

POLICY AND REGULATORY RECOMMENDATIONS

FOR DIGITAL HEALTH IN
LATIN AMERICA AND THE CARIBBEAN

The Americas Business Dialogue Perspective



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Background

[The Americas Business Dialogue](#) (ABD) is an initiative housed within the Inter-American Development Bank (IDB) that represents over 400 companies and business organizations from all sectors of the economy and all countries in the Americas. **The overall mission of the ABD is to develop, disseminate, and support the implementation of policy recommendations that enable increased investment, innovation and productivity, generate more and better jobs, and foster sustained economic growth in countries across the Americas.**

ABD members are organized into thematic working groups that address the main priorities and opportunities for public-private collaboration in the Americas. One such ABD working group — the ABD Health Working Group — is comprised of over 50 companies and associations from across the health value chain¹ (from medical devices and biopharmaceuticals to insurance, digital solutions, and express delivery)

interested in promoting public-private collaboration on health and economic issues. Working in partnership with the IDB Social Protection and Health Division, the ABD Health Working Group offers this paper as a response to the IDB publications on regulatory frameworks for [telemedicine](#) and [electronic health records](#) in Latin America and the Caribbean.



1. The ABD Health Working Group includes AB InBev; ABB Group; Abbott; Advanced Medical Technology Association (AdvaMed); Amazon Web Services (AWS); Asociación de Dispositivos Médicos de Chile A.G. (ADIMECH); Asociación Ecuatoriana de Distribuidores e Importadores de Productos Médicos (ASEDIM); Asociación Nacional de Empresarios de Colombia (ANDI); Asociación Nacional de Laboratorios Farmacéuticos (ALAFARPE); Associação Brasileira da Indústria de Alta Tecnologia de Produtos para a Saúde (ABIMED); Associação Brasileira de Importadores e Distribuidores de Produtos para Saúde (ABRADI); Astellas; Brazilian Innovative Health Industry Alliance (ABIIS); Bayer AG; Cámara Argentina de Insumos, Implantables y Equipamiento Médico (CADIEM); Coca-Cola FEMSA; Council of the Americas (COA); Crowell & Moring International; Development Finance International (DFI); DHL Express; EMD Serono; Federación de Entidades Privadas de Centro América, Panamá y República Dominicana (FEDEPRICAP); Federación Latinoamericana de la Industria Farmacéutica (FIFARMA); Genentech; General Electric (GE); GlaxoSmithKline; Grupo de Inversiones Suramericana (Grupo Sura); Industria Latinoamericana de Autocuidado Responsable (ILAR); Inter-American Coalition for Business Ethics in the Medical Technology Sector; Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector; International Council of Beverages Associations (ICBA) - Regional Group Latin America; Johnson & Johnson; McLarty Associates; Medtronic; Merck; MetLife; Novus Civitas; Personal Care Products Council (PCPC); Pfizer; PhRMA; RELX; Roche Diagnostics; Sanofi; Speyside; Synergia; The Bahamas Chamber of Commerce and Employers Confederation (BCCEC); The Digit Group; U.S. Chamber of Commerce (USCC); UnitedHealth Group (UHG); UPS Americas.

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Introduction

Digital health is transforming nearly every aspect of the healthcare system. It is empowering patients to better manage their own care, shifting how and where care is delivered, making drug research and development more efficient, and much more.

While the Latin America and the Caribbean region is making progress towards healthcare systems that embrace digital technologies, there has also never been a greater need to advance digital health solutions. **The COVID-19 pandemic clearly demonstrated the gaps in many healthcare systems in Latin America and the Caribbean that partly explain the disproportionate impact of the virus in the region.** The region's governments now face an unenviable challenge: how to raise the standard of healthcare and improve population health while managing the huge financial impact of the pandemic.

Fortunately, digital health offers the prospect of addressing both of these challenges at the same time. Digital solutions have the potential to increase the efficiency of the health system and reduce cost burdens while also radically expanding the reach of the health system and advancing access to care. This is all the more important in a region such as Latin America and the Caribbean, which has long-standing inequalities in access to care and health outcomes.

In some respects, the region is quickly adapting to a digital world, with fast-growing digital startups becoming household names and rapidly expanding their customer base. In healthcare, however, the legal, regulatory, reimbursement, and procurement systems struggle to keep pace with the rapidly evolving possibilities of the digital era. This lag could limit the transformational potential of technology. Policymakers have a critical opportunity to craft policies, regulations, and standards to enhance the development and adoption of digital health solutions. The private sector, as the primary developer of digital health tools, is a key partner to governments in designing and implementing digital health policies that are feasible, promote growth, and benefit patients. Private companies – whether large multinationals able to draw on global expertise and resources, or local start-ups with dynamic new solutions to offer – are a key part of a robust digital health ecosystem. In many parts of the world, companies are already partnering closely with governments to achieve digital health goals. The private sector stands ready to work with Latin American and Caribbean governments and health systems to advance digital health.

As such a partner, the ABD welcomes the opportunity to respond to two IDB publications on digital health: [*Telemedicine Regulatory Framework: Current Status and Pending Tasks*](#) and [*Regulatory Frameworks for Digital Health in Latin American and the Caribbean – Electronic Health Records: Progresses and Next Steps*](#).

In this paper, the ABD provides perspective on these two publications and draws attention to:

- **challenges** to implementing digital health, in relation to telemedicine and electronic health records (EHR) together, telemedicine only, and EHR only;
- **recommendations** to governments to overcome such challenges; and
- **public-private sector collaboration** opportunities.

In addition, the ABD offers three additional digital health priorities that merit further exploration with the IDB to support the digital health ecosystem:

1. **cloud adoption**, as an efficient, effective, and cost-effective way to scale digital health (including telemedicine and EHR) in the long term, and as a step to improve the privacy and security of healthcare data;
2. **distinguishing non-medical device software** from medical device software and implementing software-focused regulatory frameworks that support software's unique and iterative nature while also ensuring its safe and effective use, enabling regulators to focus their limited resources on products that pose the highest risk to individuals and public health; and
3. **cross-border data flows**, which supports sharing health data across borders and fosters innovation, research, analytics, and healthcare accessibility while ensuring patient privacy.

Overall, the ABD encourages governments in Latin America and the Caribbean to prioritize the following recommendations to improve telemedicine and EHR implementation:

- **Laws** – Pass laws that encourage the use of digital health solutions at every step of the patient journey;
- **Definitions** – Clarify and harmonize definitions — for instance, by using International

Medical Device Regulators Forum (IMDRF) guidance and nomenclature within countries — including clear definitions of funding and coverage;

- **Data: protection, flows, and secondary use** – Develop appropriate policies to protect personal health data while removing unnecessary barriers to cross-border data transfers and third-party use of anonymized data for regulatory and reimbursement decision-making; and
- **Interoperability** – Invest in interoperability at the outset by adopting standards (e.g. HL7 FHIR) and building access to data for clinicians and patients alike, among other actions.

Public-private collaboration can accelerate digital health transformation. The ABD offers several potential areas for consideration:

- **Definitions** – Collaboration to evolve common data nomenclature to improve communication of important information between individuals and organizations across the patient's care journey.
- **Data protection and secondary data use** – Collaboration to facilitate data anonymization, which can help public sector officials better respond to population-specific health challenges, target health concerns, improve quality of life, extend life expectancy, and lower the cost of treatment; and
- **Interoperability** – Collaboration to facilitate adoption of standards (e.g. HL7 FHIR), an action that enables interoperability, which in turn helps healthcare organizations leverage data, better manage their providers, improve performance, and deliver better patient care and outcomes.

This paper is not intended to be a comprehensive report on digital health. Instead, it seeks to open an ongoing dialogue between the private and public sectors to bring the benefits of digital health innovation to more patients and people in Latin America and the Caribbean.

Section 1: Definitions

The ABD agrees with the following key definitions adopted by the IDB in *Telemedicine Regulatory Framework: Current Status and Pending Tasks* and *Regulatory Frameworks for Digital Health in Latin American and the Caribbean – Electronic Health Records: Progresses and Next Steps*.

>> “Digital Health”

“A multifaceted reality covering aspects ranging from clinical considerations to information technology and other technologies, as well as organization, managing data or rights, and the obligations of patients and health professionals.”²

>> “Telemedicine”

“The area within telehealth that refers to the provision of remote health services, in the components of promotion, prevention, diagnosis, treatment and rehabilitation, by health professionals who use information and communication technologies that allow them to exchange data with the purpose of facilitating access and opportunity in the provision of services.”³

>> “Electronic Health Records” (EHR)

“Digital systems specifically designed to record, store, and analyze data, assessments, and information about events related to people’s health and diseases and the actions resulting from these events. They are thus much more than a digital version of paper health records because they enable accessibility, provide support for multiple appointments, improve communication between providers and patients, allow data to be consolidated, provide access to knowledge bases, and can be integrated into decision-support tools.”⁴

Or, more specifically, “longitudinal electronic record of an individual that contains or virtually interlines to data in multiple electronic medical records (EMRs) and Enterprise Resource Planning systems (ERPs), which is to be shared and/or interoperable across healthcare settings and is patient-centric. Patient-centric EHR often capture data from multiple point-of-service systems and enable authorized access by the various providers of care to pertinent patient data across multiple service delivery locations or organizations in order to ensure continuity of care for the patient.”⁵

2. Alexandre Bagolle, Mihwa Park, and Myrna Marti, *Regulatory Frameworks for Digital Health in Latin America and the Caribbean: Electronic Health Records: Progresses and Next Steps*, IDB, 6 (2020).

3. Marisa Aizenberg, *Regulatory Framework for Digital Health in Latin America and the Caribbean: The Case of Telemedicine: Progress and Pending Tasks*, IDB, 3 (2021).

4. Alexandre Bagolle, Mihwa Park, and Myrna Marti, *Regulatory Frameworks for Digital Health in Latin America and the Caribbean: Electronic Health Records: Progresses and Next Steps*, IDB, 5 (2020).

5. Jennifer Nelson, Gianluca Cafagna, & Luis Tejerina, *Electronic Health Record Systems Definitions, Evidence, and Practical Recommendations for Latin America and the Caribbean*, IDB 7 (2020).

Section 2: ABD Perspectives on IDB Recommendations

>> A. ABD Perspectives: A snapshot

The IDB offers governments ways to adopt regulations for telemedicine and EHR systems in two recent publications focused on digital health regulatory frameworks. Through virtual

interviews with ABD members and in-depth written responses, the authors determined that the ABD agrees with all of the IDB's recommendations. **The ABD also recommends certain priorities for the IDB and governments:**


TABLE 1 • Priorities for the IDB and governments (1/2)

IDB Telemedicine Recommendations (page 26 and 27 of the IDB publication)	ABD Suggested Priority	IDB Electronic Health Record Recommendations (page 31 of the IDB publication)	ABD Suggested Priority
Legal framework, which expressly enables the exercise of telemedicine	✗	Definition of EHR, its purposes, functions, and features	✗
Quality of complementary or substitute service for face-to-face consultation		Guiding principles of EHR in terms of purpose, reliability, completeness, confidentiality, information, accessibility, and ownership	✗
Secure means of transmitting data during teleconsultation		Scope of application	
Different modalities (synchronous or asynchronous)		Type of information and content to be exchanged	
Delimitation of professional responsibilities in the exercise of telemedicine		Interoperability and standards	✗

6. Marisa Aizenberg, *Regulatory Framework for Digital Health in Latin America and the Caribbean: The Case of Telemedicine: Progress and Pending Tasks*, IDB, 26-27 (2021).

7. Alexandre Bagolle, Mihwa Park and Myrna Marti, *Regulatory Frameworks for Digital Health in Latin America and the Caribbean: Electronic health records: progress and next steps*, IDB, 31 (2020).

TABLE 1 • Priorities for the IDB and governments (2/2)

IDB Telemedicine Recommendations (page 26 and 27 of the IDB publication)	ABD Suggested Priority	IDB Electronic Health Record Recommendations (page 31 of the IDB publication)	ABD Suggested Priority
Certification, authorization, accreditation of professionals, institutions and technological developers		Data protection, security, and confidentiality	
Modalities assumed by informed consent in digital practice		Safeguarding and custody of the information	
Terms and conditions of use of the platforms and applications		Access and identifying and authenticating users	
Determination of rules and powers that govern the provision of cross-border services		Implementation plan and timeframe	
Principles that govern the matter		Managing files and transitioning from paper to digital format	
Fees and insurance		Role of public, private, and professional stakeholders, as well as users	
Rights and obligations of patients		Funding	
Registration of the act and its interoperability with electronic /digital medical history, digital prescription, etc			
Creation of an application authority and its financing			

Source: Own work.

>> B. ABD Perspectives in Depth

a. ABD Perspectives: Telemedicine *and* EHR

The successful implementation of both telemedicine *and* EHR ultimately depends on the existence of a digital-friendly health ecosystem. For this ecosystem to emerge, a number of fundamental enablers must be in place. As patients navigate the healthcare system, their records should be easy to access and transfer between all organizations to ensure continuity of care. Additionally, the growth of value-based payment programs (allowing payers and suppliers to share costs based on the patient achieving their target outcomes⁸) has driven the need for prompt and complete access to clinical information in healthcare systems around the world. To that end, it is essential that countries invest in interoperability at the outset by adopting standards (i.e., HL7 FHIR) and building access to data for clinicians and patients alike, among other actions.

The IDB recognizes two main challenges that apply to implementing both telemedicine and EHR: a lack of health data interoperability and fragmented nomenclature. The ABD agrees with this assessment, and highlights the following additional challenges from a private-sector perspective:

- **Public sector use of outdated systems** that lack advanced cybersecurity tools and analytic capabilities that enable multi-model analyses⁹ (use of several modeling techniques and presentation of results in multiple views);
- **Limited data set availability** due to the lack of digitized health records or ability to merge different data sets — such as genomics, imaging, and clinical information;
- **Regulatory barriers** to third-party use of anonymized data and challenges to cross-border data flows, which inhibit the

exchange of information in the healthcare system;

- **Lack of harmonized**, appropriate data privacy policies;
- **Lack of regulations** that reflect the new available technologies; and
- **Lack of infrastructure** for telemedicine, such as access to connectivity and broadband internet, robust imaging technology, technical support staff, and quality training.

To help address these challenges, the ABD recommends that governments consider the following steps to ensure the presence of key enablers for digital health:

- **Relevant authorities should work together** to harmonize regulations for digital health across all areas (e.g., privacy, interoperability, product regulation)
- **Relevant authorities should strive for** product, service, and health system inter-operability through regulatory convergence. They should prioritize using harmonized international standards as a basis for national technical regulations across these disciplines.
- **Authorities should apply the principles** of foundational [good regulatory practices](#) in these regulatory processes to ensure outcomes align with intent.
- **Countries should invest** in strengthening and enhancing their capacity to collect, aggregate, and appropriately share data to advance medical understanding and progress, improve health outcomes, and reduce costs.
- **Governments should promote**, facilitate, and create incentives for the uptake of telemedicine and EHR at every step of the patient journey in order to facilitate coordinated care across the health ecosystem.
- **Governments should create or facilitate pathways** for companies to propose value-based healthcare solutions when presenting applications for inclusion in national formularies. These pathways should

8. Judy Han & Nicolo Olghi, *A Sustainable Organization in Healthcare*, Roche, 11 (2018)

9. Amal S, Safarnejad L, Omiye JA, Ghazouri I, Cabot JH, Ross EG. Use of Multi-Modal Data and Machine Learning to Improve Cardiovascular Disease Care. *Front Cardiovasc Med*. 2022 Apr 27;9:840262. doi: 10.3389/fcvm.2022.840262. PMID: 35571171; PMCID: PMC9091962.

incentivize healthcare providers to focus on the quality of services rendered, as opposed to the quantity or modality, and potentially pair traditional technologies with digital technologies, rather than just presenting individual products.

- **Governments should enable the use of global cloud-based solutions** and establish standards to further accelerate interoperability, enable multi-modal analyses of patient and population-health, and improve privacy and security.

In addition to these recommendations for improving digital health, the ABD recommends that governments give equal consideration to creating incentives for use of digital health within the health system, scaling up access and innovation in Latin America and the Caribbean. This could entail, for instance, creating financial incentives within the health system for providers and patients to adopt telemedicine solutions, and ensuring the recognition of real-world evidence generated from EHR and its value in regulatory and reimbursement decisions. For example, the [European Union's Innovative Health Initiative](#) has digital health projects that the public and private sectors co-finance equally via monetary or in-kind contributions. This alleviates the financial pressure on the public sector, supports public-private partnerships, and enables innovative ways to increase access to digital health tools and services.

An example of a multi-stakeholder initiative to increase access to digital tools is the ongoing Trials@Home project, which aims to explore the potential of digital technologies in remote decentralized clinical trials (RDCTs). The objective of this project is to develop and test methods to streamline data collection as well as patient recruitment and retention, supporting an innovative digital health-ecosystem and improving data collection overall. It also includes discussing RDCTs with patients as well as regulators,

payers, health technology assessment bodies (HTAs), and ethics bodies to effectively implement project outcomes across the health ecosystem.

The IDB did not discuss cloud adoption (or cloud-first policies) in either of its reports, although it is explored in other IDB publications.¹⁰ The ABD recommends that the IDB consider adding cloud adoption as a priority recommendation because it enables both telemedicine and EHR and can help optimize patient and physician experiences, reduce costs, and improve health outcomes. A cloud environment can also allow a much more responsive and proactive security approach than traditional IT infrastructure. The ABD also recommends working with the IDB to include cloud adoption in future iterations of the [IDB's Social Digital Dashboard](#).¹¹

b. ABD Perspectives: Telemedicine only

Telemedicine brings health services closer to remote or isolated populations that may not have access to health resources. It is an effective tool for maintaining care throughout a patient's journey, improving continuity of care in a way not dependent on location.¹² Without consistent norms and regulations for telemedicine, patients do not fully benefit from telemedicine solutions.

To ensure the successful implementation of telemedicine, governments need to modernize their regulations. For example, in 2020, hospitals in Mexico tried to set up a telemedicine project that would enable physicians to digitally prescribe medications. However, existing regulations only allowed pharmacies to fill prescriptions issued on paper with a wet signature. Due to this regulation, pharmacies could not accept digital prescriptions, which meant patients were less likely to receive their medicines quickly and efficiently during the pandemic.¹³

10. García Zaballos, Antonio; Iglesias Rodríguez, Enrique, *Cloud Computing: Opportunities and Challenges for Sustainable Economic Development in Latin America and the Caribbean*, IDB, April 2018, <https://publications.iadb.org/en/cloud-computing-opportunities-and-challenges-sustainable-economic-development-latin-america-and>

11. Social Digital Dashboard, IDB, <https://socialdigital.iadb.org/en/sph/dashboard>

12. Marisa Aizenberg, *Regulatory Framework for Digital Health in Latin America and the Caribbean: The Case of Telemedicine: Progress and Pending Tasks*, IDB, 3 (2021).

13. Example provided by an ABD member in written input for this document.

Of the IDB's recommendations for implementing telemedicine rules and regulations, the ABD recommends prioritizing:

- **A legal framework** in each country that expressly enables the adoption and use of telemedicine across the entire population.

As noted earlier, the IDB did not discuss cloud adoption (cloud-first policies) in its telemedicine report. Cloud-based solutions can allow telehealth services to scale up more quickly in times of increased usage like a global pandemic. Cloud-based technologies can also support the data interoperability and data access needed for remote care. Finally, cloud services can eliminate the significant infrastructure investments needed to develop and maintain telemedicine data centers onsite at healthcare facilities and can allow countries to forgo those up-front and ongoing maintenance costs and scale up and scale down their telemedicine IT investments based on their needs. Healthcare providers that run their own data centers face the challenge of guessing how much storage they will require in the future and estimating the processing power needed to run analytics on the data to extract meaningful trends about the populations they serve.

i. Legal framework that, which expressly enables the exercise of telemedicine

Some countries in Latin America and the Caribbean do not have a legal framework for telemedicine. For example, Mexico's legal framework does not regulate telemedicine. This regulatory gap hinders the overall ability of private sector providers to implement digital health tools. The IDB recognizes two main challenges to implementing a legal framework for telemedicine: the lack of unified nomenclature and underinvestment in individual/state capacity for using telemedicine. The ABD agrees with this assessment and also highlights the following additional challenges:

- **Out-of-date laws** governing electronic tools necessary for telemedicine; and
- **Lack of effective, ongoing monitoring and oversight** of telemedicine services (e.g., to ensure that only approved parties are engaged in the practice, or that privacy safeguards are respected).

As noted above, countries need to pass permanent laws that allow and encourage telemedicine. For example, one of Chile's 2022 health objectives is [Bulletin No. 13,375-11](#), a bill that, if made law, would authorize health providers to use telemedicine. Chile's implementation of telemedicine during the pandemic exemplified the need to codify the use of telemedicine into law. [Teleker](#), a telehealth platform for remote patient monitoring, joined forces with the Ministry of Health of Chile to monitor the COVID symptoms of the 900,000 people who entered the country during the pandemic. The platform also worked with the Hospital de Carabineros to develop a telehealth strategy, which included conducting teleconsultations to provide services to the 600,000 people within the orbit of the hospital and its network. These services have continued throughout the pandemic, and Teleker is currently working with several municipalities in Chile on a platform for implementing programs for chronic patients, telemedicine, telemonitoring, and unified clinical registry for citizens of these communities to improve delivery of health services in the public system.¹⁴

To help address these challenges, the ABD recommends that governments take the following critical actions:

- **Pass permanent laws** that allow and encourage use of telemedicine in medical consultations and all aspects of the patient journey.

14. <https://twitter.com/hospitalcarab/status/1395495518575464455>

- **Foster interoperability** associated with telemedicine, so patients can obtain care in the home and have data (e.g., from their devices) sent to providers.
- **Promote cloud technology** as a way to scale telemedicine services.

Additionally, while the IDB publications did not reference financing as a specific challenge, the ABD strongly recommends that governments develop clearer definitions of funding and coverage for telemedicine. As telemedicine becomes common practice, a clear pathway to funding and coverage is critical.

C. **ABD Perspectives:** **Electronic health records only**

Transitioning from paper-based records to EHR systems can have multiple benefits: cost-efficiency, better patient outcomes, patient access to personal health records, population health information, and better overall quality of care.¹⁵ While EHR systems are already starting to bring benefits to health systems, stakeholders have yet to realize the full potential of EHR to transform health systems. Health systems should therefore consider not only how they can best implement EHR, but also how they can fully harness EHR data to improve health systems overall.

As noted in the IDB publication, progress on implementing EHR in Latin America and the Caribbean is uneven. Some countries have included all, or nearly all, dimensions of the suggested EHR conceptual framework (a framework the IDB created by integrating categories from multiple sources¹⁶). Other countries have only implemented a limited number of these dimensions.

For example, Argentina's legal and regulatory framework allows public data or EHR to be used to conduct studies or for managed entry agreements, as long as the uses comply with the Declaration of Helsinki and local laws (Law 25.326 on personal data protection). Nevertheless, when trying to conduct a real-world example study or designing and implementing a managed entry agreement, the main obstacles for the private sector are a lack of digitalization and the heterogeneity of existing EHR. In Argentina, very few payers or institutions have EHR; many still collect records in paper format. Among those that do have EHR, there is huge variance in the format and the way data is collected, since EHR is not standardized. This makes it difficult to gather data effectively and efficiently, potentially impacting patients' quality of care and overall population health support.¹⁷

Of the IDB recommendations for implementing EHR rules and regulations, the ABD recommends prioritizing:

- Guiding principles of EHR in terms of purpose, reliability, completeness, confidentiality, information, accessibility, and ownership;
- Interoperability and standards; and
- Data protection, security, and privacy.

The ABD also suggests that the IDB consider adding public cloud adoption as a recommendation because cloud services enable EHR use. Cloud adoption can support the interoperability needed for EHR by standardizing data and helping providers share information while maintaining privacy and security safeguards. Cloud use can also release medical service providers from having to create, maintain, and store paper files, or maintain large and expensive onsite data centers. Medical service providers can also use cloud adoption to add population health management tools and other services that can improve the health and clinical care of patients and the entire population.

¹⁵. Jennifer Nelson, Gianluca Cafagna, & Luis Tejerina, *Electronic Health Record Systems: Definitions, Evidence, and Practical Recommendations for Latin America and the Caribbean*, IDB (2020).

¹⁶. Jennifer Nelson, Gianluca Cafagna & Luis Tejerina, *Electronic Health Record Systems: Definitions, Evidence, and Practical Recommendations for Latin America and the Caribbean*, IDB (2020)

¹⁷. Example provided by an ABD member in written input for this document.

i. Guiding principles of EHR in terms of purpose, reliability, completeness, confidentiality, information, accessibility, and ownership

The IDB recognizes several key challenges to implementing the guiding principles of EHR, including novelty, variety, and the balance between protecting data and allowing it to flow efficiently. **The ABD agrees with this assessment, and also highlights the following challenge:**

- **“Downtime”** – any period when the EHR system is fully or partially unavailable,¹⁸ which can harm patients. Downtime can often result in a transition back to paper records, but health systems increasingly train clinicians to deliver care with digital systems that provide alerts and other key safety features. Downtime can occur as a result of cyberattacks, for example, and is another area where public cloud technology can mitigate risk.

Modern IT systems, such as public cloud services, can provide the resiliency needed to avert downtime and recover systems when it occurs—mitigating the risk of lapses in patient safety due to temporary use of paper-based systems.

ii. Interoperability and Standards

The IDB recognizes two main challenges for implementing interoperability and standards: a lack of uniform standards for EHR interoperability and outdated regulations on sharing health data. The private sector agrees with this assessment.

To help address these challenges, the ABD recommends that governments take the following critical actions:

- **Clearly define the type of data** and information that can be exchanged by focusing on use cases (starting with data that is critical for care coordination and patient access, such as medication lists, problem lists, lab results).
- **Invest in interoperability** at the outset by adopting standards (e.g., HL7 FHIR), organizing connect-a-thons, and ensuring access to data for clinicians and patients alike by partnering with international organizations that have supported the adoption of standards (e.g., HL7 FHIR) in other geographical regions.
- **Increase adoption of public cloud solutions** that have already incorporated global standards into their data architectures.
- **Develop a strategy** for partnering with private-sector organizations to use their data and measures in combination with existing interoperability efforts. More explicit alignment between the public and private sectors, including a variety of stakeholders such as provider organizations, EHR vendors, and standards development organizations, would most effectively address the current gaps. By developing a framework to involve private-sector organizations in interoperability efforts, governments may catalyze additional data sharing and make meaningful progress on national or regional efforts to enable interoperability.

Recognizing a need to improve patient care by connecting a complex and diverse health ecosystem, in 2021 Puerto Rico **launched** the Puerto Rico Health Information Exchange (PRHIE) in collaboration with the private-sector health platform Health Gorilla. This initiative has expanded interoperability by enabling healthcare providers to access and share

18. Larsen, E., Hoffman, D., Rivera, C., Kleiner, B. M., Wernz, C., & Ratwani, R. M. (2019). “Continuing Patient Care during Electronic Health Record Downtime.” *Applied Clinical Informatics*, 10(3), 495–504. <https://doi.org/10.1055/s-0039-1692678>

patient medical record data securely and electronically across more than 400 care sites, 4,200 providers, and over 700,000 patients. The PRHIE will ultimately connect a “health ecosystem with 70+ hospitals, 9,000+ active providers, 900+ pharmacies, 900+ laboratories, and 22 Federally Qualified Health Centers. This will allow health information to flow seamlessly throughout the island via Health Gorilla.” This flow of information will make patient health information more readily available for medical professionals in Puerto Rico, improving the quality of patient care and creating a comprehensive aggregation of patient data that improves patient outcomes over time.

Another example of investing in interoperability is the [CARIN Alliance](#), a bipartisan, multi-sector collaborative effort to advance consumer-directed exchange of health information in the United States. The CARIN Alliance is comprised of consumers, including advocates and purchasers, HIPAA-covered entities (providers, plans, clearinghouses, and their business associates), and entities not covered under HIPAA. CARIN’s vision is to “rapidly advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want.” The Alliance focuses on overcoming barriers to consumer-directed health information exchange and developing policy recommendations to help inform including the Department of Health and Human Services, the Office of the National Coordinator for Health IT, the Office of Civil Rights, the Federal Trade Commission, and other regulators about ways to help the private sector implement the strategies described above.

The ABD believes that to improve health outcomes for individuals and populations, there has to be an interoperable healthcare system where the patient is at the center of care. This type of system requires common standards to accelerate interoperability, access to timely and robust clinical and claims data for patients and providers, and regulatory alignment that facilitates innovation.

iii. **Data protection, security, and confidentiality**

The IDB recognizes one main challenge to implementing data protection, security, and confidentiality: a lack of personal data protection regulations specific to health data. **The ABD agrees with the assessment, and also highlights the following additional challenges:**

- **Lack of consistent**, appropriate data privacy policies embedded in the processes and solutions used;
- **Lack of harmonized consent management** for the secondary use of information within countries (e.g., between different provider networks and different sectors of the health system); and
- **Significant legal and/or technological barriers** to anonymization and third-party access.

To help address these challenges, the ABD recommends that governments take the following critical action:

- **Ensure legal certainty** regarding secondary use of data for regulatory decision-making and innovation (e.g., further product development). It will not be possible to use real-world data or evidence for regulatory, reimbursement, development, and other activities if third parties cannot access such data for these uses.

Section 3: Additional Areas Meriting Further Exploration

>> A. Cloud Adoption

To successfully use EHR and telehealth, all parties must be able to effectively share and integrate data. Clinicians need data at their fingertips to care for patients, whether in a hospital, clinic, or the patient’s home. To support the use of those technologies, countries need to invest in the technical backbone that enables reliable and secure information sharing. Public cloud technology has demonstrated—on a global scale—the [ability to accelerate interoperability for EHR and telehealth](#) so clinicians can provide high-quality, safe, and coordinated care for patients. Cloud adoption also allows countries to leverage more advanced tools—including multi-modal analytics—to enhance care for patients. Countries in the region can draw on the proven success of public cloud providers and their partners all over the world to help scale EHR and telehealth efforts much faster rate than if they start from scratch.

Resourcing EHR and telemedicine can also prove challenging—a problem cloud solutions can also alleviate. By adopting cloud-based solutions, countries can avoid the significant infrastructure investments needed to develop and maintain onsite data centers. Cloud-based solutions allow countries to forgo those up-front and ongoing onsite maintenance costs, and enable them to scale up and scale down their IT investments according to their needs.

Cloud adoption can also address government concerns about the privacy and security of healthcare data in EHR systems and telemedicine. Many countries currently rely on outdated systems that lack robust privacy and security tools and features. To bridge this gap, countries should adopt governance and data management policies to adapt and implement cloud-first policies that facilitate public cloud adoption. Because of their scale, large cloud service providers can invest more in security and countermeasures than many large organizations could afford themselves. Public cloud solutions also provide redundancies so users can store data in multiple locations, ensuring accessibility even when disasters or cyberattacks occur.

EHR and telemedicine services also require high levels of reliability. For example, EHR system downtime often results in a transition back to paper records. Since health systems increasingly train clinicians to deliver care with digital systems that provide alerts and other key safety features, downtime can end up harming patients. Similarly, spikes in telemedicine use—such as the ones seen during the COVID-19 pandemic—mean systems need to be scalable to easily accommodate increased volume. With on-premise systems, each organization has to establish and fund their own infrastructure that can accommodate these spikes in volume; otherwise, they risk service disruptions. Cloud solutions, on the other hand, can support seamless increases in organizations’ compute capacity to accommodate these fluctuations.

In early 2020, just before the onset of the COVID-19 pandemic, the Hospital Israelita Albert Einstein in Brazil worked with the [private sector](#) to review its existing telemedicine architecture, on which services were experiencing downtime, and built a new, highly scalable model. The changes significantly improved the availability of telemedicine services, and just in time. The telemedicine service had more than 2 million patients in 2020, compared to 300,000 the previous year. This scalability would not have been possible without cloud infrastructure.

When the Australian government encouraged an expansion of [telemedicine](#) due to COVID-19, demand sharply increased. [CareMonitor](#), an Australian startup, rose to the challenge with cloud-based services. CareMonitor implemented a new dashboard for COVID-19 patients and developed a workflow to automate patient processing, from admission to continuous remote monitoring to discharge. CareMonitor collaborated with the Western Sydney Primary Health Network and the Western Sydney Local Health District to set up the first-ever citywide remote monitoring solution for COVID-19 patients in record time, bringing relief to overburdened hospitals.

Countries should also adopt comprehensive legislation or policies that will promote cross-border data flows and leverage public cloud resources. Data localization/sovereignty policies can disrupt patients' access to services—including EHR and telemedicine services that leverage sophisticated algorithms and merge data streams to improve patient care. For example, certain benefits of EHR require the ability to merge multiple data sets, convert information into standard formats, and leverage AI tools—all of which can be achieved faster and more effectively via cloud technology.

To help spur cloud adoption, the ABD recommends that governments take the following critical actions:

- **Establish governance and data management policies** to accelerate public cloud adoption and eliminate the significant upfront infrastructure investments needed to develop, maintain, and scale data centers.
- **Acknowledge the value of public cloud adoption**—in terms of interoperability, reliability, availability, and advanced analytics—to raise the profile of cloud solutions.
- **Define clear governance, policies, and rules** that promote or encourage public cloud adoption, data standardization, and cross-border data flows.
- **Invest in procurement** modernization.
- **Address the digital skill needs** of the public sector and broader digital literacy.
- **Leverage programs** offered by the private sector and collaborate on pilot projects.
- **Advance interoperability** to implement solutions that merge data from multiple sources—including primary care, inpatient settings, imaging centers, genomics, and laboratories.

For example, the [Brazilian National Digital Health Strategy](#) was developed to guide Brazil's digital health strategy from 2020-2028, with the aim of “building the organizational, legal, regulatory, and governance framework that enables effective collaboration in digital health.” One key actionable item is 7.2: “Develop an ecosystem in which the Brazilian NHS (SUS), public and private healthcare organizations, technology companies, research centers, universities, and other stakeholders can, while respecting established ethical and legal criteria, share data and experiences, as well as use, test, and evaluate new models, patterns, technologies, and designs.” This actionable item is expected to bring benefits that include “strengthening cloud solutions, making infrastructure cheaper, and allowing gains.” This is a successful example of concrete recognition that strengthening cloud solutions can make digital health infrastructure cheaper and more effective.

>> B. Software Regulation: Software qualification and implementation of fit-for-purpose regulatory approaches

The healthcare community uses a number of different types of software, from EHR and telemedicine systems to clinical decision support systems. But when should software be qualified as a medical device?

The International Medical Device Regulators Forum (IMDRF) recognizes¹⁹ that only a subset of software used in a healthcare meets the definition of a medical device, and that the intended purpose of a software program must fulfill the definition of a medical device in order to qualify as one. Software used in a healthcare setting but without a medical purpose, such as software used to store and transfer information, should not be considered a medical device.

It is crucial to qualify software appropriately because then regulators can focus their limited resources on products that represent the highest risk to individuals and public health. This in turn supports innovation by reducing the regulatory burden for entities developing minimal-risk software products. For example, Section 3060(a) of the 21st Century Cures Act removed low-risk software—or software that is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition but rather promotes a healthy lifestyle—from the previous definition of medical device outlined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).²⁰ Following passage of the Cures Act in 2016, the FDA released robust policy guidance for low-risk devices to provide clarity on compliance. Yet very few countries in Latin American and the Caribbean have similarly well-defined software qualification policies.

To help address these challenges, the ABD recommends that governments take the following critical actions:

- **Establish clear, harmonized policies and/or regulations**, in alignment with IMDRF, regarding whether a software program qualifies as a medical device.
- **Evolve existing regulatory frameworks** in a harmonized fashion to incorporate unique rules and pathways for software as a medical device (SaMD).
- **Implement unique device identification (UDI) regulations** that follow IMDRF guidance. This includes implementing an internationally accepted UDI coding system (e.g., GS1, HIBCC, or ICCBBA), UDI labeling, and already identified triggers for unique device identifier updates.
- **Implement UDI requirements** in a phased-in approach, starting first with the highest risk products.

For example, Brazil's recently published regulation RDC #657/2022 (formalizing a regulatory framework for registering software as a medical device) only briefly references software qualification: it states that software for well-being and for administrative and financial management in health services does not qualify as a medical device. This regulation fails to reference many other types of software functions that should not qualify as a medical device. Brazil and the entire region need a more comprehensive, harmonized approach to software qualification.

Beyond software qualification, it is important that countries establish risk-based, fit-for-purpose regulatory frameworks tailored to the unique needs of software as a medical device (SaMD). In particular, such frameworks should include unique approaches for classifying SaMD (as distinct from traditional medical devices)

19. IMDRF Software as a Medical Device (SaMD) Working Group, *Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations*, September 2014, <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>

20. 21st Century Cures Act. H.R. 34, 114th Congress. 2016, <https://www.gpo.gov/fdsys/pkg/BILLS-114hr34enr/pdf/BILLS-114hr34enr.pdf>

and more modern approaches to change management that take into account software's iterative nature. This is another area that countries in Latin America and the Caribbean need to focus on; most countries apply traditional medical device regulatory frameworks to software as a medical device, and such frameworks were not originally created with this type of technology in mind.

Further, even when countries have published SaMD-focused regulations (such as regulation #657/2022 in Brazil), these regulations do not necessarily provide progressive or innovative approaches tailored to the needs of SaMD products. To enable innovation and accelerate the development and commercialization of SaMD products that can benefit patients and health-care professionals, it is imperative that regulatory authorities in Latin America and the Caribbean reimagine their approach to regulating SaMD. One example of a good regulatory approach to managing the special needs and nature of SaMD products over their life-cycle is the FDA's predetermined change control plan introduced during a company's premarket submissions. The U.S. agency established this approach as part of its Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan. Regulators in Latin America and the Caribbean could adopt similar approaches to boost innovation and accelerate and ensure continuous patient access to these new technologies in the health ecosystems.

Lastly, many of the points this paper raises regarding interoperability and data access are also very important for medical devices. To be able to use real-world data to develop medical devices, regulate healthcare, and provide reimbursements, the data must be accessible and formatted in a user-friendly way. A harmonized, region-wide unique device identification (UDI) approach would help achieve this goal.

>> C. Cross-Border Data Flows

Digital transformation has rapidly changed health data sharing, including across borders.

Cross-border data flows support the entire health value chain, and telemedicine and EHR are no exception. Telemedicine services often consist of a virtual medical consultation between a health care provider and a patient in the same region or locality, but that consultation frequently requires cross-border access to remote health care technologies that offer security and privacy features needed to protect, store, and/or access patient data.

We need to find the most efficient way to unlock the power of health data while protecting individual privacy. A free and secure flow of personal and health data contributes significantly to digital innovation, technological advancements, and even more effective healthcare. We recommend adopting a more risk-based regulatory approach to protect data, especially sensitive personal health information, allowing a secure and controlled exchange of information while supporting innovation.

Cross-border data flows can also facilitate: international collaboration for research or expert consultations; trans-border exchange of data with laboratories with expertise in specific analyses or tests; and international consolidation of anonymized data sets for real-time statistical tracking, analytics, and monitoring to help identify health trends, epidemiological patterns, or localized disease outbreaks (vital during the COVID-19 pandemic and for future pandemics).²¹

As healthcare becomes increasingly digital, the volume of health data to manage is growing. We therefore need to build a systems approach to health data sharing arrangements at the national and regional levels. One aspect of these arrangements is a trusted health data sharing

21. Global Data Alliance, *Cross-Border Data Transfers & Remote Health Services*, <https://globaldataalliance.org/wp-content/uploads/2020/09/09152020cbdtremotehealth.pdf>

ecosystem at the country, regional and global level. This ecosystem should be duly harmonized, be based upon international best practices, involve stakeholders like the healthcare industry, and keep the best interest of patients in mind. We also need to facilitate and support ongoing international research collaborations and information exchange to have more globally diverse research capacity for tackling future unmet clinical needs and health emergencies.

Cross-border data flows can also foster interoperability within Latin America and the Caribbean. For example, [LACPass](#), with support from

the IDB and the Pan American Health Organization (PAHO), hosted the first international connect-a-thon focused on digital health in the Americas region in 2022. The objective of the connect-a-thon was to strengthen a digital pan-American network in health, with the aim of opening more opportunities for interoperable regional health. The event demonstrated the enabling technical conditions needed to implement such a system in the region.




Section 4: Public-Private Cooperation

The ABD supports public-private cooperation to implement IDB’s recommendations for telemedicine and EHR. The private sector can serve as a knowledge partner and technical expert to support government efforts to implement these

digital tools, improving access to healthcare services for communities across the region.

The ABD can contribute in several ways, as detailed below in a normative framework inspired by the IDB’s telemedicine framework.

 REGULATIONS General questions about telemedicine and EHR regulations; service delivery; enforcement authority; functions.		
Telemedicine + EHR	Telemedicine	EHR
Support adoption of interoperability standards and common data nomenclature.	Share best practices for legal frameworks.	Facilitate development of uniform terms and definitions.
		Evolve interoperability standards and common data nomenclature to support the seamless transfer of information.
		Offer case studies of successful interoperability initiatives that could help determine future standards.
Medical Devices		
Share international best practices and collaborate on policies and regulatory frameworks for software qualification.		
Collaborate with regulators on fit-for-purpose regulatory frameworks tailored to the unique aspects of SaMD, and share best practices/global convergence opportunities.		
Collaborate with regulators on implementing unique device identifiers (UDI) and share best practice/global convergence opportunities.		



GOVERNANCE

Related to national strategies/specific government plans; education and training; scope of implementation.

Telemedicine + EHR	Telemedicine	EHR
Develop and support the implementation of digital literacy programs for healthcare providers to ensure that they have proper training on utilizing telemedicine and EHR systems.	Host pilot projects (e.g., a Massive Open Online Course) for key digital concepts and to generate evidence to quantify the benefits of investing in interoperability or using standards-based interoperable solutions that merge data from multiple sources—including primary care, inpatient settings, imaging centers, and laboratories.	Develop and deliver training programs that help medical professionals and local communities learn to use EHR systems.
Facilitate data anonymization, which can map health concerns in local communities and can help public sector officials: better respond to population-specific health challenges, target health concerns, improve quality of life conditions, extend life expectancy, and lower the cost of treatment.	Help the public sector (regulators, payers, and other key decision makers) improve decision-making processes through educational activities and by generating evidence.	
Create a partnership focused on digital transformation of healthcare, potentially leveraging best practices from the EU's Innovative Healthcare Initiative.	Provide the public sector with insights on funding and coverage for telemedicine.	
	Determine certification, qualification, and accreditation criteria needed to ensure patients benefit from safe and effective telemedicine systems.	
	Recommend best practices for on certification, qualification, and accreditation from other regions.	



TECHNOLOGY

Infrastructure and connectivity; technical specificities; digital services and tools.

Telemedicine + EHR	Telemedicine	EHR
Foster an exchange of experiences and lessons learned to identify and scale up best practices in cloud adoption.		Support use of standards-based interoperable solutions that merge data from multiple sources, including primary care, inpatient settings, imaging centers, and laboratories.
Conduct pilots to transition digital health workloads to the cloud and accelerate the use of telemedicine and EHR.		Help create portals and regulations for compliant third-party access to anonymized data.
		Provide novel remote monitoring tools that healthcare providers can use when providing telecare to their patients. If added to patients' EHR, the health data gathered from these new digital tools created by the private sector would ensure easy access for healthcare providers.



PRINCIPLES AND HUMAN RIGHTS

Related to reduction of digital gaps and barriers; environmental protections; principals of bio-ethics.

Telemedicine + EHR	Telemedicine	EHR
Identify communities that suffer from the “digital divide” – defined by the IDB “as the difficulty of part of the population to access information, knowledge, and education through information and communication technologies,” ²² and provide additional support and resources to access telemedicine and EHR systems.		

22. Cave, Martin; Elbittar, Alexander; Garcia Zaballo, Guerrero, Rubén; Antonio; Iglesias, Enrique; Mariscal, Elisa; Webb, William; *The Impact of Digital Infrastructure on the Consequences of COVID-19 and on the Mitigation of Future Effects*, IDB, 3 (2020).

Section 5: Conclusions and Recommendations

Digital health is rapidly becoming a critical part of our healthcare system. It is changing how the health system operates and delivers care to patients in Latin America and the Caribbean. To implement digital tools such as a telemedicine and EHR, we need a multi-sector approach – with health ministries engaging with digital ministries, and private sector actors serving as knowledge partners and solutions providers to help governments effectively and safely reach more patients.

Finally, all relevant stakeholders should be involved in designing, developing, and implementing digital health strategy and solutions. This requires education to make all stakeholder groups more aware of digital health policies and standards and their potential benefits. These groups include the mobile industry, tech industry, healthcare providers, medical device/pharma industry, and governments.

The ABD agrees with the IDB's recommendations in its *Telemedicine Regulatory Framework* and *Electronic Health Records: Progresses and Next Steps* reports. The ABD encourages governments to prioritize:

- **Laws** – Passing laws that allow and encourage the use of digital health solutions at every step of the patient journey;
- **Definitions** – Clarifying and harmonizing definitions and nomenclature within countries, including clear definitions of funding and coverage, to enable digital health adoption;

- **Data protection and Secondary Data Use** – Developing appropriate policies to protect personal health data while removing unnecessary barriers to third-party use of anonymized data for regulatory and reimbursement decision-making, as well as to spur product development and other forms of innovation; and
- **Interoperability** – Investing in interoperability at the outset by adopting standards (i.e., HL7 FHIR) and providing access to data for clinicians and patients alike, among other actions.

Public-private collaboration can accelerate digital health transformation. **The ABD offers several potential areas that are ripe for this type of cooperation:**

- **Definitions** – Evolving common data nomenclature to improve communication of important information between individuals and organizations across the patient's care journey.
- **Data protection** – Facilitating data anonymization, which can help public sector officials better respond to population-specific health challenges, target health concerns, improve quality of life, extend life expectancy, and lower the cost of treatment; and
- **Interoperability** – Facilitating the adoption of standards (e.g. HL7 FHIR), an action that enables interoperability, which in turn helps

healthcare organizations leverage data, better manage their providers, improve performance, and deliver better patient care and outcomes.

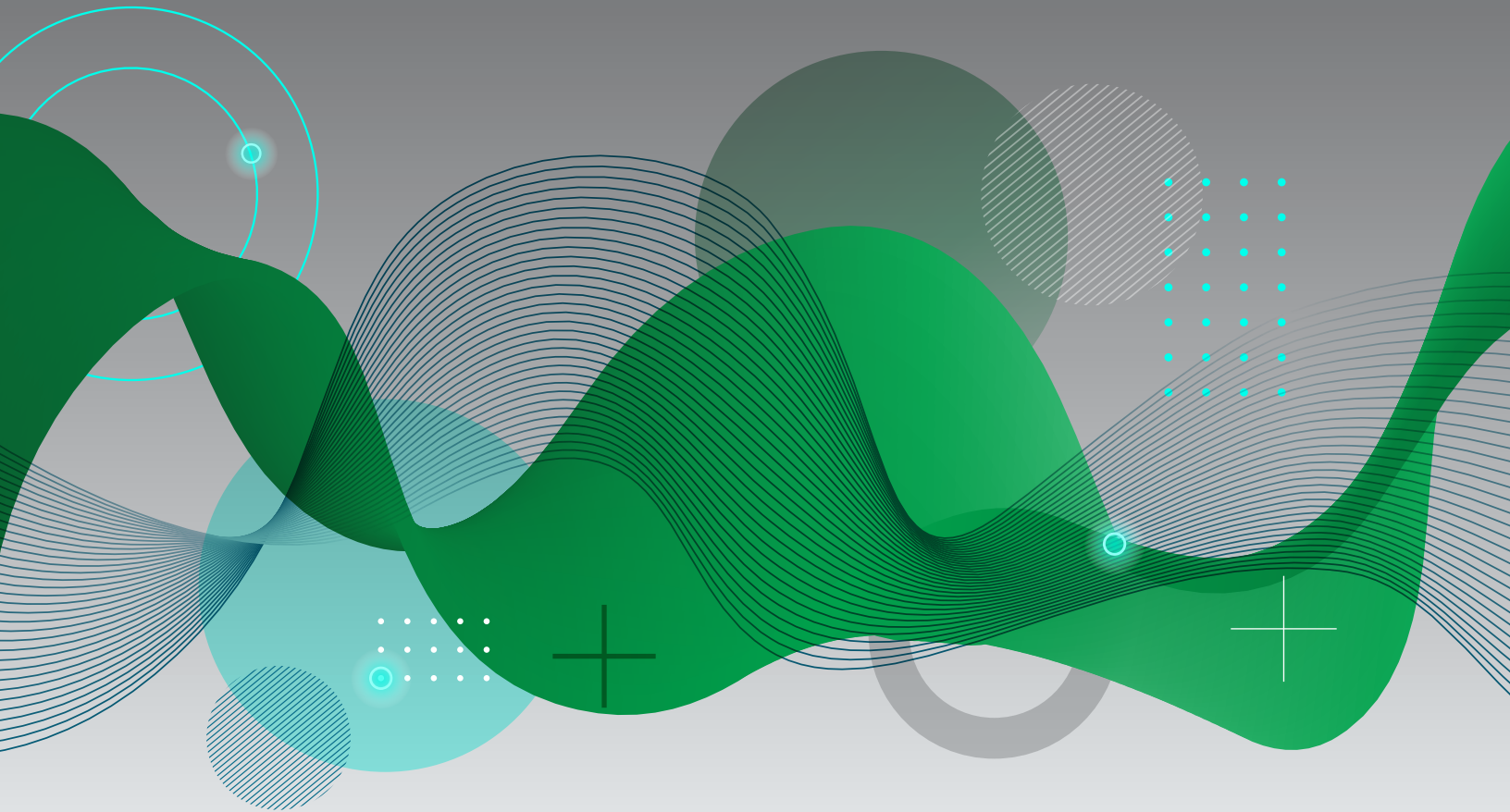
Finally, the ABD offers three areas that may merit further exploration with the IDB:

- **Cloud-based services can accelerate digital transformation** and help digital health systems operate in an effective, efficient, and cost-effective manner. Yet many public-sector entities continue to use on-premise data storage facilities, such as paper files or data centers, which require significant investment in infrastructure, maintenance, and care. Public cloud solutions make operations resilient and allow health care organizations to scale up or down to accommodate emerging needs. It also offers the capability of robust multi-modal analytics by combining different data sets to provide more comprehensive care for patients and populations.
- **Appropriate software qualification is critical**, as it enables regulators to focus their limited resources on products that pose the highest risk to individuals and public health

and supports innovation by reducing regulatory burden for entities developing software products with minimal risk. Very few countries in Latin America and the Caribbean have well-defined policies for software qualification.

- **Cross-border data flows facilitate international collaboration** for research or expert consultations; trans-border exchanges of data with laboratories with expertise in specific analyses or tests; and international consolidation of anonymized data sets for real-time statistical tracking, analytics, and monitoring to help identify health trends, epidemiological patterns, or localized disease outbreaks (vital during the COVID-19 pandemic and for future pandemics).

The ABD welcomes collaboration with the IDB and governments in the region to enable the adoption of digital health solutions. It stands ready to serve as a resource and implementing partner.



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