NAM Leadership Consortium

Collaboration for a Value & Science-Driven Health System

Digital Health and Evidence Mobilization Action Collaboratives Joint Webinar

Developing a nationwide coordinated system of shared health data with insight from COVID-19

April 22, 2021 | 9:30 AM – 12:30 PM EST

Share your thoughts!

@theNAMedicine

NATIONAL ACADEMY OF MEDICINE

Welcome & Introduction

Michael McGinnis
Leonard D. Schaeffer Executive Officer

Evidence Mobilization Action Collaborative Chairs

Richard Kuntz
Medtronic

Richard Platt
Harvard University

Digital Health Action Collaborative Chairs

Reed Tuckson
Tuckson Health Connections

Jonathan Perlin
HCA Healthcare

NAM LEADERSHIP CONSORTIUM

Stakeholder leaders in private, public, and independent organizations from key health sectors, collaborating under the auspices of the National Academy of Medicine for action on their common interests in advancing effectiveness, efficiency, equity, and continuous learning in health, medical care, and biomedical science.

NAM LEADERSHIP CONSORTIUM

Advancing the Learning Health System

A learning health system is one in which science, informatics, incentives, and culture are aligned for continuous improvement, innovation, and equity—with best practices and discovery seamlessly embedded in the delivery process, individuals and families active participants in all elements, and new knowledge generated as an integral by-product of the delivery experience.

Leadership Consortium Charter 2006

focus:

COLLABORATIVE ACTION

COLLABORATIVE ACTION

SCIENCE: Evidence Mobilization Action Collaborative

FOCUS: *continuous learning through real-world evidence*

INFORMATICS: Digital Health Action Collaborative

FOCUS: *digital infrastructure & data as a core utility*

INCENTIVES: Value Incentives & Systems Action Collaborative

FOCUS: *payment based on health outcomes for people and populations*

CULTURE: Culture, Inclusion & Equity Action Collaborative

FOCUS: *full and equitable health engagement for people and communities*

CORE ELEMENTS FOR EACH COLLABORATIVE

ORGANIZATIONAL NETWORKS

ANCHOR PRINCIPLES

KEY PROGRESS INDICATORS

COLLABORATIVE PROJECTS

Agenda

Welcome — 9:30 – 9:45 AM

Michael McGinnis, National Academy of Medicine
Richard Platt, Harvard University

Strategic Framing — 9:45 – 10:05 AM

Facilitator: **Michael McGinnis,** National Academy of Medicine
Nakela Cook, PCORI
Peter Lee, Microsoft
Sarah Green, National Academy of Medicine

Insights driven by the burning platform of COVID-19 — 10:05 – 10:50 AM

Facilitators: **Richard Kuntz,** Medtronic & **Richard Platt**, Harvard University
David Meyers, AHRQ/CHARGE & **Ken Sands**, HCA Healthcare/CHARGE
Ken Gersing, NIH/NC3

Nation-wide Data Governance: Progress and Promise — 10:50 – 12:05 PM

Facilitator: **Reed Tuckson,** Tuckson Health Connections
Micky Tripathi, ONC
Peter Margolis, Cincinnati Children's Hospital Medical Center; ImproveCareNow
Amy Abernethy, FDA

Open Discussion — 12:05 – 12:25 PM

Richard Kuntz, Medtronic & **Michael McGinnis**, National Academy of Medicine

Closing Remarks & Adjourn — 12:25 – 12:30 PM

Michael McGinnis, National Academy of Medicine

Zoom Instructions

Panelists

- Always keep your line muted unless you are called on to speak
- If possible, turn on video while speaking to the group. To enable video click the 'start video' option at the bottom left of your screen

Attendees - Q & A

- Please type in questions into the Q&A located at the bottom of the screen on your zoom interface
- Question format:
  - Your name and organization
  - To whom
  - Question

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Strategic Framing

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COVID-19 Sector Impact Assessments Lead Authors

Sector Assessment	Lead Authors
Patients, families, & consumers	**CEO, Families USA** **Director, Center for Health Transitions** **CEO, AAMC**
Clinicians & professional societies	**CEO, American Medical Association** **CEO, American Academy of Nursing**
Care delivery organizations	**CEO, Vanderbilt University Medical Center** **CEO, Geisinger**
Digital health	**Principal Deputy Commissioner, FDA** **Research Director, Microsoft**
State & local public health	**Chief Health Officer, Google** **President, Missouri Health Foundation**
Health payers	**Former Administrator, CMS** **COO, Optum Care Solutions**
Health product manufacturers & innovators	**Global R&D Head, J&J/Janssen** **CEO, Novartis**
Health & biomedical research	**Executive Director, PCORI** **Deputy Director, NIH**
Quality, safety, & standards	**Deputy Under Secretary, VA** **SVP, Humana**

DISCUSSION PAPER

Public Health COVID-19 Impact Assessment: Lessons Learned and Compelling Needs

Karen DeSalvo, MD, MPH, MSc, Dell Medical School at The University of Texas at Austin; **Bob Hughes, PhD,** Missouri Foundation for Health; **Mary Bassett, MD, MPH,** Harvard University; **Georges Benjamin, MD,** American Public Health Association; **Michael Fraser, PhD, CAE,** Association of State and Territorial Health Officials; **Sandro Galea, MD, MPH, DrPH,** Boston University School of Public Health; **J. Nadine Gracia, MD, MSCE,** Trust for America's Health; and **Jeffrey Howard, MD, MBA, MPH,** former Public Health Commissioner, Kentucky

April 7, 2021

About the NAM series on Emerging Stronger After COVID-19: Priorities for Health System Transformation
This discussion paper is part of the National Academy of Medicine's Emerging Stronger After COVID-19: Priorities for Health System Transformation initiative, which commissioned papers from experts on how 9 key sectors of the health, health care, and biomedical science fields responded to and can be transformed in the wake of the COVID-19 pandemic. The views presented in this discussion paper and others in the series are those of the authors and do not represent formal consensus positions of the NAM, the National Academies of Sciences, Engineering, and Medicine, or the authors' organizations.
Learn more: **nam.edu/TransformingHealth**

Introduction

Gains in life expectancy and quality of life over the course of American history can be attributed to forward-looking investments in public health infrastructure [1]. For example, the creation of municipal public health authorities in the 19th century supported improvements in sanitation and reduced the mortality burden from infectious diseases such as typhoid and cholera. Likewise, strategies to promote healthier environments and improve access to clinical services have improved the prevention and management of chronic diseases such as cardiovascular disease and cancer. In addressing each population health challenge, the public health sector has played a multifaceted role, from surveilling the causes and consequences of disease (e.g., the National Notifiable Diseases Surveillance System), to convening stakeholders across sectors to develop coordinated solutions (e.g., historical collaborations with housing authorities), to informing policymakers and the public about best practices (e.g., resources to promote tobacco cessation) [2,3,4].

These interdisciplinary functions are more important than ever due to the complexity and scope of population health challenges in the modern era. For the first time in generations, life expectancy in the United States (U.S.) has begun to decline, with primary driv-

Nakela Cook, MD, MPH
Executive Director,
Patient-Centered Outcomes
Research Institute (PCORI)

Peter Lee, PhD
Corporate Vice President,
Research and Incubations,
Microsoft

Sarah Greene, MPH
Strategic Advisor,
National Academy of Medicine

Data Sharing During the COVID-19 Pandemic

Insights from the COVID-19 Biomedical Research Sector Assessment

Nakela L. Cook, MD, MPH
Executive Director, PCORI

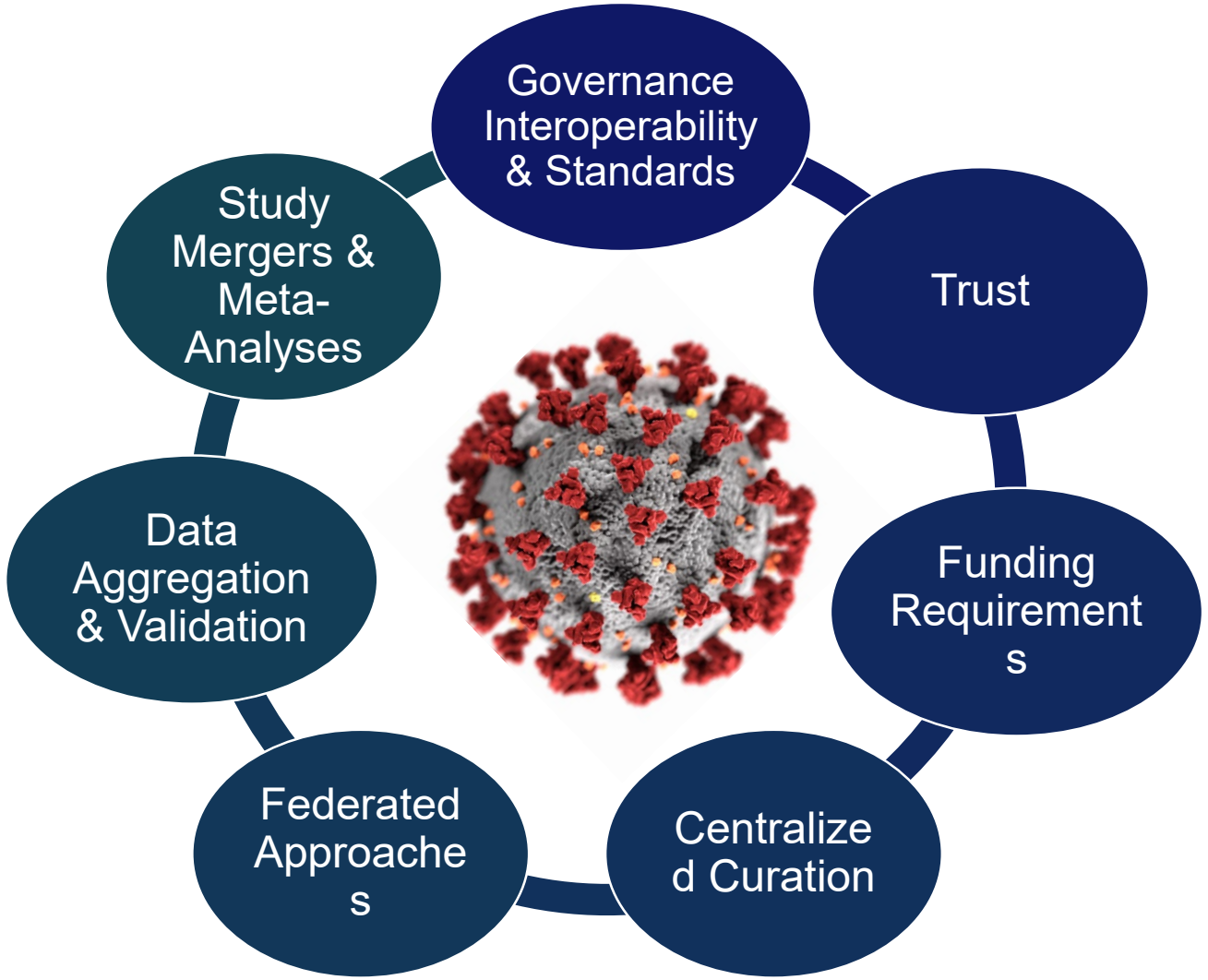
pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

A Stress Test and Learning Opportunity

Research Sector's Experience with Data Sharing During COVID-19

Advancing Data Sharing in Research

Embracing Opportunities in a Crisis for Short and Long-term Learning and Impact



COVID-19 Use Case for Data Sharing
Lessons Learned

Trust

- Imbue and communicate trust
- Data sharing governance to reinforce

Incentives

- Data sharing is feasible and not prohibited by technical issues
- Alignment of incentives to advance

Methods & Technology

- Standards, harmonization, interoperability critical to path forward
- Infrastructure investment to support sharing

Health Data Sharing Governance Framework: Do we regress to the mean when the urgency is gone or capitalize on the progress made?

Impact Assessment:
Digital Health and COVID-19

Amy Abernethy, Peter Lee, David Shaywitz
Murali Doraiswamy, Adi Gundlapalli, Subha Madhavan, Kevin Shulman, Jim Weinstein

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Digital Health: Observations Across All Sectors

- Telehealth became real, practical, and essential during COVID-19 response.
- Data proved critical for coordination, forecasting, and quality, but also a time-consuming, and sometimes chaotic, burden on clinicians and administrators.
- Data interoperability and scaling proved to be more theory than reality in health and public health.
- Effective public-private partnerships proved essential in crisis response.
- The digital divide was occasionally bridged but more frequently contributed to and often exacerbated health inequities.
- Digital and AI tools became key to advancing knowledge and coping with information

Digital Health Across All Sectors

Sectors	Digital Health Challenges and Opportunities					
	Telehealth became real	Data proved critical for coordination, forecasting & quality	Need for data interoperability	Effective public-private partnerships	Addressing health inequities	AI tools to address information overload
1. Health product manufacturers	X	X		X		
2. Clinicians & Professional Societies	X	X	X		X	X
3. Payers		X	X			
4. Care delivery organizations	X	X	X		X	
5.Quality & Safety		X	X			
6.Patients/Families/Communities	X		X		X	
7. Public Health		X	X	X		
8. Research	X		X			X

Digital Health in COVID-19 Response

The U.S. health care community looked to the interconnected system of devices, digital platforms, and data to help address questions [critical for COVID-19 response], since surely the answers lurked within the petabytes of digital data being generated daily by the health care system. The notion was that it only needed to be extracted, integrated, and disseminated in useful form – actions that are commonplace in many other industries with the use of a wide range of digital tools.

Instead, during the first nine plus months of the pandemic in the U.S., decision-makers were essentially "flying blind…" Legions of technologists rushed to address these crises in access, connectivity, and interoperability. Hundreds, and perhaps thousands, of new data systems were created and deployed with incredible speed… But these valiant efforts, while locally impactful, also resulted in the creation of yet more data silos that not only struggled to interoperate with the rest of the health care ecosystem, but contributed even more to its staggering, ineluctable complexity.

Health Data: Water, Water, Everywhere…

- Data without architecture leads to data silos

> One is reminded of the poem, *The Rime of the Ancient Mariner*, which contains the verse, "Water, water, everywhere, nor any drop to drink." Despite nearly complete digitization, and so many tools at our disposal for data analysis, machine learning, AI, and visualization, the health care community remained thirsting for the high-quality, actionable data upon which these technologies, patients, and caregivers foundationally depended, including data not only from health systems, but from all other relevant sources -- personal, social, infrastructural, biological, population-wide, and more. Thus, the tremendous advances in computer science that today powers global supply chains, massive retail markets, internet search, social media, and more, remained and still remains a stark contrast to the ongoing creation of yet more inaccessible data silos in health care. The ongoing challenges encountered in vaccine distribution and monitoring are only the most current and urgent example of the existing limitations of data visibility, fluidity, transparency, and access.

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Advancing Progress toward Health Data Sharing

Sarah M. Greene, MPH

April 22, 2021

DHAC/EMAC Joint Meeting

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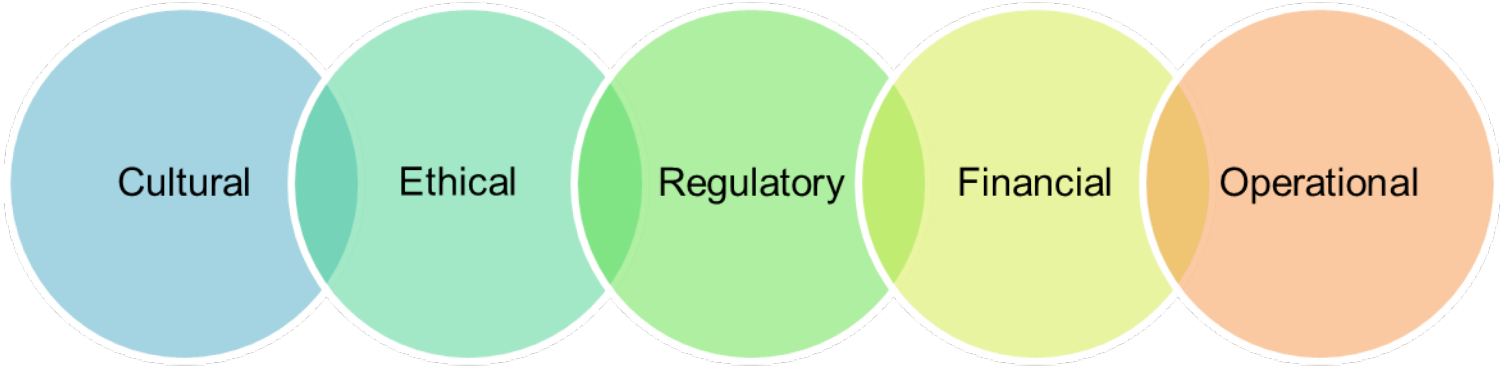
(Biggest) Barriers to Sharing Health Data



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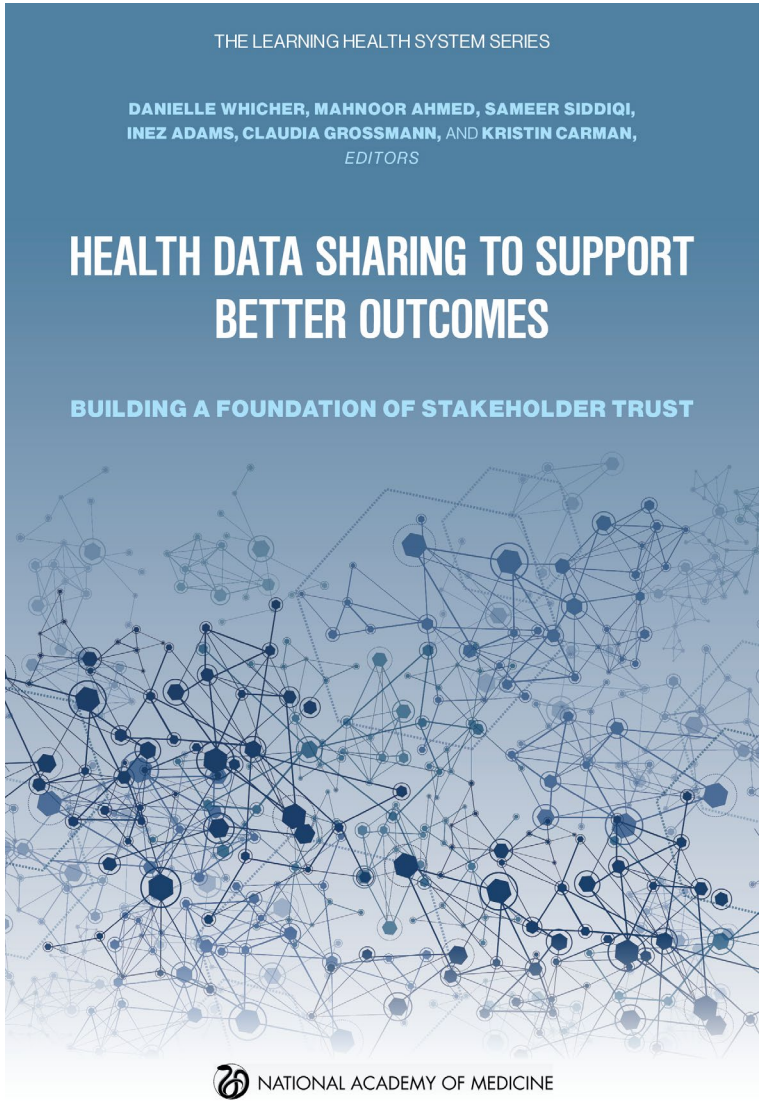
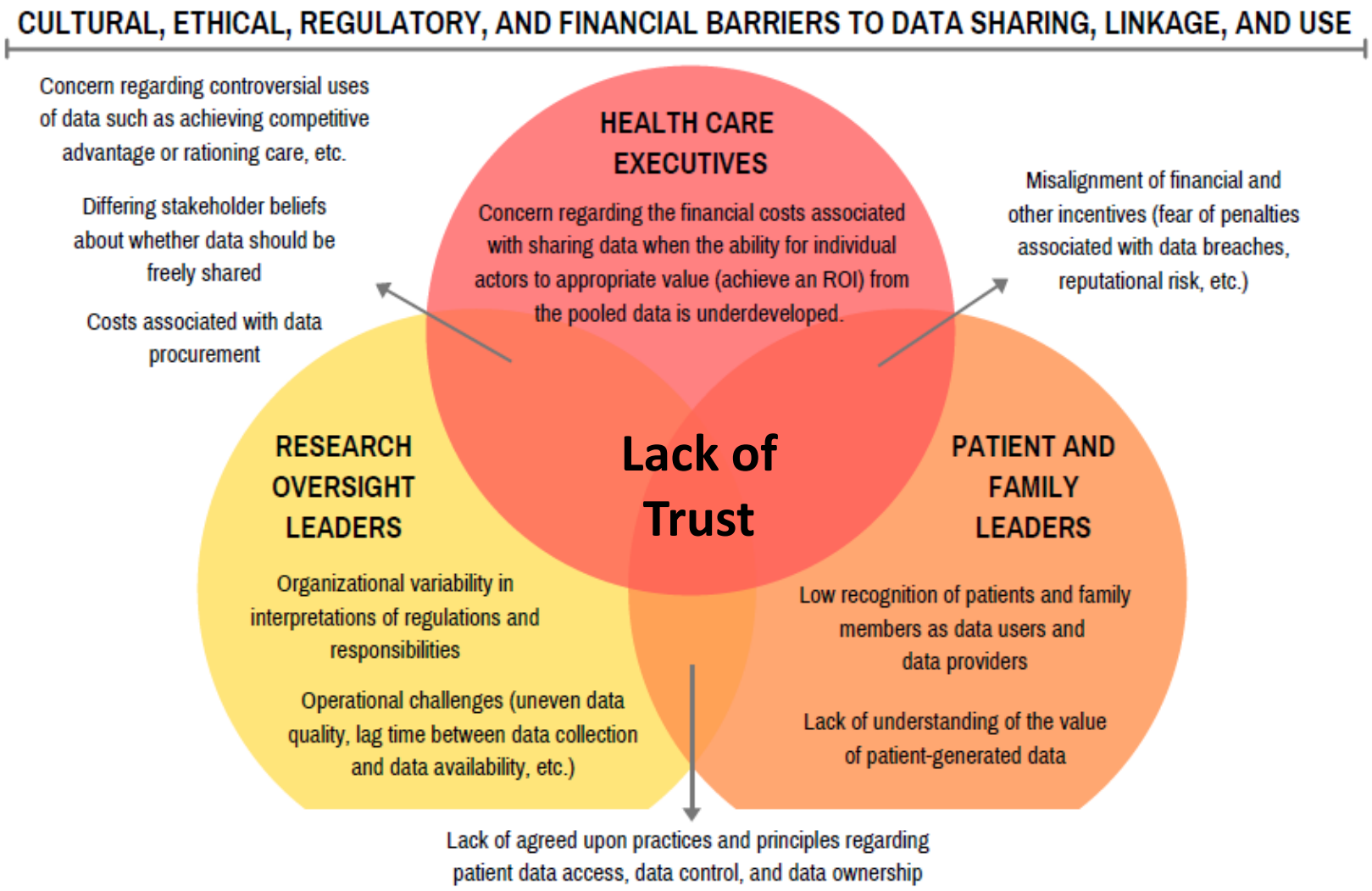


Read the publication at nam.edu/DataSharingTrust

Key Findings from the Report



Proposed Action Steps

1. Develop business case for data sharing
2. **Create and prioritize use cases**
3. Engage in a public information campaign
4. Incentivize data sharing via new payment models
5. Institute legislation and policy levers
6. Forge consensus on data stewardship, accessibility, and control principles
7. Build trust & transparency

11 Data Sharing Exemplars across the health/care ecosystem

- *Aim*: Develop an accessible reference, based on real-world examples, to show how organizations can collaborate to share and link data while safeguarding consumer interests around data protection and privacy

- *Anchor*: Map case studies to common barriers identified in the report

- *Case Study Summaries*: value proposition, success factors, barriers they addressed, data governance and organizational governance, advice for others, and “magic wand request”

- *Timeline*: In progress, anticipated completion Nov 2021

Prevalent Themes from the Case Studies – Value Proposition

Data get better with use--

Sharing data will enable discovery, lead to better care, and enhance reputation

"Every single touchpoint provides information about our patients and populations.

If we just let it sit there, we are not fulfilling part of our responsibility as a health system."

Prevalent Themes from the Case Studies – Build the Evidence Base

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Several groups are publishing their experiences, and promulgating transparency and engagement

"We need to learn from past incidents in which patient trust was damaged as a result of data breaches or intentional data sharing without patient consent…

*We want to **contribute** to the evidence base on engagement and data sharing and simultaneously **use** that evidence to shape our policies and procedures, and **create** a roadmap for others."*

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The Imperative: Cultivating Trust

Thank you to Case Study Project Collaborators Noor Ahmed & Peak Sen-Chua!

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Insights driven by the burning platform of COVID-19

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David Meyers, MD
Acting Director,
Agency for Healthcare
Research and Quality (AHRQ)

Ken Sands, MD, MPH
Chief Epidemiologist and Chief
Patient Safety Officer,
HCA Healthcare

Ken Gersing, MD
Director of Informatics,
National Institutes of Health



AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ

The COVID-19 Consortium of HCA Healthcare and Academia for Research GEneration (CHARGE)

David Meyers
Acting Director

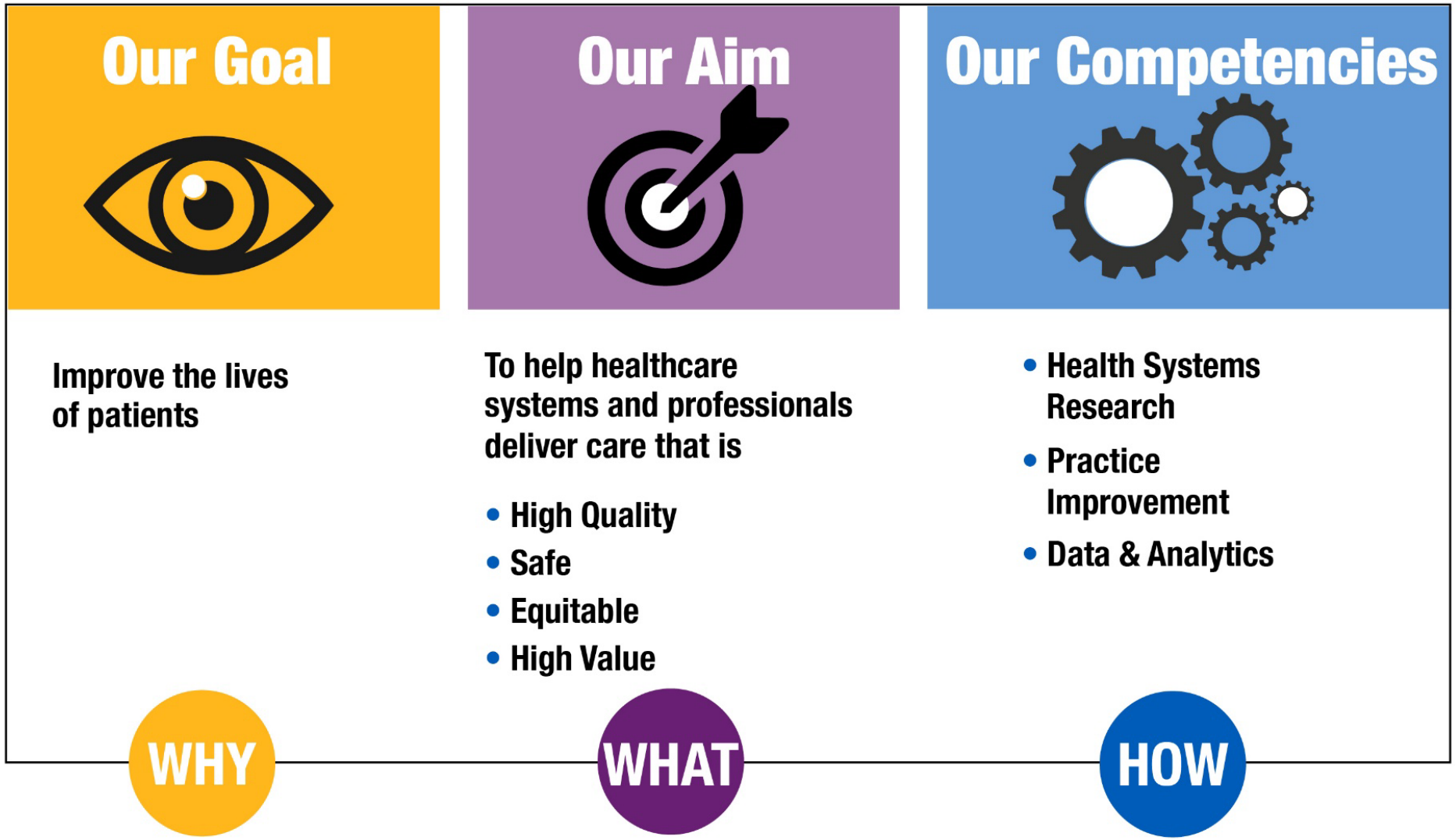
April 22, 2021

AHRQ's Role

- Making evidence-based, patient-centered care a reality for all Americans

- While science and research to discover cures is needed, ***science, research, and implementation to improve care is imperative***.

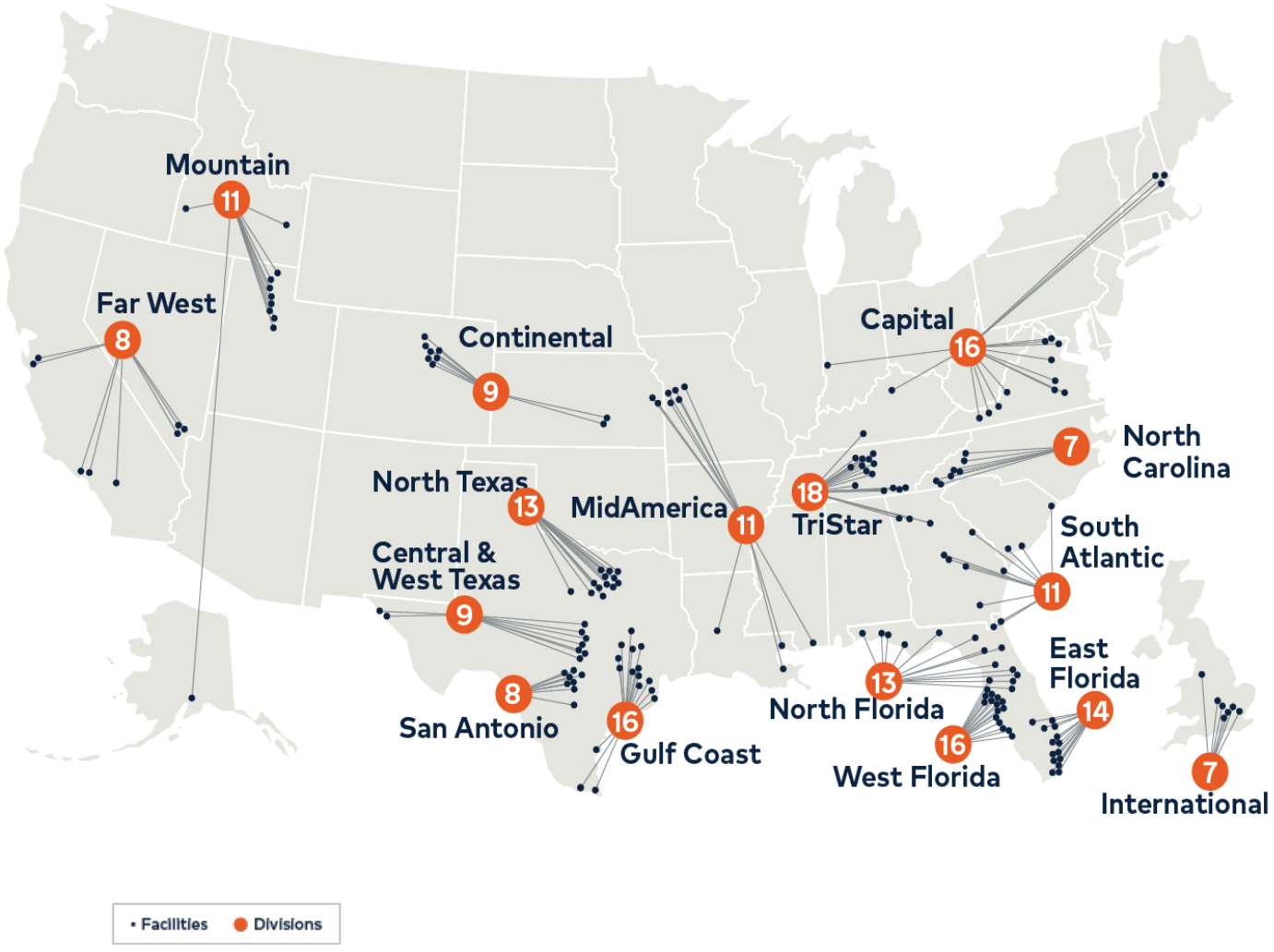
AHRQ's Vision, Aim and Core Competencies: *Why, What and How*



Innovation in a Time of Crisis

- The urgency of the COVID-19 pandemic provided motivation to overcome conventional barriers in healthcare delivery, healthcare evidence generation, and healthcare data sharing.

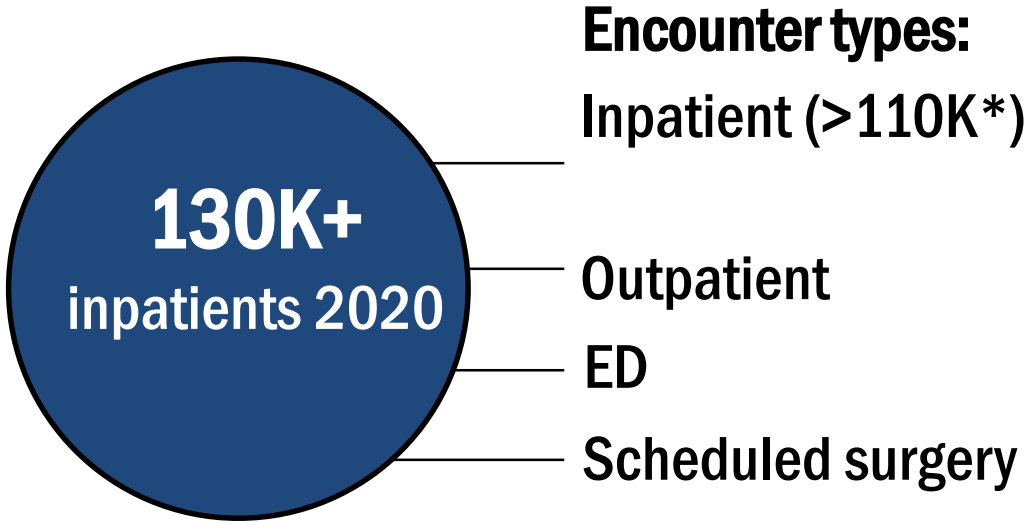
A Few Words About HCA Healthcare



- **187 hospitals**
- 154 freestanding surgery centers
- > 1,000 physician practices
- > 120 urgent care centers
- 37 million patient episodes annually
- **Located in 21 states** and UK
- Approximately 5% of major hospital services in U.S. including **~ 2.4 million admissions**
- ~ Hospitals range from complex tertiary referral and academic medical centers to urban and suburban community medical centers
- ~ 287,000 employees, including
  - > 98,000 nurses and 35,000 allied health professionals
- > 40,000 affiliated physicians, including
  - > 6,000 employed physicians and practitioners
  - > 4,000 housestaff
- > 45,000 licensed beds

HCA Healthcare COVID-19 Registry

Data collected from patients who tested positive for COVID-19 at an HCA Healthcare facility since March 1, 2020.



Research Consortium Objectives

1. Accelerate Understanding of COVID-19 and its Treatment
2. Introduce Novel Technology For Collaborative Research That Protects Privacy
3. Create Platform for New Paradigm of Research Partnership *(Governance)*
4. **Create an Engine to Accelerate Quality and Safety**

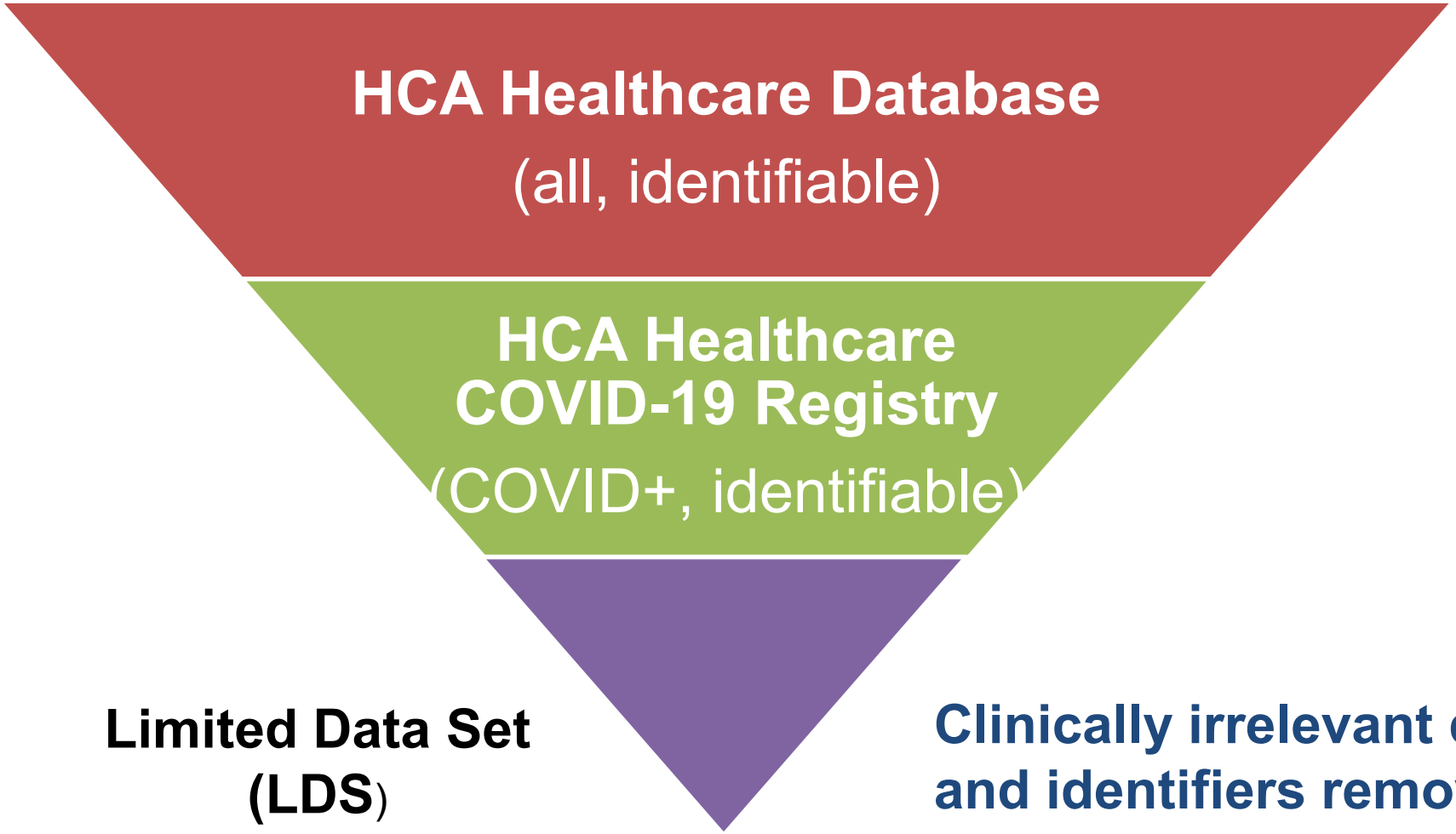
Founding CHARGE Organizations

- HCA Healthcare
- Sarah Cannon/ HCA Research Institute
- Agency for Healthcare Research and Quality (AHRQ)
- Columbia University
- Duke University
- Harvard Pilgrim Healthcare Institute
- Johns Hopkins University
- Meharry Medical College

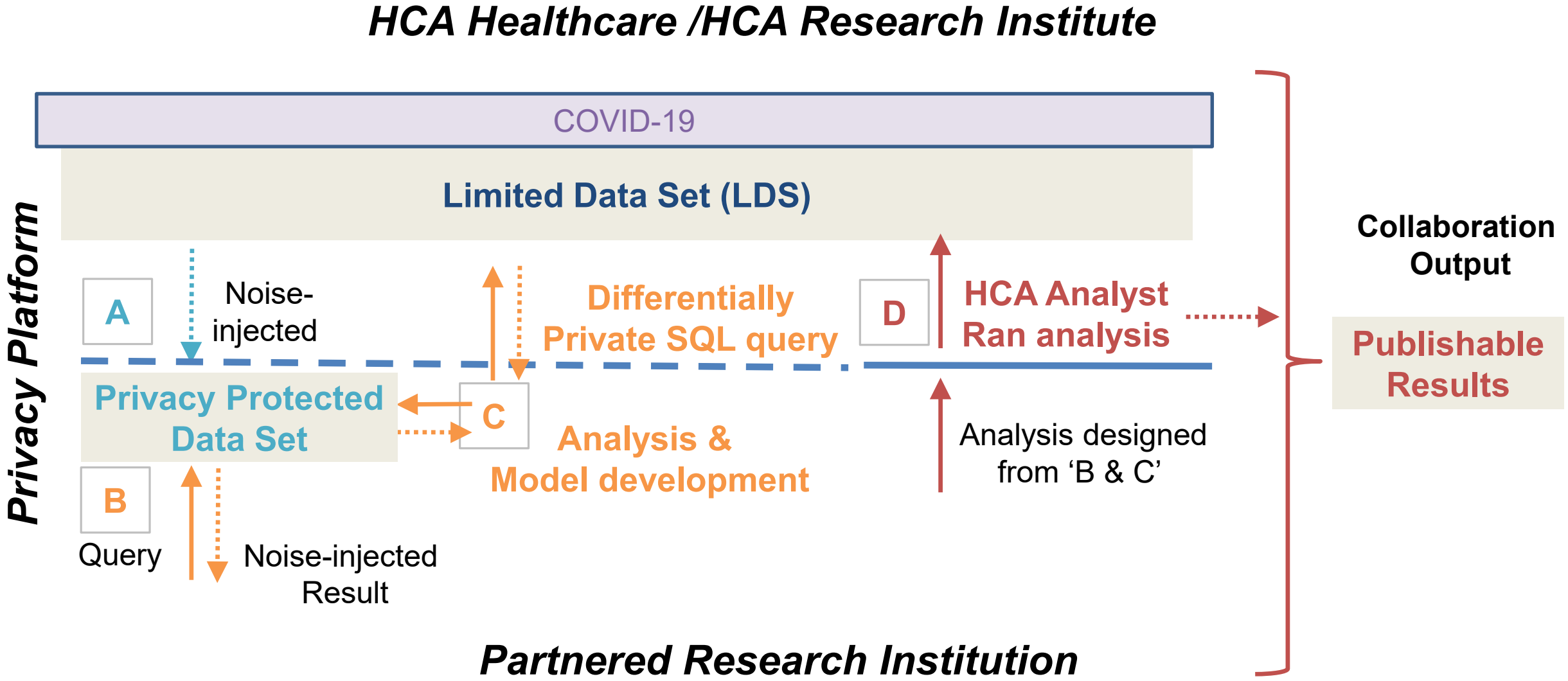
Hospital Medicine Reengineering Network (HOMERuN):

- Beth Israel Deaconess Medical
- Brigham and Women's Hospital
- Cleveland Clinic
- Univ. California San Francisco
- UMass Medical School – Baystate

Refining the Data Set



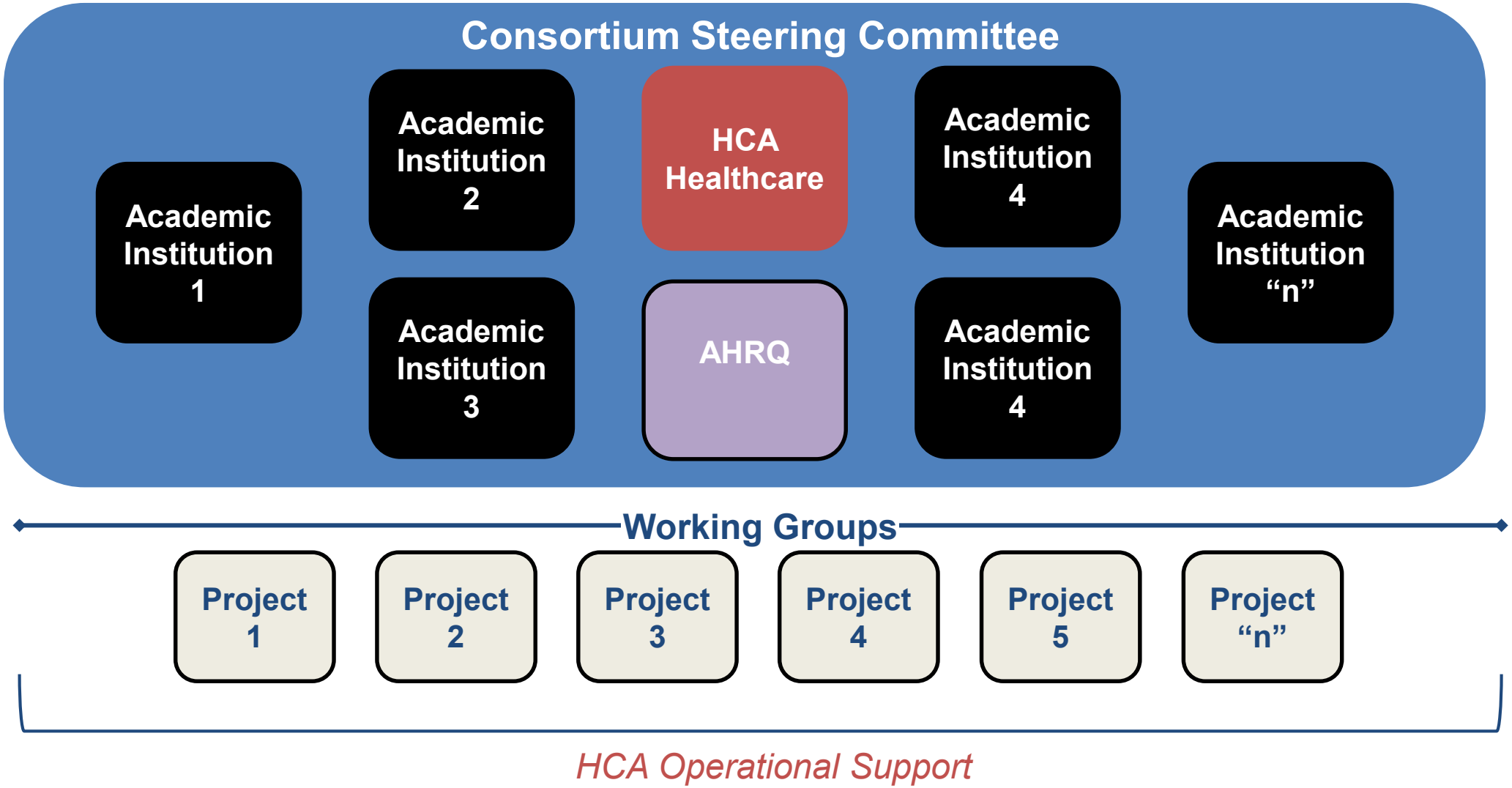
Potential Models for Ensuring Data Privacy



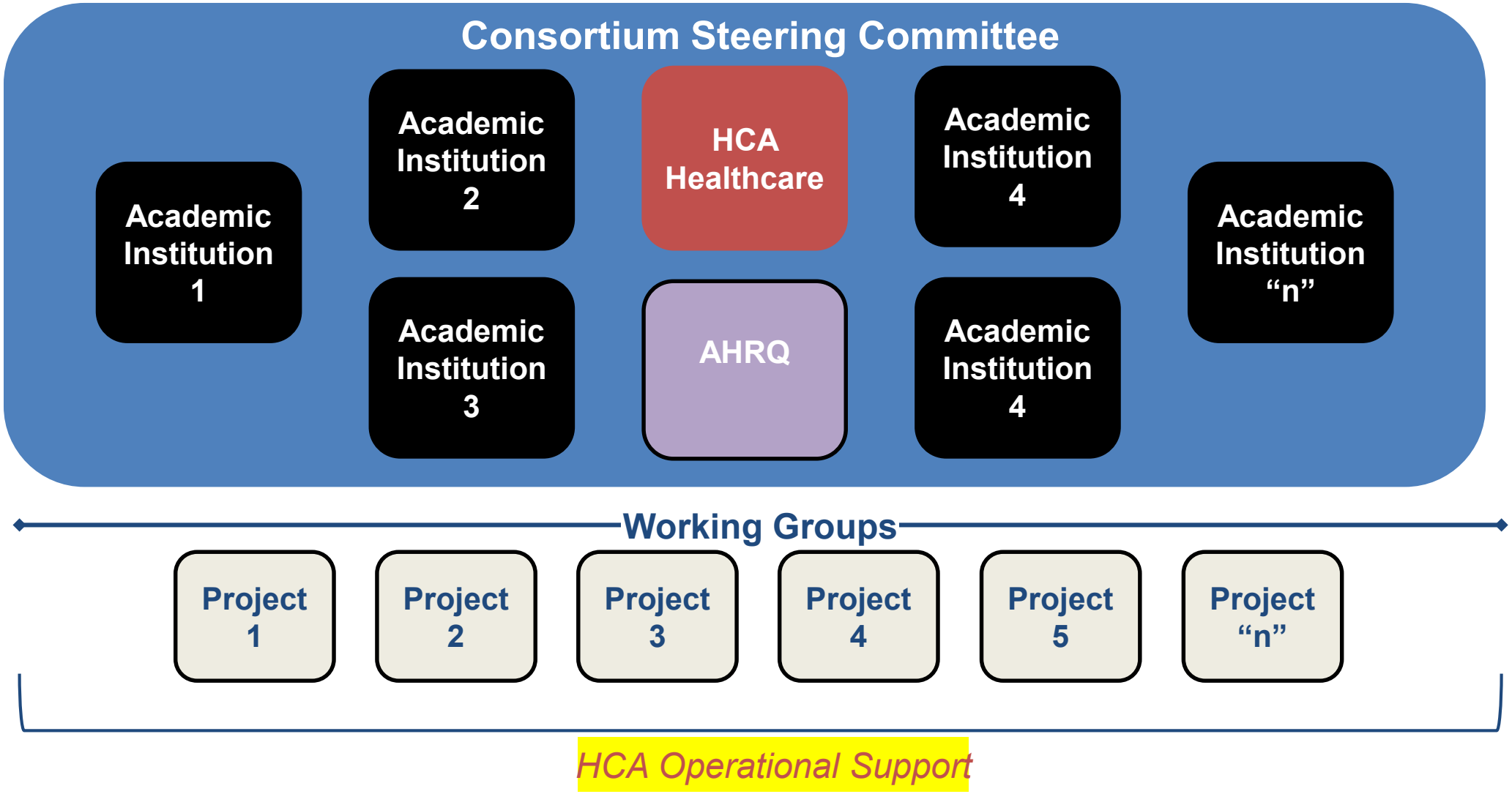
Governance

- CHARGE governance established by formal signed memorandum between each partner and HCA Healthcare/HCA Research Institute
- HCA maintains full control of its registry data sets and their use
- MOU establishes a Consortium Steering Committee (CSC)
- Common IRB framework established through HCA
- CSC reviews all study proposals
  - All organizations may provide feedback to improve methodology and relevance.
  - CSC members provide initial rating of enthusiasm for each proposal
  - HCA makes final determination of study approval
- Consortium MOU protects academic freedom for approved studies
- CSC meets regularly and addresses additional issues such as guidance for grant applications using CHARGE infrastructure

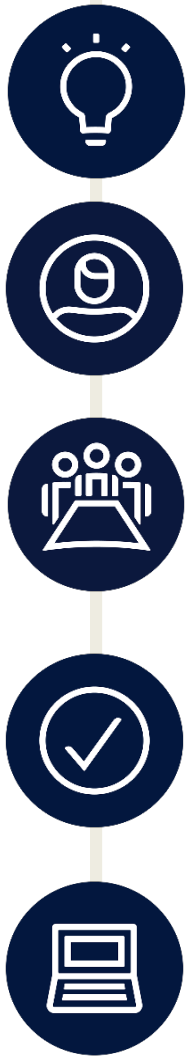
Consortium Steering Committee



Consortium Steering Committee



Research Flow



1. Research Institution(s) submits research proposal to Consortium
2. Experienced HCA Investigator(s) assigned to work with Project Team
3. Proposal submitted to Consortium Steering Committee (CSC) for review
4. CSC provides feedback and approval (confirmed by HCA)
5. Project Team develops analytic plan and conducts preliminary analysis using a privacy protected pathway
6. If needed, HCA analyst repeats analysis on full LDS and shares outputs
7. Team prepares manuscript
8. Internal peer review by CSC prior to submission for publication and pre-publication posting

Approved COVID-19 CHARGE Studies

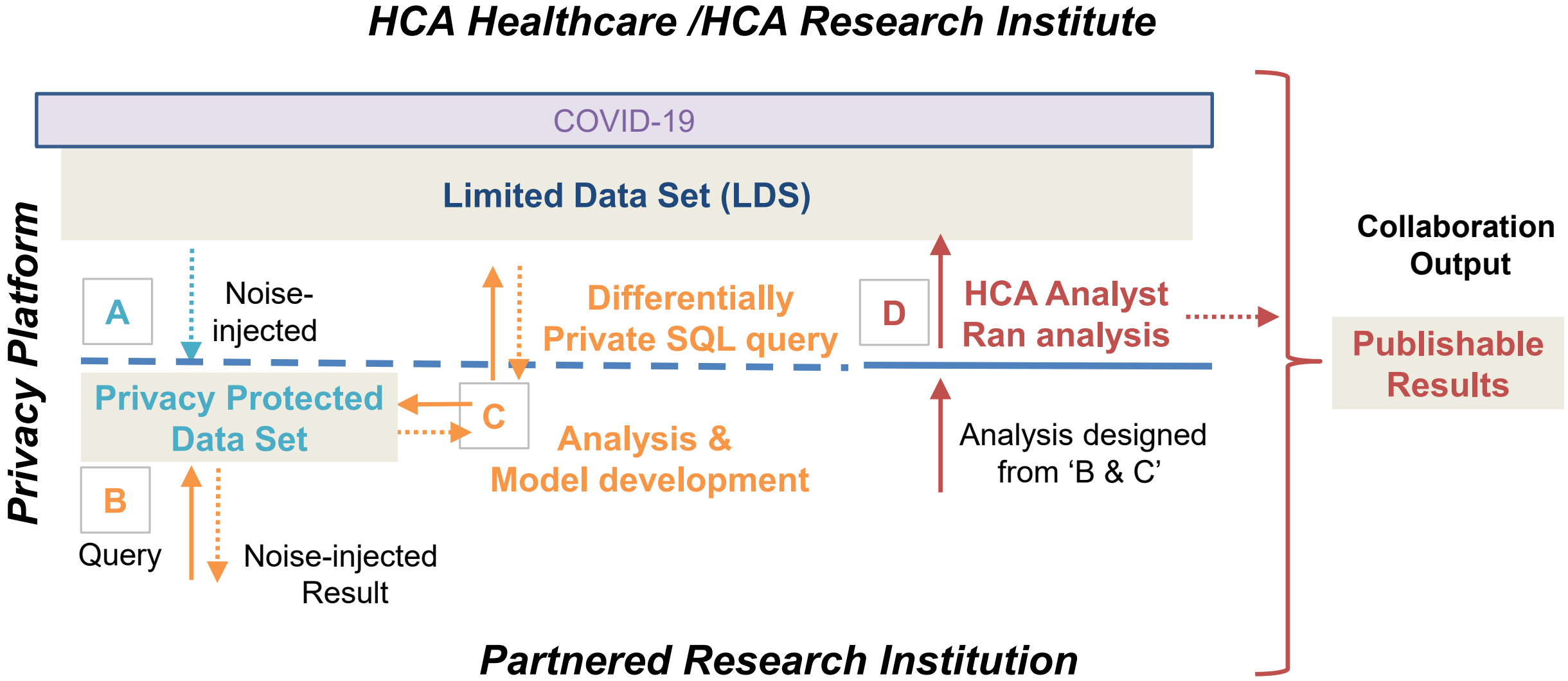
Institution	Title	Study Focus
Johns Hopkins	Comparative effectiveness of therapeutics for hospitalized patients with COVID-19	COVID-19 Clinical Care
BWH & UCSF	Analysis of Clinical Criteria to Determine Stability for Discharge among Patients Hospitalized with COVID-19	COVDI-19 Clinical Care
UMMS Bay State	Trends in ventilation and effects on outcomes	COVID-19 Clinical Care
UCSF	Risk Stratification Scores and Prediction of Clinical Outcomes among COVID-19 Patients	COVID-19 Clinical Care
Duke University	Causal inference machine learning to estimate heterogeneous treatment effects for COVID-19 therapies	Analytic Methodology
Cleveland Clinic	Effect of antibiotic classes on risk of Clostridioides difficile	Other Clinical Care
Meharry Medical College	Developing Phenotype Adjustment Models for COVID-19 Disease Study	Preparatory for Research Grant Application

Concluding Observations

- The pandemic provided motivation to overcome some of the barriers to data sharing
- This effort is possible because the health system was willing to invest substantial funds to make it possible.
  - This also allowed the health system to keep control of their data and its uses
  - Data governance is simplified by HCA maintaining full control
- At this moment, research teams are interested in partnering with health systems (including working without funding)
- This effort has significant potential to advance methodologies for ensuring data privacy in research
- A major potential next step would be if CHARGE can evolve to welcome other health systems to contribute additional data
- Sustainability of this data sharing infrastructure needs to be determined

Discussion

Potential Models for Ensuring Data Privacy



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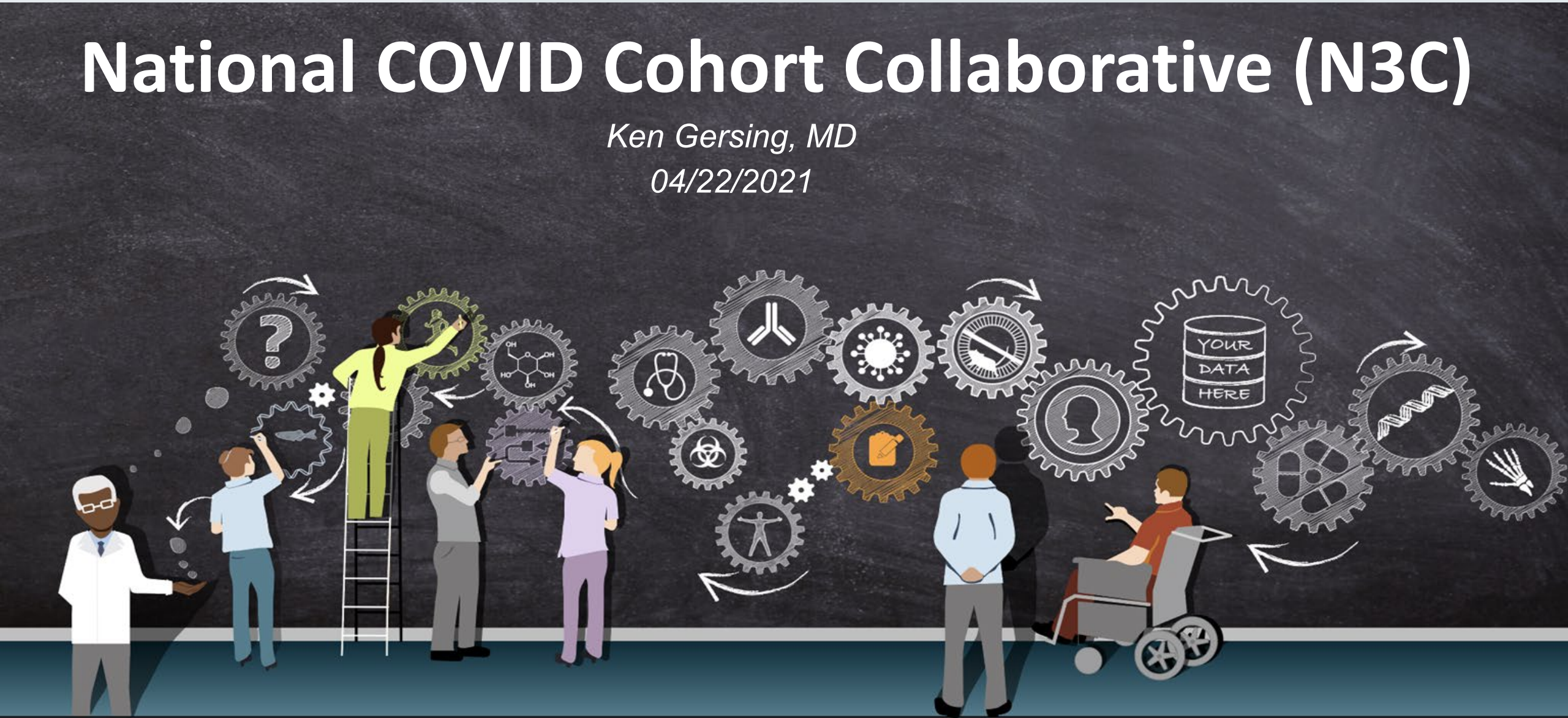
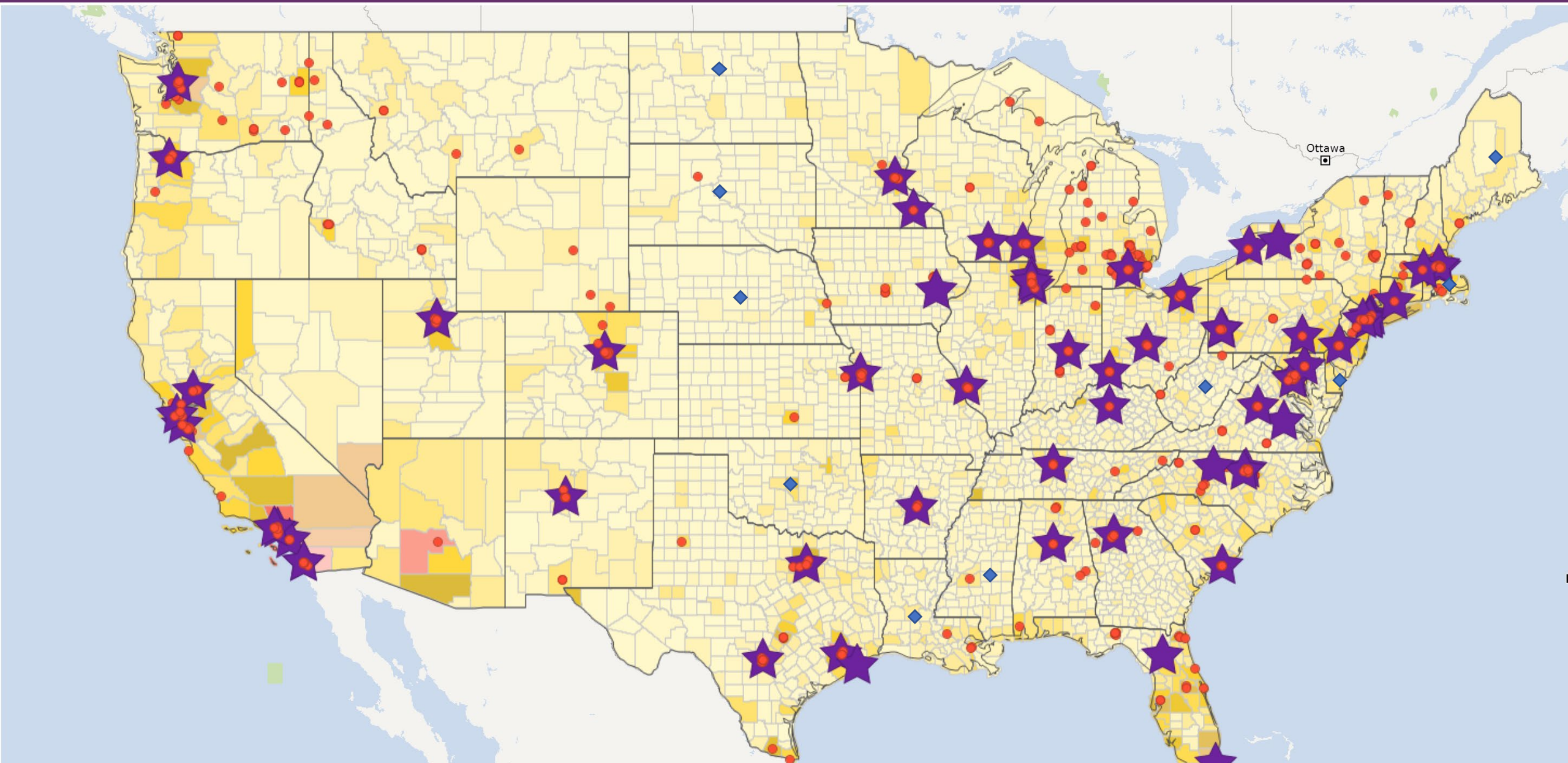
National COVID Cohort Collaborative (N3C)

Ken Gersing, MD

04/22/2021



CTSA Plus IDeA States



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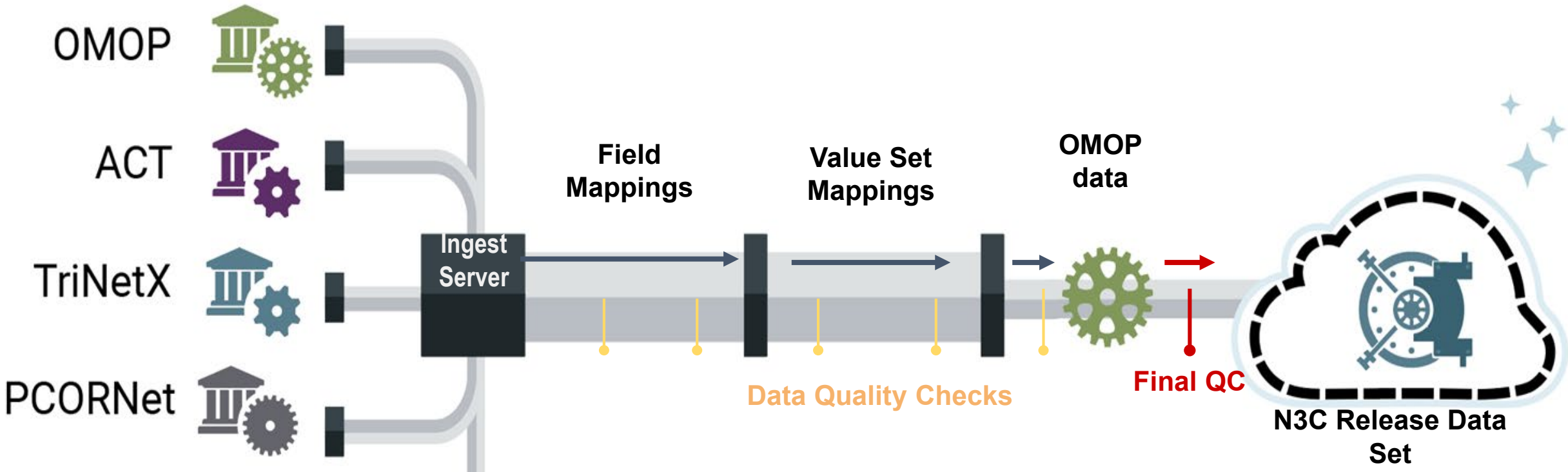
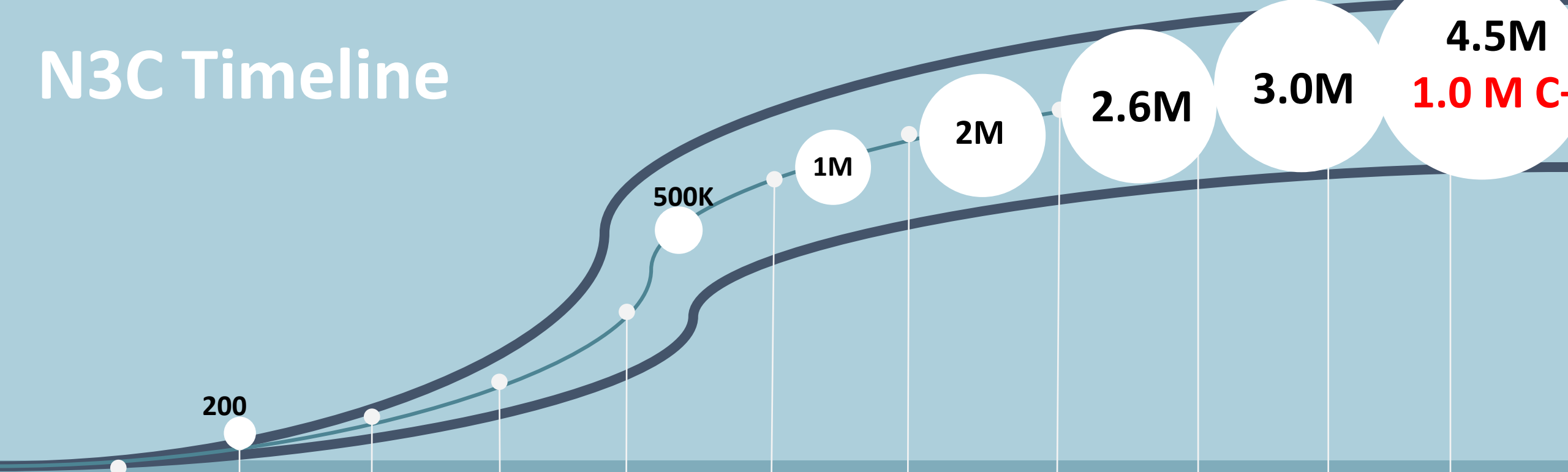
Data Ingestion & Harmonization Pipeline



Up-to-date phenotype description will always be here.

Scripts for sites to extract data, customized for each data model, are here.

N3C Timeline



April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
Kick off	1st DTA	17 DTAs	43 DTAs 4 DUAs	48 DTAs 29 DUAs	59 DTAs 88 DUAs 30 DURs 12 Sites Avail.	69 DTAs 116 DUAs 67 DURs 25 Sites Avail.	73 DTAs 129 DUAs 103 DURs 34 Sites Avail.	75 DTAs 139 DUAs 140 DURs 38 Sites Avail.	78 DTAs 141 DUAs 181 DURs 39 Sites Avail	80 DTAs 160 DUAs 210 DURs 42 Sites Avail	86 DTAs 186 DUAs 248 DURs 47 Sites Avail
DTA Done IRB JHU G-Suite	Palantir Phenotype 1.0	DUA Complete CDMs Mapped	COC Complete 1st Manuscript Domain Teams	DAC Charter Initial Training	NIH IRB Support Desk Harm/QA Comp.	Synthetic Avail	201 Objects PPRL Contract	1st IDeA CTR Knowledge Store Cohort Paper	Phenotype Explorer Export Results Validation Tool Image Linkage	N3C Public Dashboard External Data	24th Dom. Teams 40+ (Pre)/ publications

N3C Enclave Data: Current Stats

(4/09/21)

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National COVID Cohort Collaborative

COVID-19 Positive Patients	Total Patients	Sites	Rows of Data
1,222,296	4,960,128	50	5.8b
Projected 3.6M+	7,200,000+	86+	8B+

Procedures	Lab Results	Drug Exposures	Visits	Observations
287.3m	2.6b	949.0m	257.8m	721.4m

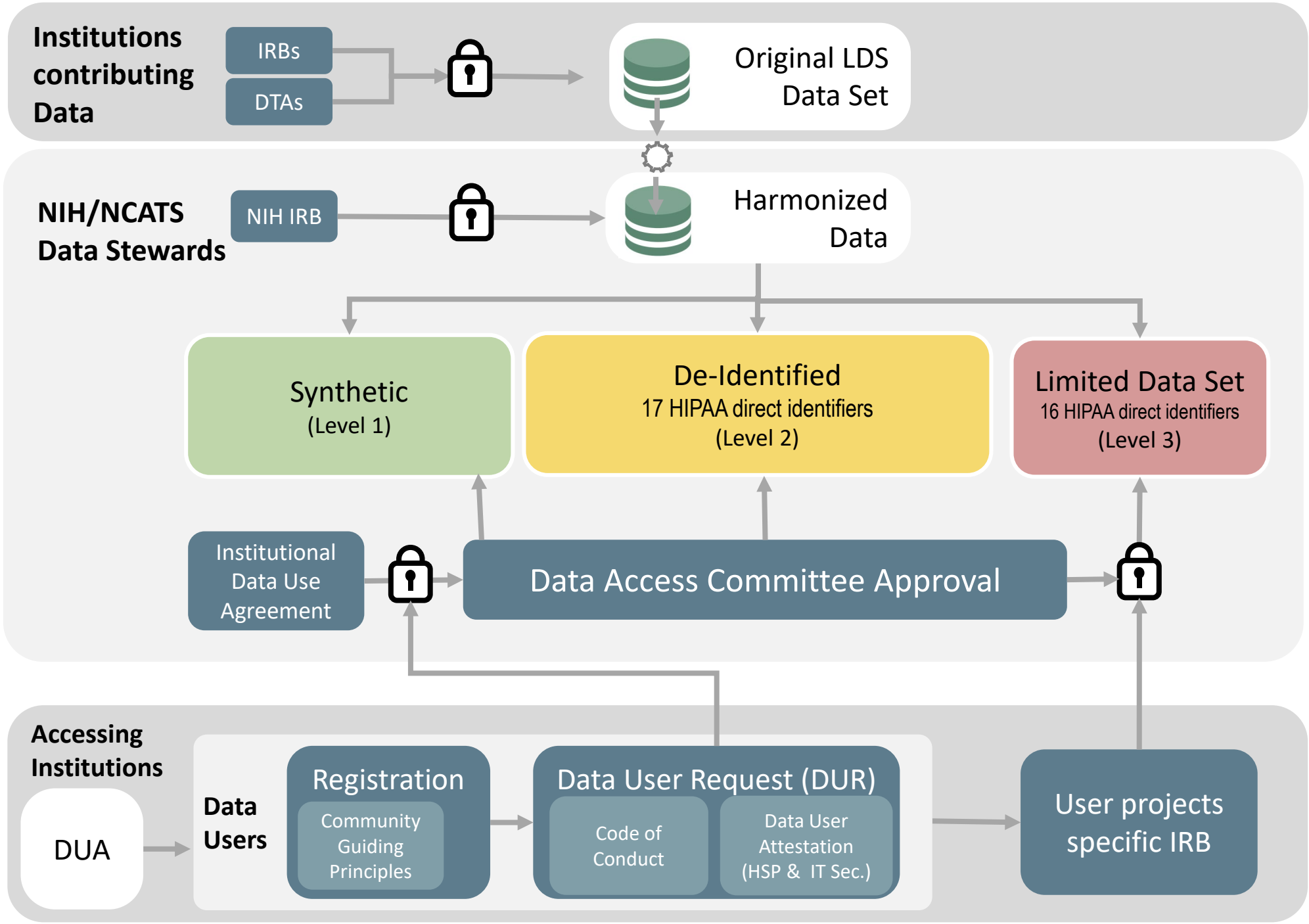
1231 participants

[N3C Dashboard]

	COVID (N = 1,222,296)	NON-COVID (N = 3,737,832)	OVERALL (N = 4,960,128)
Gender			
Male	551,310	1,656,758	2,208,068
Female	669,672	2,078,740	2,748,412
Unknown		2,325	2,325
Age			
0 - 17	114,360	509,058	623,418
18 - 29	226,827	554,036	780,863
30 - 49	370,783	1,015,853	1,386,636
50 - 64	278,815	818,380	1,097,195
65+	215,511	790,963	1,006,474
Unknown	16,000	49,542	65,542
Race			
White	741,252	2,520,020	3,261,272
Other	10,472	36,422	46,894
Black or African American	185,122	565,573	750,695
Asian	33,339	109,435	142,774
Pacific Islander	2,983	6,633	9,616
Unknown	228,809	450,553	679,362
Ethnicity			
Not Hispanic or Latino	831,135	2,906,243	3,737,378
Hispanic or Latino	211,020	403,031	614,051
Unknown	178,874	423,839	602,713

National COVID Cohort Collaborative

N3C: Governance and Access



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Getting Access to the Data

First Time Users

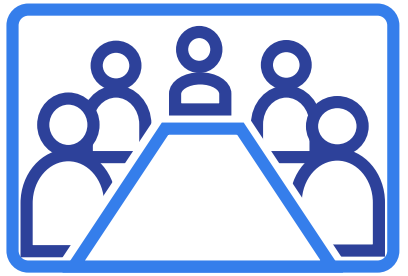
Register at N3C

Sign DUA

HSP / Security Training

Returning Users

Submit DUR



Data Access Committee

Research !!!

National COVID Cohort Collaborative

Data Use and Privacy

Goal of the Data Use Agreement is Privacy Protection to Promote broad access:

- COVID-Related research only
- No re-identification of individuals or data source
- No download or capture of raw data
- Open platform to all researchers
- Security: Activities in the N3C Data Enclave are recorded and can be audited
- Disclosure of research results to the N3C Data Enclave for the public good
- Analytics provenance
- Contributor Attribution tracking

NCATS

COLLABORATE. INNOVATE. ACCELERATE.

First-Day ML Models to Predict Patient Severity

32k COVID *Inpatients*

Demographics, Labs & Vitals

Machine learning:

Predict Mortality, IMV, or ECMO

Ranked list of predictive features

Random Forest Top 10 Predictors

- Age
- AST
- BUN
- Cr
- Glucose
- pH
- RR
- SBP
- SpO2
- WBC

✓ **High confidence.**
✓ **Repeatable.**
✓ **Clinically relevant.**
✓ **Readily deployable.**
✓ **Easily refined.**

RF **Mar-May** AUROC: 0.864
RF **Jun-Oct** AUROC: 0.865

Variable	Random Forest	XG Boost	Logistic Regression None	Logistic Regression L1	Logistic Regression L2	Mean
pH	0	0	1	1	1	0.6
Age at visit start (years)	3	4	0	0	0	1.4
Respiratory rate	7	3	2	2	2	3.2
Oxygen saturation (SpO2)	2	2	5	4	3	3.2
Systolic blood pressure (SBP)	9	8	4	3	5	5.8
Blood urea nitrogen (BUN)	1	1	11	11	10	6.8
Albumin	21	6	6	5	4	8.4
Lactate	18	9	7	7	7	9.6
C-reactive protein (CRP)	16	11	8	8	8	10.2
Aspartate aminotransferase (AST)	6	5	12	22	18	12.6
Absolute neutrophil count	12	25	9	9	9	12.8
Ethnicity = missing or unknown	45	7	3	6	6	13.4
Glucose	5	18	16	15	14	13.6
Platelet count	10	22	14	13	13	14.4
Diastolic blood pressure (DBP)	13	15	21	17	16	16.4
B-type natriuretic peptide (BNP)	32	12	18	14	15	18.2
Sodium	15	27	15	18	17	18.4
Troponin	14	10	30	21	23	19.6
Erythrocyte sedimentation rate (ESR)	36	30	13	12	12	20.6
Sex = male	38	36	10	10	11	21
Body weight	19	49	19	16	19	24.4
Hemoglobin	17	51	24	20	21	26.6
Charlson Diabetes mellitus	37	24	25	27	24	27.4
Creatinine	8	46	26	32	26	27.6
D-dimer	25	42	31	23	20	28.2
Ferritin	20	38	34	25	25	28.4
Bilirubin total	28	50	29	19	22	29.6
Charlson Dementia	42	13	37	28	28	29.6
Temperature	26	43	32	26	29	31.2
Potassium	23	53	33	29	27	33
Body mass index	27	41	38	31	31	33.6
Bilirubin conjugated	34	28	40	35	34	34.2
Charlson Q Score	30	20	48	38	40	35.2
Charlson Metastases	56	31	36	24	30	35.4
Absolute lymphocyte count	11	14	56	48	51	36
Charlson Renal Disease	44	23	39	39	36	36.2
Alamine aminotransferase (ALT)	24	40	23	57	43	37.4
Heart rate	31	33	51	36	37	37.6
Race = missing or unknown	46	32	17	58	42	39
Race = Asian	54	26	55	30	32	39.4
Chloride	22	57	28	60	39	41.2
Charlson Diabetes mellitus with complications	47	19	42	52	47	41.4
White blood cell count	4	17	62	61	63	41.4
Charlson Peripheral vascular disease	48	45	41	37	38	41.8
Hemoglobin - glycosylated (A1C)	33	48	45	43	41	42
Charlson Congestive heart failure	40	29	46	53	50	43.6
Race = Native Hawaiian or Pacific Islander	60	55	44	33	33	45
Race = Black or African-American	43	54	22	59	49	45.4
Charlson Peptic Ulcer Disease	57	59	43	34	35	45.6
Charlson Stroke	49	44	49	42	45	45.8
Procalcitonin	29	21	61	62	57	46
NTproBNP	35	39	53	50	55	46.4
Charlson Liver Disease (mild)	53	34	52	41	53	46.6
Charlson hemiplegia or paralysis	58	16	58	46	56	46.8
Ethnicity = not Hispanic or Latino	41	52	27	63	52	47
Race = white	39	60	20	54	62	47
Charlson Myocardial Infarction	52	47	50	45	48	48.4
Race = other	61	63	35	47	46	50.4
Sex = other	63	62	47	40	44	51.2
Charlson Cancer	51	56	54	44	54	51.8
Charlson Pulmonary disease	50	37	59	55	59	52
Charlson Rheumatologic disease	55	35	57	56	58	52.2
Charlson Liver Disease (severe)	59	58	63	49	60	57.8
Charlson HIV	62	61	60	51	61	59

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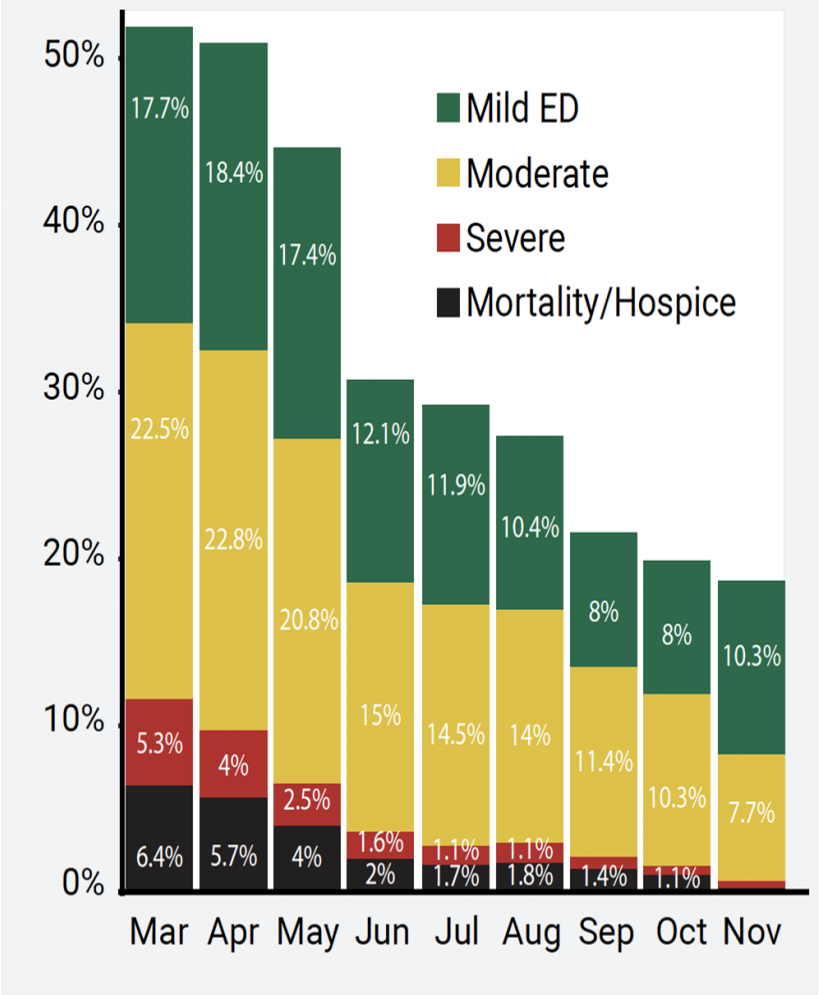
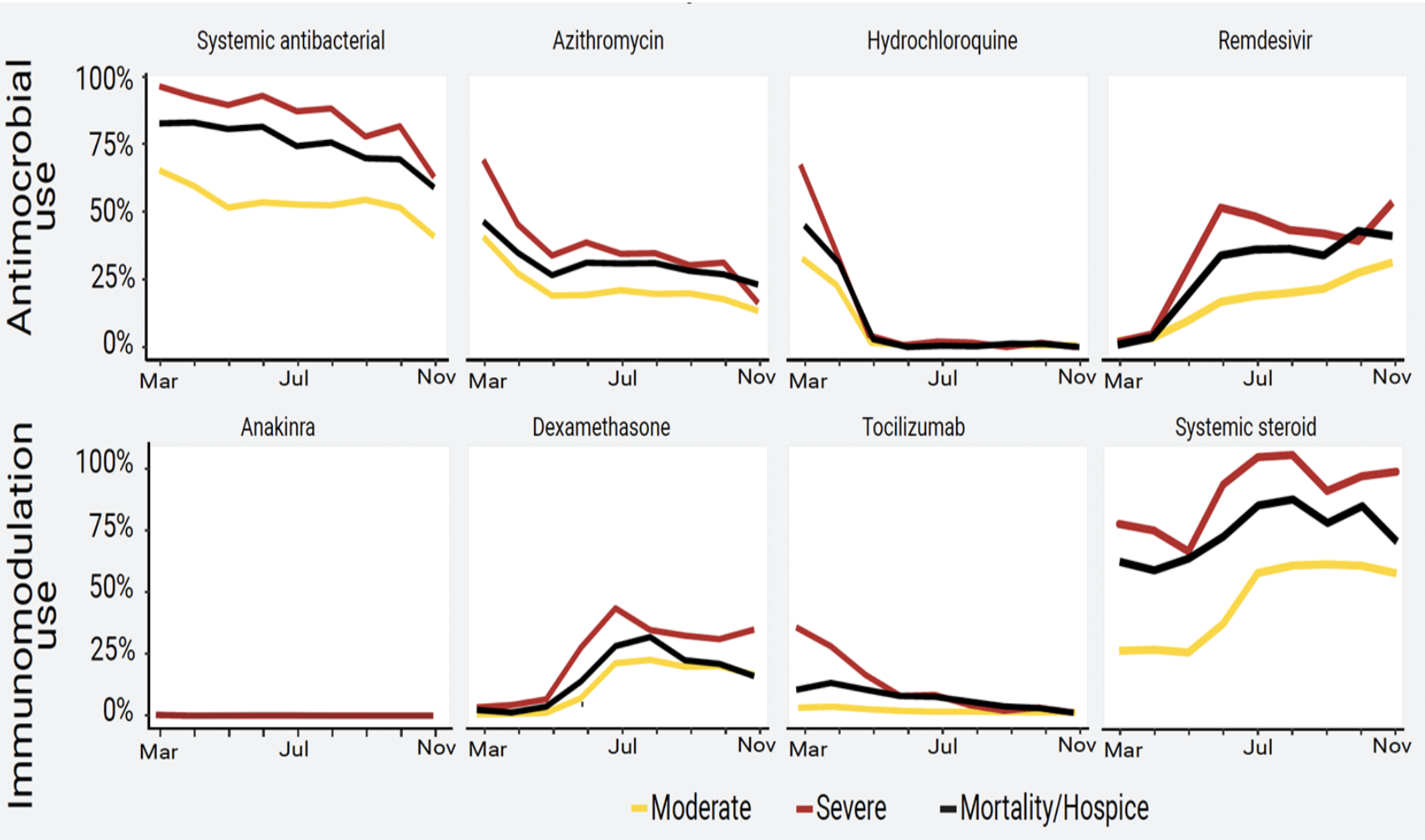
Over time, severity has decreased and use patterns of antimicrobials and immunomodulation have shifted

National COVID Cohort Collaborative

Severity



Medications

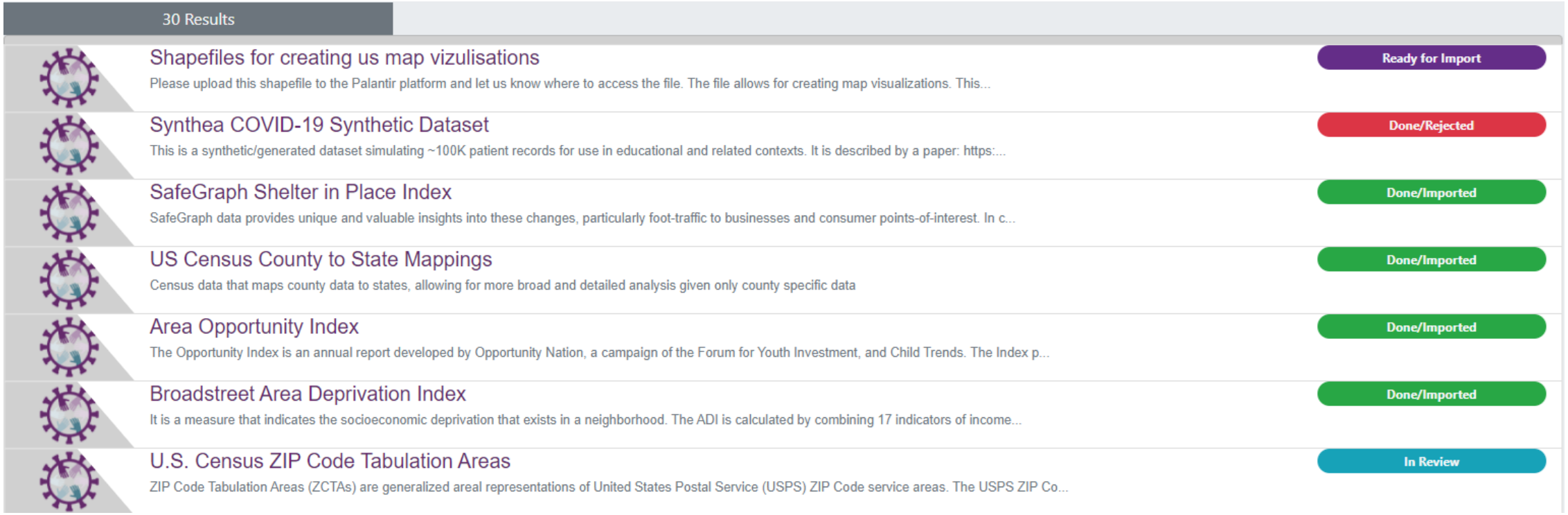


National COVID Cohort Collaborative

External Dataset Registry

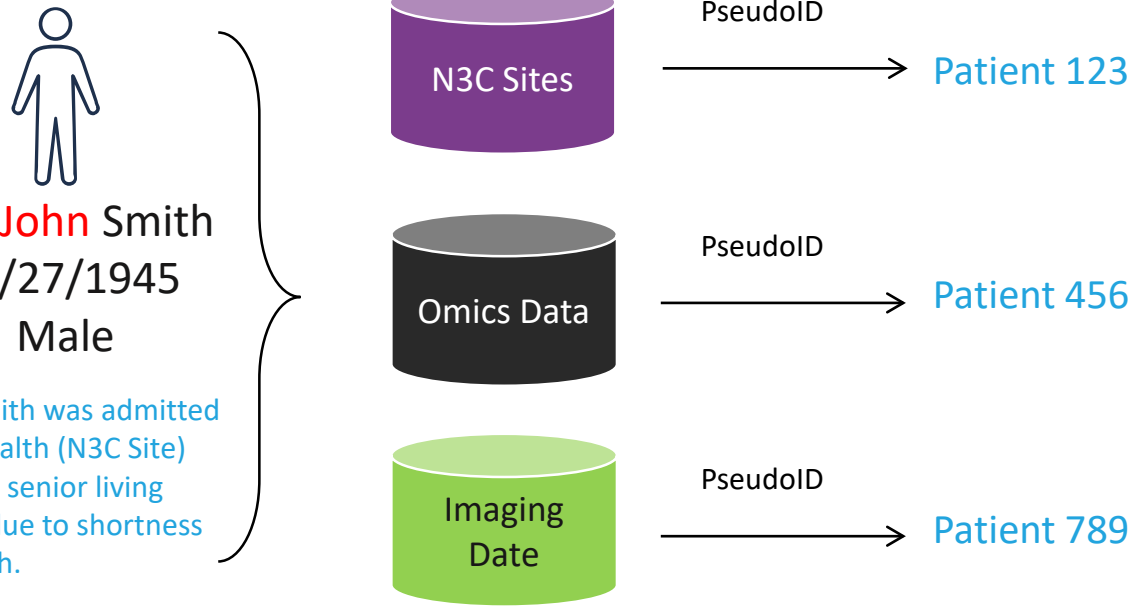
Users can view the list of external datasets that have been imported into the Enclave, as well as the datasets requested and their current status in the review process by viewing the External Dataset Registry

https://discovery.biothings.io/dataset?guide=/guide/n3c/dataset

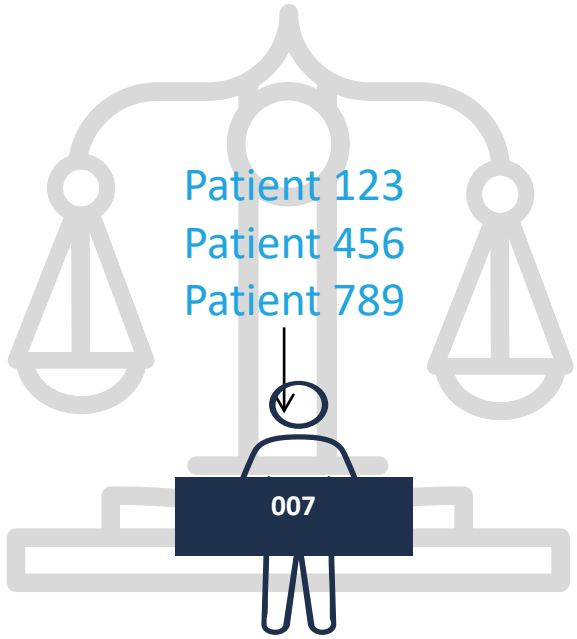


Shared PPRL on different types of data

Data Contributors

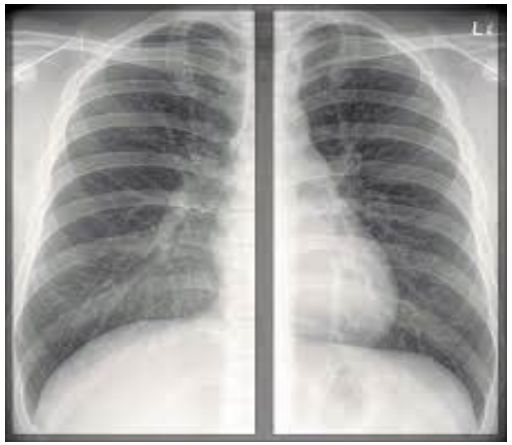


Honest Broker

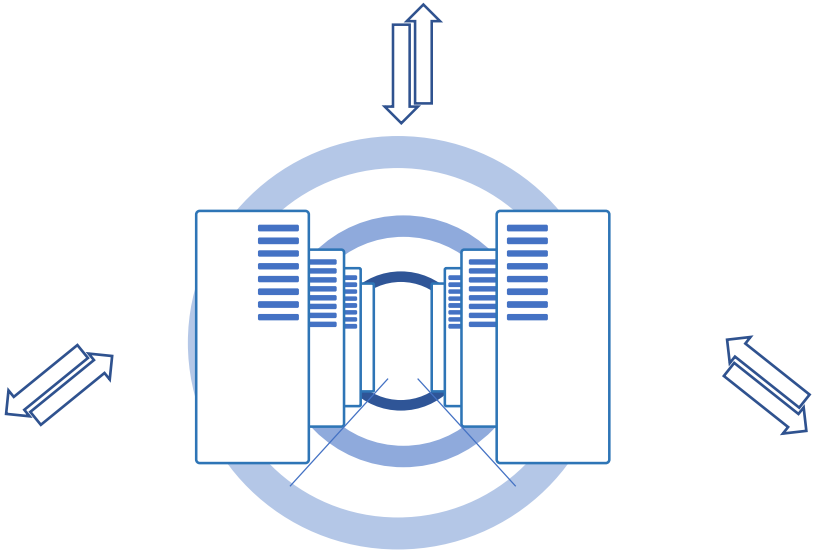


Honest Broker has NO PHI

Step 4: Federated Analytics HPC



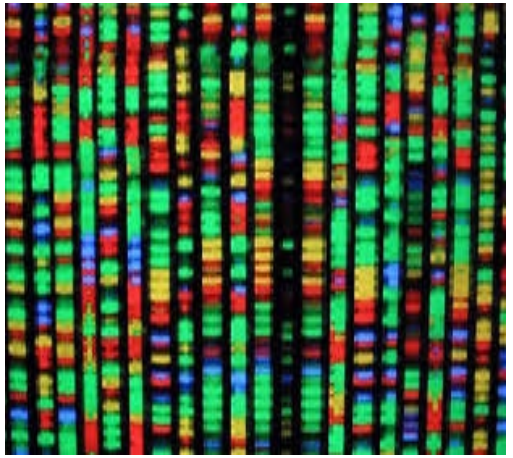
NIBIB: Imaging Data



HPC

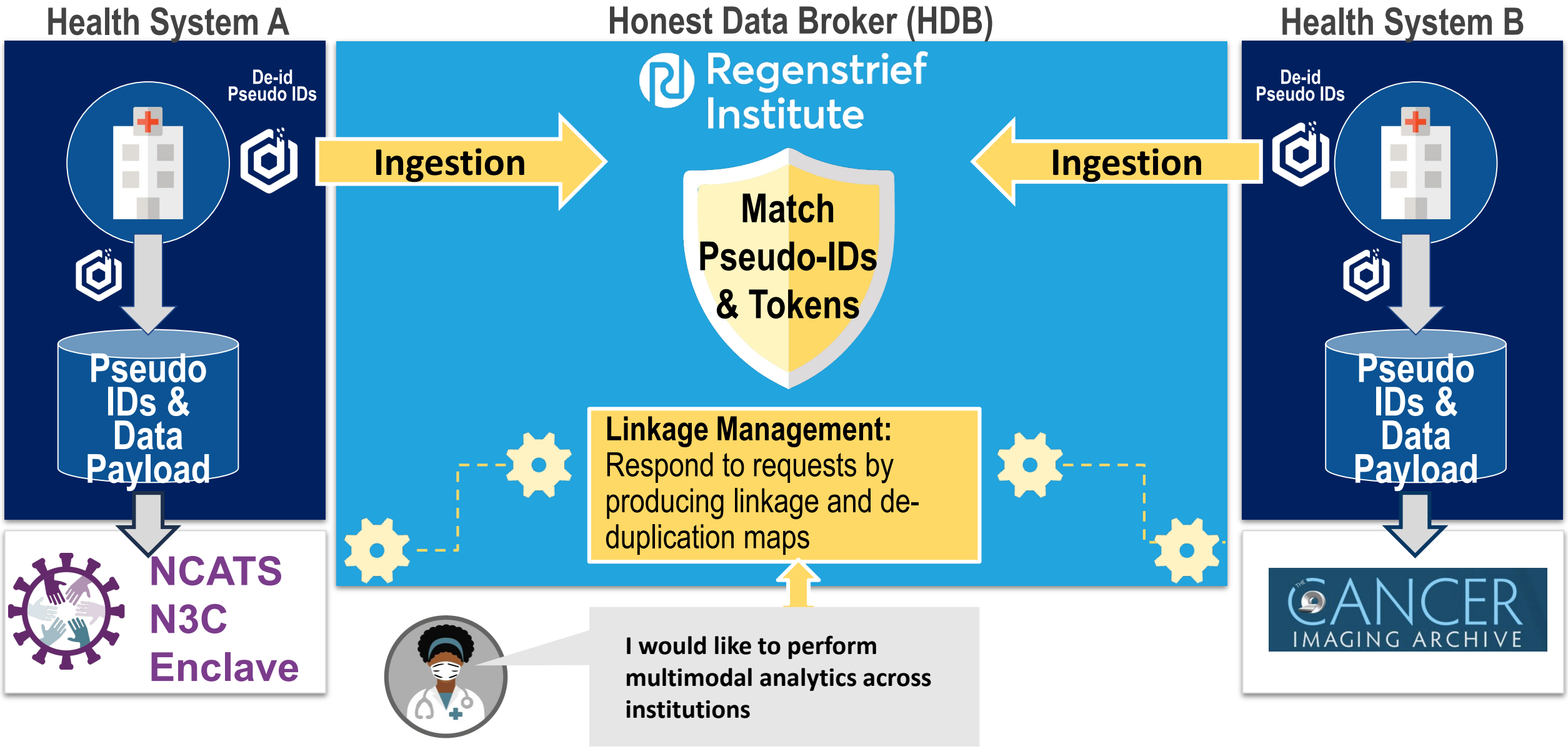
Federated Analytics

NCATS: EHR Data



NHLBI: Omics Data

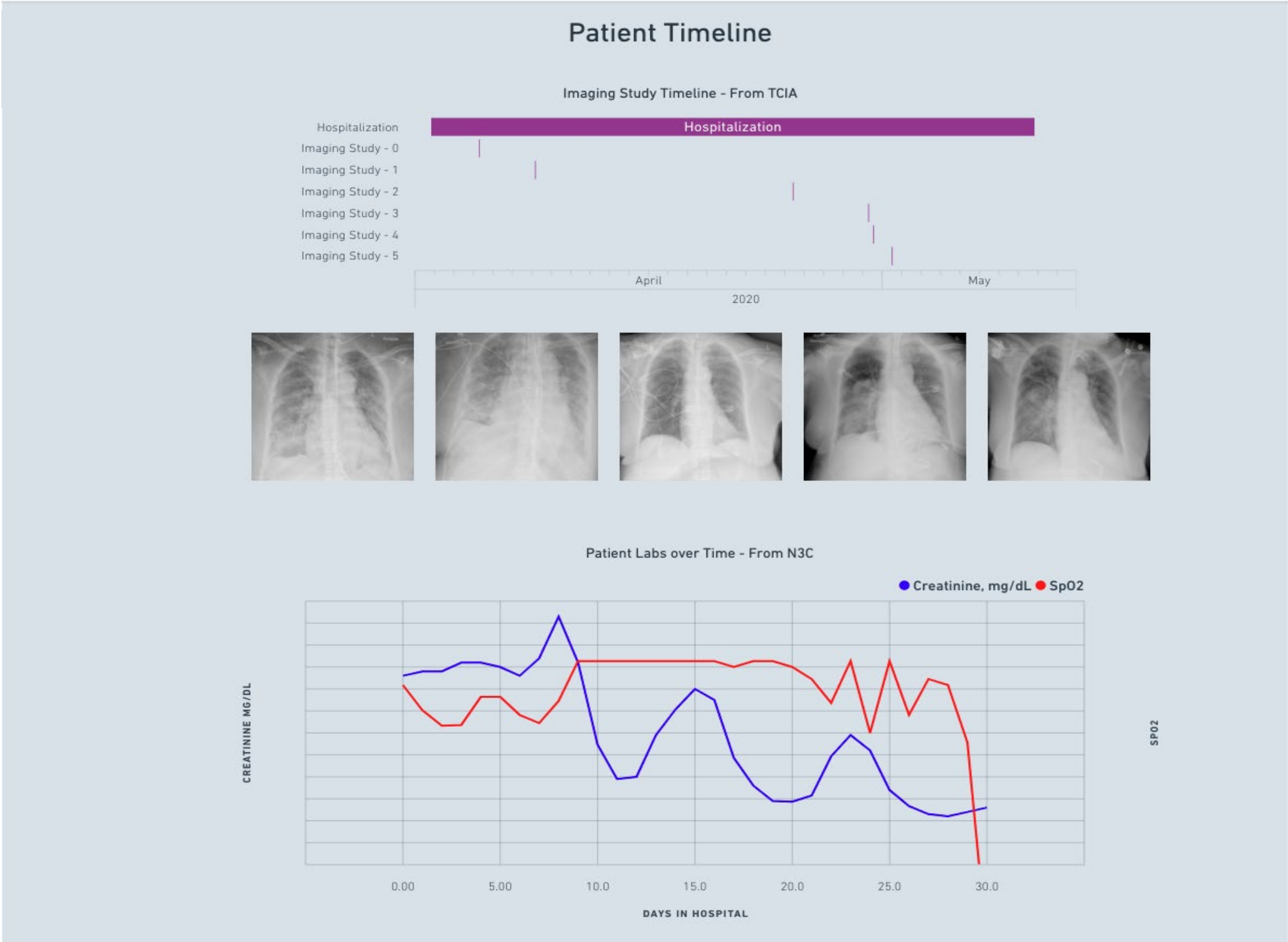
The Honest Data Broker fulfills linkage requests, ensuring privacy & compliance



Multi-model Data
EHR and Imaging

Hospital Course

Chest Xray's with serial
Lab Correlation of SpO2
and Creatinine



Data Sharing Initiative: Synthetic Data

*Computer Derived Synthetic Data:
Public / Private Partnership

- Gates Foundation
- Microsoft
- MDClone
- Syntegra
- FDA
- NCATS
- Wash U
- U of Washington
- Northwestern

Validation of Sepsis Prediction

		Trained on real data Tested on real data	Trained on synthetic data Tested on real data
Train	Accuracy	0.925	0.911
	Precision	0.95	0.925
	Recall	0.817	0.799
	F-Score	0.879	0.858
10-fold cross-validation	Accuracy	0.839	0.816
	Precision	0.802	0.754
	Recall	0.704	0.666
	F-Score	0.745	0.704
Test	Accuracy	0.846	0.841
	Precision	0.836	0.845
	Recall	0.671	0.645
	F-Score	0.745	0.731

ML model performance (random forest)

*Wash. U. Philip Payne

NAM Leadership Consortium

Collaboration for a Value & Science-Driven Health System

Nation-wide data governance: Progress and Promise

NATIONAL ACADEMY OF MEDICINE

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology, ONC

Peter Margolis, MD, PhD
Professor of Pediatrics, Cincinnati Children's

Amy Abernethy, MD, PhD
Principal Deputy Commissioner, U.S. Food and Drugs Administration

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology, ONC

Data Governance in a National Pediatric Learning Health Network

Peter Margolis, MD, PhD

April 22, 2021

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changing the outcome together

A scenario…..

Cincinnati Children's
changing the outcome together

ImproveCareNow Network Mission

Transform the health, care and costs for all children and adolescents with Crohn's disease and ulcerative colitis by building a sustainable collaborative chronic care network that enables patients, families, clinicians and researchers to work together in a Learning Health System to accelerate innovation, discovery and the application of new knowledge.

Network Organizing

1. Unrelenting focus on outcomes - exceptional, equitable health and well being

2. Engage all stakeholders in co-design and unleash inherent motivation, insight and expertise

3. Shared platform/infrastructure of technology, policies, and processes

4. Rapid learning system

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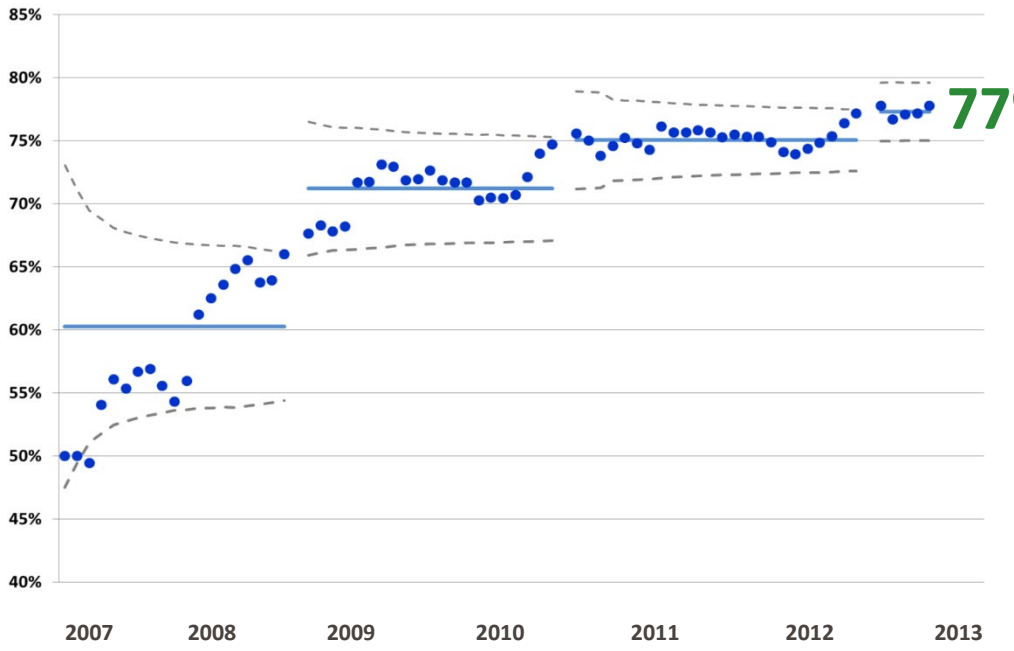
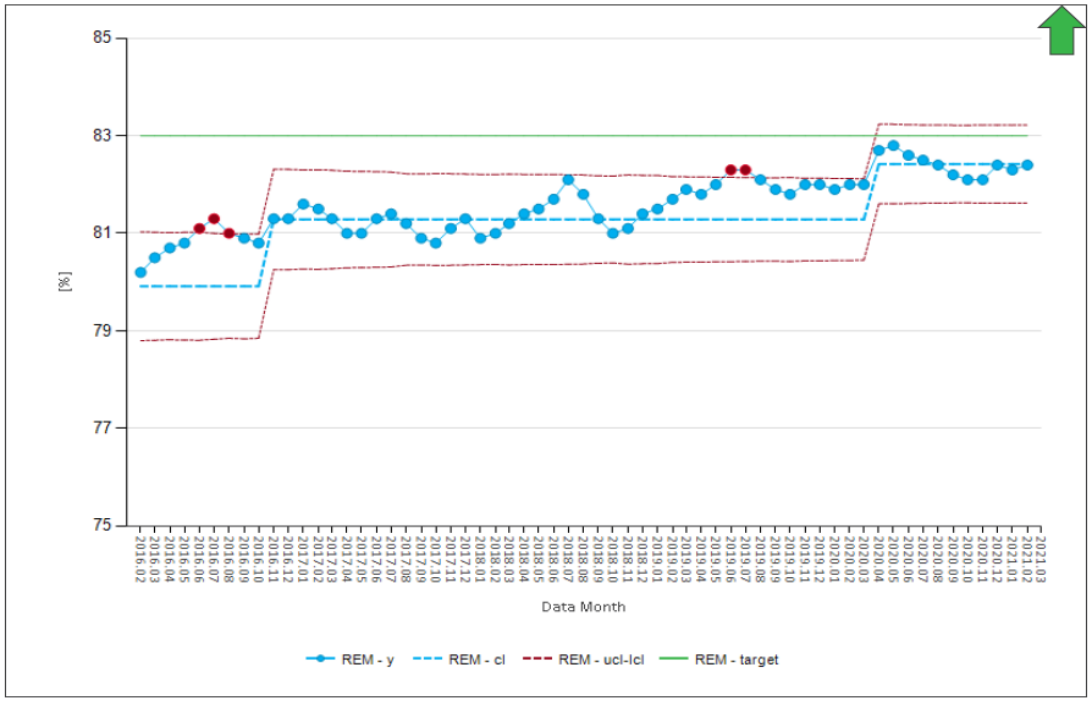
Share Data to Build Will and Common Purpose



77%



82%

Percent of Patients in Clinical Remission: 2013 - 2021

11,000 additional children in remission in past 7 years

Co-Design of Resources

Learning Health Systems
Open Access

EXPERIENCE REPORT | Open Access

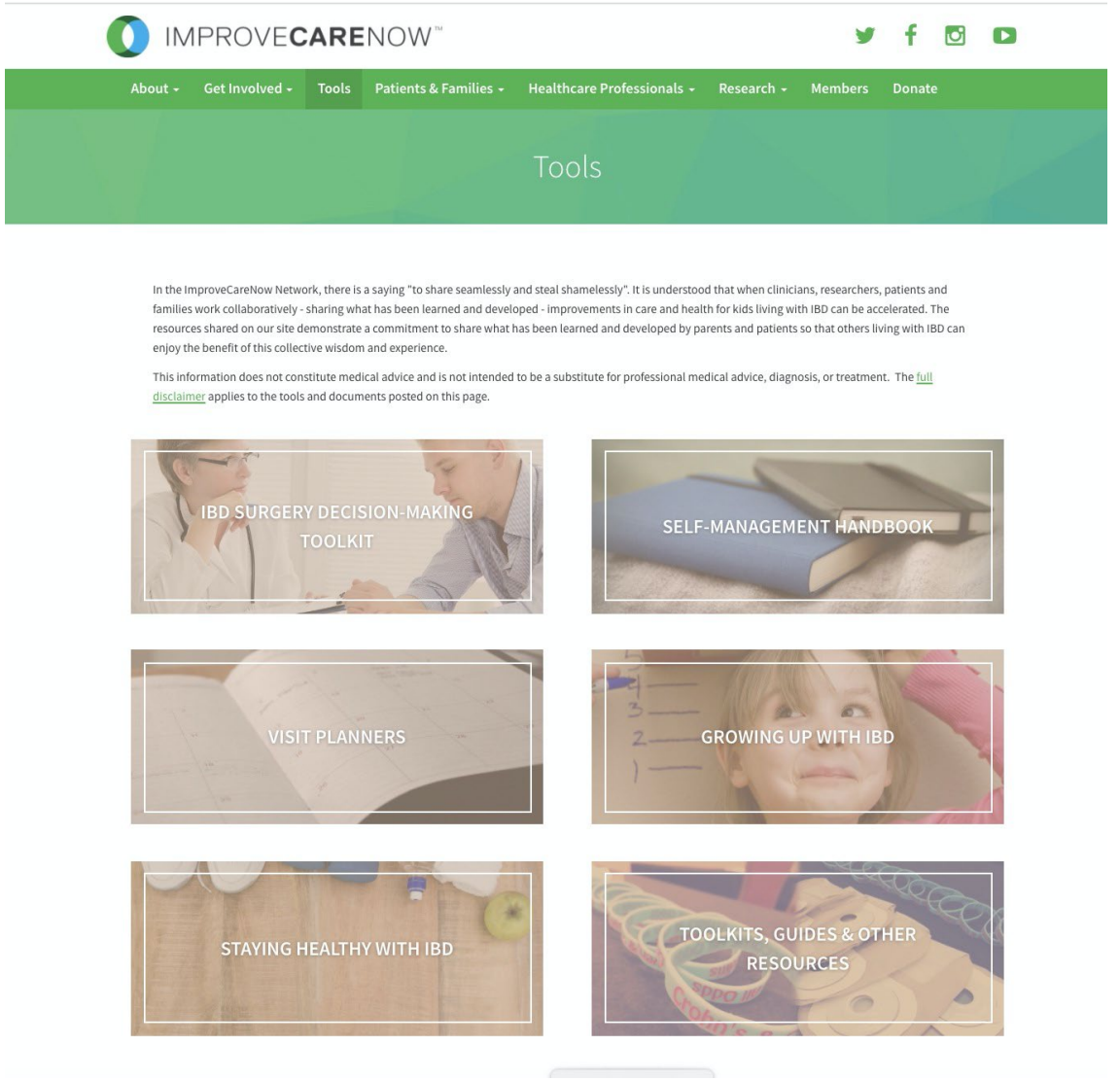
Sustainable generation of patient-led resources in a learning health system

Jennie David ✉, Catalina Berenblum Tobi, Samantha Kennedy, Alexander Jofriet, Madeleine Huwe, Rosa Kelekian, Melissa Neihart, Michelle Spotts, Michael Seid, Peter Margolis ... See all authors

First published: 12 February 2021 | https://doi.org/10.1002/lrh2.10260

Funding information: National Institute of Diabetes and Digestive and Kidney Diseases; Patient-Centered Outcomes Research Institute

https://onlinelibrary.wiley.com/doi/full/10.1002/lrh2.10260



Network infrastructure fuels a portfolio of activities

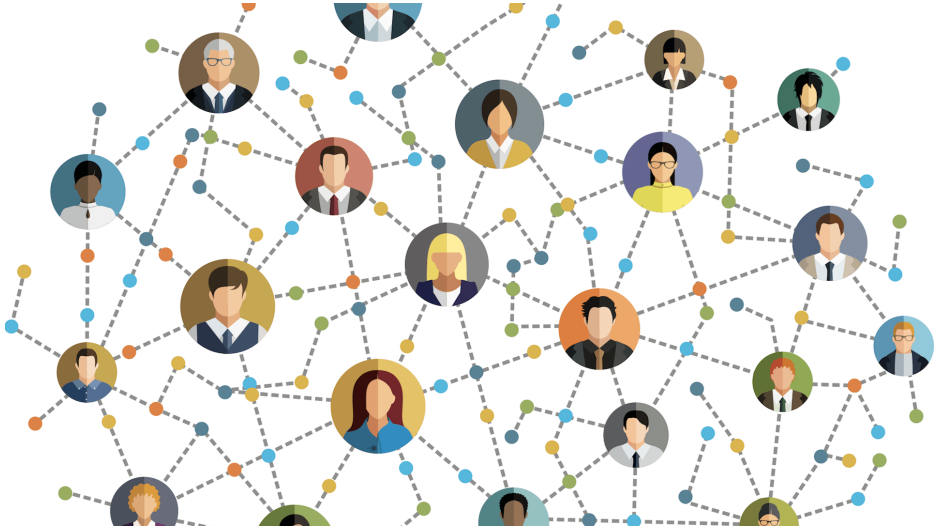
- **Technology Infrastructure**
  - Direct upload of 70% of data from EHR
  - Real-time comparative performance data
  - Community knowledge sharing hub
- **Continuous Improvement Pathway**
  - Registry implementation and QI training
  - Chronic care management to achieve clinical remission
  - Advanced chronic care management to achieve sustained remission
- **Innovation communities** (“Trailblazers”)
  - Therapeutic Drug Monitoring
  - Auto-immune Liver Disease
  - Adherence
  - COVID Response
  - Clinical Research Optimization
  - Health Disparities
  - Payment models
  - Engagement Campaign
- **Research**
  - 30 investigator initiated projects
  - Network-wide Federal, Foundation and Industry-sponsored observational and intervention research

Community Values

Inclusivity
Honesty
Transparency
Community
Empowerment
Learning
Continuous Improvement

community ♥ values
improvecarenow.org

Data Sharing in Learning Health Networks Should be Easy



Communities of Practice

Values of Open Science

Trust

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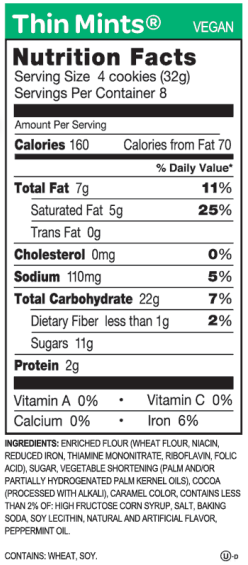
What could accelerate progress?



Thin Mints® VEGAN

Nutrition Facts

Serving Size 4 cookies (32g)
Servings Per Container 8

Amount Per Serving	
Calories 160	Calories from Fat 70
	% Daily Value*
Total Fat 7g	**11%**
Saturated Fat 5g	**25%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 110mg	**5%**
Total Carbohydrate 22g	**7%**
Dietary Fiber less than 1g	**2%**
Sugars 11g	
Protein 2g	
Vitamin A 0% •	Vitamin C 0%
Calcium 0% •	Iron 6%

INGREDIENTS: ENRICHED FLOUR (WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID), SUGAR, VEGETABLE SHORTENING (PALM AND/OR PARTIALLY HYDROGENATED PALM KERNEL OILS), COCOA (PROCESSED WITH ALKALI), CARAMEL COLOR, CONTAINS LESS THAN 2% OF: HIGH FRUCTOSE CORN SYRUP, SALT, BAKING SODA, SOY LECITHIN, NATURAL AND ARTIFICIAL FLAVOR, PEPPERMINT OIL.

CONTAINS: WHEAT, SOY.

Network Facts

Values

Standards

Risks

Decision Support Tools

Certification Framework

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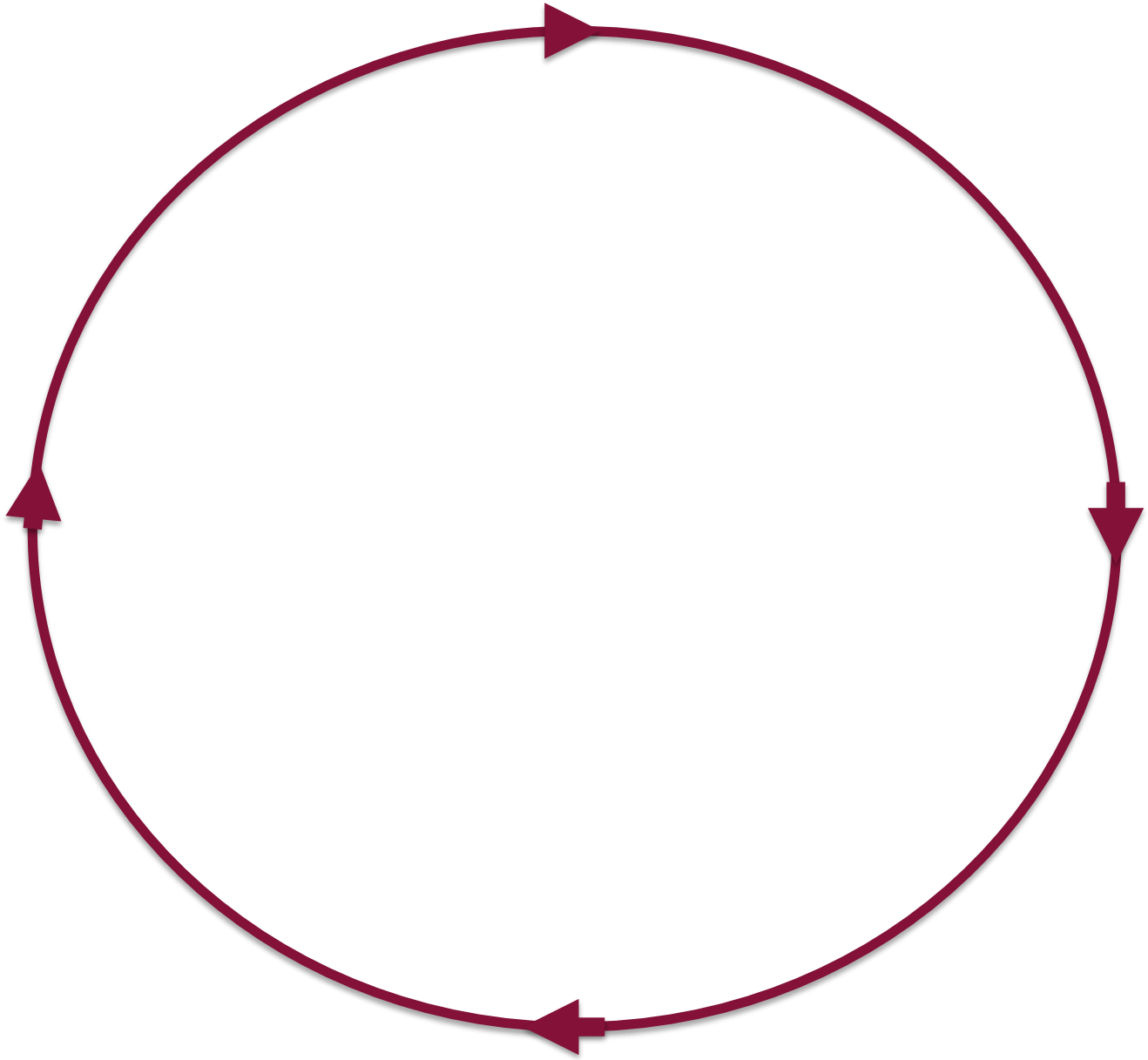

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changing the outcome together

Impact Assessment:
Digital Health and COVID-19

Amy Abernethy, Peter Lee, David Shaywitz
Murali Doraiswamy, Adi Gundlapalli, Subha Madhavan, Kevin Shulman, Jim Weinstein

NAM Leadership Consortium
Collaboration for a Value & Science-Driven Health System

NATIONAL ACADEMY OF MEDICINE

Health Data: Water, Water, Everywhere…

- Data without architecture leads to data silos

> One is reminded of the poem, *The Rime of the Ancient Mariner*, which contains the verse, "Water, water, everywhere, nor any drop to drink." Despite nearly complete digitization, and so many tools at our disposal for data analysis, machine learning, AI, and visualization, the health care community remained thirsting for the high-quality, actionable data upon which these technologies, patients, and caregivers foundationally depended, including data not only from health systems, but from all other relevant sources -- personal, social, infrastructural, biological, population-wide, and more. Thus, the tremendous advances in computer science that today powers global supply chains, massive retail markets, internet search, social media, and more, remained and still remains a stark contrast to the ongoing creation of yet more inaccessible data silos in health care. The ongoing challenges encountered in vaccine distribution and monitoring are only the most current and urgent example of the existing limitations of data visibility, fluidity, transparency, and access.

Digital Health
Priority Actions and Actors

- Data architecture, modularity, and data infrastructure

> Imagine for a moment that we are setting out to build a house. We would, of course, need good tools and an adequate supply of lumber. And we would need to understand the architecture of the house we are trying to build. But if we lacked the skilled tradespeople, heavy equipment, building inspectors, and other infrastructure that support the process of construction, it would be impossible to connect the tools and lumber to the architecture and realize a completed house. Furthermore, without modularity that is both intentionally designed and agreed upon, for example in industry standards and building codes, orchestrating the construction of components such as electrical systems, plumbing, roofing, heating, doors and windows, appliances and more, would be wildly complex and unwieldy. Even more important, innovators who make technological advances in those component systems would find it hard to survive in the marketplace, because they would not have standard places to "plug in" their new ideas at industrial scale. Instead, home construction would be a low-productivity, artisanal activity, much like, say, early automobile production – or today's health care data ecosystem.

Data Architecture+
New Solutions are Needed

- Data architecture, modularity, and data infrastructure
- Challenge is on the scale of some of the largest public challenges ever addressed, especially in public health and health care
- Similar to the need for an interstate highway system, a common financial system, or our modern flight control system
  - All of these efforts were well-served by public-private partnerships
  - Fostered ingenuity and innovation, and greatly expanded economic activity for the country at large
  - All were federal investments
  - The Federal Reserve provides a practical architecture into which innovators and the banking industry have been able to “plug in”
    - Infrastructure = secure data architecture, parsimonious common data standards, business incentives, and regulatory enforcement

Data Architecture+
New Solutions are Needed

- Hard things are hard – and worth doing
- There are real reasons to believe that meaningful progress can and will be made
  - Much of the raw material is already at hand:
    - Rapid digitization of health care (98% of clinical health records are digital)
    - Rapid advances in enabling digital technologies outside of health care
  - Recognized need to align around basic governing rules and an approach to modularity so that consistent components can “plug in,” work efficiently, and bring unique elements to the overall design
- A modular approach fosters competition around components, enabling improved quality, reduced costs, and the ability to connect and optimize relevant modules to address distinct challenges in different domains

Data Architecture+
New Solutions are Needed

- What do we need to do?
  - Data governance
  - Focus on public trust
  - APIs and interconnections
  - Right-sized data standards
  - Driver projects & programs
  - PPPs to define and advance business incentives
  - Bring all actors to the table
  - Talent development

Digital Health
Priority Actions and Actors

- Data architecture, modularity, and data infrastructure – **proposed Office of Health and Health Care Digital Integration (OHDI)**
  - Government's role in advancing such a modular architecture includes several elements, including:
    - Fostering the regulatory conditions for innovation and establishing the relevant ground rules, while avoiding excessive specification of what the "right" solutions should be
    - Ensuring a commitment to public trust, equity, and health
    - Facilitating vital private-public partnerships
    - Embracing incremental innovation, recognizing that solutions will emerge gradually

Digital Health
Collaborative Initiatives Within and Across Sectors

- Data architecture, modularity, and data infrastructure – **proposed Office of Health and Health Care Digital Integration (OHDI)**
  - **Many of the identified priority actions are dependent on this step**
    - Incentivize novel clinical evidence generation approaches
    - Harness AI and other capabilities dependent on a coherent data infrastructure
    - Get individuals the healthcare they need (e.g., reduce bias in AI, match treatments to patients, generalizable clinical research)
    - Realize the potential of a learning health system
- Advancing telehealth by right-sizing healthcare regulation
  - Example actor = Office of Civil Rights
- Business solutions are needed
  - Example actor = public private partnerships
- Cybersecurity
- Digital health training

Open Discussion

Closing Remarks

Thank you for joining!

For more information about the National Academy of Medicine's initiatives, please visit us at: **nam.edu**

NAM Leadership Consortium

Collaboration for a Value & Science-Driven Health System

Digital Health and Evidence Mobilization Action Collaboratives

For more information about the
Digital Health and Evidence Mobilization Action Collaboratives
or to share opportunities to address and
advance this work, please contact:

Noor Ahmed
National Academy of Medicine
MAhmed@nas.edu

NATIONAL ACADEMY OF MEDICINE