Data Transfers Under the Abu Dhabi Healthcare Information and Cyber Security Standard

This Global Data Alliance (GDA) position paper addresses restrictions on access, storage, and transfer of health data under the Abu Dhabi Healthcare Information and Cyber Security Standard ("Abu Dhabi Health Cyber Standard"). The GDA is a cross-industry coalition of companies that are committed to high standards of data privacy and security and that rely on the ability to transfer data responsibly around the world. GDA members represent every sector of the global economy.[1]

The cross-border data restrictions found in the Abu Dhabi Health Cyber Standard threaten Abu Dhabi's (and the UAE's) status as a hub of international commerce because they will undermine the ability of non-nationals to benefit from healthcare or their global health insurance coverage while traveling to, or residing in, Abu Dhabi, as the Standard would prevent providers from verifying coverage eligibility with their insurers, and those persons from sharing their own health data with their doctors, clinics, or insurance providers located outside of Abu Dhabi and the UAE. The Standard also undermines the ability to provide medical treatment to persons resident in Abu Dhabi – in part because it mandates that Abu Dhabi health data can no longer be used in clinical trials, remote servicing of medical devices, or remote healthcare delivery. Denying Abu Dhabi and UAE citizens, residents, and travelers access to international medical advances and healthcare will impose economic and health-related costs on those persons. Among other things, these costs could undermine Abu Dhabi and the UAE's attractiveness as a work or travel destination for foreign business persons, engineers, professionals, and travelers.

Furthermore, these restrictions can increase cybersecurity risks, particularly if data is stored solely in the UAE. The ability to locate and transfer data in the most functionally and technically secure manner is a cybersecurity risk management best practice. This is in part because cross-border visibility into cyber-related data allows cybersecurity tools to monitor traffic patterns, identify anomalies, and divert potential threats in ways that depend on global access to real-time data.

We respectfully urge Abu Dhabi and UAE authorities to undertake a comprehensive assessment of the broader commercial and health-related risks of the restrictions on cross-border access, transfer, and storage of health-related data in the Abu Dhabi Health Cyber Standard. To promote legal certainty and compliance, it is important to closely align the health data regulation in Abu Dhabi with the UAE more broadly and with international best practices.

I. Health Data Access, Storage, and Transfer Restrictions in the Abu Dhabi Health Cyber Standard

The Abu Dhabi Health Cyber Standard contains three distinct set of cross-border data restrictions: (1) Restrictions on the ability to access health data stored in Abu Dhabi from outside of Abu Dhabi; (2) Restrictions on the ability to transfer health data from Abu Dhabi to other jurisdictions; and (3) Restrictions on the ability to storage health data anywhere other than Abu Dhabi. Several restrictions in the Abu Dhabi Health Cyber Standard are listed below:

- Communications and Operations Management control number 9 (e) mandates that covered entities shall: "[e]nsure PII and PHI or its backup is not stored, processed or transferred outside UAE, except in cases where a valid exemption is issued by [the Department of Health]."

- Control number 9(f) mandates that covered entities shall "[e]nsure that employees of the entity and third-party users involved in service delivery fulfill their responsibilities and provide assistance from within the UAE, unless a valid exemption has been issued by the DoH."

- Control number 11 mandates that: "Transfer of Health Information outside the UAE is normally not allowed unless exception to do so is granted by DoH."

- Data Privacy Policy Article 1.4(d) states that a covered entity:

    - "Should ensure that only people who are physically present in the UAE or who have a valid license to practice their profession there have access to systems and applications that contain protected health information."

    - [S]hall not transfer health information and its copies in any form, whether encrypted, anonymized, deidentified, pseudonymized, etc., are not stored, processed, or transferred outside the UAE. Any exemptions must be approved by entity management and then submitted to the Department of Health (DoH) for further approval."

II. Impact of Health Data Access, Storage, and Transfer Restrictions in the Abu Dhabi Health Cyber Standard

Imposing the above-referenced restrictions would likely isolate Abu Dhabi and the UAE from the transnational healthcare ecosystem, producing unintended consequences.

First, these restrictions would mean that foreign travelers and business people will face challenges in using their existing global insurance providers to support their health needs, because they will no longer be able to transfer or permit access to their own personal health data by foreign insurers.

Second, these restrictions would curtail the capacity and readiness of healthcare providers, biopharmaceutical companies, and medical technology companies to respond to emergent health risks in the UAE or to include UAE patient data in R&D related to longstanding medical challenges.

Third, such restrictions would likely impact the healthcare availability in the UAE to the extent that they would impede cross-border digital access to medical experts and professionals based in other parts of the world, and would undermine the ability to receive the benefits of data analytics and artificial intelligence (AI) technologies applied to broader transnational datasets that include UAE-based data.[2]

To the extent that these restrictions create depress economic activity and investment in the healthcare sector (specifically) and the economy (broadly), and to the extent that these restrictions produce negative healthcare outcomes for patients, they will likely impose both economic and health impacts. Numerous economic studies and surveys confirm the importance of data transfers in the context of biopharmaceutical R&D, medical technologies, and healthcare delivery.[3]

III. Conclusion

We urge Abu Dhabi and UAE authorities to avoid applying restrictions that could undermine the availability of data-enabled advances in biopharmaceutical R&D and medical technologies, or the availability of basic healthcare delivery and health insurance within these jurisdictions.

Annex

Cross-Border Access, Transfer, and Storage of Health Data

A. The Role of Health Data Transfers in Healthcare Research

From a technical perspective, the seamless and responsible transfer of data across transnational IT networks enables the deployment of modern and emerging technologies and services that underpin healthcare delivery and the development of new treatments. These technologies and services, accessed across transnational IT networks, support many important health-related objectives, as summarized below with respect to: (1) biopharmaceutical R&D; and (2) healthcare delivery, which often involves state-of-the-art medical devices and technologies. We address each in turn below.

Cross-border data transfers are critical to the research, development, and delivery of new biopharmaceutical medicines to prevent and treat medical conditions and improve patients' health, as summarized below:

- **Cross-border data analytics and R&D collaboration.** Cross-border data analytics can help speed the early identification of potentially useful drug candidates, shortening discovery timelines from years to months. The health data-sets and genomic data used in this analysis can come from multiple sources, such as clinical trials, data registries, and real-world evidence, but the required expertise, technology, and computer facilities often are not in the same country as where the data originates and, indeed, may be spread among many countries. Pharmaceutical R&D also depends on cross-border access to medical journals fand scientific collaboration, reflected in a high degree of international co-authorship and new methods of sharing research and computing resources for cross-border R&D.

- **Cross-border digitization of clinical trial processes.** Cross-border data flows are essential to the conduct of clinical trials. Data flows are necessary to identify and establish clinical trial sites, identify clinical trial participants, and monitor the conduct of clinical trials. Cross-border data transfers also help companies address different countries' drug regulatory approval requirements, and requirements of Independent Ethics Committees (IEC) and Institutional Review Boards (IRB). Cross-border digitization of clinical trial processes is also reflected in the growing prevalence of cloud-based clinical tools, including wearables, Internet of Things (IoT) devices, data exchange initiatives, and Regulatory Information Management Systems (RIMS) that support safety and efficacy reviews and regulatory compliance across multiple countries.

- **Cross-border demographic representation.** Cross-border studies are also critical to ensuring that new products are safe and effective across different demographics, populations, and regions. Cross-border cloud-enabled technologies can help improve patient access, diversity, and representation in clinical trials, given the importance of a sufficiently large and diverse population of participants. In addition, clinical trials for rare disease drug development are conducted in multiple countries to gather data from a sufficient number of qualified participants.

- **Cross-border regulatory collaboration.** Each country has their own national regulatory agency to ensure that a new medicine is safe and effective. Such agencies require clinical trial sponsors to provide the underlying clinical trial data so they can make their own assessments. As a result, even after the clinical trial data moves from the trial site to the clinical trial sponsor, it must also be able to flow to governments in whatever countries where the new medicine may be approved. Cross-border data transfers also help regulators do their jobs, as reflected in cross-border collaborative frameworks to share information in regulatory reviews among health authorities in different jurisdictions.

- **Cross-border data transfers and good pharmacovigilance practice (GVP).** Cross-border data transfers are also key to post-marketing surveillance of approved products. This often includes

cross-border reporting of data on adverse reactions with global regulators; virtual inspections of global manufacturing facilities; and submission of post-authorization safety studies in different countries.

B. The Role of Cross-Border Data Transfers in Healthcare Delivery

Cross border data transfers are essential to the responsible, precise, and effective delivery of healthcare via medical devices and technologies, which hold significant promise for improving patient lives through the safe and efficacious treatment of health conditions, as summarized below.

- **Cross-border data transfers and healthcare diagnosis.** Cross-border data enabled diagnostic technologies have allowed for significant improvements in the quality and accuracy of medical diagnosis. Cross-border data transfers allow for the cross-referencing of larger trans-national data sets containing relevant diagnoses (with sufficient representation across regions and time periods). In this way, cross-border access to a deep reserve of diagnostic data can facilitate more precise diagnoses, thus helping to prevent misjudgments based on inadequate information and avoiding unnecessary treatments.[4]

- **Cross-border data transfers and healthcare delivery via medical technologies.** Advances in healthcare therapy via medical technologies[5] depend to a significant degree on responsible access, aggregation, and use of health data from diverse sources. In the medical technology context, data transfers can be critical to: (a) providing relevant information to clinicians for purposes of monitoring safety and efficacy of ongoing treatments, (b) health economic analysis of therapy and patient outcomes, and (c) researching and engineering therapy improvements and innovations.

- **Cross-border data transfers and responsible AI in medical technologies.** The responsible integration of medical technologies with AI and other data analytics tools can help doctors and patients better understand and predict patterns and responses in healthcare delivery contexts. Cross-border data transfers play a critical role in allowing for the aggregation of larger, more representative datasets to which these analytical tools can be applied.[6] For example, the aggregation from various regions of surgical image data in actual clinical use or from videos recorded of surgeries anywhere in the world can be used for purposes of training and developing AI systems that help refine surgical techniques and improve healthcare outcomes.

- **Cross-border data transfers and remote health services.** Cross-border data enabled remote health services (both "telemedicine"[7] and "telehealth"[8]) also hold significant promise for improving patients outcomes.[9] This can include providers and patients located in the same country, where both provider and patient require cross-border access to overseas-based remote health platforms, portals, or other technologies that can offer the highest levels of security, privacy, and functionality.[10] More specifically, cross-border data transfers are critical to remote health services, as described below:

    - **Cross-border access to state-of-the-art cyber, encryption, authentication, and blockchain technologies** provided from cloud-based servers in another jurisdiction—protecting the privacy and guarding against unauthorized monitoring, intrusion, or data exfiltration;

    - **Cross-border access to health care data analytics solutions** that can analyze local data samples against databases of relevant information gathered from all over the world—enhancing the reliability and accuracy of diagnoses and treatment recommendations;[11]

    - **Cross-border telehealth collaboration and research conducted among medical researchers** and professionals inside and outside the European Union via (for example): (a) expert consultations among providers or other specialists located in different countries,

(b) cross-border exchange of data with laboratories or advanced research facilities in other countries with particular expertise in different types of analysis or testing; and (c) cross-border consolidation of anonymized data sets from around the world for purposes of real-time statistical tracking, analytics, and monitoring of aggregated anonymized data—e.g., to identify health trends, epidemiological patterns, or localized disease outbreaks; and

- Depending upon medical licensure and other legal requirements, **cross-border provision to patients of consultations, remote second opinions, or other information** from a provider in one country to a patient in another; and/or **cross-border humanitarian assistance** to underserved populations around the world.[12]

C. The Role of Cross-Border Data in Health Insurance

The ability to access and transfer health data across borders is critical to the provision of health insurance and financing services.

- **Cross-border data transfers & actuarial risk analysis:** Cross-border access to demographic, health, and financial data is necessary to develop sufficiently large data sets to build accurate prediction models, e.g., period and cohort life tables, for understanding risk levels of financial loss or uncertainty and reflecting insurance prices.

- **Cross-border data transfers & insurance payment**. Cross-border data transfers allow insurers to cross-reference the authenticity of claims with international databases and different branches or partners of a firm for more efficient payouts. Manual data entry and payment processes increase operational costs and cannot track claim progress in real time, increasing the risk of fraud and human error. For instance, in the event of a natural disaster, cross-border transfers make real-time sharing and gathering of information about damages and one's deducible possible, expediting the payout to those affected and providing timely disaster recovery.

- **Cross-border data transfers & insurance affordability and product range.** Health data transfer restrictions and localization mandates deprive end customers of access to the full range of insurance options and increase costs. First, because insurers rely on centralized data analytics and processing to generate their full service options, such restrictions can mean that customers will have access to fewer insurance options and support systems. Second, such restrictions also undermine economies of scale, results in higher costs. The inability to share health data with reinsurers outside the country may also indirectly limit the capacity of local health providers to offer the care that they need.

D. The Role of Cross-Border Data in Health Data Security

- **Cross-border data transfers & health data cybersecurity.** Because cross-border data transfers allow for data- and cybersecurity tools that depend on access to global data in real-time to monitor traffic patterns, identify anomalies, and divert potential threats. Conversely, data localization mandates and transfer restrictions impede visibility of data- and cybersecurity risks, not only at the intra- and inter-organizational levels, but also at national and international levels. If network defenders cannot access threat indicators or other cybersecurity data collected in one jurisdiction in real time, it becomes harder to address malicious activity or privacy breaches and develop preventive measures in other jurisdictions. This would leave our collective cybersecurity defense more at risk.

[1] *See e.g.,* Global Data Alliance, *Creating Jobs and Trust in Every Sector of the Economy* (2020); Global Data Alliance, *Cross-Border Data Transfers Across Sectors* (2022).
[2] Requiring localization of non-personal data in the healthcare context or unduly restricting transfers thereof would not only restrict the access to AI technologies outside the EU, but could also prevent EU-based enterprises from commercializing in other markets any AI solutions that they create via data subject to the EHDS requirements.
[3] All European Academies (ALLEA), European Academics Science Advisory Council (EASAC), Federation of European Academies of Medicine (FEAM), *International Sharing of Personal Health Data for Research* (2021), at https://allea.org/wp-content/uploads/2021/03/International-Health-Data-Transfer_2021_web.pdf (*hereinafter* "ALLEA, EASAC, FEAM, *International Health Data Sharing*"). EFPIA, IPMPC, MedTech Europe, and AdvaMed, *Innovation Without Borders: The Importance of Transatlantic Data Flows to Healthcare Innovation and Delivery*, Discussion Paper (2020) (hereinafter *"EFPIA, IPMPC, MedTechEurope, and AdvaMed, Transatlantic Healthcare Data Flows"*); Tania Rabesandratana, *European data law is impeding studies on diabetes and Alzheimer's, researchers warn,* Science (Nov. 20, 2019), https://www.sciencemag.org/news/2019/11/european-data-law-impeding-studies-diabetes-and-alzheimer-s-researchers-warn ; *See also, EFPIA, IPMPC, MedTechEurope, and AdvaMed, Transatlantic Healthcare Data Flows*; Hallian et al., *International Transfers of Health Research Data Following Schrems II: A Problem in Need of a Solution* (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3688392 ; Peloquin et al., *Disruptive and Avoidable: GDPR Challenges to Secondary Research Uses of Data,* Eur. J. Hum. Genetics (2020), at: https://www.nature.com/articles/s41431-020-0596-x ; Slokenberga, EU data transfer rules and African legal realities: is data exchange for biobank research realistic? 9 Int'l Data Priv. L. 30 (2019), at https://academic.oup.com/idpl/article-abstract/9/1/30/5076710?redirectedFrom=fulltext ; Robert Eiss, Confusion Over Europe's Data Protection Law is Stalling Scientific Progress, Nature (2020), at: https://www.nature.com/articles/d41586-020-02454-7 ; PHG Foundation, The GDPR and Genomic Data (2021), at https://www.phgfoundation.org/report/the-gdpr-and-genomic-data
[4] Diagnostic technologies include capital equipment including diagnostic ECG, diagnostic informatics, implantable or disposable equipments including portable testing kits.
[5] Therapeutic technologies include capital equipment including radiotherapy equipment for oncology treatments, implantable or disposable equipments including insertable cardiac monitor, implantable cardioverter defibrillator, and grid mapping catheters.
[6] It is important to understand conditions of patients and prospective patients across different countries.
Diverse and representative data is critical to identify clinically relevant differences among patient cohorts to detect potential biases in treatment protocols, access, and other disparities. The more data, the more accurate, safe, and unbiased AI.
[7] An example of a telemedicine service might include an online consultation with a local doctor who makes a diagnosis and treatment recommendations after (often AI-enhanced) analysis of images of suspicious skin tissue. Michael Rucker, Health Tech Is Successful in Developing Countries, VeryWell Health (March 2020), https://www.verywellhealth.com/digital-health-developing-countries-1739155.
[8] An example of a remote telehealth service might include the WHO's efforts to make available remotely to health care providers worldwide information relating to the classification of illnesses, their causes, and symptoms. *See e.g.,* World Health Organization, *WHO Releases New International Classification of Diseases (ICD 11)* (2018), https://www.who.int/news-room/detail/18-06-2018-who-releases-new-international-classification-of-diseases-(icd-11).
[9] Broadly understood to involve the provision of remote clinical services to support patients, "telemedicine" includes the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, and patient and professional health-related education. "Telehealth" has been defined to cover a *broader* scope of services, including remote non-clinical services, such as provider training, administrative meetings, and continuing medical education. *See e.g.,* World Health

Organization, *Telemedicine—Opportunities and Developments*, Report on the Second Global Survey on eHealth (2010), https://www.who.int/goe/publications/goe_telemedicine_2010.pdf.

[10] In some contexts, telemedicine services offered by a provider to a patient within the same country may nevertheless involve ***cross-border*** access to a secure remote health technology hosted in another country. Such cross-border technology access may be necessary to offer a secure provider-patient interaction and to add new insights and functionality to diagnoses and treatment recommendations via AI-enhanced data analytics involving larger trans-national data sets. Relatedly, because internet traffic between providers and patients often transits among computing equipment and servers across borders, cross-border data transfers may be relevant to remote health services even in cases in which the remote health technologies are stored on servers in-country. See e.g., Casalini and Lopez González, *Trade and Cross-Border Data Flows*, OECD Trade Policy Papers (2019), http://dx.doi.org/10.1787/b2023a47-en (explaining that, "[t]he internet is a global network of computers, each with its own Internet Protocol (IP) address. When a file is sent from a computer in Country A to a recipient in Country B it is first broken down into different 'packets' …marked with the IP address of the sender, that of the recipient and a code identifying the sequence in which the packets are to be reassembled at destination. Once the packets are ready, they leave the origin computer, crossing different networks and taking different routes to destination.…In some instances, what might seem to be a domestic transfer involves a cross-border flow.")

[11] For example, algorithms can be trained to distinguish benign and malignant cancers based on a referential analysis of thousands of images of benign and malignant tissue samples, resulting in more accurate detection rates than a dermatological oncologist. See e.g., Computer Learns to Detect Skin Cancer More Accurately Than Doctors, *Agence France Presse* (May 2018), https://www.theguardian.com/society/2018/may/29/skin-cancer-computer-learns-to-detect-skin-cancer-more-accurately-than-a-doctor; Charles Towers-Clark, The Cutting-Edge of AI Cancer Detection, *Forbes* (April 2019), https://www.forbes.com/sites/charlestowersclark/2019/04/30/the-cutting-edge-of-ai-cancer-detection/#43acb1b67336; Taylor Kubota, Deep Learning Algorithm Does as Well as Dermatologists in Identifying Skin Cancer, *Stanford News* (January 2017), https://news.stanford.edu/2017/01/25/artificial-intelligence-used-identify-skin-cancer/.

[12] According to the WHO, "telemedicine networks around the world deliver humanitarian services on a routine basis, many to low-income countries. These networks provide tele-consultations for physicians and other health professionals needing advice about the clinical management of difficult cases, and some also provide education." *See* World Health Organization, Long-Running Telemedicine Networks Delivering Humanitarian Services, *Bulletin of the World Health Organization* (2012), https://www.who.int/bulletin/volumes/90/5/11-099143.pdf.