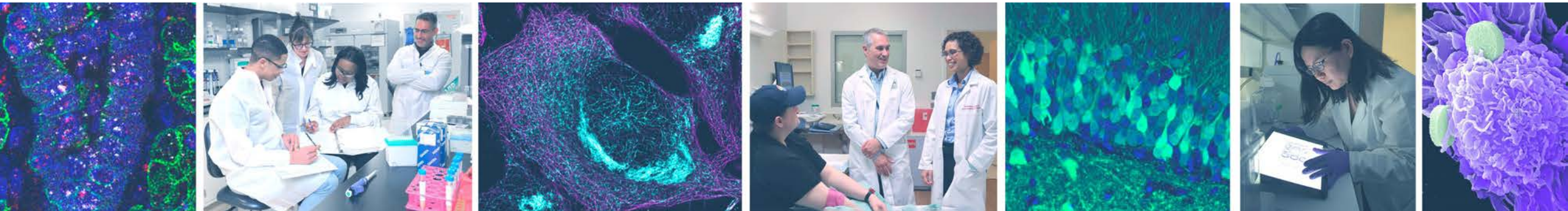


NIH Director's Welcome

Advancing the Use and Development of Common Data Elements in Research
March 6, 2024



Monica M. Bertagnoli, MD
Director, National Institutes of Health



Thank you: Workshop Planning Committee

- Lew Berman, NIH OD
- Deborah Duran, NIMHD
- Kerry Goetz, NEI
- Anupama Gururaj, NIAID
- Sweta Ladwa, NHLBI
- Snipta Mallick, NIH OD
- Steve Tsang, NIH OD
- Denise Warzel, NCI
- Victoria Shanmugam, NIH OD
- Susan Gregurick, NIH OD

Agenda

- Session 1: The **Value** of Common Data Elements (CDEs)
- Session 2: Current NIH **Resources** for CDEs
- Session 3: Overcoming **Barriers** in CDE Adoption and Use in Community Research
- Session 4: **Technical Implementation** Aspects of Mapping, Transformation and Harmonization of CDEs
- Session 5: Approaches to Improve **Interoperability**
- Session 6: **Use Cases** for Preparing and Applying CDEs for Intelligent Technologies



Today's Discussion

- The Importance of Common Data Elements
- The Health of the U.S. Population
- Guiding Principles
- My Vision for NIH

Common Data Elements

- **What they are:**
 - **Standardized**, precisely defined questions paired with a set of specific allowable responses
 - Used **systematically** across sites, studies, or clinical trials
- **Advantages:**
 - **Consistent** data, **readable** for humans and machines
 - Enable **sharing**, enhance interpretation and **analysis**, simplify **collaboration**, **reduce time** to start projects and obtain results

NIH encourages the use of CDEs

A common language to support research and health care



Interoperability

- **Fast Healthcare Interoperability Resources (FHIR®)**: application programming interfaces (APIs) to facilitate health data collection and exchange across different health system **EHRs**
- Promotes the development of patient-centric **mobile health applications or devices** for clinical research and supporting clinical decisions
- **US Core Data for Interoperability (USCDI)**: Office of the National Coordinator (ONC) requirement for healthcare data
 - USCDI+ Initiative supports extension beyond existing USCDI elements

Minimal Common Oncology Data Elements (mCODE)

A core set of non-proprietary, open-source structured data elements for oncology

Goals:

- Increase high-quality shareable data for all cancer types
- Allow data to be collected once and used for multiple purposes by clinicians and researchers to support patient care

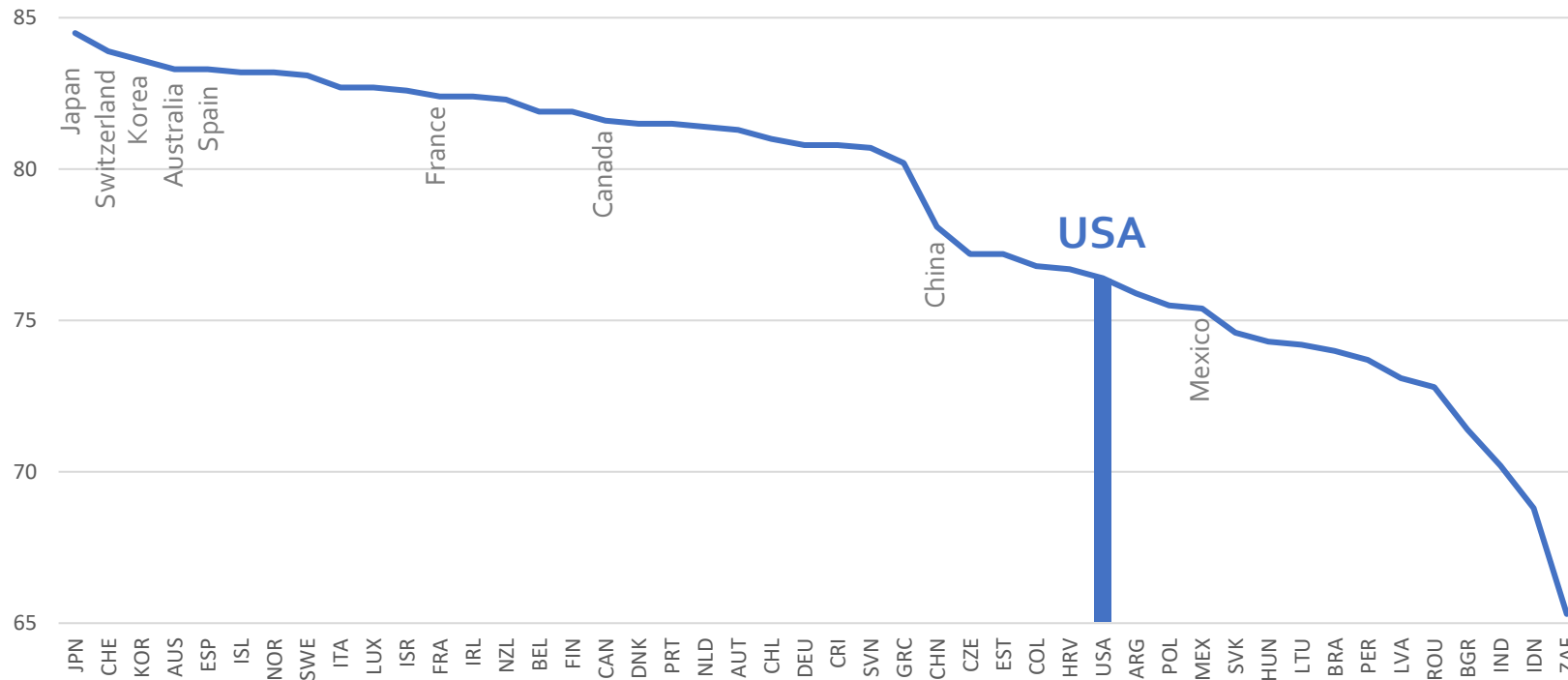
mCODE™



Challenges

U.S. life expectancy ranks low among peers

2021 Life Expectancy Throughout World³

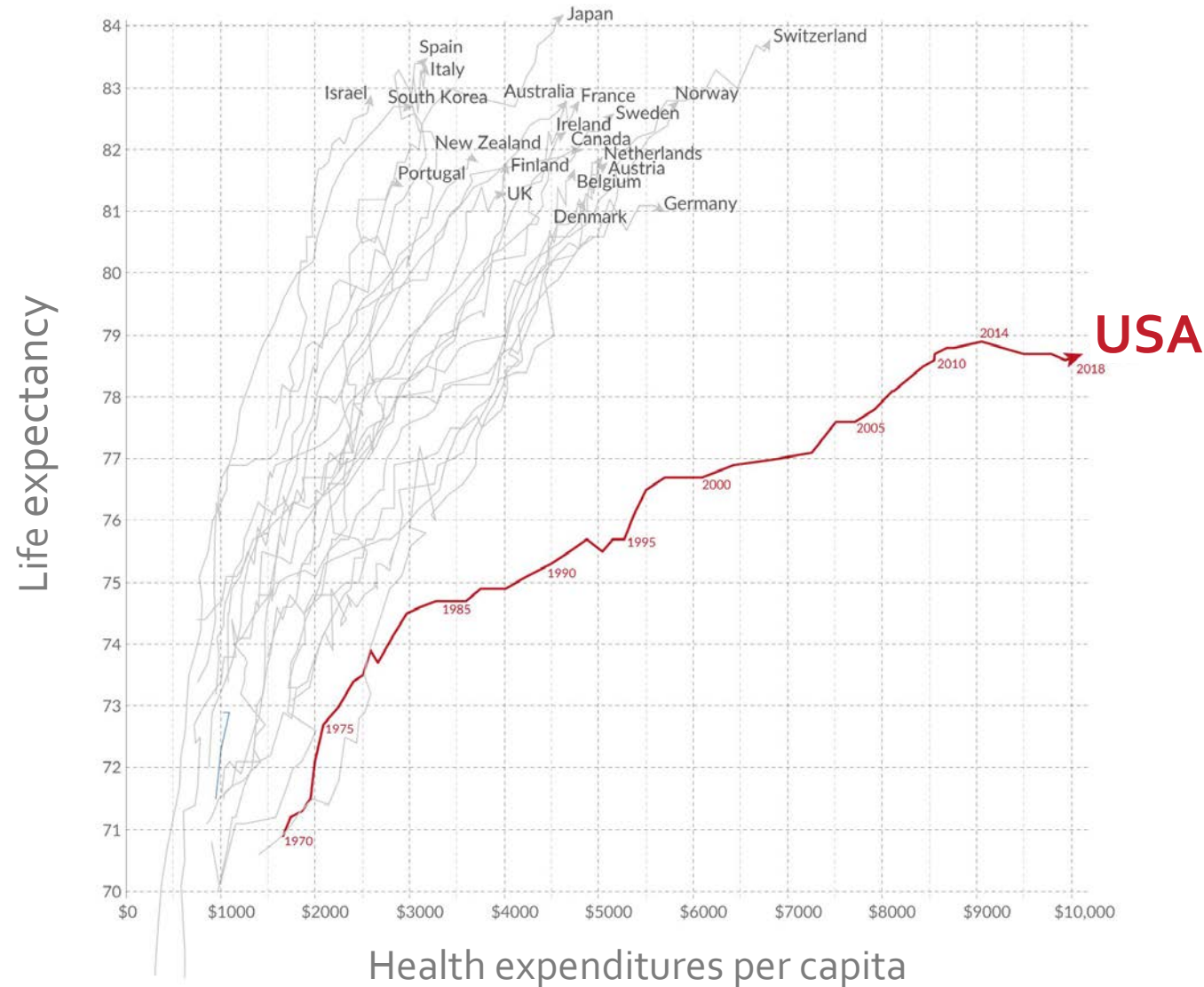


Another concerning trend: Life expectancy in the U.S. has dipped since 2014, a trend that is not due entirely to the COVID-19 pandemic

(1) National Academies of Sciences, Engineering, and Medicine. 2021. *High and Rising Mortality Rates Among Working-Age Adults*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25976>.
(2) Arias E, Kochanek KD, Xu JQ, Tejada-Vera B. Provisional life expectancy estimates for 2022. Vital Statistics Rapid Release; no 31. Hyattsville, MD: National Center for Health Statistics. November 2023. <https://dx.doi.org/10.15620/cdc:133703>.
(3) Chart data: OECD (2024), Life expectancy at birth (indicator). DOI: 10.1787/27e0fc9d-en (Accessed on 10 January 2024)

Life expectancy vs. health expenditures

1970-2018



Source: Max Roser (2020) - "Why is life expectancy in the US lower than in other rich countries?" Published online at OurWorldInData.org. Retrieved from: <https://ourworldindata.org/us-life-expectancy-low> Data source for table: Organisation for Economic Co-operation and Development (OECD)

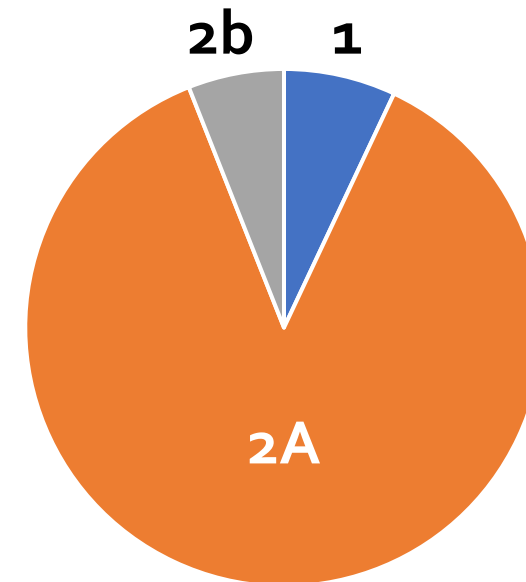
Category of evidence and consensus underlying National Comprehensive Cancer Network guidelines: Is there evidence of progress?

Aakash P Desai ¹, Ronald S Go ², Thejaswi K Poonacha ³

NCCN Levels of Evidence

- 7% **Category 1:** High level evidence such as randomized controlled trials with uniform consensus
- 87% **Category 2A:** Lower level of evidence with uniform consensus
- 6% **Category 2B:** Lower level of evidence without a uniform consensus but with no major disagreement
- 0% **Category 3:** Any level of evidence but with major disagreement

Distribution in 2019





People who are not adequately represented in clinical research

- Are older
- Are uninsured
- Belong to minority groups
- Live in rural locations
- Have co-morbid conditions
- Are more likely to receive non-standard treatment

Research and health data are fragmented and underused

- Accessibility issues hamper effective use of data to inform research and improve health.
- Advanced scientific methods and data sharing requirements have unleashed a rush of information that is not readily benefitting patients and providers.

Guiding Principles





Our work is not finished when we deliver scientific discoveries, our work is finished when all people are living long and healthy lives.



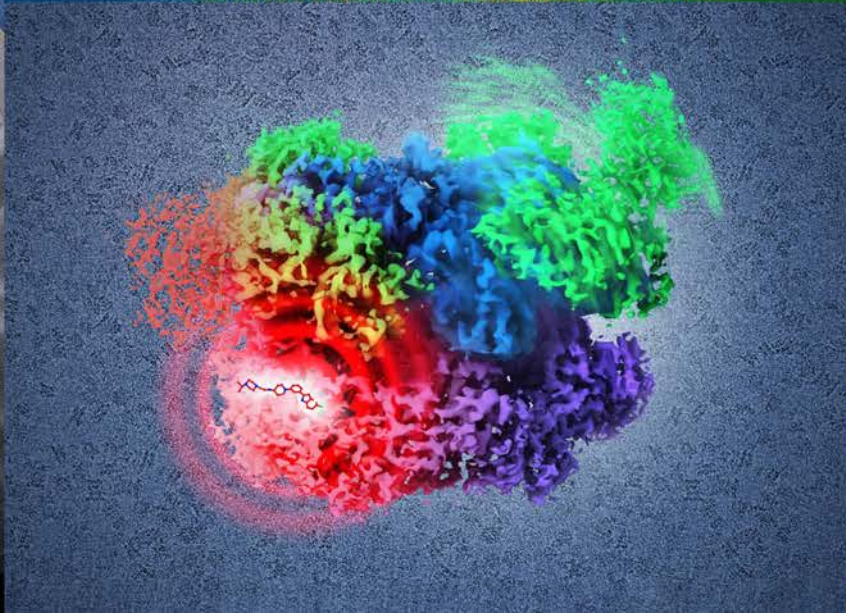
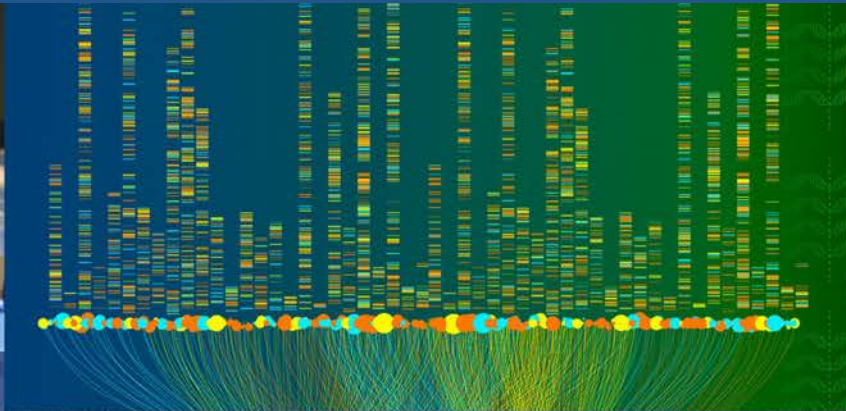


NIH research encompasses the laboratory, the clinic, and the community.



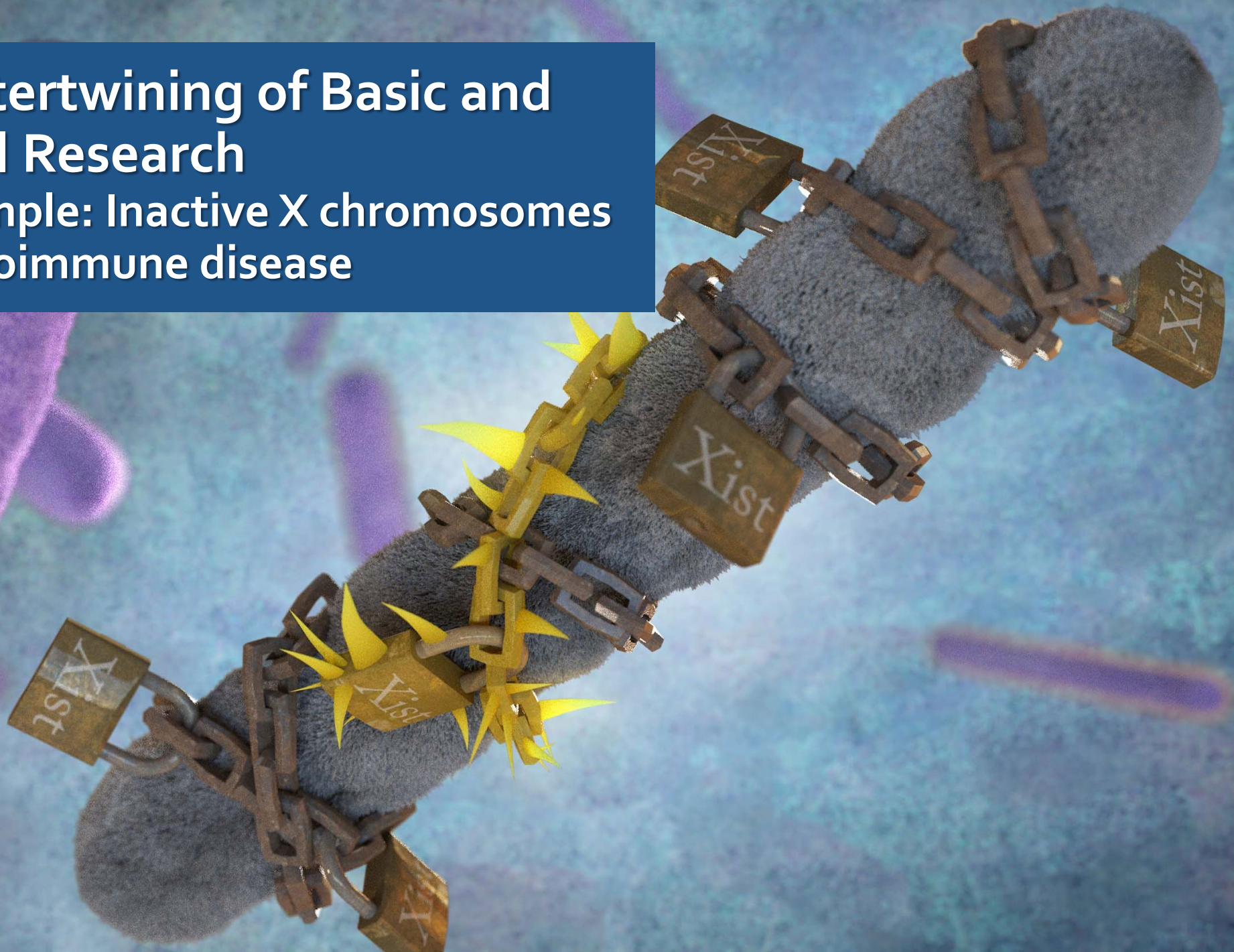


Progress is accelerated when advanced scientific methods, such as new data analytics, are applied to data that includes everyone, and when new discoveries are rapidly and equitably adopted in clinical care.



The Intertwining of Basic and Clinical Research

An example: Inactive X chromosomes and autoimmune disease





Priorities

Connect research to primary care to optimize outcomes for patients



Meet people where they already **receive care** to better engage underrepresented communities in research.



Use **EHR** to respectfully engage people in research with their permission.



Increase research capabilities and efficiency with **innovative study designs** that address common health issues, prevention and implementation relevant to individual communities.



Rapidly **disseminate evidence** to guide patient and provider decisions.

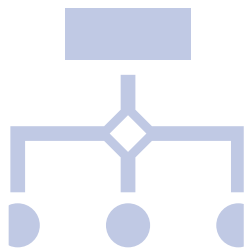
Expand biomedical research data use to inform new research and improve health outcomes



Integrate data from basic and social science research, public health, and clinical care.



Increase capacity for data hosting,
Enable low-cost **access** to data using open-industry data standards,
Support broad access to advanced analytics and computational power.



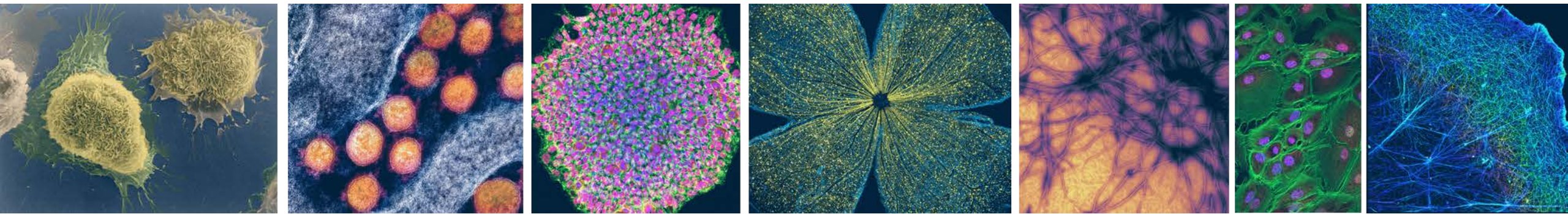
Employ a **federated architecture** for data sharing and use.



Provide **education** and workforce development.

Meeting Charge

- Encourage the **adoption and use of CDEs** for research across diseases and conditions, including autoimmune and immune-mediated conditions
- **Discuss strategies:** resources, approaches, methods for cross-study analyses
- **Engage all** interested parties, including NIH staff, extramural researchers, professional societies and patient organizations



NIH

Turning Discovery Into Health

