

PERSONAL DATA'S ROLE IN ADVANCING HEALTH CARE INNOVATION

Why Health Care Companies' Access and Use of **Personal Data** is Critical to Improving Care and Saving Lives



DEFINITIONS

Health Care Companies –

Diagnostic, pharmaceutical, biotech, and medical device companies

Personal Data –

Any information, stand alone or in combination, that relates to an identifiable or identified living individual

Real-world Data –

Routinely collected data relating to patient health status and/or the delivery of health care; may include personal data

RISK

As the identifiability of personal information decreases (anonymized, pseudonymized, de-identified) so does the potential for the collection, use, or disclosure of that information to cause real injury, and so do the legitimate interests of individuals in controlling such information.

HEALTH CARE INNOVATION IS INFORMATION DRIVEN



Effective health care innovation relies on identifying information that generates tangible insights, leading to the development of personalized medicine, products, and testing.

HEALTH CARE COMPANIES HAVE LEGITIMATE DATA NEEDS



Effective health care delivery, and the solutions to enable it, rely on the ability to use and share Personal Data across the health ecosystem.



Real-world Data aids in identifying potential adverse events from prescribed drugs or medical devices.

Evaluation of new treatment protocols requires access and use of Personal Data.



Data is critical in discovering genetic patterns to identify possible treatments, and evaluate and monitor a patient's response.



Real-world Data aids in locating appropriate patients to participate in research and clinical studies.

THE USE OF PERSONAL DATA IN HEALTH CARE IS ALREADY REGULATED

Protections already apply to Personal Data in health care under various frameworks. As new laws are developed to address gaps in existing requirements and provide more comprehensive privacy protections, efforts should be made to harmonize new and existing frameworks, or consider exemptions for the entities and types of data covered by those laws.



NOT ALL ENTITIES THAT COLLECT DATA ARE THE SAME

As State and Federal legislators in the U.S. consider new privacy protections, it is important to keep in mind the legitimate needs of Health Care Companies to access and use Personal Data to improve and save lives, as well as existing frameworks that already protect health information.

Health Care Companies are also increasingly expected to collect and submit Real-world Data as part of regulatory approval and post-market monitoring activities. Comprehensive privacy laws that do not distinguish between traditional consumer companies and Health Care Companies, including the access and use of data, could inhibit future medical discoveries, and ultimately negatively impact patients.

