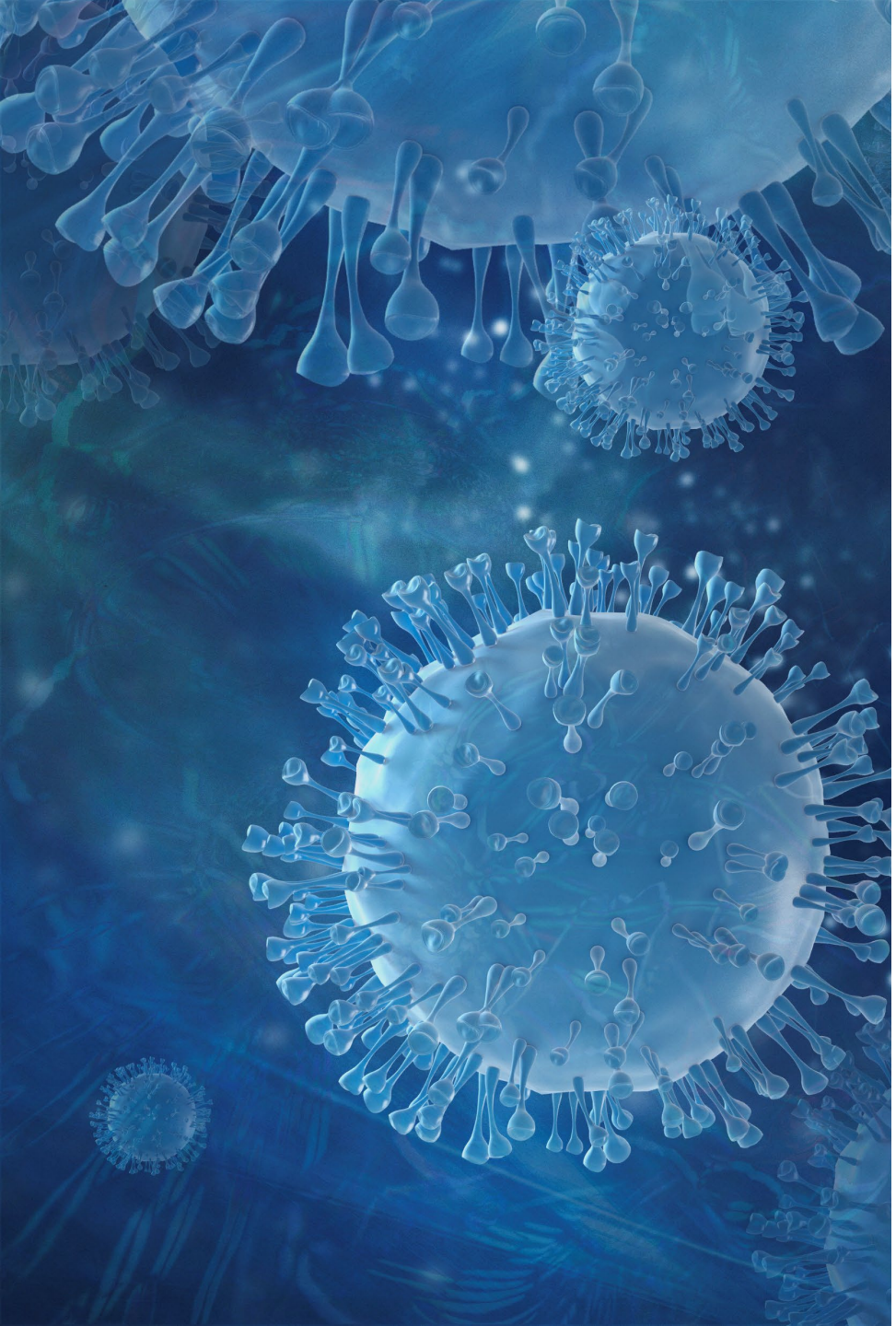
REAGAN-UDALL FOUNDATION FOR THE FDA

FRIENDS of CANCER RESEARCH

COVID-19 Evidence Accelerator: Public Meeting

October 20, 2022
1-4 p.m. Eastern Time



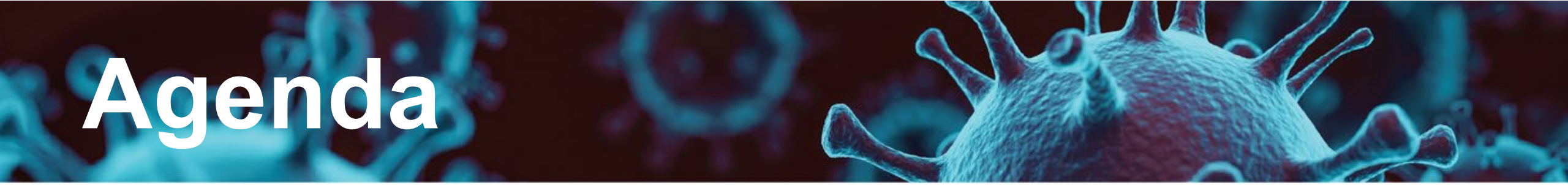
Thank you for joining

This webinar is being recorded. The slides, transcript, and video recording will be available on the Evidence Accelerator website after the meeting.

Due to the meeting size, your microphone and video will remain off during the meeting.

While we won't have time to directly address audience questions during today's meeting, you may use the Zoom chat function for comments.

Agenda



1 p.m.	Welcome & Introduction – Susan C. Winckler, RPh, Esq.
1:03 p.m.	Opening Remarks – Namandjé N. Bumpus, PhD
1:08 p.m.	Remarks – Robert M. Califf, MD, MACC
1:10 p.m.	Keynote Speech – Amy Abernethy, MD, PhD
1:25 p.m.	Session One: FDA Perspectives on the COVID-19 Evidence Accelerator
2:10 p.m.	Session Two: Research Findings and Methodologies
3:10 p.m.	Session Three: How COVID-19 and the Evidence Accelerator Have Shaped the Use of Real-World Data
3:50 p.m.	Closing Thoughts

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Opening Remarks

Namandjé N. Bumpus, PhD
Chief Scientist
FDA

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Keynote Speech

Amy Abernethy, MD, PhD
President of Clinical Studies Platforms
Verily

FDA Perspectives on the COVID-19 Evidence Accelerator

Moderator

Jeff Allen, PhD, *President and CEO, Friends of Cancer Research*

Panelists

Sara Brenner, MD, MPH, *Center for Devices and Radiological Health, FDA*

Jacqueline Corrigan-Curay, JD, MD, *Center for Drug Evaluation and Research, FDA*

Peter Marks, MD, PhD, *Center for Biologics Evaluation and Research, FDA*

Research Findings and Methodologies

Moderator

Dr. Carla Rodriguez-Watson, *Director of Research, Reagan-Udall Foundation for the FDA*

Panelists

Dr. Nicolle Gatto, *Chief Science Officer, Aetion, Inc*

Sandy Leonard, *SVP of Partnerships and RWD Solutions at HealthVerity*

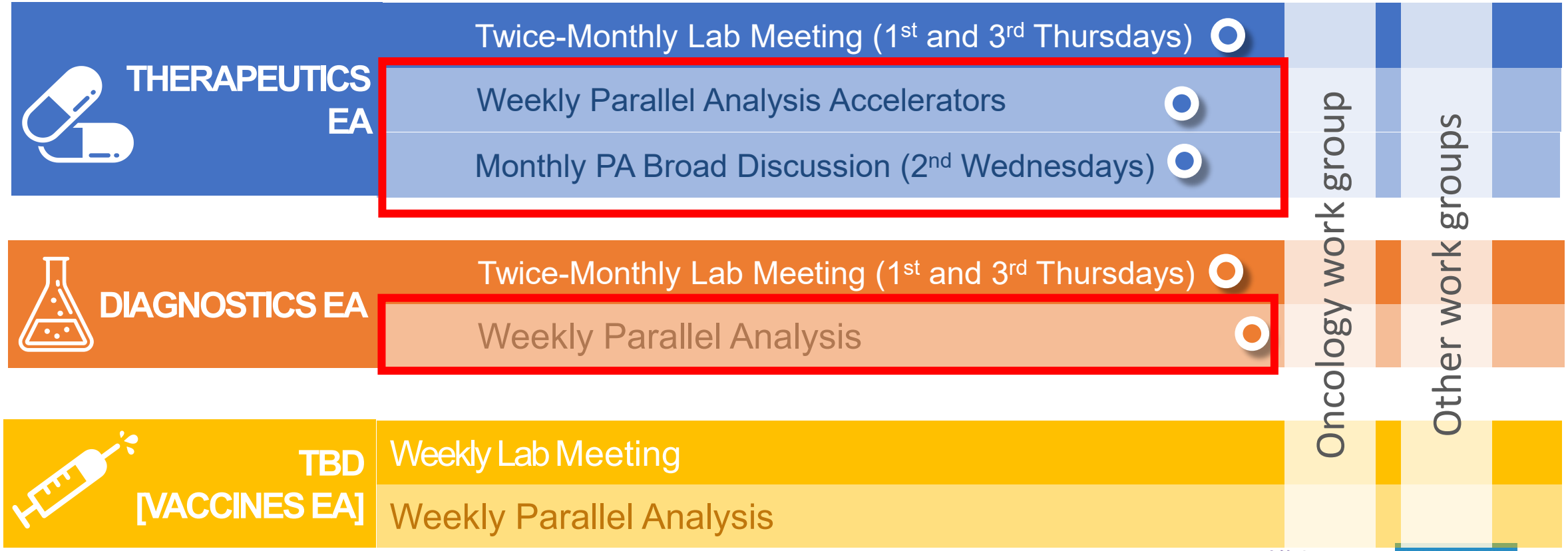
Dr. Vincent Lo Re III, *tenured Associate Professor of Medicine at the University of Pennsylvania Division of Infectious Diseases*

Dr. Anand Chokkalingam, *Executive Director and Head of Real-World Evidence for Gilead's Virology Therapeutic Area*

Dr. Nancy Lin, *Director of Epidemiology, Real World Solutions at IQVIA*

Dr. Aloka Chakravarty, *Director of Data Analytics and Senior Statistical Advisor in the Office of the Commissioner, FDA*

Reagan-Udall Foundation for the FDA/Friends of Cancer Research
Evidence Accelerator
Work Streams



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PARALLEL APPROACH TO ANALYSIS (PA)

Purpose: to assemble a community where questions about COVID-19 could be *urgently* explored through the lens of RWD and RWE generation.

Community Took a Step by Step Approach to Parellel Analysis

Started with FDA prioritized research questions.

Identified common data elements and developed translation tables between common data models.

Created common protocol for repeated analysis of priority research questions across multiple data partners—the “parallel analysis.”

Held meetings and forum for rapid cycle feedback and learning.

Focused individual accelerator communities on specific topics (e.g., therapeutics, diagnostics).

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COVID-19 EVIDENCE ACCELERATOR PRINCIPLES

Together, we will **create** and **lead**.

C **CONTEXT** — tie data to the question, address bias, explain validation strategies.

R **RESPECT** — for patient privacy and the patient voice is paramount.

E **EARN TRUST** — show processes, analytic approaches, and comparisons. Be open to input. Challenge with productive intent.

A **ACT FAST AND DO GOOD WORK** — act with a sense of urgency, but not at the expense of quality or credibility.

T **TRANSPARENCY** — ruthless transparency.

E **EMBRACE AND EXPLORE** —convergence and discordance to facilitate understanding and generate knowledge.

L **LEARN** — continually integrate best practices from **sharing** process, limitations, pitfalls, and successes.

E **EXERCISE PATIENCE** — state when a question can't be answered right away and institute action to answer it.

A **ACCESSIBILITY AND TRACEABILITY** — document data generation, processing, curation, and analytics.

D **DISSEMINATE WORK** — to show what good looks like. *Teach, Don't Preach.*

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HYDROXYCHLOROQUINE

Nicolle Gatto, PhD

Chief Science Officer, Aetion, Inc

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The Process

- First COVID-19 Evidence Accelerator research project (+ publication)
- 7 research groups; 9 total partners
- Piloted the common protocol and collaborative, but independent parallel analysis approaches
- 6 EMR data sources + 1 hospital chargemaster with linked claims
- Parallel analysis by each partner, allowed for flexibility due to differences and unique limitations of each data source

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COVID-19 Evidence Accelerator: A parallel analysis to describe the use of Hydroxychloroquine with or without Azithromycin among hospitalized COVID-19 patients

Mark Stewart, Carla Rodriguez-Watson, Adem Albayrak, Julius Asubonteng, Andrew Belli, Thomas Brown, Kelly Cho, Ritankar Das, Elizabeth Eldridge, Nicolle Gatto, Alice Gelman, Hanna Gerlovin, Stuart L. Goldberg, Eric Hansen, Jonathan Hirsch, Yuk-Lam Ho, Andrew Ip, Monika Izano, Jason Jones, Amy C. Justice, Reyna Klesh, Seth Kuranz, Carson Lam, Qingqing Mao, Samson Mataraso, Robertino Mera, Daniel C. Posner, Jeremy A. Rassen, Anna Siefkas, Andrew Schrag, Georgia Tourassi, Andrew Weckstein, Frank Wolf, Amar Bhat, Susan Winckler, Ellen V. Sigal, Jeff Allen [view less]

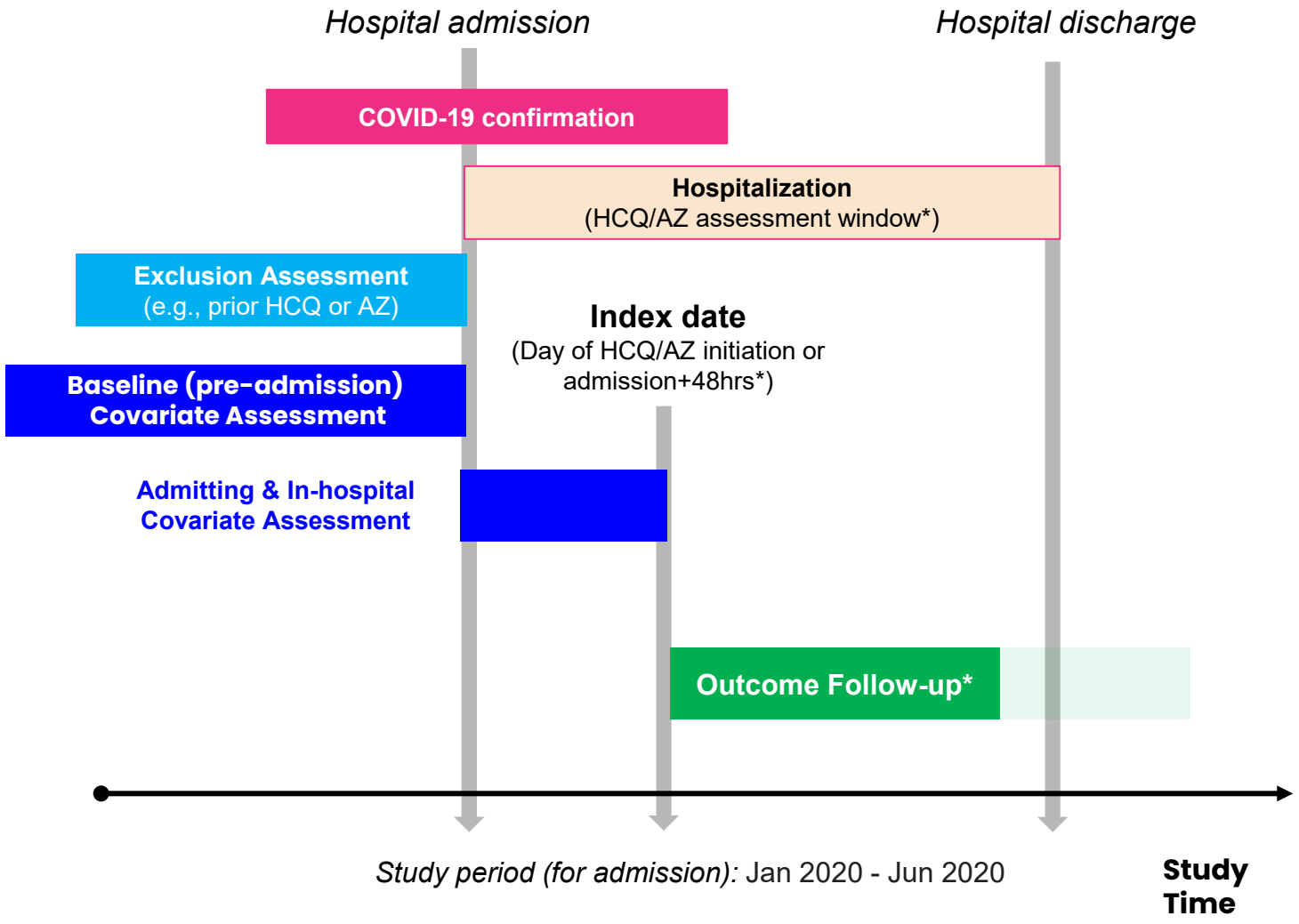
PLOS ONE

Research Question & Objectives

Using a parallel analysis format, describe outcomes associated with the use of hydroxychloroquine (HCQ) with/without azithromycin (AZ) for hospitalized COVID-19 patients across seven real-world datasets in the United States.

1. Characterize the baseline demographics, comorbidities and medical history of hospitalized patients with COVID-19
2. Characterize treatment patterns of HCQ (with or without AZ) therapy administered in the inpatient setting
3. Describe safety and effectiveness outcomes of interest among hospitalized patients receiving HCQ (with or without AZ)

Common Design & Analytic Approach



Inclusion Criteria: Patients hospitalized with COVID-19 between Jan 2020 - Jun 2020

Treatment groups: HCQ alone, HCQ+AZ, and neither HCQ nor AZ.

Outcomes: Time-to-event for outcomes of mechanical ventilation, discharge, and mortality.

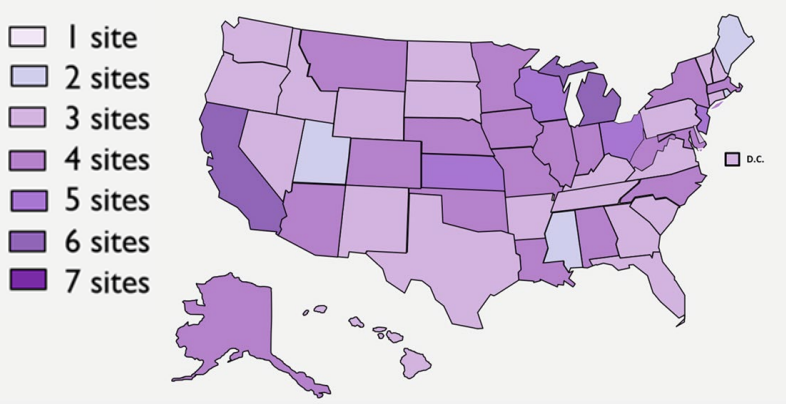
Analytic approaches: Cox proportional hazards models were used for outcome associations among HCQ+AZ-treated vs. neither treatment populations; various propensity score methods undertaken to adjust for confounding.

**Approach for index date assignment (and start of follow-up) varied across data partners.*

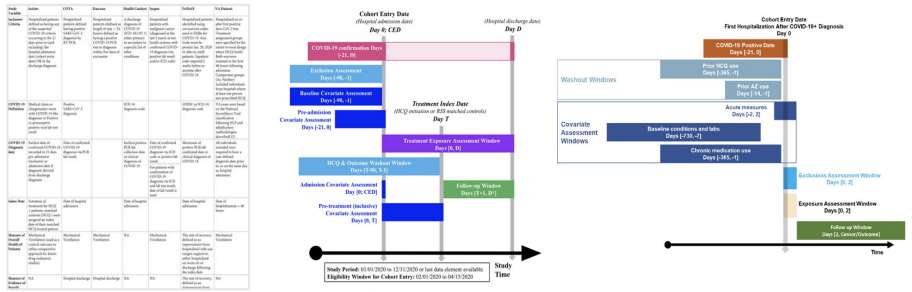
7 parallel analysis partners -- 20,371 total COVID-19 patient hospitalizations

Aetion/HealthVerity
COTA/Hackensack Meridian Health
Dascena
Health Catalyst
Syapse
TriNetX
Veteran's Health Administration

Analytic Partner Coverage

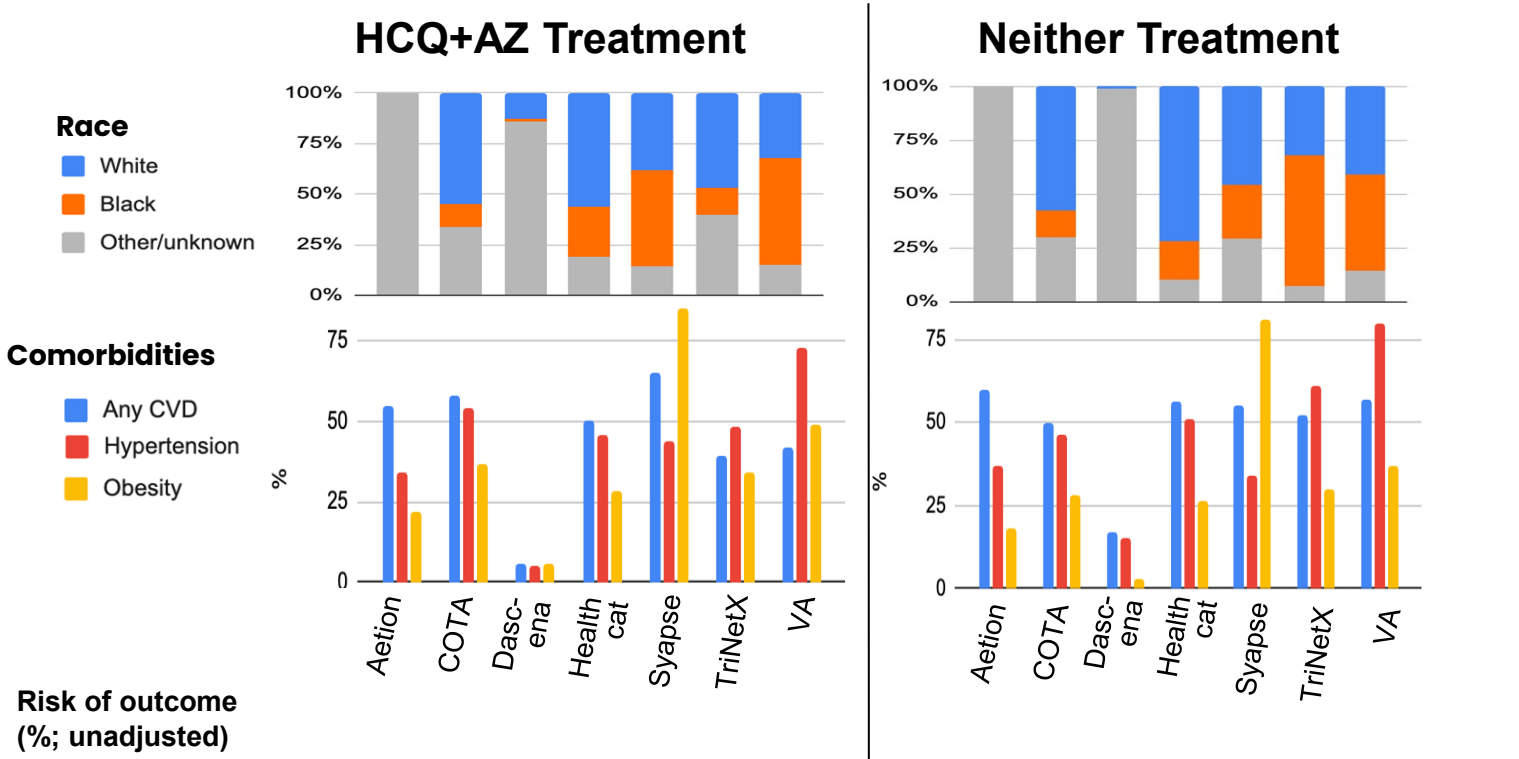


Side-by-side comparisons to evaluate differences and similarities in datasets, populations, design aspects and analytic approaches.



Example: Differences in data characteristics, definitions, & design aspects across data partners

Results: Baseline data and unadjusted risks



Risk of outcome (%; unadjusted)

	Aetion	COTA	Dasc-ena	Health Cat	Sy-apse	Tri-NetX	VA
N	*790*	*1711*	*206*	*1157*	*108*	*578*	*429*
Mortality %	-	25%	29%	18%	30%	11%	21%
Mech. vent %	16%	29%	35%	-	35%	-	15%

Aetion	COTA/ HMH	Dasc-ena	Health Cat	Sy-apse	Tri-NetX	VA
1302	*688*	*1284*	*1101*	*256*	*1243*	*737*
-	18%	4%	18%	13%	15%	19%
7%	6%	3%	-	6%	-	9%

- Demographic and comorbidity distributions varied across datasets, but trends were generally similar for HCQ+AZ versus no treatment groups within each dataset
- Patients receiving HCQ+AZ were typically older than 45 with a larger proportion of males
- Prior to adjustment, risks of mortality and mechanical ventilation were generally higher among HCQ+AZ patients as compared to those with neither treatment

Results: Primary outcome comparative analysis

- Confounders generally well-balanced across treatment groups, after adjustment
- Overall, across the 5 groups who ran adjusted comparative analyses, we observed no clear association between HCQ treatment (w/out AZ) and mortality or mechanical ventilation

Hazard ratios for outcomes, HCQ+AZ vs. neither

	Mortality HR (95% CI)	Mechanical Ventilation HR (95% CI)
Aetion/HV*	Not assessed	1.29 (0.96, 1.74)
COTA/HMH	1.16 (0.90, 1.51)	Not assessed
Dascena	1.90 (0.91, 4.1)	2.50 (1.20, 5.20)
Health Catalyst	1.09 (0.76, 1.56)	Not assessed
TriNetX	0.99 (0.73, 1.35)	Not assessed
VA	1.18 (0.88, 1.58)	1.54 (1.07, 2.23)

*Includes all HCQ users, regardless of AZ exposure

Process learnings for future parallel analyses

- Consider a stepwise approach to first evaluate sample sizes, geographic coverage and patient characteristics, with feasibility assessment for the research question of interest
- Use information from initial descriptive assessment to optimally design the subsequent comparative study and identify appropriate analyses
- Apply uniform definitions and methods where possible, tailor analysis as needed to accommodate dataset variation (where dataset otherwise deemed fit for purpose)
- Clearly describe any variations and limitations for each dataset / analysis

REMDESIVIR

Anand Chokkalingam, PhD

Executive Director and Head of Real-World Evidence for Gilead's Virology Therapeutic Area

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REMDESIVIR AIMS

Aim 1*:* Characterize use of remdesivir among hospitalized patients with COVID-19 after implementation of the EUA

Aim 2: Develop and construct a propensity score model to achieve balance on observed characteristics to apply in aim 4

Aim 3: Assess weighting technique assumptions and diagnostics, and confirm that baseline balancing is achievable

Aim 4: Assess risk for AKI, ventilation, discharged alive, in-hospital mortality, and length of stay among hospitalized COVID-19 patients treated with remdesivir vs. untreated.

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PARTNERS

dascena

Target RWE
Health Evidence Solutions

VA | U.S. Department of Veterans Affairs

HealthCatalyst

With special thanks to:

GILEAD
Creating Possible

TriNetX

AETION

UNIVERSITY OF CALIFORNIA

OneFlorida
Clinical Research Consortium

PCORNet

Sutter Health

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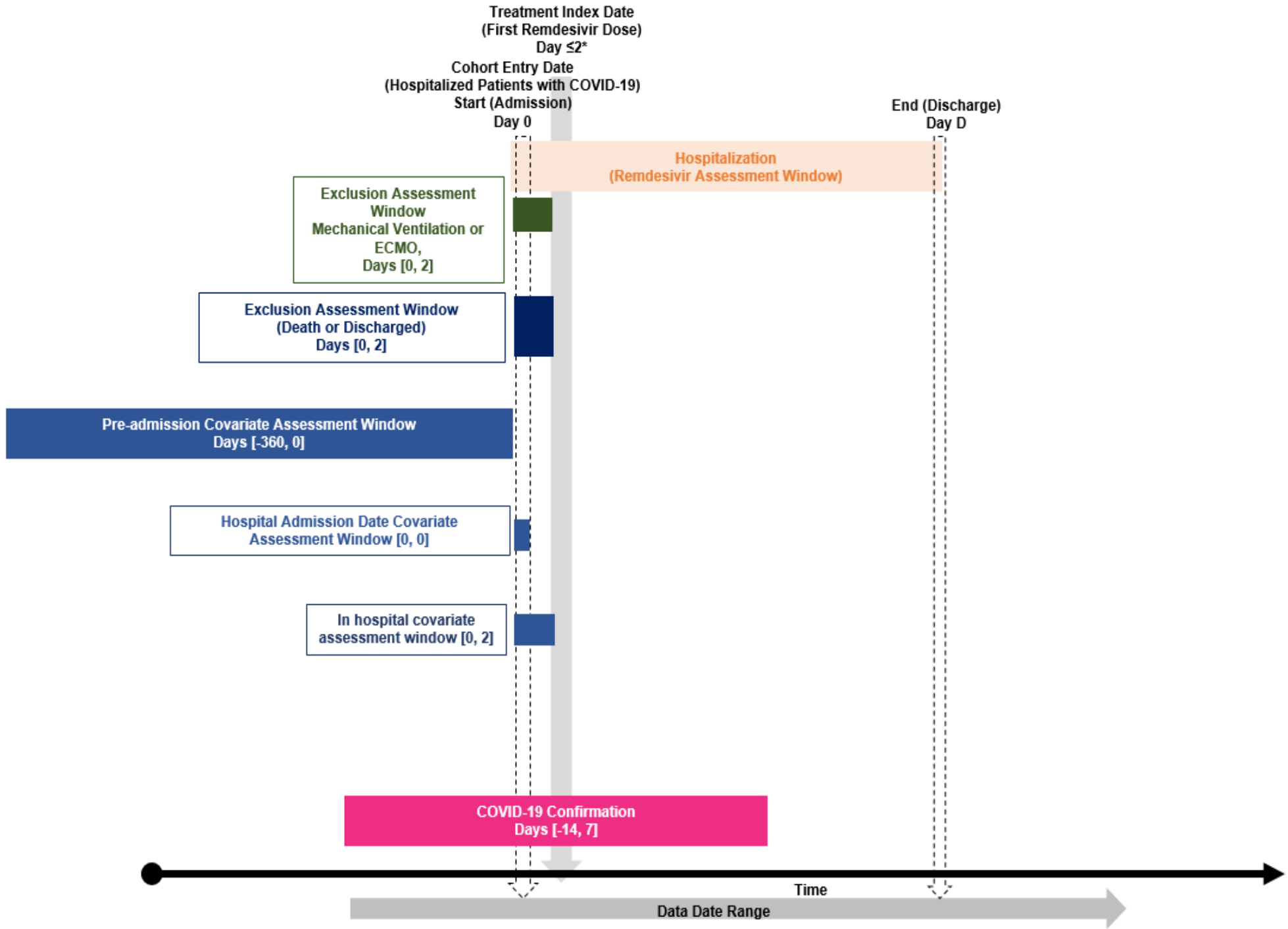
Treatment Index Date
(First Remdesivir Dose)
Day ≤2*
Cohort Entry Date
(Hospitalized Patients with COVID-19)
Start (Admission)
Day 0
End (Discharge)
Day D
Hospitalization
(Remdesivir Assessment Window)
Exclusion Assessment Window
Mechanical Ventilation or ECMO,
Days [0, 2]
Exclusion Assessment Window
(Death or Discharged)
Days [0, 2]
Pre-admission Covariate Assessment Window
Days [-360, 0]
Hospital Admission Date Covariate Assessment Window [0, 0]
In hospital covariate assessment window [0, 2]
COVID-19 Confirmation
Days [-14, 7]
Time
Data Date Range

RESULTS

- Importance of accounting for COVID-19 severity
- Methodological considerations such as immortal time bias, channelling bias that were especially acute at the start of the pandemic
- Importance of common operational definitions of medications, both for exposure and covariates
- Challenge of examining narrow window of exposure and of subsequent outcomes

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COAGULOPATHY

Vincent Lo Re III, M.D., M.S.C.E

Associate Professor of Medicine, University of Pennsylvania, Division of Infectious Diseases

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COAGULOPATHY AIMS

Aim: 90-day absolute risk of ATE and VTE in:

Patients initially diagnosed with **COVID-19** in hospital (Apr 2020 – May 2021)

vs.

Patients initially diagnosed with **influenza** in hospital (October 2018 - April 2019)

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PARTNERS | Data Types

DATAVANT

Symphony Health
A PRAHEALTHSCIENCES COMPANY

HEALTHPALS

veradigm

Sentinel

Syapse

Data varied by Partner:

- EHR + claims (Sentinel, HealthPals)
- Claims, retail pharmacy, remittance (Datavant)
- Cancer EHR + linked mortality, SEER data (Syapse)

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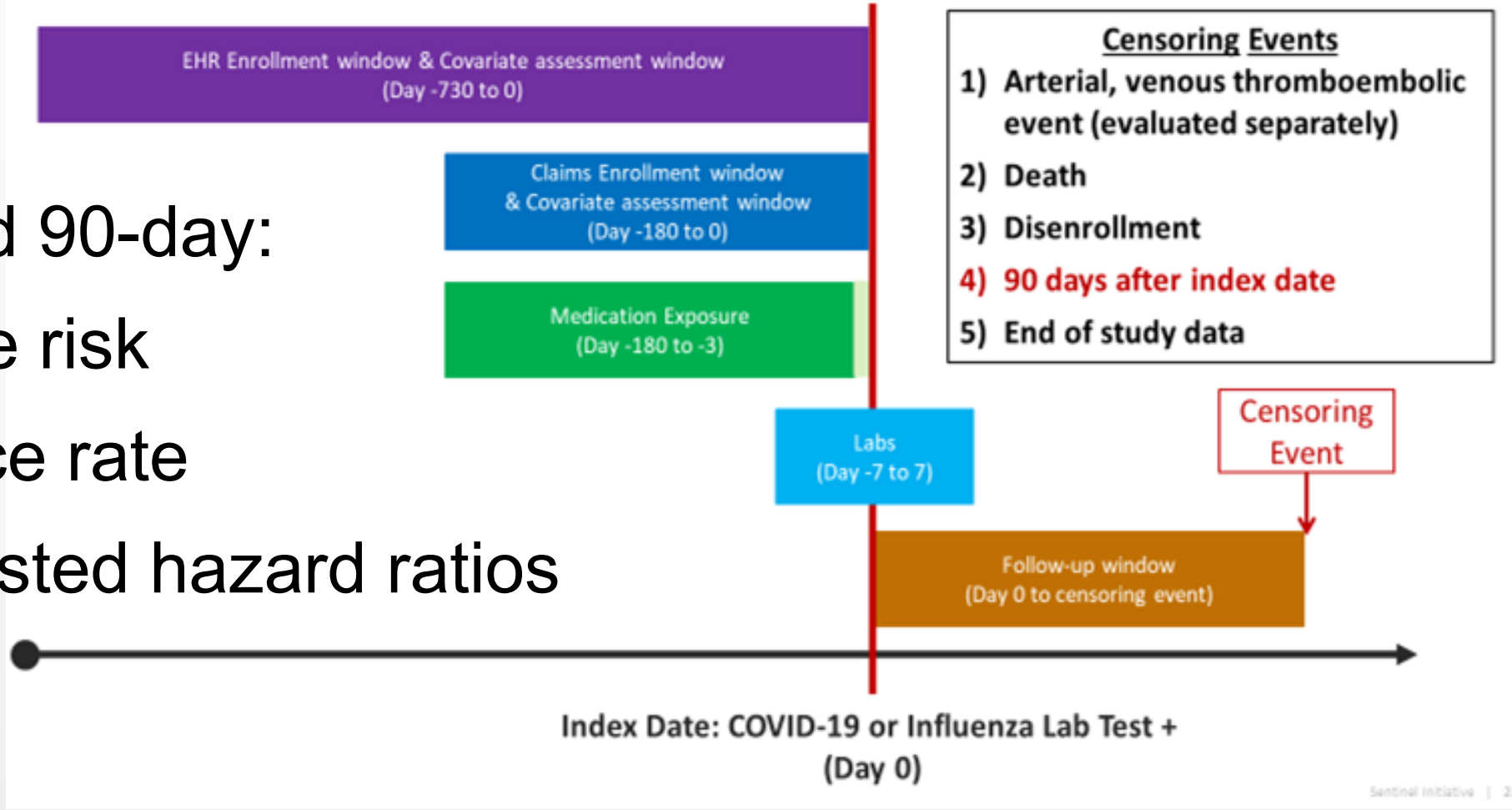
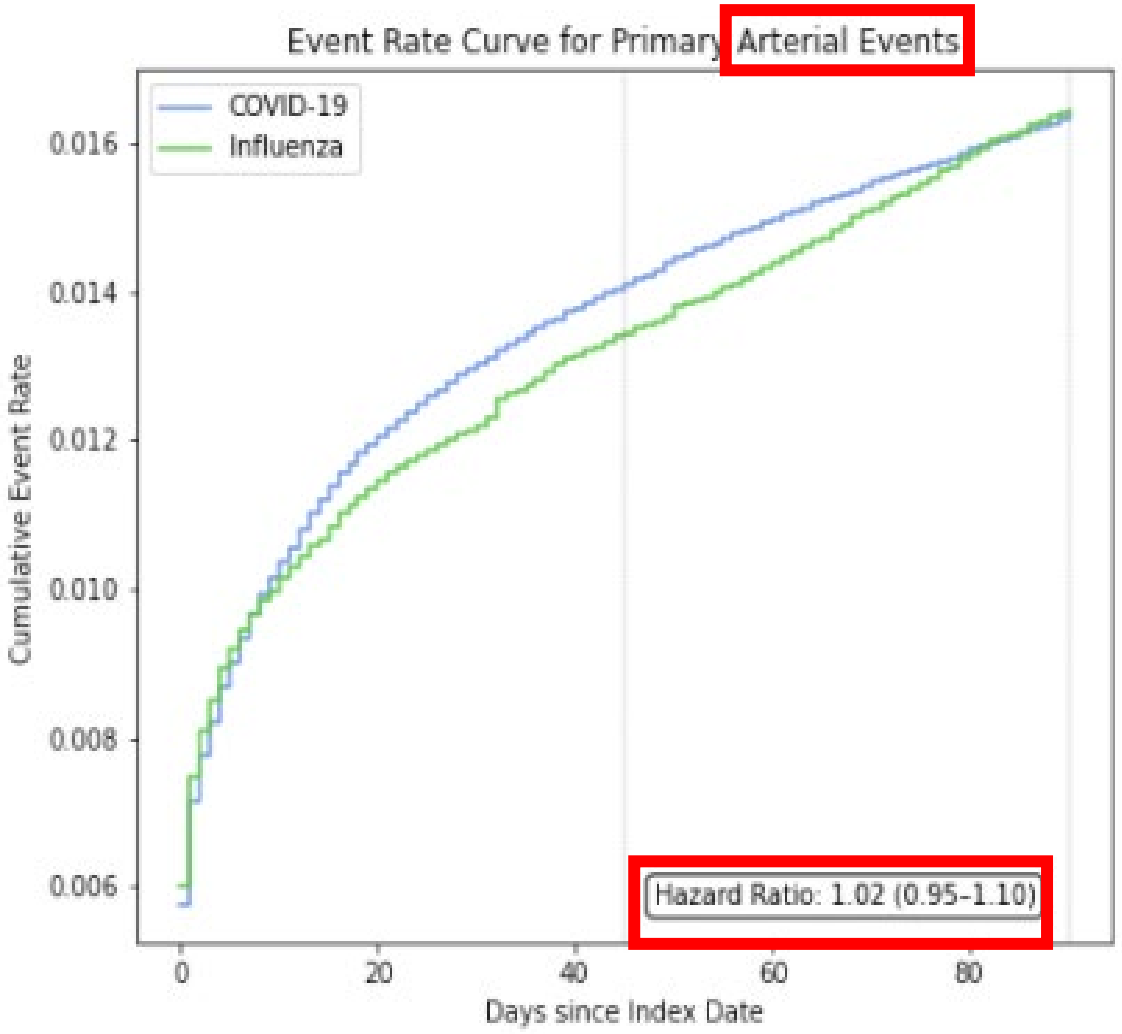
COMMON ANALYTIC APPROACH

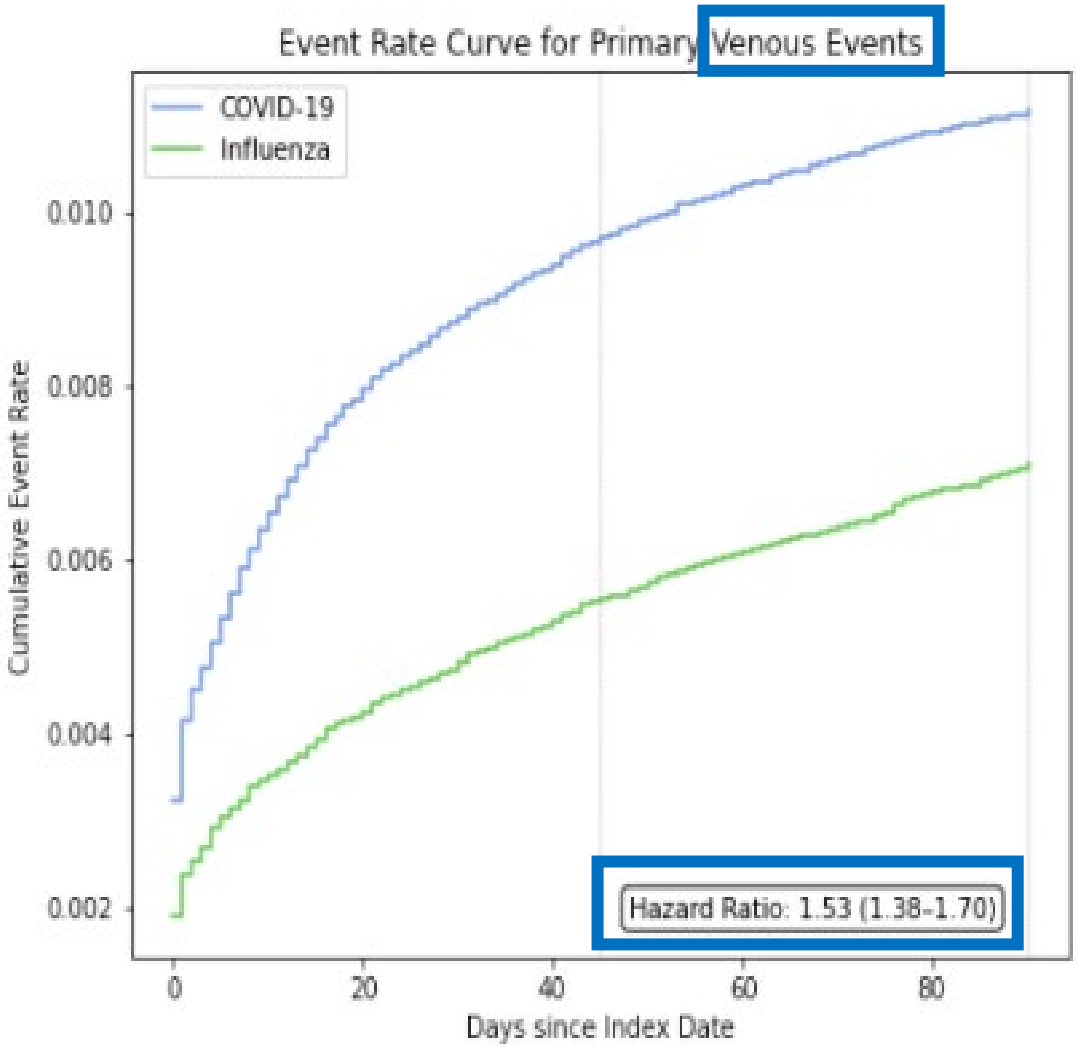
Calculated 90-day:

- Absolute risk
- Incidence rate
- PS-adjusted hazard ratios



COVID-19 (n=417,985) // Influenza (n=345,934)





Ward A, Sarraju A, Lee D, Bhasin K, Gad S, et al. (2022) COVID-19 is associated with higher risk of venous thrombosis, but not arterial thrombosis, compared with influenza: Insights from a large US cohort. PLOS ONE 17(1): e0261786. https://doi.org/10.1371/journal.pone.0261786
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261786

HEALTHPALS veradigm

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Sentinel

RESULTS

HRs for 90-Day ATE Among Patients Hospitalized With COVID-19 vs. Influenza

Cohort	COVID-19 Period 1 Cohort (Apr 1, 2020-Nov 30, 2020)			COVID-19 Period 2 Cohort (Dec 1, 2020-May 31, 2021)		
	No. Patients	No. Events	Weighted Hazard Ratio* (95% CI)	No. Patients	No. Events	Weighted Hazard Ratio* (95% CI)
Overall						
COVID-19	41,443	6,559	1.04 (0.97-1.11)	44,194	7,202	1.07 (1.00-1.14)
Influenza	8,269	1,190		8,269	1,190	
All-cause 30-day mortality after inpatient ATE event						
COVID-19	6,559	1,482	3.45 (2.68-4.45)	7,202	1,618	3.45 (2.69-4.44)
Influenza	1,190	94		1,190	94	

* HRs calculated after adjustment for Data Partner and propensity score fine stratification with stratum-specific weighting.

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Sentinel

RESULTS

HRs for 90-Day VTE Among Patients Hospitalized With COVID-19 vs. Influenza

Cohort	COVID-19 Period 1 Cohort (Apr 1, 2020-Nov 30, 2020)			COVID-19 Period 2 Cohort (Dec 1, 2020-May 31, 2021)		
	No. Patients	No. Events	Weighted Hazard Ratio* (95% CI)	No. Patients	No. Events	Weighted Hazard Ratio* (95% CI)
Overall						
COVID-19	41,443	3,917	1.60 (1.43-1.79)	44,194	4,799	1.89 (1.68-2.12)
Influenza	8,269	440		8,269	440	
All-cause 30-day mortality after inpatient VTE event						
COVID-19	3,917	714	2.96 (1.84-4.76)	4,799	985	3.80 (2.41-6.00)
Influenza	440	24		440	24	

* HRs calculated after adjustment for Data Partner and propensity score fine stratification with stratum-specific weighting.

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RESULTS

Unweighted (total sample and by place of service) and propensity score matched hazard ratios and 95% CI of arterial events or venous thrombotic events among patients diagnose with COVID-19 compared to influenza

	Hazard Ratio (95% CI)			
	All patients - Hazard Ratio (95% CI)	Inpatient - Hazard Ratio (95% CI)	Outpatient - Hazard Ratio (95% CI)	Site and PS matched Hazard Ratio (95% CI)
Primary arterial endpoint	0.87 (0.68-1.10)	0.69 (0.28-1.65)	0.85 (0.47-1.55)	1.10 (0.72-1.67)
Primary venous endpoint	0.82 (0.61-1.10)	0.54 (0.20-1.45)	0.74 (0.39-1.38)	0.74 (0.21-2.67)

•-Models adjusted for age, gender, ethnicity, oral anticoagulant use, hypertension, diabetes mellitus, chronic kidney disease, cerebrovascular disease, cancer, asthma, heart failure, venous thromboembolism (arterial endpoints), peripheral arterial disease (venous endpoints), atrial fibrillation, neurological disease

DATAVANT

Symphony Health
A PRAHEALTHSCIENCES COMPANY

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RESULTS

Among persons with cancer, rate of venous thromboembolism higher in COVID-19 vs. influenza.
Absolute risk, rate of arterial thrombosis not higher in COVID-19 vs. influenza.

	COVID-19 cohort (N = 7,591)			Influenza cohort (N = 319)		
	Absolute risk (N, %)		Incidence rates (per person-year)	Absolute risk (N, %)		Incidence rates (per person-year)
Primary Endpoints (primary or secondary Hospital Discharge ICD-10-CM Diagnosis)						
Arterial thrombosis, first event (combined)	160	(2%)	0.0935	10	(3%)	0.1335
Acute MI	81		0.0470	7		0.0930
Acute ischemic or embolic stroke	80		0.0464	3		0.0393
Venous thromboembolism, first event (combined)	240	(3%)	0.1414	5	(1.5%)	0.0661
Acute upper/lower deep venous thrombosis (DVT)	99		0.0575	3		0.0395
Acute pulmonary embolism (PE)	158		0.0924	2		0.0262

Syapse

RESULTS Summary

- Different data sources, including one specific to cancer patients, to address study aim
- 3 of 4 partners observed similar findings:
  - ↑ 90-day risk of VTE in COVID-19 vs. influenza
  - No ↑ 90-day risk of ATE in COVID-19 vs. influenza

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JAMA | Original Investigation

Association of COVID-19 vs Influenza With Risk of Arterial and Venous Thrombotic Events Among Hospitalized Patients

Vincent Lo Re III, MD, MSCE; Sarah K. Dutcher, PhD; John G. Connolly, ScD; Silvia Perez-Vilar, PharmD, PhD; Dena M. Carbonari, MS; Terese A. DeFor, MS; Djeneba Audrey Djibo, PhD; Laura B. Harrington, PhD, MPH; Laura Hou, MS; Sean Hennessy, PharmD, PhD; Rebecca A. Hubbard, PhD; Maria E. Kempner, BA; Jennifer L. Kuntz, PhD; Cheryl N. McMahill-Walraven, PhD; Jolene Mosley, MS; Pamala A. Pawloski, PharmD; Andrew B. Petrone, MPH; Allyson M. Pishko, MD, MSCE; Meighan Rogers Driscoll, MPH; Claudia A. Steiner, MD, MPH; Yunping Zhou, MS; Noelle M. Cocoros, DSc, MPH

PLOS ONE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

COVID-19 is associated with higher risk of venous thrombosis, but not arterial thrombosis, compared with influenza: Insights from a large US cohort

Andrew Ward, Ashish Sarraju, Donghyun Lee, Kanchan Bhasin, Sanchit Gad, Rob Beetel, Stella Chang, Mac Bonafede, Fatima Rodriguez, Rajesh Dash

Published: January 12, 2022 • https://doi.org/10.1371/journal.pone.0261786

See the preprint

DIAGNOSTICS

Nancy Lin, ScD

Director of Epidemiology, Real World Solutions, IQVIA

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DIAGNOSTICS
Utilization/Performance of Serology

Aim 1: Describe serological testing by demographic, geographic, location, baseline clinical presentation, & key comorbidities

- Understand current state of data interoperability across instrument, laboratory & clinical data

Aim 2: Estimate the positive percent agreement (PPA) of serological samples from people with positive SARS-CoV-2 by molecular assay

- Identify factors associated with seropositivity.

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PARTNERS | Data Types

AETION / healthverity	Optum Labs	UNIVERSITY OF CALIFORNIA UCHealth	HealthCatalyst ignite outcomes improvement	CERSI Yale-Mayo Clinic	Regenstrief Institute
Mar 1, 2020-Dec 31, 2020	Mar 1, 2020-Dec 31, 2020	Mar 1, 2020-Dec 31, 2020	Mar 1, 2020-Dec 31, 2020	Mar 1, 2020-Dec 31, 2020	Mar 1, Apr 30, 2021
Claims & Chargemaster Data from 75 unique data sources	Claims data from Large US Payor	EHR from the UC Healthcare System	EHR from 17 US Healthcare Systems	EHR data from Mayo Clinic	EHR data from Indiana HIE

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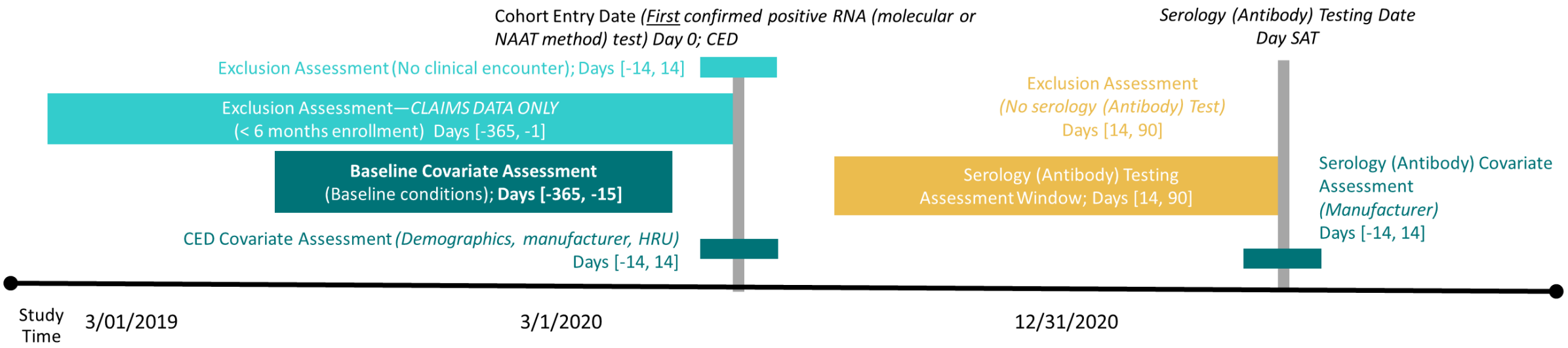
COMMON ANALYTIC APPROACH

Study Design



- **Descriptive Statistics** to describe utilization of serology by baseline characteristics
- **Positive Percent Agreement** = (No. of +antibody results ÷ No.of +RNA results) x 100.
- Binomial Distribution to estimate **odds ratio** for seropositivity by baseline characteristics

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RESULTS 1

FIGURE 1: Distribution of Serological Tests by Days After Positive PCR

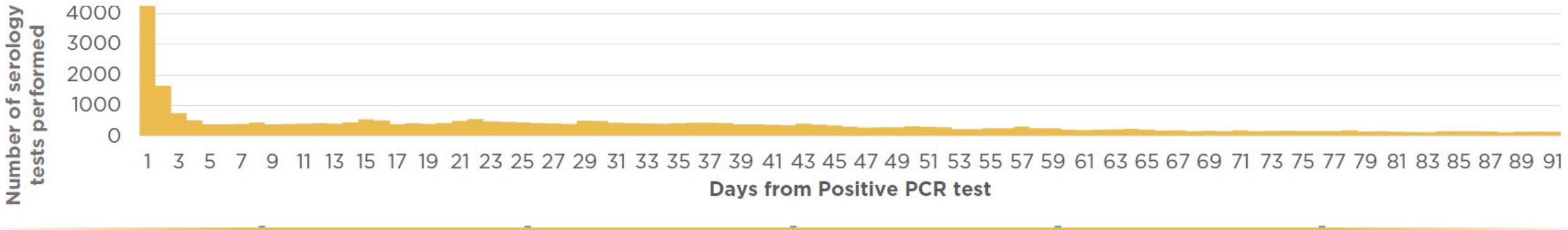
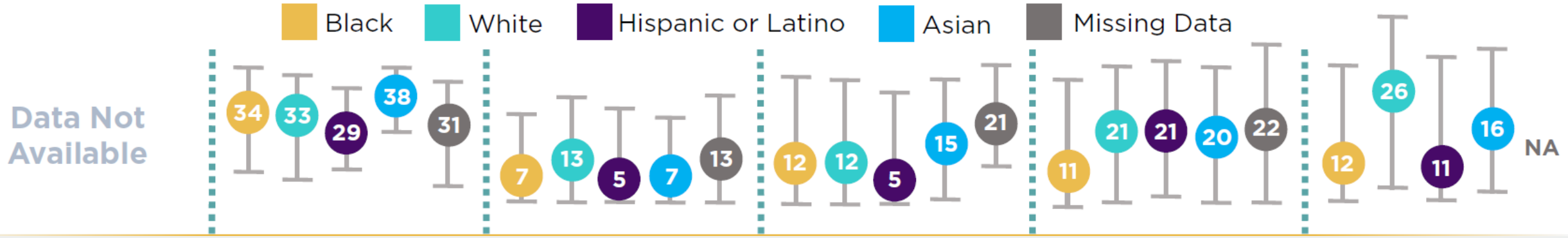


FIGURE 5: Median (IQR) Days Between RNA and Serology Tests Among Those Serotested



RESULTS 1

FIGURE 4: Race/Ethnicity Data Among Those Serotested

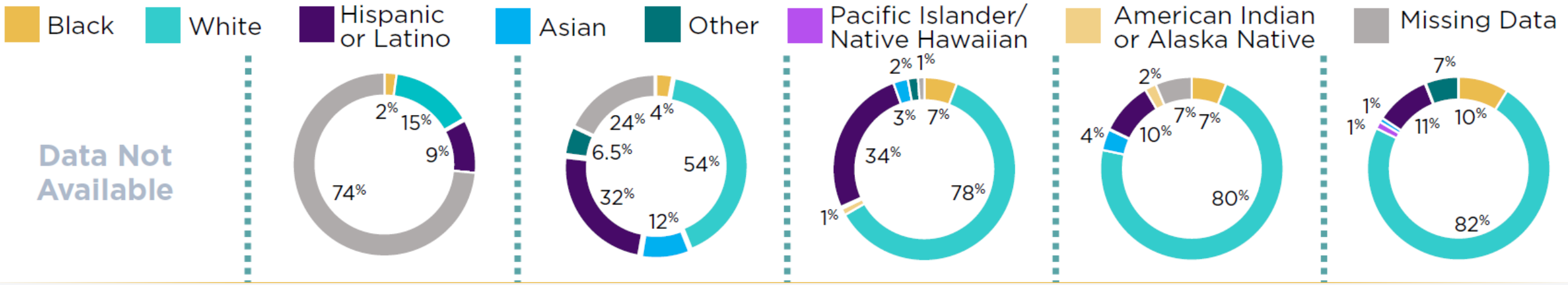
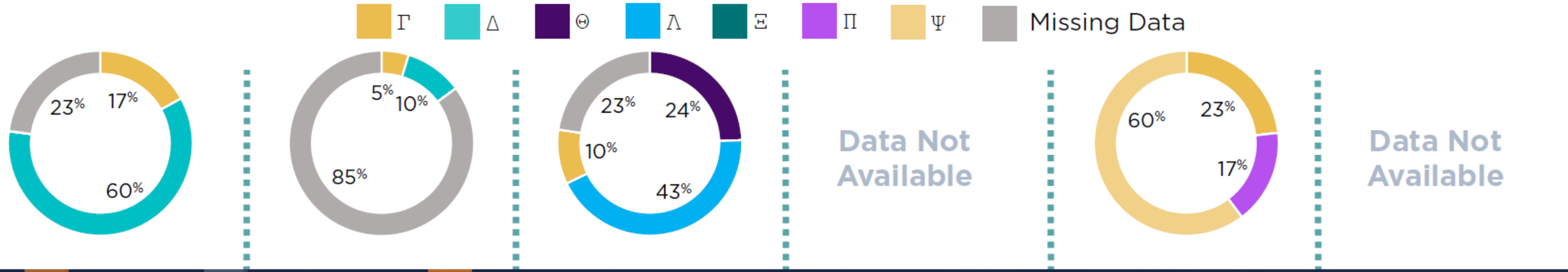
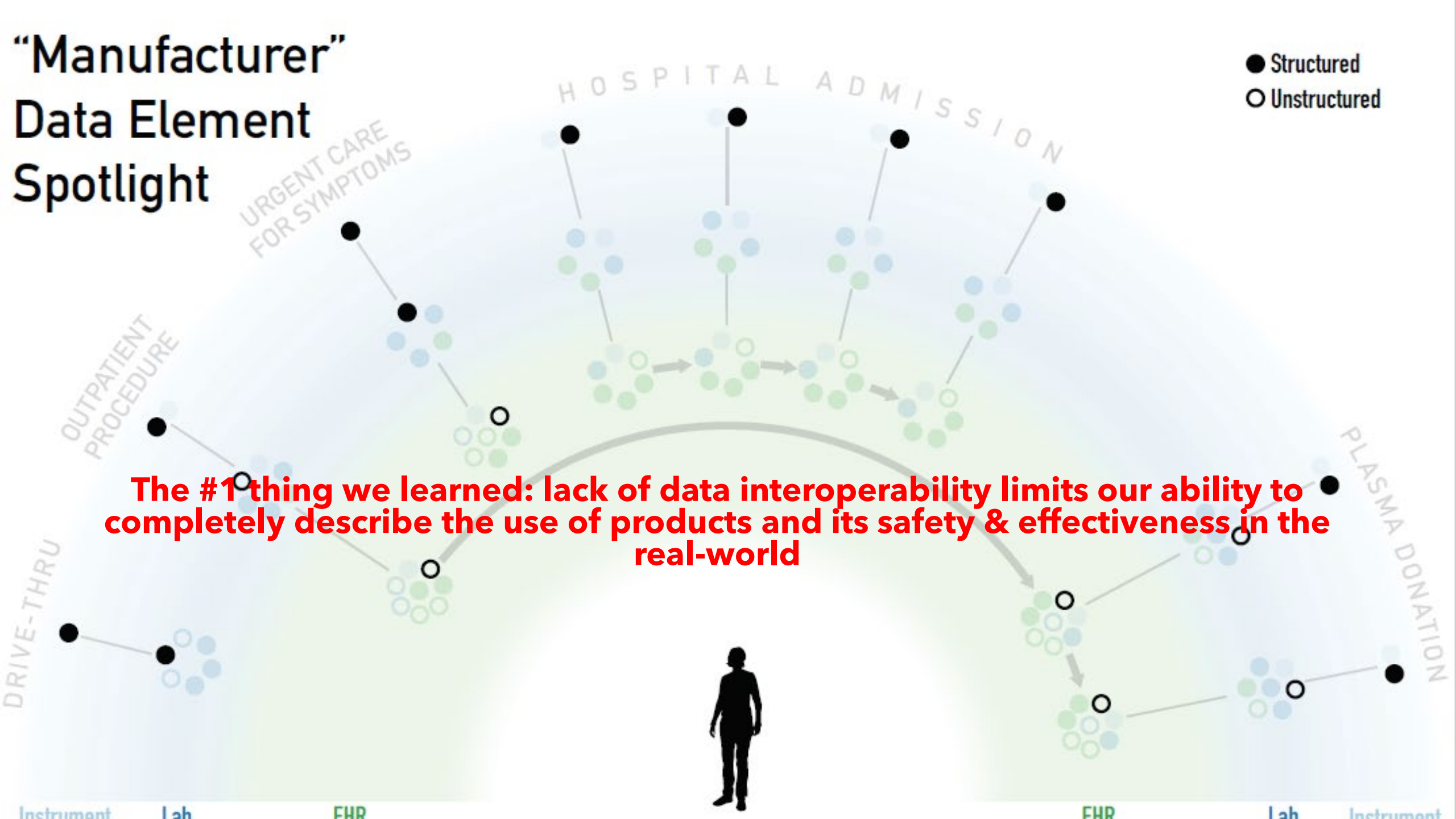


FIGURE 6: Manufacturer—Serological Test Name Among Those Serotested

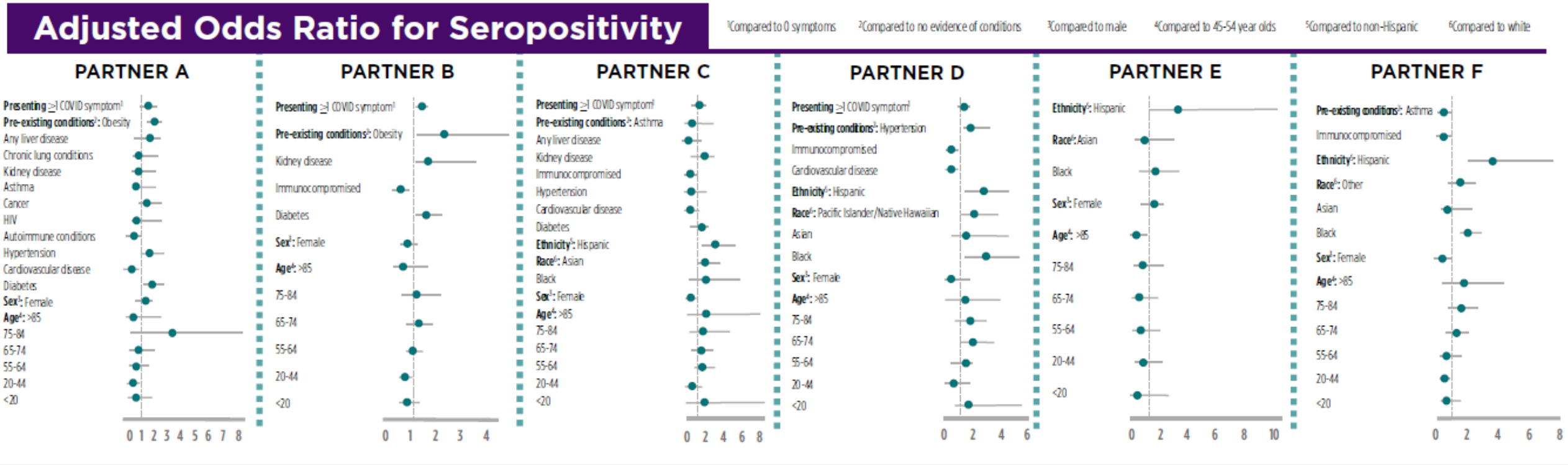


“Manufacturer” Data Element Spotlight



The #1 thing we learned: lack of data interoperability limits our ability to completely describe the use of products and its safety & effectiveness in the real-world

RESULTS 2



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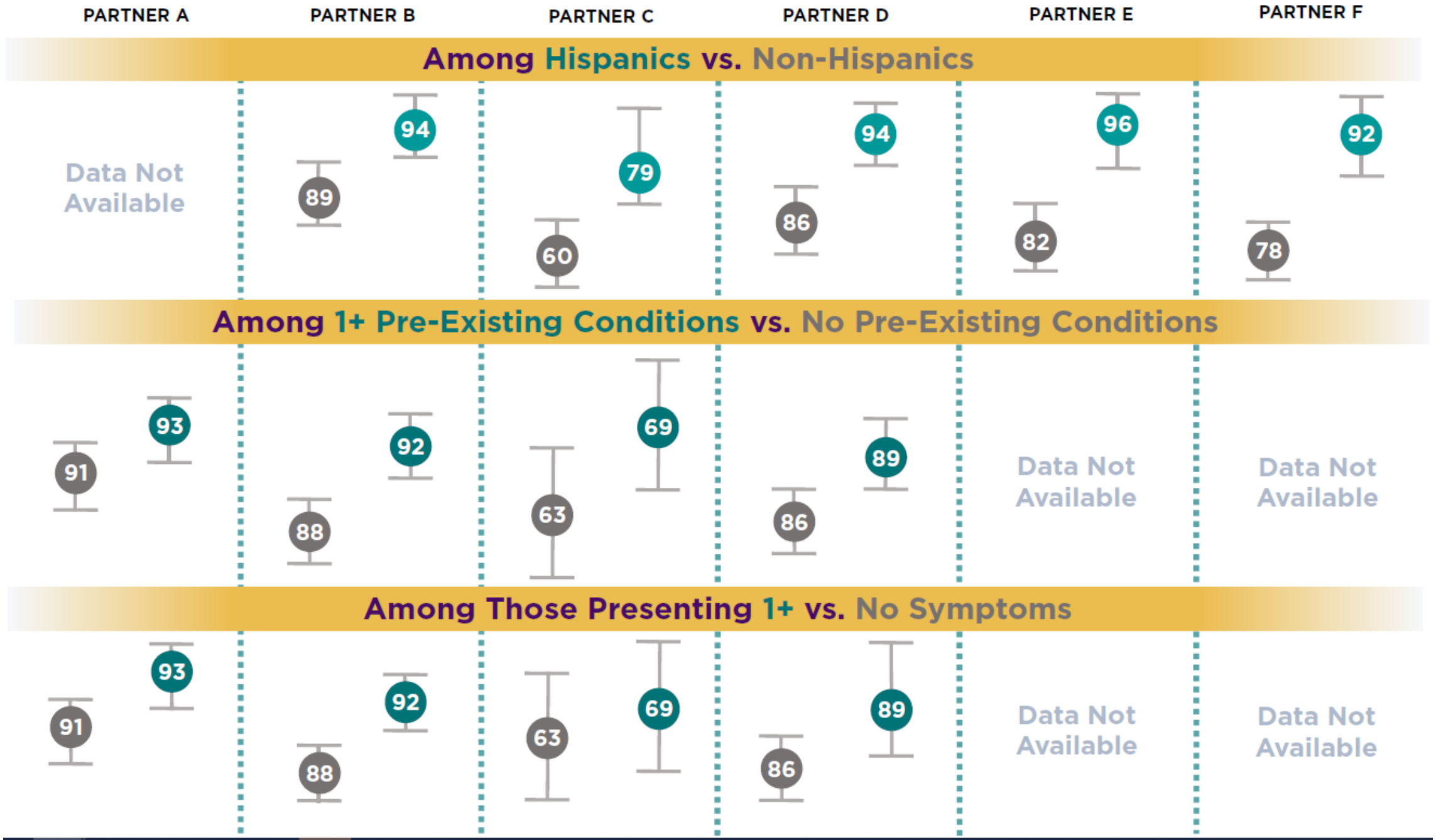
Positive Percent Agreement (95% CI) of +Serology for +Molecular Tests of SARS-CoV-2



DISCUSSION

What were some of the most salient methodological or data issues you saw arise and what was an important lesson about how your group drove towards a common protocol?

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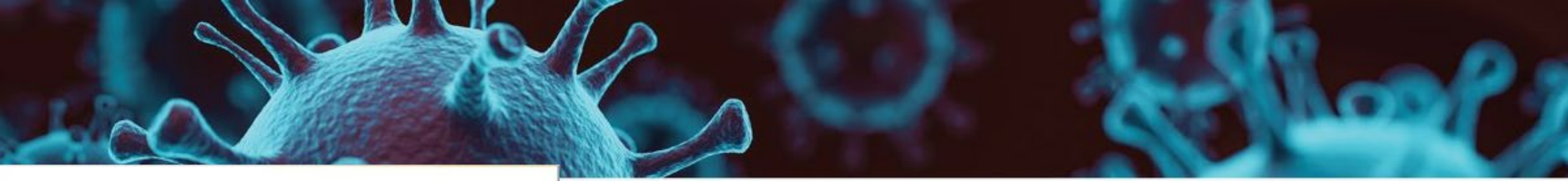

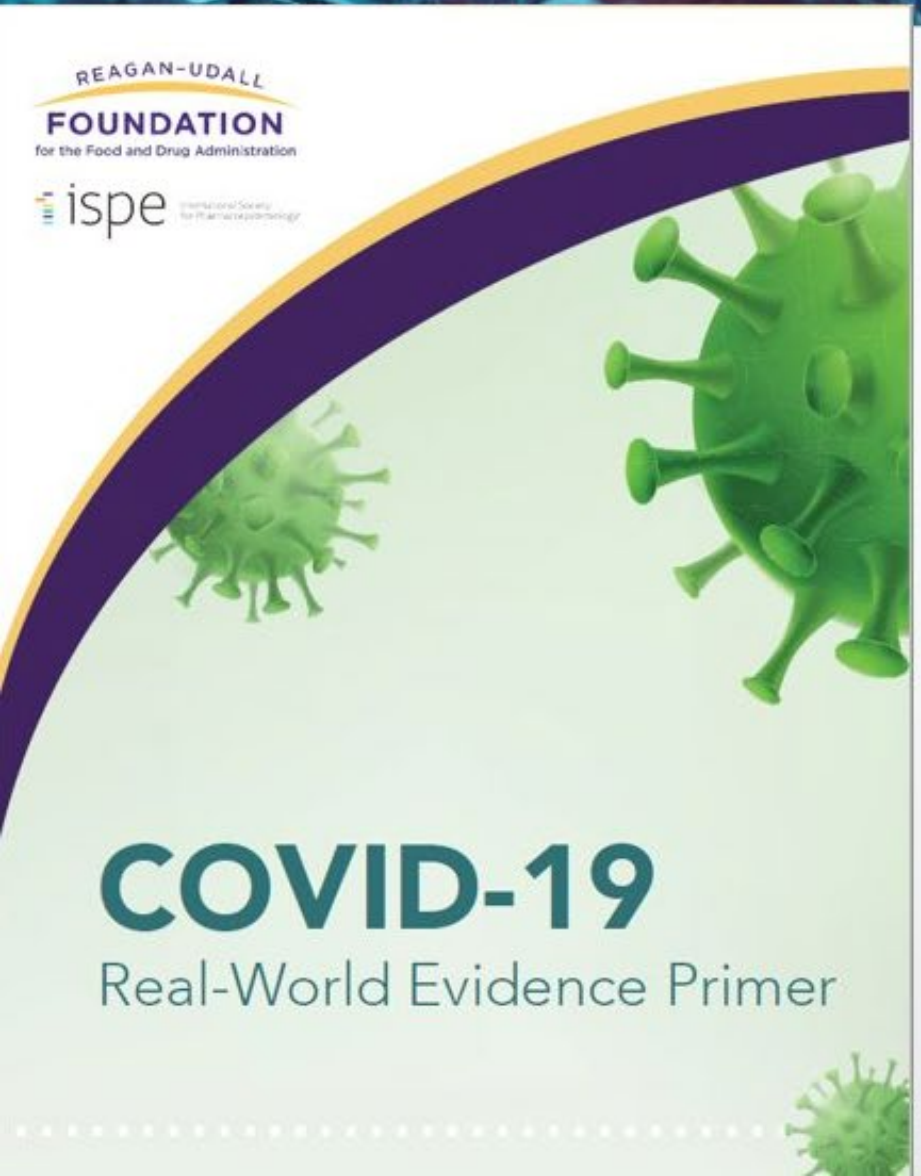

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Join the Conversation **starting January 1, 2023**

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How COVID-19 and the Evidence Accelerator Have Shaped the Use of Real-World Data

Moderator

Susan C. Winckler, *RPh, Esq, CEO, Reagan-Udall Foundation for the FDA*

Panelists

Nancy Dreyer, *PhD, MPH, IQVIA*

Adrian Hernandez, *MD, MHS, Duke University of School of Medicine*

Harvey Kaufman, *MD, Quest Diagnostics*

Nilay Shah, *PhD, Delta Airlines*

Closing Thoughts

Speakers

Susan C. Winckler, *RPh, Esq, CEO, Reagan-Udall Foundation for the FDA*

Ellen V. Sigal, *PhD, Chairperson and Founder, Friends of Cancer Research, and Chair of Board of Directors, Reagan-Udall Foundation for the FDA*


Thank you!
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