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Regulation of digital health and health data in the Asia Pacific region

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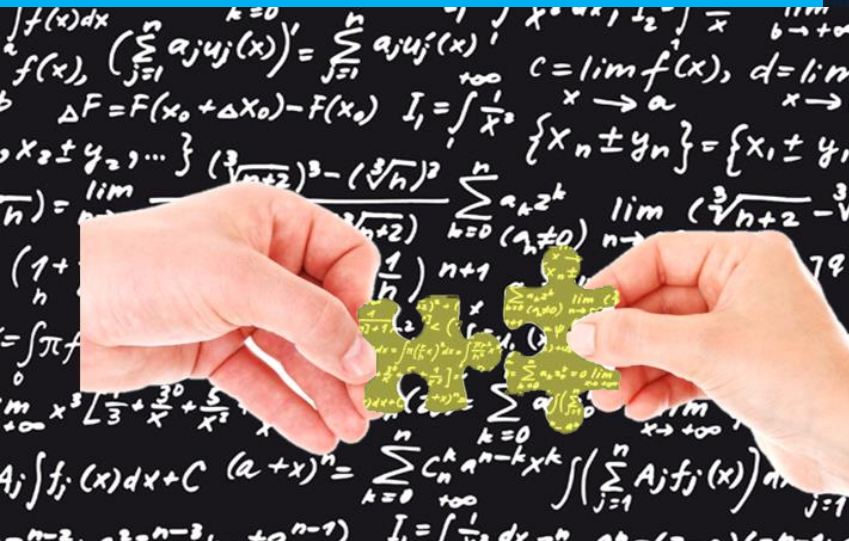
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ESCAP
Economic and Social Commission
for Asia and the Pacific

Regulation of Digital Health and Health Data in the Asia Pacific Region



Antonio Postigo

ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

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ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

WORKING PAPER

Regulation of Digital Health and Health Data in the Asia Pacific Region

Antonio Postigo¹

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Abstract

The COVID-19 pandemic has accelerated the adoption of digital health (DH) interventions in the Asia Pacific. This is evidenced in the 2022 Global Digital Health Monitor, with 58% of ESCAP members scoring 4 or higher, countries like Australia, Malaysia, PR China, and Thailand lead in DH categories. It is critical that countries establish national DH strategies that integrate goals and resources in digital health. The integration of national DH strategies into overall health policies faces challenges in regulation, implementation, and enforcement in the Asia Pacific, including LMICs. Regulatory inconsistencies in sharing health data hinder innovations and undermine trust, particularly in developing countries with limited resources. Except for Thailand and Vietnam, the Asia Pacific lacks frameworks for secure cross-border health data exchange. Regulation of health data should balance health data protection and privacy with ensuring cross-border data flows. As a multilateral data governance regime for cross-border data flows is pending, reliance on regional and bilateral free trade agreements to regulate health data persists. Multilateral organizations can play a crucial role in establishing effective governance for secure health data exchange. Key actions include collecting best practices, enhancing policymakers' capacity, and supporting efforts to harmonize data privacy frameworks globally.

Keywords: Digital health, Global Digital Health Monitor, National Digital Health Strategy, Domestic Governance of health data, Regulation of cross-border flows of health data, Asia-Pacific

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1. Introduction

Digital health (DH) expands electronic health (eHealth) and refers to the development and use of digital technologies including smart devices, artificial intelligence (AI), big data, and robotics to enhance health services and improve outcomes (WHO, 2021a). DH tools enable cross-border data sharing, reduce the reliance on in-person healthcare, and address healthcare shortages in rural and remote areas. Low and middle-income countries (LMICs) can particularly benefit from DH solutions to overcome traditional barriers related to healthcare infrastructure and staffing limitations. AI can help with accurate diagnoses, address human resource shortages, prevent emerging health issues, and speed up drug development.

During the COVID-19 pandemic, countries underwent rapid digital transformation in their healthcare services. This involved the establishment or enhancement of telemedicine services, contact tracing, case forecasting, and vaccination monitoring. As a result, various aspects of health research, interventions, and services have potentially become permanently digitized and integrated into digital platforms. Similar to other regions, the COVID-19 pandemic has also accelerated the growth and utilization of digital health (DH) tools in the Asia Pacific region, with telehealth usage doubling since 2019 and projected to reach penetration rates of 60-76% by 2024, led by China and Indonesia. DH services are prominently featured in many of Asia's super apps (APEC 2021; Kapur et al., 2022).

The *2022 Global Digital Health Monitor (GDHM)*, updated from the former Global Digital Health Index, assesses the preparedness and adoption of DH using 23 indicators across 7 categories. Notably, 58% of surveyed ESCAP members scored 4 or higher on the 1-5 scale (Table 1) (Michael and Edelman, 2019; GDHM, 2022), with Australia, Malaysia, PR China, and Thailand leading in several categories.

Table 1: Status of ESCAP members in the seven key indicator categories in GDHM 2022

	OVERALL GDHM	LEADERSHIP & GOVERNANCE	STRATEGY & INVESTMENT	LEGISLATION, POLICY, & COMPLIANCE	WORKFORCE	STANDARDS & INTEROPERABILITY	INFRASTRUCTURE	SERVICES & APPLICATIONS
Afghanistan	2	3	1	1	1	2	1	2
Armenia	4	3	N/A	4	N/A	N/A	4	N/A
Australia	5	5	N/A	5	N/A	N/A	5	N/A
Azerbaijan	4	3	N/A	4	N/A	N/A	4	N/A
Bangladesh	4	5	4	2	3	2	4	5
Bhutan	3	N/A	N/A	1	N/A	N/A	4	N/A
Brunei Darussalam	4	N/A	N/A	3	N/A	N/A	4	N/A
Cambodia	2	2	1	2	1	2	2	2
PR China	5	5	N/A	4	N/A	N/A	4	N/A
Fiji	3	N/A	N/A	2	N/A	N/A	4	N/A
France	5	5	N/A	5	N/A	N/A	5	N/A

Georgia	4	4	N/A	4	N/A	N/A	4	N/A
India	4	3	N/A	4	N/A	N/A	3	N/A
Indonesia	4	4	3	4	3	3	4	4
IR of Iran	4	4	N/A	3	N/A	N/A	4	N/A
Japan	3	3	2	3	2	3	3	2
Kazakhstan	4	4	N/A	4	N/A	N/A	4	N/A
Kyrgyzstan	4	4	N/A	3	N/A	N/A	3	N/A
Lao PDR	3	4	3	3	2	3	4	3
Malaysia	4	5	4	5	4	3	4	4
Mongolia	4	4	N/A	3	N/A	N/A	3	N/A
Myanmar	2	3	4	1	1	2	2	3
Nepal	3	2	2	2	3	2	3	3
Netherlands, The	5	5	N/A	5	N/A	N/A	5	N/A
New Zealand	3	3	3	3	3	2	4	3
Pakistan	2	2	2	2	2	2	2	2
Papua New Guinea	2	3	1	2	1	1	2	3
Philippines	4	2	4	4	2	4	4	4
Russian Federation	4	4	N/A	4	N/A	N/A	4	N/A
Samoa	3	N/A	N/A	2	N/A	N/A	4	N/A
Singapore	5	5	N/A	5	N/A	N/A	5	N/A
Solomon Islands	2	N/A	N/A	1	N/A	N/A	3	N/A
Sri Lanka	3	3	2	3	3	3	3	3
Tajikistan	3	3	N/A	2	N/A	N/A	3	N/A
Thailand	4	5	4	5	4	3	3	5
Timor-Leste	2	N/A	N/A	1	N/A	N/A	3	N/A
Tonga	3	N/A	N/A	2	N/A	N/A	3	N/A
Türkiye	4	4	N/A	4	N/A	N/A	4	N/A
United Kingdom	5	5	N/A	4	N/A	N/A	5	N/A
United States of America	5	5	N/A	5	N/A	N/A	5	N/A
Uzbekistan	4	N/A	N/A	4	N/A	N/A	3	N/A
Vanuatu	2	N/A	N/A	1	N/A	N/A	3	N/A
Viet Nam	4	4	3	4	3	3	4	4

Source: Global Digital Health Monitor website (<https://monitor.digitalhealthmonitor.org/map>)

2. National DH Strategies and the Domestic Governance of Health Data in the Asia Pacific Region

A national DH strategy maximizes the potential of technology in healthcare by setting goals, allocating resources, and promoting collaboration among all stakeholders to overcome challenges, improve access to quality healthcare, and enhance health outcomes. A successful national DH strategy should identify, prioritize, and address barriers in key enablers for DB (WHO & ITU, 2012; Scott & Mars, 2013 WHO, 2020). This requires leadership and collaboration between government agencies, non-governmental stakeholders, and, in the case of low-income countries, overseas development agencies. It also necessitates a comprehensive approach that integrates health agencies with other relevant sectors within the country (OECD, 2022). While many countries in the Asia Pacific region, including LMICs, have implemented national DH strategies, these strategies are often not integrated into overall health policies and may lack proper regulations, implementation, and enforcement (Cornelius, 2022; GDHM, 2022) (Table 2).

Table 2: Status of ESCAP members in indicators included in the GDHM category “Legislation, Policy and Compliance” (2022)

	Indicator 7: Data Protection	Indicator 8: Data Privacy	Indicator 10: Cross-border data security and sharing
Afghanistan	1	1	1
Armenia	3	4	N/A
Australia	5	5	N/A
Azerbaijan	5	3	N/A
Bangladesh	1	1	2
Bhutan	1	N/A	N/A
Brunei Darussalam	3	N/A	N/A
Cambodia	2	1	1
PR China	5	2	N/A
Fiji	2	N/A	N/A
France	5	4	N/A
Georgia	5	4	N/A
India	5	3	N/A
Indonesia	4	3	3
IR of Iran	5	1	N/A
Japan	4	4	1
Kazakhstan	5	2	N/A
Kyrgyzstan	3	3	N/A
Lao PDR	4	3	2
Malaysia	4	5	4
Mongolia	2	3	N/A
Myanmar	1	1	1

Nepal	2	2	1
Netherlands, The	5	5	N/A
New Zealand	4	4	3
Pakistan	2	1	2
Papua New Guinea	3	1	1
Philippines	5	4	4
Russian Federation	3	N/A	N/A
Samoa	2	N/A	N/A
Singapore	5	3	N/A
Solomon Islands	1	N/A	N/A
Sri Lanka	3	2	N/A
Tajikistan	1	2	N/A
Thailand	5	5	5
Timor-Leste	1	N/A	N/A
Tonga	2	N/A	N/A
Türkiye	5	3	N/A
United Kingdom	5	3	N/A
United States of America	5	4	N/A
Uzbekistan	4	N/A	N/A
Vanuatu	1	N/A	N/A
Viet Nam	3	3	5

Source: Global Digital Health Monitor website (<https://monitor.digitalhealthmonitor.org/map>)

For some authors, information is regarded as a new factor of production in the digital economy (Mueller and Grindal, 2019), highlighting the significance of ensuring the security and protection of data as well as the transfer of data within and across countries as drivers of economic growth and innovation. New digital technologies offer opportunities to generate, collect, and utilize vast quantities of health-related data. At the same time, the use, sharing, and transfer of health data face stricter restrictions compared to other types of data, often requiring specific legislation. The digitalization of health tests and records, along with the use of wearable devices, apps, and monitoring technologies, has led to a significant increase in health data. Currently, the healthcare industry generates around 30% of the world's data volume, and it is projected that the compound annual growth rate of healthcare data will reach 36% by 2025 (Thomason, 2021). Health data has been commodified and its value has attracted the interest of world-leading technology companies, who have made substantial investments in acquiring and investing in creating electronic health record aggregators (e.g., Google Health, Microsoft HealthVault) as well as leading venture capital for health genomics companies (Khedo et al., 2020). However, the adoption and implementation of appropriate and electronic health record systems in developing countries has been hindered by constraints in their digital infrastructure (Ssembatya and Zawedde, 2014). Developing countries face data collection challenges, requiring collaborative efforts from their government, regulatory agencies, and international

partners to ensure comprehensive and representative data that is not influenced by social and economic inequalities.

Health data regulations mainly prioritize individuals' control over data usage, while the promotion of personal data sharing for the collective benefit receives limited regulatory focus. Sharing health data within countries and across borders is crucial for enhancing individual patient care, advancing medical research, and informing policy decisions by examining the relationship between health data and data on other social/economic variables (WHO, 2021a). Public research agencies can link R&D grant funding for universities with open data requirements and encourage voluntary data sharing among private firms, researchers, and medical organizations.

Effective data security and privacy protection are crucial in healthcare due to the sensitive nature of personal health data. However, studies show that beyond a certain level of digital data protection, stronger security, and privacy measures do not necessarily lead to increased adoption and use of digital technologies, but rather can hinder them (McQuinn and Castro, 2018). Laws on health data security, as well as privacy, consent, confidentiality, and access to health information, have been implemented by many countries worldwide, including within the Asia Pacific region (GDHM, 2022 and Table 2). Many countries in Asia and Pacific countries, including some developing ones, score high in the existence, implementation, and enforcement of legislation on data security. Australia, Malaysia, and Thailand have emerged as leaders in the region in the legislative development and practical implementation of regulations concerning data privacy.

3. Regulation of Cross-border Flows of Health Data in the Asia Pacific Region

Countries worldwide, regardless of their development stage, grapple with the challenge of striking a balance between safeguarding sensitive health data and enabling the necessary cross-border flow of health data for medical and technological progress. The COVID-19 pandemic has underscored the importance of swift and reliable cross-border health data flows, not only in mounting effective epidemiological responses but also in the rapid development of new diagnostic tools and therapeutic approaches. Regulatory approval applications for drugs frequently include data derived from clinical trials conducted in foreign countries. Restrictions in health data flows can also introduce bias in Artificial Intelligence (AI) and its use for diagnosis or drug development. Researchers from the International Cancer Genome Consortium (ICGC), that have identified cancer-related genes using datasets from multiple countries, have expressed concerns regarding potential hindrances to similar collaborations in the future due to post-COVID-19 legislative changes worldwide (Phillips et al., 2020).

The number of countries that have enacted data localization policies—legal or administrative requirements to store and/or process data within a country’s borders—has nearly doubled from 35 in 2017 to 62 in 2021. Additionally, 144 countries have imposed some form of restriction on data flows (Cory and Dascoli, 2021). Countries restrict data transfers, including health-related data, to protect individual rights and privacy, national security, and promote domestic high-tech activities, similar to rules of origin in traditional goods trade. Cory and Dascoli (2021) categorize data localization into three main types: 1) explicit restrictions on specific types of data (e.g., health and genomic data), 2) restrictions on broad categories of data considered "sensitive," and 3) de facto localization achieved by making data transfers more complex, expensive, and legally uncertain. The Information Technology and Innovation Foundation (ITIF) has created the Data Restrictiveness Index (DRI) (on a scale 0 to 6) to assess the level of restrictions in a country's regulations on cross-border data flows and found that increases in the DRI associated with declined gross trade output and productivity (Cory and Stevens, 2020). Asia Pacific countries have enacted the largest number of data localization measures in the world and ten of them have explicit data localization measures although they differ in their level of restrictiveness (Australia, China, India, Indonesia, Kazakhstan, New Zealand, Republic of Korea, Russian Federation, Türkiye and Viet Nam) (Cory and Dascoli, 2021; APN, 2022; Cory, 2022). In 2021, over half of the top 21 countries with the highest DRI are in Europe, while five countries from the Asia Pacific Region (China, Indonesia, Japan, Russian Federation, Türkiye) have seen an increase compared to three in 2018 (China, Indonesia, Türkiye).

Medical, health, and genomic data is not always legally defined or regulated differently than other data types in some countries, but is considered as “personal data” in other countries. Similar to other regions, most countries in the Asia Pacific lack frameworks to ensure secure and privacy-respecting cross-border exchange of health data. Among the countries in the Asia Pacific region, only Thailand and Vietnam received the highest score in this indicator (GDHM, 2022) (Table 2).

As detailed in Box 1, **China** has the most comprehensive set of measures on data localization in the world. In India, health-related data, such as physical, physiological, and mental health conditions, as well as medical records and history, is considered 'personal data.' Except for payment data and insurance-related data, the current legislation in **India** does not explicitly require 'personal information' and/or 'sensitive personal data and information' to be stored within the country (Bailey and Parsheera, 2021; APN, 2022; Feigenbaum and Nelson, 2022). In the **Russian Federation**, health data is classified as 'personal data' and is governed by the Federal Law on Personal Data, which requires all collectors and processors of data from Russian citizens to utilize databases located within the country for the purposes of recording, storing, and systematizing the data (Andreeva et al., 2021). In **Australia**, the Australian Privacy Principles (APPs) prohibit the storage, processing, or handling of personal health data

outside the country's borders, including backups (OneTrust, 2022). In the **Republic of Korea**, while there are no general laws for data localization of "personal data," data localization measures do apply to specific sectors such as the financial industry. However, health-related data, including genetic data, biometric data, health and medical records, are classified as "sensitive data" under the Personal Information Protection Act (PIPA). These types of data are subject to stricter regulations compared to other personal data, requiring explicit separate consent from individuals and notification about the data being collected, the purpose, and the retention period (Bae, Kim & Lee LLC, 2020; APN, 2022). Outside of the financial sector, **Thailand's** Personal Data Protection Act (PDPA) (2019) does not specifically mandate data localization. Health-related personal data is classified as "sensitive personal data" and is treated similarly to other categories of sensitive personal data under the PDPA. This means that explicit consent from the data subject is required for the processing of health-related personal data, as is the case for other sensitive personal data. On April 17, 2023, **Viet Nam** introduced the Personal Data Protection Decree (PDPD) under which health-related information in medical records is considered 'sensitive' and requires stricter regulations, such as obtaining explicit consent from the individual for data collection and processing and the registration with the PDPC for data collectors and processors (APN, 2002; Hille, 2023). Data localization in Viet Nam is regulated by a separate decree that specifically targets telecom, internet, and service providers which are required to have a physical presence in the country, to store locally personal data of their service users, and retain the data for at least 2 years. The decree's stance on cross-border transfer of personal data, even after fulfilling all requirements, remains uncertain, indicating a de facto localization approach. At the other end of the spectrum, in **Singapore**, there are no data localization requirements under the Personal Data Protection Act (2012), and health-related data is not subject to different regulations compared to other personal data.

Restrictions on the flow of anonymized health-related data, can impede the efforts of governments, healthcare providers, researchers and the private sector to advance healthcare breakthroughs, hinder global efforts to address global health challenges, and limit the delivery of innovative healthcare services and solutions. In telemedicine, digital health data can be transmitted beyond national borders, falling under mode 1 of cross-border supply of services specified by the WTO's General Agreement on Trade in Services (GATS). Regulations on health data (safety, privacy, and flows) can be facilitated or hindered by regulations on transnational telemedicine. Additionally, ambiguity and inconsistency between countries' regulations for sharing health data, among countries in Asia Pacific and worldwide hinders both domestic and global efforts to enhance health services and drive health innovations. The lack of a global approach to health data governance and regulatory inconsistency across national DH frameworks increases costs and reduces efficiency for healthcare organizations. It can also cause researchers and healthcare professionals to feel uncertain and unprotected when it comes to collecting and sharing anonymized health data. The regulatory inconsistency not only hinders the development of new international partnerships but

also undermines societal trust in the handling of health data by healthcare and research institutions, leading to hesitancy among individuals to provide consent for the collection and sharing of their personal health data. These challenges are exacerbated in low-income countries, where limited resources often limit effective enforcement of data security and protection laws. Additionally, the absence of a multilateral data governance regime creates difficulties for these countries to participate in international data sharing, as the current global standards for data protection have been primarily designed by developed nations to suit their specific needs.

Box 1: Regulatory framework of health data in China

In China, the legal framework for data management consists of the Cybersecurity Law (CSL) enacted in 2017, along with the Personal Information Protection Law (PIPL) and the Data Security Law (DSL) both implemented in 2021 (Cory and Dascoli, 2021; LAN, 2022). Under Chinese law, there currently is no uniform definition of medical data/healthcare data, and regulations on its management are scattered across different laws. Under the PIPL, health-related personal data in China is categorized as "sensitive personal information" and is subjected to more stringent requirements compared to other types of personal data. For instance, the processing of health-related personal information is allowed only for specific purposes and when there is a genuine necessity, it requires explicit consent from individuals, and data handlers are responsible for conducting protection impact assessments and informing individuals about the necessity of processing their sensitive personal information. The Population Health Information Measures (2017) which governs health data including basic population information and health service information, stipulates that population health information should not be stored or hosted on servers outside of China and mandates data holders with the storage of population health information in a graded manner based on its sensitivity. The Electronic Medical Records Measures (2018) includes additional provisions concerning the establishment, recording, modification, use, preservation, and management of electronic medical records. The Health Care Big Data Measures (2018) mandates that healthcare big data—data related to disease prevention, treatment, and health management—be stored on servers within the country.

4. Moving Forward: Towards the Harmonization and Interoperability of Regulatory Frameworks in the Governance of Health Data

There is a pressing need for an international regime on cross-border data flows that involves all stakeholders, striking a balance between protecting the confidentiality and

integrity of sensitive personal health data and harnessing the benefits of sharing anonymized health data to drive advancements in health-related breakthroughs.

The pursuit of a global data regime remains elusive at present. Within the World Trade Organization (WTO), progress is primarily concentrated in the Joint Initiative on Electronic Commerce (JIEC), a negotiating platform consisting of 86 members that aims to achieve consensus on trade-related aspects of electronic commerce. During their March 2023 meeting, JIEC members engaged in discussions regarding proposals concerning data flow issues. Other plurilateral initiatives include the Cross-Border Privacy Rules (CBPR) system launched in 2005 by the Asia-Pacific Economic Cooperation (APEC) forum. The CBPR system is a voluntary government-backed data privacy certification system aimed at ensuring secure and privacy-respecting data flows among APEC economies. Currently, nine economies participate in the system: Australia, Canada, Japan, the Republic of Korea, Mexico, the Philippines, Singapore, Taiwan Province of China, and the United States of America. The CBPR system is enforceable across participating jurisdictions, and certified companies and governments are required to comply with CBPR requirements to safeguard the transfer of personal data across borders (APEC, undated).

As a multilateral digital trade agreement is yet to materialize, countries are currently relying on regional and bilateral free trade agreements (FTAs) and ad hoc digital economy agreements as the primary mechanisms to establish international rules concerning digital trade. While neither the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) nor the Regional Comprehensive Economic Partnership (RCEP) specifically address health data security and flows, there are differences in their approaches to data flow restrictions. The CPTPP prohibits localization requirements and cross-border data transfer restrictions, promoting open data flows; meanwhile, the RCEP allows for greater flexibility in restricting data flows if it is deemed necessary to achieve legitimate public policy objectives or protect security interests. These distinctions highlight varying perspectives on data governance and the balance between free flow and regulatory control. (Leblond, 2021; Chin and Zhao, 2022), emphasizing the importance of harmonization and standardization of data rules and interoperability not only between organizations, legislations, policies, but also between data systems as well as semantic interoperability (Lehne et al., 2019). While there is widespread agreement among national and international stakeholders on the importance of achieving interoperability in regulatory frameworks and data standards for data governance, there is less consensus on the specific approach to achieve this goal

In the context of significant variations in regulatory frameworks on data governance and digital capacities among countries, the ASEAN framework on Digital Data Governance (2017) holds great relevance. The framework places importance on digital sovereignty and takes into account the diverse capacities of ASEAN countries in data collection and handling. It utilizes two primary methods. First, certification of organizations and businesses demonstrating compliance with national data protection

laws, as well as reliable and effective data management practices. Second, Model Contractual Clauses (MCCs), which are contractually enforceable data transfer agreements ensuring the full protection of personal data when transferred to an overseas territory (UNDP, 2021). Other voluntary mechanisms that can aid in achieving interoperability and facilitating cross-border data flows are Binding Corporate Rules (BCRs) and Codes of Conduct. BCRs require enterprises to adhere to data protection protocols when transferring personal data between corporate groups within and across borders. Similarly, Codes of Conduct, developed by professional societies, allow participating members to voluntarily adopt specific data protection provisions. For example, an international scientific consortium has advocated for an international code of conduct, led by scientists themselves, which offers greater flexibility for updates compared to the slower process of developing national and international laws (Phillips et al., 2020). Likewise, the Global Alliance for Genomics and Health (GA4GH), comprising prominent research and healthcare institutions, has proposed a toolkit to enhance interoperability in policy frameworks and standards for the responsible international sharing of clinical and genomic data (Rehm et al., 2021).

Multilateral organizations have a crucial role in establishing an effective governance framework to facilitate secure and privacy-respecting collection and cross-border flow of health data. For instance, in 2021, WHO organized two health data governance summits and set forth five data principles to shape its involvement in data governance (WHO, 2021b). These principles include treating data as a public good, upholding Member States' trust in data, supporting Member States' data and health information systems capacity, being a responsible data manager and steward, and striving to address public health data gaps. Given the multiple initiatives from multilateral organizations, think tanks, and the scientific community, it is important to avoid duplication of efforts and instead work closely with existing initiatives. Some actions multilateral organizations can take include: 1) Collecting and assessing best practices for reliable and equitable data collection, storage, and transfer; 2) Collaborating with other stakeholders to enhance the capacity and expertise of policymakers in developing countries regarding data collection, storage, and transfer; and 3) Supporting endeavors to harmonize data privacy and security frameworks and standards at the regional and/or global level.

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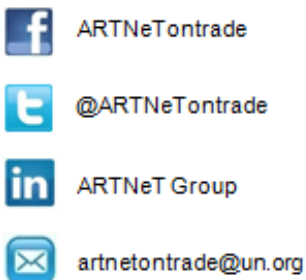
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