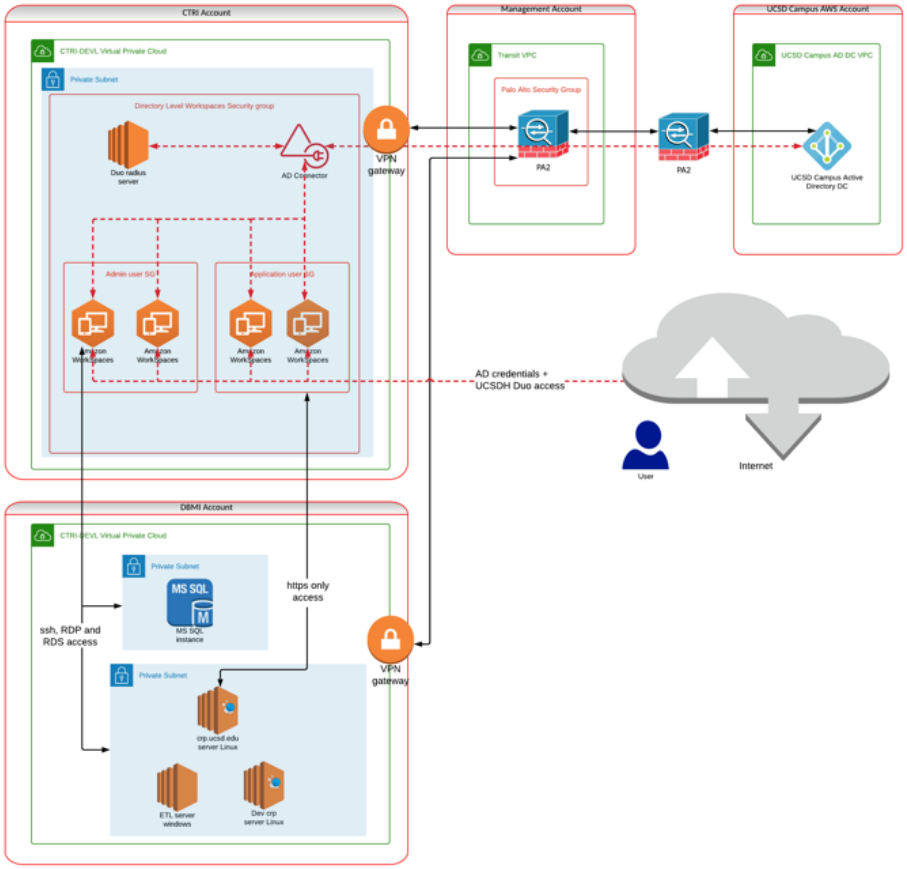
Use Case 2: Access to COVID Data – Translational Research Portal

- Analysis application for dataset exploration, building reproducible data queries
- Clinical data warehouse using a common data model (OMOP)
- This is now being used for COVID research and registry work
- Access through “Virtual Research Desktop” -- AWS Workspace confined to the research enclave



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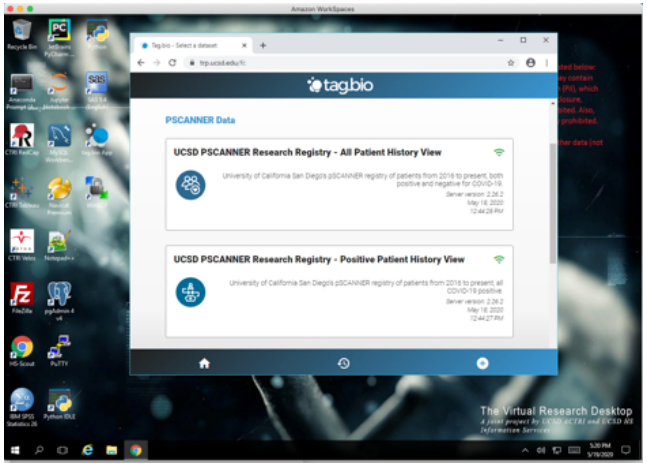
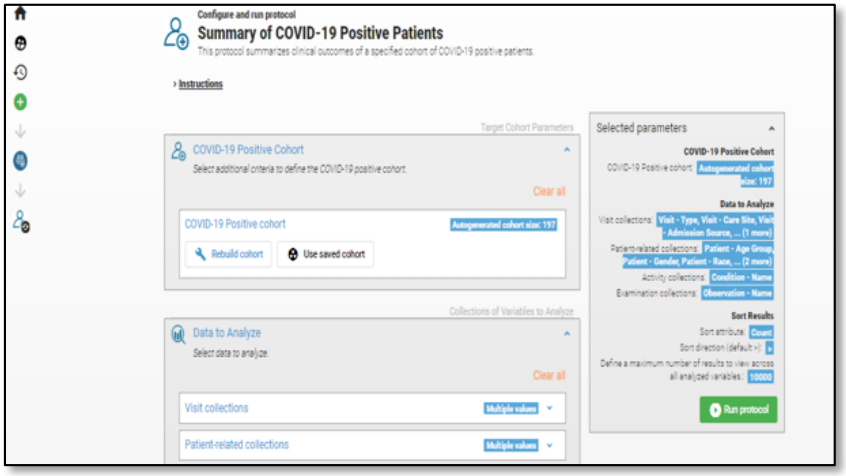
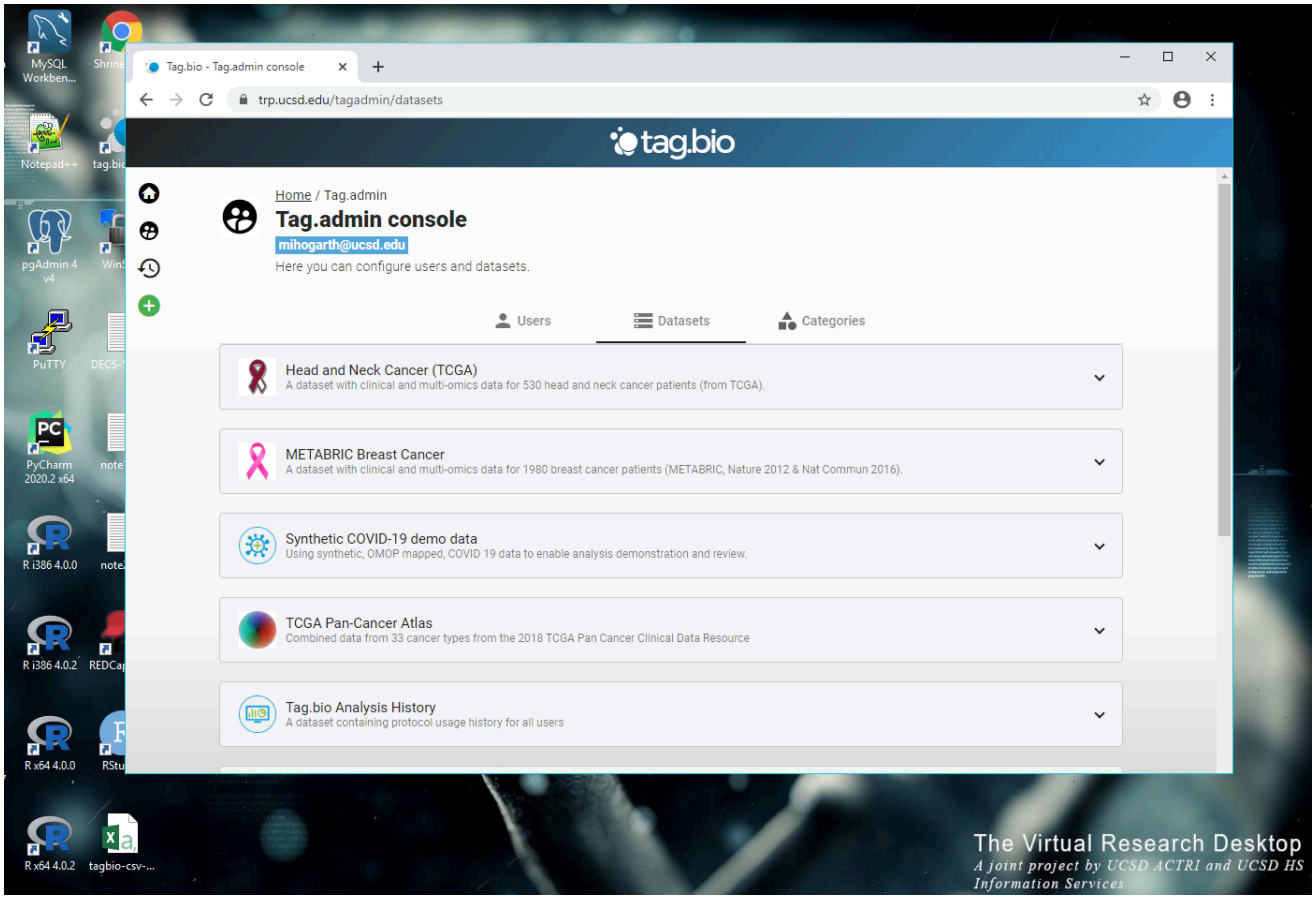
THE TRANSLATIONAL RESEARCH PORTAL: A TOOL FOR DATA EXPLORATION AND ANALYSIS

- we have installed the tag.bio system in our research cloud and it has access to data sets in our 'secure data commons database'
- the tag.bio system provides population level access and ability to perform analysis
- a user can 'slice' the cohort and select specific analyses (demographic, survival, comparison between cohorts)
- planned → with approval, provide 'download' of limited data set (LDS) row-level data from selected data set into the investigator's virtual research desktop for further analysis





Use Case 2: Access to COVID Data – Translational Research Portal Additional Dataset



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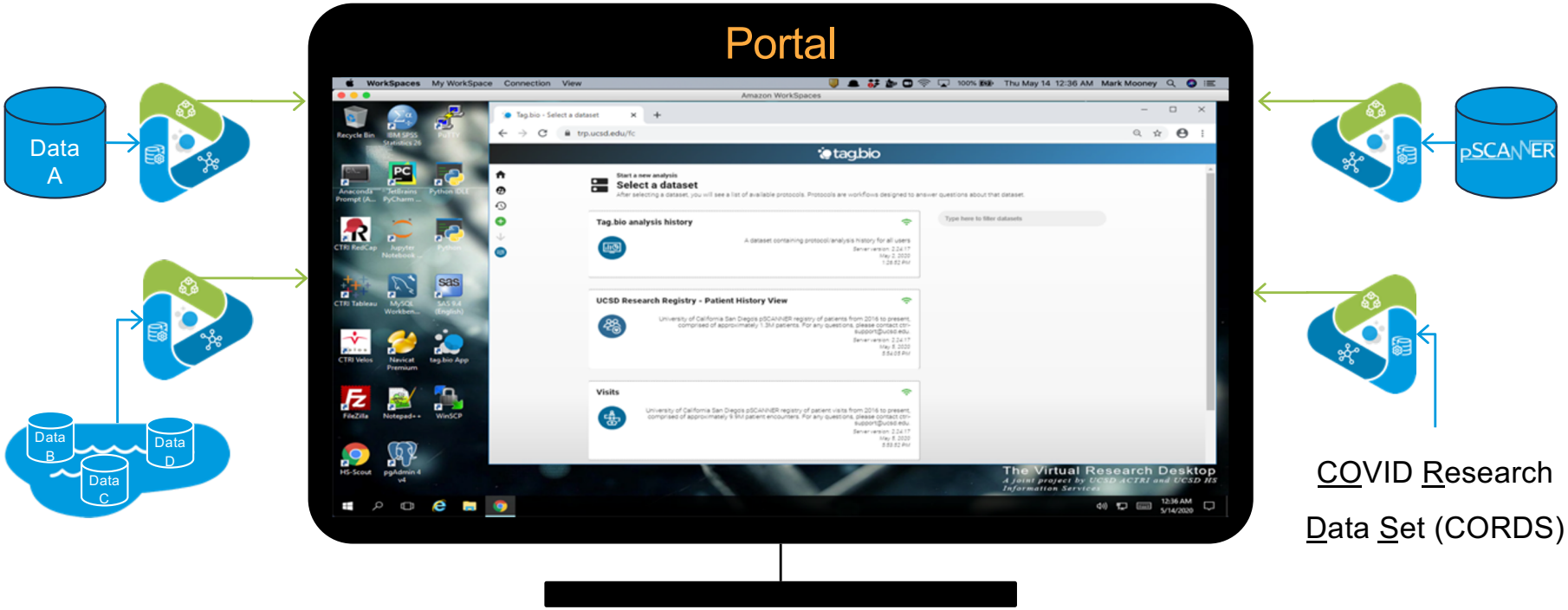
The Translational Research Portal allows access to data nodes



Decentralized data. Centralized analysis.

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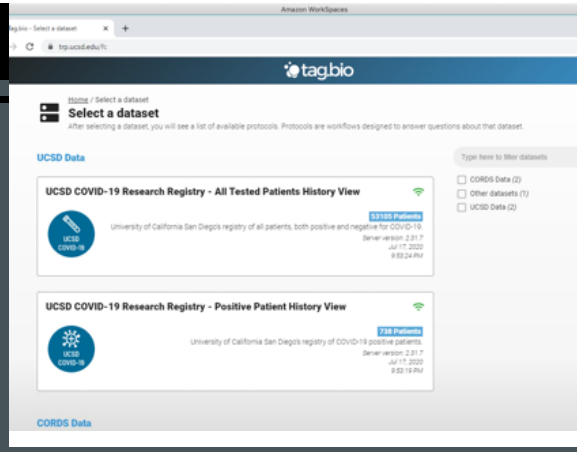
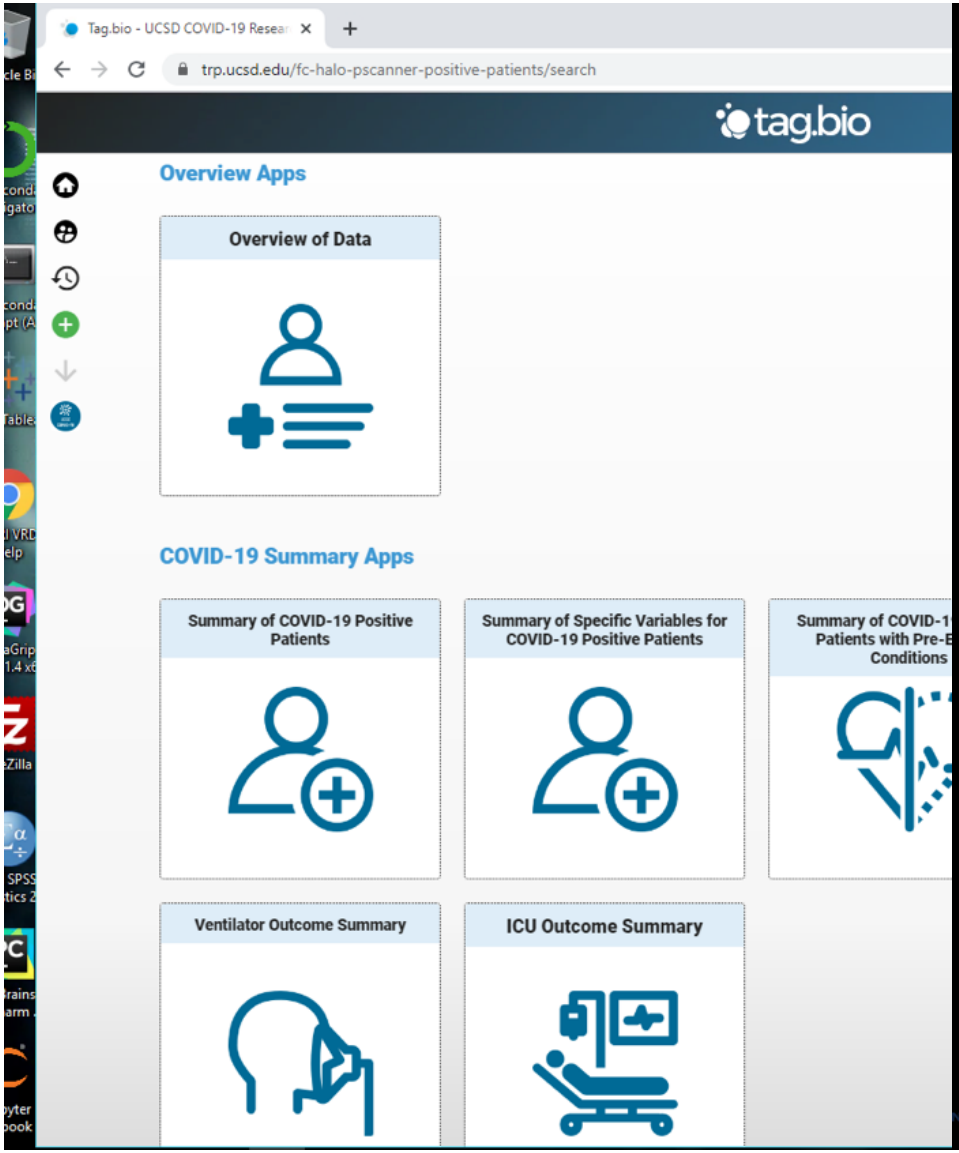


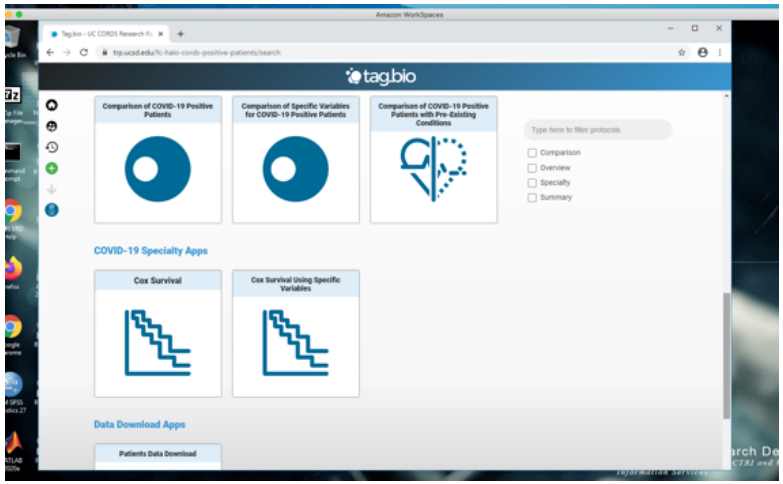
USING THE EXPLORATION TOOL

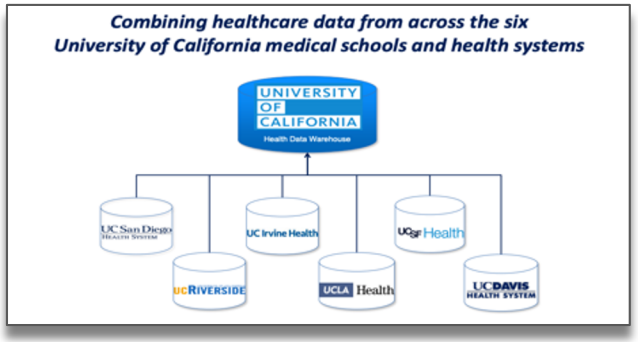
- the ucsd tag.bio system was loaded with data from the COVID-19 registry in the secure research data commons database
- the system provides a simple way to interact with the data set through "analysis protocols"



Use Case 2: UC CORDS - COVID-19

- UC Health 2019:
  - 19 health professional schools,
  - 5 academic medical centers,
  - 12 hospitals
  - 173,000 annual inpatient admissions
  - 4.8M annual outpatient visits
- UC Health Data Warehouse 2019:
  - ~5M patients seen since 2012
  - 100M encounters
  - 300M procedures
  - 1B measurements





The UC COVID Research Data Set (UC CORDS)

Aug 14 2020
- 175,517 COVID tested patients
- 6,056 COVID+ patients
- all labs, meds, vitals, 29 ICU data elements
- 319,952,837 “data points/”

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Acknowledgments

- Health Information Services – Dr. Chris Longhurst, John Torello, Ken Wottge, Alan Sato, Derek Dutt, Dr. Amy Sitapati
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- ITS – Declan Fleming, Nick Marangella, James Dotson, Brian DeMeulle
- Xpertech Solutions Inc. – www.Xpertech.io
- Tag.bio – Mark Mooney, Tom Covington, Jesse Paquette, Wade Webster, Kenn Broadhagen
- AWS – Dr. Prathima Srinivas, Heather Matson, Randy Ridgley, Danyell Wilt
- DBMI – Paulina Paul
- The Campus LISA Team!!!!!

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