



RAD_x RAD DCC D_x Core

Monthly All Hands



**Rapid Acceleration
of Diagnostics (RADx)**

Agenda

April 12, 2021

RADx-rad All Hands Meeting

Meeting is being
recorded



Updates from the core



Variant Deep Dive with Dr.
Carlin

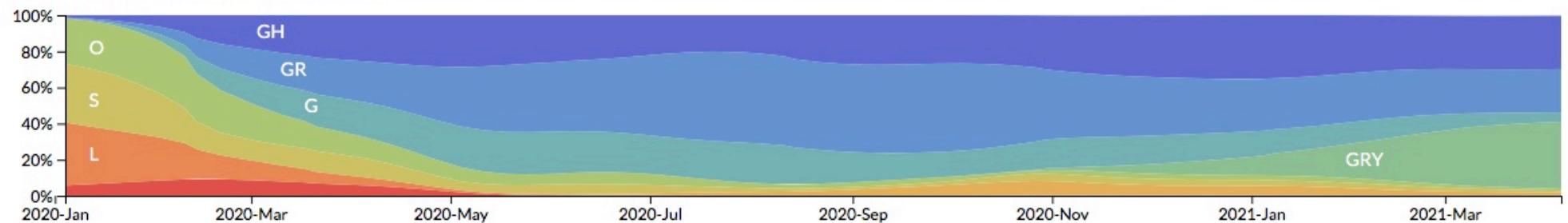


Questions

- Variant shipping:
 - 15 Awardees MTA's request, 15 in process or complete
 - 2 Shipped
 - 1st Virus received last week

SARS-CoV-2 changes in clade frequency

Frequencies (colored by GISAID Clade)



Data updated 2021-04-09 • [DOWNLOAD DATA](#) • Auspice v2.25.1

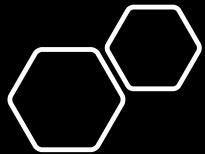


Powered by Nextstrain ([Hadfield et al Bioinformatics](#))

SARS-CoV-2 production for VQA panels

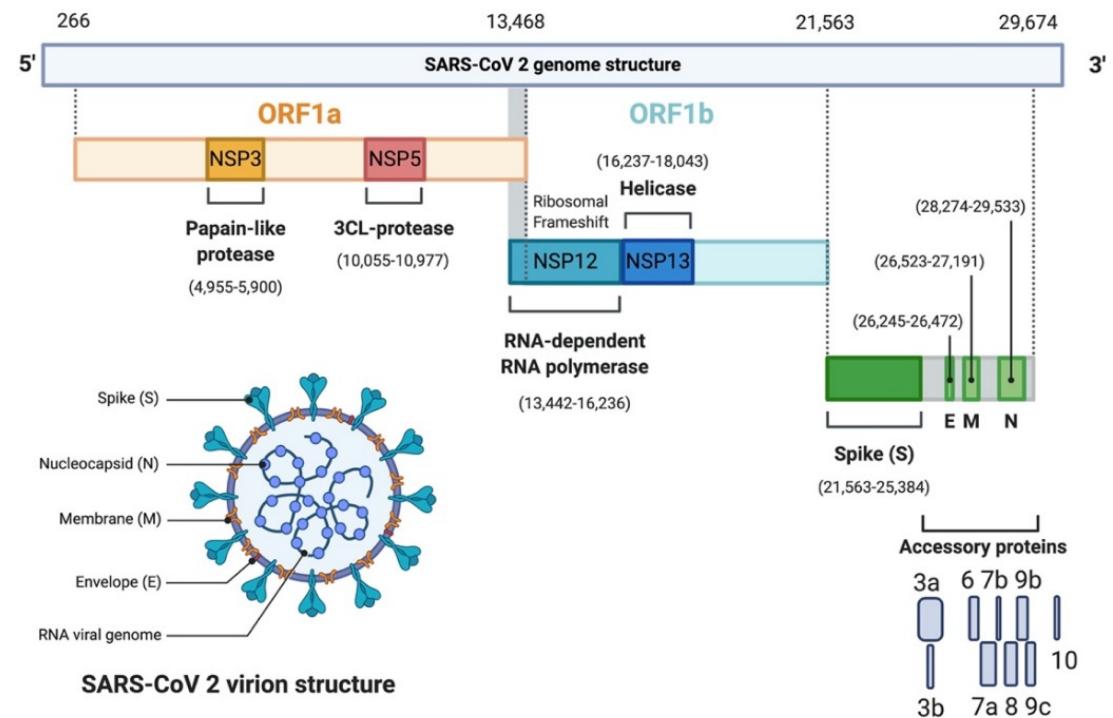
Methods of SARS-CoV-2 variant acquisition:

- Laboratory isolated strains (clinical samples, repositories)
 - Strain must be accessible – Time
 - Each variant production is independent (non-interchangeable) – Time
 - Isolation via multiple passages often selects for mutations – Accuracy
- Recombinant viral production
 - Any strain can be built regardless of accessibility
 - New variant production can be built on interchangeable parts
 - Recombinant strains will require less passages and growth conditions optimized

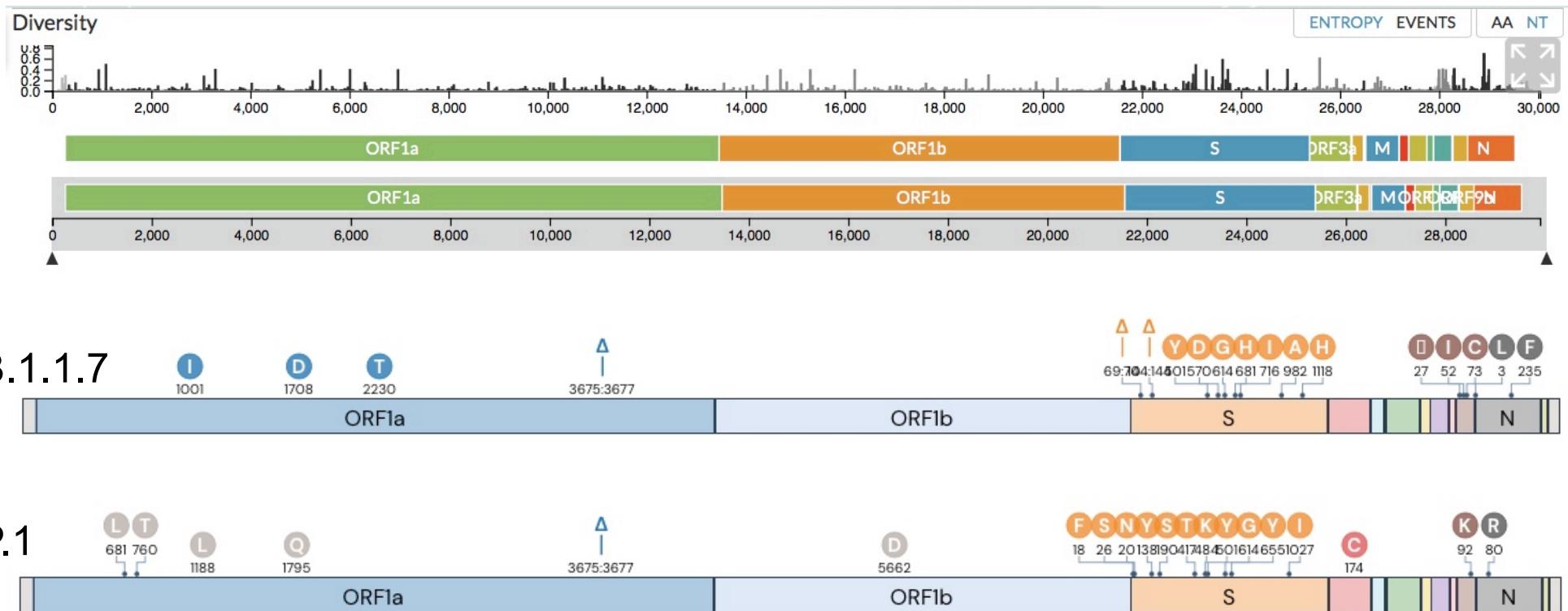


SARS-CoV-2 30kb (+)ssRNA genome

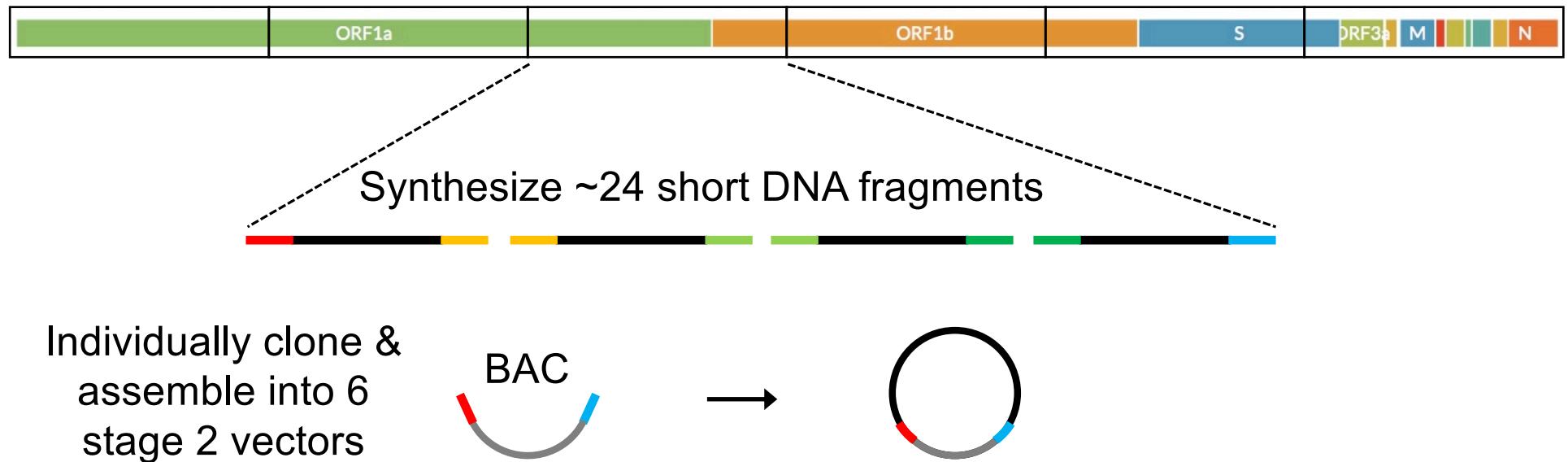
- *Pathogens* 2020, 9(5), 331; <https://doi.org/10.3390/pathogens9050331>



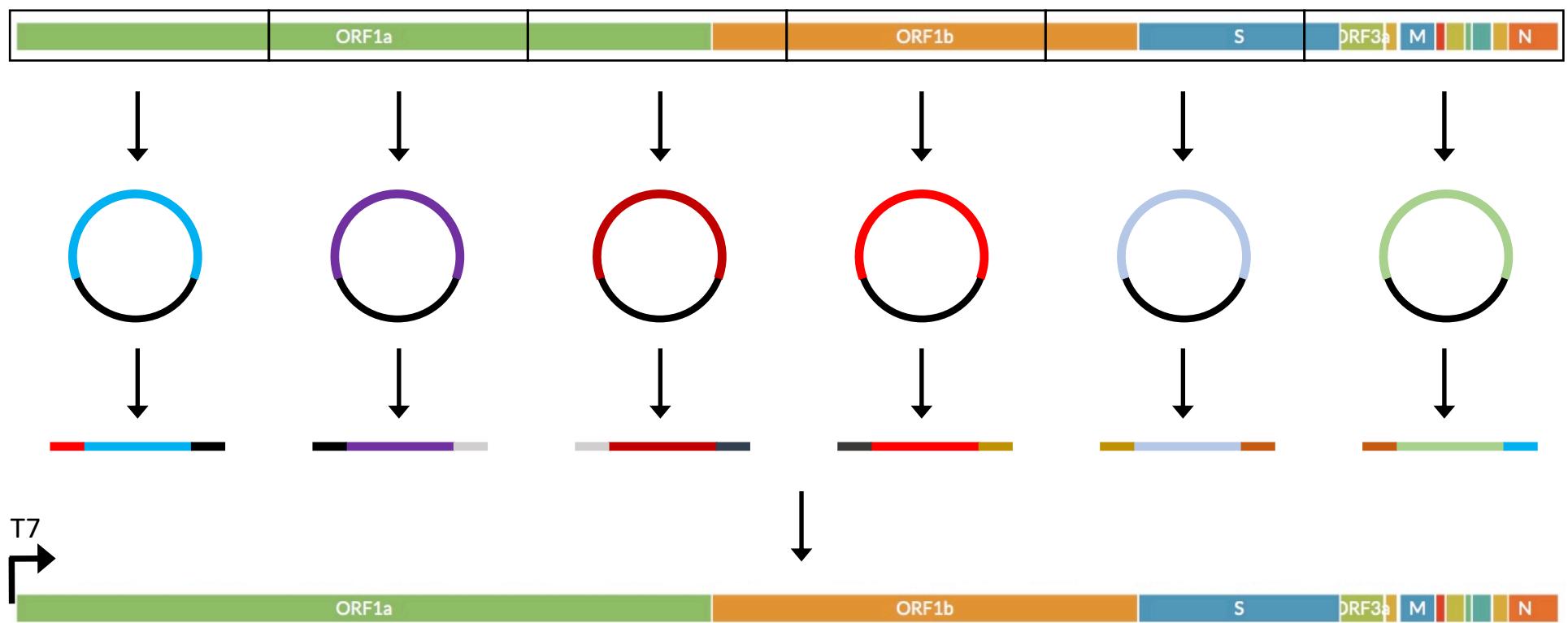
SARS-CoV-2 mutations occur throughout the genome



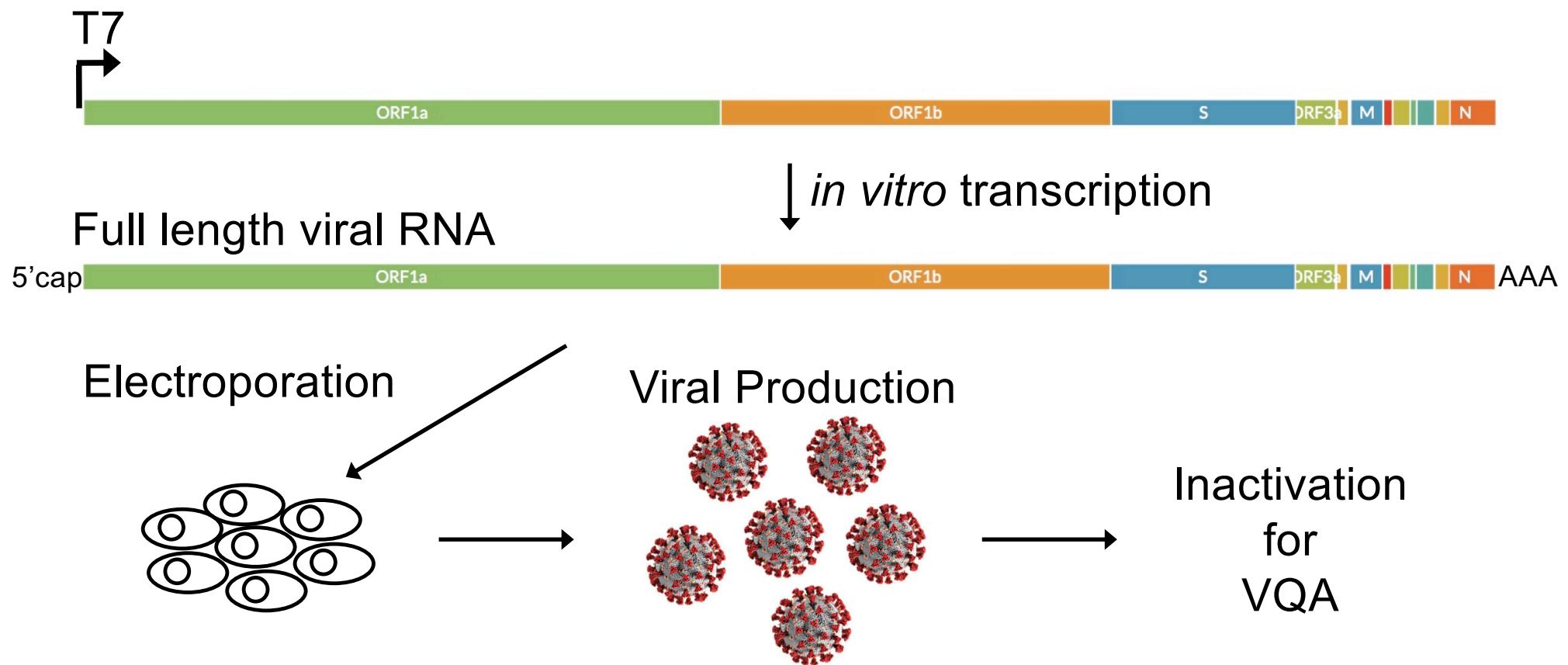
Recombinant SARS-CoV-2 stage 2 assembly



Stage 2 vector assembly into full length viral DNA



SARS-CoV-2 DNA to RNA to Virus production



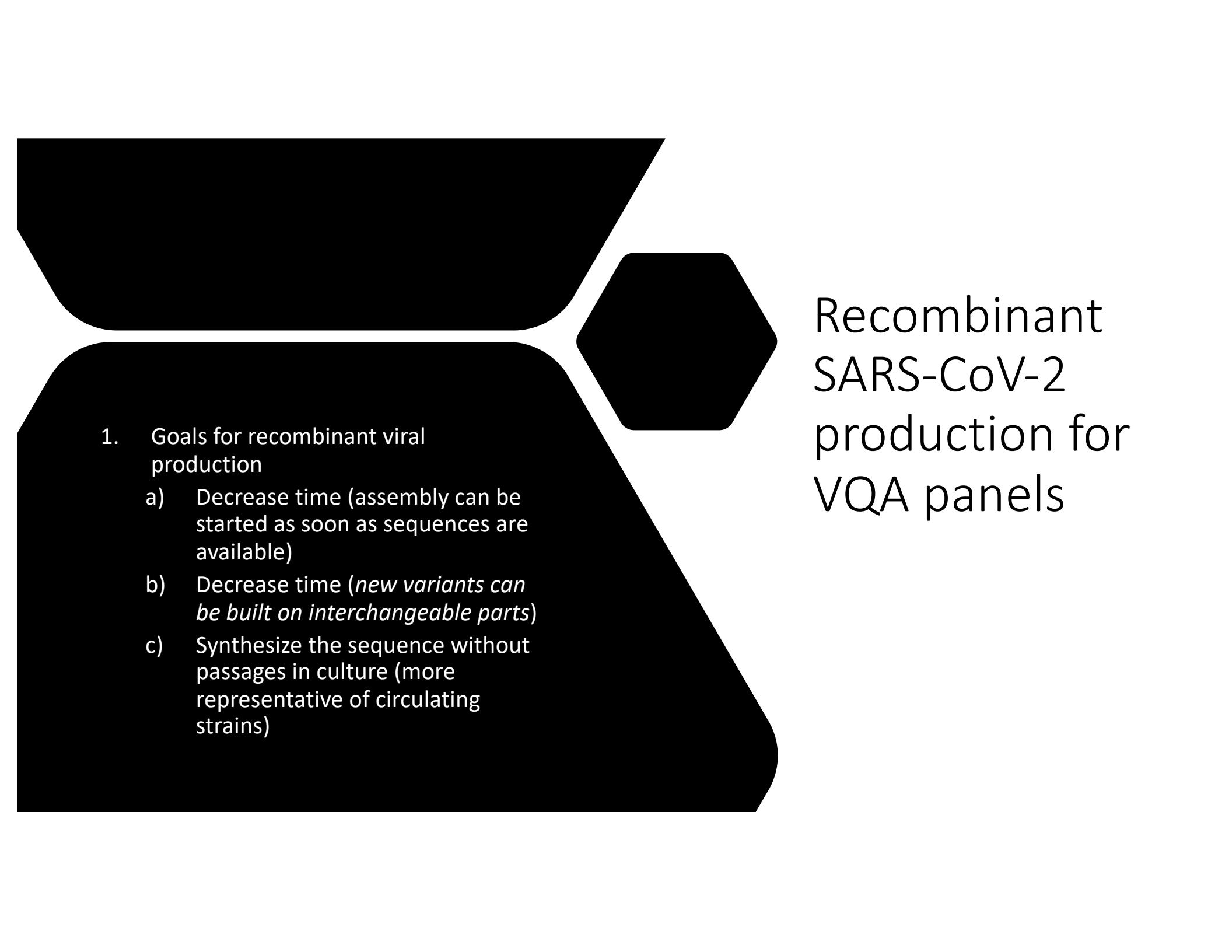
VQA panel progress

Laboratory isolated SARS-CoV-2 strains

- Ready now
 - WA1 (S clade)
- Viral production in progress
 - B.1.1.7 (20B/501Y.V1, 20I/501Y.V1, VOC-202012/01, UK variant)
 - B.1.351 (20H/501Y.V2, South African variant)
- Obtaining isolates
 - B.1.427 and B.1.429 (CA VUI1, CAL.20C)
 - P.1 (B.1.1.28.1, 20J/501Y.V3)
 - B.1.526 (.1 .2) ?

Recombinant viral production

- P.1 in progress

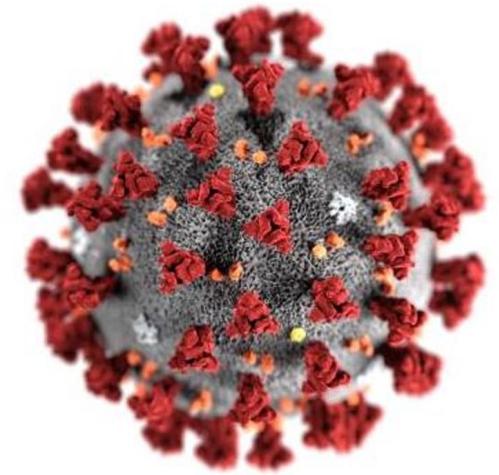


Recombinant SARS-CoV-2 production for VQA panels

1. Goals for recombinant viral production
 - a) Decrease time (assembly can be started as soon as sequences are available)
 - b) Decrease time (*new variants can be built on interchangeable parts*)
 - c) Synthesize the sequence without passages in culture (more representative of circulating strains)



Thank you

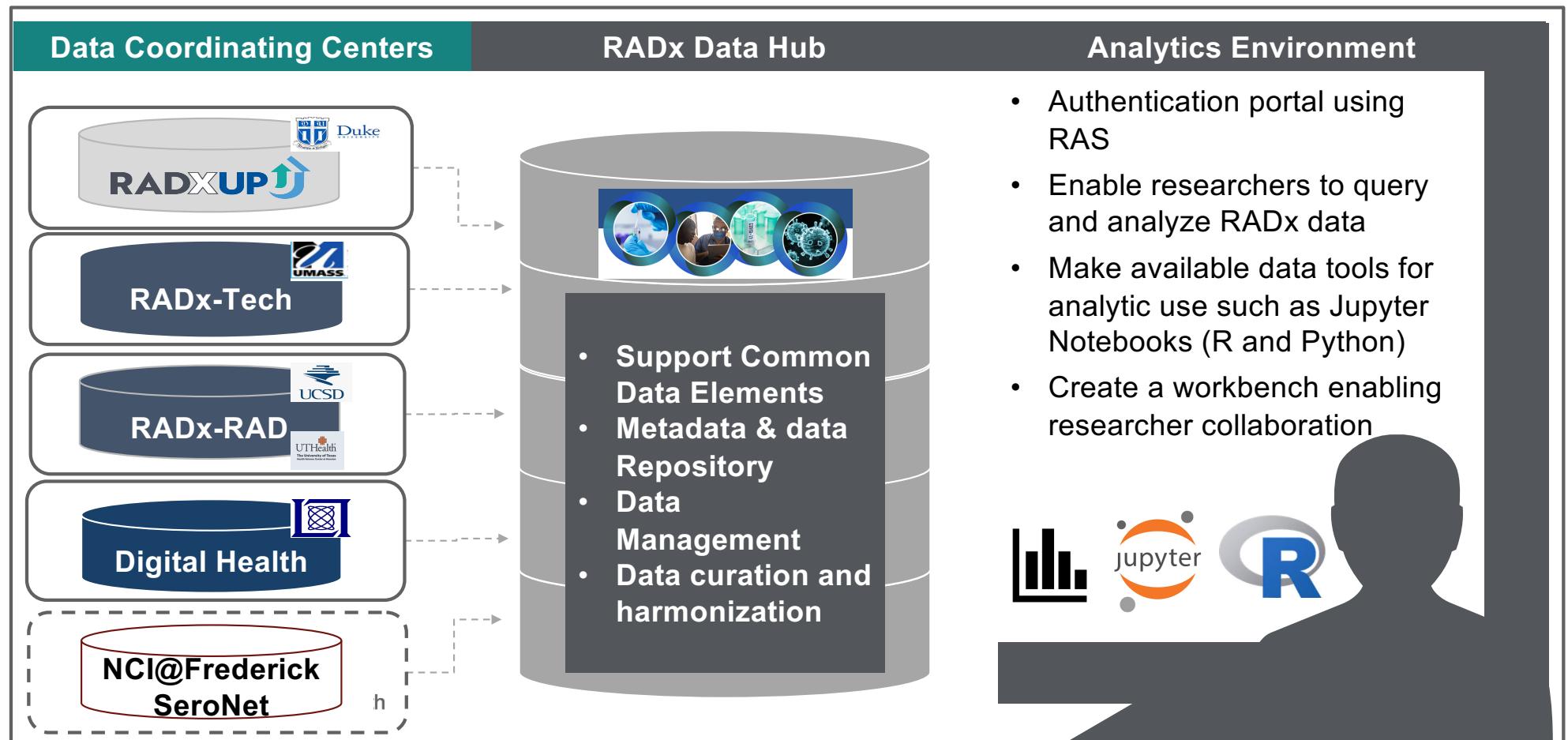


RADx-RAD DCC All-hands meeting

[NIH Office of Data Science Strategy](#)

April 12th, 2021

End Goal: Provide researchers with a single access point to de-identified RADx and related data, algorithms, and other capabilities generated by various digital health solutions and RADx technologies.

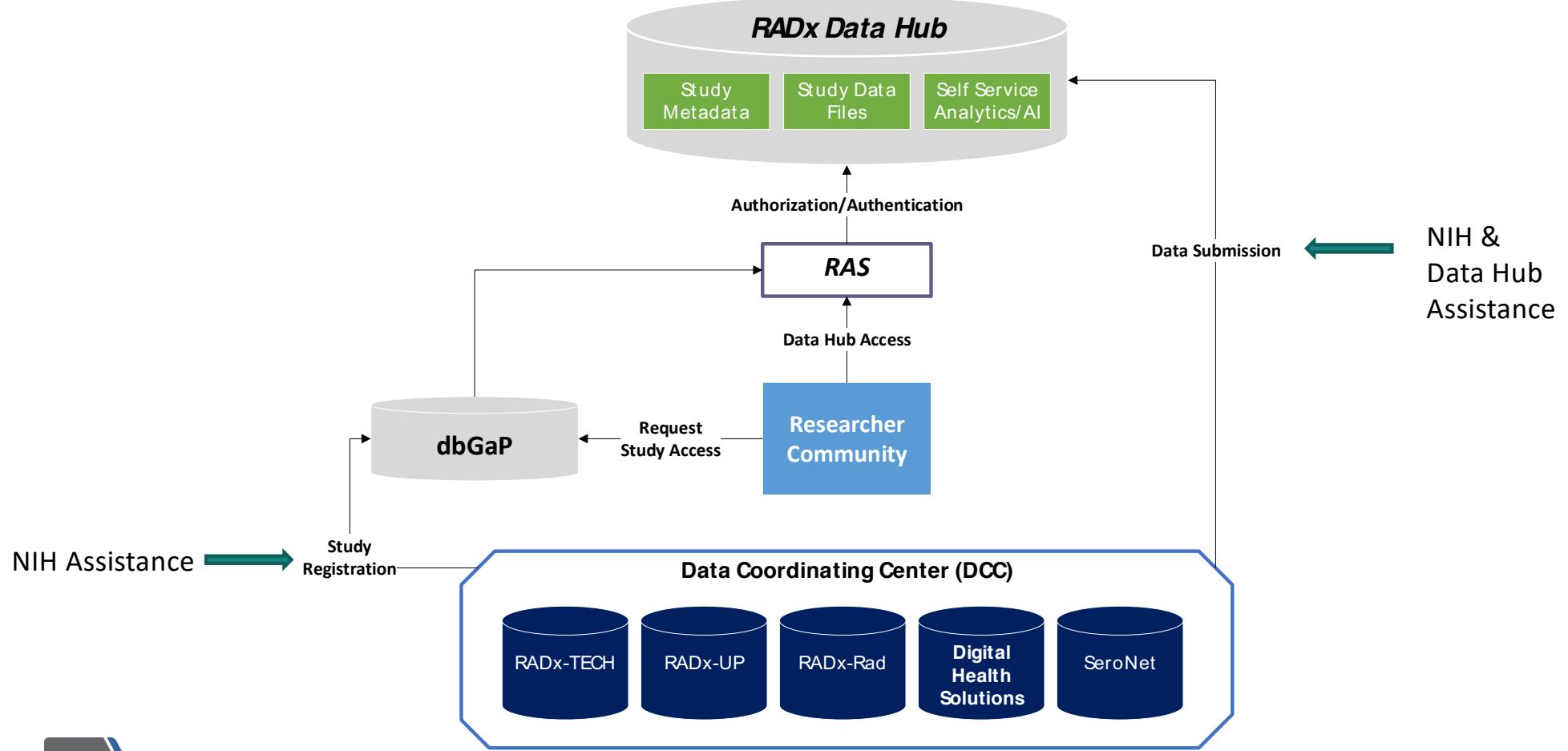


RADx Data Hub: Purpose & Vision

Purpose of the Data Hub, CDE usage, end user, and data access control

KEY QUESTIONS	ANSWERS
 What is the purpose of the Data Hub?	Adhering to NIH data FAIR principles; Solution to store, compute, and share testing data related to COVID-19 to provide researchers a single access point to find and analyze de-identified data and other capabilities generated by various programs funded by NIH.
 Who is the end user?	Researcher community focusing on the conducting COVID-19 related research
 Why do PI's need to utilize the CDEs?	Synchronization of the common data elements across programs enable data harmonization to support advanced analytics and machine learning
 What data access control is in place?	The Data Hub is using dbGAP and RAS for data access control at the study level per researcher. Each research must request access through dbGaP to attain access to a study. <ul style="list-style-type: none">Researchers will have greater access to a wider variety of data to support their efforts.Researchers will be able to use a variety of tools to facilitate discovery and enable analysis of the dataset and collaboration with other researchers.Manual efforts to support the data ingestion process and data access management will be greatly reduced through automation.
 Benefits of the RADx Data Hub	

RADx Data Hub | High-level Data Context Diagram



DCC Expectations for Data Sharing

Discussion on the expected cadence for DCC data sharing with the RADx Data Hub

Data Sharing Question: Is it feasible for **all DCCs** share project data with the Data Hub on a **regular cadence of 3 months?**



RADx-rad DCC - Data Core

Updates

Hua Xu, PhD

Information Web Portal

The screenshot displays the RADx™ Radical Information Web Portal with three main sections:

- Home:** Features a banner for "RADx-rad Discoveries and Data Coordinating Center (DCC)" with the tagline "Accelerating COVID-19 Diagnostic Innovation". Below the banner, there's a section titled "About RADx™ Radical" with a brief description and a "Resources" section containing four items: "Data flow for RADx-rad awardees", "Guidance for Use of Common Data Elements (CDEs)", "HIPAA "Safe Harbor" Checklist From for RADx-rad", and "Diagnostic Core Resources".
- Resources:** A page titled "Resources" featuring a "Key Resources" section with links to "Data flow for RADx-rad awardees", "Diagnostic Core Resources", "Guidance for Use of Common Data Elements (CDEs)", "HIPAA "Safe Harbor" Checklist From for RADx-rad", and "Minimum CDEs Required by NIH".
- Events:** A page titled "Protected: DCC Weekly Office Hours: Data Core" with details: Start Date: 2021-04-01 13:00:00 (Pacific Time) and End Date: 2021-04-01 14:00:00 (Pacific Time). It includes a video player showing a recording titled "01APR2021_DataCoreOfficeHours.mp4" from "RADx-rad" and a "Data dictionary guideline".

Final version of minimum CDEs approved by NIH RADx Executive Committee

Concept	Stimulus	Response	Medical History	Vaping use	Yes, no
Identity	None	Project-specific identifier			
Race ¹	What race do you identify with?	AI/AN; Asian Black or African American; Native Hawaiian or other Pacific Islander; White		Nicotine use	Yes, no
Ethnicity ¹	What ethnicity do you identify with?	Hispanic or Latino; not Hispanic or Latino		Alcohol use	Yes, no
Sex	What was your assigned sex at birth?	Male, Female, Intersex		Asthma	Yes, no
Age	What is your age?	Age in years		Cancer	Yes, no
Education	How many years of education have you completed?	0 - +20		Cardiovascular disease	Yes, no
Domicile	Where do you live?	Zip Code		Chronic kidney disease	Yes, no
Employment	Are you employed?	Permanent, temporary or not		Chronic lung disease	Yes, no
Insurance Status	What kind of insurance do you have?	Private, Public, none		Diabetes	Yes, no
Disability status ²	Are you deaf or do you have serious difficulty hearing?	Yes, no		Hypertension	Yes, no
	Are you blind or do you have serious difficulty seeing, even when wearing glasses?	Yes, no		Immunosuppressive condition	Yes, no
	Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions?	Yes, no		Serious mental illness	Yes, no
	Do you have serious difficulty walking or climbing stairs?	Yes, no		Sickle cell disease	Yes, no
	Do you have difficulty dressing or bathing ?	Yes, no		Pregnancy status	Currently pregnant, not
	Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping?	Yes, no		Cough ³	Yes, no
				Fever ²	Yes, no
				SoB or Difficulty breathing ²	Yes, no
				Headache ²	Yes, no
				Muscle ache ²	Yes, no
				New Loss of taste or smell ²	Yes, no
				Chills ²	Yes, no
				Excessive fatigue ²	Yes, no
				Nausea/vomiting ²	Yes, no
				Diarrhea ²	Yes, no
				Abdominal pain ⁴	Yes, no
				Skin rash ³	Yes, no
				conjunctivitis ³	Yes, no
			Health Status	BMI	Weight & height
				Would you say that (your) health in general is excellent, very good, good, fair or poor? ⁵	Excellent, very good, good, fair, poor

REDCap Codebook for minimum CDEs

Study ID	<input type="text"/>
Race	
What is your race? Mark one or more boxes.	
<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Some other race	
Ethnicity	
Are you of Hispanic or Latino origin?	
<input type="checkbox"/> Yes, of Hispanic or Latino origin <input type="checkbox"/> No, not of Hispanic or Latino origin	
Age	
What is your age?	<input type="text"/>
Age in years. For babies less than 1 year old, write 0 as the age	
Sex	
What is your biological sex assigned at birth?	
<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Intersex <input type="radio"/> None of these describe me	
Education	
How many years of education have you completed?	<input type="text"/>
Years of education from 0 - 20+	
Domicile	
Zip or Postal Code:	<input type="text"/>
5-digit zip code	

Variable / Field Name	Form Name	Section Header	Field Type	Field Label	Choices, Calc	Field Note	Text Validation	Text Validation
record_id	form_1		text	Record ID				
study_id	form_1		text	Study ID				
race	form_1	Race	checkbox	What is your 1, American Indian or Alaska Native 2, Asian 3, Bl				
ethnicity	form_1	Ethnicity	checkbox	Are you of 1, Yes, of Hispanic or Latino origin 0, No, not of His				
age	form_1	Age	text	What is your age?	Age in years.	integer		
sex	form_1	Sex	radio	What is your 1, Male 2, Female 3, Intersex 4, None of these c				
education	form_1	Education	text	How many years of educa	Years of edu	integer		
zip	form_1	Domicile	text	Zip or Postal Code:	5-digit zip code			
employment	form_1	Employment	radio	Are you emp 1, Employed in a permanent position 2, Employed in				
insurance	form_1	Insurance Sta	radio	What kind of 1, Private insurance 2, Public insurance 3, None				
deaf	form_1	Disability Stat	yesno	Are you deaf or do you have serious difficulty hearing?				
blind	form_1		yesno	Are you blind or do you have serious difficulty seeing, even when w				
memory_dis	form_1		yesno	Because of a physical, mental, or emotional condition, do you have				
walking_climbing_dis	form_1		yesno	Do you have serious difficulty walking or climbing stairs?				
dress_bathe_dis	form_1		yesno	Do you have difficulty dressing or bathing?				
errand_dis	form_1		yesno	Because of a physical, mental, or emotional condition, do you have				
cancer	form_1	Medical History	yesno	Cancer				
cardiovascular_disease	form_1		yesno	Cardiovascular disease				
chronic_kidney_disease	form_1		yesno	Chronic kidney disease				
chronic_lung_disease	form_1		yesno	Chronic lung disease				
diabetes	form_1		yesno	Diabetes				
hypertension	form_1		yesno	Hypertension				
immunosuppressive	form_1		yesno	Immunosuppressive condition				
serious_mental_illness	form_1		yesno	Serious mental illness				
sickle_cell_disease	form_1		yesno	Sickle cell disease				
pregnancy_status	form_1		radio	Pregnancy st 1, Currently pregnant 0, Not pregnant				
cough	form_1	Symptoms	yesno	Cough				
fever	form_1		yesno	Fever				
shortness_of_breath	form_1		yesno	Shortness of breath or difficulty breathing				
headache	form_1		yesno	Headache				
muscle_ache	form_1		yesno	Muscle ache				
new_loss_of_taste	form_1		yesno	New loss of taste or smell				
chills	form_1		yesno	Chills				
excessive_fatigue	form_1		yesno	Excessive fatigue				

Data Dictionary Template

Columns	Example1	Example2	Example3
Variable/Field Name	race	abdominal_pain	age
Form Name/Variable Classification	sociodemographics	condition_symptom	sociodemographics
Field Label/Variable Description	the race of the participants	if the participant is experiencing the symptom of abdominal pain	the age of the participant
Variable Question	What is your race?	Are you currently experience abdominal pain?	what is your age?
Field Type	checkbox	boolean	text
Choices, Calculations OR Slider Labels	1, American Indian or Alaska Native 2, Black or African American 3, Asian 4, Native Hawaiian or Other Pacific Islander 5, White 15, Some other race 99, Prefer not to answer	1, Yes 2, No	
Validation			integer: min 0, max 120
Field Notes			
Candidate CDEs	https://cde.nlm.nih.gov/deView?tinyId=hU6IJ3BLM	https://cde.nlm.nih.gov/deView?tinyId=F_Vsk6QDVb	



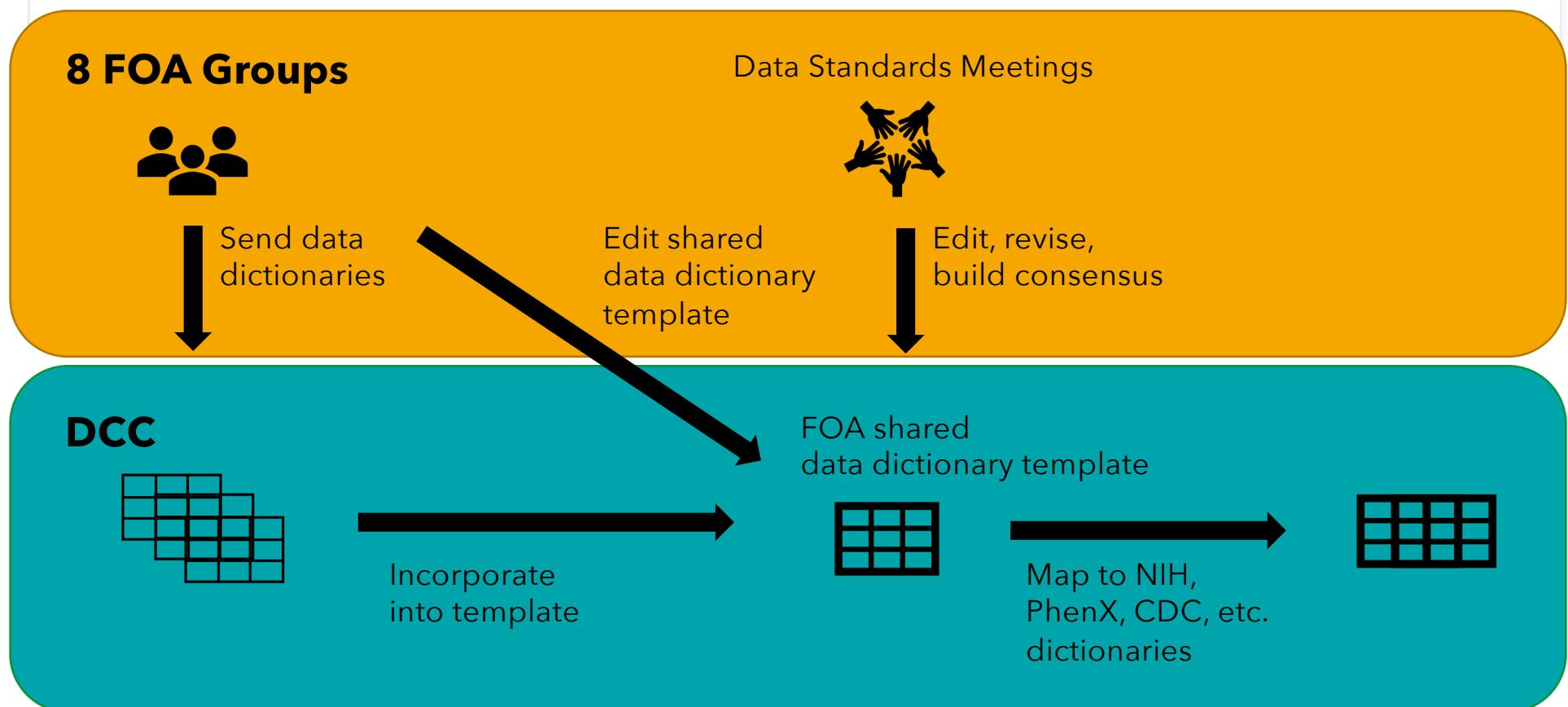
Recommended CDEs for FOA Research Areas

Peter Rose, PhD

Activities on Data Standards for FOAs

	Automatic Detection and Tracking	Chemo- sensory Testing	Exosome Based	Multimodal Surveillance	Novel Biosensing and VOC	PreVAIL kIDS	SCENT	Wastewater
Minimum CDE communication								
Data Standards Kick-Off								
Data Standards Follow-up	Monthly	Ad Hoc	Monthly	Ad Hoc	Ad Hoc	Monthly	Ad Hoc	Bi-weekly
Data Dictionary Template sent out								
Study Data Dictionaries received	(1)	(1)				(3)	(1)	(4) + CDC NWSS

Developing Recommended CDEs



Plans and Timelines

- Combine SCENT and VOC groups for CDE development
 - Both groups develop similar technologies
- Novel Biosensing
 - Diverse technologies, SBIR grants, data-sharing may be limited due to IP concerns
- Timeline
 - Recommended CDEs depend on data submission readiness
- Off-line work on Data Dictionary template will reduce number of meetings!