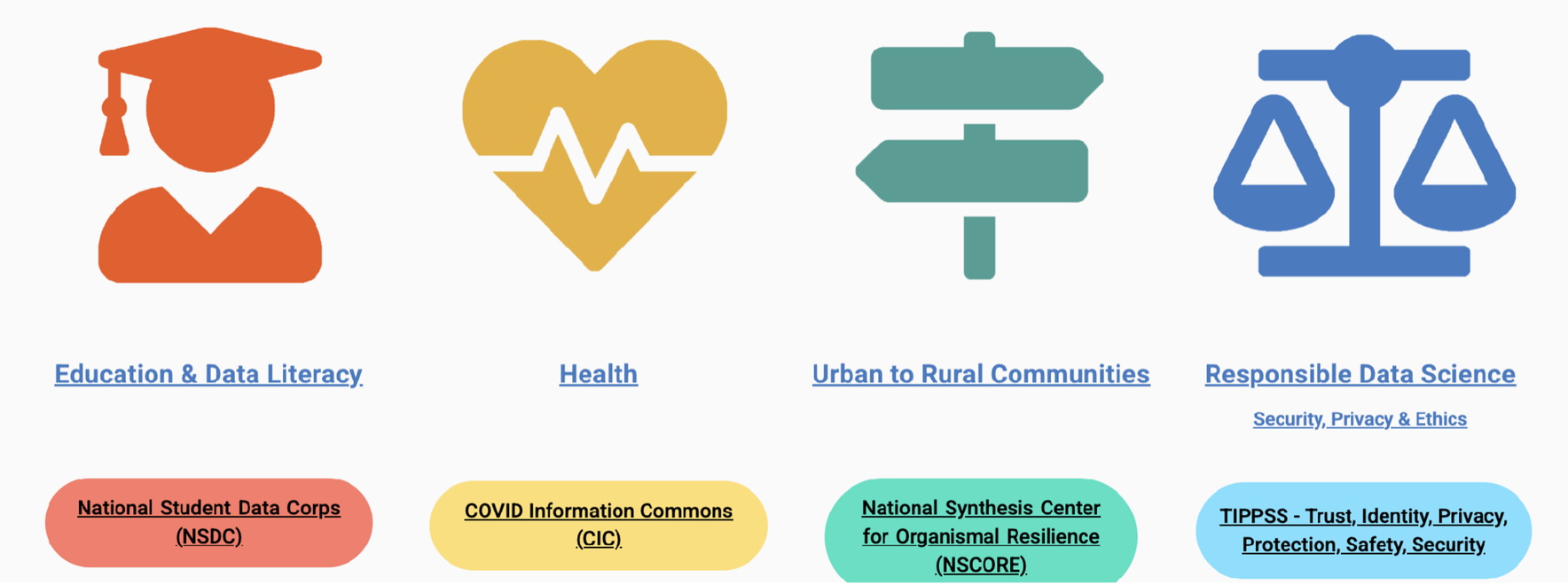
US leadership in Healthcare and Medical Technology: TIPPSS, AI and beyond

Research Frontiers and Future Needs Panel
NIST/NIBIB Symposium on Medical Metrology and Standards
Institute for Bioscience and Biotechnology Research (IBBR) - Rockville, MD
September 24, 2026

Florence Hudson, Executive Director, Northeast Big Data Innovation Hub, Columbia University
Interim Executive Director for Sponsored Research, Data Science Institute, Columbia University
IEEE Vice Chair, Engineering Medicine & Biology Society, Standards Committee
National Academies of Sciences, Engineering and Medicine - REDI Initiative (Resilient and Enduring Data Infrastructure for Biomedical and Life Sciences Research and Innovation)

Northeast Big Data Innovation Hub

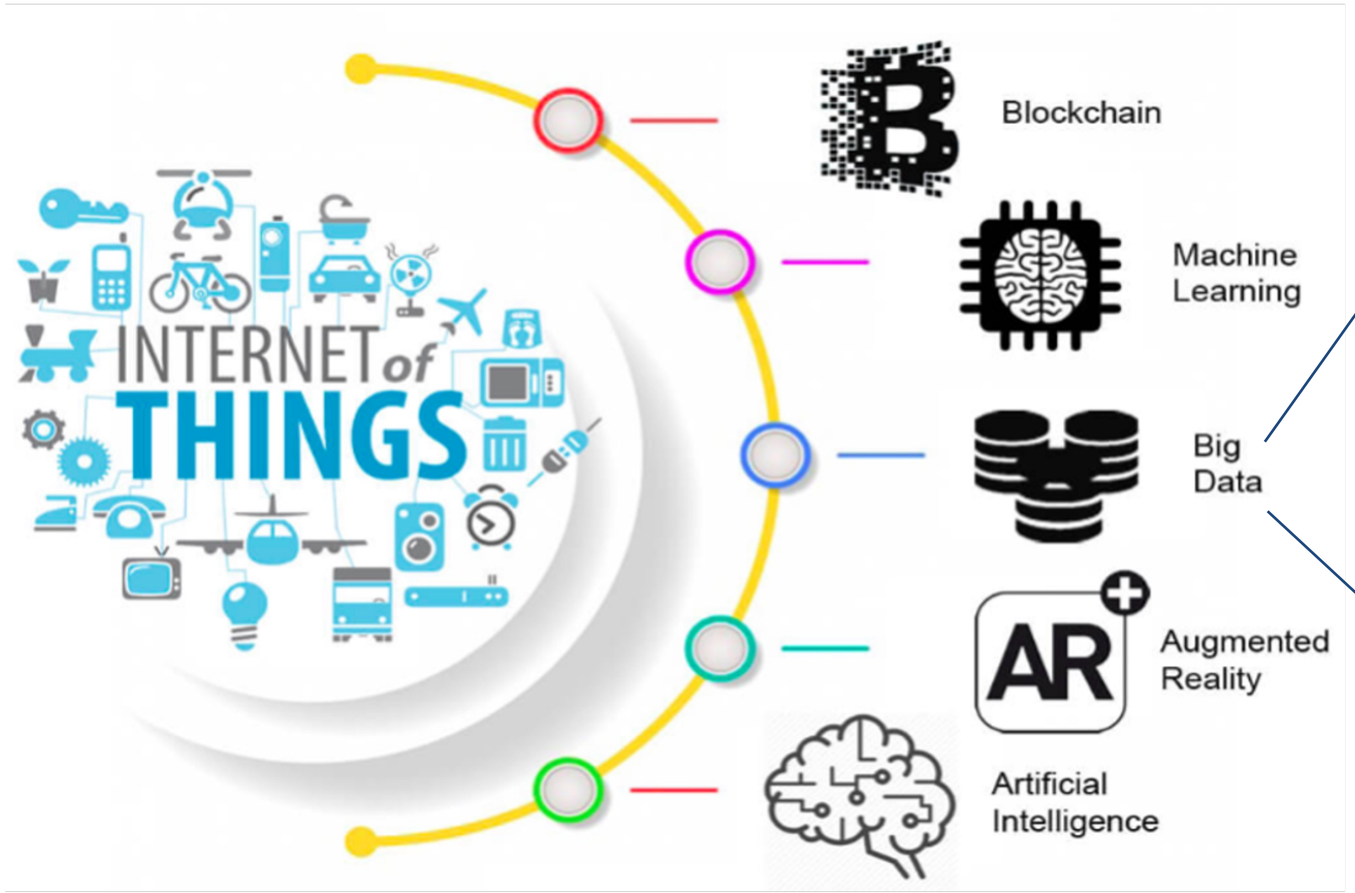
- The NEBDHub is a Community convener, collaboration hub, and catalyst for data science awareness, education and innovation.
- The Hub Community includes 28,758 individuals at 2,325 academic, industry, nonprofit & government institutions.
- The Hub's following four focus areas guide our work:

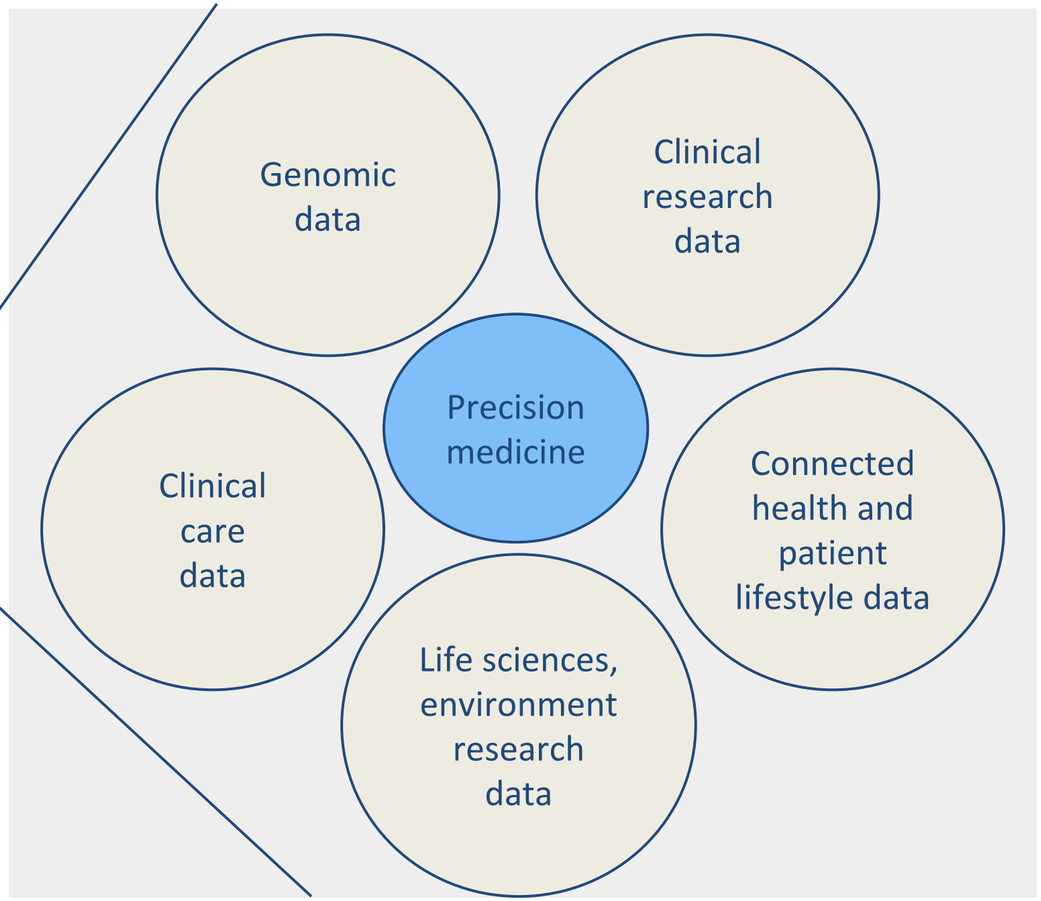


http://nebigdatahub.org/about/

Funded by NSF #1550284, 1748395, 1848988, 1916585, 2028999, 2139391, 2333532, 2438843, 2625174; National Institutes of Health (NIH); US Department of Transportation Federal Highway Administration; Defense Advanced Research Projects Agency (DARPA)

Advanced technologies can harness and analyze vast amounts of data to enable precision medicine and improve outcomes… and add risk

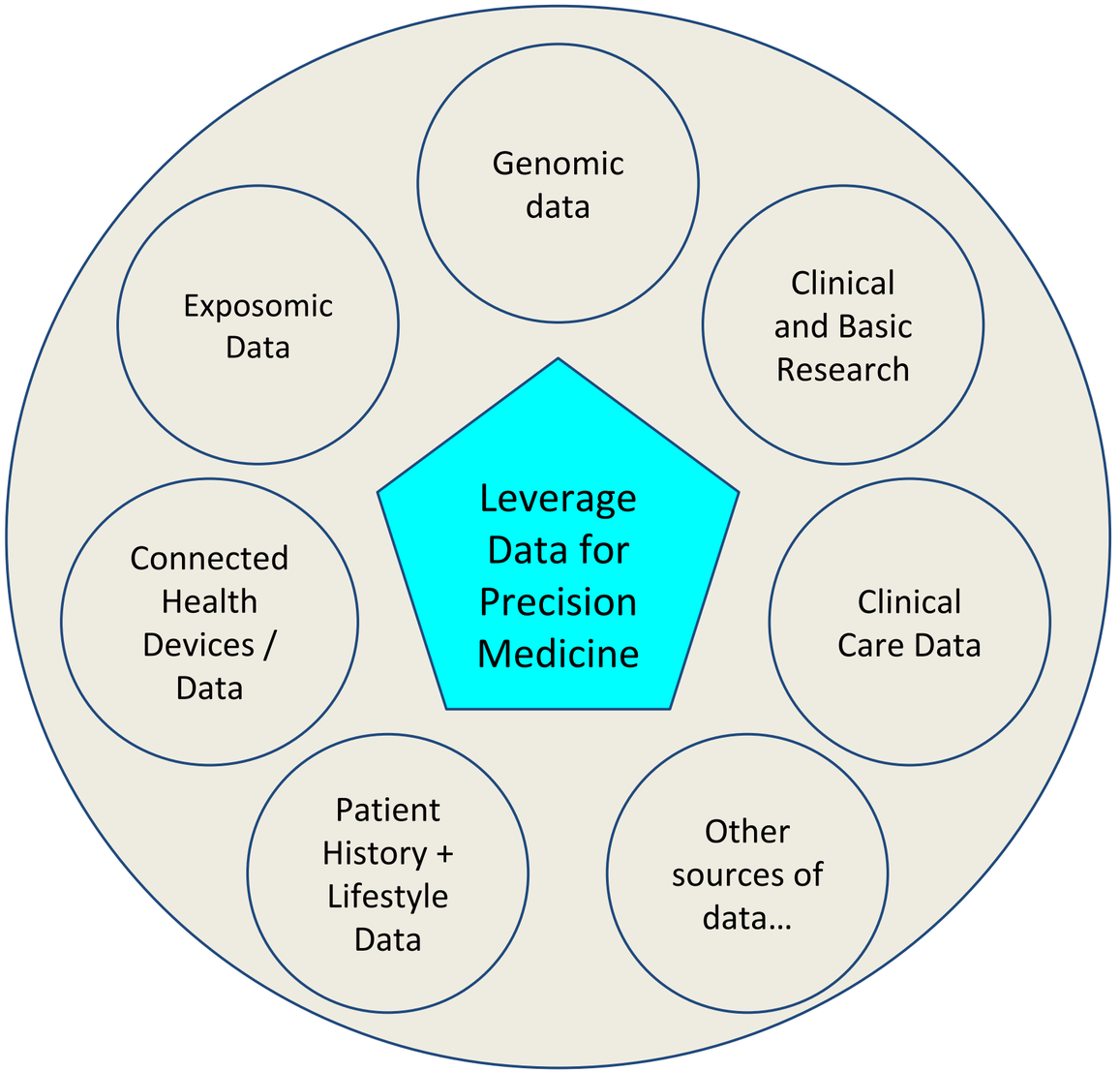




Reference: Handbook of Statistics, Volume 35, Cognitive Computing: Theory and Applications, ***Elsevier 2016,*** *Editors: VV Raghavan, VN Gudivada, V Govindaraju, CR Rao; Chapter 11, The Internet of Things and Cognitive Computing, Authors FD Hudson and EW Nichols, ISBN 9780444637444*

As we leverage more data and devices, risk will continue to grow

- More data and devices – Clinical, imaging, lifestyle, exposome, etc.
- New devices, especially mobile devices, “in the wild” in less secure environments
- More physical and virtual access points and attack vectors
- More accessibility to devices and data - by providers, patients, payers, researchers, vendors, governments, malicious actors, etc.
- Malicious motivations include financial, political, institutional, personal



More devices, data and access create more security and privacy attack vectors and risk

"Any medical device connected to a communications network, like Wi-Fi, or public or home Internet, may have cybersecurity vulnerabilities that could be exploited by unauthorized users."

Dr. Suzanne Schwartz
Director, Office of Strategic Partnerships &
Technology Innovation,
Center for Devices & Radiological Health, US FDA
July 2019



Source: https://www.drugwatch.com/news/2019/07/11/medical-device-cyber-attacks-tv-plot-or-dangerous-reality/

We must secure healthcare devices & data while enabling interoperability to help protect the humans

Top concerns:

- Connected healthcare devices and data
- Connected hospitals, campuses, cities, vehicles
- Clinical, scientific and research device and data integrity

Protection needed regarding:

- Device, hardware, software, service hacks
- Physical health and safety risk
- Financial risk, reputational harm
- Data theft, data integrity, loss of privacy
- Defense in depth – Hardware, firmware, software, service

Need to evolve policy and culture.

"They're going to try to hack everything," warns Florence Hudson of IBM. "I am most worried about security in healthcare, in cars and moving vehicles and in critical infrastructure.



"Security really needs to be designed into IoT solutions right at the start. You need to think about it at the hardware level, the firmware level, the software level and the service level. And you need to continuously monitor it and stay ahead of the threat."
- Florence Hudson, IBM Vice President, 2015

Source: https://assets.kpmg/content/dam/kpmg/pdf/2015/12/security-and-the-iot-ecosystem.pdf

Leverage the IEEE 2933-2024 Standard for Clinical IoT Data & Device Interoperability with TIPPSS

This standard establishes the framework with **TIPPSS principles (Trust, Identity, Privacy, Protection, Safety, Security)** for Clinical Internet of Things (IoT) data and device Interoperability. This includes wearable clinical IoT and interoperability with healthcare systems such as Electronic Health Records (EHR), Electronic Medical Records (EMR), other clinical IoT devices, in-hospital devices, *and future devices and connected healthcare systems. All large and small connected devices are in the scope of IoT.*

- Working Group Launched 2019
- 300+ WG members from 33 countries, 6 continents
- Standard approved by IEEE and UL in June 2024
- Standard published by IEEE and UL in September 2024
- Awarded the 2024 IEEE Emerging Technology Award
- Developing TIPPSS Maturity Model
- *New IEEE TIPPSS Roadmap Task Group - join the team!*



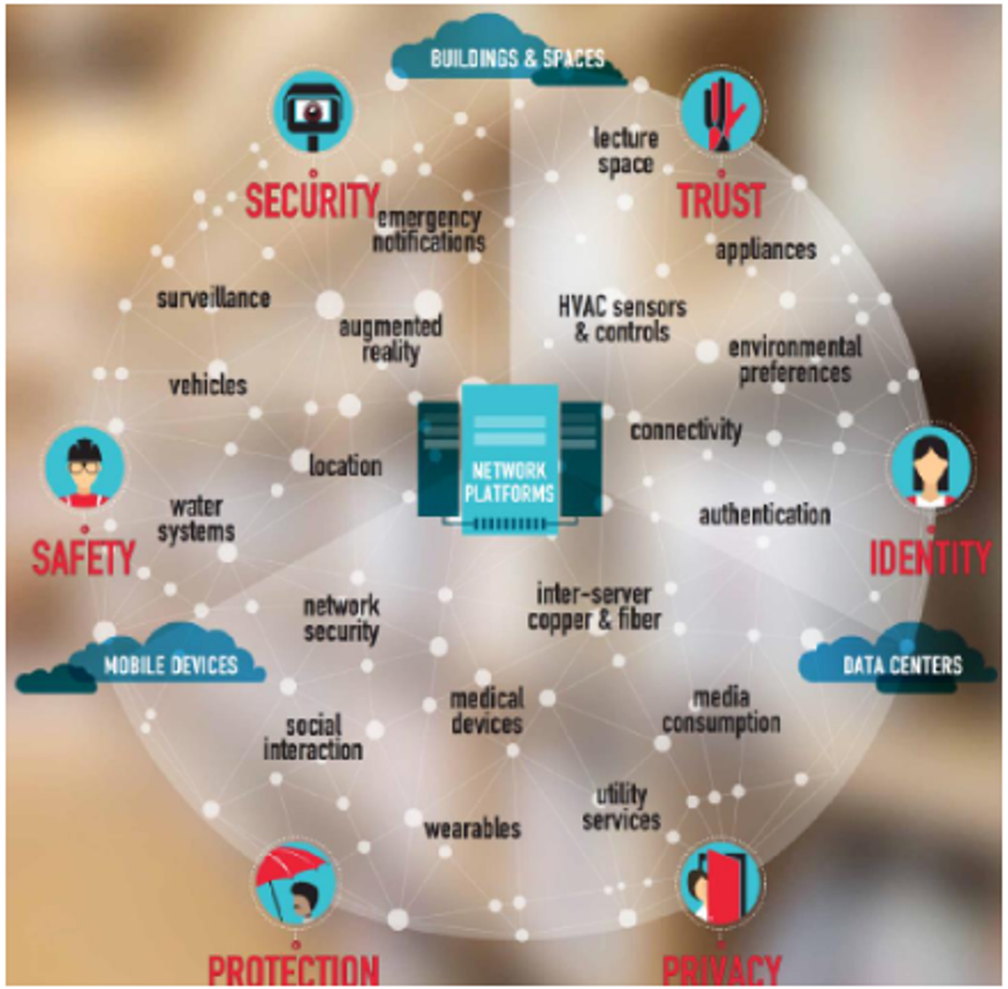




https://nebigdatahub.org/tippss/

TIPPSS is the new Cybersecurity Paradigm - Trust, Identity, Privacy, Protection, Safety, Security

- **Trust**: Allow only designated people/services to have device or data access
- **Identity**: Validate the identity of people, services, and “things”
- **Privacy:** Ensure device, personal, and sensitive data is kept private
- **Protection:** Protect devices and users from harm – physical, digital, financial, reputation
- **Safety**: Provide safety for devices, infrastructure and people
- **Security**: Maintain security of data, devices, people, etc.



IEEE is Extending the TIPPSS Standard further into Healthcare and Many Cyber-physical Systems



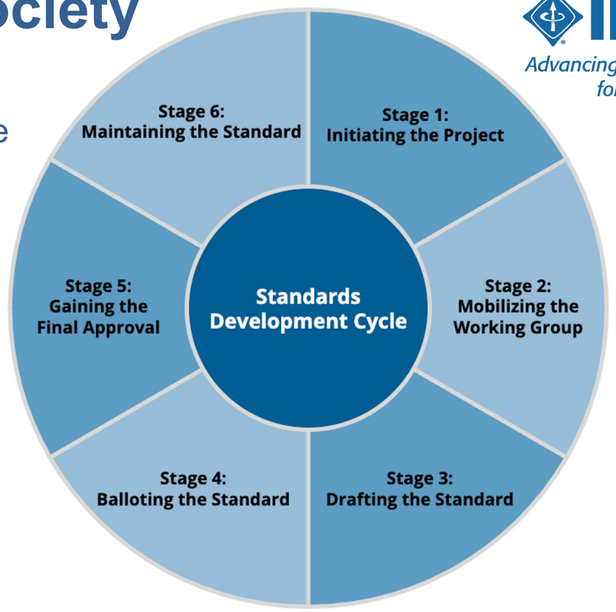
TIPPSS Roadmap Task Group launched to create new standards opportunities:

- *AI-Based Coaching for Healthcare with TIPPSS*
- *Remote Subject Monitoring with TIPPSS in Clinical Trials and Care*
- *Smart Energy Systems Data and Device Interoperability Incorporating TIPPSS*
- *Research Infrastructure*
- *Cyberinfrastructure*
- *Connected Vehicles*
- *Smart Cities*
- *Digital Twins for Healthcare*
- *etc.*

Join us! https://nebigdatahub.org/tippss/

IEEE Engineering Medicine & Biology Society Standards Committee Activities

Florence Hudson, Vice Chair, IEEE EMBS Standards Committee
florence.hudson@columbia.edu



IEEE Overview

- 533K members in 190+ countries
- Members include engineers, scientists, professionals in electrical/computer science, health and related disciplines
- 1,358 active standards and 1,242 under development

IEEE EMBS Overview

- 17K+ members in 190+ countries (members up 43% YoY)
- 17 active standards, 29 under development (up 70% YoY)
- Standards and recommended practices are in these areas:
  - Wearable and wireless consumer electronics, cuffless BP and diabetes device security
  - Clinical IoT data and device interoperability with TIPPSS (Trust, Identity, Privacy, Protection, Safety, Security)
  - Classification of medical electrical equipment with robotics
  - Open mobile health data, metadata and measures
  - Performance & safety evaluation of AI based medical devices
  - Quality management of datasets for medical AI
  - Shared analytics across secure & unsecured networks
  - Endocrine disrupting chemical hazard labelling
  - Electroencephalography (EEG) neurofeedback systems
  - Bioinformatics
  - Structural, vascular, functional brain imaging device safety
  - Common framework and accuracy user acceptance testing of location services for Healthcare

Source: https://www.ieee.org/about/at-a-glance

EMBS Standards Committee Mission & Activities

- Liaison between EMBS & IEEE Standards Association
- Foster innovation in technical standards & practices
- Guide technical roadmaps for emerging technologies
- Provide support & guidance for EMB standards
- Support pre-standards efforts / Industry Connections
- Support standards working groups and task groups
- Host workshops & webinars

EMBS SC - Participation Options

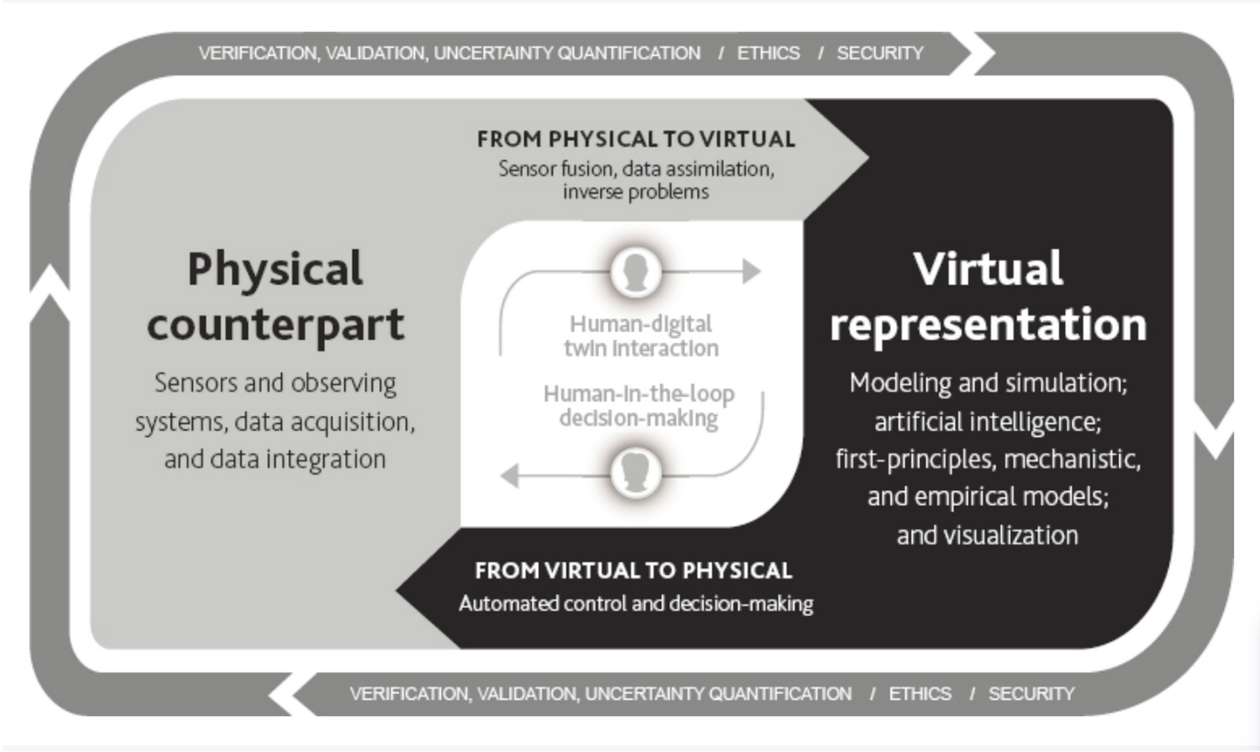
- Community membership - open to all
- Standards Study Group or Working Group
- Committee member (nomination & selection)

Future Challenges and Opportunities

- Keeping pace with: AI in healthcare; Cybersecurity; Interoperability; Regulatory harmonization; Agility

The data and measurements may inform a Digital Twin

A digital twin is a set of virtual information constructs that mimics the structure, context, and behavior of a natural, engineered, or social system (or system-of-systems), is dynamically updated with data from its physical twin, has a predictive capability, and informs decisions that realize value. The bidirectional interaction between the virtual and the physical is central to the digital twin.

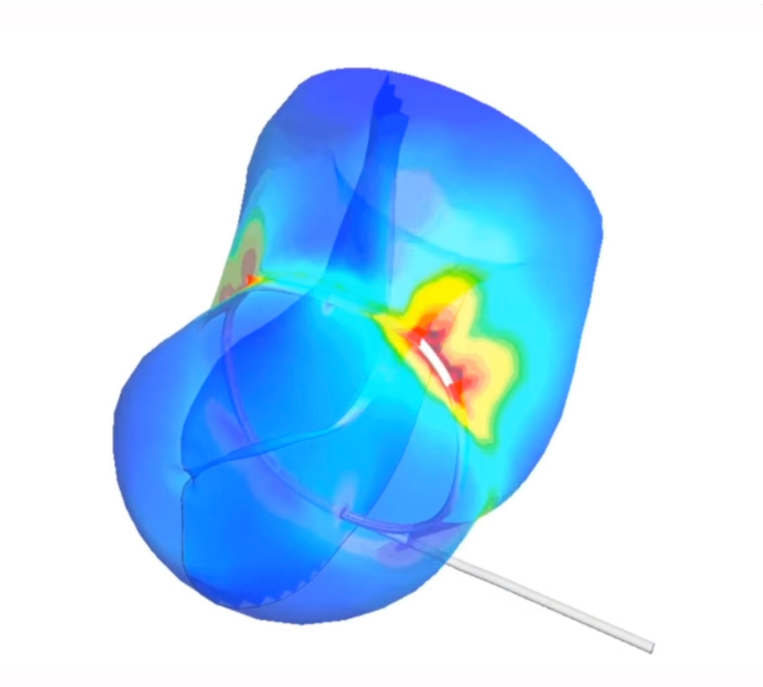


Source: "National Academies of Sciences, Engineering, and Medicine. 2024. Foundational Research Gaps and Future Directions for Digital Twins. Washington, DC: The National Academies Press. doi: 10.17226/26894. Modified from a definition published by the American Institute of Aeronautics and Astronautics (AIAA Digital Engineering Integration Committee 2020).

Examples of Digital Twin Use Cases in Health Care

Pre-Term Birth

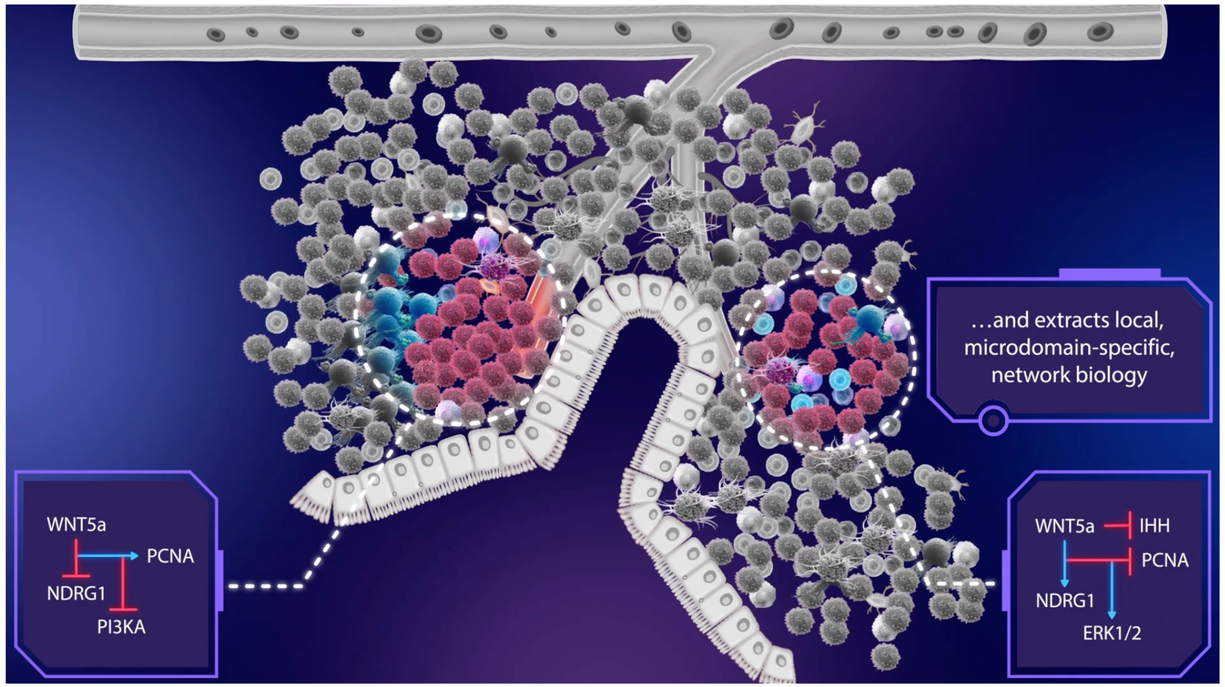
- Create 3D digital twins from ultrasound images
- Generate hypotheses and predictions
- Simulate potential interventions to improve outcomes



Source: Dr. Kristin Myers, Columbia University; https://www.facebook.com/watch/?v=1499988937845159

Cancer

- Translate complex solid tumor tissue biology into decision-grade insights
- From early discovery through clinical development



Source: Dr. Chakra Chennubhotla; https://predxbio.com/spaceiq-platform/

Protect the data, devices and humans from harm, including Digital Twins for Health and, by extension, the humans

The challenge:
Reducing the risks to humans, data, devices, and organizations due to growing cybersecurity challenges in connected systems.

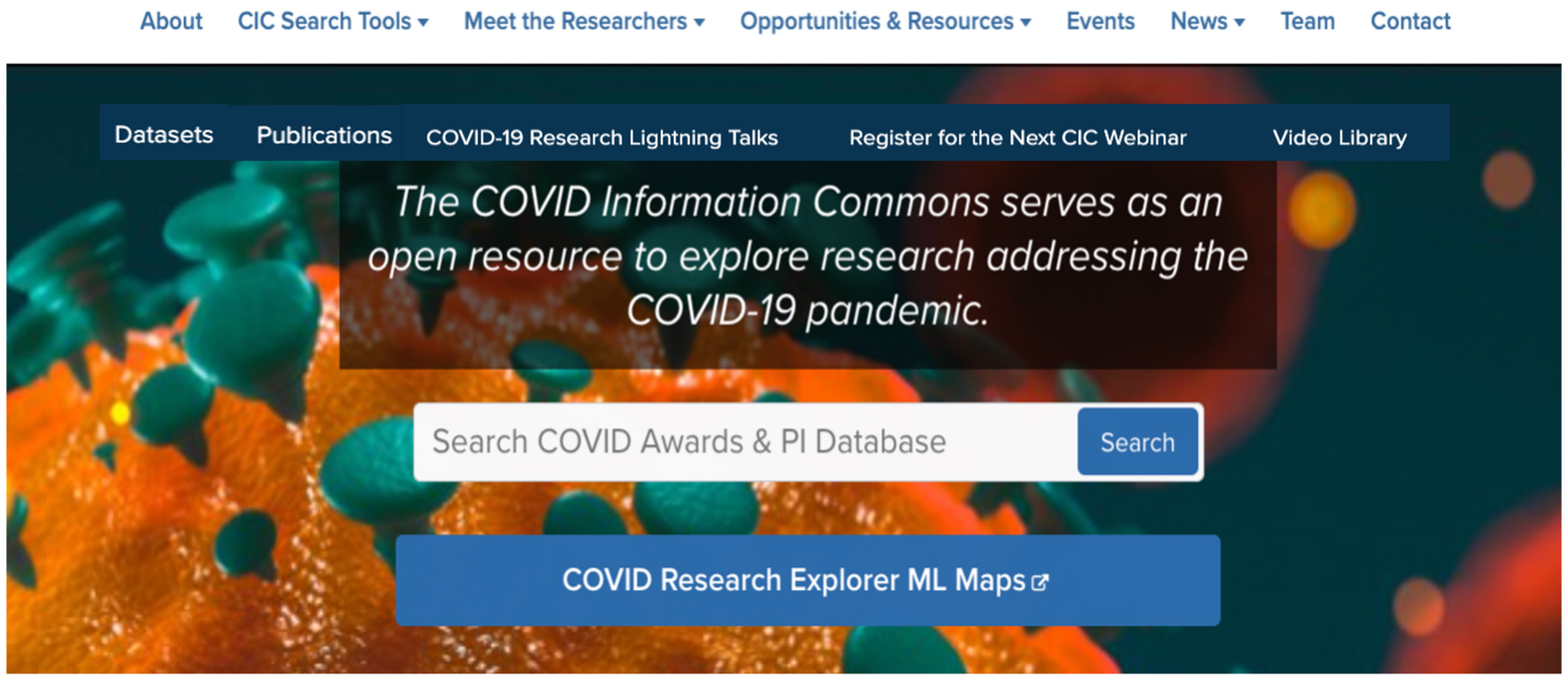
Digital twins for health provide value, both for healthcare … and hackers.

The questions:

- What if the digital twin is hacked?
- What if the data informing the digital twin is hacked, changed, compromised?
- What if the research informing the digital twin design, development, algorithms, or recommendations are compromised?
- How to secure the digital twins and all the inputs and outputs?
- How to detect breaches, malicious or accidental, from humans, devices, systems, services?
- How to enable trust and confidence in the digital twins for health and the underlying data?

We can Share Research and Insights through an Information Commons for Researcher and Practitioner Collaboration

Leverage the model of the COVID Information Commons (CIC) Portal and Community

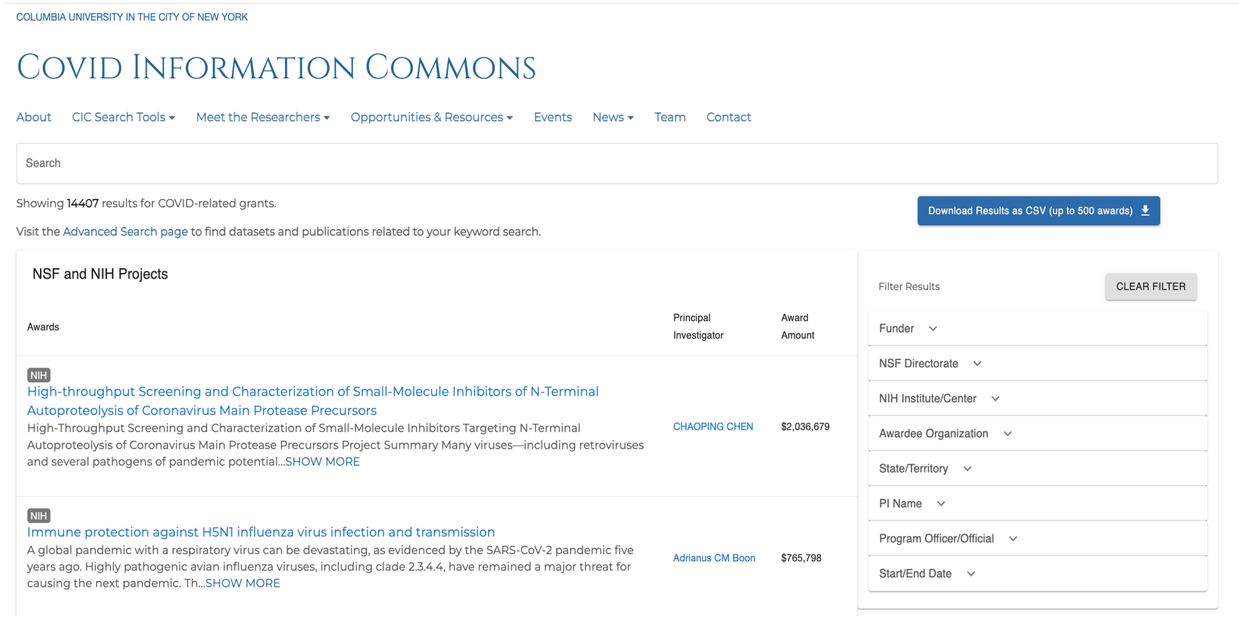


CIC supported by NSF awards #2028999 and #2139391

https://covidinfocommons.net/

Benefits of an Information Commons Portal and Community

- Easily find pertinent research, projects and resources - e.g., CIC has 14,407 NSF/ NIH COVID-related awards, metadata, PI's, links to datasets, publications, video's
- Search by topic, project, PI, institution, funder, location
- Updated via NSF and NIH API pulls
- Build community with research lightning talk webinars, topical working groups, student projects and groups
- Research lightning talks in video library
- Provide PI profiles to inspire collaboration
- Attract tens of thousands of video views
- Inspire student working groups and paper challenges



https://covidinfocommons.net/

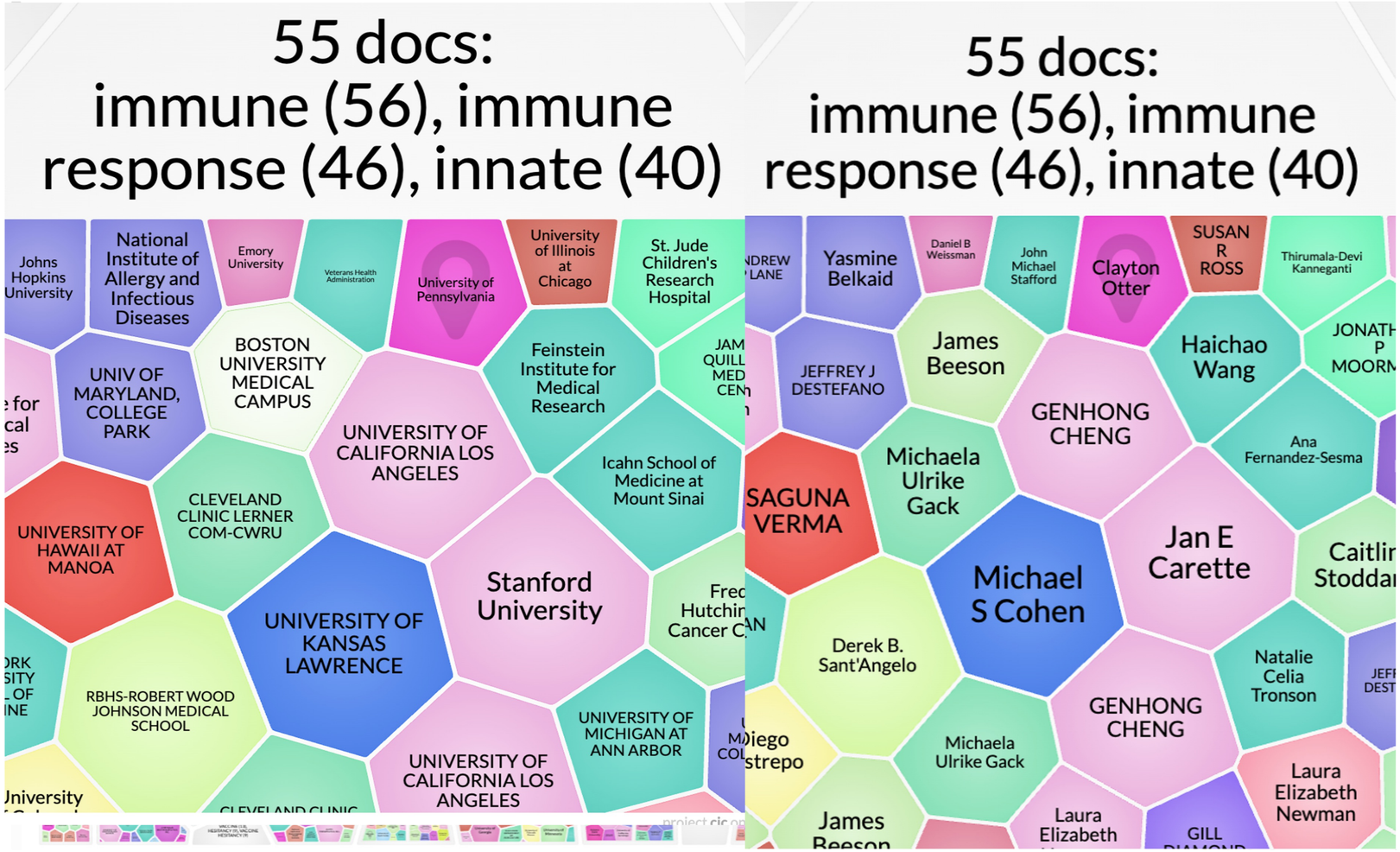
COVID Information Commons - COVID Research Explorer ML Maps Clustering Tool

Architected for visualization of NSF and NIH funded COVID projects, with drill down

Maps COVID research projects and researchers by topic, Principal Investigator, Institution, or State

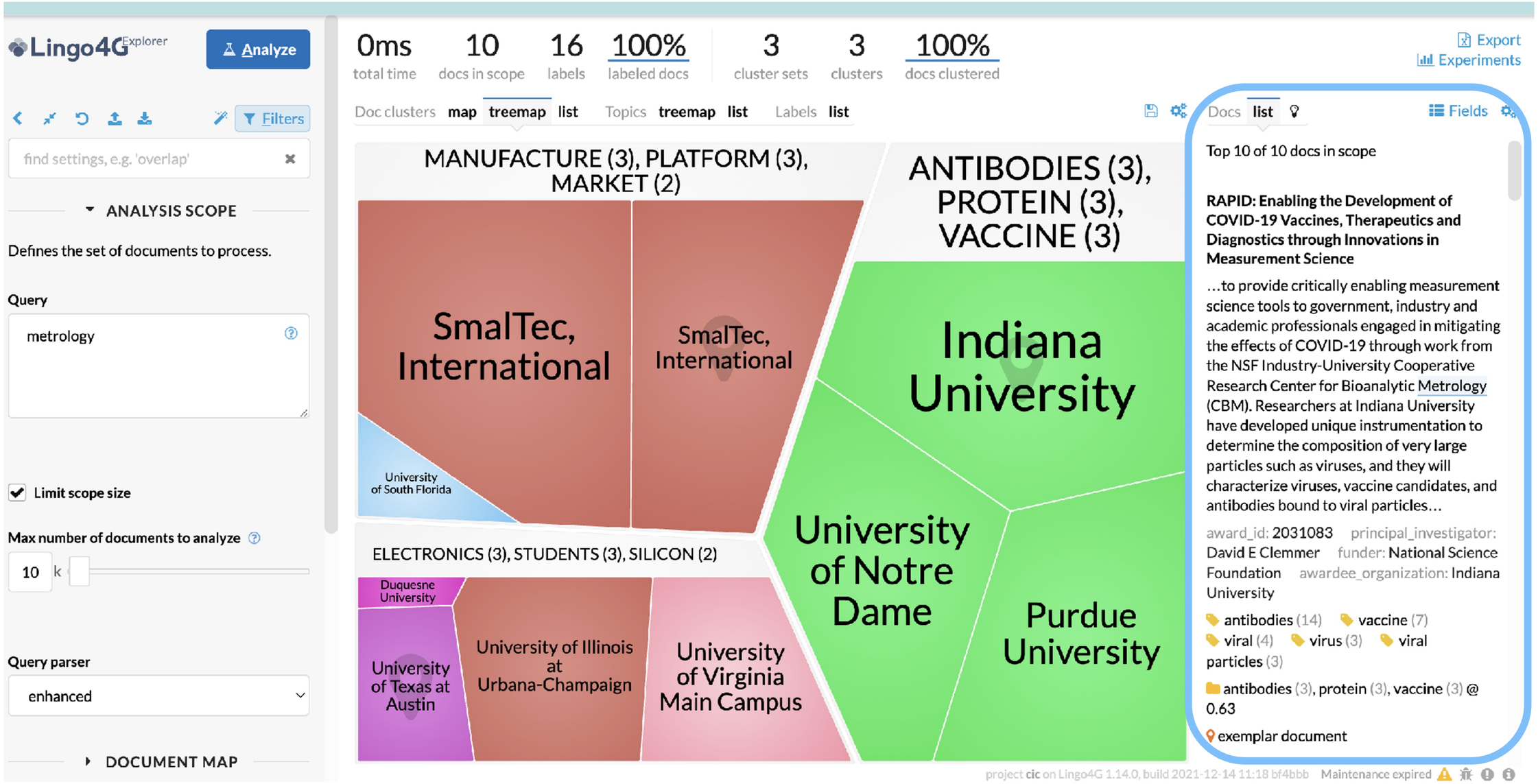
Users can input keyword queries to focus on target domains

Find research, PIs, publications, datasets, funders, and more

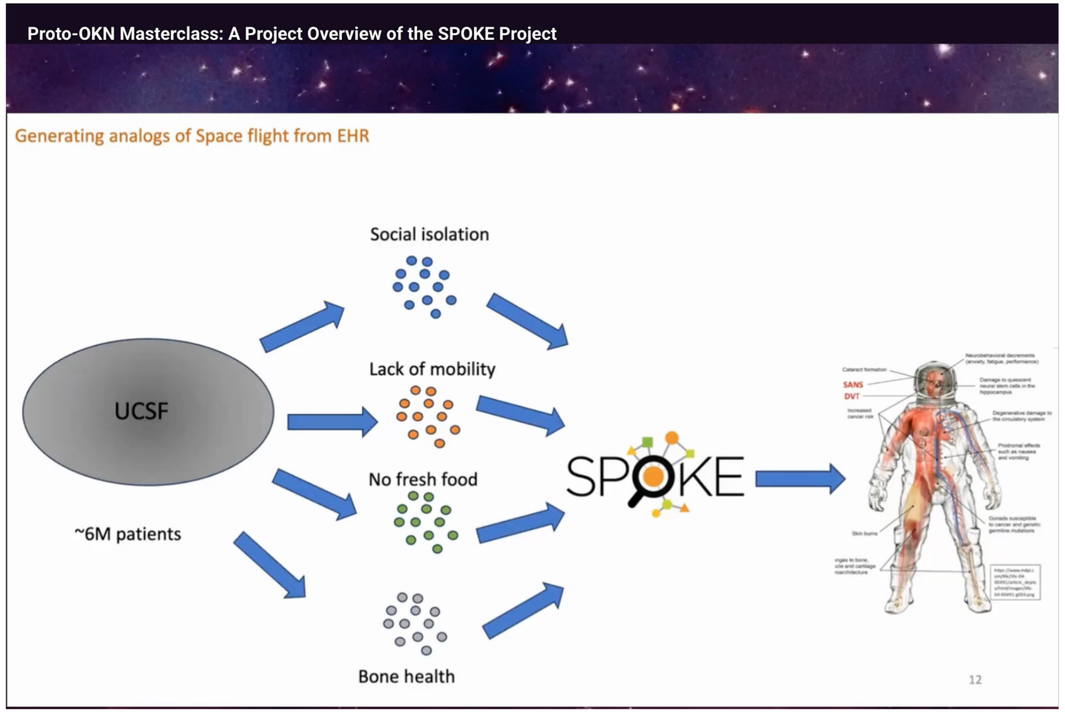


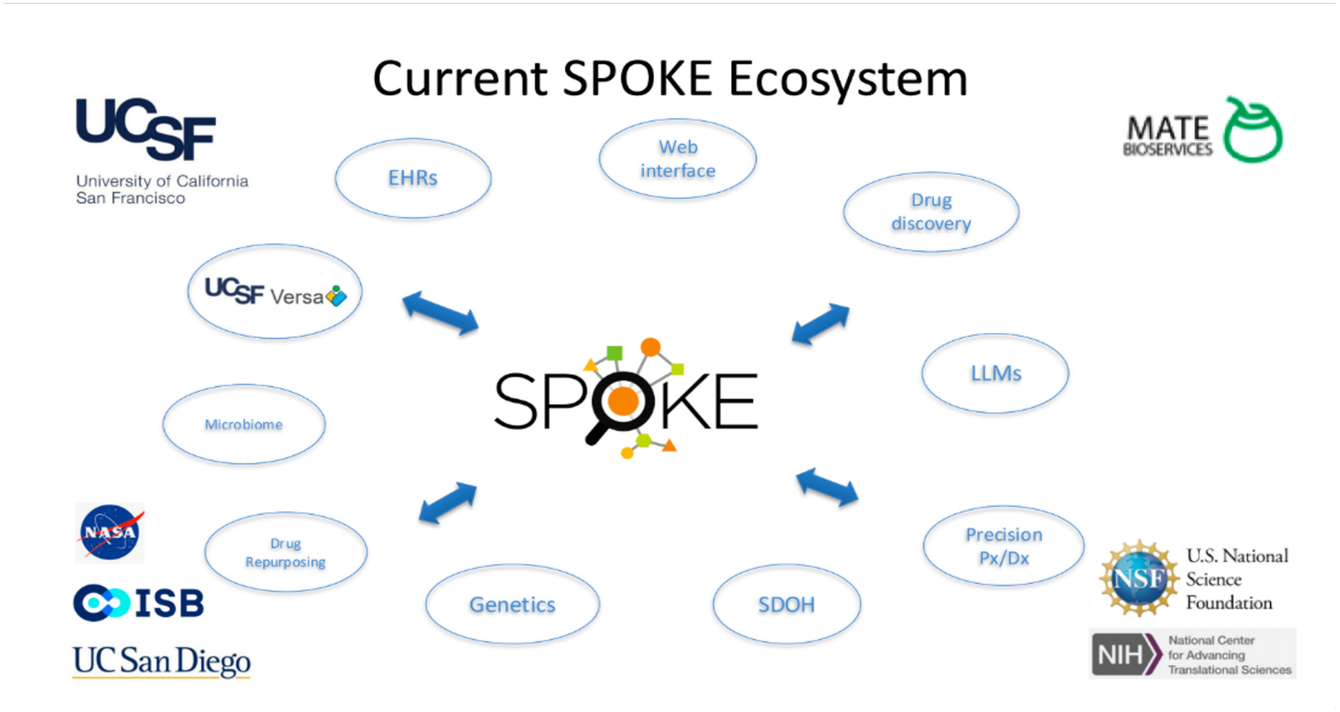
https://covidinfocommons.net/

Sample NSF and NIH Metrology Awards in the CIC - *We could create a Metrology Info Commons like this.*



More broadly, we can leverage Health Knowledge Graphs and Open Knowledge Networks to Share Data and Insights



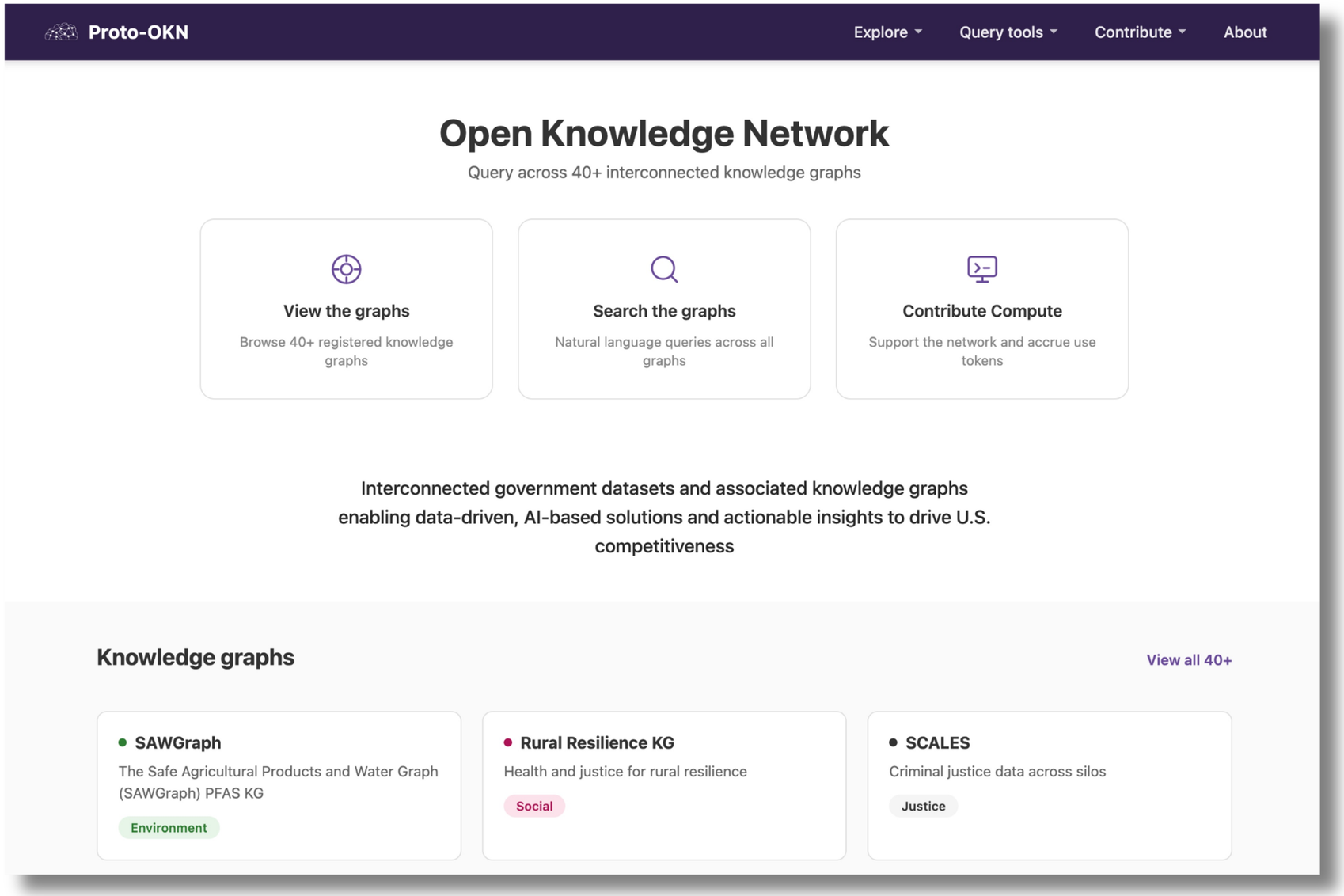


Example project: SPOKE: Scalable Precision Medicine Open Knowledge Engine

Funded by the NSF Prototype Open Knowledge Network https://proto-okn.net/projects

Source: *https://spoke.ucsf.edu/projects*

The Open Knowledge Network (OKN.US) MVP Launched May 8, 2026



Interested in the OKN.US Minimum Viable Product (MVP)? Let us know!

bitly

Read more about TIPPSS, Biomedical digital twins, Open Knowledge Networks and COVID Information Commons



https://www.fdhint.com/writing

Thank you

Florence D. Hudson

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Interim Executive Director for Sponsored Research

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