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Legal Guides

Practical cross-border insights into digital health law

Digital Health

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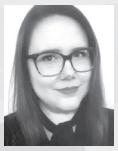
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1 Digital Health

1.1 What is the general definition of "digital health" in your jurisdiction?

The Brazilian Ministry of Health defines "digital health" as the use of Information and Communication Technology (ICT) resources in healthcare, producing and delivering reliable health status information to citizens, health professionals and public managers, in order to solve issues in the public and private healthcare systems. It also includes innovative ICT resources in healthcare, e.g., social networking applications, Internet of Things (IoT), Artificial Intelligence (AI), use of personal devices and emerging technologies.

1.2 What are the key emerging digital health technologies in your jurisdiction?

The key emerging technologies implemented by the Brazilian National Digital Health Strategy 2020–2028 (BNDHS 2020–2028) include: telemedicine and telehealth; AI/IoT; wearables and automation; big data; and mobile health applications.

Telemedicine and telehealth intend to provide safe integrated care and monitoring for patients in a remote manner, through the use of ICT resources. Artificial Intelligence of Things (AIoT) includes the use of AI algorithms to manage the operation of machines by integrating the systems to the internet. Wearables and mobile health applications are used to record, analyse, regulate, and even treat diseases to maintain the health of the user, by monitoring their clinical information through electronic mobile devices.

1.3 What are the core legal issues in digital health for your jurisdiction?

The main legal issues faced by digital health in Brazil include: (i) the lack of specific and unified regulation that ensures the safety and transparency in the collaboration of stakeholders, in addition to the legal uncertainty regarding essential rights and the different authorities that rule these matters; (ii) the risks involving data protection and security of sensitive data; and (iii) the lack of computer integration of the Brazilian public health system in different jurisdictions and private and public sectors.

1.4 What is the digital health market size for your jurisdiction?

According to the study published by PwC Brasil (https://www.pwc.com.br/pt/sala-de-imprensa/release/Estudo-da-liga-ventures-e-pwc-brasil-aponta-aumento-no-numero-de-healthtechs-entre-2019-e-2022.html), the number of healthtechs in Brazil has increased by more than 16% between 2019–2022. Such growth is directly associated with the COVID-19 pandemic, and the implementation of governmental programs in the Brazilian Unified Health System (SUS), especially the program ConecteSUS. According to the same research, Mergers & Acquisitions (M&A) transactions and investments in the Brazilian digital healthcare market actually involved BRL 1.79 billion in such period (2019–2022).

1.5 What are the five largest (by revenue) digital health companies in your jurisdiction?

The five largest digital health service companies in Brazil, based on the values of rounds collected by healthtechs in 2022, are Alice, Bionexo, Memed, Conexa Saúde and 3778 based on the recent Healthtech Report 2022 (https://7735036.fs1.hubspotusercontent-na1.net/hubfs/7735036/MINING-HEALTHTECH-2022-20220909-3.pdf?utm_campaign=techtrends_healthtech&utm_medium=email&_hsmi=224604938&_hsenc=p2ANqtz-8kzlwp8j5PQIN5YEHFA-eigzcO_pCx4jyxk0bW7i9B164WJBCa0T20thiATJ45lJB8giDKAkkqo4Nf2lW8-LXmVNw2YSDK-RC-NVWSFT-tm_sLGVRo&utm_content=224604938&utm_source=hs_automation).

2 Regulatory

2.1 What are the core healthcare regulatory schemes related to digital health in your jurisdiction?

Currently, there is no legal framework for digital health in Brazil that compilates all regulatory rules regarding this matter. The

Ministry of Health and other local agencies (such as the National Health Surveillance Agency (ANVISA) and the National Supplementary Health Agency (ANS)), have issued different norms regarding digital health.

Following the global strategy on digital health (created in 2019 by the World Health Organization), the Ministry of Health delivered the National Digital Health Strategy (ESD28), which includes the Digital Health Action Plan 2020–2028 and a Monitoring and Evaluation (M&E) Plan.

The Action Plan describes the necessary resources and activities for the implementation of the Strategic Digital Health. The M&E Plan defines the organisation and governance of the M&E actions, as well as the activities to be performed and the respective responsible stakeholders.

Later, the Ministry of Health implemented the ConecteSUS and established the National Healthcare Data Network, providing health interoperability standards.

2.2 What other core regulatory schemes (e.g., data privacy, anti-kickback, national security, etc.) apply to digital health in your jurisdiction?

Data privacy is regulated by the Brazilian General Data Protection Act (Law No. 13,709/2018 (LGPD) (https://iapp.org/resources/article/brazilian-data-protection-law-lgpd-english-translation/)), which provides for the processing of personal data, including in digital media. The Internet Act (Law No. 12,965/2014 (https://www.planalto.gov.br/ccivil_03/_ato2011-2014/2014/lei/l12965.htm)), regulated by Decree No. 8,771/2016 (https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/d8771.htm) also applies to digital health since it sets important guidelines for the use of the internet applications in Brazil. The CIT Resolution No. 19 of June 22, 2017 (http://wwa.tjto.jus.br/elegis/Home/Imprimir/1201#:~:text=RESOLU%C3%87%C3%83O%0D%20N%C2%BA%2019%2C%20de%2022%20de%20junho%20de,do%20Estado%20do%20Tocantins%2C%20e%20adota%20outras%20provid%C3%AAncias.) of the Ministry of Health, launched the digital health strategy in Brazil (digiSUS) (https://digisus.saude.gov.br/gestor/#/). The digiSUS managing platform aims to provide municipal, state and federal health managers with tools to assist in the planning and management of SUS. Other Resolutions of the Ministry of Health, such as CIT Resolution No. 6/13 (https://bvsms.saude.gov.br/bvs/saudelegis/cit/2013/res0006_06_11_2013.html) and CIT Resolution No. 7/16 (https://bvsms.saude.gov.br/bvs/saudelegis/cit/2016/res0007_24_11_2016.html) also set important rules for implementation of new applications, health information systems or new versions of systems involving SUS.

Telemedicine services in Brazil are currently allowed, but in a limited and regulated manner. In 2022, the Federal Council of Medicine (CFM) also issued CFM Resolution No. 2.314/2022 (https://www.in.gov.br/web/dou/-/resolucao-cfm-n-2.314-de-20-de-abril-de-2022-397602852#:~:text=RESOLU%C3%87%C3%83O%20CFM%20N%C2%BA%202.314%2C%20de%2020%20de%20abril,de%20servi%C3%A7os%20m%C3%A9dicos%20mediados%20por%20tecnologias%20de%20comunica%C3%A7%C3%A3o.) in this regard. Bill No. 1,998/2020 also regulates this matter and it should be analysed by the Brazilian Senate. CFM also issued other Resolutions regulating digital prescriptions and teleradiology, for example, and Law No. 13,787/2018 (https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13787.htm) implements the digitalisation and computerisation of the healthcare system.

In this regard, ANVISA is also giving special attention to medical devices used in the digital health market, so it issued RDC No. 657/2022 (http://antigo.anvisa.gov.br/documents/10181/5141677/RDC_657_2022_.pdf/f1c32f0e-21c7-415b-8b5d-06f4c539bbc3), regulating software as medical devices.

2.3 What regulatory schemes apply to consumer healthcare devices or software in particular?

ANVISA's RDC No. 657/2022 (http://antigo.anvisa.gov.br/documents/10181/5141677/RDC_657_2022_.pdf/f1c32f0e-21c7-415b-8b5d-06f4c539bbc3) provides for the regularisation of software as a medical device (SaMD). In 2022, ANVISA also approved the proposal to update the text of the RDC Resolution No. 185/2001 (https://www.emergogroup.com/sites/default/files/file/rdc_185_2001_classification_and_registration_requirements_of_medical_products_0.pdf) to include regulation on new technologies, including medical devices in Brazil.

CIT Resolution No. 6/13 (https://bvsms.saude.gov.br/bvs/saudelegis/cit/2013/res0006_06_11_2013.html) also applies to healthcare devices and software within SUS.

In any case, the Brazilian Consumer Protection Code (Law No. 8,078/1990 (CDC)) applies to any consumer relationship, including the ones related to healthcare devices.

2.4 What are the principal regulatory authorities charged with enforcing the regulatory schemes? What is the scope of their respective jurisdictions?

The main regulatory authorities in healthcare in Brazil are: (i) ANVISA; (ii) the Ministry of Health; (iii) ANS; and (iv) CFM.

2.5 What are the key areas of enforcement when it comes to digital health?

The key areas of enforcement regarding digital health include digital laws, data protection laws, consumer laws and the rules issued by local authorities.

Nonetheless, AI and other technologies are subject to specific laws and regulation (e.g., intellectual property rights and rules issued by the Brazilian Ministry of Sciences, Technology and Innovation).

2.6 What regulations apply to software as a medical device and its approval for clinical use?

ANVISA's RDC No. 657/2022 (http://antigo.anvisa.gov.br/documents/10181/5141677/RDC_657_2022_.pdf/f1c32f0e-21c7-415b-8b5d-06f4c539bbc3) regulates the use of SaMD in the healthcare system. Other rules related to the registration/approval of medical devices are provided for by ANVISA's RDC No. 185/2001 (https://www.emergogroup.com/sites/default/files/file/rdc_185_2001_classification_and_registration_requirements_of_medical_products_0.pdf).

2.7 What regulations apply to artificial intelligence/machine learning powered digital health devices or software solutions and their approval for clinical use?

There is no legal framework specifically regulating the use of AI or other IoT devices and their approval for clinical use.

However, Bill No. 21/2020 (https://www25.senado.leg.br/web/atividade/materias/-/materia/151547), which is under discussion in the Senate, sets forth principles and guidelines for the development and application of AI in Brazil.

3 Digital Health Technologies

3.1 What are the core issues that apply to the following digital health technologies?

- **Telemedicine/Virtual Care**
  Data protection and medical confidentiality.
- **Robotics**
  There are heated debates about liability in the event of a machine's malfunction that can cause potential damage to a patient's health, especially if supervised by medical professionals.
- **Wearables**
  Most wearable devices are not considered medical devices under ANVISA's regulation, so there is a lack regulation regarding them.
- **Virtual Assistants (e.g. Alexa)**
  Data privacy matters in connection with the use of such Virtual Assistants raises further discussions about the liability of their manufacturers and distributors.
- **Mobile Apps**
  Most mobile apps are not regulated by ANVISA, which results in the lack of rules regarding the safety and accuracy of their use by patients.
- **Software as a Medical Device**
  According to ANVISA's Regulatory Impact Analysis Report on SaMD (https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/participacao-social/dialogos-setoriais/arquivos/dialogo-setorial-sobre-o-relatorio-preliminar-de-air-de-software-medico/relatorio-de-definicao-e-analise-do-problema-regulatorio-v-0-4-pos-rev-ggreg.pdf#:~:text=Os%20softwares%20como%20dispositivos%20m%C3%A9dicos%20e%20v%C3%A1rios%20equipamentos,ou%20ISO%20que%20possibilite%20a%20certifica%C3%A7%C3%A3o%20do%20mesmo.), the main issues are: (i) lack of guidance to health professionals and the population about the risks in their use; (ii) difficulty in inspection, monitoring and sanitary control; (iii) lack of updated regulatory requirements due to their fast and disruptive pace of innovation; and (iv) omission of potential risks already identified by their manufacturer.
- **Clinical Decision Support Software**
  Clinical decision support software is also subject RDC No. 657/2022. The topic is still quite recent and encounters the same challenges faced by SaMD.
- **Artificial Intelligence/Machine Learning Powered Digital Health Solutions**
  The CDC holds all the chain of supply liable for any product purchased by consumers. This means that the manufacturer of a machine that uses AI and the hospital that uses such machine are equally liable before patients. Medical professionals, however, that may rely on such technologies, are not consumers and, thus, liability is highly debatable.
- **IoT (Internet of Things) and Connected Devices**
  The use of such technology in healthcare relies specifically on the absence of knowledge by medical professionals and other agents that have little to no experience in the use of these devices. These devices also face the lack of specific rules related to civil liability of the service or product provider.
- **3D Printing/Bioprinting**
  The high cost and the lack of scientific resources and knowledge about its various functionalities and efficiency.
- **Digital Therapeutics**
  Risks arising from the violation of data privacy.
- **Natural Language Processing**
  Since natural language processing concerns AI technology, it faces the same issues applied to AI.

3.2 What are the key issues for digital platform providers?

Digital platform providers are deemed application providers under the Internet Act. Their main concerns involve: (i) civil liability in relation to users; (ii) lack of specific regulation regarding emerging technologies (e.g., AI, IoT); (iii) civil liability regarding a service/product offered by the digital platform; and (iv) cybersecurity, due to the sensitivity of the data involved.

4 Data Use

4.1 What are the key issues to consider for use of personal data?

The LGPD aims to protect the fundamental rights of freedom and privacy. Therefore, the key issues for using personal data include, among others, the observance of the principles that should guide the personal data processing activities, such as: the principle of necessity and non-discrimination; processing activity grounded on a legal basis; the adoption of technical and administrative security measures; and the guarantee of rights to the data subjects.

4.2 How do such considerations change depending on the nature of the entities involved?

The LGPD is not applicable for the following purposes: (i) private and non-economic processing activity performed by a natural person; (ii) journalistic and artistic; (iii) academic; (iv) public security, national defense, state security or activities of investigation and repression of criminal offences; or (v) when the personal data come from outside the Brazilian territory and is not subject to communication and/or shared use of data with Brazilian processing agents or subject to international data transfer with a country other than the country of provenance.

4.3 Which key regulatory requirements apply?

The processing of personal data must be carried out for legitimate, specific, explicit purposes informed to the data subject and compatible with the informed purpose, and limited to what is necessary to achieve it. The processing must also be supported by one of the hypotheses provided for in the LGPD (legal basis). Specifically with regard to health data, considered by the LGPD as sensitive data, only the following legal bases apply: (i) upon provision of consent by the data subject; (ii) compliance with legal or regulatory obligations by the controller; (iii) for execution of public policies, by the public administration; (iv) for the performance of studies by research organisations; (v) for the regular exercise of rights in legal, administrative or arbitration proceedings; (vi) for the protection of the life or physical safety of the data subject or of a third party; (vii) for the protection of health, exclusively in procedures performed by health professionals,

health services or health authorities; and (viii) for fraud prevention and data-subject security, in identification and authentication processes of registration in electronic systems. Processing of sensitive personal data based on the legitimate interest of the controller or a third party is not permitted by the LGPD.

Based on the sensitivity of health data, the LGPD prohibits communication or shared use between controllers with the aim of obtaining economic advantage (except for the provision of health services, pharmaceutical assistance, healthcare and auxiliary services of diagnosis and therapy, in addition to portability or financial and administrative transactions resulting from the use and/or provision of the aforementioned services), as well as the use of such data for risk selection for contracting private healthcare insurance plans, and for the hiring or exclusion of beneficiaries.

4.4 Do the regulations define the scope of data use?

Brazilian laws and regulation provide that data can be used when the processing agents observe the principles of: purpose; adequacy; necessity; free access; data quality; transparency (subject to commercial and industrial secrets); security; prevention; non-discrimination; and accountability. In addition, the processing activity must be adequate to one of the legal bases provided for in the LGPD.

4.5 What are the key contractual considerations?

Brazil, unlike the European Union, does not oblige processing agents to enter into Data Processing Agreements (DPAs). However, this is a highly recommended practice, especially as the LGPD establishes that processing agents will be able to formulate good practices and governance rules. Therefore, the adoption of DPAs is a reality in the Brazilian market, and the agreement usually addresses the responsibilities of each processing agent, fines for non-compliance, transfer rules and deadlines for communications, among others.

4.6 What are the key legal issues in your jurisdiction with securing comprehensive rights to data that is used or collected?

The Federal Constitution states that a person's privacy, private life, honour and image are inviolable, and ensures the right to compensation for economic and non-economic damages resulting from violation thereof. It also states that confidentiality of mail, telegraphic communications, data and telephone communications is inviolable except by court orders, in the manner established by law for purposes of criminal investigations or discovery. Recently, the protection of personal data was also considered a fundamental right (Amendment No. 115/2022 to the Federal Constitution). In addition, the LGPD has an extensive list of rights provided to data subjects, which can be exercised at any time, at no cost, which include rights to: (i) confirmation of the existence of processing activities; (ii) access; (iii) correction of incomplete, inaccurate or outdated data; (iv) anonymisation, blocking or deletion of unnecessary, excessive personal data or data processed in violation of the law; (v) portability of data to another service or product provider; (vi) obtainment of information on the sharing of personal data with third parties (public and/or private entities); (vii) erasure of data processed with the consent of the data subject; (viii) information on the possibility of the data subject not giving consent, and consequences in the event of refusal; (ix) withdrawal of consent; (x) opposition; and (xi) review of automated decisions. Finally, the data subject will always have the right to file a petition against the data controller and/or the Brazilian Regulatory Authority (ANPD), and this does not prevent him/her from filing lawsuits in Courts.

4.7 How are issues with data inaccuracy, bias and/or discrimination addressed by the regulatory authorities in your jurisdiction?

Processing agents that violate the rules set out in the LGPD, including but not limited to unlawful processing activities, will be subject to administrative sanctions, applicable by the ANPD, ranging from a warning, financial sanctions, such as a fine based on the turnover of the economic group established in the country, blocking or deletion of data, publication of the violation, and total or partial prohibition of the exercise of activities related to data processing.

5 Data Sharing

5.1 What are the key issues to consider when sharing personal data?

The key issue to be considered is to ensure that there is an adequate legal basis for data sharing (as provided for in the LGPD) and, if the legal basis used is consent, it will be necessary to obtain free, informed and unequivocal consent from the data subject. The formalisation of DPAs between the processing agents is also important in order to mitigate risks and to be aligned with the law. Moreover, data sharing must be provided for in privacy policies/notices.

Also, the communication or the shared use of sensitive personal data related to health among data controllers for economic gain may be prohibited, except in cases related to the provision of healthcare services, pharmaceutical and healthcare assistance.

Finally, the international transfer of personal data will only be allowed in the events provided for in Article 33 of the LGPD, which include: (i) transfers to countries or international bodies that provide a degree of personal data protection in line with the LGPD; (ii) the data controller offers and substantiates guarantees of compliance with principles, data subject's rights and a data protection system by using standard contractual clauses or binding corporate rules, for example; (iii) the transfer is necessary for international legal cooperation between public intelligence, investigation and prosecution agencies, in accordance with international law; (iv) the transfer is necessary to protect the life or physical safety of the data subject or a third party; (v) ANPD authorises such transfer; (vi) the transfer results in a commitment assumed in an international cooperation agreement; (vii) the transfer is necessary for the execution of public policy or due public services; or (viii) the data subject has provided his/her specific and highlighted consent for the transfer, with prior information on the international nature of the operation, clearly distinguishing it from other purposes.

5.2 How do such considerations change depending on the nature of the entities involved?

The LGPD does not materially change the obligations that entities of different natures will have in relation to the core aspects of the LGPD, so all data processing agents must follow the principles that guide the law.

5.3 Which key regulatory requirements apply when it comes to sharing data?

The key regulatory requirement is to find an appropriate legal basis for the processing activity, and comply with all the principles established by the LGPD, such as purpose, adequacy, necessity, free access, data quality, transparency, security, prevention, non-discrimination and accountability.

6 Intellectual Property

6.1 What is the scope of patent protection?

The Industrial Property Law (Law No. 9,279/1996 (LPI)) encompasses patent protection, as well as trademarks and industrial designs. Brazil is part of the World Trade Organization, so it complies with all basic international rules and requirements provided for in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Brazil is also part of the Patent Cooperation Treaty.

The LPI protects both patent types: (i) Patent of Invention (PI), that are products or processes considered inventive, new and that have industrial application, and; (ii) Utility Models (MU) – in Europe known as "petit" patents – are usually related to functional improvements in other technologies. PIs are valid for a period of 20 years from the date of filing with the Brazilian National Institute of Industrial Property (INPI), and MUs are valid for 15 years from filing.

Brazil has a "first-to-file" system, which provides patent protection to the first applicant to file an application for an invention. In general, the INPI follows European standards for patentability. Under the approach, creations must solve technical problems and yield technical effects to be considered inventions and, thus, patentable.

In any case, the LPI expressly states that "surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to human or animals" are not subject to patent protection.

6.2 What is the scope of copyright protection?

Copyrights are ruled by the Copyright Law (Law No. 9,610/1998 (LDA)). Software is protected as a copyright, although there is a specific law in this regard (Law 9,609/1998). These laws protect copyrights related to artistic, literary and scientific creations for the author or creator. Contrary to industrial property, the registration of copyrights before the INPI is not mandatory.

Copyright protection in Brazil, among other things, also encompasses databases.

Since Brazil is part of the TRIPS Agreement and the Berne Convention for copyrights, it complies with all basic international rules and requirements related to copyrights.

6.3 What is the scope of trade secret protection?

Trade secret protection relates to confidential information that gives some competitive advantage to a company. They differ from patents and trademarks because their protection is not guaranteed by a registration. The protection of trade secrets is usually enforced by contracts and unfair competition laws.

Article 195 of the LPI lists several unfair competition crimes, which include the unauthorised use of confidential information (trade secrets) obtained during a contractual or employment relationship, or that have been obtained in an illicit or fraudulent manner.

6.4 What are the rules or laws that apply to academic technology transfers in your jurisdiction?

Technology transfer agreements are regulated by the INPI (Resolution No. 199/2017), as provided for in the LPI. Their submission and registration with the INPI are mostly recommended for tax purposes, so academic technology transfers among Brazilian parties usually are not registered with the INPI.

In general, academic Research and Development (R&D) is strictly related to public universities and other public Science, Technology and Innovation Entities (ICTs), so the most important law in this regard is Law No. 10,973/2004 (Innovation Law – as further amended and regulated).

6.5 What is the scope of intellectual property protection for software as a medical device?

The registration of software as a copyright is not mandatory for protection in Brazil. As a rule, following the European approach, the INPI does not grant patent protection for software (source code), although a medical device could be considered an invention and, thus, protection granted as a patent.

Additionally, it is important to mention that SaMD has been regulated by RDC No. 657/2022, and the registration of this type of software must be required before the ANVISA, not the INPI.

In this regard, said Resolution establishes that certain software should not be considered medical devices, as follows: (i) for well-being, without performing activities of prevention, diagnosis, treatment, rehabilitation or contraception; (ii) used exclusively for administrative and financial management in health services; (iii) those that process medical demographic and epidemiological data, without any clinical diagnostic or therapeutic purpose; and (iv) shipped in a medical device under a health surveillance regime.

6.6 Can an artificial intelligence device be named as an inventor of a patent in your jurisdiction?

Since industrial property rights are generally granted to individuals by the Federal Constitution, although the LPI does not expressly prohibit the registration of patents by AI, the INPI has never granted a patent indicating an AI as an inventor. Unless specific legislation is created regarding this matter, it is likely the INPI will never name an AI device as an inventor for a patent.

6.7 What are the core rules or laws related to government funded inventions in your jurisdiction?

The most important law in this regard is the Innovation Law, which is regulated by Decree No. 9,283/2018. These laws establish several ground rules for cooperation between the Government (as well as public ICTs) and private entities, providing valuable tax incentives to them. In addition, there are several local agencies and public entities created to promote and develop R&D activities in Brazil, such as FINEP (created by Decree No. 61,056/1967) and hundreds of public ICTs.

7 Commercial Agreements

7.1 What considerations apply to collaborative improvements?

R&D agreements usually have strong IP sections providing for the rights related to collaborative improvements. The LPI and the Copyright Law have provisions regarding the development

of technology by employees and service providers; however, joint improvements and other improvements created under any kind of technology transfer/licence agreement should be contractually regulated.

7.2 What considerations apply in agreements between healthcare and non-healthcare companies?

Agreements between healthcare service providers and non-healthcare companies must include specific provisions concerning liability of the parties, data privacy, cybersecurity, confidentiality and intellectual property rights.

8 Artificial Intelligence and Machine Learning

8.1 What is the role of machine learning in digital health?

Technology has radically changed patient care and hospital management. The use of AI in healthcare, accompanied by machine learning, has several applications, such as: (i) management of patient risk levels, in order to prioritise diseases that require more attention; (ii) creation of health protocols by states and municipalities to gather relevant information about diseases, such as on the evolution of COVID-19, allowing monitoring of virus dissemination; (iii) bed management, avoiding hospital collapse; (iv) automation of tasks, such as requesting medications; (v) cost and fraud reduction, since the system relies on organised processes; and (vi) personalised care, since the technology is able to identify the individual risks and needs of each patient.

8.2 How is training data licensed?

It is good practice that training data is not actual personal data, in order to protect real personal data. Otherwise, personal data subjects need to be informed that their data will be used for training data in compliance with the LGPD.

8.3 Who owns the intellectual property rights to algorithms that are improved by machine learning without active human involvement in the software development?

The intellectual property sector has a major challenge related to the evolution of machine learning, which enables evolving algorithms to teach a machine which actions to take.

Intellectual property laws in Brazil generally protect creations of the human mind, thus, theoretically, a machine cannot be considered an inventor or a copyright holder. At the time of writing, in Brazil, algorithms resulting from machine learning are not covered by intellectual property laws.

Bill No. 5,051/2019 aims to establish the principles for the use of AI, and Bill No. 5,691/2019 establishes the National Policy for Artificial Intelligence. Both Bills aim to establish that AI must respect the constitutional principles of dignity, human rights, protection of personal data and privacy. Nonetheless, even after its approval, more specific regulations will be necessary.

8.4 What commercial considerations apply to licensing data for use in machine learning?

If the data used in the machine-learning process corresponds to personal data, the use must be linked to an adequate legal basis provided for in the LGPD. To date, there is no specific regulation for data that is used for machine learning; however, the principles provided for in the LGPD must be observed, informing the data subject that his/her data may be used for machine learning.

Furthermore, since the Copyright Law protects databases organised in a creative and unique way, which constitute an intangible property of the company, its use and transfer can be the object of a licence agreement, including in a machine-learning environment.

9 Liability

9.1 What theories of liability apply to adverse outcomes in digital health solutions?

Based on the CDC, the entire chain of products/services suppliers is liable before consumers – the CDC establishes strict liability related to products'/services' defects and errors. Additionally, the LGPD provides for administrative penalties in the event of violation of subjects' rights concerning personal data and privacy.

9.2 What cross-border considerations are there?

The international transfer of personal data is permitted by the LGPD, provided that it is in compliance with the requirements set forth in Article 33 of the referred law.

10 General

10.1 What are the key issues in Cloud-based services for digital health?

Possible violation of the LGPD, including data breach and exposure of the subject's medical data.

10.2 What are the key issues that non-healthcare companies should consider before entering today's digital healthcare market?

Non-healthcare companies may face issues involving compliance with data privacy regulation, as well as capacitation of professionals to be adequately trained to use the new technologies, in addition to any regulatory adjustments.

10.3 What are the key issues that venture capital and private equity firms should consider before investing in digital healthcare ventures?

Despite its growing market, the digital healthcare sector lacks legal certainty with regard to venture capital and private equity firms, especially regarding liability before consumers, users and the Government in general.

10.4 What are the key barrier(s) holding back widespread clinical adoption of digital health solutions in your jurisdiction?

Lack of specific and unique regulation encompassing all the technologies related to digital health, or at least the technologies already implemented in the healthcare system, is a strong barrier, since it creates legal uncertainty.

10.5 What are the key clinician certification bodies (e.g., American College of Radiology, etc.) in your jurisdiction that influence the clinical adoption of digital health solutions?

The Ministry of Health, ANVISA, ANS and CFM. The approval and certification of a clinical or medical facility and/or product depend on the authorisation/registration by ANVISA. ANVISA is also responsible for the registration of medical devices in general, including SaMD.

10.6 Are patients who utilise digital health solutions reimbursed by the government or private insurers in your jurisdiction? If so, does a digital health solution provider need to comply with any formal certification, registration or other requirements in order to be reimbursed?

There are two types of healthcare systems in Brazil: the public healthcare system (SUS), and the private healthcare insurance system. The reimbursement by a private insurer depends on the type of insurance agreement held by the consumer, in that case the value differs according to the insurance plan. The SUS provides free healthcare, including the use of digital health solutions at the disposal of the population, such as ConecteSUS.

10.7 Describe any other issues not considered above that may be worthy of note, together with any trends or likely future developments that may be of interest.

In addition to the legal concerns involving digital health in Brazil, there are practical difficulties for the implementation of digital health systems, such as: low availability of financial resources in the public sphere; proper training for medical and administrative teams to handle these new technologies and knowledge about their risks; and the informatisation of the population in general about the new health functionalities.

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