

# Global Health and Genomic Data Localization and Governance

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# About ITIF

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- Independent, nonpartisan research & education institute focusing on intersection of technological innovation and public policy, including:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Life sciences, agricultural biotech, and energy
- World's top think tank for science & technology policy, according to the University of Pennsylvania's authoritative *Global Go To Think Tank Index*

# Cross-Border Transfers of Health, Genomic, and Personal Data

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- Dynamic domestic and international situation = regulatory uncertainty and legal compliance vigilance.
- Restrictions on transferring health data get caught up in health specific, general privacy, and national security and industrial development policies.
  - E.g. Biden admin draft EOs on protecting U.S. sensitive data explicitly mentions health and genetic data.
  - UK data privacy reforms. EU GDPR and Health Data Space.

# What's At Stake: Key Driver of Productivity/Innovation

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- Data is a key input in the modern global economy.
- Competitiveness and productivity: Increasingly depends on how firms leverage data and digital tools.
- Businesses use data to create value, and many can only maximize that value when data can flow freely across borders.
- Value of data comes from how it's used—not where it's stored.

# Critical Need for Transatlantic & Global Health Data Transfers

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- 2010 - 80% of applications for drugs/biologics contained data from clinical studies conducted outside the United States.
- October 2020 - 293 healthcare/biopharma/medical device firms certified under EU-U.S. Privacy Shield.
- February 2021 - 1,303 active FDA registers clinical trials in both the United States and EU.



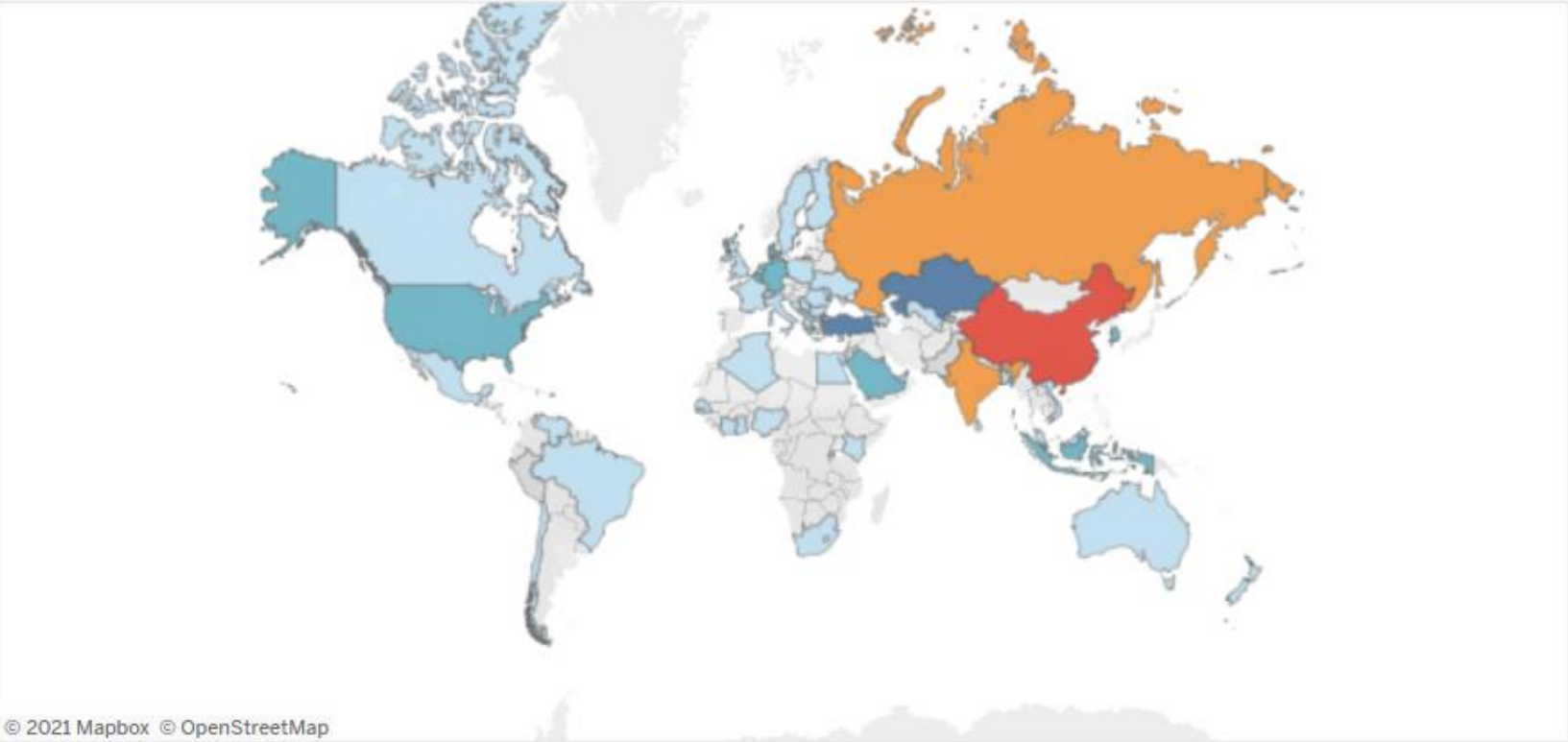
# Data Localization Prevents Data Transfers

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- Explicit and de facto forced local storage – known as data localization.
  - Explicit – must be stored within a country's borders.
  - De facto – transfers are so uncertain, difficult, and costly that firms have no other realistic option but to store locally, especially in the face of large fines.
- E.g. UK study on use of standard contractual clauses - \$68,000 to \$136,000 for a data-sharing agreement between a UK university and a U.S. organization.

# 2021: Data Localization Spreads to More Countries

National Data Regulations by Type and Status



**Filter by Regulation Type**

- Explicit
- De Facto
- Total Enacted

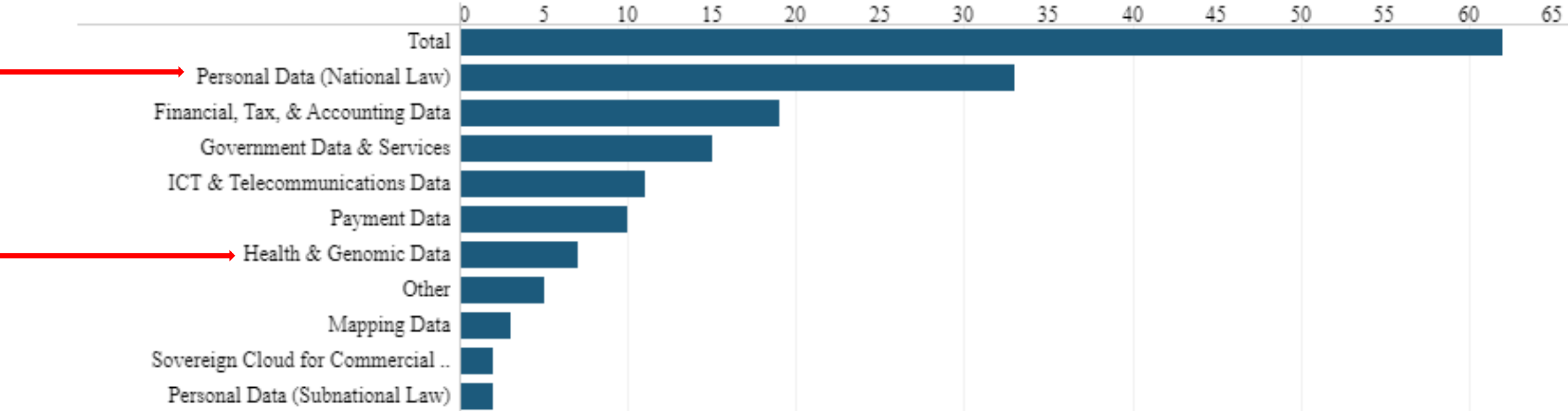
**Number of Regulations**

- 0
- 1 to 2
- 3 to 4
- 5 to 8
- 9 to 19
- 20+

# 2021: Data Localization Spreads to More Types of Data

## Number of Barriers by Data Type\*

Number of Countries per Barrier Type



\*Altogether, there were 144 data-localization measures in force around the world as of July 2021. Some of these enacted policies affect more than one type of data, so the total count of barriers by data type is greater than the sum of the enacted barriers.



# Health and Genomic Data Localization

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- Explicit Requirements - Australia, China, & the UAE.
  - U.S. – 4 U.S. State Medicaid agencies prohibit offshore outsourcing of admin functions.
- Indirect and De facto Restrictions– UK, Indonesia, and EU (GDPR).
- Considering policies that include restrictions – Kenya, Jordan, India, and the UAE.
- Sensitive personal/health data is captured in many more localization policies.

# GDPR's Negative Impact on EU-U.S. Health Research Initiatives

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- U.S. NIH-Finland joint research on diabetes and Alzheimer's.
  - In 2018, with GDPR's introduction, Finnish stopped all data sharing.
- Some EU members of International Genomics of Alzheimer's Project restricted data sharing with foreign counterparts.
  - Consortium runs separate analysis on each side of the Atlantic – hardly ideal.

SCIENCEINSIDER | EUROPE

## European data law is impeding studies on diabetes and Alzheimer's, researchers warn

Researchers share frustrations with GDPR privacy regulations at seminar in Brussels

20 NOV 2019 • BY TANIA RABESANDRATANA

# Evolving Motivations for Data Localization

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1. Misguided data privacy, protection, and cybersecurity concerns.
2. “Data sovereignty” subsumes digital protectionism.
3. Law enforcement and regulatory concerns over access to data.
4. Data localization as a cudgel for censorship and surveillance.
5. In reaction/preparation for hypothetical geopolitical risks, such as sanctions.

# Key Pillars to an Open & Rules-Based Global Digital Economy

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- Build Interoperability Into Global Data & Digital Economy Governance
- Pursue New Digital Trade/Economy Agreements (DEA & DEPA).
  - Work with Australia, Chile, New Zealand, & Singapore.
- New – U.S. initiative to create a Global Cross-Border Privacy Rules.
- Build a Framework for Government Access to Data.
  - G7/OECD process is a tightrope process to a critical outcome.



# Health Data Protection and Innovation

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- Increased use of data and AI holds enormous potential.
- Health data is sensitive, but also one of the most valuable categories.
- Need to ensure it's protected, but severely restricted data does not lead to better health outcomes.
- The challenge: Develop domestic/international legal frameworks that allow for the reasonable, responsible, and ethical sharing of health data.

# Sectoral Pillars: Build Health Data Governance

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- Build Health Data Sharing Frameworks.
  - Create clear rules/frameworks to facilitate the reasonable, responsible, & ethical cross-border sharing of health and genomic data.



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COMMENT | 05 February 2020

### **Genomics: data sharing needs an international code of conduct**

Efforts to protect people's privacy in a massive international cancer project offer lessons for data sharing.

# Key ITIF Reports

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- How Barriers to Cross-Border Data Flows Are Spreading Globally, What They Cost, and How to Address Them
- Building a Global Framework for Digital Health Services in the Era of COVID-19
- Viruses Cross Borders. To Fight Them, Countries Must Let Medical Data Flow, Too
- Comments to the European Commission on Health Data Spaces

# Thank You!

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